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.	)	C.A. No. _____ **JURY TRIAL DEMANDED**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Alnylam Pharmaceuticals, Inc. ("Alnylam"), by its attorneys, alleges as follows for its Complaint for Patent Infringement against 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 cationic biodegradable lipids used to form lipid nanoparticles ("LNP") that carry and safely deliver in the body RNA-based therapeutics or vaccines (the "Alnylam LNP Technology"). The Alnylam LNP Technology is foundational to the success of the recently-developed messenger RNA ("mRNA") based COVID vaccines. The United States Patent Office repeatedly recognized Alnylam's inventive work, including by issuing United States Patent No. 11,382,979 (the "'979 Patent"), which is one of several patents that protects the Alnylam LNP Technology.[1] The '979 Patent issued from U.S. Application No. 17/644,907 (the "'907 Application). (Exhibit 1.)

[1] The United States Patent Office also issued United States Patent No. 11,246,933 (the "'933 Patent") to Alnylam. (Exhibit 26.) The '933 Patent protects other aspects of Alnylam LNP Technology.

2. Moderna infringes Alnylam's '979 Patent through the use of Alnylam's patented LNPs that protect and deliver the vaccine's mRNA. The "Moderna Infringing LNPs" 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 LNP Technology since at least early 2014, when Alnylam and Moderna entered into a business discussion regarding a license to Alnylam technology including the Alnylam LNP Technology. Alnylam brings this action to recover monetary compensation for Moderna's unlicensed use of Alnylam's '979 Patent. Alnylam does not seek injunctive relief under 35 U.S.C. § 283 against such use.

THE PARTIES

4. Plaintiff Alnylam is a corporation organized under the laws of the State of Delaware with a principal place of business at 675 West Kendall Street, Henri A. Termeer Square, Cambridge, Massachusetts 02142. Founded in 2002, Alnylam is a groundbreaking life science company that has worked to harness the potential of RNA interference ("RNAi") therapeutics to transform the lives of people living with diseases that have limited or inadequate treatment options. Utilizing an earlier version of in licensed LNP Technology, in 2018 Alnylam delivered the world's first approved RNAi therapeutic, ONPATTRO® (patisiran). ONPATTRO® is currently approved for the treatment of polyneuropathy caused by an illness called hereditary ATTR (hATTR) amyloidosis. Alnylam has developed an additional delivery modality distinct from the LNP Technology, termed GalNAc Delivery, which is utilized in three marketed products, GIVLAARI® (givosiran), approved in 2019, and OXLUMO® (lumasiran), approved in 2020, both marketed by Alnylam and LEQVIO®(inclisiran), approved in 2021, developed initially by Alnylam and licensed to Novartis.

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

6. Upon information and belief, Defendant 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 3 at 98-100.)

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 4 at 3). Defendant ModernaTX, Inc. is listed as the entity to contact in the prescribing information for SPIKEVAX®. (Exhibit 5 at 1.) According to the prescribing information, SPIKEVAX® is a trademark of Defendant ModernaTX, Inc. (*Id.* at 17).

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 5 at 17.)

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

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 containing LNPs made with Moderna's Infringing Lipids.

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, made using the Moderna Infringing LNPs, 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 LNPs made with Moderna's Infringing Lipids, 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 LNPs made with Moderna's Infringing Lipids, 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 15 at 1-2.)

18. One approach was to develop a lipid[3] system for use with RNA-based therapeutics. These lipids would form a nanoparticle, called a Lipid Nanoparticle or LNP. The LNPs 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 LNP had to be positively charged (cationic) to create the protective bubble around the RNA. Cationic lipids do not exist in nature, and therefore had to be synthesized. There were toxicity issues with early attempts to use them in therapeutics due to the high dose of LNP needed to be effective.

[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.

