

No. 23-2357

In the
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.

On appeal from a final judgment of the
United States District Court for the District of Delaware
Case Nos. 1:22-cv-00335-CFC, 1:22-cv-00925-CFC

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TABLE OF CONTENTS

INTRODUCTION.....	1
ARGUMENT	3
I. The Patentee did not Clearly Express intent to Exclude alpha- branched Secondary carbons.....	3
A. Lexicography requires assessing all evidence to determine intent.....	3
B. The intrinsic record does not establish clearly expressed intent.....	6
1. The alleged lexicographic statement does not establish clear intent to exclude secondary carbons.	7
2. The claims' scope encompasses secondary-carbon α - branching relative to M ¹	14
3. The written description provides specific disclosures of secondary-carbon α -branching.	21
4. The prosecution history confirms that the claims' scope encompasses secondary carbons.....	33
5. The case law favors Alnylam's position.	36
II. In the alternative, Even if this Court finds Lexicography, the Intrinsic Evidence Requires Construing the Claims to include alpha-branched secondary carbon structures.....	39
CONCLUSION.....	42

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>3M Innovative Proprs. Co. v. Avery Dennison Corp.</i> , 350 F.3d 1365 (Fed. Cir. 2003)	13
<i>Abbott Labs. v. Andrx Pharms., Inc.</i> , 473 F.3d 1196 (Fed. Cir. 2007)	11
<i>Abbott Labs. v. Syntron Bioresearch, Inc.</i> , 334 F.3d 1343 (Fed. Cir. 2003)	11
<i>AK Steel Corp. v. Sollac & Ugine</i> , 344 F.3d 1234 (Fed. Cir. 2003)	20, 21
<i>Allergan, Inc. v. Apotex, Inc.</i> , 754 F.3d 952 (Fed. Cir. 2014)	6, 30
<i>Amgen, Inc. v. Hoechst Marion Roussel, Inc.</i> , 314 F.3d 1313 (Fed. Cir. 2003)	41
<i>Ariad Pharms., Inc. v. Eli Lilly & Co.</i> , 598 F.3d 1336 (Fed. Cir. 2010) (en banc)	8, 9, 25, 27
<i>AstraZeneca AB v. Mutual Pharm. Co.</i> , 384 F.3d 1333 (Fed. Cir. 2004)	5, 6, 13
<i>AstraZeneca UK Ltd. v. Watson Labs., Inc.</i> , 905 F. Supp. 2d 589 (D. Del. 2012).....	11
<i>August Tech. Corp. v. Camtek, Ltd.</i> , 655 F.3d 1278 (Fed. Cir. 2011)	37
<i>Baran v. Med. Device Techs., Inc.</i> , 616 F.3d 1309 (Fed. Cir. 2010)	37
<i>Baxalta Inc. v. Genentech, Inc.</i> , 972 F.3d 1341 (Fed. Cir. 2020)	1, 4, 5

Biogen MA Inc. v. EMD Serono, Inc.,
976 F.3d 1326 (Fed. Cir. 2020) 13

CVI/Beta Ventures, Inc. v. Tura LP,
112 F.3d 1146 (Fed. Cir. 1997) 35

Finnigan v. Int’l Trade Comm’n,
180 F.3d 1354 (Fed. Cir. 1999) 42

Fresenius USA, Inc. v. Baxter Int’l, Inc.,
582 F.3d 1288 (Fed. Cir. 2009) 42

GE Lighting Sols., LLC v. AgiLight, Inc.,
750 F.3d 1304 (Fed. Cir. 2014) 7

In re Google Tech. Holds. LLC,
980 F.3d 858 (Fed. Cir. 2020) 42

Helmsderfer v. Bobrick Washroom Equip., Inc.,
527 F.3d 1379 (Fed. Cir. 2008) 4

Hill-Rom Servs., Inc. v. Stryker Corp.,
755 F.3d 1367 (Fed. Cir. 2014) 4, 5

K-fee Sys. GmbH v. Nespresso USA, Inc.,
89 F.4th 915 (Fed. Cir. 2023)..... 5

Kyocera Senco Indus. Tools Inc. v. Int’l Trade Comm’n,
22 F.4th 1369 (Fed. Cir. 2022)..... 11, 13

Martek Biosciences Corp. v. Nutrinova, Inc.,
579 F.3d 1363 (Fed. Cir. 2009) 33

Medicines Co. v. Mylan, Inc.,
853 F.3d 1296 (Fed. Cir. 2017) 40, 41

Mentor Graphics Corp. v. EVE-USA, Inc.,
851 F.3d 1275 (Fed. Cir. 2017) 13

Merck & Co., Inc. v. Teva Pharms. USA, Inc.,
395 F.3d 1364 (Fed. Cir. 2005) 10

Myco Indus., Inc. v. BlephEx, LLC,
 955 F.3d 1 (Fed. Cir. 2020) 41

Oatey Co. v. IPS Corp.,
 514 F.3d 1271 (Fed. Cir. 2008) 16, 38, 39

Parkervision, Inc. v. Vidal,
 88 F.4th 969 (Fed. Cir. 2023)..... 11, 13

Philips v. AWH Corp.,
 415 F.3d 1303 (Fed. Cir. 2005) (en banc) 4

PPC Broadband, Inc. v. Corning Optical Commc’ns RF, LLC,
 815 F.3d 747 (Fed. Cir. 2016) 36

PSN Illinois, LLC v. Ivoclar Vivadent, Inc.,
 525 F.3d 1159 (Fed. Cir. 2008) 38

Roche Diagnostics Operations, Inc. v. Lifescan Inc.,
 660 Fed. App’x 932 (Fed. Cir. 2016) 37, 38

Rolls-Royce PC v. United Techs. Corp.
 603 F.3d 1325 (Fed. Cir. 2010) 35

Sinorgchem Co., Shandong v. Int’l Trade Comm’n,
 511 F.3d 1132 (Fed. Cir. 2007) 9, 10, 11, 13

Takeda Pharm. Co. v. Zydus Pharms. USA, Inc.,
 743 F.3d 1359 (Fed. Cir. 2014) 12

Thorner v. Sony Computer Ent’mt Am. LLC,
 669 F.3d 1362 (Fed. Cir. 2012) *passim*

TIP Sys., LLC v. Phillips & Brooks/Gladwin, Inc.,
 529 F.3d 1364 (Fed. Cir. 2008) 37

Trustees of Columbia Univ. in City of N.Y., v. Symantec Corp.,
 811 F.3d 1359 (Fed. Cir. 2016) 37

United States v. Great Am. Ins. Co. of N.Y.,
 738 F.3d 1320 (Fed. Cir. 2013) 41

United States v. Ladeau,
688 Fed. App'x 342 (6th Cir. 2017).....9

United States v. Lovaas,
241 F.3d 900 (7th Cir. 2001).....9

Vasudevan Software, Inc. v. MicroStrategy, Inc.,
782 F.3d 671 (Fed. Cir. 2015) 11

Yee v. City of Escondido, Cal.,
503 U.S. 519 (1992)..... 41

INTRODUCTION

This case is resolved by reference to a principle that is deeply rooted in this Court’s case law: The words of a claim are given their ordinary and customary meaning, unless the Court concludes—based on consideration of the entire intrinsic record—that “the patentee [has] clearly express[ed] an intent to redefine the term.” *Thorner v. Sony Computer Ent’mt Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012); see *Baxalta Inc. v. Genentech, Inc.*, 972 F.3d 1341, 1345, 1347 (Fed. Cir. 2020).

As explained in Alnylam’s Brief, the Branched Alkyl terms here should carry their ordinary meanings, which would include secondary carbons. This conclusion is bolstered by several aspects of the intrinsic record, including in the very language of the alleged lexicographic statement on which Moderna relies. That sentence plainly notes that its description does not apply in circumstances where the patent “specified otherwise.” Relevant here, the claims, through their reference to alpha branching at the carbon next to the biodegradable group (—C(O)O—), do specify otherwise.

