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. **JURY TRIAL DEMANDED**

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 1–6 (the "Patents-in-Suit," as defined in paragraph 8, *infra*).

2. In 2008, the named inventors of the Patents-in-Suit, Christian Mandl, Andrew Geall, Gillis Otten, and Katrin Ramsauer—accomplished scientists with M.D.'s and/or Ph.D.'s and years of research experience 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*, lipid formulations encapsulating mRNA molecules encoding viral protein immunogens that, following administration, provide protection against infection by the corresponding virus. The Mandl team described the inventions now claimed in the Patents-in-Suit, in patent applications filed in 2010.

3. A major advance of the Mandl team's inventions over preexisting vaccine technologies is the speed with which new vaccine candidates can be made and tested—simply by altering the mRNA molecules to encode for a new immunogen. 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 [influenza] sequence was available." Exhibit 7 (Dolgin, "Injection of Hope," *Nature* 574, S10 (2019)) at S11. The prestigious science journal *Nature* recognized this achievement as "[t]he current speed record" of vaccine development. *Id*.

4. The Mandl team's innovation has been revolutionary for vaccine development. *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.

5. GSK's patented inventions provide the foundation for Moderna's mRNA vaccine portfolio, including its mRESVIA® respiratory syncytial virus (RSV) fusion glycoprotein (F protein) mRNA vaccine, the product at issue in this action. But Moderna has consistently failed to acknowledge how it applied the Mandl team's revolutionary platform to design and develop its vaccines.

6. Moderna stands to reap significant revenues by infringing GSK's Patents-in-Suit without ever obtaining a license. GSK brings this suit to recover a reasonable royalty for Moderna's infringing sales of mRESVIA®.

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 ongoing infringing manufacture, use, sale, marketing, offer for sale, and/or importation of mRESVIA® RSV F protein mRNA vaccine product (the "Accused Product," as further defined in paragraphs 35–44, *infra*).

8. As alleged herein, Moderna's activity with respect to the Accused Product does and will 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. 11,324,770 (the "'770 patent") (Exhibit 1), 11,690,861 (the "'861 patent") (Exhibit 2), 11,690,864 (the "'864 patent") (Exhibit 3), 11,717,529 (the "'529 patent") (Exhibit 4), 11,786,467 (the "'467 patent") (Exhibit 5), and 11,883,534 (the "'534 patent") (Exhibit 6) (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 Product 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 Product (BLA 125796) in the United States. Exhibit 9 (May 31, 2024, FDA 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 Product 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 Product 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 Product 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*.

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, they offer for sale and/or sell the Accused Product in Delaware and 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/or sales of the Accused Product as well as offers for sale and sales of other mRNA vaccine products, they have engaged in and maintain systematic and continuous business contacts within 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 mRNA vaccine 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 mRNA vaccine products in *Arbutus Biopharma Corp. et al. v. Moderna, Inc. et al.*, C.A. No. 22-cv-252-MSG.

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 mRNA vaccine 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 mRNA vaccine 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. Inside a patient's cells, existing cellular machinery reads the instructions encoded by the mRNA to produce the protein—a process called "translation"—and the protein triggers various responses from the patient's immune system. *See* Exhibit 1 ('770 Patent) at col. 13, ll. 36–45 ("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. … The immune response may comprise an antibody response … and/or a cell-mediated immune response.").

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. 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 the 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 10 (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. The Mandl team's seminal publication on this work has been cited over 500 times and viewed over 60,000 times. *See* Exhibit 11 (Geall *et al*., "Nonviral delivery of self-amplifying RNA vaccines," *Proc. Natl. Acad. Sci.* 109(36), 14604-609 (2012) with supplementary information).[1]

26. 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 12 (Lizotte, "Novartis Receives $14M Award from DARPA," Global Biodefense, January 31, 2012) (describing award of DARPA Contract HR0011-12-3-0001).

27. In 2017, years before commercializing any mRNA vaccine, 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 10 (Stanton (2017)) at 241.

28. 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.

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

29. 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

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

acquired a substantial portion of Novartis's global vaccines business. *See* Exhibit 13 (March 2, 2015, GSK press release). In that transaction, GSK obtained, among other things, the Mandl team's inventions, including all rights to the parent applications to the Patents-in-Suit.

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

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

31. Indeed, years before seeking commercial marketing approval for the Accused Product, Moderna obtained technical know-how relating to GSK Biologicals's mRNA vaccine platform technology by hiring several former Novartis and GSK employees who had first-hand knowledge of the Mandl team's innovations.

32. 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 14 (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* Exhibit 15 (printout of patent filings and patent applications citing to patents or patent applications in the family of the '770, '861, '864 and '529 Patents-in-Suit from the Derwent Patents Citation Index, preserved May 30, 2024[2]); Exhibit 17 (printout of patent filings and patent applicants citing to patents or patent applications in the

[2] 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 16 (Google Patents, Cite By section for the '770 patent, available at https://patents.google.com/patent/US11324770B2/en?oq=US11324770B2, preserved August 3, 2023).

family of the ’467 and ’534 Patents-in-Suit from the Derwent Patents Citation Index, preserved April 19, 2024).[3] And, as noted, in 2017, Moderna researchers cited the Mandl team’s seminal publication on this work as the first successful use of lipid-mRNA formulations for *in vivo* protein translation. Exhibit 10 (Stanton (2017)) at 241.

33. Moderna’s mRESVIA® RSV F mRNA vaccine product exploits 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 Product. But Moderna did not acquire a license to practice the GSK inventions before or since manufacturing and obtaining approval to commercially market the Accused Product.

34. 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 Product at least since October 11, 2024, by communications with GSK. *See* Exhibit 56.

MODERNA’S INFRINGING ACTIVITIES

35. Moderna’s manufacture, use, sale, marketing, offer for sale, and/or importation of the Accused Product, mRESVIA®, directly and indirectly infringes and/or will infringe the Patents-in-Suit.

A. The Accused Product

36. The Accused Product “consists of lipid nanoparticles (LNPs) that encapsulate linear mRNA” provided as a single-dose suspension in a prefilled syringe. *See*, *e.g.*, Exhibit 19 (FDA

[3] Similar information is available publicly through Google Patents. *See*, *e.g.*, Exhibit 18 (Google Patents, Cited By section, for the ’467 patent, available at https://patents.google.com/patent/US11786467B2/en?oq=11786467; preserved July 3, 2024).

Chemistry, Manufacturing, and Controls (CMC) Review Memo) at i; Exhibit 20 (May 2024, mRESVIA® Package Insert) at 2.

37. On information and belief, and as set forth by example, *infra*, Moderna uses the same composition of mRNA, composition of lipid particles, and methods of manufacture for the Accused Product, 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.

38. Moderna and FDA refer to the mRNA in the Accused Product as "RNA-100-AR02." *See*, *e.g.*, Exhibit 19 (FDA CMC Review Memo) at, *e.g.*, 13.

39. Moderna and FDA refer to the lipid particles in the Accused Product as "LNP-100-AR02." *See*, *e.g.*, Exhibit 19 (FDA CMC Review Memo) at, *e.g.*, 13.

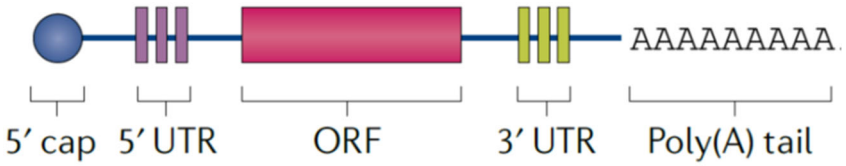
40. Moderna, FDA, and EMA refer to the Accused Product as "mRNA-1345" or "mRNA-1345 DP" (for Drug Product). *See*, *e.g.*, Exhibit 19 (FDA CMC Review Memo) at, *e.g.*, 11, 165; Exhibit 21 (excerpt from May 31, 2024, FDA List of Licensed Products); Exhibit 22 (May 31, 2024, Moderna press release) at 1–3; Exhibit 23 (May 15, 2023, EMA Study Decision) *passim*; Exhibit 24 (March 27, 2024, Moderna Vaccine & Business Updates Presentation ("Moderna Vaccine Updates")) at 3, 4, 76–82, 84–95; Exhibit 25 (February 29, 2024, Moderna Advisory Committee on Immunization Practices (ACIP) for the Centers for Disease Control and Prevention (CDC) Presentation ("Moderna ACIP Presentation")) *passim*; Exhibit 26 (February 15, 2024, Moderna Respiratory Syncytial Virus Foundation Conference Presentation ("Moderna ReSViNET Presentation)) *passim*; Exhibit 27 (June 27, 2024, EMA mResvia® Assessment Report) *passim.*

41. On information and belief, the mRNA in the Accused Product includes, among other things, a 5' cap, a 5' untranslated region (UTR), an open reading frame (ORF) region coding

for the RSV F protein, a 3' untranslated region, and a 3' polyA tail. *See*, *e.g.*, Exhibit 28 (Moderna International Patent Publication No. WO/2022/221336 A1 ("Moderna WO336 Publication")) at 73–79 ("Example I – Phase I Study" using mRNA-1345), 80–81 (Table I. Vaccine Sequences, Prefusion RSV F Protein dCT Variant) (providing the general structure of the "Cap" ("7mG(5')ppp(5')N1mpNp", where N represents any nucleotide; *see infra* for the specific cap Moderna used in its COVID-19 mRNA vaccine products), the sequence of the "5' UTR" (SEQ ID NO: 33), the sequence of the "ORF of mRNA (excluding the stop codon)" (SEQ ID NO: 34), the sequence of the "3' UTR" (SEQ ID NO: 35), and the length of the "PolyA tail" ("100 nt")); *see also* Exhibit 29 (Chaudhary *et al.*, "mRNA vaccines for infectious diseases: principles, delivery and clinical translation," *Nature Rev. Drug Disc.* 20, 817–838 (2021) ("Chaudhary (2021)")) at 818 ("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 endogenous 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, *infra*); January 18, 2023, CNBC Television Interview, "Moderna CEO: We're preparing our FDA filing for our RSV vaccine," ("2023 CNBC Interview")[4] at 2:21 ("And the other great news about mRNA is: because all the 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 30 (U.S. Patent No. 10,703,789 Spikevax® Patent Term Extension Application ("'789 PTE"), filed March 30, 2022) at 1–3 (providing the specific structure of the "Cap" ("m7G-5'-ppp-5'-Gm") used in Moderna's COVID-19 mRNA

[4] Available at https://www.youtube.com/watch?v=FzgSE3yG-7E, last accessed September 27, 2024.

vaccine products; Exhibit 27 (June 27, 2024, EMA mResvia® Assessment Report) at 11 ("The active substance RNA-100-AR02 (internal name CX-032753), encodes for the respiratory syncytial virus (RSV) F glycoprotein stabilised in the pre-fusion conformation. The molecular sequence of RNA-100-AR02, including the 5' cap, the 5' untranslated region (UTR), the Open Reading Frame (ORF), the 3' UTR, and the 3' polyA tail, is provided in the dossier.").



42. The mRNA in the Accused Product encodes an RSV F protein. *See*, *e.g.*, Exhibit 20 (May 2024, mRESVIA® Package Insert) at 6 ("Each 0.5 mL dose of MRESVIA contains 50 mcg of nucleoside modified mRNA encoding the RSV F glycoprotein stabilized in the prefusion conformation (pre-F protein."); Exhibit 19 (FDA CMC Review Memo) at, *e.g.*, i; Exhibit 28 (Moderna WO336 Publication) *passim*, *e.g.*, at 80–81 (providing sequence of the "ORF of mRNA (excluding the stop codon)" (SEQ ID NO: 34) and "Corresponding amino acid sequence" (SEQ ID NO: 8)); Exhibit 25 (February 29, 2024, Moderna ACIP Presentation) at 3; Exhibit 22 (May 31, 2024, Moderna press release) at 2; Exhibit 23 (May 15, 2023, EMA Study Decision) at 1; Exhibit 26 (February 15, 2024 Moderna ReSViNET Presentation) at 5; Exhibit 27 (June 27, 2024, EMA mResvia® Assessment Report) at 10 ("The active substance is a single-stranded 5' capped mRNA encoding the RSV-A glycoprotein F stabilised in the prefusion conformation.").

43. The lipid particles in the Accused Product 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)

See, *e.g.*, Exhibit 20 (May 2024, mRESVIA® Package Insert) at 6 ("Each 0.5 mL dose of MRESVIA also contains the following ingredients: a total lipid content of 1.02 mg (SM-102 (heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate), polyethylene glycol 2000 dimyristoyl glycerol [PEG2000-DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]) ….") (bracketed text in original); Exhibit 31 (Shaw *et al*., "Safety, Tolerability, and Immunogenicity of an mRNA-Based Respiratory Syncytial Virus Vaccine in Healthy Young Adults in a Phase 1 Clinical Trial", *J. Infect. Dis.*, jiae035 (2024) with supplementary information ("Shaw, *JID*, jiae035 (2024)")) at 2 ("mRNA-1345 contains a single nucleoside-modified mRNA sequence encoding the membrane-anchored RSV F glycoprotein (RSV-A2 strain protein sequence) stabilized in the preF conformation through structural engineering and formulated in lipid nanoparticles (LNPs). The LNP formulation consists of an ionizable lipid promoting assembly of LNPs into delivery vehicles, a phospholipid that forms lipid bilayer structures in LNPs, a poly-ethylene glycol lipid, and a sterol that improves the stability of the formulations."); Exhibit 32 (Shaw *et al*., "Safety and Immunogenicity of an mRNA-Based RSV Vaccine Including a 12-Month Booster in a Phase 1 Clinical Trial in Healthy Older Adults", *J. Infect. Dis.*, jiae081 (2024) with supplementary information ("Shaw, *JID*, jiae081 (2024)")) at 2 (similar); Exhibit 19 (FDA CMC Review Memo) at, *e.g.*, i, 165; Exhibit 27 (June 27, 2024, EMA mResvia® Assessment Report) at 10 ("Other ingredients are: SM-102 (heptadecan-9-yl 8-((2-

hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino)octanoate), cholesterol, 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC), 1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 (PEG2000-DMG),").

