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FEATURE

COVID-19 Patent Wars: mRNA and Lipid Nanoparticle Pioneers Clash over Vaccine Delivery Patents

Daniel L. Shores

While the COVID-19 pandemic has caused widespread tragedy for millions of families worldwide, it has also spurred concomitant advancements in health care, not the least of which include the first-ever regulatory approvals of therapies based on messenger ribonucleic acid (mRNA) technology. The two leading COVID-19 vaccines on the market, introduced by Moderna Inc. and BioNTech SE (in collaboration with Pfizer Inc.), are based on this technology and are currently the subject of major patent litigations relating to how those therapies are delivered. This article provides an overview of these cases and the current patent litigation landscape in the mRNA space.

Background on mRNA Technology

Our cells naturally produce mRNA to facilitate the production of proteins. During the "transcription" process, enzymes within our cells use segments of DNA as templates to form mRNA in cell nuclei.[1] Then, during the "translation" process, different enzymes use the produced mRNA as templates to form proteins in cell cytoplasm.[2] The primary structure of each protein produced by our cells corresponds to the primary structure of the mRNA molecules from which the protein was derived.[3]

Pioneers have developed therapies where the applicable mRNA sequences are synthesized in the lab and introduced into the cytoplasm of cells for translation into proteins.[4] Importantly, in these therapies, the synthesized mRNA sequence can encode for proteins not derived from a recipient's genome, which may facilitate cells' production of specific proteins applicable to a variety of therapies including, but not limited to, vaccines.[5]

In the case of the COVID-19 vaccines, pioneers BioNTech and Moderna developed mRNA configured to encode for the characteristic spike protein appearing on the surface of the COVID-19 virus.[6] In these therapies, the mRNA are introduced into the recipient's cells, and copies of the unique spike protein are created and

expressed. This allows the recipient's immune system to identify the spike protein as an antigen without exposure to the COVID-19 virus and build its defenses against it, in preparation for potential actual exposure.[7]

But introducing the mRNA "payload" into cells is no easy task. These molecules are inherently unstable—if introduced into the recipient's body without any protective layer, they may tend to degrade or otherwise be destroyed by the recipient's biochemistry, rather than being taken into cells for translation into the desired proteins.[8] To address this problem, the BioNTech and Moderna vaccines utilize certain lipid nanoparticle (LNP) delivery systems, which surround mRNA molecules with a combination of lipid molecules to prevent the mRNA molecules from being destroyed following injection and to facilitate effective uptake into cells. LNP delivery systems are therefore critical to the delivery of the mRNA payload in these COVID-19 vaccines and potential future therapies.

The potential applicability of mRNA technology goes well beyond COVID-19. Pioneers such as BioNTech, Moderna, and several others had been building pipelines of mRNA-based drugs to combat infectious disease, cancer, and other diseases for many years prior to the pandemic, but had not yet achieved regulatory approval.[9] Because the synthesis of specialty mRNA molecules and the creation of resulting vaccine candidates can be performed much more quickly than traditional vaccines (which require, for example, growing and then killing quantities of an actual virus), BioNTech and Moderna began clinical trials utilizing their respective vaccines within months from the date that COVID-19's molecular blueprint was known, giving each of their vaccine candidates a head start in the race for regulatory approval to confront the pandemic.[10]

The clinical trial results of the BioNTech and Moderna COVID-19 vaccines proved very promising, with each vaccine yielding an effectiveness rate of approximately 95%.[11] In December 2020, less than a year after applying for regulatory approval, each company received emergency use authorization from the FDA to distribute their vaccines for widespread public use.[12] This provided the world with key early weapons to combat the pandemic, while also launching mRNA-based therapeutics as a new platform to treat human disease.

