IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ADVANCED ACCELERATOR APPLICATIONS, USA, INC., and ADVANCED ACCELERATOR APPLICATIONS, SA,	)	
Plaintiffs,	)	
v.	)	C.A. No. 24-95 (MN)
LANTHEUS MEDICAL IMAGING, INC., LANTHEUS HOLDINGS, INC,	)	
Defendants.	)	
ADVANCED ACCELERATOR APPLICATIONS, USA, INC., and ADVANCED ACCELERATOR APPLICATIONS, SA,	)	
Plaintiffs,	)	
v.	)	C.A. No. 24-1161 (MN) CONSOLIDATED
CURIUM US LLC, CURIUM US HOLDINGS LLC, CURIUM NETHERLANDS BV, and CURIUM INTERNATIONAL TRADING BV,	)	
Defendants.	)	

MEMORANDUM ORDER

At Wilmington, this 13th day of August 2025:

The Court heard argument about the disputed claim terms of U.S. Patent Nos. 10,596,276 ("'276 Patent"), 11,904,027 ("'027 Patent"), 12,144,873 ("'873 Patent"), 12,151,003 ("'003 Patent"), 12,161,732 ("'732 Patent"), and 12,168,063 ("'063 Patent") (collectively, "patents-at-issue") on July 25, 2025. (D.I. 239). IT IS HEREBY ORDERED that the claim terms

of the patents-at-issue with agreed-upon constructions are construed as follows (*see* D.I. 160 at 2)[1]:

1. "somatostatin receptor binding peptide" means "any peptide that binds to the somatostatin receptor" ('276 Patent, cl. 1; '027 Patent, cl. 1; '873 Patent, cls. 1, 27; '003 Patent, cls. 1, 14, 23; '732 Patent, cl. 1; '063 Patent, cl. 1);

2. "somatostatin receptor binding peptide linked to the chelating agent DOTA" means "[t]he somatostatin receptor binding peptide is either directly linked to the chelating agent or connected via a linker molecule. The linking bond(s) is (are) either covalent or noncovalent bond(s) between the somatostatin receptor binding peptide and the chelating agent DOTA" ('276 Patent, cl. 1; '027 Patent, cl. 1; '873 Patent, cls. 1, 27; '003 Patent, cls. 1, 14, 23; '732 Patent, cl. 1; '063 Patent, cl. 1); and

3. "pharmaceutical aqueous solution [obtained / manufactured] by the process . . ." is a "product-by-process limitation." ('276 Patent, cl. 20; '027 Patent, cls. 20, 23; '732 Patent, cl. 7; '063 Patent, cl. 7).

The Court will construe two of the five disputed claim terms of the patents-at-issue at a later time.[2]

Further, as announced at the hearing on July 25, 2025, IT IS HEREBY ORDERED that the remaining disputed claim terms of the patents-at-issue are construed as follows:

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[1] The filings relevant to claim construction are filed in both C.A. No. 24-95 (MN) and C.A. No. 24-1161 (MN). The docket items referenced in this Order correspond to the docket entries in C.A. No. 24-95 (MN).

[2] The Court will not construe the term, "A process for manufacturing a pharmaceutical aqueous solution . . ." ('276 Patent, cl. 1; '027 Patent, cl. 1; '732 Patent, cl. 1; '063 Patent, cl. 1) at this time. As explained in further detail below, it became apparent during oral argument that Plaintiff's proposed construction of this term utilized other terms that are themselves subject to dispute. (D.I. 239 at 10:3-15:4). The parties' experts are to provide opinions under both proposed constructions, including any opinions reliant on disputed terms like "drug product." The Court will also reserve its ruling on the term, "in the obtained pharmaceutical aqueous solution . . . is present"/ "is present in the pharmaceutical aqueous solution" ('276 Patent, cl. 1; '027 Patent, cl. 1; '732 Patent, cl. 1; '063 Patent, cl. 1). The parties are to have their experts opine on the proposed constructions and take the Court's concerns, as set forth below, into account to the extent possible. The Court may construe these terms after trial.