44. On information and belief, the same processes (apart from differences involved in setting the sequence of the mRNA open reading frame) are used to manufacture the mRNA, lipid particles, and finished suspension form of the Accused Product as are used to manufacture the mRNA, lipid particles, and finished suspension form of Moderna's Spikevax® SARS-CoV-2 vaccine products. *See*, *e.g.*, Exhibit 33 (FDA CMC Statistical Review Memo) at, *e.g.*, 5 ("Moderna's RNA manufacturing process and process control strategy for vaccines, termed RNA-100, was originally developed for Moderna's vaccine Spikevax. Moderna claimed that its prior experience has demonstrated the RNA-100 process and that the process control strategy established for Spikevax RNA manufacture could be applied to other RNA sequences, including mRNA-1345."); Exhibit 19 (FDA CMC Review Memo) at, *e.g.*, 12 ("ModernaTX manufactures all mRNA vaccines according to the 100 process, using similar process steps, equipment, materials, with similar or identical in-process parameters …."); 2023 CNBC Interview at 2:21 ("And the other great news about mRNA is: because all the 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 34 (January 17, 2023, Moderna press release) at 3 ("mRNA-1345 is an investigational RSV vaccine that consists of a single mRNA sequence encoding for a stabilized prefusion F glycoprotein. The vaccine uses the same lipid nanoparticles (LNPs) as in the Moderna COVID-19 vaccines."); Exhibit 27 (June 27, 2024, EMA mResvia® Assessment Report) at 12 ("The commercial active substance manufacturing process was developed in parallel with the clinical development programme and the process development is

described in detail. It is appreciated that certain aspects especially from the licensed vaccine Spikevax are used to support the process development of RNA-100-AR02.").

45. The mRNA and lipid particles 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, the Accused Product and its process of manufacture.

B. Moderna's Ongoing Infringement in the United States

46. On March 27, 2024, Moderna indicated in an investor presentation that it was "[a]waiting regulatory approvals; preparing for 2024 U.S. launch" of mRESVIA®. Exhibit 24 (March 27, 2024, Moderna Vaccine Updates) at 76, 84. In the same presentation, Moderna specified that it was "[e]xpecting to launch in the U.S. in 2024 after ACIP recommendation." *Id*. at 83.

47. On May 2, 2024, Moderna CEO Stephane Bancel stated during television interviews that Moderna is "anticipating the launch of RSV vaccine very soon this spring." *See* May 2, 2024, CNBC Television Interview, "Moderna CEO Stephane Bancel on Q1 results: The vaccine platform is coming along together very nicely" ("2024 CNBC Interview")[5] around 2:06; May 2, 2024, Bloomberg Television Interview, "Moderna Focused on Cutting Costs, RSV Vaccine" ("2024 Bloomberg Interview")[6] around 1:07.

48. On May 10, 2024, in a press release, Moderna announced that FDA "expect to complete the review" of its mRESVIA® BLA "by the end of May." Exhibit 35 (May 10, 2024, Moderna press release) at 1. Moderna also stated that it "remains on track for mRNA-1345 to be

[5] Available at https://youtu.be/4qvz5dD88Fg?si=gJnv9pLmaO3IgEqA; last accessed September 27, 2024.
[6] Available at https://youtu.be/cxyLzd58xfU?si=QLMdtubItCHVFDwH; last accessed September 27, 2024.

reviewed at the CDC's Advisory Committee on Immunization Practices (ACIP) June 26–27, 2024, meeting, which is necessary prior to commercial launch." *Id*.

49. On May 31, 2024, FDA approved the use of the Accused Product "for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older." Exhibit 9 (May 31, 2024, FDA Approval Letter); Exhibit 20 (May 2024, mRESVIA® Package Insert). Moderna has also publicly disclosed its plan to file a supplemental Biologics License Application for U.S. approval in 2024 to expand the indication of mRESVIA to high-risk adults 18 to 59 years old. Exhibit 36 (September 12, 2024, Moderna press release) at 3–4.

50. Also on May 31, 2024, in a press release announcing FDA approval of the mRESVIA® BLA, Moderna stated that it "expects to have mRESVIA available for eligible populations in the U.S. by the 2024/2025 respiratory virus season." Exhibit 22 (May 31, 2024, Moderna press release).

51. On June 26, 2024, the Advisory Committee on Immunization Practices (ACIP) for the Centers for Disease Control and Prevention (CDC) recommended that providers and other public health officials make a universal recommendation for adults 75 years and older and a risk-based recommendation for adults aged 60 to 74 years to receive a single dose of any FDA-approved RSV vaccine "in the late summer and early fall to optimize public health benefits." *See* Exhibit 37 (2024-06-24 CDC ACIP Guidance 1) at 5–6; Exhibit 38 (2024-06-24 CDC ACIP Guidance 2) at 4–11; Exhibit 39 (2024-06-24 CDC ACIP Guidance 3).

52. On information and belief, Moderna now offers for sale and sells, the Accused Product in the United States. *See* Exhibit 40 (August 1, 2024, Moderna press release) ("Following U.S. Food and Drug Administration (FDA) approval in May and the Advisory Committee on

Immunization Practices (ACIP) recommendation in June, Moderna's RSV vaccine, mRESVIA®, has launched in the U.S. and deliveries are underway as of July 2024."); Exhibit 41 (Moderna Second Quarter 2024 Earnings Presentation) at 5, 27; Exhibit 42 (CDC Webpage Moderna RSV Vaccine Summary; preserved September 27, 2024)[7] (indicating that Moderna has implemented pre-ordering and reservation programs for mRESVIA®); Exhibit 43 (Modernadirect.com; preserved September 27, 2024) (permitting mRESVIA® orders to be placed through a Moderna website; also stating that mResvia® is currently shipping); Exhibit 44 (https://products.modernatx.com/mresviapro/ordering; preserved September 27, 2024) (similar).

53. On information and belief, Moderna makes and/or has third-party manufacturers make, the mRNA, the lipid particles, and the finished form of the Accused Product, both inside and outside the United States. *See*, *e.g.*, Exhibit 9 (May 31, 2024, FDA Approval Letter) at 1; Exhibit 24 (March 27, 2024, Moderna Vaccine Updates) at 132–135; Exhibit 45 (excerpts from February 24, 2023, Moderna, Inc. 2022FY Annual Report (Form 10-K)) at 32–33; Exhibit 46 (excerpts from February 23, 2024, Moderna, Inc. 2023FY Annual Report (Form 10-K)) at 24–25. Exhibit 27 (June 27, 2024, EMA mResvia® Assessment Report) at 11−12.

54. On information and belief, Moderna packages, promotes, offers for sale and sells the Accused Product with labeling and prescribing information that instructs healthcare practitioners to "administer" the Accused Product to patients in the United States in accordance with the FDA-approved use. Exhibit 20 (May 2024, mRESVIA® Package Insert) at 2 ("2.3 Administration … Administer MRESVIA intramuscularly."); Exhibit 47 (https://products.modernatx.com/mresvia; preserved September 27, 2024) (directing healthcare practitioners to the prescribing information for mRESVIA®).

[7] Available at https://www.cdc.gov/vaccines/php/info-by-product/moderna-rsv-summary.html

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

56. When administered to patients in accordance with the FDA-approved use, the Accused Product elicits an immune response to, *inter alia*, the encoded RSV F protein. *See*, *e.g.*, Exhibit 20 (May 2024, mRESVIA® Package Insert) at 6 ("MRESVIA induces an immune response against RSV pre-F protein that protects against LRTD caused by RSV."); Exhibit 24 (March 27, 2024, Moderna Vaccine Updates) at 78–81, 83, 86, and 90; Exhibit 25 (February 29, 2024, Moderna ACIP Presentation) at 3, 22–25, 27–31, 33–36, 39–40, 47; Exhibit 26 (February 15, 2024, Moderna ReSViNET Conference Presentation) at 10, 16–20, 27–29; Exhibit 31 (Shaw, *JID*, jiae035 (2024)) *passim*; Exhibit 32 (Shaw, *JID*, jiae081 (2024)) *passim*; Exhibit 48 (Wilson *et al*., "Efficacy and Safety of an mRNA-Based RSV PreF Vaccine in Older Adults", *New Engl. J. Med.* 389(24), 2233–44 (2023) with excerpts of the supplementary information ("Wilson (2023))") *passim*; Exhibit 27 (June 27, 2024, EMA mResvia® Assessment Report) at 67 ("Antibody persistence: One month after a single 50 µg mRNA-1345 vaccination, the nAb GMFR from baseline was 12.03 for RSV-A and 8.96 for RSV-B. RSV nAb titres remained above baseline … demonstrating the persistence of the immune response.").

57. The Accused Product constitutes a material part of, is especially made and especially adapted for, and is not a staple article or commodity of commerce suitable for substantial use in the United States other than in, its FDA-approved use.

58. The first RSV F vaccine to be approved anywhere in the world was GSK's Arexvy®. Arexvy® was approved by FDA in May 2023 for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV)

in individuals 60 years of age and older, the same indication later pursued by Moderna for mResvia®. Exhibit 49 (May 2023, Arexvy® Package Insert). Arexvy® was the result of more than 15 years of research and development.

59. Moderna's "commercial focus [for mResvia®] is on reaching vaccinators in a highly competitive market." Exhibit 40 (August 1, 2024, Moderna press release).

60. Moderna stands to profit significantly and negatively impact GSK sales of Arexvy® through continued infringement of GSK Biologicals's Patents-in-Suit without taking a license. *See*, *e.g.*, Exhibit 24 (March 27, 2024, Moderna Vaccine Updates) at 115–118 (anticipating a potential peak market of ~$10 billion for all RSV vaccine products); "2024 CNBC Interview" around 2:45 (identifying Moderna's RSV vaccine launch as one of several upcoming "multibillion dollar opportunities").

61. A real, substantial, and immediate controversy currently exists between GSK and Moderna concerning Moderna's infringement of the Asserted Patents.

COUNT I

(Infringement of the '770 Patent)

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

63. 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 1.

64. Each claim of the '770 patent is valid and enforceable.

65. Moderna infringes, under 35 U.S.C. § 271(a), (b), and/or (c), 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 the Accused Product.

66. Moderna has had knowledge of the ’770 patent and specific notice of its infringement of that patent at least since October 11, 2024, by communications between GSK and Moderna. *See* Exhibit 56.

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

> **6.** An immunogenic composition comprising lipid particles and 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.

68. The Accused Product is “an immunogenic composition comprising lipid particles and messenger ribonucleic acid (mRNA) molecules.” *See* paragraphs 36–44, *supra*; *e.g.*, Exhibit 20 (May 2024, mRESVIA® Package Insert) at 6 (“MRESVIA is a sterile white to off-white injectable suspension for intramuscular use. Each 0.5 mL dose of MRESVIA contains 50 mcg of nucleoside modified mRNA encoding the RSV F glycoprotein stabilized in the prefusion conformation (pre-F protein). Each 0.5 mL dose of MRESVIA also contains the following ingredients: a total lipid content of 1.02 mg (SM-102 (heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate), polyethylene glycol 2000 dimyristoyl glycerol

[PEG2000-DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), 0.25 mg tromethamine, 1.2 mg tromethamine hydrochloride, 0.021 mg acetic acid, 0.10 mg sodium acetate trihydrate, 44 mg sucrose, and water for injection. … MRESVIA induces an immune response against RSV pre-F protein that protects against LRTD caused by RSV."); Exhibit 48 (Wilson (2023)) at 2234 ("The mRNA-1345 vaccine is a lipid nanoparticle-encapsulated mRNA-based vaccine encoding the membrane-anchored RSV-F glycoprotein, derived from an RSV A strain, and stabilized in the preF conformation. A phase 1 clinical trial of this vaccine did not show safety concerns and showed immunogenicity in younger and older adults …."); Exhibit 31 (Shaw, *JID*, jiae035 (2024)) at 2 ("mRNA-1345 contains a single nucleoside-modified mRNA sequence encoding the membrane-anchored RSV F glycoprotein (RSV-A2 strain protein sequence) stabilized in the preF conformation through structural engineering and formulated in lipid nanoparticles (LNPs). The LNP formulation consists of an ionizable lipid promoting assembly of LNPs into delivery vehicles, a phospholipid that forms lipid bilayer structures in LNPs, a poly-ethylene glycol lipid, and a sterol that improves the stability of the formulations."), 8 ("This phase 1 trial showed that mRNA-1345 is well tolerated and immunogenic in younger adults."); Exhibit 32 (Shaw, *JID*, jiae081 (2024)) at 2 ("mRNA-1345 contains a nucleoside-modified mRNA sequence encoding the membrane-anchored RSV F glycoprotein (RSV-A2 strain protein sequence) stabilized in the preF conformation through structural engineering and formulated in LNPs. The LNP formulation consists of an ionizable lipid, a phospholipid that forms lipid bilayer structures in LNPs, a polyethylene glycol lipid, and a sterol that improves stability."), 8 ("This phase 1 trial demonstrated that the mRNA-1345 vaccine is well tolerated and immunogenic in adults aged 65 to 79 years …."); Exhibit 26 (February 15, 2024, Moderna ReSViNET Conference

Presentation) at 5 ("LNP encapsulated mRNA-based vaccine encoding the RSV fusion (F) glycoprotein"); Exhibit 25 (February 29, 2024, Moderna ACIP Presentation) at 3 (similar).

