UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 9, 2025

Arbutus Biopharma Corporation
(Exact name of registrant as specified in its charter)

British Columbia, Canada	**001-34949**	**98-0597776**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

701 Veterans Circle Warminster, Pennsylvania	**18974**
(Address of principal executive offices)	(Zip Code)

(267) 469-0914
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Shares, without par value	ABUS	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01. Other Events.

On September 9, 2025, the U.S. District Court for the District of New Jersey issued a claim construction ruling in the lawsuit brought by Arbutus Biopharma Corporation and its licensee Genevant Sciences against Pfizer Inc. and BioNTech SE (Pfizer/BioNTech) seeking damages for infringement of U.S. Patent Nos. 9,504,561, 8,492,359, 11,141,378, 11,298,320 and 11,318,098 in the manufacture and sale of Pfizer/BioNTech's COVID-19 mRNA-based vaccines. A copy of the Court's claim construction order and opinion is filed herewith as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Claim Construction Order and Opinion, dated September 9, 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Arbutus Biopharma Corporation

Date: September 10, 2025

By: /s/ Tuan Nguyen
Name: Tuan Nguyen
Title: Chief Financial Officer

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ARBUTUS PHARMA CORP., *et al.,* Plaintiffs, v. **PFIZER, INC., *et al.,*** Defendants.	Civil Action No. 3:23-cv-1876-ZNQ-TJB **CLAIM CONSTRUCTION ORDER**

QURAISHI, District Judge

For the reasons set forth in the accompanying Opinion, the Court hereby construes the parties' disputed terms as set forth below .

TERM	COURT'S CONSTRUCTION
"lipid vesicle"	"any lipid composition that can be used to deliver a compound including, but not limited to, liposomes, wherein an aqueous volume is encapsulated by an amphipathic lipid bilayer; or wherein the lipids coat an interior comprising a large molecular component, such as a plasmid, with a reduced aqueous interior; or lipid aggregates or micelles, wherein the encapsulated component is contained within a relatively disordered lipid mixture"
"fully encapsulated"	"contained inside"
"mol %"	"the recited mol % ranges are understood to encompass their standard variation based on the significant figures recited in the claim"
"consisting essentially of"	"consisting of only the listed ingredients and those that do not materially affect the increased activity of the encapsulated nucleic acid and the improved tolerability of the formulations in vivo, or the stability in circulation"

DATED : September 9, 2025

ZAHID N. QURAISHI
UNITED STATES DISTRICT JUDGE

NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ARBUTUS PHARMA CORP., *et al.,* Plaintiffs, V. **PFIZER, INC., *et al.,*** Defendants.	Civil Action No. 3:23-cv-1876-ZNQ-TJB **CLAIM CONSTRUCTION OPINION**

QURAISHI, District Judge

In this Opinion, the Court construes claim terms from five patents directed to compositions and methods for preparing lipid nanoparticles containing therapeutic agents. The parties submitted the following briefs in support of their respective positions: Defendants' Opening Brief (ECF No. 83); Plaintiffs' Opening Brief (ECF No. 84); Defendants' Response Brief (ECF No. 135); and Plaintiffs' Response Brief (ECF No. 136). After reviewing the parties' submissions and conducting a *Markman* hearing on the record on December 18, 2024, the Court construes the parties' four disputed terms as set forth herein.

I. PROCEDURAL HISTORY

Plaintiffs Arbutus Pharma Corp. and Genevant Sciences GmbH (collectively, "Plaintiffs") brought this patent infringement suit against Defendants Pfizer, Inc., and BioNTech SE. (collectively, "Defendants") for infringement of United States Patent Nos. 9,504,651 ("the '651 Patent"), 8,492,359 ("the '359 Patent"), 11,141,378 ("the '378 Patent"), 11,298,320 ("the '320 Patent"), and 11,318,098 ("the '098 Patent") (collectively, "the patents in suit"). *See generally*

Complaint (ECF No. 1.) Defendants answered the Complaint. The parties are currently engaged in discovery. (ECF Nos. 33, 148).

II. FACTUAL BACKGROUND

By design, the inside of a human body is a hostile place. Our bloodstreams contain a series of enzymes that digest various proteins and nucleic acids. This poses certain well-known challenges to medical science: therapeutics vulnerable to these enzymes survive only briefly in a patient's blood stream after they are administered by injection.

In succinct terms, the inventors of the patents in suit address this problem by tucking a vulnerable therapeutic inside nanoscopic particles of fat with a particular structure-referred to as "liposomes" or "lipid nanoparticles" or "lipid vesicles." Inside these structures, the therapeutics are shielded from enzymatic digestion.

Messenger ribonucleic acid (mRNA) is an example of a vulnerable therapeutic when it is administered to patients to treat a disease or disorder. It is well-known that mRNA figured prominently in the world's response to COVID-19. Notably, it formed the basis of Defendants' COMIRNATY® COVID-19 vaccine. The Complaint in this case accuses Defendants of infringing the patents in suit by using Plaintiffs' liposome technology in Defendants' vaccine without Plaintiffs' permission.

At this stage of the proceedings, the Court is called upon to construe disputed terms in the patents' claims. The four disputed claim terms are: (1) "lipid vesicle," (2) "fully encapsulated," (3) "mol %," and (4) "consisting essentially of."

III. LEGAL STANDARD

A patent infringement case typically involves two steps: construing the claims and determining whether the accused product infringes the claims. *See Markman v. Westview*

Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd,* 517 U.S. 370 (1996); *Hormone Research Found., Inc. v. Genentech, Inc.,* 904 F.2d 1558, 1562 (Fed. Cir. 1990), *cert. dismissed,* 499 U.S. 955 (1991).

Claim construction is primarily a question of law. *See Teva Pharm. U S.A., Inc. v. Sandoz, Inc.,* 574 U.S. 318, 325-26 (2015). It begins with the claim language. *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.,* 381 F.3d 1111, 1115 (Fed. Cir. 2004); *Markman,* 52 F.3d at 980. Claim language is generally "given [its] ordinary and customary meaning." *Vitronics Corp. v. Conceptronic, Inc.,* 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("[W]e look to the words of the claims themselves . . . to define the scope of the patented invention."); *see also Interactive Gift Express, Inc. v. Compuserve, Inc.,* 256 F.3d 1323, 1331 (Fed. Cir. 2001) ("In construing claims, the analytical focus must begin and remain centered on the language of the claims themselves, for it . is that language that the patentee chose to use to 'particularly point [] out and distinctly claim[] the subject matter which the patentee regards as his invention.'") (quoting 35 U.S.C. § 112). Ordinary meaning is determined by "a person of ordinary skill in the art in question at the time of the invention."[1] *Phillips v. AHW Corp.,* 415 F.3d 1303, 1313 (Fed. Cir. 2005) (collecting cases); *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.,* 334 F.3d 1294, 1298 (Fed. Cir. 2003). However, if a patentee has used the claim language in some manner other than its ordinary meaning, as indicated by the balance of intrinsic evidence, such as the specification, then that meaning controls. *See, e.g., Phillips,* 415 F.3d at 1226; *Ecolab, Inc. v. Envirochem, Inc.,* 264 F.3d 1358, 1366 (Fed. Cir. 2001); *Allen Engineering Corp. v. Bartell Industries, Inc.,* 299 F.3d 1336, 1344 (Fed. Cir.

