IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GMBH,	:	
	:	**CIVIL ACTION**
Plaintiffs,	:	
v.	:	
	:	**NO. 22-252**
MODERNA, INC. and MODERNATX, INC.,	:	

MEMORANDUM

Goldberg, J. **November 2, 2022**

During the course of the COVID-19 pandemic, Defendants Moderna, Inc. and ModernaTX, Inc. (collectively, "Moderna") brought to market an mRNA-based vaccine in an effort to combat the effect of the COVID-19 virus. Plaintiffs Arbutus Biopharma Corporation ("Arbutus") and Genevant Sciences GmbH ("Genevant") (collectively "Plaintiffs") claim that, in order for the vaccine to succeed, Moderna used a revolutionary lipid nanoparticule ("LNP") delivery platform—created and patented by Plaintiffs—without paying for it or requesting a license.

On February 28, 2022, Plaintiffs filed suit seeking compensation for the use of the patented technology they claim to have developed. On May 6, 2022, Moderna filed a partial Motion to Dismiss, arguing that to the extent Plaintiffs seek royalties on the sale and provision of COVID-19 Vaccine doses to the United States Government, such claims can only proceed in the Court of Federal Claims and must be dismissed from this Court. For the following reasons, I will deny Moderna's Motion.[1]

[1] On May 18, 2017, then Chief Judge D. Brooks Smith of the United States Court of Appeals for the Third Circuit designated me as a visiting judge for the District of Delaware, pursuant to 28 U.S.C. § 292(b), to handle this matter and other District of Delaware cases.

I. FACTUAL BACKGROUND

The following facts are taken from Plaintiff's Complaint.[2]

A. General Background Regarding Virus Vaccines

As explained in the Complaint, viruses are typically described as small packets of deoxyribonucleic acid ("DNA") or ribonucleic acid ("RNA"). If a virus enters a living host cell, the virus's DNA or RNA can hijack the cell's machinery and instruct the cell to make copies of the virus. These copies, often numbering into the millions, leave the infected cell and enter other cells where the process repeats. Infected cells can be damaged or die while hosting the virus, and, left unchecked, the host organism itself can die. Vaccines traditionally work by injecting into the body a weakened or inactive form of the virus that is unable to cause infection, but nonetheless retains features of the infectious virus and can teach the immune system to recognize and attack the infectious virus it if it invades in the future. (Id. ¶¶ 19–20.)

Moderna's COVID-19 vaccine belongs to a new class of medicines that deliver nucleic acids into the cells of the body to treat diseases or trigger an immune response to protect a person from future infection. Nucleic acids are molecules that encode the genetic information essential to sustain life. One type of nucleic acid is DNA, which is found within chromosomes and contains genetic information. In order to make the protein encoded by a particular gene, the cell first converts the genetic code in the gene's DNA into another type of nucleic acid known as messenger ribonucleic acid, or "mRNA," which is effectively a copy of the portion of DNA that the cell's protein-making machinery uses as a blueprint to assemble the protein encoded by the gene. (Id. ¶¶ 21–23.)

[2] In deciding a motion under Federal Rule of Civil Procedure, the court must accept all factual allegations in the complaint as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading, the plaintiff may be entitled to relief. See Erickson v. Pardus, 551 U.S. 89, 93–94 (2007).

Vaccines using RNA technologies are an emerging frontier in medicine to address many previously intractable diseases and new viruses. RNA-based medicines, however, have been difficult to develop because RNA molecules are fragile and, without adequate protection, are susceptible to degradation in the body. For decades, the need for an effective delivery technology had been the most significant challenge in the development of RNA-based products since, without the means to protect the mRNA, mRNA-based vaccines have been ineffective. (Id. ¶¶ 24–25.)

B. Plaintiffs' Invention

Plaintiffs allege that functional RNA-based medicines eluded researchers until the work by Plaintiffs' scientists. After years of research, Plaintiffs developed lipid nano-particle ("LNP") technology that relies on fat-like molecules called lipids to encapsulate and protect nucleic acids like mRNA from degradation in the body. Once inside, the LNP releases the nucleic acid so that it can express the protein it encodes. The lipid components of Plaintiffs' technology include structural lipids, such as phospholipids and cholesterol; "cationic" (positive charge-bearing) lipids, including "ionizable" lipids that are positive charge-bearing at certain pH levels; and conjugated lipids, which are lipids attached to a polymer such polyethyleneglycol ("PEG"). (Id. ¶¶ 26–27.)

