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.)

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 particles 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.

[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.

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 (*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 lipid particles and vaccines containing 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 1 of the '229 Patent is representative and recites:

A pharmaceutical composition comprising a lipid particle and a pharmaceutically acceptable diluent, excipient, or carrier, wherein the lipid particle comprises:

(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 1-(monomethoxy-polyethylene glycol)-2,3-dimyristoyl glycerol (PEG-DMG),

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 independently consists of a first hydrophobic chain, an ester group, and a second hydrophobic chain, wherein the first and second hydrophobic chains are aliphatic and linked by the ester group, and the first hydrophobic chain is bonded directly to the central moiety, wherein each ester group is -C(O)O-:

each hydrophobic tail has a total carbon atom content from 17 to 26 carbon atoms; and

one of the hydrophobic tails has (a) the formula $-R^{12}-M^{1}-R^{13}$, wherein R^{12} is a C_4-C_{14} alkyl group, M^{1} is -C(O)O-, and R^{13} is a C_{10}-C_{20} branched alkyl group, (b) a chain length for formula $-R^{12}-M^{1}-R^{13}$ of 18 to 20 atoms, and (c) a total carbon atom content of 21 to 26 carbon atoms.

(Exhibit 1 at Claim 1.)

26. Independent claim 11 of the ’229 Patent is representative of the method of delivery claims and recites:

A method for delivering a nucleic acid, comprising administering to a subject a pharmaceutical composition comprising a lipid particle and a pharmaceutically acceptable diluent, excipient, or carrier, wherein the lipid particle comprises:

(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 1-(monomethoxy-polyethylene glycol)-2,3-dimyristoyl glycerol (PEG-DMG),

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 independently consists of a first hydrophobic chain, an ester group, and a second hydrophobic chain, wherein the first and second hydrophobic chains are aliphatic and linked by the ester group, and the first hydrophobic chain is bonded directly to the central moiety, wherein each ester group is -C(O)O-;

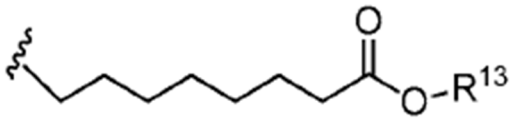
each hydrophobic tail has a total carbon atom content from 17 to 26 carbon atoms; and

one of the hydrophobic tails has (a) the formula $-R^{12}-M^{1}-R^{13}$, wherein R^{12} is a C_4-C_{14} alkyl group, M^{1} is -C(O)O-, and R^{13} is a C_{10}-C_{20} branched alkyl group, (b) a chain length for formula $-R^{12}-M^{1}-R^{13}$ of 18 to 20 atoms, and (c) a total carbon atom content of 21 to 26 carbon atoms.

(Exhibit 1 at Claim 11.)

27. Independent claim 21 of the ’229 Patent is representative of the vaccine claims 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 1-(monomethoxy-polyethylene glycol)-2,3-dimyristoyl glycerol (PEG-DMG),
>
> 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 independently consists of a first hydrophobic chain, an ester group, and a second hydrophobic chain, wherein the first and second hydrophobic chains are aliphatic and linked by the ester group, and the first hydrophobic chain is bonded directly to the central moiety, wherein each ester group is -C(O)O-:
>
> each hydrophobic tail has a total carbon atom content from 17 to 26 carbon atoms; and
>
> one of the hydrophobic tails has the formula



, wherein:

R^{13} is a C_{13}-C_{17} branched alkyl; and

the chain length of the hydrophobic tail is from 18 to 20 atoms.

(Exhibit 1 at Claim 21.)

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

29. 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 Patent issued to Alnylam as assignee of the inventors.

30. The ’479 Patent claims a lipid compound and a method of delivering a nucleic acid comprising administering lipid particles that can deliver lipid compounds along with an active agent, including mRNA. Each lipid compound contains one or more protonatable group.

