

## Patents

# Lawyers ponder impact of COVID cocktail lawsuit

Allele Biotech explains why it sued over tech used to treat Trump for COVID – and lawyers debate whether the case indicates future such litigation

*By* Rani Mehta

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Two COVID-related patent lawsuits have left lawyers contemplating the possibility of future litigation on treatments for the disease.

Biotech company Allele filed lawsuits against Pfizer and Regeneron on October 5 and claimed both defendants infringed its patent for mNeonGreen technology, a high-performance monomeric, yellow-green fluorescent protein.

Allele said that Regeneron had used the technology in the development of its experimental antibody cocktail, which was used to treat President Donald Trump for COVID-19 in early October. The company also targeted Pfizer and its partner BioNTech over the development of their potential COVID-19 vaccine.

Allele said in a press release sent to Managing IP that hundreds of organisations and universities had licences to its technology and that it had contacted Regeneron on multiple occasions to negotiate a licence but its requests went unanswered.

The plaintiff did not reach out to Pfizer, but argued that neither defendant had sought a licence before using the technology.

Attorneys have mixed opinions on whether Allele's decision to file a complaint might be the start of a swathe of patent litigation over technologies related to COVID, or whether this lawsuit might prove to be a one-off.

On the one hand, lawyers say, patent owners may be wary of the negative publicity they could receive if they file a lawsuit related to a COVID treatment or vaccine. Some companies have announced intentions to collaborate with other businesses or not to enforce their intellectual property.

For example, biotech company Moderna [said on October 8](#) that it would not assert any of its seven patents that cover its developing COVID vaccine during the pandemic.

Some lawyers expect more patent litigation to arise anyway. Wendy Ward, partner at Green Griffith in Wisconsin, says that as companies develop more IP as they work hard to bring therapies and vaccines to market, it will inevitably lead to future patent litigation.

## No contentious battles

Some lawyers say it's simply too difficult to tell whether this case will have any wider implications for COVID patent litigation.

Chelsea Loughran, shareholder at Wolf Greenfield in Boston, says the circumstances in this suit are relatively narrow, and that it's hard to extrapolate any larger trends related to COVID. She adds that Allele isn't known to be particularly litigious.

She suggests that the COVID patent litigation landscape could follow the same path as that of CRISPR, a genome-editing technology. Even though there have been contentious battles over who invented it, there aren't a lot of entities suing people who are doing research and drug development in the CRISPR space, she says.

She hopes that the situation for COVID will be similar, in the sense that companies and organisations will know that they need to take licences and that licensors will offer them on reasonable terms.

Loughran adds that this co-operation won't always work out, as shown by the Allele case. "But I would hope in the COVID space, researchers and patent owners can move research forward without a whole lot of litigation, much like they have for CRISPR."

## Public backlash risk

Ward at Green Griffith says that even though there has been unprecedented co-operation between academic institutions and commercial entities in the fight against COVID, she still expects to see more patent lawsuits.

Dorothy Auth, partner at Cadwalader in New York, agrees and adds: "My question is whether the filing of this complaint now, when the world desperately needs more COVID treatments, is the appropriate time to bring the case or whether there will be a public backlash against Allele."

She added that it's likely that Allele filed now because the company assumed the use of its patented molecules would only occur during the initial testing of the defendants' drugs and vaccines.

She says that because the patented molecules are only used during this part of the testing, they would not necessarily be submitted for US Food and Drug Administration (FDA) approval, and the business would not have a good case for infringement if it waited.

Jiwu Wang, CEO of Allele, says he supports researchers working hard to find the best way to combat COVID, but counters that Allele, as a small company, relies heavily on its technology and IP. "COVID doesn't change the fundamental principles of innovation and business," he says.

Wang adds that his business licenses its IP to hundreds of licensees on reasonable terms. "When a large company is using our patent to benefit from the speed, reliability and consistency of the tool, there should be the proper process of contacting and negotiating with us."

He adds that almost all the business's licensees approached it to ask about obtaining a licence, rather than Allele having to approach them.

## Safe harbour to the rescue?

[Managing IP](#) reached out to the defendants for comment. Pfizer did not respond.

A spokesperson from Regeneron said: "Regeneron is aware of the lawsuit filed by Allele Biotech. We are still reviewing the details in the complaint, but we disagree that Regeneron has infringed any valid patent, and we will vigorously defend our position against this lawsuit."

One possible defence for Regeneron and Pfizer is the safe harbour provision in Section 271e (1) under Title 35 of the US Code.

This statute says patent infringement does not occur when an invention is primarily manufactured using certain techniques solely for uses reasonably related to the development and submission of information to the FDA. The techniques included recombinant DNA, recombinant RNA, hybridoma technology or other processes involving site-specific genetic manipulation techniques.

Auth at Cadwalader says the case involves the issue of how research tools are used in developing pharmaceutical products and is in an area that has been litigated before.

She doesn't believe the case will go away on a motion to dismiss. "But the defendants have a reasonable position that they fall under the safe harbour of Section 271e."

Ward at Green Griffith also believes this statute could come into play. She says the case law that has developed so far around research tools has left unanswered questions, and this case could clarify what specific research activities would qualify for safe harbour protection.

The plaintiff does not believe this issue will sink its case.

Daniel Catron, executive director of licensing and business development at Allele, says the company considered the safe harbour issue prior to filing. "We are confident that we are firmly within the decision rejecting such defence as in [Proveris v Innovasystems](#)."

According to [analysis from Finnegan](#), this 2008 US Court of Appeals for the Federal Circuit case determined that the safe harbour provision did not apply to patented inventions that were not subject to FDA approval.

Allele will have to await the defendants' responses to see whether they claim safe harbour, have another argument for why the patent was not infringed or ask to negotiate licences.

In the meantime, lawyers will watch the market with excitement – or dread – to see whether other patent owners enforce, and what the consequences of those decisions will be.

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