**2023-2357**

# United States Court of Appeals for the Federal Circuit

ALNYLAM PHARMACEUTICALS, INC.,

*Plaintiff-Appellant,*

*v.*

MODERNA, INC., MODERNATX, INC., AND MODERNA US, INC.,

*Defendants-Appellees.*

*Appeal from the United States District Court for the District of Delaware, in Case Nos. 1:22-cv-00335-CFC, 1:22-cv-00925-CFC (Hon. Colm F. Connelly, Judge)*

## CORRECTED BRIEF FOR DEFENDANTS-APPELLEES

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**U.S. Patent No. 11,246,933**

**18.** A cationic lipid comprising a primary group and two biodegradable hydrophobic tails, wherein the primary group comprises

(i) a head group that optionally comprises a primary, secondary, or tertiary amine, and

(ii) a central moiety to which the head group and the two biodegradable hydrophobic tails are directly bonded; the central moiety is a central carbon or nitrogen atom;

each biodegradable hydrophobic tail independently has the formula -(hydrophobic chain)-(biodegradable group)-(hydrophobic chain), wherein the biodegradable group is —OC(O)— or —C(O)O—;

for at least one biodegradable hydrophobic tail, the terminal hydrophobic chain in the biodegradable hydrophobic tail is a branched alkyl, where the branching occurs at the $\alpha$-position relative to the biodegradable group and the biodegradable hydrophobic tail has the formula —$R^{12}$-$M^1$- $R^{13}$, where $R^{12}$ is a $C_4$-$C_{14}$ alkylene or $C_4$-$C_{14}$ alkenylene, $M^1$ is the biodegradable group, $R^{13}$ is a branched $C_{10}$-$C_{20}$ alkyl, and the total carbon atom content of the tail —$R^{12}$-$M^1$-$R^{13}$ is 21 to 26;

in at least one hydrophobic tail, the biodegradable group is separated from a terminus of the hydrophobic tail by from 6 to 12 carbon atoms; and

the lipid has a pKa in the range of about 4 to about 11 and a logP of at least 10.1.

**U.S. Patent No. 11,382,979**

**1.** A lipid particle comprising:

(i) a nucleic acid,

(ii) 35-65 mol % of a cationic lipid,

(iii) 3-12 mol % distearoylphosphatidylcholine (DSPC), (iv) 15-45 mol % cholesterol, and

(v) 0.5-10 mol % of a PEG-modified lipid,

wherein the mol % is based on 100% total moles of lipids in the lipid particle; and

the cationic lipid comprises a head group, two hydrophobic tails, and a central moiety to which the head group and the two hydrophobic tails are directly bonded, wherein

(a) the central moiety is a central carbon or nitrogen atom;

(b) each hydrophobic tail independently has the formula -(hydrophobic chain)-(ester group)-(hydrophobic chain), wherein the ester group is — OC(O)— or —C(O)O—; and

(c) for at least one hydrophobic tail,

(I) the terminal hydrophobic chain in the hydrophobic tail is a branched alkyl, where the branching occurs at the $\alpha$-position relative to the ester group;

(II) the hydrophobic tail has the formula — $R^{12}$-$M^1$-$R^{13}$, wherein $R^{12}$ is a $C_4$-$C_{14}$ alkylene or $C_4$-$C_{14}$ alkenylene, $M^1$ is the ester group, and $R^{13}$ is a branched $C_{10}$-$C_{20}$ alkyl;

(III) the total carbon atom content of the tail — $R^{12}$-$M^1$-R13 is 21 to 26; and

(IV) the ester group is separated from a terminus of the hydrophobic tail by from 6 to 12 carbon atoms.

**18.** A method for preparing a lipid particle mixture comprising mixing a first solution comprising an organic solvent, a cationic lipid, distearoylphosphatidylcholine (DSPC), cholesterol, and a PEG-modified lipid, with a second solution comprising a nucleic acid and water to form a mixture containing lipid particles, wherein each lipid particle comprises

(i) the nucleic acid,

(ii) 35-65 mol % of the cationic lipid,

(iii) 3-12 mol % distearoylphosphatidylcholine (DSPC),

(iv) 15-45 mol % cholesterol, and

(v) 0.5-10 mol % of the PEG-modified lipid, and

wherein the mol % is based on 100% total moles of lipids in the lipid particle, and

the cationic lipid comprises a head group, two hydrophobic tails and a central moiety to which the head group and the two hydrophobic tails are directly bonded, wherein

(a) the central moiety is a central carbon or nitrogen atom;

(b) each hydrophobic tail independently has the formula -(hydrophobic chain)-(ester group)-(hydrophobic chain), wherein the ester group is —OC(O)— or —C(O)O—; and

(c) for at least one hydrophobic tail,

(I) the terminal hydrophobic chain in the hydrophobic tail is a branched alkyl, where the branching occurs at the $\alpha$-position relative to the ester group;

(II) the hydrophobic tail has the formula — $R^{12}$-

$M^1$-$R^{13}$, wherein $R^{12}$ is a $C_4$-$C_{14}$ alkylene or $C_4$-$C_{14}$ alkenylene, $M^1$ is the ester group, $R^{13}$ is a branched $C_{10}$-$C_{20}$ alkyl;

(III) the total carbon atom content of the tail — $R^{12}$-$M^1$-$R^{13}$ is 21 to 26; and

(IV) the ester group is separated from a terminus of the hydrophobic tail by from 6 to 12 carbon atoms.

# UNITED STATES COURT OF APPEALS
# FOR THE FEDERAL CIRCUIT

## CERTIFICATE OF INTEREST

**Case Number** 23-2357

**Short Case Caption** Alnylam Pharmaceuticals, Inc. v. Moderna, Inc.

**Filing Party/Entity** Moderna, Inc., ModernaTX, Inc., Moderna US, Inc.

**Instructions:**

1. Complete each section of the form and select none or N/A if appropriate.
2. Please enter only one item per box; attach additional pages as needed, and check the box to indicate such pages are attached.
3. In answering Sections 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance.
4. Please do not duplicate entries within Section 5.
5. Counsel must file an amended Certificate of Interest within seven days after any information on this form changes. Fed. Cir. R. 47.4(c).

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 03/01/2024

Signature: /s/ W. Chad Shear

Name: W. Chad Shear

| **1. Represented Entities.** Fed. Cir. R. 47.4(a)(1). | **2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2). | **3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3). |
|---|---|---|
| Provide the full names of all entities represented by undersigned counsel in this case. | Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities.<br><br>☑ None/Not Applicable | Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities.<br><br>☑ None/Not Applicable |
| Moderna, Inc. | | |
| ModernaTX, Inc. | | |
| Moderna US, Inc. | | |
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☐ Additional pages attached

**4. Legal Representatives.** List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

☐ None/Not Applicable ☑ Additional pages attached

| | | |
|---|---|---|
| Cooley LLP | Brianna Lee Chamberlin, Cooley LLP | Naina Soni, Cooley LLP |
| Dean Fanelli, Cooley LLP | Brittany Cazakoff, Cooley LLP | Michael J. Farnan, Farnan LLP |
| Elizabeth L.Stameshkin, Cooley LLP | Angela Madrigal, Cooley LLP | Brian E. Farnan, Farnan LLP |

**5. Related Cases.** Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

☑ Yes (file separate notice; see below) ☐ No ☐ N/A (amicus/movant)

If yes, concurrently file a separate Notice of Related Case Information that complies with Fed. Cir. R. 47.5(b). **Please do not duplicate information.** This separate Notice must only be filed with the first Certificate of Interest or, subsequently, if information changes during the pendency of the appeal. Fed. Cir. R. 47.5(b).

**6. Organizational Victims and Bankruptcy Cases**. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

☑ None/Not Applicable ☐ Additional pages attached

| | | |
|---|---|---|
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| | | |

***Alnylam Pharmaceuticals, Inc. v. Moderna, Inc.***
**Appeal No. 23-2357**

**Attachment to Amended Certificate of Interest**

**4. Legal Representatives (continued).**

*Fish & Richardson* – Caitlin M. Dean (former), Megan A. Chacon, Rosalynd D. Upton, Ryan V. Petty, Yun Dong

*Gibson Dunn & Crutcher* – Anne Y. Brody, Emil N. Nachman, Jane M. Love, Robert W. Trenchard

*MoloLamken LLP* – Jeffrey A. Lamken, Sara E. Margolis, Sara Tofighbakhsh

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## STATEMENT OF RELATED CASES

The Court's decision may affect a pending case in the United States District Court for the District of Delaware, *Alnylam Pharmaceuticals, Inc. v. Moderna, Inc., et al.*, Case No. 23-cv-580-CFC (D. Del.). There, Alnylam asserts related U.S. Patent No. 11,633,479 against Defendants-Appellees Moderna, Inc., ModernaTX, Inc. and Moderna US, Inc.

The Court's decision in this case may also affect a pending case in the United States District Court for the District of Delaware, *Alnylam Pharmaceuticals, Inc. v. Pfizer Inc., et al.*, Case No. 22-cv-336-CFC (D. Del.) (consolidated for all purposes, including trial, with *Alnylam Pharmaceuticals, Inc. v. Pfizer Inc. et al.*, Case No. 22-cv-00924-CFC (D. Del.) and *Alnylam Pharmaceuticals, Inc. v. Pfizer Inc., et al.*, Case No. 23-cv-578-CFC (D. Del.)). There, Alnylam asserts the two patents at issue in this appeal, U.S. Patent Nos. 11,246,933 and 11,382,979, as well as related U.S. Patent Nos. 11,590,229, 11,612,657, 11,633,479 and 11,633,480, against Pfizer Inc., Pharmacia & Upjohn Co. LLC, BioNTech SE, and BioNTech Manufacturing GmbH (collectively, "Pfizer").

## INTRODUCTION

This Court has long held that patentees are free to define terms in their patents, that is, to act as their own lexicographers. Here, Alnylam did exactly that. It provided an express definition for the term "branched alkyl." The problem for Alnylam is that, under this express definition, the claims do not cover Moderna's products.

It is no surprise that the patents do not reach the accused products. Moderna invented SM-102, the proprietary lipid used in its lifesaving COVID-19 vaccine, SPIKEVAX®. Alnylam had nothing to do with the development of Moderna's vaccine. Alnylam did not invent Moderna's foundational mRNA technology, the vehicle that delivers it, or SM-102 itself. What Alnylam did was dust off an almost decade-old patent application and, based on the public disclosure of SM-102, unsuccessfully try to ensnare Moderna's innovation. Alnylam failed because the definition it chose to include in that old application – and in the specification of the patents as granted – explicitly excludes SM-102.

This appeal arises because Alnylam now seeks to walk away from its chosen definition. It wants to disavow the definition of "branched alkyl" in its patents because, under that express definition, its infringement action fails. The district court properly rejected Alnylam's attempt to abandon its own express definition.

The definition of "branched alkyl" is clearly intended to give the term its meaning – it is not merely illustrative – and easily satisfies this Court's lexicography

standard. Clear, deliberate, and precise, it declares:

> Unless otherwise specified, the terms ***"branched alkyl"***, "branched alkenyl", and "branched alkynyl" ***refer to an alkyl***, alkenyl, or alkynyl ***group in which one carbon atom in the group (1) is bound to at least three other carbon atoms*** and (2) is not a ring atom of a cyclic group.

This definition bears all the hallmarks of intentional lexicography. It appears in a section dedicated to "Definitions." It includes the defined term set off in quotation marks. It uses the definitional linking term "refer[s] to," not language of example, like "includes" or "for example." It is clear and unambiguous to skilled artisans: the term "branched alkyl" requires that a "carbon atom in the group" be "bound to at least three other carbon atoms"; being bound to two or fewer is thus insufficient.

Moreover, the inclusion of "unless otherwise specified" makes the definitional intent of this text even more explicit. The phrase "unless other specified" would be unnecessary ***unless*** the definition was meant to apply as a general matter. And, further, the phrase makes clear that, in any instance the definition does not apply, the patent will so "specify," *i.e.*, so declare clearly, explicitly and unambiguously. But nothing in the claims or the specification so declare.

Alnylam's contrary arguments are fatally flawed. Alnylam argues that specification's express definition cannot be the correct construction because, implicitly, the claims must encompass branched alkyls where the carbon atoms are bound to fewer than three other carbons. Alnylam argues that the claims "expressly contemplate" an α-carbon bound to only two other carbons because they allow the

carbon atom at the "α-position" to bind with an oxygen atom. But Alnylam's argument deliberately ignores that carbon atoms can have four bonds; the α-carbon can bind with oxygen ***and*** three carbon atoms, consistent with the express definition.

Alnylam also wrongly asserts that the district court's construction reads out disclosed embodiments. This Court's precedents do not dictate that every claim needs to cover every embodiment. And, in any event, not only do all of the examples Alnylam points to fall outside the scope of the claims regardless of the meaning of "branched alkyl," but the patents do not even indicate that most of those examples include a "branched alkyl." As to the prosecution history, it is far too unclear to overcome the express definition.

Finally, Alnylam's proposed constructions should be rejected. Alnylam's purported "plain and ordinary meaning" lacks support. And Alnylam's argument for a different outcome if lexicography applies is waived and meritless.

## COUNTERSTATEMENT OF THE ISSUE

The patents-in-suit provide an express definition of the term "branched alkyl," directing that the definition applies "[u]nless otherwise specified." The question presented is whether the district court properly construed the terms "branched alkyl," "branched $C_{10}$-$C_{20}$ alkyl," and "$R^{13}$ is a $C_{10}$-$C_{20}$ branched alkyl" in accordance with the patents' express definition where the claims in no way "specify" that the definition should not apply.

# COUNTERSTATEMENT OF THE CASE

## I. FACTUAL BACKGROUND

### A. Moderna Developed the Novel Ionizable Lipid SM-102 for the Delivery of mRNA Vaccines

Founded in 2010, Moderna's mission was to make mRNA-based medicines a reality. (Appx720; Appx726-727.) The operating concept was to use messenger RNA ("mRNA") to instruct cells to make proteins with a therapeutic benefit, including for use in vaccines. (*Id*.) While the concept was scientifically sound, it was incredibly difficult to implement.

The story of mRNA-based medicines begins with proteins. Proteins are the workhorses of our cells, performing functions necessary for survival. (Appx342-343; Appx4996.) Our cells make more than 100,000 different proteins for functions as varied as building muscles, powering chemical reactions, and regulating the immune system. (*Id*.) Cells make proteins from the instructions encoded in our DNA. (Appx342-343; Appx4996.) Before proteins are made, the instructions in DNA are transcribed into mRNA for delivery to ribosomes, the protein-making machinery of the cell. (*Id*.) Ribosomes then use the instructions in mRNA to make proteins. (*Id*.)

Scientists have long recognized the possibility of medicines using mRNA to instruct cells to make proteins with therapeutic benefits. (Appx718; Appx726-727.) But mRNA does not last long, inside the body or out. (Appx663; Appx673-675;

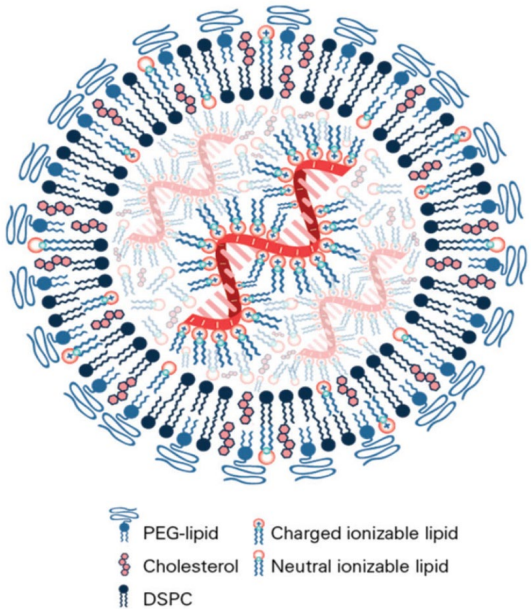
Appx5000-5001; Appx5052.) Nature designed it to deliver its informational payload and then quickly disappear. (*Id.*) And, even if a medicine could get it through the body intact, mRNA is large and tends not to cross cell membranes because it is negatively charged. (Appx347; Appx5002; Appx5032; Appx5035.)

