

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

GLAXOSMITHKLINE BIOLOGICALS SA)
and GLAXOSMITHKLINE LLC,)
)
Plaintiffs,)

v.)

PFIZER INC., PHARMACIA & UPJOHN)
CO. LLC, BIONTECH SE, BIONTECH)
MANUFACTURING GMBH, and)
BIONTECH US INC.,)
)
Defendants.)

C.A. No. 24-512 (GBW)

JURY TRIAL DEMANDED

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs GlaxoSmithKline Biologicals SA (“GSK Biologicals”) and GlaxoSmithKline LLC (“GSK LLC”) (collectively, “GSK”), by their attorneys for this Complaint against Defendants Pfizer Inc. and Pharmacia & Upjohn Co. LLC (collectively, “Pfizer”), and BioNTech SE, BioNTech Manufacturing GMBH, and BioNTech US Inc. (collectively, “BioNTech”), allege as follows:

INTRODUCTION

1. GSK Biologicals researches, develops, and manufactures innovative vaccines and specialty medicines to serve patients and healthcare professionals worldwide. GSK Biologicals is the sole owner and assignee of numerous United States patents directed to formulations comprising lipids and messenger ribonucleic acid (“mRNA”) molecules encoding an immunogen, and methods of administering the same. *See* Exhibits 1–5, 83–85 (the “Patents-in-Suit,” as defined in paragraph 9, below).

2. In 2008, more than a decade before the SARS-CoV-2 (2019) coronavirus disease (COVID-19) pandemic, a team of accomplished scientists, including the named inventors of the

Patents-in-Suit, Andrew Geall and Ayush Verma, working under the leadership of vaccinologist Christian Mandl (the “Mandl team”), set their sights on developing mRNA vaccines. These talented 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.

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) (“Dolgin (2021)”) at 323.

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

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 Defendants have consistently failed to acknowledge how they

applied the Mandl team's revolutionary platform to do so, while at the same time consistently relying on the Mandl team's published work to contest the patent rights of competitors.

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

NATURE OF THE ACTION

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

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 55–92, 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").

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), 11,786,467 (the "467 patent") (Exhibit 5),

11,759,422 (the “422 patent”) (Exhibit 83), 11,655,475 (the “475 patent”) (Exhibit 84), and 11,851,660 (the “660 patent”) (Exhibit 85) (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.

THE PARTIES

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

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.

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.

13. 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.

14. 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.

15. 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.

16. 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); *ModernaTX, Inc. v. Pfizer Inc.*, No. 1:22-CV-11378, D.I. 45 at 20 (D. Mass. Dec. 5, 2022).

17. 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. On information and belief, BioNTech US Inc. 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).

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,

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

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).

JURISDICTION AND VENUE

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

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.

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

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.

23. This Court also has personal jurisdiction over Defendants Pfizer Inc., Pharmacia & Upjohn Co. LLC, BioNTech SE, BioNTech Manufacturing GmbH, and BioNTech US Inc. 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 55–92, 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

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.

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.

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.

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.

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.

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.

BACKGROUND

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

A. The Claimed Inventions

29. In conventional vaccines, a protein (or “polypeptide”) 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. *See Exhibit 1 (’693 Patent) at col. 9, ll. 29–38 (“RNA molecules used with the invention encode a polypeptide immunogen. After administration ... the RNA is translated in vivo and the immunogen can elicit an immune response in the recipient.”).*

30. By 2008, there were many well-understood and significant hurdles to employing mRNA in vaccines. Getting mRNA molecules, intact, from where they are made in the laboratory into a patient’s 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. *See Exhibit 6 (Dolgin (2021)) at 320 (“In the 1990s and for most of the 2000s, nearly every vaccine company that considered working on mRNA opted to invest its resources elsewhere. The conventional wisdom held that mRNA was too prone to degradation[.]”).*

31. Despite unsuccessful efforts by others dating back decades, in 2008, a talented team of researchers led by Christian Mandl set out to overcome these hurdles and develop vaccines using mRNA. *Exhibit 6 (Dolgin (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.

32. The Mandl team first described their inventions in provisional patent applications filed in July and August 2010.³ As stated therein, and in the Patents-in-Suit, “[t]he invention utilizes liposomes in which immunogen-encoding RNA is encapsulated. Thus the RNA is (as in a natural virus) separated from any external medium by the liposome’s bilayer[.]” *See, e.g.*, Exhibit 1 (’693 patent) at 2:2–5. “These liposomes are suitable for in vivo delivery of the RNA to a vertebrate cell and so they are useful as components in pharmaceutical compositions for immunizing subjects against various diseases.” *Id.* at 1:58–61.

33. “Liposomes” of the inventions, as Defendants have explained to other tribunals, may be referred to as “lipid nanoparticles” (“LNPs”):

Geall [(Int’l Patent App. Pub. No. WO2012/006369 (“WO369”))⁴] explains that the liposomes of the invention can be formed “from a mixture of lipids” and provides useful liposomes ideally have a diameter in the range of 50-220nm. A [person of ordinary skill in the art] would have therefore understood Geall [(WO369)] as teaching the use of lipid nanoparticles (i.e., particles made of lipids that are nanosized, in the form of liposomes) for delivery of RNA.

³ *See* Exhibit 86 (U.S. Prov. Patent App. No. 61/361,830, filed July 6, 2010 (“’830 Prov.”)); Exhibit 87 (U.S. Prov. Patent App. No. 61/378,837, filed August 31, 2010 (“’837 Prov.”)); Exhibit 88 (U.S. Prov. Patent App. No. 61/378,826, filed August 31, 2010 (“’826 Prov.”)); Exhibit 89 (U.S. Prov. Patent App. No. 61/361,794, filed July 6, 2010 (“’794 Prov.”)). The ’693, ’694, ’534, ’401, and ’467 Patents-in-Suit (Exhibits 1–5) state a claim of priority to and incorporate by reference, the ’830 and ’837 Provs. The ’422 Patent-in-Suit (Exhibit 83) states a claim of priority to and incorporates by reference, the ’826 Prov. The ’475 and ’660 Patents-in-Suit (Exhibits 84 and 85) state a claim of priority to and incorporate by reference, the ’794 Prov.

⁴ Exhibit 90. The application published as WO369 is in the chain of priority of the ’475 and ’660 Patents-in-Suit and itself states a claim of priority to and incorporates the ’794 Prov.

See Exhibit 91 (August 28, 2023, Moon Declaration in IPR2023-01358 (“Moon Decl.”)) at 39 (citations omitted), citing Exhibit 90 (WO369) at 4:25, 5:8–9⁵.⁶ Describing the invention using their preferred terminology, Defendants have stated: “WO 369 demonstrated that exogenous mRNA ... encoding a selection of proteins ... could be successfully encapsulated in LNPs, administered to large mammals, and expressed.” Exhibit 94 (January 10, 2024, Alabi Report 1 in *ModernaTx, Inc. v. Pfizer Ltd. et al.*, Case Nos. HP-2022-000022/27 (EWHC)) at 116.

