

Moderna and U.S. at Odds Over Vaccine Patent Rights

Moderna's patent application names several employees as the sole inventors of a crucial component of its coronavirus vaccine, excluding three government scientists.

By Sheryl Gay Stolberg and Rebecca Robbins

Nov. 9, 2021

Updated 7:23 p.m. ET

WASHINGTON — [Moderna](#) and the National Institutes of Health are in a bitter dispute over who deserves credit for inventing the central component of the company's powerful coronavirus vaccine, a conflict that has broad implications for the vaccine's long-term distribution and billions of dollars in future profits.

The vaccine grew out of a four-year collaboration between Moderna and the N.I.H., the government's biomedical research agency — a partnership that was widely hailed when the shot was found to be highly effective. A year ago this month, the government called it the “N.I.H.-Moderna Covid-19 vaccine.”

The agency says three scientists at its Vaccine Research Center — Dr. John R. Mascola, the center's director; Dr. Barney S. Graham, who recently retired; and Dr. Kizzmekia S. Corbett, who is now at Harvard — worked with [Moderna](#) scientists to design the genetic sequence that prompts the vaccine to produce an immune response, and should be named on the “principal patent application.”

Moderna disagrees. In a July [filing](#) with the United States Patent and Trademark Office, the company said it had “reached the good-faith determination that these individuals did not co-invent” the component in question. Its application for the patent, which has not yet been issued, names several of its own employees as the sole inventors.

[Read [Moderna's filing](#) with the United States Patent and Trademark Office.]

The N.I.H. had been in talks with Moderna for more than a year to try to resolve the dispute; the company's July filing caught the agency by surprise, according to a government official familiar with the matter. It is unclear when the patent office will act, but its role is simply to determine whether a patent is warranted. If the two sides do not come to terms by the time a patent is issued, the government will have to decide whether to go to court — a battle that could be costly and messy.

The dispute is about much more than scientific accolades or ego. If the three agency scientists are named on the patent along with the Moderna employees, the federal government could have more of a say in which companies manufacture the vaccine, which in turn could influence which countries get access. It would also secure a nearly unfettered right to license the technology, which could bring millions into the federal treasury.

The fight comes amid mounting frustration in the U.S. government and elsewhere with Moderna's limited efforts to get its vaccine to poorer countries. The company, which has not previously brought a product to market, received nearly \$10 billion in taxpayer funding to develop the vaccine, test it and provide doses to the federal government. It has already lined up supply deals worth about \$35 billion through the end of 2022. Drs. Mascola, Graham and Corbett declined to comment. But in statements to The New York Times, the N.I.H. and Moderna confirmed the conflict, which has been simmering for more than a year behind closed doors.

“N.I.H. disagrees with Moderna's inventorship determination,” said Kathy Stover, a spokeswoman for the National Institute for Allergy and Infectious Diseases, the branch of the institutes that oversees vaccine research. “Omitting N.I.H. inventors from the

principal patent application deprives N.I.H. of a co-ownership interest in that application and the patent that will eventually issue from it.”

A spokeswoman for Moderna, Colleen Hussey, said the company had “all along recognized the substantial role that the N.I.H. has played in developing Moderna’s Covid-19 vaccine.”

But she said the company was legally bound to exclude the agency from the core application, because “only Moderna’s scientists designed” the vaccine.

Scientists familiar with the situation said they saw it as a betrayal by Moderna, which has received [\\$1.4 billion](#) to develop and test its vaccine and another \$8.1 billion to provide the country with half a billion doses. John P. Moore, a professor of microbiology and immunology at Cornell University, called it a matter of “fairness and morality at the scientific level,” adding, “These two institutions have been working together for four or five years.”

As is typical in the pharmaceutical industry, Moderna has sought [a number of patents](#) in the United States and overseas related to different aspects of its Covid vaccine technology. But experts said the disputed patent was the most important one in Moderna’s growing intellectual property portfolio. It seeks to patent the genetic sequence that instructs the body’s cells to make a harmless version of the spike proteins that stud the surface of the coronavirus, which triggers [an immune response](#).

While it has not publicly acknowledged the rift until now, the Biden administration has expressed frustration that Moderna has not done more to [provide its vaccine to poorer nations](#) even as it racks up huge profits.

Activists have pleaded with the government to push Moderna to share its vaccine formula and transfer its technology to manufacturers who could produce it at a lower cost for poorer nations. But administration officials say they [lack the authority](#) to require the company to do so.

A medical worker administers the Moderna vaccine in Philadelphia in May.

Credit...

Rachel Wisniewski for The New York Times

Last week, [the advocacy group Public Citizen wrote to Dr. Francis S. Collins](#), the director of the N.I.H., urging him “to publicly clarify the role of the N.I.H. in the invention of the vaccine” and to explain what he intended to do “to ensure the contributions of federal scientists are fully recognized.” The group has not gotten a response.

[The Coronavirus Pandemic: Latest Updates](#)

“It’s not just about bragging rights,” said [Zain Rizvi](#), a drug policy expert at Public Citizen who researched Moderna’s patent filings. “It’s also about supply. Patents are development monopolies, and in a pandemic it is a terrible idea to have a private corporation have a monopoly on part of a lifesaving technology.”

