Keith J. Miller, Esq.
Bradley A. Suiters, Esq.
ROBINSON MILLER LLC
Ironside Newark
110 Edison Place, Suite 302
Newark, New Jersey 07102
Tel.: (973) 690-5400
kmiller@rwmlegal.com
bsuiters@rwmlegal.com

Attorneys for Plaintiffs, Translate Bio, Inc., Translate Bio MA, Inc., Sanofi Vaccines US, Inc., and VaxServe, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TRANSLATE BIO, INC., TRANSLATE BIO MA, INC., SANOFI VACCINES US, INC., and VAXSERVE, INC. Plaintiffs, v. MODERNA, INC. MODERNATX, INC., and MODERNA US, INC., Defendants.	C.A. No. _____ **JURY TRIAL DEMANDED**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Translate Bio, Inc., Translate Bio MA, Inc. (together, "Translate Bio"), Sanofi Vaccines US Inc., and VaxServe, Inc. (collectively, "Sanofi"), by their attorneys, allege as follows for their Complaint for Patent Infringement against Moderna, Inc., ModernaTX, Inc., and Moderna US, Inc. (collectively, "Moderna").

NATURE OF THE ACTION

1. Translate Bio, and its predecessors in interest, worked to develop mRNA-based therapeutics. Beginning in 2018, Translate Bio entered into a collaboration with Sanofi Pasteur

Inc. (now Sanofi Vaccines US Inc.),[1] to develop mRNA vaccines. In 2021, Sanofi acquired Translate Bio in order to bolster its development work on mRNA vaccines. Ex. 23. Translate Bio's inventions relate to mRNA purity, therapeutic mRNA delivery in humans, and corresponding lipid compositions for delivery of mRNA, like Moderna's products. The Patent Office has repeatedly recognized Translate Bio's inventive contribution to mRNA technology, issuing, *inter alia*, United States Patent Nos. 10,238,754 (the "'754 Patent"), 10,413,618 (the "'618 Patent"), 11,291,734 (the "'734 Patent"), 11,338,044 (the "'044 Patent"), 11,547,764 (the "'764 Patent"), 12,331,005 (the "'005 Patent"), 12,459,885 (the "'885 Patent"), 9,850,269 (the "'269 Patent"), 11,059,841 (the "'841 Patent"), and 12,577,554 (the "'554 Patent") (collectively, the "Patents-in-Suit"). These ten patents protect Translate Bio's methods and compositions for mRNA Delivery. Exs. 1-10.

2. Moderna currently markets several mRNA vaccines including, but not limited to, its COVID-19 SPIKEVAX® and MNEXSPIKE® vaccines and its RSV MRESVIA® vaccine (collectively, the "Accused Products"). Each vaccine contains purified mRNA, which is protected and delivered by lipid nanoparticles ("LNPs"), which, in turn, are composed of four separate lipids, including SM-102. These LNPs safely deliver mRNA into human cells, which triggers the immune system to begin developing defenses. The Accused Products are sold with corresponding prescribing information, which instructs healthcare professionals how to administer the mRNA-based vaccines to humans. In using purified mRNA, encapsulated in an LNP containing SM-102,

[1] Sanofi, the ultimate parent company of Plaintiffs Sanofi Vaccines US Inc., Translate Bio, Inc., Translate Bio MA, Inc., and VaxServe, Inc., is a global research-driven pharmaceutical company based in France, with a rich history of discovering, developing, manufacturing, and marketing a broad range of innovative products to improve human health. Sanofi has experienced tremendous success across multiple markets, including vaccines, expanding into 100 countries worldwide and employing more than 100,000 individuals worldwide. Sanofi supplies millions of vaccine doses to fight multiple diseases, including influenza, RSV, diphtheria, tetanus, pertussis, poliomyelitis, haemophilus influenzae type b (Hib), meningococcal meningitis Groups A, C, Y, and W, hepatitis A, rabies, yellow fever, and typhoid fever.

providing the prescribing information, and other actions, Moderna infringes one or more claims of each of the Patents-in-Suit either directly or by actively induced or contributory infringement.

3. Sanofi brings this action to recover monetary compensation for Moderna's unlicensed use of the Patents-in-Suit.

THE PARTIES

4. Plaintiff Translate Bio, Inc. is a corporation organized under the laws of the State of Delaware with a principal place of business at 200 West Street, Waltham MA 02451.

5. Plaintiff Translate Bio MA, Inc. is a corporation organized under the laws of the State of Delaware with a principal place of business at 200 West Street, Waltham MA 02451. Translate Bio MA, Inc. is a wholly owned subsidiary of Translate Bio.

6. Plaintiff Sanofi Vaccines US Inc. is a corporation organized under the laws of the State of Delaware with a principal place of business at 1 Discovery Drive, Swiftwater, PA 18370. Sanofi Vaccine US Inc. has more than 200 employees based in Morristown, New Jersey.

7. Plaintiff VaxServe, Inc. is a corporation organized under the laws of the Commonwealth of Pennsylvania with a principal place of business at 54 Glenmaura National Blvd. Suite 301, Moosic, PA 18507.

8. 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 325 Binney Street, Cambridge, Massachusetts 02142. Upon information and belief, Defendant Moderna, Inc., is the parent company of the other Defendants and recognizes the sales for Moderna's Accused Products. Ex. 11.

9. 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 325 Binney Street, Cambridge, Massachusetts 02142. Upon information and belief, Defendant ModernaTX, Inc. is a

wholly owned subsidiary of Defendant Moderna, Inc. Defendant ModernaTX, Inc. is the entity to which the FDA's Biologics License Application Approvals for the Accused Products were addressed. Exs. 12-14. Furthermore, ModernaTX, Inc. is the entity to which the Accused Products' prescribing information instructs individuals to report issues regarding the respective vaccine. Exs. 15-17. The same prescribing information also asserts that ModernaTX, Inc. owns the SPIKEVAX®, MNEXSPIKE®, and MRESVIA® trademarks. Exs. 15-17.

10. 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 325 Binney Street, Cambridge, Massachusetts 02142. Upon information and belief, Defendant Moderna US, Inc. is a wholly owned subsidiary of Defendant Moderna, Inc. The prescribing information and packaging for the Accused Products list Moderna US, Inc. as the entity for which the Accused Products are manufactured and provide its Princeton, New Jersey location. Exs. 15-17.

JURISDICTION AND VENUE

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

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

13. This Court has personal jurisdiction over Defendant Moderna, Inc. because, upon information and belief, it directly or indirectly, uses, offers for sale, and/or sells its Accused Products 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, uses, offers for sale, and/or sells its Accused Products 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, uses, offers for sale, and/or sells its Accused Products throughout the United States, including in this judicial district. Furthermore, Moderna US, Inc. is referenced on both the Accused Products' prescribing information and packaging as operating out of this jurisdiction, in Princeton, NJ.

16. Venue is proper in this Court under 28 U.S.C. § 1400(b) because, upon information and belief, Moderna directly or indirectly uses, offers for sale, and/or sells its Accused Products throughout the United States, including in this judicial district.

17. Furthermore, venue is proper because, upon information and belief, Moderna has a regular and established place of business in this judicial district. The Accused Products' prescribing information specifically states that the Accused Products are "[m]anufactured for" "Moderna US, Inc., Princeton, NJ 08540", an address within this District. Exs. 15-17. Specifically, on information and belief, Moderna has a facility at 5 Vaughn Drive, Princeton, NJ 08540. For example, the New Jersey Department of Treasury lists a Princeton location for Moderna US, Inc. Ex. 18. Likewise, the New Jersey Department of Health lists the 5 Vaughn Drive address as Moderna US, Inc.'s address for its Drug and Medical Device Registration. Ex. 19. The company is registered as both a manufacturer and a distributor therein. *Id.*


njgov.healthinspections.us/_templates/636/1/certificate/_report_full.cfm?permitID=19659&parentTableName=tblPermit&dsn=dhd_636_1&doma...