1. "stabilizer[(s)] against radiolytic degradation" means "an agent which protects organic molecules from degradation due to radioactivity" ('276 Patent, cl. 1; '027 Patent, cl. 1; '873 Patent, cls. 1, 27; '003 Patent, cls. 1, 14, 23; '732 Patent, cl. 1; '063 Patent, cl. 1);

2. "the stabilizers . . . in a total concentration of [1.0 to 5.0 mg/mL or 0.5 to 10.0 mg/mL]" means "the first stabilizer, the second stabilizer, and the at least one stabilizer to the extent present add up to a concentration of [1.0 to 5.0 mg/mL or 0.5 to 10.0 mg/mL]" ('276 Patent, cl. 1; '027 Patent, cl. 1; '873 Patent, cl. 1; '003 Patent, cl. 1; '732 Patent, cl. 1; '063 Patent, cl. 1); and

3. "ethanol . . . in a concentration of less than [1 or 2]%" / "comprises less than [1 or 2]% ethanol" means "if ethanol is present in the obtained pharmaceutical aqueous solution, it is present in a concentration of less than [1% or 2%] by weight (w/w)" (cl. 1 of '276, '027, '873, '003, '732, '063 Patents; '003 Patent, cls. 14, 23).

The parties briefed the issues (D.I. 160) and submitted exhibits containing intrinsic and extrinsic evidence (D.I.161). The Court carefully reviewed all submissions in connection with the parties' contentions regarding the disputed claim terms, heard oral argument (D.I. 239), and applied the legal standards below in reaching its decision.

I. LEGAL STANDARDS

A. Claim Construction

"[T]he ultimate question of the proper construction of the patent [is] a question of law," although subsidiary fact-finding is sometimes necessary. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 325 (2015). "[T]he words of a claim are generally given their ordinary and customary meaning [which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc) (internal citations and quotation marks omitted). Although "the claims themselves provide substantial guidance as to the meaning of particular claim terms," the context of the surrounding words of the claim must also be considered. *Id.* at 1314. "[T]he ordinary meaning of a claim term is its meaning

to the ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted).

The patent specification "is always highly relevant to the claim construction analysis . . . [as] it is the single best guide to the meaning of a disputed term." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). It is also possible that "the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316. "Even when the specification describes only a single embodiment, [however,] the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (internal quotation marks omitted) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)).

In addition to the specification, a court "should also consider the patent's prosecution history, if it is in evidence." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). The prosecution history, which is "intrinsic evidence, . . . consists of the complete record of the proceedings before the PTO [Patent and Trademark Office] and includes the prior art cited during the examination of the patent." *Phillips*, 415 F.3d at 1317. "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

In some cases, courts "will need to look beyond the patent's intrinsic evidence and [] consult extrinsic evidence in order to understand, for example, the background science or the

meaning of a term in the relevant art during the relevant time period." *Teva*, 574 U.S. at 331. Extrinsic evidence "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. Expert testimony can be useful "to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Phillips*, 415 F.3d at 1318. Nonetheless, courts must not lose sight of the fact that "expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence." *Id.* Overall, although extrinsic evidence "may be useful to the court," it is "less reliable" than intrinsic evidence, and its consideration "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1318-19. Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics*, 90 F.3d at 1583).

II. THE COURT'S RULING

The Court's ruling regarding the disputed claim terms of the '276 Patent, '027 Patent, '873 Patent, '003 Patent, '732 Patent and '063 Patent was announced from the bench at the conclusion of the *Markman* hearing on July 25, 2025, as follows:

> At issue, there are five disputed claim terms in six patents.[3] I am prepared to rule on three of the disputes. I will not be issuing a written opinion, but I will issue an order stating my rulings. I want to emphasize before I announce my decisions that although I am not issuing a written opinion, we have followed a full and thorough process before making the decisions I am about to state. I have reviewed the patents, and the evidence submitted by the parties.

[3] U.S. Patent Nos. 10,596,276 ("'276 Patent"), 11,904,027 ("'027 Patent"), 12,144,873 ("'873 Patent"), 12,151,003 ("'003 Patent"), 12,161,732 ("'732 Patent"), and 12,168,063 ("'063 Patent").

There was joint briefing[4] on each of the disputed terms and we had argument today. All of that has been carefully considered.

