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.	Civil Action No. 24-512-GBW
GLAXOSMITHKLINE BIOLOGICALS SA and GLAXOSMITHKLINE LLC, Plaintiffs, v. MODERNA, INC., MODERNATX, INC., and MODERNA US, INC., Defendants.	Civil Action No. 24-1135-GBW
GLAXOSMITHKLINE BIOLOGICALS SA and GLAXOSMITHKLINE LLC, Plaintiffs, v. MODERNA, INC., MODERNATX, INC., and MODERNA US, INC., Defendants.	Civil Action No. 24-1136-GBW

Kelly E. Farnan, Sara M. Metzler, RICHARDS, LAYTON & FINGER, P.A., Wilmington, Delaware; John Desmarais, Kerri-Ann Limbeek, Michael E. Furrow, Karl Mullen, DESMARAIS LLP, New York, New York; Justin P. D. Wilcox, Thomas J. Derbish, Rebecca A. Lindhorst, Eric Speckhard, Jamie Dohopolski, Washington, District of Columbia; Ada Locke, DESMARAIS LLP, San Francisco, California.

Counsel for Plaintiffs GlaxoSmithKline Biologicals SA and GlaxoSmithKline LLC

Brian E. Farnan, Michael J. Farnan, FARNAN LLP, Wilmington, Delaware; William A. Rakoczy, Deanne M. Mazzochi, Eric R. Hunt, Heinz J. Salmen, Neil B. McLaughlin, Katie A. Boda, Conly S. Wythers, Greg L. Goldblatt, Ph.D., Adrianne C. Rose, Sarah M.L. Wilkening, Alejandro V. Hernandez, RAKOCZY MOLINO MAZZOCHI SIWIK LLP, Chicago, Illinois.

Counsel for Defendants Moderna, Inc., ModernaTX, Inc. and Moderna US, Inc.

Jack B. Blumenfeld, Jeremy A. Tigan, Megan E. Dellinger, MORRIS, NICHOLS, ARSHT & TUNELL LLP, Wilmington, Delaware.

Counsel for Defendants Pfizer Inc., Pharmacia & Upjohn Co. LLC, BioNTech SE, BioNTech Manufacturing GmbH, and BioNTech US Inc.

Sara Tonnies Horton, Ren-How Harn, WILLKIE FARR & GALLAGHER LLP, Chicago, Illinois; Matthew Freimuth, Nicholas Vennekotter, WILLKIE FARR & GALLAGHER LLP, New York, New York.

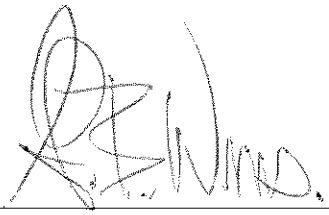
Counsel for Defendants Pfizer Inc. and Pharmacia & Upjohn Co. LLC

Charles B. Klein, Jovial Wong, Claire Fundakowski, WINSTON & STRAWN LLP, Washington, District of Columbia; David P. Dalke, Michael A. Meneghini, Zoe A. Goldstein, WINSTON & STRAWN LLP, Chicago, Illinois; Eimeric Reig-Plessis, Noorossadat Torabi, WINSTON & STRAWN LLP, San Francisco, California.

Counsel for BioNTech SE, BioNTech Manufacturing GmbH, and BioNTech US Inc.

MEMORANDUM OPINION

June 23, 2026
Wilmington, Delaware



GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE

Pending before the Court are eight claim construction disputes across the three above-captioned actions: two claim terms are in dispute in all actions (Civil Action Nos. 24-512, 24-1135 and 24-1136); one claim term is in dispute in two actions (Civil Action Nos. 24-1135 and 24-1136); and five terms are in dispute in one action (Civil Action No. 24-512). The Court has considered the parties' briefing, accompanying exhibits, expert declarations, and the arguments presented during the *Markman* hearing held on April 23, 2025. Upon consideration of the full record, the Court issues the following constructions.

I. BACKGROUND

The above-captioned patent infringement actions were filed by Plaintiffs GlaxoSmithKline Biologicals SA and GlaxoSmithKline LLC (collectively, "GSK" or "Plaintiffs").

In Civil Action No. 24-512, Plaintiffs' First Amended Complaint alleges that Defendants Pfizer Inc. and Pharmacia & Upjohn Co. LLC (collectively, "Pfizer"), as well as BioNTech SE, BioNTech Manufacturing GMBH, and BioNTech US Inc. (collectively, "BioNTech," and together with Pfizer, "PBNT") infringe eight patents: U.S. Patent Nos. 11,638,693 (the "'693 Patent"), 11,638,694 (the "'694 Patent"), 11,666,534 (the "'6534 Patent"), 11,766,401 (the "'401 Patent"), 11,786,467 (the "'467 Patent"), 11,759,422 (the "'422 Patent"), 11,655,475 (the "'475 Patent"), and 11,851,660 (the "'660 Patent"). D.I. 26 in Civil Action ("C.A.") 24-512.

In Civil Action No. 24-1135, Plaintiffs' First Amended Complaint alleges that Defendants Moderna, Inc., ModernaTX, Inc., and Moderna US, Inc. (collectively, "Moderna") infringe seven patents: U.S. Patent Nos. 11,291,682 (the "'682 Patent"), 11,324,770 (the "'770 Patent"),

11,596,645 (the "'645 Patent"), 11,690,862 (the "'862 Patent"), 11,707,482 (the "'482 Patent"), the '6534 Patent, and the '467 Patent. D.I. 91 in C.A. 24-1135.

In Civil Action No. 24-1136, Plaintiffs' Complaint alleges that Moderna infringes six patents: U.S. Patent Nos. 11,690,861 (the "'861 Patent"), 11,690,864 (the "'864 Patent"), 11,717,529 (the "'529 Patent"), 11,883,534 (the "'3534 Patent"), the '467 Patent, and the '770 Patent (together, with the '693 Patent; the '694 Patent; the '6534 Patent; the '401 Patent; the '467 Patent; the '422 Patent; the '475 Patent; the '660 Patent; the '645 Patent; the '862 Patent; and the '482 Patent, the "Asserted Patents"). D.I. 1 in C.A. 24-1136.

The parties in each of the actions have submitted joint claim construction briefs. D.I. 166 in C.A. 24-512; D.I. 161 in C.A. 24-1135; D.I. 146 in C.A. 24-1136.

II. LEGAL STANDARDS

A. Claim Construction

"It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)); *see also Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989) ("A claim in a patent provides the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using, or selling the protected invention."). "[T]here is no magic formula or catechism for conducting claim construction." *Phillips*, 415 F.3d at 1324. The Court is free to attach the appropriate weight to appropriate sources "in light of the statutes and policies that inform patent law." *Id.* The ultimate question of the proper construction of a patent is a question of law, although subsidiary fact-finding is sometimes necessary. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 326 (2015); *see also Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 378, 388-91 (1996).

"The words of a claim are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art when read in the context of the specification and prosecution history." *Thorner v. Sony Comput. Ent. Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (citing *Phillips*, 415 F.3d at 1313). A person of ordinary skill in the art "is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Phillips*, 415 F.3d at 1313.

"When construing claim terms, [the court] first look[s] to, and primarily rel[ies] on, the intrinsic evidence, including the claims themselves, the specification, and the prosecution history of the patent, which is usually dispositive." *Sunovion Pharms., Inc. v. Teva Pharms. USA, Inc.*, 731 F.3d 1271, 1276 (Fed. Cir. 2013). "Other claims of the patent in question, both asserted and unasserted, can . . . be valuable" in discerning the meaning of a disputed claim term, because "claim terms are normally used consistently throughout the patent" and so "the usage of a term in one claim can often illuminate the meaning of the same term in other claims." *Phillips*, 415 F.3d at 1314 (citations omitted). In addition, "[d]ifferences among claims can also be a useful guide in understanding the meaning of particular claim terms." *Id.* (citing *Laitram Corp. v. Rexnord, Inc.*, 939 F.2d 1533, 1538 (Fed. Cir. 1991)). "For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Id.* at 1314-15 (citing *Liebel–Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 910 (Fed. Cir. 2004)).

In addition to the claims, the court should analyze the specification, which "is always highly relevant to the claim construction analysis . . . [as] it is the single best guide to the meaning of a disputed term." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). It is also possible that "the specification may reveal a special definition given to a claim term by

the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316 (citing *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002)). "[E]ven when the specification describes only a single embodiment, [however,] the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction.'" *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (quoting *Liebel-Flarsheim*, 358 F.3d at 906). Furthermore, the specification "is not a substitute for, nor can it be used to rewrite, the chosen claim language." *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004).

The court "should also consider the patent's prosecution history, if it is in evidence." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 33 (1966)). The prosecution history "can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution . . . ." *Phillips*, 415 F.3d at 1317 (citations omitted).

In some cases, the court "will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period." *Teva*, 574 U.S. at 331 (citing *Seymour v. Osborne*, 20 L.Ed. 33 (1871)). Extrinsic evidence "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. Overall, while extrinsic evidence may be useful, it is "less significant than the intrinsic record in determining the legally operative meaning of claim language." *Phillips*, 415 F.3d at 1317 (cleaned up).

B. Indefiniteness

Section 112 of the Patent Act requires that the claims of a patent "particularly point[] out and distinctly claim[] the subject matter which the inventor or a joint inventor regards as the invention." 35 U.S.C. § 112(b). The "primary purpose of the definiteness requirement" that § 112(b) contains "is to ensure that the claims are written in such a way that they give notice to the public of the extent of the legal protection afforded by the patent, so that interested members of the public, e.g., competitors of the patent owner, can determine whether or not they infringe." *All Dental Prodx, LLC v. Advantage Dental Prods., Inc.*, 309 F.3d 774, 779-80 (Fed. Cir. 2002) (citation omitted).

"[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). While a "potential infringer" need not "be able to determine *ex ante* if a particular act infringes the claims," the patentee must "apprise the public of what is still open to them," such that "a person of ordinary skill in the art could determine whether or not an accused product or method infringes the claim." *Niazi Licensing Corp. v. St. Jude Med. S.C., Inc.*, 30 F.4th 1339, 1346-47 (Fed. Cir. 2022) (quotation marks and citations omitted).