34. Defendants have also repeatedly explained that “RNA” of the inventions includes “self-replicating RNA”⁷ (or “saRNA”) and conventional, non-self-replicating RNA. See Exhibit 96 (January 23, 2024, Paper 015 in IPR2023-01358) at 2 (WO369 “doesn’t limit its disclosure to saRNA”), 3 (similar). This is manifest from the limitation of “RNA” to “self-replicating RNA” only in dependent claims in the 2010 priority applications and the Patents-in-Suit,⁸ as Defendants have noted. See Exhibit 97 (July 25, 2023, BioNTech submission in EP3718565 Opposition) at 3 (WO369 “discloses that the mRNA, only of optional embodiments, is self-replicating (see *dependent claim 9*)”), citing Exhibit 90 (WO369) at 48. Indeed:

⁵ See, e.g., Exhibit 1 (’693 patent) at 2:29–30, 3:24–25; Exhibit 83 (’422 patent) at 2:45–46, 5:10–12; Exhibit 84 (’475 patent) at 4:11–12, 4:40–42.

⁶ See also Exhibit 92 (August 28, 2023, Petition for *Inter Partes* Review of U.S. Patent No. 10,702,600 in IPR2023-01358 (“IPR Petition”)) at 18–19; Exhibit 91 (Moon Decl.) at 8–9; Exhibit 93 (Int’l PCT App. Pub. No. WO2017/162266 (“WO266”)) at 109–112 (“As used herein, the term ‘nanoparticle’ refers to any particle having a diameter making the particle suitable for systemic, in particular parenteral, administration, of, in particular, nucleic acids, typically a diameter of 1000 nanometers (nm) or less. ... In some embodiments, a nanoparticulate composition is a lipid-containing pharmaceutical formulation, such as a liposome formulation or an emulsion.”).

⁷ “[A] form of mRNA which is capable of reproduction.” Exhibit 95 (July 15, 2024, BioNTech SE Paper in DE Utility Model 202021004130 Cancellation Proceeding) at 15.

⁸ See, e.g., Exhibit 88 (’826 Prov.) at 42, claims 1 (“RNA encoding an immunogen”) and 6 (“wherein the RNA is a self-replicating RNA”); Exhibit 86 (’830 Prov.) at 29, claims 1 and 3; Exhibit 87 (’837 Prov.) at 34, claims 1 and 5; Exhibit 89 (’794 Prov.) at 38, claims 1 and 9; Exhibit 1 (’693 patent), claims 1 and 29; Exhibit 2 (’694 patent), claims 1 and 11; Exhibit 3 (’534 patent), claims 1 and 33; Exhibit 4 (’401 patent), claims 1 and 28; Exhibit 5 (’467 patent), claims 1 and 15; Exhibit 83 (’422 patent) claims 1 and 5; Exhibit 84 (’475 patent) claims 1 and 32.

the Delivery Chemist would not consider the disclosure of WO 369 to be limited to saRNA. ... [T]he Delivery Chemist would consider that the LNPs of WO 369 could be used to efficiently encapsulate non-self-amplifying mRNA and successfully deliver it in vivo to target cells to achieve antigen expression and a consequent immune response.

Exhibit 98 (February 26, 2024, Alabi Report 2 in *ModernaTx, Inc. v. Pfizer Ltd. et al.*, Case Nos. HP-2022-000022/27 (EWHC)) at 8.

35. According to Defendants, the Mandl team’s patent filings also “list[] in a clear and unambiguous, and easily identifiable manner possible immunogens that can be used in the context of LNP-formulated mRNA vaccines.” Exhibit 99 (July 25, 2023, Pfizer Paper in EP3718565 Opposition) at 24, citing Exhibit 90 (WO369) at 16, 19. For example, the encoded “immunogen” of the inventions, again as explained by Defendants, includes a coronavirus spike polypeptide:

Geall [(WO369)] discloses the use of RNA vaccines encoding the spike protein of a betacoronavirus. It “provides a method of raising an immune response in a large mammal comprising administering to the mammal a dose of between 2 µg and 100 µg of immunogen-encoding RNA.” ... Geall [(WO369)] instructs that the “immunogen will typically be a surface polypeptide, e.g. ... a spike glycoprotein”, and discloses that “[v]iral immunogens include, but are not limited to, those derived from a SARS coronavirus ... The coronavirus immunogen may be a spike polypeptide.”

See Exhibit 92 (IPR Petition) at 18 (citations omitted), citing Exhibit 100 (August 28, 2023, Griffin Decl. in IPR2023-01358) at 28–29 and Exhibit 90 (WO369) at Abstract, 16:6–7, 19:27–30.⁹

B. Industry Recognition and Adoption

36. 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

⁹ See, e.g., Exhibit 84 (’475 patent) at Abstract, 13:63–65, 16:38–43; Exhibit 1 (’693 patent) at 9:44–46, 12:20–25, 16:7–11, 16:23–47; Exhibit 83 (’422 patent) at 9:13–15, 11:59–64, 15:45–49, 16:4–25, 41:64–42:8.

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).

37. The Mandl team’s seminal 2012 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 (“Geall (2012)”).¹⁰ In 2021, *Nature*, citing Geall (2012), identified the Mandl team as “the first team to combine LNPs with an RNA vaccine,” and labeled this 2012 contribution the “First mRNA vaccine in lipid nanoparticles tested in mice” on a timeline of events in “The History of mRNA Vaccines.” Exhibit 6 (Dolgin (2021)) at 323. Pfizer scientists, in a 2024 review article, adopted the 2021 *Nature* timeline, rephrasing the Geall (2012) entry as the “First LNP-encapsulated RNA vaccine in mice.” Exhibit 101 (Jones *et al.*, “Breaking the mold with RNA—a ‘RNAissance’ of life science,” *npj Genom. Med.* 9, article no. 2 (2024) (“Jones (2024)”) at 2.

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

The authors [of Geall (2012)] state that the platform has the potential to “address multiple disease targets” and that the “unique nucleic acid vaccine technology could enable a new generation of potent, versatile, and easily produced vaccines to address the health challenges of the 21st century.” ... I agree with Pfizer/BioNTech on the significance of Geall 2012. Being CGK [(common general knowledge)], it would lead to the skilled team thinking that there was unlikely to be difficulty applying LNPs in the context of mRNA (as opposed to siRNA) and, more importantly ... that LNPs could

¹⁰ Metrics available at <https://www.pnas.org/doi/full/10.1073/pnas.1209367109>.

reasonably be tried for delivering mRNA for vaccine purposes for a range of pathogens: that is what “platform” implies.

Exhibit 102 (July 2, 2024, Judgment in *ModernaTx, Inc. v. Pfizer Ltd. et al.*, [2024] EWHC 1695 (Pat) in Case Nos. HP-2022-000022/27) at 123. Previously, and wholly consistent with that finding, in a 2022 presentation for healthcare professionals concerning its COVID-19 vaccines entitled “Overview of mRNA vaccine development,” Pfizer cited Geall (2012) for the following contribution: “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 2022 (“Pfizer 2022 Presentation”)¹¹).

39. 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.

