IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALNYLAM PHARMACEUTICALS, INC., Plaintiff, v. PFIZER INC. and PHARMACIA & UPJOHN CO. LLC, Defendants.	)	C.A. 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 Defendants Pfizer Inc. and Pharmacia & Upjohn Co. LLC (collectively, "Defendants").

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 cationic biodegradable lipids used to form lipid nanoparticles ("LNP") that carry and safely deliver in the body RNA-based therapeutics or vaccines (the "Alnylam LNP Technology"). The Alnylam LNP Technology is foundational to the success of the recently-developed messenger RNA ("mRNA") based COVID vaccines. The United States Patent Office recognized Alnylam's inventive work, issuing United States Patent No. 11,246,933 (the "'933 Patent") that protects the Alnylam LNP Technology. (Exhibit 1.)

2. Defendants' mRNA COVID-19 uses a cationic biodegradable lipid covered by '933 Patent. Specifically, Defendants infringe Alnylam's '933 Patent through the use of ALC-

0315,[1] a cationic biodegradable lipid formulated into LNPs that protect and deliver the vaccine's mRNA. Alnylam brings this action to recover monetary compensation for Defendants' unlicensed use of Alnylam's '933 Patent. Alnylam does not seek injunctive relief under 35 U.S.C. § 283 against such use.

THE PARTIES

3. 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 LNP Technology, in 2018 Alnylam delivered 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 distinct from LNP Technology, 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.

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

5. Upon information and belief, Defendant Pfizer Inc. is a company organized and existing under the laws of the State of Delaware with its principal place of business at 235 East

[1] ALC-0315's chemical name is ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate). (Exhibit 5 at 22.)

42nd Street, New York, New York 10017. The Biologic License Approval ("BLA") Approval for COMIRANTY® is addressed to Pfizer Inc., 235 East 42nd Street, New York, NY 10017. (Exhibit 3 at 1.) Upon information and belief, all regulatory correspondence regarding Defendants' COVID-19 Vaccine is sent to Pfizer Inc.'s principal place of business. (Exhibit 3 at 1.) The prescribing information for COMIRNATY®[2] states it is "[m]anufactured by Pfizer Inc." (Exhibit 4 at 20.) Upon information and belief, Defendant Pfizer Inc. maintains one or more facilities, including in Kalamazoo, Michigan, under the name PfizerCentre One, as a subsidiary of Pfizer Inc. and/or Defendant Pfizer Inc. is doing business as PfizerCentre One at one or more facilities, including in Kalamazoo, Michigan. Upon information and belief, Pfizer Laboratories, a division of Defendant Pfizer Inc., prepared the package insert for COMIRNATY® that was accepted by the FDA. (Exhibit 7 at 19.) Upon information and belief, Defendant Pfizer Inc. recognizes the revenue from sales of Defendants' COVID-19 Vaccine. (Exhibit 6 at 1, 4, 5, 14, 27, 29, 33-36.)

6. Upon information and belief, Defendant Pharmacia & Upjohn Co. LLC is a company organized and existing under the laws of the State of Delaware with its principal place of business at 100 Route 206 N, Peapack, New Jersey, 07977. Upon information and belief, Defendant Pharmacia & Upjohn Co. LLC is a wholly-owned subsidiary of Defendant Pfizer Inc. The BLA Approval Letter for COMIRNATY® states that, "[t]he final formulated product will be manufactured, filled, labeled and packaged . . . at Pharmacia & Upjohn Company LLC, 7000 Portage Road, Kalamazoo, Michigan." (Exhibit 3 at 1.)

7. On information and belief, Defendants Pfizer Inc. and Pharmacia & Upjohn Co. LLC are agents of each other and/or work in concert with each other with respect to the

[2] Defendants' mRNA COVID-19 Vaccine is approved under the tradename COMIRNATY®.

development, regulatory approval, marketing, making, sales, offers for sale, import and export, and distribution of Defendants' COVID-19 Vaccine containing ALC-0315.

JURISDICTION AND VENUE

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

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

10. This Court has personal jurisdiction over Defendant Pfizer Inc. because it is a Delaware corporation.

11. This Court also has jurisdiction over Defendant Pfizer Inc. because, upon information and belief, it directly or indirectly makes, uses, offers for sale, and/or sells Defendants' COVID-19 Vaccine, containing ALC-0315, throughout the United States, including in this judicial district.

12. This Court has personal jurisdiction over Defendant Pharmacia & Upjohn Co. LLC because it is a Delaware corporation.

13. This Court also has jurisdiction over Defendant Pharmacia & Upjohn Co. LLC because, upon information and belief, it directly or indirectly makes, uses, offers for sale, and/or sells Defendants' COVID-19 Vaccine, containing ALC-0315, throughout the United States, including in this judicial district.

14. Venue is proper in this Court under 28 U.S.C. § 1400(b) because Defendant Pfizer Inc. is a Delaware corporation.

15. Venue is proper in this Court under 28 U.S.C. § 1400(b) because Defendant Pharmacia & Upjohn Co. LLC is a Delaware corporation.

BACKGROUND

A. RNA THERAPEUTICS

16. 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.)

17. One approach was to develop a lipid[3] system for use with RNA-based therapeutics. These lipids would form a nanoparticle, called a Lipid Nanoparticle or LNP. The LNP would encapsulate and protect the fragile RNA upon administration to the body so the RNA could be delivered to the cells where the RNA would provide its therapeutic effect. Because the RNA is negatively charged, the lipids had to be positively charged (cationic) to create the protective bubble around the RNA. Cationic lipids do not exist in nature, and therefore had to be synthesized. There were toxicity issues with early attempts to use them in therapeutics due to the high dose of LNP needed to be effective.

18. To harness the full promise and power of LNPs to deliver revolutionary RNA therapies, scientists needed to develop a more potent LNP system that could safely and effectively deliver the RNA to the target cells, and then be metabolized and eliminated from the body.

19. Alnylam overcame some of the issues associated with earlier versions of LNPs using an in-licensed LNP system containing the cationic lipid compound known as MC3, a highly potent molecule. With MC3, Alnylam developed ONPATTRO®. MC3, while safe and effective, is more stable in the body and thus has a relatively long half-life. Alnylam recognized the need

[3] A lipid is a molecule that is minimally soluble in water while soluble in nonpolar solvents. Examples include macro biomolecules such as fats, oils, certain vitamins, and hormones.

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