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HHS is urged to use its patents for the Moderna Covid-19 vaccine to widen global access



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Alex Hogan/STAT

Seeking to quickly widen global access to Covid-19 vaccines, academics, and

patient advocates are urging the Biden administration to use a key patent owned by the U.S. government to boost manufacturing and distribution of the Moderna (MRNA) shot.

In a letter to federal officials, the group noted that a soon-to-be-issued-patent covering the use of spike proteins in the vaccine was jointly developed by the company and the National Institute of Allergy and Infectious Diseases. The patent has not been licensed to Moderna; the group maintains it is an "important policy tool" that can be used to ensure any licensing agreement fosters greater access.

Specifically, members of the group argue the U.S. government should compel Moderna to transfer its manufacturing know-how to contract manufacturers to scale up production. Currently, Moderna relies on just one contract manufacturer, Lonza, to produce drug substance for its vaccine. They also say technology should be shared with the World Health Organization's technology access pool, known as C-TAP.

In addition, they maintain the federal government could gain leverage over the company to lower its pricing through a licensing deal, since "Moderna's lack of planned market entry for many low- and middle-income countries, may prevent those most in need from accessing" the vaccine. Moderna charges between \$10 and \$40 a dose, although the group claimed it costs less than \$3 a dose to make.

"U.S. taxpayers have invested over \$2.5 billion in the development of (the vaccine). Now it is time for our government to ensure that this critical lifesaving technology be made available to all. This could contribute to saving millions of lives globally. It also will help protect public health here at home. Global vaccination with highly effective vaccines is our best defense against the development of vaccine-resistant variants of SARS-CoV2," the group wrote to officials at the Department of Health and Human Services and the National Institutes of Health.

"Moderna appears to rely on foundational coronavirus vaccine technology invented and patented by NIH in every vial it sells," Christopher Morten, a signatory and the deputy director of the Technology Law and Policy Clinic at the New York University School of Law, wrote us.

Among those signing the letter were several advocacy groups, including Prep4All, Public Citizen, I-Mak, and HealthGAP, as well as the deans of public health schools at Columbia University, New York University, the City University of New York, and other academics.

We asked Moderna for comment and will update you accordingly.

This is the not the first time that Moderna has been singled out in a bid to widen access. Last fall, an advocacy group issued a report detailing the role played by the U.S. government in developing the vaccine. And another group complained to federal officials that Moderna received federal grants that were not properly disclosed in its vaccine patents or patent applications.

The company <u>responded</u> by declaring it would not enforce its patent rights related to its vaccine and will license its intellectual property to any Covid-19 vaccines to others after the pandemic ends. But advocates criticized the move as a way to potentially deflect litigation since Moderna disclosed it was uncertain whether it was the first to make inventions claimed in patents or pending patent applications. They also argued the company should provide its intellectual property to the WHO.

The missive is the latest attempt to push wealthy governments to foster wider access to Covid-19 vaccines to low- and middle-income countries. Over the past years, the U.S., the U.K., and the European Union have invested heavily in vaccine production and reached agreements with various manufacturers to lock in supplies for their own populations.

Through procurement deals, high-income countries hold 4.6 billion doses, upper middle-income countries hold 1.5 billion doses, lower middle-income countries hold 703 million doses, and low-income countries hold 670 million. Wealthy countries have hedged their bets by purchasing enough doses to vaccinate their population several times over, according to the Duke Global Health Innovation

Center.

The issue has prompted a clash at the World Trade Organization, where South Africa and India <u>proposed</u> the agency to temporarily waive provisions in a trade agreement that would make it possible for manufacturers to access production know-how in order to produce Covid-19 vaccines that can be more readily supplied to low and middle-income countries.

Several wealthy countries, including the U.S., have so far pushed back against the proposal with the <u>urging</u> of the pharmaceutical industry, which has argued that patents are not a barrier to greater access. However, dozens of Democratic lawmakers last week urged the Biden administration to alter its stance and support the proposal.

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