Registration Number: 5006265 **Registered As:** Manufacturer,Distributor Information Recorded in the System as of 06/05/2026

Name: MODERNA US, INC. New Jersey Department of Health

DBA:

Address: 5 VAUGHN DR STE 200 PRINCETON, NJ 08540

Original Issue Date: 12/20/2023 **Expiration Date:** 01/31/2027

Current Issue Date: 11/19/2025

Disciplines: No

Permit Status: Active

18. Other States likewise refer to Moderna US, Inc. as a manufacturer based in New Jersey. For example, the Oklahoma State Board of Pharmacy lists Moderna's New Jersey location as a manufacturer facility in good standing. Ex. 20.

19. Moderna US, Inc. maintains a regular and established place of business at 5 Vaughn Drive, Princeton, NJ, as depicted in the photographs below.

20. As of the writing of this Complaint, Moderna has six job listings for the Princeton, NJ address. Ex. 21.

21. Finally, Moderna's regular and established place of business at 5 Vaughn Drive, Princeton, NJ, appears to be well known, based at least on an article published online by the building's management, listing Moderna as one of the more prominent tenants. Ex. 22.

BACKGROUND

RNA Therapeutics

22. Ribonucleic acid ("RNA") is a class of biological macromolecules that performs essential roles in living organisms. Like DNA, RNA is a nucleic acid. It is composed of sugar-phosphate backbone (where the sugar is ribose) and a sequence of bases (adenine (A), cytosine (C), guanine (G), or uracil (U)). Unlike DNA, which is typically double stranded, RNA is usually single stranded.

23. There are many different types of RNA that perform different biological roles. One type that has been of particular interest in developing pharmaceuticals is messenger RNA ("mRNA"). mRNA is a single stranded type of RNA that is involved in protein synthesis. The sequence of bases presented in a specific mRNA molecule provides a cell with the information necessary to synthesize a particular protein or portion of a protein.

24. Scientists recognized that mRNA offered significant therapeutic potential, given its ability to induce the production of proteins in cells. However, manufacturing sufficient quantities of purified mRNA presented challenges. There were also significant challenges for the effective delivery of mRNA, which required years of research and development to arrive at safe, functional delivery mechanisms.

25. Delivery systems for RNA therapeutics, and in particular RNA-based vaccines, utilize a synthetic molecule called an ionizable cationic lipid to overcome the obstacles in safely and effectively delivering RNA (including mRNA) into human cells.

26. Although not found in nature, these ionizable cationic lipids, synthesized by scientists, are positively charged under certain conditions and can be used to form LNPs. LNPs encapsulate mRNA for transport of the RNA across cell membranes. Once in the cell, mRNA is used to produce the specified protein or peptide.

27. Even with breakthroughs in delivery systems, however, scientists struggled to create a system that permitted the mRNA to produce sufficiently high quantities of proteins that persisted in the body.

Translate Bio's Contributions to mRNA Delivery Methods and Ionizable Cationic Lipid Composition

28. Translate Bio and its predecessor companies have been dedicated to RNA therapeutic research and development for nearly two decades. Specifically, certain Patents-in-Suit disclose compositions and methods for delivering mRNA using LNPs resulting in persistence of the protein for a certain period of time, in addition to certain lipids for use in mRNA delivery. *See* Exs. 1-5. Other Translate Bio's patented inventions cover specific nanoparticles including ionizable cationic lipids of a particular structure. *See* Exs. 6-7. Yet other of Translate Bio's patents cover mRNA of specific purities. *See* Exs. 8-10.

29. In the early 2000s, scientists all over the world were working on potential nucleic acid-based therapeutics, mostly focusing on using siRNA and antisense nucleotides. In 2008, the pharmaceutical company Shire became interested in entering the nucleic acid space. The Shire team worked to develop mRNA-based therapeutics delivered via lipid nanoparticles.

30. The mRNA therapeutics team at Shire was among the first to use lipid nanoparticles to deliver mRNA in vivo. It also developed methods of synthesizing mRNA that produced high purity and high potency mRNA. This work resulted in the first mRNA therapeutic to enter human clinical trials in the chronic disease space. The team worked on therapies for a number of diseases.

31. In 2013, scientists from Shire presented at the 1st International mRNA Health Conference in Germany. Ex. 24. Their presentation included efficacy data that showed the early successes that they had had with mRNA manufacture and delivery.

32. In 2016, the Shire mRNA therapeutics team was acquired by Rana Therapeutics, and in 2017, was renamed Translate Bio. In June 2018, Translate Bio entered into a collaboration with Sanofi focusing on mRNA vaccine development. This agreement covered up to five infectious disease areas. Translate Bio and Sanofi entered into a second collaboration agreement in the summer of 2020, expanding to all infectious disease areas. Later, in September 2021, Sanofi acquired Translate Bio.

33. At the start of the COVID-19 pandemic, it was clear to both Sanofi and Translate Bio that developing safe and effective COVID-19 vaccines was a necessary step to ease the public health crisis. To that end, Sanofi entered into an agreement with Translate Bio in March 2020 to develop an mRNA-based COVID-19 vaccine. Ex. 25. At the same time, in April 2020, Sanofi partnered with GSK to develop a protein vaccine. Ex. 26. Because of the scale of the crisis in 2020, pursuing multiple platform technologies allowed for more potential success. Ultimately, the Sanofi/Translate Bio vaccine had positive interim results in its early clinical trials, but Sanofi chose to pursue its protein vaccine instead. Ex. 27. The protein vaccine was approved in 2022 in Europe and was on the market until 2024. Ex. 35. As of 2024, Sanofi, in collaboration with Novavax, has marketed another COVID-19 protein vaccine, both in the US and abroad. Ex. 36.

The Patents-in-Suit

34. Translate Bio developed and began filing provisional applications related to the Patents-in-Suit approximately 15 years ago. On June 8, 2011, Translate Bio filed U.S. Provisional Application No. 61/494,881, to which the ’754 Patent, ’618 Patent, ’734 Patent, ’044 Patent, and ’764 Patent claim priority. Exs. 1-5. On March 29, 2012, Translate Bio filed U.S. Provisional

Application No. 61/617,468, to which the '005 Patent and '885 Patent claim priority. Exs. 6-7. On April 25, 2014, Translate Bio filed U.S. Provisional Application No. 61/984,503, to which the '269 Patent and '841 Patent claim priority. Exs. 8-9. On March 14, 2013, Translate Bio filed U.S. Provisional Application No. 61/784,996, to which the '554 Patent claims priority. Ex. 10. To date, over 600 patents, including 123 U.S. patents, have issued to Translate Bio out of its mRNA delivery inventions.

35. On March 26, 2019, the United States Patent & Trademark Office granted the '754 Patent, entitled "Lipid Nanoparticle Compositions and Methods for mRNA Delivery." The named inventors for the '754 Patent are Braydon Charles Guild, Frank DeRosa, and Michael Heartlein. As shown on the face of the patent, Translate Bio is the assignee of the '754 Patent.

36. The '754 Patent claims methods for delivering mRNA to human cells, including mRNA that encodes a protein or peptide, wherein the mRNA is encapsulated in an LNP, such that the protein or peptide is detectable in serum at least 72 hours after administration.

37. The independent claim of the '754 Patent, Claim 1, recites:

> A method for delivery of messenger RNA (mRNA) for in vivo production of a protein, comprising administering to a human, a composition comprising an mRNA that encodes a protein or a peptide, wherein the mRNA is encapsulated within a lipid nanoparticle and wherein the administering of the composition results in expression of the protein or peptide encoded by the mRNA that is detectable in serum at least 72 hours after administration, wherein the lipid nanoparticle comprises one or more PEG-modified lipids.

