The TRIPS Waiver Compromise Draft Text: A Preliminary Assessment

By:

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After nearly 18 months of negotiations, some progress has finally been made with regard to the request to waive certain provisions of the TRIPS Agreement in response to the covid-19 pandemic. This waiver request was initially tabled by India and South Africa during the meeting of the WTO's TRIPS Council in October 2020 and a revised proposal was subsequently submitted in May 2021. On the 15th of March 2022, after intensive quadrilateral negotiations between India, South Africa, the United States (US), and the European Union (EU), a compromise agreement was tentatively reached that will now be presented to other WTO members for their consideration and possible adoption.

While this outcome is being celebrated by the head of the WTO and the United States, the compromise draft text has managed to draw the ire of both those who support and oppose the waiver request. For the proponents of the waiver request, the compromise draft text is underwhelming to say the least (see here

and here). Meanwhile, opponents of the waiver request maintain the view that the compromise draft is a solution in search of a problem (see here and here). As this compromise draft text is likely to constitute the basis of any final waiver that may be adopted by the TRIPS Council, it is therefore pertinent to critically assess its key provisions. Nevertheless, prior to this assessment, it is helpful to provide a brief background as to what has happened between October 2020 when the initial waiver request was submitted and March 2022 when the compromise draft text was adopted by the states taking part in the quadrilateral negotiations.

As noted previously, India and South Africa submitted a revised waiver proposal in May 2021. Essentially, the revised proposal sought a waiver of TRIPS obligations relating to the application and enforcement of copyright, patent rights, industrial designs, and the protection of undisclosed information. These obligations were to be waived 'in relation to health products and technologies including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment or containment of COVID-19.' According to the revised proposal, the waiver should be in place for at least 3 years.

During the same period, although initially opposed to the waiver request, the US eventually expressed its support for the waiver proposal in May 2021. This support was however strictly limited to the production of vaccines. Meanwhile, in the following month, i.e. June 2021, the EU tabled its own counter-proposal at the TRIPS Council which essentially revolves around clarifying the rules relating to compulsory licensing in Articles 31 and 31bis of the TRIPS Agreement. This was the state of play at the TRIPS Council until the quadrilateral negotiations started and a tentative agreement was reached in March 2022. So, how helpful is the outcome of these quadrilateral negotiations in terms of the fight against covid-19?

To start with, it should be noted that the provisions of the compromise draft text are far from the demands contained in the revised waiver proposal. Indeed, one could plausibly argue that the text is probably closer to the positions of both the EU and the US in this regard. In other words, the compromise text merely provides some concessions regarding the rules

governing compulsory licensing contained in Article 31 of the TRIPS Agreement and its scope is limited (at least for now) to the production and supply of covid-19 vaccines. Nevertheless, when compared with the permanent waiver codified in Article 31bis of the TRIPS Agreement, one could say that the provisions of the compromise draft text are not as cumbersome and complex as the provisions contained in Article 31bis of the TRIPS Agreement.

In terms of aspects of the compromise draft text that may be considered as positive or gains for proponents of the waiver request, a few points are worth pointing out. Paragraph 2 of the text allows an 'eligible Member' to 'authorize the use of patented subject matter under Article 31 … through any instrument.' So, this could be done via executive orders, emergency decree, government use authorisations, and judicial or administrative orders. In this regard, the 'law of a Member' pursuant to Article 31 of the TRIPS Agreement is deemed as not limited to legislative acts for the purposes of the text. Paragraph 3(a) of the text permits an 'eligible Member' to 'issue a single authorization to use the subject matter of multiple patents necessary for the production or supply of a COVID-19 vaccine.' This single authorisation can equally be updated to add other patents. This obviates the need to issue separate compulsory licences for each patented subject matter needed for the production of a vaccine.

Perhaps, the most significant concession in the text can be found in paragraph 3(c) which permits an eligible member to 'waive the requirement of Article 31(f) that authorized use under Article 31 be predominantly to supply its domestic market'. Paragraph 3(c) goes on to provide that an eligible member '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.' This is a crucial departure from the strictures codified in Article 31bis of the TRIPS Agreement which was ironically originally intended to address the problems associated with Article 31(f) of the TRIPS Agreement especially for countries with no or insufficient domestic manufacturing capacity. Although the scope of the compromise text is currently limited to the production of vaccines, paragraph 3(c) of the compromise text is an implied admission of the practical difficulties associated with the use of Article 31bis of the TRIPS Agreement.

There seems to be no consensus yet regarding the duration of the compromise waiver as paragraph 6 which addresses this question contains both 3 and 5 years in square brackets. Nevertheless, this appears to suggest that the waiver could be in force for at least 3 years. Paragraph 6 further provides that the 'General Council may extend such a period taking into consideration the exceptional circumstances of the COVID-19 pandemic.' Another positive aspect of the compromise text can be found in paragraph 4 which provides that '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.' One could however contend that this merely confirms the existing flexibilities in Article 39.3 of the TRIPS Agreement, although it is certainly helpful to clarify this in the text of the compromise waiver.

An examination of what could be perceived as the negative aspects of the compromise text provides an insight as to why the proponents of the waiver proposal are disappointed with the outcome of the quadrilateral negotiations. Firstly, whereas the waiver proposal requests for the waiver of obligations relating to copyright, patents, industrial designs and the protection of undisclosed information, the compromise text only covers the compulsory licensing of patents.

Secondly, as noted previously, the scope of the compromise text is limited in paragraph 1 to the production and supply of covid-19 vaccines. Paragraph 8 of the compromise text provides that WTO members will decide on any extension to cover the production and distribution of covid-19 diagnostics and therapeutics within six months from the date that the compromise waiver is adopted. It is however not yet clear when WTO members will finally agree to adopt this compromise text. It is equally unclear why it was deemed necessary to postpone the decision on diagnostics and therapeutics to a later date.

Thirdly, the definition of an 'eligible Member' in the compromise waiver text is quite restrictive to say the least. Footnote 1 of the text defines an 'eligible Member' for the purpose of the text as 'any developing country Member that exported less than 10 percent of world exports of COVID-19 vaccine doses in 2021.' This automatically excludes developed countries from the scope of the compromise waiver. It further narrows down the number of developing countries that can effectively use the waiver to export vaccines to other

developing countries. Fourthly, while the waiver proposal requests for the waiver of all obligations relating to the protection of undisclosed data, the compromise waiver text only addresses Article 39.3 of the TRIPS Agreement in its paragraph 4.

It is perhaps too early to predict what a final waiver text may look like. Nevertheless, it is probably not too far-fetched to assume that the outcome of the quadrilateral negotiations between India, South Africa, the EU, and the US, i.e. the compromise waiver text, would constitute the basis of any final waiver decision. One could also question whether the use of quadrilateral negotiations that is open to only a few WTO members to resolve an issue that affects the entire globe is an optimal approach. Ultimately, however, one has to wait and see the reaction of the other WTO members to the compromise waiver text. It will be up to these remaining WTO members to decide if they consider this text to be a promising text or a compromising text.

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