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

40. 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).

41. 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.

¹¹ 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.

42. As reflected in various published patent applications and issued patents, GSK has prosecuted patent claims to both conventional and self-amplifying mRNA liposomal vaccines and methods of their use around the world since the priority applications to the Patents-in-Suit were filed in 2010, including throughout 2020,¹² before Defendants allege information about the composition of the Accused Products was made public (D.I. 22 at 87 (¶ 56)).

43. GSK continues to research and develop mRNA vaccines—both conventional and self-amplifying, including through various collaborations—and has several vaccine candidates currently advancing in human clinical trials.¹³

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

44. On information and belief, Defendants did not begin investigating liposomal encapsulation and delivery of immunogen-encoding RNA for vaccination purposes until after the Mandl team’s seminal work became public.

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

¹² See, e.g., Exhibit 103 (European Patent No. 2590626, issued October 29, 2015) at, e.g., claim 1 (“A liposome for *in vivo* delivery of RNA to a vertebrate cell...”) and 7 (“The liposome of any preceding claim, wherein the RNA molecule encodes (i) a RNA-dependent RNA polymerase which can transcribe RNA from the RNA molecule...”); Exhibit 104 (July 23, 2020, Publication No. US 2020/0230058 A1, of the application later issuing as the ’422 Patent-in-Suit) at, e.g., claim 1 (“a liposome within which RNA encoding an immunogen of interest is encapsulated”) and 7 (“wherein the RNA is a self-replicating RNA”); Exhibit 105 (European Patent No. 2729126, issued November 12, 2020) at, e.g., claim 1 (“A liposome in which immunogen encoding RNA is encapsulated...”) and claim 3 (“The liposome of any preceding claim, wherein the RNA is a self-replicating RNA...”).

¹³ See <https://www.gsk.com/en-gb/innovation/pipeline/>; https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwiulqCA-NGHAXWnAHkGHbNaDegQFnoECC0QAQ&url=https%3A%2F%2Fwww.gsk.com%2Fmedia%2F11102%2Fq1-2024-pipeline-assets-and-clinical-trials-report.pdf&usg=AOvVaw2DKoP_69C3GaSTBcW5m4h&opi=89978449.

46. 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.

47. 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 mRNA LNP vaccine patent applications since at least 2016. *See, e.g.*, Exhibit 93 (WO266) at, *e.g.*, 110–114. *See also* Exhibits 17, 106, 107 (printouts of patent filings and patent applicants citing to patents or patent applications in each family of the Patents-in-Suit from the Derwent Patents Citation Index, preserved April 19, 2024, August 4, 2024, and August 4, 2024, respectively).¹⁴

48. 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 evidenced by various contemporaneous communications between GSK and BioNTech.

¹⁴ 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?qoq=+11%2c666%2c534>; preserved August 3, 2023); Exhibit 108 (Google Patents, Cited By section, for the '422 patent, available at <https://patents.google.com/patent/US11759422B2/en?qoq=11%2c759%2c422>; preserved August 5, 2024); Exhibit 109 (Google Patents, Cited By section, for the '475 patent, available at <https://patents.google.com/patent/US11655475B2/en?qoq=11%2c655%2c475>; preserved August 5, 2024).

49. And as noted, Pfizer recognized the contributions of the Mandl team in published scientific articles and presentations posted on its website concerning the development of its COVID-19 vaccines. *See, e.g.*, Exhibit 101 (Jones (2024)); Exhibit 12 (Pfizer 2022 Presentation).

50. Defendants continue to advance mRNA vaccines—both conventional and self-amplifying—against various targets. *See* Exhibit 110 (excerpts from BioNTech 2023 Annual Report) at 105*ff.*; Exhibit 111 (excerpts from July 30, 2024, Pfizer Pipeline presentation¹⁵).

51. 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.

52. 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.

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

DEFENDANTS’ INFRINGING ACTIVITIES

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

A. The Accused Products

55. 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

¹⁵ Available at <https://www.pfizer.com/science/drug-product-pipeline>.

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)”).

56. 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.

57. Defendants, FDA and EMA have also referred to the Accused Products as “BNT162b2” vaccine products. *See, e.g.*, Exhibit 19 (December 10, 2020, 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); Exhibit 72 (Schoenmaker *et al.*, “mRNA-lipid nanoparticle COVID-19 vaccines: Structure and stability,” *Intl. J. Pharm.* 601, 120586 (2021) (“Schoenmaker (2021)”) at 2, 3 (Table 1); D.I. 22 at 87 (¶ 56).

58. 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.

59. 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; Exhibit 72 (Schoenmaker (2021)) at 2–4; D.I. 22 at 87 (¶ 56).

60. 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.

61. 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)).

62. 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.”).

63. 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. *See, e.g.*, 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.

64. 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. *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.

65. 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.

66. 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. *See, e.g.,* 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.

67. 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. *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.

68. 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.

69. 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).

70. 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.

71. 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. *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.

72. 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.

73. 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; Exhibit 72 (Schoenmaker (2021)) at 3 (Table 1), 8; D.I. 22 at 87 (¶ 56).

74. 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; Exhibit 72 (Schoenmaker (2021)) at 2–4; D.I. 22 at 87 (¶ 56).

B. Defendants’ Infringement in the United States

75. 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.*

76. 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).

77. 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).

78. 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).

79. 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).

80. 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).

81. 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).

82. 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).

83. 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).

84. 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).

85. 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, 2022¹⁶); Exhibit 51 (May 17, 2022, FDA Comirnaty® (original monovalent) EUA Review Memo).

¹⁶ Available at <https://web.archive.org/web/20220517152524/https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-expands-eligibility-pfizer-biontech-covid-19-vaccine-booster-dose>; preserved April 9, 2024.

86. 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).

87. 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, 2022¹⁷); 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).

88. 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, 2022¹⁸); Exhibit 57 (October 11, 2022, FDA Comirnaty® (bivalent BA.4/5) EUA Review Memo).

¹⁷ Available at <https://web.archive.org/web/20220901002611/https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-pfizer-biontech-bivalent-covid-19-vaccines-use>; preserved April 9, 2024.

¹⁸ Available at <https://web.archive.org/web/20221013015339/https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-and-pfizer-biontech-bivalent-covid-19-vaccines>; preserved April 9, 2024.

89. 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, 2022¹⁹); Exhibit 59 (December 8, 2022, FDA Comirnaty® (bivalent BA.4/5) EUA Review Memo).

90. 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 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).

91. 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.*

92. 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

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

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).

93. 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. *See, e.g.*, D.I. 22 at 27–28 (¶ 85).

94. 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.

95. 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.*, D.I. 22 at 28 (¶ 87); 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.

96. 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.*, D.I. 22 at 28–29 (¶ 88); 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.

97. 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 110 (excerpts from March 20, 2024, BioNTech 2023FY Annual Report (Form 20-F)) at 165.

