**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| ALNYLAM PHARMACEUTICALS, INC.,<br><br>Plaintiff,<br><br>v.<br><br>PFIZER INC., AND PHARMACIA & UPJOHN CO. LLC,<br><br>Defendants. | Civil Action No. ___<br><br>DEMAND FOR JURY TRIAL |

**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" or "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 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. 11,633,479 (the "'479 Patent"), 11,633,480 (the "'480 Patent"), 11,612,657 (the "'657 Patent"), and 11,590,229 (the "'229 Patent") (collectively, the "Patents-in-Suit"), which are four of the patents that protect the

Alnylam Lipid Particle Technology. (Exhibits 1, 2, 3, and 4.) The '479 Patent issued from U.S. Application No. 17/651,017 (the "'017 Application"). (Exhibit 1.) The '480 Patent issued from U.S. Application No. 17/651,023 (the "'023 Application"). (Exhibit 2.) The '657 Patent issued from U.S. Application No. 17/651,038 (the "'038 Application"). (Exhibit 3.) The '229 Patent issued from U.S. Application No. 17/651,029 (the "'029 Application"). (Exhibit 4.)

2. Defendants infringe Alnylam's '479 Patent through the use of ALC-0315,[1] a lipid compound used in Defendants' COVID-19 Vaccine. Similarly, Defendants infringe the '480 Patent through the use of ALC-0315, which is formulated into a lipid particle that protects and delivers the vaccine's mRNA. Defendants infringe Alnylam's'657 Patent and '229 Patent through the use of Alnylam's patented lipid particles that protect and deliver Defendants' COVID-19 Vaccine's mRNA. The "Defendants' Infringing Lipid Particles" comprise four lipids: ALC-0315 (a protonatable 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 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

[1] ALC-0315's chemical name is ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate). (Exhibit 28 at 8.)

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 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 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 COMIRNATY® is addressed to Pfizer Inc., 500 Arcola Road, Collegeville, PA 19426. (Exhibit 5 at 1.) Upon information and belief, all regulatory correspondence regarding Defendants' COVID-19 Vaccine is sent to Pfizer Inc.'s principal place of business. (*Id.*) The prescribing information for COMIRNATY®[2] states it is "[m]anufactured by Pfizer Inc." (*Id.*, Exhibit 6 at 78, Exhibit 7 at 26, Exhibit 8 at 24.) 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

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

division of Defendant Pfizer Inc., prepared the package insert for COMIRNATY® that was accepted by the FDA. (Exhibit 6 at 78; Exhibit 7 at 26; Exhibit 8 at 24.) Upon information and belief, Defendant Pfizer Inc. recognizes the revenue from sales of Defendants' COVID-19 Vaccine. (Exhibit 9 at 1, 4, 5, 14, 27, 29, 33-36; Exhibit 10 at 1, 4, 5, 6, 15, 21-22, 27, 28-29, 32-36, 42, 65, 67-69.)

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 of business at 7000 Portage Road, Kalamazoo, MI 49001. 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, the product will be "manufactured at … Pharmacia & Upjohn Company LLC, Kalamazoo, Michigan." (Exhibit 5 at 1.)

8. 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 development, regulatory approval, marketing, making, sales, offers for sale, import and export, and distribution of Defendants' COVID-19 Vaccine which contain Defendants' Infringing Lipid Particles. One of the lipids in Defendants' Infringing Lipid Particles is ALC-0315.

## JURISDICTION AND VENUE

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

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

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

12. 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 Defendants' Infringing Lipid Particles, which include ALC-0315, throughout the United States, including in this judicial district.

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

14. 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 Lipid Particles, including ALC-0315, throughout the United States, including in this judicial district.

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

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

## 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 11 at 1-2.)

18. One approach was to develop a lipid[3] system for use with RNA-based therapeutics. These lipids would form a lipid particle. The lipid particle 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, certain of the lipids in the lipid particle had to be protonatable to create the protective bubble around the RNA. Protonatable 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 lipid particle needed to be effective.

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

20. Alnylam overcame some of the issues associated with earlier versions of lipid particles using an in-licensed lipid particle system containing the protonatable 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 for further improvements in lipid particle technology and internally embarked on a research program to develop a new class of lipids with improved properties.

### B. ALNYLAM'S BREAKTHROUGH BIODEGRADABLE LIPID PARTICLE TECHNOLOGY FOR DELIVERY OF RNA TO CELLS

21. Over a decade ago, Alnylam scientists solved these pressing issues by inventing a new class of non-natural lipid particles comprising a protonatable lipid with biodegradable groups

[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.

(*i.e.*, the Alnylam Lipid Particle Technology). Lipid particles with these biodegradable groups protect the RNA until delivery to inside the cell, and then are metabolized and eliminated from the body ensuring no dose-limiting toxicity. Alnylam's seminal work to create these novel biodegradable lipid particles has been employed in potential RNA therapeutics in development and now mRNA-based vaccines.

### C. THE PATENTS-IN-SUIT

22. Alnylam filed a series of provisional and utility patent applications on its novel protonatable biodegradable lipids. Utility applications disclosing these novel protonatable biodegradable lipids published on February 2, 2012 and August 1, 2013. At least forty-nine patents world-wide have issued to Alnylam based on these groundbreaking inventions described in its provisional and utility patent applications.

23. On February 28, 2023, The United States Patent & Trademark Office issued the '229 Patent, entitled "Biodegradable Lipids for the Delivery of Active Agents." The '229 Patent issued to Alnylam as assignee of the inventors.

