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Proposal for a new Article 11*bis* in the WHO Pandemic Accord: a Pandemic Technology Transfer Mechanism

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The COVID-19 pandemic demonstrates the failure of voluntary mechanisms during global emergencies and exemplifies the need for effective involuntary technology transfer tools. The WHO Pandemic Accord offers an opportunity to provide an effective mechanism to build upon existing TRIPS flexibilities in the specific pandemic context. We propose a new provision (Article 11*bis*) that outlines a mechanism on cross-border procedure of non-voluntary technology transfer during a pandemic. This procedure could be invoked in a pandemic scenario in which voluntary technology transfer mechanisms have failed to provide sufficient supplies of a needed pandemic product.

La pandémie de COVID-19 démontre l'échec des mécanismes volontaires dans les situations d'urgence mondiales et illustre la nécessité de disposer d'outils efficaces de transfert de technologie involontaire. L'accord de l'OMS sur les pandémies offre la possibilité de mettre en place un mécanisme efficace pour exploiter les flexibilités existantes de l'accord sur les ADPIC dans le contexte spécifique des pandémies. Nous proposons une nouvelle disposition (article 11 bis) qui décrit un mécanisme de procédure transfrontalière de transfert de technologie non volontaire en cas de pandémie. Cette procédure pourrait être invoquée dans un scénario de pandémie dans lequel les mécanismes de transfert volontaire de technologie n'ont pas réussi à fournir des quantités suffisantes d'un produit essentiel à la lutte contre la pandémie.

La pandemia de COVID-19 demuestra el fracaso de los mecanismos voluntarios durante las emergencias mundiales y ejemplifica la necesidad de herramientas eficaces de transferencia de tecnología involuntaria. El Acuerdo de Pandemias de la OMS ofrece la oportunidad de proporcionar un mecanismo efectivo que se basa en las flexibilidades existentes de los ADPIC en el contexto específico de una pandemia. Proponemos una nueva disposición (Artículo 11bis) que describe un mecanismo sobre el procedimiento transfronterizo de transferencia de tecnología no voluntaria durante una pandemia. Este procedimiento podría invocarse en un escenario pandémico en el que los mecanismos voluntarios de transferencia de tecnología no hayan podido proporcionar suficientes suministros de un producto pandémico necesario.

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It is acknowledged that intellectual property (IP) barriers played a role in delaying access to life-saving technologies, such as vaccines, during the COVID-19 pandemic.[1]While the voluntary sharing of vaccine technologies allowed the transfer of certain vaccine technologies, such as Corbevax and the Oxford-AstraZeneca vaccine, to a small number of producers, such voluntary sharing was insufficient. In 2021, at the apex of the pandemic, private companies – vaccine technology holders – were simply unable to produce enough vaccines to inoculate the majority of the world population within an optimal period to contain and combat the pandemic. Despite production levels falling short, pharmaceutical companies rejected the voluntary sharing of COVID-19 vaccine technologies with the World Health Organization (WHO) COVID-19 Technology Access Pool (C-TAP) initiative and/or the WHO mRNA hub, and refused licensing requests from several other manufacturers with production capacities.[2] The lack of voluntary technology transfer made it difficult to swiftly scale up vaccine production and hindered efforts to combat the spread and mutation of the virus. This led to lives being lost in low- and middle-income countries (LMICs) – lives that could have been saved if the vaccine technologies had been shared rapidly and more widely.[3] This demonstrates the failure of voluntary mechanisms during global emergencies and exemplifies the need for effective involuntary technology transfer tools.

The currently available compulsory licensing mechanisms in the Agreement on Trade-related Aspects of Intellectual Property Rights (the TRIPS Agreement) are also unworkable to facilitate the non-voluntary transfer of complex biologic products, such as vaccines.[4] While the TRIPS Agreement allows compulsory licensing of a patent protecting any medical product, relying solely on this mechanism would be insufficient for vaccine production. This is because the production of biologics involves highly complex processes, requiring tailored facilities, specific equipment, and, above all, specialist knowledge. Access to this knowledge is vital, otherwise it may take a lot of time and effort for new manufacturers to develop the knowledge themselves, delaying the increase in the distributed production of vaccines. Key vaccine knowledge is typically protected in part by patents, and in part by privately held undisclosed information (trade secrets). However, the currently available compulsory licensing mechanism in the TRIPS Agreement, while allowing compulsory licensing of one or more patents, does not contain a provision to compel pharmaceutical companies to share key trade secrets with alternative manufacturers.

