

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GLAXOSMITHKLINE BIOLOGICALS SA	)	
and GLAXOSMITHKLINE LLC,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 24-512 (GBW)
	)	
PFIZER INC., PHARMACIA & UPJOHN	)	JURY TRIAL DEMANDED
CO. LLC, BIONTECH SE, BIONTECH	)	
MANUFACTURING GMBH, and	)	
BIONTECH US INC.,	)	
	)	
Defendants.	)	

**ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS IN RESPONSE TO
COMPLAINT FOR PATENT INFRINGEMENT**

Defendants Pfizer Inc. (“Pfizer”) and Pharmacia & Upjohn Co. LLC (“Pharmacia”) (collectively, “Pfizer”) and BioNTech SE, BioNTech Manufacturing GmbH (“BioNTech Manufacturing”), and BioNTech US Inc. (“BioNTech US”) (collectively, “BioNTech,” and together with Pfizer, “Defendants”) hereby answer the Complaint for Patent Infringement (“Complaint”) filed by Plaintiffs GlaxoSmithKline Biologicals SA (“GSK Biologicals”) and GlaxoSmithKline LLC (“GSK LLC”) (collectively, “GSK” or “Plaintiffs”). Any allegations not expressly admitted are denied. This answer follows the numbering provided in Plaintiffs’ Complaint. To the extent that the section headings of Plaintiffs’ Complaint contain allegations, those allegations are denied. To the extent Plaintiffs’ footnotes contain allegations, those allegations are denied.

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 formulations comprising lipids and messenger ribonucleic acid (“mRNA”) molecules encoding an immunogen, and

methods of administering the same. See Exhibits 1–5 (the “Patents-in-Suit,” as defined in paragraph 9, below).

RESPONSE: Defendants admit that GSK Biologicals is listed as the assignee on the face of the Patents-in-Suit. Defendants otherwise lack the knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 1 and therefore deny the same.

2. In 2008, more than a decade before the SARS-CoV-2 (2019) coronavirus disease (COVID-19) pandemic, Andrew Geall, an accomplished formulation scientist and the named inventor of the Patents-in-Suit, joined a team of talented researchers working under the leadership of vaccinologist Christian Mandl (the “Mandl team”) focused on developing mRNA vaccines. These individuals discovered formulations comprising lipids and mRNA molecules encoding a viral immunogen that provide protection from viral infection. The Mandl team described the inventions now claimed in the Patents-in-Suit, in patent applications filed in 2010.

RESPONSE: Defendants deny that “the Mandl team described the inventions now claimed in the Patents-at-Issue, in patent applications filed in 2010.” Defendants further deny that the Patents-at-Issue are valid, enforceable, or infringed by Defendants. Defendants otherwise lack the knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 2 and therefore deny the same.

3. The Mandl team’s innovation has been revolutionary for vaccine development. A significant advantage over other approaches to vaccine design is the ability to employ the technology as a platform to formulate and administer mRNA encoding a wide range of immunogens. The prestigious science journal *Nature* noted in 2021 that “[e]very mRNA company now uses some variation of [the Mandl team’s] delivery platform and manufacturing system[.]” Exhibit 6 (Dolgin, “The Tangled History of mRNA Vaccines,” *Nature* 597, 318 (2021)) at 323.

RESPONSE: To the extent the allegations of Paragraph 3 purport to rely on Exhibit 6, that exhibit speaks for itself. Otherwise, at least because of the scope, breadth, and vagueness of these allegations, Defendants lack the knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 3 and therefore deny the same.

4. Another major advance of the Mandl team’s inventions over preexisting vaccine technologies is the speed with which a new vaccine candidate can be made and tested. Indeed, in response to the 2013 influenza outbreak in China, the Mandl team created a new mRNA vaccine candidate in just eight days—“in real time the moment that sequence was available.” Exhibit 7

(Dolgin, “Injection of Hope,” *Nature* 574, S10 (2019)) at S11. *Nature* recognized this achievement as “[t]he current speed record” of vaccine development. *Id.*

RESPONSE: To the extent the allegations of Paragraph 4 purport to rely on Exhibit 7, that exhibit speaks for itself. Defendants also note that before they began a collaborative effort focused on bringing a COVID-19 disease vaccine to market, no mRNA vaccines previously had been approved by FDA. Otherwise, at least because of the scope, breadth, and vagueness of these allegations, Defendants lack the knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 4 and therefore deny the same.

5. The foundation of Defendants’ technical and financial success with COVID-19 vaccines is the technology of GSK’s patented inventions. Defendants have repeatedly touted the speed at which they produced their original COVID-19 vaccine and were later able to modify it to address new viral strains but have consistently failed to acknowledge how they applied the Mandl team’s revolutionary platform to do so. Defendants have reaped billions of dollars in revenue from infringing GSK’s Patents-in-Suit and continue to benefit, without ever obtaining a license.

RESPONSE: Denied.

6. GSK brings this suit to recover a reasonable royalty for Defendants’ infringing sales of mRNA vaccines that apply the Mandl team’s inventions.

RESPONSE: Defendants deny infringement of any valid and enforceable claim of the Patents-in-Suit and that Plaintiffs are entitled to any relief.

NATURE OF THE ACTION

7. GSK incorporates by reference paragraphs 1–6.

RESPONSE: Defendants incorporate by reference their responses contained in Paragraphs 1 through 6.

8. 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 Defendants’ infringing manufacture, use, sale, marketing, offer for sale, and/or importation of its following products (as defined in paragraphs 47–66, below): (1) the original “monovalent” (containing a single mRNA active ingredient) Comirnaty® COVID-19 vaccine; (2) the “bivalent” (containing two different mRNA active ingredients) Comirnaty® COVID-19 original plus BA.1 variant vaccine; (3) the bivalent Comirnaty® COVID-19 original plus BA.4/5 variant vaccine; and (4) the monovalent Comirnaty®

COVID-19 XBB.1.5 variant vaccine (collectively, the “Accused Products” or “Defendants’ COVID-19 vaccines”).

RESPONSE: Paragraph 8 states legal conclusions to which no response is required. To the extent a response is required, Defendants admit that the Complaint purports to state a claim for infringement arising under 35 U.S.C. § 100 *et seq.* but deny that they have infringed or will infringe, directly or indirectly, the Patents-in-Suit and that Plaintiffs are entitled to any relief. Defendants deny the remaining allegations of Paragraph 8.

9. As alleged herein, Defendants’ manufacture, use, sale, marketing, offer for sale, and/or importation of the Accused Products directly infringed and continues to directly infringe, actively induced and continues to actively induce infringement of, and/or contributed to and continues to contribute to the infringement of, one or more claims of the following GSK Biologicals patents directed to mRNA vaccine technology: U.S. Patent Nos. 11,638,693 (the “’693 patent”) (Exhibit 1), 11,638,694 (the “’694 patent”) (Exhibit 2), 11,666,534 (the “’534 patent”) (Exhibit 3), 11,766,401 (the “’401 patent”) (Exhibit 4), and 11,786,467 (the “’467 patent”) (Exhibit 5) (collectively, the “Asserted Patents” or “Patents-in-Suit”). 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.

RESPONSE: Defendants deny infringement of any valid and enforceable claim of the Patents-in-Suit and that Plaintiffs are entitled to any relief. To the extent the allegations of Paragraph 8 purport to rely on Exhibits 1-5, those exhibits speak for themselves. Defendants lack the knowledge or information sufficient to form a belief as to the truth of the allegations of the remainder of Paragraph 9 and therefore deny the same.

THE PARTIES

10. GSK incorporates by reference paragraphs 1–9.

RESPONSE: Defendants incorporate by reference their responses contained in Paragraphs 1 through 9.

11. 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.

RESPONSE: Defendants admit that GSK Biologicals purports to be a corporation organized and existing under the laws of Belgium, with its principal place of business at Avenue Fleming 20, 1300 Wavre, Belgium. Defendants otherwise lack the knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 11 and therefore deny the same.

12. 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.

RESPONSE: Defendants admit that GSK LLC purports to be 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. Defendants otherwise lack the knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 12 and therefore deny the same.

13. On information and belief, Defendant Pfizer Inc. is a corporation organized and existing under the laws of Delaware, with its principal place of business at 66 Hudson Boulevard East, New York, New York 10001. Pfizer Inc., itself and through its subsidiaries and business partners, develops, manufactures, imports, markets, distributes, offers to sell, and/or sells the Accused Products and other medicines in the State of Delaware and throughout the United States, for use in the State of Delaware and throughout the United States.

RESPONSE: Defendants admit that Pfizer is incorporated in Delaware with a principal place of business at 66 Hudson Boulevard East, New York, New York 10001. Paragraph 13 otherwise states legal conclusions to which no response is required. To the extent a response is required, Defendants respond that, solely for the purposes of this action and solely for the claims asserted in the Complaint, they do not contest personal jurisdiction. Defendants otherwise deny the remaining allegations of this Paragraph.

14. On information and belief, Defendant Pharmacia & Upjohn Co. LLC is a wholly owned subsidiary of Pfizer Inc. Pharmacia & Upjohn Co. LLC is a company organized and existing under the laws of Delaware with its principal place of business at 100 Route 206 N, Peapack, New Jersey 07977. On information and belief, Pharmacia & Upjohn Co. LLC manufactures, labels, and packages the Accused Products in facilities located at 7000 Portage Road, Kalamazoo, Michigan 49001. Exhibit 8 (August 23, 2021, FDA Comirnaty® (original monovalent) COVID-19 vaccine Approval Letter) at 1.

RESPONSE: Defendants admit that Pharmacia & Upjohn Co. LLC is a wholly owned subsidiary of Pfizer Inc. organized and existing under the laws of Delaware with its principal place of business at 100 Route 206 N. Peapack, New Jersey 07977. Paragraph 14 otherwise states legal conclusions to which no response is required. To the extent the allegations of Paragraph 14 purport to rely on Exhibit 8, that exhibit speaks for itself. Defendants otherwise deny the remaining allegations of this Paragraph.

15. On information and belief, Defendant BioNTech SE is a corporation organized and existing under the laws of Germany, with its principal place of business at An der Goldgrube 12, 55131 Mainz, Germany.

RESPONSE: Defendants admit that BioNTech SE is a corporation organized and existing under the laws of Germany, with its principal place of business at An der Goldgrube 12, 55131 Mainz, Germany.

16. On information and belief, Defendant BioNTech Manufacturing GmbH, a wholly owned subsidiary of BioNTech SE, is a limited liability company organized and existing under the laws of Germany, with its principal place of business at An der Goldgrube 12, 55131 Mainz, Germany, and is the Biologics License Application (“BLA”) holder for the Accused Products in the United States. Exhibit 8 (August 23, 2021, FDA Comirnaty® (original monovalent) vaccine Approval Letter); *see also ModernaTX, Inc. v. Pfizer Inc.*, No. 1:22-CV-11378, D.I. 45 at 20 (D. Mass. Dec. 5, 2022).

RESPONSE: Defendants admit that BioNTech Manufacturing GmbH is a wholly owned subsidiary of BioNTech SE organized and existing under the laws of Germany, with its principal place of business at An der Goldgrube 12, 55131 Mainz, Germany, and is holder of the BLA for Comirnaty® (original monovalent). Paragraph 16 otherwise states legal conclusions to which no

response is required. To the extent the allegations of Paragraph 16 purport to rely on Exhibit 8, that exhibit speaks for itself.

17. On information and belief, Defendant BioNTech US Inc., a wholly owned subsidiary of BioNTech SE, is a corporation organized and existing under the laws of Delaware, has its principal place of business at 40 Erie St., Suite 110, Cambridge, MA 02139, serves as the North American Headquarters for BioNTech SE,¹ and is BioNTech SE's agent for service of process in the United States. Exhibit 9 (excerpts from March 30, 2022, BioNTech SE 2021FY Annual Report (Form 20-F)), at 81; *see also ModernaTX, Inc. v. Pfizer Inc.*, No. 1:22-CV-11378, D.I. 45 at 21 (D. Mass. Dec. 5, 2022).

RESPONSE: Defendants admit that BioNTech US Inc. is a wholly owned subsidiary of BioNTech SE organized and existing under the laws of Delaware, with its principal place of business at 40 Erie St., Suite 110, Cambridge, MA 02139. Defendants deny that BioNTech US Inc. is BioNTech SE's agent for service of process in the United States. Paragraph 17 otherwise states legal conclusions to which no response is required. To the extent the allegations of Paragraph 17 purport to rely on Exhibit 9, that exhibit speaks for itself.

18. On information and belief, Defendants are agents of one another or work in concert with each other regarding the development, regulatory approval, manufacturing, marketing, offering for sale, sale, or distribution of the Accused Products in the United States. *See ModernaTX, Inc. v. Pfizer Inc.*, No. 1:22-CV-11378, D.I. 45 at 21 (D. Mass. Dec. 5, 2022).

RESPONSE: Paragraph 18 states legal conclusions to which no response is required. To the extent the allegations of Paragraph 18 rely on a document filed in a proceeding before the U.S. District Court for the District of Massachusetts, captioned *ModernaTX, Inc. v. Pfizer Inc.*, No. 1:22-CV-11378 (D. Mass Dec. 5, 2022), that document speaks for itself. Defendants otherwise deny the remaining allegations of this Paragraph.

JURISDICTION AND VENUE

19. GSK incorporates by reference paragraphs 1–18.

¹ See www.biontech.com/int/en/home/about/biontech-us-website.html, last visited April 20, 2024.

RESPONSE: Defendants incorporate by reference their responses contained in Paragraphs 1 through 18.

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

RESPONSE: Paragraph 20 purports to characterize GSK’s complaint, which speaks for itself, and states legal conclusions to which no response is required. To the extent a response is required, Defendants admit that the Complaint purports to state a claim for patent infringement arising under the patent laws of the United States, including 35 U.S.C. § 100 *et seq.* and 35 U.S.C. § 271 *et seq.* Defendants otherwise deny the remaining allegations of this Paragraph.

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

RESPONSE: Paragraph 21 states legal conclusions to which no response is required. To the extent a response is required, Defendants respond that, solely for purposes of this action only, they do not contest that this Court has subject matter jurisdiction over this action.

22. This Court has personal jurisdiction over Defendants Pfizer Inc., Pharmacia & Upjohn Co. LLC, and BioNTech US, Inc. because each is organized under the laws of Delaware.

RESPONSE: Paragraph 22 states legal conclusions to which no response is required. To the extent a response is required, Defendants respond that, solely for purposes of this action and solely for the claims asserted in the Complaint, they do not contest personal jurisdiction.

23. This Court also has personal jurisdiction over Defendants Pfizer Inc., Pharmacia & Upjohn Co. LLC, BioNTech SE, BioNTech Manufacturing GmbH, and BioNTech US Inc. because, on information and belief, each has conducted and continues to conduct business in Delaware at least by offering for sale or selling the Accused Products in Delaware, and because each has committed and continues to commit acts of infringement in Delaware. For example, as reported by the United States Center for Disease Control and Prevention (“CDC”), by May 10, 2023, Defendants had delivered to the State of Delaware over 1.65 million doses of Comirnaty® (original monovalent) COVID-19 vaccine and over 300 thousand doses of Comirnaty® (bivalent BA.4/5) (both products as defined in paragraphs 47–66, below). Exhibit 10 (printout of CDC Data on Comirnaty® (original monovalent and bivalent BA.4/5) doses distributed in Delaware, May

10, 2023).² On information and belief, Defendants continue to deliver doses of Comirnaty® COVID-19 vaccine products to the State of Delaware. Therefore, Defendants Pfizer Inc., Pharmacia & Upjohn Co. LLC, BioNTech SE, BioNTech Manufacturing GmbH, and BioNTech US, Inc. have transacted and continue to transact business within Delaware relating to GSK's claims and have engaged in and maintain systematic and continuous business contacts in Delaware.

RESPONSE: Paragraph 23 states legal conclusions to which no response is required. To the extent a response is required, Defendants respond that, solely for purposes of this action and solely for the claims asserted in the Complaint, they do not contest personal jurisdiction. To the extent the allegations of Paragraph 23 purport to rely on Exhibit 10, that exhibit speaks for itself. Defendants otherwise deny the remaining allegations of this Paragraph.

24. Defendants Pfizer Inc., Pharmacia & Upjohn Co. LLC, BioNTech SE, and BioNTech Manufacturing GmbH have consented to this Court's exercise of personal jurisdiction in other litigations involving the Accused Products, including in *Alnylam Pharmaceuticals, Inc. v. Pfizer Inc., et al*, C.A. No. 22-cv-336-CFC and *Alnylam Pharmaceuticals, Inc. v. Pfizer Inc., et al*, C.A. No. 23-cv-578-CFC.

RESPONSE: Paragraph 24 states legal conclusions to which no response is required. To the extent a response is required, Defendants respond that, solely for purposes of this action and solely for the claims asserted in the Complaint, they do not contest personal jurisdiction. To the extent the allegations of Paragraph 24 rely on documents filed in other proceedings, those documents speak for themselves. Defendants otherwise deny the remaining allegations of this Paragraph.

25. Venue is proper in this judicial District with respect to Defendants Pfizer Inc., Pharmacia & Upjohn Co. LLC, and BioNTech US Inc. pursuant to 28 U.S.C. § 1400(b) because Pfizer Inc., Pharmacia & Upjohn Co. LLC, and BioNTech US, Inc. are entities organized and existing under the laws of the State of Delaware and reside in Delaware for purposes of venue.

² Spreadsheet available at https://data.cdc.gov/Vaccinations/COVID-19-Vaccinations-in-the-United-States-Jurisd/uns-k-b7fc/data_preview; Delaware specific data last accessed, April 10, 2024.

RESPONSE: Paragraph 25 states legal conclusions to which no response is required. To the extent a response is required, Defendants respond that, solely for purposes of this action and solely for the claims asserted in the Complaint, they do not contest venue. Defendants otherwise deny the remaining allegations of this Paragraph.

26. Venue is proper in this District with respect to BioNTech SE and BioNTech Manufacturing GmbH under 28 U.S.C. § 1391(c)(3) because BioNTech SE and BioNTech Manufacturing GmbH are not residents of the United States.

RESPONSE: Paragraph 26 states legal conclusions to which no response is required. To the extent a response is required, Defendants respond that, solely for purposes of this action and solely for the claims asserted in the Complaint, they do not contest venue. Defendants otherwise deny the remaining allegations of this Paragraph.

27. Defendants Pfizer Inc., Pharmacia & Upjohn Co. LLC, BioNTech SE, and BioNTech Manufacturing GmbH have consented to this Court as a proper venue in other litigations involving the Accused Products, including in *Alnylam Pharmaceuticals, Inc. v. Pfizer Inc., et al*, C.A. No. 22-cv-336-CFC and *Alnylam Pharmaceuticals, Inc. v. Pfizer Inc., et al*, C.A. No. 23-cv-578-CFC.

RESPONSE: Paragraph 27 states legal conclusions to which no response is required. To the extent a response is required, Defendants respond that, solely for purposes of this action and solely for the claims asserted in the Complaint, they do not contest venue. To the extent the allegations of Paragraph 27 rely on documents filed in other proceedings, those documents speak for themselves. Defendants otherwise deny the remaining allegations of this Paragraph.

BACKGROUND

28. GSK incorporates by reference paragraphs 1–27.

RESPONSE: Defendants incorporate by reference their responses contained in Paragraphs 1 through 27.

A. The Claimed Inventions

29. By 2008, there were many well-understood and significant hurdles to employing mRNA in vaccines. See Exhibit 6 (Dolgin, “The Tangled History of mRNA Vaccines,” *Nature* 597, 318 (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.”).

RESPONSE: To the extent the allegations of Paragraph 29 purport to rely on Exhibit 6, that exhibit speaks for itself. Defendants otherwise lack the knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 29 and therefore deny the same.

30. In conventional vaccines, a protein is administered to a patient, is recognized as foreign by the body, and triggers the patient’s immune response (hence the protein is an “immunogen”). With mRNA vaccines, mRNA that encodes for an immunogenic protein is administered to a patient. If the mRNA can reach the inside of a patient’s cells, existing cellular machinery will read instructions encoded by the mRNA to make the protein—a process called “translation”—which then triggers the immune response.

RESPONSE: Defendants lack the knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 30 and therefore deny the remaining same.

31. But getting mRNA molecules, intact, from where they are made in the laboratory into a patient’s cell had historically presented seemingly insurmountable challenges. For example, mRNA is chemically fragile—it can degrade quickly even in a controlled laboratory environment. It needs to be protected from the moment of preparation through formulation, storage, handling, administration, and even inside the body following administration. And even if the mRNA remains intact following administration to a patient, the mRNA still needs some way to get into the cell so it can be translated and the immunogenic protein can effectuate an immune response.

RESPONSE: At least because of the scope, breadth, and vagueness of these allegations, Defendants lack the knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and therefore deny the same.

32. Despite unsuccessful efforts by others dating back decades, a talented team of researchers led by Christian Mandl set out in 2008 to overcome these hurdles and develop vaccines using mRNA. Exhibit 6 (Dolgin, “The Tangled History of mRNA Vaccines,” *Nature* 597, 318 (2021)) at 323. Through extensive experimentation, perseverance, and the unique insights and preferences of these talented scientists, the Mandl team successfully overcame the many challenges and discovered the novel lipid and mRNA formulations and methods for their use to raise an immune response against immunogens that are described and claimed in the Patents-in-Suit.

RESPONSE: To the extent the allegations of Paragraph 32 purport to rely on Exhibit 6, that exhibit speaks for itself. Defendants lack the knowledge or information sufficient to form a belief as to whether “the Mandl team successfully overcame the many challenges and discovered the novel lipid and mRNA formulations and methods for their use to raise an immune response against immunogens.” Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

33. 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).³ In a 2022 presentation for healthcare professionals concerning its COVID-19 vaccines entitled “Overview of mRNA vaccine development,” Pfizer cited this Mandl team publication for the statement: “Lipid nanoparticles were developed to protect the mRNA strands that encode the spike protein from degradation, thus helping them reach their target cells.” Exhibit 12 (Pfizer “Overview of mRNA vaccine development” presentation, dated August 2022⁴).

RESPONSE: To the extent the allegations of Paragraph 33 purport to rely on Exhibit 11 and Exhibit 12, those exhibits speak for themselves. Defendants lack the knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and therefore deny the same.

34. 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 13 (Lizotte, “Novartis Receives \$14M Award from DARPA,” *Global Biodefense*, January 31, 2012) (describing award of DARPA Contract HR0011-12-3-0001).

³ Metrics available at <https://www.pnas.org/doi/full/10.1073/pnas.1209367109>.

⁴ Available at https://covid19.pfizerpro.com/api/vc/en/content/material/561b4c91-800b-4ec0-af5c-efddf0aead8c/COVID19_PP-CVV-USA-0984_1.pdf?download=true; preserved April 10, 2024.

RESPONSE: To the extent the allegations of Paragraph 34 purport to rely on Exhibit 13, that exhibit speaks for itself. Otherwise, at least because of the scope, breadth, and vagueness of these allegations, Defendants lack the knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and therefore deny the same.

35. 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 6 (Dolgin, “The Tangled History of mRNA Vaccines,” *Nature* 597, 318 (2021)) at 323.

RESPONSE: To the extent the allegations of Paragraph 35 purport to rely on Exhibit 6, that exhibit speaks for itself. Otherwise, at least because of the scope, breadth, and vagueness of these allegations, Defendants lack the knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and therefore deny the same.

B. GSK Biological’s Acquisition of the Mandl Team’s Inventions

36. At the time the Mandl team began working on mRNA vaccines, they were employed by Novartis AG subsidiaries. In 2015, GSK Biologicals acquired a substantial portion of Novartis AG’s global vaccines business. See Exhibit 14 (March 2, 2015, GSK press release).

RESPONSE: To the extent the allegations of Paragraph 36 purport to rely on Exhibit 14, that exhibit speaks for itself. Otherwise, at least because of the scope, breadth, and vagueness of these allegations, Defendants lack the knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and therefore deny the same.

37. In that transaction, GSK Biologicals obtained, among other things, the Mandl team’s inventions, including all rights to the parent applications to the Patents-in-Suit and progeny, including the Patents-in-Suit.

RESPONSE: Defendants lack the knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and therefore deny the same.

C. Defendants’ Use and Knowledge of the Mandl Team’s Patented Technology

38. Defendants were aware of the Mandl team’s mRNA vaccine innovations long before they ever developed and commercialized the Accused Products.

RESPONSE: Denied.

39. Indeed, years before marketing the Accused Products, Defendants hired former Novartis AG vaccines business employees who had first-hand knowledge of the Mandl team's innovations.

