

Comments on the leaked draft text of discussions facilitated by the Director-General of the World Trade Organization with respect to the TRIPS Waiver proposal

Third World Network

A. INTRODUCTION

Recently the media leaked a draft text on discussions facilitated by the World Trade Organization (WTO) Director-General with respect to the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Waiver proposal. **This text has not been agreed to among the US, EU, India and South Africa, who are involved in the discussions.**

The text is a mix of clarifications (on Article 31 and Article 39.3) and a waiver of Article 31(f) of TRIPS, which is the only waiver in the draft text.

Article 31 of TRIPS allows the issuance of authorisation that allows the use of subject matter of a patent without the consent of the patent holder (also often known as ‘compulsory licence’ or ‘non-voluntary authorisation/licence’). The use of Article 31 is subject to several terms and conditions including:

- Article 31(a): authorisation of such use shall be considered on its individual merits;
- Article 31(b): need to show attempts to obtain a voluntary licence from the patent holder before issuing a non-voluntary authorisation except in situations of national emergency, other circumstances of extreme urgency and public non-commercial use.
- Article 31(f): any such use shall be authorised predominantly for the supply of the domestic market of the Member authorising such use.
- Article 31(h): payment of adequate remuneration to the patent holder.

Article 31bis including its Annex applies in the specific situations where waiver of Article 31(f) is operationalised. This mechanism reflects the temporary waiver solution adopted by the General Council on 30 August 2003 (WT/L/540)¹ but which has been criticised for being unworkable due to its many cumbersome procedures.

¹ https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm

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Article 39 of TRIPS concerns protection of undisclosed information i.e. trade secrets, relevant especially in the context of COVID-19 vaccines.

Generally, the leaked draft text is a significant departure from the TRIPS Waiver proposal (IP/C/W/669/Rev.1) that sought straightforward waivers of TRIPS obligations with respect to patents, protection of undisclosed information, copyright and industrial designs. The original TRIPS Waiver proposal aimed to clear the pathway for the early entry of follow-on/generic manufacturers by waiving intellectual property (IP) barriers, so that manufacturing may be diversified and supply options expanded rapidly. In this sense the text does not reflect a meaningful outcome with respect to the TRIPS Waiver proposal. It does however contain the hard-line positions of the EU, i.e. that the text should be about existing elements of compulsory licence, and the US, that the text should be limited to vaccines and who has also demanded eligibility criteria.

Overall the text does not waive TRIPS obligations to provide manufacturers with the freedom to operate; they need to facilitate independent manufacturing and to address access inequities. Instead the text appears to have complicated the use of existing TRIPS flexibilities, and erected further barriers that will hinder local manufacturing and access.

This paper provides a brief analysis of each paragraph in the leaked text.

B. SPECIFIC COMMENTS

I. Paragraph 1

1. Notwithstanding the provision of patent rights under its domestic legislation, **an eligible Member [1]** may limit the rights provided for under Article 28.1 of the TRIPS Agreement (hereinafter ‘the Agreement’) by authorizing the use of patented subject matter [2] required for the production and supply of COVID-19 vaccines without the consent of the right holder **to the extent necessary to address the COVID-19 pandemic**, in accordance with the provisions of Article 31 of the Agreement, as clarified and waived in paragraphs 2 to 6 below.

Footnote 1: For the purpose of this Decision, an ‘eligible Member’ means any developing country Member that exported less than 10 percent of world exports of COVID-19 vaccine doses in 2021.

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.

Comment:

1. The overall application of the text appears limited to ‘the extent necessary to address the COVID-19 pandemic’. This raises two issues:

- (a) First, there is no legal definition of a ‘pandemic’ even in the World Health Organization (WHO). Second, what happens when the situation is no longer a ‘pandemic’? Soon, COVID-19 may no longer be a pandemic (e.g. if the WHO DG suggests so in any statement). It may become ‘endemic’, where it is consistently present or an epidemic as an unexpected increase in the number of disease cases in a specific geographical area. Whatever the case may be, access challenges (i.e. availability and affordability) will continue. With this sentence, even with the stated duration, it may be argued that the ‘solution’ is no longer applicable when COVID-19 is no longer a pandemic. With such uncertainty, local manufacturers may not be motivated to invest in manufacturing vaccines.