[1] The parties disagree on the proper definition of a person of ordinary skill in the art, but concede that the Court need not decide that issue for the purpose of resolving their present claim construction dispute. *See* Markman Tr., at 23:8- 12, ECF No. 159.

2002) ("It is thus necessary to review [intrinsic evidence] to determine whether the patentee has assigned any special meaning to claim terms.").

Because "there is no magic formula or catechism" for determining ordinary meaning, nor a "rigid algorithm" or "specific sequence," *Phillips,* 415 F.3d at 1324, a court must read claims in context. *See Medrad Inc. v. MRI Devices Corp.,* 401 F.3d 1313, 1319 (Fed. Cir. 2005) ("We cannot look at the ordinary meaning of the term ... in a vacuum."); *see also DeMarini Sports, Inc. v. Worth, 239 F.3d 1314, 1324 (Fed. Cir. 2001). To this end, a court must consider "the written description and prosecution history," Medrad, 401 F.3d at 1319, "the specification," Phillips, 415 F.3d at 1313, which is "always highly relevant to the claim construction analysis," Vitronics, 90 F.3d at 1582, because it "may reveal whether the patentee has used a term in a way different from its plain meaning," Brookhill-Wilk, 334 F.3d at 1298, and "the surrounding words of the claim." ACTV, Inc. v. Walt Disney Co., 346 F.3d 1082, 1088 (Fed. Cir. 2003).*

In addition to "the words of the claims themselves, the remainder of the specification, [and] the prosecution history," a court may also consider "extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Innova,* 381 F.3d at 1116; *see also Gemstar-TV Guide Int'l, Inc. v. Int'l Trade Comm'n,* 383 F.3d 1352, 1364 (Fed. Cir. 2004). Even "[o]ther claims of the patent in question, both asserted and unasserted, can [] be valuable sources of enlightenment as to the meaning of a claim term." *Vitronics,* 90 F.3d at 1582. In short, the "entire patent" matters, *Phillips,* 415 F.3d at 1313; *Multiform Desiccants, Inc. v. Medzam, Ltd,* 133 F.3d 1473, 1477 (Fed. Cir. 1998), and "[t]he construction that stays true to the claim language" while "most naturally align[ing] with the patent's description of the invention will be, in the end, the correct construction." *Renishaw PLC v. Marposs Societa' per Azioni,* 158 F.3d 1243, 1250 (Fed. Cir. 1998).

IV. DISCUSSION

The Court considers the parties' disputed terms below.

A. "Lipid vesicle"

The parties dispute the scope of the first term to be construed. Plaintiffs argue that the Court should construe the term "lipid vesicle" rather than just "vesicle" alone because this better aligns with the claim language; "vesicle" alone is never recited by the patents' claims. Plfs Op. Br. at 2-3. Also, the patent specification includes an express definition for "lipid vesicle," which Plaintiffs contend this Court should treat as controlling in accordance with Federal Circuit precedent. *Id.* at 3-4. Based on a portion of this express definition, Plaintiffs ask the Court to interpret "lipid vesicle" to mean "a lipid composition that can be used to deliver a compound." *Id.* at 2.

Defendants ask the Court to instead construe "vesicle" alone, and to interpret it to mean "a sac containing an aqueous layer or a relatively disordered lipid mixture." Defs Op. Br. at 10-11. Defendants focus on exemplary language later in the same definition paragraph of the patent specification to reach this conclusion, in conjunction with a dictionary definition, which they assert is corroborated by surrounding language in the claims and examples in the patents. Defs Op. Brief at 11-13. In the alternative, Defendants ask the Court to adopt the full express definition for "lipid vesicle" set forth in the specification. *Id.* at 15.

The Court first resolves the scope of its construction for this term. First, as Plaintiffs note, "vesicle" does not appear anywhere in the claims alone. Second, even a casual reading of the patents' disclosure makes clear that the invention is focused on lipid vesicles, not vesicles in general. *See, e.g.,* '651 Patent 5:46-49 (Under "General" subheading: "the present invention provides processes and apparatus for making lipid vesicles."); ABSTRACT ("The present invention provides apparatus and processes for producing liposomes.") The Court therefore finds

that it would be inappropriate to consider "vesicle" divorced from the patent's specific, lipid context as Defendants propose.

1. The Claim Language

"Lipid vesicle" appears in the '651 Patent, the '320 Patent, and the '098 Patent. The term figures prominently in the patents' claims. For example, claim 1 is the only independent claim of the '651 Patent and it recites:

> **1.** A ***lipid vesicle*** formulation comprising:
> (a) a plurality of ***lipid vesicles,*** wherein each ***lipid vesicle*** comprises:
> a cationic lipid;
> an amphipathic lipid; and
> a polyethyleneglycol (PEG)-lipid; and
> (b) messenger RNA (mRNA), wherein at least 70% of the mRNA in the formulation is fully encapsulated in the ***lipid vesicles***.

'651 Patent 19:4- 12 (emphases added).

As a general rule, a claim term is given its ordinary and customary meaning, *i.e.,* the one that a person of ordinary skill in the art would ascribe to it at the time of the invention. *Phillips ,* 415 F.3d at 1312-3. There are only two exceptions to this general rule: "1) when a patentee sets out a definition and acts as his own lexicographer, and 2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution." *DDR Holdings, LLC v. Priceline.com LLC,* 122 F.4th 911, 915 (Fed. Cir. 2024) (citing *Golden Bridge Tech., Inc. v. Apple Inc.,* 758 F3d 1362, 1265 (Fed. Cir. 2014).

2. *The Specification*

An inventor acts as its own lexicographer by providing an explicit definition for a claim term in the specification. *Level Sleep LLC v. Sleep Number Corp.,* App. No. 2020-1718, 2021 WL 2934816, at *4 (Fed. Cir. July 13, 2021) (citing *Renishaw,* 158 F.3d at 1249). To successfully define its own term in this way, the inventor must "clearly express that intent in the written description" and do so "with sufficient clarity to put one reasonably skilled in the art on notice that

the [it] intended to redefine the claim term." *Merck & Co. v. Teva Pharm.,* 395 F.3d 1364, 1370 (Fed. Cir. 2005). "It is not enough . . . to simply disclose a single embodiment or use a word in the same manner in all embodiments, the patentee must 'clearly express an intent' to redefine the term." *Thorner ,* 669 F.3d at 1362 (citation omitted).