RESPONSE: At least because of the scope, breadth, and vagueness of these allegations, Defendants lack the knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and therefore deny the same.

40. Since at least 2013, publications on the Mandl team's mRNA vaccine work have been identified by patent examining authorities as relevant prior art to BioNTech's own patent applications. This art includes published predecessor applications to the Patents-in-Suit. *See, e.g.*, Exhibit 15 (June 14, 2013, Written Opinion of the International Searching Authority on application PCT/EP2013/000902). BioNTech has also cited the Mandl team's patent application publications within the text of its own patent applications since at least 2016. *See, e.g.*, Exhibit 16 (excerpts from International PCT Application Publication Number WO2017/162266 of International PCT Application Number PCT/EP2016/056165, filed March 21, 2016). *See also* Exhibit 17 (printout of patent filings and patent applicants citing to patents or patent applications in the family of the Patents-in-Suit from the Derwent Patents Citation Index, preserved April 19, 2024).⁵

RESPONSE: To the extent the allegations of Paragraph 40 purport to rely on Exhibit 15, Exhibit 16, and Exhibit 17, those exhibits speak for themselves. Defendants otherwise lack the knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and therefore deny the same. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit.

41. BioNTech's familiarity with the families of patent applications describing and claiming the Mandl team's work prior to and during the COVID-19 pandemic is also evidenced by various communications between GSK and BioNTech.

⁵ Information on the Derwent Patents Citation Index is available at <https://clarivate.com/products/ip-intelligence/ip-data-and-apis/derwent-patents-citation-index/>. Similar information is available publicly through Google Patents. *See, e.g.*, Exhibit 18 (Google Patents, Cited By section, for the '534 patent, available at <https://patents.google.com/patent/US11666534B2/en?q=+11%2c666%2c534>; preserved August 3, 2023).

RESPONSE: At least because of the scope, breadth, and vagueness of these allegations, Defendants lack the knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and therefore deny the same.

42. And as noted, Pfizer recognized the contributions of the Mandl team in at least one presentation posted on its website concerning the development of its COVID-19 vaccines. Exhibit 12 (Pfizer “Overview of mRNA vaccine development” presentation, dated August 2022).

RESPONSE: To the extent the allegations of Paragraph 42 purport to rely on Exhibit 12, that exhibit speaks for itself. Defendants deny the remaining allegations of this Paragraph.

43. Defendants’ COVID-19 mRNA vaccines exploit the fundamental technologies invented by the Mandl team and claimed in the Patents-in-Suit. Defendants leveraged their knowledge of the Mandl team’s work to design and develop the Accused Products. But Defendants did not acquire a license to practice the GSK inventions before or since commercializing the Accused Products.

RESPONSE: Denied.

44. Defendants have had knowledge of and specific notice of their infringement of the Patents-in-Suit by the manufacture and sale of the Accused Products at least since April 24, 2024, as evidenced by communications with GSK. See Exhibits 81-82.

RESPONSE: To the extent the allegations of Paragraph 44 purport to rely on Exhibits 81–82, those exhibits speak for themselves. Defendants deny the remaining allegations of this Paragraph.

45. Defendants continue to infringe the Patents-in-Suit through the manufacture and sale of the Accused Products.

RESPONSE: Denied.

DEFENDANT’S INFRINGING ACTIVITIES

46. GSK incorporates by reference paragraphs 1–45.

RESPONSE: Defendants incorporate by reference their responses contained in Paragraphs 1 through 46.

A. The Accused Products

47. Defendants’ manufacture, use, sale, marketing, offer for sale, and/or importation of the following Accused Products infringe the Patents-in-Suit: all dosage forms of (1) the original monovalent Comirnaty® COVID-19 vaccine (“Comirnaty® (original monovalent)”); (2) the bivalent Comirnaty® COVID-19 original plus BA.1 variant vaccine (“Comirnaty® (bivalent BA.1)”); (3) the bivalent Comirnaty® COVID-19 original plus BA.4/5 variant vaccine (“Comirnaty® (bivalent BA.4/5)”); and (4) the monovalent Comirnaty® COVID-19 XBB.1.5 variant vaccine (“Comirnaty® (monovalent XBB.1.5)”).

RESPONSE: Denied.

48. On information and belief, for each of the foregoing Accused Products, Defendants previously used and continue to use the same method of manufacture, composition of mRNA drug substance (apart from differences in the sequence encoding the immunogens), and composition of drug product when applying for regulatory authorization or approval by the Food and Drug Administration (“FDA”) in the United States and European Medicines Agency (“EMA”) in Europe.

RESPONSE: Denied.

49. Defendants, FDA and EMA have also referred to the Accused Products as “BNT162b2” vaccine products. *See, e.g.*, Exhibit 19 (December 10, 2022, Pfizer press release); Exhibit 20 (December 11, 2020, FDA Comirnaty® (original monovalent) Emergency Use Authorization (“EUA”) Review Memo); Exhibit 21 (February 19, 2021, EMA Comirnaty® (original monovalent) Assessment Report).

RESPONSE: To the extent the allegations of Paragraph 49 purport to rely on Exhibit 19, Exhibit 20, and Exhibit 21, those exhibits speak for themselves. Defendants admit that the Pfizer-BioNTech COVID-19 vaccine has been referred to as BNT162b2. Defendants deny the remaining allegations of this Paragraph.

50. Comirnaty® (original monovalent) includes the active substance “tozinameran,” mRNA encoding a spike protein of the original (2019) strain of the SARS-CoV-2 coronavirus. *See, e.g.*, Exhibit 22 (December 15, 2023, EMA Comirnaty® European Public Assessment Report (“EPAR”) Product Information) at 2 (“Tozinameran is a single-stranded, 5’-capped messenger RNA (mRNA) ... encoding the viral spike (S) protein of SARS-CoV-2.”) and 79 (referring to the viral strain as “SARS-CoV-2 (Original)”; Exhibit 23 (Proposed International Nonproprietary Names List 124 – COVID-19) at 666.

RESPONSE: To the extent the allegations of Paragraph 50 purport to rely on Exhibit 22 and Exhibit 23, those exhibits speak for themselves. Defendants admit that Comirnaty® (original

monovalent) contains the active substance tozinameran. Defendants deny the remaining allegations of this Paragraph.

51. The tozinameran mRNA active ingredient includes, among other things, a 5' cap, a 5' untranslated region (UTR), an open reading frame region coding for the spike protein, a 3' untranslated region, and a 3' polyA tail. *See, e.g.*, Exhibit 22 (December 15, 2023, EMA Comirnaty® EPAR Product Information) at 2; Exhibit 23 (Proposed International Nonproprietary Names List 124 – COVID-19) at 666.

RESPONSE: To the extent the allegations of Paragraph 51 purport to rely on Exhibit 22 and Exhibit 23, those exhibits speak for themselves. Defendants otherwise deny the remaining allegations of this Paragraph.

52. Comirnaty® (original monovalent) elicits an immune response to the viral spike protein of the original (2019) strain of SARS-CoV-2 coronavirus. *See, e.g.*, Exhibit 21 (February 19, 2021, EMA Comirnaty® (original monovalent) Assessment Report) at 13; Exhibit 22 (December 15, 2023, EMA Comirnaty® EPAR Product Information) at 8–16.

RESPONSE: To the extent the allegations of Paragraph 52 purport to rely on Exhibit 21 and Exhibit 22, those exhibits speak for themselves. Defendants admit that Comirnaty® (original monovalent), when properly administered, has been shown to elicit an immune response. Defendants deny the remaining allegations of this Paragraph.

53. In response to the emergence of new strains of SARS-CoV-2, Defendants advanced dosage forms of two bivalent vaccines for commercial marketing authorization or approval: the Comirnaty® (bivalent BA.1) vaccine; and the Comirnaty® (bivalent BA.4/5) vaccine. *See, e.g.*, Exhibit 24 (September 1, 2022, Pfizer press release) (reporting on Comirnaty® (bivalent BA.1); Exhibit 25 (November 4, 2022, Pfizer press release) (reporting on Comirnaty® (bivalent BA.4/5).

RESPONSE: To the extent the allegations of Paragraph 53 purport to rely on Exhibit 24 and Exhibit 25, those exhibits speak for themselves. Defendants admit that they sought regulatory approval for Comirnaty® (bivalent BA.1) and Comirnaty® (bivalent BA.4/5). Defendants deny the remaining allegations of this Paragraph.

54. Both the Comirnaty® (bivalent BA.1) and Comirnaty® (bivalent BA.4/5) vaccines contain the tozinameran mRNA active substance. *See, e.g.*, Exhibit 22 (December 15, 2023, EMA Comirnaty® EPAR Product Information) at 79, 98; Exhibit 26 (December 7, 2022, EMA

Comirnaty® (bivalent BA.1) Assessment Report) at 6 (“The active substance tozinameran is already approved in the existing Comirnaty conditional marketing authorization. No changes to the information related to tozinameran are proposed.”); Exhibit 24 (September 1, 2022, Pfizer press release) (“Apart from the addition of the mRNA sequence of the Omicron BA.1 spike protein, all other components of the vaccine remain unchanged.”); Exhibit 27 (September 12, 2022, EMA Comirnaty® (bivalent BA.4/5) Assessment Report) at 5 (“The active substance tozinameran is already approved for the original Comirnaty vaccine formulations (EU/1/20/1528/001-005). No changes to the information related to tozinameran are proposed.”); Exhibit 25 (November 4, 2022, Pfizer press release) (“Apart from the addition of the mRNA sequence of the Omicron BA.4/BA.5 spike protein, all other components of the vaccine remain unchanged.”).

RESPONSE: To the extent the allegations of Paragraph 54 purport to rely on Exhibit 22, Exhibit 26, Exhibit 24, Exhibit 27, and Exhibit 25, those exhibits speak for themselves. Defendants admit that Comirnaty® (bivalent BA.1) and Comirnaty® (bivalent BA.4/5) contain tozinameran. Defendants deny the remaining allegations of this Paragraph.

55. In addition to tozinameran, the Comirnaty® (bivalent BA.1) vaccine also contains the active substance “riltozinameran,” mRNA encoding a viral spike protein of the Omicron BA.1 variant of SARS-CoV-2. Exhibit 22 (December 15, 2023, EMA Comirnaty® EPAR Product Information) at 79 (“Riltozinameran is a single-stranded, 5’-capped messenger RNA (mRNA) ... encoding the viral spike (S) protein of SARS-CoV-2 (Omicron BA.1).”); Exhibit 26 (December 7, 2022, EMA Comirnaty® (bivalent BA.1) Assessment Report) at 6; Exhibit 28 (Proposed International Nonproprietary Names List 126 – COVID-19 Addendum) at 1147.

RESPONSE: To the extent the allegations of Paragraph 55 purport to rely on Exhibit 22, Exhibit 26, and Exhibit 28, those exhibits speak for themselves. Defendants admit that Comirnaty® (bivalent BA.1) contains riltozinameran. Defendants deny the remaining allegations of this Paragraph.

56. On information and belief, apart from the open reading frame region coding for a viral spike protein of the SARS-CoV-2 Omicron BA.1 coronavirus variant, the components of the riltozinameran mRNA active ingredient are unchanged as compared to the tozinameran mRNA active ingredient as set forth above in paragraph 51. *See, e.g.*, Exhibit 22 (December 15, 2023, EMA Comirnaty® EPAR Product Information) at 79; Exhibit 28 (Proposed International Nonproprietary Names List 126 – COVID-19 Addendum) at 1147.

RESPONSE: To the extent the allegations of Paragraph 56 purport to rely on Exhibit 22 and Exhibit 28, those exhibits speak for themselves. Otherwise, at least because of the scope,

breadth, and vagueness of these allegations, Defendants lack the knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and therefore deny the same.

57. The Comirnaty® (bivalent BA.1) vaccine product elicits an immune response to the spike proteins of both the original SARS-CoV-2 strain and Omicron BA.1 SARS-CoV-2 variant. *See, e.g.*, Exhibit 22 (December 15, 2023, EMA Comirnaty® EPAR Product Information) at 86–94; Exhibit 26 (December 7, 2022, EMA Comirnaty® (bivalent BA.1) Assessment Report) at 62–66.

RESPONSE: To the extent the allegations of Paragraph 57 purport to rely on Exhibit 22 and Exhibit 26, those exhibits speak for themselves. Defendants admit that Comirnaty® (bivalent BA.1), when properly administered, has been shown to elicit an immune response. Defendants deny the remaining allegations of this Paragraph.

58. In addition to tozinameran, the Comirnaty® (bivalent BA.4/5) vaccine also contains the active substance “famtozinameran,” mRNA encoding a viral spike protein of the Omicron BA.4/5 variant of SARS-CoV-2. Exhibit 22 (December 15, 2023, EMA Comirnaty® EPAR Product Information) at 98 (“Famtozinameran is a single-stranded, 5’-capped messenger RNA (mRNA) ... encoding the viral spike (S) protein of SARS-CoV-2 (Omicron BA.4-5).”); Exhibit 27 (September 12, 2022, EMA Comirnaty® (bivalent BA.4/5) Assessment Report) at 5; Exhibit 29 (March 2023, FDA Comirnaty® (bivalent BA.4/5) Fact Sheet and Prescribing Information), Prescribing Information at 52.

RESPONSE: To the extent the allegations of Paragraph 58 purport to rely on Exhibit 22, Exhibit 27, and Exhibit 29, those exhibits speak for themselves. Defendants admit that Comirnaty® (bivalent BA.4/5) contains famtozinameran. Defendants deny the remaining allegations of this Paragraph.

59. On information and belief, apart from the open reading frame region coding for a viral spike protein of the SARS-CoV-2 Omicron BA.4/5 coronavirus variants, the components of the famtozinameran mRNA active ingredient are unchanged as compared to the tozinameran mRNA active ingredient as set forth above in paragraph 51. *See, e.g.*, Exhibit 22 (December 15, 2023, EMA Comirnaty® EPAR Product Information) at 98; Exhibit 30 (Proposed International Nonproprietary Names List 128 – COVID-19 Addendum) at 3.

RESPONSE: To the extent the allegations of Paragraph 59 purport to rely on Exhibit 22 and Exhibit 30, those exhibits speak for themselves. Defendants deny the remaining allegations of this Paragraph.

60. The Comirnaty® (bivalent BA.4/5) vaccine product elicits an immune response to the spike proteins of both the original SARS-CoV-2 strain and Omicron BA.4/5 SARS-CoV-2 variants. *See, e.g.*, Exhibit 22 (December 15, 2023, EMA Comirnaty® EPAR Product Information) at 105–114; Exhibit 27 (September 12, 2022, EMA Comirnaty® (bivalent BA.4/5) Assessment Report) at 24; Exhibit 29 (March 14, 2023, FDA Comirnaty® (bivalent BA.4/5) Fact Sheet and Prescribing Information), Prescribing Information at 52.

RESPONSE: To the extent the allegations of Paragraph 60 purport to rely on Exhibit 22, Exhibit 27, and Exhibit 29, those exhibits speak for themselves. Defendants admit that Comirnaty® (bivalent BA.4/5), when properly administered, has been shown to elicit an immune response. Defendants deny the remaining allegations of this Paragraph.

61. In response to the continued evolution of SARS-CoV-2, Defendants subsequently advanced dosage forms of a new monovalent vaccine for commercial marketing authorization and/or approval: the Comirnaty® (monovalent XBB.1.5) vaccine. *See, e.g.*, Exhibit 31 (June 23, 2023, Pfizer press release).

RESPONSE: To the extent the allegations of Paragraph 61 purport to rely on Exhibit 31, that exhibit speaks for itself. Defendants admit that they sought regulatory approval for Comirnaty® (monovalent XBB.1.5). Defendants deny the remaining allegations of this Paragraph.

62. The Comirnaty® (monovalent XBB.1.5) vaccine contains a single mRNA active ingredient, “raxtozinameran,” which encodes a viral spike protein of the Omicron XBB.1.5 variant of SARS-CoV-2. *See, e.g.*, Exhibit 22 (December 15, 2023, EMA Comirnaty® EPAR Product Information) at 190 (“Raxtozinameran is a single-stranded, 5’-capped messenger RNA (mRNA) ... encoding the viral spike (S) protein of SARS-CoV-2 (Omicron XBB.1.5).”); Exhibit 32 (Proposed International Nonproprietary Names List 129 – COVID-19) at 3; Exhibit 33 (September 2023, FDA Comirnaty® (monovalent XBB.1.5) Package Insert) at 20.

RESPONSE: To the extent the allegations of Paragraph 62 purport to rely on Exhibit 22, Exhibit 32, and Exhibit 33, those exhibits speak for themselves. Defendants admit that

Comirnaty® (bivalent XBB.1.5) contains raxtozinameran. Defendants deny the remaining allegations of this Paragraph.

63. On information and belief, apart from the open reading frame region coding for a viral spike protein of the SARS-CoV-2 Omicron XBB.1.5 coronavirus variant, the components of the raxtozinameran mRNA active ingredient are unchanged as compared to the tozinameran mRNA active ingredient as set forth above in paragraph 51. *See, e.g.*, Exhibit 22 (December 15, 2023, EMA Comirnaty® EPAR Product Information) at 190; Exhibit 32 (Proposed International Nonproprietary Names List 129 – COVID-19) at 3.

RESPONSE: To the extent the allegations of Paragraph 63 purport to rely on Exhibit 22 and Exhibit 32, those exhibits speak for themselves. Otherwise, at least because of the scope, breadth, and vagueness of this these allegations, Defendants lack the knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and therefore deny the same.

64. The Comirnaty® (monovalent XBB.1.5) vaccine product elicits an immune response to the spike protein of the Omicron XBB.1.5 SARS-CoV-2 variant. *See, e.g.*, Exhibit 22 (December 15, 2023, EMA Comirnaty® EPAR Product Information) at 197–207; Exhibit 33 (September 2023, FDA Comirnaty® (monovalent XBB.1.5) Package Insert) at 20.

RESPONSE: To the extent the allegations of Paragraph 64 purport to rely on Exhibit 22 and Exhibit 33, those exhibits speak for themselves. Defendants admit that Comirnaty® (monovalent XBB.1.5), when properly administered, has been shown to elicit an immune response. Defendants deny the remaining allegations of this Paragraph.

65. In addition to the mRNA active substance(s), all of Defendants’ accused Comirnaty® COVID-19 vaccines contain the following four lipid ingredients:

Chemical Name	Shorthand
((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)	“ALC-0315”
2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide	“ALC-0159”
1,2-distearoyl-sn-glycero-3-phosphocholine	“DSPC”
cholesterol	(N/A)

Exhibit 22 (December 15, 2023, EMA Comirnaty® EPAR Product Information) at 17, 95, 114, 208, 288, 304, 308, 324; Exhibit 34 (April 2023, FDA Comirnaty® (original monovalent) Package Insert) at 19; Exhibit 35 (July 14, 2023, FDA Comirnaty® (bivalent BA.4/5) EUA Fact Sheet and

Package Insert) at 53; Exhibit 33 (September 2023, FDA Comirnaty® (monovalent XBB.1.5) Package Insert) at 20.

RESPONSE: To the extent the allegations of Paragraph 65 purport to rely on Exhibit 22, Exhibit 34, Exhibit 35, and Exhibit 33, those exhibits speak for themselves. Defendants otherwise lack the knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and therefore deny the same.

66. Each of the Accused Products comprises lipid formulations with the same relative molar percentages of the foregoing lipid ingredients. *See, e.g.*, Exhibit 34 (April 2023, FDA Comirnaty® (original monovalent) Package Insert) at 19 (“Each 0.3 mL dose of the COMIRNATY... also includes the following ingredients: lipids (0.43 mg ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg 2-(polyethylene glycol 2000)-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.2 mg cholesterol[.]”); Exhibit 26 (December 7, 2022, EMA (bivalent BA.1) Assessment Report) at 11; Exhibit 35 (July 14, 2023, FDA Comirnaty (bivalent BA.4/5) EUA Fact Sheet and Package Insert) at 53; Exhibit 33 (September 2023, Comirnaty® (monovalent XBB.1.5) vaccine Package Insert) at 20.

RESPONSE: To the extent the allegations of Paragraph 66 purport to rely on Exhibit 34, Exhibit 26, Exhibit 35, and Exhibit 33, those exhibits speak for themselves. Defendants otherwise deny the remaining allegations of this Paragraph.

B. Defendants’ Infringement in the United States

67. On December 11, 2020, FDA granted the first Emergency Use Authorization (EUA) for the use of Defendants’ monovalent BNT162b2 original SARS-CoV-2 (2019) vaccine (later named Comirnaty®; here Comirnaty® (original monovalent)) to prevent COVID-19 caused by SARS-CoV-2. Exhibit 36 (December 11, 2020, FDA News Release); Exhibit 20 (December 11, 2020, FDA Comirnaty® (original monovalent) EUA Review Memo). The authorized regimen was a two-dose primary vaccination series administered 21 days apart in individuals 16 years of age and older. *Id.*

RESPONSE: To the extent the allegations of Paragraph 67 purport to rely on Exhibit 36 and Exhibit 20, those exhibits speak for themselves. Defendants otherwise deny the remaining allegations of this Paragraph.

68. On May 10, 2021, FDA expanded EUA for Comirnaty® (original monovalent) two-dose primary vaccination series to children and adolescents 12 years through 15 years of age. Exhibit 37 (May 10, 2021, FDA Comirnaty® (original monovalent) EUA Letter).

RESPONSE: To the extent the allegations of Paragraph 68 purport to rely on Exhibit 37, that exhibit speaks for itself. Defendants otherwise deny the remaining allegations of this Paragraph.

69. On August 12, 2021, FDA expanded EUA for Comirnaty® (original monovalent) to a third primary dose (at least 28 days after the second dose) for certain higher risk individuals 12 years of age or older. Exhibit 38 (August 12, 2021, FDA News Release); Exhibit 39 (August 12, 2021, FDA Comirnaty (original monovalent) EUA Review Memo).

RESPONSE: To the extent the allegations of Paragraph 69 purport to rely on Exhibit 38 and Exhibit 39, those exhibits speak for themselves. Defendants otherwise deny the remaining allegations of this Paragraph.

70. On August 23, 2021, FDA granted full approval of Defendants' BLA for Comirnaty® (original monovalent) COVID-19 vaccine two-dose primary vaccination series in individuals 16 years of age and older. Exhibit 8 (August 23, 2021, FDA Comirnaty® (original monovalent) Approval Letter).

RESPONSE: To the extent the allegations of Paragraph 70 purport to rely on Exhibit 8, that exhibit speaks for itself. Defendants otherwise deny the remaining allegations of this Paragraph.

71. On September 22, 2021, FDA expanded EUA for Comirnaty® (original monovalent) to a third dose (a first booster) six months after completion of the primary two-dose vaccination series for individuals 65 years of age or older, or certain other higher risk individuals 18 to 64 years of age. Exhibit 40 (September 22, 2021, FDA News Release); Exhibit 41 (September 22, 2021, FDA Comirnaty® (original monovalent) EUA Review Memo).

RESPONSE: To the extent the allegations of Paragraph 71 purport to rely on Exhibit 40 and Exhibit 41, those exhibits speak for themselves. Defendants otherwise deny the remaining allegations of this Paragraph.

72. On October 29, 2021, FDA expanded EUA for Comirnaty® (original monovalent) two-dose primary vaccination series to children 5 through 11 years of age. Exhibit 42 (October 29, 2021, FDA News Release); Exhibit 43 (October 29, 2021, FDA Comirnaty® (original monovalent) EUA Review Memo).

RESPONSE: To the extent the allegations of Paragraph 72 purport to rely on Exhibit 42 and Exhibit 43, those exhibits speak for themselves. Defendants otherwise deny the remaining allegations of this Paragraph.

73. On November 19, 2021, FDA expanded EUA for Comirnaty® (original monovalent) to a third dose (a first booster) for all individuals 18 years and older who had completed an authorized primary vaccination series. Exhibit 44 (November 19, 2021, FDA News Release); Exhibit 45 (November 19, 2021, FDA Comirnaty® (original monovalent) EUA Review Memo).

RESPONSE: To the extent the allegations of Paragraph 73 purport to rely on Exhibit 44 and Exhibit 45, those exhibits speak for themselves. Defendants otherwise deny the remaining allegations of this Paragraph.

74. On December 9, 2021, FDA expanded EUA for Comirnaty® (original monovalent) to a third dose (a first booster) dose for all individuals 16 and 17 years of age who had completed an authorized primary vaccination series. Exhibit 46 (December 9, 2021, FDA News Release); Exhibit 47 (December 8, 2021, FDA Comirnaty® (original monovalent) EUA Review Memo).