31. Independent claim 1 of the ’479 Patent recites:

A lipid compound, comprising a head group, two 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 of the two hydrophobic tails independently consists of an aliphatic group interrupted by an ester group; and

at least one of the 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 an ester group, 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;

the total carbon atom content of the at least one hydrophobic tail is 21 to 26 carbon atoms; and

wherein the lipid compound contains a protonatable group such that the lipid compound is positively charged at a pH at or below pH 7.4.

(Exhibit 2 at Claim 1)

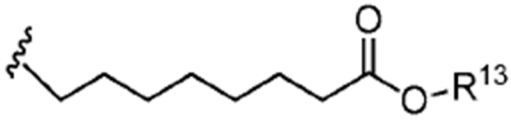
32. Dependent claim 5 of the ’479 Patent recites:

The lipid compound of claim 1, wherein the ester group in each hydrophobic tail is -C(O)O-.

(Exhibit 2 at Claim 5)

33. Dependent claim 6 of the ’479 Patent is representative and recites:

The lipid compound of claim 5, wherein the at least one hydrophobic tail has the formula:



where R^{13} is branched at the α-position relative to the -C(O)O- group, and
where R^{13} is a C_{13}-C_{17} alkyl and the maximum length of R^{13} is 11 carbon atoms.

(Exhibit 2 at Claim 6)

34. Independent claim 13 of the ’479 Patent recites:

A method for delivering a nucleic acid comprising administering to a subject a lipid particle comprising a nucleic acid, a lipid compound, a neutral lipid, a PEG-lipid, and a sterol, wherein:

the lipid compound comprises a head group, two 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 of the two hydrophobic tails independently consists of an aliphatic group interrupted by an ester group; and

at least one of the 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 an ester group, 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 the at least one hydrophobic tail is 21 to 26 carbon atoms; and

wherein the lipid compound contains a protonatable group such that the lipid compound is positively charged at a pH at or below pH 7.4.

(Exhibit 2 at Claim 13).

35. Dependent claim 14, which depends from claim 13, of the ’479 Patent recites:

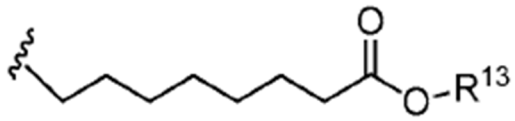
The method of claim 13, wherein the nucleic acid comprises RNA.

36. Dependent claim 15, which depends from claim 14 ,of the ’479 Patent recites:

The method of claim 14, wherein the ester group in each hydrophobic tail is -C(O)O-.

37. Dependent claim 16, which depends from claim 15, of the ’479 Patent is representative and recites:

The method of claim 15, wherein the at least one hydrophobic tail has the formula:



where R^{13} is branched at the α-position relative to the -C(O)O- group, and

where R^{13} is a C_{13}-C_{17} alkyl and the maximum length of R^{13} is 11 carbon atoms.

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

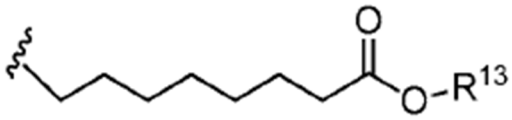
39. On April 25, 2023, The United States Patent & Trademark Office issued the ’480 Patent, entitled “Biodegradable Lipids for the Delivery of Active Agents.” The ’480 Patent issued to Alnylam as assignee of the inventors.

40. 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.

41. Independent claim 5 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 PEG-modified lipid is 1-(monomethoxy-polyethylene glycol)-2,3-dimyristoyl glycerol (PEG-DMG),
>
> 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 two 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 independently consists of a first hydrophobic chain, an ester group, and a second hydrophobic chain, wherein the first and second hydrophobic chains are aliphatic and linked by the ester group, and the first hydrophobic chain is bonded directly to the central moiety, wherein each ester group is -C(O)O-;
>
> wherein each hydrophobic tail has a total carbon atom content from 17 to 26 carbon atoms; and
>
> wherein one hydrophobic tail has the formula:



, wherein

R^{13} is a C_{13}-C_{17} branched alkyl; and

the chain length of the one hydrophobic tail is from 18 to 20 atoms.

(Exhibit 3 at Claim 5.)

