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## U.S. announces support for waiving patent protections on COVID-19 vaccines

By Juliet DeFrancisco

The Biden-Harris Administration announced this Wednesday, May 5, 2021, that it supported the waiver of patent rights for COVID-19 vaccines. In a statement from the Office of the United States Trade Representative, Ambassador Katherine Tai stated that although the “Administration believes strongly in intellectual property protections,” given the current global health crises in India and other developing nations, the “Administration’s aim is to get as many safe and effective vaccines to as many people as fast as possible.”

### **How would a waiver work? What body would be responsible for its implementation?**

#### ***The World Trade Organization.***

All members of the World Trade Organization (WTO) must adhere to its Trade-Related Aspects of Intellectual Property (TRIPS) agreement. The TRIPS agreement requires that members recognize intellectual property rights and provide intellectual property rights holders with civil judicial procedures for enforcement and recovery that can be initiated against infringers.

An intellectual property waiver would allow the governments of WTO members and third parties contracted by these governments to use patented COVID-19 vaccine technology without the consent of the rights holders and without repercussion. Under the waiver, countries would not allow COVID-19 patent rights holders to recover from infringers. The waiver would be put in place for a limited period of time.

WTO decisions, however, are based on consensus. All 164 WTO members must agree to a waiver if it is to be implemented, and there is little agreement between the members on the appropriateness of any such waiver.

### **Where did this idea come from? Where do things stand?**

The initial proposal for a waiver of intellectual property protections for certain COVID-19-related technologies was submitted to the TRIPS Council by South Africa and India on October 2, 2020. This initial proposal called for a sweeping waiver of all intellectual property protections, for an

indeterminate time period, on all technologies that relate to the “prevention, containment, or treatment” of COVID-19. Several countries with emerging economies, including Kenya, Eswatini, Pakistan, Mozambique, and Bolivia, promptly co-sponsored the proposal.

Since its introduction, there have been ten rounds of talks on the proposal. As of May 5, 60 countries, mostly those with emerging economies, supported the proposal. Developed countries, such as those in the European Union, Switzerland, and Canada, countries where many pharmaceutical companies are based, continue to staunchly oppose waiving any intellectual property protections, including those on COVID-19 vaccines.

The TRIPS Council will meet for further discussions on June 8–9. Supporters of the proposal have indicated that they will narrow the scope of the October 2020 text in advance of the next meeting date.

### **International response to U.S. announcement**

In response to the U.S. announcement in support of waiving patent protections on COVID-19 vaccines, the European Union announced that it would consider the Administration’s decision. However, European Commission President Ursula von der Leyen said that she did not endorse a waiver. A spokeswoman for Germany’s Chancellor Angela Merkel similarly responded that a waiver could trigger “significant implications” for the production of vaccines. In that same statement, speaking on behalf of Ms. Merkel, the spokeswoman argued that the “limiting factor in vaccine manufacturing is production capacity and high-quality standards, not patents.”

Ms. Merkel is not, however, alone in her sentiment that waiver might not be the most suitable way to get vaccines to poorer parts of the world. WTO Director-General Ngozi Okonjo-Iweala has also suggested as a “compromise” that a plan for “global action to increase vaccine access” be developed amongst members.

### **Industry response to the administration’s announcement**

Moderna, Pfizer, and BioNTech oppose patent waivers. Vaccine development is costly and strong patent protections incentivize the development of vaccines. The waiver of patent protections now could have long-lasting consequences. A waiver now might delay any emergency work required to inoculate the public against new COVID-19 variants. A delay which would pause or even reverse our recovery. Similarly, in the next crisis, pharmaceutical companies may not be as ready and willing to invest their capital in the life-saving technologies on which we depend.

We will await the outcome of the TRIPS Council meeting on June 8–9 to see the level of consensus of its members. Until then, the waiver of intellectual property seems more verbiage than decree at this stage.

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