38. The '754 Patent has been owned by Translate Bio at all times, is fully maintained, and is valid and enforceable.

39. On September 17, 2019, the United States Patent & Trademark Office granted the '618 Patent, entitled "Lipid Nanoparticle Compositions and Methods for mRNA Delivery." The named inventors for the '618 Patent are Braydon Charles Guild, Frank DeRosa, and Michael Heartlein. As shown on the face of the patent, Translate Bio is the assignee of the '618 Patent.

40. The ’618 Patent claims methods for delivering mRNA to human cells, including mRNA that encodes a protein, wherein the mRNA is encapsulated in an LNP, such that the protein is detectable in serum at least 72 hours after administration.

41. The independent claim of the ’618 Patent, Claim 1, recites:

> A method for delivery of messenger RNA (mRNA) for in vivo production of a protein, comprising administering, to a human, a composition comprising an mRNA that encodes the protein wherein the mRNA is encapsulated within a lipid nanoparticle, wherein the administering of the composition results in expression of the protein encoded by the mRNA that is detectable in serum at least 72 hours after administration, and wherein the lipid nanoparticle comprises one or more PEG-modified lipids.

42. The ’618 Patent has been owned by Translate Bio at all times, is fully maintained, and is valid and enforceable.

43. On April 5, 2022, the United States Patent & Trademark Office granted the ’734 Patent, entitled “Lipid Nanoparticle Compositions and Methods for mRNA Delivery.” The named inventors for the ’734 Patent are Braydon Charles Guild, Frank DeRosa, and Michael Heartlein. As shown on the face of the patent, Translate Bio is the assignee of the ’734 Patent.

44. The ’734 Patent claims methods for delivering mRNA to human cells, including mRNA that encodes a protein or peptide, wherein the mRNA is encapsulated in an LNP, such that the protein or peptide is detectable in a target tissue at least 48 hours after administration.

45. The independent claim of the ’734 Patent, Claim 1, recites:

> A method for delivery of messenger RNA (mRNA) for in vivo production of a protein or a peptide[2] comprising
>
> > administering to a human a composition comprising an mRNA that encodes a protein or a peptide, wherein the mRNA is encapsulated within a lipid nanoparticle and

[2] Added in an August 2, 2022, Certificate of Correction. Ex. 3.

> wherein the administering of the composition results in the expression of the protein or the[3] peptide encoded by the mRNA that is detectable in a target tissue at least 48 hours after administration, wherein the lipid nanoparticle comprises one or more PEG-modified lipids.

46. The '734 Patent has been owned by Translate Bio at all times, is fully maintained, and is valid and enforceable.

47. On May 24, 2022, the United States Patent & Trademark Office granted the '044 Patent, entitled "Lipid Nanoparticle Compositions and Methods for mRNA Delivery." The named inventors for the '044 Patent are Braydon Charles Guild, Frank DeRosa, and Michael Heartlein. As shown on the face of the patent, Translate Bio is the assignee of the '044 Patent.

48. The '044 Patent claims methods for delivering mRNA to human cells, including mRNA that encodes a protein or peptide, wherein the mRNA is encapsulated in an LNP, such that the protein or peptide is expressed. The '044 Patent further claims specific lipid ratios for the LNP.

49. The independent claim of the '044 Patent, Claim 1, recites:

> A method for delivery of messenger RNA (mRNA) for in vivo production of a protein or a peptide comprising
>
> > administering to a subject a composition comprising an mRNA that encodes the protein or the peptide, wherein the mRNA is encapsulated within a lipid nanoparticle and
> >
> > wherein the administering of the composition results in the expression of the protein or the peptide encoded by the mRNA, wherein the lipid nanoparticle comprises
> >
> > > (i) a PEG-modified lipid at a molar ratio of greater than 1% of the total lipids in the lipid nanoparticle,
> > >
> > > (ii) a cationic lipid at a molar ratio of greater than 10% of the total lipids in the lipid nanoparticle,
> > >
> > > (iii) a non-cationic lipid at a molar ratio of greater than 5% of total lipids in the lipid nanoparticle, and

[3] Added in an August 2, 2022, Certificate of Correction. Ex. 3.

> (iv) cholesterol at greater than 10% of the total lipids in the lipid nanoparticle
>
> wherein the non-cationic lipid comprises DOPE or DSPC.

50. The ’044 Patent has been owned by Translate Bio at all times, is fully maintained, and is valid and enforceable.

51. On January 10, 2023, the United States Patent & Trademark Office granted the ’764 Patent, entitled “Lipid Nanoparticle Compositions and Methods for mRNA Delivery.” The named inventors for the ’764 Patent are Braydon Charles Guild, Frank DeRosa, and Michael Heartlein. As shown on the face of the patent, Translate Bio is the assignee of the ’764 Patent.

52. The ’764 Patent claims an mRNA that encodes a protein or peptide, encapsulated in an LNP. The ’764 Patent further claims specific lipid ratios and other molecular attributes for the LNP.

53. The independent claim of the ’764 Patent, Claim 1, recites:

> A composition comprising an mRNA encoding a protein or a peptide, encapsulated within a lipid nanoparticle, wherein the lipid nanoparticle has a size less than 150 nm and comprises (i) a PEG-modified lipid at a molar ratio of greater than 1%[4] of the total lipids in the lipid nanoparticle, (ii) a cationic lipid at a molar ratio of greater than 10% of the total lipids in the lipid nanoparticle, (iii) a non-cationic lipid at a molar ratio of greater than 5% of total lipids in the lipid nanoparticle, and (iv) cholesterol at a molar ratio greater than 10% of the total lipids in the lipid nanoparticle, and wherein the mRNA comprises (i) a 5′-UTR, (ii) a 3′-UTR, (iii) a 5′ cap structure, and (iv) a poly A tail.

54. The ’764 Patent has been owned by Translate Bio at all times, is fully maintained, and is valid and enforceable.

55. On June 17, 2025, the United States Patent & Trademark Office granted the ’005 Patent, entitled “Ionizable Cationic Lipids.” The named inventors for the ’005 Patent are Frank

[4] Amended from 10% in a March 21, 2023, Certificate of Correction. Ex. 5.

DeRosa, Braydon Charles Guild, and Michael Heartlein. As shown on the face of the patent, Translate Bio is the assignee of the ’005 Patent.

56. The ’005 Patent claims LNPs comprising mRNA and specific classes of lipids, a method of treating disease by administering such LNPs to a patient, and transfecting mRNA into human cells by utilizing the LNPs.

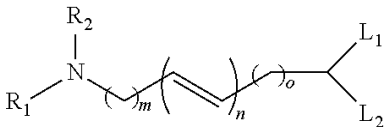
57. The independent claim of the ’005 Patent, Claim 1, recites:

A lipid nanoparticle comprising:

mRNA;

one or more helper lipids, one or more non-cationic lipids, and/or one or more PEG-modified lipids; and

a cationic lipid having the structure:



wherein

R_1 and R_2 are each independently an optionally substituted saturated C_1-C_{20} alkyl or an optionally substituted variably unsaturated C_2-C_{20} alkenyl

L_1 is selected from the group consisting of hydrogen, an optionally substituted C_3-C_{30} alkyl, and an optionally substituted variably unsaturated C_3-C_{30} alkenyl;

L_2 is selected from the group consisting of an optionally substituted C_3-C_{30} alkyl and an optionally substituted variably unsaturated C_3-C_{30} alkenyl;

m is three, four, five, six, seven, eight, nine, ten, eleven, twelve, thirteen, fourteen, fifteen, sixteen, seventeen, eighteen, nineteen, or twenty;

o is zero, one, two, three, four, five, six, seven, eight, nine, ten, eleven, twelve, thirteen, fourteen, fifteen, sixteen, seventeen, eighteen, nineteen, or twenty; and

n is zero, one, two, three, four, five, six, seven, eight, nine, ten, eleven, twelve, thirteen, fourteen, fifteen, sixteen, seventeen, eighteen, nineteen, or twenty.