RESPONSE: To the extent the allegations of Paragraph 74 purport to rely on Exhibit 46 and Exhibit 47, those exhibits speak for themselves. Defendants otherwise deny the remaining allegations of this Paragraph.

75. On January 3, 2022, FDA expanded EUA for Comirnaty® (original monovalent) to a third dose (a first booster) for all individuals 12 years of age and older. Exhibit 48 (January 3, 2022, FDA News Release).

RESPONSE: To the extent the allegations of Paragraph 75 purport to rely on Exhibit 48, that exhibit speaks for itself. Defendants otherwise deny the remaining allegations of this Paragraph.

76. On March 29, 2022, FDA expanded EUA for Comirnaty® (original monovalent) to a fourth dose (a second booster) at least four months after receipt of a first booster dose of any FDA authorized or approved COVID-19 vaccine for individuals over 50 years of age and for immunocompromised patients 12 years of age and older. Exhibit 49 (March 29, 2022, FDA News Release).

RESPONSE: To the extent the allegations of Paragraph 76 purport to rely on Exhibit 49, that exhibit speaks for itself. Defendants otherwise deny the remaining allegations of this Paragraph.

77. On May 17, 2022, FDA expanded EUA for Comirnaty® (original monovalent) to a third dose (a first booster) for children 5 years through 11 years of age. Exhibit 50 (May 17, 2022, FDA News Release as preserved by The Wayback Machine, May 17, 2022⁶); Exhibit 51 (May 17, 2022, FDA Comirnaty® (original monovalent) EUA Review Memo).

RESPONSE: To the extent the allegations of Paragraph 77 purport to rely on Exhibit 50 and Exhibit 51, those exhibits speak for themselves. Defendants otherwise deny the remaining allegations of this Paragraph.

78. On June 17, 2022, FDA expanded EUA for Comirnaty® (original monovalent) to a three-dose primary vaccination series for children 6 months through 4 years of age. Exhibit 52 (June 17, 2022, FDA News Release); Exhibit 53 (June 16, 2022, FDA Comirnaty® (original monovalent) EUA Review Memo).

RESPONSE: To the extent the allegations of Paragraph 78 purport to rely on Exhibit 52 and Exhibit 53, those exhibits speak for themselves. Defendants otherwise deny the remaining allegations of this Paragraph.

79. On August 31, 2022, FDA granted EUA for Comirnaty (bivalent BA.4/5) as a single booster dose in patients 12 years of age and older who had received a primary series or primary series and first booster of any authorized or approved COVID-19 vaccine. Exhibit 54 (August 31, 2022, FDA News Release as preserved by The Wayback Machine, September 1, 2022⁷); Exhibit 55 (August 31, 2022, FDA Comirnaty® (bivalent BA.4/5) EUA Review Memo). FDA also revised the EUA for Comirnaty® (original monovalent) to no longer include use as a booster dose in individuals 12 years of age and older. Exhibit 54 (August 31, 2022, FDA News Release as preserved by The Wayback Machine, September 1, 2022); Exhibit 55 (August 31, 2022, FDA Comirnaty® (bivalent BA.4/5) EUA Review Memo).

⁶ Available at <https://web.archive.org/web/20220517152524/https://www.fda.gov/newsevents/press-announcements/coronavirus-covid-19-update-fda-expands-eligibility-pfizerbiontech-covid-19-vaccine-booster-dose>; preserved April 9, 2024.

⁷ Available at <https://web.archive.org/web/20220901002611/https://www.fda.gov/newsevents/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-pfizerbiontech-bivalent-covid-19-vaccines-use>; preserved April 9, 2024.

RESPONSE: To the extent the allegations of Paragraph 79 purport to rely on Exhibit 54 and Exhibit 55, those exhibits speak for themselves. Defendants otherwise deny the remaining allegations of this Paragraph.

80. On October 12, 2022, FDA expanded EUA for Comirnaty® (bivalent BA.4/5) as a booster dose in children 5 through 11 years of age who had received a primary series or primary series and booster of any authorized or approved COVID-19 vaccine. Exhibit 56 (October 12, 2022, FDA News Release as preserved by The Wayback Machine, October 13, 2022⁸); Exhibit 57 (October 11, 2022, FDA Comirnaty® (bivalent BA.4/5) EUA Review Memo).

RESPONSE: To the extent the allegations of Paragraph 80 purport to rely on Exhibit 56 and Exhibit 57, those exhibits speak for themselves. Defendants otherwise deny the remaining allegations of this Paragraph.

81. On December 8, 2022, FDA expanded EUA for Comirnaty® (bivalent BA.4/5) as the third dose in a primary series in children under 5 years of age who had received two primary doses of Comirnaty® (original monovalent) and revised the EUA for Comirnaty® (original monovalent) to no longer include its use as the third primary dose for this patient population. Exhibit 58 (December 8, 2022, FDA News Release as preserved by The Wayback Machine, December 9, 2022⁹); Exhibit 59 (December 8, 2022, FDA Comirnaty® (bivalent BA.4/5) EUA Review Memo).

RESPONSE: To the extent the allegations of Paragraph 81 purport to rely on Exhibit 58 and Exhibit 59, those exhibits speak for themselves. Defendants otherwise deny the remaining allegations of this Paragraph.

82. On March 14, 2023, FDA expanded EUA for Comirnaty® (bivalent BA.4/5) as a fourth dose (a first booster) dose in children 6 months through 4 years of age who had received a three-dose primary series of Comirnaty® (original monovalent or original monovalent followed

⁸ Available at <https://web.archive.org/web/20221013015339/https://www.fda.gov/newsevents/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-and-pfizerbiontech-bivalent-covid-19-vaccines>; preserved April 9, 2024.

⁹ Available at <https://web.archive.org/web/20221209225236/https://www.fda.gov/newsevents/press-announcements/coronavirus-covid-19-update-fda-authorizes-updated-bivalentcovid-19-vaccines-children-down-6-months>; preserved April 9, 2024.

by bivalent BA.4/5) vaccine. Exhibit 60 (March 14, 2023, FDA News Release); Exhibit 29 (March 14, 2023, FDA Comirnaty® (bivalent BA.4/5) EUA Fact Sheet and Prescribing Information).

RESPONSE: To the extent the allegations of Paragraph 82 purport to rely on Exhibit 60 and Exhibit 29, those exhibits speak for themselves. Defendants otherwise deny the remaining allegations of this Paragraph.

83. On April 18, 2023, FDA expanded EUA for Comirnaty® (bivalent BA.4/5) to be used for all doses (primary and booster) in most adults and pediatric populations as well as other dosage regimes for certain individuals based on age or immunocompromised status. Exhibit 61 (April 18, 2023, FDA News Release). FDA also rescinded all authorizations for use of Comirnaty® (original monovalent) vaccine in the United States. *Id.*

RESPONSE: To the extent the allegations of Paragraph 83 purport to rely on Exhibit 61, that exhibit speaks for itself. Defendants otherwise deny the remaining allegations of this Paragraph.

84. On September 11, 2023, FDA granted full approval of Defendants' supplemental BLA for Comirnaty® (monovalent XBB.1.5) COVID-19 vaccine single dose regimen for individuals 12 years of age and older. Exhibit 62 (September 11, 2023, FDA Comirnaty® (monovalent XBB.1.5) Approval Letter). FDA also granted EUA for Comirnaty® (monovalent XBB.1.5) as a single dose for individuals 6 months through 11 years of age. Exhibit 63 (September 11, 2023, FDA News Release); Exhibit 64 (September 11, 2023, FDA Comirnaty® (monovalent XBB.1.5) EUA Review Memo). FDA also rescinded EUAs for the Comirnaty® (bivalent BA.4/5) vaccine. Exhibit 63 (September 11, 2023, FDA News Release); Exhibit 64 (September 11, 2023, FDA Comirnaty® (monovalent XBB.1.5) EUA Review Memo).

RESPONSE: To the extent the allegations of Paragraph 84 purport to rely on Exhibit 62, Exhibit 63, and Exhibit 64, those exhibits speak for themselves. Defendants otherwise deny the remaining allegations of this Paragraph.

85. Pursuant to these FDA authorizations and approvals, Defendants have offered to sell and continue to offer for sale, and have sold and continue to sell, the Accused Products in Delaware, the United States, and worldwide.

RESPONSE: Paragraph 85 states a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that the Accused Products have been or are distributed in the United States, including in Delaware, pursuant to FDA approval or authorization.

Defendants deny the remaining allegations of this Paragraph and deny infringement of any valid and enforceable claim of the Patents-in-Suit.

86. Defendants have directed and instructed, and continue to direct and instruct, the administration of the Accused Products in the United States, in accordance with the FDA authorized and approved uses of those products.

RESPONSE: Paragraph 86 states a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of this Paragraph and deny infringement of any valid and enforceable claim of the Patents-in-Suit.

87. On information and belief, Defendants have made and continue to make, and have had made and continue to have made, the Accused Products in the United States. *See, e.g.*, Exhibit 8 (August 23, 2021, FDA Comirnaty® (original monovalent) Approval Letter) at 1; Exhibit 9 (excerpts from March 30, 2022, BioNTech SE 2021FY Annual Report (Form 20-F)) at 89; Exhibit 26 (December 7, 2022, EMA Comirnaty® BA.1 Assessment Report) at 13, 16–17; Exhibit 62 (September 11, 2023, FDA Comirnaty® (monovalent XBB.1.5) Approval Letter) at 1; Exhibit 27 (September 12, 2022, EMA Comirnaty® BA.4/5 Assessment Report) at 13, 16–17.

RESPONSE: Paragraph 87 states a legal conclusion to which no response is required. To the extent the allegations of Paragraph 87 purport to rely on Exhibit 8, Exhibit 9, Exhibit 26, Exhibit 62, and Exhibit 27, those exhibits speak for themselves. Defendants admit that the Accused Products have been or are manufactured in the United States. Defendants deny the remaining allegations of this Paragraph and deny infringement of any valid and enforceable claim of the Patents-in-Suit.

88. On information and belief, Accused Products manufactured by or for Defendants in the United States were and are still distributed for sale and sold both in the United States and outside the United States. *See, e.g.*, Exhibit 26 (December 7, 2022, EMA Comirnaty® BA.1 Assessment Report) at 13, 16–17; Exhibit 27 (September 12, 2022, EMA Comirnaty® BA.4/5 Assessment Report) at 13, 16–17; Exhibit 9 (excerpts from March 30, 2022, BioNTech SE 2021FY Annual Report (Form 20-F)) at 89.

RESPONSE: Paragraph 88 states a legal conclusion to which no response is required. To the extent the allegations of Paragraph 88 purport to rely on Exhibit 26, Exhibit 27, and Exhibit 9, those exhibits speak for themselves. Defendants admit that the Accused Products have been or are

manufactured and distributed in the United States. Defendants deny that sales outside the United States are relevant to this litigation. Defendants deny the remaining allegations of this Paragraph and deny infringement of any valid and enforceable claim of the Patents-in-Suit.

89. Defendants have profited significantly from the inventions claimed in the Patents-in-Suit. From sales of the Accused Products alone, Defendant Pfizer reported over \$8 billion in U.S. revenue (and over \$37 billion globally) in 2022 and over \$2 billion in U.S. revenue (and over \$11 billion globally) in 2023. Exhibit 65 (excerpts from February 23, 2023, Pfizer Inc. 2022FY Annual Report (Form 10-K)) at 33; Exhibit 66 (excerpts from February 22, 2024, Pfizer Inc. 2023FY Annual Report (Form 10-K)) at 38. Defendant BioNTech reported over €12 billion in revenues from shares of profits and milestones from sales of the Accused Products from collaboration partners (and over €17 billion in total COVID-19 vaccine revenue) in 2022 and over €3 billion in revenues from shares of profits from sales of the Accused Products from collaboration partners in 2023. Exhibit 67 (excerpts from March 27, 2023, BioNTech SE 2022FY Annual Report (Form 20-F)) at 162; Exhibit 68 (excerpts from March 20, 2024, BioNTech 2023FY Annual Report (Form 20-F)) at 165.

RESPONSE: To the extent the allegations of Paragraph 89 purport to rely on Exhibit 65, Exhibit 66, Exhibit 67, and Exhibit 68, those exhibits speak for themselves. Defendants otherwise deny the remaining allegations of this Paragraph.

90. Defendants stand to continue to profit significantly through continued infringement of GSK Biologicals's Patents-in-Suit without taking a license. In September 2023, Defendants set the list price of their Comirnaty® COVID-19 vaccine product at \$120 per dose, an approximately four-fold increase from the pandemic pricing. Exhibit 69 (September 12, 2023, *Reuters* article, "COVID vaccine manufacturers set list price between \$120-\$130 per dose"¹⁰); Exhibit 70 (October 21, 2022, *Reuters* article, "Pfizer expects to hike U.S. COVID vaccine price to \$110-130 per dose"¹¹) (noting original pandemic price of Comirnaty® COVID-19 vaccine was around \$30 per dose).

RESPONSE: To the extent the allegations of Paragraph 90 purport to rely on Exhibit 69 and Exhibit 70, those exhibits speak for themselves. Defendants otherwise deny the remaining allegations of this Paragraph.

¹⁰ Available at <https://www.reuters.com/business/healthcare-pharmaceuticals/covid-vaccinemanufacturers-set-list-price-between-120-130-per-dose-2023-09-12/>; preserved April 3, 2024.

¹¹ Available at <https://www.reuters.com/business/healthcare-pharmaceuticals/pfizer-expectsprice-covid-vaccine-110-130-per-dose-2022-10-20/>; preserved April 3, 2024.

COUNT I

(Infringement of the '693 Patent)

91. GSK incorporates by reference paragraphs 1–90.

RESPONSE: Defendants incorporate by reference their responses contained in Paragraphs 1 through 90.

92. GSK Biologicals is the lawful owner by assignment of the '693 patent, which is entitled "Vaccine for Eliciting Immune Response Comprising RNA Encoding an Immunogen and Lipid Formulations Comprising Mole Percentage of Lipids" and was duly and legally issued by the U.S. Patent and Trademark Office on May 2, 2023. A true and correct copy of the '693 patent is attached as Exhibit 1. The patent application issuing into the '693 patent was published on November 17, 2022, as Publication No. US 2022/0362152 A1. See Exhibit 1 at Prior Publication Data.

RESPONSE: Defendants admit that the U.S. Patent and Trademark Office issued U.S. Pat. No. 11,638,693 entitled "Vaccine for Eliciting Immune Response Comprising RNA Encoding an Immunogen and Lipid Formulations Comprising Mole Percentage of Lipids" on May 2, 2023, that Exhibit 1 purports to be a copy of the '693 patent, and that Publication No. U.S. 2022/0362152 A1 was published on November 17, 2022 and issued into the '693 patent, but deny that the patent is valid, enforceable, or infringed by Defendants. Defendants deny any remaining allegations of Paragraph 92.

93. Each claim of the '693 patent is valid and enforceable.

RESPONSE: Denied.

94. Defendants have directly infringed and continue to directly infringe one or more claims of the '693 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, or selling within the United States, or importing into the United States, each of the Accused Products embodying GSK Biologicals's patented inventions as disclosed by and claimed in the '693 patent, without authority or license to do so, during the term of the '693 patent.

RESPONSE: Denied.

95. In addition or in the alternative, Defendants have induced, and continue to induce, direct infringement by third parties of one or more claims of the '693 patent under 35 U.S.C. §

271(b), either literally or under the doctrine of equivalents, by making, selling and/or offering for sale in the United States, and/or importing into the United States, each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products embodying GSK Biologicals's patented inventions as disclosed by and claimed in the '693 patent, without authority or license to do so, during the term of the '693 patent.

RESPONSE: Denied.

96. In addition or in the alternative, Defendants have contributed, and continue to contribute, to the direct infringement by third parties of one or more claims of the '693 patent under 35 U.S.C. § 271(c), either literally or under the doctrine of equivalents, by making, selling and/or offering for sale in the United States, and/or importing into the United States, each of the Accused Products embodying GSK Biologicals's patented inventions as disclosed by and claimed in the '693 patent, without authority or license to do so, during the term of the '693 patent, knowing that those products constitute a material part of the inventions of the '693 patent, knowing that those products are especially made or adapted to infringe the '693 patent, and knowing that those products are not staple articles or commodities of commerce suitable for substantial non-infringing use.

RESPONSE: Denied.

97. For example, on information and belief, each of the Accused Products satisfies each and every element of at least claim 1 of the '693 patent. Defendants' actions with respect to each of the Accused Products have therefore infringed at least this exemplary claim of the '693 patent.

RESPONSE: Denied.

98. Claim 1 of the '693 patent recites:

A formulation comprising:

ribonucleic acid (RNA) molecules comprising a sequence that encodes an immunogen; and

lipids comprising: (a) from 20 mole % to 70 mole % cationic lipid, (b) an anionic or a zwitterionic lipid, (c) a polyethylene glycolconjugated (PEG-conjugated) lipid, and (d) from 5 mole % to 80 mole % cholesterol; wherein:

the lipids encapsulate at least half of the RNA molecules;

the formulation is immunogenic in vivo by eliciting an antibody response against the immunogen in vivo; and

the cationic lipid comprises a tertiary amine and has a pKa from 6.07 to 7.6; and

whereby the pKa is determined at standard temperature and pressure by the following:

(1) admixing 400 μL of 2 mM cationic lipid that is in ethanol and 800 μL of 0.3 mM fluorescent probe 6-(p-toluidino)-2-naphthalenesulfonic acid (TNS), which is in 90 volume % ethanol and 10 volume % methanol, thereby obtaining a lipid/TNS mixture;

(2) admixing 7.5 μL of the lipid/TNS mixture and 242.5 μL of a first buffer consisting essentially of a sodium salt buffer comprising 20 mM sodium phosphate, 25 mM sodium citrate, 20 mM sodium acetate, and 150 mM sodium chloride, wherein the first buffer has a pH from 4.44 to 4.52, which has been adjusted with 12N hydrochloric acid or 6N sodium hydroxide, thereby obtaining a first mixture, and dispensing 100 μL of the first mixture in a first well of a 96-well plate, which has a clear bottom;

(3) admixing 7.5 μL of the lipid/TNS mixture and 242.5 μL of a second buffer consisting essentially of the sodium salt buffer, wherein the second buffer has a pH of 5.27, which has been adjusted with 12N hydrochloric acid or 6N sodium hydroxide, thereby obtaining a second mixture, and dispensing 100 μL of the second mixture in a second well of the 96-well plate;

(4) admixing 7.5 μL of the lipid/TNS mixture and 242.5 μL of a third buffer consisting essentially of the sodium salt buffer, wherein the third buffer has a pH from 6.15 to 6.21, which has been adjusted with 12N hydrochloric acid or 6N sodium hydroxide, thereby obtaining a third mixture, and dispensing 100 μL of the third mixture in a third well of the 96-well plate;

(5) admixing 7.5 μL of the lipid/TNS mixture and 242.5 μL of a fourth buffer consisting essentially of the sodium salt buffer, wherein the fourth buffer has a pH of 6.57, which has been adjusted with 12N hydrochloric acid or 6N sodium hydroxide, thereby obtaining a fourth mixture, and dispensing 100 μL of the fourth mixture in a fourth well of the 96-well plate;

(6) admixing 7.5 μL of the lipid/TNS mixture and 242.5 μL of a fifth buffer consisting essentially of the sodium salt buffer, wherein the fifth buffer has a pH from 7.10 to 7.20, which has been adjusted with 12N hydrochloric acid or 6N sodium hydroxide, thereby obtaining a fifth mixture, and dispensing 100 μL of the fifth mixture in a fifth well of the 96-well plate;

(7) admixing 7.5 μ L of the lipid/TNS mixture and 242.5 μ L of a sixth buffer consisting essentially of the sodium salt buffer, wherein the sixth buffer has a pH from 7.72 to 7.80, which has been adjusted with 12N hydrochloric acid or 6N sodium hydroxide, thereby obtaining a sixth mixture, and dispensing 100 μ L of the sixth mixture in a sixth well of the 96-well plate;

(8) admixing 7.5 μ L of the lipid/TNS mixture and 242.5 μ L of a seventh buffer consisting essentially of the sodium salt buffer, wherein the seventh buffer has a pH from 8.27 to 8.33, which has been adjusted with 12N hydrochloric acid or 6N sodium hydroxide, thereby obtaining a seventh mixture, and dispensing 100 μ L of the seventh mixture in a seventh well of the 96-well plate;

(9) admixing 7.5 μ L of the lipid/TNS mixture and 242.5 μ L of an eighth buffer consisting essentially of the sodium salt buffer, wherein the eighth buffer has a pH from 10.47 to 11.12, which has been adjusted with 12N hydrochloric acid or 6N sodium hydroxide, thereby obtaining an eighth mixture, and dispensing 100 μ L of the eighth mixture in an eighth well of the 96-well plate;

(10) measuring the fluorescence at a wavelength of 431 nm with an excitation wavelength of 322 nm and a cut-off below a wavelength of 420 nm of each of the first through eighth wells and an empty well of the 96-well plate, thereby obtaining a measured fluorescence for each of the p empty well and the first through eighth wells;

(11) subtracting the measured fluorescence of the empty well from each of the measured fluorescences of the first through eighth wells, thereby obtaining a blank-subtracted fluorescence for each of the first through eighth mixtures;

(12) normalizing each of the blank-subtracted fluorescences of the first through eighth mixtures to the blank-subtracted fluorescence of the first mixture thereby obtaining a relative fluorescence for each of the first through eighth mixtures, the relative fluorescence being 1 for the first mixture;

(13) obtaining a line of best fit of the pHs of the first through eighth buffers versus the respective relative fluorescences of the first through eighth mixtures; and

(14) defining the pKa as the pH on the line of best fit at which a relative fluorescence of 0.5 is obtained.

RESPONSE: Defendants admit that Claim 1 of the '693 patent appears to include the above language. Defendants otherwise deny the remaining allegations of this Paragraph.

99. Each of the Accused Products comprises a “formulation.” See paragraphs 47–66, above; *e.g.*, Exhibit 34 (April 2023, FDA Comirnaty® (original monovalent) Package Insert) at 19 (“The nucleoside-modified mRNA in COMIRNATY is formulated in lipid particles[.]”); Exhibit 21 (February 19, 2021, EMA Comirnaty® (original monovalent) Assessment Report) at 58 (“The nucleoside-modified messenger RNA in the vaccine is formulated in lipid nanoparticles[.]”).

RESPONSE: Paragraph 99 states a legal conclusion to which no response is required. To the extent the allegations of Paragraph 99 purport to rely on Exhibit 34 and Exhibit 21, those exhibits speak for themselves. Defendants incorporate by reference their responses contained in Paragraphs 47 through 66. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

100. Each of the Accused Products comprises “ribonucleic acid (RNA) molecules comprising a sequence that encodes an immunogen.” See paragraphs 47–66, above; *e.g.*, Exhibit 34 (April 2023, FDA Comirnaty® (original monovalent) Package Insert) at 19 (“COMIRNATY ... contains 30 mcg of a nucleoside-modified messenger RNA (mRNA) encoding the viral spike glycoprotein of SARS-CoV-2.”); Exhibit 21 (February 19, 2021, EMA Comirnaty® (original monovalent) Assessment Report) at 15 (“The active substance consists of ... mRNA that is translated into a codon-optimized sequence encoding the spike antigen of SARS-CoV-2[.]”).

RESPONSE: Paragraph 100 states a legal conclusion to which no response is required. To the extent the allegations of Paragraph 100 purport to rely on Exhibit 34 and Exhibit 21, those exhibits speak for themselves. Defendants incorporate by reference their responses contained in Paragraphs 47 through 66. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

101. Each of the Accused Products comprises “lipids comprising: (a) ... [a] cationic lipid, (b) an anionic or a zwitterionic lipid, (c) a polyethylene glycol-conjugated (PEG-conjugated)

lipid, and (d) ... cholesterol.” See paragraphs 47–66, above; *e.g.*, Exhibit 34 (April 2023, FDA Comirnaty® (original monovalent) Package Insert) at 19 (identifying lipid ingredients).

RESPONSE: Paragraph 101 states a legal conclusion to which no response is required. To the extent the allegations of Paragraph 101 purport to rely on Exhibit 34, that exhibit speaks for itself. Defendants incorporate by reference their responses contained in Paragraphs 47 through 66. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

102. ALC-0315 is a “cationic lipid.” See, *e.g.*, Exhibit 21 (February 19, 2021, EMA Comirnaty® (original monovalent) Assessment Report) at 23–24 (“The ALC-0315 novel excipient is a cationic lipid containing a tertiary amine ...”); Exhibit 71 (ALC-0315 Product Information, Cayman Chemical) (providing structure); Exhibit 72 (Schoenmaker *et al.*, “mRNA-lipid nanoparticle COVID-19 vaccines: Structure and Stability,” *Intl. J. Pharm.* 601, 120586 (2021)) at Fig. 6 (providing structure and identifying ALC-0315 as an “[i]onizable cationic lipid”).