The rest of the intrinsic record is in accord with an intent to encompass secondary carbons in the context of a branched alkyl at the alpha

(α)-position. The claims encompass such secondary carbons through their plain requirement that the “branched alkyl” occur at the alpha (α)-position relative to M^1 , *viz.* “a branched alkyl, *where the branching occurs at the α -position relative to the biodegradable group.*” Unlike other possible branching positions, which inherently *require* at least tertiary carbons, alpha-branching does not. More, the specification’s words and figures clearly specify a secondary carbon in the context of branching at the α -position. And during prosecution, the patentee plainly identified within the claims’ scope branched alkyls where the carbon at the α -position was a secondary carbon.

Despite this, Moderna—like the district court—errs by failing to give weight to this clear contrary intent to encompass secondary carbon branching in the claimed context of alpha branching. And in doing so, Moderna raises irrelevant sections of the specification that do not involve the claimed α -position branching.

Under this Court’s precedent, lexicography is found only if the complete document, upon weighing all available evidence, establishes clearly expressed intent. Where parts of the specification do not comport with a proposed definition, the intent to redefine terms cannot be clearly

expressed, and there is, accordingly, no lexicography. Properly weighed, it is apparent that the patentee intended to give the Branched Alkyl terms their full scope in the claimed context of branching at the α -position—and at the very least, it is certainly not clear that the patentee intended the opposite.

Finally, even if the Court finds that the patentee acted as its own lexicographer, the district court erred in failing to appreciate that the effects of the phrase “unless otherwise specified.” In multiple places, the intrinsic record “otherwise specifie[s]” that the branching carbon at the α -position relative to M¹ may be a secondary carbon.

For both of these reasons—there was no lexicography and, even if there was, the “unless otherwise specified” language governs—the Court should reverse.

ARGUMENT

I. THE PATENTEE DID NOT CLEARLY EXPRESS INTENT TO EXCLUDE ALPHA-BRANCHED SECONDARY CARBONS.

A. Lexicography requires assessing all evidence to determine intent.

In assessing whether a patentee engaged in lexicography, the Court canvasses the entire written description, and all other intrinsic evidence,

to determine whether the patentee has clearly expressed intent to redefine terms with something other than their ordinary and customary meaning. It is not enough, as Moderna attempts, to consider only a snippet of the specification that arguably supports a finding of lexicography, while disregarding all evidence cutting the other way. Once that scope is understood, Moderna's arguments largely fall by the wayside.

As explained in Alnylam's Brief, this Court's precedent is unambiguous—lexicography results only where a patentee has "clearly express[ed] an intent" in the written description to redefine a term. *Thorner*, 669 F.3d at 1365 (quoting *Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1381 (Fed. Cir. 2008)); see also *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1371 (Fed. Cir. 2014); Blue Br. ("BB") at 37-39 (collecting cases).

Critically, this inquiry necessarily requires not just "a plausible reading of [an] excerpt [in the patent] in isolation," but rather, is "considered in the context of the remainder of the written description and the claims." *Baxalta*, 972 F.3d at 1347. This straightforward principle accords with this Court's pronouncements that claims are always construed in view of the entire patent. See *Philips v. AWH Corp.*, 415 F.3d 1303,

1313 (Fed. Cir. 2005) (en banc) (POSITA is “deemed to read the claim term” in the “context of the entire patent, including the specification”).

Moderna’s arguments are largely contrary to this well-established law. Moderna first argues that a patentee’s “definition need only appear with reasonable clarity, deliberateness and precision to control.” Red Br. (“RB”) at 34. But that articulation disregards the second requirement, that intent is always part of the lexicography legal analysis. *See, e.g., Hill-Rom*, 755 F.3d at 1371 (“To act as its own lexicographer, a patentee must clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning *and* must clearly express an intent to redefine the term.”) (emphasis added); *K-fee Sys. GmbH v. Nespresso USA, Inc.*, 89 F.4th 915, 923 (Fed. Cir. 2023); *Baxalta*, 972 F.3d at 1349; BB.38.

Indeed, Moderna is forthright that it advocates ignoring the rest of the intrinsic record. *See, e.g.,* RB.33 (“Under this Court’s precedents, that should end the inquiry: the definition controls.”). But even cases Moderna cites do not stand for a truncated legal inquiry that divorces the alleged lexicographical statement from the rest of the specification. *See, e.g., Thorner*, 669 F.3d at 1368; *AstraZeneca AB v. Mutual Pharm. Co.*,

384 F.3d 1333, 1340-42 (Fed. Cir. 2004); *Allergan, Inc. v. Apotex, Inc.*, 754 F.3d 952, 958 (Fed. Cir. 2014).

Such an approach would be particularly erroneous here, given that the purportedly definitional text *itself* contains an “unless otherwise specified” clause, requiring an examination of the intrinsic record. *See infra* pages 7-14. And when the totality of intrinsic record is included in the analysis—rather than the myopic focus Moderna advocates—it is plain that patentee did not “clearly express[] an intent” (*Thorner*, 669 F.3d at 1365) to exclude formulations with secondary carbons at the α -position. *See* BB.40-67.¹ We take the elements of that analysis in turn.

B. The intrinsic record does not establish clearly expressed intent.

The largely undisputed intrinsic record—including the claims themselves, the rest of the specification, and the prosecution history—is contrary to finding a clearly expressed intent to limit the ordinary and customary scope of the claims that require “*a branched alkyl, where the branching occurs at the α -position relative to the biodegradable group.*”

¹ Moreover, even the purported definition itself does not clearly and precisely express the meaning Moderna would ascribe to it. *See* pages 39-40, *infra*.

Appx320 (538:27-29). Moderna’s myopic focus on one sentence and its plucked examples from the specification that—unlike the claims at issue—*do not* reflect a branched alkyl at the α -position should be rejected. Under lexicography’s “exacting” standards (*GE Lighting Sols., LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1309 (Fed. Cir. 2014), the scales must tip in favor of ordinary and customary meaning.

1. *The alleged lexicographic statement does not establish clear intent to exclude secondary carbons.*

While the entire intrinsic record needs to be examined, *supra*, even taking the alleged definition in isolation as Moderna suggests does not establish clear intent to redefine the Branched Alkyl terms, particularly where the very language being addressed is qualified by the phrase “unless otherwise specified.”

a. Moderna contends that the “unless otherwise specified” qualifier somehow “reinforces” and “cements” lexicography. RB.38.² To the contrary, the qualifier demonstrates exactly why the definition is *not* “clear and precise”—it instructs the reader to look elsewhere to understand the

² If that were true, the district court should have included the qualifier in its construction, and therefore erred on this point alone. *See also* Section II, *infra*.

scope of the term. BB.58-61. As discussed, this qualifier demonstrates a plain intent to leave open-ended the alleged definition where, as here, the claims and examples reflect a different intended scope in the context of branching at the α -position; in this context, unlike other branching positions, a tertiary carbon is not required. *See* pages 21-33, *infra*.

To defend a contrary result, Moderna suggests an overly rigid approach to establishing whether something is “otherwise specified”—but its argument assumes a controlling definition in the first place. *See* RB.39-40. Where a POSITA would understand that the specification “otherwise specifies” a secondary carbon structure, it need not be set out with the level of precision and clarity necessary to limit the claim through lexicography. Moderna’s approach errs by assuming lexicography before evaluating the complete specification. *See* pages 5-6, *supra*.