24. The '229 Patent claims a class of vaccines using lipid particles that contain a protonatable lipid compound, distearoylphosphatidylcholine (DSPC), cholesterol, and a PEG-modified lipid for use in delivering a nucleic acid, including mRNA, and a method of delivering the same.

25. Independent claim 27 of the '229 Patent is representative and recites:

> A vaccine comprising a lipid particle and a pharmaceutically acceptable diluent, excipient, or carrier, wherein the lipid particle comprises:
>
> (i) a nucleic acid, wherein the nucleic acid comprises RNA,
>
> (ii) 35-65 mol% of a protonatable lipid compound,
>
> (iii) 3-12 mol% distearoylphosphatidylcholine (DSPC),

(iv) 15-45 mol% cholesterol, and

(v) 0.5-10 mol% of the PEG-modified lipid

wherein the mol% is based on 100% total moles of lipids in the lipid particle,

wherein the protonatable lipid compound comprises a head group, hydrophobic tails, and a central moiety to which the head group and the hydrophobic tails are directly bonded, wherein:

the central moiety is a nitrogen atom;

the hydrophobic tails consist of two hydrophobic tails;

each of the two hydrophobic tails has the formula $-R^{12}-M^{1}-R^{13}$, wherein:

$R^{12}$ is a $C_1$-$C_{14}$ alkyl group,

$M^{1}$ is -OC(O)-, and

$R^{13}$ is a $C_{10}$-$C_{20}$ branched alkyl, wherein $R^{13}$ is branched at the alpha position relative to the -OC(O)- group;

the chain length of formula $-R^{12}-M^{1}-R^{13}$ is 17 atoms; and

the total carbon atom content of each hydrophobic tail is 21 to 26 carbon atoms.

(Exhibit 4 at Claim 27.)

26. The ’229 Patent has been owned by Alnylam at all times, is fully maintained, and is valid and enforceable.

27. On March 28, 2023, The United States Patent & Trademark Office issued the ’657 Patent, entitled “Biodegradable Lipids for the Delivery of Active Agents.” The ’657 Patent issued to Alnylam as assignee of the inventors.

28. The ’657 Patent claims a pharmaceutical composition having a lipid particle that can be used for the delivery of an active agent, including mRNA. Each lipid particle contains a

plurality of protonatable lipid compounds. Additional dependent claims including a method of delivering a nucleic acid by administering the claimed pharmaceutical composition.

29. Independent claim 15 of the '657 Patent is representative and recites:

> A pharmaceutical composition comprising a lipid particle and a pharmaceutically acceptable diluent, wherein the lipid particle comprises:
>
> (i) a nucleic acid,
>
> (ii) about 45-65 mol % of a protonatable lipid compound,
>
> (iii) about 5-10 mol % distearoylphosphatidylcholine (DSPC),
>
> (iv) about 25-40 mol % of cholesterol,
>
> (v) 0.5-5 mol % of a PEG-modified lipid,
>
> wherein the mol % is based on 100% total moles of lipids in the lipid particle;
>
> wherein the nucleic acid comprises an RNA;
>
> wherein the protonatable lipid compound comprises a head group, hydrophobic tails, and a central moiety to which the head group and the two hydrophobic tails are directly bonded, wherein:
>
> the central moiety is a nitrogen atom;
>
> the hydrophobic tails consist of two identical hydrophobic tails; and
>
> each hydrophobic tail has the formula —$R^{12}$-$M^1$-$R^{13}$, wherein:
>
> $R^{12}$ is a $C_4$-$C_{14}$ alkyl group;
>
> $M^1$ is —OC(O)—;
>
> $R^{13}$ is a $C_{10}$-$C_{20}$ alkyl group that is branched at the α-position relative to $M^1$;
>
> the chain length of formula —$R^{12}$-$M^1$-$R^{13}$ is from 17 to 24 atoms; and
>
> the total carbon atom content of each hydrophobic tail is 21 to 26 carbon atoms.

(Exhibit 3 at Claim 15.)

30. The ’657 Patent has been owned by Alnylam at all times, is fully maintained, and is valid and enforceable.

31. On April 25, 2023, The United States Patent & Trademark Office issued the ’479 Patent, entitled “Biodegradable Lipids for the Delivery of Active Agents.” The ’479 issued to Alnylam as assignee of the inventors.

32. The ’479 Patent claims a lipid compound that can be used in a lipid particle for the delivery of active an active agents.

33. Independent claim 10 of the ’479 Patent recites:

A lipid compound, comprising a head group, two identical hydrophobic tails, and a central moiety to which the head group and the two hydrophobic tails are directly bonded, wherein:

the central moiety is a nitrogen atom;

each hydrophobic tail has the formula $-R^{12}-M^{1}-R^{13}$, wherein:

$R^{12}$ is a $C_4$-$C_{14}$ alkyl group,

$M^{1}$ is -OC(O)-, and

$R^{13}$ is a $C_{10}$-$C_{20}$ alkyl group that is branched at the α-position relative to $M^{1}$;

the chain length of formula $-R^{12}-M^{1}-R^{13}$ is from 17 to 24 atoms; and

the total carbon atom content of each hydrophobic tail is 21 to 26 carbon atoms.

34. Dependent claim 11 of the ’479 Patent, which depends from claim10, is representative and recites:

The lipid compound of claim 10, wherein $R^{12}$ is n-hexyl.

35. The ’479 Patent has been owned by Alnylam at all times, is fully maintained, and is valid and enforceable.

36. On April 25, 2023, The United States Patent & Trademark Office issued the ’480 Patent, entitled “Biodegradable Lipids for the Delivery of Active Agents.” The ’480 Patent issued to Alnylam as assignee of the inventors.

