Covid-19 vaccines

Vaccine patent gives US government 'leverage' over manufacturers

Washington can boost global access to Covid shots by compelling groups to share technology, says top scientist



Donato Paolo Mancini in Rome and Kiran Stacey in Washington 46 MINUTES AGO

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The US government can use its ownership of a crucial vaccine patent to push companies to share their expertise with other manufacturers and boost global access to coronavirus jabs, according to a top scientific official.

Barney Graham, one of the US National Institutes of Health scientists who invented a key piece of technology used in the Moderna and BioNTech/Pfizer jabs, told the Financial Times the government's patent gave Washington "leverage" over manufacturers.

"Virtually everything that comes out of the government's research labs is a non-exclusive licensing agreement so that it doesn't get blocked by any particular company," said Graham, who plans to retire from the US government this year. "That's one of the reasons [I joined the NIH]: it's to be able to use the leverage of the public funding to solve public health issues."

Graham's rare public comments come as vaccine manufacturers are facing increasing pressure to boost supply by waiving intellectual property rights and sharing technology that would enable other producers around the world to produce similar <u>coronavirus vaccines</u> locally.

The specific US government patent in question — US patent number 10,960,070, better known as the '070 patent — relates to how the spike protein is stabilised in the vaccine, a technique that was developed by the NIH's Vaccine Research Center. It is a key component of the mRNA vaccine jointly developed by Moderna and the NIH last year.

Several companies have licensed the '070 patent for their vaccines and pay the US government royalties, including Germany's BioNTech, which developed its Covid-19 jab with Pfizer. According to several observers, Moderna has not licensed the patent and the US government has not enforced its rights.

If the US government decides to sue Moderna, Moderna could conceivably owe over \$1bn just for its sales through [to] the end of this year

Christopher Morten, New York University

It is unclear why the US government has not demanded royalties from <u>Moderna</u>, but Nooman Haque, a managing director of life sciences at Silicon Valley Bank, said NIH might be "seeking to put peer pressure on Moderna" to share their expertise with other producers.

Although Moderna has said it would not enforce Covid-19 related patents against rivals making vaccines to combat the pandemic, critics say that waiving its intellectual property rights does not go far enough. They have called on the company to

share its technological expertise and work with rival producers around the world so they can develop and manufacture their own vaccines.

Haque said the US government's decision not to enforce the '070 patent was "probably an attempt to play a moral card" that "nudges it towards actual collaboration rather than non-enforcement of its own rights".

Moderna said its policy was "to respect valid patents", but declined to answer specific questions. In investor filings, Moderna has previously acknowledged that "one or more organisations will hold patent rights to which we may need a licence, or hold patent rights which could be asserted against us".

Researchers at New York University argued in a new study seen by the FT that the '070 patent could entitle the US government to as much as \$1.8bn this year alone.

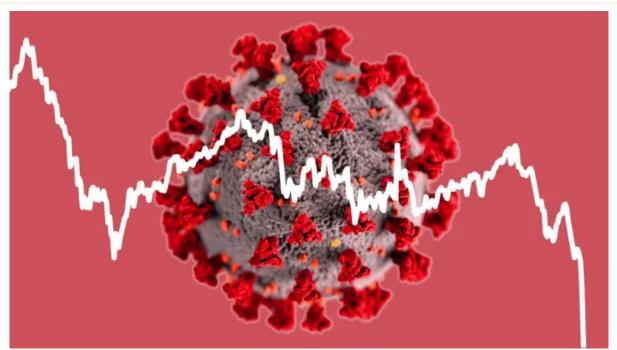
"Moderna infringes the National Institute of Health's patent with every dose of vaccine it makes or sells in the US," said Christopher Morten, deputy director of NYU's Technology Law and Policy Clinic and an author of the study. "If the US government decides to sue Moderna, Moderna could conceivably owe over \$1bn just for its sales through [to] the end of this year." The NIH said it sought patents to protect the US government's rights related to public investment in research "and to leverage these rights to attract partners that can advance the development and commercialisation of the inventions to realise public benefit". It said it took enforcement of those rights "very seriously" but declined to comment on licensing discussions with specific companies.

The US government has enforced its patents in the courts before. In 2019 it sued <u>Gilead Sciences</u> alleging that the company had infringed a government patent on its HIV prevention drug Truvada, after activists pressured Washington to assert its rights. Truvada can cost as much as \$20,000 a year in the US but is sold as a generic elsewhere for as little as \$6 a month. The litigation is ongoing.

Graham said the partnership between Moderna and NIH, struck in 2017 to research pandemic preparedness, had worked "pretty well" but that it was important the technology developed to create the vaccine could now be used as widely as possible.

"It's really up to . . . the political will and the use of public dollars to ask: are we going to use our technologies to solve these problems, and to solve them with global co-ordination, and with the recognition that we are all in this together?"

Additional reporting by Erika Solomon in Berlin



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