Under Moderna’s constrained approach, a patent drafter must label figures and chemical structures with details that would be readily apparent to a POSITA for fear of the figures/structures not being considered for their full disclosure. Such a result would serve no purpose other than to add bloat to patent specifications, and it is contrary to case law that treats such figures equally. *Ariad Pharms., Inc. v. Eli Lilly & Co.*,

598 F.3d 1336, 1350 (Fed. Cir. 2010) (en banc) (explaining disclosure “by structure, formula, chemical name, physical properties, or other properties” is adequate).

Moderna’s cases about statutory interpretation do not undermine this Court’s requirement of reading the rest of the specification through the eyes of a POSITA to determine clear intent. *See United States v. Lovaas*, 241 F.3d 900, 904 (7th Cir. 2001) (evaluating a section and a commentary to it in analyzing another section with “unless otherwise specified” language, even though that section does not expressly identify the other section or the commentary); *United States v. Ladeau*, 688 Fed. App’x 342, 350 (6th Cir. 2017) (same).

Moderna’s reliance on *Sinorgchem* to suggest intent from the qualifier here is misplaced. *See* RB.40-41. Unlike the court below, the *Sinorgchem* court adopted a definition with the qualifier “up to about 4% H₂O ... when aniline is utilized as a solvent.” *Sinorgchem Co., Shandong v. Int’l Trade Comm’n*, 511 F.3d 1132, 1137 (Fed. Cir. 2007). The Court explained that the specification repeatedly disclosed using up to about 4% H₂O when aniline is used as a solvent and “the definition refers specifically to reactions in which aniline is the solvent.” *Id.* at 1136-38. As for

the “varying” language referenced by Moderna, the Court noted that “[t]he quoted ‘will vary’ language appears to refer to the four other solvents for which a specific percentage was not provided.” *Id.* Nothing in the *Sinorgchem* definition contradicted the rest of the specification, unlike here.

Similarly, *Merck* supports Alnylam’s reading. RB.46; BB.66. There, the specification was amenable to a second interpretation of “about” (in this case, including a secondary carbon). *Merck & Co., Inc. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1371 (Fed. Cir. 2005). The Court concluded that “the patentee did not clearly redefine ‘about’ in the specification,” reversed the court’s construction and held that the term “should be given its ordinary and accepted meaning.” *Id.* at 1372.

b. Moderna further argues that being in the Definitions section “implies” lexicography. RB.34-35. But as we have already explained, that is not dispositive. BB.62-63. Moderna also quotes *Sinorgchem* and *Astra-Zeneca* to argue the use of quotation marks around a “term” is “often a strong indication” (RB.35), but those cases do not involve a term where a qualifier of “unless otherwise specified” was used *before* the quotation

marks. *See Sinorgchem*, 511 F.3d at 1136; *AstraZeneca UK Ltd. v. Watson Labs., Inc.*, 905 F. Supp. 2d 589, 593 (D. Del. 2012).

Moderna next latches onto the use of “refer to” in the definition. RB.36-37. “Refer to” also does not require lexicography. *See, e.g., Abbott Labs. v. Syntron Bioresearch, Inc.*, 334 F.3d 1343, 1355 (Fed. Cir. 2003) (declining to find lexicographic redefinition despite express definition “[a]s used herein, ‘analyte’ refers”); *Abbott Labs. v. Andrx Pharms., Inc.*, 473 F.3d 1196 (Fed. Cir. 2007) (“is” is not definitional).

Notably, this Court recognizes that the context in which “refers to” is used matters. *Parkervision, Inc. v. Vidal*, 88 F.4th 969, 976 (Fed. Cir. 2023) (“The critical paragraph clearly expresses an intent to define the term”); *Vasudevan Software, Inc. v. MicroStrategy, Inc.*, 782 F.3d 671, 680 (Fed. Cir. 2015) (“Taken in its entirety, the prosecution history is clear that the applicant was relying on the provided definition of ‘disparate databases’”); *Kyocera Senco Indus. Tools Inc. v. Int’l Trade Comm’n*,

22 F.4th 1369, 1378 (Fed. Cir. 2022) (“The surrounding written description language supports this interpretation”).³

Moderna does not even attempt to grapple with the context here. Moderna disregards that the patents in several other definitions use “refers to” without the phrase “unless otherwise specified.” BB.59. Such distinctions are strong evidence that the patentee lacked a clear intent to limit the term “branched alkyl” to exclude secondary carbons.

Moderna argues the definition is “clear and precise” because it “identifies the chemical structure (an ‘alkyl group’).” RB.37. But Moderna never reconciles the fact that the broad definition of “alkyl” in the written description—which is the basis for Alnylam’s construction—is also not prefaced with “unless otherwise specified.” Appx257 (411:53-61). That definition provides clear intent that “representative saturated *branched alkyl groups*” include isopropyl and sec-butyl compounds that have secondary carbon α -branching. *Id.*; see section I.B.3.a, *infra*. This highlights

³ *Sandoz and Takeda* are not on point. *Sandoz* does not address claim construction and the *Takeda* court declined to find lexicography because the claim language itself was clear. *Takeda Pharm. Co. v. Zydus Pharms. USA, Inc.*, 743 F.3d 1359, 1363-64 (Fed. Cir. 2014).

the error in finding a clear intent to limit “branched alkyl” when secondary carbons are encompassed.

The cases Moderna claims as analogies are not squarely on point and none resulted in a court ignoring a qualifier expressly included in a purported definition, as the court here did below. *See Thorner*, 669 F.3d at 1367 (finding no lexicography); *AstraZeneca*, 384 F.3d at 1339 (no qualifier in “solubilizer” “defined below”); *Sinorgchem*, 511 F.3d at 1136 (construing term to include a qualifier in the definition); *Parkervision*, 88 F.4th at 976 (no qualifier in the definition); *Kyocera*, 22 F.4th at 1378 (same); *Biogen MA Inc. v. EMD Serono, Inc.*, 976 F.3d 1326, 1335 (Fed. Cir. 2020) (same); *3M Innovative Props. Co. v. Avery Dennison Corp.*, 350 F.3d 1365, 1369 (Fed. Cir. 2003) (same); *Mentor Graphics Corp. v. EVE-USA, Inc.*, 851 F.3d 1275, 1294 (Fed. Cir. 2017) (including an example identified in the specification to find patent ineligibility).⁴

In sum, the alleged lexicographic language on its face and in the context of the specification’s definitions section demonstrates an intent

⁴ The same applies to Moderna’s district court cases, which also carry no precedential weight. *See* RB.35 n.11 (citing cases with no qualifier in definition or no lexicography).

to not adopt a limited definition that turns a blind eye to the claim language itself, the specification, and the prosecution history—all of which demonstrates a branched alkyl comprising a secondary carbon at the α -position.

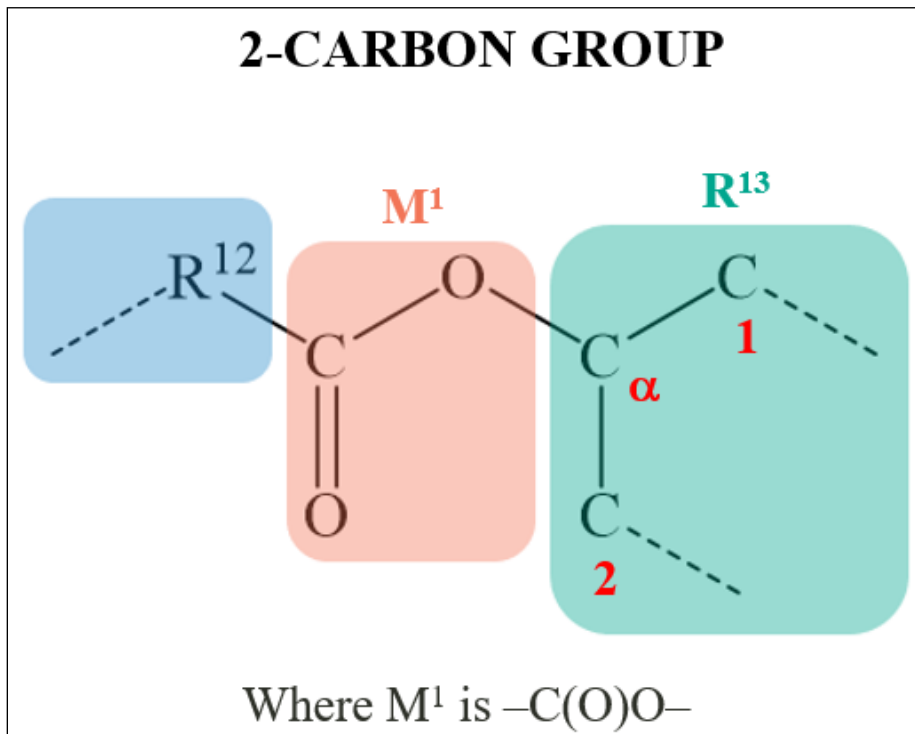
2. *The claims' scope encompasses secondary-carbon α -branching relative to M^1 .*

a) The claims' scope is undisputed.

