IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GLAXOSMITHKLINE BIOLOGICALS SA and GLAXOSMITHKLINE LLC, Plaintiffs, v. MODERNA, INC., MODERNATX, INC., and MODERNA US, INC., Defendants.	)	C.A. No. 24-1135 (GBW) **JURY TRIAL DEMANDED**

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs GlaxoSmithKline Biologicals SA ("GSK Biologicals") and GlaxoSmithKline LLC ("GSK LLC") (collectively, "GSK"), by their attorneys for this Complaint against Defendants Moderna, Inc., ModernaTX, Inc., and Moderna US, Inc. (collectively, "Moderna"), allege as follows:

INTRODUCTION

1. GSK Biologicals researches, develops, and manufactures innovative vaccines and specialty medicines to serve patients and healthcare professionals worldwide. GSK Biologicals is the sole owner and assignee of numerous United States patents directed to compositions and formulations comprising lipids and messenger ribonucleic acid ("mRNA") molecules encoding a protein immunogen, methods for obtaining the same, and methods of administering the same to elicit an immune response against the immunogen. *See* Exhibits 1–7 (the "Patents-in-Suit," identified in paragraph 8, *infra*).

2. In 2008, more than a decade before the SARS-CoV-2 (2019) coronavirus disease (COVID-19) pandemic, the named inventors of the Patents-in-Suit, Christian Mandl, Andrew Geall, Gillis Otten, Katrin Ramsauer, and Ayush Verma—accomplished scientists with M.D.'s

and/or Ph.D.'s and years of research experience in immunology, biochemistry, microbiology, or formulation science—set their sights on developing mRNA vaccines. Working under the leadership of vaccinologist Christian Mandl (the "Mandl team"), these talented individuals discovered, *inter alia*, formulations comprising lipids and mRNA molecules encoding a viral immunogen that provide protection from viral infection. The Mandl team described the inventions now claimed in the Patents-in-Suit, in patent applications filed in 2010.

3. The Mandl team's innovation has been revolutionary for vaccine development. A significant advantage over other approaches to vaccine design is the ability to employ the technology as a platform to formulate and administer mRNA encoding a wide range of immunogens. The prestigious science journal *Nature* noted in 2021 that "[e]very mRNA company now uses some variation of [the Mandl team's] delivery platform and manufacturing system[.]" Exhibit 8 (Dolgin, "The Tangled History of mRNA Vaccines," *Nature* 597, 318 (2021) ("Dolgin (2021)")) at 323.

4. Another major advance of the Mandl team's inventions over preexisting vaccine technologies is the speed with which a new vaccine candidate can be made and tested. Indeed, in response to the 2013 influenza outbreak in China, the Mandl team created a new mRNA vaccine candidate in just eight days—"in real time the moment that sequence was available." Exhibit 9 (Dolgin, "Injection of Hope," *Nature* 574, S10 (2019)) at S11. *Nature* recognized this achievement as "[t]he current speed record" of vaccine development. *Id*.

5. GSK's patented inventions provide the foundation for Moderna's mRNA vaccine portfolio, including its Spikevax® family of SARS-CoV-2 spike (S) protein mRNA vaccines. Moderna has repeatedly touted the speed at which it produced its original Spikevax® vaccine and

was later able to modify it to address new viral strains. But Moderna has consistently failed to acknowledge how it applied the Mandl team's revolutionary platform to do so.

6. Moderna has reaped billions of dollars in revenue from infringing GSK's Patents-in-Suit, and continues to benefit, without ever obtaining a license. GSK brings this suit to recover a reasonable royalty for Moderna's infringing sales of mRNA vaccines that apply the Mandl team's inventions.

NATURE OF THE ACTION

7. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq*., seeking damages for Moderna's infringing manufacture, use, sale, marketing, offer for sale, and/or importation of its Spikevax® SARS-CoV-2 S protein mRNA vaccine family of products and of its mNEXSPIKE® SARS-CoV-2 S protein mRNA vaccine family of products (collectively, the "Accused Products," as further described and exemplified in paragraphs 38–69, *infra*).

8. As alleged herein, Moderna's activity with respect to the Accused Products has and continues to directly infringe, actively induce infringement of, and/or contribute to the infringement of, one or more claims of the following GSK Biologicals patents directed to lipid-mRNA vaccine formulation technology: U.S. Patent Nos. 11,291,682 (the "'682 patent") (Exhibit 1), 11,324,770 (the "'770 patent") (Exhibit 2), 11,596,645 (the "'645 patent") (Exhibit 3), 11,690,862 (the "'862 patent") (Exhibit 4), 11,707,482 (the "'482 patent") (Exhibit 5), 11,666,534 (the "'534 patent") (Exhibit 6), and 11,786,467 (the "'467 patent") (Exhibit 7) (collectively, the "Patents-in-Suit").

9. At all relevant times, GSK Biologicals has lawfully owned, and continues to lawfully own, all rights, title, and interest in the Patents-in-Suit, including the right to sue and recover for past infringement.

THE PARTIES

10. Plaintiff GSK Biologicals is a corporation organized and existing under the laws of Belgium, with its principal place of business at Avenue Fleming 20, 1300 Wavre, Belgium. GSK Biologicals is the owner of all patents asserted in this litigation.

11. Plaintiff GSK LLC is a limited liability corporation organized and existing under the laws of Delaware, with its principal place of business at 2929 Walnut Street, Suite 1700, Philadelphia, PA 19104. GSK LLC produces and distributes pharmaceutical products. GSK Biologicals has designated GSK LLC as the exclusive distributor of any products covered by the Patents-in-Suit in the United States.

12. On information and belief, Defendant Moderna, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 325 Binney Street, Cambridge, Massachusetts 02142. Moderna, Inc., itself and through its subsidiaries, including ModernaTX, Inc. and Moderna US, Inc., and business partners, develops, manufactures, imports, markets, distributes, offers to sell, and/or sells the Accused Products in the State of Delaware and throughout the United States, for use in the State of Delaware and throughout the United States.

13. On information and belief, Defendant ModernaTX, Inc. is a wholly owned subsidiary of Moderna, Inc. ModernaTX, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 325 Binney Street, Cambridge, Massachusetts 02142. ModernaTX, Inc. is the Biologics License Application (BLA) holder for the Accused Products (BLA 125752) in the United States. Exhibit 10 (January 31, 2022, FDA Spikevax® (original monovalent) vaccine Approval Letter) at 1. ModernaTX, Inc., itself and through its parent company, Moderna, Inc., and sister company, Moderna US, Inc., develops, manufactures, imports, markets, distributes, offers to sell, and/or sells the Accused

Products in the State of Delaware and throughout the United States, for use in the State of Delaware and throughout the United States.

14. On information and belief, Defendant Moderna US, Inc. is a wholly owned subsidiary of Moderna, Inc. Moderna US, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 325 Binney Street, Cambridge, Massachusetts 02142. Moderna US, Inc. itself and through its parent company, Moderna, Inc., and sister company, ModernaTX, Inc., develops, manufactures, imports, markets, distributes, offers to sell, and/or sells the Accused Products in the State of Delaware and throughout the United States, for use in the State of Delaware and throughout the United States.

15. On information and belief, Defendants Moderna Inc., ModernaTX, Inc., and Moderna US, Inc. are agents of one another or work in concert with each other regarding the development, regulatory approval, manufacturing, marketing, offering for sale, sale, or distribution of the Accused Products in the United States.

JURISDICTION AND VENUE

16. This action arises under the patent laws of the United States, including 35 U.S.C. § 100 *et seq*. generally and 35 U.S.C. § 271 *et seq*. specifically.

17. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

18. This Court has personal jurisdiction over Defendants Moderna, Inc., ModernaTX, Inc., and Moderna US, Inc. because each is organized under the laws of Delaware.

19. This Court also has personal jurisdiction over Defendants Moderna, Inc., ModernaTX, Inc., and Moderna US, Inc. because, on information and belief, each has conducted and continues to conduct business in Delaware at least by offering for sale and/or selling the Accused Products in Delaware, and because each has committed and continues to commit acts of

infringement in Delaware. For example, as reported by the United States Center for Disease Control and Prevention ("CDC"), by May 10, 2023, Moderna had delivered to the State of Delaware over 1.07 million doses of Spikevax® (original monovalent) and over 160 thousand doses of Spikevax® (bivalent BA.4/5) (products as described in paragraphs 38–69, *infra*). Exhibit 11 (printout of CDC Data on Spikevax® (original monovalent and bivalent BA.4/5) doses distributed in Delaware, May 10, 2023).[1] And, on information and belief, Defendants Moderna, Inc., ModernaTX, Inc., and Moderna US, Inc. continue to deliver doses of Spikevax® products to the State of Delaware. Therefore, Defendants Moderna, Inc., ModernaTX, Inc., and Moderna US, Inc. have transacted and continue to transact business within Delaware relating to and giving rise to GSK's claims. This Court also has personal jurisdiction over Defendants Moderna, Inc., ModernaTX, Inc., and Moderna US, Inc. because, in connection with its offers for sale and sales of the Accused Products as well as offers for sale and sales of other mRNA vaccine products, they have engaged in and maintain systematic and continuous business contacts in Delaware.

20. Defendants Moderna, Inc., ModernaTX, Inc., and Moderna US, Inc. have consented to this Court's exercise of personal jurisdiction in other litigations involving the Accused Products, including in *Alnylam Pharmaceuticals, Inc. v. Moderna, Inc. et al.*, C.A. No. 22-cv-335-CFC and *Alnylam Pharmaceuticals, Inc. v. Moderna, Inc. et al.*, C.A. No. 23-cv-580-CFC, and Defendants Moderna, Inc. and ModernaTX, Inc. have also consented to this Court's jurisdiction in litigation involving the Accused Products in *Arbutus Biopharma Corp. et al. v. Moderna, Inc. et al.*, C.A. No. 22-cv-252-MSG.

[1] Spreadsheet available at https://data.cdc.gov/Vaccinations/COVID-19-Vaccinations-in-the-United-States-Jurisdi/unsk-b7fc/data_preview; Delaware specific data last accessed, April 10, 2024.

21. Venue is proper in this judicial District pursuant to 28 U.S.C. § 1400(b) because Defendants Moderna, Inc., ModernaTX, Inc., and Moderna US, Inc. are entities organized and existing under the laws of the State of Delaware and therefore reside in Delaware for purposes of venue.

22. Defendants Moderna, Inc., ModernaTX, Inc., and Moderna US, Inc. have consented to this Court as a proper venue in other litigations involving the Accused Products, including in *Alnylam Pharmaceuticals, Inc. v. Moderna, Inc. et al.*, C.A. No. 22-cv-335-CFC and *Alnylam Pharmaceuticals, Inc. v. Moderna, Inc. et al.*, C.A. No. 23-cv-580-CFC, and Defendants Moderna, Inc. and ModernaTX, Inc. have also consented to this Court as a proper venue in litigation involving the Accused Products in *Arbutus Biopharma Corp. et al. v. Moderna, Inc. et al.*, C.A. No. 22-cv-252-MSG.

BACKGROUND

A. The Claimed Inventions

23. In conventional vaccines, a protein (or "polypeptide") is administered to a patient, is recognized as foreign in the body, and triggers the patient's immune response (hence the protein is an "immunogen"). With mRNA vaccines, mRNA that encodes for an immunogenic protein is administered to a patient. If the mRNA can reach the inside of a patient's cells, existing cellular machinery will read instructions encoded by the mRNA to make the protein—a process called "translation"—which then triggers the immune response. *See* Exhibit 1 ('682 Patent) at col. 13, ll. 40–49 ("RNA molecules used with the invention encode a polypeptide immunogen. After administration of the RNA the immunogen is translated in vivo and can elicit an immune response in the recipient.").

24. By 2008, there were many well-understood and significant hurdles to employing mRNA in vaccines. Getting mRNA molecules, intact, from where they are made in the laboratory

into a patient's cells where they could be translated had historically presented seemingly insurmountable challenges. For example, mRNA is chemically fragile—it can degrade quickly even in a controlled laboratory environment. It needs to be protected from the moment of preparation through formulation, storage, handling, administration, and even inside the body following administration. And even if the mRNA remains intact following administration to a patient, the mRNA still needs some way to get into a cell so it can be translated and the immunogenic protein can effectuate an immune response. *See* Exhibit 8 (Dolgin (2021)) at 320 ("In the 1990s and for most of the 2000s, nearly every vaccine company that considered working on mRNA opted to invest its resources elsewhere. The conventional wisdom held that mRNA was too prone to degradation[.]"); Exhibit 12 (Stanton *et al.*, "Messenger RNA as a Novel Therapeutic Approach," *RNA Therapeutics* (*Topics in Med. Chem.* Vol. 27), 237 (2017) ("Stanton (2017)")) at 237 ("The concept of mRNA as a therapeutic platform has historically been ignored owing to challenges in oligonucleotide delivery and, maybe more importantly, the perceived shortcomings of mRNA with regard to stability and immunogenicity.").

25. Despite unsuccessful efforts by others dating back decades, in 2008, Christian Mandl focused his talented team on overcoming the hurdles that had long-hindered development of mRNA vaccines. Exhibit 8 (Dolgin (2021)) at 323. Through extensive experimentation, perseverance, and the unique insights and preferences of these scientists, the Mandl team discovered the novel lipid-mRNA formulations and methods for their preparation and use to raise an immune response that are described and claimed in the Patents-in-Suit.

26. The Mandl team first described their inventions in provisional patent applications filed in July and August 2010.[2] As stated therein, and in the Patents-in-Suit, "[t]he invention utilizes liposomes in which immunogen-encoding RNA is encapsulated. Thus the RNA is (as in a natural virus) separated from any external medium by the liposome's lipid bilayer, and encapsulation in this way has been found to protect RNA …." *See, e.g.,* Exhibit 6 ('534 patent) at 1:65–2:2. "These liposomes are suitable for in vivo delivery of the RNA to a vertebrate cell and so they are useful as components in pharmaceutical compositions for immunizing subjects against various diseases." *Id.* at 1:54–57.

B. Industry Recognition and Adoption

27. The United States government immediately recognized the value of the Mandl team's work. In the wake of the 2009 H1N1 flu pandemic virus outbreak, the Defense Advanced Research Projects Agency ("DARPA"), awarded a contract to fund further research and development by the Mandl team into mRNA vaccine technology for quick deployment in response to new pandemic threats. Exhibit 16 (Lizotte, "Novartis Receives $14M Award from DARPA," Global Biodefense, January 31, 2012) (describing award of DARPA Contract HR0011-12-3-0001).

28. The Mandl team's seminal 2012 publication on this work has been cited over 500 times and viewed over 60,000 times. *See* Exhibit 17 (Geall *et al*., "Nonviral delivery of self-amplifying RNA vaccines," *Proc. Natl. Acad. Sci.* 109(36), 14604-609 (2012) with

[2] *See* Exhibit 13 (U.S. Prov. Patent App. No. 61/361,789, filed July 6, 2010 ("'789 Prov.")); Exhibit 14 (U.S. Prov. Patent App. No. 61/361,830, filed July 6, 2010 ("'830 Prov.")); Exhibit 15 (U.S. Prov. Patent App. No. 61/378,837, filed August 31, 2010 ("'837 Prov.")). The '682, '770, '645, '862, and '482 Patents-in-Suit (Exhibits 1–5) state a claim of priority to and incorporate by reference, the '789 Prov. The '534 and '467 Patents-in-Suit (Exhibits 6 and 7) state a claim of priority to and incorporate by reference, the '830 and '837 Provs.

supplementary information ("Geall (2012)")).[3] In 2017, long before the COVID-19 pandemic, Moderna researchers recognized the Mandl team's published work as "the first" to employ lipid formulations to "form stable particles with mRNA and effectively release the mRNA for protein translation in vivo." Exhibit 12 (Stanton (2017)) at 241. In 2021, *Nature*, citing Geall (2012), identified the Mandl team as "the first team to combine LNPs with an RNA vaccine," and labeled this 2012 contribution the "First mRNA vaccine in lipid nanoparticles tested in mice" on a timeline of events in "The History of mRNA Vaccines." Exhibit 8 (Dolgin (2021)) at 323.

29. As recently recognized by the High Court of Justice of England and Wales:

> The authors [of Geall (2012)] … state that the platform has the potential to "address multiple disease targets" and that the "unique nucleic acid vaccine technology could enable a new generation of potent, versatile, and easily produced vaccines to address the health challenges of the 21st century." … Being CGK [(common general knowledge)], it would lead to the skilled team thinking that there was unlikely to be difficulty applying LNPs in the context of mRNA (as opposed to siRNA) and, more importantly … that LNPs could reasonably be tried for delivering mRNA for vaccine purposes for a range of pathogens: that is what "platform" implies.

Exhibit 18 (July 2, 2024, Judgment in *ModernaTx, Inc. v. Pfizer Ltd. et al.*, [2024] EWHC 1695 (Pat) in Case Nos. HP-2022-000022/27) at 123. Indeed, this robust platform has proven suitable for obtaining an immune response from a wide range of immunogen-encoding mRNA molecules, manifest through its adoption by "[e]very mRNA company." Exhibit 8 (Dolgin (2021)) at 323.

C. GSK Biologicals's Acquisition of the Mandl Team's Inventions

30. At the time that the Mandl team began working on mRNA vaccines, they were employed by Novartis AG or subsidiaries (collectively, "Novartis"). In 2015, GSK Biologicals acquired a substantial portion of Novartis's global vaccines business. *See* Exhibit 19 (March 2, 2015, GSK press release). In that transaction, GSK obtained, among other things, the Mandl

[3] Metrics available at https://www.pnas.org/doi/full/10.1073/pnas.1209367109.

team's inventions, including all rights to the parent applications to the Patents-in-Suit and progeny, including the Patents-in-Suit.

31. GSK continues to research and develop mRNA vaccines—both conventional and self-amplifying, including through various collaborations—and has several vaccine candidates currently advancing in human clinical trials.[4]

D. Moderna's Use and Knowledge of the Mandl Team's Patented Technology

32. On information and belief, Moderna did not begin investigating lipid encapsulation and delivery of immunogen-encoding RNA for vaccination purposes until after the Mandl team's seminal work became public.

33. Moderna was aware of the Mandl team's mRNA vaccine innovations long before it ever developed and commercialized the Accused Products.

34. Indeed, years before marketing the Accused Products, Moderna obtained technical know-how relating to GSK Biologicals's mRNA vaccine platform technology by hiring several former Novartis and GSK employees with first-hand knowledge of the Mandl team's innovations.

35. Since at least 2013, Moderna has cited—indeed, incorporated the full content of—Mandl team patent filings within the text of its own patent applications. *See*, *e.g.*, Exhibit 20 (excerpts from International Publication No. WO2014/152211) at 150–151 ("[T]he nucleic acid molecules, modified nucleic acid molecules and/or mmRNA encoding an immunogen may be delivered to cells to trigger multiple innate response pathways (see International Pub. No. WO2012006377 … and US Patent Publication No. US20130177639; each of which is herein incorporated by reference in its entirety)."); *see also* Exhibits 21–23 (printouts of patent filings and patent applications citing to patents or patent applications in each family of the Patents-in-

[4] *See* https://www.gsk.com/en-gb/innovation/pipeline/; https://www.gsk.com/media/11415/q2-2024-pipeline-assets-and-clinical-trials-report.pdf.

Suit from the Derwent Patents Citation Index, preserved May 30, 2024, April 19, 2024, and August 4, 2024, respectively).[5] And, as noted, in 2017, Moderna researchers identified the Mandl team's seminal publication on this work as the first successful use of lipid-mRNA formulations for *in vivo* protein translation. Exhibit 12 (Stanton (2017)) at 241.

36. Moderna's Accused Products exploit the fundamental technologies invented by the Mandl team and claimed in the Patents-in-Suit. Moderna leveraged the public disclosures of the Mandl team's work and the specialized knowledge of former Novartis and GSK employees to design and develop the Accused Products. But Moderna did not acquire a license to practice the GSK inventions before or since manufacturing and commercializing the Accused Products.

37. Moderna has had knowledge of and specific notice of its infringement of the Patents-in-Suit through its actions in the United States with respect to the Accused Products at least since February 16, 2024. *See* Exhibit 93.

MODERNA'S INFRINGING ACTIVITIES

38. Moderna's manufacture, use, sale, marketing, offer for sale, and/or importation of the Accused Products—including, but not limited to, the original (2019) strain monovalent vaccine ("Spikevax® (original monovalent)"), the bivalent original strain plus BA.1 variant vaccine ("Spikevax® (bivalent BA.1)"), the bivalent original strain plus BA.4/5 variant vaccine ("Spikevax® (bivalent BA.4/5)"), the monovalent XBB.1.5 variant ("Spikevax® (monovalent XBB.1.5)"), the monovalent KP.2 variant ("Spikevax® (monovalent KP.2)"), the monovalent

[5] Information on the Derwent Patents Citation Index is available at https://clarivate.com/products/ip-intelligence/ip-data-and-apis/derwent-patents-citation-index/. Similar information is available publicly through Google Patents. *See*, *e.g.*, Exhibit 24 (Google Patents, Cite By section for the '770 patent, available at https://patents.google.com/patent/US11324770B2/en?oq=US11324770B2, preserved August 3, 2023); Exhibit 25 (Google Patents, Cited By section, for the '534 patent, available at https://patents.google.com/patent/US11666534B2/en?oq=+11%2c666%2c534; preserved August 3, 2023).