Plaintiffs' scientists' efforts led to the first FDA-approved RNA-based therapeutic in the form of a drug called Onpattro®, used to treat a rare disease called amyloidosis. The company that developed Onpattro® did so under an LNP license from Plaintiffs. Building on this initial success, Plaintiffs have granted licenses for its LNP technology to other companies. From 2011 to 2021, the United States Patent and Trademark Office ("PTO") issued to Plaintiffs six different patents for its LNP-based inventions. (Id. ¶ 28–29.)

C. The Alleged Infringement and Related Litigation

According to the Complaint, Moderna has been on actual notice of Plaintiffs' patents before development of its COVID-19 vaccine, the "Accused Product" in this matter. Indeed, in May 2015, Moderna attempted to acquire rights to Plaintiffs' LNP delivery technology for four specific viral targets

through sublicense from a Canadian company called Acuitas Therapeutics ("Acuitas"). Although Acuitas had licensed the LNP technology in 2012, its license agreement limited its ability to grant sublicenses. Nonetheless, Acuitas granted Moderna the sublicense. In August 2016, after learning of the sublicense agreements, Plaintiffs notified Acuitas of material breach, and Acuitas filed suit in the Supreme Court of British Columbia seeking to prevent Plaintiffs from terminating the license. In February 2018, Plaintiffs and Acuitas settled their dispute and agreed that Acuitas could no longer use the LNP technology except for the specific sublicenses given to Moderna for vaccines targeting specific viruses remaining in effect. SARS-CoV-2, the virus that causes COVID-19, was not among the surviving sublicenses. (Id. ¶¶ 31–34.)

Moderna then began filing *inter partes* review ("IPR") petitions, requesting that the PTO cancel certain of Plaintiffs' patents, including some asserted here. Although the first IPR petition was successful, the remaining IPR petitions were not. (Id. ¶¶ 35–38.)

On January 10, 2020, with the novel SARS-CoV-2 virus quickly spreading around the world, scientists identified the virus's complete genetic sequence and posted it for free on the internet, thus revealing the complete RNA sequence that encodes the virus's components, including its distinctive "spike protein." With that information in the public domain, researchers around the world, including Moderna, begin designing vaccines to target the virus. (Id. ¶ 39.)

Relying on Plaintiffs' LNP technology covered by the Asserted Patents, Moderna was able to begin producing its COVID-19 vaccine within just a few days of the genomic sequence entering the public domain. Moderna's success was unprecedented. On February 24, 2020, Moderna shipped clinical drug product, and, less than one month later, Phase I trials began. Plaintiffs contend that Moderna's COVID-19 vaccine could not have been developed on such a short timeline without Plaintiffs' proven and patented LNP delivery technology. Plaintiffs further allege that published articles and statements released by Moderna explicitly showed Moderna's use of Plaintiff's patents. (Id. ¶¶ 41–49.)

Moderna's distribution of its Accused Product and its administration to persons in the United States and worldwide commenced around December 18, 2020, immediately after the FDA granted Moderna's COVID-19 vaccine an Emergency Use Authorization ("EUA"). In 2021, Moderna shipped 807 million doses, and, as of February 2022, Moderna had signed advance purchase agreements worth approximately $19 billion for all of 2022. The Complaint alleges that the vaccine doses made and administered in the United States were distributed to hospitals, pharmacies, clinics, and numerous other entities for the benefit of individual vaccine recipients in the United States. (Id. ¶ 51.)

On June 1, 2021, Moderna announced that it had initiated the FDA process for a Biologics License Application ("BLA")—full-fledged licensure of its COVID-19 vaccine. The FDA approved the BLA on January 31, 2022. As of February 24, 2022, the vaccine had received at least emergency authorization from more than seventy countries. Moderna has contracted with a number of companies around the world to manufacture its COVID-19 vaccine, including companies that employ facilities in the United States. (Id. ¶¶ 52–54.)

Plaintiffs claim that they did not seek to inhibit development and distribution of the vaccine but only requested fair and reasonable compensation. As such, they proposed that Moderna pay for a mutually acceptable license, but Moderna has declined to engage meaningfully in licensing discussion, necessitating this lawsuit. (Id. ¶¶ 55–61.)

On February 28, 2022, Plaintiffs filed suit alleging infringement of six different patents, prompting Modern to file the partial motion to dismiss currently pending before me. [3]

II. STANDARD OF REVIEW

Under Federal Rule of Civil Procedure 12(b)(6), a defendant bears the burden of demonstrating that the plaintiff has not stated a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6); see

[3] The Complaint seeks damages for all sales of the COVID-19 Vaccine within the United States. Moderna's Motion to Dismiss addresses only those sales that were made to the United States Government and does not seek dismissal of claims relating to any other sales.

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