Sales of Moderna's Spikevax® and BioNTech/Pfizer's Comirnaty® COVID-19 vaccine products are expected to total tens of billions of dollars combined by the end of 2022, signaling promise for the success of other mRNA-based therapies and the creation of new markets.[13] But at the dawn of this new commercial space, patent battles have already emerged, with the following six patent lawsuits being filed this year (as of July 14, 2022), all involving LNP delivery technology:

- *Arbutus Biopharma Corp. & Genevant Sciences GmbH v. Moderna, Inc. & ModernaTX, Inc.* (*Arbutus v. Moderna*), No. 1:22-cv-00252 (D. Del. filed Feb. 28, 2022);
- *Alnylam Pharmaceuticals, Inc. v. Moderna, Inc., ModernaTX, Inc. & Moderna U.S., Inc.* (*Alnylam v. Moderna I*), No. 1:22-cv-00335 (D. Del. filed Mar. 17, 2022);

- *Alnylam Pharmaceuticals, Inc. v. Pfizer Inc. & Pharmacia & Upjohn Co. LLC* (*Alnylam v. Pfizer I*), No. 1:99-mc-09999 (D. Del. filed Mar. 17, 2022);
- *Acuitas Therapeutics Inc. v. Genevant Sciences GmbH & Arbutus Biopharma Corp.* (*Acuitas v. Arbutus*), No. 1:22-cv-02229 (S.D.N.Y. filed Mar. 18, 2022);
- *Alnylam Pharmaceuticals, Inc. v. Moderna, Inc., ModernaTX, Inc. & Moderna U.S., Inc.* (*Alnylam v. Moderna II*), No. 22-cv-00925 (D. Del. filed July 12, 2022); and
- *Alnylam Pharmaceuticals, Inc. v. Pfizer Inc., Pharmacia & Upjohn Co. LLC, BioNTech SE & BioNTech Manufacturing GmbH* (*Alnylam v. Pfizer II*), No. 1:22-cv-00924 (D. Del. filed July 12, 2022).

Arbutus v. Moderna

In February 2022, Arbutus Biopharma Corp. (patent owner) and Genevant Sciences GmbH (an exclusive licensee to certain rights under the asserted patents) sued Moderna Inc. and ModernaTX Inc. (collectively Moderna) in the U.S. District Court for the District of Delaware, alleging that Moderna infringed several Arbutus patents (i.e., U.S. Patent Nos. 8,058,069, 8,492,359, 8,822,668, 9,364,435, 9,504,651, and 11,141,378) directed to LNP delivery systems through, for example, its manufacture and sale of its Spikevax® vaccine product.[14] The complaint seeks monetary damages (including based on willful infringement) but does not seek an injunction, which is another remedy available to patent holders should they meet the applicable criteria.[15]

This is not the first dispute between the parties involving Arbutus's LNP delivery technology. Moderna had sublicensed certain of Arbutus's LNP delivery technology several years ago; however, its right to use such technology was undercut following a 2018 settlement involving Arbutus and Moderna's sublicensor,[16] and, according to the complaint, Moderna does not currently have any rights to use Arbutus's LNP technology in connection with COVID-19.[17]

Following the 2018 settlement, Moderna challenged three of Arbutus's LNP-based patents through inter partes review (IPR) proceedings before the U.S. Patent and Trademark Office's Patent Trial and Appeal Board (PTAB), a process that allows petitioners to challenge claims of issued patents. The Moderna IPRs had varying outcomes, with one Moderna win (canceling all claims of U.S. Patent No. 9,404,127), one mixed result (canceling some claims of the '435 patent but not all), and one Moderna loss (all claims of the '069 patent survived). Moderna appealed the PTAB's ruling on the '069 patent, but it was upheld by the U.S. Court of Appeals for the Federal Circuit in late 2021, opening the door for the current lawsuit involving the '069 and other asserted patents.[18] For its part, Moderna has long denied it has infringed the Arbutus patents, stating that the Arbutus LNP technology "was just ok" and that it innovated past Arbutus's LNP technology in developing its own.[19]

Claim 1 of the '069 patent, which is representative of some of the claims being asserted in this case, requires a combination of four types of lipid molecules (i.e., a cationic lipid, phospholipid, cholesterol, and conjugated lipid) and is recited as follows:

> A nucleic acid-lipid particle comprising:
>
> (a) a nucleic acid;
>
> (b) a **cationic lipid** comprising from *50 mol % to 65 mol %* of the total lipid present in the particle;
>
> (c) a non-cationic lipid comprising a mixture of a **phospholipid** and **cholesterol** or a derivative thereof, wherein the phospholipid comprises from *4 mol % to 10 mol %* of the total lipid present in the particle and the cholesterol or derivative thereof comprises from *30 mol % to 40 mol %* of the total lipid present in the particle; and
>
> (d) a **conjugated lipid** that inhibits aggregation of particles comprising from *0.5 mol % to 2 mol %* of the total lipid present in the particle.[20]

Under U.S. patent law, for the plaintiffs to succeed in their claim for infringement of the '069 patent, the plaintiffs would need to show that the accused Spikevax® product contains an LNP formulation that has all of the claimed lipids in amounts that fall within the claimed ranges. A typical approach to avoid infringement is to "design around" patent claims such that a product does not contain at least one limitation of the subject claim (e.g., in the above claim, if a phospholipid was not used).

It may seem that designing around a claim such as the '069 patent would be straightforward. However, designing an effective LNP to deliver mRNA as a therapy can be a potentially complex engineering challenge. For example, commentators have indicated that a desired LNP should (1) maintain stability while being stored prior to use, (2) encapsulate the mRNA payload and protect both the payload and itself from the recipient's biochemistry post-injection, (3) be configured such that the entire LNP can be taken up into the cell's cytoplasm, and (4) allow the mRNA payload to release from the surrounding lipids once in the cytoplasm while avoiding attack by intracellular endosomes.[21]

With the structure and polarity of lipids and mRNA molecules affecting the overall characteristics of a given nanoparticle, the types and amounts of such particles that would meet all of the above design criteria may be somewhat limited, requiring additional engineering efforts.

This case is in its early stages and, as of the date of this writing, Moderna has moved to dismiss the claims directed to Moderna's sales to the U.S. government pursuant to 28 U.S.C. § 1498(a) (a statute allegedly requiring plaintiffs to seek redress for such infringing sales from the federal government in the Court of Federal Claims, rather than from Moderna), which plaintiffs have opposed.[22] This motion does not appear to affect the allegations relating to Moderna's other (non-U.S. government) sales.

Alnylam v. Moderna I, II and *Alnylam v. Pfizer I, II* (with BioNTech)

Within weeks of Arbutus and Genevant filing their lawsuit against Moderna, Alnylam Pharmaceuticals Inc. filed two separate patent infringement lawsuits in the U.S. District Court for the District of Delaware, each asserting a single patent: U.S. Patent No. 11,246,933. One suit was filed against Pfizer Inc. and Pharmacia & Upjohn Co. LLC (*Alnylam v. Pfizer I*), and the other suit was filed against Moderna Inc., ModernaTX Inc., and Moderna US Inc. (*Alnylam v. Moderna I*).[23]

The '933 patent's claims are directed to a specific cationic lipid (as compared to an entire LNP as in *Arbutus v. Moderna*).[24] Alnylam has alleged that each of the Spikevax® and Comirnaty® vaccine products use lipids that are covered by at least one of the claims of the '933 patent.[25] The complaints seek monetary damages only (no injunctions).

As in the Arbutus case, Moderna has moved to dismiss the claims directed to Moderna's sales to the U.S. government pursuant to 28 U.S.C. § 1498(a), which Alnylam has opposed.[26] Interestingly, third parties Arbutus and Genevant are seeking to file an amicus brief in the Alnylam case with respect to the § 1498(a) issue, indicating the larger battle being waged involving the Arbutus LNP technology in *Arbutus v. Moderna*. As for Pfizer, it answered Alnylam's complaint and asserted counterclaims joined by BioNTech SE and BioNTech Manufacturing GmbH, bringing those BioNTech entities into the case.

Contemporaneously as this writing was being submitted for publication, Alnylam filed two new patent infringement lawsuits against (1) Pfizer Inc., Pharmacia & Upjohn Co. LLC, BioNTech SE, and BioNTech Manufacturing GmbH (*Alnylam v. Pfizer II*); and (2) Moderna Inc., ModernaTX Inc., and Moderna US Inc. (*Alnylam v. Moderna II*), respectively, in the District of Delaware, each for infringement of U.S. Patent No. 11,382,979. The '979 patent issued on July 12, 2022 (the same day the suits were filed). *Alnylam v. Pfizer I* and *II* were recently consolidated, as were *Alnylam v. Moderna I* and *II*, and each consolidated case is before Judge Colm F. Connolly.