JN.1 variant ("Spikevax® (monovalent JN.1)"), and the mNEXSPIKE® JN.1 variant ("mNEXSPIKE® (monovalent JN.1)") products—directly and indirectly infringed and/or continue to infringe the Patents-in-Suit.

A. The Accused Products

39. Each of the Accused Products consists of a suspension of mRNA "encapsulated in lipid particles" supplied as multi-dose vials. *See*, *e.g.*, Exhibit 26 (U.S. Patent No. 10,703,789 Patent Term Extension Application ("'789 PTE"), filed March 30, 2022) at Exhibit 4 thereto (January 2022 Spikevax® (original monovalent) Package Insert) at 1–3, 12, 16; Exhibit 27 (August 31, 2022, FDA Spikevax® (bivalent BA.4/5) EUA Review Memo) at 41; Exhibit 28 (September 2023 FDA Spikevax® (monovalent XBB.1.5) Package Insert) at 1–3, 28, 42–43; Exhibit 29 (August 2024 FDA Spikevax® (monovalent KP.2) Package Insert) at 1–3, 27–28, 42–43; Exhibit 30 (September 2024 FDA Spikevax® (monovalent JN.1) Product Information) at 105, 114, 257, 262; Exhibits 94–97 (mNEXSPIKE® (monovalent JN.1)).

40. On information and belief, and as set forth by example, *infra*, for each of the Accused Products, Moderna used and continues to use the same composition of mRNA, composition of lipid particles, and methods of manufacture whether applying for commercial marketing authorization or approval by the Food and Drug Administration ("FDA") in the United States or the European Medicines Agency ("EMA") in Europe.

41. On information and belief, and as set forth by example, *infra*, for all of the Accused Products, Moderna used and continues to use the same the same composition of mRNA (apart from the sequence encoding the immunogen), composition of lipid particles, and methods of manufacture.

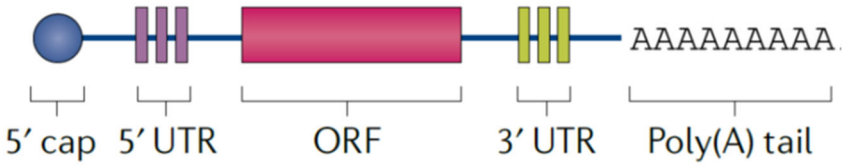
42. Moderna, FDA, and EMA refer to the Spikevax® family of vaccines as "mRNA-1273" products. *See*, *e.g.*, Exhibit 31 (May 18, 2020, Moderna press release); Exhibit 32 (October

18, 2021, FDA Spikevax® (original monovalent) Emergency Use Authorization ("EUA") Review Memo, as revised November 4, 2021); Exhibit 33 (March 11, 2021, EMA Spikevax® (original monovalent) Assessment Report).

43. Spikevax® (original monovalent) contains the mRNA "CX-024414" or "elasomeran" encoding a spike protein of the original (2019) strain of the SARS-CoV-2 coronavirus. *See*, *e.g.*, Exhibit 33 (March 11, 2021, EMA Spikevax® (original monovalent) Assessment Report) at 16–17; Exhibit 34 (January 2, 2024, EMA Spikevax® European Public Assessment Report ("EPAR") Product Information) at 3 ("Elasomeran is a single-stranded, 5'-capped messenger RNA (mRNA) … encoding the viral spike (S) protein of SARS-CoV-2 (original)."); Exhibit 26 ('789 PTE) at 3, 11, Exhibit 4 thereto (January 2022 Spikevax® (original monovalent) Package Insert) at 11, Exhibit 8 thereto (Spikevax® BLA 125752/0 Section 3.2.P.1) at 1, Exhibit 11 thereto (BLA 125752/0 Section 3.2.S.1.2.1) at 1–3 (providing the sequence of the "ORF", a "Codon-optimized sequence encoding full-length SARS-CoV-2 spike (S) glycoprotein …" (position 59–3880)), Exhibit 14 thereto (May 6, 2020, FDA Letter) at 1, and Exhibit 15 thereto (May 11, 2020, FDA Letter) at 1; Exhibit 35 (Proposed International Nonproprietary Names List 125 – COVID-19) at 3.

44. The elasomeran mRNA includes, among other things, a 5' cap, a 5' untranslated region (UTR), an open reading frame region coding for the spike protein, a 3' untranslated region, and a 3' polyA tail. *See*, *e.g.*, Exhibit 33 (March 11, 2021, EMA Spikevax® (original monovalent) Assessment Report) at 17; Exhibit 34 (January 2, 2024, EMA Spikevax® EPAR Product Information) at 3; Exhibit 26 ('789 PTE) at 2–4, 11–12, Exhibit 11 thereto (Spikevax® BLA 125752/0 Section 3.2.S.1.2.1 Molecular Sequence) at 1–3 (providing the structure of the "Cap" ("m7G-5'-ppp-5'-Gm"), the sequence of the "5' UTR" (position 3–58), the sequence of

the "ORF" (position 59–3880), the sequence of the "3' UTR" (position 3881–3996), and the length of the "PolyA tail" ("100-nucleotide")), and Exhibit 12 thereto (Spikevax® BLA 125752/0 Section 3.2.S.1.2.1) at 9–11; Exhibit 35 (Proposed International Nonproprietary Names List 125 – COVID-19) at 3; *see also* Exhibit 36 (Chaudhary *et al.*, "mRNA vaccines for infectious diseases: principles, delivery and clinical translation," *Nature Rev. Drug Disc.* 20, 817–838 (2021) ("Chaudhary (2021)")) at 817–18 ("mRNA vaccines comprise synthetic mRNA molecules that direct the production of the antigen that will generate an immune response. In vitro-transcribed (IVT) mRNA mimics the structure of endogeneous mRNA, with five sections, from 5' to 3': 5' cap, 5' untranslated region (UTR), an open reading frame that encodes the antigen, 3' UTR and a poly(A) tail (Fig. 1)."), 819 (Fig. 1a, reproduced in part, below).



45. In response to the emergence of new strains of SARS-CoV-2, Moderna advanced two bivalent vaccine products for commercial marketing authorization or approval: Spikevax® (bivalent BA.1) and Spikevax® (bivalent BA.4/5). *See*, *e.g.*, Exhibit 37 (October 19, 2022, Moderna press release) (reporting on Spikevax® (bivalent BA.1)); Exhibit 38 (November 14, 2022, Moderna press release) (reporting on Spikevax® (bivalent BA.4/5)).

46. Moderna, FDA, and EMA refer to the Spikevax® (bivalent BA.1) subset of Spikevax® vaccine products as "mRNA-1273.214" products. *See*, *e.g.*, Exhibit 37 (October 19, 2022, Moderna press release); Exhibit 27 (August 31, 2022, FDA Spikevax® (bivalent BA.4/5) EUA Review Memo) at 41; Exhibit 39 (December 16, 2022, EMA Spikevax® (bivalent BA.1) Assessment Report) at 15.

47. Moderna, FDA, and EMA have referred to the Spikevax® (bivalent BA.4/5) subset of Spikevax® vaccine products as "mRNA-1273.222" products. *See*, *e.g.*, Exhibit 38 (November 14, 2022, Moderna press release); Exhibit 27 (August 31, 2022, FDA Spikevax® (bivalent BA.4/5) EUA Review Memo) *passim*; Exhibit 40 (October 19, 2022, EMA Spikevax® (bivalent BA.4/5) Assessment Report) at 13.

48. Both Spikevax® (bivalent BA.1) and Spikevax® (bivalent BA.4/5) contain the elasomeran mRNA. *See*, *e.g.*, Exhibit 34 (January 2, 2024, EMA Spikevax® EPAR Product Information) at 27, 52; Exhibit 39 (December 16, 2022, EMA Spikevax® (bivalent BA.1) Assessment Report) at 9 ("The active substance elasomeran (also known as CX-024414) is already approved in the existing Spikevax® conditional marketing authorisation."); Exhibit 40 (October 19, 2022, EMA Spikevax® (bivalent BA.4/5) Assessment Report) at 8 ("The active substance elasomeran (also known as CX-024414) is already approved in the existing Spikevax® conditional marketing authorisation. No changes were introduced for the manufacturing of the mRNA-024414 (elasomeran).").

49. In addition to elasomeran, Spikevax® (bivalent BA.1) contains the mRNA "CX-031302" or "imelasomeran" encoding a viral spike protein of the Omicron BA.1 variant of SARS-CoV-2. Exhibit 34 (January 2, 2024, EMA Spikevax® EPAR Product Information) at 3, 28 ("Imelasomeran is a single-stranded, 5'-capped messenger RNA (mRNA) … encoding the viral spike (S) protein of SARS-CoV-2 (Omicron BA.1)."); Exhibit 39 (December 16, 2022, EMA (bivalent BA.1) Assessment Report) at 9–10; Exhibit 41 (Proposed International Nonproprietary Names List 127 – COVID-19) at 2.

50. On information and belief, apart from the open reading frame region coding for a viral spike protein of the SARS-CoV-2 Omicron BA.1 coronavirus variant, the components of

the imelasomeran mRNA are unchanged as compared to elasomeran as set forth *supra* in paragraph 43. Exhibit 34 (January 2, 2024, EMA Spikevax® EPAR Product Information) at 3, 28; Exhibit 39 (December 16, 2022, EMA Spikevax® (bivalent BA.1) Assessment Report) at 9–10; Exhibit 41 (Proposed International Nonproprietary Names List 127 – COVID-19) at 2.

51. In addition to elasomeran, Spikevax® (bivalent BA.4/5) contains the mRNA "CX-0344476" or "davesomeran" encoding a viral spike protein of the BA.4/5 omicron variants of SARS-CoV-2. *See*, *e.g.*, Exhibit 27 (August 31, 2022, FDA Spikevax® (bivalent BA.4/5) EUA Review Memo) at 41; Exhibit 34 (January 2, 2024, EMA Spikevax® EPAR Product Information) at 53 ("Davesomeran is a single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2 (Omicron BA.4-5). The S-proteins of the SARS-CoV-2 Omicron variant lineages BA.4 and BA.5 are identical."); Exhibit 40 (October 19, 2022, EMA Spikevax® (bivalent BA.4/5) Assessment Report) at 8; Exhibit 42 (Proposed International Nonproprietary Names List 128 – COVID-19 Addendum) at 2; Exhibit 43 (April 18, 2023, FDA Spikevax® (bivalent BA.4/5) Fact Sheet) at 48.

52. On information and belief, apart from the open reading frame region coding for a viral spike protein of the SARS-CoV-2 Omicron BA.4/5 coronavirus variant, the components of the davesomeran mRNA are unchanged as compared to elasomeran as set forth *supra* in paragraph 43. *See*, *e.g.*, Exhibit 34 (January 2, 2024, EMA Spikevax® EPAR Product Information) at 3, 53; Exhibit 40 (October 19, 2022, EMA Spikevax® (bivalent BA.4/BA.5) Assessment Report) at 8; Exhibit 42 (Proposed International Nonproprietary Names List 128 – COVID-19 Addendum) at 2.

53. In response to the continued evolution of SARS-CoV-2, Moderna subsequently advanced another monovalent vaccine for commercial marketing authorization and/or approval: the Spikevax® (monovalent XBB.1.5) vaccine. *See*, *e.g.*, Exhibit 44 (June 22, 2023, Moderna press release).

54. Moderna, FDA and EMA refer to the Spikevax® (monovalent XBB.1.5) subset of Spikevax® vaccine products as "mRNA-1273.815" products. *See*, *e.g.*, Exhibit 44 (June 22, 2023, Moderna press release); Exhibit 45 (September 11, 2023, FDA Spikevax® (monovalent XBB.1.5) vaccine Clinical Review Memo) at 16.

55. Spikevax® (monovalent XBB.1.5) contains the mRNA "andusomeran" encoding a viral spike protein of the Omicron XBB.1.5 variant of SARS-CoV-2. *See*, *e.g.*, Exhibit 28 (September 2023 FDA Spikevax® (monovalent XBB.1.5) Package Insert) at 28 ("Each 0.5 mL dose of SPIKEVAX (2023-2024 Formula) contains 50 mcg nucleoside-modified messenger RNA (mRNA) encoding the pre-fusion Spike glycoprotein (S) of the SARS-CoV-2 Omicron variant lineage XBB.1.5"; "The vaccine elicits an immune response to the S antigen, which protects against COVID-19."); Exhibit 34 (January 2, 2024, EMA Spikevax® EPAR Product Information) at 78, 208; Exhibit 46 (Proposed International Nonproprietary Names List 129 – COVID-19) at 2.

56. On information and belief, apart from the open reading frame region coding for the viral spike protein of the Omicron XBB.1.5 variant, the components of the andusomeran mRNA are unchanged as compared to elasomeran as set forth *supra* in paragraph 43. *See*, *e.g.*, Exhibit 28 (September 2023 FDA Spikevax® (monovalent XBB.1.5) Package Insert) at 28; Exhibit 46 (Proposed International Nonproprietary Names List 129 – COVID-19) at 2.

57. In response to the continued evolution of SARS-CoV-2, Moderna subsequently advanced additional monovalent vaccines for commercial marketing authorization and/or approval: the Spikevax® (monovalent KP.2) vaccine and the Spikevax® (monovalent JN.1) vaccine. *See*, *e.g.*, Exhibit 47 (August 22, 2024, Moderna Media Blog); Exhibit 48 (September 5, 2024, Moderna press release).

58. Moderna, FDA and EMA refer to the Spikevax® (monovalent KP.2) subset of Spikevax® vaccine products as "mRNA-1273.712" products. *See*, *e.g.*, Exhibit 49 (August 22, 2024, FDA Spikevax® (monovalent KP.2) vaccine EUA Review Memo) at 17.

59. Spikevax® (monovalent KP.2) contains mRNA encoding a viral spike protein of the Omicron KP.2 variant of SARS-CoV-2. *See*, *e.g.*, Exhibit 29 (August 2024 FDA Spikevax® (monovalent KP.2) Package Insert) at 27–28 ("Each 0.5 mL dose of SPIKEVAX (2024-2025 Formula) contains 50 mcg nucleoside-modified messenger RNA (mRNA) encoding the pre-fusion stabilized Spike glycoprotein (S) of the SARS-CoV-2 Omicron variant lineage KP.2."; "The vaccine elicits an immune response to the S antigen, which protects against COVID-19.").

60. On information and belief, apart from the open reading frame region coding for the viral spike protein of the Omicron KP.2 variant, the components of the mRNA are unchanged as compared to elasomeran as set forth *supra* in paragraph 43. *See*, *e.g.*, Exhibit 29 (August 2024 FDA Spikevax® (monovalent KP.2) Package Insert) at 27–28.

61. Moderna and EMA refer to the Spikevax® (monovalent JN.1) subset of Spikevax® vaccine products as "SARS-CoV-2 JN.1 mRNA" products. *See*, *e.g.*, Exhibit 30 (September 2024 EMA Spikevax® (monovalent JN.1) Product Information) at 105.

62. Spikevax® (monovalent JN.1) contains mRNA encoding a viral spike protein of the Omicron JN.1 variant of SARS-CoV-2. *See*, *e.g.*, Exhibit 30 (September 2024 EMA

Spikevax® (monovalent JN.1) Product Information) at 257 ("The active substance in Spikevax JN.1 is mRNA encoding the SARS-CoV-2 spike protein"; "Spikevax JN.1 uses a substance called messenger ribonucleic acid (mRNA) to carry instructions that cells in the body can use to make the spike protein that is also on the virus. The cells then make antibodies against the spike protein to help fight off the virus. This will help to protect you against COVID-19.").

63. On information and belief, apart from the open reading frame region coding for the viral spike protein of the Omicron JN.1 variant, the components of the mRNA are unchanged as compared to elasomeran as set forth *supra* in paragraph 43. *See*, *e.g.*, Exhibit 30 (September 2024 EMA Spikevax® (monovalent JN.1) Product Information) at 114, 257.

64. Moderna, FDA, and EMA refer to the mNEXSPIKE® family of vaccines as "mRNA-1283" products. *See*, *e.g.*, Exhibits 94–97 (mNEXSPIKE® (monovalent JN.1)).

65. mNEXSPIKE® (monovalent JN.1) contains mRNA encoding a viral spike protein of the Omicron JN.1 variant of SARS-CoV-2. *See*, *e.g.*, Exhibits 94–97 (mNEXSPIKE® (monovalent JN.1)).

66. On information and belief, apart from the open reading frame region coding for the viral spike protein of the Omicron JN.1 variant, the components of the mRNA are unchanged as compared to elasomeran as set forth *supra* in paragraph 43. *See*, *e.g.*, Exhibits 94–97 (mNEXSPIKE® (monovalent JN.1)).

67. The lipid particles in the Accused Products contain the mRNA and the following four lipids:

Chemical Name	**Shorthand**
heptadecan-9-yl 8-{(2-hydroxyethyl)[6-oxo-6-(undecyloxy)hexyl]amino}octanoate	"SM-102"
1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000	"PEG2000-DMG"
1,2-distearoyl-sn-glycero-3-phosphocholine	"DSPC"
cholesterol	(N/A)

Exhibit 26 (’789 PTE) at 4–6, 10–12, Exhibit 4 thereto (January 2022 Spikevax® (original monovalent) Package Insert) at 11; Exhibit 34 (January 2, 2024, EMA Spikevax® EPAR Product Information) at 20, 44, 71, 97, 109, 121, 137, 149; Exhibit 32 (October 18, 2021, FDA Spikevax® (original monovalent) EUA Review Memo, as revised November 4, 2021) at 11; Exhibit 39 (December 16, 2022, EMA Spikevax® (bivalent BA.1) Assessment Report) at 60; Exhibit 27 (August 31, 2022, FDA Spikevax® (bivalent BA.4/5) EUA Review Memo) at 40–41; Exhibit 28 (September 2023 FDA Spikevax® (monovalent XBB.1.5) Package Insert) at 28; Exhibit 29 (August 2024 FDA Spikevax® (monovalent KP.2) Package Insert) at 27; Exhibit 30 (September 2024 EMA Spikevax® (monovalent JN.1) Product Information) at 262; Exhibits 94–97 (mNEXSPIKE® (monovalent JN.1)).

68. Each of the Accused Products comprises formulations with the same relative molar percentages of the foregoing lipid ingredients. *See*, *e.g.*, Exhibit 32 (October 18, 2021, FDA Spikevax® (original monovalent) EUA Review Memo, as revised November 4, 2021) at 11 (“Each dose of the Moderna COVID-19 Vaccine contains the following ingredients: a total lipid content of 1.93 mg (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC] …”); Exhibit 39 (December 16, 2022, EMA Spikevax® (bivalent BA.1) Assessment Report) at 15-16; Exhibit 27 (August 31, 2022, FDA Spikevax® (bivalent BA.4/5) EUA Review Memo) at 40–41; Exhibit 28 (September 2023, FDA Spikevax® (monovalent XBB.1.5) Package Insert) at 28; Exhibit 29 (August 2024 FDA Spikevax® (monovalent KP.2) Package Insert) at 27; Exhibit 30 (September 2024 EMA Spikevax® (monovalent JN.1) Product Information) at 262; Exhibits 94–97 (mNEXSPIKE® (monovalent JN.1)).

69. On information and belief, the same processes are used to manufacture the mRNA, lipid particles, and finished forms of all of the Accused Products. *See*, *e.g.*, Exhibit 27 (August 31, 2022, FDA Spikevax® (bivalent BA.4/5) EUA Review Memo) at 6, 14–15, 41, 48; Exhibit 39 (December 16, 2022, EMA Spikevax® (bivalent BA.1) Assessment Report) at 19 ("As described above, there are no changes in the manufacturing process with respect to the existing 0.1 mg/mL formulation except for the pooling of the two mRNA-loaded LNP finished product intermediates containing either [elasomeran] or [imelasomeran]"); Exhibit 40 (October 19, 2022, EMA Spikevax® (bivalent BA.4/5) Assessment Report) at 41 ("The manufacturing and quality testing sites as well as all unit operations and process controls used to manufacture CX-034476 mRNA, mRNA-1273.045 LNP-B DS, and Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) DP are consistent with the previously filed DS and DP processes and controls for the authorized 0.10 mg/mL original Moderna COVID-19 Vaccine.") and 14 ("Since the [Moderna bivalent BA.4/5 vaccine] shares the same compositional platform as the authorized 0.1 mg/mL formulation … and the bivalent Original/Omicron BA.1 …, all aspects of Spikevax® 0.1 mg/mL development can be extrapolated to the bivalent [vaccine product]."); Exhibit 34 (January 2, 2024, EMA Spikevax® EPAR Product Information) at 144 ("The safety and effectiveness of Spikevax (Original monovalent) and Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) are relevant to Spikevax (2023-2024 Formula) because these vaccines are manufactured using a similar process.") and 146, 150; January 18, 2023, CNBC Television Interview, "Moderna CEO: We're preparing our FDA filing for our RSV vaccine," ("2023 CNBC Interview")[6] at 2:21 ("And the other great news about mRNA is: because all the

[6] Available at https://www.youtube.com/watch?v=FzgSE3yG-7E, last accessed September 26, 2024.

products use the same manufacturing process, we don't have capacity constraint because we can use exactly the same equipment, people, and raw materials, as for the COVID shot."); Exhibit 50 (August 22, 2024, FDA Spikevax® (monovalent KP.2) vaccine EUA Review Memo) at 21 ("Effectiveness and safety data accrued with the Moderna COVID-19 Vaccine (Original monovalent), Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5), and Moderna COVID-19 Vaccine (2023-2024 Formula) are relevant to Moderna COVID-19 Vaccine (2024-2025 Formula), because all these vaccines are manufactured using the same process."); Exhibits 94–97 (mNEXSPIKE® (monovalent JN.1)).