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

D. ALNYLAM PRESENTED CONFIDENTIAL INFORMATION REGARDING ITS PATENTED LIPID PARTICLE TECHNOLOGY TO MODERNA IN 2014

43. In late-2013 or 2014, Alnylam and Moderna began discussions about a potential license to some of Alnylam's intellectual property along with a potential business relationship or a collaboration. Among the Alnylam intellectual property under consideration for license were the pending Alnylam Lipid Particle Technology patent applications and all patents that would issue from such applications. On February 7, 2014, Moderna and Alnylam entered into a Mutual Confidentiality Agreement (the "Agreement"), allowing Alnylam and Moderna to share confidential information "for the purpose of enabling the other party to evaluate the feasibility or desirability of such business or research relationship." (Exhibit 9, § 1.) The Agreement stated that recipients of confidential information "shall not use or exploit such Confidential Information for its own benefit or the benefit of another without the prior written consent of the Disclosing Party." (*Id.* § 3.)

44. Pursuant to this Agreement, on or about April 28, 2014, Alnylam met with Moderna to disclose and discuss the Alnylam Lipid Particle Technology. Attendees from Moderna included Stephen Hoge (then Senior VP of Corporate Development), Said Francis (then Director of

Business Development), Matt Stanton (then VP of Chemistry), and Örn Almarsson (then Senior VP of Formulation and Delivery Technology).

45. In the April 28, 2014 meeting, Alnylam presented a detailed PowerPoint disclosing Alnylam Lipid Particle Technology and how those lipid particles could be used for developing RNA-based pharmaceuticals. Alnylam further disclosed valuable rodent and non-human primate pharmacology experiments that showed superior *in vivo* elimination of its biodegradable lipid particles, while also showing superior potency.

46. The discussions between Moderna and Alnylam continued through at least September 30, 2014. The discussions ended without Moderna agreeing to take a license to Alnylam's patents, patent applications, or trade secrets embodied in the Confidential Information on the Alnylam Lipid Particle Technology.

47. Upon information and belief, as of 2014, Moderna did not possess a protonatable lipid with biodegradable groups sufficient to form a lipid particle with desirable properties to deliver RNA materials for use in therapeutics and vaccines. Upon information and belief, Moderna did not make the infringing SM-102 – a protonatable lipid with biodegradable groups that uses the Alnylam Lipid Particle Technology – until sometime in 2015 for use in non-COVID vaccines Moderna was developing. (*See* Exhibit 10 at 8.)

E. MODERNA'S COVID-19 VACCINE

48. Upon information and belief, in either December 2019 or January 2020, Moderna began work on developing and formulating a vaccine for the prevention of the novel coronavirus (SARS-CoV-2). Despite lacking a license to the Alnylam Lipid Particle Technology, as part of that development and formulation, Moderna developed its COVID-19 Vaccine using Moderna's Infringing Lipid Particles.

49. Upon information and belief, Moderna, working in conjunction with researchers from the NIH, finalized the mRNA sequence on January 13, 2020, for use as a potential vaccine against SARS-CoV-2. (*See* Exhibit 11 at 3.)

50. Upon information and belief, the first clinical batch of Modena's vaccine candidate incorporating Moderna's Infringing Lipid Particles was completed on February 7, 2020. The first patient in Moderna's Phase 1 clinical study received a dose on March 16, 2020. (*See* Exhibit 12 at 1.)

51. Upon information and belief, Moderna filed its IND for its COVID-19 vaccine candidate incorporating Moderna's Infringing Lipid Particles on April 27, 2020. (*See* Exhibit 12 at 1.) On May 12, 2020, the FDA granted Fast Track status to Moderna's vaccine candidate. (*See* Exhibit 13 at 1.)