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

20. Alnylam overcame some of the issues associated with earlier versions of LNPs using an in-licensed LNP system containing the cationic lipid compound known as MC3, a highly potent molecule. With MC3, Alnylam developed ONPATTRO®. MC3, while safe and effective, is more stable in the body and thus has a relatively long half-life. Alnylam recognized the need for further improvements in LNP technology and internally embarked on a research program to develop a new class of lipids with improved properties.

B. ALNYLAM'S BREAKTHROUGH BIODEGRADABLE LNP 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 LNPs comprising a cationic lipid with biodegradable groups (*i.e.*, the Alnylam LNP Technology). LNPs 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 LNPs has been employed in potential RNA therapeutics in development and now mRNA-based vaccines.

C. THE PATENT-IN-SUIT

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

23. On July 12, 2022, The United States Patent & Trademark Office issued the '979 Patent, entitled "Biodegradable Lipids for the Delivery of Active Agents." The '979 Patent issued to Alnylam as assignee of the named inventors Martin Maier, Muthusamy Jayaraman, Akin Akinc, Shigeo Matsuda, Pachamuthu Kandasamy, Kallanthottathil G. Rajeev, and Muthiah Manoharan.

24. The '979 Patent claims a class of cationic biodegradable lipids that can be used in the formation of LNPs for the delivery of an active agent, including mRNA. Each cationic lipid contains one or more biodegradable group.

25. Independent claim 1 of the '979 Patent is representative of the LNP composition claims and recites:

> A lipid particle comprising:
>
> (i) a nucleic acid,
>
> (ii) 35-65 mol% of a cationic lipid,
>
> (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; and
>
> the cationic lipid 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
>
> (a) the central moiety is a central carbon or nitrogen atom;
>
> (b) each hydrophobic tail independently has the formula -(hydrophobic chain)-(ester group)-(hydrophobic chain), wherein the ester group is -OC(O)- or -C(O)O-; and
>
> (c) for at least one hydrophobic tail,
>
> (I) the terminal hydrophobic chain in the hydrophobic tail is a branched alkyl, where the branching occurs at the α-position relative to the ester group;

(II) the hydrophobic tail has the formula -R^{12}-M^1-R^{13}, wherein R^{12} is a C_4-C_{14} alkylene or C_4-C_{14} alkenylene, M^1 is the ester group, and R^{13} is a branched C_{10}-C_{20} alkyl;

(III) the total carbon atom content of the tail -R^{12}-M^1-R^{13} is 21 to 26; and

(IV) the ester group is separated from a terminus of the hydrophobic tail by from 6 to 12 carbon atoms.

(Exhibit 1 at 493:41-494:42.)

26. Independent claim 18 of the ’979 Patent is representative of the method of manufacture claims and recites:

A method for preparing a lipid particle mixture comprising mixing a first solution comprising an organic solvent, a cationic lipid, distearoylphosphatidylcholine (DSPC), cholesterol, and a PEG-modified lipid, with a second solution comprising a nucleic acid and water to form a mixture containing lipid particles, wherein each lipid particle comprises

(i) the nucleic acid,

(ii) 35-65 mol% of the cationic lipid,

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

(iv) 15-45 mol% cholesterol, and

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

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

the cationic lipid 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

(a) the central moiety is a central carbon or nitrogen atom;

(b) each hydrophobic tail independently has the formula -(hydrophobic chain)-(ester group)-(hydrophobic chain), wherein the ester group is -OC(O)- or -C(O)O-; and

(c) for at least one hydrophobic tail,

(I) the terminal hydrophobic chain in the hydrophobic tail is a branched alkyl, where the branching occurs at the α-position relative to the ester group;

(II) the hydrophobic tail has the formula $-R^{12}-M^1-R^{13}$, wherein R^{12} is a C_4-C_{14} alkylene or C_4-C_{14} alkenylene, M^1 is the ester group, R^{13} is a branched C_{10}-C_{20} alkyl;

(III) the total carbon atom content of the tail $-R^{12}-M^1-R^{13}$ is 21 to 26; and

(IV) the ester group is separated from a terminus of the hydrophobic tail by from 6 to 12 carbon atoms.

