

United States Senate

Washington, D.C. 20510

November 23, 2021

The President
The White House
1600 Pennsylvania Avenue, NW
Washington, DC 20500

Dear President Biden:

We applauded Ambassador Tai's May 5, 2021 announcement of your Administration's support for waiving intellectual property barriers imposed by the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) for COVID-19 vaccines. Unfortunately, six months have passed since the announcement of American support and no agreement on a waiver has been reached at the WTO. We urge you to engage with your counterparts—particularly those in the European Union (EU)—to reach an agreement on a meaningful waiver at the upcoming WTO Ministerial Conference, which begins on November 30, 2021.

A waiver will unlock local production of vaccines in developing countries, which is necessary both to overcome absolute shortfalls in supply and to ensure people in the developing world have reliable access to vaccines. The only way to end the pandemic is to increase vaccination rates to ensure that new variants cannot emerge from mass outbreaks. Today, only 5 percent of people in low-income countries are vaccinated.

Despite the claims of pharmaceutical executives, there are many capable vaccine manufacturers in the developing world—and several that are already developing their own mRNA vaccines.¹ Local production is necessary to meet local needs as current U.S. and European vaccine manufacturers are well short of the dose targets required to meet the 70 percent worldwide vaccination goal announced by President Biden at the United Nations Global Assembly in September. As former Centers for Disease Control and Prevention (CDC) Director Tom Frieden recently noted, “[a]t this current rate, it would take [Pfizer and Moderna] three years to produce the 11 billion doses [needed to vaccinate the world] and by then, additional boosters or tweaked vaccines may well be needed.”²

¹ Nolen, Stephanie. “Here’s Why Developing Countries Can Make mRNA Covid Vaccines”. *The New York Times*. 22 Oct 2021. Accessible at: <https://www.nytimes.com/interactive/2021/10/22/science/developing-country-covid-vaccines.html>

² Frieden, Tom. “Opinion: Pfizer and Moderna’s mRNA vaccines are our best chance to end this pandemic. Break up their duopoly”. *Washington Post*. 12 Oct 2021. Accessible at: <https://www.washingtonpost.com/opinions/2021/10/12/its-time-break-up-pfizer-modernas-duopoly-their-vaccine-technology/>

In our April 15, 2021 letter, we warned that “[e]merging COVID-19 variants show more resistance to vaccines and are more infectious,” “further delay in developing immunity around the world will only lead to faster and stronger mutations,” and “our vaccination efforts here at home will only be successful if vaccination efforts in the developing world happen simultaneously.”³ The highly contagious Delta variant led to a serious summer surge in hospitalizations and deaths, stalling the U.S. pandemic recovery. This variant emerged from India where the mutation was able to develop through uncontrolled viral spread. Without a more serious focus on global vaccination efforts, new variants will continue to emerge.

The United States and European Union nations have provided billions to pharmaceutical companies for the development and distribution of the most effective vaccines.⁴ Despite this public investment, the intellectual property is now privately held, pitting pharmaceutical profits against public health interests. If the TRIPS rules remain in force as an obstacle to public health, even in the face of a global pandemic that has claimed more than five million lives, then such rules are clearly ill-conceived. The fallout from a failure to provide a waiver could deliver a possibly fatal blow to the WTO’s credibility.

The May 5, 2021 announcement initially generated significant enthusiasm and support at the WTO for a TRIPS waiver. Today, three WTO members are opposed to a waiver—the European Union (on behalf of Germany), the United Kingdom, and Switzerland.⁵ Your Administration has not appeared to elevate the issue with German or European Union leaders in bilateral summits or G7 or G20 meetings.

The EU has tried to redirect the process away from the needed waiver and on to discussions clarifying procedures countries may use to issue compulsory licenses—an already existing aspect of the TRIPS Agreement.⁶ The EU approach has been criticized by some advocates as a delay tactic.⁷ Compulsory licensing, which requires country-by-country, license-by-license, and product-by-product negotiations and agreements, would be unlikely to yield the broad increase in vaccine production necessary to meet the global needs under the current time constraints.