52. On November 30, 2020, Moderna announced the results of its Phase 3 trial of its vaccine candidate incorporating Moderna's Infringing Lipid Particles. (*See* Exhibit 14 at 1.) It announced on the same day that it would submit its Emergency Use Authorization to the FDA. (*See id.*)

53. On December 18, 2020, the FDA granted an Emergency Use Authorization (EUA) to Moderna's COVID-19 Vaccine incorporating Moderna's Infringing Lipid Particles, under the tradename "Moderna COVID-19 Vaccine," allowing commercial sales of its Covid-19 vaccine to commence. (*See* Exhibit 15 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. According to the EUA approximately 30,000 individuals had received at least one dose of Moderna COVID-19 Vaccine during clinical trials and millions of doses have been distributed since the EUA.

54. On January 31, 2022, Moderna announced that it received FDA approval for its COVID-19 Vaccine, under the tradename SPIKEVAX®. (*See* Exhibit 15 at 2).

55. On February 25, 2022, Moderna stated that it recognized $17.7 billion dollars in revenue in 2021 from sales of 807 million doses of its COVID-19 Vaccine. (Exhibit 4 at 100.) Moderna stated that it recognized $18,435,000,000 in revenue in 2022 globally from sales of its COVID-19 Vaccine, and $4,405,000,000 in revenue from U.S. COVID-19 Vaccine sales. (Exhibit 5 at 128). Moderna reported that it expected at least $5.0 billion in revenue from COVID-19s delivered in 2023.

56. Upon information and belief, on June 17, 2022, the FDA approved Moderna's COVID-19 Vaccine under the tradename SPIKEVAX® for ages 12 years and older (Primary Series – "Light Blue Border"), for ages 6 to 11 years (Primary Series – "Teal Border" and Primary Series "Booster Doses Only" – "Purple Border"), and for ages 6 months to 5 years (Primary Series – "Magenta Border"). (Exhibit 15 at n.13.) Upon information and belief, on August 31, 2022, the FDA approved Moderna's COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) ("Bivalent") for individuals 18 and older (Bivalent – "Gray Border"). (Exhibit 15 at n.14) Upon information and belief, on October 12, 2022, the FDA approved Moderna's COVID-19 Vaccine, Bivalent for individuals 12 through 17 years of age and 6 through 11 years of age. (Exhibit 15 at n. 14.) Upon information and belief, on December 8, 2022, the FDA revised and reissued the October 12, 2022 letter of authorization to authorize the use of Moderna's COVID-19 Vaccine, Bivalent for individuals 6 months through 5 years of age (Bivalent – "Yellow Border"). (New Exhibit 15 at 1, n. 18;

57. Upon information and belief, on April 18, 2023 the FDA amended the EUA, rescinding its authorization for use of monovalent SPIKEVAX® in the United States (Exhibit 16,

FDA announcement). The amendment authorized the use of Moderna's COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) ("Bivalent") ("Gray Border") for all doses administered to all individuals 6 months of age or older (Exhibit 15 at 1). Moderna's COVID-19 Vaccine, Bivalent contains the infringing lipid particles made with Defendants' Infringing lipid particles. (Exhibit 15 at 20).

58. Upon information and belief, Moderna has manufactured doses of its COVID-19 Vaccine in the United States and has shipped those doses to other countries. (Exhibit 17 at 2.) The U.S. government confirmed that Moderna has exported U.S. made doses. (*Id*.) Upon information and belief, Moderna shipped U.S. made doses of its COVID-19 Vaccine to Canada. (Exhibit 18.) Upon information and belief, Moderna has an agreement with the Canadian government to provide Moderna's COVID-19 Vaccine through at least 2024, including "[u]p to 35 million for 2022 table, up to 35 million in 2023, and up to 35 million in 2024." (Exhibit 19 at 3.) On April 23, 2023, the FDA updated the "Conditions Related to Export" for Moderna's COVID-19 Vaccine, regarding what doses Defendants are "permitted" to "export" from the United States. (Exhibit 19 at 17).