A major hurdle in making mRNA-based medicines a reality was transporting the mRNA safely through the body and into cells. (Appx673-675; Appx717; Appx728.) Moderna investigated many different technologies to overcome this delivery hurdle, ultimately settling on "lipid nanoparticles" ("LNPs"). (Appx347; Appx721; Appx727-728; Appx4299-4300.)

LNPs are drug delivery vehicles comprising lipids—fatty compounds that are generally insoluble in water. (Appx675; Appx717.) The lipids in an LNP form a protective complex that can house a drug substance and transport it through the body and across cell membranes. (*Id.*; Appx672) In theory, once it gets into the target cell, the LNP will fall apart, release the drug substance, and instruct the cell to make a protein. (Appx347; Appx672.)

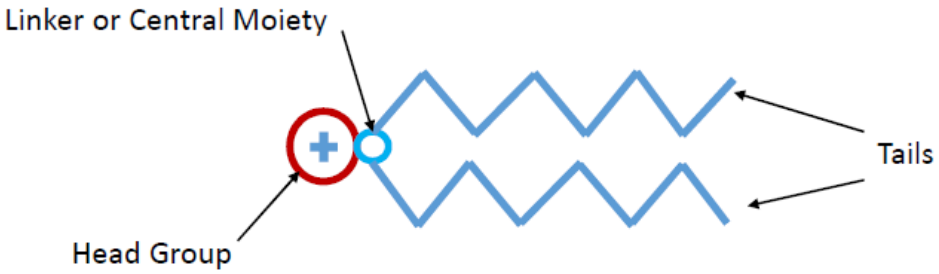
In the case of Moderna's vaccine, the drug substance is mRNA that, if successfully transported into the cell, can instruct the body to make the SARS-CoV-2 Spike protein. (Appx728-729; Appx4978.) Production of that protein, itself harmless, allows the body's immune system to develop a prophylactic response to the COVID-19 virus. (*Id*.)

The LNPs at issue here comprise four separate lipid components: a polyethylene-glycol ("PEG") lipid, cholesterol, a phospholipid, and a cationic lipid. (Appx48(Abstract); Appx52(1:42-44); Appx347.) Those components can form a complex that protects mRNA, as illustrated below:




(Appx5056.)

One portion of the cationic lipid is the subject of this case. Cationic lipids are termed "cationic" because they are or can become positively charged under certain conditions, allowing them to bind to negatively charged mRNA and form an LNP. (Appx249(395:53-64); Appx5065.) Cationic lipids generally include three distinct domains: a head group, a linker (referred to by the patents-in-suit as a "central moiety"), and one or more hydrophobic (water-resistant) tails:




(Appx4433.)

When Moderna started its work, cationic lipids were well known but none had proven able to successfully deliver mRNA in an LNP. (Appx718-722; Appx4303-4304.) Off-the-shelf LNP formulations designed for other types of RNA, such as those designed by Alnylam for small interfering RNA ("siRNA"), did not work as well as desired for larger mRNA. (Appx721-722; Appx4303-4304.)

Moderna invested years to develop LNPs tailored to work with mRNA. (Appx347; Appx728; Appx784-785; Appx4299-4300.) As part of its work, Moderna conducted extensive research to discover a cationic lipid for use in an LNP that could protect mRNA during transit through the body, effectively deliver it into target cells, and then biodegrade for easy clearance. (Appx664; Appx721-722; Appx727-728; Appx785; Appx4299-4300.) The result of Moderna's significant effort was the novel cationic lipid known as SM-102. (Appx721-722; Appx4299-4300.) LNPs including SM-102 proved capable of successfully delivering mRNA to cells. (Appx722.)

In the face of the COVID-19 pandemic, Moderna leveraged its proprietary LNP and mRNA technology, including SM-102, to quickly develop the life-saving

vaccine, SPIKEVAX®. (Appx343-344; Appx645; Appx686-689; Appx727-729; Appx4300; Appx5060.) On December 18, 2020, FDA granted Emergency Use Authorization for SPIKEVAX®, and full FDA approval followed. (Appx342; Appx686; Appx4978.) Moderna quickly manufactured and provided doses of SPIKEVAX® worldwide at record speed, saving countless lives. (Appx342; Appx686-688; Appx4300.)

### B. Alnylam Pursued a Completely Different Type of Therapy

Alnylam never developed an mRNA-based therapy. Instead, Alnylam focused on therapies using siRNA, a different type of RNA. (Appx719; Appx4303.) mRNA and siRNA are markedly different. (Appx674-676; Appx4303.) Structurally, mRNA is significantly larger than siRNA, and this size difference makes it much harder to package mRNA into drug delivery vehicles, like LNPs. (Appx674-676; Appx721; Appx4303.) Alnylam never developed a cationic lipid capable of achieving the more difficult goal of mRNA delivery, much less received FDA approval for a mRNA product. (Appx4303-4304; Alnylam.Br.6-7.) Instead, as Alnylam concedes, Alnylam's FDA-approved products all involve methods of delivering siRNA. (Alnylam.Br.6-7.)

In 2012, in conjunction with its work on LNPs for delivery of siRNA, Alnylam filed the first non-provisional application in the '933 and '979 patent family. (Appx48-49.) Alnylam's application included multiple generic chemical

formulas, over a thousand representative cationic lipids, and test results for dozens of examples, all of which are quite different than SM-102. (*See* Appx52-319; U.S. Patent No. 9,061,063.) Over the next eight years, Alnylam prosecuted only three applications in the patent family, resulting in three issued patents. (Appx52(1:4-13); USPTO, Application 61/623,274, https://patentcenter.uspto.gov/applications/61623274/continuity?application (last visited March 1, 2024).) None of those patents are at issue here, nor do they include any claim that would arguably cover SM-102. (*See* U.S. Patent Nos. 9,061,063, 10,369,226, 11,071,784.)

In 2021, Alnylam changed course. After the structure of SM-102 became public, and Moderna received Emergency Use Authorization for SPIKEVAX®, Alnylam suddenly filed a series of applications in an apparent effort to cobble together claims that might cover SM-102. (USPTO, Application 13/708,383, https://patentcenter.uspto.gov/applications/13708383/continuity?application (last visited March 1, 2024).) Despite its silence during nearly a decade of previous prosecution, Alnylam now claimed that it, not Moderna, invented SM-102 and Moderna's groundbreaking LNP technology used in SPIKEVAX®.

Alnylam has now sued Moderna on five different patents obtained since 2022, two of which, the '933 and '979 patents, are directly at issue in this appeal. (Appx33-771; Appx949-952; *Alnylam Pharms., Inc. v. Moderna, Inc. et al.*, No. 1:23-cv-00580-CFC (D. Del.) (filed May 26, 2023).)

### C. The Patents-in-Suit

The ’933 and ’979 patents issued on February 15, 2022 and July 12, 2022, respectively. (Appx48; Appx2385.) They generally disclose and claim cationic lipids that include a head group, central moiety and two hydrophobic tails, an assembly well known in the art.[1] (Appx48(Abstract).) The cationic lipids of the invention also have one or more “biodegradable groups” in the hydrophobic tails, again something far from new in 2012. (Appx48(Abstract); Appx4940-4941.)

#### 1. The Disputed Claim Terms

Alnylam asserts claims 18 and 20-27 of the ’933 patent and claims 1-3, 5-14, 18-20 and 22-30 of the ’979 patent. Unlike the claims of most pharmaceutical patents, the asserted claims describe the claimed lipids in words, instead of by chemical structure.[2] Claim 18 of the ’933 patent is exemplary:

> 18. A cationic lipid comprising a primary group and two biodegradable hydrophobic tails, wherein
>
> the primary group comprises (i) a head group that optionally comprises a primary, secondary, or tertiary amine, and (ii) a central moiety to which the head group and the two biodegradable hydrophobic tails are directly bonded;
>
> the central moiety is a central carbon or nitrogen atom;

[1] The patents-in-suit share the same specification in all substantive respects. For brevity, we only cite to the ’933 patent (Appx48-321).

[2] Alnylam likely took that approach because none of the chemical structures included in the patents’ specification encompass Moderna’s invention and words were the only way to potentially reach SM-102. (*Compare* Appx52-66(2:7-29:61) *with* Appx5057 (Moderna Lipid H, SM-102).)

> each biodegradable hydrophobic tail independently has the formula -(hydrophobic chain)-(biodegradable group)-(hydrophobic chain), wherein the biodegradable group is —OC(O)— or —C(O)O—;
>
> for at least one biodegradable hydrophobic tail, the terminal hydrophobic chain in the biodegradable hydrophobic tail is a ***branched alkyl***, where the branching occurs at the α-position relative to the biodegradable group and the biodegradable hydrophobic tail has the formula —$R^{12}$-$M^1$-$R^{13}$, where $R^{12}$ is a $C_4$-$C_{14}$ alkylene or $C_4$-$C_{14}$ alkenylene, $M^1$ is the biodegradable group, ***$R^{13}$ is a branched $C_{10}$-$C_{20}$ alkyl***, and the total carbon atom content of the tail —$R^{12}$-$M^1$-$R^{13}$ is 21 to 26;
>
> in at least one hydrophobic tail, the biodegradable group is separated from a terminus of the hydrophobic tail by from 6 to 12 carbon atoms; and
>
> the lipid has a pKa in the range of about 4 to about 11 and a logP of at least 10.1.

(Appx320(538:13-38).) The dispute here focuses on the biodegradable hydrophobic tails and, specifically, the terms "branched alkyl," "branched $C_{10}$-$C_{20}$ alkyl," and "$R^{13}$ is a branched $C_{10}$-$C_{20}$ alkyl."

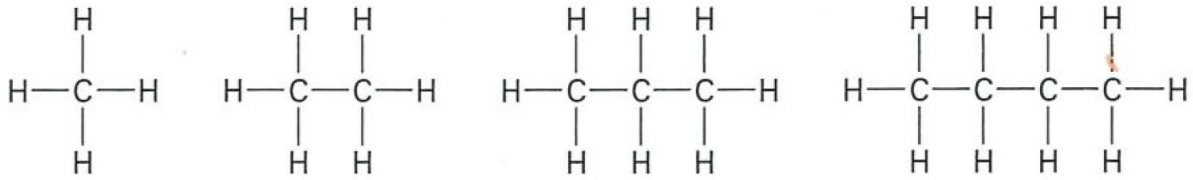
The patents explicitly define both "alkyl" and "branched alkyl" in a "Definitions" section that also defines more than a dozen other terms. (Appx256-258(410:55-413:28).) The term "alkyl" is defined as follows:

> The terms "alkyl" and "alkylene" refer to a ***straight or branched*** chain ***saturated hydrocarbon*** moiety.

(Appx257(411:53-54) (emphasis added.)[3]

[3] Alnylam does not challenge that that definition of "alkyl" is lexicography.

A "hydrocarbon" is a molecule made up entirely of carbon and hydrogen atoms. (Appx5008.) A hydrocarbon is "saturated" when it contains the maximum possible number of hydrogen atoms per carbon atom, so that the bonds between the carbon atoms are exclusively single bonds (as opposed to double or triple bonds). (*Id.*) Some saturated hydrocarbon examples are depicted below:



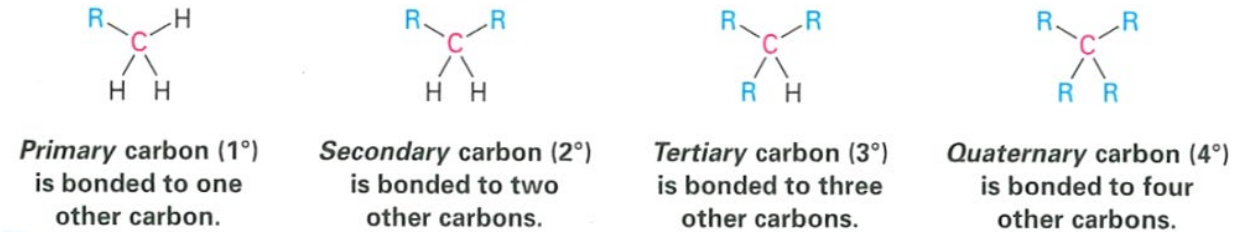

(Appx5008.) Importantly, as shown above, each carbon atom in a saturated hydrocarbon is bound to ***four other*** carbon or hydrogen ***atoms***. (*Id.*) Finally, the "alkyl" definition provides that the saturated hydrocarbon may be "straight or branched." (Appx257(411:53-54).)

"Branched alkyl" is defined a few paragraphs later:

> Unless otherwise specified, the terms ***"branched alkyl"***, "branched alkenyl", and "branched alkynyl" ***refer to an alkyl***, alkenyl, or alkynyl ***group in which one carbon atom in the group (1) is bound to at least three other carbon atoms*** and (2) is not a ring atom of a cyclic group.

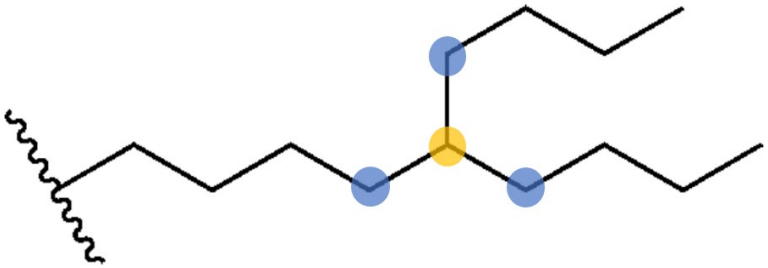
(Appx257(412:13-19) (emphasis added).) A carbon atom "bound to … three other carbon atoms," like that referred to in the definition, is commonly referred to by scientists as a "tertiary" carbon. (Appx5011-5012.) As shown below, other carbons are referred to as "primary" (carbon bound to one other carbons), "secondary"

(carbon bound to two other carbons), and "quaternary" (carbon bound to four other carbons):




(Appx5012.)[4]

The express definition of "branched alkyl" makes scientific sense. In the alkyl group below, which the patents expressly identify as a "branched alkyl," the carbon atom highlighted in yellow is tertiary because it is bound to the three other carbon atoms highlighted in blue (all secondary carbons), creating a natural branching point.

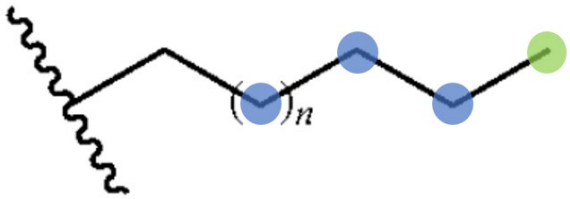


(Appx5588; Appx79(55:11-14, 55:52-58) (annotated).)[5] In contrast, the alkyl group

[4] Alnylam appears to use "two-carbon" group, "three-carbon" group, and "four-carbon" group to refer to secondary, tertiary, and quaternary carbon atoms, respectively. (*See, e.g.*, Alnylam.Br.13.) Respectfully, Alnylam's terminology is inaccurate because, for instance, its "two-carbon" groups really include three carbons – the secondary carbon atom and the two attached carbon atoms. We thus use the scientifically accurate and accepted terms, *e.g.*, tertiary carbon, throughout.

[5] In this style of chemical structure, each line represents a bond, each corner where lines connect represents a carbon atom, and hydrogen atoms are not shown.

below, which all parties would agree is "straight," includes only primary carbon atoms (shown in green) and secondary carbon atoms (shown in blue), but no tertiary carbon atoms, and thus no natural branching point.




(Appx5588; Appx88(74:32-36) (annotated).)

**2. The Claim Language**

The claims do not state or suggest that they deviate from the patents' express definition of "branched alkyl." Nor do they "expressly specify" a secondary carbon at the α-position, as Alnylam contends. (Alnylam.Br.15.)

The claims first lay out the general structure of the claimed cationic lipids, including a "head group," "two biodegradable hydrophobic tails," and a "central moiety," to which the head group and tails are directly bonded:

> **18**. A cationic lipid comprising a primary group and two biodegradable hydrophobic tails, wherein
> the primary group comprises (i) a head group that optionally comprises a primary, secondary, or tertiary amine, and (ii) a central moiety to which the head group and the two biodegradable hydrophobic tails are directly bonded;
> the central moiety is a central carbon or nitrogen atom;

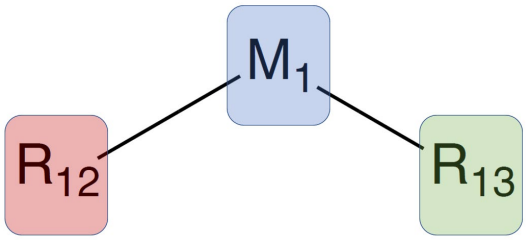
(Appx4949.) Thus, this structure represents the carbon atom in yellow bound to three other carbons atoms and a hydrogen atom, which is not shown.

