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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. PFIZER INC. AND PHARMACIA & UPJOHN CO. LLC, 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 Pfizer Inc. and Pharmacia & Upjohn Co. LLC (collectively, "Pfizer").

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. 35. Translate Bio's inventions relate to mRNA purity, therapeutic mRNA delivery in humans, and corresponding lipid compositions for delivery of mRNA, like Pfizer'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"), 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 eight patents protect Translate Bio's methods and compositions for mRNA delivery. Exs. 1-8.

2. Among its various products, Pfizer currently markets mRNA vaccines, including under an Emergency Use Authorization and under the trade name COMIRNATY® (collectively, "COMIRNATY®"). COMIRNATY® contains purified mRNA, which is protected and delivered by lipid nanoparticles ("LNPs"), which, in turn, are composed of four separate lipids, including ALC-0315. These LNPs safely deliver mRNA into human cells, which triggers the immune system to begin developing defenses. COMIRNATY® is sold with corresponding prescribing information, which instructs healthcare professionals how to administer the mRNA-based vaccine to humans. In using purified mRNA, encapsulated in an LNP containing ALC-0315, providing the prescribing

[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 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.

information, and other actions, Pfizer 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 Pfizer'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 Vaccines 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 Pfizer Inc. is a company organized under the laws of the State of Delaware with its principal place of business at 66 Hudson Boulevard East New York, NY 10001. Upon information and belief, Defendant Pfizer Inc. maintains business operations in at least two New Jersey locations. The Morris County Chamber of Commerce lists a Pfizer site at 400 Webro Road, Parsippany, NJ 07054. Ex. 9. Likewise, upon information and belief, Defendant Pfizer Inc. has a location in Hudson County at 15 Enterprise Ave N in Secaucus, New Jersey 07094. Ex. 10.

9. Upon information and belief, Defendant Pfizer Inc. maintains one or more facilities, including in Kalamazoo, Michigan, under the name Pfizer CentreOne, as a subsidiary of Pfizer Inc. and/or Defendant Pfizer Inc. is doing business as Pfizer CentreOne at one or more facilities, including in Kalamazoo, Michigan. Upon information and belief, Pfizer Laboratories, a division of Defendant Pfizer Inc., prepares the package inserts for COMIRNATY® that are accepted by the FDA. Ex. 11. Upon information and belief, Defendant Pfizer Inc. recognizes the revenue from sales of Defendants' COVID-19 Vaccine. Ex. 12.

10. Upon information and belief, Defendant Pharmacia & Upjohn Co. LLC is a company organized under the laws of the State of Delaware with its principal place of business at 100 Route 206 N, Peapack, New Jersey, 07977. Upon information and belief, Defendant Pharmacia & Upjohn Co. LLC is a wholly-owned subsidiary of Defendant Pfizer Inc. The initial BLA Approval Letter for COMIRNATY® states that, "[t]he final formulated product will be manufactured, filled, labeled and packaged . . . at Pharmacia & Upjohn Company LLC, 7000 Portage Road, Kalamazoo, Michigan." Ex. 13, at 1.

11. On information and belief, Defendants Pfizer Inc. and Pharmacia & Upjohn Co. LLC are agents of each other and/or work in concert with each other with respect to the development, regulatory approval, marketing, making, sales, offers for sale, import and export, and distribution of Defendants' COMIRNATY® product containing ALC-0315.

JURISDICTION AND VENUE

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

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

14. This Court has personal jurisdiction over Defendant Pfizer Inc. because it has purposefully availed itself of this forum. Upon information and belief, it directly or indirectly uses, offers for sale, and/or sells COMIRNATY® throughout the United States, including in this judicial district.

15. And, as mentioned above, Defendant Pfizer Inc. also, upon information and belief, has at least two regularly established places of business within this District: one in Parsippany and another in Secaucus.

16. Furthermore, Defendant Pfizer Inc., on more than one occasion, either brought suit or chose not to contest personal jurisdiction in this District. *See, e.g.*, *Pfizer Inc. v. Zydus Pharmaceuticals (USA) Inc.*, Civil Action No. 1:22-cv-00899 (D.N.J. 2022) (bringing a patent infringement suit in this District); *Arbutus Biopharma Corp. v. Pfizer Inc.*, Civil Action No. 3:23-cv-1876 (D.N.J. 2023) (not contesting personal jurisdiction in a patent case in this District).

17. This Court has jurisdiction over Defendant Pharmacia & Upjohn Co. LLC because, upon information and belief, it directly or indirectly, uses, offers for sale, and/or sells COMIRNATY® throughout the United States, including in this judicial district. This Court also has jurisdiction over Defendant Pharmacia & Upjohn Co. LLC because, based on information and belief, it has a principal place of business in this District, at 100 Route 206 N, Peapack, New Jersey, 07977.

