



December 3, 2021

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

Dear Ambassador Tai,

On November 18, 2021, Knowledge Ecology International (KEI) provided comments to USTR on three issues that were important for any WTO waiver of the TRIPS agreement. In this letter KEI will address a different issue, the relationship between a waiver and the plethora of bilateral and regional trade agreements that govern intellectual property, pharmaceutical, investment and other provisions that are relevant to the scaling of manufacturing of and equitable access to pandemic countermeasures.

A TRIPS waiver, if and when one is adopted, should include a statement that the WTO members will agree to waive enforcement of similar or more extensive provisions in any other trade or investment agreements. Otherwise, the TRIPS waiver will be ineffective for many countries.

Related to this is a specific concern we have about the trade agreement between the Dominican Republic, Central America, and the United States (US-DR-CAFTA). On December 3, 2021, KEI filed a petition with the Dominican Republic patent office for a compulsory license for the patents on Pfizer's combination drug PF-07321332+ritonavir, sold by Pfizer under the brand name Paxlovid.

One of the challenges for importing and distributing affordable generic versions of PF-07321332+ritonavir in the Dominican Republic is the US-DR-CAFTA trade agreement, and specifically Article 15.10: Measures Related to Certain Regulated Products, which requires the Dominican Republic to provide five years of exclusive rights in the data submitted to drug regulators from tests including clinical trials to demonstrate that a drug is safe and effective.

There is no serious argument that a government should wait five years before making available a drug to treat COVID-19. In this regard there is an August 5, 2004 agreement between the

United States, the Dominican Republic and five other countries, titled “Understand Regarding Certain Public Health Measures”¹ which refers to the CAFTA trade agreement and states:

The obligations of Chapter Fifteen do not affect a Party’s ability to take necessary measures to protect public health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency.

KEI asks that USTR provide KEI and the government of the Dominican Republic with a letter providing assurances that the USTR will not sanction the Dominican Republic if the government permits the registration and sale of generic drugs or biosimilar vaccines related to COVID-19, when the registration relies upon third party test data, and specifically will not enforce the provision regarding five years for test data exclusivity.

Sincerely,

A handwritten signature in cursive script that reads "James Love".

James Love
Director
Knowledge Ecology International
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<https://keionline.org>

Cc: Loyce Pace, Director, Office of Global Affairs, HHS

Attachment: KEI Application for compulsory license on Paxlovid patents in the Dominican Republic (EN), December 3, 2021

Attachment: November 18, 2021 letter to Ambassador Katherine Tai

¹ https://tcc.export.gov/static/CAFTA_understandings_IP.pdf