1. As explained in Alnylam's Brief, in the independent claims, *e.g.*, when the formula of the biodegradable group M^1 is —C(O)O— , the carbon in R^{13} at the α -position may be bound to two other carbons, an oxygen in M^1 , and a hydrogen. BB.10-13, 42-44, 47; Appx320; *see also* Appx2635-2636 (claims 1, 18). The claims specify this scope through the express modification of "branched alkyl" by the requirements of alpha branching and the orientation of the biodegradable group (M^1) as " —C(O)O— ", *i.e.*, (i) a "branched alkyl, *where the branching occurs at the α -position relative to the biodegradable group*" (M^1) and (ii) "*wherein the biodegradable group*" is " —C(O)O— ." Appx320 (538:23-24, 27-29).

This precise claim language specifies a scope encompassing secondary or tertiary carbons and evinces an intent *not to redefine branched*

alkyl to exclude α -position secondary carbons binding to the biodegradable group's oxygen:



Highlighting this intended scope, dependent '933 Patent claim 20 and '979 Patent claim 5 are limited to where the biodegradable group (ester) is $-\text{C}(\text{O})\text{O}-$. BB.14-15, 44-45, 69; Appx320 (538:41-42); Appx2635 (494:52-53). Those dependent claims also permit a secondary carbon at the α -position specified by the claim. Moderna fails to address these dependent claims. *See* RB.14, 15, 44-45.

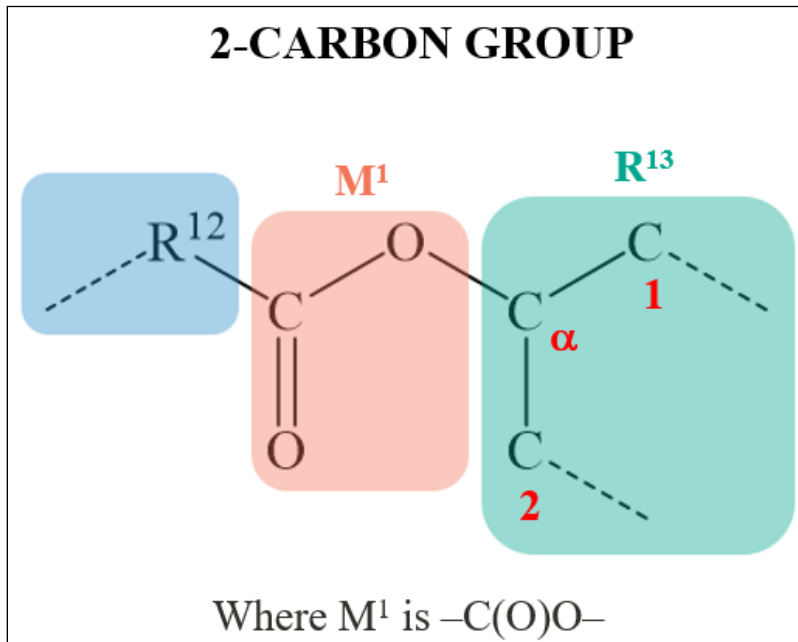
Moderna contends that “[n]othing in the claim language *requires* a secondary carbon at the α -position.” RB.20 (emphasis added); *see also id.* at 54. Of course, the claim is broad enough to *also* include structures

where there is not a secondary carbon at the α -position, *e.g.*, if it is —C(O)O— and a third carbon is substituted for the hydrogen. BB.13, 16. But that does not change the fact that the express claim language, including the alpha branching requirement and the specific identification of the “—C(O)O—” biodegradable group, plainly identify a claim scope that encompasses secondary binding at the α -position—contrary to any clear intent to redefine the term.

Indeed, where the biodegradable group is “—C(O)O—”, the embodiments are limited to either a secondary or tertiary carbon (*i.e.*, 50% of the embodiments are secondary carbons and 50% are tertiary carbons). The net effect of redefining the term to exclude secondary carbons would be to read out half of the embodiments where the biodegradable group is —C(O)O—. But it is black-letter law that “where claims can reasonably [be] interpreted to include a specific embodiment, it is incorrect to construe the claims to exclude that embodiment.” *Oatey Co. v. IPS Corp.*, 514 F.3d 1271, 1277 (Fed. Cir. 2008); *see* BB.64-67; *see also* pages 36-39, *infra*, addressing additional case law.

2. Moderna baselessly asserts, with a string of misguided arguments, that “Alnylam is wrong on the facts and the science.” RB.53. Not

so. As just explained, there is no dispute that secondary carbons are specified by the claim language. Alnylam illustrated this point using this image:



See, e.g., BB.43-44.

Moderna first contends that “[t]he patents do not include this image, much less refer to the structure as a ‘branched alkyl.’” RB.53. That is irrelevant—Moderna, too, advances multiple illustrative images found nowhere in the patents. *See, e.g.*, RB.15-20, 22, 51-52, 60. But unlike many of Moderna’s images, the structure Alnylam advances is disclosed in the specification and prosecution history, *infra*, and accurately depicts a formula $-\text{R}^{12}-\text{M}^1-\text{R}^{13}$, where M^1 is $-\text{C}(\text{O})\text{O}-$, that would fall within the claims. BB.13-14. Moderna does not—indeed, it cannot—disagree.

Moderna next contends that “Alnylam ignores the α -carbon’s necessary fourth bond.” RB.53. Again, that is incorrect. *See* BB.13 n.7. As we explained (BB.47), when the biodegradable group has the orientation —C(O)O—, the α -branched alkyl carbon may be bound to two other carbons, a hydrogen, and an oxygen in the biodegradable group. It is common practice to not draw a hydrogen atom, as Moderna’s brief admits. RB.13 n.5; Appx4949 (explaining in skeletal structures “hydrogen atoms are not shown”).⁵ Alnylam also acknowledged that the α -branched alkyl carbon may be (but is not required to be) bound to three other carbons when the biodegradable group has the orientation —C(O)O— where a third carbon could be present. BB.46.

Next, Moderna accuses Alnylam of arguing that “the claims implicitly require a secondary carbon at the α -position when the ester group is in the —C(O)O— orientation.” RB.50-51. Again, that is incorrect. Alnylam seeks to give the claims their full breadth as encompassing *both* secondary and tertiary carbons at the α -position. Just because the claim

⁵ Moderna’s brief similarly includes structures where the hydrogen is present but not shown, consistent with convention. *See, e.g.*, RB.13, 13 n.5, 14, 24.

language permits a tertiary carbon at the α -position does not mean that the same claim language is not also specifying a scope that encompasses a secondary carbon at the α -position. *See* BB.13-16.