59. Upon information and belief, Moderna plans to sell doses of its COVID-19 Vaccine on the private market in the United States, should Congress not allocate sufficient funds for the purchase of additional doses. (Exhibit 20.) Specifically, on May 4, 2022, Moderna's CEO said "I think it will come through. I just need to be ready for the alternative which is we have to go to a typical, what every pharmaceutical product does, private market." Additionally, he stated that Moderna would charge approximately $60 on the private market, rather than the $16.50 Moderna receives from the U.S. government, which he said "might actually provide some upside not only on sales, because there's zero sales assumed in the $21 billion, but (also) on pricing. CMS [Centers

for Medicare & Medicaid Services] has basically come up saying for fiscal year 2023, which starts in October, the price for COVID-19 vaccines should be around $60." (Exhibit 20 at 2.) Despite these projections, upon information and belief, Moderna plans to sell doses of its COVID-19 Vaccine on the private market in the United States for between $110 - $130 per dose. (Exhibit 21.)

60. In addition to its COVID-19 Vaccine, Moderna has stated that mRNA-1345 "uses the same lipid nanoparticles (LNPs) as in the Moderna COVID-19 vaccines." (Exhibit 22 at 3) On information and belief, Moderna plans to file a BLA on mRNA-1345 in the first half of 2023. (*Id.* at 1.)

F. ALNYLAM'S PATENTED LIPID PARTICLE TECHNOLOGY IS ESSENTIAL TO MODERNA'S COVID-19 VACCINE

61. The patented Alnylam Lipid Particle Technology is essential to Moderna's COVID-19 Vaccine's efficacy and safety. The Vaccine's mRNA is very delicate and subject to rapid degradation by various enzymes upon administration. (*See* Exhibit 8 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 need 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.

62. Moderna turned to the Moderna's Infringing Lipid Particles to meet these requirements for its COVID-19 Vaccine. Moderna publicly recognized the central role biodegradable lipids in the lipid particles play in the efficacy and safety of Moderna's COVID-19 vaccine. For example, Giuseppe Ciaramella, who was head of infectious diseases at Moderna from 2014 to 2018, has said that lipid particle technology "is the unsung hero of the whole thing." (*See* Exhibit 8 at 2.) Ciaramella credits the use of ester linkages to make the lipids more biodegradable

to the success of Moderna's lipid particles. (*Id.* at 6.) Those biodegradable properties and ester linkages employ the patented Alnylam Lipid Particle Technology.

63. On July 21, 2020, Dr. Stephen Hoge, the President of Moderna, Inc., testified before the House Energy and Commerce Committee, Subcommittee on Oversight and Investigations about Moderna's COVID-19 Vaccine. In his testimony, he touted that "Moderna has developed a proprietary lipid-nanoparticle-delivery system that enhances safety and tolerability." (*See* Exhibit 23 at 4.) Moderna's "proprietary lipid-nanoparticle-delivery system" relies on the patented Alnylam Lipid Particle Technology.

64. On February 24, 2021, Stéphan Bancel, Moderna, Inc.'s CEO, publicly stated that its lipid system "is biodegradable, so it's a big competitive advantage for us." (*See* Exhibit 24 at 5.) The biodegradability of Moderna's lipid system employs the patented Alnylam Lipid Particle Technology.

MODERNA'S INFRINGING ACTIVITIES

65. On information and belief, Moderna and/or its end users employ in their COVID-19 Vaccine Moderna's Infringing Lipid Particles, which meets (or the delivery of which meets) every limitation of at least claims 1-7, 10-18 and 21-25 of the '229 Patent.

66. Attached as Exhibit 26 and incorporated herein by reference is a claim chart describing Moderna's infringement of claims 1-7, 10-18 and 21-25 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 Moderna infringe the identified claim or any other claims of the '229 Patent or any other patents.

67. Upon information and belief, Moderna's Infringing Lipid Particles are in every dose of the COVID-19 Vaccine that it made, offered for sale, or sold, and will continue to do so.