70. The mRNA and lipid particles constitute material parts of and are especially made and especially adapted for use in, each of the Accused Products and its process of manufacture, and are not staple articles or commodities of commerce suitable for any other substantial use.

B. Moderna's Infringement in the United States

71. On December 18, 2020, FDA granted Emergency Use Authorization (EUA) for Spikevax® (original monovalent) to prevent COVID-19 caused by SARS-CoV-2. The authorized regimen was a two-dose primary vaccination series administered one month apart in individuals 18 years of age and older. Exhibit 51 (December 18, 2020, FDA News Release); Exhibit 52 (December 18, 2020, FDA Spikevax® (original monovalent) EUA Review Memo).

72. On August 12, 2021, FDA expanded EUA for Spikevax® (original monovalent) to a third primary dose (at least 1 month after the second dose) for certain immunocompromised individuals 18 years of age and older. Exhibit 53 (August 12, 2021, FDA News Release); Exhibit 54 (August 12, 2021, FDA Spikevax® (original monovalent) EUA Review Memo).

73. On October 20, 2021, FDA expanded EUA for Spikevax® (original monovalent) to a third dose (a first booster) six months after completion of the primary two-dose vaccination series for individuals 65 years of age or older, or certain other higher risk individuals 18 to 64

years of age. Exhibit 55 (October 20, 2021, FDA News Release); Exhibit 56 (October 20, 2021, FDA Spikevax® (original monovalent) EUA Review Memo, as revised, November 4, 2021).

74. On November 19, 2021, FDA expanded EUA for Spikevax® (original monovalent) to a third dose (a first booster) six months after completion of the primary two-dose vaccination for all individuals 18 years and older who had completed any authorized primary vaccination regimen. Exhibit 57 (November 19, 2021, FDA News Release); Exhibit 58 (November 19, 2021, FDA Spikevax® (original monovalent) EUA Review Memo).

75. On January 31, 2022, FDA granted full approval of Moderna's BLA for Spikevax® (original monovalent) two-dose primary vaccination series in individuals 18 years of age and older. Exhibit 10 (January 31, 2022, FDA Spikevax® (original monovalent) Approval Letter).

76. On March 29, 2022, FDA expanded EUA for Spikevax® (original monovalent) to a fourth dose (second booster) at least four months after receipt of a first booster dose of any FDA authorized or approved COVID-19 vaccine for individuals over 50 years of age and for immunocompromised patients 18 years of age and older. Exhibit 59 (March 29, 2022, FDA News Release); Exhibit 60 (March 28, 2022, FDA Spikevax® (original monovalent) EUA Review Memo).

77. On June 17, 2022, FDA expanded EUA for Spikevax® (original monovalent) to a two-dose primary vaccination series for children 6 months through 17 years of age. Exhibit 61 (June 17, 2022, FDA News Release); Exhibit 62 (June 16, 2022, FDA Spikevax® (original monovalent) EUA Review Memo).

78. On August 31, 2022, FDA granted EUA for Spikevax® (bivalent BA.4/5) as a single booster dose in patients 18 years of age and older who had received a primary series or primary series and first booster of any authorized or approved COVID-19 vaccine. FDA also

revised EUA for Spikevax® (original monovalent) to no longer include use as a first or second booster dose. Exhibit 63 (August 31, 2022, FDA News Release as preserved by The Wayback Machine, September 1, 2022[7]); Exhibit 27 (August 31, 2022, FDA Spikevax® (bivalent BA.4/5) EUA Review Memo).

79. On October 12, 2022, FDA expanded EUA for Spikevax® (bivalent BA.4/5) as a booster dose in children and adolescents 6 through 17 years of age who had received a primary series or primary series and booster of any authorized or approved COVID-19 vaccine. Exhibit 64 (October 12, 2022, FDA News Release as preserved by The Wayback Machine, October 13, 2022[8]); Exhibit 65 (October 11, 2022, FDA Spikevax® (bivalent BA.4/5) EUA Review Memo).

80. On December 8, 2022, FDA expanded EUA for Spikevax® (bivalent BA.4/5) as a single booster dose in children 6 months through 5 years of age who had received a primary series of Spikevax® (original monovalent). Exhibit 66 (December 8, 2022, FDA News Release as preserved by The Wayback Machine, December 9, 2022[9]); Exhibit 67 (December 7, 2022, FDA Spikevax® (bivalent BA.4/5) EUA Review Memo).

81. On April 18, 2023, FDA expanded EUA for Spikevax® (bivalent BA.4/5) to be used for all doses (primary and booster) in most adults and pediatric populations as well as other dosage regimes for certain individuals based on age or immunocompromised status. FDA also rescinded all authorizations for use of Spikevax® (original monovalent) vaccine in the United

[7] Available at https://web.archive.org/web/20220901002611/https://www.fda.gov/newsevents/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-pfizerbiontech-bivalent-covid-19-vaccines-use; preserved April 9, 2024.
[8] Available at https://web.archive.org/web/20221013015339/https://www.fda.gov/newsevents/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-and-pfizerbiontech-bivalent-covid-19-vaccines; preserved April 9, 2024.
[9] Available at https://web.archive.org/web/20221209225236/https://www.fda.gov/newsevents/press-announcements/coronavirus-covid-19-update-fda-authorizes-updated-bivalentcovid-19-vaccines-children-down-6-months; preserved April 9, 2024.

States. Exhibit 68 (April 18, 2023, FDA News Release); Exhibit 69 (April 17, 2023, FDA Spikevax® (bivalent BA.4/5) EUA Review Memo).

82. On September 11, 2023, FDA granted full approval of Moderna's supplemental BLA for Spikevax® (monovalent XBB.1.5) single dose regimen for individuals 12 years of age and older. FDA also granted EUA for Spikevax® (monovalent XBB.1.5) as a single dose for individuals 6 months through 11 years of age. FDA also rescinded EUAs for the Spikevax® (bivalent BA.4/5) vaccine. Exhibit 70 (September 11, 2023, FDA News Release); Exhibit 71 (September 11, 2023, FDA Spikevax® (monovalent XBB.1.5) Approval Letter); Exhibit 45 (September 11, 2023, FDA Spikevax® (monovalent XBB.1.5) EUA Review Memo).

83. On August 22, 2024, FDA granted full approval of Moderna's supplemental BLA for Spikevax® (monovalent KP.2) single dose regimen for individuals 12 years of age and older. FDA also granted EUA for Spikevax® (monovalent KP.2) as a single dose for individuals 6 months through 11 years of age. Exhibit 72 (August 22, 2024, FDA News Release); Exhibit 50 (August 22, 2024, FDA Spikevax® (monovalent KP.2) Approval Letter); Exhibit 29 (August 22, 2024, FDA Spikevax® (monovalent KP.2) EUA Review Memo).

84. On May 30, 2025, FDA granted full approval of Moderna's BLA for mNEXSPIKE® (monovalent JN.1) one-dose primary vaccination series in individuals 12 years of age and older. *See, e.g.*, Exhibit 98.

85. Moderna did and continues to, make and/or have third-party manufacturers make, the mRNA, the lipid particles, and the finished forms of the Accused Products, both inside and outside the United States. *See*, *e.g.*, Exhibit 73 (January 28, 2022, FDA Chemistry, Manufacturing, and Controls (CMC) Review Memo) at vii ("The on-site pre-licensure inspections of ModernaTX, Inc. (Norwood, MA), Lonza Biologics, Inc. (Portsmouth, NH), and Aldevron

(Fargo, ND) manufacturing facilities that are involved in the manufacture, controls, and storage of CX-024414 mRNA, [] and mRNA-1273 LNP DS were accomplished by the FDA inspection team … For the subject BLA, inspections for Catalent Biologics, LLC (Bloomington, IN) and Baxter Pharmaceutical Solutions, LLC (Bloomington, IN) facilities used for the fill/finish, in-process testing, release testing (sterility), and storage of mRNA-1273 DP were waived as these facilities were determined to have an acceptable compliance history for manufacturing of previously approved FDA licensed products ….”), 2, 8, 62–63, 86, 90, 93–94, 96–97; Exhibit 10 (January 31, 2022, FDA Spikevax® (original monovalent) Approval Letter) at 1 (“Under this license, you are approved to manufacture COVID-19 Vaccine, mRNA, drug substance at ModernaTX, Inc., 1 Moderna Way, Norwood, MA, and Lonza Biologics, Inc., 101 International Drive, Portsmouth, NH. The final formulated product will be manufactured, filled, labeled and packaged at Catalent Indiana, LLC (a subsidiary of Catalent Pharma Solutions, LLC), 1300 S. Patterson Drive, Bloomington, IN, and Baxter BioPharma Solutions, 927 S. Curry Pike, Bloomington, IN.”); Exhibit 34 (January 2, 2024, EMA Spikevax® EPAR Product Information) at 105 (under “Name and address of the manufacturers of the biological active substances” are listed: ModernaTX, Inc.; Lonza AG in Visp, Switzerland; and Lonza Biologics, Inc. in Portsmouth, NH; under “Name and address of the manufacturers responsible for batch release” are listed: Moderna Biotech Spain S.L., Madrid, Spain; Rovi Pharma Industrial Services, S.A., Madrid, Spain; Recipharma Monts, Monts, France; Patheon Italia S.p.a., Monza and Ferentino, Italy); Exhibit 39 (December 16, 2022, EMA Spikevax® (bivalent BA.1) Assessment Report) at 17–18 (identifying the following “manufacturing sites”: Moderna MTC; Lonza, Portsmouth; Lonza, Visp; Catalent, Indiana; Patheon, Monza; Rovi, San Sebastian de los Reyes; Rovi, Granada; and Recipharm, Monts); Exhibit 71 (September 11, 2023, FDA Spikevax® (monovalent

XBB.1.5) Approval Letter) at 1 (identifying as manufacturers for "COVID-19 Vaccine, mRNA (SPIKEVAX)", Catalent Indiana, LLC and Patheon Manufacturing Services, LLC); Exhibit 50 (August 22, 2024, FDA Spikevax® (monovalent KP.2) Approval Letter) at 1 (identifying as manufacturers for "COVID-19 Vaccine, mRNA (SPIKEVAX)", Catalent Indiana, LLC and Patheon Manufacturing Services, LLC); Exhibit 30 (September 2024 EMA Spikevax® (monovalent JN.1) Product Information) at 133 ("Name and address of the manufacturers of the biological active substances … ModernaTX, Inc. One Moderna Way Norwood, MA 02062 USA"); Exhibit 73 (excerpts from February 24, 2023, Moderna, Inc. 2022FY Annual Report (Form 10-K)) at 32–33 ("[W]e have built a dedicated in-house multi-building manufacturing campus in Norwood, MA, the Moderna Technology Center (MTC). … In addition substantial manufacturing capabilities are realized via CMO relationships in the United States and abroad providing drug substance and fill-finish capacity for our COVID-19 vaccines."); Exhibit 75 (excerpts from February 23, 2024, Moderna, Inc. 2023FY Annual Report (Form 10-K)) at 24–25 (similar).

86. Moderna did and/or does offer for sale and/or sell Accused Products in the United States. *See*, *e.g.*, Exhibit 11 (printout of CDC Data on Spikevax® (original monovalent and bivalent BA.4/5) doses distributed in Delaware, May 10, 2023); Exhibit 73 (excerpts from February 24, 2023, Moderna, Inc. 2022FY Annual Report (Form 10-K)) at 32–33; Exhibit 75 (excerpts from February 23, 2024, Moderna, Inc. 2023FY Annual Report (Form 10-K)) at 24–25.

87. Moderna did and/or does package, promote, offer for sale, and sell Accused Products in the United States with labeling and prescribing information that instructs healthcare practitioners to "administer" each product to patients in accordance with the FDA authorized and approved use(s). *See*, *e.g.*, Exhibit 26 ('789 PTE) at Exhibit 4 thereto (January 2022 Spikevax®

(original monovalent) Package Insert) ("2.2 Administration … Administer a single 0.5 mL dose"); Exhibit 43 (April 18, 2023, FDA Spikevax® (bivalent BA.4/5) Fact Sheet) at 5 ("2.2 Administration … Administer Moderna COVID-19 Vaccine, Bivalent intramuscularly."); Exhibit 28 (September 2023, FDA Spikevax® (monovalent XBB.1.5) Package Insert) at 3 ("2.2 Administration … Administer SPIKEVAX intramuscularly"); *see also*, *e.g.*, Exhibit 76 (https://spikevax.com as preserved by The Wayback Machine, February 3, 2022[10]) (directing healthcare practitioners to the prescribing information for Spikevax® (original monovalent)); Exhibit 77 (https://spikevax.com as preserved by The Wayback Machine, June 20, 2023[11]) (directing healthcare practitioners to the prescribing information for Spikevax® (bivalent BA.4/5)); Exhibit 78 (https://spikevax.com/healthcare-provider-guide/helpful-vaccine-resource-tools; preserved June 4, 2024) (directing healthcare practitioners to the prescribing information for Spikevax® (monovalent XBB.1.5)); Exhibit 29 (August 2024, FDA Spikevax® (monovalent KP.2) Package Insert) at 2 ("2.2 Administration … Administer SPIKEVAX intramuscularly").

88. On information and belief, healthcare practitioners follow the instructions in Moderna's labeling and prescribing information when administering Accused Products to patients in the United States.

89. When administered to patients in accordance with the FDA authorized and approved uses, Spikevax® (original monovalent) elicits an immune response to, *inter alia*, the viral spike protein of the original (2019) strain of SARS-CoV-2 coronavirus. *See*, *e.g.*, Exhibit

[10] Available at https://web.archive.org/web/20220203181738/https://spikevax.com/; preserved on June 4, 2024.
[11] Available at https://web.archive.org/web/20230620105159/https://spikevax.com/; preserved on June 14, 2024.

33 (March 11, 2021, EMA Spikevax® (original monovalent) Assessment Report) at 60–111; Exhibit 34 (January 2, 2024, EMA Spikevax® EPAR Product Information) at 11–19.

90. When administered to patients in accordance with the FDA authorized and approved uses, Spikevax® (bivalent BA.4/5) elicits an immune response to, *inter alia*, the spike proteins of both the original SARS-CoV-2 strain and the Omicron BA.4/5 SARS-CoV-2 variants. *See*, *e.g.*, Exhibit 34 (January 2, 2024, EMA Spikevax® EPAR Product Information) at 61–71; Exhibit 40 (October 19, 2022, EMA Spikevax® (bivalent BA.4/5) Assessment Report) at 8, 24–41.

91. When administered to patients in accordance with the FDA authorized and approved uses, Spikevax® (monovalent XBB.1.5) elicits an immune response to, *inter alia*, the spike protein of the Omicron XBB.1.5 SARS-CoV-2 variant. *See*, *e.g.*, Exhibit 34 (January 2, 2024, EMA Spikevax® EPAR Product Information) at 87–96; Exhibit 45 (September 11, 2023, FDA Spikevax® (monovalent XBB.1.5) Clinical Review Memo) at 20, 25–142; Exhibit 28 (September 2023 FDA Spikevax® (monovalent XBB.1.5) Package Insert) at 28.

92. When administered to patients in accordance with the FDA authorized and approved uses, Spikevax® (monovalent KP.2) elicits an immune response to, *inter alia*, the spike protein of the Omicron KP.2 SARS-CoV-2 variant. *See*, *e.g.*, Exhibit 29 (August 2024 FDA Spikevax® (monovalent KP.2) Package Insert) at 27–28.

93. When administered to patients in accordance with the FDA authorized and approved uses, mNEXSPIKE® (monovalent JN.1) elicits an immune response to, *inter alia*, the spike protein of the Omicron JN.1 SARS-CoV-2 variant. Exhibits 94–97 (mNEXSPIKE® (monovalent JN.1)).

94. The Accused Products constitute a material part of, and are especially made and especially adapted for, FDA authorized and/or approved uses in the United States, and are not staple articles or commodities of commerce suitable for any other substantial use.

95. Moderna has profited significantly from the inventions claimed in the Patents-in-Suit. From sales of the Accused Products, Moderna reported more than $4 billion in U.S. revenue (and over $18 billion globally) in 2022 and over $1.7 billion in U.S. revenue (and over $6 billion globally) in 2023. *See* Exhibit 74 (excerpts from February 24, 2023, Moderna, Inc. 2022FY Annual Report (Form 10-K)) at 18, 127; Exhibit 75 (excerpts from February 23, 2024, Moderna, Inc. 2023FY Annual Report (Form 10-K)) at 6, 87.

96. Moderna stands to continue to profit significantly through continued infringement of GSK Biologicals's Patents-in-Suit without taking a license. In September 2023, Moderna set the list price of its updated COVID-19 vaccine at $129 per dose, a nearly five-fold increase from the pandemic pricing. *See* Exhibit 79 (September 12, 2023, *Reuters* article, "COVID vaccine manufacturers set list price between $120-$130 per dose"[12]); Exhibit 80 (March 24, 2023, *Oversight* article, "Moderna Plan to Hike COVID Vaccine Price to $130 a Dose Rebuked at U.S. Senate Hearing"[13]) (noting original pandemic price of Spikevax® COVID-19 vaccine was less than $30 per dose). Moderna anticipates a 2024 market of "~$10B" for all "COVID-19 vaccines." *See* Exhibit 81 (March 27, 2024, Moderna Vaccine & Business Updates Presentation ("Moderna Vaccine Updates")) at 108.

[12] Available at https://www.reuters.com/business/healthcare-pharmaceuticals/covid-vaccine-manufacturers-set-list-price-between-120-130-per-dose-2023-09-12/; preserved April 3, 2024.
[13] Available at https://www.govexec.com/oversight/2023/03/moderna-plan-hike-covid-vaccine-price-130-dose-rebuked-us-senate-hearing/384389/; preserved August 1, 2023.

COUNT I

(Infringement of the ’682 Patent)

97. GSK incorporates each of the preceding paragraphs as if fully set forth herein.

98. GSK Biologicals is the lawful owner by assignment of the ’682 patent, which is entitled “Delivery of RNA to Trigger Multiple Immune Pathways” and was duly and legally issued by the U.S. Patent and Trademark Office on April 5, 2022. A true and correct copy of the ’682 patent is attached as Exhibit 1. The patent application issuing into the ’682 patent was published on November 14, 2019, as Publication No. US 2019/0343862 A1. *See* Exhibit 82.

99. Each claim of the ’682 patent is valid and enforceable.

100. Moderna has infringed and continues to infringe, under 35 U.S.C. § 271(a), (b), (c), and/or (f), one or more claims of the ’682 patent either literally or under the doctrine of equivalents, through its actions in the United States with respect to each of the Accused Products.

101. Moderna has had knowledge of the ’682 patent and specific notice of its infringement of that patent at least since February 16, 2024. *See* Exhibit 93.

102. For purposes of illustration and example, claims 1 and 11 of the ’682 patent recite:

> **1.** A method of raising an immune response in a vertebrate, the method comprising administering to the vertebrate an effective amount to raise the immune response of a pharmaceutical composition comprising liposomes and messenger ribonucleic acid (mRNA) molecules, wherein:
>
> (a) (i) at least 80% of the liposomes have a diameter in the range of 20-220 nm, (ii) a polydispersity index of less than 0.2, (iii) or both (i) and (ii);
>
> (b) at least half of the mRNA molecules are encapsulated within the liposomes; and
>
> (c) the mRNA molecules encode an immunogen and comprise a 7’-methylguanosine and a first 5’ ribonucleotide, the 7’-methylguanosine being linked 5’-to-5’ to the first 5’ ribonucleotide, and the first 5’ ribonucleotide comprising a 2’-methylated ribose.

> **11.** A pharmaceutical composition comprising liposomes and messenger ribonucleic acid (mRNA) molecules, wherein:
>
> (a) (i) at least 80% of the liposomes have a diameter in the range of 20-220 nm, (ii) a polydispersity index of less than 0.2, (iii) or both (i) and (ii);
>
> (b) at least half of the mRNA molecules are encapsulated within the liposomes; and
>
> (c) the mRNA molecules encode an immunogen and comprise a 7'-methylguanosine and a first 5' ribonucleotide, the 7'-methylguanosine being linked 5'-to-5' to the first 5' ribonucleotide, and the first 5' ribonucleotide comprising a 2'-methylated ribose.