Like claim construction, definiteness is a question of law, but courts must sometimes render factual findings based on extrinsic evidence to resolve the ultimate issue of definiteness. *See Sonix Tech. Co. v. Publications Int'l, Ltd.*, 844 F.3d 1370, 1376 (Fed. Cir. 2017). "Patent claims are presumed to be valid and definite." *B.E. Tech., LLC v. Twitter Inc.*, No. 20-621, 2024 WL 579076, at *1 (D. Del. Feb. 13, 2024) (citing 35 U.S.C. § 282). Thus, the challenger must prove indefiniteness by clear and convincing evidence. *See Nippon Shinyaku Co. v. Sarepta Therapeutics, Inc.*, No. 21-1015, 2023 WL 4314485, at *6 (D. Del. July 3, 2023).

III. AGREED-UPON TERMS

The parties submitted agreed-upon constructions for claim terms below only in C.A. 24-512.

Claim Term	Agreed-Upon Construction
"eliciting an antibody response against an immunogen" 24-512 ('475 Patent, All Asserted Claims) and "eliciting an antibody response against a coronavirus spike polypeptide immunogen" 24-512 ('660 Patent, All Asserted Claims)	Preamble language is limiting.
"cationic lipid" 24-512 ('422 Patent, Claims 3, 12-13)	"lipid capable of being positively charged"
"tertiary amine cationic lipid" 24-512 ('693 Patent, Claims 14-16) ('694 Patent, Claims 5, 6, 14, 30) ('6534 Patent, All Asserted Claims) ('401 Patent, All Asserted Claims) ('467 Patent, All Asserted Claims) and "cationic lipid comprising a tertiary amine" 24-512	"lipid with a tertiary amine capable of being positively charged"

('693 Patent, All Asserted Claims) ('694 Patent, All Asserted Claims) ('475 Patent, All Asserted Claims) ('660 Patent, All Asserted Claims)	

D.I. 166 in C.A. 24-512 at 4-5. The Court will adopt these agreed-upon constructions in C.A. 24-512.

IV. DISPUTED TERMS

A. "Liposome" / "Liposomes"

Disputed Term	Plaintiffs' Construction	PBNT's Construction	Moderna's Construction	The Court's Construction
"liposomes / "liposome" 24-512 ('475 Patent, All Asserted Claims) ('422 Patent, All Asserted Claims) 24-1135 ('682 Patent, Claims 1 and 11) ('770 Patent, Claims 11, 16) ('862 Patent, Claim 1) ('482 Patent, Claim 1) 24-1136 ('770 Patent, Claims 11, 16)	lipid vesicle(s) having a lipid bilayer and an aqueous core	lipid particle(s) having a lipid bilayer encapsulating an aqueous core	lipid vesicles having a lipid bilayer encapsulating an aqueous core	lipid vesicles having a lipid bilayer encapsulating an aqueous core

('864 Patent, Claim 1) ('529 Patent, Claim 1)				

The parties dispute how the claim term "liposome" should be construed. In Plaintiffs' view, "liposome" "means 'lipid vesicles having a lipid bilayer and an aqueous core.'" D.I. 161 at 9, C.A. No. 24-1135. Plaintiffs assert that construing "liposome" to require a lipid bilayer that "encapsulates" an aqueous core would introduce a new limitation not present in the claim language. *Id.* at 9. Furthermore, Plaintiffs allege that including the word "encapsulating" in the construction of "liposome" would introduce unnecessary complexity and confuse the jury, especially in light of Defendants' contention that "encapsulating" itself requires construction. *Id.*

Defendants disagree.[1] Defendants assert that, although "[b]oth parties agree that liposomes require three structural components – a lipid vesicle, a lipid bilayer, and an aqueous core," Plaintiffs' proposed construction removes any structural interplay between the three. D.I. 161 at 14-15, C.A. No. 24-1135. Moreover, Defendants assert that their construction is not *needlessly* complex, but required to properly describe the structural interplay between the three components of a "liposome." *Id.* at 24. Defendants also posit that they do not ask the Court to merely construe "encapsulating," standing alone, but request that the Court opine on "*which structures perform* the half-the-RNA encapsulation" in a later claim term. *Id.* (emphasis in original).

As discussed *supra* § II.A, when the Court construes a claim term, it primarily relies on "intrinsic evidence, including the claims themselves, the specification, and the prosecution history

[1] Moderna proposes the same construction as Pfizer and BioNTech in Civil Action No. 24-512. D.I. 116 at 9, C.A. No. 24-1135.

of the patent, which is usually dispositive." *Sunovion Pharms*, 731 F.3d at 1276. The patents-in-suit describe liposomes as "[v]arious amphiphilic lipids" that "form bilayers in an aqueous environment to encapsulate a RNA-containing aqueous core . . . ." '770 Patent at 3:45-48; '475 Patent at 3:53-55; '422 Patent at 2:07-10. "Liposomes can be formed from a single lipid or from a mixture of lipids." '770 Patent at 4:03-04; '475 Patent at 4:11-12; *see also* '422 Patent at 2:45-46. "Liposomes are usually divided into three groups: multilamellar vesicles (MLV); small unilamellar vesicles (SUV); and large unilamellar vesicles (LUV)." '770 Patent at 4:26-28; '475 Patent at 4:34-36; '422 Patent at 5:04-06. "MLVs have multiple bilayers in each vesicle, forming several separate aqueous compartments," while "SUVs and LUVs have a single bilayer encapsulating an aqueous core . . . ." '770 Patent at 4:28-32; '475 Patent at 4:36-39; '422 Patent at 5:06-09.

Thus, "liposome," as used in the Asserted Patents, requires a structural interplay between its three components. The Asserted Patents provide guidance as to how the three components of a liposome are structurally arranged: "[v]arious amphiphilic lipids . . . *form* bilayers in an aqueous environment to *encapsulate* a[n] RNA-containing aqueous core . . . ." '770 Patent, 3:45-48; '475 Patent, 3:53-55; '422 Patent, 2:07-10. Therefore, the proper construction of "liposome" as used in the Asserted Patents requires this structural interplay; it cannot be three disjointed components as Plaintiffs suggest.

The prosecution history further supports Defendants' proposed construction. WO2005-121348 ("WO-348"), cited in the '770 Patent, describes a liposome as a molecule "wherein an aqueous volume is encapsulated by an amphipathic lipid bilayer." WO-348 ¶ 55. Thus, prior patent applications, cited by the Asserted Patents, support the Court's construction of "liposome."

Although the Court need not turn to extrinsic evidence to arrive at the proper construction, the cited prior art describes several instances of liposomes as having an aqueous core (or compartment or other volume) encapsulated (or otherwise enclosed) by the lipid bilayer. *See, e.g.*, D.I. 164, Ex. 13 at 147, C.A. No. 24-1135 (liposomes "are spherical, self-closed structures formed by one or several concentric lipid bilayers with an aqueous phase inside and between the lipid bilayers."); *id.* Ex. 6 ("Liposomes are vesicles composed of a bilayer (uni-lamellar) and/or a concentric series of multiple bilayers (multi-lamellar) separated by aqueous compartments formed by amphipathic molecules such as phospholipids that enclose a central aqueous compartment. In a liposome drug product, the drug substance is generally contained in liposomes.").

Plaintiffs' assertions to the contrary are unpersuasive. *First*, Plaintiffs acknowledge a required structural interplay between the three components of a liposome. D.I. 161 at 27, C.A. No. 24-1135 ("A POSA would have understood that one or more 'aqueous cores' are separated from the external medium by the liposome's 'lipid bilayers.'"). Thus, Plaintiffs agree that a "liposome" has the structural interplay present in the Court's construction. *Id.* Plaintiffs' first argument is therefore unpersuasive.

Second, Plaintiffs assert that having the lipid bilayer "encapsulate" the aqueous core, which in turn "encapsulates" the RNA is convoluted. The Court disagrees.[2] To the contrary, the construction of the Asserted Claims where "liposome" appears is no more complicated than a Russian nesting doll, where the outer doll "encapsulates" and inner doll, which further "encapsulates" the smallest doll. Thus, the Court "finds that this construction is clear enough for

[2] The Court further notes that it does not adopt Defendants' proposed construction for the "encapsulating" terms, and thus Plaintiffs' concerns are devoid of merit.

a juror to understand." *Blackbird Tech v. Shapers Unlimited, Inc.*, No. 14-1255-GMS, 2016 WL 1104037, at *1 n.4 (D. Del. Mar. 21, 2016).

Third, although Plaintiffs allege that liposomes featuring "nonspherical and with non-concentric arrangements of lipid bilayers and aqueous cores" fall within the scope of the invention, (D.I. 161 at 32, C.A. No. 24-1135), nothing in the Court's construction requires that the liposomes be spherical, concentric, or contain a single aqueous core. Although Plaintiffs *do* point to instances where the specification cites to prior art where "the 'inter-bilayer binding is discontinuous'" within a liposome, (D.I. 161 at 32, C.A. No. 24-1135), in light of the overwhelming descriptions in the specification describing how the core is encapsulated, this one citation is unpersuasive. Moreover, the Court finds that all three types of liposomes described in the specifications of the Asserted Patents, MLVs, SUVs, and LUVs, have the required structure. Although LUVs and SUVs are described as having "a single bilayer encapsulating an aqueous core," MLVs are described as having "multiple bilayers in each vesicle, forming several separate aqueous compartments." '770 Patent at 4:28-32; '475 Patent at 4:36-39; '422 Patent at 5:06-09. Plaintiffs agree that MLVs must still have one or more aqueous cores; they only dispute that there can be multiple cores and that the liposomes do not have to be arranged concentrically, such that a single aqueous core is in the center of the liposome, surrounded by multiple lipid bilayers and aqueous compartments. D.I. 161 at 31-32, C.A. No. 24-1135. However, the Court's construction does not exclude any such arrangement. If a liposome were to have *multiple* lipid bilayers encapsulating *multiple* aqueous cores, said liposome would nonetheless be encompassed by the Court's construction that the liposome contain at least *a* lipid bilayer and *an* aqueous core. The Court's construction should not be read to be as limiting as Plaintiffs attempt to assert. Thus, Plaintiffs' arguments are unpersuasive.