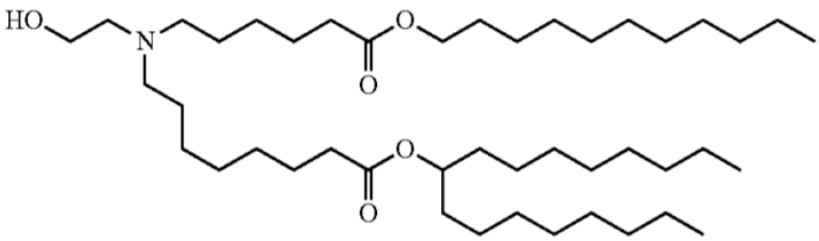
68. Moderna has known of the ’229 Patent since at least as early as February 28, 2023, when the ’229 Patent issued. Alnylam notified Defendants of the published ’029 Application on June 23, 2022. Alnylam informed Moderna of the Notice of Allowability and payment of issue fee for the ’029 Application on January 23, 2023. Alnylam provided Moderna with the claims as allowed on the same date. The claims are publicly available and have been known to Moderna since at least December 1, 2022. Alnylam notified Moderna 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.

69. On information and belief, Moderna and/or its end users employ in its COVID-19 vaccine SM-102, which meets every limitation of at least claims 6-9 and 16-20 of the ’479 Patent, in its COVID-19 Vaccine.

70. The prescribing information, dated April, 2023, states that Moderna’s Covid-19 Vaccine contains a total lipid content of 0.20 mg per 0.2mL dose and 1.01 mg per 0.5mL dose, consisting of SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]). (Exhibit 7 at 48.)

71. Upon information and belief, the lipids are in molar lipid ratio of 50:10:38.5:1.5 for the protonatable lipid : neutral lipid : cholesterol : PEGylated lipid. (Exhibit 25 at 3.) 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.

72. Upon information and belief, and as described in publications, SM-102 is 9-heptadecanyl 8-{(2-hydroxyethyl)[6-oxo-6-(undecyloxy)hexyl]amino}octanoate and has the chemical structure:



(*See* Exhibit 25 at 3, 8.)

73. Upon information and belief, SM-102 is in every dose of the COVID-19 Vaccine that Moderna has made, offered for sale, and sold, and will continue to do so.

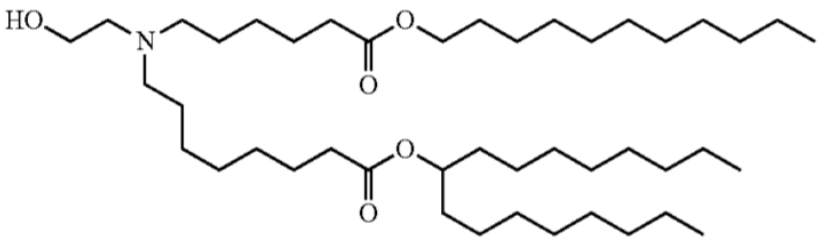
74. Attached as Exhibit 27 and incorporated herein is infringement claim chart describing Moderna's infringement of claims 6-9 and 16-20 of the '479 Patent. The claim chart is not intended to limit Alnylam's right to modify the chart or allege that other activities of Moderna infringe the identified claim or any other claims of the '479 Patent or any other patents.

75. Moderna has known of the '479 Patent since at least as early as April 25, 2023, when the '479 Patent issued.

76. On information and belief, Moderna and/or its end users employ in their COVID-19 Vaccine SM-102, which meets every limitation of at least claims 5-10 of the '480 Patent.

77. The prescribing information, dated April 2023, states that Moderna's Covid-19 Vaccine contains a total lipid content of 0.20 mg per 0.2 mL dose and 1.01 mg per 0.5 mL dose, consisting of SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]). (Exhibit 7 at 48.)

78. Upon information and belief, and as described in publications, SM-102 is 9-heptadecanyl 8-{(2-hydroxyethyl)[6-oxo-6-(undecyloxy)hexyl]amino}octanoate and has the chemical structure:



(*See* Exhibit 25 at 3, 8.)

79. Upon information and belief, SM-102 is in every dose of the COVID-19 Vaccine that Moderna has made, offered for sale, and sold, and will continue to do so.

80. Attached as Exhibit 28 and incorporated herein are Alnylam's Asserted Claims and Infringement Contentions describing Moderna's infringement of claims 5-10 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 Moderna infringe the identified claim or any other claims of the '480 Patent or any other patents.

