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How Should the WHO Pandemic Treaty Negotiations Tackle Intellectual Property?

By Viviana Muñoz Tellez

The WHO pandemic instrument should commit the Parties to limit the exclusionary effects that government-granted patents and other IPRs may have during pandemics in support of rapid diffusion of new vaccines, diagnostics, medicines and other tools and facilitate collaboration and freedom to operate. The current draft text of Article 11 would not make any change to the status quo.

L'instrument de l'OMS sur les pandémies devrait engager les parties à limiter les effets d'exclusion que les brevets accordés par les gouvernements et d'autres DPI peuvent avoir pendant les pandémies afin de soutenir la diffusion rapide de nouveaux vaccins, diagnostics, médicaments et autres outils et de faciliter la collaboration et la liberté d'action. Le projet de texte actuel de l'article 11 n'apporterait aucun changement au statu quo.

El instrumento de la OMS sobre pandemias debería comprometer a las Partes a limitar los efectos excluyentes que las patentes concedidas por los gobiernos y otros DPI puedan tener durante las pandemias para apoyar la rápida difusión de nuevas vacunas, diagnósticos, medicamentos y otras herramientas, y facilitar la colaboración y la libertad para operar. El actual proyecto de texto del artículo 11 no introduciría ningún cambio en el statu quo.

The World Health Organization (WHO) Intergovernmental Negotiating Body (INB) agreed on 18th February 2024 to provide “relevant stakeholders” the current texts of the proposals for the negotiating text of the WHO Pandemic agreement. The texts reflect the work of the drafting group and subgroups.

Article 11 would cover issues related to “technology transfer”. One of the aspects being considered is whether in situations of emergency, such as a pandemic, certain requirements on the protection or enforcement of intellectual property rights (IPRs) can be temporarily lifted.

The transnational pharmaceutical industry is adamantly opposed to the incorporation of any reference to IPRs arguing that it could undermine the protection of IPRs that helps it to reap huge profits from vaccine and medicine sales, including during the COVID-19 pandemic.

The current proposal for the negotiating text shared on Article 11.5 does not require or even commit the Parties to any best endeavor to temporarily limit the enforcement of patents or other intellectual property rights.

It is perplexing that after the protracted and faulty negotiation on a waiver of IPRs in the World Trade Organization (WTO) to advance timely development of and access to pandemic related products,[1] and after almost two years since the start of INB discussions, the Article 11.5 text currently does not provide for more options.

The current text as proposed would not make any change to the status quo.

5. The Parties ~~reaffirm~~ recognize that WTO Members have the right to use to the full, the flexibilities inherent in the TRIPS Agreement, the Doha Declaration on the TRIPS Agreement and Public Health of

2001 and subsequent relevant decisions* which provide flexibility to protect public health including in future pandemics, since the TRIPS Agreement does not and should not prevent members from taking measures to protect public health and that it 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.

* Reference is made here to what is known as Paragraph 6 System of the Declaration which was an amendment to the Agreement adopted by the WTO General Council on 30 August 2003, that became permanent by the GC Decision on 6 December 2005 and entered into force on 23 January 2017.

6. Each Party shall review and update as necessary its national legislation in order to ensure the implementation of such flexibilities in a timely and effective manner.

[1] See Nirmalya Syam and Muhammad Zaheer Abbas, *TRIPS Waiver Decision for Equitable Access to Medical Countermeasures in the Pandemic: COVID-19 Diagnostics and Therapeutics*, Research Paper, No. 191 (Geneva, South Centre, 2024); Carlos Correa and Nirmalya Syam, *The WTO TRIPS Decision on COVID-19 Vaccines: What is Needed to Implement it?*, Research Paper, No. 169 (Geneva, South Centre, 2022).

A glaring omission in the note to the “subsequent relevant decisions” in Article 11.5 is the absence of any reference to the WTO Ministerial Decision in 2022 concerning the waiver and clarification of certain provisions of Article 31 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in relation to COVID-19 vaccines.

It is important for countries to make full use of the TRIPS flexibilities available to support public health, particularly during emergencies, and to revise their current policies and legislative and other measures to ensure that they can make full and timely use of these. Such flexibilities include: 1) applying rigorous standards of patentability criteria, use of the compulsory license system, including government use for noncommercial purposes, as provided for in Article 31 of the WTO TRIPS Agreement, 2) introducing exceptions under patent law for manufacture and export consistent with a permissible interpretation of Article 30 of the TRIPS Agreement, among others.[2] The South Centre recognizes this and has a standing program of technical assistance for developing countries in this area. However, while referring to such flexibilities is pertinent, there is currently no restriction for WTO Members to make use thereof so as to require a new norm to be created as part of the pandemic instrument. **The main challenge is rather dealing with the urgency of facilitating access to technologies during a pandemic if inhibited by IPRs.**

The proposed obligation in Article 11.6 for countries to review and update “such flexibilities” refers to the flexibilities ‘inherent’ in the TRIPS Agreement. This could be helpful for the **WHO to increase monitoring of the implementation of TRIPS flexibilities for public health** based on country reports on implementation of this obligation.

One of the arguments made against reference to IPRs in the pandemic treaty is that as there is an international instrument regulating IPRs under the WTO, the WHO does not have competence. That is disingenuous, and there is no limitation for the WHO to address aspects relating to the exercise of IPRs, particularly if it is not in contradiction of existing multilateral instruments such as the WTO TRIPS Agreement.[3] Mention to the WTO or its TRIPS Agreement is unnecessary. Subsequent international instruments regularly include clauses on mutual supportiveness with existing international instruments, and any tensions that may arise are to be resolved in the implementation through national legislation.

What the WHO pandemic instrument can, and should do, is commit Parties to limit the exclusionary effects that government-granted patents and other IPRs may have during pandemics in support of rapid diffusion of new vaccines, diagnostics, medicines and other tools and facilitate collaboration and freedom to operate. The pandemic instrument can create an obligation for Parties **to suspend the enforcement of IPRs that may create barriers to manufacture and supply pandemic related products** and not to challenge those Parties that adopt this measure, which would only prevent the right holder to take action against any potential infringement during pandemics without constraining the grant or the procedures to obtain IPRs protection.

[2] For further description of TRIPS flexibilities for public health, see “Public Health Related Flexibilities in the TRIPS Agreement”. The TRIPS Agreement Article 73 Security Exceptions can also be included. See Frederick Abbott, *The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic*, Research Paper, No. 116 (Geneva, South Centre, 2020).

[3] See Ellen ‘t Hoen, “WHO is an essential forum for debates on intellectual property and public health”, *Medicines Law & Policy*, November 20, 2023.

Many WHO Members are Parties not only to the WTO, but also to various regional and bilateral agreements covering trade, intellectual property and investment, that may pose barriers for the temporary suspension of the enforcement of IPRs. To address this situation, Article 11 should also provide that **Parties shall not challenge the measures taken by another Party to suspend the enforcement of IPRs, based on international obligations that the Party suspending the obligation may have.**

The INB drafting subgroup on Article 11 should urgently invite discussion from experts, including from the South Centre, to discuss with negotiators over the implications of potential approaches to IPRs.

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