98. 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”²⁰); Exhibit 70 (October 21, 2022, *Reuters* article, “Pfizer expects to hike U.S. COVID vaccine price to \$110-130 per

²⁰ Available at <https://www.reuters.com/business/healthcare-pharmaceuticals/covid-vaccine-manufacturers-set-list-price-between-120-130-per-dose-2023-09-12/>; preserved April 3, 2024.

dose²¹) (noting original pandemic price of Comirnaty® COVID-19 vaccine was around \$30 per dose).

COUNT I

(Infringement of the '693 Patent)

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

100. 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 112.

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

102. 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.

103. 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®

²¹ Available at <https://www.reuters.com/business/healthcare-pharmaceuticals/pfizer-expects-price-covid-vaccine-110-130-per-dose-2022-10-20/>; preserved April 3, 2024.

(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.

104. 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.

105. 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.

106. 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 glycol-conjugated (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 μL of the lipid/TNS mixture and 242.5 μL 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 μL of the sixth mixture in a sixth well of the 96-well plate;

(8) admixing 7.5 μL of the lipid/TNS mixture and 242.5 μL 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 μL of the seventh mixture in a seventh well of the 96-well plate;

(9) admixing 7.5 μL of the lipid/TNS mixture and 242.5 μL 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 μL 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.

107. Each of the Accused Products comprises a “formulation.” *See* paragraphs 55–92, 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[.]”).

108. Each of the Accused Products comprises “ribonucleic acid (RNA) molecules comprising a sequence that encodes an immunogen.” *See* paragraphs 55–92, 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[.]”); Exhibit 72 (Schoenmaker (2021)) at 2–4; D.I. 22 at 87 (¶ 56).

109. 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 55–92, above; *e.g.*, Exhibit 34 (April 2023, FDA Comirnaty® (original monovalent) Package Insert) at 19 (identifying lipid ingredients); Exhibit 72 (Schoenmaker (2021)) at 2–4; D.I. 22 at 87 (¶ 56).

110. 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 (2021)) at Fig. 6 (providing structure and identifying ALC-0315 as an “[i]onizable cationic lipid”); D.I. 22 at 87 (¶ 56).

111. 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.”).

112. 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 (2021)) at Fig. 6 (identifying ALC-0159 to be a “PEG-lipid”); D.I. 22 at 87 (¶ 56).

113. Each of the Accused Products comprises “lipids comprising ... from 20 mole % to 70 mole % cationic lipid.” *See* paragraphs 55–92, 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 (2021)) at 3, Table 1 (reporting ionizable cationic lipid ALC-0315 makes up 46.3 mole % of the lipids present in Comirnaty® products); D.I. 22 at 87 (¶ 56).

114. Each of the Accused Products comprises “lipids comprising ... from 5 mole % to 80 mole % of cholesterol.” *See* paragraphs 55–92, 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 (2021)) at 3, Table 1 (reporting cholesterol makes up 42.7 mole % of the lipids present in Comirnaty® products); D.I. 22 at 87 (¶ 56).

115. On information and belief, the lipids of each of the Accused Products “encapsulate at least half of the RNA molecules.” *See* paragraphs 55–92, 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 (2021)) at 4 (“In mRNA-LNP formulations, such as those used in mRNA vaccines ... encapsulation efficiencies ... are typically > 90%.”); D.I. 22 at 87 (¶ 56).

116. 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 55–92, 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.”).

117. 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).

118. 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 75–98, 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).

119. 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, 2021²²); Exhibit 79 (www.comirnaty.com/eua-bivalent as preserved by The Wayback Machine, September, 22, 2022²³); Exhibit 80 (www.comirnaty.com/eua-six-months-to-eleven-years; preserved April 5, 2024).

120. 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 75–98 infringes at least exemplary claim 1 of the '693 patent.

121. 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 75–98 and thereby infringe at least exemplary claim 1 of the '693 patent.

²² Available at <https://web.archive.org/web/20210827220339/https://www.comirnaty.com/>; preserved on April 5, 2024.

²³ Available at <https://web.archive.org/web/20220922181232/https://www.comirnaty.com/eua-bivalent>; preserved on April 5, 2024.

122. 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 75–98.

123. 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.

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

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

126. 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.

127. 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.*

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

COUNT II

(Infringement of the '694 Patent)

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

130. 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 113.

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

132. 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.

133. 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.

134. 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.

135. 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.

136. 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 (PEG-conjugated) 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 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 μL of the lipid/TNS mixture and 242.5 μL 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 μL of the sixth mixture in a sixth well of the 96-well plate;

(8) admixing 7.5 μL of the lipid/TNS mixture and 242.5 μL 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 μL of the seventh mixture in a seventh well of the 96-well plate;

(9) admixing 7.5 μL of the lipid/TNS mixture and 242.5 μL 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 μL 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 pK_a as the pH on the line of best fit at which a relative fluorescence of 0.5 is obtained.

137. Each of the Comirnaty® (bivalent BA.1) and Comirnaty® (bivalent BA.4/5) products comprises a “formulation.” *See* paragraphs 55–92, 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 Prescribing Information), Prescribing Information at 52 (“The modRNA in the Pfizer-BioNTech 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).”).

138. 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 55–92, 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.”); Exhibit 72 (Schoenmaker (2021)) at 2–4; D.I. 22 at 87 (¶ 56).

139. 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 55–92, 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).”).

140. 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 55–92, 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) ; Exhibit 72 (Schoenmaker (2021)) at 2–4; D.I. 22 at 87 (¶ 56).

141. 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 (2021)) at Fig. 6 (providing structure and identifying ALC-0315 as an “[i]onizable cationic lipid”); D.I. 22 at 87 (¶ 56).

142. 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.”).

143. 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 (2021)) at Fig. 6 (identifying ALC-0159 to be a “PEG-lipid”); D.I. 22 at 87 (¶ 56).

144. 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 55–92, 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 (2021)) at 4 (“In mRNA-LNP formulations, such as those used in mRNA vaccines ... encapsulation efficiencies ... are typically > 90%.”); D.I. 22 at 87 (¶ 56).

145. 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).

146. 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 55–92, 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.”).

147. 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 75–98, above; *e.g.*, Exhibit 35 (July 14, 2023, FDA Comirnaty® (bivalent BA.4/5) EUA Fact Sheet and Package Insert).

148. 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, 2022²⁴).

149. 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 75–98 infringed at least exemplary claim 1 of the '694 patent.

150. 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 75–98 and thereby infringed at least exemplary claim 1 of the '694 patent.

151. 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 75–98.

152. 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.

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

²⁴ Available at <https://web.archive.org/web/20220922181232/https://www.comirnaty.com/eua-bivalent>; preserved on April 5, 2024.

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

155. 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.

156. 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.*

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

COUNT III

(Infringement of the '534 Patent)

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

159. 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 114.

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

161. 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.

162. 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.

163. 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.

164. 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.

165. Each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products comprises a “formulation.” *See* paragraphs 55–92, 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[.]”).

166. 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 55–92, 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[.]”); Exhibit 72 (Schoenmaker (2021)) at 2–4; D.I. 22 at 87 (¶ 56).