For the foregoing reasons, the Court will adopt Defendants' proposed construction,[3] and construe "liposome" as "lipid vesicles having a lipid bilayer encapsulating an aqueous core."

B. "Lipid Particles" / "Lipids"

Disputed Term	Plaintiffs' Construction	Moderna's Construction	The Court's Construction
"lipid particles" 24-1135 ('770 Patent, Claim 1) ('645 Patent, Claim 1) 24-1136 ('770 Patent, Claim 1) ('861 Patent, Claim 1) ('3534 Patent, Claim 1)	No construction necessary: Plain and ordinary meaning, *i.e.*: "lipid particles"	"lipid vesicles having a lipid bilayer encapsulating an aqueous core"	No further construction necessary: Plain and ordinary meaning, *i.e.*: "lipid particles"
"lipids" 24-1135 ('6534 Patent, Claim 1) 24-1136 ('467 Patent, Claim 1)	No construction necessary: Plain and ordinary meaning, *i.e.*: "lipids"	"lipid vesicles having a lipid bilayer encapsulating an aqueous core"	No further construction necessary: Plain and ordinary meaning, *i.e.*: "lipids"

The parties dispute whether the claim terms "lipids" and "lipid particles" require construction. D.I. 165 at 44-68, C.A. 24-1135; D.I. 146 at 44-68, C.A. 24-1136.[4] Plaintiffs

[3] Both Defendants agree that there is no substantive difference between "particle" and "vesicle" as used in their proposed constructions, and as such the Court will construe the "liposome" to require lipid *vesicles*. *See* D.I. 166 at 11 n.11, C.A. No. 24-512; D.I. 146 at 13 n.15, C.A. No. 24-1136.

[4] The parties filed identical briefs with respect to these disputed claim terms. For this section, the Court cites to D.I. 146 in C.A. 24-1136.

contend that no construction is necessary and both terms should be construed consistently with their plain and ordinary meanings. *Id.* Moderna, on the other hand, contends that "lipid particles" and "lipids" should have the same construction that Moderna proposes for "liposome," which is "lipid vesicles having a bilayer encapsulating an aqueous core." *Id.*

The Asserted Patents containing the disputed claim terms are replicated, in relevant part, below:

> An immunogenic composition comprising **lipid particles** and messenger ribonucleic acid (mRNA) molecules; . . . the **lipid particles comprising a polyethylene glycol-ylated (PEGylated) lipid, cholesterol, a first phospholipid, and a cationic lipid**; . . . the **lipid particles** encapsulating at least half of the mRNA molecules; . . . .

'770 Patent, Claim 1 (emphasis added).

> A composition comprising **lipid particles** and messenger ribonucleic acid (mRNA) molecules; . . . the **lipid particles comprising: (a) a polyethylene glycol-ylated lipid, (b) cholesterol, (c) an anionic phospholipid or a zwitterionic phospholipid, and (d) a cationic lipid comprising a tertiary amine**; and the **lipid particles** encapsulating at least half of the mRNA molecules.

'861 Patent, Claim 1 (emphasis added).

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

'3534 Patent, Claim 1 (emphasis added).

> A formulation comprising:

> . . . **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.

'467 Patent, Claim 1 (emphasis added).

Plaintiffs contend that the terms do not require construction because the surrounding claim language, as seen emphasized above, defines the terms by their chemical composition. D.I. 146 at 45-46. Plaintiffs further contend that the claims describe relevant function characteristics of the terms. *Id.* at 47. Specifically, the claims detail that "lipid particles" and "lipids" must encapsulate at least half of the mRNA molecules of immunogenic composition. *Id.* Thus, Plaintiffs conclude that "the claims already define – using plain and ordinary language – both what the 'lipid particles' and 'lipids' ***are*** and what they ***do***." *Id.* (emphasis in original).

Plaintiffs further claim that the specifications confirm that the claim terms bear distinct plain and ordinary meanings because the specifications explain that a "liposome includes lipids" and can be "formed from a single lipid or mixture of lipids." *Id.* (citing '3534 Patent at 1:41-61, 2:30-3:11; '467 Patent at 1:37-56, 2:27-3:9). However, lipids are not themselves liposomes. *Id.*

Moderna contends that its proposed construction is warranted because both claim terms must remain within the scope of a liposome's delivery system. *Id.* at 49. *First,* Moderna turns to the prosecution history to support its position that the disputed claim terms are limited to the boundaries of a liposome's delivery system. *Id.* Moderna contends that Plaintiffs never informed the United States Patent and Trademark Office ("PTO") that the scope of its lipid particles and lipids delivery systems was expanded. *Id.* Instead, Moderna contends that Plaintiffs "repeatedly told the PTO that, notwithstanding these changes, '[n]o new matter is added.'" *Id.* Moderna refers to specific portions of the specification that Plaintiffs cited to the PTO as support for the newly added claims directed to "lipid" and "lipid particles" delivery systems, and contends that these

representations demonstrate that Plaintiffs clearly and unequivocally tied the disputed claim terms to liposome delivery systems. *Id.* at 51-52. Moderna further contends that Plaintiffs' representations are binding. *Id.* at 53.

Second, Moderna argues that the claims and specification are consistent with and support its proposed construction because "liposomes," "lipid particles," and "lipids" impose structural meanings on the delivery system. *Id.* at 54. Specifically, the specification for the patents in the 243 Family state, "the invention provides a liposome," and that the "invention utilises liposomes." '467 Patent, 1:48-49, 1:63-65. Therefore, Moderna submits that these disclosures constrain the scope of "lipid particles" or "lipids" delivery systems to liposomes, such that the claims should be construed as "a lipid vesicle having a lipid bilayer encapsulating the aqueous core." D.I. 146 at 54-55.

The Court finds that the claim terms "lipid particles" and "lipids" require no further construction and shall be interpreted according to their plain and ordinary meaning. In construing the claim terms, the Court first turns to the claim language itself. *Phillips*, 415 F. 3d at 1312-14. In determining the proper construction of a claim term, the context of the surrounding words of the claim is important. *ACTV Inc. v. Walt Disney Co.*, 346 F. 3d 1082, 1088 (Fed. Cir. 2003). The surrounding claim language provides additional details about "lipid particles" and "lipids." Claim 1 of the '770 Patent, which is representative for the term "lipid particles," details that lipid particles are comprised of: (1) "a polyethylene glycol-ylated (PEGylated) lipid," (2) "cholesterol," (3) " a . . . phospholipid," and (4) "a cationic lipid." '770 Patent, Claim 1; *see also* '861 Patent, Claim 1 and '3534 Patent, Claim 1.[5] Similarly, Claim 1 of the '467 Patent describes that "lipids" are comprised of (1) "a tertiary amine cationic lipid," (2) "a polyethylene glycol-conjugated (PEG-

[5] The language of Claim 1 of the '3534 Patent does not contain a phospholipid.

conjugated) lipid" and (3) "cholesterol." '467 Patent, Claim 1. The Federal Circuit has held that a court can "rely[] heavily on the claim language to construe the claim term," especially when "the claim itself contains a precise definition of the term." *TIP System, LLC v. Phillips & Books/Gladwin, Inc.*, 529 F. 3d 1364, 1369 (Fed. Cir. 2008). As illustrated above, the claim language itself defines and provides context for the terms "lipid particles" and "lipids." The claim terms are used in a manner that conveys its scope through the surrounding language, including its relationships with other cited elements. Therefore, the Court finds that a person of ordinary skill in the art would understand the meaning of "lipids" and "lipid particles" without the need for further elaboration. *Celgene Corp. v. Hetero Labs Ltd.*, No. CV173387ESMAH, 2020 WL 3249117, at *9 (D.N.J. June 16, 2020) ("[A] plain and simple reading of the claim terms cannot deviate from the objective base line from which to begin claim interpretation; that is, how a person of ordinary skill in the art understands a claim term.")

Moderna does not dispute that the surrounding claim language defines and provides context to the disputed claim terms. Instead, Moderna contends that "lipid particles" and "lipids" are constrained to the boundaries of liposomes' delivery system due to Plaintiffs' representations to the PTO. In essence, Moderna argues that "lipid particles" and "lipids" as delivery systems are not adequately described or disclosed in the specifications. This argument implicates issues related to the validity of the patents rather than claim construction. *See TQ Beta LLC v. Dish Network Corp.*, No. 14-848, 2016 WL 356024, at *5 (D. Del. Jan. 28, 2016) ("Generally, questions of validity such as inadequate written description or enablement are premature at the claim construction stage of litigation."); *see also Phillips*, 415 F. 3d at 1327 ("While we have acknowledged the maxim that claims should be construed to preserve their validity, . . . we have certainly not endorsed a regime in which validity analysis is a regular component of claim

construction. . . . Instead, we have limited the maxim to cases in which the court concludes, after applying all the available tools of claim construction, that the claim is still ambiguous."). Moderna's argument is better suited for summary judgment, not claim construction. Accordingly, the Court declines to resolve the validity issue at this juncture. *See Ampex Corp. v. Eastman Kodak Co.*, 460 F. Supp. 2d 541, 543 n.1 (D. Del. 2006).

The Court turns next to the specification for the '770 Patent,[6] which is of limited utility because it does not set forth an explicit definition of "lipid particles." Nothing in the specification demonstrates a lexicographic definition or clear intent to disavow or limit the term from its ordinary and customary meaning. Accordingly, it supports Plaintiffs' construction. The specification for the '467 Patent likewise supports Plaintiffs' construction by describing "lipids" through various characteristics aligned with the claim language. *See* '467 Patent 2:9-10, 2:55-57, 3:4-11.

For the reasons discussed above, the Court finds that the claim terms "lipid particles" and "lipids" are adequately supported by and readily understandable in light of the intrinsic evidence and require no further construction. Therefore, "lipid particles" and "lipids" shall be interpreted according to their plain and ordinary meaning.

C. "Encapsulating" Terms

Claim Term	Plaintiffs' Construction	Moderna's Construction	PBNT's Construction	The Court's Construction
"lipid particles [/liposomes/ lipids] encapsulating [/encapsulate] at least half of the mRNA [/RNA] molecules"	No construction necessary: Plain and ordinary meaning, *i.e.*:	lipid vesicles having a lipid bilayer encapsulating an aqueous core and in which at least half of the		No further construction necessary: Plain

[6] The specification for the'770 Patent is the representative for the 242 Family patents in C.A. 24-1135 and C.A. 24-1136.

