A few comments on April 16, 2024 draft of the Pandemic agreement

James Love, KEI, 19 April 2024

1. Note on the experience in delaying outcomes related to access

This negotiation is taking place at the World Health Organization (WHO), but it is useful to reflect on negotiations that have taken place at the World Trade Organization (WTO), where delayed outcomes were disappointing outcomes.

In the negotiations over the 2001 Doha Declaration on TRIPS and Public Health, paragraph 6 of that agreement concerned one of the most contentious topics, a restriction in the TRIPS on the exports of products manufactured under a compulsory license. That export restriction undermines the ability to benefit from economies of scale and comparative advantage, is clearly protectionist and designed to reduce the utility of compulsory licenses, has a negative impact on both exporters and importers, and has a particularly harmful impact on countries with smaller market (something noted by the WTO in DS114):

> 6. We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instructed the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

The WTO failed resolve the issue by 2002, and the eventual August 30, 2003 decision, now part of the TRIPS as Article 31*bis* (with an annex and appendix), was complex, also protectionist, widely criticized and only used once by a company that indicated it would never use it again.

The WTO eventually took up the export issue in the context of the COVID-19 pandemic, and the result was another agreement on exports, one that was temporary, restricted to COVID-19, also protectionist (limiting imports to and exports from developing countries) and limited to vaccines. The WTO agreed to consider an extension of the decision to diagnostics and therapeutics, two areas where it may have been more useful at that point, however the WTO went on to miss deadlines and eventually did nothing on the issue.

2. The TRIPS language

Article 11.4 of the April 16 draft includes this language on 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.

While this language is welcome, the part reaffirming the right to use the flexibilities in the TRIPS agreement adds absolutely nothing to a country's rights in the WTO, and could even be somewhat unhelpful if it is used to suggest those flexibilities only apply in emergencies. The phrase "shall fully respect the use of the TRIPS flexibilities by WTO members" is a watered down version of the peace clause, however it does have some value, and should be protected in negotiations going forward. (See: The WHO pandemic treaty: The Peace Clause and its discontents, https://www.keionline.org/39585)

What has disappeared from the text is language from the March 13, 2024 INB text, based upon a US government proposal, following a suggestion that KEI made to the US government.

KEI had suggested the following text:

> "Parties will review and modify domestic laws to ensure that there are sufficient exceptions to exclusive rights in intellectual property in order to respond to a pandemic."

The language that ended up in an earlier INB text read:

> "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."

At INB9-1, this proposal was subject to 14 brackets, including five from the USA.

> 5. [Each Party [that is a Member of the WTO (PSE, IRN)] [shall (DEL CHE, AUS) may (CHE)] [will endeavor to (AUS)], [review and consider amending (USA)] as necessary and appropriate, [review [and update (DEL USA)] (DEL EU, CHE)]] its [national (DEL EU) domestic (EU)] legislation [in order (DEL USA)] to [ensure (DEL EU, CHE) enable (EU, CHE)] [it is able to implement (USA)] [the implementation of such flexibilities [for the protection of public health (MYS, BGD, TUN)] referred to in paragraph 4 of (DEL USA) (RETAIN TUN)] this Article in a timely and effective manner [including ensuring adequate exceptions and limitations in their intellectual property laws and regulations to facilitate the manufacture, export and import of the health products needed during health emergencies (BGD, TUN, SYR)] (DEL CAN)]. RETAIN Bureau's text: RUS, BRA, NIC, IND, FJI, TUR

One of the problems WHO members face is the lack of appropriate exceptions to deal with emergencies. Typical problems are complex and lengthy periods of time before compulsory licenses on patents can be issued, restrictions on exports, and a lack of exceptions to rights in regulatory test data.

A typical intellectual property agreement will involve mandatory rights and permissive exceptions, and technical assistance from the WTO, WIPO, USPTO, EPO, etc, always insists on the mandatory rights but almost never insistence of exceptions. There are a handful of mandatory exceptions in international agreements (examples), and one treaty in particular which is relevant. The WIPO "Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired, or Otherwise Print Disabled," which was concluded in 2013 and today has 94 members, making it the fastest ratified treaty in the history of intellectual

property. The exceptions are mandatory, and they also work cross-border. The motivation for the treaty was to address a human rights issue, and to make access more equitable globally.