167. 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 55–92, above, *e.g.*, Exhibit 34 (April 2023, FDA Comirnaty® (original monovalent) Package Insert) at 19 (identifying lipid ingredients); Exhibit 72 (Schoenmaker (2021)) at 2–4; D.I. 22 at 87 (¶ 56).

168. 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 (2021)) at Fig. 6 (providing structure and identifying ALC-0315 as an “[i]onizable cationic lipid”); D.I. 22 at 87 (¶ 56).

169. 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 (2021)) at Fig. 6 (identifying ALC-0159 to be a “PEG-lipid”); D.I. 22 at 87 (¶ 56).

170. 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 55–92, 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 (2021)) at 4 (“In mRNA-LNP formulations, such as those used in mRNA vaccines ... encapsulation efficiencies ... are typically > 90%.”); D.I. 22 at 87 (¶ 56).

171. 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 55–92, 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.”).

172. 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 75–98, 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).

173. 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, 2021²⁵); Exhibit 79 (www.comirnaty.com/eua-bivalent as preserved by The Wayback Machine, September, 22, 2022²⁶); Exhibit 80 (www.comirnaty.com/eua-six-months-to-eleven-years; preserved April 5, 2024).

²⁵ Available at <https://web.archive.org/web/20210827220339/https://www.comirnaty.com/>; preserved on April 5, 2024.

²⁶ Available at <https://web.archive.org/web/20220922181232/https://www.comirnaty.com/eua-bivalent>; preserved on April 5, 2024.

174. 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 75–98 infringes at least exemplary claim 1 of the '534 patent.

175. 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 75–98 and thereby infringe at least exemplary claim 1 of the '534 patent.

176. 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 75–98.

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

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

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

180. 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.

181. 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.*

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

COUNT IV

(Infringement of the '401 Patent)

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

184. 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 115.

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

186. 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.

187. 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.

188. 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.

189. 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.

190. Each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products comprises a “formulation.” *See* paragraphs 55–92, 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[.]”).

191. 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 55–92, 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[.]”); Exhibit 72 (Schoenmaker (2021)) at 2–4; D.I. 22 at 87 (¶ 56).

192. 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 55–92, above; *e.g.*, Exhibit 34 (April 2023, FDA Comirnaty® (original monovalent) Package Insert) at 19 (identifying lipid ingredients); Exhibit 72 (Schoenmaker (2021)) at 2–4; D.I. 22 at 87 (¶ 56).

193. 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 (2021)) at Fig. 6 (providing structure and identifying ALC-0315 as an “[i]onizable cationic lipid”); D.I. 22 at 87 (¶ 56).

194. 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 (2021)) at Fig. 6 (identifying ALC-0159 to be a “PEG-lipid”); D.I. 22 at 87 (¶ 56).

195. 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 55–92, 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 (2021)) at 4 (“In mRNA-LNP formulations, such as those used in mRNA vaccines ... encapsulation efficiencies ... are typically > 90%.”); D.I. 22 at 87 (¶ 56).

196. 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 55–92, 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.”).

197. 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 75–98, 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).

198. 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, 2021²⁷); Exhibit 79 (www.comirnaty.com/eua-bivalent as preserved by The Wayback Machine, September, 22, 2022²⁸); Exhibit 80 (www.comirnaty.com/eua-six-months-to-eleven-years; preserved April 5, 2024).

199. 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 75–98 infringes at least exemplary claim 1 of the '401 patent.

²⁷ Available at <https://web.archive.org/web/20210827220339/https://www.comirnaty.com/>; preserved on April 5, 2024.

²⁸ Available at <https://web.archive.org/web/20220922181232/https://www.comirnaty.com/eua-bivalent>; preserved on April 5, 2024.

200. 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 75–98 and thereby infringe at least exemplary claim 1 of the '401 patent.

201. 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 75–98.

202. 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.

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

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

205. 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.

206. 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.*

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

COUNT V

(Infringement of the '467 Patent)

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

209. 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 116.

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

211. 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.

212. 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.

213. 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.

214. 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.

215. 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.

216. Each of the Accused Products comprises a “formulation.” *See* paragraphs 55–92, 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[.]”).

217. Each of the Accused Products comprises “ribonucleic acid (RNA) molecules comprising a sequence that encodes an immunogen.” *See* paragraphs 55–92, 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[.]”); Exhibit 72 (Schoenmaker (2021)) at 2–4; D.I. 22 at 87 (¶ 56).

218. Each of the Accused Products comprises “lipids comprising a tertiary amine cationic lipid, a polyethylene glycol-conjugated (PEG-conjugated) lipid, and cholesterol.” *See* paragraphs 55–92, above at, *e.g.*, Exhibit 34 (April 2023, FDA Comirnaty® (original monovalent) Package Insert) at 19 (identifying lipid ingredients); Exhibit 72 (Schoenmaker (2021)) at 2–4; D.I. 22 at 87 (¶ 56).

219. 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 (2021)) at Fig. 6 (providing structure and identifying ALC-0315 as an “[i]onizable cationic lipid”); D.I. 22 at 87 (¶ 56).

220. 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 (2021)) at Fig. 6 (identifying ALC-0159 to be a “PEG-lipid”); D.I. 22 at 87 (¶ 56).

221. 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 55–92, 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.”).

222. On information and belief, the lipids of each of the Accused Products “encapsulate at least half of the RNA molecules.” *See* paragraphs 55–92, 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 (2021)) at 4 (“In mRNA-LNP formulations, such as those used in mRNA vaccines ... encapsulation efficiencies ... are typically > 90%.”); D.I. 22 at 87 (¶ 56).

223. 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 75–98, 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).

224. 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, 2021²⁹); Exhibit 79 (www.comirnaty.com/eua-bivalent as preserved by The Wayback Machine, September, 22, 2022³⁰); Exhibit 80 (www.comirnaty.com/eua-six-months-to-eleven-years; preserved April 5, 2024).

225. 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 75–98 infringes at least exemplary claim 1 of the '467 patent.

226. 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 75–98 and thereby infringe at least exemplary claim 1 of the '467 patent.

²⁹ Available at <https://web.archive.org/web/20210827220339/https://www.comirnaty.com/>; preserved on April 5, 2024.

³⁰ Available at <https://web.archive.org/web/20220922181232/https://www.comirnaty.com/eua-bivalent>; preserved on April 5, 2024.

227. 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 75–98.

228. 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.

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

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

231. 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.

232. 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.*

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

COUNT VI

(Infringement of the '422 Patent)

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

235. GSK Biologicals is the lawful owner by assignment of the '422 patent, which is entitled "PEGylated Liposomes for Delivery of Immunogen-Encoding RNA" and was duly and legally issued by the U.S. Patent and Trademark Office on September 19, 2023. A true and correct copy of the '422 patent is attached as Exhibit 83. The patent application issuing into the '422 patent was published on July 23, 2020, as Publication No. US 2020/0230058 A1. *See* Exhibit 104.

236. Each claim of the '422 patent is valid and enforceable.

237. Defendants have induced, and continue to induce, direct infringement by third parties of one or more claims of the '422 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 '422 patent, without authority or license to do so, during the term of the '422 patent.

