

The last mile: A few suggestions for the WHO Pandemic Agreement's last two weeks of talks

On 16 April, the Bureau of the *Intergovernmental Negotiating Body (INB)* to draft and negotiate a convention, agreement or other international instrument under the Constitution of the World Health Organization to strengthen pandemic prevention, preparedness and response, published its Proposal for the WHO Pandemic Agreement to be discussed at the resumed session of INB9. This Proposal is based on discussions and negotiations among WHO member states that have taken place over the last two years.

It has not been an easy two years. The spirit of solidarity that was fuelling the decision to start negotiating a Pandemic Agreement vanished quickly when proposals regarding product sharing, technology transfer, management of intellectual property (IP), access to know-how, transparency, and pathogen access and benefit sharing (PABS) were put on the table. These are all essential elements of greater equity in access to pandemic countermeasures.

We have been following several key elements of the equity agenda, in particular, the issues related to technology transfer and IP, including access to undisclosed information and know-how.

See [here](#), [here](#), and [here](#), for example.

The last round of the Pandemic Agreement negotiations will commence on Monday, 29th April. Member states will meet in Geneva to conclude the talks based on the [Bureau's last draft](#).

The Bureau's Proposal for the Pandemic Agreement covers many of the key elements that are needed to improve equitable access to products and know-how when the next pandemic comes around, but it is too often couched in language that gives parties room to disregard certain obligations. The Agreement may be a binding instrument, but if too many of the provisions are formulated in a non-binding manner, subject to voluntary actions or only 'as appropriate', the instrument will be significantly weakened.

Considering that the parties will have a chance to strengthen the Agreement further in the coming two weeks, here are a few suggestions:

Voluntary and mutually agreed terms

When problems can be solved because parties are willing to do so and can agree on the terms of the solution, that is preferable. But it is equally vital to recognise that there are and will be circumstances in which such voluntary arrangements do not emerge while the problem still needs to be solved. The vulnerability of voluntary arrangements was recently demonstrated by Moderna's [announcement](#) that it would abandon its plans to build an mRNA vaccine

manufacturing facility in Kenya which would have contributed significantly to the transfer of mRNA technology and know-how, [angering the African Centre for Disease Control \(CDC\)](#).

Undisclosed information and know-how

Various limitations to patent protection have long been familiar in national and international law. The limitations of the protection offered to undisclosed information and know-how are perhaps less familiar. As we have argued, however, ([here](#)) and as the European Union has now recognised ([here](#)), access to undisclosed information and know-how can play a vital role in enabling compulsory patent licences to work effectively. Granting pandemic related compulsory patent licences could be rendered ineffective without this access. Powers therefore have to be in place to guarantee that access can be obtained in a non-voluntary way during a pandemic if voluntary agreement fails.

The text in the current Proposal tries to address this as follows:

(f) encourage manufacturers within its jurisdiction to share as appropriate, during pandemics, information that is relevant to the production of pandemic-related health products when the withholding of such information prevents or hinders urgent manufacture of a pharmaceutical product that is necessary to respond to the pandemic.

Since this current text falls short of the necessary guarantee, we suggest this as an alternative:

(f) ensure that manufacturers within its jurisdiction share information relating to the production of pandemic-related health products with appropriate third parties, subject to the protection of their legitimate interests, when the withholding of such information prevents or hinders urgent manufacture of such products which are necessary to respond to a pandemic.

The 'Peace clause'

Article 11.4 of the Bureau's draft contains the following text about the use of TRIPS Flexibilities:

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

The sentence 'shall fully respect the use of the TRIPS flexibilities by WTO members' reflects provisions of the 1995 TRIPS Agreement and the 2001 Doha Declaration on TRIPS and Public Health. Nevertheless, countries that use TRIPS Flexibilities are often confronted with political and trade pressures, mostly from European countries and the U.S., to discourage them from moving forward with the compulsory licence (see Box 1.)