(b) It imposes **necessity tests**, which have been difficult to satisfy at the WTO. For example, a study has found that governments fail them 61% of the time.² The necessity test is included in several other paragraphs as well.

2. Inclusion of eligibility criteria sets a very **negative and harmful precedent** in the WTO where developed countries have persistently tried to further categorise ‘developing countries’ with the aim of limiting the number of developing countries that may benefit from special and differential treatment in the WTO. **It is also a major step backwards for addressing global public health concerns** and a significant departure from the Doha Declaration on TRIPS and Public Health adopted at the height of the HIV/AIDS crisis that is applicable to all WTO Members. Even Article 31*bis* of TRIPS is applicable to all WTO Members, with countries having the option to self-opt out from using the mechanism for purposes of importing products, which would have been a better approach, but this approach has not been followed in the text.

3. In addition the eligibility criteria have other flaws:

- (i) Least Developed Countries (LDCs) are not explicitly included in the eligibility criteria. LDCs enjoy full exemption from the TRIPS obligations but this is no reason to exclude them. Unless they are explicitly included, eligible developing country Members may not be able to export to them under the solution. While some may argue that LDCs are included as ‘developing country Members’, it is important to note that the TRIPS Agreement explicitly differentiates between developing countries and LDCs.
- (ii) Non-WTO Members (about 28 developing countries³) are not explicitly included in the definition of eligible Members, and so may not be able to benefit from exports under the proposed solution in the text.
- (iii) The definition of ‘eligible Members’ may also affect some developing countries that have decided to forgo their status of benefiting from special and differential treatment as ‘developing country’ Members in WTO negotiations.

II. Paragraph 2

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.

Comment:

1. Article 1.1. of TRIPS read together with paragraph 4 of the Doha Declaration on TRIPS and Public Health suggests that WTO Members have flexibility on how they interpret and implement provisions of the TRIPS Agreement. Article 1.1 of the TRIPS Agreement states: ‘Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.’ Paragraph 4 of the Doha Declaration states: ‘We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.’

² https://www.citizen.org/wp-content/uploads/WTO-General-Exceptions-Paper_.pdf

³ There are 28 non-WTO Member LMICs (low- and middle-income countries), nine from the African continent: Algeria, Azerbaijan, Belarus, Bhutan, Bosnia and Herzegovina, Comoros, Equatorial Guinea, Eritrea, Ethiopia, Iran, Iraq, Kiribati, DPRK, Lebanon, Libya, Marshall Islands, Micronesia, Sao Tome and Principe, Serbia, Somalia, South Sudan, Sudan, Syria, Timor Leste, Turkmenistan, Tuvalu, and Uzbekistan. Source: <https://msfaccess.org/msf-comments-reported-draft-text-trips-waiver-negotiation>

Against this background, arguably WTO Members should generally have flexibility to determine the nature of instrument by which to operationalise Article 31. In any case, some Members may still find the clarification in paragraph 2 useful with respect to nature of instrument under Article 31.

However, limiting the clarification to COVID-19 and to 'Eligible Members' introduces significant legal uncertainty. Would this clarification not apply to situations beyond COVID-19? It would be odd to suggest so. And would non-eligible Members not be able to rely on this clarification? These are just some of the legal uncertainties that arise from the structure of the text. See Part C below on concluding considerations.

III. Paragraph 3 (a)

(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.**

Comment

(1) Article 31(a) says that non-voluntary authorisations 'shall be considered on its individual merits', i.e. each country decides on the grounds for compulsory licences, and assesses individual situations for granting authorisations. It does NOT detail information that should be included in the non-voluntary licence. On this countries have national discretion and full flexibility.