If the N.I.H. scientists were named as co-inventors on the patent, the agency would generally not need Moderna’s permission to license it to other companies or organizations, patent law experts said. In theory, that could help expand the supply of the Moderna vaccine.

Moderna has [pledged](#) not to enforce its Covid vaccine patents during the pandemic. But a license from the government would provide additional legal reassurance to manufacturers and allow them to keep producing the vaccine after the pandemic, experts said.

With a license from the U.S. government, “you’ve got the force of law rather than just a statement in the public domain,” said Ameet Sarpatwari, an expert on pharmaceutical policy and law at Harvard Medical School.

But even with a license, manufacturers would lack crucial components for quickly making Moderna’s vaccine — including the recipe and the company’s technical know-how.

A patent license is “just one piece of an otherwise very large jigsaw puzzle,” said Jacob S. Sherkow, an expert on biotechnology patent law at the University of Illinois College of Law. “The patent license does not build factories, it doesn’t source raw materials, it doesn’t train workers.”

The N.I.H. could benefit financially from licensing out the patent. Several experts said it was difficult to know how much, but Mr. Sarpatwari estimated the agency could reap tens of millions of dollars.

For the company, having patents solely in its name helps “support a narrative that Moderna was not just the lucky recipient of unprecedented massive investment by the U.S. government, but that Moderna made unique and essential contributions on its own,” said Christopher Morten, an expert on pharmaceutical patent law at Columbia Law School.

That could help the company justify its prices and rebuff pressure to make its vaccine available to poorer countries.

“Moderna wants exclusive ownership and control of this patent,” Mr. Morten said. “They want to be the only organization that decides where mRNA-1273 is made, how it’s made, who makes it, what price it’s sold for. And co-ownership of this patent is a threat to that control.”

The story of the public-private collaboration has been one of the few bright spots of the pandemic. The three government scientists — especially Dr. Corbett, who emerged as a role model for young Black women in science and has worked to address vaccine hesitancy in minority communities — have been hailed as heroes.

Moderna, a young company that had never before brought a product to market, became a household name virtually overnight. The vaccine is on track to bring in [up to \\$18 billion](#) in revenue for Moderna this year. The company has already booked deals for next year worth up to \$20 billion. Sales of its vaccine both this year and next are likely to rank among the highest in a single year for any medical product in history.

Dr. Graham, who was the Vaccine Research Center’s deputy director before his retirement, began his work on coronaviruses long before the pandemic. In 2017, Dr. Graham and Jason McLellan, a scientist now at the University of Texas at Austin, led a team of researchers, including Dr. Corbett, that figured out how to employ protein engineering to stabilize the spike proteins on the coronavirus before they fuse with other cells.

That technology, which has been [patented by N.I.H.](#) and its academic collaborators, is foundational to a number of coronavirus vaccines, including the ones made by both Moderna and its main competitor, Pfizer-BioNTech. But while BioNTech and other companies have paid to license the technology, Moderna has not — another sore point between the company and the government, a senior administration official said. Moderna declined to comment on it.

Moderna and the government researchers had been working together for four years on projects involving other coronaviruses when the new one emerged in China. In January 2020, N.I.H. and Moderna “agreed to collaborate and jointly develop” a vaccine, Ms. Stover said.

The Vaccine Research Center quickly zeroed in on the gene for the virus’s spike protein and sent the data to Moderna in a Microsoft Word file, Dr. Graham said [in an interview last year](#). Moderna said at the time that its scientists had independently identified the same gene. The company’s chief executive, Stéphane Bancel, said Moderna plugged the data into its computers and came up with the design for an mRNA vaccine.

“We had two teams working in parallel, to increase the chances,” Mr. Bancel told the [M.I.T. Technology Review](#).

When Moderna [announced](#) a year ago that the vaccine had been found in a key trial to be spectacularly protective, the N.I.H. called it “[the N.I.H.-Moderna Covid-19 vaccine](#)” in its own news release. Dr. Anthony S. Fauci, who oversaw the research in his role as director of the allergy and infectious diseases institute, [said](#) that the “vaccine was actually developed in my institute’s vaccine research center by a team of scientists led by Dr. Barney Graham and his close colleague, Dr. Kizzmekia Corbett.”

[Asked late last year about the comment](#), Mr. Bancel pushed back. “The vaccine technology was developed by Moderna,” he insisted.

Consumer advocacy groups and government watchdogs have long complained that the N.I.H. is not aggressive enough in protecting and asserting legal rights to its work — to the detriment of taxpayers, who often face high costs for drugs developed with government funding and research.

“It points to these broader issues that N.I.H. has with basically getting taken advantage of by pharma,” said James Krellenstein, a founder of PrEP4All, an AIDS advocacy group that successfully urged the Trump administration to sue [Gilead Sciences](#), accusing the company of making billions by infringing on government patents for H.I.V.-prevention drugs. The [suit is pending](#) in the U.S. District Court in Delaware.

Ms. Hussey, the Moderna spokeswoman, said that the “N.I.H. having rights under the patent application is not dependent on being listed as co-inventors.” She declined to answer additional questions about the rights she was referring to.

Scientists from the agency are named on a minor [patent application](#) that does not confer licensing power over the technology covered by the primary patent application. Ms. Stover, the spokeswoman for the National Institute for Allergy and Infectious Diseases, said that none of the agency’s collaboration agreements with Moderna “include language controlling the licensing of inventions that might result from that work.”