37. The ’480 Patent claims a lipid particle for delivery of an active agent, including mRNA, containing a protonatable lipid compound, distearoylphosphatidylcholine (DSPC), cholesterol, and a PEG-modified lipid. Each protonatable lipid compound contains a head group, hydrophobic tails, and a central moiety to which the head group and the two hydrophobic tails are directly bonded.

38. Independent claim 1 of the ’480 Patent is representative of the lipid particle composition claims and recites:

A lipid particle comprising:

(i) a nucleic acid,

(ii) 35-65 mol % of a protonatable lipid compound,

(iii) 3-12 mol % distearoylphosphatidylcholine (DSPC),

(iv) 15-45 mol % cholesterol, and

(v) 0.5-10 mol % of a PEG-modified lipid,

wherein the mol% is based on 100% total moles of lipids in the lipid particle,

wherein the protonatable lipid compound comprises a head group, hydrophobic tails, and a central moiety to which the head group and the hydrophobic tails are directly bonded, wherein:

the central moiety is a nitrogen atom;

the hydrophobic tails consist of two hydrophobic tails;

each of the two hydrophobic tails has the formula $-R^{12}-M^{1}-R^{13}$, wherein

$R^{12}$ is a $C_4$-$C_{14}$ alkyl group, $M^{1}$ is a -OC(O)- group, and $R^{13}$ is a $C_{10}$-$C_{20}$ branched alkyl group;

the chain length of formula $-R^{12}-M^{1}-R^{13}$ is at most 21 atoms; and

the total carbon atom content of each hydrophobic tail is 21 to 26 carbon atoms.

(Exhibit 2 at Claim 1.)

39. The ’480 Patent has been owned by Alnylam at all times, is fully maintained, and is valid and enforceable.

### D. DEFENDANTS' COVID-19 VACCINE

40. On March 17, 2020, Defendants Pfizer Inc. and BioNTech SE announced a plan to jointly develop a COVID-19 vaccine. (Exhibit 12 at 2.) A redacted copy of the Collaboration Agreement by and between Pfizer Inc. and BioNTech, dated March 17, 2020, is publicly available. (Exhibit 13.) Under the Collaboration Agreement, Defendant Pfizer Inc. has the sole right in the United States to "market, promote, distribute, offer for sale, sell, have sold, import, have imported, export, have exported or otherwise commercialize" Defendants' COVID-19 Vaccine. (Exhibit 12, §1.25 (defining "Commercialize"); §1.6 (defining "BioNTech Commercialization Territory"); §1.88 (defining "Pfizer Commercialization Territory").) Under the Collaboration Agreement, Defendant Pfizer Inc. has the right in the United States to "make, produce, manufacture, process, fill, finish, package, label, perform quality assurance testing, release, ship or store, and for the purposes of further manufacturing, distribute, import or export" Defendants' COVID-19 Vaccine or "any component thereof." (*Id.*, §1.75 (defining "Manufacture"); §3.2 ("Licenses for Commercial Manufacturing").)

41. On April 9, 2020, Defendants provided additional details about this collaboration, including that "BioNTech will contribute multiple mRNA vaccine candidates as part of its BNT162 COVID-19 vaccine program" and that "Pfizer will contribute its leading global vaccine clinical research and development, regulatory, manufacturing and distribution infrastructure and capabilities." (Exhibit 13 at 1.)

42. On April 22, 2020, Defendants announced their first clinical trial in Germany of four mRNA vaccine candidates. (Exhibit 14 at 1.) Each vaccine candidate used a lipid particle to deliver the mRNA. (*Id.*)

43. On May 5, 2020, Defendants announced that the first doses of Defendants' four vaccine candidates were administered to individuals in the United States as part of Defendants' Phase 1/2 clinical trial. (Exhibit 15 at 1.) Defendants stated that "Pfizer plans to activate its extensive manufacturing network and invest at risk in an effort to produce an approved COVID-19 vaccine as quickly as possible for those most in need around the world . . . . Pfizer-owned sites in three U.S. states (Massachusetts, Michigan, and Missouri) and Puurs, Belgium, have been identified as manufacturing centers for COVID-19 vaccine production, with more sites to be selected." (*Id.* at 2.)

44. On July 13, 2020, Defendants announced that the FDA granted Fast Track Designations to two of Defendants' candidate vaccines. (Exhibit 16 at 1.) Peter Honig, Pfizer's Senior Vice President, Global Regulatory Affairs, commented "[w]e look forward to continue working closely with the FDA throughout the clinical development of this program, Project Lightspeed, to evaluate the safety and efficacy of these vaccine candidates." (*Id.* at 1-2.)

45. On July 27, 2020, Defendants announced that they had advanced the "nucleoside-modified messenger RNA (modRNA) candidate BNT162b2,[4] which encodes an optimized SARS-CoV-2 full-length spike glycoprotein, at a 30µg dose level in a 2 dose regimen into Phase 2/3 Study." (Exhibit 17 at 1.) Upon information and belief, the vaccine that Defendants selected contains Defendants' Infringing Lipid Particles, including ALC-0315.

46. On November 18, 2020, Defendants announced that their Phase 3 clinical trial met all primary efficacy endpoints. (Exhibit 18 at 1.) Defendants stated that "[f]our of Pfizer's

[4] Upon information and belief, BNT162b2 was the code name for Defendants' mRNA COVID-19 Vaccine during clinical trials. (Exhibit 6 at 11.)

facilities are part of the manufacturing and supply chain; St. Louis, MO; Andover, MA; and Kalamazoo, MI in the U.S.; and Puurs in Belgium." (*Id.* at 2.)

