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 Anylam LNP Technology is foundational to the success of the recently-developed messenger RNA ("mRNA") based COVID vaccines. The United States Patent Office recognized Alnylam's inventive work, issuing United States Patent No. 11,246,933 (the "'933 Patent") that protects the Alnylam LNP Technology. (Exhibit 1.)

2. Moderna's mRNA COVID-19 Vaccine uses a cationic biodegradable lipid covered by '933 Patent. Specifically, Moderna infringes Alnylam's '933 Patent through its SM-102 cationic biodegradable lipid formulated into LNPs that protect and safely deliver the vaccine's

mRNA. Moderna executives have described the infringing SM-102 biodegradable lipid as the "unsung hero" of its COVID-19 Vaccine.

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 '933 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®[1] 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.)

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

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

development, regulatory approval, marketing, manufacturing, sales, offers for sale, and distribution of Moderna's COVID-19 Vaccine.

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 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, made using 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, made using 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 15 at 1-2.)

18. One approach was to develop a lipid[2] 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, the lipids had to be positively charged (cationic) to create the protective bubble around the RNA. Cationic lipids do not exist in nature, and therefore had to be synthesized. There were toxicity issues with early attempts to use them in therapeutics due to the high dose of LNP needed to be effective.

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 LNP 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

[2] 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.

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-two patents world-wide have issued to Alnylam based on these groundbreaking inventions described in its provisional and utility patent applications.

23. On February 15, 2022, The United States Patent & Trademark Office issued the '933 Patent, entitled "Biodegradable Lipids for the Delivery of Active Agents." The '933 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 '933 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 18 of the '933 Patent is representative and recites:

> A cationic lipid comprising a primary group and two biodegradable hydrophobic tails, wherein
>
> the primary group comprises (i) a head group that optionally comprises a primary, secondary, or tertiary amine, and (ii) a central moiety to which the head group and the two biodegradable hydrophobic tails are directly bonded;
>
> the central moiety is a central carbon or nitrogen atom;
>
> each biodegradable hydrophobic tail independently has the formula -(hydrophobic chain)(biodegradable group)-(hydrophobic chain), wherein the biodegradable group is -OC(O)- or -C(O)O-;
>
> for at least one biodegradable hydrophobic tail, the terminal hydrophobic chain in the biodegradable hydrophobic tail is a branched alkyl, where the branching occurs at the α-position relative to the biodegradable group and the biodegradable hydrophobic tail has the formula $-R^{12}-M^1-R^{13}$, where R^{12} is a C_4-C_{14} alkylene or C_4-C_{14} alkenylene, M^1 is the biodegradable group, R^{13} is a branched C_{10}-C_{20} alkyl, and the total carbon atom content of the tail $-R^{12}-M^1-R^{13}$ is 21 to 26;
>
> in at least one hydrophobic tail, the biodegradable group is separated from a terminus of the hydrophobic tail by from 6 to 12 carbon atoms; and
>
> the lipid has a pKa in the range of about 4 to about 11 and a logP of at least 10.1.

(Exhibit 1 at 538:13-38.)

26. The '933 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

27. 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.)

28. 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).

29. 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.

30. 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.

31. 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

32. 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 used its infringing LNP containing SM-102 to formulate and develop its COVID-19 Vaccine.

33. 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.)

34. Upon information and belief, the first clinical batch of Modena's vaccine candidate incorporating the SM-102 lipid 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.)

35. Upon information and belief, Moderna filed its IND for its COVID-19 vaccine candidate comprising SM-102 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.)

36. On November 30, 2020, Moderna announced the results of its Phase 3 trial of its vaccine candidate comprising SM-102. (*See* Exhibit 12 at 1.) It announced on the same day that it would submit its Emergency Use Authorization to the FDA. (*See id.*)

37. On December 18, 2020, the FDA granted an Emergency Use Authorization to Moderna's COVID-19 Vaccine comprising SM-102, under the tradename "Moderna COVID-19 Vaccine," allowing commercial sales of its Covid-19 vaccine to commence. (*See* Exhibit 13 at 1.)

38. 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).

39. 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.)

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

40. 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.

41. Moderna turned to its SM-102 lipid 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.

42. 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.

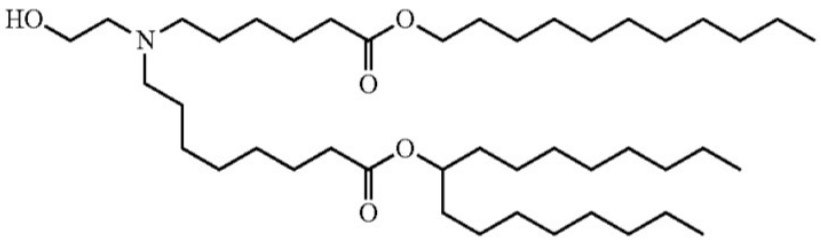
43. On February 24, 2021, Stéphan Bancel, Moderna, Inc.'s CEO, publicly stated that its lipid system "is biodegradable, so it's a big competitive advantage for us." (*See* Exhibit 17 at 5.) The biodegradability of Moderna's lipid system employs the patented Alnylam LNP Technology.

MODERNA'S INFRINGING ACTIVITIES

44. 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 18, 20-22, and 24-27 of the '933 Patent, in its COVID-19 Vaccine.

45. The prescribing information, dated January 28, 2022, states that Moderna's Covid-19 Vaccine contains SM-102. (Exhibit 5 at 11.)

46. 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.)

47. Upon information and belief, every dose of Moderna's COVID-19 Vaccine that it made, offered for sale, or sold contains SM-102, and will continue to do so.

48. Attached as Exhibit 2 is a preliminary claim chart describing Moderna's infringement of claims 18, 20-22, and 24-27 of the '933 Patent. Exhibits 5, 8, 18, and 19 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 '933 Patent or any other patents.

49. Moderna has known of the '933 Patent since at least as early as February 15, 2022, when the '933 Patent issued.

FIRST CAUSE OF ACTION
(Infringement of the '933 Patent)

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

51. On information and belief, Moderna has infringed and will continue to infringe at least one claim of the '933 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 SM-102 within the United States and without authority.

52. 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 '933 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 '933 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 '933 Patent.

53. 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 '933 Patent;

B. A judgment that Moderna induces infringement of the '933 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.

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