³ Sanders, Bernard et al. “NEWS: Senators Urge Biden to Approve Vaccine Patent Waiver to Boost Production and End Pandemic”. *Office of Senator Bernard Sanders*. 17 Apr 2021. *Accessible at:*

<https://www.sanders.senate.gov/press-releases/news-senators-urge-biden-to-approve-vaccine-patent-waiver-to-boost-production-and-end-pandemic/>

⁴ Government Accountability Office. “Operation Warp Speed Dashboard”. *Accessible at:*

<https://ows.gaoinnovations.gov/the-funding>; European Commission. “EU Support for Vaccines”. *Accessible at:*

https://ec.europa.eu/info/research-and-innovation/research-area/health-research-and-innovation/coronavirus-research-and-innovation/vaccines_en; Blankenship, Kyle. “BioNTech, CureVac bag \$745M in German funding for COVID-19 vaccine hopefuls”. *Fierce Pharma*. 15 Sep 2020. *Accessible at:*

<https://www.fiercepharma.com/manufacturing/biontech-curevac-bag-745m-german-funding-for-covid-19-vaccine-hopefuls>

⁵ Lazare, Sarah; Oamek, Paige. “Big Pharma’s Big Lie About Vaccine Patents”. *In These Times*. 3 Nov 2021.

Accessible at: <https://inthesetimes.com/article/pfizer-moderna-vaccine-apartheid-trips-waiver-wto-intellectual-property-patents>

⁶ Marans, Daniel. “New European Vaccine Proposal Offers Limited Help To Developing Countries”. *HuffPost*. 13 Oct 2021. *Accessible at:*

https://www.huffpost.com/entry/european-union-covid-vaccine-intellectual-property-proposal_n_61664498e4b0f26084edbbff

⁷ *Ibid.*

Further, the ambiguity that remains with respect to the extent that these existing WTO flexibilities apply to manufacturing know-how and trade secrets make this approach unworkable in the context of a global pandemic when dramatic increases in the production of vaccines, tests, and treatments are desperately needed to improve access globally.

According to media reports, a summary of a September 14, 2021 meeting of the TRIPS Council at the WTO suggested that the United States does not support the Indian and South African proposal as it currently stands.⁸ If the U.S. does not support the Indian and South African proposal as-is, then we must engage actively and productively with other WTO members to develop a meaningful waiver text that can be adopted at the November 30 Ministerial Conference. The waiver agreement must allow vaccine production in the developing world to scale up dramatically—a standard that the EU’s approach does not meet.

By securing a waiver agreement at the WTO Ministerial, your Administration can demonstrate real and impactful American global leadership. If the Ministerial Conference cannot deliver a solution, the WTO—and the wealthy nations blocking the waiver—will continue to lose credibility with the developing world. We urge you to seize this opportunity to engage actively and productively at the WTO deliver on your promise to defeat the pandemic.

Sincerely,



Tammy Baldwin
United States Senator



Bernard Sanders
United States Senator

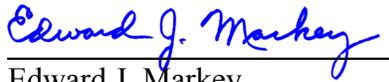


Elizabeth Warren
United States Senator



Sherrod Brown
United States Senator

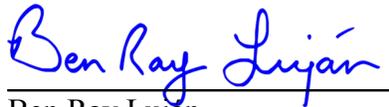
⁸ Lazare, Sarah. “U.S. Says It Supports a Covid Vaccine Patent Waiver, But Document Reveals It Is Dragging Feet at WTO”. *In These Times*. 15 Sep 2021. Accessible at: <https://inthesetimes.com/article/world-trade-organization-trips-waiver-council-proposal-patents-vaccines>



Edward J. Markey
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CC: Ambassador Katherine Tai, United States Trade Representative