58. The ’005 Patent has been owned by Translate Bio at all times, is fully maintained, and is valid and enforceable.

59. On November 4, 2025, the United States Patent & Trademark Office granted the ’885 Patent, entitled “Ionizable Cationic Lipids.” The named inventors for the ’885 Patent are Frank DeRosa, Braydon Charles Guild, and Michael Heartlein. As shown on the face of the patent, Translate Bio is the assignee of the ’885 Patent.

60. The ’885 Patent claims LNPs comprising mRNA and specific classes of lipids, a method of treating disease by administering such LNPs to a patient, and transfecting mRNA into human cells by utilizing the LNPs.

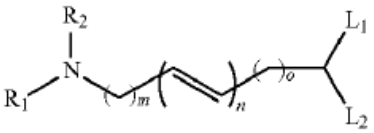
61. The independent claim of the ’885 Patent, Claim 1, recites:

A lipid nanoparticle comprising:

mRNA;

one or more helper lipids, one or more non-cationic lipids, and/or one or more PEG-modified lipids; and

a cationic lipid having the structure:



wherein

R_1 and R_2 are each independently an optionally substituted saturated C_1-C_{20} alkyl;

L_1 is selected from the group consisting of hydrogen, an optionally substituted saturated C_3-C_{30} alkyl, and an optionally substituted variably unsaturated C_3-C_{30} alkenyl;

> L_2 is selected from the group consisting of an optionally substituted saturated C_2-C_{30} alkyl and an optionally substituted variably unsaturated C_2-C_{30} alkenyl;
>
> m is three, four, five, six, seven, eight, nine, ten, eleven, twelve, thirteen, fourteen, fifteen, sixteen, seventeen, eighteen, nineteen, or twenty;
>
> o is zero; and
>
> n is zero or one.

62. The ’885 Patent has been owned by Translate Bio at all times, is fully maintained, and is valid and enforceable.

63. On December 26, 2017, the United States Patent & Trademark Office granted the ’269 Patent, entitled “Methods for Purification of Messenger RNA.” The named inventors for the ’269 Patent are Frank DeRosa, Anusha Dias, Shrirang Karve, and Michael Heartlein. As shown on the face of the patent, Translate Bio is the assignee of the ’269 Patent.

64. The ’269 Patent claims an mRNA composition with less than 1% prematurely aborted RNA sequences and/or enzyme reagents.

65. An independent claim of the ’269 Patent, Claim 14, recites:

> A composition comprising in vitro synthesized messenger RNA, wherein the composition contains less than 1 % of prematurely aborted RNA sequences and/or enzyme reagents used in in vitro synthesis.

66. The ’269 Patent has been owned by Translate Bio at all times, is fully maintained, and is valid and enforceable.

67. On July 13, 2021, the United States Patent & Trademark Office granted the ’841 Patent, entitled “Methods for Purification of Messenger RNA.” The named inventors for the ’841 Patent are Frank DeRosa, Anusha Dias, Shrirang Karve, and Michael Heartlein. As shown on the face of the patent, Translate Bio is the assignee of the ’841 Patent.

68. The ’841 Patent claims an mRNA composition with less than 5% prematurely aborted RNA sequences and/or enzyme reagents.

69. An independent claim of the ’841 Patent, Claim 18, recites:

> A composition comprising in vitro synthesized messenger RNA, wherein the composition comprises less than 5% of prematurely aborted RNA sequences and/or enzyme reagents used in in vitro synthesis.

70. The ’841 Patent has been owned by Translate Bio at all times, is fully maintained, and is valid and enforceable.

71. On March 17, 2026, the United States Patent & Trademark Office granted the ’554 Patent, entitled “Methods for Purification of Messenger RNA.” The named inventors for the ’554 Patent are Frank DeRosa, Anusha Dias, Michael Heartlein, and Shrirang Karve. As shown on the face of the patent, Translate Bio is the assignee of the ’554 Patent.

72. The ’554 Patent claims an mRNA composition that is substantially free of prematurely aborted RNA sequences of less than 15 bases, wherein the mRNA contains a modification to enhance efficacy, and is safe for use in humans.

73. The independent claim of the ’554 Patent, Claim 1, recites:

> A pharmaceutically acceptable composition comprising a purified messenger RNA (mRNA), wherein:
>
> (a) the purified mRNA is in vitro synthesized and substantially free of prematurely aborted RNA sequences of less than 15 bases in length;
>
> (b) the purified mRNA comprises one or more 1-methylpseudouracil nucleosides; and
>
> (c) the composition is suitable for administration as a pharmaceutical product to a human subject.

74. The ’554 Patent has been owned by Translate Bio at all times, is fully maintained, and is valid and enforceable.

Moderna's Accused Products

75. Upon information and belief, in or around January 2020, Moderna began working toward a coronavirus (SARS-CoV-2) vaccine. Moderna assigned it the product code mRNA-1273.

76. Upon information and belief, Moderna had completed development and produced sufficient doses for a clinical trial in early 2020. It delivered its first dose to a patient as part of such a clinical trial on March 16, 2020. *See* Ex. 28.

77. The clinical trial was completed on November 30, 2020, and Moderna submitted an application for Emergency Use Authorization to the FDA that same day. *See* Ex. 29.

78. On December 18, 2020, the FDA granted the Emergency Use Authorization (EUA), which permitted commercial sales of the vaccine under the tradename "Moderna COVID-19 Vaccine" to commence. *See* Ex. 30.

79. On January 31, 2022, the Moderna COVID-19 Vaccine received FDA approval under the tradename SPIKEVAX®. Ex. 12.

80. Since the original EUA grant, Moderna has sold millions of doses of Moderna COVID-19 Vaccine and SPIKEVAX®, resulting in billions of dollars of revenue. *See, e.g.*, Ex. 11, at 118; Ex. 37, at 127.

81. Each dose of Moderna's COVID-19 Vaccine and SPIKEVAX® made, sold, and used contains LNPs that include mRNA and the ionizable cationic lipid SM-102. Ex. 15.

82. On May 30, 2025, the FDA approved MNEXSPIKE®. Ex. 13.

83. Each dose of MNEXSPIKE® made, sold, and used contains LNPs that include mRNA and the ionizable cationic lipid SM-102. Ex. 16.

84. On June 14, 2024, the FDA approved MRESVIA®. Ex. 14.

85. Each dose of MRESVIA® made, sold, and used contains LNPs that include mRNA and the ionizable cationic lipid SM-102. Ex. 17.

86. Upon information and belief, the Accused Products have been very successful on the market. Indeed, Moderna enjoyed net sales of over $1.8 billion globally, and over $1.1 billion nationally, on the Accused Products in 2025 alone. Ex. 11, at 118.

MODERNA'S INFRINGING ACTIVITIES

87. Each of the claims of the '754 Patent, the '618 Patent, the '734 Patent, and the '044 Patent are directed to a method for delivery of mRNA. These patented methods are essential to the safe and effective administration of Moderna's Accused Products. In order to deliver the delicate mRNA into human cells, healthcare professionals administering the Accused Products must follow the prescribing information, which instructs them, ultimately, to infringe at least one claim in each of the '754 Patent, the '618 Patent, the '734 Patent, and the '044 Patent.

88. Administration of the SPIKEVAX® vaccine infringes the '754 Patent, the '618 Patent, the '734 Patent, and the '044 Patent. Moderna actively induces health care professionals to deliver SPIKEVAX® through its prescribing information and advertisements. Ex. 15.

89. The prescribing information instructs healthcare professionals to administer the vaccine intramuscularly to human patients. *See* Ex. 15, at 3, 4.

1 INDICATIONS AND USAGE

SPIKEVAX is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

SPIKEVAX is approved for use in individuals who are:

- 65 years of age and older, or
- 6 months through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.

2.2 Administration

Administer SPIKEVAX intramuscularly. Discard after single use.