Acuitas v. Arbutus

On March 18, 2022, one day after *Alnylam v. Pfizer I* and *Alnylam v. Moderna I* were filed, Acuitas Therapeutics Inc. filed a declaratory judgment action in the U.S. District Court for the Southern District of New York against Genevant Sciences GmbH and Arbutus Biopharma Corp.[27] The complaint seeks a declaratory judgment that the Pfizer Comirnaty® product does not infringe U.S. Patent Nos. 8,058,069, 8,492,359, 8,822,668, 9,364,435, 9,504,651, and 11,141,378 (all owned by Arbutus and asserted in the *Arbutus v. Moderna* suit) and U.S. Patent Nos. 9,006,417, 9,404,127, and 9,518,272 (all also owned by Arbutus) and that the subject Arbutus patents are invalid.

Neither Pfizer nor BioNTech has been named as a plaintiff in the case, but Acuitas has alleged that Pfizer and BioNTech's Comirnaty® products contain "the lipids and lipid nanoparticles innovated by Acuitas" that are grounded in collaborations between Acuitas and BioNTech.[28] This allegation is supported by agreements Acuitas has forged with BioNTech (July 2017 development and option agreement and April 2020 nonexclusive

license agreement)[29] and Pfizer (January 2022 development and option agreement)[30] relating to Acuitas's LNP technology.

One of the key threshold issues in this case is whether Acuitas has standing to sue. Under *MedImmune, Inc. v. Genentech, Inc.*, to establish standing to sue for declaratory judgment of noninfringement and invalidity under the Declaratory Judgment Act, Acuitas must establish that "the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment."[31] Here, presumably to help plead proper standing, Acuitas has alleged that Arbutus and Genevant sent enforcement letters relating to the Arbutus patent portfolio to Pfizer, and such conduct harms Acuitas's business interests.[32] As of the date of this writing, the defendants have indicated their intention to move to dismiss for lack of standing.[33]

Current mRNA LNP Litigation Landscape

The initial patent litigation landscape for LNP delivery technology is beginning to take shape. Arbutus and Genevant[34] were the first to initiate major litigation by filing their patent infringement lawsuit against Moderna. As indicated, Arbutus and Moderna have been in an ongoing dispute relating to the Arbutus LNP delivery technology. With Moderna losing its appeal to the Federal Circuit relating to the '069 patent, and with Spikevax® sales expected to exceed $40 billion by the end of 2022, the fact that Arbutus filed this lawsuit for monetary damages based on those sales was not surprising, especially if Moderna had not engaged in meaningful licensing discussions as alleged in the complaint.[35]

To date, Moderna has reportedly refused to disclose to Arbutus exactly what LNP formulation it is using in its commercial Spikevax® products.[36] The lawsuit could force Moderna's hand to disclose that information, at least under a protective order, perhaps early on in the case through the District of Delaware's local patent rules.[37] Given the current early motions practice, and given the possibility for Moderna to file one or more new petitions for IPR, it may be some time before such details are revealed.

The next lawsuits had Alnylam suing each of Moderna and Pfizer in separate cases for allegedly infringing its '933 patent. These suits appeared somewhat surprising given that Alnylam does not seem to have commercial or pipeline products directed to mRNA technology; however, Alnylam does have LNP technology and related patents that it utilizes in its approved rare-disease drug product Onpattro® to deliver "small interfering" RNA molecules (or siRNA, which are functionally different than mRNA).

The '933 patent was filed on April 29, 2021, after the pandemic began and public disclosure of at least the LNP formulation used in the Comirnaty® vaccine product.[38] That a patent application with claims allegedly covering an existing commercial product could be filed *after* the configuration of those products is publicly known may seem unusual. However, under U.S. patent law, once a parent patent application seeking certain claims is filed, additional later "continuing" applications may be filed claiming priority back to the parent application so long as the new claims being sought in the continuing application have support in the originally filed application.