69. The mRNA molecules of the Accused Product comprise "a sequence that encodes an immunogen." *See* paragraphs 36–44, *supra*; *e.g.*, Exhibit 20 (May 2024, mRESVIA® Package Insert) at 6 ("Each 0.5 mL dose of MRESVIA contains 50 mcg of nucleoside modified mRNA encoding the RSV F glycoprotein stabilized in the prefusion conformation (pre-F) protein. … MRESVIA induces an immune response against RSV pre-F protein that protects against LRTD caused by RSV."); Exhibit 28 (Moderna WO336 Publication) *passim*, *e.g.*, at 80–81 (providing sequence of the "ORF of mRNA (excluding the stop codon)" (SEQ ID NO: 34) and "Corresponding amino acid sequence" (SEQ ID NO: 8)); Exhibit 25 (February 29, 2024, Moderna ACIP Presentation) at 3; Exhibit 22 (May 31, 2024, Moderna Press Release) at 2; Exhibit 23 (May 15, 2023, EMA Study Decision) at 1; Exhibit 26 (February 15, 2024 Moderna ReSViNET Presentation) at 5; Exhibit 48 (Wilson (2023)) *passim*; Exhibit 31 (Shaw, *JID*, jiae035 (2024)) *passim*; Exhibit 32 (Shaw, *JID*, jiae081 (2024)) *passim*.

70. The mRNA molecules of the Accused Product 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 36–44, *supra*; *e.g.*, Exhibit 28 (Moderna WO336 Publication) at 73–79 ("Example I – Phase I Study" using mRNA-1345), 80–81 (Table I. Vaccine Sequences, Prefusion RSV F Protein dCT Variant) (providing the structure of the "Cap" ("7mG(5')ppp(5')N1mpNp"), the sequence of the "5' UTR" (SEQ ID NO: 33), the sequence of the "ORF of mRNA (excluding the stop codon)" (SEQ ID NO: 34), the sequence of the "3' UTR" (SEQ ID NO: 35), and the length of the "PolyA tail" ("100 nt")); *see also* Exhibit 29 (Chaudhary (2021)) at 818 ("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 endogenous 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); 2023 CNBC Interview around 2:21 ("And the other great news about mRNA is: because all the 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 30 ('789 PTE) at 1–3 (providing the specific structure of the "Cap" ("m7G-5'-ppp-5'-Gm") used in Moderna's COVID-19 mRNA vaccine products).

71. The lipid particles of the Accused Product 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 36–44, *supra*; *e.g.*, Exhibit 20 (May 2024, mRESVIA® Package Insert) at 6 ("Each 0.5 mL dose of MRESVIA also contains the following ingredients: a total lipid content of 1.02 mg (SM-102 (heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate), polyethylene glycol 2000 dimyristoyl glycerol [PEG2000-DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]) …."') (bracketed text in original); Exhibit 31 (Shaw, *JID*, jiae035 (2024)) at 2 ("mRNA-1345 contains a single nucleoside-modified mRNA sequence encoding the membrane-anchored RSV F glycoprotein (RSV-A2 strain protein sequence) stabilized in the preF conformation through structural engineering and formulated in lipid nanoparticles (LNPs). The LNP formulation consists of an ionizable lipid promoting assembly of LNPs into delivery vehicles, a phospholipid that forms lipid bilayer structures in LNPs, a poly-

ethylene glycol lipid, and a sterol that improves the stability of the formulations."); Exhibit 32 (Shaw, *JID*, jiae081 (2024)) at 2 (similar); *see also* paragraphs 72–74, *infra*.

72. 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 30 ('789 PTE) at 4–5, 10, 12, 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)"))[8] at 16989, 16993; Exhibit 50 (Schoenmaker *et al*., "mRNA-lipid nanoparticle COVID-19 vaccines: Structure and Stability," *Intl. J. Pharm.* 601, 120586 (2021) ("Schoenmaker (2021)")) at 4, 8.

73. 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 30 ('789 PTE) at 5, 10–11, Exhibit 3 thereto (Tenchov (2021)) at 16989; Exhibit 50 (Schoenmaker (2021)) at 3, 4, 8.

74. DSPC (in chemical nomenclature, 1,2-distearoyl-sn-glycero-3-phosphocholine) is a "phospholipid comprising … a zwitterionic phospholipid." *See*, *e.g.*, Exhibit 30 ('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. Phar. Sci.* 100 (7), 2724 (2011) ("Kaur (2011)"))[9] at 2728 ("the zwitterionic lipid DSPC"); Exhibit 50 (Schoenmaker (2021)) at 3, 4, 8.

[8] *See* Exhibit 51 for a higher quality copy of Tenchov (2021) including the Supporting Information.
[9] *See* Exhibit 52 for a higher quality copy of Kaur (2011).

75. On information and belief, the lipid particles of the Accused Product "encapsulat[e] at least half of the mRNA molecules." *See* paragraphs 36–44, *supra*; *e.g.*, Exhibit 19 (FDA CMC Review Memo) at 1 ("MRESVIA is a vaccine that consists of lipid nanoparticles (LNPs) that encapsulate linear mRNA"), 165 ("mRNA-1345 Drug Product (DP) is a white to off-white suspension of nanoparticles composed for four lipids … that protect and deliver mRNA …"); Exhibit 48 (Wilson (2023)) at 2234 ("The mRNA-1345 vaccine is a lipid nanoparticle-encapsulated mRNA-based vaccine…."); Exhibit 26 (February 15, 2024, Moderna ReSViNET Conference Presentation) at 5 ("LNP encapsulated mRNA-based vaccine encoding the RSV fusion (F) glycoprotein"); Exhibit 25 (February 29, 2024, Moderna ACIP Presentation) at 3 (similar); Exhibit 31 (Shaw, *JID*, jiae035 (2024)) at 1 ("A lipid nanoparticle-encapsulated mRNA-based RSV vaccine (mRNA-1345) that encodes the membrane-anchored RSV prefusion-stabilized F glycoprotein is under clinical investigation."); *see also* Exhibit 50 (Schoenmaker (2021)) at 4 ("In mRNA-LNP formulations, such as those used in mRNA vaccines ... encapsulation efficiencies ... are typically > 90%."); Exhibit 53 (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%").

76. When administered to a patient in accordance with the FDA-approved use, the Accused Product 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* paragraph 56, *supra*; *e.g.*, Exhibit 48 (Wilson (2023)) at 2234 ("A phase 1 clinical trial of this vaccine did not show safety concerns and showed immunogenicity in younger and older adults; the vaccine induced neutralizing antibodies against both the RSV A and B subtypes …."),

2241–2242; Exhibit 31 (Shaw, *JID*, jiae035 (2024)) at 1 ("mRNA-1345 boosted RSV neutralising antibody titers … and RSV prefusion binding antibody concentrations"), 6–7, Supplementary Information *passim*; Exhibit 32 (Shaw, *JID*, jiae081 (2024)) at 1 ("mRNA-1345 injection boosted RSV-A and RSV-B neutralizing antibody titers and prefusion F binding antibody (preF bAb) concentrations"), 8, Supplementary Information *passim*; Exhibit 26 (February 15, 2024, Moderna ReSViNET Conference Presentation) at 5; Exhibit 25 (February 29, 2024, Moderna ACIP Presentation) at 3.

77. The FDA-approved use for the Accused Product 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 Product. *See* paragraphs 46–56, *supra*; *e.g.*, Exhibit 20 (May 2024, mRESVIA® Package Insert) at 2 ("Administer MRESVIA intramuscularly."), 6 ("MRESVIA is a sterile white to off-white injectable suspension for intramuscular use. Each 0.5 mL dose of MRESVIA contains 50 mcg of nucleoside modified mRNA encoding the RSV F glycoprotein stabilized in the prefusion conformation (pre-F protein). … MRESVIA induces an immune response against RSV pre-F protein that protects against LRTD caused by RSV."); Exhibit 48 (Wilson (2023)) at 2234 ("The mRNA-1345 vaccine is a lipid nanoparticle-encapsulated mRNA-based vaccine encoding the membrane-anchored RSV-F glycoprotein, derived from an RSV A strain, and stabilized in the preF conformation. A phase 1 clinical trial of this vaccine did not show safety concerns and showed immunogenicity in younger and older adults …."); Exhibit 31 (Shaw, *JID*, jiae035 (2024)) at 6 ("One mRNA-1345 injection of 50 … μg increased RSV-A and RSV-B neutralizing antibody titers (Figure 3, Supplementary Table 4) as well as preF and postF binding antibody concentrations (Figure 4, Supplementary Table 5)."), 8 ("This phase 1 trial showed that mRNA-1345 is well tolerated and immunogenic in

younger adults."); Exhibit 32 (Shaw, *JID*, jiae081 (2024)) at 6–7 (E.g., "A single mRNA-1345 injection elicited nAb responses against RSV-A and RSV-B subtypes at all dose levels evaluated."); Exhibit 26 (February 15, 2024, Moderna ReSViNET Conference Presentation) at 5; Exhibit 25 (February 29, 2024, Moderna ACIP Presentation) at 3.

78. The Accused Product satisfies each and every element of exemplary claim 6 of the '770 patent, either literally or under the doctrine of equivalents.

79. On information and belief, Moderna has been aware at least since it received notice of its infringement from GSK on October 11, 2024, that the Accused Product satisfies each and every element of exemplary claim 6 of the '770 patent, either literally or under the doctrine of equivalents.

80. On information and belief, Moderna actively, knowingly, and specifically intended and intends, at least since it received notice of its infringement from GSK on October 11, 2024, to induce third-party manufacturers to directly infringe at least claim 6 of the '770 patent by making the Accused Product within the United States without authority or license to do so, during the term of the '770 patent.

81. On information and belief, Moderna has been aware at least since it received notice of its infringement from GSK on October 11, 2024, that the mRNA and lipid particles in the Accused Product 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, the Accused Product and its process of manufacture, and therefore to infringe at least claim 6 of the '770 patent.

82. Administration of the Accused Product to patients in the United States in accordance with the instructions in Moderna's labeling and prescribing information and therefore

with its FDA-approved use satisfies each and every element of exemplary claims 6 and 24 of the ’770 patent, either literally or under the doctrine of equivalents.

83. On information and belief, Moderna has been aware at least since it received notice of its infringement from GSK on October 11, 2024, that administration of the Accused Product to patients in the United States in accordance with the instructions in Moderna’s labeling and prescribing information and therefore with its FDA-approved use satisfies each and every element of exemplary claims 6 and 24 of the ’770 patent, either literally or under the doctrine of equivalents.

84. On information and belief, Moderna actively, knowingly, and specifically intended and intends, at least since it received notice of its infringement from GSK on October 11, 2024, to induce healthcare practitioners to directly infringe at least claims 6 and 24 of the ’770 patent by administering the Accused Product within the United States in accordance with the instructions in Moderna’s labeling and prescribing information and therefore with its FDA-approved use, without authority or license to do so, during the term of the ’770 patent.

85. On information and belief, Moderna has been aware at least since it received notice of its infringement from GSK on October 11, 2024, that the Accused Product constitutes a material part of, is especially made and especially adapted for, and is not a staple article or commodity of commerce suitable for substantial use in the United States other than in, its FDA-approved use, and therefore to infringe at least claim 24 of the ’770 patent.

86. For the foregoing reasons, Moderna directly infringes 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, the Accused Product, without authority or license to do so, during the term of the ’770 patent.

87. In addition or in the alternative, Moderna infringes 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 the Accused Product within the United States without authority or license to do so, during the term of the ’770 patent.

88. In addition or in the alternative, Moderna infringes 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 the Accused Product to patients within the United States in accordance with the instructions in Moderna’s labeling and prescribing information and therefore with its FDA-approved use, without authority or license to do so, during the term of the ’770 patent.

89. In addition or in the alternative, Moderna contributorily infringes 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, the Accused Product without authority or license to do so, during the term of the ’770 patent, knowing that it constitutes a material part of the inventions of, and is especially made or adapted to infringe, at least claim 24 of the ’770 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

90. In addition or in the alternative, Moderna contributorily infringes 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 Accused Product, 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.

91. GSK is suffering damages from Moderna's infringement of the '770 patent.

92. GSK is entitled to an award of monetary damages, including lost profits and/or a reasonable royalty, for Moderna's infringement of the '770 patent.

93. Moderna's infringement of the '770 patent is willful and deliberate at least since it received notice of its infringement from GSK on October 11, 2024.

94. 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 those actions with respect to the Accused Product.

COUNT II

(Infringement of the '861 Patent)

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

96. GSK Biologicals is the lawful owner by assignment of the '861 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 '861 patent is attached as Exhibit 2.

97. Each claim of the '861 patent is valid and enforceable.

98. Moderna infringes, under 35 U.S.C. § 271(a), (b), and/or (c), one or more claims of the '861 patent either literally or under the doctrine of equivalents, through its actions in the United States with respect to the Accused Product.