Paragraph 2 of the text does not waive Article 31(a). Instead it provides a partial clarification which, arguably, could be viewed as limiting the existing flexibilities contained in Article 31(a).

(2) Generally when using Article 31, countries have issued one non-voluntary authorisation to cover multiple products as well as multiple patents and patent holders. For instance, Malaysia issued a compulsory licence to cover four products and two patent holders while Indonesia issued one compulsory licence for seven products.⁴

But Article 31(a) only clarifies that one COVID-19 vaccine may have multiple patents (and presumably patent holders) and overriding those patents only requires one authorisation. **The text speaks of 'a COVID-19 vaccine', suggesting that it will require authorisation product by product.** While one could argue that there is no problem and a government can issue multiple authorisations, in reality, what we have seen is that requiring repeated government action is always a challenge. It involves many inter-ministerial consultations, is usually cumbersome and often fails to be realised. **The text does not waive Article 31(a). The partial clarification does not create the full freedom to operate for manufacturers of 'COVID-19 vaccines' as manufacturers will have to wait for the government to take action to issue an authorisation for each product and list all the patents (see below) before freedom to operate may be created.**

(3) Para 3(a) also includes a **necessity test** which is usually not required when using Article 31 of TRIPS and is a standard that is difficult to meet in the WTO as explained above. Under Article 31 **any** patent relating to COVID-19 may be subject to a non-voluntary authorisation.

(4) Para 3(a) also requires listing of 'all patents covered' and an 'eligible Member may update the authorization to include other patents'. **This requirement is TRIPS-plus and is going to be extremely problematic. The use of Article 31 or even Article 31bis has never required the listing of patents.** Further, it is not possible to comply with this requirement as often there is no visibility as to the patent landscape. In addition, if we consider the over 200 components that are involved in the development of mRNA vaccines,

⁴ <https://www.twn.my/title2/books/pdf/CompulsoryLicense.pdf>

and the multiple patent holders, it is almost impossible to know the full patent landscape. Even in the current context, it has taken more than a year to figure out the main patents involved in the development of mRNA vaccines and we still do not have the full picture. **Reference to the World Intellectual Property Organization (WIPO)'s patent landscaping report does not help to resolve the problem since the report itself says that it is unable to provide a full patent landscape.**⁵ For second-generation vaccines which will be needed soon, we really do not have an idea of the patent landscape and won't know anytime soon.

From the text it would seem that no manufacturer can benefit from the authorisation until a patent is listed. This will truly handicap the use of the authorisation and complicate the situation for manufacturers e.g. the mRNA Hub. There are several scenarios – First, the patent applications are unpublished for about 18 months from the filing date, and so neither the government nor patent office nor the manufacturer will know the patent landscape. Hence these cannot be included in the authorisation, although they may be relevant. And unless included the manufacturer will be reluctant to manufacture and enter the market for it may face the risk of patent infringement. Secondly, as mentioned, unless a patent is listed in the authorisation, it is not covered. Given the uncertainty with respect to the patent landscape, and the complex patenting environment for vaccines, one can never be sure that all patents have been listed, hence there is a risk of infringements. **As mentioned, this condition is extremely problematic. It is not required with respect to the use of Article 31 and creates a problematic precedent for using Article 31. Thus far most compulsory licences or government use authorisations that have been issued under Article 31 do not list any patents.**⁶

In addition, often it is also a matter of dispute as to which third party patents are 'necessary' for production and supply and may be affected. A case in point is the several patent infringement lawsuits taken out by Arbutus⁷ and more recently Alnylam Pharmaceuticals Inc⁸ against Moderna. What this shows is that it is never possible to list all patents and **whether or not a third party's patents are being infringed is often a matter of dispute.**

Some may argue that the paragraph allows updating of an authorisation to include other patents. In practical terms, this safeguard is inadequate. **The listing requirement will always leave the potential risk of infringement a possibility, which is likely to deter potential manufacturers.** The possibility that the government may update the authorisation may not be sufficient to alleviate that concern. After all, for a government to continuously update an authorisation, meaning inter-ministerial consultations, political pressure, etc. means that there is always a possibility the updating may not happen.