Finally, Moderna incorrectly contends that Alnylam’s “logic” would require the claim to specify that the definition applies, and that a simple hypothetical claim of a “lipid compound with a branched alkyl” would “otherwise specify” a secondary carbon. RB. 54-55. But that hypothetical disregards the express claim language here that specifies (i) a “branched alkyl, *where the branching occurs at the α -position relative to the biodegradable group*” (M¹) and (ii) “*wherein the biodegradable group*” is “—C(O)O—.” This language specifies secondary or tertiary carbons—and evinces an intent not to redefine the term to exclude the secondary carbons.

- b) Moderna’s reliance on unasserted claim 14 is flawed.

Against this plain scope, Moderna relies primarily on a purported requirement of tertiary carbon binding based on *unasserted* dependent Claim 14 that depends from *unasserted* Claim 1 of the ’933 Patent. RB.42-43.

To start with, *there is no such dependent language from the asserted claims*, confirming again a plain intent *not to limit* those claims to a tertiary carbon. Moderna's argument fails out of the gate.

In any event, Moderna's argument on unasserted claims 1 and 14 is wrong. Moderna contends that "claim 1 must allow for more than one tertiary carbon atom." RB.42. Moderna confuses what the claims permit with what the claims require. Claim 1 does not limit the structure of the biodegradable groups as containing even a carbon, as dependent claim 6 makes clear with reference to biodegradable groups like "—S—". It also does not specify in any manner that a carbon in the branched alkyl group next to the biodegradable group must be a tertiary carbon. In sum, (i) Claim 1 plainly permits secondary carbons at the α -position where the biodegradable group could be, *e.g.*, —S— or —C(O)O— (see dependent claim 6), (ii) there is no express claim requirement that the alpha branched alkyl be a tertiary carbon, and thus (iii) Claim 14 can also be interpreted to mean that Claim 1 does not require at least a tertiary carbon atom at all.

Moderna's reliance on *AK Steel* (RB.42) is misplaced. *AK Steel* does not require that the same limitation in the independent claim be broader

or even present in the independent claim. *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1242 (Fed. Cir. 2003).

3. *The written description provides specific disclosures of secondary-carbon α -branching.*

The specification repeatedly shows branching at the α -position, as claimed, that specifies when the biodegradable group is —C(O)O—, resulting in one of those bonds being to an oxygen, the alpha carbon next to that biodegradable group is a secondary carbon. BB.10-16. Moderna's specification examples are irrelevant because they rely on branching at a point *other than the α -position*, and instead are examples of tertiary branching. The juxtaposition between the alpha branched teachings Alnylam relies upon and the non-alpha branched teachings Moderna cites highlights exactly what the patentee intended in stating “unless otherwise specified.”

- a) Moderna's attempts to distinguish the specification's clear examples of branched alkyls with a secondary carbon at the α -position are unconvincing.

As explained in Alnylam's Brief, the written description includes:

(1) exemplary Formulas I, II, and VII (and their related descriptions), which encompass alkyls with α -branched secondary carbons (BB.17-19);

(2) Compound 1, which contains α -branched secondary carbons (BB.20-

21); (3) representative hydrophobic chains of the “present invention” that contain alkyls with α -branched secondary carbons (BB.21-25); and (4) that “representative saturated branched alkyl groups include” isopropyl and sec-butyl, each of which may include secondary carbons. BB.25-26; *see generally* BB.46-53. All these features countermand any suggestion that the patentee clearly expressed intent to limit the Branched Alkyl terms in the context of α -branching.

Formulas I and II. Moderna concedes that Formula I and II depict a “branched alkyl at the alpha position,” but then fails to faithfully read the text and drawing that specify a secondary carbon at the α -position. RB.22, 58-63. The text expressly calls out “a branched alkyl at the alpha position adjacent to the biodegradable group” (Appx52-53 (2:7-9, 3:64-65)) and the text lists as a biodegradable group ((M¹) and (M²)) to include “—C(O)O—.” Appx53 (3:3-4).

Formulas I and II each specifically identify a hydrogen atom (H) binding to the “branched alkyl at the alpha position,” *viz.*:

—C(O)O—, precisely what Alnylam contends is within the scope of the claims.⁶

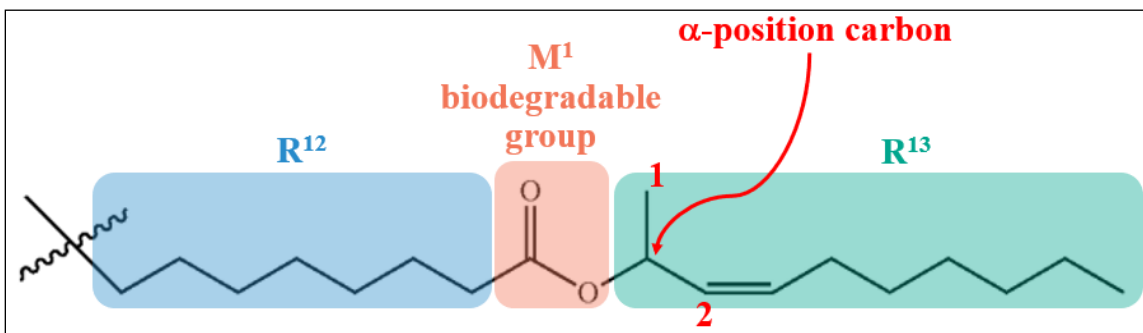
Moderna says Formulas I and II “include myriad potential species, many of which *include* a tertiary carbon at the α -position” (RB.22 (emphasis added)), but never disputes that these formulas depict a secondary carbon at the α -position. Tellingly, Moderna does not contend that Formulas I and II always “require a tertiary carbon atom” as it does with Formulas III, IIIA, and IV—which are not relevant in the first place, because they do not even depict a branched alkyl at the α -position adjacent to the biodegradable group, as discussed below. *See* Section I.B.3.b, *infra*.

Compound 1. With respect to Compound 1 and the representative hydrophobic chains of the present invention, Moderna again does not dispute that these structures depict examples of a secondary carbon at the α -position. RB.60-63.

⁶ For Formula VII, Moderna argues it does not have branching in the tails. RB.23. But Moderna does not dispute that it similarly is informative of the scope of α -branched secondary carbons.

“Present Invention” and Table 1C and 2D & 2E Groups.

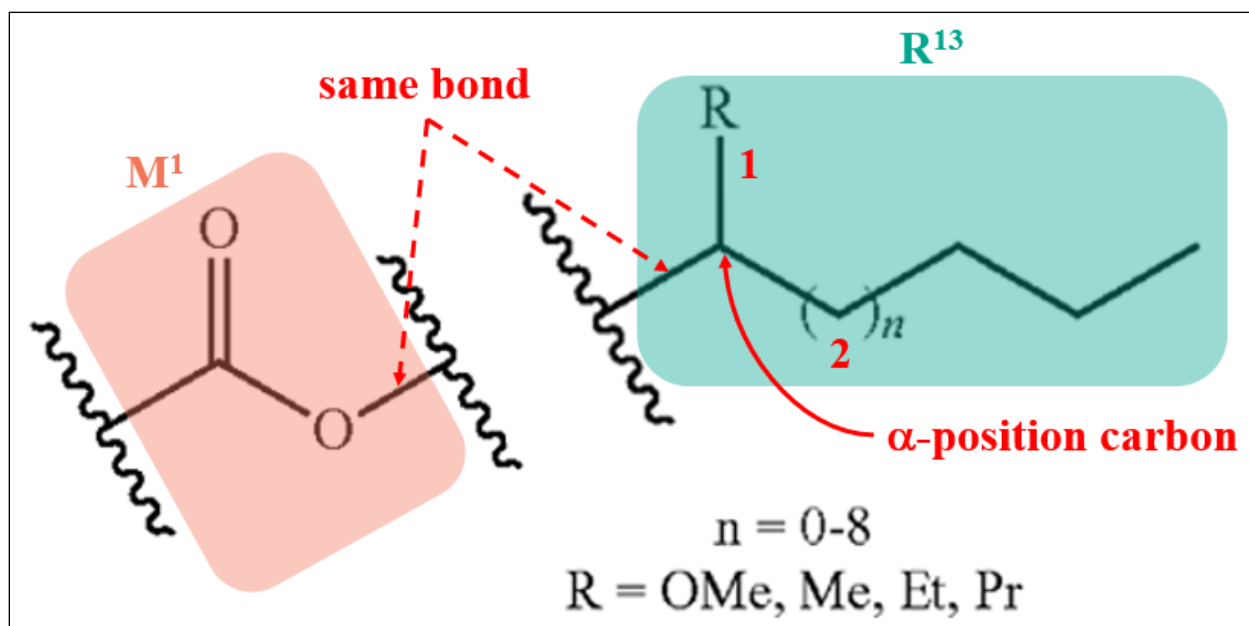
Moderna disregards the drawing of the “present invention” in Table 1C, which, again, shows an α -branched secondary carbon:



BB.24-25.