99. Moderna has had knowledge of the '861 patent and specific notice of its infringement of that patent at least since October 11, 2024, by communications between GSK and Moderna. *See* Exhibit 56.

100. For purposes of illustration and example, claims 1 and 14 of the ’861 patent recite:

> **1.** A composition comprising lipid particles and messenger ribonucleic acid (mRNA) molecules; the mRNA molecules comprising: (i) a 5’ cap nucleoside, (ii) a first 5’ ribonucleoside, (iii) a triphosphate bridge, and (iv) a sequence that encodes a respiratory syncytial virus (RSV) surface fusion glycoprotein (F-protein) immunogen; the first 5’ ribonucleotide comprising a 2’-methylated ribose; the 5’ cap nucleoside linked 5’-to-5’ to the first 5’ ribonucleoside by the triphosphate bridge; the lipid particles comprising: (a) a polyethylene glycol-ylated 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.
>
> **14.** A method of eliciting in a human an immune response comprising an antibody response against the RSV F-protein immunogen or a cell-mediated immune response against the RSV-F protein immunogen, the method comprising administering to the human an effective amount of the composition of claim **1** to elicit the immune response.

101. The Accused Product is a “composition comprising lipid particles and messenger ribonucleic acid (mRNA) molecules.” *See* paragraphs 36–44, *supra*; *e.g.*, Exhibit 20 (May 2024, mRESVIA® Package Insert) at 6 (“MRESVIA is a sterile white to off-white injectable suspension for intramuscular use. Each 0.5 mL dose of MRESVIA contains 50 mcg of nucleoside modified mRNA encoding the RSV F glycoprotein stabilized in the prefusion conformation (pre-F protein). Each 0.5 mL dose of MRESVIA also contains the following ingredients: a total lipid content of 1.02 mg (SM-102 (heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate), polyethylene glycol 2000 dimyristoyl glycerol [PEG2000-DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), 0.25 mg tromethamine, 1.2 mg tromethamine hydrochloride, 0.021 mg acetic acid, 0.10 mg sodium acetate trihydrate, 44 mg sucrose, and water for injection..”); Exhibit 48 (Wilson (2023)) at 2234 (“The mRNA-1345 vaccine is a lipid nanoparticle-encapsulated mRNA-based vaccine encoding the membrane-anchored RSV-F glycoprotein, derived from an RSV A strain, and stabilized in the preF conformation.”); Exhibit

31 (Shaw, *JID*, jiae035 (2024)) at 2 ("mRNA-1345 contains a single nucleoside-modified mRNA sequence encoding the membrane-anchored RSV F glycoprotein (RSV-A2 strain protein sequence) stabilized in the preF conformation through structural engineering and formulated in lipid nanoparticles (LNPs). The LNP formulation consists of an ionizable lipid promoting assembly of LNPs into delivery vehicles, a phospholipid that forms lipid bilayer structures in LNPs, a poly-ethylene glycol lipid, and a sterol that improves the stability of the formulations."); Exhibit 32 (Shaw, *JID*, jiae081 (2024)) at 2 ("mRNA-1345 contains a nucleoside-modified mRNA sequence encoding the membrane-anchored RSV F glycoprotein (RSV-A2 strain protein sequence) stabilized in the preF conformation through structural engineering and formulated in LNPs. The LNP formulation consists of an ionizable lipid, a phospholipid that forms lipid bilayer structures in LNPs, a polyethylene glycol lipid, and a sterol that improves stability."); Exhibit 26 (February 15, 2024, Moderna ReSViNET Conference Presentation) at 5 ("LNP encapsulated mRNA-based vaccine encoding the RSV fusion (F) glycoprotein"); Exhibit 25 (February 29, 2024, Moderna ACIP Presentation) at 3 (similar).

102. The mRNA molecules of the Accused Product comprise "a sequence that encodes a respiratory syncytial virus (RSV) surface fusion glycoprotein (F-protein) immunogen." *See* paragraphs 36–44, *supra*; *e.g.*, Exhibit 20 (May 2024, mRESVIA® Package Insert) at 6 ("Each 0.5 mL dose of MRESVIA contains 50 mcg of nucleoside modified mRNA encoding the RSV F glycoprotein stabilized in the prefusion conformation (pre-F) protein. … MRESVIA induces an immune response against RSV pre-F protein that protects against LRTD caused by RSV."); Exhibit 28 (Moderna WO336 Publication) *passim*, *e.g.*, at 80–81 (providing sequence of the "ORF of mRNA (excluding the stop codon)" (SEQ ID NO: 34) and "Corresponding amino acid sequence" (SEQ ID NO: 8)); Exhibit 25 (February 29, 2024, Moderna ACIP Presentation) at 3;

Exhibit 22 (May 31, 2024, Moderna Press Release) at 2; Exhibit 23 (May 15, 2023, EMA Study Decision) at 1; Exhibit 26 (February 15, 2024 Moderna ReSViNET Presentation) at 5; Exhibit 48 (Wilson (2023)) *passim*; Exhibit 31 (Shaw, *JID*, jiae035 (2024)) *passim*; Exhibit 32 (Shaw, *JID*, jiae081 (2024)) *passim*.

103. The mRNA molecules of the Accused Product comprise "(i) a 5' cap nucleoside, (ii) a first 5' ribonucleoside, (iii) a triphosphate bridge, … the first 5' ribonucleotide comprising a 2'-methylated ribose; the 5' cap nucleoside linked 5'-to-5' to the first 5' ribonucleoside by the triphosphate bridge." *See* paragraphs 36–44, *supra*; *e.g.*, Exhibit 28 (Moderna WO336 Publication) at 73–79 ("Example I – Phase I Study" using mRNA-1345), 80–81 (Table I. Vaccine Sequences, Prefusion RSV F Protein dCT Variant) (providing the structure of the "Cap" ("7mG(5')ppp(5')N1mpNp"), the sequence of the "5' UTR" (SEQ ID NO: 33), the sequence of the "ORF of mRNA (excluding the stop codon)" (SEQ ID NO: 34), the sequence of the "3' UTR" (SEQ ID NO: 35), and the length of the "PolyA tail" ("100 nt")); *see also* Exhibit 29 (Chaudhary (2021)) at 818 ("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); 2023 CNBC Interview at 2:21 ("And the other great news about mRNA is: because all the 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 30 ('789 PTE) at 1–3 (providing the specific structure of the "Cap" ("m7G-5'-ppp-5'-Gm") used in Moderna's COVID-19 mRNA vaccine products).

104. The lipid particles of the Accused Product comprise "(a) a polyethylene glycol-ylated lipid, (b) cholesterol, (c) an anionic phospholipid or a zwitterionic phospholipid, and (d) a cationic lipid comprising a tertiary amine." *See* paragraphs 36–44, *supra*; *e.g.*, Exhibit 20 (May 2024, mRESVIA® Package Insert) at 6 ("Each 0.5 mL dose of MRESVIA also contains the following ingredients: a total lipid content of 1.02 mg (SM-102 (heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate), polyethylene glycol 2000 dimyristoyl glycerol [PEG2000-DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]) ….") (bracketed text in original); Exhibit 31 (Shaw, *JID*, jiae035 (2024)) at 2 ("mRNA-1345 contains a single nucleoside-modified mRNA sequence encoding the membrane-anchored RSV F glycoprotein (RSV-A2 strain protein sequence) stabilized in the preF conformation through structural engineering and formulated in lipid nanoparticles (LNPs). The LNP formulation consists of an ionizable lipid promoting assembly of LNPs into delivery vehicles, a phospholipid that forms lipid bilayer structures in LNPs, a poly-ethylene glycol lipid, and a sterol that improves the stability of the formulations."); Exhibit 32 (Shaw, *JID*, jiae081 (2024)) at 2 (similar); *see also* paragraphs 105–107, *infra*.

105. 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 30 ('789 PTE) at 4–5, 10, 12, Exhibit 3 thereto (Tenchov (2021)) at 16989, 16993; Exhibit 50 (Schoenmaker (2021)) at 4, 8.

106. 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 lipid." *See*, *e.g.*, Exhibit 30 ('789 PTE)

at 5, 10–11, Exhibit 3 thereto (Tenchov (2021)) at 16989; Exhibit 50 (Schoenmaker (2021)) at 3, 4, 8.

107. DSPC (in chemical nomenclature, 1,2-distearoyl-sn-glycero-3-phosphocholine) is a "phospholipid comprising … a zwitterionic phospholipid." *See*, *e.g.*, Exhibit 30 ('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 50 (Schoenmaker (2021)) at 3, 4, 8.

108. On information and belief, the lipid particles of the Accused Product "encapsulat[e] at least half of the mRNA molecules." *See* paragraphs 36–44, *supra*; *e.g.*, Exhibit 30 (FDA CMC Review Memo) at 1 ("MRESVIA is a vaccine that consists of lipid nanoparticles (LNPs) that encapsulate linear mRNA"), 165 ("mRNA-1345 Drug Product (DP) is a white to off-white suspension of nanoparticles composed for four lipids … that protect and deliver mRNA …"); Exhibit 48 (Wilson (2023)) at 2234 ("The mRNA-1345 vaccine is a lipid nanoparticle-encapsulated mRNA-based vaccine …."); Exhibit 26 (February 15, 2024, Moderna ReSViNET Conference Presentation) at 5 ("LNP encapsulated mRNA-based vaccine encoding the RSV fusion (F) glycoprotein"); Exhibit 25 (February 29, 2024, Moderna ACIP Presentation) at 3 (similar); Exhibit 31 (Shaw, *JID*, jiae035 (2024)) at 1 ("A lipid nanoparticle-encapsulated mRNA-based RSV vaccine (mRNA-1345) that encodes the membrane-anchored RSV prefusion-stabilized F glycoprotein is under clinical investigation."); *see also* Exhibit 53 (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 50 (Schoenmaker (2021)) at 4 ("In mRNA-LNP formulations, such as those used in mRNA vaccines ... encapsulation efficiencies ... are typically > 90%.").

109. The FDA-approved use for the Accused Product is a "method of eliciting in a human an immune response comprising an antibody response against the RSV F-protein immunogen or a cell-mediated immune response against the RSV-F protein immunogen, the method comprising administering to the human an effective amount … to elicit the immune response" of the Accused Product. *See* paragraphs 46–56, *supra*; *e.g.*, Exhibit 20 (May 2024, mRESVIA® Package Insert) at 2 ("Administer MRESVIA intramuscularly."), 6 ("MRESVIA is a sterile white to off-white injectable suspension for intramuscular use. Each 0.5 mL dose of MRESVIA contains 50 mcg of nucleoside modified mRNA encoding the RSV F glycoprotein stabilized in the prefusion conformation (pre-F protein). … MRESVIA induces an immune response against RSV pre-F protein that protects against LRTD caused by RSV."); Exhibit 48 (Wilson (2023)) at 2234 ("The mRNA-1345 vaccine is a lipid nanoparticle-encapsulated mRNA-based vaccine encoding the membrane-anchored RSV-F glycoprotein, derived from an RSV A strain, and stabilized in the preF conformation. A phase 1 clinical trial of this vaccine did not show safety concerns and showed immunogenicity in younger and older adults …."); Exhibit 31 (Shaw, *JID*, jiae035 (2024)) at 6 ("One mRNA-1345 injection of 50 … µg increased RSV-A and RSV-B neutralizing antibody titers (Figure 3, Supplementary Table 4) as well as preF and postF binding antibody concentrations (Figure 4, Supplementary Table 5)."), 8 ("This phase 1 trial showed that mRNA-1345 is well tolerated and immunogenic in younger adults."); Exhibit 32 (Shaw, *JID*, jiae081 (2024)) at 6–7 (E.g., "A single mRNA-1345 injection elicited nAb responses against RSV-A and RSV-B subtypes at all dose levels evaluated."); Exhibit 26 (February 15, 2024, Moderna ReSViNET Conference Presentation) at 5; Exhibit 25 (February 29, 2024, Moderna ACIP Presentation) at 3.

110. The Accused Product satisfies each and every element of exemplary claim 1 of the ’861 patent, either literally or under the doctrine of equivalents.

111. On information and belief, Moderna has been aware at least since it received notice of its infringement from GSK on October 11, 2024, that the Accused Product satisfies each and every element of exemplary claim 1 of the ’861 patent, either literally or under the doctrine of equivalents.

112. On information and belief, Moderna actively, knowingly, and specifically intended and intends, at least since it received notice of its infringement from GSK on October 11, 2024, to induce third-party manufacturers to directly infringe at least claim 1 of the ’861 patent by making the Accused Product within the United States without authority or license to do so, during the term of the ’861 patent.

113. On information and belief, Moderna has been aware at least since it received notice of its infringement from GSK on October 11, 2024, that the mRNA and lipid particles in the Accused Product 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, the Accused Product and its process of manufacture, and therefore to infringe at least claim 1 of the ’861 patent.

114. Administration of the Accused Product to patients in the United States in accordance with the instructions in Moderna’s labeling and prescribing information and therefore with its FDA-approved use satisfies each and every element of exemplary claims 1 and 14 of the ’861 patent, either literally or under the doctrine of equivalents.

115. On information and belief, Moderna has been aware at least since it received notice of its infringement from GSK on October 11, 2024, that administration of the Accused Product to

patients in the United States in accordance with the instructions in Moderna's labeling and prescribing information and therefore with its FDA-approved use satisfies each and every element of exemplary claims 1 and 14 of the '861 patent, either literally or under the doctrine of equivalents.

