



November 18, 2021

Ambassador Katherine Tai  
Office of the United States Trade Representative  
Washington, DC

Dear Ambassador Tai,

The negotiations on the TRIPS waiver cover a number of important topics. We recognize the rationale and benefits of the broad waiver that is before the World Trade Organization (WTO), and highlight three issues that are of particular importance.

1. There should be an unconditional waiver of Article 39.

Article 39 of the TRIPS Agreement has three numbered paragraphs, and is the only article in Section 7, which is titled "Protection of Undisclosed Information." It is the one article in the TRIPS Agreement dealing with trade secrets, know-how and rights in data, including both information held closely by a company and information and data shared with regulators. Governments need to have unambiguous flexibility to enable the sharing of know-how and data in order to scale and decentralize the manufacturing of covered COVID-19 health products, particularly for vaccines and biologic drugs, and to have expedited marketing approval of affordable versions.

If this article is not included in the waiver, measures involving patents by themselves will be insufficient to address the need to accelerate and expand access to safe, affordable and effective vaccines and some other countermeasures. Allowing a waiver of Article 39 will also remove any doubt that countries can waive or choose not to recognize or enforce exclusive rights in data used for the registration of products, which is particularly important when such provisions have terms from 5 to 12 years, and lack the type of exceptions that exist for patents on inventions.

2. There should be an unconditional waiver of Article 31.f.

Article 31.f is a 20-word single sentence paragraph, that says for any non-voluntary use of patents under Article 31 (the compulsory licensing and government use exceptions in TRIPS), "Any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use." This clause was included in the original TRIPS Agreement to undermine the use of compulsory licenses, by making it difficult to achieve efficient economies of scale and to make it difficult to find suppliers of generic or biosimilar products from a producing country.

The problem was recognized in Paragraph 6 of the 2001 Doha Declaration on TRIPS and Public Health. The “solution” adopted in 2003, shaped primarily by the European negotiators, was a massively complicated, burdensome and protectionist exception to 31.f, now 31bis, which is unambiguously seen as a failure. During a pandemic it is a terrible policy for the WTO to block exports of COVID-19 health products. This article needs a simple clean waiver, and negotiators should not attempt to place conditions on the waiver, such as those in the discredited 31bis mechanism.

3. The scope of the waiver should not be limited to vaccines.

There are many different technologies relevant to the control of a pandemic. For this pandemic, these have included diagnostic tests, cleaning and sterilization technologies, ventilators and other methods of helping patients breathe, protective equipment, therapeutics and vaccines and their relevant inputs. Any attempt to limit the scope of the waiver to vaccines is particularly appalling, given the fact that persons living in developing countries are more likely to need the other measures, given the inequality in access to vaccines.

Sincerely,

A handwritten signature in cursive script that reads "James Love". The signature is written in black ink and is positioned below the word "Sincerely,".

James Love  
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