I am not going to read into the record my understanding of claim construction law. I have a legal standard section that I have included in earlier opinions, including somewhat recently in *REX Computing, Inc. v. Cerebras Systems, Inc.*, Civil Action No. 21-525 (MN). I incorporate that law and adopt it into my ruling today and will also set it out in the order that I issue.

The first dispute is over the term, "A process for manufacturing a pharmaceutical aqueous solution . . ."[5] All parties agree the preamble is limiting.[6] Plaintiff argues that term should be construed as "a series of steps to produce a water-based drug product ready for commercial use."[7] Defendants propose what they call the "plain and ordinary meaning: a series of steps for making a water-based solution containing an active drug component."[8]

I am not going to construe this term at this time. I am concerned, as I noted during argument, that Plaintiff is asking me to construe the term using other terms like "drug products" and "commercial use" that are themselves apparently subject to dispute, which may leave us in need of possible further construction.[9] And yet, I am not convinced that Defendants' proposal accurately reflects the "present invention" described in the specification.[10]

I think the better course with respect to this term is to construe it later - either at trial or after trial - when I understand exactly what the arguments are and how the various terms in the proposals are being used. So, experts need to provide whatever opinions they have for this term under both constructions that are proposed, including

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4 (D.I. 160, 161).

5 '276 Patent, cl. 1; '027 Patent, cl. 1; '732 Patent, cl. 1; '063 Patent, cl. 1. (*See also* D.I. 160 at 3).

6 (D.I. 160 at 3).

7 (*Id.*).

8 (*Id.*).

9 (D.I. 239 at 11:21-12:7).

10 (D.I. 161, Ex. 1, '276 Patent at 1:16-19).

giving any opinions that rely on the meaning of disputed terms that are within the proposed constructions, like "commercial use" and "drug product," so that I know whether those terms are setting us up for further construction.

The second term is "stabilizer[(s)] against radiolytic degradation."[11] Plaintiff proposes the construction: "an agent which protects organic molecules from degradation due to radioactivity, also referred to as 'free radical scavengers,' 'radical scavengers,' 'radiation stability enhancers,' 'radiolytic stabilizers,' 'antioxidant,' or 'quenchers.'"[12] Defendants provide differing constructions. Lantheus proposes: "A stabilizing agent has a primary function at the claimed concentration to protect organic molecules from degradation due to radioactivity. A stabilizer against radiolytic degradation is distinct from a buffer or sequestering agent (also known as a chelating agent)."[13] Curium proposes: "A stabilizing agent which protects organic molecules against radiolytic degradation; such stabilizing agents include gentisic acid (2,5-dihydroxybenzoic acid) or salts thereof, ascorbic acid (L-ascorbic acid, vitamin C) or salt thereof (e.g., sodium ascorbate), methionine, histidine, melatonin, ethanol, and Se-methionine."[14] At the argument today, I think Curium indicated that it was okay with dropping all of the examples proposed.[15]

If I have that right, I think that where Curium seems to have landed makes sense and is consistent with the specification which includes a "Definitions" section that explicitly defines "[s]tabilizer against radiolytic degradation."[16] The Definitions section begins with the directive that, "In the following, terms as used herein are defined in their meaning."[17] "The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms

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11 '276 Patent, cl. 1; '027 Patent, cl. 1; '873 Patent, cls. 1, 27; '003 Patent, cls. 1, 14, 23; '732 Patent, cl. 1; '063 Patent, cl. 1. (*See also* D.I. 160 at 23).

12 (D.I. 160 at 23).

13 (*Id.*).

14 (*Id.*).

15 (D.I. 239 at 33:22-34:1).

16 (D.I. 161, Ex. 1, '276 Patent at 30:12).

17 (*Id.* at 28:64–67).

by implication."[18] "Where . . . the patentee has clearly defined a claim term, that definition . . . is the single best guide to the meaning of a disputed term."[19]

Plaintiff agrees that there is a definition in the specification that includes the language at the beginning of Curium's proposal, but then it skips some of the following words (providing examples) before picking up on the synonyms listed as well as at least one other purported synonym listed later in the patent, antioxidant.[20]

I am not convinced that those synonyms are necessary to include in the definition or add to it any more than the examples that Plaintiff skips. So I will not add them into the construction.

