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EU Proposals regarding Article 31*bis* of the TRIPS Agreement in the Context of the COVID-19 Pandemic

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Proposal by the EU

The proposal by the European Union (EU) for a declaration on the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and public health in the context of a pandemic makes some suggestions with regards to Article 31*bis* that are minor and do not address the main limitations of the system. As it focuses on TRIPS compulsory license provisions, it does not address the obstacles that may emerge from other intellectual property rights, such as trade secrets and regulatory test data.

The proposal to clarify that the circumstances of a pandemic fulfill the requirement of a national emergency as a ground to waive prior negotiations with the patent holder, does not imply a substantial flexibilization of the system created by Article 31*bis*, as such a possibility already exists (albeit it may be understood as applicable in relation to the importing country only).

Similarly, governments granting a compulsory license can, under the current TRIPS provisions, determine the remuneration for patent holders taking into account the economic value of the authorization, including in a way that ensures that the prices of the products supplied under the license are affordable.

The EU proposes that the exporting member using the system may provide in a single notification a list of all countries to which vaccines and medicines are to be supplied by the exporting member directly or through international joint initiatives (e.g. the COVAX Facility). This proposed solution is already available under paragraph 2 (c) of the Annex to the TRIPS Agreement, which lays down the procedure for using the system under Article 31*bis*. It allows an exporting country to issue a notification to the TRIPS Council which could include multiple countries to which such products are meant to be exported in specified quantities.

Instead, the major problems of the system which dissuade generic manufacturers and suppliers to use the system are not addressed in the proposal.

Limitations of Article 31 *bis*

Article 31*bis* and the accompanying Annex to the TRIPS Agreement establish a "special compulsory license" mech-

Abstract

This Policy Brief presents an analysis of the proposal by the European Union (EU) with regards to Article 31*bis* of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), as part of a Declaration on the TRIPS Agreement and Public Health in the circumstances of a pandemic. It discusses the EU's proposed clarifications, why Article31*bis* does not provide an effective solution to promote access to pharmaceutical products and possible options.

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Ce Rapport sur les Politiques présente une analyse de la proposition de l'Union européenne (UE) concernant l'article 31bis de l'Accord sur les aspects des droits de propriété intellectuelle qui touchent au commerce (ADPIC), dans le cadre d'une Déclaration sur l'Accord sur les ADPIC et la santé publique dans les circonstances de une pandémie. Il examine les clarifications proposées par l'UE, les raisons pour lesquelles l'article 31bis ne fournit pas une solution efficace pour promouvoir l'accès aux produits pharmaœutiques, et les options possibles.

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Este Informe sobre Políticas presenta un análisis de la propuesta de la Unión Europea (UE) con respecto al artículo 31bis del Acuerdo sobre los Aspectos de los Derechos de Propiedad Intelectual relacionados con el Comercio (ADPIC), como parte de una Declaración sobre el Acuerdo sobre los ADPIC y la Salud Pública en las circunstancias de una pandemia. Analiza las aclaraciones propuestas por la UE, las razones por las que el artículo 31bis no proporciona una solución eficaz para promover el acceso a los productos farmacéuticos, así como las posibles opciones.

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anism under which a World Trade Organization (WTO) Member could issue a compulsory license for the purpose of exporting pharmaceutical products produced under such a license to any least developed country (LDC) or any other country with insufficient or no manufacturing capacity. However, the mechanism has proved to be very cumbersome to use as it contains a number of administrative pre-requisites and layers of procedure which have to be complied with before a pharmaceutical product can be exported under the system. These requirements have discouraged the use of the system and have made it inadequate to respond speedily in situations like the global COVID-19 pandemic, where vaccines and therapeutics are required to be manufactured and supplied rapidly and on a mass scale, the like of which the world has never experienced before.

First, a potential importing country must notify the TRIPS Council specifying the names and expected quantities of the pharmaceutical products needed. Second, the importing country, other than an LDC, must confirm that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the products in question. Third, if the product is under patent protection in its territory, the importing country must confirm to the TRIPS Council that it has granted or intends to grant a compulsory license. Fourth, the compulsory license granted by the exporting Member must limit manufacturing under such license only to the amount necessary to meet the needs of the eligible importing members, and the entirety of the production must be exported to the Members who notified importation under the system to the TRIPS Council. Fifth, such products must be clearly identified through specific labeling or marking as being produced under the system, and the products must be distinguished through special packaging or coloring/shape of the product, insofar as such distinction is feasible and do not have a significant impact on price. Sixth, before the shipment of the products exported under the system, the supplier must post information on its website about the quantities supplied to each destination, and the distinguishing features of the products. Seventh, the exporting Member must notify the TRIPS Council about the grant of a compulsory license under the system for purposes of exportation and the terms of the license, including the name and address of the licensee, the product(s) for which the license has been granted, the quantity(ies) for which the license has been granted, the country(ies) to which the products are to be supplied and the duration of the license. Eighth, importing Members are required to take measures to prevent re-exportation of the products imported under the system.

