

Oral Statement of James Love, KEI, in ITC investigation 332–596, on COVID–19, Diagnostics and Therapeutics, and TRIPS Flexibilities

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Knowledge Ecology International is a non profit organization with offices in Washington, DC and Geneva, Switzerland. Through my work with KEI and in previous roles, I have closely followed trade issues, including in particular those relating to intellectual property rights, innovation, and more generally knowledge goods.

KEI was at the WTO 12's Ministerial Conference when the June 17, 2022 decision on TRIPS and COVID 19 was approved¹, and provided commentary on the decision that day, which is available on the KEI web site. More recently, KEI provided a 16-page submission to the ITC for this docket discussing these issues in depth.

KEI's written submission addresses some of the history and context surrounding the question of TRIPS Agreement exceptions for COVID-19 diagnostics and therapeutics, and addresses the question: What should the WTO do concerning therapeutics and diagnostics?

As regards the context, I note that the TRIPS has a number of areas where the government can, but rarely does use the flexibilities available to WTO members. Often the roadblock to using the flexibilities is related to problems with national laws, which may have complex and time-consuming procedures or unworkable provisions, or lack procedures of experience due to lack of use. The more substantive problems that arise when seeking to use TRIPS flexibilities include the following:.

1. A country may not be confident that if a compulsory license is issued that they will be able to find a qualified supplier, and
2. Use of the exceptions can trigger trade and political pressures, which are often not transparent (and I can elaborate on this if the Committee wants).

A temporary suspension of certain TRIPS rules, as originally proposed by India and South Africa, would be useful in eliminating the WTO's absurd restriction of exports, and would give greater certainty as regards government measures to provide more transparency of and reliance on company data submitted to regulatory agencies, or other know-how enhancing measures. Of equal importance, the temporary suspension would have sent an important signal that governments would not face political and trade pressures for expanding access to inventions, know-how, and data.

¹ <https://www.keionline.org/37830>

The US government's FAR 52.227-1 authorizations

Ironically, during the COVID-19 pandemic the United States was the most aggressive country to use TRIPS flexibilities. This included at least 59 contracts that contained a FAR 52.227-1 authorization to use patents without consent of patent holders. The beneficiaries of these government-use authorizations were well-known companies like Corning, Eli Lilly, Merck, Moderna, Novavax, Philips, Qiagen, Sanofi and Siemens, as well as many small companies and a few universities. The contracts were for diverse COVID-19 countermeasures, including vaccines, drugs, diagnostic tests and other technologies.

The June 17, 2023 decision by the WTO was a disappointment. For the most part modeled after the restrictive Article 31*bis* in TRIPS, dealing with the exports issue, but in this case only for vaccines and, of course, it is temporary. There were some useful improved procedures when compared to Article 31*bis* as regards notifications, and welcomed certainty on remuneration for compulsory licenses, but also even more restrictive and frankly protectionist provisions on the countries that could import or export under a compulsory license than were found in TRIPS Articles 30, 31.k and 31*bis*. This is a troubling trend for the WTO, which was created with a promise to enhance and not restrict trade.

The opposition to including therapeutics in the WTO's limited exceptions for COVID-19 rests on an analysis that looks backward, by emphasizing that the supply of existing drugs like Paxlovid have exceeded demand in 2023, and the fact that the Medicines Patent Pool (MPP) has executed multiple licenses for small molecule therapeutics which include in their geographic area all the lowest and several low and middle income countries.

The BIO COVID-19 Therapeutic Development Tracker illustrates how shortsighted it is to look only at the small number of FDA-approved products while ignoring the much larger number of products in development.

Not only are the current drugs of limited efficacy for many patients, the most effective treatments for infectious diseases have often been combination treatments. Looking at today's COVID-19 drugs is somewhat similar to looking at the HIV drugs before triple therapy, or at HCV treatments before combinations involving sofosbuvir.

This decision is not about the drugs on the market today, but should seek to ensure there is a path to expand access for any new game changing products that will enter the market in the future.

What the WTO should do

The least complicated way to include therapeutics and diagnostics is to extend the June 17, 2022 decision, mutatis mutandis. If the conditions and scope are reopened, the text could get better or

worse, depending on anyone's perspective, and it could also result in negotiation-related delays. That said, if the WTO members do more than a simple extension of the current June 17, 2022 agreement, there is considerable room for improvement.

One topic that should have been addressed and which could be added would be to require members to lift any test data exclusivity obligations in trade agreements, or at least provide for the same type of exceptions they have for patented inventions. It is absurd to support the freedom to use compulsory licenses on a therapeutic to treat COVID-19, but then make it impossible to register a product for 5 years or more.

A WTO decision on therapeutics and diagnostics could also take some different approaches than the June 17, 2022 decision. For example, the WTO could affirm that non-predominate exports of a product under a compulsory license could be authorized using the Article 30 three-step test, so long as the legitimate interests of the patent holder were not unduly prejudiced in the importing country, for, by example, payment of reasonable and affordable royalty.

The WTO secretariat could also be instructed to publish a model law on compulsory licensing or other exceptions for times of emergency, particularly one that uses either Article 30, or the limitations on remedies to infringement under Article 44.2 of the TRIPS that were so effectively used by the US government in the COVID-19 pandemic.

The agreement could also create a pathway for WTO members to request other members to use exceptions to ensure the supply of affordable products. Such a decision, perhaps modeled after Article 40.3 of the TRIPS, could have been used to require countries like Canada to take the steps necessary to ensure that COVID-19 is treated as a global public health problem.

KEI has also suggested in our written statement several relevant questions the ITC could pose to US federal agencies and drug manufacturers to obtain additional information for this inquiry.

Thank you.