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November 2, 2021

Dr. Francis Collins
Director, National Institutes of Health
National Institutes of Health (NIH)
9000 Rockville Pike
Bethesda, Maryland 20892

Dear Dr. Collins,

We are writing to raise our concern about new patent applications filed by Moderna that do not list federal scientists as co-inventors of the NIH-Moderna coronavirus vaccine, mRNA-1273. This exclusion may erase the critical contributions of federal scientists in inventing the vaccine.

The NIH and its academic partners have done seminal work underpinning coronavirus vaccine development.¹ Last year, we documented how nearly all the leading coronavirus vaccines use the NIH stabilized spike protein technology, starting with mRNA-1273.² However, it was clear that Moderna uniquely benefited from federal support. “We did the front end. They did the middle. And we did the back end,” said Dr. Barney Graham, a former top NIH official, referring to the process for designing the spike protein sequence, manufacturing vaccines, and running clinical trials.³ A lack of transparency precluded us from identifying additional patent applications specific to mRNA-1273.

Since then, new evidence has emerged showing that Moderna did not name NIH scientists as co-inventors in three patent applications covering the composition of the spike protein sequence encoded by mRNA-1273.⁴ Federal scientists are only acknowledged as co-inventors for one patent application covering a method of use for mRNA-1273.⁵ Because co-inventorship creates a presumption of co-ownership, this series of exclusions could have important public health consequences if and when the patent applications mature into issued patents around the world.⁶ We urge you to publicly reclaim the foundational role of the NIH, and use your leverage to champion global vaccine access.

¹ The NIH team worked with University of Texas scientists at the McLellan lab. <https://tinyurl.com/8d8e9ky2>

² U.S. 10,960,070. <https://www.axios.com/moderna-nih-coronavirus-vaccine-ownership-agreements-22051c42-2dee-4b19-938d-099afd71f6a0.html> ; <https://www.citizen.org/article/leading-covid-19-vaccines-depend-on-nih-technology/> and https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3889784. As of March 2021, Moderna did not have permission to use this technology. <https://www.nytimes.com/2021/03/21/world/vaccine-patents-us-eu.html>. A lack of transparency precluded us from identifying additional patent applications specific to mRNA-1273.

³ <https://www.nytimes.com/2021/03/21/world/vaccine-patents-us-eu.html>. The U.S. government also partnered with Moderna for manufacturing scale-up. <https://www.citizen.org/article/sharing-the-nih-moderna-vaccine-recipe/>

⁴ See Table 1.

⁵ Moderna also recently obtained two patents covering composition of betacoronavirus spike proteins formulated in a lipid nanoparticle and methods of use, but both patents claimed priority to applications filed in 2015—prior to the NIH-Moderna partnership. U.S. 10,933,127 and U.S. 10,702,600.

⁶ U.S. Application No. 17/000,215 covering the spike protein sequence has been “allowed,” meaning the U.S. Patent & Trademark Office has determined that it meets patentability criteria. The patent will be issued once Moderna pays the fee.

Table 1: Moderna Newly Filed Patent Applications Covering mRNA-1273⁷

Patent Application	Name	Inventor	Priority Claim	Sample Claim
U.S Application No. 17/000,215 ⁸	Coronavirus RNA Vaccines	Mihir Metkar; Vladimir Presnyak; Guillaume Stewart-Jones (ModernaTX, Inc.)	01/28/20	"A [mRNA] comprising an open reading frame (ORF) that comprises a nucleotide sequence having at least 80% identity to the nucleotide sequence of SEQ ID NO: 28 and encodes a polypeptide comprising the amino acid sequence of SEQ ID NO: 29. " ⁹
PCT/US2021/015145 ¹⁰	Coronavirus RNA Vaccines	Guillaume Stewart-Jones; Elisabeth Narayanan; Hamilton Bennett; Andrea Carfi; Mihir Metkar; Vladimir Presnyak (ModernaTX, Inc.)	01/28/20	"A [mRNA] comprising an open reading frame (ORF) that encodes a SARS-CoV-2 spike (S) protein having a double proline stabilizing mutation. "
PCT/US2021/016979 ¹¹	SARS-CoV-2 mRNA Domain Vaccines	Guillaume Stewart-Jones (ModernaTX, Inc.)	02/07/20	"The mRNA of claim 84 or 85, wherein the antigen comprises an amino acid sequence having at least 80% . . . identity to the amino acid sequence of SEQ ID NO: 17 or 146 , optionally wherein the antigen comprises the amino acid sequence of SEQ ID NO: 17 or 146. " ¹²
PCT/US2021/032609 ¹³	Coronavirus RNA Vaccines and Methods of Use	Hamilton Bennett; Guillaume Stewart-Jones; Elisabeth Narayanan; Andrea Carfi; Mihir Metkar; Vladimir Presnyak (ModernaTX, Inc.) Barney S. Graham; Kizzmekia S. Corbett (U.S.)	05/15/20	" A method comprising administering to a human subject a composition comprising a [mRNA] comprising an open reading frame (ORF) that encodes a SARS-CoV-2 prefusion stabilized Spike (S) protein , wherein the mRNA is formulated in a lipid nanoparticle, and wherein the composition is administered in an effective amount to induce in the subject a neutralizing antibody response to SARS-CoV-2 S protein, wherein the effective amount is a 25 µg or 100 µg dose. " ¹⁴

