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EU's "Waiver" of Some Compulsory Licensing Requirements Wouldn't Even Scratch the Surface of the COVID-19 Health Products' Inequitable Access Crisis

Although 140 countries support a temporary waiver of World Trade Organization's (WTO) various rules on intellectual property that pose significant barriers for widespread production of COVID-19 health products, the European Union (EU) is united with pharmaceutical corporations in trying to derail agreement on the waiver.

The latest EU ploy is to pretend that it has a "counterproposal" to the TRIPS waiver. In reality, as the analysis below shows, the EU is trying to include sly uses of the word "waiver" to make it seem like it is offering something new, when in fact it is basically restating existing WTO flexibilities that almost every WTO member has concluded will not help us make our way out of this pandemic. And, the offer consists in insufficiently lifting certain conditions to issue compulsory licenses, while adding some more unnecessary requirements that would continue obstructing governments' ability to facilitate greater production of COVID-19 vaccines, treatments and diagnostics. This is the reason why the rest of the world supports a broad and comprehensive waiver of the WTO Agreement on Trade-Related Aspects of Intellectual Property (TRIPS).

Here is a transcription of the leaked EU text with our analysis.

Ideas on the Points of Convergence on the TRIPS Issues for Discussion

Objective
Given the extraordinary circumstances of the COVID-19 pandemic and the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector face with access to COVID-19 vaccines, it is important to ensure that the intellectual property system plays an enabling role in deploying existing capacity or creating new capacity for the production of COVID-19 vaccines and medicines.

In that regard, ensuring that all WTO Members can make effective use of the TRIPS Agreement is crucial and consequently a waiver with respect to certain requirements related to granting compulsory licenses for the production and export of COVID-related pharmaceutical products, allowing for their rapid supplies, could be considered. The objective would be to lift or simplify the key requirements related to exporting COVID-related pharmaceutical products under a compulsory license to the Members in need.

Analysis: It is not a waiver as South Africa and India initially proposed, it is only a "waiver" with respect to only certain (not all) requirements related to a compulsory license (CL). The EU wants to give the perception that it is agreeing to a waiver of some requirements of CL but in effect it is imposing more conditions.

The objective clearly highlights that it is not about patents/trade secrets/copyright or industrial designs, it is "to lift or simplify the key requirements related to exporting COVID-related pharmaceutical products under a compulsory license to the Members in need." It is so restrictive that if adopted would make the waiver ineffective.

Form
Decision of the Ministerial Conference in a waiver format, based on the precedent of a waiver adopted in the wake of the HIV/AIDS crisis in 2003, i.e. Decision of 30 August 2003 on the implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (WT/L/540).

Analysis: The EU proposal has moved away from a declaration to a decision on a waiver.

Product Scope
Pharmaceutical products, i.e. vaccines, diagnostics, therapeutics against COVID-19

Analysis: No specific mention that scope also extends to the materials and components as well as methods and means for the manufacture of vaccines, diagnostics and therapeutics against COVID-19 as stated in the TRIPS waiver proposal of the co-sponsors.

Scope of the waiver-TRIPS provisions covered
Article 31(b) – prior negotiations with right-holders – to be waived.
Article 31(f) – requirement to supply predominantly the domestic market – to be waived.
Article 31bis – mechanism for compulsory licenses for exports – to be waived, with conditions, e.g. on eligible importing Members, for discussion.
Article 31(h) – remuneration – to be waived and replaced by specific rules on remuneration to support deliveries of the products at discounted prices.
Article 28(1), 39 and Part III of the TRIPS Agreement – outside the scope of the waiver as the inclusion of these provisions is not required for the objective described above and would not be justified or proportionate.

Analysis: The EU is proposing that the scope of the waiver be limited to CL but even this is subject to further conditions.

Article 31bis is the mechanism that was set up to export to countries with insufficient manufacturing capacity but its onerous conditions have left it unworkable. The EU is proposing its partial CL waiver but subject to further conditions. Hence it would appear that *in effect* Art.31bis is not being waived. Further EU is planning to propose new conditions which will make the waiver difficult to use.

-On Art.31(h) of TRIPS requires payment of adequate remuneration at the discretion of member state when CL is being issued. While the EU is proposing to waive this Article, it is also proposing to replace it with specific rules on remuneration. Hence, it appears that rather than waiving payment of remuneration, the EU is limiting the current discretion that WTO Members have with respect to determining adequate remuneration under Article 31(h).

The EU is proposing not to waive Article 28(1), Article 39 and Part III of the TRIPS Agreement arguing that the waiver of these provisions is not justified.

The whole purpose of the TRIPS waiver proposal is to waive provisions that grant exclusive rights and enforcement rights to the patent holder as well to waive obligations with regards to trade secret protection. The EU's proposal does not do that.

It does not waive Art. 28(1) of TRIPS that grants exclusive rights.

It does not waive Art. 39 of TRIPS on "Protection of Undisclosed Information" that is very relevant to manufacturing of vaccines, diagnostics and therapeutics. For instance, know-how is often protected as trade secret.

It does not include enforcement part of the TRIPS Agreement i.e. Part III of TRIPS.

Other aspects to be considered

- **Length:** 3 years with a possibility of further extension if the General Council so decides (e.g. if the circumstances of the pandemic persist).

Analysis: The length proposed by the EU creates an uncertain environment as the extension is uncertain and subject to further decision. Hence, it will also affect the prevention, treatment and containment of COVID-19. In addition, it creates significant uncertainty for manufacturers.

In IP/C/W/669/Rev.1, the co-sponsors proposed that "This waiver shall be in force for at least 3 years from the date of this decision. The General Council shall, thereafter, review the existence of the exceptional circumstances justifying the waiver, and if such circumstances cease to exist, the General Council shall determine the date of termination of the waiver."

The co-sponsors argued that there are many unknowns and uncertainties as the world is dealing with a novel pathogen. However, the co-sponsors proposal is not accepted by the EU.

- **Transparency:** Notification to the WTO of the measures taken and exports made.

Analysis: This element suggests that additional conditions will be attached to the waiver by the EU.