18. Venue is proper in this Court under 28 U.S.C. § 1400(b) because, upon information and belief, Pfizer Inc. directly or indirectly uses, offers for sale, and/or sells COMIRNATY® throughout the United States, including in this judicial district. Defendant Pfizer Inc. also, upon information and belief, maintains places of business in at least two locations within this Court's jurisdiction.

19. Also, as discussed above, Pfizer Inc.'s past actions have demonstrated that this forum is a convenient one in which to litigate claims against it or on its behalf.

20. Furthermore, venue is proper in this Court under 28 U.S.C. § 1400(b) because, upon information and belief, Pharmacia & Upjohn Co. LLC resides at 100 Route 206 N, Peapack, New Jersey, 07977.

BACKGROUND

RNA Therapeutics

21. 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.

22. 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.

23. 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.

24. 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.

25. 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.

26. 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

27. 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 mRNA of specific purities. *See* Exs. 6-8.

28. 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.

29. The mRNA therapeutics team at Shire was among the first to use lipid nanoparticles to deliver mRNA in vivo. The team also developed methods of synthesizing mRNA that produced

high purity and high potency mRNA. This resulted in the first mRNA therapeutic to enter human clinical trials in the chronic disease space. The scientists in the team worked on therapies for a number of diseases.

30. In 2013, scientists from Shire presented at the 1st International mRNA Health Conference in Germany. Ex. 15. Their presentation included efficacy data that showed the early successes that they had had with mRNA manufacture and delivery.

31. 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.

32. 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. 33. At the same time, in April 2020, Sanofi partnered with GSK to develop a protein vaccine. Ex. 34. 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. 24. The protein vaccine was approved in 2022 in Europe and was on the market until 2024. Ex. 25. As of 2024, Sanofi, in collaboration with Novavax, has marketed another COVID-19 protein vaccine, both in the US and abroad. Ex. 14.

The Patents-in-Suit

33. 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 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. 6-7. On March 14, 2013, Translate Bio filed U.S. Provisional Application No. 61/784,996, to which the '554 Patent claims priority. Ex. 8. To date, over 600 patents, including 123 U.S. patents, have issued to Translate Bio out of its mRNA delivery inventions.

34. 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.

35. 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.

36. 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.

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

38. 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.

39. 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.

40. 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.

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

42. 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.

43. 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.

44. 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 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
> >
> > 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.

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

46. 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.

47. 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.

48. 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

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

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

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

50. 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.

51. 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.

52. 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.

[4] Amended from 10% in a March 22, 2023, Certificate of Correction. Ex. 5.

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

54. 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.

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

56. 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.

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

58. 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.

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

60. 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.

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

62. 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.

63. 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.

64. 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.

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

Pfizer's COMIRNATY® Product

66. On March 17, 2020, Pfizer Inc. and BioNTech SE ("BioNTech"), a German biotechnology company, issued a press release that they would jointly develop a vaccine for COVID-19. Ex. 16. The Collaboration Agreement memorializing the collaboration is publicly available. Ex. 17. Therein, the parties agreed that Pfizer Inc. has the exclusive right in the United States to "market, promote, distribute, offer for sale, sell, have sold, import, have imported, export, have exported or otherwise commercialize" the resulting product. *Id.* §1.25 (defining "Commercialize"); §1.6 (defining "BioNTech Commercialization Territory"); §1.88 (defining

"Pfizer Commercialization Territory")). Furthermore, Pfizer Inc. obtained the right to "make, produce, manufacture, process, fill, finish, package, label, perform quality assurance testing, release, ship or store, and for the purposes of further manufacturing, distribute, import or export" Defendants' COVID-19 Vaccine or "any component thereof" in the United States. (*Id.*, §1.75 (defining "Manufacture"); §3.2 ("Licenses for Commercial Manufacturing")).

67. Upon information and belief, Pfizer and BioNTech had produced sufficient doses of four vaccine candidates for a clinical trial in Germany on or around April 22, 2020, and in the United States on or around May 5, 2020. Exs. 18-19.

68. By July 27, 2020, the companies had selected "nucleoside-modified messenger RNA (modRNA) candidate BNT162b2, which encodes an optimized SARSCoV-2 full-length spike glycoprotein, at a 30μg dose level in a 2 dose regimen into Phase 2/3 Study." Ex. 20 at 1. That candidate eventually became COMIRNATY®. Upon information and belief, that candidate also comprised ALC-0315.

69. The FDA first approved Pfizer's application for Emergency Use Authorization (EUA) of the vaccine on December 11, 2020, under the tradename Pfizer-BioNTech COVID-19 Vaccine. Exs. 21-22.

70. On August 23, 2021, the vaccine received FDA approval for individuals above the age of fifteen under the tradename COMIRNATY®. Ex. 23.