90. The SPIKEVAX® vaccine comprises mRNA that encodes a protein, namely, the COVID-19 spike glycoprotein. *See* Ex. 15, at 50.

> Each 0.5 mL dose of SPIKEVAX (2025-2026 Formula) contains 50 mcg nucleoside-modified messenger RNA (mRNA) encoding the pre-fusion stabilized Spike glycoprotein (S) of the SARS-CoV-2 Omicron variant sublineage LP.8.1. Each dose also contains the following

91. The mRNA in the SPIKEVAX® vaccine is encapsulated by an LNP. *See* Ex. 15, at 51.

> **12.1 Mechanism of Action**
>
> The nucleoside-modified mRNA in SPIKEVAX is formulated in lipid particles, which enable delivery of the nucleoside-modified mRNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits an immune response to the S antigen, which protects against COVID-19.

92. On information and belief, the SPIKEVAX® vaccine results in the expression of the encoded spike protein and/or peptide detectable in serum at least 72 hours after administration. *See* Ex. 33, at 716.

93. On information and belief, the SPIKEVAX® vaccine results in the expression of the encoded spike protein and/or peptide detectable in a target tissue at least 48 hours after administration. Ex. 38, at 1033.

94. The SPIKEVAX® vaccine contains PEG-modified lipids (i.e., PEG 2000 DMG) and a non-cationic lipid (DSPC). *See* Ex. 15, at 50.

> SARS-CoV-2 Omicron variant sublineage LP.8.1. Each dose also contains the following ingredients: a total lipid content of 1.01 mg (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), 0.25 mg tromethamine, 1.2 mg tromethamine hydrochloride, 0.021 mg acetic acid,

95. Likewise, administration of the MNEXSPIKE® vaccine infringes the '754 Patent, the '618 Patent, the '734 Patent, and the '044 Patent. Moderna actively induces health care

professionals to deliver MNEXSPIKE® through its prescribing information and advertisements. Ex. 16.

96. The MNEXSPIKE® prescribing information instructs healthcare professionals to administer the vaccine intramuscularly to human patients. *See* Ex. 16, at 2-3.

> **1 INDICATIONS AND USAGE**
>
> MNEXSPIKE is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).
>
> MNEXSPIKE is approved for use in individuals who are:
> - 65 years of age and older, or
> - 12 years through 64 years of age with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.

> **2.2 Administration**
>
> Administer MNEXSPIKE intramuscularly.

97. The MNEXSPIKE® vaccine comprises mRNA that encodes a protein, namely, the COVID-19 spike glycoprotein. *See* Ex. 16, at 20.

> Each 0.2 mL dose of MNEXSPIKE (2025-2026 Formula) contains 10 mcg nucleoside-modified messenger RNA (mRNA) encoding the N-terminal domain (NTD) and receptor-binding domain (RBD) of the Spike glycoprotein of the SARS-CoV-2 Omicron variant sublineage LP.8.1. Each

98. The mRNA in the MNEXSPIKE® vaccine is encapsulated by an LNP. *See* Ex. 16, at 20.

> **12.1 Mechanism of Action**
>
> The nucleoside-modified mRNA in MNEXSPIKE is formulated in lipid particles, which enable delivery of the nucleoside-modified mRNA into host cells to allow expression of the N-terminal domain (NTD) and receptor-binding domain (RBD) of the Spike (S) glycoprotein of SARS-CoV-2. The vaccine elicits an immune response which protects against COVID-19.

99. On information and belief, the MNEXSPIKE® vaccine results in the expression of the encoded spike protein and/or peptide detectable in serum at least 72 hours after administration. *See* Ex. 39, at 9.

100. On information and belief, the MNEXSPIKE® vaccine results in the expression of the encoded spike protein and/or peptide detectable in a target tissue at least 48 hours after administration. Ex. 39, at 9.

101. The MNEXSPIKE® vaccine contains PEG-modified lipids (i.e., PEG 2000 DMG) and a non-cationic lipid (DSPC). *See* Ex. 16, at 20.

102. Administration of the MRESVIA® vaccine also infringes the '754 Patent, the '618 Patent, the '734 Patent, and the '044 Patent. Moderna actively induces health care professionals to deliver MRESVIA® through its prescribing information and advertisements. Ex. 17.

103. The prescribing information instructs healthcare professionals to administer the vaccine intramuscularly to human patients. *See* Ex. 17, at 2.

1 INDICATIONS AND USAGE

MRESVIA is indicated for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in

- individuals 60 years of age and older.
- individuals 18 through 59 years of age who are at increased risk for LRTD caused by RSV.

2.3 Administration

Administer MRESVIA intramuscularly.

104. The MRESVIA® vaccine comprises mRNA that encodes a protein, namely, the F glycoprotein from RSV. *See* Ex. 17, at 8.

Each 0.5 mL dose of MRESVIA contains 50 mcg of nucleoside modified mRNA encoding the F glycoprotein from RSV subtype A stabilized in the prefusion conformation (pre-F protein).

105. The mRNA in the MRESVIA® vaccine is encapsulated by an LNP. *See* Ex. 17, at 14.

> MRESVIA contains the following ingredients:
>
> - messenger ribonucleic acid (mRNA)
> - lipids (SM-102, polyethylene glycol dimyristoyl glycerol [PEG2000-DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC])
> - tromethamine
> - tromethamine hydrochloride
> - acetic acid
> - sodium acetate trihydrate
> - sucrose
> - water

106. On information and belief, the MRESVIA® vaccine results in the expression of the encoded protein and/or peptide detectable in serum at least 72 hours after administration.

107. On information and belief, the MRESVIA® vaccine results in the expression of the encoded protein and/or peptide detectable in a target tissue at least 48 hours after administration.

108. The MRESVIA® vaccine contains PEG-modified lipids (i.e., PEG 2000 DMG) and a non-cationic lipid (DSPC). *See* Ex. 17, at 14.

109. The '764 Patent claims are directed to a composition comprising mRNA encapsulated within a lipid nanoparticle. A SPIKEVAX® dose's contents infringe at least one claim in the '764 Patent.

110. As noted above, the SPIKEVAX® vaccine includes mRNA that encodes spike protein and that is encapsulated in an LNP.

111. On information and belief, that LNP is smaller than 150 nm. Ex. 40, at 2.

112. Furthermore, on information and belief, the SPIKEVAX® vaccine's LNP has the claimed molar ratios of the '044 Patent and the '764 Patent. Ex. 41, at 4.

113. Finally, Moderna has listed each characteristic included in the '764 Patent's claimed structure as an attribute of the SPIKEVAX® vaccine's mRNA. Ex. 31, at 6.

114. A MNEXSPIKE® dose's contents also infringe at least one claim of the '764 Patent.

115. As noted above, the MNEXSPIKE® vaccine includes mRNA that encodes spike protein and that is encapsulated in an LNP.

116. On information and belief, that LNP is the same as used in the SPIKEVAX® vaccine and thus is smaller than 150 nm. *See* Ex. 40, at 2.

117. Furthermore, on information and belief, the MNEXSPIKE® vaccine's LNP has the same molar ratios as those of the SPIKEVAX® vaccine and thus has the claimed molar ratios of the '044 Patent and the '764 Patent. *Compare* Ex. 15 *with* Ex. 16 (showing that SPIKEVAX® and MNEXSPIKE®, respectively, use the same lipids); *see* Ex. 41, at 4 (providing the ratios for SPIKEVAX®).

118. Finally, Moderna has listed each characteristic included in the '764 Patent's claimed structure as an attribute of the MNEXSPIKE® vaccine's mRNA. Ex. 42, at 6.

119. A MRESVIA® dose's contents also infringe at least one claim of the '764 Patent.

120. As noted above, the MRESVIA® vaccine includes mRNA that encodes F glycoprotein from RSV and that is encapsulated in an LNP.