116. On information and belief, Moderna actively, knowingly, and specifically intended and intends, at least since it received notice of its infringement from GSK on October 11, 2024, to induce healthcare practitioners to directly infringe at least claims 1 and 14 of the '861 patent by administering the Accused Product within the United States in accordance with the instructions in Moderna's labeling and prescribing information and therefore with its FDA-approved use, without authority or license to do so, during the term of the '861 patent.

117. On information and belief, Moderna has been aware at least since it received notice of its infringement from GSK on October 11, 2024, that the Accused Product constitutes a material part of, is especially made and especially adapted for, and is not a staple article or commodity of commerce suitable for substantial use in the United States other than, its FDA-approved use, and therefore to infringe at least claim 14 of the '861 patent.

118. For the foregoing reasons, Moderna directly infringes at least claim 1 of the '861 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, the Accused Product, without authority or license to do so, during the term of the '861 patent.

119. In addition or in the alternative, Moderna infringes at least claim 1 of the '861 patent under 35 U.S.C. § 271(b) by actively inducing third-party manufacturers to directly infringe at least claim 1 of the '861 patent by making the Accused Product within the United States without authority or license to do so, during the term of the '861 patent.

120. In addition or in the alternative, Moderna infringes at least claims 1 and 14 of the ’861 patent under 35 U.S.C. § 271(b) by actively inducing healthcare practitioners to directly infringe at least claims 1 and 14 of the ’861 patent by administering the Accused Product to patients within the United States in accordance with the instructions in Moderna’s labeling and prescribing information and therefore with its FDA-approved use, without authority or license to do so, during the term of the ’861 patent.

121. In addition or in the alternative, Moderna contributorily infringes at least claim 14 of the ’861 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 Accused Product without authority or license to do so, during the term of the ’861 patent, knowing that it constitutes a material part of the inventions of, and is especially made or adapted to infringe, at least claim 14 of the ’861 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 contributorily infringes at least claim 1 of the ’861 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 Accused Product, without authority or license to do so, during the term of the ’861 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 ’861 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

123. GSK is suffering damages from Moderna’s infringement of the ’861 patent.

124. GSK is entitled to an award of monetary damages, including lost profits and/or a reasonable royalty, for Moderna’s infringement of the ’861 patent.

125. Moderna's infringement of the '861 patent is willful and deliberate at least since it received notice of its infringement from GSK on October 11, 2024.

126. Moderna's conduct with respect to the '861 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 those actions with respect to the Accused Product.

COUNT III

(Infringement of the '864 Patent)

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

128. GSK Biologicals is the lawful owner by assignment of the '864 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 '864 patent is attached as Exhibit 3.

129. Each claim of the '864 patent is valid and enforceable.

130. Moderna infringes, under 35 U.S.C. § 271(a), (b), and/or (c), one or more claims of the '864 patent either literally or under the doctrine of equivalents, through its actions in the United States with respect to the Accused Product.

131. Moderna has had knowledge of the '864 patent and specific notice of its infringement of that patent at least since October 11, 2024, by communications between GSK and Moderna. *See* Exhibit 56.

132. For purposes of illustration and example, claims 1 and 14 of the '864 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 respiratory syncytial virus (RSV) surface

> fusion glycoprotein (F-protein) 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 RSV F-protein immunogen or a cell-mediated immune response against the RSV F-protein immunogen, the method comprising administering to the human an effective amount of the composition of claim **1** to elicit the immune response.

133. The Accused Products is a "composition comprising liposomes and messenger ribonucleic acid (mRNA) molecules." *See* paragraphs 36–44, *supra*; *e.g.*, Exhibit 20 (May 2024, mRESVIA® Package Insert) at 6 ("MRESVIA is a sterile white to off-white injectable suspension for intramuscular use. Each 0.5 mL dose of MRESVIA contains 50 mcg of nucleoside modified mRNA encoding the RSV F glycoprotein stabilized in the prefusion conformation (pre-F protein). Each 0.5 mL dose of MRESVIA also contains the following ingredients: a total lipid content of 1.02 mg (SM-102 (heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate), polyethylene glycol 2000 dimyristoyl glycerol [PEG2000-DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), 0.25 mg tromethamine, 1.2 mg tromethamine hydrochloride, 0.021 mg acetic acid, 0.10 mg sodium acetate trihydrate, 44 mg sucrose, and water for injection."); Exhibit 48 (Wilson (2023)) at 2234 ("The mRNA-1345 vaccine is a lipid nanoparticle-encapsulated mRNA-based vaccine encoding the membrane-anchored RSV-F glycoprotein, derived from an RSV A strain, and stabilized in the preF conformation."); Exhibit 31 (Shaw, *JID*, jiae035 (2024)) at 2 ("mRNA-1345 contains a single nucleoside-modified mRNA sequence encoding the membrane-anchored RSV F glycoprotein (RSV-A2 strain protein sequence) stabilized in the preF conformation through structural engineering and formulated in

lipid nanoparticles (LNPs). The LNP formulation consists of an ionizable lipid promoting assembly of LNPs into delivery vehicles, a phospholipid that forms lipid bilayer structures in LNPs, a poly-ethylene glycol lipid, and a sterol that improves the stability of the formulations."); Exhibit 32 (Shaw, *JID*, jiae081 (2024)) at 2 ("mRNA-1345 contains a nucleoside-modified mRNA sequence encoding the membrane-anchored RSV F glycoprotein (RSV-A2 strain protein sequence) stabilized in the preF conformation through structural engineering and formulated in LNPs. The LNP formulation consists of an ionizable lipid, a phospholipid that forms lipid bilayer structures in LNPs, a polyethylene glycol lipid, and a sterol that improves stability."); Exhibit 26 (February 15, 2024, Moderna ReSViNET Conference Presentation) at 5 ("LNP encapsulated mRNA-based vaccine encoding the RSV fusion (F) glycoprotein"); Exhibit 25 (February 29, 2024, Moderna ACIP Presentation) at 3 (similar); Exhibit 30 ('789 PTE) at 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.").

134. The mRNA molecules of the Accused Product 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 36–44, *supra*; *e.g.*, Exhibit 28 (Moderna WO336 Publication) at 73–79 ("Example I – Phase I Study" using mRNA-1345), 80–81 (Table I. Vaccine Sequences, Prefusion RSV F Protein dCT Variant) (providing the structure of the "Cap" ("7mG(5')ppp(5')N1mpNp"), the sequence of the "5' UTR" (SEQ ID NO: 33), the sequence of the "ORF of mRNA (excluding the stop codon)" (SEQ ID NO: 34), the sequence of the "3' UTR" (SEQ ID NO: 35), and the length of the "PolyA tail" ("100 nt")); *see also* Exhibit 29 (Chaudhary (2021)) 817–818 ("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 endogenous 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); 2023 CNBC Interview at 2:21 ("And the other great news about mRNA is: because all the 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 30 ('789 PTE) at 1–3 (providing the specific structure of the "Cap" ("m7G-5'-ppp-5'-Gm") used in Moderna's COVID-19 mRNA vaccine products).

135. The mRNA molecules the Accused Products comprise "a sequence that encodes a respiratory syncytial virus (RSV) surface fusion glycoprotein (F-protein) immunogen." *See* paragraphs 36–44, *supra*; *e.g.*, Exhibit 20 (May 2024, mRESVIA® Package Insert) at 6 ("Each 0.5 mL dose of MRESVIA contains 50 mcg of nucleoside modified mRNA encoding the RSV F glycoprotein stabilized in the prefusion conformation (pre-F) protein. … MRESVIA induces an immune response against RSV pre-F protein that protects against LRTD caused by RSV."); Exhibit 28 (Moderna WO336 Publication) *passim*, *e.g.*, at 80–81 (providing sequence of the "ORF of mRNA (excluding the stop codon)" (SEQ ID NO: 34) and "Corresponding amino acid sequence" (SEQ ID NO: 8)); Exhibit 25 (February 29, 2024, Moderna ACIP Presentation) at 3; Exhibit 22 (May 31, 2024, Moderna Press Release) at 2; Exhibit 23 (May 15, 2023, EMA Study Decision) at 1; Exhibit 26 (February 15, 2024 Moderna ReSViNET Presentation) at 5; Exhibit 48 (Wilson (2023)) *passim*; Exhibit 31 (Shaw, *JID*, jiae035 (2024)) *passim*; Exhibit 32 (Shaw, *JID*, jiae081 (2024)) *passim*.

136. The liposomes of the Accused Product comprise "cholesterol and a cationic lipid comprising a tertiary amine." *See* paragraphs 36–44, *supra*; *e.g.*, Exhibit 20 (May 2024,

mRESVIA® Package Insert) at 6 ("Each 0.5 mL dose of MRESVIA also contains the following ingredients: a total lipid content of 1.02 mg (SM-102 (heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate), polyethylene glycol 2000 dimyristoyl glycerol [PEG2000-DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]) ….") (bracketed text in original); Exhibit 31 (Shaw, *JID*, jiae035 (2024)) at 2 ("mRNA-1345 contains a single nucleoside-modified mRNA sequence encoding the membrane-anchored RSV F glycoprotein (RSV-A2 strain protein sequence) stabilized in the preF conformation through structural engineering and formulated in lipid nanoparticles (LNPs). The LNP formulation consists of an ionizable lipid promoting assembly of LNPs into delivery vehicles, a phospholipid that forms lipid bilayer structures in LNPs, a poly-ethylene glycol lipid, and a sterol that improves the stability of the formulations."); Exhibit 32 (Shaw, *JID*, jiae081 (2024)) at 2 (similar); *see also* paragraph 137, *infra*.

137. 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 30 ('789 PTE) at 4–5, 10, 12, Exhibit 3 thereto (Tenchov (2021)) at 16989, 16993; Exhibit 50 (Schoenmaker (2021)) at 4, 8.

138. On information and belief, the liposomes of each of the Accused Products "encapsulat[e] at least half of the mRNA molecules." *See* paragraphs 36–44, *supra*; *e.g.*, Exhibit 19 (FDA CMC Review Memo) at i ("MRESVIA is a vaccine that consists of lipid nanoparticles (LNPs) that encapsulate linear mRNA"), 165 ("mRNA-1345 Drug Product (DP) is a white to off-white suspension of nanoparticles composed for four lipids … that protect and deliver mRNA …"); Exhibit 48 (Wilson (2023)) at 2234 ("The mRNA-1345 vaccine is a lipid nanoparticle-encapsulated mRNA-based vaccine …."); Exhibit 26 (February 15, 2024, Moderna ReSViNET

Conference Presentation) at 5 ("LNP encapsulated mRNA-based vaccine encoding the RSV fusion (F) glycoprotein"); Exhibit 25 (February 29, 2024, Moderna ACIP Presentation) at 3 (similar); Exhibit 31 (Shaw, *JID*, jiae035 (2024)) at 1 ("A lipid nanoparticle-encapsulated mRNA-based RSV vaccine (mRNA-1345) that encodes the membrane-anchored RSV prefusion-stabilized F glycoprotein is under clinical investigation."); *see also* Exhibit 53 (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 50 (Schoenmaker (2021)) at 4 ("In mRNA-LNP formulations, such as those used in mRNA vaccines ... encapsulation efficiencies ... are typically > 90%.").

139. The FDA-approved use for the Accused Product is a "method of eliciting in a human an immune response comprising an antibody response against the RSV F-protein immunogen or a cell-mediated immune response against the RSV F-protein immunogen, the method comprising administering to the human an effective amount … to elicit the immune response" of the Accused Product. *See* paragraphs 46–56, *supra*; *e.g.*, Exhibit 20 (May 2024, mRESVIA® Package Insert) at 2 ("Administer MRESVIA intramuscularly."), 6 ("MRESVIA is a sterile white to off-white injectable suspension for intramuscular use. Each 0.5 mL dose of MRESVIA contains 50 mcg of nucleoside modified mRNA encoding the RSV F glycoprotein stabilized in the prefusion conformation (pre-F protein). … MRESVIA induces an immune response against RSV pre-F protein that protects against LRTD caused by RSV."); Exhibit 48 (Wilson (2023)) at 2234 ("The mRNA-1345 vaccine is a lipid nanoparticle-encapsulated mRNA-based vaccine encoding the membrane-anchored RSV-F glycoprotein, derived from an RSV A strain, and stabilized in the preF conformation. A phase 1 clinical trial of this vaccine did not show

safety concerns and showed immunogenicity in younger and older adults ….”); Exhibit 31 (Shaw, *JID*, jiae035 (2024)) at 6 (“One mRNA-1345 injection of 50 … μg increased RSV-A and RSV-B neutralizing antibody titers (Figure 3, Supplementary Table 4) as well as preF and postF binding antibody concentrations (Figure 4, Supplementary Table 5).”), 8 (“This phase 1 trial showed that mRNA-1345 is well tolerated and immunogenic in younger adults.”); Exhibit 32 (Shaw, *JID*, jiae081 (2024)) at 6–7 (E.g., “A single mRNA-1345 injection elicited nAb responses against RSV-A and RSV-B subtypes at all dose levels evaluated.”); Exhibit 26 (February 15, 2024, Moderna ReSViNET Conference Presentation) at 5; Exhibit 25 (February 29, 2024, Moderna ACIP Presentation) at 3.

140. The Accused Product satisfies each and every element of exemplary claim 1 of the ’864 patent, either literally or under the doctrine of equivalents.