(Appx320(538:13-20) (annotated).)

The claims next explain that each biodegradable hydrophobic tail has the formula -(hydrophobic chain)-(biodegradable group)-(hydrophobic chain), also represented by the formula $R^{12}$-$M^1$-$R^{13}$:

> each biodegradable hydrophobic tail independently has the formula -(hydrophobic chain)-(biodegradable group)-(hydrophobic chain), wherein the biodegradable group is —OC(O)— or —C(O)O—;
> for at least one biodegradable hydrophobic tail, the terminal hydrophobic chain in the biodegradable hydrophobic tail is a branched alkyl, where the branching occurs at the α-position relative to the biodegradable group and the biodegradable hydrophobic tail has the formula —$R^{12}$-$M^1$-$R^{13}$, where $R^{12}$ is a $C_4$-$C_{14}$ alkylene or $C_4$-$C_{14}$ alkenylene, $M^1$ is the biodegradable group, $R^{13}$ is a branched $C_{10}$-$C_{20}$ alkyl, and the total carbon atom content of the tail —$R^{12}$-$M^1$-$R^{13}$ is 21 to 26;

(Appx320(538:21-33) (annotated).) That structure is depicted below:

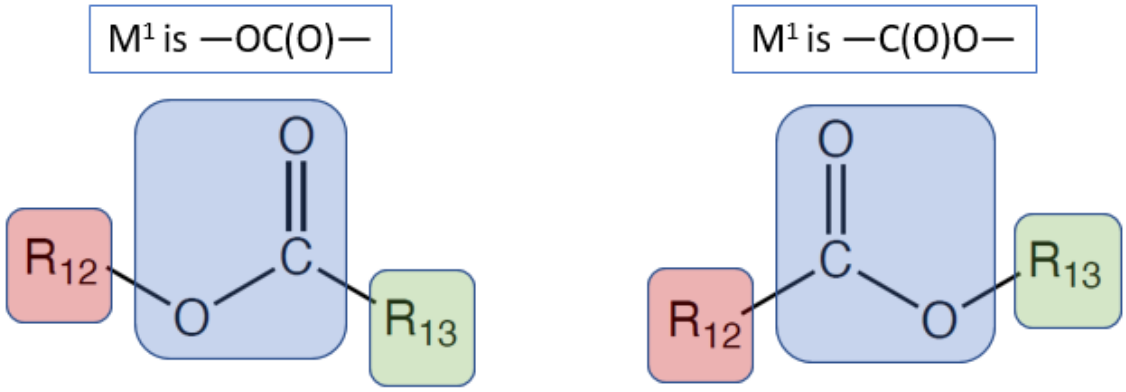



(Appx5646.)

The biodegradable group, or $M^1$, is an ester group, with one of two possible orientations, —OC(O)— or —C(O)O—:

each biodegradable hydrophobic tail independently has the formula -(hydrophobic chain)-(biodegradable group)-(hydrophobic chain), wherein the biodegradable group is —OC(O)— or —C(O)O—;
for at least one biodegradable hydrophobic tail, the terminal hydrophobic chain in the biodegradable hydrophobic tail is a branched alkyl, where the branching occurs at the α-position relative to the biodegradable group and the biodegradable hydrophobic tail has the formula —$R^{12}$-$M^1$-$R^{13}$, where $R^{12}$ is a $C_4$-$C_{14}$ alkylene or $C_4$-$C_{14}$ alkenylene, $M^1$ is the biodegradable group, $R^{13}$ is a branched $C_{10}$-$C_{20}$ alkyl, and the total carbon atom content of the tail —$R^{12}$-$M^1$-$R^{13}$ is 21 to 26;

(Appx320(538:21-33) (annotated).)[6] Both $M^1$ orientations are depicted below:



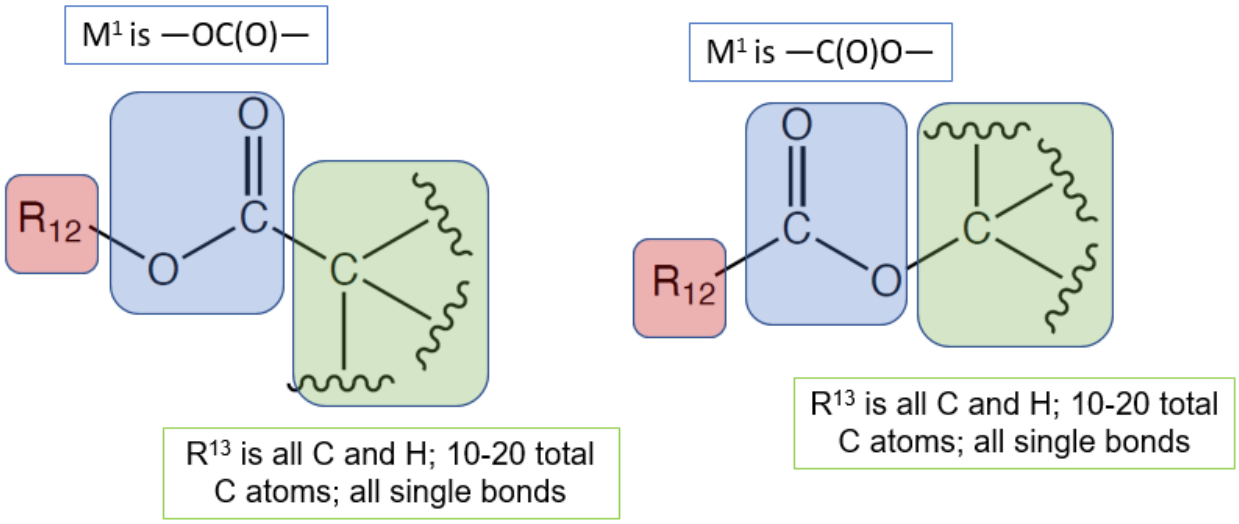

(*See id.*; Appx5646.)

The claims next provide that "the terminal hydrophobic chain … is a branched alkyl" and further specify that "$R^{13}$" (*i.e.*, the terminal hydrophobic chain) is "a branched $C_{10}$-$C_{20}$ alkyl":

[6] The '933 patent claims use the term "biodegradable group" (Appx320(538:13-14)), while the corresponding claims in the '979 Patent use the more specific term "ester group." (Appx2635(493:54-57).) For purposes of this appeal, those terms are used synonymously in the clams, and we thus use "$M^1$," "ester," and "biodegradable" group interchangeably.

each biodegradable hydrophobic tail independently has the formula -(hydrophobic chain)-(biodegradable group)-(hydrophobic chain), wherein the biodegradable group is —OC(O)— or —C(O)O—;
for at least one biodegradable hydrophobic tail, the terminal hydrophobic chain in the biodegradable hydrophobic tail is a branched alkyl, where the branching occurs at the α-position relative to the biodegradable group and the biodegradable hydrophobic tail has the formula —$R^{12}$-$M^1$-$R^{13}$, where $R^{12}$ is a $C_4$-$C_{14}$ alkylene or $C_4$-$C_{14}$ alkenylene, $M^1$ is the biodegradable group, $R^{13}$ is a branched $C_{10}$-$C_{20}$ alkyl, and the total carbon atom content of the tail —$R^{12}$-$M^1$-$R^{13}$ is 21 to 26;

(*Id.* (annotated).) Consistent with the definition of "alkyl," the parties agree that "branched $C_{10}$-$C_{20}$ alkyl" requires that the $R^{13}$ group consist entirely of carbon and hydrogen atoms (a "hydrocarbon"), with only single bonds between the carbon atoms ("saturated"), and a total of 10-20 carbon atoms ("$C_{10}$-$C_{20}$" alkyl). This is illustrated below for both ester orientations, with the squiggly lines representing additional carbon or hydrogen atoms:



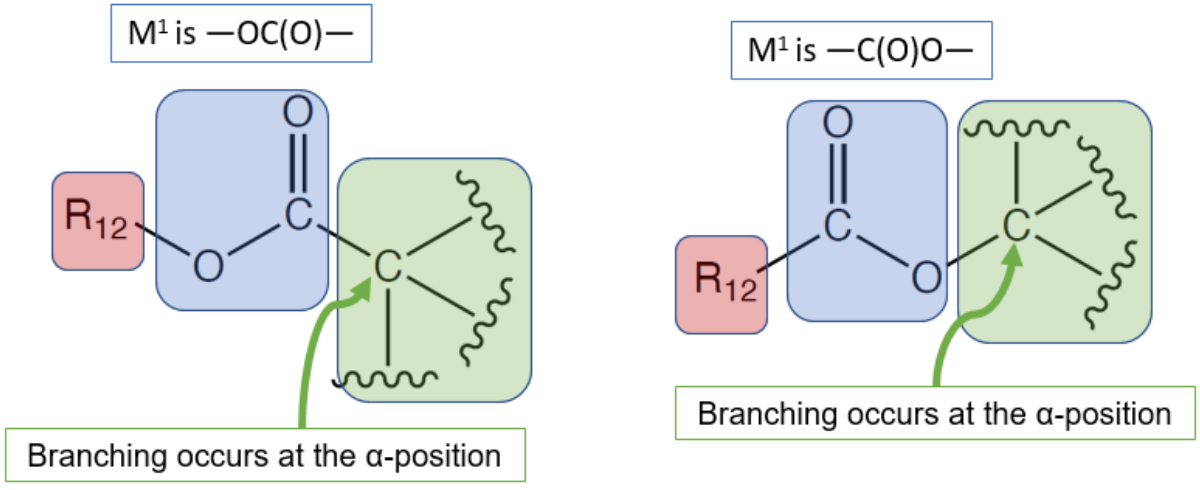
(Appx257(411:53-54); Appx5008; Appx5591.) We know that the carbon in the green box must be bound to three additional atoms (at each squiggly line) because every carbon in a saturated hydrocarbon is bound to four total atoms. (Appx5008.)

Finally, the claims provide that "the branching occurs at the α-position relative to the [biodegradable/ester] group":

> for at least one biodegradable hydrophobic tail, the terminal hydrophobic chain in the biodegradable hydrophobic tail is a branched alkyl, where the branching occurs at the α-position relative to the biodegradable group and the biodegradable hydrophobic tail has the formula —$R^{12}$-$M^1$-$R^{13}$, where $R^{12}$ is a $C_4$-$C_{14}$ alkylene or $C_4$-$C_{14}$ alkenylene, $M^1$ is the biodegradable group, $R^{13}$ is a branched $C_{10}$-$C_{20}$ alkyl, and the total carbon atom content of the tail —$R^{12}$-$M^1$-$R^{13}$ is 21 to 26;

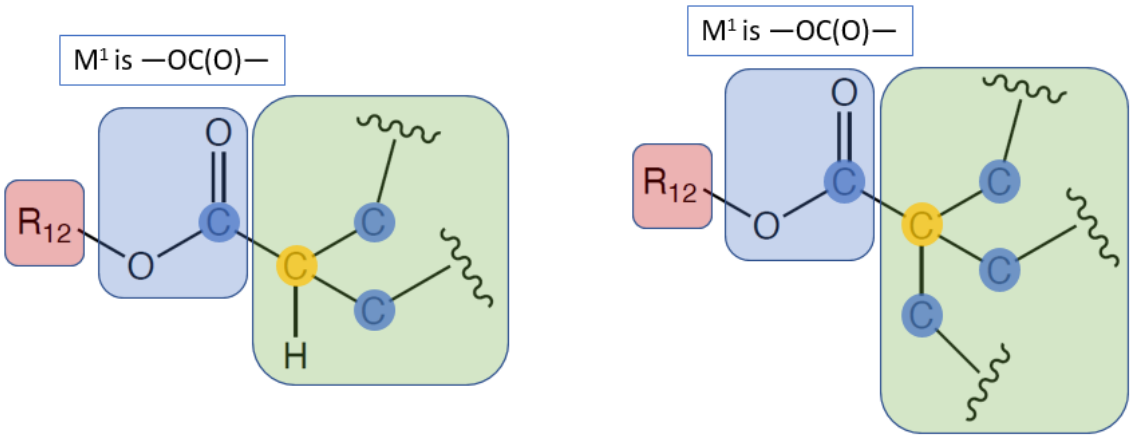
(Appx320(538:25-33) (annotated).) The parties agreed this term means "where the branching occurs at the carbon atom next to the [biodegradable/ester] group." (Appx4.)

The α-position, or α-carbon atom, is identified below:



(Appx257(411:53-54); Appx5008; Appx5591.)

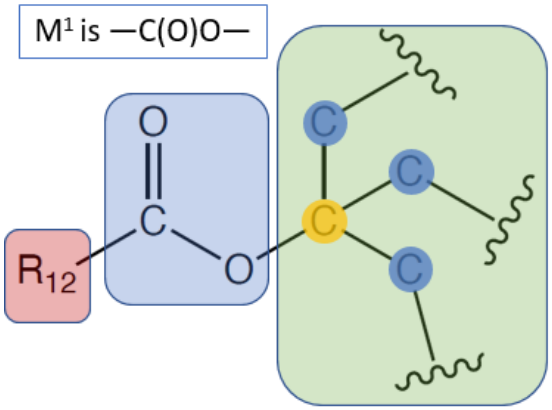
Each of the open bonds could be ***either a carbon atom or a hydrogen atom***.[7] As a result, when the ester is in the —OC(O)— orientation, the claim language permits the $R^{13}$ group to include a tertiary carbon (below, left) or quaternary carbon (below, right) (both highlighted in yellow) at the α-position, consistent with the express definition of "branched alkyl":




(Appx257(411:53-54); Appx320(538:25-33); Appx5008; Appx5591-5592.)

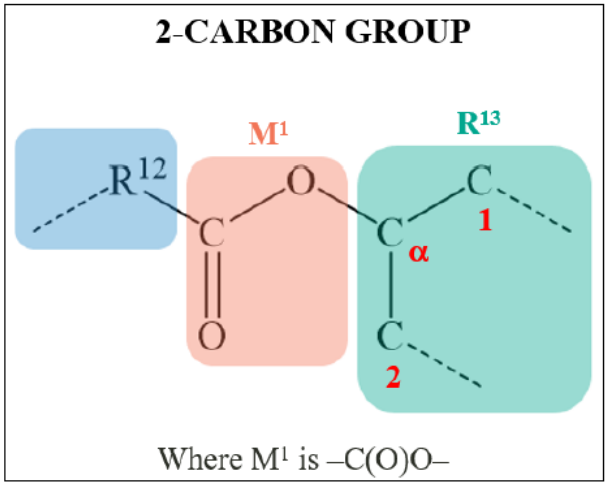
Crucially, when the ester is in the ***—C(O)O— orientation***, the claims permit the $R^{13}$ group to include a tertiary carbon (a carbon bonded to three others) at the α-position, consistent with the express definition (as depicted below in yellow):

[7] All three squiggly lines cannot be hydrogen atoms, or the molecule would end before reaching the required 10-20 carbon atoms.



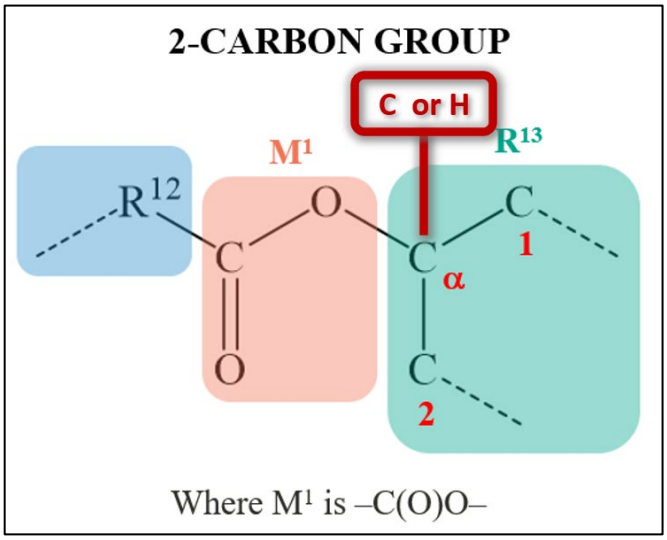

(Appx257(411:53-54); Appx5008; Appx5591-5592.) Nothing in the claim language requires a secondary carbon at the α-position (highlighted in yellow above). Nor does the claim language, construed consistently with the express definition of "branched alkyl," exclude compounds containing the —C(O)O— ester orientation.