103. Each of the Accused Products is a "pharmaceutical composition comprising liposomes and messenger ribonucleic acid (mRNA) molecules." *See* paragraphs 38–96, *supra*; *e.g.*, Exhibit 26 ('789 PTE) at 2 ("The active ingredient of SPIKEVAX is mRNA-1273, which is a nucleoside-modified messenger RNA (mRNA) … encapsulated in a lipid nanoparticle."), 10 (representing that Spikevax® (original monovalent) is "A pharmaceutical composition"), Exhibit 3 thereto (Tenchov *et al*., "Lipid Nanoparticles – From Liposomes to mRNA Vaccine Delivery, a Landscape of Research Diversity and Advancement," *ACS Nano* 15, 16982-17015 (2021) ("Tenchov (2021)"))[14] at 16982–83 (E.g., "Since liposomes are made of lipids and in most cases are nanosized, they are rightfully considered as the earliest generation of lipid nanoparticles."), Exhibit 4 thereto (January 2022 Spikevax® (original monovalent) Package Insert) at 11, Exhibit 8 thereto (Spikevax® BLA 125752/0 Section 3.2.P.1) at 1, Exhibit 14 thereto (May 6, 2020, FDA Letter) at 1, and Exhibit 15 thereto (May 11, 2020, FDA Letter) at 1.

104. On information and belief, at least 80% of the liposomes in each of the Accused Products has a "diameter in the range of 20–220 nm," a "polydispersity index of less than 0.2," or "both." *See* paragraphs 38–96, *supra*; *e.g.*, Exhibit 26 ('789 PTE) at 11 (representing that

[14] *See* Exhibit 83 for a higher quality copy of Tenchov (2021) including the Supporting Information.

Spikevax® (original monovalent) LNPs have "a particle size of 80-160 nm") citing Exhibit 10 thereto (Spikevax® BLA 125752/0 Section 3.2.S.1.3) at 1; *see also* Exhibit 84 (Schoenmaker *et al*., "mRNA-lipid nanoparticle COVID-19 vaccines: Structure and Stability," *Intl. J. Pharm.* 601, 120586 (2021) ("Schoenmaker (2021)")) at 4 ("Together with the mRNA, these components form particles of about 60-100 nm in size.").

105. On information and belief, "at least half of the mRNA molecules are encapsulated within the liposomes" of each of the Accused Products. *See* paragraphs 38–96, *supra*; *e.g.*, Exhibit 31 (December 16, 2022, EMA Spikevax® (bivalent BA.1) Assessment Report) at 45 ("Testing of original retains of this material stored in a different freezer unit at -70°C for > 12 months resulted in %encapsulation > 90% for both lots."), 58 ("specification limit NLT 85%"); Exhibit 26 ('789 PTE) at 2 ("The active ingredient of SPIKEVAX is … encapsulated in a lipid nanoparticle."), 5 ("SM-102 is provided in excess in the LNP to provide a stoichiometric excess of cationic charge and enable full charge complexation of the mRNA and efficient encapsulation"), and Exhibit 4 thereto (January 2022 Spikevax® (original monovalent) Package Insert) at 12 ("The nucleoside-modified mRNA in Spikevax is encapsulated in lipid particles, which enable delivery of the nucleoside-modified mRNA into host cells…"); *see also* Exhibit 84 (Schoenmaker (2021)) at 4 ("In mRNA-LNP formulations, such as those used in mRNA vaccines ... encapsulation efficiencies ... are typically > 90%.").

106. The mRNA molecules of each of the Accused Products "encode an immunogen." *See* paragraphs 38–96, *supra*; *e.g.*, Exhibit 33 (March 11, 2021, EMA Spikevax® (original monovalent) Assessment Report) at 15 ("Upon delivery and uptake by body cells, the mRNA is translated in the cytosol and SARS-CoV-2 spike protein is generated by the host cell machinery. The spike protein is presented and elicits an adaptive humoral and cellular immune response.

Neutralizing antibodies are directed against it and hence it is considered a relevant target antigen for vaccine development.") and 16–17; Exhibit 34 (January 2, 2024, EMA Spikevax® EPAR Product Information) at 3; Exhibit 26 ('789 PTE) at 2–4, 11, Exhibit 4 thereto (January 2022 Spikevax® (original monovalent) Package Insert) at 11, Exhibit 8 thereto (Spikevax® BLA 125752/0 Section 3.2.P.1) at 1, Exhibit 11 thereto (BLA 125752/0 Section 3.2.S.1.2.1) at 1–3 (providing the sequence of the "ORF", a "Codon-optimized sequence encoding full-length SARS-CoV-2 spike (S) glycoprotein …" (position 59–3880)), Exhibit 14 thereto (May 6, 2020, FDA Letter) at 1, and Exhibit 15 thereto (May 11, 2020, FDA Letter) at 1.

107. The mRNA molecules of each of the Accused Products comprise "a 7'-methylguanosine and a first 5' ribonucleotide, the 7'-methylguanosine being linked 5'-to-5' to the first 5' ribonucleotide, and the first 5' ribonucleotide comprising a 2'-methylated ribose." *See* paragraphs 38–96, *supra*; *e.g.*, Exhibit 26 ('789 PTE) at 2, 11 ("[T]he molecular sequence of the mRNA component of SPIKEVAX includes the 5'-cap1 structure m7G-5'-ppp-5'-Gm."), 13, and Exhibit 11 thereto (BLA 125752/0 Section 3.2.S.1.2.1) at 1–3 (providing the structure of the "Cap" ("m7G-5'-ppp-5'-Gm"), the sequence of the "5' UTR" (position 3–58), the sequence of the "ORF" (position 59–3880), the sequence of the "3' UTR" (position 3881–3996), and the length of the "PolyA tail" ("100-nucleotide")).

108. Each FDA authorized and approved use for the Accused Products is "a method of raising an immune response in a vertebrate, the method comprising administering to the vertebrate an effective amount to raise the immune response" of the Accused Products. *See* paragraphs 71–96, *supra*; *e.g.*, Exhibit 26 ('789 PTE) at Exhibit 4 thereto (January 2022 Spikevax® (original monovalent) Package Insert) at 1–3 ("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) in individuals 18 years of age and older. … SPIKEVAX is administered intramuscularly as a series of two doses (0.5 mL each) one month apart."), 11 ("Each 0.5 mL dose of SPIKEVAX contains 100 mcg of nucleoside-modified messenger RNA (mRNA) encoding the pre-fusion stabilized Spike glycoprotein (S) of SARS-CoV-2 virus."), 12 ("The vaccine elicits an immune response to the S antigen, which protects against COVID-9."); Exhibit 43 (April 18, 2023, FDA Spikevax® (bivalent BA.4/5) Fact Sheet) at 1, 3, 4–6; Exhibit 28 (September 2023, FDA Spikevax® (monovalent XBB.1.5) Package Insert) at 1–3; Exhibit 29 (August 2024 FDA Spikevax® (monovalent KP.2) Package Insert) at 1–3; Exhibits 94–97 (mNEXSPIKE® (monovalent JN.1)).

109. Each of the Accused Products satisfies each and every element of exemplary claim 11 of the '682 patent, either literally or under the doctrine of equivalents.

110. On information and belief, Moderna has been aware at least since it received notice of its infringement from GSK on February 16, 2024, that each of the Accused Products satisfies each and every element of exemplary claim 11 of the '682 patent, either literally or under the doctrine of equivalents.

111. On information and belief, Moderna actively, knowingly, and specifically intended and intends, at least since it received notice of its infringement from GSK on February 16, 2024, to induce third-party manufacturers to directly infringe at least claim 11 of the '682 patent by making each of the Accused Products within the United States without authority or license to do so, during the term of the '682 patent.

112. On information and belief, Moderna has been aware at least since it received notice of its infringement from GSK on February 16, 2024, that the mRNA and liposomes in each of the Accused Products constitute material parts of, are especially made and especially adapted for use

in, and are not staple articles or commodities of commerce suitable for any other substantial use in the United States other than in, each of the Accused Products and its process of manufacture, and therefore to infringe at least claim 11 of the ’682 patent.

113. Administration of Accused Products to patients in the United States in accordance with the instructions in Moderna’s labeling and prescribing information and therefore with FDA authorized and/or approved uses satisfies each and every element of exemplary claims 1 and 11 of the ’682 patent, either literally or under the doctrine of equivalents.

114. On information and belief, Moderna has been aware at least since it received notice of its infringement from GSK on February 16, 2024, that administration of Accused Products to patients in the United States in accordance with the instructions in Moderna’s labeling and prescribing information and therefore with FDA authorized and/or approved uses satisfies each and every element of exemplary claims 1 and 11 of the ’682 patent, either literally or under the doctrine of equivalents.

115. On information and belief, Moderna actively, knowingly, and specifically intended and intends, at least since it received notice of its infringement from GSK on February 16, 2024, to induce healthcare practitioners to directly infringe at least claims 1 and 11 of the ’682 patent by administering Accused Products within the United States in accordance with the instructions in Moderna’s labeling and prescribing information and therefore with FDA authorized and/or approved uses without authority or license to do so, during the term of the ’682 patent.

116. On information and belief, Moderna has been aware at least since it received notice of its infringement from GSK on February 16, 2024, that the Accused Products constitute a material part of, are especially made and especially adapted for, and are not staple articles or

commodities of commerce suitable for substantial use other than, FDA authorized and/or approved uses in the United States, and therefore to infringe at least claim 1 of the ’682 patent.

117. For the foregoing reasons, Moderna has directly infringed and continues to directly infringe at least claim 11 of the’682 patent under 35 U.S.C. § 271(a), by making, offering to sell, or selling within the United States, or importing into the United States, each of the Accused Products, without authority or license to do so, during the term of the ’682 patent.

118. In addition or in the alternative, Moderna has infringed and continues to infringe at least claim 11 of the ’682 patent under 35 U.S.C. § 271(b) by actively inducing third-party manufacturers to directly infringe at least claim 11 of the ’682 patent by making each of the Accused Products within the United States without authority or license to do so, during the term of the ’682 patent.

119. In addition or in the alternative, Moderna has infringed or continues to infringe at least claims 1 and 11 of the ’682 patent under 35 U.S.C. § 271(b) by actively inducing healthcare practitioners to directly infringe at least claims 1 and 11 of the ’682 patent by administering Accused Products to patients within the United States in accordance with the instructions in Moderna’s labeling and prescribing information and therefore with FDA authorized and/or approved uses without authority or license to do so, during the term of the ’682 patent.

120. In addition or in the alternative, Moderna has contributorily infringed and continues to contributorily infringe at least claim 1 of the ’682 patent under 35 U.S.C. § 271(c) by offering to sell or selling within the United States or importing into the United States, Accused Products without authority or license to do so, during the term of the ’682 patent, knowing that the Accused Products constitute a material part of the invention of, and are especially made or adapted to

infringe, at least claim 1 of the ’682 patent, and are not staple articles or commodities of commerce suitable for substantial non-infringing use.

121. In addition or in the alternative, Moderna has contributorily infringed and continues to contributorily infringe at least claim 11 of the ’682 patent under 35 U.S.C. § 271(c) by offering to sell or selling within the United States or importing into the United States, the mRNA and/or lipid particles to be used in the manufacture of each of the Accused Products, without authority or license to do so, during the term of the ’682 patent, knowing that each constitutes a material part of the inventions of, and is especially made or adapted to infringe, at least claim 11 of the ’682 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

122. In addition or in the alternative, Moderna has indirectly infringed and continues to indirectly infringe at least claim 11 of the ’682 patent under 35 U.S.C. § 271(f)(1) by supplying or causing to be supplied in or from the United States mRNAs and/or other components of LNPs and vaccines of the Accused Products, where such components are uncombined in whole or in part, in such a manner as to actively induce the combination of said components outside of the United States in a manner that would infringe at least claim 11 of the ’682 patent if such combination occurred within the United States.

123. In addition or in the alternative, Moderna indirectly infringed and continues to indirectly infringe at least claim 11 of the ’682 patent under 35 U.S.C. § 271(f)(2) by supplying or causing to be supplied in or from the United States mRNAs and/or other components especially made or especially adapted for use in LNPs and vaccines of the Accused Products and not a staple article or commodity of commerce suitable for substantial non-infringing use, where such components are uncombined in whole or in part, knowing that such component is so made or

adapted and intending that such component will be combined outside of the United States in a manner that would infringe at least claim 11 of the ’682 patent if such combination occurred within the United States.

124. GSK has suffered and continues to suffer damages from Moderna’s infringement of the ’682 patent.

125. GSK is entitled to an award of monetary damages, including a reasonable royalty, for Moderna’s infringement of the ’682 patent.

126. Moderna’s infringement of the ’682 patent has been and continues to be willful and deliberate at least since it received notice of its infringement from GSK on February 16, 2024, because, despite an objectively high likelihood that its actions constitute infringement of a valid patent, Moderna continues all the aforementioned actions with respect to the Accused Products.

127. Moderna’s conduct with respect to the ’682 patent makes this case exceptional under 35 U.S.C. § 285.

COUNT II

(Infringement of the ’770 Patent)

128. GSK incorporates each of the preceding paragraphs as if fully set forth herein.

129. GSK Biologicals is the lawful owner by assignment of the ’770 patent, which is entitled “Delivery of RNA to Trigger Multiple Immune Pathways” and was duly and legally issued by the U.S. Patent and Trademark Office on May 10, 2022. A true and correct copy of the ’770 patent is attached as Exhibit 2. The patent application issuing into the ’770 patent was published on October 15, 2020, as Publication No. US 2020/0323896 A1. *See* Exhibit 85.

130. Each claim of the ’770 patent is valid and enforceable.

131. Moderna has infringed and continues to infringe, under 35 U.S.C. § 271(a), (b), (c), and/or (f), one or more claims of the '770 patent either literally or under the doctrine of equivalents, through its actions in the United States with respect to each of the Accused Products.

132. Moderna has had knowledge of the '770 patent and specific notice of its infringement of that patent at least since February 16, 2024. *See* Exhibit 93.

133. For purposes of illustration and example, claims 6 and 24 of the '770 patent recite:

> **6.** An immunogenic composition comprising lipid particles and messenger ribonucleic acid (mRNA) molecules; the mRNA molecules comprising a 7'-methylguanosine, a first 5' ribonucleotide, and a sequence that encodes an immunogen; the first 5' ribonucleotide comprising a 2'-methylated ribose; the 7' methylguanosine linked 5'-to-5' to the first 5' ribonucleotide; the lipid particles comprising a PEGylated lipid, cholesterol, a first phospholipid, and a cationic lipid; the cationic lipid comprising a tertiary amine; the first phospholipid comprising an anionic phospholipid or a zwitterionic phospholipid; the lipid particles encapsulating at least half of the mRNA molecules; and the immunogenic composition being immunogenic in vivo by eliciting at least: (i) an antibody response against the immunogen, (ii) a cell-mediated immune response against the immunogen, or (iii) both (i) and (ii).
>
> **24.** A method of eliciting an immune response in a vertebrate, the method comprising administering to the vertebrate an effective amount to elicit the immune response of the immunogenic composition of claim **6**; the immune response comprising the antibody response against the immunogen or the cell-mediated immune response against the immunogen.

134. Each of the Accused Products is "an immunogenic composition comprising lipid particles and messenger ribonucleic acid (mRNA) molecules." *See* paragraphs 38–96, *supra*; *e.g.*, Exhibit 26 ('789 PTE) at 2 ("The active ingredient of SPIKEVAX is mRNA-1273, which is a nucleoside-modified messenger RNA (mRNA) encoding the pre-fusion stabilized Spike glycoprotein (S) of SARS-CoV-2 virus encapsulated in a lipid nanoparticle."), 10 (representing that Spikevax® (original monovalent) is "A pharmaceutical composition"), Exhibit 4 thereto

(January 2022 Spikevax® (original monovalent) Package Insert) at 11–12 (*e.g.*, "The nucleoside-modified mRNA in SPIKEVAX is encapsulated in lipid particles, which enable delivery of the nucleoside-modified mRNA into host cells to allow expression of the SARS-Co-V-2 S antigen. The vaccine elicits an immune response to the S antigen, which protects against COVID-19."), Exhibit 8 thereto (Spikevax® BLA 125752/0 Section 3.2.P.1) at 1, Exhibit 14 thereto (May 6, 2020, FDA Letter) at 1, and Exhibit 15 thereto (May 11, 2020, FDA Letter) at 1; Exhibit 33 (March 11, 2021, EMA Spikevax® (original monovalent) Assessment Report) at 15 ("Upon delivery and uptake by body cells the mRNA is translated in the cytosol and SARS-CoV-2 spike protein is generated by the host cell machinery. The spike protein is presented and elicits an adaptive humoral and cellular immune response.") and 16–17; Exhibit 34 (January 2, 2024, EMA Spikevax® EPAR Product Information) at 3 ("Spikevax is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2[.]"); *Alnylam v. Moderna III* – C.A. No. 23-cv-580-CFC – Moderna Counterclaims and Answer (D.I. 012), A.65 ("Moderna admits that SPIKEVAX® vaccine contains lipid particles.").

135. The mRNA molecules of each of the Accused Products comprise "a sequence that encodes an immunogen." *See* paragraphs 38–96, *supra*; *e.g.*, Exhibit 33 (March 11, 2021, EMA Spikevax® (original monovalent) Assessment Report) at 15–17; Exhibit 34 (January 2, 2024, EMA Spikevax® EPAR Product Information) at 3; Exhibit 26 ('789 PTE) at 2–4, 11, Exhibit 4 thereto (January 2022 Spikevax® (original monovalent) Package Insert) at 11, Exhibit 8 thereto (Spikevax® BLA 125752/0 Section 3.2.P.1) at 1, Exhibit 11 thereto (BLA 125752/0 Section 3.2.S.1.2.1) at 1–3 (providing the sequence of the "ORF", a "Codon-optimized sequence encoding full-length SARS-CoV-2 spike (S) glycoprotein …" (position 59–3880)), Exhibit 14 thereto (May 6, 2020, FDA Letter) at 1, and Exhibit 15 thereto (May 11, 2020, FDA Letter) at 1.

136. The mRNA molecules of each of the Accused Products comprise a "7'-methylguanosine, a first 5' ribonucleotide … the first 5' ribonucleotide comprising a 2'-methylated ribose; the 7' methylguanosine linked 5'-to-5' to the first 5' ribonucleotide." *See* paragraphs 38–96, *supra*; *e.g.*, Exhibit 26 ('789 PTE) at 2, 11 ("[T]he molecular sequence of the mRNA component of SPIKEVAX includes the 5'-cap1 structure m7G-5'-ppp-5'-Gm."), 13, and Exhibit 11 thereto (BLA 125752/0 Section 3.2.S.1.2.1) at 1–3 (providing the structure of the "Cap" ("m7G-5'-ppp-5'-Gm"), the sequence of the "5' UTR" (position 3–58), the sequence of the "ORF" (position 59–3880), the sequence of the "3' UTR" (position 3881–3996), and the length of the "PolyA tail" ("100-nucleotide")).

137. The lipid particles of each of the Accused Products comprise "a PEGylated lipid, cholesterol, a first phospholipid, and a cationic lipid; the cationic lipid comprising a tertiary amine; the first phospholipid comprising an anionic phospholipid or a zwitterionic phospholipid." *See* paragraphs 38–96, *supra*; *e.g.*, Exhibit 33 (March 11, 2021, EMA Spikevax® (original monovalent) Assessment Report) at 21; Exhibit 34 (January 2, 2024, EMA Spikevax® EPAR Product Information) at 20; Exhibit 26 ('789 PTE) at 4–6, 10–11, Exhibit 3 thereto (Tenchov (2021)) at 16989, and Exhibit 4 thereto (January 2022 Spikevax® (original monovalent) Package Insert) at 11 ("Each 0.5 mL dose of SPIKEVAX also contains the following ingredients: … SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC][.]"); *see also* paragraphs 138–140, *infra*.

138. SM-102 (in chemical nomenclature, heptadecan-9-yl 8-((2-hydroxyethyl)(6-oxo-6-(undecyloxy)hexyl)amino)octanoate) is a "cationic lipid comprising a tertiary amine." *See*, *e.g.*, Exhibit 33 (March 11, 2021, EMA Spikevax® (original monovalent) Assessment Report) at 22;

Exhibit 26 (’789 PTE) at 4–5, 10, 12, Exhibit 3 thereto (Tenchov (2021)) at 16989, 16993; Exhibit 84 (Schoenmaker (2021)) at 4, 8.

139. Polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], also referred to as PEG2000-DMG (in chemical nomenclature, 1,2-dimyristoyl-rac-glyxero-3-methylpolyoxyethylene), is “a PEGylated lipid.” *See*, *e.g.*, Exhibit 33 (March 11, 2021, EMA Spikevax® (original monovalent) Assessment Report) at 24; Exhibit 26 (’789 PTE) at 5, 10–11, Exhibit 3 thereto (Tenchov (2021)) at 16989; Exhibit 84 (Schoenmaker (2021)) at 3, 4, 8.