141. On information and belief, Moderna has been aware at least since it received notice of its infringement from GSK on October 11, 2024, that the Accused Product satisfies each and every element of exemplary claim 1 of the ’864 patent, either literally or under the doctrine of equivalents.

142. On information and belief, Moderna actively, knowingly, and specifically intended and intends, at least since it received notice of its infringement from GSK on October 11, 2024, to induce third-party manufacturers to directly infringe at least claim 1 of the ’864 patent by making the Accused Product within the United States without authority or license to do so, during the term of the ’864 patent.

143. On information and belief, Moderna has been aware at least since it received notice of its infringement from GSK on October 11, 2024, that the mRNA and lipid particles in the Accused Product 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, the Accused Product and its process of manufacture, and therefore to infringe at least claim 1 of the ’864 patent.

144. Administration of the Accused Product to patients in the United States in accordance with the instructions in Moderna’s labeling and prescribing information and therefore with its FDA-approved use satisfies each and every element of exemplary claims 1 and 14 of the ’864 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 October 11, 2024, that administration of the Accused Product to patients in the United States in accordance with the instructions in Moderna’s labeling and prescribing information and therefore with its FDA-approved use satisfies each and every element of exemplary claims 1 and 14 of the ’864 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 October 11, 2024, to induce healthcare practitioners to directly infringe at least claims 1 and 14 of the ’864 patent by administering the Accused Product within the United States in accordance with the instructions in Moderna’s labeling and prescribing information and therefore with its FDA-approved use, without authority or license to do so, during the term of the ’864 patent.

147. On information and belief, Moderna has been aware at least since it received notice of its infringement from GSK on October 11, 2024, that the Accused Product constitutes a material part of, is especially made and especially adapted for, and is not a staple article or commodity of

commerce suitable for substantial use in the United States other than in, its FDA-approved use, and therefore to infringe at least claim 14 of the ’864 patent.

148. For the foregoing reasons, Moderna directly infringes at least claim 1 of the ’864 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, the Accused Product, without authority or license to do so, during the term of the ’864 patent.

149. In addition or in the alternative, Moderna infringes at least claim 1 of the ’864 patent under 35 U.S.C. § 271(b) by actively inducing third-party manufacturers to directly infringe at least claim 4 of the ’861 patent by making the Accused Product within the United States without authority or license to do so, during the term of the ’864 patent.

150. In addition or in the alternative, Moderna infringes at least claims 1 and 14 of the ’864 patent under 35 U.S.C. § 271(b) by actively inducing healthcare practitioners to directly infringe at least claims 1 and 14 of the ’864 patent by administering the Accused Product to patients within the United States in accordance with the instructions in Moderna’s labeling and prescribing information and therefore with its FDA-approved use, without authority or license to do so, during the term of the ’864 patent.

151. In addition or in the alternative, Moderna contributorily infringes at least claim 14 of the ’864 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 Accused Product without authority or license to do so, during the term of the ’864 patent, knowing that it constitutes a material part of the inventions of, and is especially made or adapted to infringe, at least claim 14 of the ’864 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

152. In addition or in the alternative, Moderna contributorily infringes at least claim 1 of the ’864 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 Accused Product, without authority or license to do so, during the term of the ’864 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 ’864 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

153. GSK is suffering damages from Moderna’s infringement of the ’864 patent.

154. GSK is entitled to an award of monetary damages, including lost profits and/or a reasonable royalty, for Moderna’s infringement of the ’864 patent.

155. Moderna’s infringement of the ’864 patent is willful and deliberate at least since it received notice of its infringement from GSK on October 11, 2024.

156. Moderna’s conduct with respect to the ’864 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 those actions with respect to the Accused Product.

COUNT IV

(Infringement of the ’529 Patent)

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

158. GSK Biologicals is the lawful owner by assignment of the ’529 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 August 8, 2023. A true and correct copy of the ’529 patent is attached as Exhibit 4.

159. Each claim of the ’529 patent is valid and enforceable.

160. 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 '529 patent either literally or under the doctrine of equivalents, through its actions in the United States with respect to the Accused Product.

161. Moderna has had knowledge of the '529 patent and specific notice of its infringement of that patent at least since October 11, 2024, by communications between GSK and Moderna. *See* Exhibit 56.

162. For purposes of illustration and example, claim 1 of the '529 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 respiratory syncytial virus (RSV) surface fusion glycoprotein (F-protein) 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.

163. The Accused Product comprises "a composition, the composition comprising liposomes and messenger ribonucleic acid (mRNA) molecules." *See* paragraphs 36–44, *supra*; *e.g.*, Exhibit 20 (May 2024, mRESVIA® Package Insert) at 6 ("MRESVIA is a sterile white to off-white injectable suspension for intramuscular use. Each 0.5 mL dose of MRESVIA contains

50 mcg of nucleoside modified mRNA encoding the RSV F glycoprotein stabilized in the prefusion conformation (pre-F protein). Each 0.5 mL dose of MRESVIA also contains the following ingredients: a total lipid content of 1.02 mg (SM-102 (heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate), polyethylene glycol 2000 dimyristoyl glycerol [PEG2000-DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), 0.25 mg tromethamine, 1.2 mg tromethamine hydrochloride, 0.021 mg acetic acid, 0.10 mg sodium acetate trihydrate, 44 mg sucrose, and water for injection."); Exhibit 48 (Wilson (2023)) at 2234 ("The mRNA-1345 vaccine is a lipid nanoparticle-encapsulated mRNA-based vaccine encoding the membrane-anchored RSV-F glycoprotein, derived from an RSV A strain, and stabilized in the preF conformation."); Exhibit 31 (Shaw, *JID*, jiae035 (2024)) at 2 ("mRNA-1345 contains a single nucleoside-modified mRNA sequence encoding the membrane-anchored RSV F glycoprotein (RSV-A2 strain protein sequence) stabilized in the preF conformation through structural engineering and formulated in lipid nanoparticles (LNPs). The LNP formulation consists of an ionizable lipid promoting assembly of LNPs into delivery vehicles, a phospholipid that forms lipid bilayer structures in LNPs, a poly-ethylene glycol lipid, and a sterol that improves the stability of the formulations."); Exhibit 32 (Shaw, *JID*, jiae081 (2024)) at 2 ("mRNA-1345 contains a nucleoside-modified mRNA sequence encoding the membrane-anchored RSV F glycoprotein (RSV-A2 strain protein sequence) stabilized in the preF conformation through structural engineering and formulated in LNPs. The LNP formulation consists of an ionizable lipid, a phospholipid that forms lipid bilayer structures in LNPs, a polyethylene glycol lipid, and a sterol that improves stability."); Exhibit 26 (February 15, 2024, Moderna ReSViNET Conference Presentation) at 5 ("LNP encapsulated mRNA-based vaccine encoding the RSV fusion (F) glycoprotein"); Exhibit 25 (February 29, 2024, Moderna ACIP

Presentation) at 3 (similar); Exhibit 30 ('789 PTE) at 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.").

164. The mRNA molecules of the Accused Product 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 36–44, *supra*; *e.g.*, Exhibit 28 (Moderna WO336 Publication) at 73–79 ("Example I – Phase I Study" using mRNA-1345), 80–81 (Table I. Vaccine Sequences, Prefusion RSV F Protein dCT Variant) (providing the structure of the "Cap" ("7mG(5')ppp(5')N1mpNp"), the sequence of the "5' UTR" (SEQ ID NO: 33), the sequence of the "ORF of mRNA (excluding the stop codon)" (SEQ ID NO: 34), the sequence of the "3' UTR" (SEQ ID NO: 35), and the length of the "PolyA tail" ("100 nt")); *see also* Exhibit 29 (Chaudhary (2021)) 818–819 ("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 endogenous 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); 2023 CNBC Interview at 2:21 ("And the other great news about mRNA is: because all the 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 30 ('789 PTE) at 1–3 (providing the specific structure of the "Cap" ("m7G-5'-ppp-5'-Gm") used in Moderna's COVID-19 mRNA vaccine products).

165. The mRNA molecules of the Accused Product comprise "a sequence that encodes a respiratory syncytial virus (RSV) surface fusion glycoprotein (F-protein) immunogen." *See* paragraphs 36–44, *supra*; *e.g.*, Exhibit 20 (May 2024, mRESVIA® Package Insert) at 6 ("Each 0.5 mL dose of MRESVIA contains 50 mcg of nucleoside modified mRNA encoding the RSV F glycoprotein stabilized in the prefusion conformation (pre-F) protein. … MRESVIA induces an immune response against RSV pre-F protein that protects against LRTD caused by RSV."); Exhibit 28 (Moderna WO336 Publication) *passim*, *e.g.*, at 80–81 (providing sequence of the "ORF of mRNA (excluding the stop codon)" (SEQ ID NO: 34) and "Corresponding amino acid sequence" (SEQ ID NO: 8)); Exhibit 25 (February 29, 2024, Moderna ACIP Presentation) at 3; Exhibit 22 (May 31, 2024, Moderna Press Release) at 2; Exhibit 23 (May 15, 2023, EMA Study Decision) at 1; Exhibit 26 (February 15, 2024 Moderna ReSViNET Presentation) at 5; Exhibit 48 (Wilson (2023)) *passim*; Exhibit 31 (Shaw, *JID*, jiae035 (2024)) *passim*; Exhibit 32 (Shaw, *JID*, jiae081 (2024)) *passim*.

166. The liposomes of the Accused Product comprise "lipids comprising cholesterol and a cationic lipid comprising a tertiary amine." *See* paragraphs 36–44, *supra*; *e.g.*, Exhibit 20 (May 2024, mRESVIA® Package Insert) at 6 ("Each 0.5 mL dose of MRESVIA also contains the following ingredients: a total lipid content of 1.02 mg (SM-102 (heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate), polyethylene glycol 2000 dimyristoyl glycerol [PEG2000-DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]) ….") (bracketed text in original); Exhibit 31 (Shaw, *JID*, jiae035 (2024)) at 2 ("mRNA-1345 contains a single nucleoside-modified mRNA sequence encoding the membrane-anchored RSV F glycoprotein (RSV-A2 strain protein sequence) stabilized in the preF conformation through structural engineering and formulated in lipid nanoparticles (LNPs). The

LNP formulation consists of an ionizable lipid promoting assembly of LNPs into delivery vehicles, a phospholipid that forms lipid bilayer structures in LNPs, a poly-ethylene glycol lipid, and a sterol that improves the stability of the formulations."); Exhibit 32 (Shaw, *JID*, jiae081 (2024)) at 2 (similar); *see also* paragraph 167, *infra*.

167. 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 30 ('789 PTE) at 4–5, 10, 12, Exhibit 3 thereto (Tenchov (2021)) at 16989, 16993; Exhibit 50 (Schoenmaker (2021)) at 4, 8.

168. On information and belief, the liposomes of the Accused Product "encapsulat[e] at least half of the mRNA molecules." *See* paragraphs 36–44, *supra*; *e.g.*, Exhibit 19 (FDA CMC Review Memo) at i ("MRESVIA is a vaccine that consists of lipid nanoparticles (LNPs) that encapsulate linear mRNA"), 165 ("mRNA-1345 Drug Product (DP) is a white to off-white suspension of nanoparticles composed for four lipids … that protect and deliver mRNA …"); Exhibit 48 (Wilson (2023)) at 2234 ("The mRNA-1345 vaccine is a lipid nanoparticle-encapsulated mRNA-based vaccine …."); Exhibit 26 (February 15, 2024, Moderna ReSViNET Conference Presentation) at 5 ("LNP encapsulated mRNA-based vaccine encoding the RSV fusion (F) glycoprotein"); Exhibit 25 (February 29, 2024, Moderna ACIP Presentation) at 3 (similar); Exhibit 31 (Shaw, *JID*, jiae035 (2024)) at 1 ("A lipid nanoparticle-encapsulated mRNA-based RSV vaccine (mRNA-1345) that encodes the membrane-anchored RSV prefusion-stabilized F glycoprotein is under clinical investigation."); *see also* Exhibit 52 (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 50 (Schoenmaker (2021)) at

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

169. On information and belief, the method by which Moderna manufactures the Accused Product 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* paragraph 44, *supra*; *e.g.*, Exhibit 33 (FDA CMC Statistical Review Memo) at, *e.g.*, 5 (“Moderna’s RNA manufacturing process and process control strategy for vaccines, termed RNA-100, was originally developed for Moderna’s vaccine Spikevax.”); Exhibit 19 (FDA CMC Review Memo) at, *e.g.*, 12 (“ModernaTX manufactures all mRNA vaccines according to the 100 process, using similar process steps, equipment, materials, with similar or identical in-process parameters ….”); 2023 CNBC Interview at 2:21 (“And the other great news about mRNA is: because all the 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 54 (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 55 (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.").

170. The process by which the Accused Product is manufactured satisfies each and every element of exemplary claim 1 of the '529 patent, either literally or under the doctrine of equivalents.

171. On information and belief, Moderna has been aware at least since it received notice of its infringement from GSK on October 11, 2024, that the process by which the Accused Product is manufactured satisfies each and every element of exemplary claim 1 of the '529 patent, either literally or under the doctrine of equivalents.

172. On information and belief, Moderna actively, knowingly, and specifically intended and intends, at least since it received notice of its infringement from GSK on October 11, 2024, to induce third-party manufacturers to directly infringe at least claim 1 of the '529 patent by making the Accused Product using the process of claim 1 of the '529 patent within the United States without authority or license to do so, during the term of the '529 patent.