The "DETAILED DESCRIPTION" section of the specification for the '651 Patent, includes a "Definitions" subsection. It contains the following express definition for "lipid vesicle" in the form of a one-sentence paragraph:

> ***"Lipid vesicle" refers to any lipid composition that can be used to deliver a compound*** including, but not limited to, liposomes, wherein an aqueous volume is encapsulated by an amphipathic lipid bilayer; or wherein the lipids coat an interior comprising a large molecular component, such as a plasmid, with a reduced aqueous interior; or lipid aggregates or micelles, wherein the encapsulated component is contained within a relatively disordered lipid mixture.

'651 Patent 5:30-37 (emphasis added).

The phrase "refers to" as used in the foregoing paragraph has been recognized as a clear expression of a patentee's intent to define a term. *See, e.g., Parkervision, Inc. v. Vidal,* 88 F.4th 969, 976 (Fed. Cir. 2023); *Meds. Co. v. Mylan, Inc.,* 853 F.3d 1296, 1306 (Fed Cir. 2017). The emphasized language in the definition in this case serves to define a "lipid vesicle" insofar as it clearly states the term and that it "refers to" the remainder of the sentence. Plaintiffs would prefer to trim the construction to "any lipid composition that can be used to deliver a compound," and ignore the remainder of the specification's definition. Indeed, the remainder is unwieldy, but it is not so easily dismissed. It is part of the patents' own express definition and serves the nontrivial function of providing those of skill in the art with three non-limiting examples that fall within the

scope of the contemplated lipid vesicle.[2] The Court therefore finds that the specification favors Defendants' alternative position: that the entire definition in the specification be adopted as the Court' s construction of "lipid vesicle."

3. *The Prosecution History*

Neither party cites evidence from the prosecution history that is relevant to the construction of "lipid vesicle."

4. *Extrinsic Evidence*

Both parties offer extrinsic evidence in favor of their preferred construction for "lipid vesicle" in the form of dictionaries and prior art. Courts may consider such evidence if they deem it helpful to discern the meaning of claim terms. *Phillips,* 415 F3.d at 1319; *Markman,* 52 F.3d at 980. But extrinsic evidence is "less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'" *C.R. Bard, Inc. v. US Surgical Corp.,* 388 F.3d 858, 862 (Fed. Cir. 2004) (quoting *Vanderlande Indus. Nederland BV v. Int'l Trade Comm'n,* 366 F.3d 1311, 1318 (Fed. Cir. 2004)).

Here, the Court's analysis can end because it has concluded, based on the intrinsic evidence, that "lipid vesicle" unambiguously means

> "any lipid composition that can be used to deliver a compound including, but not limited to, liposomes, wherein an aqueous volume is encapsulated by an amphipathic lipid bilayer; or wherein the lipids coat an interior comprising a large molecular component, such as a plasmid, with a reduced aqueous interior; or lipid aggregates or micelles, wherein the encapsulated component is contained within a relatively disordered lipid mixture."

[2] At this early stage of the proceedings, it is easy to envision a scenario where the parties later dispute the scope of what is taught by a particular piece of prior art and to what extent it teaches the same or similar "lipid vesicle." In that scenario, even the non-limiting examples might prove informative.

See Vitronics, 90 F.3d at 1584. Accordingly, the Court' s claim construction order will instruct the parties to use that definition.[3]

B. "fully encapsulated"

Plaintiffs argue that "fully encapsulated" should be interpreted to mean "contained inside" in the claims of the '651, '359, and '378 Patents.[4] Plfs Op. Br. at 6-13; Plfs Resp. Br. at 6- 13. They posit that this construction is consistent with the way one of skill in the art would understand the invention as described in the specification and reinforced by the patents' prosecution histories. *Id.* In support of this argument Plaintiffs cite the specification and prosecution histories in combination with a declaration from their expert, David H. Thompson, Ph.D.[5] *Id.* Plaintiffs also dispute the claim construction for "fully encapsulated" already reached by a Delaware district court in Plaintiffs' separate infringement suit in that district: *Arbutus Biopharma Corp. v. Moderna Inc.,* Civ. No. 22-252, 2024 WL 1434526 (D. Del. Apr. 3, 2024) *("Moderna* Opinion").

Defendants, in their responsive brief, withdraw their initially proposed construction. Defs Resp. Br. at 10 ("In view of Plaintiffs' arguments and the deposition of their expert, Defendants withdraw their original construction and, per the Court's order, will argue indefiniteness at a later stage.") Defendants now maintain that the claim term is indefinite and ask the Court to reject

[3] The Court is also mindful that this full construction may prove unwieldy at trial given that it anticipates trial to a jury. As a matter of trial logistics, the Court suggests the parties confer and consider stipulating to a shorter claim construction in light of the Court' s conclusion here.

[4] More accurately, Plaintiffs seek construction of "fully encapsulated" as their primary position for the '359 and '378 Patents, and their secondary position for the '651 Patent. For the '651 Patent, Plaintiffs' first position is that the Court should construe the entire phrase "wherein at least 70% of the mRNA in the formulation is fully encapsulated in the lipid vesicles" to mean "wherein at least 70% of the mRNA in the formulation is contained in the lipid vesicles." The remainder of the phrase proposed by Plaintiffs merely restates the language of the wherein clause. The Court finds no value in presenting this more complicated phrase to the jury. Accordingly, the Court herein construes only "fully encapsulated" for the benefit of the parties and the jury.

[5] Dr. Thompson is a professor of chemistry at Purdue University and is the former Director of the Medicinal Chemistry Group in the Purdue Center for Cancer Research. (Thompson Decl. ¶1, ECF No. 84-5.) At least for the purposes of claim construction, Defendants do not challenge his qualifications to opine as to the knowledge of one of skill in the art. To be clear, Plaintiffs do not ask the Court to find—nor does the Court find, given Dr. Thompson's extensive education and experience—that he is himself a person of just ordinary skill in the art.

Plaintiffs' construction and to instead later address "fully encapsulated" when the Court considers Defendants' indefiniteness defense. *Id.*

Plaintiffs object to Defendants' proposal to delay claim construction on the basis that this would impermissibly impose upon the jury a claim construction dispute that the Court is obligated to first resolve. Plfs Resp. Br. at 6. Because the Court agrees that it has a duty to resolve any claim construction disputes in advance of any presentation to the jury, the Court proceeds with its claim construction analysis.

I. Delaware District Court's Construction in Moderna Litigation

The Court begins with its sister court's construction in the *Moderna* Opinion. That decision construed "fully encapsulated" in the '651 Patent as part of the longer phrase "wherein at least 70%/at least 80%/about 90% of the mRNA in the formulation is encapsulated in the lipid vesicles." There, Arbutus sought the same construction of "fully encapsulated" that they seek here: "contained inside." The court, however, adopted Moderna's proposed construction: "wherein at least 70%/at least 80%/about 90% of the mRNA in the formulation is ***fully, as distinct from partially, contained inside*** the lipid vesicles." *Moderna* Opinion, 2024 WL 1434526, at *18. In reaching that conclusion, the court sought to apply the plain meaning of the claim terms and to give effect to the word "fully" that was consistent with its reading of the specification. *Id.* at *17- 18.