Accordingly, multiple patents may issue claiming priority to a single parent application. Indeed, here, public records indicate that Alnylam has filed for other patents potentially applicable to this case, including U.S. Patent No. 11,382,979, which recently issued on July 12, 2022, and which Alnylam asserted against both Moderna and Pfizer/BioNTech that same day.[39]

It is important to note that both Arbutus and Alnylam are seeking monetary damages in their cases, but neither seeks an injunction. That makes sense for at least two major reasons: First, the plaintiffs' chances of obtaining an injunction may be low since it appears (i) neither plaintiff is a direct competitor, and a finding of irreparable harm is less likely in such situations; (ii) harm to the plaintiffs could be remedied through monetary damages, and the balance of harms favors the defendants since they, and not the plaintiffs, would lose sales; and (iii) the public interest of keeping the vaccine on the market (during a pandemic or otherwise) vastly outweighs any harm to the plaintiffs.[40] Second, from a practical perspective, there is little doubt that if the plaintiffs sought an injunction to prevent the distribution of Spikevax® or Comirnaty® or related boosters, the public backlash against the plaintiffs, and perhaps the patent system in general, would be severe.

Ultimately, if infringement is found in either case, an aspect of patent damages would likely be assessed pursuant to a "reasonably royalty" reached as a result of a "hypothetical negotiation" between the parties.[41] Since it is estimated that sales of Spikevax® and Comirnaty® will reach in the tens of billions of dollars by the end of 2022, any royalty rate ultimately applied to those sales could be quite significant.[42] While a damages award could be high, there are also potential risks for plaintiffs in filing their actions, including that their patents could be invalidated in district court cases or canceled through IPR or post-grant review (PGR) proceedings (which are similar to IPRs but must be filed within nine months of patent grant and have broader bases for cancellation).

With respect to the Arbutus patents, even though the '069 patent and some claims of the '435 patent survived the Moderna IPRs, a broader range of prior art and bases for invalidity would be available in the district court proceeding that were not available during the Moderna IPRs, for example, including subject matter ineligibility under 35 U.S.C. § 101, insufficient written description or enablement under 35 U.S.C. § 112, prior public uses or sales, and other potential bases for invalidity in addition to prior art under 35 U.S.C. § 102 and § 103. Also, four of the asserted patents were not subject to Moderna's previous IPRs and, if the case were to proceed to trial, may be tested for the first time before a jury, assuming Moderna has not sought to challenge those patents in new parallel IPRs (i.e., U.S. Patent Nos. 8,492,359, 8,822,668, 9,504,651, and 11,141,378). Moreover, all of the asserted Arbutus patents, as well as Arbutus U.S. Patent Nos. 9,006,417, 9,404,127, and 9,518,272, are subject to potential invalidation on all grounds in the Acuitas case should that case move forward.

In the Alnylam cases, Pfizer and/or Moderna may try to challenge the '933 patent via PGRs. Because PGRs must be filed within nine months of grant, the '933 patent would need to be challenged on or before November 15, 2022. If such a challenge is made, then the parties may seek to stay the district court litigation(s), pending the outcome of PGR. Interestingly, the Arbutus '378 patent, which is in suit in the Moderna and Acuitas cases, has claims directed to lipid ranges similar to the '069 patent, but it does not appear that any party has filed a PGR

against that patent (the deadline to do so was July 12, 2022). This may be due to the fact that under 35 U.S.C. § 325(e)(2), a petitioner that brings a PGR proceeding resulting in a final decision is estopped from asserting invalidity in a later district court proceeding "on any ground that the petitioner raised or reasonably could have raised during that post-grant review," and the parties seeking to invalidate may therefore feel they have better odds in a district court proceeding.