47. On December 11, 2020, the FDA authorized Defendants' BNT162b2 candidate with the infringing lipid particles made from Defendants' Infringing Lipid Particles, including ALC-0315, (Defendants' COVID-19 Vaccine) for emergency use against COVID-19 in individuals 16 years of age or older. (Exhibit 19 at 1) Upon information and belief, every dose of Defendants' COVID-19 Vaccine sold pursuant to this emergency use authorization contains the infringing lipid particles. Albert Bourla, Chairman and Chief Executive Officer of Pfizer said, "[a]s a U.S. company, today's news brings great pride and tremendous joy that Pfizer has risen to the challenge to develop a vaccine that has the potential to help bring an end to this devastating pandemic. We have worked tirelessly to make the impossible possible, steadfast in our belief that science will win." (Exhibit 20 at 1-2.)

48. On May 11, 2021, the FDA authorized Defendants' COVID-19 Vaccine for emergency use against COVID-19 in children ages twelve to fifteen. (Exhibit 19 n. 5.) Upon information and belief, every dose of Defendants' COVID-19 Vaccine sold pursuant to this emergency use authorization contains the infringing lipid particles made with Defendants' Infringing Lipid Particles, including ALC-0315.

49. On August 23, 2021, the FDA approved Defendants' COVID-19 Vaccine under the tradename COMIRNATY® for use in individuals sixteen and over. (Exhibit 19 n. 9.) Upon information and belief, every dose of Defendants' COVID-19 Vaccine sold under the tradename COMIRNATY® contains the infringing lipid particles made with Defendants' Infringing Lipid Particles, including ALC-0315.

50. On October 29, 2021, the FDA authorized Defendants' COVID-19 Vaccine for emergency use against COVID-19 in children ages five to eleven. (Exhibit 19 n.12) Upon information and belief, every dose of Defendants' COVID-19 Vaccine sold pursuant to this emergency use authorization contains the infringing lipid particles made with Defendants' Infringing Lipid Particles, including ALC-0315.

51. Upon information and belief, on December 16, 2021, the FDA approved a new formulation of Defendants' COVID-19 Vaccine under the tradename COMIRNATY® (gray cap) in individuals sixteen and over. (Exhibit 19 n. 15, Exhibit 8 at 1.) Upon information and belief, Defendants continue to market their prior COVID-19 Vaccine formulation under the tradename COMIRNATY® (purple cap) for use in individuals sixteen and over. (Exhibit 7 at 1.) Upon information and belief, every dose of Defendants' COVID-19 Vaccine sold under the tradename COMIRNATY® (gray cap (monovalent) and purple cap)[5] contains the infringing lipid particles made with Defendants' Infringing Lipid Particles, including ALC-0315.

52. Upon information and belief, on October 29, 2021, the FDA approved Defendants' COVID-19 Vaccine under the tradename COMIRNATY® (orange cap) in individuals 5 years through 11 years of age. (Exhibit 19 n.12.) Upon information and belief, on June 17, 2022, the FDA approved Defendants' COVID-19 Vaccine under the tradename COMIRNATY® (maroon cap) in individuals 6 months through 4 years of age. (Exhibit 19 n.19.) Upon information and belief, on August 31, 2022, the FDA approved Defendants' COVID-19 Bivalent Booster Dose under the tradename COMIRNATY® (gray cap (bivalent)) in individuals 12 years of age or older. (Exhibit 19 n.22.) Upon information and belief, on October 12, 2022, the FDA approved

[5] The prescribing information for both versions state that Defendant Pfizer Inc. manufactures Defendants' COVID-19 Vaccine. (*Compare* Exhibit 7 at 36 *with* Exhibit 8 at 24)

Defendants' COVID-19 Bivalent Booster Dose under the tradename COMIRNATY® (orange cap (bivalent)) in individuals 5 years through 11 years of age. (Exhibit 19 n.25.) Upon information and belief, every dose of Defendants' COVID-19 Vaccine sold under the tradename COMIRNATY® (maroon cap, orange cap (monovalent and bivalent) and gray cap (bivalent)) contains the infringing lipid particles made with Defendants' Infringing Lipid Particles, including ALC-0315.

53. Upon information and belief, on April 18, 2023, the FDA amended the EUA, rescinding its authorization for use of monovalent COMIRNATY® in the United States (Exhibit 19 at 3, 15, and n.28) The amendment authorized the use of the Bivalent COMIRNATY® vaccines (gray cap, orange cap, maroon cap) for all doses administered to all individuals 6 months of age or older (Exhibit 6 at 1). The Bivalent COMIRNATY® vaccine contains the infringing lipid particles made with Defendants' Infringing Lipid Particles, including ALC-0315. (Exhibit 6 at 52-53, Exhibit 7 at 19, Exhibit 8 at 16-17). A new revision of the label for the purple cap doses was also released in April 2023. (Exhibit 7.)

54. On February 8, 2022, Defendant Pfizer Inc. stated that it expected 2022 worldwide revenue of $32,000,000,000 for Defendants' COVID-19 Vaccine. (Exhibit 9 at 29.) Defendant Pfizer Inc.'s reported revenues suggest that U.S. sales in 2021 accounted for approximately 21% of the sales of Defendants' COVID-19 Vaccine in 2021. (*Id.* at 35.) One February 23, 2023, Defendant Pfizer Inc. reported a global revenue of $37,806,000,000 for Defendant's COVID-19 Vaccine. (Exhibit 10 at 38). Of that $8,775,000,000 is from U.S. sales. (*Id.*). As of January 31, 2023, Defendants Pfizer Inc. forecast 2023 COMIRNATY® revenues of approximately $13.5 billion.