The *Moderna* court's construction is, of course not binding on this Court. For the reasons set forth below—faced with different arguments and a different record—this Court reaches a similar but somewhat different construction. The Court agrees that "fully encapsulated" means "contained inside" (as proposed by Plaintiffs), but the Court declines to add the language "as distinct from partially" that was inserted by the *Moderna* court.

2. The Claim Language

The term "fully encapsulated" appears in the '651, '359, and '378 Patents, though in slightly different contexts. The '651 Patent uses the term in the context of claiming the overall formulation, while the '359 and '378 Patents use the term in the context of claiming the individual nucleic acid-lipid particles.

Claim 1 of the '651 Patent is set forth below:

> 1. A lipid vesicle formulation comprising:
>
> (a) a plurality of lipid vesicles, wherein each lipid vesicle comprises:
> a cationic lipid;
> an amphipathic lipid; and
> a polyethyleneglycol (PEG)-lipid; and
>
> (b) messenger RNA (mRNA), wherein at least 70% of the mRNA in the formulation is ***fully encapsulated*** in the lipid vesicles.

'651 Patent 19: 4-12 (emphasis added). Claim 1 of the '359 Patent is set forth below with its dependent claim 20 that adds a "fully encapsulated" claim limitation:

> 1. A nucleic acid-lipid particle comprising:
> (a) a nucleic acid;
> (b) a cationic lipid comprising from 50 mol % to 65 mol % of the total lipid present in the particle;
> (c) a non-cationic lipid comprising a mixture of a phospholipid and cholesterol or a derivative thereof, wherein the phospholipid comprises from 3 mol % to 15 mol % of the total lipid present in the particle and the cholesterol or derivative thereof comprises from 30 mol % to 40 mol % of the total lipid present in the particle; and
> (d) a conjugated lipid that inhibits aggregation of particles comprising from 0.5 mol % to 2 mol % of the total lipid present in the particle.
>
> 20. The nucleic acid-lipid particle of claim 1, wherein the nucleic acid is ***fully encapsulated*** in the nucleic acid-lipid particle.

'359 Patent 91:13-25; 92:43-45 (emphasis added). "Fully encapsulated" appears in the claims of the '378 Patent via a more elongated chain of dependent claims. Claim 9, which ultimately

depends from claim 1**,** is directed to a pharmaceutical composition comprising the fully encapsulated nucleic acid-lipid particles:

> 9. The pharmaceutical composition of claim 8, wherein the RNA is ***fully encapsulated*** in the nucleic acid-lipid particle.

'378 Patent 93:46-48 (emphasis added). The claims of the three patents provide no guidance as to the meaning of "fully encapsulated."

3. The Specification

The Definitions section within the specification of the '651 Patent also provides no explicit definition for "fully encapsulated." It does, however, imply a distinction between "full encapsulation" and "partial encapsulation" in the following sentence: "As used herein, 'lipid encapsulated' can refer to a lipid formulation which provides a compound with full encapsulation, partial encapsulation, or both." '651 Patent 5:38-40. Thus, full encapsulation and partial encapsulation were conditions deemed distinct by the inventors. This distinction was important to the court in *Moderna.* Unfortunately, the specification does not define "partial encapsulation."

A second hint lies in the definition of a "lipid vesicle" that provides three-nonlimiting examples:

> "Lipid vesicle" refers to any lipid composition that can be used to deliver a compound including, but not limited to,
>
> liposomes, wherein an aqueous volume is encapsulated by an amphipathic lipid bilayer; or
>
> wherein the lipids coat an interior comprising a large molecular component, such as a plasmid, with a reduced aqueous interior; or
>
> lipid aggregates or micelles, wherein the encapsulated component is contained within a relatively disordered lipid mixture.

'651 Patent 5:30-37.[6] This sentence suggests that the word "fully" in the claim term "fully encapsulated" does have a purpose: to distinguish the first two examples from the third one. Thus, in the parlance of the third example, while the mRNA of Claim 1 may be considered an "encapsulated component," it is not "fully encapsulated." The mRNA is merely "contained within a relatively disordered lipid mixture."

4. The Prosecution History

The prosecution history of the '651 Patent reinforces this view. In a Non-Final Office Action issued by the USPTO on August 14, 2014, the Examiner rejected a version of Claim 1 of the '651 Patent that included the "fully encapsulated" language. That rejection was based on the teachings of Unger *et al.* (U.S. Patent No. 5,830,430) in combination with three other references. Plfs Op. Br., Exhibit 10 at pp. 5-9, ECF No. 84-2.[7] The inventors responded to the rejection on October 22, 2014, in relevant part, by distinguishing their invention from what was taught by Unger with a supporting Declaration from Dr. James Heyes. The distinction the inventors drew between their invention and Unger was that Unger teaches aggregates (like the third example from the specification noted above) that differ from their claimed lipid vesicles with encapsulated RNA:

> Dr. Heyes points out that lipoplexes [of Unger] are heterogeneous, metastable aggregates that are effective when used to transfect cells in culture, but have relatively poor performance *in vivo*. *See, id.* Importantly, Dr. Heyes explains that the encapsulated mRNA present within the lipid vesicles of the present invention will be protected from nuclease degradation upon systemic administration, while nucleic acid that is merely associated with the surface of a preformed liposome (such as the DNA of the lipoplexes of Unger *et al.)* will be more readily degraded by serum nucleases.

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[6] This is the same passage the Court also relies upon to construe "lipid vesicle."

[7] Plaintiffs' Opening Brief appears to inadvertently refer to a later-issued Office Action dated February 13, 2015 (Exhibit 13) rather than the Office Action issued on August 14, 2014 (Exhibit 10). *See* Plfs Op. Br. at 7 (citing Exhibit 13). This matters only insofar as the inventors' response, filed October 22, 2014, was for obvious reasons responsive to the 2014 Office Action rather than the 2015 one. As set forth, *infra,* there were in fact two Office Actions and two responses from the inventors. In both responses, the inventors distinguished the invention's fully encapsulated mRNA from the mere aggregates taught be Unger.

Exhibit 11 at p. 7. The inventors reiterated this distinction in their May 12, 2015 response (Exhibit 14) to the next Office Action issued February 13, 2015 (Exhibit 13), again based in part on Unger.