I will also not include Lantheus' proposed language: "primary function" or state that a "stabilizer" cannot be a buffer. I understand Lantheus' argument[21] about the *Regeneron*[22] case. But at least what I understand so far, it seems that there may be some different facts. I don't, for example, have any concept of whether Plaintiff is arguing that one thing is being relied on to meet multiple different claim requirements. If, however, you want to try to convince me to change my mind during trial when I understand all of the arguments, you may for this term. And to that end, the parties' experts should think about providing opinions on the issue and how it impacts infringement and validity.

So my construction of this term is: "an agent which protects organic molecules from degradation due to radioactivity."

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18 *Vitronics*, 90 F.3d at 1582.

19 *Jack Guttman, Inc. v. Kopykake Enters., Inc.*, 302 F.3d 1352, 1360 (Fed. Cir. 2002) (citing *Vitronics*, 90 F.3d at 1582). *See also Braintree Lab'ys, Inc. v. Novel Lab'ys, Inc.*, 749 F.3d 1349, 1356 (Fed. Cir. 2014); *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1380 (Fed. Cir. 2009) (citations omitted) ("When a patentee explicitly defines a claim term in the patent specification, the patentee's definition controls").

20 (D.I. 160 at 23-24).

21 (*Id.* at 33, 43-44).

22 *Regeneron Pharms. Inc. v. Mylan Pharms. Inc.*, 130 F.4th 1372, 1380 (Fed. Cir. 2025).

The third disputed term is "in the obtained pharmaceutical aqueous solution . . . is present," or "is present in the pharmaceutical aqueous solution,"[23] as it appears across the multiple patents-at-issue.

Plaintiff proposes: "is existing at the time of end of production (aka EOP, end of synthesis, or t0) through the time of administration or the end of shelf life."[24] Defendants propose what they contend is the plain and ordinary meaning: "the water-based solution containing an active drug component immediately after the addition of the dilution solution."[25] The parties' disagreement centers on at what point the component concentration parameters that the claims set forth must be measured.[26] Lantheus additionally contends that the "end of shelf-life" language in Plaintiffs' proposed construction is subjective, making the Asserted Claims invalid as indefinite under Section 112.[27]

I am going to reserve on this term. At first blush, the language of claim 1 of the '276 Patent about the solution obtained seems to support Defendants' reading. But the parties are also positing the same constructions for different language in other claims, like claim 1 of the '732 Patent, which is not as clear to me. And the specification, which provides context for the claims, seems to support Plaintiffs.

All that being said, I have concerns about Plaintiffs' added terms "end of production" and "shelf life" as well as the words "immediately after" in Defendants' proposal.

So I'm not prepared to decide this. Have your experts opine on any proposed constructions and take my concerns into account to the extent you can.

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23 '276 Patent, cl. 1; '027 Patent, cl. 1; '732 Patent, cl. 1; '063 Patent, cl. 1. (*See also* D.I. 160 at 44).

24 (D.I. 160 at 44).

25 (*Id.*).

26 (*Id.* at 44-47).

27 (*Id.* at 44).

The fourth disputed term is "the stabilizers . . . in a total concentration of [1.0 to 5.0 mg/mL or 0.5 to 10.0 mg/mL]."[28] Plaintiff proposes: "the non-ethanol stabilizers add up to a concentration of [1.0 to 5.0 mg/mL or 0.5 to 10.0 mg/mL]."[29] Defendants together propose the construction: "all of the stabilizers add up to a total concentration of [from 1.0 to 5.0 mg/mL or 0.5 to 10.0 mg/mL]."[30]

I will construe this term to mean the stabilizers that provide antecedent basis for the term in the claim. So that will be "the first stabilizer, the second stabilizer and the at least one stabilizer" but not ethanol. Although the parties agree that ethanol is a stabilizer, it is treated differently than other stabilizers throughout the patent.[31]

I think that is also supported by the file history, which also treats ethanol differently. For example, in addressing prior art issues, the Examiner and the patentee did not include ethanol in the calculation of the total concentration of stabilizers.[32]

So my construction of this term is: "the first stabilizer, the second stabilizer and the at least one stabilizer" to the extent present add up to a concentration of [1.0 to 5.0 mg/mL or 0.5 to 10.0 mg/mL]." That does not include ethanol.