[For more information please see '*The proposed WTO agreement on intellectual property and COVID 19 vaccines should not require that authorizations of non-voluntary use of patents list all patents covered*'. <https://jamie-love.medium.com/the-wto-agreement-of-intellectual-property-and-covid-19-vaccines-should-not-require-that-c8e3a6fec169/>]

IV. Paragraph 3(b)

(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).

⁵ E.g. it is only patent filings to the end of September 2021, it is called 'Preliminary insights' and it says 'The current study should therefore be viewed as a first indication of patenting activity during the pandemic' and 'It should not be treated as complete information, while the report would need to be updated at a later stage to capture the full patenting activity which will be made publicly available in the meantime.' https://www.wipo.int/edocs/mdocs/mdocs/en/wipo_ip_covid_ge_22/publication_1075_e.pdf

⁶ See <https://www.twn.my/title2/books/pdf/CompulsoryLicense.pdf>

⁷ <https://www.reuters.com/business/healthcare-pharmaceuticals/arbutus-files-patent-infringement-lawsuit-against-moderna-2022-02-28/>

⁸ <https://www.bloombergquint.com/onweb/pfizer-moderna-sued-over-alleged-covid-19-patent-infringement>

Comment: This paragraph merely restates existing flexibility available under Article 31(b) of TRIPS. Article 31(b) of TRIPS is very clear that there is no need to undertake prior negotiations with the patent holder in situations of national emergency, other circumstances of extreme urgency and public non-commercial use.

V. Paragraph 3(c)

(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.

Comment: This paragraph waives the condition in Article 31(f) of TRIPS which requires that non-voluntary authorisations under Article 31 are subject to the condition that the authorisation is ‘predominantly for the supply of the domestic market’. With this condition, a country may still export provided most of the supply under the authorisation is for domestic consumption. Waiver of Article 31(f) enables the majority or all of the production under the non-voluntary authorisation to be exported.

Waiver of Article 31(f) is not novel. On 30 August 2003, a temporary waiver of Article 31(f) was agreed to by the General Council⁹ (WT/L/540) but the use of this decision was subject to many cumbersome procedures, and widely recognised as not being workable.¹⁰ The temporary waiver in the 30 August 2003 decision has been converted into a permanent mechanism as Article 31*bis* of TRIPS, which continues to be criticised as being unworkable for the many procedures attached to its use.

A waiver of Article 31(f) is only applicable in limited circumstances i.e. when most of the production is for export. **While the text waives Article 31(f) and it may seem that the procedures of Article 31*bis* are not applicable, the text does not explicitly clarify this.** In the absence of such clarification, legal uncertainty continues especially as national laws also subject waiver of Article 31(f) to the requirements of Article 31*bis* of TRIPS. In addition, **the usefulness of paragraph 3(c) is hindered by the other restrictions and TRIPS-plus requirements contained in the text. Without effectively addressing IP barriers to production, waiver of Article 31(f) has very little value for without production, there is nothing to export.**

VI. Paragraph 3(d)

(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.

Comment:

(1) **The condition in paragraph 3(d) is generally not applicable when issuing non-voluntary authorisation according to Article 31 of TRIPS, and hence it is an additional obligation that is TRIPS-plus.** A provision similar to paragraph 3(d) exists in the context of Article 31*bis* of TRIPS¹¹, but this Article is only used in the limited situations where waiver of Article 31(f) is used. To date, the Article 31*bis* mechanism has only ever been used once.