(Exhibit 1 at 495:42-496:19.)

27. The '979 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 LNP TECHNOLOGY TO MODERNA IN 2014

28. 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 LNP 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 6, § 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.)

29. Pursuant to this Agreement, on or about April 28, 2014, Alnylam met with Moderna to disclose and discuss the Alnylam LNP 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).

30. In the April 28, 2014 meeting, Alnylam presented a detailed PowerPoint disclosing Alnylam's LNP Technology and how those LNPs 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 LNPs, while also showing superior potency.

31. 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 LNP Technology.

32. Upon information and belief, as of 2014, Moderna did not possess a cationic lipid with biodegradable groups sufficient to form a LNP 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 cationic lipid with biodegradable groups that uses the Alnylam LNP Technology – until sometime in 2015 for use in non-COVID vaccines Moderna was developing. (*See* Exhibit 7 at 8.)

E. MODERNA'S COVID-19 VACCINE

33. 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 LNP Technology, as part of that development and formulation, Moderna developed its COVID-19 Vaccine using Moderna Infringing LNPs.

34. 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 9 at 3.)

35. Upon information and belief, the first clinical batch of Modena's vaccine candidate incorporating Moderna Infringing LNPs 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 10 at 1.)

36. Upon information and belief, Moderna filed its IND for its COVID-19 vaccine candidate incorporating Moderna Infringing LNPs on April 27, 2020. (*See* Exhibit 10 at 1.) On May 12, 2020, the FDA granted Fast Track status to Moderna's vaccine candidate. (*See* Exhibit 11 at 1.)

37. On November 30, 2020, Moderna announced the results of its Phase 3 trial of its vaccine candidate incorporating Moderna Infringing LNPs. (*See* Exhibit 12 at 1.) It announced on the same day that it would submit its Emergency Use Authorization to the FDA. (*See id.*)

38. On December 18, 2020, the FDA granted an Emergency Use Authorization to Moderna's COVID-19 Vaccine incorporating Moderna Infringing LNPs, under the tradename "Moderna COVID-19 Vaccine," allowing commercial sales of its Covid-19 vaccine to commence. (*See* Exhibit 13 at 1.)

39. On January 31, 2022, Moderna announced that it received FDA approval for its COVID-19 Vaccine, under the tradename SPIKEVAX®. (*See* Exhibit 14 at 1).

40. 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 3 at 100.)

41. 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 20 at 2.)

The U.S. government confirmed that Moderna has exported U.S. made doses. (Exhibit 20 at 2.) Upon information and belief, Moderna shipped U.S. made doses of its COVID-19 Vaccine to Canada. (Exhibit 21.) 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 22 at 3.)

42. 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 23.) 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 23 at 2.)

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

43. The patented Alnylam LNP 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 15 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 LNP

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

44. Moderna turned to the Moderna Infringing LNPs to meet these requirements for its COVID-19 Vaccine. Moderna publicly recognized the central role biodegradable lipids in the LNPs 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 LNP technology "is the unsung hero of the whole thing." (*See* Exhibit 15 at 2.) Ciaramella credits the use of ester linkages to make the lipids more biodegradable to the success of Moderna's LNPs. (*Id.* at 6.) Those biodegradable properties and ester linkages employ the patented Alnylam LNP Technology.

45. 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 16 at 4.) Moderna's "proprietary lipid-nanoparticle-delivery system" relies on the patented Alnylam LNP Technology.

46. 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 17 at 5.) The biodegradability of Moderna's lipid system employs the patented Alnylam LNP Technology.