As a result, during the COVID-19 pandemic, knowledge critical to facilitating the rapid diversification and scaling up of vaccine production was kept secret by pharmaceutical companies; whereas, had it been shared through open technology transfer, this would have facilitated more widespread and distributed production of vaccines worldwide, assisting in attaining widespread global coverage.[5]

[1] O. Gurgula and L. McDonagh, "Access Denied: the Role of Trade Secrets in Preventing Global Equitable Access to COVID-19 Tools", (STOPAIDS & JUST TREATMENT, 2023). Available from https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4484507, accessed 12 March 2024.
[2] S. Thambisetty, A. McMahon, L. McDonagh, H.Y. Kang and G. Dutfield, "Addressing vaccine inequity during the COVID-19 pandemic: the TRIPS intellectual property waiver proposal and beyond", *Cambridge Law Journal*, Vol. 81 (2022), p. 384.
[3] H. Ledford, "Covid Vaccine hoarding might have cost more than a million lives", *Nature* (2 November 2022).
[4] *ibid*.
[5] M. Mguni, "Botswana Approves Corbevax Covid Vaccine, Plans Local Output", *Bloomberg*, 28 March 2022.

Therefore, we welcome the inclusion of Article 11 'Technology transfer and know-how' in the draft Pandemic Accord in the version discussed at the 9th session of the WHO Intergovernmental Negotiating Body (INB9). It contains important provisions on technology transfer to encourage Parties to promote and facilitate the transfer of pandemic-related technologies.

While the draft Article 11 is an important first step towards better access to life-saving technologies, considering the experience of the COVID-19 pandemic, it does not go far enough. With the risk of similar failures of voluntary technology transfer recurring in the next pandemic, it is necessary to allow for non-voluntary measures.

In light of this, we support the creation of a non-voluntary mechanism within the WHO Pandemic Accord, that would allow the transfer of a relevant, needed pandemic technology such as a vaccine or treatment. This mechanism should be part of the international pandemic preparedness toolbox.

The WHO Pandemic Accord offers an opportunity to build resilience into the international legal system as part of a pandemic response and to adopt a workable and effective mechanism for non-voluntary technology transfer of knowledge and technology for production of complex biological products, such as vaccines, during a pandemic.

Specifically, as noted above, the TRIPS Agreement, while providing for compulsory licensing of patents, provides no equivalent mechanismto compel pharmaceutical companies to disclose trade secrets that protect their life-saving technologies without their voluntary authorisation.[6] Nonetheless there is nothing in the TRIPS Agreement, including in Article 39, to suggest that taking measures to compel disclosure of trade secrets is prohibited.[7]

Moreover, for an effective cross-border technology transfer an international approach is necessary. This is because if a specific mechanism of compelling the disclosure of trade secrets were implemented by a Party to the Pandemic Accord at a national level, this could enable domestic transfer of technology,[8] but it would not solve the problem of how to facilitate cross-border technology transfer. In other words, domestic reform would not provide a solution where an alternative producer (a third party) in, e.g. a developing country, seeks the non-voluntary transfer of technology held by a firm residing in another jurisdiction e.g. a developed country. This requires the adoption of a specific mechanism at the international level.

[6] O. Gurgula and L. McDonagh, "On Compulsory Licensing of Trade Secrets", SSRN Working Paper (2024). Available from https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4771745; O. Gurgula and J. Hull, "Compulsory licensing of trade secrets: ensuring access to COVID-19 vaccines via involuntary technology transfer", *Journal of Intellectual Property Law & Practice*, Vol. 16 (2021), p. 1242; O. Gurgula, "Accelerating COVID-19 Vaccine Production via Involuntary Technology Transfer", Policy Brief, No. 102 (Geneva, South Centre, 2021).

[7] Whereas compulsory licensing of trademarks is expressly prohibited by the TRIPS Agreement, this is not the case for trade secrets.

[8] The European Union (EU) has acknowledged a lack of adequate legal options in the IP system regarding access to trade secrets. In April 2023, the European Commission proposed a new EU-wide compulsory licences mechanism for emergencies. The Commission proposed that the owner of the technology must disclose all "necessary information" required for production of a compulsory licenced product. In early 2024, the Committee on Legal Affairs of the European Parliament (JURI) strengthened this provision by specifically requiring the disclosure of relevant trade secrets. These EU reforms, if implemented, will make access to trade secrets and clinical trial data more straightforward during a crisis.

