

Xavier Becerra
United States Secretary of Health and Human Services

Francis S. Collins, MD
Director
National Institutes of Health (NIH)

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases (NIAID)

RE: Moderna and Its Use of an NIH-Owned Patent For COVID-19 Vaccines

24 March 2021

Dear Secretary Becerra, Dr. Collins, and Dr. Fauci:

We write about the soon-to-issue-patent, U.S. Patent No. 10,960,070 (“the ’070 patent”),¹ that protects the use of proline-substituted coronavirus spike proteins stabilized in their prefusion conformation as a vaccine immunogen. The mRNA-1273 vaccine, co-developed by NIAID and Moderna, utilizes this technology for its immunogen.² The ’070 patent is owned by the United States Government, reflecting the critical contributions that NIAID and NIH made to the invention of this technology.³

This government-owned patent is an important policy tool that the U.S. government could use to facilitate scale up of production of mRNA-1273 and ensure rapid, equitable global access. Currently, at best, only one billion doses of mRNA-1273 will be produced in 2021⁴, far short of global demand.

The U.S. government has not licensed the patent to Moderna.⁵ It is imperative that the NIH uses any licensing agreement to include provisions to help increase global access to this lifesaving technology, rather than just a monetary royalty.

Specifically, the licensing agreement should:

1. Empower the U.S. government to authorize manufacturing of mRNA-1273 – including by government-owned production facilities.

¹ According to the U.S. Patent & Trademark Office, the ’070 patent will issue on March 30, 2021 from pending U.S. Patent Application No. 16/344,774.

² See, e.g. Rizvi Z. “The NIH Vaccine.” (25 June 2020) URL: <https://www.citizen.org/article/the-nih-vaccine/>

³ US NIH, Office of Technology Transfer. “Prefusion Coronavirus Spike Proteins and Their Use.” URL: <https://www.ott.nih.gov/technology/e-234-2016> (Accessed on 17 March 2021). The ’070 patent is jointly owned by the U.S. Government, The Scripps Research Institute, and the Trustees of Dartmouth College.

⁴ Moderna Inc. “Moderna Announces Additional Capital Investments to Increase Global Manufacturing Capacity for COVID-19 Vaccine” (24 Feb 2021). URL: <https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-additional-capital-investments-increase-global#:~:text=Moderna%20also%20announces%20it%20is,doses%20in%20fiscal%20year%202021.>

⁵ Gebrekidan S and Appuzo M. Rich Countries Signed Away a Chance to Vaccinate the World. (Accessed on March 21, 2021) URL: <https://www.nytimes.com/2021/03/21/world/vaccine-patents-us-eu.html>

Currently, Moderna has only contracted with a single contract manufacturing organization (CMO), Lonza Group AG, to produce drug substance for mRNA-1273. By contracting with other CMOs to produce drug substance and help perform other manufacturing steps, more doses of mRNA-1273 could be produced. Such provisions should include the ability for the U.S. government to compel transfer of know-how from Moderna to other CMOs to facilitate scale up for all production steps of the manufacturing process.

2. Require technology sharing with the World Health Organization to help ramp up global production.

The Director-General of the World Health Organization has urged countries to share vaccine technology and know-how openly to help build global manufacturing capacity.⁶ Moderna has so far ignored requests from developing country manufacturers to share technology.⁷ Requiring Moderna to work with the WHO's COVID-19 technology access pool can help unlock additional production.

3. Include requirements for accessible pricing universally.

Moderna is currently charging between US\$10 and US\$40 a dose for mRNA-1273⁸, despite it costing less than \$3 a dose to manufacture⁹. This high price, coupled with Moderna's lack of planned market entry for many low- and middle-income countries, may prevent those most in need from accessing mRNA-1273. Licensing the '070 patent gives the U.S. government leverage to increase global access by requiring accessible pricing to mRNA-1273.

Assertion of U.S. government-owned intellectual property to increase access to pharmaceutical products is not unprecedented. In 2019, the federal government sued Gilead Sciences for its infringement of government owned patents protecting the use of Truvada and Descovy for HIV pre-exposure prophylaxis (PrEP) – and per the complaint itself, is using that litigation to increase access to PrEP.¹⁰ That lawsuit is ongoing.

U.S. taxpayers have invested over \$2.5 billion in the development of mRNA-1273.¹¹ 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, like mRNA-1273, is our best defense against the development of vaccine-resistant variants of SARS-CoV2.

Thank you.

⁶ Tedros Ghebreyesus, "Vaccine Nationalism Harms Everyone and Protects No One" (2 Feb 2021), <https://foreignpolicy.com/2021/02/02/vaccine-nationalism-harms-everyone-and-protects-no-one/#>

⁷ Associated Press, "Countries urge drug companies to share vaccine know-how" (1 Mar 2021) <https://apnews.com/article/drug-companies-called-share-vaccine-info-22d92afbc3ea9ed519be007f8887bcf6>

⁸ See, e.g. AVAC. Vaccine Access Cheat Sheet. URL: [COVID Candidate Comparison March15-2021.pdf \(avac.org\)](https://www.avac.org/COVID-Candidate-Comparison-March15-2021.pdf)

⁹ Kis Z et al. Resources, Production Scales and Time Required for Producing RNA Vaccines for the Global Pandemic Demand. *Vaccines* 2021, 9(1), 3; <https://doi.org/10.3390/vaccines9010003>

¹⁰ ECF Filing No. 1. *United States v. Gilead Sciences, Inc.*, No. 1:19-cv-02103-UNA (D. Del. Nov. 6, 2019).

¹¹ See, e.g. Grady D. Early Data Show Moderna's Coronavirus Vaccine Is 94.5% Effective. URL: <https://www.nytimes.com/2020/11/16/health/Covid-moderna-vaccine.html>

Please do not hesitate to contact us with any questions, comments or concerns. We would like to meet with you and your teams as soon as possible regarding this issue.

Sincerely,

PrEP4All

Public Citizen

I-MAK

HealthGAP

Health Justice Initiative

AVAC

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¹ Academic title provided for informational purposes and does not imply university or institutional endorsement