> In fact, Unger *et al.* fails to provide any clear and specific teaching with regard to the successful encapsulation and delivery of mRNA. Indeed, ***none of the examples in Unger et al. discloses or suggests a lipid vesicle of the present invention comprising fully encapsulated mRNA*** or the desirability of forming smaller lipid vesicles that are more effective at delivering encapsulated nucleic acid molecules such as mRNA to living cells. ***The cationic lipid compounds and cationic liposome formulations disclosed in Unger et al. are only exemplified in the context of their use for preparing preformed liposomes to form complexes with DNA called lipoplexes.*** As explained by Dr. Reyes in paragraph 10 of his Declaration submitted on October 22, 2014, lipoplexes are electrostatic complexes in which little, if any, of the DNA payload is encapsulated within the preformed cationic liposomes.
>
> The Examiner alleges that Unger *et al.* teaches that bioactive agents can be entrapped within the internal void of a lipid vesicle, but ***Applicants point out that Unger et al. still fails to exemplify encapsulation of nucleic acid of any kind,*** let alone mRNA.

Exhibit 14 at p. 6 (emphases added).

The Court is mindful of the Federal Circuit's caution that prosecution histories generally lack the clarity of specifications and thus are less useful for claim construction purposes. Nevertheless, in this instance it appears the inventors drafted their claims to exclude mere aggregates/complexes. To the extent that language wasn't clear enough, the inventors then clearly and repeatedly touted their distinction during prosecution, thereby "demonstrating how the inventor[s] understood the invention." *Phillips,* 415 F.3d at 1317 (citations omitted). This suggests that "the inventor[s] limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.* (citations omitted).[8]

[8] The Court emphasizes that it is not applying the doctrine of prosecution history estoppel here. It is only "employ[ing] the prosecution history to inform the claim construction." *Eye Therapies, LLC v. Slayback Pharma, LLC,* 141 F.4th 1264, 1271 n.5 (Fed. Cir. 2025) (observing the distinction between estoppel analysis and claim construction).

5. Extrinsic Evidence

As set forth above, Plaintiffs submitted extrinsic evidence in the form of a Declaration of Dr. Thompson. The Court reviewed his Declaration and finds that it is consistent with the intrinsic evidence considered by the Court. The Declaration is both persuasive and unrebutted by Defendants. Accordingly, the Court finds that Dr. Thompson's Declaration further supports its construction.

In sum, for the reasons articulated, the Court concludes that "fully encapsulated" in the claims of the '651, '359, and '378 Patents should be construed to mean "contained inside."

C. Precision of "mol %" claim terms

The Court next considers the proper construction of "mol %" terms in the '359 Patent. The parties disagree as to the precision to be assigned to the mol % numbers recited by the claims. Plaintiffs propose that the mol % numbers be construed consistent with general rules of significant figures and rounding. Plfs Op. Br. at 13-19. Under their proposal, for example, 50 mol% would be deemed to encompass values from 49.5 to 50.4 mol %. A range would be treated thusly: 50% to 65 mol % would encompass 49.5 to 65.4 mol %.

Defendants argue that, based on the prosecution history, the mol % numbers should instead be treated as "numerical boundaries." Defs Op. Br. 19-25. Under their proposal, a range of 50% to 65 mol % would be construed to mean no less than 50 and no more than 65 mol%. That is, a value of 49.9 or 65.1 would fall outside the claimed range.

For this dispute, the Court again has the benefit of the analysis conducted by the Delaware district court in *Moderna.* There, the defendants posed arguments similar to those advanced by

Defendants here.[9] The Delaware district court rejected them in a well-reasoned and thorough opinion that this Court provides below:[10]

> Moderna contends that, based on Plaintiffs' explicit prosecution history disclaimer of the word "about," the ranges are numerically "exact," meaning that the patent allows for no deviation above the high end or below the low end of the range. Plaintiffs, on the other hand, posit that the plain meaning of the numbers in its claims adheres to the standard scientific conventions of significant figures and rounding. The Federal Circuit has emphasized that endpoints of a claimed range should not be given any more precision than the claim language warrants. United States Philips Corp. v. Iwasaki Elec. Co. Ltd., 505 F.3d 1371, 1377 (Fed. Cir. 2007). "In some scientific contexts, '1' represents a less precise quantity than '1.0,' and '1' may encompass values such as 1.1 that '1.0' may not." Id. Under this "standard scientific convention" of significant figures and rounding, a POSITA must look to the last significant figure of a number and include values that round up and down to that number. See AstraZeneca AB v. Mylan Pharms, Inc., 19 F.4th 1325, 1329-30 (Fed. Cir. 2021). For example, the number "9.1" would encompass values between 9.05 and 9.14, while the number 9.10 would encompass more specific values between 9.095 and 9.104. Similarly, the number "9" would encompass 8.5 through 9.4, while "9.0" would encompass 8.95 through 9.04.
>
> At the time the parties submitted their claim construction briefing, controlling case law reflected that the application of the rules of significant figures and rounding varied on a case-by-case basis. See Par Pharm, Inc. v. Eagle Pharms, Inc., 44 F.4th 1379, 1382-83 (Fed. Cir. 2022) (affirming construction where patent claiming a pH range of 3.7-3.9 was deemed to actually encompass a range of 3.65- 3.94); San Huan New Materials High Tech, Inc. v. Int'l Trade Comm' n, 161 F.3d 1347, 1361 (Fed. Cir. 1998) (affirming judgment of infringement where the asserted claim recited a range of 30% to 36% of chemical compound TRE, and the accused product had up to 36.45% TRE, and concluding that it "was not shown to be error, legal or scientific, for the Commission to recognize these limits of accuracy, and to round the measured weight percentages to the nearest integer."); Vifor Fresenius Med. Care Renal Pharm Ltd. v. Teva Pharms USA, Inc., 623 F. Supp. 3d 389, 416-17 (D. Del. 2022)

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[9] Defendants attempt to distinguish their position from the one advanced by the defendants in *Moderna,* but the Court finds their arguments unpersuasive. *See* Defs Resp. Br. at 22.

[10] The *Moderna* Opinion addresses U.S. Patent No. 8,058,069 ('069 Patent). The '359 Patent in this case is a continuation of the '069 Patent. The *Moderna* court's decision explicitly states that its construction regarding the precision of the mol % terms applies to '069 Patent and several patents within the same family, including the '359 Patent. 2024 WL 1434526, at *4 n.4.