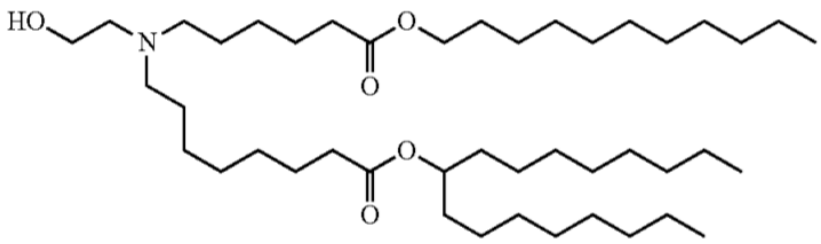
MODERNA'S INFRINGING ACTIVITIES

47. On information and belief, Moderna and/or its end users employ in its COVID-19 Vaccine the Moderna Infringing Lipids, which meets every limitation of at least claims 1-3, 5-14, 18-20, and 22-30 of the '979 Patent, in its COVID-19 Vaccine.

48. The prescribing information, dated January 28, 2022, states that Moderna's Covid-19 Vaccine contains a total lipid content of 1.93 mg, consisting of SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]). (Exhibit 5 at 11.)

49. Upon information and belief, the lipids are in molar lipid ratio of 50:10:38.5:1.5 for the ionizable cationic lipid : neutral lipid : cholesterol : PEGylated lipid. (Exhibit 8 at 3.)

50. 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 8 at 3, 8.)

51. Upon information and belief, every dose of Moderna's COVID-19 Vaccine that it made, offered for sale, or sold contains the Moderna Infringing LNPs, and will continue to do so. Upon information belief, the Moderna Infringing LNPs are manufactured in a manner that uses the patented Alnylam methods.

52. Attached as Exhibit 2 and incorporated herein is a preliminary claim chart describing Moderna's infringement of claims 1-3, 5-14, 18-20, and 22-30 of the '979 Patent. Exhibits 5, 8, 18, 19, 24, and 25 are supporting documents for the chart. 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 '979 Patent or any other patents.

53. Moderna has known of the '979 Patent since at least as early as July 12, 2022, when the '979 Patent issued. Alnylam notified Moderna of the published '907 Application on June 23, 2022, which set forth the same claims as in the subsequently-issued '979 Patent.

FIRST CAUSE OF ACTION
(Infringement of the '979 Patent)

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

55. On information and belief, Moderna has infringed and will continue to infringe at least one claim of the '979 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 Infringing LNPs within the United States and without authority.

56. Defendants Moderna, Inc., ModernaTX, Inc., and Moderna US, Inc. without authority have infringed and will continue to infringe at least one of the asserted claims of the '979 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 Infringing LNPs. 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 Infringing LNPs with the knowledge and specific intent that the others

will directly infringe Alnylam's '979 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 Infringing LNPs with the knowledge and specific intent that such end user, distributor, importer, and/or exporter end-users directly infringe Alnylam's '979 Patent.

57. 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 directly infringes the '979 Patent;

B. A judgment that Moderna induces infringement of the '979 Patent;

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

D. Costs and expenses in this action; and

E. 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.

OF COUNSEL:

William G. Gaede, III
McDERMOTT WILL & EMERY LLP
415 Mission Street, Suite 5600
San Francisco, CA 94105
(650) 815-7400

Sarah Chapin Columbia
Sarah J. Fischer
McDERMOTT WILL & EMERY LLP
200 Clarendon Street, Floor 58
Boston, MA 02116-5021
(617) 535-4000

Ian B. Brooks
McDERMOTT WILL & EMERY LLP
500 N. Capitol Street NW
Washington, DC 20003
(202) 756-8000

Dated: July 12, 2022

McDERMOTT WILL & EMERY LLP

/s/ Ethan H. Townsend

Ethan H. Townsend (#5813)
The Nemours Building
1007 North Orange Street, 10th Floor
Wilmington, DE 19801
(302) 485-3910
ehtownsend@mwe.com

Attorneys for Alnylam Pharmaceuticals, Inc.