Empirical evidence demonstrates that the system is so cumbersome that the generic pharmaceutical industry has considered that the system is unworkable. Indeed, to use the system, potential generic or biosimilar manufacturers would have to make considerable investment of resources and time to develop a limited quantity of products (in accordance with the quantities specified in the compulsory license of the exporting country and the notification of quantities required by the importing country). Moreover, even if they venture into manufacturing of such products under the system by making significant investment of resources and time, they would always have to confront the risk of the patent owner lowering the price or donating the required medicines or vaccines to the country in need, and thus jeopardizing their entire investment. The products developed by them under the system cannot be redirected to supplying any other market should such an event occur.[1]

Another requirement under the system is that before issuing a compulsory license the exporting country must try to negotiate a voluntary license from the patent holder. Though this requirement does not apply in situations of a public health emergency, such as the COVID-19 pandemic, a compulsory license can always be challenged before a court of law through strategic litigation (including the request of an interim injunction)[2] and the implementation of the compulsory license can be frustrated. Moreover, in countries where test data are protected under the so-called 'data exclusivity' regime, an additional hurdle may be created by the marketing approval of the product to be imported under a granted compulsory license.[3]

Thus, "[w]hatever humanitarian reasons may underpin a country's demand of a given drug, nothing in the adopted system compels the patent owner to supply the required drugs or to grant a voluntary license to a potential exporter. The patent owner may just passively watch how the country in need and a potential supplier strive to fulfil the conditions imposed by the WTO Decision (now article 31*bis*), while people remain without treatment."[4]

Options for a better system

In view of the ineffectiveness of the system under Article 31*bis,* the need for a better system has been recognized even before the current pandemic. Notably, the report of the United Nations Secretary-Generals' High-Level Panel on Access to Medicines in 2016 had specifically recommended that "WTO Members should revise the paragraph 6 decision in order to find a solution that enables a swift and expedient export of pharmaceutical products produced under compulsory license. WTO Members should, as necessary, adopt a waiver and permanent revision of the TRIPS Agreement to enable this reform."[5] Indeed, it is critical to explore options for improving the system.

Possible options include:

a) Interpreting Article 30 of the TRIPS Agreement (exceptions to patent rights) so as to allow for the manufacture for export of pharmaceuticals. In accordance with academic studies, such an interpretation would be TRIPS-consistent.[6] Interestingly, the EU introduced in 2019 the so-called 'manufacturing waiver' which provides for an exception in relation to the manufacture, stockpiling and export of medicines during the extended term of patent protection conferred under Supple-

mentary Protection Certificates (SPCs). The SPC medicinal regulation, as modified by Regulation (EU) 2019/933, allows EU-based companies to manufacture a generic version or biosimilar of an SPC-protected medicine during the term of the certificate, if done either for the purpose of exporting to a non-EU market, or for stockpiling during the final 6 months of an SPC ahead of entry into the EU market.[7]

b) Deleting Article 31(f) of the TRIPS Agreement which restricts the grant of compulsory licenses predominantly for domestic purposes. If this amendment were introduced, the exception incorporated through Article 31*bis* would become unnecessary in this regard.

c) Removing the restrictive conditions under Article 31*bis* and the Annex to the TRIPS Agreement.[8]

While the first option could be implemented through national interpretations (and eventually facilitated by an authoritative interpretation under Article IX.2 of the Agreement Establishing the WTO), the referred to amendments would require thorough deliberation and time for negotiation. In comparison, the adoption of a waiver for selected provisions of the TRIPS Agreement for enabling scaled-up manufacturing and supply of health technologies for COVID-19 would provide a faster response.

Endnotes:

[1] Carlos M. Correa, "Will the Amendment to the TRIPS Agreement Enhance Access to Medicines?", Policy Brief, No. 57 (Geneva, South Centre, 2019), p. 4. 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.

[2] Ibid.

[3] Ibid, p. 5.

[4] Ibid.

[5] *Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines: Promoting innovation and access to health technologies* (New York, 2016). Available from https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf.

[6] Xavier Seuba, Luis Mariano Genovesi and Pedro Roffe, "A Manufacturing for Export Exception", in *Contemporary Issues in Pharmaceutical Patent Law: Setting the Framework and Exploring Policy Options*, Bryan Mercurio and Daria Kim, eds. (Routledge, 2017). pp. 161-185. See also Carlos Correa and Juan Correa, "Manufacturing For Export: A TRIPS Consistent Pro-Competitive Exception" (Springer, forthcoming 2021).

[7] Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products, Official Journal of the European Union, L 153/1, published 11 June 2019.

[8] Correa, "Will the Amendment to the TRIPS Agreement Enhance Access to Medicines?", p. 7.

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