121. On information and belief, that LNP is the same as used in the SPIKEVAX® vaccine and thus is smaller than 150 nm. *See* Ex. 40, at 4.

122. Furthermore, on information and belief, the MRESVIA® vaccine's LNP has the same molar ratios as those of the SPIKEVAX® vaccine, and thus has the claimed molar ratios of the '044 Patent and the '764 Patent. *Compare* Ex. 15 *with* Ex. 17 (showing that SPIKEVAX® and MRESVIA®, respectively, use the same lipids); *see* Ex. 41, at 4 (providing the ratios for SPIKEVAX®).

123. Finally, Moderna has listed each characteristic included in the '764 Patent's claimed structure as an attribute of the MRESVIA® vaccine's mRNA. *See* Ex. 43, at 11.

124. The claims of the '005 Patent and the '885 Patent are addressed to a lipid nanoparticle compound comprising an ionizable cationic lipid having the claimed structure. On information and belief, every dose of the Accused Products utilizes the ionizable cationic lipid SM-102, which meets every limitation of at least one claim of each of the '005 Patent and the '885 Patent.

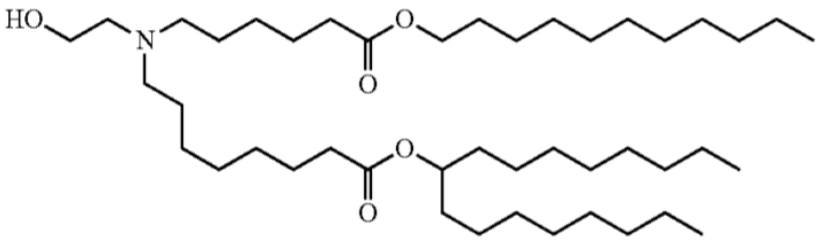
125. As discussed above, the Accused Products comprise LNPs encapsulating mRNA and, at least, PEG-modified lipids.

126. The prescribing information for SPIKEVAX®, dated August 2025, states that in addition to mRNA, each vaccine dose contains SM-102. Ex. 15, at 50.

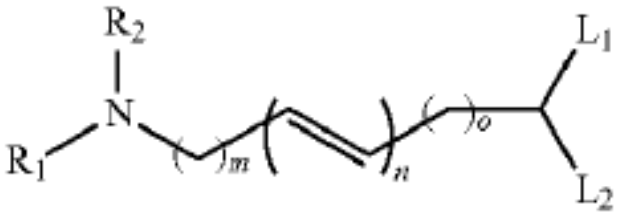
127. The prescribing information for MNEXSPIKE®, dated August 2025, states that in addition to mRNA, each vaccine dose contains SM-102. Ex. 16, at 20.

128. The prescribing information for MRESVIA®, dated June 2025, states that in addition to mRNA, each vaccine dose contains SM-102. Ex. 17, at 8.

129. Upon information and belief, SM-102 has the chemical structure:



130. The '005 Patent and the '885 Patent provide the following generic structure for the claimed ionizable cationic lipids:



131. This structure depicts SM-102 where the following values are assigned to each variable:

m is three, four, five, six, seven, eight, nine, ten, eleven, twelve, thirteen, fourteen, fifteen, sixteen, seventeen, eighteen, nineteen, or twenty;

o is zero; n is zero;

R_1 is a hydroxyl-substituted C_1–C_{20} alkyl;

R_2 is an ester-substituted C_1–C_{20} alkyl;

L_1 is hydrogen; and

L_2 is an ester-substituted C_3–C_{30} alkyl.

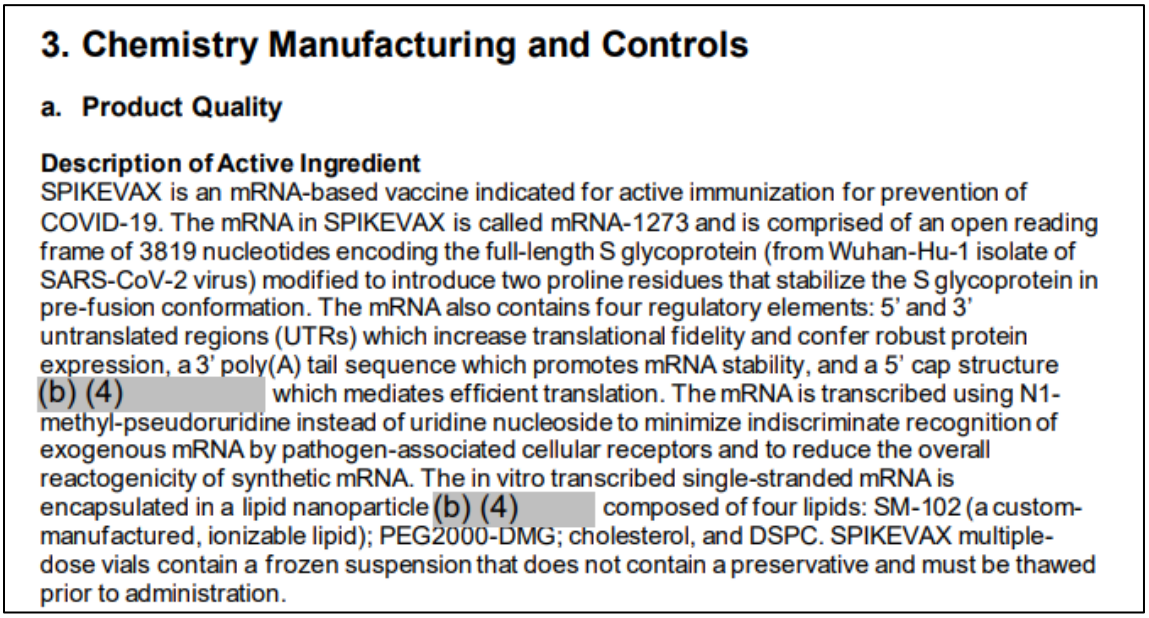
132. Because at least one claim of the ’005 Patent and the ’885 Patent claim those values, SM-102 infringes both patents.

133. Certain claims of the ’269 Patent and the ’841 Patent are directed to compositions of mRNA wherein the composition comprises less than 1% or 5%, respectively, of prematurely aborted RNA sequences and/or enzyme reagents used in in vitro synthesis. By virtue of how Moderna purifies its Accused Products, the Accused Products infringe at least one claim of the ’269 Patent and the ’841 Patent.

134. Each claim of the ’554 Patent is directed to pharmaceutically acceptable compositions of purified mRNA wherein the mRNA is made in vitro and is substantially free of

prematurely aborted RNA sequences that are less than 15 bases long, wherein the mRNA is modified to improve efficacy and suitable for human use. On information and belief, by virtue of how Moderna purifies the Accused Products, the Accused Products infringe at least one claim of the '554 Patent.

135. The '269 Patent, the '841 Patent, and the '554 Patent all claim a composition comprising in vitro synthesized mRNA. As discussed above, each of the Accused Products includes mRNA, which is synthesized in vitro.



3. Chemistry Manufacturing and Controls

a. Product Quality

Description of Active Ingredient

SPIKEVAX is an mRNA-based vaccine indicated for active immunization for prevention of COVID-19. The mRNA in SPIKEVAX is called mRNA-1273 and is comprised of an open reading frame of 3819 nucleotides encoding the full-length S glycoprotein (from Wuhan-Hu-1 isolate of SARS-CoV-2 virus) modified to introduce two proline residues that stabilize the S glycoprotein in pre-fusion conformation. The mRNA also contains four regulatory elements: 5' and 3' untranslated regions (UTRs) which increase translational fidelity and confer robust protein expression, a 3' poly(A) tail sequence which promotes mRNA stability, and a 5' cap structure (b) (4) which mediates efficient translation. The mRNA is transcribed using N1-methyl-pseudoruridine instead of uridine nucleoside to minimize indiscriminate recognition of exogenous mRNA by pathogen-associated cellular receptors and to reduce the overall reactogenicity of synthetic mRNA. The in vitro transcribed single-stranded mRNA is encapsulated in a lipid nanoparticle (b) (4) composed of four lipids: SM-102 (a custom-manufactured, ionizable lipid); PEG2000-DMG; cholesterol, and DSPC. SPIKEVAX multiple-dose vials contain a frozen suspension that does not contain a preservative and must be thawed prior to administration.