71. Since the original EUA grant, Pfizer has sold millions of doses of COMIRNATY®. *See, e.g.*, Ex. 12.

72. Upon information and belief, each dose of COMIRNATY® made, sold, and used contains LNPs that include mRNA and the ionizable cationic lipid ALC-0315. Ex. 26.

73. Upon information and belief, COMIRNATY® has been very successful on the market. Indeed, Pfizer enjoyed revenue of over $4.3 billion globally, and over $1.6 billion nationally, on COMIRNATY® in 2025 alone. Ex. 12, at 38.

PFIZER'S INFRINGING ACTIVITIES

74. 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 COMIRNATY®. In order to deliver the delicate mRNA into human cells, healthcare professionals administering COMIRNATY® 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.

75. Administration of the COMIRNATY® vaccine infringes the '754 Patent, the '618 Patent, the '734 Patent, and the '044 Patent. Pfizer actively induces health care professionals to deliver COMIRNATY® through its prescribing information and advertisements. *See* Ex. 26.

76. The prescribing information instructs healthcare professionals to administer the vaccine intramuscularly to human patients. *See* Ex. 26, at 2.

1 INDICATIONS AND USAGE

COMIRNATY 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).

COMIRNATY is approved for use in individuals who are:

- 65 years of age and older, or
- 5 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 Information

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. For the prefilled syringe, the vaccine will be a white to off-white suspension and for the vial, the vaccine will be clear to slightly opalescent suspension. Do not administer if vaccine is discolored or contains particulate matter.

Administer the 0.3 mL dose intramuscularly immediately after preparation. For the prefilled syringe, administer the entire volume to deliver a single 0.3 mL dose.

77. The COMIRNATY® vaccine comprises mRNA that encodes a protein, namely, the COVID-19 spike glycoprotein. *See* Ex. 26, at 29.

> Each 0.3 mL dose of COMIRNATY (2025-2026 Formula) is formulated to contain 30 mcg of a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2 Omicron variant sublineage LP.8.1.

78. The mRNA in the COMIRNATY® vaccine is encapsulated by an LNP. *See* Ex. 26, at 30.

> **12.1 Mechanism of Action**
>
> The nucleoside-modified mRNA in COMIRNATY is formulated in lipid particles, which enable delivery of the 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.

79. On information and belief, the COMIRNATY® vaccine results in the expression of the encoded spike protein and/or peptide detectable in serum at least 72 hours after administration. *See* Ex. 27, at 1033.

80. On information and belief, the COMIRNATY® 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. 28, at 1.

81. The COMIRNATY® vaccine contains PEG-modified lipids (i.e., ALC-0159) and a non-cationic lipid (DSPC). *See* Ex. 26, at 29.

> Each 0.3 mL dose of COMIRNATY also includes the following ingredients:
> lipids (0.14 mg ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate),
> 0.02 mg 2-(polyethylene glycol 2000)-N,N-ditetradecylacetamide,
> 0.03 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.06 mg cholesterol), 0.06 mg tromethamine, 0.4 mg tromethamine hydrochloride, and 31 mg sucrose.

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

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

84. On information and belief, that LNP is smaller than 150 nm. Ex. 29, at 2.

85. Furthermore, on information and belief, the COMIRNATY® vaccine's LNP has the claimed molar ratios of the '044 Patent and the '764 Patent. Ex. 30, at 4.

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

87. 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 Pfizer purifies COMIRNATY®, COMIRNATY® infringes at least one claim of the '269 Patent and the '841 Patent.

88. 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 Pfizer purifies COMIRNATY®, COMIRNATY® infringes at least one claim of the '554 Patent.

89. The '269 Patent, the '841 Patent, and the '554 Patent all claim a composition comprising in vitro synthesized mRNA. As discussed above, COMIRNATY® includes mRNA, which is synthesized in vitro.

3. Chemistry, Manufacturing and Controls (CMC)

a. Product Quality

COMIRNATY Manufacturing Overview

COMIRNATY contains a nucleoside-modified messenger RNA (mRNA) encoding the viral spike glycoprotein (S) of SARS-CoV-2 that is formulated in lipids including ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2- hexyldecanoate), 2-(polyethylene glycol 2000)-N,N-ditetradecylacetamide, 1,2-distearoyl-sn-glycero-3-phosphocholine, and cholesterol. COMIRNATY is supplied as a frozen suspension to be diluted with a diluent, 0.9% Sodium Chloride Injection, USP, that is supplied separately or can be acquired elsewhere, if necessary. Manufacture of the mRNA drug substance will take place in Andover, MA, USA. The final formulated drug product will be manufactured, filled, finished, labeled and packaged in Puurs, Belgium or in Kalamazoo, MI, USA. The 0.9% Sodium Chloride Injection, USP diluent will be manufactured by Fresenius-Kabi USA, LLC ((b) (4)) and Hospira, Inc. ((b) (4)).

