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.,	:	

Goldberg, J. **April 3, 2024**

MEMORANDUM OPINION[1]

During the COVID-19 pandemic, Defendants Moderna, Inc. and ModernaTX, Inc. (collectively, "Moderna") brought to market an mRNA-based vaccine. On February 28, 2022, after many of the quarantine orders had been lifted in the United States, Plaintiffs Arbutus Biopharma Corporation ("Arbutus") and Genevant Sciences GmbH ("Genevant") (collectively, "Plaintiffs") brought this infringement suit claiming that Defendant used—without payment or a license—a revolutionary lipid nanoparticle ("LNP") delivery platform, created and patented by Plaintiffs. Plaintiffs now demand compensation for the use of the technology they claim to have developed.

Presently, the parties seek construction of several terms of the patents-in-suit pursuant to Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995), aff'd, 517 U.S. 370 (1996). I have construed the disputed claims as set forth in this Opinion and accompanying Order.

[1] The Chief of the United States Court of Appeals for the Third Circuit has designated me as a visiting judge for the District of Delaware, pursuant to 28 U.S.C. § 292(b), to handle this and other Delaware cases.

I. FACTUAL BACKGROUND

A. Background on mRNA Vaccines[2]

Viruses are typically small packets of DNA or RNA. If a viral DNA or RNA enters the host cell, it hijacks the cell's machinery and instructs the cell to make copies of the virus. These copies, often numbering into the millions, leave the infected cell and hijack other cells where the process repeats. Infected cells can become damaged or die while hosting the virus, and left unchecked, the host organism can itself die.

Vaccines traditionally work by injecting a weakened or inactive form of the virus that is unable to cause infection but nonetheless retains features of the virus, which can teach the body's immune system to recognize and attack the infectious virus if it invades in the future. Moderna's COVID-19 vaccine, however, 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 our chromosomes and contains our 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." The mRNA then carries the code to the cell's protein-making machinery, which assembles the protein from the code stored in the mRNA.

RNA-based medicines have been difficult to develop because mRNA molecules are fragile and, without adequate protection, are susceptible to degradation before entering the cell. For decades, the need for an effective delivery technology had been a significant challenge in the

[2] This background was taken from the parties' technology tutorials.

development of RNA-based products. Without the means to protect the mRNA outside the cell, mRNA-based vaccines have been ineffective.

B. The Lipid Nano-Particle Delivery Approach

One delivery approach found to be effective for mRNA vaccines is the use of a 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. The LNP releases the nucleic acid so that it can express the protein it encodes.

According to Plaintiffs, early lipoplex structures were unsuccessful in delivering nucleic acids to cells in living systems because the nucleic acids were simply interspersed with the liposomes, leaving them susceptible to degradation in the body. In the late 1990s to early 2000s, ionizable cationic lipids were developed, and Plaintiffs' scientists used them to create LNPs.

LNPs are comprised of several different types of lipids. Cationic lipids carry positive charges which attract negatively charged nucleic acid. Conjugated lipids contain a lipid attached to a compound to help prevent the LNP from sticking to other LNPs during manufacture and to shield the LNP during delivery. Structural lipids, such as phospholipids and cholesterol, help keep the structure of the particles. These various lipids exist in specified ratios, expressed in terms of the "mol %" which refers to the percentage of each type of lipid molecule counted by number of molecules.

C. The Patents-in-Suit

The parties agree that there are two categories of patents-in-suit. The first category is the "Encapsulation Patent," which includes only U.S. Patent No. 9,504,651, "Lipid Compositions for Nucleic Acid Delivery," issued on November 29, 2016. The '651 patent claims a new method for

developing LNPs which involves continuously and rapidly mixing two solutions to form lipid vesicles that can encapsulate nucleic acids.

The second category of patents-in-suit are the "Molar Ratio Patents, which include U.S. Patent No. 8,058059 (the "'069 patent") issued on November 15, 2011, U.S. Patent No. 8,492,359 (the "'359 patent") issued on July 23, 2013, U.S. Patent No. 8,822,668 (the "'668 patent") issued on September 2, 2014, U.S. Patent No. 9,364,435 (the "'435 patent") issued on June 14, 2016, and U.S. Patent No. 11,141,378 (the "'378 patent") issued on October 12, 2021. These patents claim particles comprising a nucleic acid and specific molar ratio amounts of phospholipids, cationic lipids, PEG lipids, and cholesterol.

II. STANDARD OF REVIEW

The first step in a patent infringement analysis is to define the meaning and scope of the claims of the patent. Markman, 52 F.3d at 976. Claim construction, which serves this purpose, is a matter of law exclusively for the court. Id. at 979. "'[T]here is no magic formula or catechism for conducting claim construction.' Instead, the court is free to attach the appropriate weight to appropriate sources 'in light of the statutes and policies that inform patent law.'" SoftView LLC v. Apple Inc., No. 10-cv-389, 2013 WL 4758195, at *1 (D. Del. Sept. 4, 2013) (quoting Phillips v. AWH Corp., 415 F.3d 1303, 1324 (Fed. Cir. 2005)).

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." Phillips, 415 F.3d at 1312 (internal quotation marks omitted). The focus of a court's analysis must therefore begin and remain on the language of the claims, "for it is that language that the patentee chose to use to 'particularly point[ ] out and distinctly claim[ ] the subject matter which the patentee regards as his invention.'" Interactive Gift Express, Inc. v. Compuserve, Inc., 256 F.3d 1323, 1331 (Fed. Cir. 2001) (quoting 35 U.S.C. § 112,

¶ 2). The terms used in the claims bear a "heavy presumption" that they mean what they say and have their ordinary and customary meaning. Texas Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1202 (Fed. Cir. 2002). That ordinary meaning "is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." Phillips, 415 F.3d at 1313.

Generally, a person of ordinary skill in the art ("POSITA") would not understand the ordinary and customary meaning of a claim term in isolation. As such, the ordinary meaning may be derived from a variety of sources including intrinsic evidence, such as the claim language, the written description, drawings, and the prosecution history; as well as extrinsic evidence, such as dictionaries, treatises, or expert testimony. Dow Chem. Co. v. Sumitomo Chem. Co., Ltd., 257 F.3d 1364, 1373 (Fed. Cir. 2001).

The "most significant source" of authority is "the intrinsic evidence of record, *i.e.*, the patent itself, including the claims, the patent specification[3] and, if in evidence, the prosecution history." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996); see also Phillips, 415 F.3d at 1313 (holding that a person of ordinary skill in the art is deemed to have read the claim terms in the context of the entire patent, including the specification). The specification "is the single best guide to the meaning of a disputed term" and is usually dispositive as to the meaning of words. Vitronics, 90 F.3d at 1582. Although it is improper to import limitations from the specification into the claims, "one may look to the written description to define a term already in a claim limitation, for a claim must be read in view of the specification of which it is a part."

[3] The specification is "that part of a patent application which precedes the claim and in which the inventor specifies, describes, and discloses the invention in detail." McCarthy's Desk Encyclopedia of Intellectual Property 408 (2d ed. 1995).

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