24-1136 ('770 Patent, Claims 1, 11, 16) ('861 Patent, Claim 1) ('864 Patent, Claim 1) ('529 Patent, Claim 1) ('467 Patent, Claim 1) ('3534 Patent, Claim 1)	lipid particles [/liposomes / lipids] enclosing [/ enclose] at least half of the mRNA [/ RNA] molecules	mRNA [/ RNA] molecules are in the aqueous core and separated from any external medium by the lipid bilayer		and ordinary meaning, *i.e.*: lipid particles [/liposomes / lipids] enclosing [/ enclose] at least half of the mRNA [/ RNA] molecules
"lipid particles [/liposomes/ lipids] encapsulating [/encapsulate] at least half of the mRNA [/RNA] molecules" 24-1135 ('770 Patent, Claims 1, 11, 16) ('645 Patent, Claims 1, 40) ('862 Patent, Claim 1) ('482 Patent, Claim 1) ('534 Patent, Claims 1, 37) ('467 Patent, Claim 1)	No construction necessary: Plain and ordinary meaning, *i.e.*: lipid particles [/liposomes / lipids] enclosing [/ enclose] at least half of the mRNA [/ RNA] molecules AND at least half of the mRNA molecules are enclosed within the liposomes	lipid vesicles having a lipid bilayer encapsulating an aqueous core and in which at least half of the mRNA [/ RNA] molecules are in the aqueous core and separated from any external medium by the lipid bilayer		Plain and ordinary meaning, which is lipid particles [/liposomes / lipids] enclosing [/ enclose] at least half of the mRNA [/ RNA] molecules AND at least half of the mRNA molecules are enclosed within the liposomes

(US2023/0111638, Claim 13) (US2023/0181618, Claim 13) (US2022/0125722, Claim 1)				
"the liposomes encapsulating at least half of the mRNA molecules" <u>24-512</u> ('475 Patent, All Asserted Claims)	No construction necessary: Plain and ordinary meaning, *i.e.*: "the liposomes enclosing at least half of the mRNA molecules"		at least half of the mRNA molecules are present in an aqueous core separated from any external medium by the liposomes' lipid bilayer	No further construction necessary: Plain and ordinary meaning, *i.e.*: "the liposomes enclosing at least half of the mRNA molecules"
"a liposome within which at least one ribonucleic acid (RNA) that encodes an immunogen of interests is encapsulated" <u>24-512</u> ('422 Patent, All Asserted Claims)	No construction necessary: Plain and ordinary meaning, *i.e.*: "a liposome within which at least one ribonucleic acid (RNA) that encodes an immunogen of interest is enclosed		at least half of the mRNA molecules are present in an aqueous core separated from any external medium by the liposomes' lipid bilayer	No further construction necessary: Plain and ordinary meaning, *i.e.*: "a liposome within which at least one ribonucleic acid (RNA) that encodes an immunogen of interest is enclosed
"the lipid particles encapsulating at least half of the RNA molecules"	No construction necessary: Plain and		at least one RNA that encodes an immunogen of interest is	No further construction necessary: Plain

24-512 ('660 Patent, All Asserted Claims)	ordinary meaning, *i.e.*: the lipid particles enclosing at least half of the mRNA molecules		present in an aqueous core separated from any external medium by the liposome's lipid bilayer	and ordinary meaning, *i.e.*: the lipid particles enclosing at least half of the mRNA molecules
"the lipids encapsulate at least half of the RNA molecules" 24-512 ('693 Patent, All Asserted Claims) ('594 Patent, All Asserted Claims) ('6534 Patent, All Asserted Claims) ('401 Patent, All Asserted Claims) ('467 Patent, All Asserted Claims)	No construction necessary: Plain and ordinary meaning, *i.e.*: the lipids enclosing at least half of the RNA molecules		at least half of the mRNA molecules are present in an aqueous core separated from any external medium by the lipid particles' lipid bilayer	No further construction necessary: Plain and ordinary meaning, *i.e.*: the lipids enclosing at least half of the RNA molecules
"the lipids encapsulate at least half of the first species of RNA molecules and at least half of the second species of RNA molecule" 24-512 ('694 Patent, All Asserted Claims)	No construction necessary: Plain and ordinary meaning, *i.e.*: the lipids enclosing at least half of the first species of RNA molecules and at least half of the second		at least half of the RNA molecules are present in an aqueous core separated from any external medium by the lipid's lipid bilayer	No further construction necessary: Plain and ordinary meaning, *i.e.*: the lipids enclosing at least half of the first species of RNA molecules and at least half of the second species of RNA molecule

	species of RNA molecule			

Next, the parties dispute how the claim term "encapsulate" should be construed across the Asserted Patents. Although the claim term varies slightly across the Asserted Claims, the "encapsulating" claim term generally takes the form of: "lipid particles [/liposomes/ lipids] encapsulating [/encapsulate] at least half of the mRNA [/RNA] molecules." *See, e.g.*, '770 Patent at Claim 1; '475 Patent at Claim 1.

Plaintiffs assert that the "encapsulating" claim terms do not require further construction. *See, e.g.*, D.I. 161 at 69, C.A. No. 24-1135.[7] In Plaintiffs' view, the specifications of the Asserted Patents repeatedly use "encapsulate" to mean "enclose," and distinguish RNA/mRNA "encapsulated" by the lipid structure to those that are external to the lipid structure. *Id.* at 70 (citing '467 Patent at 1:48-2:1, 18:50-20:43, 21:7-16; '770 Patent at 3:35-47, 4:50-56, 25:64-27:56, 28:21-29; '467 Patent at 2:1-6, 13:20-25, 21:7-16; '770 Patent at 4:50-56, 19:11-16, 28:21-29). In Plaintiffs' view, Defendants attempt to add new limitations into the claims by requiring the "encapsulation" to occur in "the aqueous core" of the lipid structures. *Id.* at 71.

Moderna asserts that the proper construction of the "encapsulating" claim term requires that the claimed lipid delivery systems "encapsulate" RNA/mRNA in their aqueous cores. D.I. 161 at 73. Moderna identifies several embodiments in the specifications of the Asserted Patents where the lipid delivery systems encapsulate the RNA/mRNA in the aqueous core of said delivery system. *Id.* at 75 (citing '770 Patent at 4:50-56; '467 Patent at 1:63-2:9). Thus, in Moderna's

[7] Plaintiffs' arguments concerning the "encapsulating" claim terms are the same across all three cases, and unless noted otherwise, the Court will cite to D.I. 161 in C.A. No. 24-1135 when discussing Plaintiffs' arguments regarding this claim term.

view, the lipid delivery system described by the specifications of the Asserted Patents *necessitates* that the RNA/mRNA be encapsulated by the aqueous core of said delivery system. *Id.* at 75-76.

PBNT also requests that the Court construe the "encapsulating" claim term in the Asserted Patents to require that the claimed lipid delivery systems encapsulate the RNA/mRNA in the aqueous core of said delivery system. D.I. 166 at 32, C.A. No. 24-512. Also citing to the specifications of the Asserted Patents, PBNT identifies several instances where, in its view, the RNA/mRNA is encapsulated by the aqueous core of the claimed lipid delivery system. *Id.* at 33 (citing '693 Patent at 2:2-6; '422 Patent at 2:37-44; '475 Patent at 4:58-64). Moreover, PBNT points to the prosecution history of unasserted U.S. Patent No. 9,254,265 (the "'265 Patent"), where the applicant specifically stated that the "'encapsulation requires that the RNA be present in the aqueous 'core' of the liposome . . . ." D.I. 168, JA-014 Ex. 7 at 6, C.A. No. 24-512.

The Court agrees with Plaintiffs. Importantly, the "encapsulating" element in all Asserted Claims contain no requirement as to where the mRNA is encapsulated within the liposome, whether or not it is in the aqueous core. *See, e.g.*, '694 Patent, All Asserted Claims; '467 Patent, All Asserted Claims; '693 Patent, All Asserted Claims; '594 Patent, All Asserted Claims; '6534 Patent, All Asserted Claims; '401 Patent, All Asserted Claims; '660 Patent, All Asserted Claims; '422 Patent, All Asserted Claims; '475 Patent, All Asserted Claims. "[U]nless required by the specification, limitations that do not otherwise appear in the claims should not be imported into the claims." *N. Am. Container, Inc. v. Plastipak Packaging, Inc.*, 415 F.3d 1335, 1348 (Fed. Cir. 2005). Although the specifications of the Asserted Patents do describe the RNA/mRNA as residing in the "aqueous core" of the lipid delivery system (*see, e.g.*, '693 Patent at 2:07-09; '770 Patent at 4:50-53), the specifications of the Asserted Patents also decline to specify this limitation in other embodiments, '770 Patent at 21:35-37 ("Where the RNA is delivered with a liposome, the

liposome comprises DSDMA, DODMA, DLinDMA and/or DLcnDMA."); *id.* at 38:40 ("Where the RNA is encapsulated in a liposome, the hydrophilic portion of a lipid in the liposome is PEGylated."). Importantly, specifications of the Asserted Patents describe situations where the RNA/mRNA is not "encapsulated" by the lipid delivery system, by placing the RNA/mRNA external to the *entire* lipid delivery system. *See, e.g.*, '693 Patent at 2:02-06 ("The invention utilizes liposomes in which immunogen-encoding RNA is encapsulated. Thus the RNA is (as in a natural virus) separated from any external medium by the liposome's lipid bilayer, and encapsulation in this way has been found to protect RNA from RNase digestion."); *id.* at 2:07-09 ("The liposomes can include some *external RNA (e.g. on their surface)*, but at least half of the RNA (and ideally all of it) is encapsulated in the liposome's core" (emphasis added)). Thus, "encapsulated," as used by the specifications of the Asserted Patents, means enclosed within the lipid structure, not within the aqueous core.