While Moderna previously pledged in 2020 not to enforce its own patents during the pandemic,[43] it updated its pledge in March 2022 "to *never* enforce [its] patents for COVID-19 vaccines" in low- and middle-income countries, while also stating that it "remains willing to license its technology" to developers in other countries.[44] It therefore appears that Moderna expanded its pledge for poorer nations but effectively repealed it for wealthier nations. Moderna has a substantial patent portfolio of its own, including directed to LNP delivery technology, and it is possible Moderna could assert its patents where applicable.[45]

Also of interest is that Genevant and BioNTech are parties to a July 2018 license agreement under which Genevant licensed certain of its LNP technology to BioNTech in the field of oncology.[46] However, while the parties appear to have this relationship, it does not seem that the license extends to COVID-19 or the Comirnaty® vaccine products, highlighted by the fact that Acuitas alleged in its complaint that Genevant sent enforcement letters to Pfizer relating to Comirnaty®.[47] Accordingly, it is possible that BioNTech and/or Pfizer may also be subject to future lawsuits from Arbutus and Genevant.

On another front for BioNTech, on July 7, 2022, early pioneer and German company CureVac N.V. reportedly sued BioNTech SE and subsidiaries (but not Pfizer) in the German Regional Court in Düsseldorf for infringement of one European Patent (EP1857122B1) and three German patents (DE202015009961U1, DE202021003575U1, and DE202015009974U1).[48] These patents appear to be directed to features of the mRNA payload as well as lipids. On July 26, 2022, BioNTech entities and Pfizer Inc. sued CureVac AG in the U.S. District Court for the District of Massachusetts for a declaratory judgment that they do not infringe CureVac's counterpart U.S. patents. These are cases to watch, as BioNTech (and, by extension, Pfizer) is now confronting infringement allegations by CureVac on two continents.

Conclusion

At the dawn of new mRNA-based markets spurred by the COVID-19 pandemic, mRNA pioneers Moderna and BioNTech (with Pfizer) find themselves succeeding with large sales of their flagship COVID-19 vaccines while also being attacked by third-party mRNA and LNP pioneers. The outcome of these litigations could have a major impact on how other mRNA market players approach which delivery technology to use in therapies for years to come.

If broad legacy LNP patents are invalidated or canceled during litigation, then other market players could be free to use such technology without licensing costs. Alternatively, if such patents survive these challenges,

market players may need to license surviving patents (which could be a significant barrier to entry) or design around them by developing new mRNA delivery technologies.

mRNA-based companies would be wise to monitor this landscape very closely to identify white space, forge synergistic partnerships, and develop new innovations to freely operate and carve out niches in this dynamic growth area.

Endnotes

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15. *Id.*

16. *See* Press Release, Arbutus Biopharma, Arbutus Settles Litigation, Terminating Acuitas' Rights to LNP Technology (Feb. 22, 2018), https://investor.arbutusbio.com/news-releases/news-release-details/arbutus-settles-litigation-terminating-acuitas-rights-lnp-0.

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26. Singh, *supra* note 22.

27. Complaint, Acuitas Therapeutics Inc. v. Genevant Scis. GmbH, No. 1:22-cv-02229 (S.D.N.Y. Mar. 18, 2022) [hereinafter *Acuitas v. Arbutus* Complaint], https://fingfx.thomsonreuters.com/gfx/legaldocs/movandxaxpa/IP%20ACUITAS%20PATENTS%20complaint.pdf.

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32. *See Acuitas v. Arbutus* Complaint, *supra* note 27, ¶¶ 45–46.

33. *See* Scheduling Order, Acuitas Therapeutics Inc. v. Genevant Scis. GmbH, No. 1:22-cv-02229 (S.D.N.Y. June 27, 2022), ECF No. 37.

34. *See Arbutus v. Moderna* Complaint, *supra* note 14, ¶ 9.

35. *See id.* ¶¶ 55–61.

36. Vardi, *supra* note 19.

37. *See* U.S. Dist. Ct. for the Dist. of Del., Default Standard for Discovery, Including Discovery of Electronically Stored Information ("ESI") (2011), https://www.ded.uscourts.gov/sites/ded/files/pages/Electronic%20Discovery%20Default%20Standard_0.pdf.

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Authors

Daniel L. Shores
Rothwell, Figg, Ernst & Manbeck, P.C.

Daniel L. Shores is a partner at Rothwell Figg in Boston, where he focuses his practice on serving emerging biotech, medtech, and other technology-based companies.