140. DSPC (in chemical nomenclature, 1,2-distearoyl-sn-glycero-3-phosphocholine) is a “phospholipid comprising … a zwitterionic phospholipid.” *See*, *e.g.*, Exhibit 26 (’789 PTE) at 4, 6, 10, Exhibit 3 thereto (Tenchov (2021)) at 16989, and Exhibit 9 thereto (Kaur *et al.*, “Preparation, Characterisation and Entrapment of a Non-glycosidic Threitol Ceramide into Liposomes for Presentation to Invariant Natural Killer T Cells,” *J. Pharm. Sci.* 100 (7), 2724 (2011) (“Kaur (2011)”))[15] at 2728 (“the zwitterionic lipid DSPC”); Exhibit 84 (Schoenmaker (2021)) at 3, 4, 8.

141. On information and belief, the lipid particles of each of the Accused Products “encapsulat[e] at least half of the mRNA molecules.” *See* paragraphs 38–96, *supra*; *e.g.*, Exhibit 31 (December 16, 2022, EMA Spikevax® (bivalent BA.1) Assessment Report) at 45 (“Testing of original retains of this material stored in a different freezer unit at -70 C for > 12 months resulted in %encapsulation > 90% for both lots.”), 58 (“specification limit NLT 85%”); Exhibit 26 (’789 PTE) at 2 (“The active ingredient of SPIKEVAX is … encapsulated in a lipid nanoparticle.”), 5 (“SM-102 is provided in excess in the LNP to provide a stoichiometric excess of cationic charge and enable full charge complexation of the mRNA and efficient

[15] *See* Exhibit 86 for a higher quality copy of Kaur (2011).

encapsulation"), and Exhibit 4 thereto (January 2022 Spikevax® (original monovalent) Package Insert) at 12 ("The nucleoside-modified mRNA in Spikevax is encapsulated in lipid particles, which enable delivery of the nucleoside-modified mRNA into host cells…"); *see also* Exhibit 84 (Schoenmaker (2021)) at 4 ("In mRNA-LNP formulations, such as those used in mRNA vaccines ... encapsulation efficiencies ... are typically > 90%.").

142. Each of the Accused Products is "immunogenic in vivo by eliciting at least: (i) an antibody response against the immunogen, (ii) a cell-mediated immune response against the immunogen, or (iii) both (i) and (ii)." *See* paragraphs 38–96, *supra*; *e.g.*, Exhibit 33 (March 11, 2021, EMA Spikevax® (original monovalent) Assessment Report) at 15 ("Upon delivery and uptake by body cells, the mRNA is translated in the cytosol and SARS-CoV-2 spike protein is generated by the host cell machinery. The spike protein is presented and elicits an adaptive humoral and cellular immune response. Neutralizing antibodies are directed against it and hence it is considered a relevant target antigen for vaccine development."), 60 ("The expressed, membrane-bound spike protein of SARS-CoV-2 is then recognised by immune cells as a foreign antigen. This elicits both T-cell and B-cell responses to generate functional neutralising antibodies, which may contribute to protection against COVID-19.") and 60–79 (Section 2.4.2. Clinical Pharmacology); Exhibit 34 (January 2, 2024, EMA Spikevax® EPAR Product Information) at 11–19, 35–44, 61–71, 87–97.

143. Each FDA authorized and approved use for the Accused Products is "a method of eliciting an immune response in a vertebrate, the method comprising administering to the vertebrate an effective amount to elicit the immune response" of the Accused Products. *See* paragraphs 71–96, *supra*; *e.g.*, Exhibit 26 ('789 PTE) at Exhibit 4 thereto (January 2022 Spikevax® (original monovalent) Package Insert) at 1–3 ("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) in individuals 18 years of age and older. … SPIKEVAX is administered intramuscularly as a series of two doses (0.5 mL each) one month apart."), 11 ("Each 0.5 mL dose of SPIKEVAX contains 100 mcg of nucleoside-modified messenger RNA (mRNA) encoding the pre-fusion stabilized Spike glycoprotein (S) of SARS-CoV-2 virus."), 12 ("The vaccine elicits an immune response to the S antigen, which protects against COVID-9."); Exhibit 43 (April 18, 2023, FDA Spikevax® (bivalent BA.4/5) Fact Sheet) at 1, 3, 4–6; Exhibit 28 (September 2023, FDA Spikevax® (monovalent XBB.1.5) Package Insert) at 1–3; Exhibits 94–97 (mNEXSPIKE® (monovalent JN.1)).

144. Each of the Accused Products satisfies each and every element of exemplary claim 6 of the '770 patent, either literally or under the doctrine of equivalents.

145. On information and belief, Moderna has been aware at least since it received notice of its infringement from GSK on February 16, 2024, that each of the Accused Products satisfies each and every element of exemplary claim 6 of the '770 patent, either literally or under the doctrine of equivalents.

146. On information and belief, Moderna actively, knowingly, and specifically intended and intends, at least since it received notice of its infringement from GSK on February 16, 2024, to induce third-party manufacturers to directly infringe at least claim 6 of the '770 patent by making each of the Accused Products within the United States without authority or license to do so, during the term of the '770 patent.

147. On information and belief, Moderna has been aware at least since it received notice of its infringement from GSK on February 16, 2024, that the mRNA and lipid particles in each of the Accused Products constitute material parts of, are especially made and especially adapted for

use in, and are not staple articles or commodities of commerce suitable for any other substantial use in the United States other than in, each of the Accused Products and its process of manufacture, and therefore to infringe at least claim 6 of the ’770 patent.

148. Administration of Accused Products to patients in the United States in accordance with the instructions in Moderna’s labeling and prescribing information and therefore with FDA authorized and/or approved uses satisfies each and every element of exemplary claims 6 and 24 of the ’770 patent, either literally or under the doctrine of equivalents.

149. On information and belief, Moderna has been aware at least since it received notice of its infringement from GSK on February 16, 2024, that administration of Accused Products to patients in the United States in accordance with the instructions in Moderna’s labeling and prescribing information and therefore with FDA authorized and/or approved uses satisfies each and every element of exemplary claims 6 and 24 of the ’770 patent, either literally or under the doctrine of equivalents.

150. On information and belief, Moderna actively, knowingly, and specifically intended and intends, at least since it received notice of its infringement from GSK on February 16, 2024, to induce healthcare practitioners to directly infringe at least claims 6 and 24 of the ’770 patent by administering Accused Products within the United States in accordance with the instructions in Moderna’s labeling and prescribing information and therefore with FDA authorized and/or approved uses without authority or license to do so, during the term of the ’770 patent.

151. On information and belief, Moderna has been aware at least since it received notice of its infringement from GSK on February 16, 2024, that the Accused Products constitute a material part of, are especially made and especially adapted for, and are not staple articles or

commodities of commerce suitable for substantial use other than, FDA authorized and/or approved uses in the United States, and therefore to infringe at least claim 24 of the ’770 patent.

152. For the foregoing reasons, Moderna has directly infringed and continues to directly infringe at least claim 6 of the’770 patent under 35 U.S.C. § 271(a), by making, offering to sell, or selling within the United States, or importing into the United States, each of the Accused Products, without authority or license to do so, during the term of the ’770 patent.

153. In addition or in the alternative, Moderna has infringed and continues to infringe at least claim 6 of the ’770 patent under 35 U.S.C. § 271(b) by actively inducing third-party manufacturers to directly infringe at least claim 6 of the ’770 patent by making each of the Accused Products within the United States without authority or license to do so, during the term of the ’770 patent.

154. In addition or in the alternative, Moderna has infringed or continues to infringe at least claims 6 and 24 of the ’770 patent under 35 U.S.C. § 271(b) by actively inducing healthcare practitioners to directly infringe at least claims 6 and 24 of the ’770 patent by administering Accused Products to patients within the United States in accordance with the instructions in Moderna’s labeling and prescribing information and therefore with FDA authorized and/or approved uses without authority or license to do so, during the term of the ’770 patent.

155. In addition or in the alternative, Moderna has contributorily infringed and continues to contributorily infringe at least claim 24 of the ’770 patent under 35 U.S.C. § 271(c) by offering to sell or selling within the United States or importing into the United States, Accused Products without authority or license to do so, during the term of the ’770 patent, knowing that the Accused Products constitute a material part of the invention of, and are especially made or adapted to

infringe, at least claim 24 of the ’770 patent, and are not staple articles or commodities of commerce suitable for substantial non-infringing use.

156. In addition or in the alternative, Moderna has contributorily infringed and continues to contributorily infringe at least claim 6 of the ’770 patent under 35 U.S.C. § 271(c) by offering to sell or selling within the United States or importing into the United States, the mRNA and/or lipid particles to be used in the manufacture of each of the Accused Products, without authority or license to do so, during the term of the ’770 patent, knowing that each constitutes a material part of the inventions of, and is especially made or adapted to infringe, at least claim 6 of the ’770 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

157. In addition or in the alternative, Moderna has indirectly infringed and continues to indirectly infringe at least claim 6 of the ’770 patent under 35 U.S.C. § 271(f)(1) by supplying or causing to be supplied in or from the United States mRNAs and/or other components of LNPs and vaccines of the Accused Products, where such components are uncombined in whole or in part, in such a manner as to actively induce the combination of said components outside of the United States in a manner that would infringe at least claim 6 of the ’770 patent if such combination occurred within the United States.

158. In addition or in the alternative, Moderna indirectly infringed and continues to indirectly infringe at least claim 6 of the ’770 patent under 35 U.S.C. § 271(f)(2) by supplying or causing to be supplied in or from the United States mRNAs and/or other components especially made or especially adapted for use in LNPs and vaccines of the Accused Products and not a staple article or commodity of commerce suitable for substantial non-infringing use, where such components are uncombined in whole or in part, knowing that such component is so made or

adapted and intending that such component will be combined outside of the United States in a manner that would infringe at least claim 6 of the ’770 patent if such combination occurred within the United States.

159. GSK has suffered and continues to suffer damages from Moderna’s infringement of the ’770 patent.

160. GSK is entitled to an award of monetary damages, including a reasonable royalty, for Moderna’s infringement of the ’770 patent.

161. Moderna’s infringement of the ’770 patent has been and continues to be willful and deliberate at least since it received notice of its infringement from GSK on February 16, 2024.

162. Moderna’s conduct with respect to the ’770 patent makes this case exceptional under 35 U.S.C. § 285, because, despite an objectively high likelihood that its actions constitute infringement of a valid patent, Moderna continues all the aforementioned actions with respect to the Accused Products.

COUNT III

(Infringement of the ’645 Patent)

163. GSK incorporates each of the preceding paragraphs as if fully set forth herein.

164. GSK Biologicals is the lawful owner by assignment of the ’645 patent, which is entitled “Delivery of RNA to Trigger Multiple Immune Pathways” and was duly and legally issued by the U.S. Patent and Trademark Office on March 7, 2023. A true and correct copy of the ’645 patent is attached as Exhibit 3. The patent application issuing into the ’645 patent was published on February 24, 2022, as Publication No. US 2022/0054525 A1. *See* Exhibit 87.

165. Each claim of the ’645 patent is valid and enforceable.

166. Moderna has infringed and continues to infringe, under 35 U.S.C. § 271(a), (b), (c), and/or (f), one or more claims of the '645 patent either literally or under the doctrine of equivalents, through its actions in the United States with respect to each of the Accused Products.

167. Moderna has had knowledge of the '645 patent and specific notice of its infringement of that patent at least since February 16, 2024. *See* Exhibit 93.

168. For purposes of illustration and example, claims 1 and 24 of the '645 patent recite:

> **1.** A composition comprising lipid particles and messenger ribonucleic acid (mRNA) molecules; the mRNA molecules comprising a 5' cap nucleoside, a first 5' ribonucleoside, a triphosphate bridge, and a sequence that encodes an immunogen; the immunogen comprising a respiratory syncytial virus (RSV) surface fusion glycoprotein (F-protein) immunogen, an Epstein-Barr virus glycoprotein immunogen, a cytomegalovirus glycoprotein immunogen, a coronavirus spike polypeptide immunogen, an influenza virus immunogen, a *Varicella zoster* virus glycoprotein immunogen, a human papillomavirus 16 (HPV16) E6 immunogen, a HPV 16 E7 immunogen, or a flavivirus immunogen; the first 5' ribonucleoside comprising a 2'-methylated ribose; the 5' cap nucleoside being linked 5'-to-5' to the first 5' ribonucleoside by the triphosphate bridge; the lipid particles comprising: (a) a polyethylene glycol-ylated (PEGylated) lipid, (b) cholesterol, (c) an anionic phospholipid or a zwitterionic phospholipid, and (d) a cationic lipid comprising a tertiary amine; and the lipid particles encapsulating at least half of the mRNA molecules.
>
> **24.** A method of eliciting in a human an immune response comprising an antibody response against the immunogen or a cell-mediated immune response against the immunogen, the method comprising administering to the human an effective amount to elicit the immune response of the composition of claim **1**.

169. Each of the Accused Products is a "composition comprising lipid particles and messenger ribonucleic acid (mRNA) molecules." *See* paragraphs 38–96, *supra*; *e.g.*, Exhibit 26 ('789 PTE) at 2 ("The active ingredient of SPIKEVAX is mRNA-1273, which is a nucleoside-modified messenger RNA (mRNA) encoding the pre-fusion stabilized Spike glycoprotein (S) of SARS-CoV-2 virus encapsulated in a lipid nanoparticle."), 10 (representing that Spikevax®

(original monovalent) is "A pharmaceutical composition"), Exhibit 4 thereto (January 2022 Spikevax® (original monovalent) Package Insert) at 11–12 ("The nucleoside-modified mRNA in SPIKEVAX is encapsulated in lipid particles, which enable delivery of the nucleoside-modified mRNA into host cells to allow expression of the SARS-Co-V-2 S antigen. The vaccine elicits an immune response to the S antigen, which protects against COVID-19."), Exhibit 8 thereto (Spikevax® BLA 125752/0 Section 3.2.P.1) at 1, Exhibit 14 thereto (May 6, 2020, FDA Letter) at 1, and Exhibit 15 thereto (May 11, 2020, FDA Letter) at 1; *Alnylam v. Moderna III* – C.A. No. 23-cv-580-CFC – Moderna Counterclaims and Answer (D.I. 012), A.65 ("Moderna admits that SPIKEVAX® vaccine contains lipid particles.").

170. The mRNA molecules of each of the Accused Products comprise a "5' cap nucleoside, a first 5' ribonucleoside, … a triphosphate bridge … the first 5' ribonucleoside comprising a 2'-methylated ribose; the 5' cap nucleoside being linked 5'-to-5' to the first 5' ribonucleoside by the triphosphate bridge." *See* paragraphs 38–96, *supra*; *e.g.*, Exhibit 26 ('789 PTE) at 2, 11 ("[T]he molecular sequence of the mRNA component of SPIKEVAX includes the 5'-cap1 structure m7G-5'-ppp-5'-Gm."), 13, and Exhibit 11 thereto (BLA 125752/0 Section 3.2.S.1.2.1) at 1–3 (providing the structure of the "Cap" ("m7G-5'-ppp-5'-Gm"), the sequence of the "5' UTR" (position 3–58), the sequence of the "ORF" (position 59–3880), the sequence of the "3' UTR" (position 3881–3996), and the length of the "PolyA tail" ("100-nucleotide")).

171. The mRNA molecules of each of the Accused Products comprise "a sequence that encodes an immunogen; the immunogen comprising … a coronavirus spike polypeptide immunogen." *See* paragraphs 38–96, *supra*; *e.g.*, Exhibit 33 (March 11, 2021, EMA Spikevax® (original monovalent) Assessment Report) at 15–17; Exhibit 34 (January 2, 2024, EMA Spikevax® EPAR Product Information) at 3; Exhibit 26 ('789 PTE) at 2–4, 11, Exhibit 4 thereto

(January 2022 Spikevax® (original monovalent) Package Insert) at 11, Exhibit 8 thereto (Spikevax® BLA 125752/0 Section 3.2.P.1) at 1, Exhibit 11 thereto (BLA 125752/0 Section 3.2.S.1.2.1) at 1–3 (providing the sequence of the "ORF", a "Codon-optimized sequence encoding full-length SARS-CoV-2 spike (S) glycoprotein …" (position 59–3880)), Exhibit 14 thereto (May 6, 2020, FDA Letter) at 1, and Exhibit 15 thereto (May 11, 2020, FDA Letter) at 1.

172. The lipid particles of each of the Accused Products comprise "(a) a polyethylene glycol-ylated (PEGylated) lipid, (b) cholesterol, (c) an anionic phospholipid or a zwitterionic phospholipid, and (d) a cationic lipid comprising a tertiary amine." *See* paragraphs 38–96, *supra*; *e.g.*, Exhibit 33 (March 11, 2021, EMA Spikevax® (original monovalent) Assessment Report) at 21; Exhibit 34 (January 2, 2024, EMA Spikevax® EPAR Product Information) at 20; Exhibit 26 ('789 PTE) at 4–6, 10–11, Exhibit 3 thereto (Tenchov (2021)) at 16989, and Exhibit 4 thereto (January 2022 Spikevax® (original monovalent) Package Insert) at 11 ("Each 0.5 mL dose of SPIKEVAX also contains the following ingredients: … SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC][.]"); *see also* paragraphs 173–175, *infra*.

173. SM-102 (in chemical nomenclature, heptadecane-9-yl 8-((2-hydroxyethyl)(6-oxo-6-(undecyloxy)hexyl)amino)octanoate) is a "cationic lipid comprising a tertiary amine." *See*, *e.g.*, Exhibit 33 (March 11, 2021, EMA Spikevax® (original monovalent) Assessment Report) at 22; Exhibit 26 ('789 PTE) at 4–5, 10, 12, Exhibit 3 thereto (Tenchov (2021)) at 16989, 16993; Exhibit 84 (Schoenmaker (2021)) at 4, 8.

174. Polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], also referred to as PEG2000-DMG (in chemical nomenclature, 1,2-dimyristoyl-rac-glyxero-3-methylpolyoxyethylene), is "a polyethylene glycol-ylated (PEGylated) lipid." *See*, *e.g.*, Exhibit

33 (March 11, 2021, EMA Spikevax® (original monovalent) Assessment Report) at 35; Exhibit 26 ('789 PTE) at 5, 10–11, Exhibit 3 thereto (Tenchov (2021)) at 16989; Exhibit 84 (Schoenmaker (2021)) at 3, 4, 8.

175. DSPC (in chemical nomenclature, 1,2-distearoyl-sn-glycero-3-phosphocholine) is "a zwitterionic phospholipid." *See*, *e.g.*, Exhibit 26 ('789 PTE) at 4, 6, 10, Exhibit 3 thereto (Tenchov (2021)) at 16989, and Exhibit 9 thereto (Kaur (2011)) at 2728 ("the zwitterionic lipid DSPC"); Exhibit 84 (Schoenmaker (2021)) at 3, 4, 8.

176. On information and belief, the lipid particles of each of the Accused Products "encapsulat[e] at least half of the mRNA molecules." *See* paragraphs 38–96, *supra*; *e.g.*, Exhibit 39 (December 16, 2022, EMA Spikevax® (bivalent BA.1) Assessment Report) at 45 ("Testing of original retains of this material stored in a different freezer unit at -70 C for > 12 months resulted in %encapsulation > 90% for both lots."), 58 ("specification limit NLT 85%"); Exhibit 26 ('789 PTE) at 2 ("The active ingredient of SPIKEVAX is … encapsulated in a lipid nanoparticle."), 5 ("SM-102 is provided in excess in the LNP to provide a stoichiometric excess of cationic charge and enable full charge complexation of the mRNA and efficient encapsulation"), and Exhibit 4 thereto (January 2022 Spikevax® (original monovalent) Package Insert) at 12 ("The nucleoside-modified mRNA in Spikevax is encapsulated in lipid particles, which enable delivery of the nucleoside-modified mRNA into host cells…"); *see also* Exhibit 84 (Schoenmaker (2021)) at 4 ("In mRNA-LNP formulations, such as those used in mRNA vaccines ... encapsulation efficiencies ... are typically > 90%.").

177. Each FDA authorized and approved use for the Accused Products is "a method of eliciting in a human an immune response comprising an antibody response against the immunogen or a cell-mediated response against the immunogen, the method comprising

administering to the human an effective amount to elicit the immune response" of the Accused Products. *See* paragraphs 71–96, *supra*; *e.g.*, Exhibit 26 ('789 PTE) at Exhibit 4 thereto (January 2022 Spikevax® (original monovalent) Package Insert) at 1–3 ("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) in individuals 18 years of age and older. … SPIKEVAX is administered intramuscularly as a series of two doses (0.5 mL each) one month apart."), 11 ("Each 0.5 mL dose of SPIKEVAX contains 100 mcg of nucleoside-modified messenger RNA (mRNA) encoding the pre-fusion stabilized Spike glycoprotein (S) of SARS-CoV-2 virus."), 12 ("The vaccine elicits an immune response to the S antigen, which protects against COVID-9."); Exhibit 43 (April 18, 2023, FDA Spikevax® (bivalent BA.4/5) Fact Sheet) at 1, 3, 4–6; Exhibit 28 (September 2023, FDA Spikevax® (monovalent XBB.1.5) Package Insert) at 1–3; Exhibit 29 (August 2024 FDA Spikevax® (monovalent KP.2) Package Insert) at 1–3.