Box 1:

On 23 April 2024, Colombia issued a CL for the HIV medicine dolutegravir. The medicine is available from Medicines Patent Pool (MPP) sublicensees. However, the MPP licence only allowed the paediatric formulation to be supplied to Colombia. ViiV charges US\$ 1224 per patient per year, while MPP licensees offer the treatment for US\$ 44. This recent case will be watched closely because previous attempts by Colombia to purchase lower-priced generic products with the use of a CL have failed. In 2015 Colombia had planned to issue a compulsory licence to lower the price of cancer treatment imatinib, which sold for US\$ 20,000 while the GNI per capita was US\$ 7,780. Colombia had come under pressure from industry and [Switzerland](#) to abandon the plan for a compulsory licence. The patent holder, Novartis, had threatened Colombia with international investment arbitration, an investor-state dispute settlement (ISDS) available to them under the Swiss-Colombian bilateral investment treaty (BIT). The compulsory licence was never issued.

It was, therefore not surprising that a group of developing countries proposed the following wording at the INB in March:

4bis. The Parties shall not challenge, or otherwise exercise any direct or indirect pressure on the Parties that undermine the right of WTO Members to use TRIPS flexibilities at any multilateral, regional, bilateral, judicial or diplomatic forum.

This provision was quickly nicknamed “the peace clause”. We [commented](#) at the time:

The proposed peace clause in the pandemic accord in fact echoes the basic principle of the WTO TRIPS Agreement Article 1.1 which specifies that countries are not obliged to adopt TRIPS-plus measures and “shall be free to determine the appropriate method of implementing the provisions of this Agreement [TRIPS] within their own legal system and practice”. In other words, the proposed peace clause is a welcome reminder of this basic principle, certainly in the context of pandemics.

The recent change in U.S. policy should help garner support for a stronger ‘peace clause.’ In the 2024 annual Special 301 Report released on 25 April 2024, the U.S. Trade Representative (USTR) Ambassador Katherine Tai highlighted the U.S.’s new “policy of declining to call out countries for exercising TRIPS flexibilities, including with respect to compulsory licenses, in a manner consistent with TRIPS obligations.”

Therefore, there should be broader support to include a stronger-worded peace clause in the final text. We propose the following wording for Article 11.1(f):

The Parties shall assume that the use of TRIPS flexibilities by any WTO Member is undertaken in good faith and shall not therefore be challenged, whether formally or informally and in whatever forum, save in exceptional cases where an evidently unjustifiable breach of obligations under the TRIPS Agreement has occurred.

National implementation of TRIPS Flexibilities

The lack of provisions in national legislation for compulsory licensing, including the use of IP by the government that can be swiftly deployed, is an important barrier to the effectiveness of TRIPS flexibilities. Most high-income countries have such provisions and some rapidly amended their legislation in the early days of the Covid-19 outbreak. See [here](#) for examples of state practice in the US where a reference to the relevant statute in a contract is sufficient to grant permission to use a patent without the consent of the patent holder. Many national IP laws are not sufficiently adapted to respond to a pandemic. The European Commission has also recognised this and a year ago, proposed a Regulation for EU-wide compulsory licensing for crisis situations. For details see [here](#).

During the previous round of negotiations, the draft (A/INB/9/3) contained the following article:

Article 11.5 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.

It would be important to include the above provision in the final text.

Transparency

The Bureau's draft includes several important provisions to increase transparency in R&D, procurement, and the pharmaceutical and vaccine market. The need for greater transparency was recognised in the WHA resolution "Improving the transparency of markets for medicines, vaccines, and other health products" ([WHA72.8](#)), adopted on 28 May 2019.

Transparency in science, research and development, decision-making, licensing and cost is essential to counter misinformation, build public trust in pandemic countermeasures, inform policy-making and encourage meaningful community engagement.

It is important to protect and strengthen, where needed, the provisions that refer to greater transparency.

Conclusion

With just two weeks of negotiation time left, WHO member states still have the opportunity to create a robust, actionable pandemic agreement that can lead to a better response and fewer lives lost when the next pandemic eventually comes. We have outlined above some of the key elements that are needed to make that happen, and it is now up to member states to follow through.