(applying basic rounding principles to a pH range between 2.5 and 3.4); Johnson Matthey Inc. v. Noven Pharms., Inc., No. 07-cv-260, 2009 WL 2208214, at *5 (E.D. Tex. July 21, 2009) ("[T]he parties agree that a person of ordinary skill in the art would regard such disclosure as incorporating generally accepted principles of rounding, such that numbers ranging from 40.5 to 41.4 would be rounded to 41, and numbers ranging from 41.5 to 42.4 would be rounded to 42 when comparing a measured melting point to the asserted claims."); but see AstraZeneca AB v. Mylan Pharms. Inc., 19 F.4th 1325, 1329-32 (Fed. Cir. 2021) (noting that within the context of the particular claim, specification, and prosecution history which touted the superior stability of formulation within the concentration of "0.001%" meant precisely 0.001% with only minor variations—*i.e.* 0.00095% to 0.00104%— as opposed to normal rounding of 0.0005% to 0.0014%); Noven Pharms, Inc. v. Amneal Pharms LLC, Nos. 18-cv-699, 18-cv-758, 2019 WL 1102681, at *4 (D. Del. Mar. 8, 2019) (finding that term "coat weight of greater than 10 mg/cm^2 was not subject to a significant digits analysis because the claims recited a range unbounded by "an unambiguous lower end"); Aventis Pharms S.A. v. Amphstar Pharms., Inc., Nos. 03-cv-887, 04-cv-333, 2004 WL 5700629, at *7 (C.D. Cal. Oct. 22, 2004) (Construing numerical limitations with no modifications by approximation or otherwise because ranges and degrees reinforce the use of precise values where the patentee repeatedly emphasized the criticality of the claimed ranges to overcome prior art rejections).

Following the claim construction briefing, but before the Markman hearing, the Federal Circuit more squarely addressed the issue of whether number ranges are subject to precise reading. In Actelion Pharmaceuticals LTD v. Mylan Pharmaceuticals Inc., 85 F.4th 1167 (Fed. Cir. 2023), the sole question before the Court was the meaning of "a pH of 13 or higher" in the context of the asserted patents. Id. at 1170. The district court construed the claim term as including values that rounded to the ones place—*i.e.*, a range of 12.5 or higher—based on the rules of significant figures, while the defendant argued that the claim term created an absolute floor at 13, beneath which the pH could not fall. Id. The Federal Circuit found no merit to defendant's argument that because the claim language involved a range, it was not subject to the rules of rounding and held that "there is no blanket rule that ranges, or specifically open-ended ranges, must foreclose rounding." Id. at 1171. The Court also declined to find that the absence of approximation language-such as "about" or "approximately" —implies that the numerical range is exact. Id. Instead, the Court "reject[ed] any invitation to create a bright-line rule-either that language like 'precisely' or 'exactly' is always needed to avoid rounding or that the lack of approximation language, even when it may be found elsewhere in the claims,

dictates a precise value." Id. Finding that the proper construction of the claim language could not be resolved without reference to extrinsic evidence—*i.e.,* the background knowledge of a person of ordinary skill in the art—the Court remanded for review of such evidence, which the district court had not previously considered. Id. at 1172-74.

Guided by this framework, I now tum to the claim language before me. Using the '069 patent as exemplary, claim 1 discloses a range of "from 50 mol % to 65 mol % of the total lipid present in the particle." As noted in Actelion, the absence of language of approximation or precision does not dictate that the rules of rounding apply, and thus I tum to the specification. The specification of the '069 patent states that "[i]n one aspect, the present invention provides lipid particles comprising: (a) one or more active agents or therapeutic agents; (b) one or more cationic lipids comprising from *about* 50 mol % to *about* 85 mol % of the total lipid present in the particle; (c) one or more non-cationic lipids comprising from *about* 13 mol % to *about* 49.5 mol % of the total lipid present in the particle; and (d) one or more conjugated lipids that inhibit aggregation of particles comprising from *about* 0.5 mol % to *about* 2 mol % of the total lipid present in the particle." ('069 patent 3:10- 20 (emphasis added).)

Moderna contends that the use of the word "about" in the specification demonstrates that the inventors knew how to use words of approximation but intentionally chose not to in the claim language itself, meaning that numerical precision is required. See Baxter Healthcare Corp. v. Nevakar Injectables, Inc., Nos. 21-cv- 1184, 21-cv-1186, 2023 WL 4175261, at *15 (D. Del. June 26, 2023) (noting that "[t]he Federal Circuit has made clear that when a patent includes qualifying language for certain claim limitations but omits it from others, the claims without such approximation should be construed with numerical precision. . . . This is because a POSITA would understand that the patentees knew how to express ambiguity in claim language when they so desired.") (citing Jeneric/Pentron, Inc. v. Dillon Co., Inc., 205 F.3d 1377, 1381 (Fed. Cir. 2000)); see also Takeda Pharm. Co. v. Zydus Pharms. USA, Inc., 743 F.3d 1359, 1365 (Fed. Cir. 2014) ("[H]ad the inventors desired the average particle diameter to include a margin of error, they could easily have included the word 'about' in the claim language. In the absence of their decision not to do so, however, we will not take it upon ourselves to rewrite the claim that way.").

Notably, both cases cited by Moderna involved situations where the words of approximation appeared at various points in the claim language itself. Here, the words of approximation are only in the specification. And, in Actelion, the Federal Circuit expressly

declined to create a bright-line rule that the absence of approximation language in claim language dictates a precise value. As such, the presence of the word "about" in the specification without its similar inclusion in the claim language could support a construction that eliminates a broader range of approximation, but it does not preclude application of the scientific convention of rounding.

In fact, the specification substantiates Plaintiffs' construction. In both the portion of the specification cited above and in other sections of specification, the inventors demonstrated that they knew how to use additional significant numbers past a decimal point. For example, the inventors used 49.5%, meaning that under the rules of rounding, the claimed number would be limited to 49.45% to 49.54%. Similarly, in other portions of the specification, specifically Table 2, the inventors depicted some of the whole numbers with trailing zeros, such as "27.0" (giving a rounding range of 26.95- 27.04), "64.0" (giving a rounding range of 63.95- 64.04), "1.0" (giving a rounding range of 0.95- 1.04), and "7.0" (giving a rounding range of 6.95- 7.04). Had the inventors intended to not rely on the rules of rounding and significant figures, they would not need to have written the whole numbers in Table 2 with any trailing zeroes, *i.e.,* they would have written them as "27", "64", "1", and "7".

While the specification is instructive on the proper construction, it is not conclusive. Accordingly, I look to the last piece of intrinsic evidence, the prosecution history, which "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, making the claim scope narrower than it would otherwise be." Phillips, 415 F.3d at 1317.

During the prosecution of the earliest Molar Ratio patent—the '069 patent—the original range claims included words of approximation—*e.g.*, *"about* 50 mol % to *about* 65 mol %." (JA001801.) The Patent Examiner rejected these claims over the prior art, U.S. Pat. Pub. No. 2006/0008910 ("MacLachlan"), which taught ranges for the four lipid components that overlapped with the claimed ranges as follows:

Lipid Component	**Claim 1 as Amended**	**US 2006/0008910***
Cationic Lipid	50-65 mol %	"2-60, 5-50, 10-45, 20-40, 30 mol%"
Phospholipid	4-10 mol %	"5-90 mol%"
Cholesterol	30-40 mol %	"20-55 mol %"
Conjugated Lipid	0.5-2 mol %	"1-20 mol %"

(JA00515.) The examiner noted that the relative amount of each component in the claims "read on a broad range of amounts because of the term 'comprising about.' " The examiner went on to explain that "[t]he applicants do not provide a definition of the term in the

specification. Thus, 'comprising about' could embrace an amount +/- 10, 20, 30 mol % of a lipid component." (JA00494.)