RESPONSE: Paragraph 102 states a legal conclusion to which no response is required. To the extent the allegations of Paragraph 102 purport to rely on Exhibit 21, Exhibit 71, and Exhibit 72, those exhibits speak for themselves. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

103. DSPC is a “zwitterionic lipid.” See, *e.g.*, Exhibit 73 (DSPC Product Information, Polysciences) (“[DSPC] is a zwitterionic phospholipid that is used in the preparation of liposomes for transfection and drug delivery applications.”).

RESPONSE: Paragraph 103 states a legal conclusion to which no response is required. To the extent the allegations of Paragraph 103 purport to rely on Exhibit 73, that exhibit speaks for itself. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

104. ALC-0159 is a “polyethylene glycol-conjugated (PEG-conjugated) lipid.” See, *e.g.*, Exhibit 21 (February 19, 2021, EMA Comirnaty® (original monovalent) Assessment Report) at 24 (“The ALC-0159 novel excipient is PEGylated lipid ...”); Exhibit 74 (ALC-0159 Product Information, Echelon Biosciences) (“ALC-0159 is a PEGylated lipid which has been used to form

lipid nanoparticles for delivery of RNA. ALC-0159 is one of the components in the BNT162b2 vaccine[.]”); Exhibit 72 (Schoenmaker *et al.*, “mRNA-lipid nanoparticle COVID-19 vaccines: Structure and Stability,” *Intl. J. Pharm.* 601, 120586 (2021)) at Fig. 6 (identifying ALC-0159 to be a “PEG-lipid”).

RESPONSE: Paragraph 104 states a legal conclusion to which no response is required. To the extent the allegations of Paragraph 104 purport to rely on Exhibit 21, Exhibit 74, and Exhibit 72, those exhibits speak for themselves. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

105. Each of the Accused Products comprises “lipids comprising ... from 20 mole % to 70 mole % cationic lipid.” See paragraphs 47–66, above; *e.g.*, Exhibit 34 (April 2023, FDA Comirnaty® (original monovalent) Package Insert) at 19 (identifying the quantity of each lipid component); *see also* Exhibit 72 (Schoenmaker *et al.*, “mRNA-lipid nanoparticle COVID-19 vaccines: Structure and stability,” *Intl. J. Pharm.* 601, 120586 (2021)) at 3, Table 1 (reporting ionizable cationic lipid ALC-0315 makes up 46.3 mole % of the lipids present in Comirnaty® products).

RESPONSE: Paragraph 105 states a legal conclusion to which no response is required. To the extent the allegations of Paragraph 105 purport to rely on Exhibit 34 and Exhibit 72, those exhibits speak for themselves. Defendants incorporate by reference their responses contained in Paragraphs 47 through 66. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

106. Each of the Accused Products comprises “lipids comprising ... from 5 mole % to 80 mole % of cholesterol.” See paragraphs 47–66, above; *e.g.*, Exhibit 34 (April 2023, FDA Comirnaty® (original monovalent) Package Insert) at 19 (identifying the quantity of each lipid component); *see also* Exhibit 72 (Schoenmaker *et al.*, “mRNA-lipid nanoparticle COVID-19 vaccines: Structure and stability,” *Intl. J. Pharm.* 601, 120586 (2021)) at 3, Table 1 (reporting cholesterol makes up 42.7 mole % of the lipids present in Comirnaty® products).

RESPONSE: Paragraph 106 states a legal conclusion to which no response is required. To the extent the allegations of Paragraph 106 purport to rely on Exhibit 34 and Exhibit 72, those

exhibits speak for themselves. Defendants incorporate by reference their responses contained in Paragraphs 47 through 66. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

107. On information and belief, the lipids of each of the Accused Products “encapsulate at least half of the RNA molecules.” See paragraphs 47–66, above; *e.g.*, Exhibit 34 (April 2023, FDA Comirnaty® (original monovalent) Package Insert) at 19 (“The nucleoside-modified mRNA in COMIRNATY is formulated in lipid particles, which enable delivery of the mRNA into host cells to allow expression of the SARS-CoV-2 antigen.”); *see also* Exhibit 72 (Schoenmaker *et al.*, “mRNA-lipid nanoparticle COVID-19 vaccines: Structure and Stability,” *Intl. J. Pharm.* 601, 120586 (2021)) at 4 (“In mRNA-LNP formulations, such as those used in mRNA vaccines ... encapsulation efficiencies ... are typically > 90%.”).

RESPONSE: Paragraph 107 states a legal conclusion to which no response is required. To the extent the allegations of Paragraph 107 purport to rely on Exhibit 34 and Exhibit 72, those exhibits speak for themselves. Defendants incorporate by reference their responses contained in Paragraphs 47 through 66. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

108. Each of the Accused Products is “immunogenic in vivo by eliciting an antibody response against the immunogen in vivo” at least when used in accordance with the FDA and EMA authorized and approved indications. See paragraphs 47–90, above; *e.g.*, Exhibit 21 (February 19, 2021, EMA Comirnaty® (original monovalent) Assessment Report) at 58 (“The vaccine elicits both neutralizing antibody and cellular immune responses to the spike (S) antigen, which may contribute to protection against COVID-19.”); Exhibit 24 (September 1, 2022, Pfizer press release) (“[T]he bivalent vaccine with mRNA encoding the wild-type and the BA.1 spike proteins provides [] neutralizing antibody titers against the Omicron BA.1 and BA.4/BA.5 sublineages[.]”); Exhibit 25 (November 4, 2022, Pfizer press release) (“Among the overall study population who received the Omicron BA.4/BA.5-adapted bivalent vaccine, there was a substantially higher increase in Omicron BA.4/BA.5-neutralizing antibody titers compared to pre-booster levels.”); Exhibit 64 (September 11, 2023, FDA Comirnaty® (monovalent XBB.1.5) EUA Review Memo) at 17–18 (extrapolating immunological response from the prior Comirnaty® COVID-19 vaccine products and stating, “preclinical data demonstrate that, when compared with the Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5), Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) induces higher neutralizing antibody titers against XBB sublineages, including XBB.1.5, XBB.1.16, XBB.1.16.1, and XBB.2.3.”).

RESPONSE: Paragraph 108 states a legal conclusion to which no response is required.

To the extent the allegations of Paragraph 108 purport to rely on Exhibit 21, Exhibit 24, Exhibit 25, and Exhibit 64, those exhibits speak for themselves. Defendants incorporate by reference their responses contained in Paragraphs 47 through 90. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

109. On information and belief, when employing the “fluorescent probe 6-(p-toluidino)-2-naphthalenesulfonic acid (TNS)” and following steps (1) to (14) of claim 1 of the ’693 patent to “obtain[] a relative fluorescence” in each of the described pH-buffered mixtures and “defining the pKa as the pH on the line of best fit at which a relative fluorescence of 0.5 is obtained,” the cationic lipid used in each of the Accused Products—ALC-0315—exhibits a pKa falling between 6.07 and 7.6. *See, e.g.*, Exhibit 75 (McKenzie *et al.*, “mRNA synthesis and encapsulation in ionizable lipid nanoparticles,” *Current Protocols* 3, e898 (2023)) at 19 (reporting a pKa of 6.284 for ALC-0315 in a TNS assay); Exhibit 76 (International PCT Application Publication Number WO 2017/075531 A1) at 48 and 50, Table 3 (reporting a pKa of 6.09 for ALC-0315 (cationic lipid “No. 3”) in a TNS assay); Exhibit 77 (Tilstra *et al.*, “Iterative Design of Ionizable Lipids for Intramuscular mRNA Delivery,” *J. Am. Chem. Soc.* 145, 2294–2304 (2023) with supplementary information) at Figure S11 (reporting a pKa of 6.27 for ALC-0315 in a TNS assay).

RESPONSE: Paragraph 109 states a legal conclusion to which no response is required.

To the extent the allegations of Paragraph 109 purport to rely on Exhibit 75, Exhibit 76, and Exhibit 77, those exhibits speak for themselves. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

110. Defendants packaged, promoted, and sold, and continue to package promote and sell, each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products in the United States with FDA-approved packaging and package inserts comprising labeling and prescribing information that instruct health care practitioners on their use in accordance with the FDA authorized and approved indications. *See* paragraphs 47–90, above; *e.g.*, Exhibit 34 (April 2023, FDA Comirnaty® (original monovalent) Package Insert); Exhibit 35 (July 14, 2023, FDA Comirnaty® (bivalent BA.4/5) EUA Fact Sheet and Package Insert); Exhibit 33 (September 2023, FDA Comirnaty® (monovalent XBB.1.5) Package Insert).

RESPONSE: Paragraph 110 states a legal conclusion to which no response is required.

To the extent the allegations of Paragraph 110 purport to rely on Exhibit 34, Exhibit 35, and Exhibit 33, those exhibits speak for themselves. Defendants incorporate by reference their responses contained in Paragraphs 47 through 90. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

111. Defendants created and disseminated, and continue to create and disseminate, by means separate from the packaging and package inserts of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products, supporting materials, instructions, and/or technical information that instruct health care practitioners on the use of each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products in the United States in accordance with the FDA authorized and approved indications. *See, e.g.*, Exhibit 78 (www.comirnaty.com as preserved by The Wayback Machine, August, 27, 2021¹²); Exhibit 79 (www.comirnaty.com/eua-bivalent as preserved by The Wayback Machine, September, 22, 2022¹³); Exhibit 80 (www.comirnaty.com/eua-six-months-to-eleven-years; preserved April 5, 2024).

RESPONSE: Paragraph 111 states a legal conclusion to which no response is required.

To the extent the allegations of Paragraph 111 purport to rely on Exhibit 78, Exhibit 79, and Exhibit 80, those exhibits speak for themselves. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

112. Defendants have been and are aware that the use of each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products in the United States in accordance with the FDA authorized and approved indications identified above in paragraphs 67–90 infringes at least exemplary claim 1 of the '693 patent.

RESPONSE: Denied.

¹² Available at <https://web.archive.org/web/20210827220339/https://www.comirnaty.com/>; preserved on April 5, 2024.

¹³ Available at <https://web.archive.org/web/20220922181232/https://www.comirnaty.com/euabivalent>; preserved on April 5, 2024.

113. Defendants have been and are aware that healthcare providers use each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products in the United States in accordance with the FDA authorized and approved indications identified above in paragraphs 67–90 and thereby infringe at least exemplary claim 1 of the '693 patent.

RESPONSE: Denied.

114. None of the Accused Products is a staple article or commodity of commerce suitable for use in the United States other than in accordance with the FDA authorized and approved indications identified above in paragraphs 67–90.

RESPONSE: Denied.

115. Defendants actively, knowingly, and specifically intended to induce, and induced, and continue to actively, knowingly, and specifically intend to induce, and induce, infringement of at least claim 1 of the '693 patent by packaging, promoting, selling or otherwise supplying, directly or indirectly, each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products to healthcare providers, with the knowledge and intent that healthcare providers will use the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products supplied by Defendants according to the FDA authorized and approved infringing indications.

RESPONSE: Denied.

116. GSK has suffered and continues to suffer damages from Defendants' infringement of the '693 patent.

RESPONSE: Denied.

117. GSK is entitled to an award of monetary damages, including a reasonable royalty, for Defendants' infringement of the '693 patent.

RESPONSE: Denied.

118. Defendants have had knowledge of the '693 patent and specific notice of its infringement at least since April 24, 2024, by communications between GSK and Defendants. *See* Exhibits 81-82.

RESPONSE: Paragraph 118 states a legal conclusion to which no response is required.

To the extent the allegations of Paragraph 118 purport to rely on Exhibits 81–82, those exhibits speak for themselves. Defendants deny that the Accused Products infringe any valid and

enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

119. Defendants' infringement of the '693 patent has been and continues to be willful and deliberate at least since they received specific notice of their infringement from GSK on April 24, 2024. *See id.*

RESPONSE: Denied.

120. Defendants' conduct with respect to the '693 patent makes this case exceptional under 35 U.S.C. § 285.

RESPONSE: Denied.

COUNT II

(Infringement of the '694 Patent)

121. GSK incorporates by reference paragraphs 1–120.

RESPONSE: Defendants incorporate by reference their responses contained in Paragraphs 1 through 120.

122. GSK Biologicals is the lawful owner by assignment of the '694 patent, which is entitled "Vaccine for Eliciting Immune Response Comprising Lipid formulations and RNA Encoding Multiple Immunogens" and was duly and legally issued by the U.S. Patent and Trademark Office on May 2, 2023. A true and correct copy of the '694 patent is attached as Exhibit 2. The patent application issuing into the '694 patent was published on November 3, 2022, as Publication No. US 2022/0347097 A1. *See* Exhibit 2 at Prior Publication Data.

RESPONSE: Defendants admit that the U.S. Patent and Trademark Office issued U.S. Pat. No. 11,638,694 entitled "Vaccine for Eliciting Immune Response Comprising Lipid Formulations and RNA Encoding Multiple Immunogens" on May 2, 2023, that Exhibit 2 purports to be a copy of the '694 patent, and that Publication No. U.S. 2022/0347097 A1 was published on November 3, 2022 and issued into the '694 patent, but deny that the patent is valid, enforceable, or infringed by Defendants. Defendants deny any remaining allegations of this Paragraph.

123. Each claim of the '694 patent is valid and enforceable.

RESPONSE: Denied.

124. Defendants have directly infringed and continue to directly infringe one or more claims of the '694 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, or selling the United States, or importing into the United States, each of the Comirnaty® (bivalent BA.1) and Comirnaty® (bivalent BA.4/5) products embodying GSK Biologicals's patented inventions as disclosed by and claimed in the '694 patent, without authority or license to do so, during the term of the '694 patent.

RESPONSE: Denied.

125. In addition or in the alternative, Defendants have induced, and continue to induce, direct infringement by third parties of one or more claims of the '694 patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents, by making, selling and/or offering for sale in the United States, and/or importing into the United States, the Comirnaty® (bivalent BA.4/5) product embodying GSK Biologicals's patented inventions as disclosed by and claimed in the '694 patent, without authority or license to do so, during the term of the '694 patent.

RESPONSE: Denied.

126. In addition or in the alternative, Defendants have contributed, and continue to contribute, to the direct infringement by third parties of one or more claims of the '694 patent under 35 U.S.C. § 271(c), either literally or under the doctrine of equivalents, by making, selling and/or offering for sale in the United States, and/or importing into the United States, each of the each of the Comirnaty® (bivalent BA.1) and Comirnaty® (bivalent BA.4/5) products embodying GSK Biologicals's patented inventions as disclosed by and claimed in the '694 patent, without authority or license to do so, during the term of the '694 patent, knowing that those products constitute a material part of the inventions of the '694 patent, knowing that those products are especially made or adapted to infringe the '694 patent, and knowing that those products are not staple articles or commodities of commerce suitable for substantial non-infringing use.

RESPONSE: Denied.

127. For example, on information and belief, each of the Comirnaty® (bivalent BA.1) and Comirnaty® (bivalent BA.4/5) products satisfies each and every element of at least claim 1 of the '694 patent. Defendants' actions with respect to the Comirnaty® (bivalent BA.1) and Comirnaty® (bivalent BA.4/5) products have therefore infringed at least this exemplary claim of the '694 patent.

RESPONSE: Denied.

128. Claim 1 of the '694 patent recites:

A formulation comprising:

a first species of ribonucleic acid (RNA) molecules comprising a sequence that encodes a first immunogen;

a second species of RNA molecules comprising a sequence that encodes a second immunogen; and

lipids comprising: (a) a cationic lipid, (b) an anionic lipid or a zwitterionic lipid, (c) a polyethylene glycol-conjugated (PEGconjugated) lipid, and (d) a cholesterol, wherein:

the lipids encapsulate at least half of the first species of RNA molecules and at least half of the second species of RNA molecules;

the cationic lipid comprises a tertiary amine and has a pKa from 6.07 to 7.6; and

the formulation is immunogenic in vivo by eliciting an antibody response against the first immunogen and the second immunogen in vivo; and

whereby the pKa is determined at standard temperature and pressure by the following:

(1) admixing 400 μL of 2 mM of the cationic lipid that is in ethanol and 800 μL of 0.3 mM of fluorescent probe 6-(p-toluidino)-2-naphthalenesulfonic acid (TNS), which is in 90 volume % ethanol and 10 volume % methanol, thereby obtaining a lipid/TNS mixture;

(2) admixing 7.5 μL of the lipid/TNS mixture and 242.5 μL of a first buffer consisting essentially of a sodium salt buffer consisting of 20 mM sodium phosphate, 25 mM sodium citrate, 20 mM sodium acetate, and 150 mM sodium chloride, wherein the first buffer has a pH from 4.44 to 4.52, which has been adjusted with 12N hydrochloric acid or 6N sodium hydroxide, thereby obtaining a first mixture, and dispensing 100 μL of the first mixture in a first well of a 96-well plate, which has a clear bottom;

(3) admixing 7.5 μL of the lipid/TNS mixture and 242.5 μL of a second buffer consisting essentially of the sodium salt buffer, wherein the second buffer has a pH of 5.27, which has been adjusted with 12N hydrochloric acid or 6N sodium hydroxide, thereby obtaining a second mixture, and dispensing 100 μL of the second mixture in a second well of the 96-well plate;

(4) admixing 7.5 μL of the lipid/TNS mixture and 242.5 μL of a third buffer consisting essentially of the sodium salt buffer, wherein the third buffer has a pH from 6.15 to 6.21, which has been adjusted with 12N hydrochloric acid or 6N sodium hydroxide, thereby

obtaining a third mixture, and dispensing 100 μ L of the third mixture in a third well of the 96-well plate;

(5) admixing 7.5 μ L of the lipid/TNS mixture and 242.5 μ L of a fourth buffer consisting essentially of the sodium salt buffer, wherein the fourth buffer has a pH of 6.57, which has been adjusted with 12N hydrochloric acid or 6N sodium hydroxide, thereby obtaining a fourth mixture, and dispensing 100 μ L of the fourth mixture in a fourth well of the 96-well plate;

(6) admixing 7.5 μ L of the lipid/TNS mixture and 242.5 μ L of a fifth buffer consisting essentially of the sodium salt buffer, wherein the fifth buffer has a pH from 7.10 to 7.20, which has been adjusted with 12N hydrochloric acid or 6N sodium hydroxide, thereby obtaining a fifth mixture, and dispensing 100 μ L of the fifth mixture in a fifth well of the 96-well plate;

(7) admixing 7.5 μ L of the lipid/TNS mixture and 242.5 μ L of a sixth buffer consisting essentially of the sodium salt buffer, wherein the sixth buffer has a pH from 7.72 to 7.80, which has been adjusted with 12N hydrochloric acid or 6N sodium hydroxide, thereby obtaining a sixth mixture, and dispensing 100 μ L of the sixth mixture in a sixth well of the 96-well plate;

(8) admixing 7.5 μ L of the lipid/TNS mixture and 242.5 μ L of a seventh buffer consisting essentially of the sodium salt buffer, wherein the seventh buffer has a pH from 8.27 to 8.33, which has been adjusted with 12N hydrochloric acid or 6N sodium hydroxide, thereby obtaining a seventh mixture, and dispensing 100 μ L of the seventh mixture in a seventh well of the 96-well plate;

(9) admixing 7.5 μ L of the lipid/TNS mixture and 242.5 μ L of an eighth buffer consisting essentially of the sodium salt buffer, wherein the eighth buffer has a pH from 10.47 to 11.12, which has been adjusted with 12N hydrochloric acid or 6N sodium hydroxide, thereby obtaining an eighth mixture, and dispensing 100 μ L of the eighth mixture in an eighth well of the 96-well plate;

(10) measuring the fluorescence at a wavelength of 431 nm with an excitation wavelength of 322 nm and a cut-off below a wavelength of 420 nm of each of the first through eighth wells and an empty well of the 96-well plate, thereby obtaining a measured fluorescence for each of the empty well and the first through eighth wells;

(11) subtracting the fluorescence of the empty well from each of the measured fluorescences of the first through eighth wells, thereby obtaining a blank-subtracted fluorescence for each of the first through eighth mixtures;

(12) normalizing each of the blank-subtracted fluorescences of the first through eighth mixtures to the blank-subtracted fluorescence of the first mixture, thereby obtaining a relative fluorescence for each of the first through eighth mixtures, the relative fluorescence being 1 for the first mixture;

(13) obtaining a line of best fit of the pHs of the first through eighth buffers versus the respective relative fluorescences of the first through eighth mixtures; and

(14) determining the pKa as the pH on the line of best fit at which a relative fluorescence of 0.5 is obtained.

RESPONSE: Defendants admit that Claim 1 of the '694 patent appears to include the above language. Defendants otherwise deny the remaining allegations of this Paragraph.

129. Each of the Comirnaty® (bivalent BA.1) and Comirnaty® (bivalent BA.4/5) products comprises a “formulation.” See paragraphs 47–66, above; *e.g.*, Exhibit 26 (July 12, 2022, EMA Comirnaty® (original BA.1) Assessment Report) at 5 (“The Bivalent vaccine is formulated in Tris/Sucrose[.]”); Exhibit 29 (March 2023, FDA Comirnaty® (bivalent BA.4/5) Fact Sheet and COVID-19 Vaccine, Bivalent is formulated in lipid particles[.]”); Exhibit 27 (September 12, 2022, EMA Comirnaty® (bivalent BA.4/5) Assessment Report) at 4 (“The vaccine is based on SARS CoV-2 spike (S) glycoprotein antigens encoded in RNA and formulated in lipid nanoparticles (LNPs).”).

RESPONSE: Paragraph 129 states a legal conclusion to which no response is required. To the extent the allegations of Paragraph 129 purport to rely on Exhibit 26, Exhibit 29, and Exhibit 27, those exhibits speak for themselves. Defendants incorporate by reference their responses contained in Paragraphs 47 through 66. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

130. Each of the Comirnaty® (bivalent BA.1) and Comirnaty® (bivalent BA.4/5) products comprises “a first species of ribonucleic acid (RNA) molecules comprising a sequence that encodes a first immunogen.” See paragraphs 47–66, above; *e.g.*, Exhibit 26 (July 12, 2022,

EMA Comirnaty® (bivalent BA.1) Assessment Report) at 6 (“The active substance tozinameran is already approved in the existing Comirnaty® conditional marketing authorization. No changes to the information related to tozinameran are proposed.”); Exhibit 27 (September 12, 2022, EMA Comirnaty® (bivalent BA.4/5) Assessment Report) at 5 (“The active substance tozinameran is already approved for the original Comirnaty® vaccine formulations (EU/1/20/1528/001-005). No changes to the information related to tozinameran are proposed.”).

RESPONSE: Paragraph 130 states a legal conclusion to which no response is required.

To the extent the allegations of Paragraph 130 purport to rely on Exhibit 26 and Exhibit 27, those exhibits speak for themselves. Defendants incorporate by reference their responses contained in Paragraphs 47 through 66. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

131. Each of the Comirnaty® (bivalent BA.1) and Comirnaty® (bivalent BA.4/5) products comprises “a second species of RNA molecules comprising a sequence that encodes a second immunogen.” See paragraphs 47–66, above; *e.g.*, Exhibit 26 (July 12, 2022, EMA Comirnaty® (bivalent BA.1) Assessment Report) at 6 (“Riltozinameran is a single-stranded, 5’ capped messenger RNA (mRNA) produced using a cell-free *in vitro* transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2 (Omicron BA.1).”); Exhibit 27 (September 12, 2022, EMA Comirnaty® (bivalent BA.4/5) Assessment Report) at 5 (“Famtozinameran is a single-stranded, 5’-capped messenger RNA (mRNA) produced using a cell-free *in vitro* transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2 (Omicron BA.4-5).”).

RESPONSE: Paragraph 131 states a legal conclusion to which no response is required.

To the extent the allegations of Paragraph 131 purport to rely on Exhibit 26 and Exhibit 27, those exhibits speak for themselves. Defendants incorporate by reference their responses contained in Paragraphs 47 through 66. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

132. Each of the Comirnaty® (bivalent BA.1) and Comirnaty® (bivalent BA.4/5) products comprises “lipids comprising: (a) a cationic lipid, (b) an anionic or a zwitterionic lipid, (c) a polyethylene glycol-conjugated (PEG-conjugated) lipid, and (d) cholesterol.” See paragraphs 47–66, above; *e.g.*, Exhibit 26 (July 12, 2022, EMA Comirnaty® (bivalent BA.1) Assessment

Report) at 11 (identifying lipid ingredients); Exhibit 35 (July 14, 2023, FDA Comirnaty® (bivalent BA.4/5) EUA Fact Sheet and Package Insert) at 53 (identifying lipid ingredients).