81. Moderna has known of the '480 Patent since at least as early as April 25, 2023, when the '480 Patent issued. Alnylam notified Moderna of the published '023 Application on __which set forth the same claims as in the subsequently-issued '480 Patent.

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

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

83. On information and belief, Moderna has infringed and will continue to infringe at least claims 1-7, 10-18, and 21-25 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 Moderna's COVID-19 Vaccine containing Moderna's Infringing Lipid Particles without authority.

84. Moderna, without authority, has infringed and will continue to infringe at least claims 1-7, 10-18, and 21-25 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 Moderna’s COVID-19 Vaccine containing Moderna’s Infringing Lipid Particles. Moderna intends that each end user, distributor, importer and/or exporter make, use, sell, offer to sell, distribute, export, and/or import Moderna’s COVID-19 Vaccine and/or its components comprising Moderna’s 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.

85. Moderna’s infringement has damaged and will continue to damage Alnylam, which is entitled to recover the damages resulting from Moderna’s 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 ’479 Patent)

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

87. On information and belief, Moderna has infringed and will continue to infringe at least claims 6-9 and 16-20 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 SM-102 within the United States and without authority.

88. Defendants Moderna, Inc., ModernaTX, Inc., and Moderna US, Inc. without authority have infringed and will continue to infringe at least claims 6-9 and 16-20 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 Moderna’s COVID-19 Vaccine containing SM-102. Each of Defendant Moderna, Inc., ModernaTX, Inc., and Moderna

US, Inc. intends that the others make, use, sell, offer to sell, distribute, export, and/or import Moderna's COVID-19 Vaccine and/or its components comprising the infringing SM-102 biodegradable lipid with the knowledge and specific intent that the others will directly infringe Alnylam's '479 Patent. Defendants Moderna, Inc., ModernaTX, Inc., and Moderna US, Inc. further intend that each end user, distributor, importer and/or exporter make, use, sell, offer to sell, distribute, export, and/or import Moderna's COVID-19 Vaccine and/or its components comprising the infringing SM-102 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.

89. Moderna's infringement has damages and will continue to damage Alnylam, which is entitled to recover the damages resulting from Moderna's 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 '480 Patent)

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

91. On information and belief, Moderna has infringed and will continue to infringe at least claim 5-10 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 sell or importing its COVID-19 Vaccine containing the Moderna's Infringing Lipid Particles within the United States and without authority.

92. Defendants Moderna, Inc., ModernaTX, Inc., and Moderna US, Inc. without authority have infringed and will continue to infringe at least claims 5-10 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 Moderna's COVID-19 Vaccine containing the Moderna's Infringing Lipid Particles. Each of Defendant Moderna, Inc.,

ModernaTX, Inc., and Moderna US, Inc. intends that the others make, use, sell, offer to sell, distribute, export, and/or import Moderna's COVID-19 Vaccine and/or its components comprising the infringing the Moderna's Infringing Lipid Particles with the knowledge and specific intent that the others will directly infringe Alnylam's '480 Patent. Defendants Moderna, Inc., ModernaTX, Inc., and Moderna US, Inc. further intend that each end user, distributor, importer and/or exporter make, use, sell, offer to sell, distribute, export, and/or import Moderna's COVID-19 Vaccine and/or its components comprising the Moderna's Infringing Lipid Particles with the knowledge and specific intent that such end user, distributor, importer, and/or exporter end-users directly infringe Alnylam's '480 Patent.

93. Moderna's infringement has damaged and will continue to damage Alnylam, which is entitled to recover the damages resulting from Moderna's 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 Moderna and respectfully request the following relief:

A. A judgment that Moderna induces infringement of the '229 Patent;

B. A judgment that Moderna directly infringes the '229 Patent;

C. A judgment that Moderna directly infringes the '479 Patent;

D. A judgment that Moderna induces infringement of the '479 Patent;

E. A judgment that Moderna directly infringes the '480 Patent;

F. A judgment that Moderna induces infringement of the '480 Patent;

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

H. Costs and expenses in this action; and

I. 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.

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Dated: May 26, 2023