55. Upon information and belief, Pfizer has manufactured doses of Defendants' COVID-19 Vaccine in the United States that it has shipped to other countries, including Mexico

and Canada. (Exhibit 21). Upon information and belief, Pfizer exported those U.S.-made doses pursuant to agreements with the governments of Mexico and Canada. (Exhibits 22, 23.) An official from the Canadian government confirmed shipments of Defendants' COVID-19 vaccine from Kalamazoo, Michigan to Canada. (Exhibit 24.) A White House COVID-19 advisor confirmed that Pfizer shipped U.S.-made doses of Defendants' COVID-19 Vaccine to Mexico and Canada. (Exhibit 24.) Upon information and belief, Pfizer has an agreement with the Canadian government to provide Defendants' COVID-19 Vaccine through at least 2024, including "[u]p to 65 million for 2022, up to 60 million in 2023 and up to 60 million in 2024." (Exhibit 23.)

56. On April 23, 2023, the FDA updated the "Conditions Related to Export" for Pfizer's COVID-19 Vaccine, regarding what doses Defendants are "permitted" to "export" from the United States. (Exhibit 19 at 28).

57. Upon information and belief, Pfizer plans to sell doses of its COVID-19 Vaccine on the private market in the United States. Specifically, on October 20, 2022, during an investor call, Pfizer revealed that it planned to charge a private-market price of between $110 - $130 per dose for its COVID-19 Vaccine. (Exhibit 26 at 8.)

### E. ALNYLAM'S PATENTED LIPID PARTICLE TECHNOLOGY IS ESSENTIAL TO DEFENDANTS' COVID-19 VACCINE

58. The patented Alnylam Lipid Particle Technology is essential to the efficacy and safety of Defendants' COVID-19 Vaccine. mRNA is very delicate and subject to rapid degradation by various enzymes upon administration. (Exhibit 11 at 2.) The large, negatively-charged mRNA strands also struggle to pass through the protective lipid membranes of cells. (*Id.*) Thus, to be effective, the mRNA strands require a delivery mechanism that can ensure that the mRNA strands are not degraded before delivery to the cell and can penetrate the cell. In addition,

the lipid particle needs to be biodegradable, *i.e.*, such that the lipid particles are metabolized and eliminated after successful mRNA delivery to the cells, so as to enhance safety.

59. Regarding these lipid particles, Defendant Pfizer Inc.'s website states "[t]his tiny fat glob, known as a functional lipid, is actually one of four lipids that make up the lipid nanoparticles that go into the vaccine. *Without these lipid nanoparticles, in fact, there could be no Pfizer-BioNTech mRNA vaccine*. That's because mRNA, which is the genetic material that teaches our cells to make the protein that will help our immune systems produce antibodies that helps to protect us from COVID-19, is incredibly delicate." (Exhibit 25 (emphasis added) at 2.)

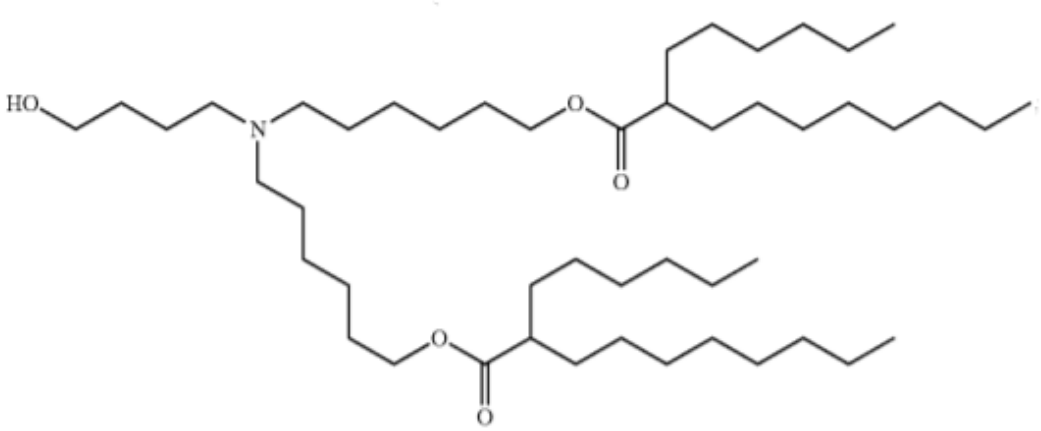
**DEFENDANTS' INFRINGING ACTIVITIES**

60. Attached as Exhibit 27 and incorporated herein is a claim chart describing Defendants' infringement of claims 27 and 28 of the '229 Patent. The claim chart is not intended to limit Alnylam's right to modify the chart or allege that other activities of Defendants infringe the identified claim or any other claims of the '229 Patent or any other patents. Upon information and belief, Defendants' Infringing Lipid Particles are in every dose of the COVID-19 Vaccine that Defendants have made, offered for sale, and sold, and will continue to do so.

61. The Prescribing Information for COMIRNATY® states that each dose contains the following lipid mixture: "0.43 mg ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg 2-(polyethylene glycol 2000)-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.19 mg cholesterol". (Exhibit 6 at 53, Exhibit 7 at 19.) Upon information and belief, the lipids are with the molar percentages of: 35-65 mol % of a protonatable lipid compound, 3-12 mol % distearoylphosphatidylcholine (DSPC), 15-45 mol % cholesterol, and 0.5-10 mol % of a PEG-modified lipid.