238. 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 '422 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 '422 patent, without authority or license to do so, during the term of the '422 patent, knowing that those products constitute a material part of the inventions of the '422 patent, knowing that

those products are especially made or adapted to infringe the '422 patent, and knowing that those products are not staple articles or commodities of commerce suitable for substantial non-infringing use.

239. 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 '422 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 '422 patent.

240. Claim 1 of the '422 patent recites:

A method for raising a protective immune response in a vertebrate, the method comprising administering to the vertebrate an effective amount of a liposome within which at least one ribonucleic acid (RNA) that encodes an immunogen of interest is encapsulated, wherein the immunogen of interest elicits in the vertebrate a protective immune response against a bacterium, a virus, a fungus, a parasite, or an allergen, wherein the liposome comprises at least one lipid that includes a polyethylene glycol (PEG) moiety, wherein the PEG moiety is present on at least the exterior of the liposome, wherein the average molecular mass of the PEG moiety is between 1 kDa and 3 kDa, wherein the at least one lipid that includes the PEG moiety is not a 1,2-dimyristoyl-sn-glycero-3-phosphoethanolamine-N-[methoxy (polyethylene glycol)].

241. Each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products comprises “a liposome.” *See* paragraphs 55–92, 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.”); 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[.]”); *see also* Exhibit 72 (Schoenmaker (2021)); D.I. 22 at 87 (¶ 56).

242. Each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products comprises “at least one ribonucleic acid (RNA) that encodes an immunogen of interest.” *See* paragraphs 55–92, 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[.]”); Exhibit 72 (Schoenmaker (2021)) at 2–4; D.I. 22 at 87 (¶ 56).

243. The liposomes of each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products comprise “at least one lipid that includes a polyethylene glycol (PEG) moiety.” *See* paragraphs 55–92, above; *e.g.*, Exhibit 34 (April 2023, FDA Comirnaty® (original monovalent) Package Insert) at 19 (identifying lipid ingredients); Exhibit 72 (Schoenmaker (2021)) at 2–4; D.I. 22 at 87 (¶ 56).

244. ALC-0159 (2-[(polyethylene glycol)-2000]-N,N ditetradecylacetamide) is a “lipid that includes a polyethylene glycol (PEG) moiety, wherein the PEG moiety is present on at least the exterior of the liposome, wherein the average molecular mass of the PEG moiety is between 1 kDa and 3 kDa, wherein the at least one lipid that includes the PEG moiety is not a 1,2-dimyristoyl-sn-glycero-3-phosphoethanolamine-N-[methoxy (polyethylene glycol)].” *See, e.g.*, Exhibit 21 (February 19, 2021, EMA Comirnaty® (original monovalent) Assessment Report) at 24 (“The ALC-0159 novel excipient is PEGylated lipid ALC-0159 is included in the formulation to

provide a steric barrier to: 1) facilitate the control of particle size and homogeneity during manufacturing and product storage, and 2) regulate the association of plasma and proteins with the LNP surface.”); 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 (2021)) at 8 (“The PEG-molecules at the surface prevent the individual LNPs from aggregating.”), Fig. 6 (identifying ALC-0159 to be a “PEG-lipid n~45 (PEG2000)”); D.I. 22 at 87 (¶ 56).

245. On information and belief, the “at least one ribonucleic acid (RNA)” is “encapsulated” “within” the liposomes of each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products. *See* paragraphs 55–92, 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 (2021)) at 4 (“In mRNA-LNP formulations, such as those used in mRNA vaccines ... encapsulation efficiencies ... are typically > 90%.”); D.I. 22 at 87 (¶ 56).

246. 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 “[a] method for raising a protective immune response in a vertebrate, the method comprising administering to the vertebrate an effective amount” of each product “wherein the immunogen of interest elicits in the vertebrate, a protective immune response against ... a virus.” *See* paragraphs 55–92, above; *e.g.*, Exhibit 21 (February 19, 2021, EMA Comirnaty® (original monovalent) Assessment Report) at 58 (“The vaccine elicits both neutralizing anti body

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.”).

247. 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 75–98, 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).

248. 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, 2021³¹); Exhibit 79 (www.comirnaty.com/eua-bivalent as preserved by The Wayback Machine, September, 22, 2022³²); Exhibit 80 (www.comirnaty.com/eua-six-months-to-eleven-years; preserved April 5, 2024).

249. 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 75–98 infringes at least exemplary claim 1 of the '422 patent.

250. 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 75–98 and thereby infringe at least exemplary claim 1 of the '422 patent.

251. 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 75–98.

³¹ Available at <https://web.archive.org/web/20210827220339/https://www.comirnaty.com/>; preserved on April 5, 2024.

³² Available at <https://web.archive.org/web/20220922181232/https://www.comirnaty.com/eua-bivalent>; preserved on April 5, 2024.

252. 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 '422 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.

253. GSK has suffered and continues to suffer damages from Defendants' infringement of the '422 patent.

254. GSK is entitled to an award of monetary damages, including a reasonable royalty, for Defendants' infringement of the '422 patent.

255. Defendants have had knowledge of the '422 patent and specific notice of its infringement at least since August 13, 2024, by communications between GSK and Defendants. *See Exhibits 117–118.*

256. Defendants' infringement of the '422 patent has been and continues to be willful and deliberate at least since they received specific notice of their infringement from GSK on August 13, 2024. *See id.*

257. Defendants' conduct with respect to the '422 patent makes this case exceptional under 35 U.S.C. § 285.

COUNT VII

(Infringement of the '475 Patent)

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

259. GSK Biologicals is the lawful owner by assignment of the '475 patent, which is entitled "Immunisation of Large Mammals with Low Doses of RNA" and was duly and legally issued by the U.S. Patent and Trademark Office on May 23, 2023. A true and correct copy of the '475 patent is attached as Exhibit 84. The patent application issuing into the '475 patent was published on February 13, 2020, as Publication No. US 2020/0048636 A1. *See* Exhibit 119.

260. Each claim of the '475 patent is valid and enforceable.

261. Defendants have induced, and continue to induce, direct infringement by third parties of one or more claims of the '475 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 '475 patent, without authority or license to do so, during the term of the '475 patent.

262. 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 '475 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 '475 patent, without authority or license to do so, during the term of the '475 patent, knowing that those products constitute a material part of the inventions of the '475 patent, knowing that those products are especially made or adapted to infringe the '475 patent, and knowing that those

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

263. 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 '475 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 '475 patent.

264. Claim 1 of the '475 patent recites:

A method of eliciting an antibody response against an immunogen by an immune system in a large mammal, the method comprising administering to the large mammal at least two unit doses; each unit dose comprising a composition comprising liposomes and messenger ribonucleic acid (mRNA) molecules; the mRNA molecules comprising a poly-adenosine monophosphate (poly(A)) tail and a sequence that encodes the immunogen; the immunogen comprising a respiratory syncytial virus (RSV) surface fusion glycoprotein (F protein) immunogen, an Epstein-Barr virus (EBV) glycoprotein immunogen, a cytomegalovirus (CMV) glycoprotein immunogen, a human papillomavirus (HPV) 16 immunogen, a coronavirus spike polypeptide immunogen, an influenza virus immunogen, a Varicella zoster virus (VZV) glycoprotein immunogen, or a flavivirus immunogen; each unit dose comprising between 2 µg and 100 µg of the mRNA molecules; the at least two unit doses being sequential and at least 1 week apart; the administering comprising contacting the composition with skeletal muscle; the liposomes comprising a cationic lipid comprising a tertiary amine; the liposomes encapsulating at least half of the mRNA molecules; and the large mammal being a human, a horse, a cow, or a pig.