RESPONSE: Paragraph 132 states a legal conclusion to which no response is required. To the extent the allegations of Paragraph 132 purport to rely on Exhibit 26 and Exhibit 35, those exhibits speak for themselves. Defendants incorporate by reference their responses contained in Paragraphs 47 through 66. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

133. ALC-0315 is a “cationic lipid” that “comprises a tertiary amine.” *See, e.g.*, Exhibit 21 (February 19, 2021, EMA Comirnaty® (original monovalent) Assessment Report) at 23–24 (“The ALC-0315 novel excipient is a cationic lipid containing a tertiary amine”); Exhibit 71 (ALC-0315 Product Information, Cayman Chemical) (providing structure); Exhibit 72 (Schoenmaker *et al.*, “mRNA-lipid nanoparticle COVID-19 vaccines: Structure and Stability,” *Intl. J. Pharm.* 601, 120586 (2021)) at Fig. 6 (providing structure and identifying ALC-0315 as an “[i]onizable cationic lipid”).

RESPONSE: Paragraph 133 states a legal conclusion to which no response is required. To the extent the allegations of Paragraph 133 purport to rely on Exhibit 21, Exhibit 71, and Exhibit 72, those exhibits speak for themselves. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

134. DSPC is a “zwitterionic lipid.” *See, e.g.*, Exhibit 73 (DSPC Product Information, Polysciences) (“[DSPC] is a zwitterionic phospholipid that is used in the preparation of liposomes for transfection and drug delivery applications.”).

RESPONSE: Paragraph 134 states a legal conclusion to which no response is required. To the extent the allegations of Paragraph 134 purport to rely on Exhibit 73, that exhibit speaks for itself. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

135. ALC-0159 is a “polyethylene glycol-conjugated (PEG-conjugated) lipid.” *See, e.g.*, Exhibit 21 (February 19, 2021, EMA Comirnaty® (original monovalent) Assessment Report) at 24 (“The ALC-0159 novel excipient is PEGylated lipid ...”); Exhibit 74 (ALC-0159 Product Information, Echelon Biosciences) (“ALC-0159 is a PEGylated lipid which has been used to form lipid nanoparticles for delivery of RNA. ALC-0159 is one of the components in the BNT162b2 vaccine[.]”); Exhibit 72 (Schoenmaker *et al.*, “mRNA-lipid nanoparticle COVID-19 vaccines: Structure and Stability,” *Intl. J. Pharm.* 601, 120586 (2021)) at Fig. 6 (identifying ALC-0159 to be a “PEG-lipid”).

RESPONSE: Paragraph 135 states a legal conclusion to which no response is required.

To the extent the allegations of Paragraph 135 purport to rely on Exhibit 21, Exhibit 74, and Exhibit 72, those exhibits speak for themselves. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

136. On information and belief, the lipids of each of the Comirnaty® (bivalent BA.1) and Comirnaty® (bivalent BA.4/5) products “encapsulate at least half of the first species of RNA molecules and at least half of the second species of RNA molecules.” *See* paragraphs 47–66, above; *e.g.*, Exhibit 34 (April 2023, FDA Comirnaty® (original monovalent) Package Insert) at 19 (“The nucleoside-modified mRNA in COMIRNATY is formulated in lipid particles, which enable delivery of the mRNA into host cells to allow expression of the SARS-CoV-2 antigen.”); *see also* Exhibit 72 (Schoenmaker *et al.*, “mRNA-lipid nanoparticle COVID-19 vaccines: Structure and Stability,” *Intl. J. Pharm.* 601, 120586 (2021)) at 4 (“In mRNA-LNP formulations, such as those used in mRNA vaccines ... encapsulation efficiencies ... are typically > 90%.”).

RESPONSE: Paragraph 136 states a legal conclusion to which no response is required.

To the extent the allegations of Paragraph 136 purport to rely on Exhibit 34 and Exhibit 72, those exhibits speak for themselves. Defendants incorporate by reference their responses contained in Paragraphs 47 through 66. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

137. On information and belief, when employing the “fluorescent probe 6-(p-toluidino) 2-naphthalenesulfonic acid (TNS)” and following steps (1) to (14) of claim 1 of the ’694 patent to “obtain[] a relative fluorescence” in each of the described pH-buffered mixtures and “determining the pKa as the pH on the line of best fit at which a relative fluorescence of 0.5 is obtained,” the cationic lipid used in each of the Comirnaty® (bivalent BA.1) and Comirnaty® (bivalent BA.4/5)

products—ALC-0315—exhibits a pKa falling between 6.07 and 7.6. *See, e.g.*, Exhibit 75 (McKenzie *et al.*, “mRNA synthesis and encapsulation in ionizable lipid nanoparticles,” *Current Protocols* 3, e898 (2023)) at 19 (reporting a pKa of 6.284 for ALC-0315 in a TNS assay); Exhibit 76 (International PCT Application Publication Number WO 2017/075531 A1) at 48 and 50, Table 3 (reporting a pKa of 6.09 for ALC-0315 (cationic lipid “No. 3”) in a TNS assay); Exhibit 77 (Tilstra *et al.*, “Iterative Design of Ionizable Lipids for Intramuscular mRNA Delivery,” *J. Am. Chem. Soc.* 145, 2294–2304 (2023) with supplementary information) at Figure S11 (reporting a pKa of 6.27 for ALC-0315 in a TNS assay).

RESPONSE: Paragraph 136 states a legal conclusion to which no response is required.

To the extent the allegations of Paragraph 136 purport to rely on Exhibit 75, Exhibit 76, and Exhibit 77, those exhibits speak for themselves. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

138. Each of the Comirnaty® (bivalent BA.1) and Comirnaty® (bivalent BA.4/5) products is “immunogenic in vivo by eliciting an antibody response against the first immunogen and the second immunogen in vivo” at least when used in accordance with the FDA and EMA authorized and approved indications. *See* paragraphs 47–90, above; *e.g.*, Exhibit 24 (September 1, 2022, Pfizer press release) (“[T]he bivalent vaccine with mRNA encoding the wild-type and the BA.1 spike proteins provides [] neutralizing antibody titers against the Omicron BA.1 and BA.4/BA.5 sublineages[.]”); Exhibit 25 (November 4, 2022, Pfizer press release) (“Among the overall study population who received the Omicron BA.4/BA.5-adapted bivalent vaccine, there was a substantially higher increase in Omicron BA.4/BA.5-neutralizing antibody titers compared to pre-booster levels.”).

RESPONSE: Paragraph 138 states a legal conclusion to which no response is required.

To the extent the allegations of Paragraph 138 purport to rely on Exhibit 24 and Exhibit 25, those exhibits speak for themselves. Defendants incorporate by reference their responses contained in Paragraphs 47 through 90. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

139. Defendants packaged, promoted, and sold Comirnaty® (bivalent BA.4/5) in the United States with FDA-approved packaging and package inserts comprising labeling and prescribing information that instruct health care practitioners on their use in accordance with the

FDA authorized indications. *See* paragraphs 47–90, above; *e.g.*, Exhibit 35 (July 14, 2023, FDA Comirnaty® (bivalent BA.4/5) EUA Fact Sheet and Package Insert).

RESPONSE: Paragraph 139 states a legal conclusion to which no response is required. To the extent the allegations of Paragraph 139 purport to rely on Exhibit 35, that exhibit speaks for itself. Defendants incorporate by reference their responses contained in Paragraphs 47 through 90. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

140. Defendants created and disseminated by means separate from the packaging and package inserts of Comirnaty® (bivalent BA.4/5), supporting materials, instructions, and/or technical information that instructed health care practitioners on the use of Comirnaty® (bivalent BA.4/5) in the United States in accordance with the FDA authorized indications. *See, e.g.*, Exhibit 79 (www.comirnaty.com/eua-bivalent as preserved by The Wayback Machine, September 22, 2022¹⁴).

RESPONSE: Paragraph 140 states a legal conclusion to which no response is required. To the extent the allegations of Paragraph 140 purport to rely on Exhibit 79, that exhibit speaks for itself. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

141. Defendants have been and are aware that the use of Comirnaty® (bivalent BA.4/5) in the United States in accordance with the FDA authorized indications identified above in paragraphs 67–90 infringed at least exemplary claim 1 of the '694 patent.

RESPONSE: Denied.

142. Defendants have been and are aware that healthcare providers used Comirnaty® (bivalent BA.4/5) in the United States in accordance with the FDA authorized indications identified above in paragraphs 67–90 and thereby infringed at least exemplary claim 1 of the '694 patent.

RESPONSE: Denied.

¹⁴ Available at <https://web.archive.org/web/20220922181232/https://www.comirnaty.com/euabivalent>; preserved on April 5, 2024.

143. None of the Comirnaty® (bivalent BA.1) or Comirnaty® (bivalent BA.4/5) products is a staple article or commodity of commerce suitable for use in the United States other than in accordance with the FDA authorized indications identified above in paragraphs 67–90.

RESPONSE: Denied.

144. Defendants actively, knowingly, and specifically intended to induce, and induced, infringement of at least claim 1 of the '694 patent by packaging, promoting, selling or otherwise supplying, directly or indirectly, the Comirnaty® (bivalent BA.4/5) product to healthcare providers, with the knowledge and intent that healthcare providers would use the Comirnaty® (bivalent BA.4/5) products supplied by Defendants according to the FDA authorized infringing indications.

RESPONSE: Denied.

145. GSK has suffered and continues to suffer damages from Defendants' infringement of the '694 patent.

RESPONSE: Denied.

146. GSK is entitled to an award of monetary damages, including a reasonable royalty, for Defendants' infringement of the '694 patent.

RESPONSE: Denied.

147. Defendants have had knowledge of the '694 patent and specific notice of its infringement at least since April 24, 2024, by communications between GSK and Defendants. *See* Exhibits 81-82.

RESPONSE: Paragraph 147 states a legal conclusion to which no response is required. To the extent the allegations of Paragraph 147 purport to rely on Exhibits 81–82, those exhibits speak for themselves. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

148. Defendants' infringement of the '694 patent has been and continues to be willful and deliberate at least since they received specific notice of their infringement from GSK on April 24, 2024. *See id.*

RESPONSE: Denied.

149. Defendants' conduct in infringing the '694 patent makes this case exceptional under 35 U.S.C. § 285.

RESPONSE: Denied.

COUNT III

(Infringement of the '534 Patent)

150. GSK incorporates by reference paragraphs 1–149.

RESPONSE: Defendants incorporate by reference their responses contained in Paragraphs 1 through 149.

151. GSK Biologicals is the lawful owner by assignment of the '534 patent, which is entitled "Methods of Administering Lipid Formulations with Viral Immunogens" and was duly and legally issued by the U.S. Patent and Trademark Office on June 6, 2023. A true and correct copy of the '534 patent is attached as Exhibit 3. The patent application issuing into the '534 patent was published on April 28, 2022, as Publication No. US 2022/0125727 A1. *See* Exhibit 3 at Prior Publication Data.

RESPONSE: Defendants admit that the U.S. Patent and Trademark Office issued U.S. Pat. No. 11,666,534 entitled "Methods of Administering Lipid Formulations with Viral Immunogens" on June 6, 2023, that Exhibit 3 purports to be a copy of the '534 patent, and that Publication No. U.S. 2022/0125727 A1 was published on April 28, 2022 and issued into the '534 patent, but deny that the patent is valid, enforceable, or infringed by Defendants. Defendants deny any remaining allegations of this Paragraph.

152. Each claim of the '534 patent is valid and enforceable.

RESPONSE: Denied.

153. Defendants have induced, and continue to induce, direct infringement by third parties of one or more claims of the '534 patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents, by making, selling and/or offering for sale in the United States, and/or importing into the United States, each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products embodying GSK Biologicals's patented inventions as disclosed by and claimed in the '534 patent, without authority or license to do so, during the term of the '534 patent.

RESPONSE: Denied.

154. In addition or in the alternative, Defendants have contributed, and continue to contribute, to the direct infringement by third parties of one or more claims of the '534 patent under 35 U.S.C. § 271(c), either literally or under the doctrine of equivalents, by making, selling and/or offering for sale in the United States, and/or importing into the United States, each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products embodying GSK Biologicals's patented inventions as disclosed by and claimed in the '534 patent, without authority or license to do so, during the term of the '534 patent, knowing that those products constitute a material part of the inventions of the '534 patent, knowing that those products are especially made or adapted to infringe the '534 patent, and knowing that those products are not staple articles or commodities of commerce suitable for substantial non-infringing use.

RESPONSE: Denied.

155. For example, on information and belief, the FDA authorized and approved uses for each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products satisfies each and every element of at least claim 1 of the '534 patent. Defendants' actions with respect to each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products have therefore infringed at least this exemplary claim of the '534 patent.

RESPONSE: Denied.

156. Claim 1 of the '534 patent recites:

A method of eliciting an immune response against an immunogen in a subject, the method comprising:

administering to the subject an immunologically effective unit dose of a formulation comprising:

ribonucleic acid (RNA) molecules comprising a sequence that encodes the immunogen, wherein the immunogen comprises a respiratory syncytial virus immunogen, an Epstein-Barr virus immunogen, a cytomegalovirus immunogen, a coronavirus spike polypeptide immunogen, an influenza virus A immunogen, a Varicella zoster virus immunogen, or a flavivirus immunogen; and

lipids comprising a tertiary amine cationic lipid, a polyethylene glycol-conjugated (PEG-conjugated) lipid, and cholesterol;

wherein the lipids encapsulate at least half of the RNA molecules; and

wherein the immune response against the immunogen comprises an antibody response against the immunogen.

RESPONSE: Defendants admit that Claim 1 of the '534 patent appears to include the above language. Defendants otherwise deny the remaining allegations of this Paragraph.

157. Each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products comprises a “formulation.” See paragraphs 47–66, above; *e.g.*, Exhibit 34 (April 2023, FDA Comirnaty® (original monovalent) Package Insert) at 19 (“The nucleoside-modified mRNA in COMIRNATY is formulated in lipid particles[.]”); Exhibit 21 (February 19, 2021, EMA Comirnaty® (original monovalent) Assessment Report) at 58 (“The nucleoside-modified messenger RNA in the vaccine is formulated in lipid nanoparticles[.]”).

RESPONSE: Paragraph 157 states a legal conclusion to which no response is required. To the extent the allegations of Paragraph 157 purport to rely on Exhibit 34 and Exhibit 21, those exhibits speak for themselves. Defendants incorporate by reference their responses contained in Paragraphs 47 through 66. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

158. Each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products comprises “ribonucleic acid (RNA) molecules comprising a sequence that encodes [an] immunogen, wherein the immunogen comprises ... a coronavirus spike polypeptide immunogen.” See paragraphs 47–66, above; *e.g.*, Exhibit 34 (April 2023, FDA Comirnaty® (original monovalent) Package Insert) at 19 (“COMIRNATY ... contains 30 mcg of a nucleoside-modified messenger RNA (mRNA) encoding the viral spike glycoprotein of SARS-CoV-2.”); Exhibit 21 (February 19, 2021, EMA Comirnaty® (original monovalent) Assessment Report) at 15 (“The active substance consists of ... mRNA that is translated into a codon-optimized sequence encoding the spike antigen of SARS-CoV-2[.]”).

RESPONSE: Paragraph 158 states a legal conclusion to which no response is required. To the extent the allegations of Paragraph 158 purport to rely on Exhibit 34 and Exhibit 21, those exhibits speak for themselves. Defendants incorporate by reference their responses contained in Paragraphs 47 through 66. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

159. Each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products comprises “lipids comprising a tertiary amine cationic lipid, a polyethylene glycol-conjugated (PEG-conjugated) lipid, and cholesterol.” See paragraphs 47–66, above, *e.g.*, Exhibit 34 (April 2023, FDA Comirnaty® (original monovalent) Package Insert) at 19 (identifying lipid ingredients).

RESPONSE: Paragraph 159 states a legal conclusion to which no response is required.

To the extent the allegations of Paragraph 159 purport to rely on Exhibit 34, that exhibit speaks for itself. Defendants incorporate by reference their responses contained in Paragraphs 47 through 66. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

160. ALC-0315 is a “tertiary amine cationic lipid.” See, *e.g.*, Exhibit 21 (February 19, 2021, EMA Comirnaty® (original monovalent) Assessment Report) at 23–24 (“The ALC-0315 novel excipient is a cationic lipid containing a tertiary amine ...”); Exhibit 71 (ALC-0315 Product Information, Cayman Chemical) (providing structure); Exhibit 72 (Schoenmaker *et al.*, “mRNA-lipid nanoparticle COVID-19 vaccines: Structure and Stability,” *Intl. J. Pharm.* 601, 120586 (2021)) at Fig. 6 (providing structure and identifying ALC-0315 as an “[i]onizable cationic lipid”).

RESPONSE: Paragraph 160 states a legal conclusion to which no response is required.

To the extent the allegations of Paragraph 160 purport to rely on Exhibit 21, Exhibit 71, and Exhibit 72, those exhibits speak for themselves. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

161. ALC-0159 is a “polyethylene glycol-conjugated (PEG-conjugated) lipid.” See, *e.g.*, Exhibit 21 (February 19, 2021, EMA Comirnaty® (original monovalent) Assessment Report) at 24 (“The ALC-0159 novel excipient is PEGylated lipid ...”); Exhibit 74 (ALC-0159 Product Information, Echelon Biosciences) (“ALC-0159 is a PEGylated lipid which has been used to form lipid nanoparticles for delivery of RNA. ALC-0159 is one of the components in the BNT162b2 vaccine[.]”); Exhibit 72 (Schoenmaker *et al.*, “mRNA-lipid nanoparticle COVID-19 vaccines: Structure and Stability,” *Intl. J. Pharm.* 601, 120586 (2021)) at Fig. 6 (identifying ALC-0159 to be a “PEG-lipid”).

RESPONSE: Paragraph 161 states a legal conclusion to which no response is required.

To the extent the allegations of Paragraph 161 purport to rely on Exhibit 21, Exhibit 74, and Exhibit

72, those exhibits speak for themselves. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

162. On information and belief, the lipids of each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products “encapsulate at least half of the mRNA molecules.” See paragraphs 47–66, above; *e.g.*, Exhibit 34 (April 2023, FDA Comirnaty® (original monovalent) Package Insert) at 19 (“The nucleoside modified mRNA in COMIRNATY is formulated in lipid particles, which enable delivery of the mRNA into host cells to allow expression of the SARS-CoV-2 antigen.”); *see also* Exhibit 72 (Schoenmaker *et al.*, “mRNA-lipid nanoparticle COVID-19 vaccines: Structure and Stability,” *Intl. J. Pharm.* 601, 120586 (2021)) at 4 (“In mRNA-LNP formulations, such as those used in mRNA vaccines ... encapsulation efficiencies ... are typically > 90%.”).

RESPONSE: Paragraph 162 states a legal conclusion to which no response is required. To the extent the allegations of Paragraph 162 purport to rely on Exhibit 34 and Exhibit 72, those exhibits speak for themselves. Defendants incorporate by reference their responses contained in Paragraphs 47 through 66. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

163. Use of each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products in accordance with the FDA authorized and approved indications comprises “administering to the subject an immunologically effective unit dose” that “elicit[s] an immune response” against “a coronavirus spike polypeptide immunogen” comprising “an antibody response against the immunogen.” See paragraphs 47–90, above; *e.g.*, Exhibit 21 (February 19, 2021, EMA Comirnaty® original Assessment Report) at 58 (“The vaccine elicits both neutralizing antibody and cellular immune responses to the spike (S) antigen, which may contribute to protection against COVID-19.”); Exhibit 25 (November 4, 2022, Pfizer press release) (“Among the overall study population who received the Omicron BA.4/BA.5 adapted bivalent vaccine, there was a substantially higher increase in Omicron BA.4/BA.5 neutralizing antibody titers compared to pre-booster levels.”); Exhibit 64 (September 11, 2023, FDA Comirnaty® (monovalent XBB.1.5) EUA Review Memo) at 17–18 (extrapolating immunological response from the prior Comirnaty® COVID-19 vaccine products and stating, “preclinical data demonstrate that, when compared with the Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5), Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) induces higher neutralizing antibody titers against XBB sublineages, including XBB.1.5, XBB.1.16, XBB.1.16.1, and XBB.2.3.”).

RESPONSE: Paragraph 163 states a legal conclusion to which no response is required.

To the extent the allegations of Paragraph 163 purport to rely on Exhibit 21, Exhibit 25, and Exhibit 64, those exhibits speak for themselves. Defendants incorporate by reference their responses contained in Paragraphs 47 through 90. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

164. Defendants packaged, promoted, and sold, and continue to package promote and sell, each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products in the United States with FDA-approved packaging and package inserts comprising labeling and prescribing information that instruct health care practitioners on their use in accordance with the FDA authorized and approved indications. See paragraphs 47–90, above; *e.g.*, Exhibit 34 (April 2023, FDA Comirnaty® (original monovalent) Package Insert); Exhibit 35 (July 14, 2023, FDA Comirnaty® (bivalent BA.4/5) EUA Fact Sheet and Package Insert); Exhibit 33 (September 2023, FDA Comirnaty® (monovalent XBB.1.5) Package Insert).

RESPONSE: Paragraph 164 states a legal conclusion to which no response is required.

To the extent the allegations of Paragraph 164 purport to rely on Exhibit 34, Exhibit 35, and Exhibit 33, those exhibits speak for themselves. Defendants incorporate by reference their responses contained in Paragraphs 47 through 90. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

165. Defendants created and disseminated, and continue to create and disseminate, by means separate from the packaging and package inserts of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products, supporting materials, instructions, and/or technical information that instruct health care practitioners on the use of each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products in the United States in accordance with the FDA authorized and approved indications. See, *e.g.*, Exhibit 78 (www.comirnaty.com as preserved by The Wayback Machine, August, 27, 2021¹⁵); Exhibit 79 (www.comirnaty.com/eua-bivalent as

¹⁵ Available at <https://web.archive.org/web/20210827220339/https://www.comirnaty.com/>; preserved on April 5, 2024.

preserved by The Wayback Machine, September, 22, 2022¹⁶); Exhibit 80 (www.comirnaty.com/eua-six-months-to-eleven-years; preserved April 5, 2024).

RESPONSE: Paragraph 165 states a legal conclusion to which no response is required.

To the extent the allegations of Paragraph 165 purport to rely on Exhibit 78, Exhibit 79, and Exhibit 80, those exhibits speak for themselves. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

166. Defendants have been and are aware that the use of each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products in the United States in accordance with the FDA authorized and approved indications identified above in paragraphs 67–90 infringes at least exemplary claim 1 of the '534 patent.

RESPONSE: Denied.

167. Defendants have been and are aware that healthcare providers use each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products in the United States in accordance with the FDA authorized and approved indications identified above in paragraphs 67–90 and thereby infringe at least exemplary claim 1 of the '534 patent.

RESPONSE: Denied.

168. None of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products is a staple article or commodity of commerce suitable for use in the United States other than in accordance with the FDA authorized and approved indications identified above in paragraphs 67–90.

RESPONSE: Denied.

169. Defendants actively, knowingly, and specifically intended to induce, and induced, and continue to actively, knowingly, and specifically intend to induce, and induce, infringement of at least claim 1 of the '534 patent by packaging, promoting, selling or otherwise supplying, directly or indirectly, each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products to healthcare providers, with the knowledge and intent that healthcare providers will use the Comirnaty® (original monovalent),

¹⁶ Available at <https://web.archive.org/web/20220922181232/https://www.comirnaty.com/euabivalent>; preserved on April 5, 2024.

Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products supplied by Defendants according to the FDA authorized and approved infringing indications.

RESPONSE: Denied.

170. GSK has suffered and continues to suffer damages from Defendants' infringement of the '534 patent.

RESPONSE: Denied.

171. GSK is entitled to an award of monetary damages, including a reasonable royalty, for Defendants' infringement of the '534 patent.

RESPONSE: Denied.

172. Defendants have had knowledge of the '534 patent and specific notice of its infringement at least since April 24, 2024, by communications between GSK and Defendants. *See* Exhibits 81-82.

RESPONSE: Paragraph 172 states a legal conclusion to which no response is required. To the extent the allegations of Paragraph 172 purport to rely on Exhibits 81–82, those exhibits speak for themselves. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

173. Defendants' infringement of the '534 patent has been and continues to be willful and deliberate at least since they received specific notice of their infringement from GSK on April 24, 2024. *See id.*

RESPONSE: Denied.