⁷ We did not examine the patent applications, and assess whether they meet patentability criteria. Some of Moderna's applications ultimately may not be granted by national patent offices. However, we note that U.S Application No. 17/000,215 has been "allowed," meaning the U.S. Patent & Trademark Office has determined that it meets patentability criteria. The patent will be issued once Moderna pays the fee.

⁸ <https://patentscope.wipo.int/search/en/detail.jsf?docId=US331909135&tab=NATIONALBIBLIO>

⁹ Sequence 29 encodes the stabilized spike protein with proline mutations. It is the same amino acid sequence described in the public mRNA-1273 reverse engineered sequence. <https://tinyurl.com/vvteva9x>.

¹⁰ This application is related to U.S Application No. 17/000,215. Both claim priority to the same U.S. provisional applications, 62/967,006 and 62/971,825.

¹¹ <https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2021159040&tab=PCTBIBLIO>.

¹² Claim 84: "A [mRNA] comprising an open reading frame (ORF) that encodes at least one domain of a SARS-CoV-2 Spike protein." Sequence 146 encodes the stabilized S2 unit of the spike protein. It is 97.9% identity in 585 residues overlap of the mRNA-1273 reverse engineered sequence. <https://tinyurl.com/vvteva9x>. Calculations available upon request.

¹³ <https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2021159130&tab=PCTBIBLIO>

¹⁴ This claim would not cover administration of the booster dose of mRNA-1273 (50 µg).

Under U.S. patent law, a person who makes a significant contribution to the conception of an invention is a joint inventor.¹⁵ Joint inventors do not have to make the same type or amount of contribution: “[A] joint inventor as to even one claim enjoys a presumption of ownership in the entire patent.”¹⁶ U.S. law requires the patent application to list the correct inventors.¹⁷

NIH scientists have noted their significant scientific contributions to the spike protein sequence encoded by mRNA-1273. “On Jan. 7, we talked to the CEO of Moderna, and he said as soon as you send us the sequence and what to make, they’ll start manufacturing,” recalled Dr. Barney Graham.¹⁸ Dr. Kizzmekia Corbett’s academic biography notes “the vaccine concept incorporated in mRNA-1273 was designed by Dr. Corbett’s NIH team from viral sequence and rapidly deployed to industry partner, Moderna, Inc.”¹⁹ According to Dr. Corbett, an earlier partnership with Moderna focused on the MERS coronavirus helped accelerate the SARS-CoV-2 response. “We worked together for several years on MERS vaccines. We even knew *based on my lab notebooks* what doses would work in animals, what exact construct to design, vaccine schedule, etc.”²⁰ (emphasis added)

Moderna acknowledges the role played by the NIH in a more limited way. Moderna says it *finalized* the sequence in collaboration with the NIH, but that it had a separate team working in parallel with the NIH that *independently* designed (i.e., conceived) the exact sequence as the NIH team.²¹ They merely “compared notes” at the end.²²

We are skeptical of Moderna’s characterization. Designating two independent teams to solve the same problem would mark an unusual style of scientific collaboration in a pandemic, and seems to go against the public statements of federal scientists.²³ The claim that two independent teams invented the same spike protein sequence and made the same design choices would also represent a notable coincidence.

¹⁵ In re VerHoef, 888 F.3d 1362, 1366-67 (Fed. Cir. 2018) (“A joint inventor must (1) contribute in some significant manner to the conception or reduction to practice of the invention, (2) make a contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention, and (3) do more than merely explain to the real inventors well-known concepts and/or the current state of the art.”)

¹⁶ Ethicon, Inc. v. U.S. Surgical Corp., 135 F.3d 1456, 1465–66 (Fed. Cir. 1998). Inventorship cannot be waived or changed via contract. Ownership can be reassigned contractually. We are not aware of any agreements that transfer NIH ownership to Moderna. NIH should disclose any relevant agreements, if any, with Moderna.