62. The Prescribing Information for COMIRNATY® states that each dose contains "30 mcg of a nucleoside-modified messenger RNA (mRNA)[6] encoding the viral spike (S) glycoprotein of SARS-CoV-2." (Exhibit 6 52-53, Exhibit 7 at 19, Exhibit 8 at 16). Upon information and belief, this document was prepared by Defendants and accepted by the FDA for distribution to providers of Defendants' COVID-19 Vaccine.

63. Upon information and belief, 4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) is known as ALC-0315. Upon information and belief, ALC-0315 has the chemical structure depicted just below:




(Exhibit 28 at 8.)

64. Upon information and belief, a pharmaceutical composition containing ALC-0315 is in every dose of the COVID-19 Vaccine that Defendants have made, offered for sale, and sold, and will continue to do so.

65. Defendants have known of the '229 Patent since at least as early as February 28, 2023, when the '229 Patent issued. Alnylam notified Defendants of the published '029 Application

[6] mRNA is a nucleic acid.

on June 23, 2022. Alnylam informed Defendants of the Notice of Allowability and payment of issue fee for the '029 Application on January 23, 2023. Alnylam provided Defendants with the claims as allowed on the same date. The claims are publicly available and have been known to Defendants since at least December 1, 2022. Alnylam notified Defendants of the Issue Notification for the '029 Application, detailing that the application would issue February 28, 2023 as U.S. Patent No. 11,590,229, on February 9, 2023.

66. On information and belief, Defendants and/or their end users employ in their COVID-19 Vaccine Defendants' Infringing Lipid Particles, which meets (or the delivery of which meets) every limitation of at least claims 27 and 28 of the '229 Patent.

67. Defendants have known of the '657 Patent since at least as early as March 28, 2023, when the '657 Patent issued. Alnylam notified Defendants of the published '023 Application on June 23, 2022.

68. On information and belief, Defendants and/or their end users employ in their COVID-19 Vaccine Defendants' Infringing Lipid Particles, which meets every limitation of at least claims 15-19, 22, 23, 26, 28, and 29 of the '657 Patent.

69. The Prescribing Information for COMIRNATY® states that each dose contains the following lipid mixture: "0.43 mg ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg 2-(polyethylene glycol 2000)-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.19 mg cholesterol". (Exhibit 6 at 53, Exhibit 7 at 19.) Upon information and belief, the lipids are within the molar percentages of: 35-65 mol % of a protonatable lipid compound, 3-12 mol % distearoylphosphatidylcholine (DSPC), 15-45 mol % cholesterol, and 0.5-10 mol % of a PEG-modified lipid.

70. The Prescribing Information for COMIRNATY® states that each dose contains "30 mcg of a nucleoside-modified messenger RNA (mRNA)[7] encoding the viral spike (S) glycoprotein of SARS-CoV-2." (Exhibit 6 at 52-53, Exhibit 7 at 19, Exhibit 8 at 16 ). Upon information and belief, this document was prepared by Defendants and accepted by the FDA for distribution to providers of Defendants' COVID-19 Vaccine.

71. Attached as Exhibit 29 and incorporated herein is a claim chart describing Defendants' infringement of claims 15-19, 22, 23, 26, 28, and 29 of the '657 Patent. The claim chart is not intended to limit Alnylam's right to modify the chart or allege that other activities of Defendants infringe the identified claim or any other claims of the '657 Patent or any other patents.

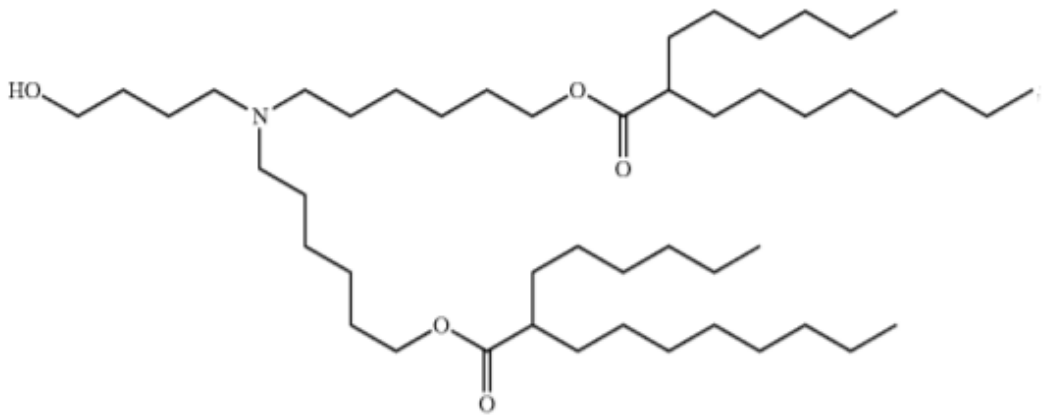
72. Upon information and belief, Defendants' Infringing Lipid Particles are in every dose of the COVID-19 Vaccine that Defendants have made, offered for sale, and sold, and will continue to do so.

73. On information and belief, Defendants and/or their end users employ in their COVID-19 Vaccine ALC-0315, the delivery of which meets every limitation of at least claims 11 and 12 of the '479 Patent.

74. The Prescribing Information for COMIRNATY® states that each dose contains ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate). (Exhibit 6 at 52-53.) Upon information and belief, this document was prepared by Defendants and accepted by the FDA for distribution to providers of Defendants' COVID-19 Vaccine. Upon information and belief, 4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) is known as ALC-0315.