Furthermore, the Court agrees with Plaintiffs that, under Defendants' proposed construction, MLVs that should be encompassed by the scope of the Asserted Claims would be excluded. The Asserted Patents teach that, in MLVs, there are "several separate aqueous compartments." *See, e.g.*, '770 Patent at 4:29-30. The Court cannot discern, nor have Defendants identified, any instance where the Asserted Patents limit the encapsulation of the RNA/mRNA to the "aqueous core" of an MLV, rather than distributing the RNA/mRNA across the various aqueous compartments. *See generally* '770 Patent (not explicitly limiting where the RNA/mRNA resides in the lipid delivery system in this regard).

Defendants' arguments to the contrary are unpersuasive. Moderna, pointing to the prosecution histories and specifications of the patents asserted against it, contends that a POSA would understand the claim language to place the RNA/mRNA in the aqueous core of the lipid

delivery system. D.I. 161 at 75, C.A. No. 24-1135. This requirement is absent from the claim language and, thus, it would be improper for the Court to construe the claims to require it. *MasterMine Software, Inc. v. Microsoft Corp.*, 874 F.3d 1307, 1310 (Fed. Cir. 2017) ("But '[w]hile we read claims in view of the specification, of which they are a part, we do not read limitations from the embodiments in the specification into the claims.'" (citing *Hill-Rom Servs., Inc.*, 755 F.3d at 1371). Importantly, with regard to MLVs, Moderna contends that MLVs containing RNA/mRNA are encompassed within the scope of the invention, as long as *half* of the RNA/mRNA are present in the MLV's core. D.I. 146 at 81, C.A. 24-1136 (citing '467 Patent at 2:4-6). However, the portion of the '467 Patent's specification that Moderna cites in support differentiates the RNA on the *surface* of the liposome with that encapsulated by the aqueous core. '467 Patent at 2:2-4 ("The liposomes can include some external RNA (e.g. on their surface), but at least half of the RNA (and ideally all of it) is encapsulated in the liposome's core."). Thus, the specification of the '467 Patent is differentiating between *external* RNA and *internal* RNA, not *internal* RNA outside of the aqueous core and *internal* RNA within said core. *Id.*

Likewise, PBNT's assertions lack merit. For the reasons discussed *supra*, PBNT's arguments relating to the intrinsic evidence of the Asserted Patents are unpersuasive. PBNT posits an additional argument regarding MLVs containing RNA/mRNA in an aqueous compartment but not in the aqueous core of said MLV, asserting that the specification never describes an embodiment where the RNA/mRNA is present in an aqueous compartment that would not be considered the aqueous core of the MLV. D.I. 166 at 41, C.A. No. 24-512. However, "[t]he specification need not describe every embodiment of the claimed invention, and the claims should not be confined to the disclosed embodiments – even when the specification discloses only one embodiment." *Woods v. DeAngelo Marine Exhaust, Inc.*, 692 F.3d 1272, 1283 (Fed. Cir. 2012)

(internal citations omitted). Thus, and for reasons previously discussed, PBNT's assertions that the claims should be limited to MLVs that contain over half the RNA/mRNA in the aqueous core of the lipid delivery systems, as opposed to encompassed by the lipid delivery systems more generally, are unpersuasive.

Moreover, PBNT's reliance on the '265 Patent's prosecution history is misplaced. In prosecuting the '265 Patent, the applicant stated that "it is evident that 'encapsulation' requires that the RNA be present in the aqueous 'core' of the liposome, which is different *from the attachment of RNA to the outer surface of pre-formed liposomes*." D.I. 168, JA-014, Ex. 7 at 6, C.A. No. 24-512 (emphasis added). Thus, the prosecution history that PBNT relies on differentiates RNA on the *exterior* of the liposome, rather than on its *interior*. *Id.* Furthermore, "because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005); *see also Bondyopadhyay v. United States*, 129 Fed. Cl. 793, 801 (2017). The prosecution history that PBNT cites to is, at best, ambiguous, and thus unpersuasive, considering the specifications of the Asserted Patents.

PBNT also identifies extrinsic evidence that teaches that a POSA would have understood "encapsulate" to mean "within an aqueous space," as opposed to "intercalated" which refers "to incorporation of the drug substance within a bilayer." D.I. 166 at 36, C.A. No. 24-512. However, the Asserted Patents use "encapsulate" in a way that is broader than the narrow technical definition that PBNT proffers, such as stating that the aqueous core is "encapsulated" within the lipid bilayer, '693 Patent, 1:53-54. The Court finds this distinction important. The Asserted Patents choosing to state that the aqueous core is *encapsulated* within the lipid bilayer, rather than *intercalated*

within said bilayer, suggests that "encapsulated" as used in the Asserted Patents means "encompassed by," which is consistent with the Court's construction.

For the foregoing reasons, the Court will adopt Plaintiffs' construction for all "encapsulating" terms cross all Asserted Claims, and will give the terms their plain and ordinary meaning, where the lipid/lipid particle/liposome must encompass at least half the RNA/mRNA.

D. "by eliciting an antibody response against the immunogen in vivo"[8]

Disputed Term	Plaintiffs' Construction	PBNT's Construction	The Court's Construction
"by eliciting an antibody response against the immunogen in vivo" ('467 Patent, All Asserted Claims)	No construction necessary: Plain & ordinary meaning, *i.e.*: "by eliciting an antibody response against the immunogen in vivo"	"by eliciting an antibody response against the immunogen encoded by the RNA in vivo"	No further construction necessary. Plain and ordinary meaning, *i.e.*: "by eliciting an antibody response against the immunogen in vivo"

The parties' next dispute whether the claim language from all asserted claims of the '467 Patent should be construed to include the phrase "encoded by the RNA." The relevant claim language is as follows:

> 1. A formulation comprising: ribonucleic acid (RNA) molecules comprising a sequence that encodes an immunogen; . . . 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.

'467 Patent, Claim 1 (emphasis added).

[8] All citations within this subsection, § IV.D, and the remaining sections (§§ IV.E-G), are to the docket in C.A. No. 24-512.

The dispute arises from the interaction between "*the* immunogen" and "*an* immunogen" and in the relevant claim language. In general, both parties agree that the claim language requires that "*the* immunogen" refer to the previously recited "*an* immunogen." *Compare* D.I. 166 at 42 (Plaintiffs) ("The claim language already recites that aspect of the claimed limitation."), *with id.* at 44 (PBNT) (noting the parties' agreement in substance), *and id.* at 45 (Plaintiffs) (stating that the "relationship is already explicit on the face of [the claim]"). However, the parties disagree as to whether construction is necessary. PBNT contends that its proposed construction makes the interaction between "an immunogen" and "the immunogen" more clear. *Id.* at 44. Plaintiffs oppose, contending that no construction is necessary, since the claim language is straightforward, and further construction "would only serve to create redundant ambiguity that would confuse the jury." *Id.* at 42. Plaintiffs also observe that "*both sides* agree that *the claim* makes clear that the 'antibody response' is 'elicit[ed]' against the 'immunogen' that – as recited earlier in the claims – *is encoded by the RNA*." *Id.* at 45 (emphasis added).

The Court agrees that it is clear from the claim language that "the immunogen" refers to the earlier recited "an immunogen," which provides the only antecedent basis for "the immunogen." Thus, the Court concludes that no construction is necessary, as "the plain and ordinary meaning of the disputed claim language is clear." *Summit 6, LLC v. Samsung Elecs. Co., Ltd.*, 802 F.3d 1283, 1291 (Fed. Cir. 2015).

Next, the parties' dispute whether Claim 1 of the '467 Patent and Claim 16 of U.S. Patent Publication No. 2022/0125722 (the "'722 Publication")[9] are "substantially identical" for the

[9] The '722 Publication is a published version of U.S. Patent Application No. 17/560,019 – from which the '467 Patent later issued – that was published on April 28, 2022.

purpose of 35 U.S.C. § 154(d).[10] Section 154(d) allows the patentee the right to obtain pre-issuance damages in limited circumstances. *See* 35 U.S.C. § 154(d)(1). This right is available only if, among other requirements, "the invention as claimed in the patent is substantially identical to the invention as claimed in the published patent application." 35 U.S.C. § 154(d)(2).

According to PBNT, Claim 16 of the '722 Publication differs from Claim 1 of the '467 Patent in two ways: *first*, Claim 16 of the '722 Publication does not require the "antibody response" to be against the antecedent "immunogen," as recited in Claim 1 of the '467 Patent; and *second*, Claim 16 of the '722 Publication does not require the "antibody response" to be "in vivo." *See* D.I. 166 at 48-49. Claim 16 of the '722 Publication depends from Claim 15, which depends from Claim 1. The relevant claim language is as follows:

> 1. A formulation comprising: ribonucleic acid (RNA) molecules comprising a sequence that encodes an immunogen; and lipids comprising a tertiary amine cationic lipid, a polyethylene glycol-conjugated (PEG-conjugated) lipid, and cholesterol; wherein the lipids encapsulate at least half of the RNA molecules.
>
> * * *
>
> 15. The formulation of claim 1, wherein the formulation is immunogenic in vivo.
>
> 16. The formulation of claim 15, wherein **the formulation elicits an antibody response**.

'722 Publication, Claims 1, 15, 16 (emphasis added).

[10] The parties preliminarily dispute whether it is timely for the Court to consider whether the scopes of Claim 1 of the '467 Patent and Claim 16 of the '722 Publication are substantially identical at the *Markman* stage, as opposed to later in the litigation. *See* D.I. 166 at 45-46. While the Court recognizes that, it may be proper in some cases to defer this determination for a later stage of proceedings, such as summary judgment, the Court concludes that the nature of the record at this stage is sufficiently developed to make the determination.

Having considered the parties' briefing and oral argument regarding whether the Claim 1 of the '467 Patent and Claim 16 of the '722 Publication are substantially identical in scope, the Court agrees with PBNT that the published and as-issued claim scopes are not "substantially identical" for the purpose of Section 154(d)(2). Claim 16 of the '722 Publication merely requires that "the formulation elicit[] an antibody response." '722 Publication, Claim 16. In contrast, Claim 1 of the '467 Patent, as provided above, more narrowly requires that "the formulation is immunogenic in vivo by eliciting an antibody response against *the immunogen* in vivo." '467 Patent, Claim 1 (emphasis added). As analyzed above, "the immunogen" recited in Claim 1 of the '467 Patent has only the earlier recited "an immunogen" as an antecedent basis. Claim 16 of the '722 Publication, however, does not explicitly link the recited antibody response, as Claim 1 of the '467 Patent does, to an antecedent "immunogen." Instead, it links the recited antibody response to an earlier recited "formulation." Thus, the claims are substantively different in scope.