¹⁷ See, e.g., 37 C.F.R. 1.41(a) (“An application must include, or be amended to include, the name of the inventor for any invention claimed in the application.”)

¹⁸ <https://www.ricethresher.org/article/2021/03/from-farming-to-designing-vaccines-alum-barney-graham-solves-problems>

¹⁹ <https://www.hsph.harvard.edu/profile/kizzmekia-s-corbett/>

²⁰ <https://twitter.com/KizzyPhD/status/1349687661661880321>. See also, NIH National Cancer Institute, Guide for Keeping Laboratory Records: Do’s & Don’t, <https://techtransfer.cancer.gov/intellectualproperty/inventions/inventor-guidance/guide-keeping-laboratory-records-dos-dont> (“Laboratory notebooks, if used properly, can serve as the basis of conception for proving inventorship.”)

²¹ <https://www.modernatx.com/blog/moderna-2020-shareholder-letter> (“In January, just two days after the Chinese authorities shared the genetic sequence of the novel coronavirus, NIH and Moderna’s infectious disease research team finalized the sequence for mRNA-1273. We recognized important similarities to the MERS virus and, based on good preclinical data and analysis from the previous two years of collaboration with NIH, decided to encode for the full-length Spike (S) protein 1273.”) <https://www.bio.org/blogs/one-one-moderna-ceo-stephane-bancel-search-covid-19-vaccine-i-am-bio-podcast-330> (“The Moderna team worked in Boston while the NIH team worked outside of D.C. and we then compared notes. We independently analyzed the genetic information and shared the different thoughts of how we planned to design the vaccine. What is very encouraging is that both teams independently came to exactly the same antigen – the same protein of a virus – that we thought was the most potent vaccine against this virus.”)

²² *Id.*

²³ Dr. Barney Graham, “We did the front end. They did the middle. And we did the back end.” He was referring to sequence design, manufacturing and clinical trials. <https://www.nytimes.com/2021/03/21/world/vaccine-patents-us-eu.html> “We

The NIH appears to share some of our concern. A filing with the U.S. Patent & Trademark Office reveals that the NIH asked Moderna to include NIH scientists as co-inventors of U.S. Application No. 17/000,215.²⁴ Moderna, however, denied the request and claimed that that the federal scientists “did not co-invent the mRNAs and mRNA compositions claimed in the present application.”²⁵

We urge you to publicly clarify the role of the NIH in the invention of the vaccine, and to explain the steps you intend to take to ensure the contributions of federal scientists are fully recognized, including any legal remedies. We also request that you publish all research agreements with Moderna. We are concerned that Moderna’s decision to file for patents alone—weeks after it knew that its NIH partners worked on the same problem and had reached the same solution—may not be consistent with the terms or the spirit of the contractual arrangement between NIH and Moderna.²⁶

Co-inventorship creates a presumption of co-ownership. Co-ownership can empower the U.S. government to authorize additional manufacturers to use some mRNA-1273 patents around the world, including through the Medicines Patent Pool, without Moderna’s permission. It can also significantly bolster the public’s understanding of the critical role played by federal scientists in the invention and development of the NIH-Moderna vaccine. With huge gaps in global vaccine access, the need for the U.S. government to assert more control over this technology—including through the Defense Production Act—only grows more urgent.

Sincerely,



Peter Maybarduk

Director, Access to Medicines Program

Public Citizen

worked together for several years on MERS vaccines. We even knew based on my lab notebooks what doses would work in animals, what exact construct to design, vaccine schedule, etc.” <https://twitter.com/KizzyPhD/status/1349687661661880321>

²⁴ Moderna, Statement Filed Pursuant to the Duty of Disclosure, U.S. PTO Docket No. M1378.70145US07 (“Pursuant to 37 C.F.R. §1.56, Applicants disclose that their collaborators at the National Institutes of Health submitted John Mascola, M.D.; Barney Graham, M.D., Ph.D; and Kizzmekia Corbett, Ph.D. to Applicants as additional co-inventors of this patent application. However, Applicants have reached the good-faith determination that these individuals did not co-invent the mRNAs and mRNA compositions claimed in the present application.”)

²⁵ *Id.*

²⁶ Moderna filed a provisional patent application January 28, 2020. Moderna acknowledges finalizing sequence with NIH on January 13, 2020. <https://www.sec.gov/Archives/edgar/data/1682852/000119312520074867/d884510dex991.htm> (“On January 13, 2020, the U.S. National Institutes of Health (NIH) and Moderna’s infectious disease research team finalized the sequence for mRNA-1273, the Company’s vaccine against the novel coronavirus.”)