Alnylam reaches a contrary conclusion by ignoring one of the bonds on the α-carbon atom. Alnylam states that the "Patents-in-Suit include dependent claims directed specifically to —C(O)O— as the $M^1$ group and accordingly ***expressly contemplate a 2-carbon group***." (Alnylam.Br.14 (emphasis added).) Alnylam then shows the following figure:



(Alnylam.Br.14.)[8]

Alnylam's "depiction," however, overlooks that the α-carbon has a fourth bond, which can be ***either*** a carbon ***or*** hydrogen atom, as depicted below:



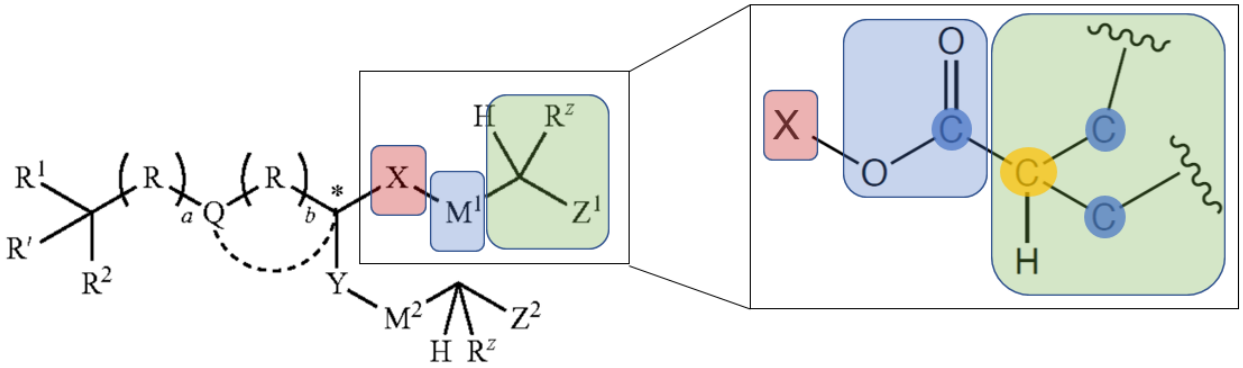

(Alnylam.Br.14 (annotated); Appx257(411:53-54); Appx5008.) If the fourth atom is a carbon atom, then the α-carbon is a tertiary carbon (*i.e.*, a carbon bound to three other carbon atoms). (Appx257(411:53-54); Appx5008; Appx5011-5012.) Accordingly, with either ester orientation, the express claim language permits the carbon at the α-position to be a tertiary carbon (a carbon bound to three others) and, in the case of —OC(O)—, a quaternary carbon (a carbon bound to four others), in conformance with the patents' express definition for "branched alkyl" (an alkyl with a carbon "bound to at least three other carbon atoms").

[8] The patents also do not include this structure or indicate that similar $R^{13}$ groups are "branched alkyls."

### 3. The Specification

The specification begins with a "Summary" section that provides ten generic formulas disclosing various embodiments of the allegedly novel cationic lipids. (Appx52-63(2:7-19:13).) Alnylam concedes that all ten generic formulas fall ***outside*** the scope of the claims. (Alnylam.Br.17-18.)

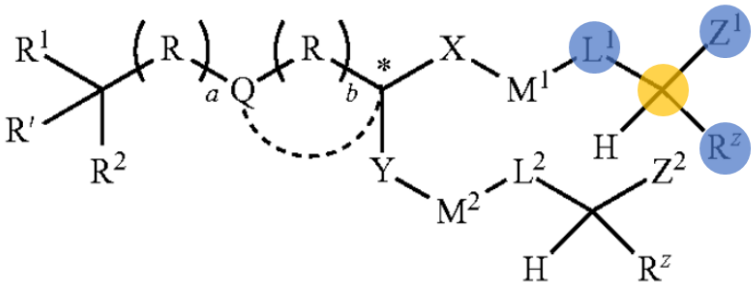
Formulas I and II have "a branched alkyl at the α-position adjacent to the biodegradable group." (Appx52-53(2:8-9; 3:63-65).) These generic formulas include myriad potential species, many of which include a tertiary carbon at the α-position, consistent with the express definition of "branched alkyl." For instance, where $M^1$ is "—OC(O)—" in Formula II (Appx54(5:1-2)), the α-carbon is a tertiary carbon, as depicted in yellow below:




(Appx52-55(2:7-5:50) (annotated).)

Formulas III, IIIA, and IV likewise each require a tertiary carbon atom in the terminal hydrophobic chain, consistent with the express definition. (Appx54-57(5:51-11:3.) The tertiary carbon in Formula III is highlighted in yellow below:

Formula (III)

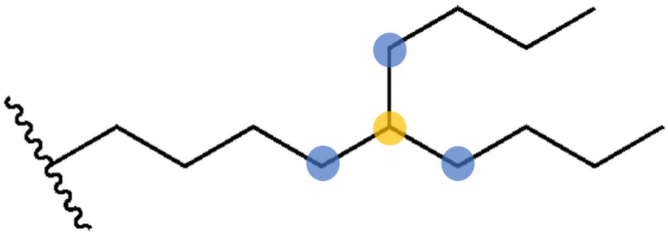


(Appx54(5:51-6:48) (annotated).)

Formulas V, VIA, VIB, and VII do not have any branching in their hydrophobic tails, showing that a "branched alkyl" is an optional feature of the alleged invention. (Appx57-59(11:9-15:65).)[9]

The "Detailed Description" section includes thousands of specific chemical structures. (Appx66-258(29:63-414:30).) Aside from the definitions discussed above, the Detailed Description uses the term "branched alkyl" ***only once***, in Column 55. (Appx79(55:11-21).) Column 55 provides that "[o]ther suitable tails groups include[] those of the formula $–R^{12}$-$M^1$-$R^{13}$ where … ***$R^{13}$ is a branched alkyl*** …" (*Id.* (emphasis added).) That section goes on to provide more than 20 "[s]uitable $R^{13}$ groups," each including a branched alkyl that has a tertiary carbon. (Appx79-81(55:49-57:20; 57:56-58:39; 58:53-65; 60:18-35).) A representative example is below, with the tertiary carbon highlighted in yellow:

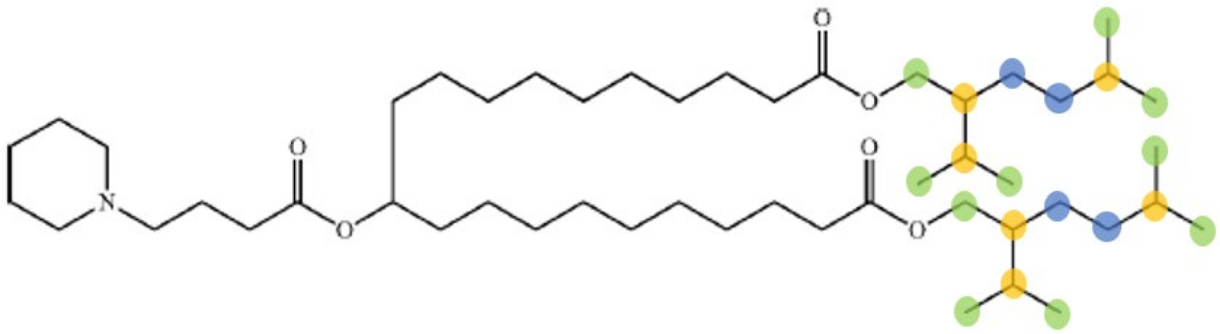
[9] Formula VIII is a generic description that refers back to earlier formulas and does not include the term "branched alkyl" or illustrate any branching. (Appx59-61(16:1-19:12).)



C13 (C21)
Length: C9 (18)

(Appx5594; Appx79(55:52-60) (annotated); *see also* Appx79-81(55:55-57:19; 57:57-58:38; 58:53-60:35) (illustrating a tertiary carbon in every "suitable" branched alkyl $R^{13}$ group).)

The specification does not explicitly state that ***any*** of the thousands of additional exemplary structures have a "branched alkyl." But most of them include a tertiary carbon in the $R^{13}$ portion of at least one hydrophobic tail. (*Id.*; Appx89-249.) One example is below with the tertiary carbons highlighted in yellow (secondary carbons are blue, and primary are green):

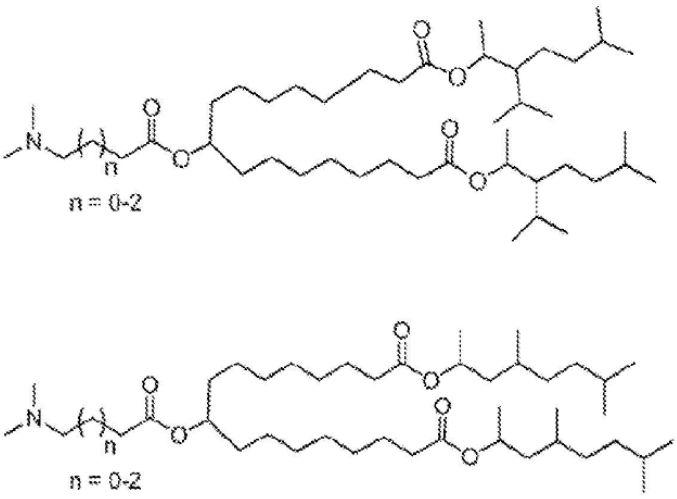



(Appx89(75:1-76:65) (annotated).)

### 4. The Prosecution History

During prosecution of the ’933 patent, the Examiner rejected the pending claims as anticipated by WO ’493. (Appx4940-4943.) The Examiner cited compounds shown on two different pages of WO ’493 (pages 51 and 58) in support of the rejection. (*Id.*)

The Examiner cited the following compounds from page 58 of WO ’493:

| | |
|---|---|
| Page 58 of WO ‘493 |   |

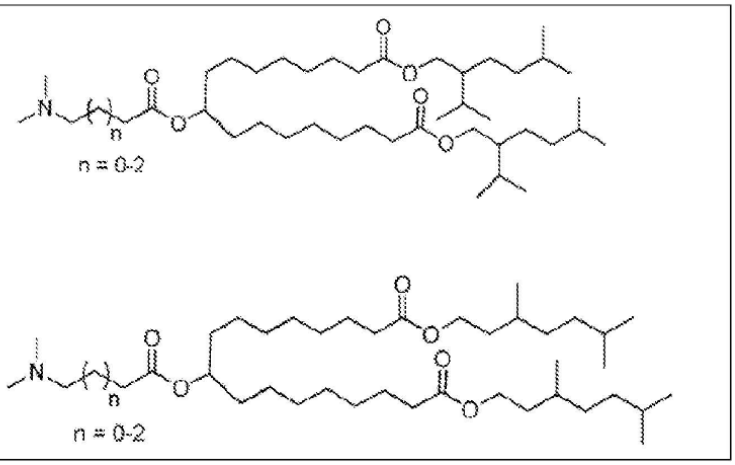
(Appx4941.) To try to overcome that rejection, the applicants added new dependent claim 32 (which later issued as claim 14):

> 32. (New) The cationic lipid of claim 1, wherein the branched alkyl group has ***only one*** carbon atom which is bound to three other carbon atoms.

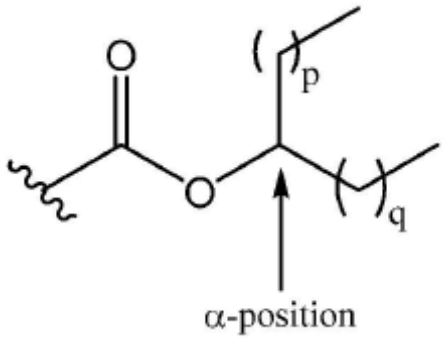
(Appx4913 (emphasis added).) The applicants argued that “[n]ew claim 32 recites that the branched alkyl group has ***only one*** carbon atom which is bound to three other carbon atoms,” whereas the prior art compounds “each have ***three carbon atoms*** which are bound to three other carbon atoms.” (Appx4942.) The applicants

thus distinguished the page 58 prior art based on the ***number*** of tertiary carbons in the "branched alkyl," in line with the express definition. (Appx257(412:13-20).)

The applicants took a different approach to the page 51 compounds, reproduced below.

| | |
|---|---|
| Page 51 of WO '493 |   |

(Appx4940-4941.) The applicants argued that the pending claims were not anticipated by those compounds because they "do ***not*** have branching in the terminal hydrophobic chain at the ***α-position*** relative to the biodegradable group as recited in the pending claims." (Appx4941.) The applicants went on to argue that "such compounds," *i.e.*, the compounds on page 51 of the prior art, "with branching at the α-position would have a moiety as shown below[]:



(Appx4941.) The picture supplied by the applicants referred to the ***prior art***; it did not depict their invention. And the applicants never used the term "branched alkyl" or suggested that the above structure showed a "branched alkyl," either in the prior art or in the applicants' purported invention. (*Id.*)

## II. Proceedings Below

In March 2022, just over a month after the '933 patent issued, Alnylam sued Moderna for patent infringement in the District of Delaware. (Appx33-771.) In July 2022, Alnylam filed a second complaint asserting the '979 patent just days after it issued. (Appx950.) The district court consolidated the two cases for all purposes. (Appx949-952.) Alnylam separately sued Pfizer and BioNTech, alleging their COVID-19 vaccine also infringes each of the patents-in-suit. *Alnylam Pharms., Inc. v. Pfizer Inc., et al.,* Nos. 1:22-cv-00336-CFC and 1:22-cv-00924 (D. Del.).

The district court subsequently held consolidated claim construction proceedings in the Moderna and Pfizer/BioNTech cases. (Appx5519-5522.) Following full briefing, the district court held a *Markman* hearing lasting more than four hours. (Appx5523-5564.) Alnylam argued that the express definition of "branched alkyl"—requiring a carbon bound to at least three others—was not a definition. (Appx4478-4483; Appx4492-4503; Appx5550(109:10-110:6); Appx5555(129:10-13).) Alnylam instead argued that the term should be given its "ordinary meaning"—purportedly "a[n] [alkyl] that is not a straight chain"—but

submitted no expert testimony to support that meaning. (Appx4478-4483; Appx4492-4503.) Nor did Alnylam explain how a skilled artisan would determine if an alkyl was "not a straight chain." (Appx4478-4483; Appx4492-4503.)

At the conclusion of the *Markman* hearing, the district court found "clear and unequivocal lexicography" for the terms "alkyl" and "branched alkyl." (Appx5559(145:20-23).) The court emphasized that, under the express terms of that lexicography, the patent would have to "specify" any departure from the definition of "branched alkyl" provided in the claims. (Appx5559(146:1-3).) And the court found that the patent did not "otherwise specify" that the express definition should not apply: "[Alnylam does not] point to anything specific or express in the claims, which is the most important thing, nor [does Alnylam] point to anything in the specification that would support that there was a departure from the lexicography provided in Column 412." (Appx5559(146:11-16).)

Later that same day, the district court issued an order clarifying one of the constructions issued at the hearing. (Appx5519-5522.) The court reaffirmed the "clear and unmistakable lexicography of 'alkyl' and 'branched alkyl'" in the patents-in-suit. (Appx5520.) But the district court reconsidered the Pfizer/BioNTech defendants' request for a construction that required that the "one carbon atom in the group" be bound to at least three other carbon atoms ***in the same group*** (thus excluding carbon atoms in the neighboring $M^1$ group). (Appx5520-5522; Appx8-

10.) The district court found that the express definitions were "silent as to whether the 'at least three other carbon atoms' are 'in the [$R^{13}$] group'" and thus ruled that they need not be in that group.[10] (Appx5520-5521; Appx8-9.)