265. Each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products comprises “a composition comprising liposomes.” *See* paragraphs 55–92, 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.”); 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[.]”); *see also* Exhibit 72 (Schoenmaker (2021)); D.I. 22 at 87 (¶ 56).

266. The liposomes of each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products comprise “a cationic lipid comprising a tertiary amine.” *See* paragraphs 55–92, above at, *e.g.*, Exhibit 34 (April 2023, FDA Comirnaty® (original monovalent) Package Insert) at 19 (identifying lipid ingredients); Exhibit 72 (Schoenmaker (2021)) at 2–4; D.I. 22 at 87 (¶ 56).

267. ALC-0315 is a “cationic lipid comprising 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 (2021)) at Fig. 6 (providing structure and identifying ALC-0315 as an “[i]onizable cationic lipid”); D.I. 22 at 87 (¶ 56).

268. The compositions of each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products comprise “messenger ribonucleic acid (mRNA) molecules; the mRNA molecules comprising a poly-adenosine monophosphate (poly(A)) tail and a sequence that encodes the immunogen; the immunogen comprising ... a coronavirus spike polypeptide immunogen.” *See* paragraphs 55–92, 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[.]”); Exhibit 72 (Schoenmaker (2021)) at 2–4; D.I. 22 at 87 (¶ 56).

269. On information and belief, the liposomes of each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products “encapsulat[e] at least half of the mRNA molecules.” *See* paragraphs 55–92, 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 (2021)) at 4 (“In mRNA-LNP formulations, such as those used in mRNA vaccines ... encapsulation efficiencies ... are typically > 90%.”); D.I. 22 at 87 (¶ 56).

270. 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 “[a] method of eliciting an antibody response against an immunogen by an immune system in a large mammal, the method comprising administering to the large mammal at least two unit doses” of the composition of each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products, “each unit dose comprising between 2 µg and 100 µg of the mRNA molecules; the at least two unit doses being sequential and at least 1 week apart; the administering comprising contacting the composition with skeletal muscle; ... and the large mammal being a human.” *See* paragraphs 55–92, above; *e.g.*, Exhibit 34 (April 2023, FDA Comirnaty® (original monovalent) Package Insert) at 1–7, 19 (Sections 1. Indications and Usage, 2. Dosage and Administration, 3. Dosage Forms and

Strengths, 11. Description); Exhibit 35 (July 14, 2023, FDA Comirnaty® (bivalent BA.4/5) EUA Fact Sheet and Package Insert) at 4–9, 52 (Sections 1. Emergency Use Authorization, 2. Dosage and Administration, 3. Dosage Forms and Strengths, 11. Description); Exhibit 33 (September 2023, FDA Comirnaty® (monovalent XBB.1.5) Package Insert) at 2, 20 (Sections 1. Indications and Usage, 2. Dosage and Administration, 3. Dosage Forms and Strengths, 11. Description); Exhibit 21 (February 19, 2021, EMA Comirnaty® (original monovalent) Assessment Report) at 58 (“The vaccine elicits both neutralizing anti body 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.”).

271. 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 75–98, 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).

272. 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, 2021³³); Exhibit 79 (www.comirnaty.com/eua-bivalent as preserved by The Wayback Machine, September, 22, 2022³⁴); Exhibit 80 (www.comirnaty.com/eua-six-months-to-eleven-years; preserved April 5, 2024).

273. 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 75–98 infringes at least exemplary claim 1 of the '475 patent.

274. 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

³³ Available at <https://web.archive.org/web/20210827220339/https://www.comirnaty.com/>; preserved on April 5, 2024.

³⁴ Available at <https://web.archive.org/web/20220922181232/https://www.comirnaty.com/eua-bivalent>; preserved on April 5, 2024.

indications identified above in paragraphs 75–98 and thereby infringe at least exemplary claim 1 of the '475 patent.

275. 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 75–98.

276. 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 '475 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.

277. GSK has suffered and continues to suffer damages from Defendants' infringement of the '475 patent.

278. GSK is entitled to an award of monetary damages, including a reasonable royalty, for Defendants' infringement of the '475 patent.

279. Defendants have had knowledge of the '475 patent and specific notice of its infringement at least since August 13, 2024, by communications between GSK and Defendants. *See Exhibits 117–118.*

280. Defendants' infringement of the '475 patent has been and continues to be willful and deliberate at least since they received specific notice of their infringement from GSK on August 13, 2024. *See id.*

281. Defendants' conduct with respect to the '475 patent makes this case exceptional under 35 U.S.C. § 285.

COUNT VIII

(Infringement of the '660 Patent)

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

283. GSK Biologicals is the lawful owner by assignment of the '660 patent, which is entitled "Immunisation of Large Mammals with Low Doses of RNA" and was duly and legally issued by the U.S. Patent and Trademark Office on December 26, 2023. A true and correct copy of the '660 patent is attached as Exhibit 85. The patent application issuing into the '660 patent was published on April 13, 2023, as Publication No. US 2023/0112809 A1. *See* Exhibit 120.

284. Each claim of the '660 patent is valid and enforceable.

285. Defendants have induced, and continue to induce, direct infringement by third parties of one or more claims of the '660 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 '660 patent, without authority or license to do so, during the term of the '660 patent.

286. 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 '660 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 '660 patent, without authority or license to do so, during the term of the '660 patent, knowing that those products constitute a material part of the inventions of the '660 patent, knowing that those products are especially made or adapted to infringe the '660 patent, and knowing that those products are not staple articles or commodities of commerce suitable for substantial non-infringing use.

287. 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 '660 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 '660 patent.

288. Claim 1 of the '660 patent recites:

A method of eliciting an antibody response against a coronavirus spike polypeptide immunogen by an immune system in a large mammal, the method comprising administering intramuscularly to the large mammal at least two unit doses, each unit dose comprising a composition comprising lipid particles and messenger ribonucleic acid (mRNA) molecules; the at least two unit doses being sequential and at least 1 week apart; the administering comprising contacting the composition with skeletal muscle; the mRNA molecules comprising a sequence that encodes the coronavirus spike polypeptide immunogen; each unit dose comprising between 2 µg and 100 µg of the mRNA molecules; the lipid particles comprising: i) a polyethylene glycol-ylated lipid, ii) cholesterol, iii) an anionic phospholipid or a zwitterionic phospholipid, and iv) a cationic lipid; the cationic lipid comprising a tertiary amine; the lipid particles encapsulating at least half of the mRNA molecules; and the large mammal being a human or a cow.

