Technical Note
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Comments on the Patent Listing Requirements in the Draft Text of the TRIPS Waiver Negotiation

Paragraph 3(a) of the reported draft text[a] of the discussion outcome between the EU, US, India and South Africa reads:

> *"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."*

Comments:
There is no restriction on how a WTO member implements Article 31(a) of the TRIPS Agreement which requires a compulsory license to be considered based on 'individual merits'. There is also no requirement that a compulsory license be issued on a product-by-product basis. The draft text restates what is already possible (e.g. single authorisation to cover multiple patents); it also imposes some TRIPS-plus requirements (e.g. listing of all patents) that go against the objectives of flexibilities contained in Article 31(a).

First, the patent listing requirement goes against the negotiation history and objectives of Article 31(a).

The draft text misrepresents the meaning of 'individual merits' under Article 31(a) of TRIPS agreement, and risks diluting existing flexibilities enjoyed by WTO members. According to literature documenting the negotiation history of the TRIPS Agreement,[1] the phrase 'individual merits' under Article 31(a) refers to the flexibility afforded to members to freely define the grounds on which a compulsory license may be granted, and to use their discretion to handle each compulsory license based on an individual situation. 'Individual merits' under Article 31(a) was therefore never meant to refer to the need to assess individual patents in the grant of a compulsory license.

[a] http://freepdfhosting.com/4d79fc6c70.pdf

It has been documented that during negotiations for the TRIPS Agreement, the US and India settled the meaning of 'individual merits' under Article 31(a) to affirm the scope of national discretion on individual cases and the freedom to define the grounds for issuing a compulsory license. It is therefore surprising that a restrictive interpretation of this phrase has emerged from discussions that US and India negotiators were parties to.

Below are the key extracts from the negotiation history that demonstrate the objectives and meaning of 'individual merits' under Article 31(a):

> *"This implied that, while automatic or across the-board grant of compulsory licences would violate Article 31(a), selective and judicious grant of compulsory licences would not fall foul of it. The grounds for the grant of a compulsory licence were not conditioned or circumscribed by that Article and were left to the judgment of the authority granting the licence, who had only to show that it was justified by the merits of the case at hand."*[2]

> *"The US delegation introduced the text of what is now in TRIPS Article 31(a), that each case of such use would be considered on its "individual merits". This was meant to tighten the provision for other countries, while allowing US government agents and contractors to use patents for public non-commercial purposes within the wording of what is now TRIPS Article 31(b)."*[1]

Second, there is no prescribed method of making a compulsory license decision nor any further indication of the level of details to include in the decision.

Neither Article 31(a) specifically nor the TRIPS Agreement in general require a particular format for a compulsory license decision. WTO members can issue one compulsory license authorisation to cover multiple products and implicitly cover multiple patents. It is redundant to repeat what is already possible.

Examples:
Malaysia issued one compulsory license in 2003 covering four antiretroviral medicines under one authorisation. Indonesia issued one compulsory license in 2012 covering seven medicines at once. A few other countries, such as Mozambique and Ghana, only mentioned the authorisation of production and importation of generic medicines in their compulsory license decisions.[3]

Third, requesting authorisations to list all patents covered on vaccines and underlying technologies is a TRIPS-plus requirement.

There is no obligation in the TRIPS Agreement requiring members to list all relevant patents when issuing a compulsory license under Article 31. In practice, when countries have issued compulsory licenses, they have rarely provided the list of patents concerned. Part of the reason for this is because one medical product might be subject to many patents due to the proliferation of patenting by pharmaceutical corporations. For vaccines, it can be even more complex to identity and specify all relevant patents.

Example:
Out of 12 countries whose compulsory license decisions are available publicly, only Indonesia provided an indicative list of patents concerning the seven medicines under a compulsory license issued in 2012. India provided one patent number when issuing the compulsory license.[3]

It is also important to note that the patent portfolio related to vaccines is substantively different from those concerning small-molecule chemical medicines.

Research has revealed that patents can be applied for and be granted at nearly all stages across the product development, production and delivery cycle.[4] For instance, for COVID-19 mRNA vaccines, research has identified a complex network of patents and licenses involving multiple patent-holding entities in different countries.[5] Focusing on the patent portfolio held by a single supplier might not be sufficient. Therefore, it would be extremely difficult to justify what is 'necessary' from among the large number of vaccine patents when the legal status and ownership of patents on vaccine technologies may evolve and change frequently. Requiring WTO members to do exhaustive research on the patent landscape in order to list all 'necessary' patents when issuing a compulsory license is contrary to the claimed objective of seeking a simplified processes to support expeditious and immediate actions.

In addition, the COVID-19 pandemic has presented unprecedented challenges with a constantly mutating virus and an ever-changing medical technology landscape.

In such an environment, it is therefore particularly problematic to require that any implementing instrument list all patents, given new patents are being filed. Many of these patent applications may remain unpublished in national patent offices, and as such, they are both unknown and pending. To suggest that WTO members should resort to World Intellectual Property Organization's (WIPO) patent landscape assistant is also ill-informed as WIPO normally does not have timely and sufficient access to information on filing and legal status in national patent offices, particularly those in developing countries.

These problems are compounded by the need to investigate and list all patented components and underlying technologies of a final vaccine, some of which are reported to have as many as 280 components. These will require needless and expensive efforts to scour the patent and pending patent landscape and to continually update previously filed instruments.

In summary, Paragraph 3(a) introduces a flexibility that is redundant and duplicative; it also adds a TRIPS-plus requirement for patent listing when WTO members issue a compulsory license. It is a restrictive clarification that risks diluting the existing flexibilities under Article 31(a).

REFERENCES

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ADDITIONAL SOURCE

Love J. 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. [Online]. 2022 Mar 18 [Cited 2022 Mar 24]. Available at: https://jamie-love.medium.com/the-wto-agreement-of-intellectual-property-and-covid-19-vaccines-should-not-require-that-c8e3a6fec169