Ex. 31, at 6.

a. Product Quality

Description of Active Ingredient and its Development

MNEXSPIKE is an mRNA-based vaccine indicated for active immunization to prevent COVID-19 disease caused by SARS-CoV-2 virus in individuals 12 years of age and older who have been previously vaccinated with any COVID-19 vaccine. The mRNA in MNEXSPIKE is called mRNA-1283 and is comprised of the N-terminal domain (NTD) and receptor-binding domain (RBD) of the SARS-CoV-2 Spike (S) glycoprotein. The NTD and RBD sequences are linked together with a 7-amino acid (aa) flexible linker (NTD-RBD). The linked NTD-RBD polypeptide is attached via a (b) (4) linker to a 23-aa influenza hemagglutinin transmembrane domain (HATM), which anchors the linked NTD-RBD antigen to the host cell membrane. The mRNA also contains four regulatory elements: 5' and 3' untranslated regions (UTRs) which increase translational fidelity and confer robust protein expression, a 3' poly(A) tail sequence which promotes mRNA stability, and a 5' cap structure ((b) (4)) which mediates efficient translation. The mRNA is transcribed using N1-methyl-pseudoruridine instead of uridine nucleoside to minimize indiscriminate recognition of exogenous mRNA by pathogen-associated cellular receptors and to reduce the overall reactogenicity of synthetic mRNA. The in vitro transcribed single-stranded mRNA is encapsulated in a lipid nanoparticle ((b) (4)) composed of four lipids: SM-102 (a custom-manufactured, ionizable lipid); PEG2000-DMG; cholesterol, and DSPC. MNEXSPIKE is supplied as a frozen suspension that does not contain a preservative and must be thawed prior to administration.

Ex. 42, at 6.

Manufacturing Overview

The manufacturing process for the DS consists of (b) (4) main steps: (b) (4) . The DP (MRESVIA) is manufactured by adjusting the concentration of the LNP-100-AR02 to the target RNA dose and formulation with a cryoprotectant, followed by sterile filtration, filling into syringes, labeling and packaging.

Ex. 44, at 6.

136. On information and belief, SPIKEVAX® contains less than 1% and/or less than 5% of prematurely aborted RNA sequences and/or enzyme reagents. Ex. 45, at 19.

137. On information and belief, MNEXSPIKE® contains less than 1% and/or less than 5% of prematurely aborted RNA sequences and/or enzyme reagents. Ex. 34, at 11.

138. On information and belief, MRESVIA® contains less than 1% and/or less than 5% of prematurely aborted RNA sequences and/or enzyme reagents. Ex. 43, at 11.

139. On information and belief, SPIKEVAX® is substantially free of prematurely aborted RNA sequences of less than 15 bases in length.

140. On information and belief, SPIKEVAX® comprises one or more 1-methyl-pseudouracil nucleosides. *See* Ex. 15 at 50; Ex. 31, at 6.

> Each 0.5 mL dose of SPIKEVAX (2025-2026 Formula) contains 50 mcg nucleoside-modified messenger RNA (mRNA) encoding the pre-fusion stabilized Spike glycoprotein (S) of the

141. As discussed above, SPIKEVAX® is suitable for administration as a pharmaceutical product to a human subject. Ex. 15, at 3.

142. On information and belief, MNEXSPIKE® is substantially free of prematurely aborted RNA sequences of less than 15 bases in length.

143. On information and belief, MNEXSPIKE® comprises one or more 1-methyl-pseudouracil nucleosides. *See* Ex. 16 at 20; Ex. 42, at 6.

> Each 0.2 mL dose of MNEXSPIKE (2025-2026 Formula) contains 10 mcg nucleoside-modified messenger RNA (mRNA) encoding the N-terminal domain (NTD) and receptor-binding domain

144. As discussed above, MNEXSPIKE® is suitable for administration as a pharmaceutical product to a human subject. Ex. 16, at 2.

145. On information and belief, MRESVIA® is substantially free of prematurely aborted RNA sequences of less than 15 bases in length.

146. On information and belief, MRESVIA® comprises one or more 1-methyl-pseudouracil nucleosides. *See* Ex. 17 at 8.

> Each 0.5 mL dose of MRESVIA contains 50 mcg of nucleoside modified mRNA encoding the F glycoprotein from RSV subtype A stabilized in the prefusion conformation (pre-F protein).

147. As discussed above, MRESVIA® is suitable for administration as a pharmaceutical product to a human subject. Ex. 16, at 2.

FIRST CAUSE OF ACTION
(Infringement of the '754 Patent)

148. Sanofi realleges and incorporates by reference the allegations contained in the foregoing paragraphs.

149. On information and belief, Moderna, without authority, has infringed and will continue to infringe at least one claim of the '754 Patent pursuant to 35 U.S.C. § 271(b). The prescribing information of Moderna's Accused Products intentionally and actively induces doctors, nurses, pharmacists, and other healthcare providers ("Healthcare Professionals") to perform the patented method of delivering a messenger RNA (mRNA) for in vivo production of a protein by administering the Accused Products to humans.

150. On information and belief, Moderna, without authority, has also infringed and will continue to infringe at least one claim of the '754 Patent pursuant to 35 U.S.C. § 271(c) by offering for sale the Accused Products, which can only be used in a manner that infringes the patented method.

151. Moderna's infringement has damaged and will continue to damage Sanofi, 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 '618 Patent)

152. Sanofi realleges and incorporates by reference the allegations contained in the foregoing paragraphs.

153. On information and belief, Moderna, without authority, has infringed and will continue to infringe at least one claim of the '618 Patent pursuant to 35 U.S.C. § 271(b). The prescribing information of Moderna's Accused Products intentionally and actively induces

Healthcare Professionals to perform the patented method of delivering a messenger RNA (mRNA) for in vivo production of a protein by administering the Accused Products to humans.

154. On information and belief, Moderna, without authority, has also infringed and will continue to infringe at least one claim of the '618 Patent pursuant to 35 U.S.C. § 271(c) by offering for sale the Accused Products, which can only be used in a manner that infringes the patented method.

155. Moderna's infringement has damaged and will continue to damage Sanofi, 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 '734 Patent)

156. Sanofi realleges and incorporates by reference the allegations contained in the foregoing paragraphs.

157. On information and belief, Moderna, without authority, has infringed and will continue to infringe at least one claim of the '734 Patent pursuant to 35 U.S.C. § 271(b). The prescribing information of Moderna's Accused Products intentionally and actively induces Healthcare Professionals to perform the patented method of delivering a messenger RNA (mRNA) for in vivo production of a protein by administering the Accused Products to humans.

158. On information and belief, Moderna, without authority, has also infringed and will continue to infringe at least one claim of the '734 Patent pursuant to 35 U.S.C. § 271(c) by offering for sale the Accused Products, which can only be used in a manner that infringes the patented method.

159. Moderna's infringement has damaged and will continue to damage Sanofi, 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.

FOURTH CAUSE OF ACTION
(Infringement of the '044 Patent)

160. Sanofi realleges and incorporates by reference the allegations contained in the foregoing paragraphs.

161. On information and belief, Moderna, without authority, has infringed and will continue to infringe at least one claim of the '044 Patent pursuant to 35 U.S.C. § 271(b). The prescribing information of Moderna's Accused Products intentionally and actively induces Healthcare Professionals to perform the patented method of delivering a messenger RNA (mRNA) for in vivo production of a protein by administering the Accused Products to humans.