The parties subsequently submitted, and the district court adopted, a Claim Construction Order construing the disputed terms as follows:

| | |
|---|---|
| "branched alkyl" | "A saturated hydrocarbon moiety group in which one carbon atom in the group (1) is bound to at least three other carbon atoms, and (2) is not a ring atom of a cyclic group." |
| "branched $C_{10}$-$C_{20}$ alkyl" | "A saturated hydrocarbon moiety group with 10 to 20 carbon atoms and in which one carbon atom in the group (1) is bound to at least three other carbon atoms, and (2) is not a ring atom of a cyclic group." |
| "$R^{13}$ is a branched $C_{10}$-$C_{20}$ alkyl" | "$R^{13}$ is a saturated hydrocarbon moiety group with 10 to 20 carbon atoms and in which one carbon atom in the group (1) is bound to at least three other carbon atoms and (2) is not a ring atom of a cyclic group." |

(Appx3-4.) We refer to the terms "branched alkyl," "branched $C_{10}$-$C_{20}$ alkyl," and "$R^{13}$ is a branched $C_{10}$-$C_{20}$ alkyl" collectively as the "Branched Alkyl Terms."

Alnylam conceded that, under the court's constructions, SM-102 did not infringe. (Appx5666-5667.) On August 30, 2023, the district court entered final judgment in Moderna's favor, and this appeal ensued. (Appx5665; Appx1.)

[10] Alnylam agrees that any carbon atom in the $M^1$ group directly bound to the α-carbon atom counts in assessing the total number of carbon atoms bound to the α-carbon atom. (*See* Alnylam.Br.13.)

## SUMMARY OF ARGUMENT

The district court correctly construed the Branched Alkyl Terms based on the patents' clear lexicography of "branched alkyl." The express definition of "branched alkyl" has all the hallmarks of lexicography. It appears in a section entitled "Definitions;" has the defined term in quotation marks; and uses the definitional linking phrase "refer[s] to" before the definition. And the definition itself is clear and precise, identifying the chemical structure (an "alkyl group"), specifying the required bonding (one carbon atom "bound to at least three other carbon atoms"), and excluding a particular structure ("a ring atom of a cyclic group").

The phrase "unless otherwise specified" cements lexicographic intent. That phrase shows that the definition must apply absent clear intent to the contrary, *i.e.*, something that "otherwise specifies." This Court has found lexicography for definitions that use similar qualified language. *See*, *e.g.*, *Sinorgchem Co.*, *Shandong v. Int'l Trade Comm'n*, 511 F.3d 1132, 1136 (Fed. Cir. 2007).

The intrinsic evidence is consistent with the express definition. Dependent claim 14 of the '933 patent limits the "branched alkyl" group to "***only one*** carbon atom which is bound to three other carbon atoms," indicating that the broader independent claim includes one or more such carbon atoms and tracking the express definition. Likewise, the specification is full of examples that include a tertiary carbon in the $M^1$ group. Finally, the '933 patent's prosecution history shows

Alnylam understood that the express definition applies, as they used what would become dependent claim 14 (narrowing "branched alkyl" to "only one" tertiary carbon) to differentiate prior art that had ***more than one*** tertiary carbon atom.

The district court also correctly found that the patents do not "otherwise specif[y]" that the express definition of "branched alkyl" does not apply to the asserted claims. The word "specify" is demanding, and there is nothing explicit, unambiguous, or detailed in the claims, or elsewhere in the patents, signaling an intentional departure from the express definition. If they had intended otherwise, Alnylam could have easily drawn the desired chemical structure or stated that the branched alkyl "includes a carbon atom bound to two other carbon atoms" at the α-position. They did not.

Alnylam's arguments against lexicography lack merit. Alnylam reads the claims to "otherwise specify" by ignoring the actual claim language (and associated science) and employing circular reasoning that assumes the result—that the claims ***require*** a secondary carbon at the α-position. As to the specification, Alnylam is wrong that the express definition improperly "reads out" examples. The entire premise of Alnylam's argument—that claim construction cannot exclude an embodiment in the specification—contradicts common sense and the well-established principle that "[i]t is not necessary that each claim read on every embodiment." *Baran v. Med. Device Techs., Inc*., 616 F.3d 1309, 1316 (Fed. Cir.

2010). Regardless, Alnylam's examples cannot be "read out" of the claims because they are already outside of the claim scope before considering the express definition. And most are not identified as depicting a "branched alkyl" in the first place. As to the prosecution history, the exchanges cited by Alnylam do not use the term "branched alkyl" and lack the clarity necessary to overcome the express definition.

Finally, Alnylam's proposed constructions should be rejected. Its "plain and ordinary meaning" construction, advanced below, lacks any record support and would not aid a jury. And, to the extent Alnylam's alternative argument seeks a different construction, that argument is forfeited because Alnylam raises it for the first time on appeal.

## ARGUMENT

### I. STANDARD OF REVIEW

Claim construction is ultimately a question of law and receives *de novo* review on appeal. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 390-91 (1996); *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 325 (2015). Where the district court reviews evidence extrinsic to the patent, and makes subsidiary factual findings about that evidence, this Court reviews that subsidiary factfinding for clear error. *Teva*, 574 U.S. at 331-32.

## II. THE DISTRICT COURT CORRECTLY CONSTRUED THE BRANCHED ALKYL TERMS

Perhaps no patent-law principle is more familiar than the rule that inventors may act as their own lexicographers. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005) (en banc); *Markman v. Westview Instruments, Inc.,* 52 F.3d 967, 980 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). As the district court found, the patents-in-suit set forth "clear and unmistakable lexicography" for the term "branched alkyl." (Appx7; Appx5519.) The lexicography is so clear that it was "an easy call" and "not complicated at all." (Appx10; Appx5559(146:17-19).)

The district court was right. The patents' definition of "branched alkyl"—located in the patents' "Definitions" section—is clear and unambiguous. And it promises that, if a contrary meaning is desired, the patent will so "specif[y]," *i.e.*, "state explicitly, unambiguously, or in detail." *Specify*, American Heritage Dictionary of the English Language ("American Heritage Dictionary") (5th ed. 2012). Under this Court's precedents, that should end the inquiry: the definition controls. The claim language, the specification, and the prosecution history confirm that conclusion.

Perhaps because of its clarity, Alnylam pretends that the patents' express definition—and more specifically its requirement that a carbon be bound to at least three other carbons—does not exist. Alnylam does not substantively address the definition until page 57 of its brief, despite that definition being the basis of the

decision below. (Alnylam.Br.57-63.) Try as it might, Alnylam cannot now excise the definition from the specification or the term from its claims. As the district court properly held, the lexicography here is clear, unmistakable, and controlling.

### A. The District Court Correctly Found the Specification's Explicit Definition of "Branched Alkyl" Is Lexicography

Where the specification reveals "a special definition given to a claim term by the patentee," the "inventor's lexicography governs." *Phillips*, 415 F.3d at 1316; *see also Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1248 (Fed. Cir. 1998) ("[T]he definition selected by the patent applicant controls."). The definition need only appear "with reasonable clarity, deliberateness, and precision" to control. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994); *see also Renishaw*, 158 F.3d at 1249. That standard is amply met here.

#### 1. The Express Definition of "Branched Alkyl" Has the Required Clarity, Deliberateness, and Precision

In a section titled "Definitions," the patents-in-suit expressly define the term "branched alkyl." (Appx256(410:55).) The patents state, "[u]nless otherwise specified, the term[] 'branched alkyl' … refer[s] to an alkyl … group in which ***one carbon atom in the group*** (1) is ***bound to at least three other carbon atoms*** and (2) is not a ring atom of a cyclic group." (Appx257(412:13-18) (emphasis added).) The district court correctly found that definition is unmistakable lexicography.

The definition appears in a section titled "Definitions," which alone strongly

implies it is definitional. *See Optima Tech Corp. v. Roxio Inc.*, No. SACV 03 1776 JVS ANX, 2004 WL 5029231, at *3 n.4 (C.D. Cal. Oct. 1, 2004) ("[T]he word 'definition' itself is defined as 'The act or process of stating ***a precise meaning*** or significance; formulation of a meaning.'") (quoting American Heritage Dictionary (4th ed.)) (emphasis added); *Definition*, Black's Law Dictionary (11th ed. 2019) ("The meaning of a term as explicitly stated in a drafted document[.]"). This Court and lower courts regularly find lexicography when the patent provides a clear definition following a phrase like "defined below," *Thorner v. Sony Comput. Ent. Am. LLC*, 669 F.3d 1362, 1366 (Fed. Cir. 2012); *Astrazeneca AB, Aktiebolaget Hassle, KBI-E, Inc. v. Mutual Pharm. Co.*, 384 F.3d 1333, 1339 (Fed. Cir. 2004), or when found in a "section of the specification dedicated to defining terms," *VLSI Tech. LLC v. Intel Corp.*, No. 17-CV-05671-BLF, 2019 WL 652892, at *6 (N.D. Cal. Feb. 15, 2019).[11]

The defined term "branched alkyl" is also set forth in quotation marks. The fact that the term at issue is "set off by quotation marks" is "often a strong indication

[11] Other district courts have held the same when patents include a dedicated "Definitions" section. *See, e.g.*, *Enanta Pharms., Inc. v. Pfizer, Inc.*, No. 22-CV-10967-DJC, 2023 WL 4014083, at *3 (D. Mass. June 15, 2023); *Intercept Pharms., Inc. v. Apotex Inc.*, No. CV 20-1105, 2022 WL 856859, at *3 (D. Del. Mar. 23, 2022); *Seagen Inc. v. Daiichi Sankyo Co.*, No. 2:20-CV-00337-JRG, 2021 WL 4168660, at *5 (E.D. Tex. Sept. 14, 2021); *Optima Tech*, 2004 WL 5029231, at *3-5.

that what follows" is lexicography. *Sinorgchem,* 511 F.3d at 1136; *see also AstraZeneca UK Ltd. v. Watson Lab'ys, Inc. (NV)*, 905 F. Supp. 2d 589, 593 (D. Del. 2012) ("Significantly, each of the defined terms is set off by quotation marks … indicating … that the inventors acted as their own lexicographers by expressly defining claim terms in the specification.").

This Court also considers whether the patent uses linking terms that "signify [the patentee] is serving as its own lexicographer." *Abbott Lab'ys v. Andrx Pharms., Inc.*, 473 F.3d 1196, 1210 (Fed. Cir. 2007). Here, the patents do just that. The definition of "branched alkyl" does not use an open-ended phrase like "including" or "comprising." *See, e.g., Lucent Techs., Inc. v. Gateway, Inc.*, 525 F.3d 1200, 1214 (Fed. Cir. 2008). The patents instead use the linking term "refers to," a reliable sign of definitional intent. As this Court has explained, the phrase " 'refer to' conveys an intent for [the sentence] to be definitional." *See Parkervision, Inc. v. Vidal*, 88 F.4th 969, 976 (Fed. Cir. 2023); *see also Vasudevan Software, Inc. v. MicroStrategy, Inc.*, 782 F.3d 671, 679 (Fed. Cir. 2015) ("An applicant's use of the phrase 'refers to' generally indicates an intention to define a term."); *Kyocera Senco Indus. Tools Inc. v. Int'l Trade Comm'n*, 22 F.4th 1369, 1378-79 (Fed. Cir. 2022) (finding lexicography where the patent provided a term's meaning when "referred to herein"); *AstraZeneca UK*, 905 F. Supp. 2d at 594 (finding "refers to" used to expressly define terms). That is likewise the case here.

Moreover, Alnylam's decision to use the definitional phrase "refers to" was deliberate. Elsewhere in the Definitions section, Alnylam used open-ended terms like "[f]or example," "include(s)," and "[n]on-limiting" to signal that the descriptions are exemplary. (*See, e.g.,* Appx256-257(411:16, 21-22, 38, 41-42, 44, 58, 60; 412:2, 11, 18, 24-25, 39, 61).)[12] Contrasted against these phrases, Alnylam's choice to use the definitional term "refers to" for the definition of "branched alkyl" speaks volumes. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. 1, 20 (2017) (applying principle that the use of different words in a statute implies different intent); *see also Takeda Pharm. Co. v. Zydus Pharms. USA, Inc.*, 743 F.3d 1359, 1364-65 (Fed. Cir. 2014) (where patentees used "about" elsewhere in the claim to "express ambiguity," finding no similar ambiguity where claim language was "not qualified by the word 'about' or any other indicator of imprecision").

Finally, the definition that follows is clear and precise. It identifies the chemical structure (an "alkyl group"); it specifies the binding that is required ("one carbon atom … bound to at least three other carbon atoms"); and it excludes a particular chemical configuration ("a ring atom of a cyclic group"). The definition further promises that, if a contrary meaning is intended, the patents will "otherwise

[12] Indeed, the very paragraph containing the definition of "branched alkyl" concludes with the exemplary sentence: "***For example***, a spirocyclic group in an alkyl . . . group is not considered a point of branching." (Appx257(412:18-20) (emphasis added).)

specif[y]," thus signaling the definition's general applicability. (Appx257(412:13).) There is no "ambiguity or incompleteness" in the definition. *Sinorgchem,* 511 F.3d at 1138 (citation omitted). Nor is the definition susceptible to multiple interpretations. *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1370-71 (Fed. Cir. 2005). Alnylam does not suggest otherwise: it does not argue that the definition is not clear or precise—only that it is not binding.

The lexicography here is not merely evident; it is inescapable. Scores of cases find lexicography based on definitions far less clear, precise, and deliberate than the definition here. *See, e.g.*, *Astrazeneca AB*, 384 F.3d at 1339-40 ("AstraZeneca seems to suggest that lexicography requires a statement in the form 'I define _____ to mean _____,' but such rigid formalism is not required."); *Mentor Graphics Corp. v. EVE-USA, Inc.*, 851 F.3d 1275, 1294 (Fed. Cir. 2017) (finding lexicography despite the definition's use of "includes" and internal inconsistency); *Parkervision*, 88 F.4th at 976 (finding explicit definition); *Kyocera*, 22 F.4th at 1378 (same); *Biogen MA Inc. v. EMD Serono, Inc.*, 976 F.3d 1326, 1335-36 (Fed. Cir. 2020) (same); *Sinorgchem*, 511 F.3d at 1136-40 (same); *3M Innovative Props. Co. v. Avery Dennison Corp.*, 350 F.3d 1365, 1371 (Fed. Cir. 2004) (same).

### 2. The Phrase "Unless Otherwise Specified" Reinforces the District Court's Finding of Lexicography

The phrase "unless otherwise specified" cements lexicographical intent. As the district court found, it makes clear that the definition is generally applicable and

that, if there are exceptions, they will be set forth with precision and clarity, *i.e.*, "specified." (Appx5563(161:16); (Appx5559(146:2-5).) Indeed, ***absent*** an understanding that the definition generally applies, the phrase "unless otherwise specified" would be meaningless. But it is not: the phrase announces ***how*** the patents will identify any exceptions to the definition. As the district court observed, "'otherwise specified'" is simply "part of the lexicography." (Appx5555(129:15-18).)

That flows directly from use of the word "specified." As the district court explained, "[b]y definition, specification is specific." (Appx5559(146:2-5).) To "specify" means to "state explicitly, unambiguously, or in detail." *Specify*, American Heritage Dictionary; *see also* Webster's *Third New International Dictionary of the English Language* (2002) ("to mention or name in a specific or explicit manner: tell or state precisely or in detail"); *Specific*, Black's Law Dictionary (11th ed. 2019) ("Of, relating to, or designating a particular or defined thing; explicit"); *Sun Life Assurance Co. of Canada*, 877 F.3d 698, 701 (6th Cir. 2017) (citing Oxford English Dictionary 159 (2d ed. 1989)). Alnylam does not—and cannot—contend otherwise.