[7] mRNA is a nucleic acid.

75. Upon information and belief, 4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) is known as ALC-0315. Upon information and belief, ALC-0315 has the chemical structure depicted just below:




(Exhibit 28 at 8.)

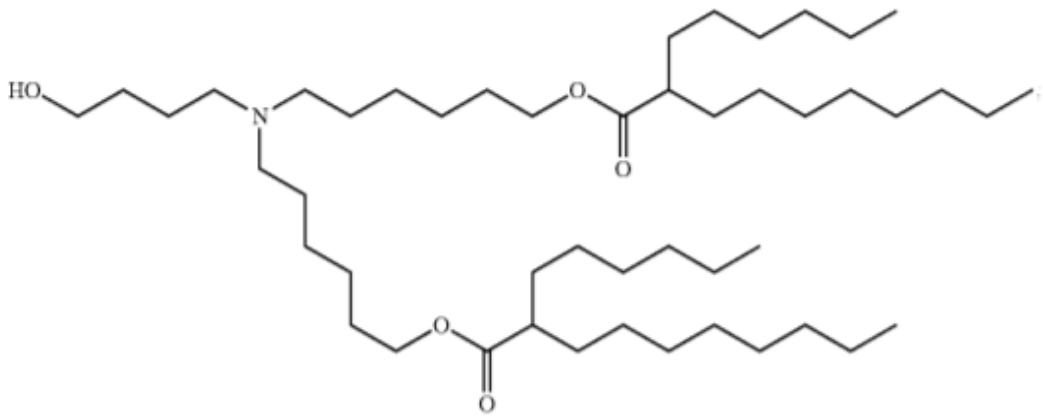
76. Upon information and belief, ALC-0315 is in every dose of the COVID-19 Vaccine that Defendants have made, offered for sale, and sold, and will continue to do so.

77. Attached as Exhibit 30 and incorporated herein is a claim chart describing Defendants' infringement of claims 11 and 12 of the '479 Patent. The claim chart is not intended to limit Alnylam's right to modify the chart or allege that other activities of Defendants infringe the identified claim or any other claims of the '479 Patent or any other patents.

78. Defendants have known of the '479 Patent since at least as early as April 25, 2023, when the '479 Patent issued.

79. On information and belief, Defendants and/or their end users employ in their COVID-19 Vaccine ALC-0315, which meets every limitation of at least claims 1-4 and 11 of the '480 Patent.

80. Upon information and belief, 4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) is known as ALC-0315. Upon information and belief, ALC-0315 has the chemical structure depicted just below:




(Exhibit 28 at 8.)

81. Upon information and belief, Defendants' ALC-0315 is in every dose of the COVID-19 Vaccine that Defendants have made, offered for sale, and sold, and will continue to do so.

82. Attached as Exhibit 31 and incorporated herein is a claim chart describing Defendants' infringement of claims 1-4, and 11 of the '480 Patent. The claim chart is not intended to limit Alnylam's right to modify the chart or allege that other activities of Defendants infringe the identified claim or any other claims of the '480 Patent or any other patents.

83. Defendants have known of the '480 Patent since at least as early as April 25, 2023, when the '480 Patent issued. Alnylam notified Defendants of the published '023 Application on June 23, 2022.

**FIRST CAUSE OF ACTION**
**(Infringement of the '229 Patent)**

84. Alnylam realleges and incorporates by reference the allegations contained in the foregoing paragraphs.

85. On information and belief, Defendants have infringed and will continue to infringe at least claims 27 and 28 of the '229 Patent, pursuant to 35 U.S.C. § 271(a), literally or under the doctrine of equivalents, by making, using, selling, or offering to sell within the United States or importing into the United States Defendants' COVID-19 Vaccine containing Defendants' Infringing Lipid Particles without authority.

86. Defendants without authority have infringed and will continue to infringe at least claims 27 and 28 of the '229 Patent pursuant to 35 U.S.C. § 271(b) by actively inducing the manufacturing, using, selling, or offering for sale within the United States or importing into the United States Defendants' COVID-19 Vaccine containing Defendants' Infringing Lipid Particles. Each Defendant intends that the other Defendant makes, uses, sells, offers to sell, distributes, exports, and/or imports Defendants' COVID-19 Vaccine and/or its components comprising the infringing Lipid Particles made with Defendants' Infringing Lipid Particles with the knowledge and specific intent that the other Defendant will directly infringe Alnylam's '229 Patent. Defendants further intend that each end user, distributor, importer and/or exporter make, use, sell, offer to sell, distribute, export, and/or import Defendants' COVID-19 Vaccine and/or its components comprising Defendants' Infringing Lipid Particles with the knowledge and specific intent that such end user, distributor, importer, and/or exporter end-users directly infringe Alnylam's '229 Patent.

87. Defendants' infringement has damaged and will continue to damage Alnylam, which is entitled to recover the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

**SECOND CAUSE OF ACTION**
**(Infringement of the '657 Patent)**

88. Alnylam realleges and incorporates by reference the allegations contained in the foregoing paragraphs.

89. On information and belief, Defendants have infringed and will continue to infringe at least claims 15-19, 22, 23, 26, 28, and 29 of the '657 Patent, pursuant to 35 U.S.C. § 271(a), literally or under the doctrine of equivalents, by making, using, selling, or offering to sell within the United States or importing into the United States Defendants' COVID-19 Vaccine containing Defendants' Infringing Lipid Particles without authority.