From a public health perspective and especially in the case of the COVID-19 pandemic, this TRIPS-plus requirement makes little sense. For example, if Country A were to import, it cannot re-export any unused vaccine doses or donate vaccine doses to any other eligible Member. It impacts South-South cooperation

⁹ https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm

¹⁰ See <https://msfaccess.org/never-expeditious-nor-solution-wto-august-30th-decision-unworkable>

¹¹ See para 3 and 4 of the Annex to Article 31*bis*

among developing countries to achieve equitable access. It also raises concerns as to consistency with para 3(c) which allows supply to international and regional initiatives (e.g. Covax), and may entail pooled procurement by a central hub, and re-exporting of vaccines. But then this would be inconsistent with paragraph 3(d).

(2) The condition may interfere with implementation of the parallel importation flexibility at the national level. Article 6 of TRIPS allows a country to import from any other country where a product is placed on the market at a cheaper price.

(3) In addition, paragraph 3(d) requires ‘All’ Members (even those not using any aspect of the solution) to implement ‘effective legal remedies’ to prevent the importation of COVID-19 vaccines using this system from being diverted to them. Hence the para imposes a further obligation even on those Members not using the solution, failing to take into account the resource constraints that developing countries may face.

VII. Paragraph 3(e)

(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.[3]

Footnote 3: This includes the Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies published by the WHO (WHO/TCM/2005.1)

Comment:

1. Paragraph (e) restates existing flexibility available in Article 31(h), whereby there is already significant national discretion for a country to determine the adequate remuneration. In some cases countries that have used Article 31 have set remuneration even at 0.5%.¹²

2. Paragraph 3(e) **does not contain any explicit provision that avoids payment of double remuneration, i.e. in situations where non-voluntary authorisation is issued under Article 31, for the same product, in the importing and exporting countries.** A precedent for such a provision that avoids payment of double remuneration does exist under Art. 31bis(2) which states: ‘*Where a compulsory licence is granted by an exporting Member under the system set out in this Article and the Annex to this Agreement, adequate remuneration pursuant to Article 31(h) shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall not apply in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.*’

VIII. Paragraph 4

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.

¹² <https://www.twn.my/title2/books/pdf/CompulsoryLicense.pdf>

Comment:

(1) The leaked text **does not waive Article 39** which concerns protection of undisclosed information although manufacturing know-how is often protected as undisclosed information and access to such information could accelerate the manufacture and regulatory approval of the product.

Paragraph 4 only offers a limited clarification with respect to Article 39.3 which generally concerns protection of test data submitted for purposes of obtaining regulatory approval. The paragraph does not address other trade secret/confidential information. Instead **paragraph 4 links clarification of Art.39.3 to issuance of authorisation under Art. 31 to overcome patent barriers**. This linking is erroneous for **Article 39 of TRIPS is a barrier independent of the patent status**. And the **entirety of Article 39 should be waived to facilitate access to information for COVID-19**, including Article 39.2 that provides persons in control of secret information with the right to prevent disclosure or unauthorised acquisition and use by third parties where it is ‘in a manner contrary to honest commercial practices’, and Article 39.3 that requires the regulatory authority to protect ‘undisclosed test data or other data’ submitted by the originator company for purposes of approving the marketing of the pharmaceutical product.

(2) The paragraph **also applies ‘necessity’ tests**, a standard which is difficult to prove in the WTO.

IX. Paragraph 5

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.[4]

Footnote 4: 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

Comment:

1. Para 5 requires that the granting of an authorisation under Article 31 be communicated to the TRIPS Council. **This is an additional TRIPS-plus condition, not required by Article 31**. Footnote 4 has been added but the use of **Article 31 has never required information about authorised entities, products, quantities and countries supplied to be provided to the TRIPS Council**.

Notification requirements are only part of the Article 31bis mechanism which only applies in the limited and very specific situation where Art. 31(f) is to be waived (i.e. when most of the production under the compulsory licence is exported). As mentioned above, this mechanism has only ever been used once. The information required by Footnote 4 is based on information required of exporting countries under Article 31bis (para 2(c) of the Annex).