In opposition, Plaintiffs assert that PBNT disregards the canons of claim dependency and antecedent basis. D.I. 166 at 52. However, by asserting that the "immunogen" recited in Claim 1 of the '722 Publication forms the antecedent basis for "the immunogen recited in claim 16," such that "claim 16's antibody response results from the immunogen required by claim 1," *see id.*, it is Plaintiffs that have misstated the claims because Claim 16 of the '722 Publication does not recite any "immunogen." Nor does this interpretation of the claim language violate any canons of claim construction: dependent Claim 16 of the '722 Publication is necessarily narrower than any claim from which it depends. *See, e.g.*, *Alcon Rsch., Ltd. v. Apotex Inc.*, 687 F.3d 1362, 1367 (Fed. Cir. 2012) ("It is axiomatic that a dependent claim cannot be broader than the claim from which it depends."). Second, Plaintiffs' citation to the specification of the '722 Publication is similarly misplaced. Given that Claim 1 of the '467 Patent is a "comprising" claim, the formulation may

have other components that the recited "antibody response" could be against. *See, e.g.*, *Boesen v. Garmin Int'l, Inc.*, 455 F. App'x 974, 977 (Fed. Cir. 2011). Thus, the Court finds that, for the purpose of Section 154, "the invention as claimed in [Claim 1 of the '467 Patent]" is not "substantially identical to the invention as claimed in [Claim 16 of the '722 Publication]." 35 U.S.C. § 154(d)(2). Given the Court's finding that the claim scopes are not substantively identical, the Court declines to engage in any further claim construction with respect to Claim 16 of the '722 Publication.

E. "at least two unit doses being sequential and at least 1 week apart" / "at least two unit doses being sequential and administered at least 1 week apart"

Disputed Term	Plaintiffs' Construction	PBNT's Construction	The Court's Construction
"at least two unit doses being sequential and at least 1 week apart" ('475 Patent, All Asserted Claims)	No construction necessary: Plain & ordinary meaning, *i.e.*: "at least two unit doses being sequential and at least 1 week apart"	"at least two unit doses being administered according to a multiple unit dose schedule at least 1 week apart"	"at least two unit doses being within a scheduled sequence or series and at least 1 week apart"
"at least two unit doses being sequential and administered at least 1 week apart" ('660 Patent, All Asserted Claims)	No construction necessary: Plain & ordinary meaning, *i.e.*: "at least two unit doses being sequential and administered at least 1 week apart"	"at least two unit doses being administered according to a multiple unit dose schedule at least 1 week apart"	"at least two unit doses being within a scheduled sequence or series and administered at least 1 week apart"

The '475 Patent and '660 Patent are from the same family. D.I. 122 at 1-2. The dispute between the parties focuses on the meaning of "sequential" and how it governs the relationship between recited "at least two unit doses." *See* D.I. 166 at 56-64.

Plaintiffs contend that the claim language does not require that "at least two unit doses" be administered as "part of a schedule." *Id.* at 62. Plaintiffs assert that the terms require no construction, and that PBNT seeks to "complicate the otherwise straightforward claim language" by importing "overly technical jargon" into the construction that will confuse the jury. *Id.* at 57; *see also id.* at 62.

PBNT disagrees and asserts that the Court should construe the term "sequential" to clarify that the unit doses are administered according to a multiple unit dose schedule. *See* D.I. 166 at 58. First, PBNT asserts that the language set forth in its proposed construction is drawn from the specifications of the patents. As to this point, PBNT is correct that the specifications of both patents reference a "multiple unit dose schedule." *See, e.g.*, '475 Patent at 21:1-2 ("Dosage can be by a single unit dose schedule or a multiple unit dose schedule.").[11] Second, PBNT asserts that the Court should reject Plaintiffs' proposal of no construction because Plaintiffs' proposed construction renders the term "sequential" superfluous. D.I. 166 at 59.

The relevant claim language is as follows:

> 1. 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; . . . **the at least two unit doses being sequential and at least 1 week apart**; the administering comprising contacting the composition with skeletal muscle; . . . .

[11] The Court will refer (as the parties have), to the specification of the '475 Patent. *See Alnylam Pharms., Inc. v. Moderna, Inc.*, 138 F.4th 1326, 1329 n.1 (Fed. Cir. 2025) (referring to the specification of only one patent where the parties had not "identified any difference in the two patents' specifications that [wa]s material to the issue on appeal").

> 35. 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, . . . ; **the at least two unit doses being sequential and at least 1 week apart**; the administering comprising contacting the composition with skeletal muscle . . . .

'475 Patent, Claims 1, 35 (emphasis added).

> 1. 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, . . . **the at least two unit doses being sequential and administered at least 1 week apart**; the administering comprising contacting the composition with skeletal muscle . . . .

> 16. 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, . . . **the at least two unit doses being sequential and administered at least 1 week apart**; . . . .

'660 Patent, Claims 1, 16 (emphasis added).

Having thoroughly considered the parties' contentions, the Court finds that construction of the claim terms is necessary to resolve the parties' dispute. The Court begins its analysis with the claim language. Each claim term contains the phrase "*sequential* and [administered] at least 1 week apart." '475 Patent, Claims 1, 35 (emphasis added); *see also* '660 Patent, Claims 1, 16. In the present case, if the term "sequential" referred solely to a time-based relationship between the recited unit doses (i.e., that the doses are not simultaneously administered), then the word "sequential" would be rendered superfluous by the subsequently recited "at least 1 week apart" language. *See Intel Corp. v. Qualcomm Inc.*, 21 F.4th 801, 810 (Fed. Cir. 2021) (noting that "[i]t is highly disfavored to construe terms in a way that renders them void, meaningless, or superfluous." (citations omitted)). In other words, because the claims require the at least two unit

doses to be "sequential" *and* "at least 1 week apart," then "there must be some distinction between those two concepts." *Intel*, 21 F.4th at 810. While Plaintiffs assert that "[t]he claims' recitation of 'sequential' makes clear that when more than one unit dose is administered, they are not administered simultaneously," D.I. 166 at 62, this is *already* made clear by the "at least 1 week apart" language and reaffirms the Court's finding that the word "sequential" requires something more than solely a time-based relationship between the at least two unit doses. While this can be drawn from the claim language, it can only "advance the claim-construction inquiry only so far." *Intel*, 21 F.4th at 810. Thus, the Court turns to the patents' specifications.

"[T]he specification 'is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'" *Phillips*, 415 F.3d at 1315 (quoting *Vitronics*, 90 F.3d at 1582); *see also Markman*, 517 U.S. at 389 ("[A claim] term can be defined only in a way that comports with the instrument as a whole."). In both patents, however, the word "sequential" appears only in the claim language and *not* in the specification; i.e., the patentee did not otherwise define the term "sequential" within the patent. *See Phillips*, 415 F.3d at 1316 (noting the "general principle" that "the specification may reveal a special definition given to a claim term"). The specifications do, however, provide some guidance. As the patents explain with respect to "dosage" and "dose schedule[s]":

> **Dosage can be by a single unit dose schedule or a multiple unit dose schedule.** Multiple doses may be used in a primary immunization schedule and/or in a booster immunization schedule. **In a multiple dose schedule the various doses may be given by the same or different routes**, e.g., a parenteral prime and mucosal boost, a mucosal prime and parenteral boost, etc. **Multiple doses will typically be administered at least 1 week apart** (e.g., about 2 weeks, about 3 weeks, about 4 weeks, about 6 weeks, about 8 weeks, about 10 weeks, about 12 weeks, about 16 weeks, etc.).

'475 Patent at 21:1-10 (emphasis added). As PBNT acknowledges – and Plaintiffs do not dispute – the patent does not disclose other overarching embodiments with respect to dosage beyond the

"single unit dose schedule" and the "multiple unit dose schedule." D.I. 166 at 58-59, 63. Nonetheless, although the specification discusses both single and multiple unit dose schedules as embodiments of the invention, the inventor deliberately declined to incorporate such language into the claims. The specification does not appear to confine the invention to that embodiment, whereas PBNT's proposed construction would do so. The Federal Circuit has recognized that, "although the specification often describes very specific embodiments of the invention," courts should not "confin[e] the claims to those embodiments." *Phillips*, 415 F.3d at 1323 (collecting cases). Thus, the Court rejects PBNT's proposed construction.

The parties confine their arguments to the claim language and specification, and neither party references the patents' prosecution history. A review of the relevant prosecution history does not indicate that the applicant's inclusion of the term "sequential" generated any discussion during prosecution of either the '475 Patent or '660 Patent.

As the Federal Circuit has explained, "extrinsic evidence may be useful to the court, but it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Phillips*, 415 F.3d at 1319. One such form of extrinsic evidence is the definition of a term from within a dictionary. *See Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1382 (Fed. Cir. 2008) ("When the intrinsic evidence is silent as to the plain meaning of a term, it is entirely appropriate for the district court to look to dictionaries or other extrinsic sources for context – to aid in arriving at the plain meaning of a claim term.").

PBNT offers several definitions of the term "sequential" and its analogs from general purpose and medical dictionaries, all of which connote occurrences within a sequence, series, or order. D.I. 166 at 60 (collecting definitions). Plaintiffs proffer no countervailing definitions of their own and did not address the definitions or dictionaries cited by PBNT. However, given

Plaintiffs' repeated assertion that the claim language is "understandable even to a lay person," the Court understands Plaintiffs not to be arguing lexicography. *See* D.I. 166 at 62-63.

Having thoroughly considered the parties' briefing, the claim language, the patent specifications, prosecution histories, and pertinent dictionary definitions, the Court construes "sequential" to mean "within a scheduled sequence or series," which is consistent with the intrinsic and extrinsic evidence presented. Therefore, the Court construes "at least two unit doses being sequential and at least 1 week apart" to mean "at least two unit doses being within a scheduled sequence or series and at least 1 week apart" and "at least two unit doses being sequential and administered at least 1 week apart" to mean "at least two unit doses being within a scheduled sequence or series and administered at least 1 week apart."

