IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALNYLAM PHARMACEUTICALS, INC., Plaintiff, v. PFIZER INC., PHARMACIA & UPJOHN CO. LLC, BIONTECH SE, and BIONTECH MANUFACTURING GMBH, 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, "Pfizer") and BioNTech SE and BioNTech Manufacturing GmbH (collectively, "BioNTech") (Pfizer and BioNTech 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 repeatedly recognized Alnylam's inventive work, including by issuing United States Patent No. 11,382,979 (the "'979 Patent"),

which is one of several patents that protects the Alnylam LNP Technology.[1] (Exhibit 1.) The '979 Patent issued from U.S. Application No. 17/644,907 (the "'907 Application). (Exhibit 1.)

2. Defendants infringe Alnylam's '979 Patent through the use of Alnylam's patented LNPs that protect and deliver Defendants' COVID-19 Vaccine's mRNA. The "Defendants' Infringing LNPs" comprise four lipids: ALC-0315 [2] (a cationic biodegradable lipid), 2-(polyethylene glycol 2000)-N,N-ditetradecylacetamide (a PEG-modified lipid), 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC), and cholesterol.

3. Alnylam brings this action to recover monetary compensation for Defendants' unlicensed use of Alnylam's '979 Patent. 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 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

[1] The United States Patent Office also issued United States Patent No. 11,246,933 (the "'933 Patent") to Alnylam. (Exhibit 34.) The '933 Patent protects other aspects of Alnylam LNP Technology.

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

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.

5. 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.

6. 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 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®[3] 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.)

7. 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

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

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.)

8. Upon information and belief, Defendant BioNTech SE is a company organized and existing under the laws of Germany, with its principal place of business located at An der Goldgrube 12 Mainz, 55131 Germany. Its shares are traded in the United States on the NASDAQ under the symbol BNTX.

9. Upon information and belief, Defendant BioNTech Manufacturing GmbH, is a company organized and existing under the laws of Germany, with its principal place of business located at An der Goldgrube 12 Mainz, 55131 Germany. Upon information and belief, Defendant BioNTech Manufacturing GmbH is 100 % controlled by Defendant BioNTech SE. (Exhibit 27 at F-29.) The prescribing information for COMIRANTY® states it is "[m]anufactured for BioNTech Manufacturing GmbH" but is "[m]anufactured by Pfizer Inc." (Exhibit 4 at 20.) The BLA Approval for COMIRANTY® states that the FDA is "issuing Department of Health and Human Services U.S. License No. 2229 to BioNTech Manufacturing GmbH, Mainz, Germany." (Exhibit 3 at 1.)

10. On information and belief, Defendants Pfizer Inc., Pharmacia & Upjohn Co. LLC, BioNTech SE, and BioNTech Manufacturing GmbH are agents of each other and/or work in concert with each other with respect to the development, regulatory approval, marketing, making, sales, offers for sale, import and export, and distribution of Defendants' COVID-19 Vaccine containing LNPs made with Defendants' Infringing LNPs.

JURISDICTION AND VENUE

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

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

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

14. 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 LNPs made with Defendants' Infringing LNPs, throughout the United States, including in this judicial district.

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

16. 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, comprising Defendants' Infringing LNPs, throughout the United States, including in this judicial district.

17. This Court has jurisdiction over Defendant BioNTech SE, upon information and belief, because it directly or indirectly manufactures, uses, offers for sale, and/or sells Defendants' COVID-19 Vaccine, containing Defendants' Infringing LNPs, throughout the United States, including in this judicial district. Further, BioNTech SE has consented to the personal jurisdiction of the Court by appearing in a litigation filed by Alnylam against Pfizer in this judicial district and filing a Counterclaim against Alnylam for a Declaratory Judgment of noninfringement and

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