Moderna’s attempts to discredit Tables 2D & 2E lack merit. RB.62.

Moderna does not dispute that the “present invention” specifies a “combination” of a biodegradable group in Table 2D and the α -branched hydrophobic moiety attached thereto (Table 2E):



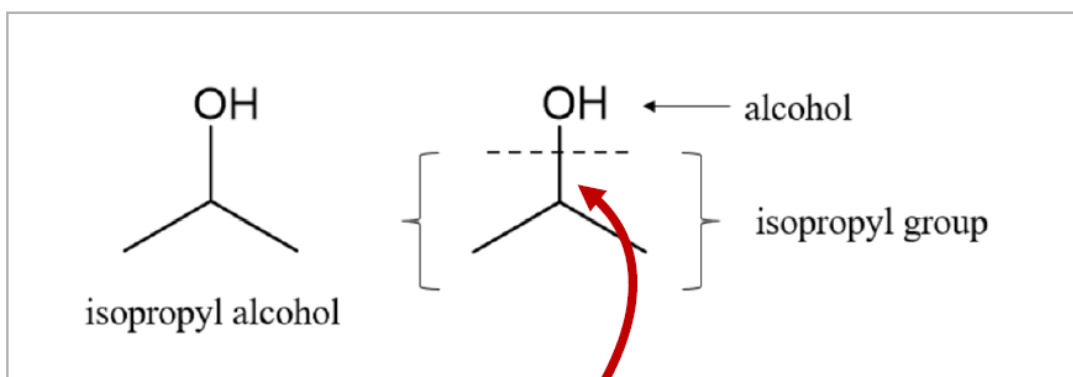
Appx87-88 (72:1-10, 74:52-57); BB.22-25, 50-51.

Moderna points out that Table 2E contains eleven representative branched hydrophobic chains that include “at least one tertiary carbon.” RB.62. That is misleading, and its accusation of Alnylam “cherry-picking” is baseless. *Id.* Unlike the figure above, the other eleven figures Moderna relies upon *do not show alpha branching* as the claims require. They show branching at positions further from the biodegradable group, *e.g.*, “at a position that is 2-6 carbons (*i.e.*, at the beta (β), gamma (γ), delta (δ), epsilon (ϵ) or zeta position (ζ))” from it. *See* Appx54 (5:53-55). That Moderna can find support for tertiary carbons elsewhere in Table 2E for *non-alpha branched alkyls* is irrelevant, as the written description otherwise specifies that a “combination” of any of the groups is the “present invention,” specifying a secondary carbon at the α -position. Appx82 (61:23-26).

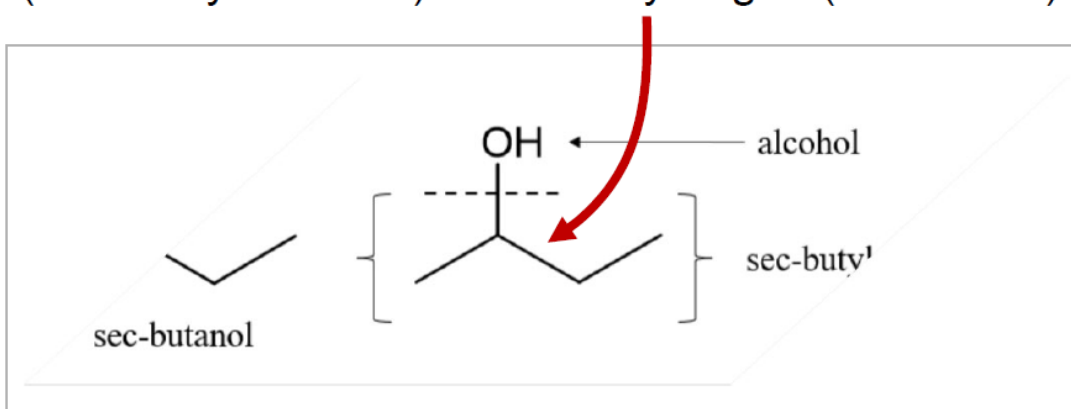
Moderna, however, would have the Court disregard this structure because it is not explicitly labeled “branched alkyl.” RB.62; BB.22-24, 50-51. But that is not how patents are interpreted. *Ariad Pharms.*, 598 F.3d at 1350. Whether labeled “branched alkyl” or not, it undisputedly depicts a secondary carbon at the α -position.

Representative Branched Alkyls from “Alkyl” Definition.

Moderna does not dispute that isopropyl and sec-butyl are “branched alkyl groups” in the specification’s definition of “alkyl.” RB.58-59, BB.52, Appx257 (411:60-61). Moderna does not dispute that isopropyl and sec-butyl can contain only secondary carbons. RB.59. Rather, Moderna incorrectly contends that Alnylam is ignoring the fourth carbon bond. *Id.* But that bond does not have to be a carbon. For example, it could be an oxygen, as depicted below.



Branch point is connected to two carbons (shown by the lines) and one hydrogen (not shown)



Appx5663. The description does not limit the groups. *See* Appx257 (411:53-61); Appx4953; Appx5011.

Moderna contends that “[t]hree of the five ‘representative’ branched alkyl groups *inherently* include a tertiary carbon.” RB.58 (emphasis added). But as to “[t]he other two examples”—*i.e.*, “isopropyl” and “sec-butyl”—Moderna does not (because it cannot) contend that these compounds inherently require a tertiary carbon.⁸ Moderna argues that they “include a tertiary carbon *when* bound to another carbon atom.” RB.59 (emphasis added). But there is no requirement that they be bound to another carbon atom.

Moderna is again wrong to argue that these representative branched alkyl examples fall outside the claims to suggest they are somehow not relevant. RB.58; *see also id.* at 53 n.17. The examples of α -branching in the written description inform the patentees’ intent and understanding of the Branched Alkyl terms in the context of claims expressly require α -branching. Moderna identifies no case law contrary to that proposition.

⁸ Moderna’s brief appears to have a typo in its identification of “isopropyl” and “isobutyl.” *See* RB.58-59.

Moderna contends that “Alnylam makes no attempt to square these examples with the express definition of ‘branched alkyl.’” RB.59. But that puts the cart before the horse: Our entire point is that what Moderna states is the “express definition” is not lexicography at all. The separate definition of “alkyl” shows no intent to limit branched alkyl as it uses the term and supplies two examples of secondary carbon branched alkyls. *See* Appx257 (411:53-54).