F. "whereby the pKa is determined at standard temperature and pressure by the following . . . is obtained"

Disputed Term[12]	Plaintiffs' Construction	PBNT's Construction	The Court's Construction
"whereby the pKa is determined at standard temperature and pressure by the following . . . is obtained" ('693 Patent, All Asserted Claims) ('694 Patent, All Asserted Claims) ('467 Patent, Claims 28, 29)	No construction necessary: Plain & ordinary meaning, *i.e.*: "whereby the pKa is determined at standard temperature and pressure by the following . . . is obtained"	This limitation is an active process step that must be performed, rendering the formulation patent claims invalid as indefinite.	Indefinite. This limitation is an active process step that must be performed, rendering the formulation patent claims invalid as indefinite.

[12] PBNT withdrew its indefiniteness challenge to other claims not involving the '693 Patent, '694 Patent, and '467 Patent at oral argument. Accordingly, the Court confines its analysis to the relevant claims of the '693 Patent, '694 Patent, and '467 Patent that were cited in the parties' briefing.

The parties dispute whether certain claims including the limitation "whereby the pKa is determined at standard temperature and pressure by the following . . . is obtained" are indefinite. *See* D.I. 166 at 64-70. The Court will refer to this term as the "pKa claim limitation." Each of the patents containing the pKa claim limitation belong to the same family. *See* D.I. 122 at 1. Plaintiffs contend that the pKa claim limitation does not render the relevant claims indefinite and requires no construction. D.I. 166 at 64. PBNT responds that the claims containing the pKa claim limitation are indefinite under *IPXL Holdings, L.L.C. v. Amazon.com, Inc.*, 430 F.3d 1377 (Fed. Cir. 2005) and its progeny. D.I. 166 at 65. Specifically, PBNT asserts that the claims containing the pKa claim limitation are indefinite because they claim a "formulation" yet also require several "method" steps. *Id.* In addition, PBNT asserts that the prosecution history, specifically the prosecution history underlying the '467 Patent, supports its position. *Id.* at 67.

The claims containing this language are replicated, in relevant part, below:

> 1. 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, . . . ; wherein . . . 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 . . . is obtained.**

'693 Patent, Claim 1 (emphasis added).

> 28. The formulation of claim 17, wherein the tertiary amine cationic lipid has a pKa from 6.07 to 7.6; **whereby the pKa is determined at standard temperature and pressure by the following . . . is obtained.**
>
> 29. The formulation of claim 28, wherein the tertiary amine cationic lipid has a pKa from 6.07 to 7.0.

'467 Patent, Claims 28-29 (emphasis added).

In *IPXL*, the Federal Circuit addressed a question of first impression, "[w]hether a single claim covering both an apparatus and a method of use of that apparatus is invalid," and answered

that question in the affirmative. 430 F.3d at 1384. The claim at issue in *IPXL*, Claim 25 of U.S. Patent No. 6,149,055, was as follows:

> The *system of claim 2* [including an input means] wherein the predicted transaction information comprises both a transaction type and transaction parameters associated with that transaction type, and *the user uses the input means* to either change the predicted transaction information or accept the displayed transaction type and transaction parameters.

Id. (emphasis and alteration in original) (citation omitted). Assessing this claim, the *IPXL* court reasoned that "it is unclear whether infringement of claim 25 occurs when one creates a system that allows the user to change the predicted transaction information or accept the displayed transaction, or whether infringement occurs when the user actually uses the input means to change transaction information or uses the input means to accept a displayed transaction." *Id.*

Since *IPXL*, the Federal Circuit has addressed many claims within this framework.[13] In these decisions, the Federal Circuit has distinguished claims that include active verbs requiring action by the *user* from claims that include verbs stating "permissible functional language

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[13] *Compare In re Katz Interactive Call Processing Pat. Litig.*, 639 F.3d 1303, 1318 (Fed. Cir. 2011) (finding indefinite claims that recited a system having "interface means for providing automated voice messages . . . to certain of said individual callers, wherein said certain of said individual callers digitally enter data"); *Rembrandt Data Techs., LP v. AOL, LLC*, 641 F.3d 1331, 1339 (Fed. Cir. 2011) (finding as indefinite a claim for an apparatus that contained four elements reciting elements of the apparatus and one element claiming "transmitting the trellis encoded frames" because the "transmitting" step was a method step), *with Microprocessor Enhancement Corp. v. Texas Instruments Inc.*, 520 F.3d 1367, 1374-75 (Fed. Cir. 2008) ("*MEC*") (finding as not indefinite an method claim reciting "[a] method of executing instructions in a pipelined processor comprising: [structural limitations of the pipelined processor]; the method further comprising: [method steps implemented in the pipelined processor]"); *HTC Corp. v. IPCom GmbH & Co., KG*, 667 F.3d 1270, 1277 (Fed. Cir. 2012) (finding as not indefinite claims to a mobile station containing, as elements, six enumerated functions of that mobile station because the claims "merely establish[ed] those functions as the underlying network environment in which the mobile station operates"); *UltimatePointer, L.L.C. v. Nintendo Co.*, 816 F.3d 816, 826-827 (Fed. Cir. 2016) (finding not indefinite claims to "a handheld device including: an image sensor, said image sensor generating data" because the claims "claim[ed] an apparatus with particular capabilities" and did not "recite functionality divorced from the cited structure").

describing the capabilities" of the system or apparatus itself. *See MasterMine Software, Inc. v. Microsoft Corp.*, 874 F.3d 1307, 1315-16 (Fed. Cir. 2017) (distinguishing *MEC*, *HTC*, and *UltimatePointer* on this basis). For example, in *MasterMine*, the court analyzed claims reciting a system that comprised a "reporting module installed within the CRM software application," wherein that reporting module "presents," "receives," and "generates." *Id.* The Federal Circuit held that these claims were not indefinite under *IPXL*. *Id.* at 1316 ("While these claims make reference to user selection, they do not explicitly claim the user's act of selection, but rather, claim the system's capability to receive and respond to user selection."); *see also id.* (distinguishing *Rembrandt* on the basis that the "functional language" recited was "specifically tied to structure" rather than "appear[ing] in isolation").

Across the relevant patents and claims, the disputed pKa claim limitation recites fourteen numbered steps, including "admixing" (several times), "measuring," "subtracting," "normalizing," and "obtaining." *See, e.g.*, '693 Patent, Claim 1. PBNT groups these claims together as the "asserted formulation claims that also recite the method step, 'whereby the pKa is determined at standard temperature and pressure by the following . . . is obtained.'" D.I. 166 at 65.

In analyzing these claims, the Court finds instructive *Aventis Pharma S.A. v. Hospira, Inc.*, 743 F. Supp. 2d 305 (D. Del. 2010), *aff'd*, 675 F.3d 1324 (Fed. Cir. 2012) (Sleet, C.J.). Both parties discuss *Aventis* in their briefing. *See* D.I. 166 at 65-66 (PBNT, relying on *Aventis*), 69 (Plaintiffs, attempting to distinguish *Aventis* but not disputing its applicability). In *Aventis*, the court analyzed two composition claims in the pharmaceutical context. *See id.* at 328 (quoting claims 2 and 10 of U.S. Patent No. 5,750,561). The two composition claims included limitations reciting, "'whereby said composition *is used to form*' for claim 2, and 'whereby said therapeutic composition forms or *is used to form*' for claim 10." *Id.* (emphasis in original) (citation omitted).

Applying *IPXL*, the court held that the two claims were indefinite. *Id.* at 329. The court reasoned that "it is quite possible that the stock solution will be discarded before it is ever 'used to form an injectable solution.' In such a case, it is not clear whether infringement ever occurred." *Id.* at 330.

Against this backdrop, Plaintiffs do not dispute that claims that impermissibly mix formulations and method steps present an indefiniteness problem under *IPXL* and *Aventis*. D.I. 166 at 68-69. Rather, Plaintiffs contend that the claims in *Aventis* are distinguishable from those in the present case, and maintains that, "[b]ecause the pKa value is a property of the ionizable cationic lipid when measured under the specified conditions, that property holds regardless of how that lipid is later employed." D.I. 166 at 68-69. In their briefing, Plaintiffs concede that the pKa claim limitation contains "recited steps" and "set[s] out a procedure," yet simultaneously assert that these "recited steps" do not "set forth a process step." *Id.* at 68. Plaintiffs further assert that the recited steps serve to eliminate ambiguity by "specifying which *procedure* and conditions to use." *Id.* (emphasis added).

The Court is not persuaded by Plaintiffs because it is unclear whether infringement of the relevant claims occurs when one creates a formulation, or whether infringement occurs when the pKa of the cationic lipid "is determined" through the steps set forth in the pKa claim limitation. *See IPXL*, 430 F.3d at 1384. As set forth below, several factors support the Court's conclusion.

First, the pKa claim limitation requires that the "pKa is determined . . . by the following [fourteen steps]." *See, e.g.*, '693 Patent, Claim 1. This is a method limitation. *See Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1468 (Fed. Cir. 1990) ("[A]pparatus claims cover what a device *is*, not what a device *does*." (emphasis in original)). Plaintiffs' reading of the claims, that infringement could occur "even if the pKa of the cationic lipid is *never measured* under

the required conditions," D.I. 166 at 69 (emphasis added), effectively reads the pKa claim limitation out of the claim language entirely.