Courts consistently recognize that the phrase "[u]nless otherwise specified" means that the stated rule applies except where a different rule is set forth with greater specificity. *See, e.g., United States v. Lovaas*, 241 F.3d 900, 904 (7th Cir. 2001) ("'[U]nless otherwise specified[]' … permits courts to consider additional

conduct when other provisions … set forth more specific rules."); *United States v. Ladeau*, 688 F. App'x 342, 350 (6th Cir. 2017) (same). Indeed, Alnylam's own statutory interpretation cases stand for that exact proposition. *See, e.g., United States v. Kluger*, 722 F.3d 549, 558-59 (3d Cir. 2013) (interpreting the phrase "unless otherwise specified" in sentencing guidelines as allowing discrete exceptions where the guidelines' commentaries "specifically describ[e]" alternative methods of calculating offense levels).[13]

This Court has likewise rejected the notion that similar qualified language renders a definition in a patent non-definitional. For instance, in *Sinorgchem*, the explicit definition of a "controlled amount" of protic material specified an upper amount "[w]hen aniline is utilized as a solvent." 511 F.3d at 1136-37. Despite that the specification discussed the use of numerous solvents and acknowledged that "the amount of protic material present in the reaction ***varies with the solvent*,"** the court rejected the notion that the qualifier "when aniline is utilized as a solvent" defeated lexicography. *Id.* at 1138 (emphasis added). Instead, the Court held that "[w]hen aniline is used as the solvent, the express definition is neither ambiguous nor

[13] The remainder of Alnylam's statutory interpretation cases (Alnylam.Br.58) are similar. *Hill v. Schilling*, 578 F. App'x 456, 460 (5th Cir. 2014) (finding exception to Texas code that provided for trustee rights "[u]nless otherwise provided" where a settlement agreement "unambiguous[ly]" provided for the exception); *Abbadessa v. Tegu*, 154 A.2d 483, 486-87 (Vt. 1959) (interpreting "unless otherwise provided" to instruct the court to defer to a more specific provision that that applied only under specified conditions).

incomplete—the 'controlled amount' is 'up to about 4% H2O based on the volume of the reaction mixture'—and we need look no further for its meaning." *Id*. So too here. The definition of "branched alkyl" requires "one carbon atom … bound to at least three other carbon atoms," and promises that the patent will "specify" any exceptions. The Court need look no further for the meaning of "branched alkyl."

Finally, the definition's use of "unless otherwise specified" is not comparable to the open-ended language at issue in the cases cited by Alnylam. The phrases used in those case—like "such as," "e.g.," and "includes"—indicate that the description is exemplary, not definitional. *See, e.g., Baxalta, Inc. v. Genentech, Inc.*, 972 F.3d 1341, 1349 (Fed. Cir. 2020) (finding no lexicography for signals like "e.g." and "such as"); *Nevro Corp. v. Bos. Sci. Corp.*, 955 F.3d 35, 43 (Fed. Cir. 2020) (same for "e.g."); *Acme Scale Co. v. LTS Scale Co.*, 615 F. App'x 673, 678-79 (Fed. Cir. 2015) (same for "include[s]," "such as," "for example," and "but not limited to"). Here, "unless otherwise specified," does not suggest the definition is exemplary. Instead, it tells skilled artisans that any departure from that definition will be "specified," *i.e.*, set forth explicitly and unambiguously, and in turn confirms that the definition is otherwise generally applicable.

### 3. The Intrinsic Evidence Supports the District Court's Finding of Lexicography

The claims, specification, and prosecution history further support the district court's decision to faithfully apply the express definition of "branched alkyl."

**The claims.** Claim differentiation confirms Alnylam's lexicographical intent and shows that Alnylam clearly understood how to "specify otherwise" in the claims. Claim 1 of the '933 patent uses the term "branched alkyl" in the exact same manner as the asserted claims.[14] Claim 14 depends from claim 1 but specifies that "the branched alkyl group has ***only one carbon atom*** which is bound to three other carbon atoms." (Appx320(537:56-58) (emphasis added).) Under the doctrine of claim differentiation, claim 14 is presumed narrower than independent claim 1, from which it depends. *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1242 (Fed. Cir. 2003).

Because dependent claim 14 recites a "branched alkyl" having ***only one*** tertiary carbon atom, claim 1 must allow for ***more than one*** tertiary carbon atom. Put differently, claim 1 allows for a branched alkyl with ***one or more*** tertiary carbons, and claim 14 narrows that scope to a branched alkyl with ***only one*** tertiary carbon. (Appx320(537:56-58).) In both instances, the branched alkyl still must have

[14] Claim 1 recites that "the terminal hydrophobic chain in the hydrophobic tail is a branched alkyl group, where the branching occurs at the α-position relative to the biodegradable group" and "at least one biodegradable hydrophobic tail has the formula $-R^{12}-M^{1}-R^{13}$, where … $R^{13}$ is a branched $C_{10}$-$C_{20}$ alkyl." (Appx319(535:51-60).) That language is materially identical to that in the disputed claims.

at least one tertiary carbon (*i.e.*, a carbon bound to three other carbons) or a quaternary carbon (*i.e.*, a carbon bound to four other carbons). Alnylam's use of the exact language used in the express definition of "branched alkyl" ("bound to three other carbon atoms") also confirms that it was well aware of the definition and intended it to apply.

**The specification.** The specification supports the same conclusion with numerous examples consistent with the express definition. As this Court has explained, "examples in the patent describ[ing] the use of claimed compositions" can confirm a definition even where there is "some ambiguity in how the patentee defined the term." *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 958 (Fed. Cir. 2014). Here, there is no ambiguity in the definition. But numerous examples in the specification nonetheless confirm what the definition's plain text makes clear.

The specification's Summary includes ten generic chemical formulas detailing the cationic lipids of the present invention. (Appx52-61(2:7-19:12).) Five of those formulas arguably have branching in the hydrophobic tails. (Appx52-53(2:15-3:67 (Formula I)); Appx53-54(4:5-5:56 (Formula II)); Appx54 (5:60-6:54 (Formula III)); Appx54-56(6:60-10:35 (Formula IIIA)); Appx56-57(10:40-11:6 (Formula IV)).) In all five of those generic formulas, the hydrophobic tail can include a tertiary carbon atom at the point of branching, consistent with the definition of "branched alkyl." (*See,* pp.22-24 (Section I.C.3.), *supra*.)

Next, the Detailed Description includes thousands of exemplary lipid and hydrophobic tail structures. (Appx66-319.) Apart from the Definitions subsection, the term "branched alkyl" appears ***only once*** in the Detailed Description. In Column 55, the specification discloses "suitable tail groups" where "$R^{13}$ is a branched alkyl." (Appx79(55:12-15).) The patents proceed to identify around twenty "suitable" $R^{13}$ groups with such "branched alkyls." (Appx79-81(55:49-57:20; 57:56-58:39; 58:53-65; 60:18-35).) ***Every single one*** of those $R^{13}$ branched alkyl groups includes a tertiary carbon atom, consistent with the express definition. (*Id*.; s*ee also,* pp.22-24 (Section I.C.3.), *supra*.)

The patent does not indicate that any of the thousands of additional exemplary structures includes a "branched alkyl." Nonetheless, the vast majority of those structures that could arguably have branching in a hydrophobic tail include at least one tertiary carbon. (*See,* pp.22-24 (Section I.C.3.), *supra*.)

**The prosecution history.** The prosecution history for the '933 patent confirms Alnylam's lexicographical intent. *See Phillips*, 415 F.3d at 1317. During prosecution, the examiner rejected the then-pending claims as anticipated by WO '493. (Appx4940-4942.) In response, Alnylam added new dependent claim 32 (which issued as claim 14), requiring that "the branched alkyl group has ***only one*** carbon atom which is bound to three other carbon atoms." (Appx4913 (emphasis added).) Alnylam differentiated certain of the prior art compounds because they had

***three*** tertiary carbons, while new claim 32 was limited to ***only one***:

> New claim 32 recites that the branched alkyl group has only one carbon atom which is bound to ***three*** other carbon atoms. The compounds on page 58 of WO '493 each have three carbon atoms which are bound to three other carbon atoms.

(Appx4942 (emphasis added).) Alnylam's invocation of the same language used in the express definition of "branched alkyl" ("bound to three other carbon atoms") shows that it understood its invention required tertiary carbons and knew exactly how to specify the number of tertiary carbons in a "branched alkyl" when it wanted. Alnylam chose not to do that for the asserted claims.

#### 4. Alnylam's Case Law Supports the District Court's Finding of Lexicography

Far from undermining lexicography, the cases cited by Alnylam in fact support the district court's finding. Indeed, most of Alnylam's cases found no lexicography because the alleged definitions in those cases were ambiguous, but here the definition of "branched alkyl" is unambiguous, making those cases inapplicable.

For instance, in *Andrx*, the Court declined to find lexicography where the patent provided unambiguous definitions for several other terms—in quotation marks and using the definitional linking term "means"—but the purported definition did not use those definitional indicators. 473 F.3d at 1210. The Court also found the purported definition internally inconsistent ("it appears that if the 'pharmaceutically acceptable polymer' is defined to be 'a water-soluble hydrophilic polymer,' that

definition would not cover some of the very polymers listed because they are not water-soluble") and undermined by claim differentiation ("the language of the claims and claim differentiation imply that the 'pharmaceutically acceptable polymer' term in claim 1 is likely broader than the 'hydrophilic water-soluble polymer' described in claim 2 and encompasses more compounds than those listed in claim 3."). *Id*. at 1209-10. No similar concerns exist here. (*See*, pp.34-38 (Section II.A.1.), *supra*.)

Alnylam's reliance on *Merck* fares worse still. 395 F.3d at 1370. There, the Court found that the patentee had not defined the phrase "about" to mean "exactly" where the purported definition was for a much longer phrase, of which "about" was not the clear focus. *Id.* Instead, the passage the patentee relied upon was "amenable to a second (and more reasonable) interpretation" that focused on another part of the phrase. *Id.* at 1371 ("The phrase's ambiguity arises from the fact that it can easily be read as Teva does—as a way of explaining what is meant by the use of the phrase 'alendronate acid active basis' rather than as a way of radically redefining what is meant by 'about.'"). Again, there is no such ambiguity here; the focus of the express definition is the term at issue, and Alnylam does not contend otherwise.

Alnylam's other cases are more of the same. (Alnylam.Br.64-66.) In *Baxalta*, this Court held that a passage in the Summary of the Invention—not a definitional section—was "a generalized introduction to antibodies" rather than "a definitional

statement." 972 F.3d at 1347. In *Ecolab, Inc. v. FMC Corp.*, this Court found the patentee "clearly chose to" act "as his own lexicographer," but refused to include a limitation not addressed by the patentee's definition. 569 F.3d 1335, 1344-45 (Fed. Cir. 2009), *amended on reh'g in part*, 366 F. App'x 154 (Fed. Cir. 2009). In *Abbott Laboratories v. Syntron Bioresearch, Inc.*, the patent did not define the disputed term with reasonable clarity, deliberateness, and precision because it included "two alternative definitions for the term at issue." 334 F.3d 1343, 1354 (Fed. Cir. 2003). And, in *Apple Inc. v. Corephotonics*, *Ltd.*, the purported definition was not for the exact term at issue and was ambiguous as to the question raised by the parties' claim construction dispute. 81 F.4th 1353, 1358 (Fed. Cir. 2023).

The definition here could not be more different. There is no ambiguity—the requirement that a carbon be bound to at least three others is stated with clarity. The patents include an express definition of the very term at issue; it appears in the "Definitions" section; it is in quotation marks; it uses the same definitional linking term, "refers to," used for all but one of the patents' other definitions; and it makes clear that the inventors intended the definition to apply unless otherwise specified. This case, therefore, bears no resemblance to Alnylam's cases.

### B. The District Court Correctly Found That the Patent Does Not "Otherwise Specify" that the Definition of "Branched Alkyl" Does Not Apply

After finding "clear and unequivocal" lexicography, the district court explained, "[b]y definition, specification is specific. (Appx5559(146:1-3).) Departure from the lexicography would thus "have to be done specifically; i.e. … in every instance in which you want to depart from the lexicography." (Appx5559(146:2-5).) The district court further ruled that Alnylam did not "point to anything specific or express" in the claims (or elsewhere) that would support "a departure from the lexicography." (Appx5559.) The district court got it right.

"Specify" is a demanding word. *See Specify*, American Heritage Dictionary. (*See also*, pp.38-41 (Section II.A.2.), *supra*.) It is not enough that one could speculate or surmise intent to depart from the express definition. Instead, Alnylam needed to indicate a contrary meaning "explicitly," "unambiguously" or "in detail." Nothing in the patents comes close. As the district court observed, all Alnylam offers is a "kind of … follow-the-dots logic" but nothing "specific or express." (Appx5559(146:10-12).)

And Alnylam knew how to "otherwise specify" when wanted. In fact, it did just that in claim 14. There, Alnylam used the exact three-carbon language from the express definition ("the branched alkyl group has only one carbon atom which is bound to three other carbon atoms") to specify the number of tertiary carbons in a

branched alkyl. (Appx320(537:56-58).) If it had intended to specify that the express definition did ***not*** apply to the disputed claims, Alnylam could have similarly stated that the claimed "branched alkyl" "includes a carbon atom bound to two other carbon atoms" at the α-position. Alnylam chose not to. *Cf. Takeda,* 743 F.3d at 1363-64 ("Indeed, the remainder of claim 1 demonstrates that the inventors knew how to express ambiguity in claim language when they so desired … in the absence of their decision to do so, however, we will not take it upon ourselves to rewrite the claim in that way").

Alnylam could also have claimed the desired $R^{13}$ group as a chemical structure, as is common in pharmaceutical patents, removing any doubt as to what was intended. In fact, Alnylam did just that in the first three patents issued in the patent family. (U.S. Patent No. 9,061,063 (col.537-576); U.S. Patent No. 10,369,226 (col.501-509); U.S. Patent No. 11,071,784 (col.513).) Alnylam chose not to do so here.[15] That should end the matter.

## III. ALNYLAM'S ARGUMENTS AGAINST LEXICOGRAPHY ARE MERITLESS

The case for lexicography is straightforward: The patents say what they say,

[15] Alnylam chose not to recite a chemical structure for the asserted claims because none of the chemical structures in the specification, including Formulas I or II, encompass SM-102. (*Compare* Appx52-66(2:7-29:61) *with* Appx5057 (Moderna Lipid H, SM-102).) And drawing a different chemical genus that did encompass SM-102 would have drawn more attention to the already fatal written description and enablement problems with its claims.

and nothing undermines the definition's clarity, deliberateness, and precision. Alnylam's argument rests largely on an effort to ignore the patents' express definition of "branched alkyl." Alnylam marches through the claims, specification, and prosecution history, arguing that that there is no "definitional intent" because the patents supposedly contradict the express definition. (Alnylam.Br.60.)

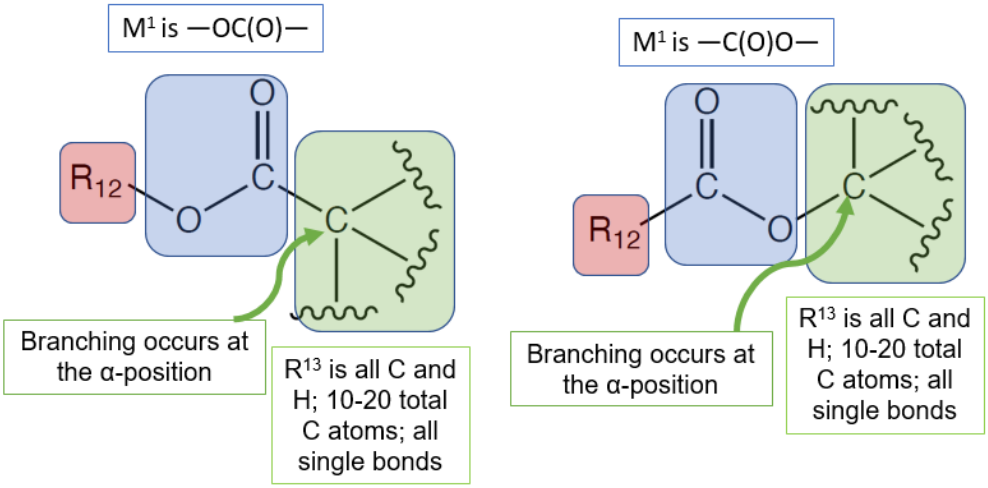
Alnylam does not come close to making that showing. Alnylam's arguments disregard the claim language and science alike, ignoring the fact that the α-carbon atom can bond to the oxygen atom in a —C(O)O— ester ***and*** three other carbons, thereby meeting the definition of "branched alkyl." Alnylam's effort to manufacture embodiments "excluded" by the express definition is based on a misunderstanding of the law. And its cherry-picked examples supposedly contradicting the express definition are actually ***consistent*** with it. Finally, Alnylam grasps at portions of the prosecution history that do not mention the disputed term and cannot prevail over the clear and unambiguous definition. Alnylam's attempt to write the definition out of the patent should be rejected.

