

## Moderna COVID Patent Case To Set Tone For Future Litigation

By Joanne Faulkner

*Law360, London (February 27, 2024, 4:45 PM GMT)* -- A legal battle between rival developers of COVID-19 jabs over the technology underlying the vaccine could set the tone for future litigation, as intellectual property lawyers expect a pledge made by Moderna at the height of the pandemic to dominate proceedings.

Moderna Inc. said in 2020, when drugmakers were racing to develop a way out of the worldwide health crisis, that it would not enforce its patents for a COVID-19 vaccine while the pandemic was underway. It said it did not want to deter other companies from researching their own shots.

Two years later, after vaccines had been developed and widely rolled out by Pfizer and BioNTech, Moderna updated its pledge and said it expected its intellectual property to be respected in middle-income countries without supply problems. Moderna brought its infringement claim against its two rivals shortly after.

"There will be lots of questions here as to whether Pfizer and BioNTech were entitled to rely on that pledge, and whether updating it in 2022 was effective," Charlie French, a senior associate at Bristows LLP, said. "The wording isn't clear."

Moderna has said that it is not seeking compensation for the time before March 2022, when it updated its statement. The U.S. pharmaceutical and biotech company is also not seeking an injunction. "There isn't really a precedent for this type of situation for this type of patent," French said.

Meanwhile, Pfizer and the Germany-based BioNTech say they reasonably relied on Moderna's promises not to sue and said the company had granted implied licenses to third parties.

"It's unclear how a court is going to come out on this," Ryan Babcock, an associate at Mayer Brown LLP in New York, said. "The industry is really waiting to see what happens here on this patent pledge. It



Pfizer and BioNTech have said that they reasonably relied on promises by Moderna that it would not sue and said the company had granted implied licenses to third parties. (Hannah Beier/Bloomberg via Getty Images)

may impact strategic decisions as far as whether you try and get a license or not in the future."

Similar litigation over the use of messenger RNA (mRNA) technology is taking place in the U.S., Ireland, the Netherlands and Germany. Pfizer and BioNTech have denied infringement and are seeking to invalidate two Moderna patents. The same family of patents is at issue in all the jurisdictions.

A consolidated trial in the English case is due to take place in April. Some decisions have been reached in other jurisdictions, but they haven't dealt with patent infringement and damages.

The European Patent Office revoked one of the Moderna patents that is at play in the High Court litigation — EP 565 — for added matter. That technical ground of invalidity compares the claims to the application to establish whether anything has been added beyond the application.

"The U.K. tends to have a much more lenient approach to added matter than the EPO, so it doesn't necessarily tell us what the U.K. courts will think of the patents," French said. "There have been cases where the U.K. has taken a different view — but there obviously will be challenges for Moderna there."

Another Moderna patent, EP949, was revoked in December by the District Court of The Hague, which found a lack of novelty. The proceedings were stayed.

"It's an uphill battle for Moderna," French said. "But, if they are successful, and they manage to maintain their patents and persuade the court that they are entitled to compensation, then it will be worth it for them."

The critical issues are likely to be whether Moderna's pledge can be seen as a unilateral contract that the company has entered into and is bound by, and then whether Moderna had the right to end its promise and start demanding royalties.

"On the other side, Biotech and Pfizer had clearly already been developing this vaccine for some time before the 2020 statement by Moderna," French continued. "Whether it actually changed their behavior in any way, or if they would have gone on and launched the vaccine anyway, and how that comes into play when considering compensation and damages..."

Huge amounts of money are at play if Moderna is successful as the company seeks a slice of the revenue for patent infringement over the Pfizer and BioNTech vaccine. Pfizer earned \$38 billion from the sale of its COVID-19 vaccine, Comirnaty, in 2023.

The mRNA technology, a delivery system and a set of instructions for cells to build proteins and create antibodies, has a much broader potential use. Scientists also hope it can be used to fight other diseases, including HIV and some types of cancer.

"The potential implications are much bigger than just the vaccine," French said. "That's why we've seen this huge upsurge in litigation in the last couple of years."

Patent pledges have been used before. There are examples of them being used in the software and automotive industry, and in the life sciences industry, although to a lesser extent. "What makes this Moderna pledge really interesting is because it occurred during a global pandemic," Babcock of Mayer Brown said.

The Moderna pledge was not indefinite: it was tied to the duration of the COVID-19 pandemic.

Moderna created a unique situation when it updated its pledge. "Moderna unilaterally announced the end of the pandemic, while the World Health Organization, on the other hand, still considered the pandemic to be ongoing," Babcock said.

Pfizer and BioNTech have argued in the U.S. litigation that Moderna's patents have "unimaginably broad claims directed to a basic idea that was known long before" the patent applications were filed. Its patents are an attempt to "co-opt an entire field of mRNA technology."

A report published by the European Patent Office in 2023 showed a huge rise in the number of applications for mRNA technology patents in 2021. It also points out that the number of mRNA inventions started to multiply long before COVID-19 emerged.

"The high proportion of international patent applications in the field of mRNA-based vaccines may be interpreted as an indication of the significant economic expectations of the patent applicants with regard to the technologies in question, as well as a corresponding multinational commercialization strategy," the report reads.

Anna Wolters-Höhne, a partner at Allen & Overy LLP, said there has been an increase in "innovator vs. innovator" patent disputes in the pharmaceutical field that are aimed at monetary participation in successful drugs.

It will be even more important with mRNA technology that the active players in the market clarify the patent position, "given that the mRNA platform technology will be used for developing all kinds of drugs," Wolters-Höhne said. "Creating precedents worldwide will strengthen the technology's value even more also for future patent battles."

Moderna and its competitors have spent billions on mRNA research. Companies will have to make choices if the courts in England or the U.S. find that Moderna had the right to unilaterally end its promise and start demanding royalties.

"I envision a situation where a larger player like Pfizer might, even if they lose this case here and have to pay damages if Moderna's pledge is upheld, be willing to take a risk on relying on a patent pledge, and deal with potential litigation later on instead of seeking a license upfront when there's a compelling opportunity for sales and commercialization of a drug," Babcock said.

Lawyers say the litigation is also a test to establish whether life sciences companies will be willing to make patent pledges — or rely on them.

"Everybody's going to be weighing their strategic options," Babcock said. "For the more litigation-savvy and deeper-pocketed companies, they might be willing to take that risk. But, for smaller companies, they are likely to be more risk-averse and may seek to get some sort of assurance from the entity making the patent pledge that they're not going to be sued."

--Editing by Ed Harris.