174. Defendants' conduct with respect to the '534 patent makes this case exceptional under 35 U.S.C. § 285.

RESPONSE: Denied.

COUNT IV

(Infringement of the '401 Patent)

175. GSK incorporates by reference paragraphs 1–174.

RESPONSE: Defendants incorporate by reference their responses contained in Paragraphs 1 through 174.

176. GSK Biologicals is the lawful owner by assignment of the '401 patent, which is entitled "Methods of Administering Lipid Formulations with Immunogens" and was duly and legally issued by the U.S. Patent and Trademark Office on September 26, 2023. A true and correct copy of the '401 patent is attached as Exhibit 4. The patent application issuing into the '401 patent was published on April 28, 2022, as Publication No. US 2022/0125724 A1. See Exhibit 4 at Prior Publication Data.

RESPONSE: Defendants admit that the U.S. Patent and Trademark Office issued U.S. Pat. No. 11,766,401 entitled "Methods of Administering Lipid Formulations with Immunogens" on September 26, 2023, that Exhibit 4 purports to be a copy of the '401 patent, and that Publication No. U.S. 2022/0125724 A1 was published on April 28, 2022 and issued into the '401 patent, but deny that the patent is valid, enforceable, or infringed by Defendants. Defendants deny any remaining allegations of this Paragraph.

177. Each claim of the '401 patent is valid and enforceable.

RESPONSE: Denied.

178. Defendants have induced, and continue to induce, direct infringement by third parties of one or more claims of the '401 patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents, by making, selling and/or offering for sale in the United States, and/or importing into the United States, each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products embodying GSK Biologicals's patented inventions as disclosed by and claimed in the '401 patent, without authority or license to do so, during the term of the '401 patent.

RESPONSE: Denied.

179. In addition or in the alternative, Defendants have contributed, and continue to contribute, to the direct infringement by third parties of one or more claims of the '401 patent under 35 U.S.C. § 271(c), either literally or under the doctrine of equivalents, by making, selling and/or offering for sale in the United States, and/or importing into the United States, each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products embodying GSK Biologicals's patented inventions as disclosed by and claimed in the '401 patent, without authority or license to do so, during the term of the '401 patent, knowing that those products constitute a material part of the inventions of the '401 patent, knowing that those products are especially made or adapted to infringe the '401 patent, and knowing that those

products are not staple articles or commodities of commerce suitable for substantial non-infringing use.

RESPONSE: Denied.

180. For example, on information and belief, the FDA authorized and approved uses for each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products satisfies each and every element of at least claim 1 of the '401 patent. Defendants' actions with respect to each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products have therefore infringed at least this exemplary claim of the '401 patent.

RESPONSE: Denied.

181. Claim 1 of the '401 patent recites:

A method of eliciting an immune response against an immunogen in a human or a cow, the method comprising:

administering to the human or the cow an immunologically effective unit dose of a formulation comprising:

RNA molecules comprising a sequence that encodes the immunogen; and

lipids comprising a tertiary amine cationic lipid, a polyethylene glycol-conjugated (PEG-conjugated) lipid, and cholesterol; and

wherein the lipids encapsulate at least half of the RNA molecules; and the immune response against the immunogen comprises an antibody response against the immunogen.

RESPONSE: Defendants admit that Claim 1 of the '401 patent appears to include the above language. Defendants otherwise deny the remaining allegations of this Paragraph.

182. Each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products comprises a "formulation." See paragraphs 47–66, above; *e.g.*, Exhibit 34 (April 2023, FDA Comirnaty® (original monovalent) Package Insert) at 19 ("The nucleoside-modified mRNA in COMIRNATY is formulated in lipid particles[.]"); Exhibit 21 (February 19, 2021, EMA Comirnaty® (original monovalent) Assessment Report) at 58 ("The nucleoside-modified messenger RNA in the vaccine is formulated in lipid nanoparticles[.]").

RESPONSE: Paragraph 182 states a legal conclusion to which no response is required.

To the extent the allegations of Paragraph 182 purport to rely on Exhibit 34 and Exhibit 21, those exhibits speak for themselves. Defendants incorporate by reference their responses contained in Paragraphs 47 through 66. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

183. Each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products comprises “RNA molecules comprising a sequence that encodes [an] immunogen.” See paragraphs 47–66, above; *e.g.*, Exhibit 34 (April 2023, FDA Comirnaty® (original monovalent) Package Insert) at 19 (“COMIRNATY ... contains 30 mcg of a nucleoside-modified messenger RNA (mRNA) encoding the viral spike glycoprotein of SARS-CoV-2.”); Exhibit 21 (February 19, 2021, EMA Comirnaty® (original monovalent) Assessment Report) at 15 (“The active substance consists of ... mRNA that is translated into a codon-optimized sequence encoding the spike antigen of SARS-CoV-2[.]”).

RESPONSE: Paragraph 183 states a legal conclusion to which no response is required.

To the extent the allegations of Paragraph 183 purport to rely on Exhibit 34 and Exhibit 21, those exhibits speak for themselves. Defendants incorporate by reference their responses contained in Paragraphs 47 through 66. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

184. Each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products comprises “lipids comprising a tertiary amine cationic lipid, a polyethylene glycol-conjugated (PEG-conjugated) lipid, and cholesterol.” See paragraphs 47–66, above; *e.g.*, Exhibit 34 (April 2023, FDA Comirnaty® (original monovalent) Package Insert) at 19 (identifying lipid ingredients).

RESPONSE: Paragraph 184 states a legal conclusion to which no response is required.

To the extent the allegations of Paragraph 184 purport to rely on Exhibit 34, that exhibit speaks for itself. Defendants incorporate by reference their responses contained in Paragraphs 47 through

66. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

185. ALC-0315 is a “tertiary amine cationic lipid.” *See, e.g.*, Exhibit 21 (February 19, 2021, EMA Comirnaty® (original monovalent) Assessment Report) at 23–24 (“The ALC-0315 novel excipient is a cationic lipid containing a tertiary amine”); Exhibit 71 (ALC-0315 Product Information, Cayman Chemical) (providing structure); Exhibit 72 (Schoenmaker *et al.*, “mRNA lipid nanoparticle COVID-19 vaccines: Structure and Stability,” *Intl. J. Pharm.* 601, 120586 (2021)) at Fig. 6 (providing structure and identifying ALC-0315 as an “[i]onizable cationic lipid”).

RESPONSE: Paragraph 185 states a legal conclusion to which no response is required. To the extent the allegations of Paragraph 185 purport to rely on Exhibit 21, Exhibit 71, and Exhibit 72, those exhibits speak for themselves. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

186. ALC-0159 is a “polyethylene glycol-conjugated (PEG-conjugated) lipid.” *See, e.g.*, Exhibit 21 (February 19, 2021, EMA Comirnaty® (original monovalent) Assessment Report) at 24 (“The ALC-0159 novel excipient is PEGylated lipid”); Exhibit 74 (ALC-0159 Product Information, Echelon Biosciences) (“ALC-0159 is a PEGylated lipid which has been used to form lipid nanoparticles for delivery of RNA. ALC-0159 is one of the components in the BNT162b2 vaccine[.]”); Exhibit 72 (Schoenmaker *et al.*, “mRNA-lipid nanoparticle COVID-19 vaccines: Structure and Stability,” *Intl. J. Pharm.* 601, 120586 (2021)) at Fig. 6 (identifying ALC-0159 to be a “PEG-lipid”).

RESPONSE: Paragraph 186 states a legal conclusion to which no response is required. To the extent the allegations of Paragraph 186 purport to rely on Exhibit 21, Exhibit 74, and Exhibit 72, those exhibits speak for themselves. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

187. On information and belief, the lipids of each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products “encapsulate at least half of the mRNA molecules.” *See* paragraphs 47–66, above; *e.g.*, Exhibit 34 (April 2023, FDA Comirnaty® (original monovalent) Package Insert) at 19 (“The nucleosidemodified mRNA in COMIRNATY is formulated in lipid particles, which enable

delivery of the mRNA into host cells to allow expression of the SARS-CoV-2 antigen.”); *see also* Exhibit 72 (Schoenmaker *et al.*, “mRNA-lipid nanoparticle COVID-19 vaccines: Structure and Stability,” *Intl. J. Pharm.* 601, 120586 (2021)) at 4 (“In mRNA-LNP formulations, such as those used in mRNA vaccines ... encapsulation efficiencies ... are typically > 90%.”).

RESPONSE: Paragraph 187 states a legal conclusion to which no response is required.

To the extent the allegations of Paragraph 187 purport to rely on Exhibit 34 and Exhibit 72, those exhibits speak for themselves. Defendants incorporate by reference their responses contained in Paragraphs 47 through 66. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

188. Use of each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products in accordance with the FDA authorized or approved uses comprises “administering to [a] human ... an immunologically effective unit dose” that “elicit[s] an immune response” against a coronavirus spike polypeptide “immunogen” comprising “an antibody response against the immunogen.” *See* paragraphs 47–90, above; *e.g.*, Exhibit 21 (February 19, 2021, EMA Comirnaty® (original monovalent) Assessment Report) at 58 (“The vaccine elicits both neutralizing antibody and cellular immune responses to the spike (S) antigen, which may contribute to protection against COVID-19.”); Exhibit 25 (November 4, 2022, Pfizer press release) (“Among the overall study population who received the Omicron BA.4/BA.5-adapted bivalent vaccine, there was a substantially higher increase in Omicron BA.4/BA.5- neutralizing antibody titers compared to pre-booster levels.”); Exhibit 64 (September 11, 2023, FDA Comirnaty® (monovalent XBB.1.5) EUA Review Memo) at 17–18 (extrapolating immunological response from the prior Comirnaty® COVID-19 vaccine products and stating, “preclinical data demonstrate that, when compared with the Pfizer-BioNTech COVID-19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5), Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) induces higher neutralizing antibody titers against XBB sublineages, including XBB.1.5, XBB.1.16, XBB.1.16.1, and XBB.2.3.”).

RESPONSE: Paragraph 188 states a legal conclusion to which no response is required.

To the extent the allegations of Paragraph 188 purport to rely on Exhibit 21, Exhibit 25, Exhibit 64, those exhibits speak for themselves. Defendants incorporate by reference their responses contained in Paragraphs 47 through 90. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

189. Defendants packaged, promoted, and sold, and continue to package promote and sell, each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products in the United States with FDA-approved packaging and package inserts comprising labeling and prescribing information that instruct health care practitioners on their use in accordance with the FDA authorized and approved indications. *See* paragraphs 47–90, above; *e.g.*, Exhibit 34 (April 2023, FDA Comirnaty® (original monovalent) Package Insert); Exhibit 35 (July 14, 2023, FDA Comirnaty® (bivalent BA.4/5) EUA Fact Sheet and Package Insert); Exhibit 33 (September 2023, FDA Comirnaty® (monovalent XBB.1.5) Package Insert).

RESPONSE: Paragraph 189 states a legal conclusion to which no response is required.

To the extent the allegations of Paragraph 189 purport to rely on Exhibit 34, Exhibit 35, and Exhibit 33, those exhibits speak for themselves. Defendants incorporate by reference their responses contained in Paragraphs 47 through 90. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

190. Defendants created and disseminated, and continue to create and disseminate, by means separate from the packaging and package inserts of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products, supporting materials, instructions, and/or technical information that instruct health care practitioners on the use of each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products in the United States in accordance with the FDA authorized and approved indications. *See, e.g.*, Exhibit 78 (www.comirnaty.com as preserved by The Wayback Machine, August, 27, 2021¹⁷); Exhibit 79 (www.comirnaty.com/eua-bivalent as preserved by The Wayback Machine, September, 22, 2022¹⁸); Exhibit 80 (www.comirnaty.com/eua-six-months-to-eleven-years; preserved April 5, 2024).

RESPONSE: Paragraph 190 states a legal conclusion to which no response is required.

To the extent the allegations of Paragraph 190 purport to rely on Exhibit 78, Exhibit 79 and Exhibit 80, those exhibits speak for themselves. Defendants deny that the Accused Products infringe any

¹⁷ Available at <https://web.archive.org/web/20210827220339/https://www.comirnaty.com/>; preserved on April 5, 2024.

¹⁸ Available at <https://web.archive.org/web/20220922181232/https://www.comirnaty.com/euabivalent>; preserved on April 5, 2024.

valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

191. Defendants have been and are aware that the use of each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products in the United States in accordance with the FDA authorized and approved indications identified above in paragraphs 67–90 infringes at least exemplary claim 1 of the '401 patent.

RESPONSE: Denied.

192. Defendants have been and are aware that healthcare providers use each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products in the United States in accordance with the FDA authorized and approved indications identified above in paragraphs 67–90 and thereby infringe at least exemplary claim 1 of the '401 patent.

RESPONSE: Denied.

193. None of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products is a staple article or commodity of commerce suitable for use in the United States other than in accordance with the FDA authorized and approved indications identified above in paragraphs 67–90.

RESPONSE: Denied.

194. Defendants actively, knowingly, and specifically intended to induce, and induced, and continue to actively, knowingly, and specifically intend to induce, and induce, infringement of at least claim 1 of the '401 patent by packaging, promoting, selling or otherwise supplying, directly or indirectly, each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products to healthcare providers, with the knowledge and intent that healthcare providers will use the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products supplied by Defendants according to the FDA authorized and approved infringing indications.

RESPONSE: Denied.

195. GSK has suffered and continues to suffer damages from Defendants' infringement of the '401 patent.

RESPONSE: Denied.

196. GSK is entitled to an award of monetary damages, including a reasonable royalty, for Defendants' infringement of the '401 patent.

RESPONSE: Denied.

197. Defendants have had knowledge of the '401 patent and specific notice of its infringement at least since April 24, 2024, by communications between GSK and Defendants. *See* Exhibits 81-82.

RESPONSE: Paragraph 197 states a legal conclusion to which no response is required. To the extent the allegations of Paragraph 197 purport to rely on Exhibits 81–82, those exhibits speak for themselves. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

198. Defendants' infringement of the '401 patent has been and continues to be willful and deliberate at least since they received specific notice of their infringement from GSK on April 24, 2024. *See id.*

RESPONSE: Denied.

199. Defendants' conduct with respect to the '401 patent makes this case exceptional under 35 U.S.C. § 285.

RESPONSE: Denied.

COUNT V

(Infringement of the '467 Patent)

200. GSK incorporates by reference paragraphs 1–199.

RESPONSE: Defendants incorporate by reference their responses contained in Paragraphs 1 through 199.

201. 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. The patent application issuing into the '467 patent was published on April 28, 2022, as Publication No. US 2022/0125722 A1. *See* Exhibit 5 at Prior Publication Data.

RESPONSE: Defendants admit that the U.S. Patent and Trademark Office issued U.S. Pat. No. 11,786,467 entitled "Lipid Formulations with Immunogens" on October 17, 2023, that Exhibit 5 purports to be a copy of the '467 patent, and that Publication No. U.S. 2022/0125722 A1

was published on April 28, 2022 and issued into the '467 patent, but deny that the patent is valid, enforceable, or infringed by Defendants. Defendants deny any remaining allegations of Paragraph 201.

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

RESPONSE: Denied.

203. Defendants have directly infringed and continue to directly infringe one or more claims of the '467 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, or selling, within the United States, or importing into the United States, each of the Accused Products embodying GSK Biologicals's patented inventions as disclosed by and claimed in the '467 patent, without authority or license to do so, during the term of the '467 patent.

RESPONSE: Denied.

204. In addition or in the alternative, Defendants have induced, and continue to induce, direct infringement by third parties of one or more claims of the '467 patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents, by making, selling and/or offering for sale in the United States, and/or importing into the United States, each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products embodying GSK Biologicals's patented inventions as disclosed by and claimed in the '467 patent, without authority or license to do so, during the term of the '467 patent.

RESPONSE: Denied.

205. In addition or in the alternative, Defendants have contributed, and continue to contribute, to the direct infringement by third parties of one or more claims of the '467 patent under 35 U.S.C. § 271(c), either literally or under the doctrine of equivalents, by making, selling and/or offering for sale in the United States, and/or importing into the United States, each of the Accused Products embodying GSK Biologicals's patented inventions as disclosed by and claimed in the '467 patent, without authority or license to do so, during the term of the '467 patent, knowing that those products constitute a material part of the inventions of the '467 patent, knowing that those products are especially made or adapted to infringe the '467 patent, and knowing that those products are not staple articles or commodities of commerce suitable for substantial non-infringing use.

RESPONSE: Denied.

206. For example, on information and belief, each of the Accused Products satisfies each and every element of at least claim 1 of the '467 patent. Defendants' actions with respect to each of the Accused Products have therefore infringed at least this exemplary claim of the '467 patent.

RESPONSE: Denied.

207. Claim 1 of the '467 patent recites:

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.

RESPONSE: Defendants admit that Claim 1 of the '467 patent appears to include the above language. Defendants otherwise deny the remaining allegations of this Paragraph.

208. Each of the Accused Products comprises a “formulation.” See paragraphs 47–66, above at, *e.g.*, Exhibit 34 (April 2023, FDA Comirnaty® (original monovalent) Package Insert) at 19 (“The nucleoside-modified mRNA in COMIRNATY is formulated in lipid particles[.]”); Exhibit 21 (February 19, 2021, EMA Comirnaty® (original monovalent) Assessment Report) at 58 (“The nucleoside-modified messenger RNA in the vaccine is formulated in lipid nanoparticles[.]”).

RESPONSE: Paragraph 208 states a legal conclusion to which no response is required. To the extent the allegations of Paragraph 208 purport to rely on Exhibit 34 and Exhibit 21, those exhibits speak for themselves. Defendants incorporate by reference their responses contained in Paragraphs 47 through 66. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

209. Each of the Accused Products comprises “ribonucleic acid (RNA) molecules comprising a sequence that encodes an immunogen.” See paragraphs 47–66, above at, *e.g.*, Exhibit 34 (April 2023, FDA Comirnaty® (original monovalent) Package Insert) at 19 (“COMIRNATY ... contains 30 mcg of a nucleoside-modified messenger RNA (mRNA) encoding the viral spike glycoprotein of SARS-CoV-2.”); Exhibit 21 (February 19, 2021, EMA Comirnaty® (original

monovalent) Assessment Report) at 15 (“The active substance consists of ... mRNA that is translated into a codon-optimized sequence encoding the spike antigen of SARS-CoV-2[.]”).

RESPONSE: Paragraph 209 states a legal conclusion to which no response is required. To the extent the allegations of Paragraph 209 purport to rely on Exhibit 34 and Exhibit 21, those exhibits speak for themselves. Defendants incorporate by reference their responses contained in Paragraphs 47 through 66. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

210. Each of the Accused Products comprises “lipids comprising a tertiary amine cationic lipid, a polyethylene glycol-conjugated (PEG-conjugated) lipid, and cholesterol.” *See* paragraphs 47–66, above at, *e.g.*, Exhibit 34 (April 2023, FDA Comirnaty® (original monovalent) Package Insert) at 19 (identifying lipid ingredients).

RESPONSE: Paragraph 210 states a legal conclusion to which no response is required. To the extent the allegations of Paragraph 210 purport to rely on Exhibit 34, that exhibit speaks for itself. Defendants incorporate by reference their responses contained in Paragraphs 47 through 66. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

211. ALC-0315 is a “tertiary amine cationic lipid.” *See, e.g.*, Exhibit 21 (February 19, 2021, EMA Comirnaty® (original monovalent) Assessment Report) at 23–24 (“The ALC-0315 novel excipient is a cationic lipid containing a tertiary amine”); Exhibit 71 (ALC-0315 Product Information, Cayman Chemical) (providing structure); Exhibit 72 (Schoenmaker *et al.*, “mRNAlipid nanoparticle COVID-19 vaccines: Structure and Stability,” *Intl. J. Pharm.* 601, 120586 (2021)) at Fig. 6 (providing structure and identifying ALC-0315 as an “[i]onizable cationic lipid”).

RESPONSE: Paragraph 211 states a legal conclusion to which no response is required. To the extent the allegations of Paragraph 211 purport to rely on Exhibit 21, Exhibit 71, and Exhibit 72, those exhibits speak for themselves. Defendants deny that the Accused Products infringe any

valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

212. ALC-0159 is a “polyethylene glycol-conjugated (PEG-conjugated) lipid.” *See, e.g.*, Exhibit 21 (February 19, 2021, EMA Comirnaty® (original monovalent) Assessment Report) at 24 (“The ALC-0159 novel excipient is PEGylated lipid ...”); Exhibit 74 (ALC-0159 Product Information, Echelon Biosciences) (“ALC-0159 is a PEGylated lipid which has been used to form lipid nanoparticles for delivery of RNA. ALC-0159 is one of the components in the BNT162b2 vaccine[.]”); Exhibit 72 (Schoenmaker *et al.*, “mRNA-lipid nanoparticle COVID-19 vaccines: Structure and Stability,” *Intl. J. Pharm.* 601, 120586 (2021)) at Fig. 6 (identifying ALC-0159 to be a “PEG-lipid”).

RESPONSE: Paragraph 212 states a legal conclusion to which no response is required. To the extent the allegations of Paragraph 212 purport to rely on Exhibit 21, Exhibit 74, and Exhibit 72, those exhibits speak for themselves. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

213. Each of the Accused Products is “is immunogenic in vivo by eliciting an antibody response against the immunogen in vivo” at least when used in accordance with the FDA and EMA authorized and approved indications. *See* paragraphs 47–90, above at, *e.g.*, Exhibit 21 (February 19, 2021, EMA Comirnaty® (original monovalent) Assessment Report) at 58 (“The vaccine elicits both neutralizing antibody and cellular immune responses to the spike (S) antigen, which may contribute to protection against COVID-19.”); Exhibit 24 (September 1, 2022, Pfizer press release) (“[T]he bivalent vaccine with mRNA encoding the wild-type and the BA.1 spike proteins provides [] neutralizing antibody titers against the Omicron BA.1 and BA.4/BA.5 sublineages[.]”); Exhibit 25 (November 4, 2022, Pfizer press release) (“Among the overall study population who received the Omicron BA.4/BA.5-adapted bivalent vaccine, there was a substantially higher increase in Omicron BA.4/BA.5-neutralizing antibody titers compared to pre-booster levels.”); Exhibit 64 (September 11, 2023, FDA Comirnaty® (monovalent XBB.1.5) EUA Review Memo) at 17–18 (extrapolating immunological response from the prior Comirnaty® COVID-19 vaccine products and stating, “preclinical data demonstrate that, when compared with the Pfizer-BioNTech COVID 19 Vaccine, Bivalent (Original and Omicron BA.4/BA.5), Pfizer-BioNTech COVID-19 Vaccine (2023-2024 Formula) induces higher neutralizing antibody titers against XBB sublineages, including XBB.1.5, XBB.1.16, XBB.1.16.1, and XBB.2.3.”).

RESPONSE: Paragraph 213 states a legal conclusion to which no response is required. To the extent the allegations of Paragraph 213 purport to rely on Exhibit 21, Exhibit 24, Exhibit 25, and Exhibit 64, those exhibits speak for themselves. Defendants incorporate by reference their

responses contained in Paragraphs 47 through 90. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

214. On information and belief, the lipids of each of the Accused Products “encapsulate at least half of the RNA molecules.” See paragraphs 47–66, above at, *e.g.*, Exhibit 34 (April 2023, FDA Comirnaty® (original monovalent) Package Insert) at 19 (“The nucleoside-modified mRNA in COMIRNATY is formulated in lipid particles, which enable delivery of the mRNA into host cells to allow expression of the SARS-CoV-2 antigen.”); *see also* Exhibit 72 (Schoenmaker *et al.*, “mRNA-lipid nanoparticle COVID-19 vaccines: Structure and Stability,” *Intl. J. Pharm.* 601, 120586 (2021)) at 4 (“In mRNA-LNP formulations, such as those used in mRNA vaccines ...encapsulation efficiencies ... are typically > 90%.”).

RESPONSE: Paragraph 214 states a legal conclusion to which no response is required. To the extent the allegations of Paragraph 214 purport to rely on Exhibit 34 and Exhibit 72, those exhibits speak for themselves. Defendants incorporate by reference their responses contained in Paragraphs 47 through 66. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

215. Defendants packaged, promoted, and sold, and continue to package promote and sell, each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products in the United States with FDA-approved packaging and package inserts comprising labeling and prescribing information that instruct health care practitioners on their use in accordance with the FDA authorized and approved indications. See paragraphs 47–90, above at, *e.g.*, Exhibit 34 (April 2023, FDA Comirnaty® (original monovalent) Package Insert); Exhibit 35 (July 14, 2023, FDA Comirnaty® (bivalent BA.4/5) EUA Fact Sheet and Package Insert); Exhibit 33 (September 2023, FDA Comirnaty® (monovalent XBB.1.5) Package Insert).