To overcome the rejection, Plaintiffs amended the claims to remove the word "about" from the claims and "point[ed] out that claim 1 as presently amended recites narrow ranges for each of the lipid components compared to ... Maclachlan." Plaintiffs also explained that "the present invention is based, in part, on the surprising discovery that 1:57 SNALP formulations provide ***new and unexpected*** results" and that SNALP formulations having increased amounts of cationic lipid present in the particle, provide ***unexpectedly superior advantages***." (JA510-12, JA515-16 (emphasis in original).) Following the removal of the word "about," the examiner allowed the claims to issue. (JA00524.) In the related IPR proceedings, Plaintiffs repeated the arguments about the importance of the narrowed ranges. (JA002294, JA2565, JA002802.)

Although the specification appears to favor Plaintiffs' construction, it does not conclusively resolve whether the endpoints on the claimed ranges are subject to rounding. In such a case, the Federal Circuit has instructed the reviewing court to examine the extrinsic evidence. Actelion, 85 F.4th at 1173-1174 (directing district court to consider extrinsic evidence to determine "how many significant figures 'a pH of 13' has or what it would mean for a number—either for a pH value or for the concentration of hydrogen ions—to have zero significant figures.").

Here, the sole extrinsic evidence of record of how a POSITA would understand the claim language is offered by Plaintiffs' expert, Dr. David Thompson, who opined that:

> [S]ignificant figures and rounding are standard scientific conventions that the POS[IT]A would have been aware of and would have applied in interpreting the claims of the Lipid Composition Patent. With respect to the recited mol % ranges, the POS[IT]A would have known that lipid concentrations could be experimentally determined, for example using high-performance liquid chromatography ("HPLC")... Accordingly, the POS[IT]A would have known that mol % values, as with measured values more generally in the field, are subject to numerical uncertainty, and would have interpreted the claimed mol % ranges, in the context of the patent specification, using the standard convention of significant figures and rounding.

(JA00431.) In support of this opinion, Dr. Thompson engages in an extensive review of the claim language, the specification, and the prosecution history. (JA00431-439.)

> …
>
> Given both Dr. Thompson's credentials and his thorough explanation for his opinion, I find that this extrinsic evidence weighs in favor of Plaintiffs' construction.
>
> …
>
> In sum, I am persuaded by Plaintiffs' construction-that the recited "mol %" ranges are understood to encompass their standard variation based on the number of significant figures recited in the claim. As noted above, the Federal Circuit has cautioned against interpreting "endpoints of the claimed range with greater precision than the claim language warrants." U.S. Philips Corp., 505 F.3d at 1377. The specification shows that Plaintiffs knew how to use trailing zeros to add more precision and explicitly did not do so with the ranges at issue. Moderna has pointed to no evidence that variations in the tenths of a mol % would have any impact on the functionality of the claimed invention such that I should construe the ranges with more specificity. And Moderna has not established that Plaintiffs' removal of the word "about" constituted a clear and unmistakable disclaimer of the rules of rounding. Indeed, the removal of the word "about" appears to have been done only to satisfy the examiner's concern that the claim language "read on a broad range of amounts" and "could embrace an amount +/-10, 20, 30 mol % of a lipid component," not to eliminate the minor variations associated with rounding. Finally, the sole extrinsic evidence of record comes from Plaintiffs' expert, Dr. Thompson, who opines that a POSITA would understand that the rules of rounding and significant figures apply to the claimed ranges.
>
> For all the foregoing reasons, I will adopt Plaintiffs' construction of the first disputed term, as follows: "**___ mol % of the total lipid present in the particle." The recited "mol % ranges are understood to encompass their standard variation based on the number of significant figures recited in the claim."**

Moderna Opinion, 2024 WL 1434526, at *8-13 (emphases in original).

The Court finds highly persuasive the *Moderna* court's thorough reasoning as to the precision of mol % terms recited by the claims of the '359 Patent. Accordingly, the Court adopts the same construction proposed by Plaintiffs here, as follows: "the recited mol % ranges are understood to encompass their standard variation based on the significant figures recited in the claim."

D. "consisting essentially of"

Finally, the Court considers the proper construction of "consisting essentially of" in the '378 patent. Relevant to that construction, the parties dispute the "basic and novel properties" of the invention claimed in the '378 patent. Plaintiffs argue that the basic and novel properties are the combination and concentration of the lipid components recited in the claims. Plfs Op. Br. at 25-27. They argue the prosecution history of the '378 Patent supports their position. *(Id.* at 26-27.)

Defendants criticize Plaintiffs' proposal as circular: the novel *properties* of an inventive combination must be more than the combination itself. Defendants propose more detailed basic and novel properties. In their view, the relevant properties are: (1) "increased activity of the encapsulated nucleic acid"; (2) "improved tolerability of the formulations in vivo"; (3) "significant increase in therapeutic index"; and (4) "stability in circulation" "when compared to formulations having less than 50 mol % cationic lipid." Defs Op. Br. at 27. In support of their position regarding features (1)-(4), Defendants rely on language from the Detailed Description of the Invention. *(Id.* at 27-28.) In support of their proposed comparison to formulations having less than 50 mol % cationic lipid, Defendants cite separate language from the Detailed Description and argue that the Court should find that it is an "unlisted feature" whose presence would "materially affect[s] the basic and novel properties of the invention." *(Id.* at 29.)

1. General Legal Principles of "Consisting Essentially Of"

"Consisting essentially of" is a transition phrase often used to signal a partially open claim. *PPG Indus. v. Guardian Indus.,* 156 F.3d 1351, 1354 (Fed. Cir. 1998). It serves as a middle ground between closed-ended claims using the phrase "consisting of" and open-ended claims using the phrase "comprising." *Id.; AK Steel Corp. v. Sollac & Ugine,* 344 F.3d 1234, 1239 (Fed. Cir. 2003). A drafter will typically employ the phrase "consisting essentially of" before "(a) a list of

ingredients when dealing with a composition claim, or (b) a series of steps when dealing with a process claim." *HZNP Medicines LLC v. Actavis Lab'ys UT Inc.,* 940 F.3d 680, 692-693 (Fed. Cir. 2019) (citation omitted). Thusly, "the drafter signals that the invention necessarily includes the listed ingredients [but] is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention." *Id.* Put differently, "[t]he phrase 'consisting essentially *of* . . . permit[s] inclusion of components not listed in the claim, provided that they do not 'materially affect the basic and novel properties of the invention.'" *AK Steel,* 344 F.3d at 1239.