Finally, we have the term "ethanol . . . in a concentration of less than [1 or 2]%" or "comprises less than [1 or 2]% ethanol."[33]

Plaintiff proposes: "if ethanol is present in the obtained pharmaceutical aqueous solution, it is present in a concentration of less than [1% or 2%] by weight (W/W)."[34] Curium proposes what

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28 '276 Patent, cl. 1; '027 Patent, cl. 1; '873 Patent, cl. 1; '003 Patent, cl. 1; '732 Patent, cl. 1; '063 Patent, cl. 1. (*See also* D.I. 160 at 57).

29 (D.I. 160 at 57).

30 (*Id.*).

31 (D.I. 161, Ex. 1, '276 Patent at 2:19-23, 4:24-28, 5:8-16, 9:38-54).

32 (*Id.*, Ex. 7 at 6; *id.*, Ex. 8 at 4; *id.*, Ex. 11 at 6-7).

33 Cl. 1 of '276, '027, '873, '003, '732, '063 Patents; '003 Patent, cls. 14, 23. (*See also* D.I. 160 at 69).

34 (D.I. 160 at 69).

it argues is the plain and ordinary meaning: "if ethanol is present in the obtained pharmaceutical aqueous solution, it is present in a concentration of less than [1% or 2%] by volume (v/v)."[35] Lantheus takes no position on the meaning of this term.[36] The crux of the dispute is whether the concentration should be measured by weight or by volume.[37] Here, I will adopt Plaintiffs' construction.

Claim 1 of the '276 Patent states that "ethanol is present in a concentration of less than 1%,"[38] using the percent symbol. The definitions section of the specification defines the % symbol, stating, "[u]nless otherwise defined, % has herein the meaning of weight percent (wt %), also referred to as weight by weight percent (w/w %)."[39]

As previously discussed, "[w]here the specification instructs as to the meaning of a claim term, the inventor's lexicography governs."[40]

Curium begins by noting that ethanol is a liquid typically measured by volume.[41] Curium contends that the '276 Patent's specification supports its construction because it discloses a reference describing ethanol as a percentage by volume.[42] Curium additionally points to the prosecution history to support its position, as the patent applicants amended originally vaguer claim language, "substantially free of ethanol," to a more specific "less than 1%" limitation for ethanol to overcome a piece of prior art that according to the Examiner referenced ethanol by volume.[43] Curium argues, by way

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35 (*Id.*).

36 (*Id.*, n.7).

37 (*Id.* at 70-75).

38 (D.I. 161, Ex. 1, '276 Patent, cl. 1).

39 (*Id.* at 29:19-21).

40 *Grace Instrument Indus., LLC v. Chandler Instruments Co.*, LLC, 57 F.4th 1001, at 1010 (Fed. Cir. 2023) (internal citation omitted).

41 (D.I. 160 at 71).

42 (*Id.* at 72; D.I. 161, Ex. 21). (*See also* D.I. 161, Ex. 1, '276 Patent at 2:18-19).

43 (D.I. 160 at 73; D.I. 161, Ex. 23 at 6, 27-29, 42; *id.*, Ex. 27 at 2, 5).

of an expert declaration, that calculating ethanol by weight would not distinguish that prior art.[44]

Here, I will defer to the definition in the specification. The symbol in question appears under the title "Definitions" and is stated to mean w/w unless otherwise defined.[45] Nowhere does the specification "otherwise define" that the % symbol should have a different meaning in reference to ethanol. Nor do I think that the prosecution history and the reference to prior art with ethanol noted as v/v "otherwise defines" the percent sign symbol. If by this construction Plaintiff walks into a prior art argument that it avoided during prosecution, I guess we will have to deal with that at trial.

Thus, I will construe "ethanol . . . in a concentration of less than [1 or 2]%" or "comprises less than [1 or 2]% ethanol" as "if ethanol is present in the obtained pharmaceutical aqueous solution, it is present in a concentration of less than [1% or 2%] by weight (w/w)."

Maryellen Noreika

The Honorable Maryellen Noreika
United States District Judge

44 (D.I. 161, Ex. 30 ¶¶ 9-11).

45 (*Id.*, Ex. 1, '276 Patent at 29:19-21).