162. On information and belief, Moderna, without authority, has also infringed and will continue to infringe at least one claim of the '044 Patent pursuant to 35 U.S.C. § 271(c) by offering for sale the Accused Products, which can only be used in a manner that infringes the patented method.

163. Moderna's infringement has damaged and will continue to damage Sanofi, 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.

FIFTH CAUSE OF ACTION
(Infringement of the '764 Patent)

164. Sanofi realleges and incorporates by reference the allegations contained in the foregoing paragraphs.

165. On information and belief, Moderna has literally infringed and will continue to literally infringe at least one claim of the '764 Patent, pursuant to 35 U.S.C. § 271(a) by making,

using, selling, offering to sell or importing its Accused Products containing patented LNP technology within the United States and without authority.

166. On information and belief, Moderna, without authority, has infringed and will continue to infringe at least one claim of the '764 Patent pursuant to 35 U.S.C. § 271(b). The prescribing information of Moderna's Accused Products intentionally and actively induces Healthcare Professionals to perform the patented method of delivering a messenger RNA (mRNA) for in vivo production of a protein by administering the Accused Products to humans.

167. Moderna's infringement has damaged and will continue to damage Sanofi, 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.

SIXTH CAUSE OF ACTION
(Infringement of the '005 Patent)

168. Sanofi realleges and incorporates by reference the allegations contained in the foregoing paragraphs.

169. On information and belief, Moderna has infringed and will continue to infringe at least one claim of the '005 Patent, pursuant to at least 35 U.S.C. § 271(a) by making, using, selling, offering to sell or importing its Accused Products containing SM-102 within the United States and without authority.

170. On information and belief, Moderna, without authority, has infringed and will continue to infringe at least one claim of the '005 Patent pursuant to 35 U.S.C. § 271(b). On information and belief, Moderna actively induces others to purify the Accused Products containing SM-102 within the United States and without authority.

171. Moderna's infringement has damaged and will continue to damage Sanofi, 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.

SEVENTH CAUSE OF ACTION
(Infringement of the '885 Patent)

172. Sanofi realleges and incorporates by reference the allegations contained in the foregoing paragraphs.

173. On information and belief, Moderna has infringed and will continue to infringe at least one claim of the '885 Patent, pursuant to at least 35 U.S.C. § 271(a), literally or under the doctrine of equivalents, by making, using, selling, offering to sell or importing its Accused Products containing SM-102 within the United States and without authority.

174. On information and belief, Moderna, without authority, has infringed and will continue to infringe at least one claim of the '885 Patent pursuant to 35 U.S.C. § 271(b). On information and belief, Moderna actively induces others to purify the Accused Products containing SM-102 within the United States and without authority.

175. Moderna's infringement has damaged and will continue to damage Sanofi, 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.

EIGHTH CAUSE OF ACTION
(Infringement of the '269 Patent)

176. Sanofi realleges and incorporates by reference the allegations contained in the foregoing paragraphs.

177. On information and belief, Moderna has infringed and will continue to infringe at least one claim of the '269 Patent, pursuant to at least 35 U.S.C. § 271(a), literally or under the doctrine of equivalents, by making, using, selling, offering to sell or importing its Accused

Products with less than 1% of prematurely aborted mRNA sequences and/or enzyme impurities within the United States and without authority.

178. On information and belief, Moderna, without authority, has infringed and will continue to infringe at least one claim of the '269 Patent pursuant to 35 U.S.C. § 271(b). On information and belief, Moderna actively induces others to purify the Accused Products such that they contain less than 1% of prematurely aborted mRNA sequences and/or enzyme impurities.

179. Moderna's infringement has damaged and will continue to damage Sanofi, 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.

NINTH CAUSE OF ACTION
(Infringement of the '841 Patent)

180. Sanofi realleges and incorporates by reference the allegations contained in the foregoing paragraphs.

181. On information and belief, Moderna has infringed and will continue to infringe at least one claim of the '841 Patent, pursuant to at least 35 U.S.C. § 271(a), literally or under the doctrine of equivalents, by making, using, selling, offering to sell or importing its Accused Products with less than 5% of prematurely aborted mRNA sequences and/or enzyme impurities within the United States and without authority.

182. On information and belief, Moderna, without authority, has infringed and will continue to infringe at least one claim of the '841 Patent pursuant to 35 U.S.C. § 271(b). On information and belief, Moderna actively induces others to purify the Accused Products such that they comprise less than 5% of prematurely aborted mRNA sequences and/or enzyme impurities.

183. Moderna's infringement has damaged and will continue to damage Sanofi, 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.

TENTH CAUSE OF ACTION
(Infringement of the '554 Patent)

184. Sanofi realleges and incorporates by reference the allegations contained in the foregoing paragraphs.

185. On information and belief, Moderna has infringed and will continue to infringe at least one claim of the '554 Patent, pursuant to at least 35 U.S.C. § 271(a), literally or under the doctrine of equivalents, by making, using, selling, offering to sell or importing the Accused Products, which are substantially free of prematurely aborted RNA sequences of less than 15 bases, comprise modified nucleosides, and are pharmacologically suitable for administration to humans within the United States and without authority.

186. On information and belief, Moderna, without authority, has infringed and will continue to infringe at least one claim of the '554 Patent pursuant to 35 U.S.C. § 271(b). On information and belief, Moderna actively induces others to purify and modify the Accused Products for administration to humans such that they are substantially free of prematurely aborted RNA sequences that are less than 15 bases long and comprise a modified nucleoside.

187. Moderna's infringement has damaged and will continue to damage Sanofi, 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, Sanofi prays for a judgment in its favor and against Moderna and respectfully requests the following relief:

A. A judgment that Moderna actively induces infringement of the '754 Patent;

B. A judgment that Moderna contributes to infringement of the '754 Patent;

C. A judgment that Moderna actively induces infringement of the '618 Patent;

D. A judgment that Moderna contributes to infringement of the '618 Patent;

E. A judgment that Moderna actively induces infringement of the '734 Patent;

F. A judgment that Moderna contributes to infringement of the '734 Patent;

G. A judgment that Moderna actively induces infringement of the '044 Patent;

H. A judgment that Moderna contributes to infringement of the '044 Patent;

I. A judgment that Moderna directly infringes the '764 Patent;

J. A judgment that Moderna actively induces infringement of the '764 Patent;

K. A judgment that Moderna directly infringes the '005 Patent;

L. A judgment that Moderna actively induces infringement of the '005 Patent;

M. A judgment that Moderna directly infringes the '885 Patent;

N. A judgment that Moderna actively induces infringement of the '885 Patent;

O. A judgment that Moderna directly infringes the '269 Patent;

P. A judgment that Moderna actively induces infringement of the '269 Patent;

Q. A judgment that Moderna directly infringes the '841 Patent;

R. A judgment that Moderna actively induces infringement of the '841 Patent;

S. A judgment that Moderna directly infringes the '554 Patent;

T. A judgment that Moderna actively induces infringement of the '554 Patent;

U. Damages or other monetary relief, including post-judgment monetary relief and pre- and post-judgment interest, to Sanofi;

V. Costs and expenses in this action;

W. An order awarding Sanofi any such other relief as the Court may deem just and proper under the circumstances.

JURY DEMAND

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

July 14, 2026

ROBINSON MILLER LLC

/s/ Keith J. Miller
Keith Miller (021561993)
110 Edison Place, Suite 302
Newark, NJ 07102
(973) 690-5400

Attorneys for Plaintiffs

OF COUNSEL:

MCDERMOTT WILL & SCHULTE LLP
Sarah Chapin Columbia (*pro hac vice forthcoming*)
Sarah Fischer (*pro hac vice forthcoming*)
Taylor MacDonald (*pro hac vice forthcoming*)
200 Clarendon Street, Floor 58
Boston, MA 02116
(617) 535-4000