IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALNYLAM PHARMACEUTICALS, INC., Plaintiff, v. MODERNA, INC., MODERNATX, INC., and MODERNA US, INC., Defendants.	)	Civil Action No. __ **JURY TRIAL DEMANDED**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Alnylam Pharmaceuticals, Inc. ("Alnylam"), by its attorneys, alleges as follows for its Complaint for Patent Infringement against Moderna, Inc., ModernaTX, Inc., and Moderna US, Inc. (collectively, "Moderna").

NATURE OF THE ACTION

1. Alnylam is a pioneering RNA therapeutics company based in Cambridge, Massachusetts. Over a decade ago, Alnylam invented a breakthrough class of protonatable biodegradable lipids used to form lipid particles that carry and safely deliver in the body RNA-based therapeutics or vaccines (the "Alnylam Lipid Particle Technology"). The Alnylam Lipid Particle Technology is foundational to the success of the recently-developed messenger RNA ("mRNA") based COVID vaccines. The United States Patent Office repeatedly recognized Alnylam's inventive work, including by issuing United States Patent Nos. 11,590,229 (the "'229 Patent), 11,633,479 (the "'479 Patent"), 11,633,480 (the "'480 Patent") (collectively, the "Patents-in-Suit"), which are three of the patents that protect the Alnylam Lipid Particle Technology. (Exhibits 1, 2, and 3.) The '229 Patent issued from U.S. Application No. 17/651,029 (the "'029 Application"). (Exhibit 1.) The '479 Patent issued from U.S. Application No. 17/651,017 (the

"'017 Application"). (Exhibit 2.) The '480 Patent issued from U.S. Application No. 17/651,023 (the "'023 Application"). (Exhibit 3.)

2. Moderna infringes Alnylam's '479 Patent and '480 Patent through the use of SM-102, [1] a protonatable biodegradable lipid formulated into lipid particles that protect and deliver the vaccine's mRNA. Similarly, Moderna infringes Alnylam's '229 Patent through the use of Alnylam's patented lipid particles that protect and deliver Moderna's COVID-19 Vaccine's mRNA. The "Moderna's Infringing Lipid Particles" comprise four lipids: SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC].

3. Moderna has been aware of the Alnylam Lipid Particle Technology since at least early 2014, when Alnylam and Moderna entered into a business discussion regarding a license to Alnylam technology including the Alnylam Lipid Particle Technology. Alnylam brings this action to recover monetary compensation for Moderna's unlicensed use of Alnylam's Patents-in-Suit. Alnylam does not seek injunctive relief under 35 U.S.C. § 283 against such use.

THE PARTIES

4. Plaintiff Alnylam is a corporation organized under the laws of the State of Delaware with a principal place of business at 675 West Kendall Street, Henri A. Termeer Square, Cambridge, Massachusetts 02142. Founded in 2002, Alnylam is a groundbreaking life science company that has worked to harness the potential of RNA interference ("RNAi") therapeutics to transform the lives of people living with diseases that have limited or inadequate treatment options. Utilizing an earlier version of in licensed Lipid Particle Technology, in 2018 Alnylam delivered

[1] SM-102's chemical name is 9-heptadecanyl 8-{(2-hydroxyethyl)[6-oxo-6-(undecyloxy)hexyl]amino}octanoate. (Exhibit 25 at 3.)

the world's first approved RNAi therapeutic, ONPATTRO® (patisiran). ONPATTRO® is currently approved for the treatment of polyneuropathy caused by an illness called hereditary ATTR (hATTR) amyloidosis. Alnylam has developed an additional delivery modality termed GalNAc Delivery, which is utilized in three marketed products, GIVLAARI® (givosiran), approved in 2019, and OXLUMO® (lumasiran), approved in 2020, both marketed by Alnylam and LEQVIO®(inclisiran), approved in 2021, developed initially by Alnylam and licensed to Novartis.

5. Alnylam has a long history of licensing or offering to license to third parties its intellectual property, including the Alnylam Lipid Particle Technology and the GalNAc Technology.