178. Each of the Accused Products satisfies each and every element of exemplary claim 1 of the '645 patent, either literally or under the doctrine of equivalents.

179. On information and belief, Moderna has been aware at least since it received notice of its infringement from GSK on February 16, 2024, that each of the Accused Products satisfies each and every element of exemplary claim 1 of the '645 patent, either literally or under the doctrine of equivalents.

180. On information and belief, Moderna actively, knowingly, and specifically intended and intends, at least since it received notice of its infringement from GSK on February 16, 2024, to induce third-party manufacturers to directly infringe at least claim 1 of the '645 patent by

making each of the Accused Products within the United States without authority or license to do so, during the term of the ’645 patent.

181. On information and belief, Moderna has been aware at least since it received notice of its infringement from GSK on February 16, 2024, that the mRNA and lipid particles in each of the Accused Products constitute material parts of, are especially made and especially adapted for use in, and are not staple articles or commodities of commerce suitable for any other substantial use in the United States other than in, each of the Accused Products and its process of manufacture, and therefore to infringe at least claim 1 of the ’645 patent.

182. Administration of Accused Products to patients in the United States in accordance with the instructions in Moderna’s labeling and prescribing information and therefore with FDA authorized and/or approved uses satisfies each and every element of exemplary claims 1 and 24 of the ’645 patent, either literally or under the doctrine of equivalents.

183. On information and belief, Moderna has been aware at least since it received notice of its infringement from GSK on February 16, 2024, that administration of Accused Products to patients in the United States in accordance with the instructions in Moderna’s labeling and prescribing information and therefore with FDA authorized and/or approved uses satisfies each and every element of exemplary claims 1 and 24 of the ’645 patent, either literally or under the doctrine of equivalents.

184. On information and belief, Moderna actively, knowingly, and specifically intended and intends, at least since it received notice of its infringement from GSK on February 16, 2024, to induce healthcare practitioners to directly infringe at least claims 1 and 24 of the ’645 patent by administering Accused Products within the United States in accordance with the instructions

in Moderna's labeling and prescribing information and therefore with FDA authorized and/or approved uses without authority or license to do so, during the term of the '645 patent.

185. On information and belief, Moderna has been aware at least since it received notice of its infringement from GSK on February 16, 2024, that the Accused Products constitute a material part of, are especially made and especially adapted for, and are not staple articles or commodities of commerce suitable for substantial use other than, FDA authorized and/or approved uses in the United States, and therefore to infringe at least claim 24 of the '645 patent.

186. For the foregoing reasons, Moderna has directly infringed and continues to directly infringe at least claim 1 of the'645 patent under 35 U.S.C. § 271(a), by making, offering to sell, or selling within the United States, or importing into the United States, each of the Accused Products, without authority or license to do so, during the term of the '645 patent.

187. In addition or in the alternative, Moderna has infringed and continues to infringe at least claim 1 of the '645 patent under 35 U.S.C. § 271(b) by actively inducing third-party manufacturers to directly infringe at least claim 1 of the '645 patent by making each of the Accused Products within the United States without authority or license to do so, during the term of the '645 patent.

188. In addition or in the alternative, Moderna has infringed or continues to infringe at least claims 1 and 24 of the '645 patent under 35 U.S.C. § 271(b) by actively inducing healthcare practitioners to directly infringe at least claims 1 and 24 of the '645 patent by administering Accused Products to patients within the United States in accordance with the instructions in Moderna's labeling and prescribing information and therefore with FDA authorized and/or approved uses without authority or license to do so, during the term of the '645 patent.

189. In addition or in the alternative, Moderna has contributorily infringed and continues to contributorily infringe at least claim 24 of the ’645 patent under 35 U.S.C. § 271(c) by offering to sell or selling within the United States or importing into the United States, Accused Products without authority or license to do so, during the term of the ’645 patent, knowing that the Accused Products constitute a material part of the invention of, and are especially made or adapted to infringe, at least claim 24 of the ’645 patent, and are not staple articles or commodities of commerce suitable for substantial non-infringing use.

190. In addition or in the alternative, Moderna has contributorily infringed and continues to contributorily infringe at least claim 1 of the ’645 patent under 35 U.S.C. § 271(c) by offering to sell or selling within the United States or importing into the United States, the mRNA and/or lipid particles to be used in the manufacture of each of the Accused Products, without authority or license to do so, during the term of the ’645 patent, knowing that each constitutes a material part of the inventions of, and is especially made or adapted to infringe, at least claim 1 of the ’645 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

191. In addition or in the alternative, Moderna has indirectly infringed and continues to indirectly infringe at least claim 1 of the ’645 patent under 35 U.S.C. § 271(f)(1) by supplying or causing to be supplied in or from the United States mRNAs and/or other components of LNPs and vaccines of the Accused Products, where such components are uncombined in whole or in part, in such a manner as to actively induce the combination of said components outside of the United States in a manner that would infringe at least claim 1 of the ’645 patent if such combination occurred within the United States.

192. In addition or in the alternative, Moderna indirectly infringed and continues to indirectly infringe at least claim 1 of the ’645 patent under 35 U.S.C. § 271(f)(2) by supplying or causing to be supplied in or from the United States mRNAs and/or other components especially made or especially adapted for use in LNPs and vaccines of the Accused Products and not a staple article or commodity of commerce suitable for substantial non-infringing use, where such components are uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe at least claim 1 of the ’645 patent if such combination occurred within the United States.

193. GSK has suffered and continues to suffer damages from Moderna’s infringement of the ’645 patent.

194. GSK is entitled to an award of monetary damages, including a reasonable royalty, for Moderna’s infringement of the ’645 patent.

195. Moderna’s infringement of the ’645 patent has been and continues to be willful and deliberate at least since it received notice of its infringement from GSK on February 16, 2024.

196. Moderna’s conduct with respect to the ’645 patent makes this case exceptional under 35 U.S.C. § 285, because, despite an objectively high likelihood that its actions constitute infringement of a valid patent, Moderna continues all the aforementioned actions with respect to the Accused Products.

COUNT IV

(Infringement of the ’862 Patent)

197. GSK incorporates each of the preceding paragraphs as if fully set forth herein.

198. GSK Biologicals is the lawful owner by assignment of the ’862 patent, which is entitled “Delivery of RNA to Trigger Multiple Immune Pathways” and was duly and legally

issued by the U.S. Patent and Trademark Office on July 4, 2023. A true and correct copy of the '862 patent is attached as Exhibit 4. The patent application issuing into the '862 patent was published on June 15, 2023, as Publication No. US 2023/0181618 A1. *See* Exhibit 88.

199. Each claim of the '862 patent is valid and enforceable.

200. Moderna has infringed and continues to infringe under 35 U.S.C. § 271(a), (b), (c), and/or (g), one or more claims of the '862 patent either literally or under the doctrine of equivalents, through its actions in the United States with respect to each of the Accused Products.

201. Moderna has had knowledge of the '862 patent and specific notice of its infringement of that patent at least since February 16, 2024. *See* Exhibit 93.

202. For purposes of illustration and example, claim 1 of the '862 patent recites:

> **1.** A method of obtaining a composition, the composition comprising liposomes and messenger ribonucleic acid (mRNA) molecules, the mRNA molecules comprising: (a) a 5' cap nucleoside, (b) a first 5' ribonucleoside, (c) a triphosphate bridge, (d) a 3' polyadenosine monophosphate tail, and (e) a sequence that encodes a coronavirus spike polypeptide immunogen, the first 5' ribonucleoside comprising a 2'-methylated ribose; the 5' cap nucleoside being linked 5'-to-5' to the first 5' ribonucleoside by the triphosphate bridge; the liposomes comprising lipids comprising cholesterol and a cationic lipid comprising a tertiary amine; and the liposomes encapsulating at least half of the mRNA molecules;
>
> the method comprising the steps of:
>
> (i) mixing the lipids and ethanol, thereby obtaining an ethanolic lipid mixture;
>
> (ii) mixing the mRNA molecules and an aqueous buffer, thereby obtaining an aqueous RNA mixture;
>
> (iii) mixing the ethanolic lipid mixture and the aqueous RNA mixture, thereby obtaining an intermediate mixture; and
>
> (iv) purifying the intermediate mixture, thereby obtaining the composition.

203. Each of the Accused Products comprises "a composition, the composition comprising liposomes and messenger ribonucleic acid (mRNA) molecules." *See* paragraphs 38–

96, *supra*; *e.g.*, Exhibit 26 ('789 PTE) at 2 ("The active ingredient of SPIKEVAX is mRNA-1273, which is a nucleoside-modified messenger RNA (mRNA) … encapsulated in a lipid nanoparticle."), 10, Exhibit 3 thereto (Tenchov (2021)) at 16982–83 (E.g., "Since liposomes are made of lipids and in most cases are nanosized, they are rightfully considered as the earliest generation of lipid nanoparticles."), Exhibit 4 thereto (January 2022 Spikevax® (original monovalent) Package Insert) at 11, Exhibit 8 thereto (Spikevax® BLA 125752/0 Section 3.2.P.1) at 1, Exhibit 14 thereto (May 6, 2020, FDA Letter) at 1, and Exhibit 15 thereto (May 11, 2020, FDA Letter) at 1.

204. The mRNA molecules of each of the Accused Products comprise "(a) a 5' cap nucleoside, (b) a first 5' ribonucleoside, (c) a triphosphate bridge, (d) a 3' polyadenosine monophosphate tail, … the first 5' ribonucleoside comprising a 2'-methylated ribose; the 5' cap nucleoside being linked 5'-to-5' to the first 5' ribonucleoside by the triphosphate bridge." *See* paragraphs 38–96, *supra*; *e.g.*, Exhibit 26 ('789 PTE) at 2, 4, 11 ("[T]he molecular sequence of the mRNA component of SPIKEVAX includes the 5'-cap1 structure m7G-5'-ppp-5'-Gm."), 12 ("the mRNA component of SPIKEVAX includes a 100-nucleotide poly(A)-tail"), 13, and Exhibit 11 thereto (BLA 125752/0 Section 3.2.S.1.2.1) at 1–3 (providing the structure of the "Cap" ("m7G-5'-ppp-5'-Gm"), the sequence of the "5' UTR" (position 3–58), the sequence of the "ORF" (position 59–3880), the sequence of the "3' UTR" (position 3881–3996), and the length of the "PolyA tail" ("100-nucleotide")); Exhibit 33 (March 11, 2021, EMA Spikevax® (original monovalent) Assessment Report) at 17.

205. The mRNA molecules of each of the Accused Products comprise "a sequence that encodes a coronavirus spike polypeptide immunogen." *See* paragraphs 38–96, *supra*; *e.g.*, Exhibit 33 (March 11, 2021, EMA Spikevax® (original monovalent) Assessment Report) at 15–

17; Exhibit 34 (January 2, 2024, EMA Spikevax® EPAR Product Information) at 3; Exhibit 26 ('789 PTE) at 2–4, 11, Exhibit 4 thereto (January 2022 Spikevax® (original monovalent) Package Insert) at 11, Exhibit 8 thereto (Spikevax® BLA 125752/0 Section 3.2.P.1) at 1, Exhibit 11 thereto (BLA 125752/0 Section 3.2.S.1.2.1) at 1–3 (providing the sequence of the "ORF", a "Codon-optimized sequence encoding full-length SARS-CoV-2 spike (S) glycoprotein …" (position 59–3880)), Exhibit 14 thereto (May 6, 2020, FDA Letter) at 1, and Exhibit 15 thereto (May 11, 2020, FDA Letter) at 1.

206. The liposomes of each of the Accused Products comprise "lipids comprising cholesterol and a cationic lipid comprising a tertiary amine." *See* paragraphs 38–96, *supra*; *e.g.*, Exhibit 33 (March 11, 2021, EMA Spikevax® (original monovalent) Assessment Report) at 21; Exhibit 34 (January 2, 2024, EMA Spikevax® EPAR Product Information) at 20; Exhibit 26 ('789 PTE) at 4–6, 10–11, Exhibit 3 thereto (Tenchov (2021)) at 16989, and Exhibit 4 thereto (January 2022 Spikevax® (original monovalent) Package Insert) at 11 ("Each 0.5 mL dose of SPIKEVAX also contains the following ingredients: … SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC][.]"); *see also* paragraph 207, *infra*.

207. SM-102 (in chemical nomenclature, heptadecane-9-yl 8-((2-hydroxyethyl)(6-oxo-6-(undecyloxy)hexyl)amino)octanoate) is a "cationic lipid comprising a tertiary amine." *See*, *e.g.*, Exhibit 33 (March 11, 2021, EMA Spikevax® (original monovalent) Assessment Report) at 22; Exhibit 26 ('789 PTE) at 4–5, 10, 12, Exhibit 3 thereto (Tenchov (2021)) at 16989, 16993; Exhibit 84 (Schoenmaker (2021)) at 4, 8.

208. On information and belief, the liposomes of each of the Accused Products "encapsulat[e] at least half of the mRNA molecules." *See* paragraphs 38–96, *supra*; *e.g.*, Exhibit

31 (December 16, 2022, EMA Spikevax® (bivalent BA.1) Assessment Report) at 45 ("Testing of original retains of this material stored in a different freezer unit at -70 C for > 12 months resulted in %encapsulation > 90% for both lots."), 58 ("specification limit NLT 85%"); Exhibit 26 ('789 PTE) at 2 ("The active ingredient of SPIKEVAX is … encapsulated in a lipid nanoparticle."), 5 ("SM-102 is provided in excess in the LNP to provide a stoichiometric excess of cationic charge and enable full charge complexation of the mRNA and efficient encapsulation"), and Exhibit 4 thereto (January 2022 Spikevax® (original monovalent) Package Insert) at 12 ("The nucleoside-modified mRNA in Spikevax is encapsulated in lipid particles, which enable delivery of the nucleoside-modified mRNA into host cells…"); *see also* Exhibit 84 (Schoenmaker (2021)) at 4 ("In mRNA-LNP formulations, such as those used in mRNA vaccines ... encapsulation efficiencies ... are typically > 90%.").

209. On information and belief, the method by which Moderna manufactures each of the Accused Products comprises the steps of "(i) mixing the lipids and ethanol, thereby obtaining an ethanolic lipid mixture; (ii) mixing the mRNA molecules and an aqueous buffer, thereby obtaining an aqueous RNA mixture; (iii) mixing the ethanolic lipid mixture and the aqueous RNA mixture, thereby obtaining an intermediate mixture; and (iv) purifying the intermediate mixture, thereby obtaining the composition." *See*, *e.g.*, Exhibit 89 (May 17, 2021, WHO Emergency Use Listing submitted by Moderna Biotech (Spain)) at 5–6 ("Manufacture of COVID-19 mRNA vaccine drug substance is divided into 2 sequential steps: *in vitro* synthesis of the active substance and its inclusion in the mRNA-1273 lipid nano particle envelope. … The manufacturing process of mRNA-1273 lipid nanoparticle (mRNA-1273 LNP) consists in different steps as follows: 1. Mixing of CX-024414 mRNA with lipid stock solution containing novel excipient SM-102, cholesterol … 3. Clarification by 0.8 and 0.2 µm dual-layer polyethersulfone (PES) filter; 4.

Dispensing in sterile, single-use bags ….”); Exhibit 33 (March 11, 2021, EMA Spikevax® (original monovalent) Assessment Report) at 29, 43 (“The LNP manufacturing process comprises lipid stock solution (LSS) preparation, nanoprecipitation mixing, tangential flow filtration (TFF), dilution and cryoprotectant addition, clarification, fill, and freezing and storage. … The mRNA is encapsulated in LNPs through a modified ethanol-drop nanoprecipitation process.”); Exhibit 39 (December 16, 2022, EMA Spikevax® (bivalent BA.1) Assessment Report) at 19 (“As described above, there are no changes in the manufacturing process with respect to the existing 0.1 mg/mL formulation except for the pooling of the two mRNA-loaded LNP finished product intermediates containing either [elasomeran] or [imelasomeran]”); Exhibit 40 (October 19, 2022, EMA Spikevax® (bivalent BA.4/5) Assessment Report) at 14–19 (E.g., “The manufacturing process and process and analytical control strategies established for mRNA-1273 LNP-B are applied directly to mRNA-1273.045 LNP-B. … [T]he same manufacturing process is used[.]”); Exhibit 27 (August 31, 2022, FDA Spikevax® (bivalent BA.4/5) EUA Review Memo) at 41 (“The manufacturing and quality testing sites as well as all unit operations and process controls used to manufacture CX-034476 mRNA, mRNA-1273.045 LNP-B DS, and Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) DP are consistent with the previously filed DS and DP processes and controls for the authorized 0.10 mg/mL original Moderna COVID-19 Vaccine.”), also 5–8, 14, 37, 47–48; Exhibit 45 (September 11, 2023, FDA Spikevax® (monovalent XBB.1.5) vaccine Clinical Review Memo) at 10 (“The safety and effectiveness of Spikevax (Original monovalent) and Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5) are relevant to Spikevax (2023-2024 Formula) because these vaccines are manufactured using a similar process.”), also 144, 146, 150; Exhibit 49 (August 22, 2024, FDA Spikevax® (monovalent KP.2) vaccine EUA Review Memo) at 21 (“Effectiveness and safety

data accrued with the Moderna COVID-19 Vaccine (Original monovalent), Moderna COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5), and Moderna COVID-19 Vaccine (2023-2024 Formula) are relevant to Moderna COVID-19 Vaccine (2024-2025 Formula), because all these vaccines are manufactured using the same process.").

210. The process by which each of the Accused Products is manufactured satisfies each and every element of exemplary claim 1 of the '862 patent, either literally or under the doctrine of equivalents.

211. On information and belief, Moderna has been aware at least since it received notice of its infringement from GSK on February 16, 2024, that the process by which each of the Accused Products is manufactured satisfies each and every element of exemplary claim 1 of the '862 patent, either literally or under the doctrine of equivalents.

212. On information and belief, Moderna actively, knowingly, and specifically intended and intends, at least since it received notice of its infringement from GSK on February 16, 2024, to induce third-party manufacturers to directly infringe at least claim 1 of the '862 patent by making each of the Accused Products using the process of claim 1 of the '862 patent within the United States without authority or license to do so, during the term of the '862 patent.

213. On information and belief, Moderna has been aware at least since it received notice of its infringement from GSK on February 16, 2024, that the mRNA and liposomes used in the manufacture of the Accused Products constitute material parts of, are especially made and especially adapted for, and are not staple articles or commodities of commerce suitable for any substantial use in the United States other than in the manufacture of the Accused Products, and therefore to infringe at least claim 1 of the '862 patent.

214. For the foregoing reasons, Moderna has directly infringed and continues to directly infringe at least claim 1 of the'862 patent under 35 U.S.C. § 271(a), by making within the United States, each of the Accused Products using the process of claim 1 of the '862 patent, without authority or license to do so, during the term of the '862 patent.

215. In addition or in the alternative, Moderna has infringed and continues to infringe at least claim 1 of the '862 patent under 35 U.S.C. § 271(b) by actively inducing third-party manufacturers to directly infringe at least claim 1 of the '862 patent by making each of the Accused Products using the process of claim 1 of the '862 patent within the United States without authority or license to do so, during the term of the '862 patent.

216. In addition or in the alternative, Moderna has contributorily infringed and continues to contributorily infringe at least claim 1 of the '862 patent under 35 U.S.C. § 271(c) by importing into the United States, the mRNA and/or liposomes to be used in the manufacture of the Accused Products using the process of claim 1 of the '862 patent, without authority or license to do so, during the term of the '862 patent, knowing that each constitutes a material part of the inventions of, and is especially made or adapted to infringe, at least claim 1 of the '862 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

217. In addition or in the alternative, Moderna has infringed and continues to infringe at least claim 1 of the '862 patent under 35 U.S.C. § 271(g) by importing into the United States, or offering to sell, or selling within the United States, Accused Products made by the process of claim 1 of the '862 patent, without authority or license to do so, during the term of the '862 patent.

218. GSK has suffered and continues to suffer damages from Moderna's infringement of the '862 patent.

219. GSK is entitled to an award of monetary damages, including a reasonable royalty, for Moderna's infringement of the '862 patent.

220. Moderna's infringement of the '862 patent has been and continues to be willful and deliberate at least since it received notice of its infringement from GSK on February 16, 2024.

221. Moderna's conduct with respect to the '862 patent makes this case exceptional under 35 U.S.C. § 285, because, despite an objectively high likelihood that its actions constitute infringement of a valid patent, Moderna continues all the aforementioned actions with respect to the Accused Products.

COUNT V

(Infringement of the '482 Patent)

222. GSK incorporates each of the preceding paragraphs as if fully set forth herein.

223. GSK Biologicals is the lawful owner by assignment of the '482 patent, which is entitled "Delivery of RNA to Trigger Multiple Immune Pathways" and was duly and legally issued by the U.S. Patent and Trademark Office on July 25, 2023. A true and correct copy of the '482 patent is attached as Exhibit 5. The patent application issuing into the '482 patent was published on April 13, 2023, as Publication No. US 2023/0111638 A1. *See* Exhibit 90.