Thus, at present, while there is legislative space, there is a lack of guidance in international law about such cross-border non-voluntary technology transfer mechanisms. As noted above, although a specific international mechanism for compulsory technology transfer is not prohibited by Article 39 of the TRIPS Agreement, it does not offer a specific mechanism for undisclosed information. Nonetheless, the TRIPS Agreement provides sufficient space within the terms of Article 39 for such a new mechanism to be created. Given this lacuna, the WHO can take up this challenge by agreeing on a new mechanism to facilitate a cross-border technology transfer of pandemic-related products (and their components). Therefore, the WHO Pandemic Accord offers an opportunity to provide an effective mechanism to build upon existing TRIPS flexibilities in the specific pandemic context.

On 18 March 2024, Medicines Law & Policy has put forward a proposal to supplement Article 11 with the following wording:

X. In addition to the undertakings in paragraph 1 of this Article, where the urgent manufacture by qualified third parties of a pandemic countermeasure is necessary to respond to a pandemic or the threat of a pandemic but the manufacture is prevented or hindered through lack of access to undisclosed information possessed by one or more private rights holders located in one or more Parties, that or those Parties shall compel that or those rights holders to share the undisclosed information with the third parties.

We fully support this proposal and concur with the rationale for introducing this provision in Article 11.[9]

[9] The full text of the proposal by Medicines Law & Policy can be found here: https://apps.who.int/gb/inb/pdf_files/INB9-written-statements/Medicines-Law-and-Policy.pdf.

Proposal on the new 'Pandemic Technology Transfer (PTT) procedure'

Building on the proposal by Medicines Law & Policy noted above, we propose a new provision (Article 11*bis*) that outlines a mechanism on cross-border procedure of non-voluntary technology transfer during a pandemic. This procedure could be invoked in a pandemic scenario in which, as noted, voluntary technology transfer mechanisms have failed to provide sufficient supplies of a needed pandemic product.

Current text of Article 11 (Bureau Text) (with an additional proposed provision in section 3(c))

Article 11. Transfer of technology and know-how

1. In order to enable sufficient, sustainable and geographically-diversified production of pandemic-related products each Party, taking into account its national circumstances, shall:

(a) promote and otherwise facilitate or incentivize the transfer of technology and know-how for both pandemic-related and routine health products, including through the use of licensing and collaboration with regional or global technology transfer partnerships and initiatives, and in particular for the benefit of developing countries and for technologies that have received public funding for their development;

(b) promote the timely publication by private rights holders of the terms of licensing agreements and/or technology transfer agreements for pandemic-related products, in accordance with national laws;

(c) make available licences, on a non-exclusive, worldwide and transparent basis and for the benefit of developing countries, for government-owned pandemic-related products, and shall publish the terms of these licences at the earliest reasonable opportunity and in accordance with national laws; and

(d) provide, within its capabilities, support for capacity-building for the transfer of technology and know-how for pandemic-related products.

2. The Parties shall develop and strengthen, as appropriate, mechanisms coordinated by WHO with the participation of other relevant technology transfer mechanisms as well as other relevant organizations, to promote and facilitate the transfer of technology and know-how for pandemic-related products to geographically diverse research and development institutes and manufacturers, particularly in developing countries, through the pooling of knowledge, intellectual property, know-how and data to all developing countries.

3. During pandemics, in addition to the undertakings in paragraph 1 of this Article, each Party shall:

(a) encourage holders of relevant patents regarding pandemic-related products, in particular those who received public funding, to forgo or otherwise charge reasonable royalties to developing country manufacturers for the use, during the pandemic, of their technology and know-how for the production of pandemic-related products;

(b) consider supporting, within the framework of relevant institutions, time-bound waivers of intellectual property rights to accelerate or scale up the manufacturing of pandemic-related products to the extent necessary to increase the availability and adequacy of affordable pandemic-related products; and

(c) take measures to ensure the effective implementation of actions required under the Pandemic Technology Transfer procedure specified in Article 11bis.

4. The Parties that are WTO Members recognize that they have the right to use to the full, the flexibilities inherent in the TRIPS Agreement as reiterated in the Doha Declaration on the TRIPS Agreement and Public Health of 2001, which provide flexibility to protect public health including in future pandemics, and shall fully respect the use thereof by others.