2. The Claim Language

Claim 1 is the only independent claim in the '378 Patent and the only claim that uses the "consisting essentially of" transitional phrase:

> 1. A nucleic acid-lipid particle consisting essentially of:
> (a) an RNA;
> (b) a cationic lipid having a protonatable tertiary amine;
> (c) a mixture of a phospholipid and cholesterol of from 30 mol % to 55 mol % of the total lipid present in the particle, wherein the phospholipid consists of from 3 mol % to 15 mol % of the total lipid present in the particle; and
> (d) a polyethyleneglycol (PEG)-lipid conjugate consisting of from 0.1 mol % to 2 mol % of the total lipid present in the particle.

'378 Patent 93:16-26. The various dependent claims do not recite any further limitations with respect to the cationic lipid limitation (b).

3. The Specification

Defendants focus on the following passage, which is the first paragraph from the Detailed Description of the Invention:

> ***The present invention*** is based, in part, ***upon the surprising discovery*** that lipid particles comprising ***from about 50 mol*** % ***to about 85 mol*** % ***of a cationic lipid,*** from about 13 mol % to about 49.5 mol % of a non-cationic lipid, and from about 0.5 mol % to about 2 mol % of a lipid conjugate provide advantages when used for the in vitro or in vivo delivery of an active agent, such as a therapeutic nucleic acid (e.g., an interfering RNA). In particular, as illustrated by the Examples herein, ***the present invention*** provides stable nucleic acid-lipid particles (SNALP) ***that advantageously impart increased activity of the encapsulated nucleic acid*** (e.g., an interfering RNA such as siRNA) and ***improved tolerability of the formulations in vivo,*** resulting in a ***significant increase in the therapeutic index*** as compared to nucleic acid-lipid particle compositions previously described. Additionally, the SNALP of the invention are ***stable in circulation,*** e.g., resistant to degradation by nucleases in serum, and are substantially non-toxic to mammals such as humans.

'378 Patent 6:6-24 (emphases added). Defendants argue that the emphasized language represents the goal of the invention and the features that distinguish the invention from the prior art. Defs Op. Br. at 28. As Plaintiffs point out, however, the first sentence of this passage describes an invention that differs from the one recited in Claim 1. Importantly, the sentence describes lipid particles comprising from about 50 mol % to about 85 mol % of a cationic lipid," whereas Claim 1 recites only "a cationic lipid having a protonatable tertiary amine" without a numerical range. The Court therefore agrees with Plaintiffs and finds that the first sentence of the paragraph is inapplicable and cannot support Defendants' proposal to insert the 50 mol% language into the claim construction. [11]

[11] The Examples section of the specification also states that "[t]hose of skill in the art will readily recognize a variety of noncritical parameters which can be changed or modified to yield essentially the same results."

The remaining language of the cited paragraph is a different matter. The first sentence refers only to the "present invention," not a composition with a particular concentration of cationic lipid.[12] Again, that sentence states as follows:

> In particular, as illustrated by the Examples herein, ***the present invention*** provides stable nucleic acid-lipid particles (SNALP) ***that advantageously impart increased activity of the encapsulated nucleic acid*** (e.g., an interfering RNA such as siRNA) and ***improved tolerability of the formulations in vivo,*** resulting in a significant increase in the therapeutic index as compared to nucleic acid-lipid particle compositions previously described. Additionally, the SNALP of the invention are ***stable in circulation,*** e.g., resistant to degradation by nucleases in serum, and are substantially non-toxic to mammals such as humans.

The Court finds that the highlighted language does support part of Defendants' position insofar as the sentence identifies two "advantageous[]" properties of the inventive nucleic acid-lipid particles: "increased activity of the encapsulated nucleic acid" and "improved tolerability of the formulations in vivo." The Court therefore agrees that the specification supports their inclusion among the "basic and novel properties" of the invention. The Court disagrees, however, that "increased therapeutic index" is a basic and novel property. The sentence articulates this feature as the result, or consequence, of a combined increase in activity and tolerability, not a property in and of its own. The Court further finds that the third sentence favors including "stable in circulation" among the basic and novel properties of the claimed invention. Importantly, there is explicit support for this notion elsewhere in the specification. In relevant part, the Brief Summary of the Invention broadly states: ***"The present invention provides novel, serum-stable lipid particles*** comprising one or more active agents or therapeutic agents, methods of making the lipid

[12] The Court recognizes that the second sentence begins with "in particular" but finds that this segue does not limit the description in the second sentence to the invention identified in the first sentence. The first sentence notes that the invention is only based "in part" on its specifically recited combination.

particles, and methods of delivering and/or administering the lipid particles (e.g., for the treatment of a disease or disorder)."[13] '378 Patent 3:24-27.

4. The Prosecution History

As noted, Plaintiffs eschew the specification in favor of the prosecution history. During prosecution, Plaintiffs repeatedly touted the novelty of the specific combination of the components as differing from what was taught by the prior art cited by the patent examiner. In short, they maintain that the prosecution history demonstrates that the basic and novel properties of the claimed invention—the specific listed ingredients—are the listed ingredients themselves. As Defendants note, this is both problematically circular and ignores the specification. The specific combination of ingredients may be the point of novelty in the context of patentability negotiations with the Patent Office, but that does not necessarily circumscribe the "the basic and novel properties," particularly in the face of clear language in the specification.

Accordingly, the Court shall construe "consisting essentially of" to mean "consisting of only the listed ingredients and those that do not materially affect the increased activity of the encapsulated nucleic acid and the improved tolerability of the formulations in vivo, or the stability in circulation."

5. Extrinsic Evidence

The Court does not resort to extrinsic evidence because it finds that the intrinsic record is clear.

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[13] Defendants did not propose that "substantially non-toxic to mammals" be included among the basic and novel properties of the invention. Even if they had, the Court identified no broad support for that property in the specification that was not limited to "certain embodiments."

V. CONCLUSION

For the foregoing reasons, the Court will construe the disputed and stipulated terms of the patents in suit in accordance with the table below. An appropriate Order will follow.

TERM	COURT'S CONSTRUCTION
"lipid vesicle"	"any lipid composition that can be used to deliver a compound including, but not limited to, liposomes, wherein an aqueous volume is encapsulated by an amphipathic lipid bilayer; or wherein the lipids coat an interior comprising a large molecular component, such as a plasmid, with a reduced aqueous interior; or lipid aggregates or micelles, wherein the encapsulated component is contained within a relatively disordered lipid mixture"
"fully encapsulated"	"contained inside"
"mol %"	"the recited mol % ranges are understood to encompass their standard variation based on the significant figures recited in the claim"
"consisting essentially of"	"consisting of only the listed ingredients and those that do not materially affect the increased activity of the encapsulated nucleic acid and the improved tolerability of the formulations in vivo, or the stability in circulation"

DATED: September 9, 2025

ZAHID N. QURAISHI
UNITED STATES DISTRICTJUDGE