289. Each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products comprises “a composition comprising lipid particles.” *See* paragraphs 55–92, 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.”); 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[.]”); *see also* Exhibit 72 (Schoenmaker (2021)); D.I. 22 at 87 (¶ 56).

290. The lipid particles of each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products comprise “: i) a polyethylene glycol-ylated lipid, ii) cholesterol, iii) an anionic phospholipid or a zwitterionic phospholipid, and iv) a cationic lipid; the cationic lipid comprising a tertiary amine.” *See* paragraphs 55–92, above at, *e.g.*, Exhibit 34 (April 2023, FDA Comirnaty® (original monovalent) Package Insert) at 19 (identifying lipid ingredients); Exhibit 72 (Schoenmaker (2021)) at 2–4; D.I. 22 at 87 (¶ 56).

291. ALC-0159 (2-[(polyethylene glycol)-2000]-N,N ditetradecylacetamide) is a “polyethylene glycol-ylated 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 (2021)) at Fig. 6 (identifying ALC-0159 to be a “PEG-lipid n~45 (PEG2000)”).

292. DSPC is a “zwitterionic phospholipid.” *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.”).

293. ALC-0315 is a “cationic lipid; the cationic lipid comprising 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 (2021)) at Fig. 6 (providing structure and identifying ALC-0315 as an “[i]onizable cationic lipid”); D.I. 22 at 87 (¶ 56).

294. The compositions of each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products comprise “messenger ribonucleic acid (mRNA) molecules; ... the mRNA molecules comprising a sequence that encodes the coronavirus spike polypeptide immunogen.” *See* paragraphs 55–92, 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[.]”); Exhibit 72 (Schoenmaker (2021)) at 2–4; D.I. 22 at 87 (¶ 56).

295. On information and belief, the lipid particles of each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products “encapsulat[e] at least half of the mRNA molecules.” *See* paragraphs 55–92, 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 (2021)) at 4 (“In mRNA-LNP formulations, such as those used in mRNA vaccines ... encapsulation efficiencies ... are typically > 90%.”); D.I. 22 at 87 (¶ 56).

296. 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 “[a] method of eliciting an antibody response against a coronavirus spike polypeptide immunogen by an immune system in a large mammal, the method comprising administering intramuscularly to the large mammal at least two unit doses” of the composition of each of the Comirnaty® (original monovalent), Comirnaty® (bivalent BA.4/5), and Comirnaty® (monovalent XBB.1.5) products, “the at least two unit doses being sequential and at least 1 week apart; the administering comprising contacting the composition with skeletal muscle; ... each unit dose comprising between 2 µg and 100 µg of the mRNA molecules; ... and the large mammal being a human.” *See* paragraphs 55–92, above; *e.g.*, Exhibit 34 (April 2023, FDA Comirnaty® (original monovalent) Package Insert) at 1–7, 19 (Sections 1. Indications and Usage, 2. Dosage and Administration, 3. Dosage Forms and Strengths, 11. Description); Exhibit 35 (July 14, 2023, FDA Comirnaty® (bivalent BA.4/5) EUA Fact Sheet and Package Insert) at 4–9, 52 (Sections 1. Emergency Use Authorization, 2. Dosage and Administration, 3. Dosage Forms and Strengths, 11. Description); Exhibit 33 (September 2023, FDA Comirnaty® (monovalent XBB.1.5) Package Insert) at 2, 20 (Sections 1. Indications and Usage, 2. Dosage and Administration, 3. Dosage Forms and Strengths, 11. Description); Exhibit 21 (February 19, 2021, EMA Comirnaty® (original monovalent) Assessment Report) at 58 (“The vaccine elicits both neutralizing anti body 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.”).

297. 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 75–98, 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).

298. 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, 2021³⁵); Exhibit 79 (www.comirnaty.com/eua-bivalent as preserved by The Wayback Machine, September, 22, 2022³⁶); Exhibit 80 (www.comirnaty.com/eua-six-months-to-eleven-years; preserved April 5, 2024).

299. 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 75–98 infringes at least exemplary claim 1 of the '660 patent.

300. 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 75–98 and thereby infringe at least exemplary claim 1 of the '660 patent.

301. 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 75–98.

302. Defendants actively, knowingly, and specifically intended to induce, and induced, and continue to actively, knowingly, and specifically intend to induce, and induce, infringement

³⁵ Available at <https://web.archive.org/web/20210827220339/https://www.comirnaty.com/>; preserved on April 5, 2024.

³⁶ Available at <https://web.archive.org/web/20220922181232/https://www.comirnaty.com/eua-bivalent>; preserved on April 5, 2024.

of at least claim 1 of the '660 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.

303. GSK has suffered and continues to suffer damages from Defendants' infringement of the '660 patent.

304. GSK is entitled to an award of monetary damages, including a reasonable royalty, for Defendants' infringement of the '660 patent.

305. Defendants have had knowledge of the '660 patent and specific notice of its infringement at least since August 13, 2024, by communications between GSK and Defendants. *See Exhibits 117–118.*

306. Defendants' infringement of the '660 patent has been and continues to be willful and deliberate at least since they received specific notice of their infringement from GSK on August 13, 2024. *See id.*

307. Defendants' conduct with respect to the '660 patent makes this case exceptional under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, GSK prays for judgment as follows:

A. That Defendants have directly infringed, either literally or under the doctrine of equivalents, at least one claim of each of the Patents-in-Suit;

B. That Defendants have induced infringement of at least one claim of each of the Patents-in-Suit;

C. That Defendants have contributorily infringed at least one claim of each of the Patents-in-Suit;

D. That Defendants' infringement of at least one claim of each of the Patents-in-Suit has been willful;

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

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

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

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

DEMAND FOR JURY TRIAL

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

OF COUNSEL:

John M. Desmarais
Michael E. Furrow
Karl Mullen
Alexander Walker
jdesmarais@desmaraisllp.com
mfurrow@desmaraisllp.com
kmullen@desmaraisllp.com
lwalker@desmaraisllp.com
DESMARAIS LLP
230 Park Ave.
New York, NY 10169
(212) 351-3400

Justin P. D. Wilcox
Rebecca A. Lindhorst
Delon Lier
jwilcox@desmaraisllp.com
rlindhorst@desmaraisllp.com
dlier@desmaraisllp.com
DESMARAIS LLP
1899 Pennsylvania Ave., NW, Suite 400
Washington, D.C. 20006
(202) 451-4900

Gabrielle E. Higgins
Ada Locke
ghiggins@desmaraisllp.com
alocke@desmaraisllp.com
DESMARAIS LLP
101 California St., Suite 3000
San Francisco, CA 94111
(415) 573-1900

Dated: August 14, 2024

/s/ Kelly E. Farnan

Kelly E. Farnan (#4395)
Sara M. Metzler (#6509)
Richards, Layton & Finger, P.A.
One Rodney Square
920 N. King Street
Wilmington, DE 19801
(302) 651-7700
farnan@rlf.com
metzler@rlf.com

*Attorneys for Plaintiffs GlaxoSmithKline
Biologicals SA and GlaxoSmithKline LLC*