2. **In paragraph 5 of the text it would apply every time Article 31 is used and it would apply to eligible Members** (i.e. to both importing and exporting countries) even if importing countries are unlikely to have the information required in footnote 4. So in this regard it is TRIPS-plus. In addition, while the para 5 and footnote 4 requirement may seem harmless, it will require repeated action/notification on the part of the government, reporting as soon as information is available, and open the government and local manufacturers’ actions to scrutiny and pressure from multinational pharmaceutical companies and developed countries.

3. Further, the footnote reinforces that the authorisation under Article 31 is on a product-by-product basis.

X. Paragraph 6

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.

Comment:

1. This paragraph would require the General Council (GC) to agree (e.g. by consensus) to extend duration, which is a rather difficult task.

2. The wording states that the GC will consider the ‘exceptional circumstances of the COVID-19 pandemic’. It would suggest that if COVID-19 is endemic, and not a pandemic, then the issue of extension does not even arise, effectively rendering the provision on extension ineffective.

XI. Paragraph 7

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.

Comment: This only safeguards against non-violation and situation complaints. It does not stop challenges under the usual WTO dispute settlement mechanism for failing to comply with TRIPS which is Art XXIII.1(a) (since Art 64 TRIPS says all of Art XXIII GATT applies to TRIPS¹³). The original TRIPS Waiver proposal did include ‘or through the WTO’s Dispute Settlement Mechanism’¹⁴ but this is not reflected in the leaked text.

XII. Paragraph 8

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.

Comment:

1. Paragraph 8 suggests that the text if agreed will be extended to therapeutics and diagnostics after no later than six months. **Delay in addressing access to therapeutics and diagnostics is unacceptable** as these are essential aspects of COVID-19 containment. **There is no guarantee that the WTO will adopt a decision in six months as it is notorious for missing deadlines** especially when it concerns development-oriented matters. For example, the WTO has missed the deadline in Art X GATS by 23 years¹⁵ while the Doha Round was supposed to be concluded by 1 January 2005 but still has not been concluded (so the deadline has been missed by 17 years so far).¹⁶

¹³ https://www.wto.org/english/docs_e/legal_e/31bis_trips_07_e.htm and https://www.wto.org/english/docs_e/legal_e/gatt47_02_e.htm#articleXXIII

¹⁴ <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True> and <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669R1.pdf&Open=True>

¹⁵ https://www.wto.org/english/docs_e/legal_e/26-gats_01_e.htm#articleX

¹⁶ https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm

2. On the other hand, **‘extension’ of the current flawed text to diagnostics and therapeutics would adversely affect local manufacturers and access more generally.** In the event that the TRIPS-plus conditions and eligibility criteria are applied to diagnostics and therapeutics, many manufacturers from developing countries could be affected and/or excluded for there is even greater capacity to manufacture and export such products. Access would be adversely impacted.

C. CONCLUDING CONSIDERATIONS

1. **The structure and design of the text introduces significant legal uncertainty.** It is unclear as to when the mechanism will be triggered, and the relationship between the text and existing TRIPS flexibilities as the text contains a mix of clarifications of existing flexibilities and a waiver of Article 31(f) of TRIPS. The text also does not clarify that it is ‘without prejudice to’ and does not affect existing TRIPS flexibilities.

2. As the text is time-limited, what is the impact on the clarifications – will they no longer be applicable following the expiry of the duration? Normally only waiver decisions are time-limited as they are issued pursuant to Article IX of the Marrakesh Agreement. Also, are the clarifications not applicable to non-eligible Members? It is important that any clarifications do not impose additional conditions or in any way restrict existing flexibilities.

3. The leaked text contains several elements such as TRIPS-plus conditions and eligibility criteria that exclude certain developing countries, which sets a very **harmful precedent for developing countries in the WTO** more generally and public health specifically.