October 26, 2022

Ambassador Katherine C. Tai
United States Trade Representative
Office of the United States Trade Representative
Executive Office of the President
Via: katherine.c.tai@ustr.eop.gov

Re: therapeutics, diagnostics, 2022 WTO TRIPS agreement

I am writing to provide additional context for why the U.S. should support the extension of the June 17, 2022 TRIPS and COVID 19 decision to therapeutics and diagnostic tests.

As you know, KEI was not very impressed with the June 17, 2022 decision, for reasons set out in this June 17, 2022 KEI blog (https://www.keionline.org/37830). That said, we do support extending the decision to therapeutics and diagnostic tests, *mutandis mutatis.* Any attempts to include more complexity and restrictive conditions should be resisted. The June 17, 2022 decision is already too complex and restrictive.

The USTR should be taking into consideration the following points when reaching a decision regarding the current WTO negotiation.

1. **Autarky is a bad trade policy.** The restrictions on exports under a compulsory license in Article 31.f of the TRIPS are an embarrassment. The restrictions have a differential impact on a large economy like the U.S. that they do on almost every other WTO member. That is because the restriction is designed to have a bigger impact, by far, on countries with domestic markets that are too small to support efficient domestic manufacturing. Economies of scale and comparative advantage are the two things that trade and the WTO are supposed to exploit, and Article 31.f is anti-economics of scale and anti-comparative advantage. It's bad enough to have a provision in the TRIPS that makes countries depend on autarky, but it's shockingly immoral to have this imposed on developing countries and applied to biomedical technologies, and certainly contrary to the many U.S. commitments to "promote access to medicines for all."

2. **The U.S. made extensive use of 28 USC 1498 during COVID.** KEI has forwarded to USTR three reports describing the U.S. government's use of 28 USC 1498 for biomedical inventions, including one that describes 59 times the U.S. government included FAR 52.227-1 in COVID related contracts.

- 2022:1 KEI Briefing Note: Selected U.S. Government COVID Contracts with Authorization and Consent to Non-Voluntary Use Of Third Party Patents.
- 2022:2: KEI Briefing Note: U.S. federal government FAR 52.227-1 authorizations (for non-voluntary use of patents) disclosed in 173 SEC exhibits
- 2022:3 KEI Briefing Note: Selected differences between Article 30, 31 and 44 of the WTO TRIPS Agreement as regards non-voluntary use of patented inventions

The U.S. contracts that include a FAR 52.227-1 authorization and consent clause for COVID 19 covered a wide range of countermeasures, including vaccines, drugs, diagnostics and many other products. Faced with the pandemic, the U.S. was remarkably promiscuous in providing its own patent waiver, a broad get out of jail free clause in contracts that applied to any U.S. granted patent, without bothering to identify patents or patent holders, or notify patent holders or the WTO. USTR is aware that the very companies complaining about the proposals for a WTO waiver were at the same time, signing contracts with FAR 52.227-1 clauses.

3. **Patents are an issue for therapeutics and diagnostic tests.** Patent litigation between CureVac and BioNTech, and Pfizer and Moderna, over their respective COVID 19 vaccines, illustrates the extent that patent claims are likely to be more aggressively pursued now that the pandemic is not considered to be as grave an emergency.

   In the Pfizer and Moderna lawsuits, injunctions are not sought for blocking sales to the U.S. government, thanks to the 28 USC 1498 exceptions to remedies for infringement in U.S. law, discussed above.

   Patents were an early issue relating to the supply of diagnostic tests and other countermeasures. I recommend Dr. Scott Gottlieb's book, *Uncontrolled Spread: Why COVID-19 Crushed Us and How We Can Defeat the Next Pandemic,* to illustrate some of the issues. On page 154, Gottlieb discusses the fact that Puritan and Copan were known for using patents to block competition and dominate the market for nasopharyngeal swabs. On pages 272-277, Gottlieb discusses the problems relating to the CDC patents on COVID 19 diagnostics. Referring to the degree to which CDC controlled patents were a problem for the development and manufacturing of COVID 19 diagnostic tests, Gottlieb says "these practices should be revisited. They don't serve an identifiable policy goal, especially in the setting of a public health emergency, where speed to testing is paramount." Gottlieb goes on to discuss the widely known problems with Chiron's patents on the hepatitis C virus (HCV).

   Chiron held patents that blocked competition for better and cheaper HCV tests. While not discussed by Gottlieb, USTR should note that concerns over the broad Chiron patents led to compulsory licensing cases in the United States (Abbott obtaining the compulsory license), Italy, Australia, the UK, and Germany (Roche using the compulsory license case to obtain a voluntary license). According to KEI conversations with Gilead, the Chiron patents delayed for years the development of effective therapeutics for HCV. (See KEI HCV timeline).

Gottlieb's book also briefly references the challenge of developing combination drugs when different companies control rights to different compounds.

Multidrug treatments are important for many diseases, including the treatment and prevention of AIDS and to treat HCV infections. None of the current treatments for COVID 19 seem to have sufficient efficacy at this point, and several of the current therapeutics were either not identified or not on the market for any indication as recently as last year. Given the enormous size of the commercial market, there is ample reason to believe that in the future, new and better drugs or combination drugs will be possible and preferred. And based upon Pfizer's recent calls with investors over the pricing of its COVID 19 products, more aggressive pricing is also likely. Asking developing countries to identify patent barriers to drugs or combinations that are not even on the market today is a negotiating tactic to block a useful agreement, and not a good faith attempt to understand the concerns.

4. **Model Law.** As an alternative to a simple extension of the June 17, 2022 WTO TRIPS decision, USTR could recommend that the WTO publish a model law for exceptions to the enforcement of patent rights. Such a model law should take advantage of the same flexibility in the TRIPS that the U.S. government used during COVID for countermeasures. This can be done without a consensus among WTO members, and would be a more efficient way to address the trade restrictive aspects of Article 31.f than the WTO's June 17, 2022 decision or the complicated, burdensome and protectionist TRIPS Article 31bis. It would also promote U.S. legal practices as a standard for addressing the need to make access to biomedical technologies more equitable.

Sincerely

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