### A. The Claims Do Not Undermine Lexicography

Alnylam does not identify anything in the claims that expressly contradict the express definition of "branched alkyl." Instead, Alnylam argues that the claims ***implicitly require*** a secondary carbon at the α-position when the ester group is in the

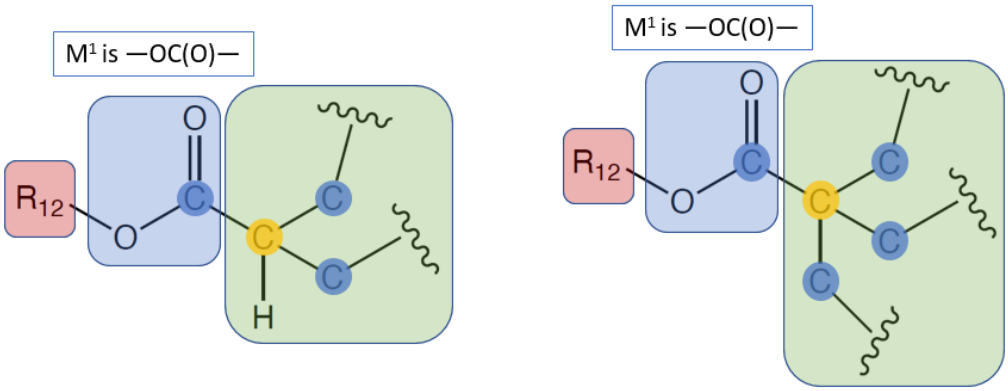
—C(O)O— orientation. (*See, e.g.*, Alnylam.Br.14, 34-35.) The actual language of the claims, and the underlying science, show otherwise.

As described above, the claim language requires (1) the $M^1$ group to be an ester, in either the —OC(O)— or —C(O)O— orientation, (2) the $R^{13}$ group to consist entirely of single-bonded carbon and hydrogen atoms with 10-20 total carbon atoms, and (3) branching at the α-position. (*See*, pp.14-21 (Section I.C.2.), *supra*.) Those requirements are depicted below for both —OC(O)— and —C(O)O— orientations:



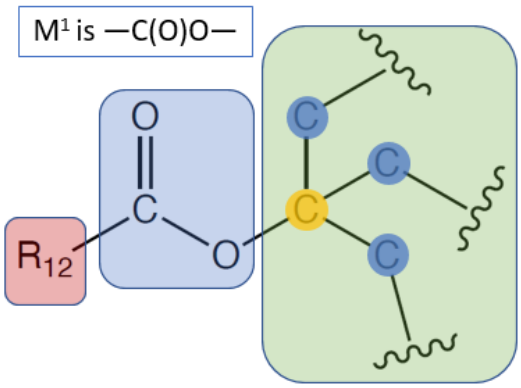

The claim language allows the remaining three atoms attached to the α-carbon atom to be either a hydrogen atom ***or*** a carbon atom.

For the —OC(O)— orientation, the α-carbon is already attached to one carbon atom in the ester group. If two of the three additional atoms attached to the α-carbon are carbon atoms, then the α-carbon is tertiary, as shown on the left below. If all three of the additional atoms are carbon atoms, then the α-carbon is quaternary, as shown on the right below.




(Appx4479; Appx320(538:13-33).)

For the —C(O)O— orientation, the α-carbon is attached to an oxygen atom in the ester group. If all three of the additional atoms attached to the α-carbon are carbon atoms, then the α-carbon is ***tertiary***, as shown below:

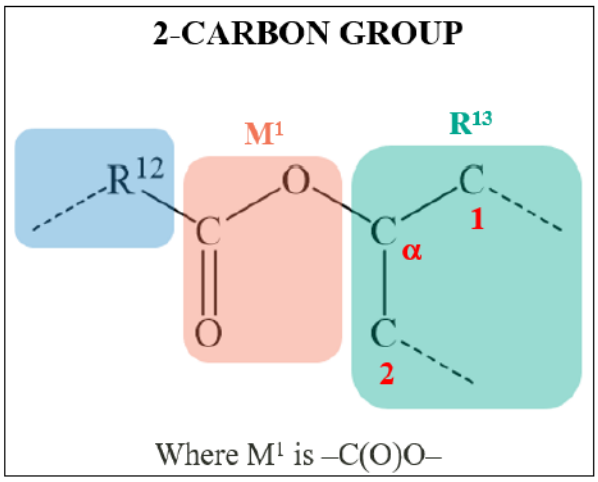



(*Id.*)[16] The claim language thus allows for a carbon atom at the α-position "bound to at least three other carbon atoms" with either ester orientation.

Nonetheless, Alnylam asserts that the claims "expressly contemplate" a "2-

[16] Alnylam complains that there are no similar exemplary structures in the patent. (Alnylam.Br.44 n.14.) That is beside the point. The claim language plainly allows for this structure, something Alnylam seems to begrudgingly concede in a footnote. (*Id.* at 13 n.7.)

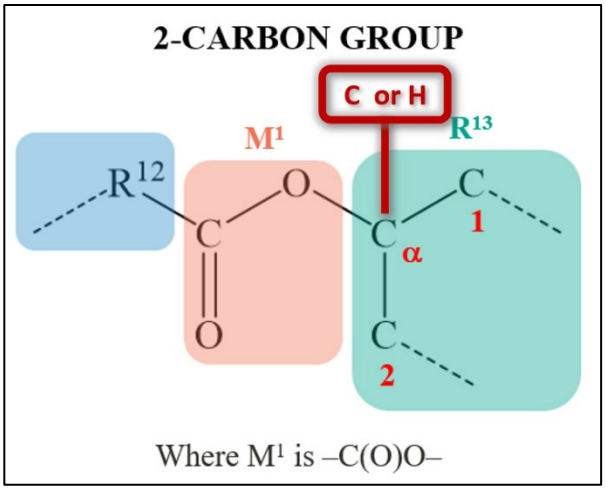
carbon group" because they claim "—C(O)O— as the $M^1$ group." (Alnylam.Br.43.) To get to that conclusion, Alnylam suggests that the image below "depict[s]" the claim language for the —C(O)O— orientation:




(Alnylam.Br.14.)[17]

Alnylam is wrong on the facts and the science. The patents do not include this image, much less refer to the structure as a "branched alkyl." And worse yet, Alnylam ignores the α-carbon's necessary fourth bond, shown below:

[17] Alnylam describes the claim scope by extrapolating a "2-Carbon Group" from an image of a single compound from the specification, "Compound 1." (*See, e.g.,* Alnylam.Br.12, 13, 14, 16, 20, 21.) That compound is never once identified in the patents as depicting a "branched alkyl," and regardless, it does not fall within the scope of the claims in any event. (*See*, pp.55-58 (Section III.B.1.), *infra.*)




If the fourth atom is a carbon atom, then the α-carbon is a tertiary carbon atom (i.e., bound to three other carbon atoms). Thus, with ***either*** ester orientation, the claim language permits a tertiary α-carbon, consistent with the express definition. Put another way, the claim language does not require, much less "expressly contemplate," (Alnylam.Br.44-45), a secondary carbon atom at the α-position because some claims require a —C(O)O— ester group.

Alnylam's real argument seems to be that the express definition can be ignored because, if ignored, the claim language ***would allow*** for a secondary carbon atom at the α-position. (Alnylam.Br.43-45.) Alnylam has it backwards. The result would be that Alnylam's express definition would only apply if the claim ***specified that it did***, rendering the definition effectively meaningless. For instance, following Alnylam's logic, a claim that recited no more than "a lipid compound with a branched alkyl" would "otherwise specify" because, ignoring the express definition,

it would otherwise ***allow*** for a secondary carbon.[18] Thus, claiming the —C(O)O— orientation of the $M^1$ group in no way shows implicit intent to deviate from the express definition.

### B. The Specification Does Not Undermine Lexicography

Alnylam argues that the district court erred in finding lexicography because the express definition of "branched alkyl" purportedly reads out disclosed embodiments. (Alnylam.Br.46-67.) Alnylam's arguments are again legally and factually wrong.

#### 1. The Claims Need Not Include Every Embodiment

Alnylam repeatedly argues that the district court's lexicography cannot be correct because it "excludes disclosed embodiments." (*See, e.g.*, Alnylam.Br.57.) But this Court has long rejected the proposition that "each and every claim ought to be interpreted to cover each and every embodiment." *PPC Broadband, Inc. v. Corning Optical Commc'ns RF, LLC*, 815 F.3d 747, 755 (Fed. Cir. 2016); *see also Baran*, 616 F.3d at 1316 ("It is not necessary that each claim read on every

[18] Alnylam also unsuccessfully tries to spin claim 14 to its advantage, arguing that claim differentiation shows that "that the independent claims allow an alpha-branched 2-carbon group . . . " (Alnylam.Br.45-46.) Alnylam's conclusion makes little sense. Claim 14 says nothing about a secondary carbon but expressly limits the claimed "branched alkyl" to "only one" tertiary carbon. (Appx319-320.) The logical conclusion is that the independent claim is broader because it allows for one ***or more*** tertiary carbons, not because it allows for other types of carbon atoms, like secondary carbons, not mentioned in either claim. (*See*, pp.42-43 (Section II.A.3.), *supra*.)

embodiment."); *TIP Sys., LLC v. Phillips & Brooks/Gladwin, Inc.*, 529 F.3d 1364, 1373 (Fed. Cir. 2008) ("Our precedent is replete with examples of subject matter that is included in the specification, but is not claimed."). Rather, "[t]he mere fact that there is an alternative embodiment disclosed in the asserted patent that is not encompassed by our claim construction does not outweigh the language of the claim, especially when the court's construction is supported by the intrinsic evidence." *August Tech. Corp. v. Camtek, Ltd.*, 655 F.3d 1278, 1285 (Fed. Cir. 2011) (cleaned up).

Based on that general proposition, this Court has frequently enforced a patentee's express definition even where the construction would exclude some disclosed embodiments. For example, in *Trustees of Columbia University v. Symantec Corp.*, this Court applied the patentee's "intended definition" despite an excluded embodiment because the patentee "cannot rely on its own use of inconsistent and confusing language in the specification to support a broad claim construction which is otherwise foreclosed." 811 F.3d 1359, 1366 (Fed. Cir. 2016); *see also Roche Diagnostics Operations, Inc. v. Lifescan Inc.*, 660 F. App'x 932, 937 (Fed. Cir. 2016) (finding examples in the specification that were inconsistent with definition in the specification were unclaimed embodiments). Here, Alnylam does not point to any excluded embodiments—all of the examples it points to are outside the claim scope regardless—and certainly nothing to suggest that the Court should

artificially stretch the claims beyond the express definition to include additional embodiments.

Alnylam also overstates any general reluctance to construe claims to exclude disclosed embodiments. (Alnylam.Br.34-35, 41-42, 52-53, 64-67.) That principle arises "where claims can reasonably [be] interpreted to include a specific embodiment" but gives way in the face of "***probative evidence [to] the contrary***." *Oatey Co. v. IPS Corp.*, 514 F.3d 1271, 1276 (Fed. Cir. 2008) (emphasis added); *Apple*, 81 F.4th at 1359 (same); *PSN Illinois, LLC v. Ivoclar Vivadent, Inc.*, 525 F.3d 1159, 1166 (Fed. Cir. 2008) ("*Oatey* is not a panacea, requiring all claims to cover all embodiments."). Alnylam does not actually point to anything inconsistent in the specification, but in any event, the express definition provides more than probative evidence to the contrary. (*See*, p.34-45 (Section II.A.), *supra*.)

The cases cited by Alnylam are in apposite because they do not involve patents with express definitions. (Alnylam.Br.41-42.) For instance, in *Oatey,* because there was no express definition, this Court construed the disputed claim terms to encompass two disclosed embodiments in the written description. 514 F.3d at 1277. Likewise, in *Sequoia Tech., LLC v. Dell, Inc.*, "the patentee did ***not*** expressly define" the disputed term. 66 F.4th 1317, 1324-25 (Fed. Cir. 2023) (emphasis added); *see also Knowles Elecs. LLC v. Iancu*, 886 F.3d 1369 (Fed. Cir. 2018) (similar).

Moreover, the specification here is replete with embodiments, reams of which are concededly outside the claims. This case is therefore unlike cases where a construction would have impermissibly excluded the specification's ***only*** preferred embodiment, *GE Lighting Sols., LLC v. AgiLight, Inc.*, 750 F.3d 1304 (Fed. Cir. 2014), or one of only a small number, *Oatey*, 514 F.3d at 1277.

### 2. The District Court's Construction Did Not "Read Out' Embodiments

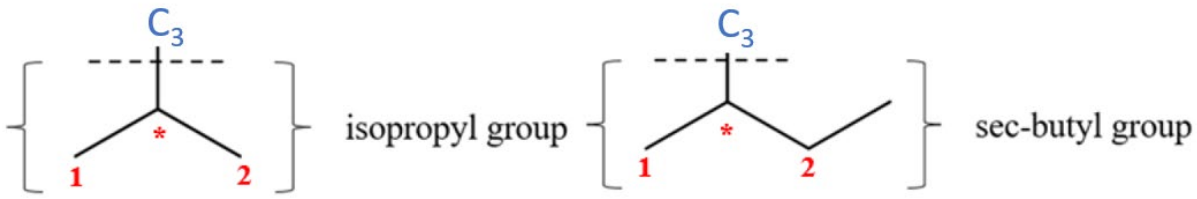
In an effort to read out the express definition, Alnylam argues that a handful of examples from the specification are inconsistent and that ***those*** purported embodiments would actually be read out by the district court's construction. Alnylam's cherry-picked examples, however, show nothing of the kind.

**"Representative" Branched Alkyls.** The "representative" "branched alkyl groups" included in the definition of "alkyl" are not inconsistent with the "branched alkyl" definition or read out by the district court's claim construction.

First, the "representative" branched alkyl examples already fall outside the claim scope because they do not have the required 10-20 carbon atoms ("$C_{10}$-$C_{20}$" alkyl). (Appx5011.) Thus, the district court's construction could not "read out" these examples. (Alnylam.Br.61-62.) They were never within claim scope to start.

Second, all of the examples can also include a tertiary carbon, just as the express definition requires. Three of the five "representative" branched alkyl groups inherently include a tertiary carbon (isopropyl, tert-butyl, isopentyl). (Appx5011.)

The other two examples (sec-butyl and isobutyl) include a tertiary carbon when bound to another carbon atom, such as if they are bound to the carbon in an ester, as shown below:




(Alnylam.Br.62 (annotated in blue).) Alnylam thus makes the same error with the example "branched alkyls" that does with the claim language, ignoring the carbon atoms' fourth bond. (*See*, pp.50-55 (Section III.A.), *supra*.)

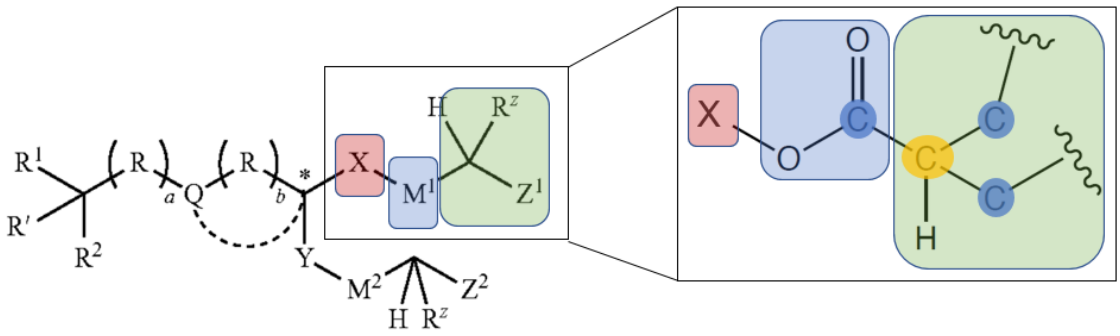
Third, Alnylam makes no attempt to square these examples with the express definition of "branched alkyl." To read these definitions as Alnylam insists, a skilled person would have to find a hidden meaning in the two of the five unclaimed representative branched alkyl examples in the "alkyl" definition but pass over the clear definition of "branched alkyl" that appears only four paragraphs later. That counterintuitive suggestion must be rejected. *See Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477-78 (Fed. Cir. 1998).

