After Long Delay, Moderna Pays N.I.H. for Covid Vaccine Technique

Moderna has paid \$400 million to the government for a chemical technique key to its vaccine. But the parties are still locked in a high-stakes dispute over a different patent.

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Experts and activists said that Moderna had for years resisted acknowledging its true debt to the government and to academic researchers. Cooper Neill for The New York



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As Moderna racked up tens of billions of dollars in sales of its coronavirus vaccine, the company held off on paying for the rights to a chemical technique that scientists said it had borrowed from government-funded research and used in its wildly successful shot.

But Moderna and the government have now reached an agreement. The company said on Thursday that it had made a \$400 million payment for the technique that will be shared by the National Institutes of Health and two American universities where the method was invented.

The payment, disclosed in <u>Moderna's latest earnings report</u>, represented a small victory for the experts and activists who long argued that the company had resisted acknowledging its debt to the government and academic researchers.

"If pharmaceutical companies are going to make billions of dollars, it seems reasonable that the scientists who helped generate some of the initial intellectual property and the universities also share some of the gains," said Jason McLellan, a structural biologist who in 2017 led efforts to devise the technique in question as a researcher at the Geisel School of Medicine at Dartmouth. "A lot of that will now be reinvested for future development and research."

Moderna is still locked in a <u>separate high-stakes dispute with the N.I.H.</u> over who invented the central component of the vaccine, the genetic sequence that helps recipients produce an immune response.

The N.I.H. said its scientists, some of whom had been collaborating for years with Moderna, had helped to design that sequence. Moderna also received nearly \$10 billion in taxpayer funding to develop and test the vaccine, and to provide doses to the federal government. The company has sold roughly \$36 billion worth of coronavirus vaccines worldwide.

But even as the fight over the sequence attracted public attention, including <u>suggestions from the N.I.H. that it might consider legal action</u>, another standoff played out largely in private, this one concerning the chemical tweak that was the subject of the payments announced on Thursday.

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That technique was integral to a number of coronavirus vaccines, including Moderna's, scientists said. It entailed changing the mRNA code within the vaccines so that they would help people generate an immune response to the version of spike proteins present on the surface of the coronavirus before they fused with human cells.

It appeared indisputable to legal experts that government and academic researchers had invented the technique. Scientists at Dartmouth, Scripps Research, in California, and the N.I.H. published findings in 2017 and filed for a patent. A patent. A patent was issued in 2021.

Other vaccine makers, too, acknowledged relying on those researchers' work. By the end of 2021, seven pharmaceutical companies had agreed to pay the three institutions for the use of their technique. Among them was BioNTech, whose coronavirus vaccine made with Pfizer became the main competitor to Moderna's.

But negotiations with Moderna were slower. The delay in licensing the spike technology became another sore point between the company and the government.

"Moderna has benefited richly from government largess, and it does owe a public duty, but it's been very begrudging and slow in acknowledging that public duty," said Lawrence Gostin, a professor of global health law at Georgetown University.

Mr. Gostin said the agreement announced on Thursday, which was finalized in December, was "a small token in the right direction."

Chris Ridley, a Moderna spokesman, said in a statement that the company and the government "have been engaged in productive discussions since 2020 regarding the licensing of certain patents related to Covid-19 vaccines." He added, "It was always our

Under the agreement with Moderna, the company made what it described as a \$400 million "catch-up payment" to the N.I.H. The government will share that money with Dartmouth and Scripps. The individual scientists who helped invent the technique are also likely to receive a portion of the payment, experts said. Moderna said the agreement also required royalty payments representing low single-digit percentages of future Covid-19 vaccine sales.

The company has forecast Covid vaccine sales of \$5 billion for 2023.

The N.I.H. tends to be uneasy about aggressively asserting legal rights to its work, experts said, a stance that some activists believ hurts taxpayers who face high prices for medicines developed wit government funding and research. In the case of the dispute over the spike-protein technique, experts said, the N.I.H. was in a particularly tricky position because of its parallel fight over who ultimately invented the vaccine.

That put more of the onus on Dartmouth and Scripps to encourage the government and Moderna to reach an agreement. For those institutions, the potential licensing fees represented a significant

Dartmouth's director of technology transfer. "This money is going to go right back into the kind of research that enables further lifesaving drugs and into educating people."

For a university of Dartmouth's size, she said, the payments were "game-changing." Royalty payments for an earlier drug developed in part at Dartmouth helped the university set up the research program where Dr. McLellan worked, Ms. Rosenfield said. Now the payments for Dr. McLellan's findings could help cultivate future discoveries.

The university said that it had already received \$117 million from vaccine makers that had reached earlier agreements to license the spike technique.

Dr. McLellan had been working at Dartmouth to respond to an outbreak of an earlier coronavirus — one that causes Middle East Respiratory Syndrome, or MERS — when he developed the trick for modifying the spike. The spikes on the surface of that virus, too, were squirmy and unstable, taking one form before invading a cell and another afterward.

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Dr. McLellan's team, working with Dr. Barney Graham at the N.I.H. and Andrew Ward at Scripps, knew that the spike needed to be locked in place if it was to elicit the strongest possible immune response. After several attempts failed, they zeroed in on a particularly loose joint of the spike and added two stiff amino acids, a tweak that made the entire thing more rigid.

Philip Hanlon, the president of Dartmouth, said that it had been a "thrilling moment" when the research had been harnessed for the coronavirus vaccines. Ensuring that the university and its scientists were paid for the work, he said, would set the stage for future research, especially experiments risky and uncertain enough that pharmaceutical companies would generally not think it worthwhile to carry them out themselves.

"I think this gives you a model for partnerships where the basic, curiosity-based research did happen on a campus, and led to eventually creating a product which saved millions of lives," he said.