RESPONSE: Paragraph 215 states a legal conclusion to which no response is required. To the extent the allegations of Paragraph 215 purport to rely on Exhibit 34, Exhibit 35, and Exhibit 33, those exhibits speak for themselves. Defendants incorporate by reference their responses contained in Paragraphs 47 through 90. Defendants deny that the Accused Products infringe any

valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

216. Defendants created and disseminated, and continue to create and disseminate, by means separate from the packaging and package inserts of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products, supporting materials, instructions, and/or technical information that instruct health care practitioners on the use of each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products in the United States in accordance with the FDA authorized and approved indications. *See, e.g.*, Exhibit 78 (www.comirnaty.com as preserved by The Wayback Machine, August, 27, 2021¹⁹); Exhibit 79 (www.comirnaty.com/eua-bivalent as preserved by The Wayback Machine, September, 22, 2022²⁰); Exhibit 80 (www.comirnaty.com/eua-six-months-to-eleven-years; preserved April 5, 2024).

RESPONSE: Paragraph 216 states a legal conclusion to which no response is required.

To the extent the allegations of Paragraph 216 purport to rely on Exhibit 78, Exhibit 79, and Exhibit 80, those exhibits speak for themselves. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

217. Defendants have been and are aware that the use of each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products in the United States in accordance with the FDA authorized and approved indications identified above in paragraphs 67–90 infringes at least exemplary claim 1 of the '467 patent.

RESPONSE: Denied.

218. Defendants have been and are aware that healthcare providers use each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products in the United States in accordance with the FDA authorized and approved indications identified above in paragraphs 67–90 and thereby infringe at least exemplary claim 1 of the '467 patent.

RESPONSE: Denied.

¹⁹ Available at <https://web.archive.org/web/20210827220339/https://www.comirnaty.com/>; preserved on April 5, 2024.

²⁰ Available at <https://web.archive.org/web/20220922181232/https://www.comirnaty.com/euabivalent>; preserved on April 5, 2024.

219. None of the Accused Products is a staple article or commodity of commerce suitable for use in the United States other than in accordance with the FDA authorized and approved indications identified above in paragraphs 67–90.

RESPONSE: Denied.

220. Defendants actively, knowingly, and specifically intended to induce, and induced, and continue to actively, knowingly, and specifically intend to induce, and induce, infringement of at least claim 1 of the '467 patent by packaging, promoting, selling or otherwise supplying, directly or indirectly, each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products to healthcare providers, with the knowledge and intent that healthcare providers will use the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products supplied by Defendants according to the FDA authorized and approved infringing indications.

RESPONSE: Denied.

221. GSK has suffered and continues to suffer damages from Defendants' infringement of the '467 patent.

RESPONSE: Denied.

222. GSK is entitled to an award of monetary damages, including a reasonable royalty, for Defendants' infringement of the '467 patent.

RESPONSE: Denied.

223. Defendants have had knowledge of the '467 patent and specific notice of its infringement at least since April 24, 2024, by communications between GSK and Defendants. *See* Exhibits 81-82.

RESPONSE: Paragraph 223 states a legal conclusion to which no response is required. To the extent the allegations of Paragraph 223 purport to rely on Exhibits 81–82, those exhibits speak for themselves. Defendants deny that the Accused Products infringe any valid and enforceable claim of the Patents-in-Suit. Defendants otherwise deny the remaining allegations of this Paragraph.

224. Defendants' infringement of the '467 patent has been and continues to be willful and deliberate at least since they received specific notice of their infringement from GSK on April 24, 2024. *See id.*

RESPONSE: Denied.

225. Defendants' conduct with respect to the '467 patent makes this case exceptional under 35 U.S.C. § 285.

RESPONSE: Denied.

PRAYER FOR RELIEF

Defendants deny all allegations not expressly admitted herein. The remainder of Plaintiffs' Complaint is a prayer for relief and does not require a response. To the extent any response is required, Defendants deny that Plaintiffs are entitled to any of the remedies or relief included in clauses (A) through (H) of Plaintiffs' Prayer for Relief.

DEMAND FOR JURY TRIAL

Defendants join Plaintiffs' request for a trial by jury on all claims so triable in this action.

AFFIRMATIVE DEFENSES

Further answering the Complaint, Defendants assert the following defenses without assuming any burden that they would not otherwise have, including without admitting or acknowledging that they bear the burden of proof as to any of them. Defendants reserve the right to amend their answer in accordance with the Federal Rules of Civil Procedure and Local Civil Rules of the U.S. District Court for the District of Delaware to assert additional defenses as further information is obtained.

FIRST AFFIRMATIVE DEFENSE
(NON-INFRINGEMENT OF THE ASSERTED PATENTS)

Defendants have not infringed any valid and enforceable claim of the Patents-in-Suit, either directly or indirectly.

SECOND AFFIRMATIVE DEFENSE
(INVALIDITY OF THE ASSERTED PATENTS)

Each and every claim of the Patents-in-Suit is invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq.*, including, without limitation, the requirements

of 35 U.S.C. §§ 101, 102, 103, 112 and/or 256 and/or any other judicially created requirements for patentability and enforceability of patent and/or in view of the defenses recognized in 35 U.S.C. § 282.

THIRD AFFIRMATIVE DEFENSE
(PATENT MISUSE)

Plaintiffs have sought to enforce the Patents-in-Suit for products and acts that Plaintiffs know are outside the claims of the Patents-in-Suit, rendering the Patents-in-Suit unenforceable on account of patent misuse.

FOURTH AFFIRMATIVE DEFENSE
(FAILURE TO STATE A CLAIM)

Plaintiffs' Complaint fails to state a claim on which relief can be granted.

FIFTH AFFIRMATIVE DEFENSE
(PROSECUTION LACHES)

Plaintiffs are barred by the doctrine of prosecution laches from enforcing the Patents-in-Suit against Defendants, as Plaintiffs unreasonably and inexcusably delayed prosecuting the patent applications that led to the Patents-in-Suit, prejudicing Defendants.

SIXTH AFFIRMATIVE DEFENSE
(NO WILLFUL INFRINGEMENT)

Defendants have not willfully infringed, and do not willfully infringe, any valid and enforceable claim of any of the Patents-in-Suit.

SEVENTH AFFIRMATIVE DEFENSE
(NO EXCEPTIONAL CASE)

Defendants' actions in defending this case or otherwise do not give rise to an exceptional case in Plaintiffs' favor under 35 U.S.C. § 285.

EIGHTH AFFIRMATIVE DEFENSE
(PROSECUTION DISCLAIMER AND ESTOPPEL)

Plaintiffs are barred, based on statements, representations, and admissions made during prosecution of the patent applications resulting in the Patents-in-Suit or related patent applications, from asserting any interpretation of any valid and enforceable claims of the Patents-in-Suit that would be broad enough to cover any Accused Product alleged to infringe the Patents-in-Suit, either literally or by application of the doctrine of equivalents, or under any theory of infringement.

NINTH AFFIRMATIVE DEFENSE
(LACK OF STANDING)

Plaintiffs do not hold all substantial right, title, and interest to the Patents-in-Suit and lack standing to bring or maintain this lawsuit in connection with the Patents-in-Suit. Plaintiffs have failed to adequately plead or prove that each Plaintiff has ownership, control, and/or exclusive rights to the Patents-in-Suit in their Complaint.

TENTH AFFIRMATIVE DEFENSE
(ESTOPPEL, WAIVER, ACQUIESCENCE, AND UNCLEAN HANDS)

Plaintiffs' claims and/or requested relief are barred by one or more of the doctrines of estoppel, waiver, acquiescence, and unclean hands from enforcing or claiming damages with respect to any claim of the Patents-in-Suit.

ELEVENTH AFFIRMATIVE DEFENSE
(35 U.S.C. § 271(e)(1))

Aspects of Defendants' alleged infringement of the Asserted Patents are reasonably related to Defendants' development and submission of information to the FDA for the Emergency Use Authorization and the Biologics License Application regarding Comirnaty®, and such claims against Defendants are barred by the safe harbor of 35 U.S.C. § 271(e)(1).

TWELFTH AFFIRMATIVE DEFENSE
(LIMITATIONS ON DAMAGES)

Pursuant to the requirements of 35 U.S.C. §§ 286–287, GSK’s ability to recover any purported damages for any alleged infringement is limited or barred.

THIRTEENTH AFFIRMATIVE DEFENSE
(NO COSTS)

Plaintiffs are barred by 35 U.S.C. § 288 from recovering any costs associated with this action.

FOURTEENTH AFFIRMATIVE DEFENSE
(ADDITIONAL DEFENSES)

Defendants reserve the right to assert further defenses in the event that discovery indicates that such defenses would be appropriate.

COUNTERCLAIMS

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Pfizer Inc. (“Pfizer”) and Pharmacia & Upjohn Co. LLC (“Pharmacia”) (collectively, “Pfizer”) and BioNTech SE, BioNTech Manufacturing GmbH (“BioNTech Manufacturing”), and BioNTech US Inc. (“BioNTech US”) (collectively, “BioNTech,” and together with Pfizer, “Counterclaimants” or “Defendants”), by and through their attorneys, bring the following Counterclaims against GlaxoSmithKline Biologicals SA (“GSK Biologicals”) and GlaxoSmithKline LLC (“GSK LLC”) (collectively, “GSK” or “Counterclaim-Defendants” or “Plaintiffs”):

1. Counterclaimants on personal knowledge as to their own acts, and on information and belief as to all others based on their own and their attorneys’ investigation, and without admitting the allegations of Counterclaim-Defendants other than those expressly admitted herein, bring the following Counterclaims against GSK for declaratory judgment that United States Patent Nos. 11,638,693 (the “’693 Patent”), 11,638,694 (the “’694 Patent”), 11,666,534 (the “’534

Patent”), 11,766,401 (the “401 Patent), and 11,786,467 (the “467 Patent”) (collectively, the “Asserted Patents” or “Patents-in-Suit”) are invalid, unenforceable, and not infringed by Counterclaimants.

2. These Counterclaims are brought by BioNTech and Pfizer who partnered together, and continue to work together, to address the greatest public health threat the United States and the world has faced in at least a century: the COVID-19 pandemic. Now, BioNTech and Pfizer must also face threats of a groundless patent infringement suit by a company, GSK, who was unable to bring to market any product in the U.S. to help in the fight against COVID-19. Instead, GSK looked to a patent portfolio it had previously acquired from Novartis AG, located a pending family that had been in prosecution for over a decade, and filed new applications in an attempt to create claims that would encompass Pfizer and BioNTech’s vaccine after the details of that vaccine became publicly available.

3. BioNTech and Pfizer partnered together to develop, manufacture, and secure regulatory approval for a vaccine that proved to be effective in preventing severe disease, hospitalization, and death from COVID-19 infection. BioNTech and Pfizer did so at great risk to their companies, by investing considerable sums of money and countless hours in an effort to address this global pandemic. BioNTech and Pfizer successfully developed a product, proved its efficacy, established global manufacturing and supply chains, and gained regulatory approval in record time. Through their efforts they were able to help the United States and the world begin to move past the COVID-19 public health crisis.

4. Unlike BioNTech’s and Pfizer’s efforts, GSK’s failed. Although GSK’s Complaint repeatedly refers to the alleged innovations of the “Mandl team,” neither that team nor anyone at GSK marketed a COVID-19 vaccine for the U.S.

5. Further, the only person from the “Mandl team” identified as a purported inventor on the applications that led to the Asserted Patents is Andrew Geall. None of the Asserted Patents list Mandl or any other members of the “Mandl team” as an inventor.

6. In an attempt to profit from the success of BioNTech and Pfizer through threats of patent infringement, GSK began to prosecute the Geall applications to obtain the Asserted Patents after detailed information regarding Pfizer and BioNTech’s vaccine was publicly known.

7. The Asserted Patents only describe liposomes and self-replicating RNA. They do not describe the lipid nanoparticles (“LNPs”) or mRNA of Pfizer and BioNTech’s COVID-19 vaccine.

8. GSK is attempting to expand the scope of the Asserted Patents beyond anything that was invented by the Mandl team or Andrew Geall to accuse Pfizer and BioNTech’s vaccine of infringement.

9. GSK is seeking damages for a product that it did not invent.

10. BioNTech and Pfizer bring these Counterclaims to resolve GSK’s meritless allegations.

11. Counterclaimants repeat and incorporate by reference each of the foregoing paragraphs of Defendants’ Answer, Affirmative Defenses, and Counterclaims in Response to Complaint for Patent Infringement, as if fully set forth herein.

THE PARTIES

12. Pfizer is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 66 Hudson Boulevard East, New York, New York 10001.

13. Pharmacia is a limited liability company organized and existing under the laws of the State of Delaware, with its principal place of business at 100 Route 206 N. Peapack, New Jersey 07977.

14. BioNTech SE is a corporation organized and existing under the laws of Germany, with its principal place of business at An der Goldgrube 12, D-55131 Mainz, Germany.

15. BioNTech Manufacturing GmbH is a limited liability company organized and existing under the laws of Germany, with its principal place of business at An der Goldgrube 12, D-55131 Mainz, Germany.

16. BioNTech US Inc. is a corporation organized and existing under the laws of Delaware, with its principal place of business at 40 Erie St., Suite 110, Cambridge, MA 02139.

17. According to its Complaint, 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.

18. According to its Complaint, 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.

JURISDICTION AND VENUE

19. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202 based on an actual controversy among the parties arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

20. Personal jurisdiction over GSK Biologicals is proper because, among other things, it has consented to the personal jurisdiction of the Court by commencing its action for patent infringement in this judicial district, as set forth in its Complaint.

21. Personal jurisdiction over GSK LLC is proper because, among other things, it has consented to the personal jurisdiction of the Court by commencing its action for patent infringement in this judicial district, as set forth in its Complaint.

22. Venue is proper in this judicial district based on the choice of forum by GSK Biologicals and GSK LLC and under 28 U.S.C. § 1391(b)–(c).

23. There is an actual and justiciable controversy among the parties concerning non-infringement and invalidity of the Asserted Patents.

CASE AND CONTROVERSY

24. The '693 Patent, titled "Vaccine for Eliciting Immune Response Comprising RNA Encoding an Immunogen and Lipid Formulations Comprising Mole Percentage of Lipids," states an issue date of May 2, 2023 and names as inventor Andrew Geall. Upon information and belief, a true and correct copy of the '693 Patent is attached to the Complaint as Exhibit 1 (D.I. 1-1).

25. The '694 Patent, titled "Vaccine for Eliciting Immune Response Comprising Lipid Formulations and RNA Encoding Multiple Immunogens," states an issue date of May 2, 2023 and names as inventor Andrew Geall. Upon information and belief, a true and correct copy of the '694 Patent is attached to the Complaint as Exhibit 2 (D.I. 1-2).

26. The '534 Patent, titled "Methods of Administering Lipid Formulations with Viral Immunogens," states an issue date of June 6, 2023 and names as inventor Andrew Geall. Upon information and belief, a true and correct copy of the '534 Patent is attached to the Complaint as Exhibit 3 (D.I. 1-3).

27. The '401 Patent, titled "Methods of Administering Formulations with Immunogens," states an issue date of September 26, 2023 and names as inventor Andrew Geall.

Upon information and belief, a true and correct copy of the '401 Patent is attached to the Complaint as Exhibit 4 (D.I. 1-4).

28. The '467 Patent, titled "Lipid Formulations with Immunogens," states an issue date of October 17, 2023 and names as inventor Andrew Geall. Upon information and belief, a true and correct copy of the '467 Patent is attached to the Complaint as Exhibit 5 (D.I. 1-5).

29. According to the Complaint, GSK Biologicals purports to be the owner by assignment of all Asserted Patents.

30. According to the Complaint, GSK LLC purports to be the exclusive distributor of any products covered by the Asserted Patents in the United States.

31. An actual, substantial, and justifiable controversy, within the meaning of 28 U.S.C. §§ 2201 and 2202, exists between Counterclaimants and Counterclaim-Defendants.

32. Counterclaimants are entitled to a judicial determination and declaration that they have not infringed and are not infringing the Asserted Patents and that the Asserted Patents are invalid, unenforceable, and not infringed.

PFIZER AND BIONTECH'S DEVELOPMENT OF COMIRNATY®

33. In December of 2019, it was discovered that an outbreak of pneumonia among people who had visited the Huanan Seafood Wholesale Market in Wuhan, China was caused by a novel coronavirus, eventually designated by the World Health Organization as SARS-CoV-2 with the disease it causes reclassified as Coronavirus disease 2019 ("COVID-19").

34. COVID-19 quickly spread around the world and tore through populations that were immunologically naïve, threatening the collapse of the healthcare system and the loss of life at scales not seen since the advent of modern medicine. What began first as small area lockdowns to prevent the transmission of disease and temporary stay-at-home orders eventually became

society altering restrictions. Many saw that the only path out of the pandemic was the development of successful vaccines against the disease.

35. On January 10, 2020, the Chinese Center for Disease Control published the genetic sequence of SARS-CoV-2.

36. BioNTech scientists had been working in the field of mRNA technology since at least the founding of the company in 2008. BioNTech was working on messenger RNA (“mRNA”)-based clinical vaccine candidates by the early- to mid-2010s. BioNTech was earning itself a reputation as an industry leader in mRNA technology.

37. To combat the pandemic, BioNTech scientists set to work on developing a COVID-19 disease vaccine. BioNTech was able to do so by building on its existing development work and experience with mRNA-based clinical vaccine candidates. BioNTech eventually identified a product candidate as a potential mRNA-based vaccine that would protect against COVID-19.

38. In March 2020, Pfizer and BioNTech began a collaborative effort focused on bringing a COVID-19 disease vaccine to market. The vaccine that ultimately emerged from this partnership was a novel mRNA vaccine now known as Comirnaty®.

39. Clinical trials of Pfizer/BioNTech vaccine candidates began in late April of 2020, with preliminary Phase 3 results demonstrating their safety and efficacy published in just over six months.

40. On November 20, 2020, Pfizer, on behalf of itself and BioNTech, submitted its clinical trial data as part of its Emergency Use Authorization (“EUA”) request to the Food and Drug Administration (“FDA”) for administering its mRNA vaccine to people 16 years of age and older.

41. On December 10, 2020, the FDA granted the first EUA for a COVID-19 vaccine to Pfizer and BioNTech's mRNA vaccine (now known as Comirnaty®) with vaccinations rolling out immediately thereafter, reflecting the fastest development of a vaccine in history.

42. The FDA provided Pfizer and BioNTech's vaccine with full approval on August 23, 2021.

43. Since being granted EUA, millions of doses of Comirnaty® have been administered worldwide, resulting in countless numbers of lives saved while easing the strain of an otherwise uncontrollable pandemic. During this same time, GSK Biologicals and GSK LLC did not develop or sell any COVID-19 vaccine.

44. On April 25, 2024, GSK sued Counterclaimants for infringement of the '693 Patent, '694 Patent, '534 Patent, '401 Patent, and '467 Patent, alleging that Counterclaimants had incorporated the claimed subject matter of the Patents-in-Suit into the Comirnaty® vaccine in an infringing manner.

45. In view of the foregoing, a conflict of asserted rights has arisen between Counterclaimants and GSK with respect to noninfringement, invalidity, and unenforceability of the claims of the '693 Patent, '694 Patent, '534 Patent, '401 Patent, and '467 Patent.

**GSK'S ACQUISITION AND SUBSEQUENT PROSECUTION OF NOVARTIS
APPLICATIONS AFTER PFIZER AND BIONTECH'S
VACCINE WAS PUBLICLY DISCLOSED**

46. On July 6, 2010, well before the beginning of the COVID-19 pandemic, Novartis Vaccines and Diagnostics, Inc. ("Novartis Vaccines") filed the first provisional application in the family of patents now asserted by GSK against Pfizer and BioNTech, U.S. Provisional Patent Application No. 61/361,830 (the "'830 Application"), entitled "Tertiary Amine Liposomes for RNA Delivery," with claims that state "[a] **liposome having a lipid bilayer encapsulating an aqueous core**, wherein: (i) the lipid bilayer comprises a lipid having a tertiary amine and a pKa

in the range of 5.0 to 7.6; and (ii) the aqueous core includes a RNA which encodes an immunogen.” (Emphasis added). The specification states “[t]he RNA is +-stranded” and “[p]referred +-stranded RNAs are **self-replicating**.” (Emphasis added). Encapsulation of mRNA is not reported.

47. On August 31, 2010, Novartis Vaccines filed the second provisional application in this family, U.S. Provisional Patent Application No. 61/378,837 (the “’837 Application”), entitled “Liposomes with Lipids Having Advantageous pKa for RNA Delivery,” with claims that state “[a] **liposome having a lipid bilayer encapsulating an aqueous core**, wherein: (i) the lipid bilayer comprises a lipid having a pKa in the range of 5.0 to 7.6; and (ii) the aqueous core includes a RNA which encodes an immunogen.” (Emphasis added). The specification states “[t]he RNA is +-stranded” and “[p]referred +-stranded RNAs are **self-replicating**.” (Emphasis added). Encapsulation of mRNA is not reported.

48. On March 14, 2013, Novartis Vaccines filed the first non-provisional patent application in this family, U.S. Patent Application No. 13/808,080 (the “’080 Application”), entitled “Liposomes with Lipids Having an Advantageous pKa Value for RNA Delivery,” which originally claimed after a preliminary amendment “[a] **liposome having a lipid bilayer encapsulating an aqueous core**, wherein: (i) the lipid bilayer comprises having a pKa in the range of 5.0 to 7.6; and (ii) the aqueous core includes a **RNA** which encodes an immunogen.” (Emphasis added).

49. On April 1, 2013, Novartis Vaccines purported to assign the ’080 Application to Novartis AG.

50. On December 16, 2014, the Examiner issued final rejections under 35 U.S.C. § 103(a) for all pending claims as obvious in light of Maclachlan et al., (WO2005/120152), in view of Martinon et al., (Eur. J. Immunol., 1993, 23:1719–1722), finding that “Maclachlan provides

multiple embodiments of siRNAs encapsulated in liposomes comprising the cationic lipid DLinDMA.”

51. On information and belief, a few months later in March 2015, GSK acquired Novartis AG’s vaccines business (excluding influenza vaccines). (Exhibit A.)

52. On June 22, 2016, assignment documents were filed with the U.S. Patent & Trademark Office purporting that the ’080 Application was assigned to GSK Biologicals as of June 15, 2016.

53. On June 16, 2015, to overcome the Examiner’s rejections, the applicant, now GSK Biologicals, amended the claims to recite that “the aqueous core comprises **a self-replicating RNA** which encodes a polypeptide immunogen.” (Emphasis added). Thus, GSK limited the claims to self-replicating RNA to overcome the prior art.

54. Thereafter, between June 2015 and December 2020, GSK Biologicals filed three requests for continued examination. During that period, all of the claims filed in connection with the ’080 Application were directed to “liposomes” and “self-replicating RNA.” Each request for continued examination resulted in a final rejection for all pending claims.

55. While GSK Biologicals was still prosecuting the ’080 Application, Pfizer and BioNTech were granted Emergency Use Authorization for their COVID-19 vaccines on December 10, 2020.

56. On April 9, 2021, the composition of the Pfizer and BioNTech COVID-19 vaccine was published in *Nature*. (Exhibit B.)

57. On August 23, 2021, FDA provided full approval to Pfizer and BioNTech for the first COVID-19 vaccine.

58. Just two months after Pfizer and BioNTech's COVID-19 vaccine received FDA full approval, on October 28, 2021, GSK Biologicals filed a fourth request for continued examination and amended the claims of the '080 Application to include "**RNA molecules**" rather than "**self-replicating RNA molecules.**" (Emphasis added). The claims continued to include "liposomes," reciting "[a] pharmaceutical composition being immunogenic *in vivo* and comprising: **liposomes** and RNA molecules; the **liposomes** being suitable for *in vivo* cellular delivery of the RNA molecules." (Emphasis added).

59. On December 22, 2021, GSK Biologicals filed six new non-provisional patent applications in this family: U.S. Patent Application Nos. 17/560,019 (the "'019 Application"), 17/560,052 (the "'052 Application"), 17/560,059 (the "'059 Application"), 17/560,092 (the "'092 Application"), 17/560,116 (the "'116 Application"), 17/560,138 (the "'183 Application"). Each of the applications sought claims reciting "RNA" wherein "the lipids encapsulate" the RNA molecules.

