

Moderna Vaccine Patent Deal Sets Up High-Stakes Immunity Appeal

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- Moderna Inc. will pay \$950 million to resolve litigation with Arbutus Biopharma Corp. and Genevant Sciences GmbH over lipid-nanoparticle technology used in its Covid-19 vaccine.
- Moderna will appeal a ruling rejecting most of its government-contractor defense and may make an additional payment of up to \$1.3 billion if the US Court of Appeals for the Federal Circuit affirms that decision.
- The settlement's structure preserves a live dispute for Federal Circuit review, allowing the court to interpret a World War I-era patent law known as Section 1498 and potentially shaping how the government-contractor defense applies to companies working on federally funded programs.

Moderna Inc.'s settlement to end a lawsuit over technology used in its Covid-19 vaccine caps its potential exposure at \$2.25 billion while teeing up a Federal Circuit fight over whether pandemic-era government contracts can shield drugmakers from patent-infringement claims.

The settlement's unusual structure reflects both the uncertainty of the jury trial that was set to begin next week and the parties' shared interest in securing appellate guidance on a government-contractor defense that gained prominence during the Covid-19 pandemic, legal observers said.

Under the deal, Moderna said it will pay \$950 million in the third quarter to resolve worldwide litigation with Arbutus Biopharma Corp. and Genevant Sciences GmbH over lipid-nanoparticle, or LNP, technology used in its Spikevax Covid-19 shot and related mRNA vaccines. Under the pact, Moderna also will appeal a ruling rejecting most of its government-contractor defense under a World War I-era patent law known as Section 1498.

If the US Court of Appeals for the Federal Circuit affirms that decision, Moderna will make an additional payment of up to \$1.3 billion.

The contingent payment “effectively prices the risk” of Moderna’s government-contractor defense while preserving a live dispute for Federal Circuit review, said Coby Nixon, chair of Buchalter’s litigation practice group in Atlanta. That structure matters because federal courts generally won’t decide purely theoretical questions once a case is settled. By tying another \$1.3 billion to the appeal’s outcome, the companies ensure the court still has a “real controversy” to resolve, Nixon said.

Deals structured around appellate outcomes are “relatively uncommon, especially in patent litigation,” and typically involve modest adjustments rather than “billion-dollar pricing mechanisms,” he said.

The Federal Circuit’s interpretation of Section 1498 “could matter beyond this case for both sides, and others,” Nixon added, potentially shaping how the government-contractor defense applies to companies working on other federally funded or emergency programs.

Duke University law professor Arti Rai agreed the appeal could reverberate well beyond this dispute “because companies might be deterred from entering procurement contracts unless they are protected from patent infringement liability.”

Settlements that preserve a single legal issue for appeal aren’t unheard of, though the Moderna agreement is “somewhat unique,” said Kevin E. Noonan, a partner at McDonnell Boehnen Hulbert & Berghoff LLP who writes widely on biotechnology patent law. Parties sometimes resolve their financial disputes while preserving a question of law that one side wants clarified, particularly if the outcome could affect future products or licensing arrangements, he said.

Judge Joshua D. Wolson on Wednesday issued a consent judgment and order reflecting the parties’ agreement that Moderna infringed the asserted patents and that the patents aren’t invalid, leaving only the government-contractor defense for appeal. The judge previously ruled that the statute shields Moderna from liability for about 6.2 million doses administered directly to US government employees but not for vaccines distributed more broadly through commercial channels.

Arbutus and its licensing partner, Roivant Sciences Ltd.’s Genevant unit, sued Moderna in 2022 alleging its Covid-19 shot infringes their patented LNP technology, which uses tiny fat globules to deliver genetic instructions to cells. The case was widely viewed as a major test of intellectual-property rights arising from the rapid development of Covid-19 vaccines.

Arbutus and Genevant are pursuing similar claims against Pfizer Inc. and BioNTech SE over their rival Covid-19 vaccine in a separate federal case pending in New Jersey. While those companies are surely looking at the eye-popping figures in the new settlement, Moderna’s appeal may not affect that case because Pfizer wasn’t part of Operation Warp Speed in the same way Moderna was, said Jacob Sherkow, a University of Illinois law professor who studies biotechnology patents.

Jury Risk

The pact came less than a week before a jury trial was set to begin in the US District Court for the District of Delaware and followed a series of rulings that reshaped the parties' trial strategies.

Wolson, sitting by designation from the Eastern District of Pennsylvania, last month limited Moderna's ability to rely on the government-contractor statute to shift liability to the US government and barred some of the company's patent-invalidity defenses while requiring Arbutus to prove literal infringement of certain formulation-patent claims.

Those recent rulings "gave each side good reason to question their chances of success, which no doubt drove the calculus of the settlement terms," said Daniel L. Shores, a partner at Rothwell, Figg, Ernst & Manbeck PC who specializes in biotech patents. The decisions narrowed the issues but left jurors to resolve highly technical questions about whether Moderna's vaccine formulation fell within the patent claims, Shores said. Putting those issues before a jury "carries tremendous risk for both sides."

Sherkow had predicted the case could produce the largest patent verdict in US history. The settlement amount appears broadly consistent with the damages exposure observers had anticipated, he said.

He called the parties' decision to leave the Section 1498 issue for appeal "very interesting," noting that how the statute applies in the pandemic context "was always a close call."

Resolving the broader infringement dispute while preserving the appeal may also help Moderna secure clearer rights to use the LNP technology in future vaccines, Noonan said. Moderna has a pipeline of mRNA-based treatments beyond Covid-19, including potential cancer vaccines, and continued access to the delivery technology could prove valuable as those programs develop.

Whether Moderna's appeal ultimately prevails could turn on the "nuts and bolts of the promises that were made with the government at the time," Noonan said.

Shaw Keller LLP represents Arbutus and Genevant. Morrison & Foerster LLP also represents Arbutus. Williams & Connolly LLP and Sullivan & Cromwell LLP also represent Genevant. Kirkland & Ellis LLP and Morris, Nichols, Arsht & Tunnell LLP represent Moderna.

The case is Arbutus Biopharma Corp. v. Moderna Inc., D. Del., No. 22-cv-252, consent judgment and order issued 3/4/26.

To contact the reporter on this story: Christopher Yasiejko in Philadelphia at cyasiejko@bloombergindustry.com

To contact the editors responsible for this story: Adam M. Taylor at ataylor@bloombergindustry.com; Kartikay Mehrotra at kmehrotra@bloombergindustry.com