224. Each claim of the '482 patent is valid and enforceable.

225. Moderna has infringed and continues to infringe, under 35 U.S.C. § 271(a), (b), (c), and/or (f), one or more claims of the '482 patent either literally or under the doctrine of equivalents, through its actions in the United States with respect to each of the Accused Products.

226. Moderna has had knowledge of the '482 patent and specific notice of its infringement of that patent at least since February 16, 2024. *See* Exhibit 93.

227. For purposes of illustration and example, claims 1 and 14 of the '482 patent recite:

> **1.** A composition comprising liposomes and messenger ribonucleic acid (mRNA) molecules; the mRNA molecules comprising: (i) a 5' cap nucleoside, (ii) a first 5' ribonucleoside, (iii) a triphosphate bridge, (iv) a 3' polyadenosine monophosphate tail, and (v) a sequence that encodes a coronavirus spike polypeptide immunogen; the first 5' ribonucleoside comprising a 2'-methylated ribose; the 5' cap nucleoside being linked 5'-to-5' to the first 5' ribonucleoside by the triphosphate bridge; the liposomes comprising cholesterol and a cationic lipid comprising a tertiary amine; and the liposomes encapsulating at least half of the mRNA molecules.
>
> **14.** A method of eliciting in a human an immune response comprising an antibody response against the coronavirus spike polypeptide immunogen or a cell-mediated immune response against the coronavirus spike polypeptide immunogen, the method comprising administering to the human an effective amount of the composition of claim **1** to elicit the immune response.

228. Each of the Accused Products comprises a "composition comprising liposomes and messenger ribonucleic acid (mRNA) molecules." *See* paragraphs 38–96, *supra*; *e.g.*, Exhibit 26 ('789 PTE) at 2 ("The active ingredient of SPIKEVAX is mRNA-1273, which is a nucleoside-modified messenger RNA (mRNA) … encapsulated in a lipid nanoparticle."), 10, Exhibit 3 thereto (Tenchov (2021)) at 16982–83 (E.g., "Since liposomes are made of lipids and in most cases are nanosized, they are rightfully considered as the earliest generation of lipid nanoparticles."), Exhibit 4 thereto (January 2022 Spikevax® (original monovalent) Package Insert) at 11, Exhibit 8 thereto (Spikevax® BLA 125752/0 Section 3.2.P.1) at 1, Exhibit 14 thereto (May 6, 2020, FDA Letter) at 1, and Exhibit 15 thereto (May 11, 2020, FDA Letter) at 1.

229. The mRNA molecules of each of the Accused Products comprise "(i) a 5' cap nucleoside, (ii) a first 5' ribonucleoside, (iii) a triphosphate bridge, (iv) a 3' polyadenosine monophosphate tail, … the first 5' ribonucleoside comprising a 2'-methylated ribose; the 5' cap nucleoside being linked 5'-to-5' to the first 5' ribonucleoside by the triphosphate bridge." *See* paragraphs 38–96, *supra*; *e.g.*, Exhibit 26 ('789 PTE) at 2, 4, 11 ("[T]he molecular sequence of

the mRNA component of SPIKEVAX includes the 5'-cap1 structure m7G-5'-ppp-5'-Gm."), 12 ("the mRNA component of SPIKEVAX includes a 100-nucleotide poly(A)-tail"), 13, and Exhibit 11 thereto (BLA 125752/0 Section 3.2.S.1.2.1) at 1–3 (providing the structure of the "Cap" ("m7G-5'-ppp-5'-Gm"), the sequence of the "5' UTR" (position 3–58), the sequence of the "ORF" (position 59–3880), the sequence of the "3' UTR" (position 3881–3996), and the length of the "PolyA tail" ("100-nucleotide")); Exhibit 33 (March 11, 2021, EMA Spikevax® (original monovalent) Assessment Report) at 17.

230. The mRNA molecules of each of the Accused Products comprise "a sequence that encodes a coronavirus spike polypeptide immunogen." *See* paragraphs 38–96, *supra*; *e.g.*, Exhibit 33 (March 11, 2021, EMA Spikevax® (original monovalent) Assessment Report) at 15–17; Exhibit 34 (January 2, 2024, EMA Spikevax® EPAR Product Information) at 3; Exhibit 26 ('789 PTE) at 2–4, 11, Exhibit 4 thereto (January 2022 Spikevax® (original monovalent) Package Insert) at 11, Exhibit 8 thereto (Spikevax® BLA 125752/0 Section 3.2.P.1) at 1, Exhibit 11 thereto (BLA 125752/0 Section 3.2.S.1.2.1) at 1–3 (providing the sequence of the "ORF", a "Codon-optimized sequence encoding full-length SARS-CoV-2 spike (S) glycoprotein …" (position 59–3880)), Exhibit 14 thereto (May 6, 2020, FDA Letter) at 1, and Exhibit 15 thereto (May 11, 2020, FDA Letter) at 1.

231. The liposomes of each of the Accused Products comprise "cholesterol and a cationic lipid comprising a tertiary amine." *See* paragraphs 38–96, *supra*; *e.g.*, Exhibit 33 (March 11, 2021, EMA Spikevax® (original monovalent) Assessment Report) at 21; Exhibit 34 (January 2, 2024, EMA Spikevax® EPAR Product Information) at 20; Exhibit 26 ('789 PTE) at 4–6, 10–11, Exhibit 3 thereto (Tenchov (2021)) at 16989, and Exhibit 4 thereto (January 2022 Spikevax® (original monovalent) Package Insert) at 11 ("Each 0.5 mL dose of SPIKEVAX also contains the

following ingredients: … SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC][.]"); *see also* paragraph 232, *infra*.

232. SM-102 (in chemical nomenclature, heptadecane-9-yl 8-((2-hydroxyethyl)(6-oxo-6-(undecyloxy)hexyl)amino)octanoate) is a "cationic lipid comprising a tertiary amine." *See*, *e.g.*, Exhibit 33 (March 11, 2021, EMA Spikevax® (original monovalent) Assessment Report) at 22; Exhibit 26 ('789 PTE) at 4–5, 10, 12, Exhibit 3 thereto (Tenchov (2021)) at 16989, 16993; Exhibit 84 (Schoenmaker (2021)) at 4, 8.

233. On information and belief, the liposomes of each of the Accused Products "encapsulat[e] at least half of the mRNA molecules." *See* paragraphs 38–96, *supra*; *e.g.*, Exhibit 39 (December 16, 2022, EMA Spikevax® (bivalent BA.1) Assessment Report) at 45 ("Testing of original retains of this material stored in a different freezer unit at -70 C for > 12 months resulted in %encapsulation > 90% for both lots."), 58 ("specification limit NLT 85%"); Exhibit 26 ('789 PTE) at 2 ("The active ingredient of SPIKEVAX is … encapsulated in a lipid nanoparticle."), 5 ("SM-102 is provided in excess in the LNP to provide a stoichiometric excess of cationic charge and enable full charge complexation of the mRNA and efficient encapsulation"), and Exhibit 4 thereto (January 2022 Spikevax® (original monovalent) Package Insert) at 12 ("The nucleoside-modified mRNA in Spikevax is encapsulated in lipid particles, which enable delivery of the nucleoside-modified mRNA into host cells…"); *see also* Exhibit 84 (Schoenmaker (2021)) at 4 ("In mRNA-LNP formulations, such as those used in mRNA vaccines ... encapsulation efficiencies ... are typically > 90%.").

234. Each FDA authorized and approved use for the Accused Products is "a method of eliciting in a human an immune response comprising an antibody response against the coronavirus

spike polypeptide immunogen or a cell-mediated immune response against the coronavirus spike polypeptide immunogen, the method comprising administering to the human an effective amount … to elicit the immune response" of the Accused Products. *See* paragraphs 71–96, *supra*; *e.g.*, Exhibit 26 ('789 PTE) at Exhibit 4 thereto (January 2022 Spikevax® (original monovalent) Package Insert) at 1–3 ("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) in individuals 18 years of age and older. … SPIKEVAX is administered intramuscularly as a series of two doses (0.5 mL each) one month apart."), 11 ("Each 0.5 mL dose of SPIKEVAX contains 100 mcg of nucleoside-modified messenger RNA (mRNA) encoding the pre-fusion stabilized Spike glycoprotein (S) of SARS-CoV-2 virus."), 12 ("The vaccine elicits an immune response to the S antigen, which protects against COVID-9."); Exhibit 43 (April 18, 2023, FDA Spikevax® (bivalent BA.4/5) Fact Sheet) at 1, 3, 4–6; Exhibit 28 (September 2023, FDA Spikevax® (monovalent XBB.1.5) Package Insert) at 1–3; Exhibit 29 (August 2024 FDA Spikevax® (monovalent KP.2) Package Insert) at 1–3.

235. Each of the Accused Products satisfies each and every element of exemplary claim 1 of the '482 patent, either literally or under the doctrine of equivalents.

236. On information and belief, Moderna has been aware at least since it received notice of its infringement from GSK on February 16, 2024, that each of the Accused Products satisfies each and every element of exemplary claim 1 of the '482 patent, either literally or under the doctrine of equivalents.

237. On information and belief, Moderna actively, knowingly, and specifically intended and intends, at least since it received notice of its infringement from GSK on February 16, 2024, to induce third-party manufacturers to directly infringe at least claim 1 of the '482 patent by

making each of the Accused Products within the United States without authority or license to do so, during the term of the ’482 patent.

238. On information and belief, Moderna has been aware at least since it received notice of its infringement from GSK on February 16, 2024, that the mRNA and liposomes in each of the Accused Products constitute material parts of, are especially made and especially adapted for use in, and are not staple articles or commodities of commerce suitable for any other substantial use in the United States other than in, each of the Accused Products and its process of manufacture, and therefore to infringe at least claim 1 of the ’482 patent.

239. Administration of Accused Products to patients in the United States in accordance with the instructions in Moderna’s labeling and prescribing information and therefore with FDA authorized and/or approved uses satisfies each and every element of exemplary claims 1 and 14 of the ’482 patent, either literally or under the doctrine of equivalents.

240. On information and belief, Moderna has been aware at least since it received notice of its infringement from GSK on February 16, 2024, that administration of Accused Products to patients in the United States in accordance with the instructions in Moderna’s labeling and prescribing information and therefore with FDA authorized and/or approved uses satisfies each and every element of exemplary claims 1 and 14 of the ’482 patent, either literally or under the doctrine of equivalents.

241. On information and belief, Moderna actively, knowingly, and specifically intended and intends, at least since it received notice of its infringement from GSK on February 16, 2024, to induce healthcare practitioners to directly infringe at least claims 1 and 14 of the ’482 patent by administering Accused Products within the United States in accordance with the instructions

in Moderna's labeling and prescribing information and therefore with FDA authorized and/or approved uses without authority or license to do so, during the term of the '482 patent.

242. On information and belief, Moderna has been aware at least since it received notice of its infringement from GSK on February 16, 2024, that the Accused Products constitute a material part of, are especially made and especially adapted for, and are not staple articles or commodities of commerce suitable for substantial use other than, FDA authorized and/or approved uses in the United States, and therefore to infringe at least claim 14 of the '482 patent.

243. For the foregoing reasons, Moderna has directly infringed and continues to directly infringe at least claim 1 of the'482 patent under 35 U.S.C. § 271(a), by making, offering to sell, or selling within the United States, or importing into the United States, each of the Accused Products, without authority or license to do so, during the term of the '482 patent.

244. In addition or in the alternative, Moderna has infringed and continues to infringe at least claim 1 of the '482 patent under 35 U.S.C. § 271(b) by actively inducing third-party manufacturers to directly infringe at least claim 1 of the '482 patent by making each of the Accused Products within the United States without authority or license to do so, during the term of the '482 patent.

245. In addition or in the alternative, Moderna has infringed or continues to infringe at least claims 1 and 14 of the '482 patent under 35 U.S.C. § 271(b) by actively inducing healthcare practitioners to directly infringe at least claims 1 and 14 of the '482 patent by administering Accused Products to patients within the United States in accordance with the instructions in Moderna's labeling and prescribing information and therefore with its FDA authorized and/or approved use(s) without authority or license to do so, during the term of the '482 patent.

246. In addition or in the alternative, Moderna has contributorily infringed and continues to contributorily infringe at least claim 14 of the ’482 patent under 35 U.S.C. § 271(c) by offering to sell or selling within the United States or importing into the United States, Accused Products without authority or license to do so, during the term of the ’482 patent, knowing that the Accused Products constitute a material part of the invention of, and are especially made or adapted to infringe, at least claim 14 of, the ’482 patent, and are not staple articles or commodities of commerce suitable for substantial non-infringing use.

247. In addition or in the alternative, Moderna has contributorily infringed and continues to contributorily infringe at least claim 1 of the ’482 patent under 35 U.S.C. § 271(c) by offering to sell or selling within the United States or importing into the United States, the mRNA and/or liposomes to be used in the manufacture of each of the Accused Products, without authority or license to do so, during the term of the ’482 patent, knowing that each constitutes a material part of the inventions of, and is especially made or adapted to infringe, at least claim 1 of the ’482 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

248. In addition or in the alternative, Moderna has indirectly infringed and continues to indirectly infringe at least claim 1 of the ’482 patent under 35 U.S.C. § 271(f)(1) by supplying or causing to be supplied in or from the United States mRNAs and/or other components of LNPs and vaccines of the Accused Products, where such components are uncombined in whole or in part, in such a manner as to actively induce the combination of said components outside of the United States in a manner that would infringe at least claim 1 of the ’482 patent if such combination occurred within the United States.

249. In addition or in the alternative, Moderna indirectly infringed and continues to indirectly infringe at least claim 1 of the ’482 patent under 35 U.S.C. § 271(f)(2) by supplying or causing to be supplied in or from the United States mRNAs and/or other components especially made or especially adapted for use in LNPs and vaccines of the Accused Products and not a staple article or commodity of commerce suitable for substantial non-infringing use, where such components are uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe at least claim 1 of the ’482 patent if such combination occurred within the United States.

250. GSK has suffered and continues to suffer damages from Moderna’s infringement of the ’482 patent.

251. GSK is entitled to an award of monetary damages, including a reasonable royalty, for Moderna’s infringement of the ’482 patent.

252. Moderna’s infringement of the ’482 patent has been and continues to be willful and deliberate at least since it received notice of its infringement from GSK on February 16, 2024.

253. Moderna’s conduct with respect to the ’482 patent makes this case exceptional under 35 U.S.C. § 285, because, despite an objectively high likelihood that its actions constitute infringement of a valid patent, Moderna continues all the aforementioned actions with respect to the Accused Products.

COUNT VI

(Infringement of the ’534 patent)

254. GSK incorporates each of the preceding paragraphs as if fully set forth herein.

255. GSK Biologicals is the lawful owner by assignment of the ’534 patent, which is entitled “Methods of Administering Lipid Formulations with Viral Immunogens” and was duly

and legally issued by the U.S. Patent and Trademark Office on June 6, 2023. A true and correct copy of the ’534 patent is attached as Exhibit 6. The patent application issuing into the ’534 patent was published on April 28, 2022, as Publication No. US 2022/0125727 A1. *See* Exhibit 91.

256. Each claim of the ’534 patent is valid and enforceable.

257. Moderna has infringed and continues to infringe, under 35 U.S.C. § 271(b) and/or (c), one or more claims of the ’534 patent either literally or under the doctrine of equivalents, through its actions in the United States with respect to the Accused Products.

258. Moderna has had knowledge of the ’534 patent and specific notice of its infringement of that patent at least since February 16, 2024. *See* Exhibit 93.

259. For purposes of illustration and example, claim 1 of the ’534 patent recites:

> **1.** A method of eliciting an immune response against an immunogen in a subject, the method comprising:
>
> administering to the subject an immunologically effective unit dose of a formulation comprising:
>
> ribonucleic acid (RNA) molecules comprising a sequence that encodes the immunogen, wherein the immunogen comprises a respiratory syncytial virus immunogen, an Epstein-Barr virus immunogen, a cytomegalovirus immunogen, a coronavirus spike polypeptide immunogen, an influenza virus A immunogen, a Varicella zoster virus immunogen, or a flavivirus immunogen; and
>
> lipids comprising a tertiary amine cationic lipid, a polyethylene glycol-conjugated (PEG-conjugated) lipid, and cholesterol;
>
> wherein the lipids encapsulate at least half of the RNA molecules; and
>
> wherein the immune response against the immunogen comprises an antibody response against the immunogen.

260. Each of the Accused Products comprises “a formulation comprising: ribonucleic acid (RNA) molecules … and lipids.” *See* paragraphs 38–96, *supra*; *e.g.*, Exhibit 26 (’789 PTE) at 2 (“The active ingredient of SPIKEVAX is mRNA-1273, which is a nucleoside-modified

messenger RNA (mRNA) encoding the pre-fusion stabilized Spike glycoprotein (S) of SARS-CoV-2 virus encapsulated in a lipid nanoparticle."), 10, Exhibit 4 thereto (January 2022 Spikevax® (original monovalent) Package Insert) at 11–12 ("The nucleoside-modified mRNA in SPIKEVAX is encapsulated in lipid particles, which enable delivery of the nucleoside-modified mRNA into host cells to allow expression of the SARS-Co-V-2 S antigen."), Exhibit 8 thereto (Spikevax® BLA 125752/0 Section 3.2.P.1) at 1, Exhibit 14 thereto (May 6, 2020, FDA Letter) at 1, and Exhibit 15 thereto (May 11, 2020, FDA Letter) at 1.

261. The RNA molecules of each of the Accused Products comprise "a sequence that encodes the immunogen, wherein the immunogen comprises … a coronavirus spike polypeptide immunogen." *See* paragraphs 38–96, *supra*; *e.g.*, Exhibit 33 (March 11, 2021, EMA Spikevax® (original monovalent) Assessment Report) at 15–17; Exhibit 34 (January 2, 2024, EMA Spikevax® EPAR Product Information) at 3; Exhibit 26 ('789 PTE) at 2–4, 11, Exhibit 4 thereto (January 2022 Spikevax® (original monovalent) Package Insert) at 11, Exhibit 8 thereto (Spikevax® BLA 125752/0 Section 3.2.P.1) at 1, Exhibit 11 thereto (BLA 125752/0 Section 3.2.S.1.2.1) at 1–3 (providing the sequence of the "ORF", a "Codon-optimized sequence encoding full-length SARS-CoV-2 spike (S) glycoprotein …" (position 59–3880)), Exhibit 14 thereto (May 6, 2020, FDA Letter) at 1, and Exhibit 15 thereto (May 11, 2020, FDA Letter) at 1.

262. The lipids of each of the Accused Products comprise "a tertiary amine cationic lipid, a polyethylene glycol-conjugated (PEG-conjugated) lipid, and cholesterol." *See* paragraphs 38–96, *supra*; *e.g.*, Exhibit 33 (March 11, 2021, EMA Spikevax® (original monovalent) Assessment Report) at 21; Exhibit 34 (January 2, 2024, EMA Spikevax® EPAR Product Information) at 20; Exhibit 26 ('789 PTE) at 4–6, 10–11, Exhibit 3 thereto (Tenchov (2021)) at 16989, and Exhibit 4 thereto (January 2022 Spikevax® (original monovalent) Package Insert) at

11 ("Each 0.5 mL dose of SPIKEVAX also contains the following ingredients: … SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC][.]"); *see also* paragraphs 263–264, *infra*.

263. SM-102 (in chemical nomenclature, heptadecane-9-yl 8-((2-hydroxyethyl)(6-oxo-6-(undecyloxy)hexyl)amino)octanoate) is a "tertiary amine cationic lipid." *See*, *e.g.*, Exhibit 33 (March 11, 2021, EMA Spikevax® (original monovalent) Assessment Report) at 22; Exhibit 26 ('789 PTE) at 4–5, 10, 12, Exhibit 3 thereto (Tenchov (2021)) at 16989, 16993; Exhibit 84 (Schoenmaker (2021)) at 4, 8.

264. Polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], also referred to as PEG2000-DMG (in chemical nomenclature, 1,2-dimyristoyl-rac-glyxero-3-methylpolyoxyethylene), is a "polyethylene glycol-conjugated (PEG-conjugated) lipid." *See*, *e.g.*, Exhibit 33 (March 11, 2021, EMA Spikevax® (original monovalent) Assessment Report) at 24; Exhibit 26 ('789 PTE) at 5, 10–11, Exhibit 3 thereto (Tenchov (2021)) at 16989; Exhibit 84 (Schoenmaker (2021)) at 3, 4, 8.

265. On information and belief, the lipids of each of the Accused Products "encapsulate at least half of the RNA molecules." *See* paragraphs 38–96, *supra*; *e.g.*, Exhibit 39 (December 16, 2022, EMA Spikevax® (bivalent BA.1) Assessment Report) at 45 ("Testing of original retains of this material stored in a different freezer unit at -70 C for > 12 months resulted in %encapsulation > 90% for both lots."), 58 ("specification limit NLT 85%"); Exhibit 26 ('789 PTE) at 2 ("The active ingredient of SPIKEVAX is … encapsulated in a lipid nanoparticle."), 5 ("SM-102 is provided in excess in the LNP to provide a stoichiometric excess of cationic charge and enable full charge complexation of the mRNA and efficient encapsulation"), and Exhibit 4 thereto (January 2022 Spikevax® (original monovalent) Package Insert) at 12 ("The nucleoside-

modified mRNA in Spikevax is encapsulated in lipid particles, which enable delivery of the nucleoside-modified mRNA into host cells…"); *see also* Exhibit 84 (Schoenmaker (2021)) at 4 ("In mRNA-LNP formulations, such as those used in mRNA vaccines ... encapsulation efficiencies ... are typically > 90%.").

266. Each FDA authorized and approved use for the Accused Products is a "method of eliciting an immune response against an immunogen in a subject, the method comprising: administering to the subject an immunologically effective unit dose of" each of the Accused Products, thereby "eliciting an immune response" against the coronavirus spike polypeptide immunogen encoded by the mRNA molecules "wherein the immune response against the immunogen comprises an antibody response against the immunogen." *See* paragraphs 71–96, *supra*; *e.g.*, Exhibit 26 ('789 PTE) at Exhibit 4 thereto (January 2022 Spikevax® (original monovalent) Package Insert) at 1–3 ("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) in individuals 18 years of age and older. … SPIKEVAX is administered intramuscularly as a series of two doses (0.5 mL each) one month apart."), 11–12 ("Administer a single 0.5 mL dose … Spikevax is administered intramuscularly as a series of two doses (0.5 mL each) 1 month apart"; "Each 0.5 mL dose of SPIKEVAX contains 100 mcg of [mRNA] encoding the pre-fusion stabilized Spike glycoprotein (S) of SARS-CoV-2 virus[.]"; "The nucleoside-modified mRNA in SPIKEVAX is encapsulated in lipid particles, which enable delivery of the nucleoside-modified mRNA into host cells to allow expression of the SARS-Co-V-2 S antigen. The vaccine elicits an immune response to the S antigen, which protects against COVID-19."), Exhibit 8 thereto (Spikevax® BLA 125752/0 Section 3.2.P.1) at 1, Exhibit 14 thereto (May 6, 2020, FDA Letter) at 1, and Exhibit 15 thereto (May 11, 2020, FDA Letter) at 1;

Exhibit 33 (March 11, 2021, EMA Spikevax® (original monovalent) Assessment Report) at 15 ("Upon delivery and uptake by body cells, the mRNA is translated in the cytosol and SARS-CoV-2 spike protein is generated by the host cell machinery. The spike protein is presented and elicits an adaptive humoral and cellular immune response. Neutralizing antibodies are directed against it and hence it is considered a relevant target antigen for vaccine development."), 16–17, 60 ("The expressed, membrane-bound spike protein of SARS-CoV-2 is then recognised by immune cells as a foreign antigen. This elicits both T-cell and B-cell responses to generate functional neutralising antibodies, which may contribute to protection against COVID-19.") and 60–79 (Section 2.4.2. Clinical Pharmacology); Exhibit 34 (January 2, 2024, EMA Spikevax® EPAR Product Information) at 3 ("Spikevax is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2[.]"), 11–19, 35–44, 61–71, 87–97; Exhibit 43 (April 18, 2023, FDA Spikevax® (bivalent BA.4/5) Fact Sheet) at 1, 3, 4–6; Exhibit 28 (September 2023, FDA Spikevax® (monovalent XBB.1.5) Package Insert) at 1–3; Exhibit 29 (August 2024 FDA Spikevax® (monovalent KP.2) Package Insert) at 1–3.

267. Administration of Accused Products to patients in the United States in accordance with the instructions in Moderna's labeling and prescribing information and therefore with its FDA authorized and/or approved use(s) satisfies each and every element of exemplary claim 1 of the '534 patent, either literally or under the doctrine of equivalents.

268. On information and belief, Moderna has been aware at least since it received notice of its infringement from GSK on February 16, 2024, that administration of Accused Products to patients in the United States in accordance with the instructions in Moderna's labeling and prescribing information and therefore with its FDA authorized and/or approved use(s) satisfies

each and every element of exemplary claim 1 of the ’534 patent, either literally or under the doctrine of equivalents.

269. On information and belief, Moderna actively, knowingly, and specifically intended and intends, at least since it received notice of its infringement from GSK on February 16, 2024, to induce healthcare practitioners to directly infringe at least claim 1 of the ’534 patent by administering Accused Products within the United States in accordance with the instructions in Moderna’s labeling and prescribing information and therefore with its FDA authorized and/or approved use(s) without authority or license to do so, during the term of the ’534 patent.

270. On information and belief, Moderna has been aware at least since it received notice of its infringement from GSK on February 16, 2024, that the Accused Products constitute a material part of, are especially made and especially adapted for, and are not staple articles or commodities of commerce suitable for substantial use other than, FDA authorized and/or approved use(s) in the United States, and therefore to infringe at least claim 1 of the ’534 patent.

271. For the foregoing reasons, Moderna has infringed or continues to infringe at least claim 1 of the ’534 patent under 35 U.S.C. § 271(b) by actively inducing healthcare practitioners to directly infringe at least claim 1 of the ’534 patent by administering Accused Products to patients within the United States in accordance with the instructions in Moderna’s labeling and prescribing information and therefore with its FDA authorized and/or approved use(s) without authority or license to do so, during the term of the ’534 patent.

272. In addition or in the alternative, Moderna has contributorily infringed and continues to contributorily infringe at least claim 1 of the ’534 patent under 35 U.S.C. § 271(c) by offering to sell or selling within the United States or importing into the United States, Accused Products without authority or license to do so, during the term of the ’534 patent, knowing that the Accused

Products constitute a material part of the invention of, and are especially made or adapted to infringe, at least claim 1 of, the ’534 patent, and are not staple articles or commodities of commerce suitable for substantial non-infringing use.

273. GSK has suffered and continues to suffer damages from Moderna’s infringement of the ’534 patent.

274. GSK is entitled to an award of monetary damages, including a reasonable royalty, for Moderna’s infringement of the ’534 patent.

275. Moderna’s infringement of the ’534 patent has been and continues to be willful and deliberate at least since it received notice of its infringement from GSK on February 16, 2024.

276. Moderna’s conduct with respect to the ’534 patent makes this case exceptional under 35 U.S.C. § 285, because, despite an objectively high likelihood that its actions constitute infringement of a valid patent, Moderna continues all the aforementioned actions with respect to the Accused Products.

COUNT VII

(Infringement of the ’467 Patent)

277. GSK incorporates each of the preceding paragraphs as if fully set forth herein.

278. GSK Biologicals is the lawful owner by assignment of the ’467 patent, which is entitled “Lipid Formulations With Immunogens” and was duly and legally issued by the U.S. Patent and Trademark Office on October 17, 2023. A true and correct copy of the ’467 patent is attached as Exhibit 7. The patent application issuing into the ’467 patent was published on April 28, 2022, as Publication No. US 2022/0125722 A1. *See* Exhibit 92.

279. Each claim of the ’467 patent is valid and enforceable.

280. Moderna has infringed and continues to infringe, under 35 U.S.C. § 271(a), (b), (c), and/or (f), one or more claims of the '467 patent either literally or under the doctrine of equivalents, through its actions in the United States with respect to each of the Accused Products.

281. Moderna has had knowledge of the '467 patent and specific notice of its infringement of that patent at least since February 16, 2024. *See* Exhibit 93.

282. For purposes of illustration and example, claim 1 of the '467 patent recites:

> **1.** A formulation comprising:
>
> ribonucleic acid (RNA) molecules comprising a sequence that encodes an immunogen; and
>
> lipids comprising a tertiary amine cationic lipid, a polyethylene glycol-conjugated (PEG-conjugated) lipid, and cholesterol;
>
> wherein the formulation is immunogenic in vivo by eliciting an antibody response against the immunogen in vivo;
>
> wherein the lipids encapsulate at least half of the RNA molecules.

283. Each of the Accused Products is a "formulation comprising: ribonucleic acid (RNA) molecules … and lipids." *See* paragraphs 38–96, *supra*; *e.g.*, Exhibit 26 ('789 PTE) at 2 ("The active ingredient of SPIKEVAX is mRNA-1273, which is a nucleoside-modified messenger RNA (mRNA) … encapsulated in a lipid nanoparticle."), 10, Exhibit 4 thereto (January 2022 Spikevax® (original monovalent) Package Insert) at 11, 12, Exhibit 8 thereto (Spikevax® BLA 125752/0 Section 3.2.P.1) at 1, Exhibit 14 thereto (May 6, 2020, FDA Letter) at 1, and Exhibit 15 thereto (May 11, 2020, FDA Letter) at 1; Exhibit 33 (March 11, 2021, EMA Spikevax® (original monovalent) Assessment Report) at 15–17, 21–22; Exhibit 34 (January 2, 2024, EMA Spikevax® EPAR Product Information) at 2, 20, 27–28, 44, 52–53, 71, 78, 97; *Alnylam v. Moderna III* – C.A. No. 23-cv-580-CFC – Moderna Counterclaims and Answer (D.I. 012), A.65 ("Moderna admits that SPIKEVAX® vaccine contains lipid particles.").

284. The RNA molecules of each of the Accused Products comprise "a sequence that encodes an immunogen." *See* paragraphs 38–96, *supra*; *e.g.*, Exhibit 33 (March 11, 2021, EMA Spikevax® (original monovalent) Assessment Report) at 15 ("Upon delivery and uptake by body cells, the mRNA is translated in the cytosol and SARS-CoV-2 spike protein is generated by the host cell machinery. The spike protein is presented and elicits an adaptive humoral and cellular immune response. Neutralizing antibodies are directed against it and hence it is considered a relevant target antigen for vaccine development.") and 16–17; Exhibit 34 (January 2, 2024, EMA Spikevax® EPAR Product Information) at 3; Exhibit 26 ('789 PTE) at 2–4, 11, Exhibit 4 thereto (January 2022 Spikevax® (original monovalent) Package Insert) at 11, Exhibit 8 thereto (Spikevax® BLA 125752/0 Section 3.2.P.1) at 1, Exhibit 11 thereto (BLA 125752/0 Section 3.2.S.1.2.1) at 1–3 (providing the sequence of the "ORF", a "Codon-optimized sequence encoding full-length SARS-CoV-2 spike (S) glycoprotein …" (position 59–3880)), Exhibit 14 thereto (May 6, 2020, FDA Letter) at 1, and Exhibit 15 thereto (May 11, 2020, FDA Letter) at 1.

285. The lipids of each of the Accused Products comprise "a tertiary amine cationic lipid, a poly-ethylene glycol-conjugated (PEG-conjugated) lipid, and cholesterol." *See* paragraphs 38–96, *supra*; *e.g.*, Exhibit 33 (March 11, 2021, EMA Spikevax® (original monovalent) Assessment Report) at 21; Exhibit 34 (January 2, 2024, EMA Spikevax® EPAR Product Information) at 20; Exhibit 26 ('789 PTE) at 4–6, 10–11, Exhibit 3 thereto (Tenchov (2021)) at 16989, and Exhibit 4 thereto (January 2022 Spikevax® (original monovalent) Package Insert) at 11 ("Each 0.5 mL dose of SPIKEVAX also contains the following ingredients: … SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC][.]"); *see also* paragraphs 286–287, *infra*.

286. SM-102 (in chemical nomenclature, heptadecane-9-yl 8-((2-hydroxyethyl)(6-oxo-6-(undecyloxy)hexyl)amino)octanoate) is a "tertiary amine cationic lipid." *See*, *e.g.*, Exhibit 33 (March 11, 2021, EMA Spikevax® (original monovalent) Assessment Report) at 22; Exhibit 26 ('789 PTE) at 4–5, 10, 12, Exhibit 3 thereto (Tenchov (2021)) at 16989, 16993; Exhibit 84 (Schoenmaker (2021)) at 4, 8.

287. Polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], also referred to as PEG2000-DMG (in chemical nomenclature, 1,2-dimyristoyl-rac-glyxero-3-methylpolyoxyethylene), is a "polyethylene glycol-conjugated (PEG-conjugated) lipid." *See*, *e.g.*, Exhibit 33 (March 11, 2021, EMA Spikevax® (original monovalent) Assessment Report) at 24; Exhibit 26 ('789 PTE) at 5, 10–11, Exhibit 3 thereto (Tenchov (2021)) at 16989; Exhibit 84 (Schoenmaker (2021)) at 3, 4, 8.

288. On information and belief, the lipids of each of the Accused Products "encapsulate at least half of the RNA molecules." *See* paragraphs 38–96, *supra*; *e.g.*, Exhibit 39 (December 16, 2022, EMA Spikevax® (bivalent BA.1) Assessment Report) at 45 ("Testing of original retains of this material stored in a different freezer unit at -70 C for > 12 months resulted in %encapsulation > 90% for both lots."), 58 ("specification limit NLT 85%"); Exhibit 26 ('789 PTE) at 2 ("The active ingredient of SPIKEVAX is … encapsulated in a lipid nanoparticle."), 5 ("SM-102 is provided in excess in the LNP to provide a stoichiometric excess of cationic charge and enable full charge complexation of the mRNA and efficient encapsulation"), and Exhibit 4 thereto (January 2022 Spikevax® (original monovalent) Package Insert) at 12 ("The nucleoside-modified mRNA in Spikevax is encapsulated in lipid particles, which enable delivery of the nucleoside-modified mRNA into host cells…"); *see also* Exhibit 84 (Schoenmaker (2021)) at 4

("In mRNA-LNP formulations, such as those used in mRNA vaccines ... encapsulation efficiencies ... are typically > 90%.").

289. Each of the Accused Products is "immunogenic in vivo by eliciting an antibody response against the immunogen in vivo." *See* paragraphs 38–96, *supra*; *e.g.*, Exhibit 33 (March 11, 2021, EMA Spikevax® (original monovalent) Assessment Report) at 15 ("Upon delivery and uptake by body cells, the mRNA is translated in the cytosol and SARS-CoV-2 spike protein is generated by the host cell machinery. The spike protein is presented and elicits an adaptive humoral and cellular immune response. Neutralizing antibodies are directed against it and hence it is considered a relevant target antigen for vaccine development."), 60 ("The expressed, membrane-bound spike protein of SARS-CoV-2 is then recognised by immune cells as a foreign antigen. This elicits both T-cell and B-cell responses to generate functional neutralising antibodies, which may contribute to protection against COVID-19.") and 62–79 (Section 2.4.2. Clinical Pharmacology); Exhibit 34 (January 2, 2024, EMA Spikevax® EPAR Product Information) at 11–19, 35–44, 61–71, 87–97.

290. Each of the Accused Products satisfies each and every element of exemplary claim 1 of the '467 patent, either literally or under the doctrine of equivalents.

291. On information and belief, Moderna has been aware at least since it received notice of its infringement from GSK on February 16, 2024, that each of the Accused Products satisfies each and every element of exemplary claim 1 of the '467 patent, either literally or under the doctrine of equivalents.

292. On information and belief, Moderna actively, knowingly, and specifically intended and intends, at least since it received notice of its infringement from GSK on February 16, 2024, to induce third-party manufacturers to directly infringe at least exemplary claim 1 of the '467

patent by making each of the Accused Products within the United States without authority or license to do so, during the term of the ’467 patent.

293. On information and belief, Moderna has been aware at least since it received notice of its infringement from GSK on February 16, 2024, that the mRNA and lipid particles in each of the Accused Products constitute material parts of, are especially made and especially adapted for use in, and are not staple articles or commodities of commerce suitable for any other substantial use in the United States other than in, each of the Accused Products and its process of manufacture, and therefore to infringe at least claim 1 of the ’467 patent.

294. Administration of Accused Products to patients in the United States in accordance with the instructions in Moderna’s labeling and prescribing information and therefore with its FDA authorized and/or approved use(s) satisfies each and every element of exemplary claim 1 of the ’467 patent, either literally or under the doctrine of equivalents.

295. On information and belief, Moderna has been aware at least since it received notice of its infringement from GSK on February 16, 2024, that administration of Accused Products to patients in the United States in accordance with the instructions in Moderna’s labeling and prescribing information and therefore with its FDA authorized and/or approved use(s) satisfies each and every element of exemplary claim 1 of the ’467 patent, either literally or under the doctrine of equivalents.

296. On information and belief, Moderna actively, knowingly, and specifically intended and intends, at least since it received notice of its infringement from GSK on February 16, 2024, to induce healthcare practitioners to directly infringe at least exemplary claim 1 of the ’467 patent by administering Accused Products within the United States in accordance with the instructions

in Moderna's labeling and prescribing information and therefore with its FDA authorized and/or approved use(s) without authority or license to do so, during the term of the '467 patent.

297. For the foregoing reasons, Moderna has directly infringed and continues to directly infringe at least claim 1 of the'467 patent under 35 U.S.C. § 271(a), by making, offering to sell, or selling within the United States, or importing into the United States, each of the Accused Products, without authority or license to do so, during the term of the '467 patent.

298. In addition or in the alternative, Moderna has infringed and continues to infringe at least claim 1 of the '467 patent under 35 U.S.C. § 271(b) by actively inducing third-party manufacturers to directly infringe at least claim 1 of the '467 patent by making each of the Accused Products within the United States without authority or license to do so, during the term of the '467 patent.

299. In addition or in the alternative, Moderna has infringed or continues to infringe at least claim 1 of the '467 patent under 35 U.S.C. § 271(b) by actively inducing healthcare practitioners to directly infringe at least claim 1 of the '467 patent by administering Accused Products to patients within the United States in accordance with the instructions in Moderna's labeling and prescribing information and therefore with its FDA authorized and approved uses without authority or license to do so, during the term of the '467 patent.

300. In addition or in the alternative, Moderna has contributorily infringed and continues to contributorily infringe at least claim 1 of the '467 patent under 35 U.S.C. § 271(c) by offering to sell or selling within the United States or importing into the United States, the mRNA drug substances to be used in the manufacture of each of the Accused Products, without authority or license to do so, during the term of the '467 patent, knowing that the mRNA drug substances constitute a material part of the inventions of, and are especially made or adapted to infringe, at

least claim 1 of, the ’467 patent, and knowing that the mRNA drug substances are not staple articles or commodities of commerce suitable for substantial non-infringing use.

301. In addition or in the alternative, Moderna has indirectly infringed and continues to indirectly infringe at least claim 1 of the ’467 patent under 35 U.S.C. § 271(f)(1) by supplying or causing to be supplied in or from the United States mRNAs and/or other components of LNPs and vaccines of the Accused Products, where such components are uncombined in whole or in part, in such a manner as to actively induce the combination of said components outside of the United States in a manner that would infringe at least claim 1 of the ’467 patent if such combination occurred within the United States.

302. In addition or in the alternative, Moderna indirectly infringed and continues to indirectly infringe at least claim 1 of the ’467 patent under 35 U.S.C. § 271(f)(2) by supplying or causing to be supplied in or from the United States mRNAs and/or other components especially made or especially adapted for use in LNPs and vaccines of the Accused Products and not a staple article or commodity of commerce suitable for substantial non-infringing use, where such components are uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe at least claim 1 of the ’467 patent if such combination occurred within the United States.

303. GSK has suffered and continues to suffer damages from Moderna’s infringement of the ’467 patent.

304. GSK is entitled to an award of monetary damages, including a reasonable royalty, for Moderna’s infringement of the ’467 patent.

305. Moderna's infringement of the '467 patent has been and continues to be willful and deliberate at least since it received notice of its infringement from GSK on February 16, 2024.

306. Moderna's conduct with respect to the '467 patent makes this case exceptional under 35 U.S.C. § 285, because, despite an objectively high likelihood that its actions constitute infringement of a valid patent, Moderna continues all the aforementioned actions with respect to the Accused Products.

PRAYER FOR RELIEF

WHEREFORE, GSK prays for judgment as follows:

A. That Moderna has directly infringed, either literally or under the doctrine of equivalents, the '682, '770, '645, '862, '482, and '467 patents;

B. That Moderna has induced infringement, either literally or under the doctrine of equivalents, of each of the Patents-in-Suit;

C. That Moderna has contributorily infringed, either literally or under the doctrine of equivalents, each of the Patents-in-Suit;

D. That Moderna's infringement of each of the Patents-in-Suit has been willful;

E. That GSK be awarded all damages adequate to compensate it for Moderna's infringement of the Patents-in-Suit, such damages to be determined by a jury, and if necessary to adequately compensate GSK for the infringement, an accounting, and that such damages be trebled and awarded to GSK with pre- and post-judgment interest;

F. That this case be declared an exceptional case within the meaning of 35 U.S.C. § 285 and that GSK be awarded the attorney fees, costs, and expenses incurred in connection with this action;

G. That GSK be awarded a compulsory ongoing licensing fee; and

H. That GSK be awarded such other and further relief at law or equity as this Court deems just and proper.

DEMAND FOR JURY TRIAL

GSK hereby demands a trial by jury on all issues so triable.

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Dated: September 3, 2025

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