173. On information and belief, Moderna has been aware at least since it received notice of its infringement from GSK on October 11, 2024, that the mRNA and liposomes used in manufacture of the Accused Product 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 as materials for use in, the manufacture of the Accused Product, and therefore to infringe at least claim 1 of the '529 patent.

174. For the foregoing reasons, Moderna directly infringes at least claim 1 of the ’529 patent under 35 U.S.C. § 271(a), by making within the United States, the Accused Product using the process of claim 1 of the ’529 patent, without authority or license to do so, during the term of the ’529 patent.

175. In addition or in the alternative, Moderna infringes at least claim 1 of the ’529 patent under 35 U.S.C. § 271(b) by actively inducing third-party manufacturers to directly infringe at least claim 1 of the ’529 patent by making the Accused Product using the process of claim 1 of the ’529 patent within the United States without authority or license to do so, during the term of the ’529 patent.

176. In addition or in the alternative, Moderna contributorily infringes at least claim 1 of the ’529 patent under 35 U.S.C. § 271(c) by importing into the United States, the mRNA and/or liposomes to be used in the Accused Product, without authority or license to do so, during the term of the ’529 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 ’529 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

177. In addition or in the alternative, Moderna infringes at least claim 1 of the ’529 patent under 35 U.S.C. § 271(g) by importing into the United States, or offering to sell, or selling within the United States the Accused Product made by the process of claim 1 of the ’529 patent, without authority or license to do so, during the term of the ’529 patent.

178. GSK is suffering damages from Moderna’s infringement of the ’529 patent.

179. GSK is entitled to an award of monetary damages, including lost profits and/or a reasonable royalty, for Moderna’s infringement of the ’529 patent.

180. Moderna's infringement of the '529 patent is willful and deliberate at least since it received notice of its infringement from GSK on October 11, 2024.

181. Moderna's conduct with respect to the '529 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 those actions with respect to the Accused Product.

COUNT V

(Infringement of the '467 Patent)

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

183. 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 5.

184. Each claim of the '467 patent is valid and enforceable.

185. Moderna infringes, under 35 U.S.C. § 271(a), (b), and/or (c), 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 the Accused Product.

186. Moderna has had knowledge of the '467 patent and specific notice of its infringement of that patent at least since October 11, 2024, by communications between GSK and Moderna. *See* Exhibit 56.

187. 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.

188. The Accused Product is a "formulation comprising: ribonucleic acid (RNA) molecules … and lipids." *See* paragraphs 36–44, *supra*; *e.g.*, Exhibit 20 (May 2024, mRESVIA® Package Insert) at 6 ("MRESVIA is a sterile white to off-white injectable suspension for intramuscular use. Each 0.5 mL dose of MRESVIA contains 50 mcg of nucleoside modified mRNA encoding the RSV F glycoprotein stabilized in the prefusion conformation (pre-F protein). Each 0.5 mL dose of MRESVIA also contains the following ingredients: a total lipid content of 1.02 mg (SM-102 (heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate), polyethylene glycol 2000 dimyristoyl glycerol [PEG2000-DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), 0.25 mg tromethamine, 1.2 mg tromethamine hydrochloride, 0.021 mg acetic acid, 0.10 mg sodium acetate trihydrate, 44 mg sucrose, and water for injection."); Exhibit 48 (Wilson (2023)) at 2234 ("The mRNA-1345 vaccine is a lipid nanoparticle-encapsulated mRNA-based vaccine encoding the membrane-anchored RSV-F glycoprotein, derived from an RSV A strain, and stabilized in the preF conformation."); Exhibit 31 (Shaw, *JID*, jiae035 (2024)) at 2 ("mRNA-1345 contains a single nucleoside-modified mRNA sequence encoding the membrane-anchored RSV F glycoprotein (RSV-A2 strain protein sequence) stabilized in the preF conformation through structural engineering and formulated in lipid nanoparticles (LNPs). The LNP formulation consists of an ionizable lipid promoting assembly of LNPs into delivery vehicles, a phospholipid that forms lipid bilayer structures in LNPs, a poly-ethylene glycol lipid, and a sterol that improves the stability of the formulations."); Exhibit 32 (Shaw, *JID*, jiae081 (2024)) at 2 ("mRNA-1345

contains a nucleoside-modified mRNA sequence encoding the membrane-anchored RSV F glycoprotein (RSV-A2 strain protein sequence) stabilized in the preF conformation through structural engineering and formulated in LNPs. The LNP formulation consists of an ionizable lipid, a phospholipid that forms lipid bilayer structures in LNPs, a polyethylene glycol lipid, and a sterol that improves stability."); Exhibit 26 (February 15, 2024, Moderna ReSViNET Conference Presentation) at 5 ("LNP encapsulated mRNA-based vaccine encoding the RSV fusion (F) glycoprotein"); Exhibit 25 (February 29, 2024, Moderna ACIP Presentation) at 3 (similar).

189. The RNA molecules of the Accused Product comprise "a sequence that encodes an immunogen." *See* paragraphs 36–44, *supra*; *e.g.*, Exhibit 20 (May 2024, mRESVIA® Package Insert) at 6 ("Each 0.5 mL dose of MRESVIA contains 50 mcg of nucleoside modified mRNA encoding the RSV F glycoprotein stabilized in the prefusion conformation (pre-F) protein. … MRESVIA induces an immune response against RSV pre-F protein that protects against LRTD caused by RSV."); Exhibit 28 (Moderna WO336 Publication) *passim*, *e.g.*, at 80–81 (providing sequence of the "ORF of mRNA (excluding the stop codon)" (SEQ ID NO: 34) and "Corresponding amino acid sequence" (SEQ ID NO: 8)); Exhibit 25 (February 29, 2024, Moderna ACIP Presentation) at 3; Exhibit 22 (May 31, 2024, Moderna Press Release) at 2; Exhibit 23 (May 15, 2023, EMA Study Decision) at 1; Exhibit 26 (February 15, 2024 Moderna ReSViNET Presentation) at 5; Exhibit 48 (Wilson (2023)) *passim*; Exhibit 31 (Shaw, *JID*, jiae035 (2024)) *passim*; Exhibit 32 (Shaw, *JID*, jiae081 (2024)) *passim*.

190. The lipids of the Accused Product comprise "a tertiary amine cationic lipid, a poly-ethylene glycol-conjugated (PEG-conjugated) lipid, and cholesterol." *See* paragraphs 36–44, *supra*; *e.g.*, Exhibit 20 (May 2024, mRESVIA® Package Insert) at 6 ("Each 0.5 mL dose of

MRESVIA also contains the following ingredients: a total lipid content of 1.02 mg (SM-102 (heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate), polyethylene glycol 2000 dimyristoyl glycerol [PEG2000-DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]) ….") (bracketed text in original); Exhibit 31 (Shaw, *JID*, jiae035 (2024)) at 2 ("mRNA-1345 contains a single nucleoside-modified mRNA sequence encoding the membrane-anchored RSV F glycoprotein (RSV-A2 strain protein sequence) stabilized in the preF conformation through structural engineering and formulated in lipid nanoparticles (LNPs). The LNP formulation consists of an ionizable lipid promoting assembly of LNPs into delivery vehicles, a phospholipid that forms lipid bilayer structures in LNPs, a polyethylene glycol lipid, and a sterol that improves the stability of the formulations."); Exhibit 32 (Shaw, *JID*, jiae081 (2024)) at 2 (similar); *see also* paragraphs 191–192, *infra*.

191. 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 30 ('789 PTE) at 4–5, 10, 12, Exhibit 3 thereto (Tenchov (2021)) at 16989, 16993; Exhibit 50 (Schoenmaker (2021)) at 3, 4, 8.

192. 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 30 ('789 PTE) at 5, 10–11, Exhibit 3 thereto (Tenchov (2021)) at 16989; Exhibit 50 (Schoenmaker (2021)) at 3, 4, 8.

193. On information and belief, the lipids of the Accused Product "encapsulate at least half of the RNA molecules." *See* paragraphs 36–44, *supra*; *e.g.*, Exhibit 19 (FDA CMC Review Memo) at i ("MRESVIA is a vaccine that consists of lipid nanoparticles (LNPs) that encapsulate

linear mRNA"), 165 ("mRNA-1345 Drug Product (DP) is a white to off-white suspension of nanoparticles composed for four lipids … that protect and deliver mRNA …"); Exhibit 48 (Wilson (2023)) at 2234 ("The mRNA-1345 vaccine is a lipid nanoparticle-encapsulated mRNA-based vaccine …."); Exhibit 26 (February 15, 2024, Moderna ReSViNET Conference Presentation) at 5 ("LNP encapsulated mRNA-based vaccine encoding the RSV fusion (F) glycoprotein"); Exhibit 25 (February 29, 2024, Moderna ACIP Presentation) at 3 (similar); Exhibit 31 (Shaw, *JID*, jiae035 (2024)) at 1 ("A lipid nanoparticle-encapsulated mRNA-based RSV vaccine (mRNA-1345) that encodes the membrane-anchored RSV prefusion-stabilized F glycoprotein is under clinical investigation."); *see also* Exhibit 53 (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 50 (Schoenmaker (2021)) at 4 ("In mRNA-LNP formulations, such as those used in mRNA vaccines ... encapsulation efficiencies ... are typically > 90%.").

194. When administered to a patient in accordance with the FDA-approved use, the Accused Products is "immunogenic in vivo by eliciting an antibody response against the immunogen in vivo." *See* paragraph 56, *supra*; *e.g.*, Exhibit 48 (Wilson (2023)) at 2234 ("A phase 1 clinical trial of this vaccine did not show safety concerns and showed immunogenicity in younger and older adults; the vaccine induced neutralizing antibodies against both the RSV A and B subtypes …."), 2241–2242; Exhibit 31 (Shaw, *JID*, jiae035 (2024)) at 1 ("mRNA-1345 boosted RSV neutralizing antibody titers … and RSV prefusion binding antibody concentrations"), 6–7, Supplementary Information *passim*; Exhibit 32 (Shaw, *JID*, jiae081 (2024)) at 1 ("mRNA-1345 injection boosted RSV-A and RSV-B neutralizing antibody titers and prefusion F binding

antibody (preF bAb) concentrations"), 8, Supplementary Information *passim*; Exhibit 26 (February 15, 2024, Moderna ReSViNET Conference Presentation) at 5; Exhibit 25 (February 29, 2024, Moderna ACIP Presentation) at 3.

195. The Accused Product satisfies each and every element of exemplary claim 1 of the '467 patent, either literally or under the doctrine of equivalents.

196. On information and belief, Moderna has been aware at least since it received notice of its infringement from GSK on October 11, 2024, that the Accused Product satisfies each and every element of exemplary claim 1 of the '467 patent, either literally or under the doctrine of equivalents.

197. On information and belief, Moderna actively, knowingly, and specifically intended and intends, at least since it received notice of its infringement from GSK on October 11, 2024, to induce third-party manufacturers to directly infringe at least exemplary claim 1 of the '467 patent by making the Accused Product within the United States without authority or license to do so, during the term of the '467 patent.

198. On information and belief, Moderna has been aware at least since it received notice of its infringement from GSK on October 11, 2024, that the mRNA and lipid particles in the Accused Product 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, the Accused Product and its process of manufacture, and therefore to infringe at least claim 1 of the '467 patent.

199. Administration of the Accused Product to patients in the United States in accordance with the instructions in Moderna's labeling and prescribing information and therefore

with its FDA-approved use satisfies each and every element of exemplary claim 1 of the ’467 patent, either literally or under the doctrine of equivalents.

200. On information and belief, Moderna has been aware at least since it received notice of its infringement from GSK on October 11, 2024, that administration of the Accused Product to patients in the United States in accordance with the instructions in Moderna’s labeling and prescribing information and therefore with its FDA-approved use satisfies each and every element of exemplary claim 1 of the ’467 patent, either literally or under the doctrine of equivalents.

201. On information and belief, Moderna actively, knowingly, and specifically intended and intends, at least since it received notice of its infringement from GSK on October 11, 2024, to induce healthcare practitioners to directly infringe at least exemplary claim 1 of the ’467 patent by administering the Accused Product within the United States in accordance with the instructions in Moderna’s labeling and prescribing information and therefore with its FDA-approved use, without authority or license to do so, during the term of the ’467 patent.

202. For the foregoing reasons, Moderna directly infringes 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, the Accused Product, without authority or license to do so, during the term of the ’467 patent.

203. In addition or in the alternative, Moderna infringes 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 the Accused Product within the United States without authority or license to do so, during the term of the ’467 patent.

204. In addition or in the alternative, Moderna infringes 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 the Accused Product to patients within the United States in accordance with the instructions in Moderna’s labeling and prescribing information and therefore with its FDA-approved use, without authority or license to do so, during the term of the ’467 patent.

205. In addition or in the alternative, Moderna contributorily infringes 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 and/or lipid particles to be used in the Accused Product, without authority or license to do so, during the term of the ’467 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 ’467 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

206. GSK is suffering damages from Moderna’s infringement of the ’467 patent.

207. GSK is entitled to an award of monetary damages, including lost profits and/or a reasonable royalty, for Moderna’s infringement of the ’467 patent.

208. Moderna’s infringement of the ’467 patent is willful and deliberate at least since it received notice of its infringement from GSK on October 11, 2024.

209. 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 those actions with respect to the Accused Product.