Second, the steps recited in the pKa claim limitation – e.g., "admixing" (several times), "measuring," "subtracting," "normalizing," and "obtaining" – recite steps performed by the *user*, rather than representing capabilities of the *claimed formulation*. *See MasterMine*, 874 F.3d at 1315. As a result, there is impermissible ambiguity as to when infringement occurs because these claims require that the cationic lipid has a certain pKa and that this pKa be determined via the steps recited in the pKa claim limitation. *See id.*

Third, Plaintiffs' reliance on the prosecution history of the '467 Patent is unpersuasive. Plaintiffs contend that "the prosecution history confirms . . . that the [pKa claim limitation] pertain[s] to a property of the ionizable lipid, not of any finished formulation." D.I. 166 at 69. The fact that the pKa refers to the pKa of the cationic lipid, rather than the whole formulation, is already made clear by the claims, since the only antecedent basis for the pKa in the pKa claim limitation is the pKa of the cationic lipid. *See, e.g.*, '467 Patent, Claim 28 ("The formulation of claim 17, wherein the tertiary amine cationic lipid has a pKa from 6.07 to 7.6; whereby the pKa is determined at standard temperature and pressure by the following . . . is obtained."). Importantly, the issue is not whether the process steps of the pKa claim limitation are performed upon the entire claimed formulation or instead a component thereof, but whether the claims apprise a person of ordinary skill in the art of their scope. The actual inquiry is whether the claims recite both an apparatus and a method of using that apparatus, given that the Federal Circuit has repeatedly held that "reciting both an apparatus and a method of using that apparatus renders a claim indefinite under section 112, paragraph 2." *Rembrandt*, 641 F.3d at 1339 (quoting *IPXL*, 430 F.3d at 1384). The answer to that question is yes.

For the foregoing reasons, the Court holds that PBNT has met its burden to show that all asserted claims of the '693 Patent, all asserted claims of the '694 Patent, and Claims 28 and 29 of the '467 Patent are invalid as indefinite under *IPXL*.

G. "the formulation is immunogenic in vivo by eliciting an antibody response against the immunogen in vivo" / "the formulation is immunogenic in vivo by eliciting an antibody response against the first immunogen and the second immunogen in vivo"

Disputed Term	Plaintiffs' Construction	PBNT's Construction	The Court's Construction
"the formulation is immunogenic in vivo by eliciting an antibody response against the immunogen in vivo" ('693 Patent, All Asserted Claims) ('467 Patent, All Asserted Claims)	No construction necessary: Plain & ordinary meaning, *i.e.*: "the formulation is immunogenic in vivo by eliciting an antibody response against the immunogen in vivo"	This limitation is an active process step that must be performed, rendering the formulation patent claims invalid as indefinite.	Not indefinite.
"the formulation is immunogenic in vivo by eliciting an antibody response against the first immunogen and the second immunogen in vivo" ('694 Patent, All Asserted Claims)	No construction necessary: Plain & ordinary meaning, *i.e.*: "the formulation is immunogenic in vivo by eliciting an antibody response against the first immunogen and the second immunogen in vivo"	This limitation is an active process step that must be performed, rendering the formulation patent claims invalid as indefinite.	Not indefinite.

The parties dispute (1) whether the claim term "the formulation is immunogenic in vivo by eliciting an antibody response against the immunogen in vivo" in all asserted claims of the '693 Patent and all asserted claims of the '467 Patent, and (2) whether the claim term "the formulation

is immunogenic in vivo by eliciting an antibody response against the first immunogen and the second immunogen in vivo" in all asserted claims of the '694 Patent are invalid under *IPXL* and *Aventis*, discussed *supra*. The Court will refer to these disputed terms as the "immunogenic" claim limitations. The pertinent claim language is as follows:

> 1. A formulation comprising: . . . ; wherein **the formulation is immunogenic in vivo by eliciting an antibody response against the immunogen in vivo** . . . .

'467 Patent, Claim 1 (emphasis added).

> 1. A formulation comprising: . . . ; wherein: . . . **the formulation is immunogenic in vivo by eliciting an antibody response against the immunogen in vivo**; . . . .

'693 Patent, Claim 1 (emphasis added).

> 1. A formulation comprising: . . . , wherein: . . . **the formulation is immunogenic in vivo by eliciting an antibody response against the first immunogen and the second immunogen in vivo** . . . .

'694 Patent at Claim 1 (emphasis added). The disputed language requires that "the formulation is immunogenic in vivo by eliciting an antibody response," either "against the immunogen in vivo" with respect to the '467 and '693 Patents or "against the first immunogen and the second immunogen in vivo" with respect to the '694 Patent.

The Court concludes that PBNT has not met its burden to show that the "immunogenic" claim limitations render the asserted claims of the '693 Patent, '467 Patent, and '694 Patent indefinite under *IPXL* and its progeny by clear and convincing evidence. *First*, the "immunogenic" claim limitations "focus on the capabilities of the [formulation], whereas the claims in *IPXL* [] ('the user uses the input means') and *Katz* ('said individual callers digitally enter data') focus on specific actions performed by the user." *See MasterMine*, 874 F.3d at 1316. *Second*, "unlike the

claims in *Rembrandt*, the functional language here does not appear in isolation, but rather, is specifically tied to [the formulation]." *See id.*

PBNT's reliance upon the prosecution history of the '467 Patent is inapposite. Claims must be read "in the context of the . . . prosecution history." *Thorner*, 669 F.3d at 1365 (citing *Phillips*, 415 F.3d at 1313). PBNT contends that the prosecution history of the '467 Patent "makes clear the claims require *more* than just characteristics of being 'suitable' for in vivo delivery or 'capable' of immunogenicity." D.I. 166 at 74 (emphasis in original). In support, PBNT relies, *inter alia*, on the examiner's notice of allowance, where the examiner stated that the "prior art does not teach or fairly suggest the superior *ability* of a composition to elicit an antibody response against an immunogen in vivo with a formulation comprising a[n] RNA encoding an immunogen" having certain characteristics. D.I. 125-2 at A2212 (emphasis added). The examiner further acknowledged that "the combination of elements in the claimed composition yielded unexpected results with respect to the composition's superior *ability* [to] elicit an antibody mediated immune response." *Id.* at A2213 (emphasis added). The examiner's emphasis on the ability of the composition further supports the Court's analysis that the "immunogenic" claim limitations recite functional language permissible under *IPXL* and its progeny.

For the foregoing reasons, the Court concludes that PBNT has not met its burden to show that the "immunogenic" claim limitations render all asserted claims of the '693 Patent, '467 Patent, and '694 Patent indefinite under *IPXL* by clear and convincing evidence.

V. CONCLUSION

The Court adopts the parties' agreed-upon constructions and construes the disputed claim terms as described above. The Court will issue Orders in each case consistent with this Memorandum Opinion.

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.	Civil Action No. 24-512-GBW

ORDER

At Wilmington this 23rd day of June 2026 and consistent with the Memorandum Opinion issued this day, **IT IS HEREBY ORDERED** that the Court construes the following claim terms as follows:

Claim Term	Agreed-Upon Construction
"eliciting an antibody response against an immunogen" ('475 Patent, All Asserted Claims) and "eliciting an antibody response against a coronavirus spike polypeptide immunogen" ('660 Patent, All Asserted Claims)	Preamble language is limiting.

"cationic lipid" ('422 Patent, Claims 3, 12-13)	"lipid capable of being positively charged"
"tertiary amine cationic lipid" 24-512 ('693 Patent, Claims 14-16) ('694 Patent, Claims 5, 6, 14, 30) ('6534 Patent, All Asserted Claims) ('401 Patent, All Asserted Claims) ('467 Patent, All Asserted Claims) and "cationic lipid comprising a tertiary amine" 24-512 ('693 Patent, All Asserted Claims) ('694 Patent, All Asserted Claims) ('475 Patent, All Asserted Claims) ('660 Patent, All Asserted Claims)	"lipid with a tertiary amine capable of being positively charged"

Disputed Term	The Court's Construction
"liposomes / "liposome" ('475 Patent, All Asserted Claims) ('422 Patent, All Asserted Claims)	lipid vesicles having a lipid bilayer encapsulating an aqueous core

"the liposomes encapsulating at least half of the mRNA molecules" ('475 Patent, All Asserted Claims)	No further construction necessary: Plain and ordinary meaning, *i.e.*: a liposome within which at least one ribonucleic acid (RNA) that encodes an immunogen of interest is enclosed
"a liposome within which at least one ribonucleic acid (RNA) that encodes an immunogen of interests is encapsulated" ('422 Patent, All Asserted Claims)	No further construction necessary: Plain and ordinary meaning, *i.e.*: the lipid particles enclosing at least half of the mRNA molecules
"the lipid particles encapsulating at least half of the RNA molecules" ('660 Patent, All Asserted Claims)	No further construction necessary: Plain and ordinary meaning, *i.e.*: the lipids enclosing at least half of the RNA molecules
"the lipids encapsulate at least half of the RNA molecules" ('693 Patent, All Asserted Claims) ('594 Patent, All Asserted Claims) ('6534 Patent, All Asserted Claims) ('401 Patent, All Asserted Claims) ('467 Patent, All Asserted Claims)	No further construction necessary: Plain and ordinary meaning, *i.e.*: the lipids enclosing at least half of the first species of RNA molecules and at least half of the second species of RNA molecule
"the lipids encapsulate at least half of the first species of RNA molecules and at least half of the second species of RNA molecule" ('694 Patent, All Asserted Claims)	No further construction necessary: Plain and ordinary meaning, *i.e.*: : the lipids enclosing at least half of the first species of RNA molecules and at least half of the second species of RNA molecule

"by eliciting an antibody response against the immunogen in vivo" ('467 Patent, All Asserted Claims)	No further construction necessary. Plain and ordinary meaning, *i.e.*: "by eliciting an antibody response against the immunogen in vivo"
"at least two unit doses being sequential and at least 1 week apart" ('475 Patent, All Asserted Claims)	"at least two unit doses being within a scheduled sequence or series and at least 1 week apart"
"at least two unit doses being sequential and administered at least 1 week apart" ('660 Patent, All Asserted Claims)	"at least two unit doses being within a scheduled sequence or series and administered at least 1 week apart"
"whereby the pKa is determined at standard temperature and pressure by the following . . . is obtained" ('693 Patent, All Asserted Claims) ('694 Patent, All Asserted Claims) ('467 Patent, Claims 28, 29)	Indefinite. This limitation is an active process step that must be performed, rendering the formulation patent claims invalid as indefinite.
"the formulation is immunogenic in vivo by eliciting an antibody response against the immunogen in vivo" ('693 Patent, All Asserted Claims) ('467 Patent, All Asserted Claims)	Not indefinite.
"the formulation is immunogenic in vivo by eliciting an antibody response against the first immunogen and the second immunogen in vivo" ('694 Patent, All Asserted Claims)	Not indefinite.

GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE