

INB 7

Written statement by Knowledge Ecology International

November 2023

The current draft of the pandemic accord includes provisions on limitations and exceptions to intellectual property rights that while well intentioned, are problematic.

Parties do not need to refer to the WTO TRIPS Agreement or a waiver. Global rules on exceptions are broad enough. What's needed is the implementation of laws and use of exceptions at the national level.

A more general approach, modeled after the WIPO Marrakesh Treaty for the Blind, would require parties to have adequate exceptions in their national laws, and to use them when needed. This could be done in two parts:

1. The first would be an obligation to review and modify domestic laws to ensure that there are sufficient exceptions to exclusive rights in intellectual property in order to respond effectively to a pandemic.
2. The second would be an obligation to use the exceptions in domestic laws, to the extent necessary, to enable the research activities, scaling of manufacturing, sharing of manufacturing technology, and distribution of countermeasures in a manner consistent with the objectives of the agreement, including those relating to the transfer of technology in a pandemic and equitable access to affordable products.

The United States and the European Union would find such provisions consistent with current policies and past practices.

The United States already has a very effective legal mechanism for the non-voluntary use of patents, and one that was used extensively by the U.S. government in 2020 and 2021, when dozens of companies received an "authorization and consent" from the federal government (FAR 52.227-1) to use any USPTO granted patents without the permission of patent holders. These contracts were used both to undertake R&D and to provide a variety of products to the public, including vaccines, diagnostic tests, therapeutics and other countermeasures.

The European Union is now considering a sweeping proposal on medical emergencies that addresses not only the use of compulsory licensing of patents, but also exceptions to regulatory test data, caps on royalties to patent holders, and extensive technology transfer measures.

Recital 32 of the European Parliament on the proposal for a regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) 816/2006 provides robust language on technology transfer that the INB Bureau and Member States may also wish to consider. Recital 32 states:

Where appropriate, the Commission should oblige the rightsholder to disclose the trade secrets which are strictly necessary in order to achieve the purpose of the Union compulsory licence. Indeed, it is possible that the detailed description of how to carry out the invention might not be sufficient and complete enough to enable the licensee to efficiently use that invention. This could encompass, without being exhaustively limited to, the comprehensive transfer of necessary technology, expertise, data, samples, and reference products essential for production and obtaining market authorisation in collaboration with the licensee, taking into account each other's public interests.