COUNT VI

(Infringement of the ’534 patent)

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

211. GSK Biologicals is the lawful owner by assignment of the ’534 patent, which is entitled “Immunisation with Lipid Formulations with RNA Encoding Immunogens” and was duly and legally issued by the U.S. Patent and Trademark Office on January 30, 2024. A true and correct copy of the ’534 patent is attached as Exhibit 6.

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

213. 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 Product.

214. Moderna has had knowledge of the ’534 patent and specific notice of its infringement of that patent at least since October 11, 2024, by communications between GSK and Moderna. *See* Exhibit 56.

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

> **1.** A method of eliciting an antibody response against an immunogen in a subject, the method comprising administering intramuscularly to the subject an effective amount of a unit dose of a pharmaceutical composition to elicit the antibody response; the pharmaceutical composition comprising ribonucleic acid (RNA) molecules and lipid particles; the RNA molecules comprising a sequence that encodes the immunogen; the immunogen comprising a respiratory syncytial virus surface fusion glycoprotein, 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; the lipid particles comprising: (a) from 40 mole % to 60 mole % cationic lipid comprising a tertiary amine, (b) a polyethylene glycol-conjugated (PEG-conjugated) lipid, and (c) from 35 mole % to 50 mole % cholesterol; at least 80% of the lipid particles having a diameter from 20 nm to 220 nm; the lipid particles encapsulating at least half of the RNA molecules; the administering comprising

contacting the pharmaceutical composition with skeletal muscle; and the subject being a human or a cow.

216. The Accused Product comprises "a pharmaceutical composition … comprising ribonucleic acid (RNA) molecules and lipid particles." *See* paragraphs 36–44, *supra*; *e.g.*, Exhibit 20 (May 2024, mRESVIA® Package Insert) at 6 ("MRESVIA is a sterile white to off-white injectable suspension for intramuscular use. Each 0.5 mL dose of MRESVIA contains 50 mcg of nucleoside modified mRNA encoding the RSV F glycoprotein stabilized in the prefusion conformation (pre-F protein). Each 0.5 mL dose of MRESVIA also contains the following ingredients: a total lipid content of 1.02 mg (SM-102 (heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate), polyethylene glycol 2000 dimyristoyl glycerol [PEG2000-DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), 0.25 mg tromethamine, 1.2 mg tromethamine hydrochloride, 0.021 mg acetic acid, 0.10 mg sodium acetate trihydrate, 44 mg sucrose, and water for injection.."); Exhibit 48 (Wilson (2023)) at 2234 ("The mRNA-1345 vaccine is a lipid nanoparticle-encapsulated mRNA-based vaccine encoding the membrane-anchored RSV-F glycoprotein, derived from an RSV A strain, and stabilized in the preF conformation."); Exhibit 31 (Shaw, *JID*, jiae035 (2024)) at 2 ("mRNA-1345 contains a single nucleoside-modified mRNA sequence encoding the membrane-anchored RSV F glycoprotein (RSV-A2 strain protein sequence) stabilized in the preF conformation through structural engineering and formulated in lipid nanoparticles (LNPs). The LNP formulation consists of an ionizable lipid promoting assembly of LNPs into delivery vehicles, a phospholipid that forms lipid bilayer structures in LNPs, a poly-ethylene glycol lipid, and a sterol that improves the stability of the formulations."); Exhibit 32 (Shaw, *JID*, jiae081 (2024)) at 2 ("mRNA-1345 contains a nucleoside-modified mRNA sequence encoding the membrane-anchored RSV F glycoprotein (RSV-A2 strain protein sequence) stabilized in the preF conformation through structural

engineering and formulated in LNPs. The LNP formulation consists of an ionizable lipid, a phospholipid that forms lipid bilayer structures in LNPs, a polyethylene glycol lipid, and a sterol that improves stability."); Exhibit 26 (February 15, 2024, Moderna ReSViNET Conference Presentation) at 5 ("LNP encapsulated mRNA-based vaccine encoding the RSV fusion (F) glycoprotein"); Exhibit 25 (February 29, 2024, Moderna ACIP Presentation) at 3 (similar).

217. The mRNA molecules of the Accused Product comprise "a sequence that encodes the immunogen; the immunogen comprising a respiratory syncytial virus surface fusion glycoprotein." *See* paragraphs 36–44, *supra*; *e.g.*, Exhibit 20 (May 2024, mRESVIA® Package Insert) at 6 ("Each 0.5 mL dose of MRESVIA contains 50 mcg of nucleoside modified mRNA encoding the RSV F glycoprotein stabilized in the prefusion conformation (pre-F) protein. … MRESVIA induces an immune response against RSV pre-F protein that protects against LRTD caused by RSV."); Exhibit 28 (Moderna WO336 Publication) *passim*, *e.g.*, at 80–81 (providing sequence of the "ORF of mRNA (excluding the stop codon)" (SEQ ID NO: 34) and "Corresponding amino acid sequence" (SEQ ID NO: 8)); Exhibit 25 (February 29, 2024, Moderna ACIP Presentation) at 3; Exhibit 22 (May 31, 2024, Moderna Press Release) at 2; Exhibit 23 (May 15, 2023, EMA Study Decision) at 1; Exhibit 26 (February 15, 2024 Moderna ReSViNET Presentation) at 5; Exhibit 48 (Wilson (2023)) *passim*; Exhibit 31 (Shaw, *JID*, jiae035 (2024)) *passim*; Exhibit 32 (Shaw, *JID*, jiae081 (2024)) *passim*.

218. On information and belief, the lipid particles of the Accused Product comprise "(a) from 40 mole % to 60 mole % cationic lipid comprising a tertiary amine, (b) a polyethylene glycol-conjugated (PEG-conjugated) lipid, and (c) from 35 mole % to 50 mole % cholesterol." *See* paragraphs 36–44, *supra*; *e.g.*, Exhibit 20 (May 2024, mRESVIA® Package Insert) at 6 ("Each 0.5 mL dose of MRESVIA also contains the following ingredients: a total lipid content of 1.02 mg

(SM-102 (heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate), polyethylene glycol 2000 dimyristoyl glycerol [PEG2000-DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]) ….") (bracketed text in original); Exhibit 31 (Shaw, *JID*, jiae035 (2024)) at 2 ("mRNA-1345 contains a single nucleoside-modified mRNA sequence encoding the membrane-anchored RSV F glycoprotein (RSV-A2 strain protein sequence) stabilized in the preF conformation through structural engineering and formulated in lipid nanoparticles (LNPs). The LNP formulation consists of an ionizable lipid promoting assembly of LNPs into delivery vehicles, a phospholipid that forms lipid bilayer structures in LNPs, a poly-ethylene glycol lipid, and a sterol that improves the stability of the formulations."); Exhibit 32 (Shaw, *JID*, jiae081 (2024)) at 2 (similar); *see also* Exhibit 50 (Schoenmaker (2021) at 3, Table 1 (reporting the "Molar lipid ratios (%) ionizable cationic lipid : neutral lipid : cholesterol : PEG-ylated lipid" as "50:10:38.5:1.5"); paragraphs 219–220, *infra*.

219. 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 30 ('789 PTE) at 4–5, 10, 12, Exhibit 3 thereto (Tenchov (2021)) at 16989, 16993; Exhibit 50 (Schoenmaker (2021)) at 3, 4, 8.

220. 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 30 ('789 PTE) at 5, 10–11, Exhibit 3 thereto (Tenchov (2021)) at 16989; Exhibit 50 (Schoenmaker (2021)) at 3, 4, 8.

221. On information and belief, "at least 80%" of the lipid particles of the Accused Product have "a diameter from 20 nm to 220 nm." *See*, *e.g.*, Exhibit 30 ('789 PTE) at 11

(representing that 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 50 (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.").

222. On information and belief, the lipid particles of the Accused Product "encapsulat[e] at least half of the RNA molecules." *See* paragraphs 36–44, *supra*; *e.g.*, Exhibit 19 (FDA CMC Review Memo) at 1 ("MRESVIA is a vaccine that consists of lipid nanoparticles (LNPs) that encapsulate linear mRNA"), 165 ("mRNA-1345 Drug Product (DP) is a white to off-white suspension of nanoparticles composed for four lipids … that protect and deliver mRNA …"); Exhibit 48 (Wilson (2023)) at 2234 ("The mRNA-1345 vaccine is a lipid nanoparticle-encapsulated mRNA-based vaccine …."); Exhibit 26 (February 15, 2024, Moderna ReSViNET Conference Presentation) at 5 ("LNP encapsulated mRNA-based vaccine encoding the RSV fusion (F) glycoprotein"); Exhibit 25 (February 29, 2024, Moderna ACIP Presentation) at 3 (similar); Exhibit 31 (Shaw, *JID*, jiae035 (2024)) at 1 ("A lipid nanoparticle-encapsulated mRNA-based RSV vaccine (mRNA-1345) that encodes the membrane-anchored RSV prefusion-stabilized F glycoprotein is under clinical investigation."); *see also* Exhibit 53 (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 50 (Schoenmaker (2021) at 4 ("In mRNA-LNP formulations, such as those used in mRNA vaccines ... encapsulation efficiencies ... are typically > 90%.").

223. The FDA-approved use for the Accused Product is a "method of eliciting an antibody response against an immunogen in a subject, the method comprising administering intramuscularly to the subject an effective amount of a unit dose of" the Accused Product, "the administering comprising contacting" the Accused Product "with skeletal muscle; and the subject being a human." *See* paragraphs 46–56, *supra*; *e.g.*, Exhibit 20 (May 2024, mRESVIA® Package Insert) at 2 ("Administer MRESVIA intramuscularly."), 6 ("MRESVIA is a sterile white to off-white injectable suspension for intramuscular use. Each 0.5 mL dose of MRESVIA contains 50 mcg of nucleoside modified mRNA encoding the RSV F glycoprotein stabilized in the prefusion conformation (pre-F protein). … MRESVIA induces an immune response against RSV pre-F protein that protects against LRTD caused by RSV."), 10 (MRESVIA is for people 60 years of age and older); Exhibit 48 (Wilson (2023)) at 2234 ("The mRNA-1345 vaccine is a lipid nanoparticle-encapsulated mRNA-based vaccine encoding the membrane-anchored RSV-F glycoprotein, derived from an RSV A strain, and stabilized in the preF conformation. A phase 1 clinical trial of this vaccine did not show safety concerns and showed immunogenicity in younger and older adults …."); Exhibit 31 (Shaw, *JID*, jiae035 (2024)) at 6 ("One mRNA-1345 injection of 50 … µg increased RSV-A and RSV-B neutralizing antibody titers (Figure 3, Supplementary Table 4) as well as preF and postF binding antibody concentrations (Figure 4, Supplementary Table 5)."), 8 ("This phase 1 trial showed that mRNA-1345 is well tolerated and immunogenic in younger adults."); Exhibit 32 (Shaw, *JID*, jiae081 (2024)) at 6–7 (E.g., "A single mRNA-1345 injection elicited nAb responses against RSV-A and RSV-B subtypes at all dose levels evaluated."); Exhibit 26 (February 15, 2024, Moderna ReSViNET Conference Presentation) at 5; Exhibit 25 (February 29, 2024, Moderna ACIP Presentation) at 3.

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

225. On information and belief, Moderna has been aware at least since it received notice of its infringement from GSK on October 11, 2024, that administration of the Accused Product to patients in the United States in accordance with the instructions in Moderna's labeling and prescribing information and therefore with its FDA-approved use satisfies each and every element of exemplary claim 1 of the '534 patent, either literally or under the doctrine of equivalents.

226. On information and belief, Moderna actively, knowingly, and specifically intended and intends, at least since it received notice of its infringement from GSK on October 11, 2024, to induce healthcare practitioners to directly infringe at least claim 1 of the '534 patent by administering the Accused Product within the United States in accordance with the instructions in Moderna's labeling and prescribing information and therefore with its FDA-approved use, without authority or license to do so, during the term of the '534 patent.

227. On information and belief, Moderna has been aware at least since it received notice of its infringement from GSK on October 11, 2024, that the Accused Product constitutes a material part of, is especially made and especially adapted for, and is not a staple article or commodity of commerce suitable for substantial use other than, its FDA-approved use in the United States, and therefore to infringe at least claim 1 of the '534 patent.

228. For the foregoing reasons, Moderna infringes 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 the Accused Product to patients within the United

States in accordance with the instructions in Moderna's labeling and prescribing information and therefore with its FDA-approved use, without authority or license to do so, during the term of the '534 patent.

229. In addition or in the alternative, Moderna contributorily infringes 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, the Accused Product, knowing that the Accused Product constitutes a material part of the inventions of, and is especially made or adapted to infringe, at least claim 1 of the '534 patent, and knowing that the Accused Product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

230. GSK is suffering damages from Moderna's infringement of the '534 patent.

231. GSK is entitled to an award of monetary damages, including lost profits and/or a reasonable royalty, for Moderna's infringement of the '534 patent.

232. Moderna's infringement of the '534 patent is willful and deliberate at least since it received notice of its infringement from GSK on October 11, 2024.

233. 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 the aforementioned actions with respect to the Accused Product.

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 '770, '861, '864, '529, 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, including, without limitation, lost profits and/or reasonable royalties, 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. Upon a judgment in GSK's favor, an order permanently enjoining Moderna, its affiliates, subsidiaries, and each of its officers, agents, servants and employees, and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States, mRESVIA®;

G. 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;

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

I. 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: October 12, 2024

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