6. Upon information and belief, Defendant Moderna, Inc. is a company organized under the laws of the State of Delaware with a principal place of business at 200 Technology Square, Cambridge, Massachusetts 02139. Upon information and belief, Defendant Moderna, Inc. was previously known as Moderna Therapeutics, Inc. Upon information and belief, Defendant Moderna, Inc. is the parent company of the other Defendants and recognizes the revenue from sales of Moderna's COVID-19 vaccine. (Exhibit 4 at 98-100; Exhibit 5 at 97, 120, 128.)

7. Upon information and belief, Defendant ModernaTX, Inc. is a company organized under the laws of the State of Delaware with a principal place of business at 200 Technology Square, Cambridge, Massachusetts 02139. Upon information and belief, Defendant ModernaTX, Inc. is a wholly owned subsidiary of Defendant Moderna, Inc. The FDA granted the Biologic License Approval ("BLA") for SPIKEVAX®[2] to Defendant ModernaTX, Inc. (Exhibit 6). Defendant ModernaTX, Inc. is listed as the entity to contact in the prescribing information for

[2] Moderna's mRNA COVID-19 Vaccine is approved under the tradename SPIKEVAX®.

SPIKEVAX®. (Exhibit 7 at 71-72.) According to the prescribing information, SPIKEVAX® is a trademark of Defendant ModernaTX, Inc. (*Id.* at 9).

8. Upon information and belief, Defendant Moderna US, Inc. is a company organized under the laws of the State of Delaware with a principal place of business at 200 Technology Square, Cambridge, Massachusetts 02139. Upon information and belief, Defendant Moderna US, Inc. is a wholly-owned subsidiary of Defendant Moderna, Inc. Defendant Moderna US, Inc. is listed in the prescribing information as the entity manufacturing SPIKEVAX®. (Exhibit 7 at 71-72.)

9. On information and belief, Defendants Moderna Inc., ModernaTX, and Moderna US, Inc. are agents of each other and/or work in concert with each other with respect to the development, regulatory approval, marketing, manufacturing, sales, offers for sale, and distribution of Moderna's COVID-19 Vaccine which contains Moderna's Infringing Lipid Particles. One of the lipids in Moderna's Infringing Lipid Particles is SM-102.

JURISDICTION AND VENUE

10. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq*.

11. This Court has jurisdiction under 28 U.S.C. §§ 1331 and 1338(a) because this is a civil action arising under the Patent Act.

12. This Court has personal jurisdiction over Defendant Moderna, Inc., Defendant ModernaTX, Inc., and Defendant Moderna US, Inc. because all three are Delaware corporations.

13. This Court also has jurisdiction over Defendant Moderna, Inc. because, upon information and belief, it directly or indirectly makes, uses, offers for sale, and/or sells its COVID-

19 Vaccine, containing Moderna's Infringing Lipid Particles, which include SM-102, throughout the United States, including in this judicial district.

14. This Court also has jurisdiction over Defendant ModernaTX, Inc. because, upon information and belief, it directly or indirectly makes, uses, offers for sale, and/or sells its COVID-19 Vaccine, containing Moderna's Infringing Lipid Particles, which include SM-102, throughout the United States, including in this judicial district.

15. This Court also has jurisdiction over Defendant Moderna US, Inc. because, upon information and belief, it directly or indirectly makes, uses, offers for sale, and/or sells its COVID-19 Vaccine, containing Moderna's Infringing Lipid Particles, which including SM-102, throughout the United States, including in this judicial district.

16. Venue is proper in this Court under 28 U.S.C. § 1400(b) because Defendant Moderna, Inc., Defendant ModernaTX, Inc., and Defendant Moderna US, Inc. are Delaware corporations.

BACKGROUND

A. RNA THERAPEUTICS

17. The promise of RNA-based therapeutics (including RNAi and mRNA) has long been known, but scientists have struggled for decades to translate the promise into successful human therapeutics. The main challenge scientists around the world struggled with was how to deliver the fragile, negatively charged RNA into the body's cells in a safe, effective, and non-toxic way. (Exhibit 8 at 1-2.)

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