3. Transfer of Technology

Article 11 on Transfer of technology and know-how for the production of pandemic related health products includes in 1(a) language to "promote and otherwise facilitate or incentivize the transfer of technology and know-how for pandemic-related health products." The contested language on "mutually agreed terms" is there but not as the exclusive option:

> "through a variety of measures such as licensing, on mutually agreed terms"

It is important to retain the notion that for technology transfer involving know-how or access to biologic resources, mandatory measures may be necessary, so voluntary or mutually agreed terms should always be possible and encouraged, but not the only option.

During the year 2020 of the COVID 19 pandemic, the US government used the Defense Production Act to force companies to break contracts and supply inputs to favored companies, and even placed armed military personnel in factories.

Note that the US defense production act is used for a variety of purposes, including recently to address the production of batteries to store electricity.

- US Department of Defense: Defense Production Act Title III, Presidential Determination for Critical Materials in Large-Capacity Batteries, April 5, 2022, https://www.defense.gov/News/Releases/Release/Article/2989973/defense-production-act-title-iii-presidential-determination-for-critical-materi/

- Heidi M. Peters, Erica A. Lee, Nina M. Hart, Brandon S. Tracy, "2022 Invocation of the Defense Production Act for Large-Capacity Batteries: In Brief, Congressional Research Service, R47124, May 27, 2022. https://crsreports.congress.gov/product/pdf/R/R47124

In the new EU emergencies legislation, the European Union has the legal means to compel the transfer of know-how needed to make a compulsory license of a patented technology effective. Some articles about the EU legislation include:

- Olga Gurgula, The European Commission's proposal on a new EU-wide compulsory licensing regime, Medicines Law and Polcy, September 8, 2023, https://medicineslawandpolicy.org/2023/09/the-european-commissions-proposal-on-a-new-eu-wide-compulsory-licensing-regime/

- Christopher Garrison: The European Parliament has now explicitly acknowledged the know-how problem too: time to include a workable solution in the draft Pandemic Accord., Medicines Law & Policy, Version date: 25.03.24 https://medicineslawandpolicy.org/wp-content/uploads/2024/04/The-European-Parliament-has-now-explicitly-acknowledged-the-know-how-problem-too-time-to-include-a-workable-solution-in-the-draft-Pandemic-Accord.-.pdf

Note also this from a European Commission Q&A about its crisis legislation:

> "Voluntary licensing agreement [sic] are most effective in ramping up production, but should voluntary agreements not be available or adequate, compulsory licensing can help provide access to key crisis-relevant products and technologies in emergencies." [See Annex]

ANNEX, the European Commission April 2023: Questions and Answers on Compulsory Licensing

https://ec.europa.eu/commission/presscorner/detail/en/qanda_23_2456

What is the objective of the initiative on compulsory licensing for crises management?

This initiative aims to create, at EU level, an efficient compulsory licensing framework to address EU-relevant crises. Voluntary licensing agreement [sic] are most effective in ramping up production, but should voluntary agreements not be available or adequate, compulsory licensing can help provide access to key crisis-relevant products and technologies in emergencies.

An effective EU compulsory licensing mechanism will:

- Serve as an effective tool in crisis times as a last resort when voluntary agreements do not work.
- Ensure an appropriate territorial reach of compulsory licensing to cover cross-border supply chains.
- Build on EU crisis mechanisms.

Currently, legislation on compulsory licensing of patents in the EU is fragmented: EU countries regulate their own national compulsory licensing schemes, subject to different conditions, scopes, and procedures. In addition, national compulsory licensing schemes are designed to meet the needs of the population of the issuing Member State and to satisfy the public interest of that Member State only. These purely national systems are unable to rely on cross-border value chains and therefore unfit to tackle EU crises. At a time where the EU is aiming to build up its resilience to crises, it is necessary for the EU to be able to rely on a Union IP crisis tool.