60. On June 23, 2022, GSK Biologicals filed five new non-provisional patent applications in this family: U.S. Patent Application Nos. 17/808,519 (the "'519 Application"), 17/848,294 (the "'294 Application"), 17/848,299 (the "'299 Application"), 17/848,325 (the "'325 Application"), and 17/848,337 (the "'337 Application"). Each of the applications sought claims reciting "RNA" wherein "the lipids encapsulate" the RNA molecules or "[a] formulation comprising . . . RNA . . . and lipids."

61. Of the eleven applications filed on December 22, 2021 and June 23, 2022, five issued as the Asserted Patents—the '693 Patent and '694 Patent issued on May 2, 2023, the '534 Patent issued on June 6, 2023, the '401 Patent issued on September 26, 2023, and the '467 Patent

issued on October 17, 2023. The Asserted Patents each issued with claims reciting “RNA” wherein “the lipids encapsulate” the RNA molecules.

**PFIZER AND BIONTECH ARE PREJUDICED BY THE DELAY IN PROSECUTION
OF GSK AND ITS PREDECESSORS-IN-INTEREST**

62. Following the first provisional application’s filing on July 6, 2010, GSK Biologicals (collectively with its predecessors-in-interest Novartis Vaccines and Novartis AG, “Applicant”) unreasonably delayed pursuing the claims of the Asserted Patents for over a decade before it pursued claims reciting “RNA” wherein “the lipids encapsulate” the RNA molecules.

63. It was not until the details of Pfizer and BioNTech’s COVID-19 vaccine became publicly available that GSK pursued the patent claims it now asserts against them.

64. As a result of Applicant’s unexplained and unreasonable delay, Pfizer and BioNTech have been prejudiced. For example, Pfizer and BioNTech invested time and resources in the development of the Accused Products during Applicant’s delay. Pfizer and BioNTech developed the first COVID-19 vaccine to combat COVID-19. Rather than market its own vaccine in the U.S., GSK filed applications at the Patent Office in an attempt to cover Pfizer and BioNTech’s successful innovations.

65. The final issued claims in the Asserted Patents are not supported by the written description. The final claims reference “RNA” when claims to RNA had already been rejected over the prior art and GSK had to specify “self-replicating RNA.” The claims also reference that the “lipids encapsulate the” RNA, whereas the only support in the specification is for “liposomes.”

66. Pfizer and BioNTech are also prejudiced because certain prior art may no longer be available now that over a decade has passed since Applicant filed the first provisional application. As a result of its delay, Applicant was able to draft claims in view of new information and products that did not exist at the time of its initial filing.

**GSK IMPROPERLY SEEKS TO PROFIT FROM PFIZER AND BIONTECH'S
COMIRNATY® COVID-19 VACCINE**

67. GSK's belated efforts to improperly expand its patent portfolio try to capitalize on Pfizer and BioNTech's success.

68. GSK now seeks to profit not from technology GSK or its predecessors invented, but rather from improperly contorting the specification and/or claims of the family of its recent patent applications to what it alleges covers Comirnaty®.

69. GSK does not report having made and used an LNP encapsulating mRNA in any of the Asserted Patents.

70. GSK's alleged lipid technology is not a COVID-19 vaccine.

71. GSK's alleged lipid technology has never been included in a COVID-19 vaccine.

72. GSK is seeking damages for an invention that it did not create, and which it did not prosecute at the Patent Office until the composition of Comirnaty® was publicly available.

COUNT I – DECLARATION OF NON-INFRINGEMENT ('693 PATENT)

73. Counterclaimants incorporate by reference paragraphs 1 through 72 of their Counterclaims as if fully set forth herein.

74. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Counterclaimants and Counterclaim-Defendants concerning the infringement of the '693 Patent. GSK has accused Counterclaimants of activities that it claims infringe the '693 Patent.

75. Counterclaimants do not and have not infringed, either directly or indirectly, any valid and enforceable claim of the '693 Patent.

76. Counterclaimants are entitled to a declaratory judgment from this Court that they do not and have not infringed any claim of the '693 Patent.

77. This is an exceptional case under 35 U.S.C. § 285, entitling Counterclaimants to an award of attorneys' fees incurred in connection with this matter.

COUNT II – DECLARATION OF NON-INFRINGEMENT ('694 PATENT)

78. Counterclaimants incorporate by reference paragraphs 1 through 77 of their Counterclaims as if fully set forth herein.

79. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Counterclaimants and Counterclaim-Defendants concerning the infringement of the '694 Patent. GSK has accused Counterclaimants of activities that it claims infringe the '694 Patent.

80. Counterclaimants do not and have not infringed, either directly or indirectly, any valid and enforceable claim of the '694 Patent.

81. Counterclaimants are entitled to a declaratory judgment from this Court that they do not and have not infringed any claim of the '694 Patent.

82. This is an exceptional case under 35 U.S.C. § 285, entitling Counterclaimants to an award of attorneys' fees incurred in connection with this matter.

COUNT III – DECLARATION OF NON-INFRINGEMENT ('534 PATENT)

83. Counterclaimants incorporate by reference paragraphs 1 through 82 of their Counterclaims as if fully set forth herein.

84. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial,

and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Counterclaimants and Counterclaim-Defendants concerning the infringement of the '534 Patent. GSK has accused Counterclaimants of activities that they claim infringe the '534 Patent.

85. Counterclaimants do not and have not infringed, either directly or indirectly, any valid and enforceable claim of the '534 Patent.

86. Counterclaimants are entitled to a declaratory judgment from this Court that they do not and have not infringed any claim of the '534 Patent.

87. This is an exceptional case under 35 U.S.C. § 285, entitling Counterclaimants to an award of attorneys' fees incurred in connection with this matter.

COUNT IV – DECLARATION OF NON-INFRINGEMENT ('401 PATENT)

88. Counterclaimants incorporate by reference paragraphs 1 through 87 of their Counterclaims as if fully set forth herein.

89. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Counterclaimants and Counterclaim-Defendants concerning the infringement of the '401 Patent. GSK has accused Counterclaimants of activities that they claim infringe the '401 Patent.

90. Counterclaimants do not and have not infringed, either directly or indirectly, any valid and enforceable claim of the '401 Patent.

91. Counterclaimants are entitled to a declaratory judgment from this Court that they do not and have not infringed any claim of the '401 Patent.

92. This is an exceptional case under 35 U.S.C. § 285, entitling Counterclaimants to an award of attorneys' fees incurred in connection with this matter.

COUNT V – DECLARATION OF NON-INFRINGEMENT ('467 PATENT)

93. Counterclaimants incorporate by reference paragraphs 1 through 92 of their Counterclaims as if fully set forth herein.

94. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Counterclaimants and Counterclaim-Defendants concerning the infringement of the '467 Patent. GSK has accused Counterclaimants of activities that they claim infringe the '467 Patent.

95. Counterclaimants do not and have not infringed, either directly or indirectly, any valid and enforceable claim of the '467 Patent.

96. Counterclaimants are entitled to a declaratory judgment from this Court that they do not and have not infringed any claim of the '467 Patent.

97. This is an exceptional case under 35 U.S.C. § 285, entitling Counterclaimants to an award of attorneys' fees incurred in connection with this matter.

COUNT VI – DECLARATION OF INVALIDITY ('693 PATENT)

98. Counterclaimants incorporate by reference paragraphs 1 through 97 of their Counterclaims as if fully set forth herein.

99. The claims of the '693 Patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq.*, including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or any other judicially created requirements of

patentability and enforceability of patents and/or in view of the defenses recognized in 35 U.S.C. § 282.

100. Counterclaimants are entitled to a declaratory judgment from this Court that the '693 Patent is invalid.

101. This is an exceptional case under 35 U.S.C. § 285, entitling Counterclaimants to an award of attorneys' fees incurred in connection with this matter.

COUNT VII – DECLARATION OF INVALIDITY ('694 PATENT)

102. Counterclaimants incorporate by reference paragraphs 1 through 101 of their Counterclaims as if fully set forth herein.

103. The claims of the '694 Patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq.*, including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or any other judicially created requirements of patentability and enforceability of patents and/or in view of the defenses recognized in 35 U.S.C. § 282.

104. Counterclaimants are entitled to a declaratory judgment from this Court that the '694 Patent is invalid.

105. This is an exceptional case under 35 U.S.C. § 285, entitling Counterclaimants to an award of attorneys' fees incurred in connection with this matter.

COUNT VIII – DECLARATION OF INVALIDITY ('534 PATENT)

106. Counterclaimants incorporate by reference paragraphs 1 through 105 of their Counterclaims as if fully set forth herein.

107. The claims of the '534 Patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq.*, including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or any other judicially created requirements of

patentability and enforceability of patents and/or in view of the defenses recognized in 35 U.S.C. § 282.

108. Counterclaimants are entitled to a declaratory judgment from this Court that the '534 Patent is invalid.

109. This is an exceptional case under 35 U.S.C. § 285, entitling Counterclaimants to an award of attorneys' fees incurred in connection with this matter.

COUNT IX – DECLARATION OF INVALIDITY ('401 PATENT)

110. Counterclaimants incorporate by reference paragraphs 1 through 109 of their Counterclaims as if fully set forth herein.

111. The claims of the '401 Patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq.*, including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or any other judicially created requirements of patentability and enforceability of patents and/or in view of the defenses recognized in 35 U.S.C. § 282.

112. Counterclaimants are entitled to a declaratory judgment from this Court that the '401 Patent is invalid.

113. This is an exceptional case under 35 U.S.C. § 285, entitling Counterclaimants to an award of attorneys' fees incurred in connection with this matter.

COUNT X – DECLARATION OF INVALIDITY ('467 PATENT)

114. Counterclaimants incorporate by reference paragraphs 1 through 113 of their Counterclaims as if fully set forth herein.

115. The claims of the '467 Patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq.*, including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or any other judicially created requirements of

patentability and enforceability of patent and/or in view of the defenses recognized in 35 U.S.C. § 282.

116. Counterclaimants are entitled to a declaratory judgment from this Court that the '467 Patent is invalid.

117. This is an exceptional case under 35 U.S.C. § 285, entitling Counterclaimants to an award of attorneys' fees incurred in connection with this matter.

COUNT XI – DECLARATION OF PATENT MISUSE ('693 PATENT)

118. Counterclaimants incorporate by reference paragraphs 1 through 117 of their Counterclaims as if fully set forth herein.

119. GSK has sought to enforce and/or license the '693 Patent for products and acts it knows are outside the claims of the '693 Patent.

120. For at least six years prior to December 22, 2021, all claims sought specified that the RNA was self-replicating RNA.

121. Prior to December 22, 2021, all claims sought were directed to a "liposome" encapsulating RNA.

122. All embodiments encapsulating an RNA in the '693 Patent disclose only self-replicating RNA molecules as the RNA, unlike the mRNA used in Comirnaty®.

123. All embodiments encapsulating an RNA in the '693 Patent disclose only liposomes encapsulating the RNA, unlike the LNPs used in Comirnaty®.

124. GSK only began prosecuting the claims of the '693 Patent, directed to "RNA" where "the lipids encapsulate" the RNA, after the composition of Comirnaty® was published and years after the alleged priority date of the '693 Patent.

125. There is no support for the claims of the '693 Patent in its specification.

126. GSK's conduct in seeking to license and enforce the '693 Patent against products and acts that it knows to be outside the scope of the claims of the '693 Patent and outside the scope of what was actually invented is an attempt to seek an improper economic benefit.

127. GSK has engaged in a course of conduct that seeks to broaden the scope of the '693 Patent with anticompetitive effect.

128. GSK's misuse of the '693 Patent renders it unenforceable.

129. This is an exceptional case under 35 U.S.C. § 285, entitling Counterclaimants to an award of attorneys' fees incurred in connection with this matter.

COUNT XII – DECLARATION OF PATENT MISUSE ('694 PATENT)

130. Counterclaimants incorporate by reference paragraphs 1 through 129 of their Counterclaims as if fully set forth herein.

131. GSK has sought to enforce and/or license the '694 Patent for products and acts it knows are outside the claims of the '694 Patent.

132. For at least six years prior to December 22, 2021, all claims sought specified that the RNA was self-replicating RNA.

133. Prior to December 22, 2021, all claims sought were directed to a "liposome" encapsulating RNA.

134. All embodiments encapsulating an RNA in the '694 Patent disclose only self-replicating RNA molecules as the RNA, unlike the mRNA used in Comirnaty®.

135. All embodiments encapsulating an RNA in the '694 Patent disclose only liposomes encapsulating the RNA, unlike the LNPs used in Comirnaty®.

136. GSK only began prosecuting the claims of the '694 Patent, directed to "RNA" where "the lipids encapsulate" the RNA after the composition of Comirnaty® was published and years after the alleged priority date of the '694 Patent.

137. There is no support for the claims of the '694 Patent in its specification.

138. GSK's conduct in seeking to license and enforce the '694 Patent against products and acts that it knows to be outside the scope of the claims of the '694 Patent and outside the scope of what was actually invented is an attempt to seek an improper economic benefit.

139. GSK has engaged in a course of conduct that seeks to broaden the scope of the '694 Patent with anticompetitive effect.

140. GSK's misuse of the '693 Patent renders it unenforceable.

141. This is an exceptional case under 35 U.S.C. § 285, entitling Counterclaimants to an award of attorneys' fees incurred in connection with this matter.

COUNT XIII – DECLARATION OF PATENT MISUSE ('534 PATENT)

142. Counterclaimants incorporate by reference paragraphs 1 through 141 of their Counterclaims as if fully set forth herein.

143. GSK has sought to enforce and/or license the '534 Patent for products and acts it knows are outside the claims of the '534 Patent.

144. For at least six years prior to December 22, 2021, all claims sought specified that the RNA was self-replicating RNA.

145. Prior to December 22, 2021, all claims sought were directed to a "liposome" encapsulating RNA.

146. All embodiments encapsulating an RNA in the '534 Patent disclose only self-replicating RNA molecules as the RNA, unlike the mRNA used in Comirnaty®.

147. All embodiments encapsulating an RNA in the '534 Patent disclose only liposomes encapsulating the RNA, unlike the LNPs used in Comirnaty®.

148. GSK only began prosecuting the claims of the '534 Patent, directed to "RNA" where "the lipids encapsulate" the RNA after the composition of Comirnaty® was published and years after the alleged priority date of the '534 Patent.

149. There is no support for the claims of the '534 Patent in its specification.

150. GSK's conduct in seeking to license and enforce the '534 Patent against products and acts that it knows to be outside the scope of the claims of the '534 Patent and outside the scope of what was actually invented is an attempt to seek an improper economic benefit.

151. GSK has engaged in a course of conduct that seeks to broaden the scope of the '534 Patent with anticompetitive effect.

152. GSK's misuse of the '534 Patent renders it unenforceable.

153. This is an exceptional case under 35 U.S.C. § 285, entitling Counterclaimants to an award of attorneys' fees incurred in connection with this matter.

COUNT XIV – DECLARATION OF PATENT MISUSE ('401 PATENT)

154. Counterclaimants incorporate by reference paragraphs 1 through 153 of their Counterclaims as if fully set forth herein.

155. GSK has sought to enforce and/or license the '401 Patent for products and acts it knows are outside the claims of the '401 Patent.

156. For at least six years prior to December 22, 2021, all claims sought specified that the RNA was self-replicating RNA.

157. Prior to December 22, 2021, all claims sought were directed to a "liposome" encapsulating RNA.

158. All embodiments encapsulating an RNA in the '401 Patent disclose only self-replicating RNA molecules as the RNA, unlike the mRNA used in Comirnaty®.

159. All embodiments encapsulating an RNA in the '401 Patent disclose only liposomes encapsulating the RNA, unlike the LNPs used in Comirnaty®.

160. GSK only began prosecuting the claims of the '401 Patent, directed to “RNA” where “the lipids encapsulate” the RNA after the composition of Comirnaty® was published and years after the alleged priority date of the '401 Patent.

161. There is no support for the claims of the '401 Patent in its specification.

162. GSK's conduct in seeking to license and enforce the '401 Patent against products and acts that it knows to be outside the scope of the claims of the '401 Patent and outside the scope of what was actually invented is an attempt to seek an improper economic benefit.

163. GSK has engaged in a course of conduct that seeks to broaden the scope of the '401 Patent with anticompetitive effect.

164. GSK's misuse of the '401 Patent renders it unenforceable.

165. This is an exceptional case under 35 U.S.C. § 285, entitling Counterclaimants to an award of attorneys' fees incurred in connection with this matter.

COUNT XV – DECLARATION OF PATENT MISUSE ('467 PATENT)

166. Counterclaimants incorporate by reference paragraphs 1 through 165 of their Counterclaims as if fully set forth herein.

167. GSK has sought to enforce and/or license the '467 Patent for products and acts it knows are outside the claims of the '467 Patent.

168. For at least six years prior to December 22, 2021, all claims sought specified that the RNA was self-replicating RNA.

169. Prior to December 22, 2021, all claims sought were directed to a “liposome” encapsulating RNA.

170. All embodiments encapsulating an RNA in the '467 Patent disclose only self-replicating RNA molecules as the RNA, unlike the mRNA used in Comirnaty®.

171. All embodiments encapsulating an RNA in the '467 Patent disclose only liposomes encapsulating the RNA, unlike the LNPs used in Comirnaty®.

172. GSK only began prosecuting the claims of the '467 Patent, directed to “RNA” where “the lipids encapsulate” the RNA after the composition of Comirnaty® was published and years after the alleged priority date of the '467 Patent.

173. There is no support for the claims of the '467 Patent in its specification.

174. GSK's conduct in seeking to license and enforce the '467 Patent against products and acts that it knows to be outside the scope of the claims of the '467 Patent and outside the scope of what was actually invented is an attempt to seek an improper economic benefit.

175. GSK has engaged in a course of conduct that seeks to broaden the scope of the '467 Patent with anticompetitive effect.

176. GSK's misuse of the '467 Patent renders it unenforceable.

177. This is an exceptional case under 35 U.S.C. § 285, entitling Counterclaimants to an award of attorneys' fees incurred in connection with this matter.

COUNT XVI – DECLARATION OF PROSECUTION LACHES ('693 PATENT)

178. Counterclaimants incorporate by reference paragraphs 1 through 177 of their Counterclaims as if fully set forth herein.

179. After amending the claims of the '080 Application on June 16, 2015 to recite “self-replicating RNA,” GSK unreasonably delayed for over six years in pursuing the claims of the '693 Patent related to “RNA” as opposed to “self-replicating RNA.”

180. The '080 Application was filed on January 2, 2013, yet GSK unreasonably delayed for over eight years in pursuing the claims of the '693 Patent related to RNA where “the lipids encapsulate” the RNA as opposed to “liposomes” encapsulating the RNA.

181. As a result of Applicant’s unexplained and unreasonable delay in prosecuting the claims of the '693 Patent, Counterclaimants have been prejudiced.

182. The '693 Patent is unenforceable against Counterclaimants under the doctrine of prosecution laches.

183. This is an exceptional case under 35 U.S.C. § 285, entitling Counterclaimants to an award of attorneys’ fees incurred in connection with this matter.

COUNT XVII – DECLARATION OF PROSECUTION LACHES ('694 PATENT)

184. Counterclaimants incorporate by reference paragraphs 1 through 183 of their Counterclaims as if fully set forth herein.

185. After amending the claims of the '080 Application on June 16, 2015 to recite “self-replicating RNA,” GSK unreasonably delayed for over six years in pursuing the claims of the '694 Patent related to “RNA” as opposed to “self-replicating RNA.”

186. The '080 Application was filed on January 2, 2013, yet GSK unreasonably delayed for over eight years in pursuing the claims of the '694 Patent related to RNA where “the lipids encapsulate” the RNA as opposed to “liposomes” encapsulating the RNA.

187. As a result of Applicant’s unexplained and unreasonable delay in prosecuting the claims of the '694 Patent, Counterclaimants have been prejudiced.

188. The '694 Patent is unenforceable against Counterclaimants under the doctrine of prosecution laches.

189. This is an exceptional case under 35 U.S.C. § 285, entitling Counterclaimants to an award of attorneys’ fees incurred in connection with this matter.

COUNT XVIII – DECLARATION OF PROSECUTION LACHES ('534 PATENT)

190. Counterclaimants incorporate by reference paragraphs 1 through 189 of their Counterclaims as if fully set forth herein.

191. After amending the claims of the '080 Application on June 16, 2015 to recite “self-replicating RNA,” GSK unreasonably delayed for over six years in pursuing the claims of the '534 Patent related to “RNA” as opposed to “self-replicating RNA.”

192. The '080 Application was filed on January 2, 2013, yet GSK unreasonably delayed for over eight years in pursuing the claims of the '534 Patent related to RNA where “the lipids encapsulate” the RNA as opposed to “liposomes” encapsulating the RNA.

193. As a result of Applicant’s unexplained and unreasonable delay in prosecuting the claims of the '534 Patent, Counterclaimants have been prejudiced.

194. The '534 Patent is unenforceable against Counterclaimants under the doctrine of prosecution laches.

195. This is an exceptional case under 35 U.S.C. § 285, entitling Counterclaimants to an award of attorneys’ fees incurred in connection with this matter.

COUNT XIX – DECLARATION OF PROSECUTION LACHES ('401 PATENT)

196. Counterclaimants incorporate by reference paragraphs 1 through 195 of their Counterclaims as if fully set forth herein.

197. After amending the claims of the '080 Application on June 16, 2015 to recite “self-replicating RNA,” GSK unreasonably delayed for over six years in pursuing the claims of the '401 Patent related to “RNA” as opposed to “self-replicating RNA.”

198. The '080 Application was filed on January 2, 2013, yet GSK unreasonably delayed for over eight years in pursuing the claims of the '401 Patent related to RNA where “the lipids encapsulate” the RNA as opposed to “liposomes” encapsulating the RNA.

199. As a result of Applicant's unexplained and unreasonable delay in prosecuting the claims of the '401 Patent, Counterclaimants have been prejudiced.

200. The '401 Patent is unenforceable against Counterclaimants under the doctrine of prosecution laches.

201. This is an exceptional case under 35 U.S.C. § 285, entitling Counterclaimants to an award of attorneys' fees incurred in connection with this matter.

COUNT XX – DECLARATION OF PROSECUTION LACHES ('467 PATENT)

202. Counterclaimants incorporate by reference paragraphs 1 through 201 of their Counterclaims as if fully set forth herein.

203. After amending the claims of the '080 Application on June 16, 2015 to recite "self-replicating RNA," GSK unreasonably delayed for over six years in pursuing the claims of the '467 Patent related to "RNA" as opposed to "self-replicating RNA."

204. The '080 Application was filed on January 2, 2013, yet GSK unreasonably delayed for over eight years in pursuing the claims of the '467 Patent related to RNA where "the lipids encapsulate" the RNA as opposed to "liposomes" encapsulating the RNA.

205. As a result of Applicant's unexplained and unreasonable delay in prosecuting the claims of the '467 Patent, Counterclaimants have been prejudiced.

206. The '467 Patent is unenforceable against Counterclaimants under the doctrine of prosecution laches.

207. This is an exceptional case under 35 U.S.C. § 285, entitling Counterclaimants to an award of attorneys' fees incurred in connection with this matter.

JURY DEMAND

Counterclaimants request a trial by jury on all claims so triable in this action.

RELIEF REQUESTED

WHEREFORE, Counterclaimants respectfully request that the Court enter a Judgment and Order in their favor and against Counterclaim-Defendants as follows:

(a) Dismissing GSK's Complaint with prejudice and denying each and every prayer for relief contained therein;

(b) Declaring that Counterclaimants do not infringe any claim of the Asserted Patents;

(c) Declaring that the manufacture, use, offer to sell, and sale of Comirnaty® within the United States, and its importation into the United States, does not infringe any claim of the Asserted Patents;

(d) Declaring that the claims of the Asserted Patents are invalid;

(e) Declaring that the claims of the Asserted Patents are unenforceable;

(f) Preliminarily and permanently enjoining GSK and its agents, representatives, attorneys, and those persons in active concert or participation with them who receive actual notice thereof from threatening or initiating infringement litigation against Counterclaimants or any of their customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors, or customers of Counterclaimants, or charging any of them either orally or in writing with infringement of the Asserted Patents;

(g) Awarding Counterclaimants their attorneys' fees, together with costs and disbursements, including because this case is exceptional under 35 U.S.C. § 285; and

(h) Awarding such other and further relief as the Court deems justified.

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July 24, 2024

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CERTIFICATE OF SERVICE

I hereby certify that on July 24, 2024, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on July 24, 2024, upon the following in the manner indicated:

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