5. Each Party shall, as necessary and appropriate, review and update its national legislation in order to ensure the implementation of such flexibilities referred to in paragraph 4 of this Article in a timely and effective manner.

6. The WHO Secretariat shall work towards the improvement of access to pandemic-related products, especially during pandemic emergencies, through transfer of technology and know-how, including through cooperation with relevant international organizations.

Suggested text of Article 11bis: Pandemic Technology Transfer (PTT) procedure (the text incorporates the proposal by Medicines Law & Policy in Article 11bis(1))

1. In addition to the undertakings in [paragraph 1 of] Article 11, where the urgent manufacture by qualified third parties of a pandemic countermeasure is necessary to respond to a pandemic or the threat of a pandemic but the manufacture is prevented or hindered through lack of access to undisclosed information possessed by one or more private rights holders located in one or more Parties, that or those Parties shall compel that or those rights holders to share the undisclosed information with the third parties.

2. Pursuant to Article 11(3c) and 11(6), and in acknowledgment of Article 11(4) and 11(5), the WHO and the Parties shall take measures to ensure the effective implementation of paragraph 1 of Article 11bis in the manner specified in this Article 11bis (3)-(6) (the 'Pandemic Technology Transfer (PTT) procedure').

3. The PTT procedure may be initiated by the request of a Party ('the Requesting Party') or a technology transfer mechanism hub (as per Article 11bis(4c)).

4. Once the PTT procedure has been initiated, the WHO shall undertake the following actions:

a) The WHO shall promptly identify and list on an ongoing basis essential pandemic-related products[10] and technologies suitable for the prevention, treatment, or diagnosis, which will be subject to the PTT procedure.

b) The WHO shall identify the Parties in the jurisdiction of which a holder of one or more listed pandemic-related products or technologies resides (the 'Facilitating Party' or 'Facilitating Parties').

c) Where appropriate the WHO shall utilise the expertise of technology hubs (such as those set up via Article 11(2)); and shall make efforts to coordinate the participation of other relevant technology transfer mechanisms (as per Article 11(2)) in order to facilitate the PTT procedure.

5. Any Party (the 'Requesting Party'), or a technology transfer mechanism hub (as per Article 11bis(4c)), can request one or more Facilitating Parties to take measures for the non-voluntary transfer of technology and information for the production and marketing authorisation of the identified pandemic-related products held by one or more right-holders located in a Facilitating Party.

6. Under the PTT procedure, the Parties undertake the following obligations:

6.1. The Facilitating Party shall:

a) take all necessary measures to compel, in an expeditious manner, the transfer of the relevant technology and information by the right-holders to a 'suitable manufacturer' identified by the Requesting Party, or to a technology transfer mechanism hub (as per Article 11bis(4c)); including via disclosure to that suitable manufacturer of all relevant information covered by intellectual property rights, including unpublished patent applications, trade secrets, know-how and clinical data required for the production and marketing authorisation of a pandemic-related product;

b) ensure that the relevant information is transferred to a suitable manufacturer identified by the Requesting Party or a technology transfer mechanism in a manner which is sufficient to enable the manufacture of the pandemic related product as well as, where relevant, to request its marketing authorisation.

6.2. The Requesting Party shall:

a) ensure that the enforcement of all intellectual property rights and data and marketing exclusivities, if any, relating to a listed pandemic related product is suspended in its jurisdiction during the pandemic;

b) provide a documented assessment of a suitable manufacturer identified by the Requesting Party, or a technology transfer mechanism hub, confirming that it is capable of producing the pandemic related product if the required technology were transferred;

c) take measures to ensure that the suitable manufacturer protects confidential information, including trade secrets and know-how, transferred as part of the PTT against unauthorised disclosure, so that the use of the technology and information remains limited to the specific suitable manufacturer;

[10] The terms 'health product' or 'pandemic-related product' include 'any components' of such products (i.e. covering patented inputs including raw materials for production of vaccines or treatments, such as lipid nanoparticles to produce mRNA vaccines).

d) take measures to ensure that the suitable manufacturer provides adequate remuneration to the right-holders who transferred the relevant technology and information, having in view the need to make accessible the pandemic related product at the lowest possible cost.

7. Measures taken under this provision will be deemed to be in compliance with the TRIPS Agreement.

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