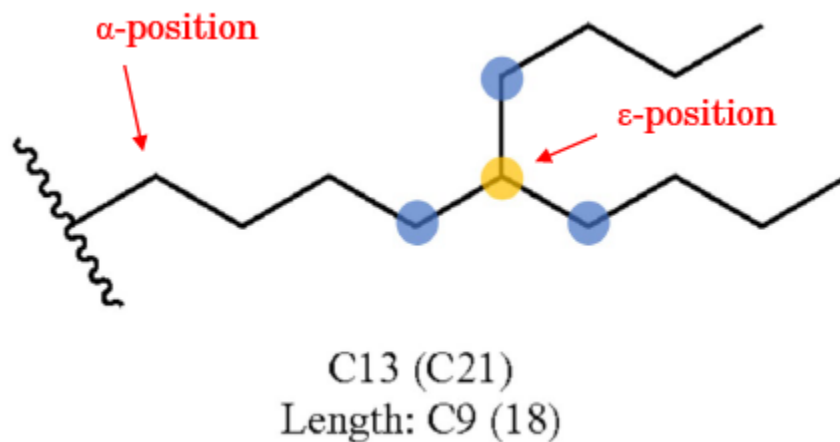
* * *

All of these examples from the written description specify and/or illustrate branching at a secondary α -carbon. This weighs strongly against the notion that the patentee redefined “branched alkyl” to exclude exactly those structures. *Cf. Allergan*, 754 F.3d at 958 (“even if there may be some ambiguity in how the patentee defined the term, numerous examples in the patent describe the use of claimed composition to” exclusively promote hair growth, which the challenger argued should fall outside the claim scope).

- b) Moderna errs by invoking irrelevant non-alpha branched alkyls to show tertiary carbons.

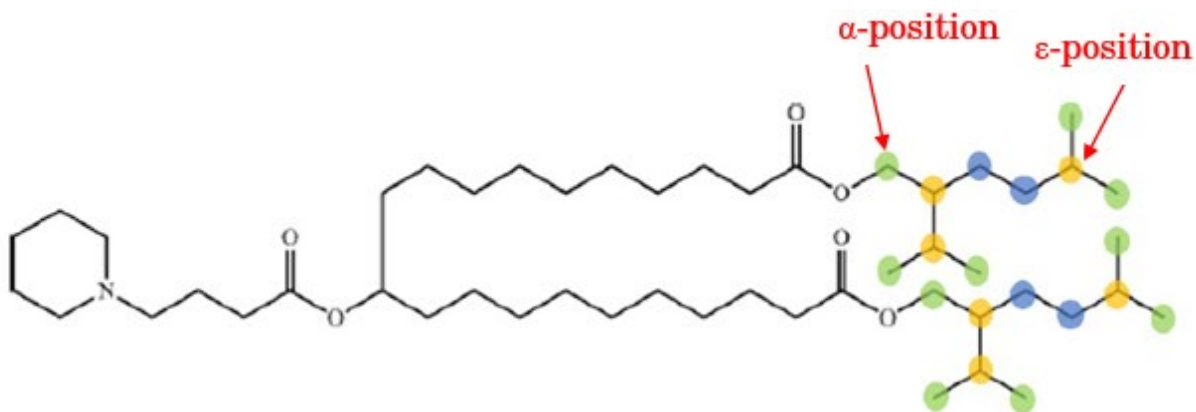
Faced with numerous drawings and formulas that plainly depict a secondary carbon at the α -position, *supra*, Moderna plucks out figures

Likewise, Moderna incorrectly raises portions of columns 55-60 that it contends shows 20 “branched alkyl” groups. RB.23-24, 43-44. Again, none of them shows an α -branched alkyl group. The very example diagram Moderna advances shows this material flaw:



RB.24 (annotated).

The same is true of the figures Moderna cites from column 75—they do not depict α -branched alkyls next to the biodegradable group:

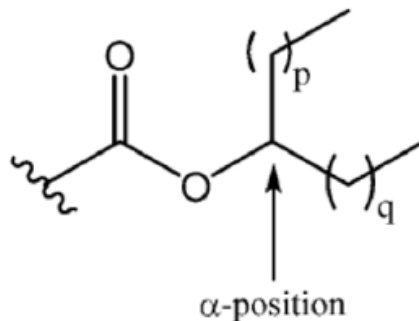


RB.24 (annotated). Moderna's non-alpha branched alkyl examples show tertiary carbons in non-alpha branched alkyls. Such irrelevant evidence fails to show a clear intent by patentee to be bound to such a limitation in the claimed context of alpha branching, which is critically different from branching at other positions because a tertiary carbon is not required. *See* page 21-30, *supra*.

4. *The prosecution history confirms that the claims' scope encompasses secondary carbons.*

The prosecution history can provide "a clear indication" that the patentee understood a term to encompass a particular feature. *See Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1377 (Fed. Cir. 2009). Here, the patentee informed the PTO examiner that α -secondary carbons are covered by the patent claims (pending at that time).
Appx4941:

The compounds on page 51 of WO '493 do not have branching in the terminal hydrophobic chain at the α -position relative to the biodegradable group as recited ***in the pending claims***. ***Such 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):



Moderna does not dispute that the above chemical structure depicts a branched alkyl with a secondary carbon at the α -position.

Moderna is wrong to contend that this prosecution history does not speak to the claim scope. RB.64. The applicants distinguished the prior art “compounds on page 51 of WO ‘493” as “not hav[ing] branching in the terminal hydrophobic chain at the α -position relative to the biodegradable group as recited ***in the pending claims***.” Appx4941 (emphases in original). The applicants then explain that “[*such compounds*]”—*i.e.*, the compounds “***in the pending claims***” “with ***branching at the α -position*** would have a moiety as shown below.” *Id.* The drawing that follows undisputedly depicts an α -branched alkyl of the claims. Moderna’s

argument that “such compounds” refers back to the prior art is belied by common sense and the use of a colon followed by a compound not found in the prior art. Moderna contends that the applicants “never used the term ‘branched alkyl’ in the exchange.” RB.64. But a drawing is no less informative than words. *CVI/Beta Ventures, Inc. v. Tura LP*, 112 F.3d 1146, 1146 (Fed. Cir. 1997).

Moderna argues that the prosecution history “is too ambiguous to overcome the express definition of ‘branched alkyl.’” RB.65. This argument fails because it is clear the patentee specified its claim scope as including secondary carbons at the α -position. And *Rolls-Royce PC v. United Techs. Corp.* is inapposite because Alnylam does not seek to unreasonably broaden a specific claim term; but rather, seeks to give it its full scope. 603 F.3d 1325 (Fed. Cir. 2010); RB.65. That full scope is consistent with—not contradicted by—the prosecution history here.

Finally, Moderna’s “remainder of prosecution history” argument is just a repackaging of its Claim 14 argument addressed above. RB.65; *supra* Section I.B.2.b. At best, the exchange about page 58 of WO ’493 suggests a dependent claim directed to one branched alkyl group that has a carbon bound to three others. But as explained above, this also

demonstrates that the independent claim, which lacks any such limitation, is broader. The independent claims were separately distinguished based on branching at the α -position and the total carbon atom count of the tail. *See* Appx4940-4942.⁹

5. *The case law favors Alnylam's position.*

Faced with all this evidence, Moderna seeks to justify the court's construction of "branched alkyl" by arguing that the claims need not include every embodiment. RB.55-58. But this general proposition does not support excluding half of the claims' embodiments where the "—C(O)O—" biodegradable group is specified.