**Formulas I and II.** Contrary to Alnylam's position, (Alnylam.Br.17-19, 46-48), Formulas I and II are entirely consistent with the definition.

First, Alnylam concedes that these formulas each fall outside the scope of the claims. (Alnylam.Br.18, n.9.) Again, the district court's construction of "branched

alkyl" cannot "read out" embodiments that were never claimed.

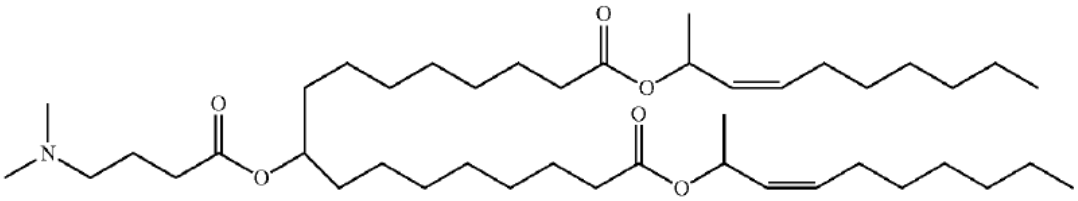
Second, Formulas I and II are consistent with the express definition. Many of the species failing with the formulas include a tertiary carbon in the portion of the tail that is branched, as required by the express definition. For instance, the patent provides that the $M^1$ group in Formula II can be "—OC(O)—." (Appx54(5:1-2).) When $M^1$ is —OC(O)—, every species of Formula II includes a tertiary carbon at the α-position, consistent with the express definition of "branched alkyl," as shown below:




(Appx53-54(4:1-5:50).) And several other $M^1$ groups listed for Formula (II) also result in a tertiary carbon. (Appx54(5:1-17 (identifying $M^1$ groups such as —SC(O)—, —OC(S)—, —N=C($R^5$)—, —O—N=C($R^5$)—, —N($R^5$)C(O) —).)

Compound 1. The patents disclose a structure identified as "Compound 1":

(Compound 1)



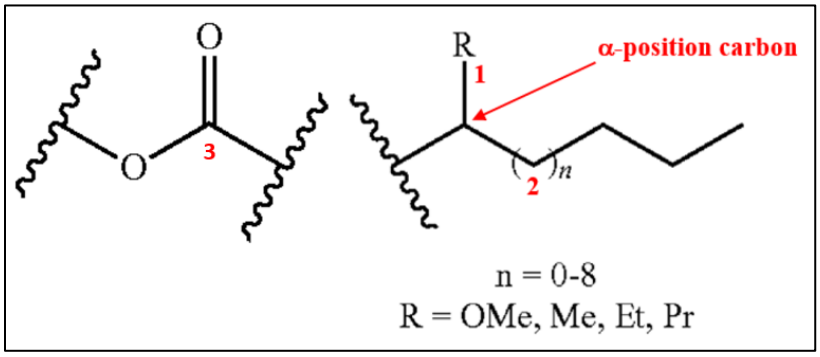
(Appx68-70(34:32-43, 36:4-33, 36:58-65, 37:2-19); Appx81(60:55-65).) Annotating that structure (Alnylam.Br.20-21, 48-49), Alnylam argues that it shows that the patentees "contemplated" a secondary α-carbon in a branched alkyl bonded to a —C(O)O— structure. (Alnylam.Br.48.) But the patent never identifies Compound 1 or the structure as a "branched alkyl." Moreover, once again, Compound 1 cannot be read out of the claims by the district court's construction because it already falls outside of them, as Alnylam concedes. (*See* Alnylam.Br.12, n.6; Appx257(411:53-54).)[19]

**Table 2D and 2E Groups**. The same problems plague Alnylam's reliance on a structure pieced together from Tables 2D and 2E. (Appx88-89(73:56-76:15); Alnylam.Br.49-50.) Like Alnylam's other examples, the patents nowhere indicate that the examples in Table 2E are "branched alkyls." They thus do not impact the express definition of that term.[20]

[19] Although not claimed in the patents-in-suit, Compound 1's prevalence in the specification is readily explained by the fact that Alnylam did claim Compound 1 (by chemical structure) in the first granted patent in the patent family. (U.S. Patent No. 9,061,063, col.549-550 (claim 19, fifth from the top).)

[20] Alnylam argues that the specification need not identify these figures as "branched alkyls" because they "use the language of chemistry." (Alnylam.Br.51, n.16.) Alnylam, however, provides no evidence (expert or otherwise) to show that a skilled artisan would understand any of these figures to include a "branched alkyl" based on their structures. Because the patent does not identify any "branched alkyls" deviating from the patents' express definition, there is no basis to depart from that definition.

To the extent those tables bear on lexicography at all, they ***support*** the express definition. Table 2E depicts fifteen "representative hydrophobic chain[s]," including twelve that arguably include branching. (Appx88-89(73:56-76:15).) Of those twelve, eleven – ***every single one,*** except the one cherry-picked by Alnylam (Alnylam.Br.22-23, 50-51) – include at least one tertiary carbon. (Appx88-89(73:56-76:15).) Indeed, Alnylam takes a cherry-picked example from Table 2E – the only one that does not have a tertiary carbon – and combines it with another cherry-picked example of a "representative biodegradable moiety" from Table 2D to create a combination nowhere called for in the patent. But Alnylam fails to acknowledge that the Table 2E example ***would*** include a tertiary carbon if Alnylam selected a different biodegradable group from Table 2D, such as —OC(O)—, as shown below:



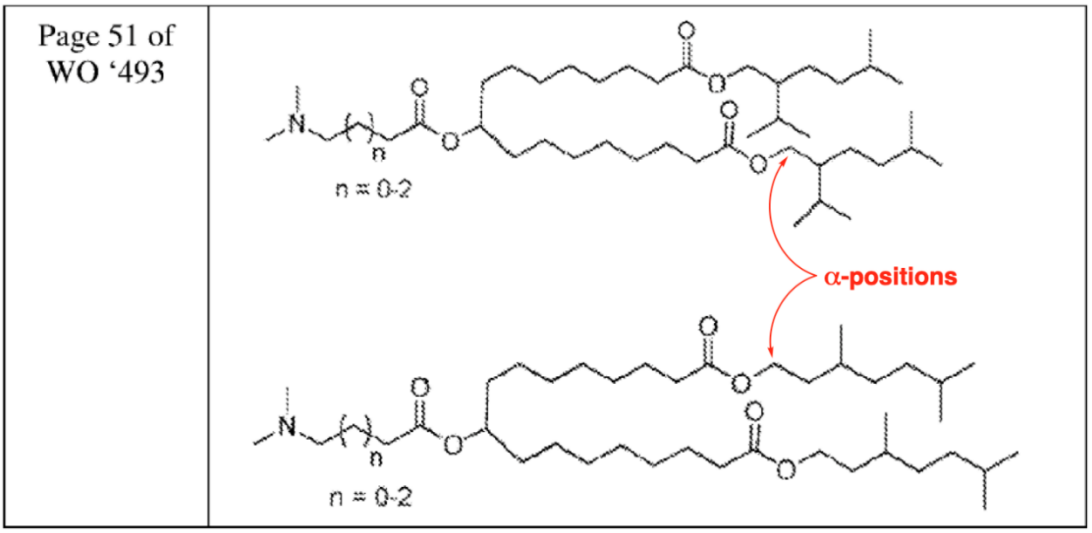

(Alnylam.Br.50-51; Appx87(72:10-15) (annotated).)

In sum, Alnylam's trawl through the specification in no way undermines the express definition. Other than Formulas I and II, the specification does not identify any of Alnylam's examples as "branched alkyls." Those formulas are consistent with the express definition because they include numerous tertiary carbon embodiments.

And the only actual exemplary "branched alkyl" structures in the entire specification, in Column 55, all include tertiary carbons, again consistent with the express definition. (*See*, pp.42-45 (Section II.A.3.), *supra*.)

### C. The Prosecution History Does Not Undermine Lexicography

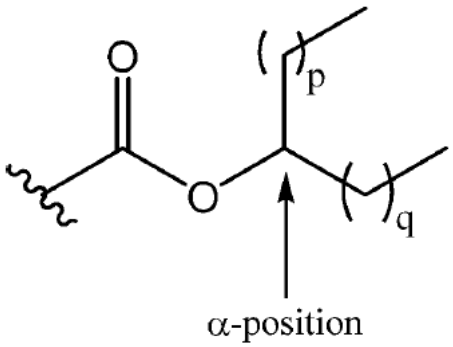
Alnylam's reliance on the prosecution history fares no better. (Alnylam.Br.53-56.) Alnylam focuses on the applicants' response to the compounds on page 51 of WO '493, shown below:




(*See* Appx4940-4941 (annotated).)

In response to an anticipation rejection, the applicants argued that those compounds "do not have branching in the terminal hydrophobic chain at the α-position relative to the biodegradable group as recited in the pending claims." (Appx4940-4941.) They went on to explain that "[s]uch compounds with branching

at the α-position would have a moiety as shown below (assuming the biodegradable group is an ester, and the variables p and q are integers)":




(Appx4941.) Alnylam insists that this exchange proves that the patentees intended for this structure—which does not appear anywhere in the specification—to fall within the claim scope. (Alnylam.Br.54-55 & n.17.) The exchange, in fact, shows no such thing.

The exchange, first, does ***not*** speak to the scope of the claimed compounds. Instead, it to the applicants' view of how ***the prior art*** would look like if it had "branching at the α-position." Even a cursory read makes clear that the phrase "such compounds" refers back to "[t]he compounds on page 51 of WO '493" clause in the previous sentence, not to the then-pending claims. (Appx4941 (emphasis added).)

The applicants also never used the term "branched alkyl" in the exchange. Instead, the applicants did no more than state that these prior art molecules did not have "branching at the α-position." (Appx4941.) If anything, the applicants' statements speak to the separate claim term "where the branching occurs at the

α-position relative to the [biodegradable/ester] group." The parties do not dispute the meaning of that term.[21] (Appx4.)

Finally, this exchange is too ambiguous to overcome the express definition of "branched alkyl." This Court "declines to unreasonably broaden a specific claim term based on questionable prosecution history when the specification requires a particular construction." *See Rolls-Royce PC v. United Techs. Corp.*, 603 F.3d 1325, 1335 (Fed. Cir. 2010); *Phillips*, 415 F.3d at 1317 ("[B]ecause 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.").

That is especially so here where, as explained above, the remainder of the prosecution history—the exchange about page 58 of WO '493—suggests that the patentees understood that a "branched alkyl group" would have at least one "carbon atom which is bound to three other carbon atoms." (Appx4940-4942; *see also,* pp. 42-45 (Section II.A.3.), *supra*.) Thus, to the extent it sheds any light on "branched alkyl," the prosecution history supports the express definition.

[21] Alnylam concedes that this exchange does not expressly discuss the Branched Alkyl Terms but nonetheless argues its relevant based on the applicants contemporaneously adding the "branched $C_{10}$-$C_{20}$ alkyl" limitation to the claims. (Alnylam.Br.55, n.18.) The effort required to try to tie this exchange to the dispute claim language itself shows that this portion of the prosecution history lacks the clarity to overcome the specification's unambiguous definition.

## IV. ALNYLAM'S PROPOSED CONSTRUCTIONS SHOULD BE REJECTED

Alnylam argued throughout this litigation that lexicography does not apply and that the Branched Alkyl Terms should carry their "full ordinary and customary meaning." (Alnylam.Br.3.) According to Alnylam, the ordinary meaning of "branched alkyl" is "a saturated hydrocarbon moiety that is not a straight chain." (*Id.*) Alnylam never offered any substantive support for its purported ordinary meaning construction. It offered no expert testimony in support of its proposed construction. It offered no explanation how one would distinguish a "branched alkyl" from a straight chain. Alnylam's construction thus does not help define the term or resolve the parties' dispute. *See Medicines Co. v. Mylan, Inc.*, 853 F.3d 1296, 1308 (Fed. Cir. 2017) (negative construction failed to define what the term was).

Alnylam argues, in the alternative, that if lexicography applies, the Court should "further enforce the entire definition and hold that the intrinsic record repeatedly 'otherwise specified' that in the context of α-branching the α-position carbon may bind to two or more carbons." (Alnylam.Br.70.) In support, Alnylam restates many of the same arguments made earlier in its brief (Alnylam.Br.67-70), and it is not entirely clear how Alnylam's alternative request differs from its main request. To the extent Alnylam merely argues that the patent "otherwise specifies," it is wrong for all the reasons previously discussed. (*See* pp.38-41, (Sections II.A.2.), 48-49 (Section II.B.), *supra*.)

However, if Alnylam is asking for a different construction if lexicography applies, Alnylam never made that request below and has thus forfeited the argument. "It is well established that arguments that are not appropriately developed in a party's briefing may be deemed waived." *United States v. Great Am. Ins. Co. of N.Y.*, 738 F.3d 1320, 1328 (Fed. Cir. 2013) (citing *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1319 (Fed. Cir. 2006)); *see also Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 582 F.3d 1288, 1296 (Fed. Cir. 2009) ("if a party fails to raise an argument before the trial court, or presents only a skeletal or undeveloped argument to the trial court, we may deem that argument waived on appeal, and we do so here."); *Finnigan Corp. v. Int'l Trade Comm'n*, 180 F. 3d 1354, 1363 (Fed. Cir. 1999) ("A party's argument should not be a moving target."); *see also In re Google Tech. Holdings LLC*, 980 F.3d 858, 862-63 (Fed. Cir. 2020) (explaining a position not timely presented to the tribunal below is forfeited).

Alnylam advanced only one construction below, its ordinary meaning construction (Appx4478-4483; Appx4492-4503; Appx5545-5555) and has waived any other construction. This Court has found waiver (or more accurately, forfeiture) under analogous circumstances. In *WSOU Investments LLC, v. Google LLC*, the appellant argued below that a claim was not written in a means-plus-function format but did not make the alternative argument below that the claim had sufficient structure if it was means-plus function. No. 2022-1063, 2023 WL 6889033, at *4

(Fed. Cir. Oct. 19, 2023). On appeal, this Court declined to consider the appellant's new argument that the specification disclosed corresponding structure for the means-plus-function claim. *See also NetMoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1368 (Fed. Cir. 2008) (declining to consider "a new and more expansive construction, which may not properly be asserted on appeal"); *Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*, 460 F.3d 1349, 1359 (Fed. Cir. 2006) ("The doctrine of waiver precludes a party from advocating a new theory of claim construction on appeal"). Thus, to the extent Alnylam is advancing any construction other than its ordinary meaning construction, the Court should find that construction forfeited.

Even if that argument were not waived, it is meritless. As explained above, the district court correctly ruled that Alnylam's use of the words "unless otherwise specified" in the express definition establishes a demanding standard. (*See* pp.38-41, (Sections II.A.2.), 48-49 (Section II.B.), *supra*.) And Alnylam comes nowhere close to meeting that standard. (*Id.*)

## CONCLUSION

For the foregoing reasons, the district court's construction should be affirmed.

Dated: March 12, 2024

Respectfully submitted,

By: /s/ W. Chad Shear

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## CERTIFICATE OF COMPLIANCE

The foregoing filing complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) and Fed. Cir. R. 32(b) and has been prepared using a proportionally-spaced typeface using Microsoft Office Word 365 in a 14 point Times New Roman font and includes 13,797 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and Fed. Cir. R. 32(b)(2).

Dated: March 12, 2024

*/s/ W. Chad Shear*
W. Chad Shear
COOLEY LLP

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

**CERTIFICATE OF SERVICE**

I, Jennifer Hendrick, being duly sworn according to law and being over the age of 18, upon my oath depose and say that: Counsel Press was retained by Cooley LLP, to print this document. I am an employee of Counsel Press.

On March 12, 2024, counsel authorized me to electronically file the foregoing CORRECTED RESPONSIVE BRIEF OF APPELLEES MODERNA, INC., MODERNATX, INC., AND MODERNA US, INC., with the Clerk of Court using the CM/ECF System, which will serve via e-mail notice of such filing to all counsel registered as CM/ECF users.

Upon acceptance by the Court of the e-filed document, six paper copies will be filed with the Court within the time provided in the Court's rules.

/s/ Jennifer Hendrick
Counsel Press