90. Defendants without authority have infringed and will continue to infringe at least claims 15-19, 22, 23, 26, 28, and 29 of the '657 Patent pursuant to 35 U.S.C. § 271(b) by actively inducing the manufacturing, using, selling, or offering for sale within the United States or importing into the United States Defendants' COVID-19 Vaccine containing Defendants' Infringing Lipid Particles. Each Defendant intends that the other Defendant makes, uses, sells, offers to sell, distributes, exports, and/or imports Defendants' COVID-19 Vaccine and/or its components comprising the infringing Lipid Particles made with Defendants' Infringing Lipid Particles with the knowledge and specific intent that the other Defendant will directly infringe Alnylam's '657 Patent. Defendants further intend that each end user, distributor, importer and/or exporter make, use, sell, offer to sell, distribute, export, and/or import Defendants' COVID-19 Vaccine and/or its components comprising Defendants' Infringing Lipid Particles with the

knowledge and specific intent that such end user, distributor, importer, and/or exporter end-users directly infringe Alnylam's '657 Patent.

91. Defendants' infringement has damaged and will continue to damage Alnylam, which is entitled to recover the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

**THIRD CAUSE OF ACTION**
**(Infringement of the '479 Patent)**

92. Alnylam realleges and incorporates by reference the allegations contained in the foregoing paragraphs.

93. On information and belief, Defendants have infringed and will continue to infringe at least claims 11 and 12 of the '479 Patent, pursuant to 35 U.S.C. § 271(a), literally or under the doctrine of equivalents, by making, using, selling, offering to sale or importing its COVID-19 Vaccine containing ALC-0315 within the United States and without authority.

94. Defendants, without authority, have infringed and will continue to infringe at least claims 11 and 12 of the '479 Patent pursuant to 35 U.S.C. § 271(b) by actively inducing the manufacturing, using, selling, or offering for sale within the United States or importing into the United States Defendants' COVID-19 Vaccine containing ALC-0315. Each Defendant intends that the others make, use, sell, offer to sell, distribute, export, and/or import Defendants' COVID-19 Vaccine and/or its components comprising the infringing ALC-0315 biodegradable lipid with the knowledge and specific intent that the others will directly infringe Alnylam's '479 Patent. Defendants further intend that each end user, distributor, importer and/or exporter make, use, sell, offer to sell, distribute, export, and/or import Defendants' COVID-19 Vaccine and/or its components comprising the infringing ALC-0315 biodegradable lipid with the knowledge and

specific intent that such end user, distributor, importer, and/or exporter end-users directly infringe Alnylam's '479 Patent.

95. Defendants' infringement has damaged and will continue to damage Alnylam, which is entitled to recover the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

**FOURTH CAUSE OF ACTION**
**(Infringement of the '480 Patent)**

96. Alnylam realleges and incorporates by reference the allegations contained in the foregoing paragraphs.

97. On information and belief, Defendants have infringed and will continue to infringe at least claims 1-4 and 11 of the '480 Patent, pursuant to 35 U.S.C. § 271(a), literally or under the doctrine of equivalents, by making, using, selling, or offering to sell within the United States or importing into the United States Defendants' COVID-19 Vaccine containing Defendants' Infringing Lipid Particles without authority.

98. On information and belief, Defendants have infringed and will continue to infringe at least claims 1-4 and 11 of the '480 Patent, pursuant to 35 U.S.C. § 271(a), literally or under the doctrine of equivalents, by making, using, selling, offering to sale or importing its COVID-19 Vaccine containing ALC-0315 within the United States and without authority. Defendants, without authority, have infringed and will continue to infringe at least one of the asserted claims of the '480 Patent pursuant to 35 U.S.C. § 271(b) by actively inducing the manufacturing, using, selling, or offering for sale within the United States or importing into the United States Defendants' COVID-19 Vaccine containing ALC-0315. Each Defendant intends that the others make, use, sell, offer to sell, distribute, export, and/or import Defendants' COVID-19 Vaccine and/or its components comprising the infringing ALC-0315 biodegradable lipid with the knowledge and

specific intent that the others will directly infringe Alnylam's '480 Patent. Defendants further intend that each end user, distributor, importer and/or exporter make, use, sell, offer to sell, distribute, export, and/or import Defendants' COVID-19 Vaccine and/or its components comprising the infringing ALC-0315 biodegradable lipid with the knowledge and specific intent that such end user, distributor, importer, and/or exporter end-users directly infringe Alnylam's '480 Patent.

99. Defendants' infringement has damaged and will continue to damage Alnylam, which is entitled to recover the damages resulting from Defendants' wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

## PRAYER FOR RELIEF

WHEREFORE, Alnylam prays for a judgment in its favor and against Defendants and respectfully requests the following relief:

A. A judgement that Defendants directly infringe the '229 Patent;

B. A judgment that Defendants induce infringement of the '229 Patent;

C. A judgement that Defendants directly infringe the '657 Patent;

D. A judgment that Defendants induce infringement of the '657 Patent;

E. A judgment that Defendants directly infringe the '479 Patent;

F. A judgment that Defendants induce infringement of the '479 Patent;

G. A judgment that Defendants directly infringe the '480 Patent;

H. A judgment that Defendants induce infringement of the '480 Patent;

I. Damages or other monetary relief, including post-judgment monetary relief and pre- and post-judgment interest;

J. Costs and expenses in this action; and

K. An order awarding Alnylam any such other relief as the Court may deem just and proper under the circumstances, except that Alnylam does not seek any form of injunctive relief.

**JURY DEMAND**

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Alnylam hereby demands a jury trial as to all issues so triable.

McDERMOTT WILL & EMERY LLP

*/s/ Ethan H. Townsend*

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Dated: May 26, 2023