Moderna's authority (RB.55-56) does not dispute the basic proposition that embodiments expressly recited in the claim should not be excluded. In fact, they support it. *See PPC Broadband, Inc. v. Corning Optical Commc'ns RF, LLC*, 815 F.3d 747, 752 (Fed. Cir. 2016) (rejecting Board's construction for failing "to account for how the claims themselves and the specification inform the ordinarily skilled artisan as to precisely

⁹ Moderna speculates on Alnylam's prosecution efforts (RB.49 n.15, 10 n.2) but identifies no evidence that suggests the PTO would not have granted claims to specific chemical structures. Subsequent patents have issued claiming chemical structures.

which ordinary definition the patentee was using”); *Baran v. Med. Device Techs., Inc.*, 616 F.3d 1309, 1315-16 (Fed. Cir. 2010) (finding that particular embodiments were covered by the claim based on the terms used in the claims); *TIP Sys., LLC v. Phillips & Brooks/Gladwin, Inc.*, 529 F.3d 1364, 1373 (Fed. Cir. 2008) (“to construe the claim term to encompass the alternative embodiment in this case would contradict the language of the claims”); *August Tech. Corp. v. Camtek, Ltd.*, 655 F.3d 1278, 1285 (Fed. Cir. 2011) (construing wafer to be a single wafer, not multiple wafers “[b]ased on the claim language as read in light of the specification”).

Here, the claim language expressly permits α -position secondary carbons; the specification supports such a reading, *supra*; and a “single sentence ... cannot overcome the overwhelming evidence in other parts of the specification.” *Trustees of Columbia Univ. in City of N.Y. v. Symantec Corp.*, 811 F.3d 1359, 1366 (Fed. Cir. 2016). Against this evidence, Alnylam is not “rely[ing] on its own use of inconsistent and confusing language in the specification to support a broad claim construction which is otherwise foreclosed.” *Id.*

Nor is this a case where including secondary carbons would be “inconsistent with the definitional paragraph.” *Roche Diagnostics*

Operations, Inc. v. Lifescan Inc., 660 Fed. App'x 932, 937 (Fed. Cir. 2016). The definitional paragraph, which includes the qualifier “unless otherwise specified,” is consistent with including secondary carbons within the claims’ scope in the context of the claimed α -branching.

Moderna contends that the cases not excluding claimed embodiments are “in apposite [*sic*].” RB.57. But Moderna does not dispute that claim terms normally are not interpreted “in a way that excludes embodiments disclosed in the specification,” or that “where claims can reasonably to [*sic*] interpreted to include a specific embodiment, it is incorrect to construe the claims to exclude that embodiment.” *Oatey*, 514 F.3d at 1277; BB.35; RB.57.

Instead, Moderna asserts that specific embodiments need be included only absent “probative evidence to the contrary” and points to “the express definition” as purportedly providing such evidence here. RB 57. The express definition here is not to the contrary: as explained, the phrase “unless otherwise specified” permits embodiments with secondary carbons. *See PSN Illinois, LLC v. Ivoclar Vivadent, Inc.*, 525 F.3d 1159, 1166 (Fed. Cir. 2008) (the “evidence on the contrary” “statement from

Oatey is not applicable in this case, because ... the term ... can and should be construed in a way that encompasses the preferred embodiment”).

Moderna seeks to distinguish *Alnylam*’s cases because “they do not involve patents with express definitions.” RB.57 (citing BB.41-42). But the pertinent issue is whether there was probative evidence of intent to exclude embodiments—and the answer here is no. Likewise, that some embodiments may be outside the claim scope due to other elements does not obliterate the requirement to construe the claim to include embodiments when the claim can reasonably be interpreted to include such embodiments. RB.58.

II. IN THE ALTERNATIVE, EVEN IF THIS COURT FINDS LEXICOGRAPHY, THE INTRINSIC EVIDENCE REQUIRES CONSTRUING THE CLAIMS TO INCLUDE ALPHA-BRANCHED SECONDARY CARBON STRUCTURES

Finally, even if lexicography applies, the district court improperly omitted the “[u]nless otherwise specified” part of the patent’s definition. With the full definition, secondary carbon α -branching would fall within the definition and the claims. BB.67-68.

Alnylam has explained that the lexicographic statement includes and is prefaced by “unless otherwise specified” and that language must be taken into consideration. Appx5546 (96:8-19); Appx5550 (110:2-9); *see*

also Appx4495-4496. Moderna does not dispute this, and the district court erred by not adopting it. RB.66. And the evidence that the intrinsic record clearly specifies secondary carbon binding in the context of alpha branching is overwhelming. *See* sections I.B.2, I.B.3, I.B.4, *supra* and BB.40-57.

As for Alnylam's ordinary meaning construction, Moderna contends that Alnylam never offered substantive support for that construction and criticizes the use of a negative limitation. RB.66. But as explained in Alnylam's Brief and shown above, there is significant substantive support in the intrinsic record. BB.9-31. While Moderna criticizes Alnylam for offering no expert support, Moderna itself has never offered expert testimony.

Regarding the use of a negative limitation, the construction Moderna advocates for here also has a negative limitation. RB.29, 34. Alnylam's construction is helpful in distinguishing a straight alkyl from a branched alkyl. It is based on the straightforward notion that that which is not a straight chemical bond is branched. That is not a difficult concept. Moderna's only binding precedent specifically states that "there is no per se rule against negative constructions." *Medicines Co. v. Mylan*,

Inc., 853 F.3d 1296, 1308 (Fed. Cir. 2017) (quoting *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1329 (Fed. Cir. 2003)). Unlike in *Medicines*, there is no prosecution history that disputes this meaning, and no ambiguity.

Moderna suggests Alnylam has somehow forfeited an argument. RB.67-68. Not so. Moderna does not dispute that the legal question of how to construct the branched alkyl terms was raised below.

Additionally, Alnylam may press any *legal* argument in support of claims or issues presented below. When a party raises a claim in the lower court, it “can make any argument in support of that claim” on appeal because “parties are not limited to the precise arguments they made below.” *Yee v. City of Escondido, Cal.*, 503 U.S. 519, 534 (1992). Moreover, the court’s failure to adopt the entire definition is itself legal error that cannot be waived. *See Myco Indus., Inc. v. BlephEx, LLC*, 955 F.3d 1, 11 n.4 (Fed. Cir. 2020).

Moderna’s cases are readily distinguishable. This is not the situation where claim construction “presents significant issues warranting substantial legal and possibly factual development.” *United States v. Great Am. Ins. Co. of N.Y.*, 738 F.3d 1320, 1328 (Fed. Cir. 2013);

Fresenius USA, Inc. v. Baxter Int'l, Inc., 582 F.3d 1288, 1297 (Fed. Cir. 2009). This is also not an appeal of a decision of administrative judge where the argument must have been raised before the commission before appeal. *Finnigan v. Int'l Trade Comm'n*, 180 F.3d 1354, 1363 (Fed. Cir. 1999). Alnylam is not seeking a construction or proposing a “particularized definition” for the first time on appeal. *In re Google Tech. Holds. LLC*, 980 F.3d 858, 863-64 (Fed. Cir. 2020).

To the extent there is any forfeiture, it is Moderna's, which never sought construction of the longer phrase “ R^{13} is a C₁₀-C₂₀ branched alkyl”—but seeks such a construction here. See RB.3, 29; Appx5512. This term was raised, briefed, and argued by Pfizer/BNT—not Moderna as the amici brief of Pfizer/BNT confirms. Document 22, at 3.

CONCLUSION

The Court should reverse and remand for further proceedings.

Respectfully submitted,

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Dated: April 22, 2024

CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(a)(7)(C), the undersigned counsel for Appellant certifies that this brief:

(i) complies with the type-volume limitation of Rule 32(a)(7)(B) because it contains 6,988 words, including footnotes and excluding the parts of the brief exempted by Rule 32(a)(7)(B)(iii); and

(ii) complies with the typeface requirements of Rule 32(a)(5) and the type style requirements of Rule 32(a)(6) because it has been prepared using Microsoft Office Word 365 and is set in Century Schoolbook font in a size equivalent to 14 points or larger.

Dated: April 22, 2024

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CERTIFICATE OF SERVICE

I hereby certify that digital versions of Plaintiff-Appellant's Reply Brief were served electronically via the Court's CM/ECF system.

Dated: April 22, 2024

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