Ex. 31, at 6.

90. On information and belief, COMIRNATY® contains less than 1% and/or less than 5% of prematurely aborted RNA sequences and/or enzyme reagents. Ex. 32, at 53, Table S.2.6.4-5; 57.

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

92. On information and belief, COMIRNATY® comprises one or more 1-methyl-pseudouracil nucleosides. *See* Ex. 26 at 29.

Each 0.3 mL dose of COMIRNATY (2025-2026 Formula) is formulated to contain 30 mcg of a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2 Omicron variant sublineage LP.8.1.

93. As discussed above, COMIRNATY® is suitable for administration as a pharmaceutical product to a human subject. Ex. 26, at 2.

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

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

95. On information and belief, Pfizer, 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 COMIRNATY® 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 COMIRNATY® to humans.

96. On information and belief, Pfizer, 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 COMIRNATY®, which can only be used in a manner that infringes the patented method.

97. Pfizer's infringement has damaged and will continue to damage Sanofi, which is entitled to recover the damages resulting from Pfizer'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)

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

99. On information and belief, Pfizer, 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 package inserts of COMIRNATY® 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 COMIRNATY® to humans.

100. On information and belief, Pfizer, 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 COMIRNATY®, which can only be used in a manner that infringes the patented method.

101. Pfizer's infringement has damaged and will continue to damage Sanofi, which is entitled to recover the damages resulting from Pfizer'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)

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

103. On information and belief, Pfizer, 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 package inserts of COMIRNATY® 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 COMIRNATY® to humans.

104. On information and belief, Pfizer, 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 COMIRNATY®, which can only be used in a manner that infringes the patented method.

105. Pfizer's infringement has damaged and will continue to damage Sanofi, which is entitled to recover the damages resulting from Pfizer'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)

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

107. On information and belief, Pfizer, 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 package inserts of COMIRNATY® 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 COMIRNATY® to humans.

108. On information and belief, Pfizer, 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 COMIRNATY®, which can only be used in a manner that infringes the patented method.

109. Pfizer's infringement has damaged and will continue to damage Sanofi, which is entitled to recover the damages resulting from Pfizer'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)

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

111. On information and belief, Pfizer 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 COMIRNATY®, which contains patented LNP technology, within the United States and without authority.

112. On information and belief, Pfizer, 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 package inserts of COMIRNATY® 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 COMIRNATY® to humans.

113. Pfizer's infringement has damaged and will continue to damage Sanofi, which is entitled to recover the damages resulting from Pfizer'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 '269 Patent)

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

115. On information and belief, Pfizer 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 COMIRNATY® with less than 1% of prematurely aborted mRNA sequences and/or enzyme impurities within the United States and without authority.

116. On information and belief, Pfizer, 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, Pfizer actively induces others to purify COMIRNATY® such that it contains less than 1% of prematurely aborted mRNA sequences and/or enzyme impurities.

117. Pfizer's infringement has damaged and will continue to damage Sanofi, which is entitled to recover the damages resulting from Pfizer'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 '841 Patent)

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

119. On information and belief, Pfizer 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 COMIRNATY® with less than 5% of prematurely aborted mRNA sequences and/or enzyme impurities within the United States and without authority.

120. On information and belief, Pfizer, 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, Pfizer actively induces others to purify COMIRNATY® such that it comprises less than 5% of prematurely aborted mRNA sequences and/or enzyme impurities.

121. Pfizer's infringement has damaged and will continue to damage Sanofi, which is entitled to recover the damages resulting from Pfizer'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 '554 Patent)

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

123. On information and belief, Pfizer 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 COMIRNATY® that is substantially free of prematurely aborted RNA sequences of less than 15 bases, comprises modified nucleosides, and is pharmacologically suitable for administration to humans within the United States and without authority.

124. On information and belief, Pfizer, 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, Pfizer actively induces others to purify and modify COMIRNATY® for administration

to humans such that it is substantially free of prematurely aborted RNA sequences that are less than 15 bases long and comprises a modified nucleoside.

125. Pfizer's infringement has damaged and will continue to damage Sanofi, which is entitled to recover the damages resulting from Pfizer'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 Pfizer and respectfully requests the following relief:

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

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

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

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

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

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

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

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

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

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

K. A judgment that Pfizer directly infringes the '269 Patent;

L. A judgment that Pfizer actively induces infringement of the '269 Patent;

M. A judgment that Pfizer directly infringes the '841 Patent;

N. A judgment that Pfizer actively induces infringement of the '841 Patent;

O. A judgment that Pfizer directly infringes the '554 Patent;

P. A judgment that Pfizer actively induces infringement of the '554 Patent;

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

R. Costs and expenses in this action;

S. 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.

Dated: July 14, 2026

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