IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CALLIDITAS THERAPEUTICS AB, **Plaintiff,** **v.** **ZYDUS PHARMACEUTICALS (USA) INC. AND ZYDUS LIFESCIENCES LTD.,** **Defendants.**	**Court No. 1:25-cv-00368-JCG** **ANDA CASE**

OPINION AND ORDER

[Providing claim construction for the patents in suit.]

Dated: November 2, 2026

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Choe-Groves, Judge: This matter is before the Court for claim construction of terms in U.S. Patent Numbers 11,896,719 ("the '719 Patent"), 12,171,882 ("the

'882 Patent"), 12,171,883 ("the '883 Patent"), and 12,311,057 ("the '057 Patent") (collectively, the "Asserted Patents"). Joint Claim Construction Br. ("Joint Br.") (D.I. 78, 85). The Parties seek construction of the following terms and phrases: "an extended release pharmaceutically-acceptable polymeric blend," "pore-forming polymer," and "about" or "about [value] wt. %." Joint Claim Construction Chart, Ex. A ("Joint Chart") (D.I. 63-1). Upon consideration of the brief and arguments of counsel, the Court construes the disputed claim terms as set forth below.

BACKGROUND

Calliditas Therapeutics AB ("Plaintiff" or "Calliditas") filed suit against Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Ltd. (collectively, "Defendants" or "Zydus") for infringement of the Asserted Patents, arising from Defendants' Abbreviated New Drug Application ("ANDA") for United States Food and Drug Administration ("FDA") approval to market and sell a generic version of TARPEYO®. Am. Compl. (D.I. 46). Calliditas markets and sells budesonide delayed-release capsules under the name TARPEYO®. Id. at ¶ 33. TARPEYO® is a corticosteroid that reduces the loss of kidney function in adults with primary immunoglobulin A ("IgA") nephropathy. Id. at ¶ 34. This Opinion concerns the first step of the two-step infringement analysis, the construction of claim terms asserted in the Asserted Patents. The Asserted Patents share a

common specification and claim priority to the same provisional applications, Nos. 63/302,226 and 63/302,216. Joint Br. at 3 n.1, 6 n.2; App'x Supp. Joint Claim Construction Br. Vol. 2 Exs. (D.I. 80-1, 87), Ex. 1 ("'719 Patent"), Ex. 2 ("'882 Patent"), Ex. 3 ("'883 Patent"), Ex. 4 ("'057 Patent").[1] The '719 Patent was issued by the United States Patent and Trademark Office ("USPTO") on February 13, 2024, the '882 and '883 Patents were issued on December 24, 2024, and the '057 Patent was issued on May 27, 2025. '719 Patent at [45]; '882 Patent at [45]; '883 Patent at [45]; '057 Patent at [45]. All Asserted Patents are directed toward a method of treatment of IgA nephropathy. '719 Patent at [57].

The Parties filed a joint claim construction brief and chart. See Joint Br.; Joint Chart. The Court held a claim construction hearing on August 14, 2026, and the Parties did not call expert witnesses. See Oral Order (D.I. 90).

CLAIM CONSTRUCTION STANDARD

When the meaning of a patent claim's language is disputed, the Court must construe the claim as a matter of law. Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996). "[T]he construction of a patent, including terms of art within its claim, is exclusively within the province of the court." Markman, 517 U.S. at 372. "The purpose of

[1] The '882 and '883 Patents are continuations of the '719 Patent, and the '057 Patent is a continuation of the '882 Patent. See '882 Patent at [63]; '883 Patent at [63]; '057 Patent at [63].

claim construction is to 'determin[e] the meaning and scope of the patent claims asserted to be infringed.'" O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co., 521 F.3d 1351, 1360 (Fed. Cir. 2008) (quoting Markman, 52 F.3d at 976).

"The patent is a fully integrated written instrument." Markman, 52 F.3d at 978. For the purpose of claim construction, "[a] court should look first to the intrinsic evidence of record, i.e., the patent itself, including the claims, the specification and, if in evidence, the prosecution history." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996) (citing Markman, 52 F.3d at 979). "The words of a claim are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art when read in the context of the specification and prosecution history." Thorner v. Sony Comput. Ent. Am. LLC, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (citing Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc)).

Limitations from dependent claims, the specification, and embodiments will not be read into the claims. "The doctrine of claim differentiation [ ] creates a presumption that [ ] dependent claim limitations are not included in the independent claim." GE Lighting Sols., LLC v. AgiLight, Inc., 750 F.3d 1304, 1310 (Fed. Cir. 2014) (citation omitted). Limitations found in the specification are not imposed into the claims. Phillips, 415 F.3d at 1323–24. In the same vein, "[i]t is improper to read limitations from a preferred embodiment described in the

specification—even if it is the only embodiment—into the claims absent a clear indication in the intrinsic record that the patentee intended the claims to be so limited." GE Lighting Sols., LLC, 750 F.3d at 1309 (citation omitted) (discussing a figure as a "depicted embodiment").

DISCUSSION

The Parties disagree on three claim terms in the Asserted Patents. The Court examines each disputed claim term and the Parties' arguments in turn.

A. "an extended release pharmaceutically-acceptable polymeric blend"

Zydus asserts that the term "an extended release pharmaceutically-acceptable polymeric blend" is indefinite pursuant to 35 U.S.C. § 112(b), and Plaintiff asserts that the term is not indefinite. Joint Chart at A-1. If the Court finds that the term requires construing, Zydus' proposed construction is "a water-insoluble polymer, a pore-forming polymer, and optionally a fatty acid, medium chain triglyceride, or further water soluble polymer." Id. Although Plaintiff argues that no construction is necessary, in the alternative, Plaintiff proposes construing the disputed term as "a coating that extends the release of the pharmaceutical composition and includes pharmaceutically-acceptable polymers and optionally other excipients." Id.

A patent is presumed valid under 35 U.S.C. § 282, and a defense of invalidity must be proven by clear and convincing evidence. Microsoft Corp. v.

I4I Ltd. P'ship, 564 U.S. 91, 95 (2011). A patent is invalid for indefiniteness if "its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." Nautilus, Inc. v. Biosig Instruments, Inc., 572 U.S. 898, 901 (2014). "[A] context-specific inquiry into whether particular functional language actually provides the required reasonable certainty" is needed to determine indefiniteness. BASF Corp. v. Johnson Matthey Inc., 875 F.3d 1360, 1366 (Fed. Cir. 2017).

The disputed term is found in multiple claims of the Asserted Patents. Joint Chart at A-1–A-4. Claim 1 of the '719 Patent recites in part:

> 1. A method of treating IgA nephropathy in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising one or more cores comprising budesonide;
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> wherein the one or more cores are coated with an extended release pharmaceutically-acceptable polymeric blend comprising ethylcellulose in an amount of about 51.8 wt. % of the extended release pharmaceutically-acceptable polymeric blend and hydroxypropylmethyl cellulose in an amount of about 27.3 wt. % of the extended release pharmaceutically-acceptable polymeric blend;
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> wherein the extended release pharmaceutically-acceptable polymeric blend is present in an amount of from about 5 wt. % to about 18 wt. % of the total coated core weight . . . .

'719 Patent at 63:59–64:7. Claim 7 of the '719 Patent also recites the language of Claim 1, but features different claimed weight percentages for the polymeric

blends. Id. at 64:48–63.[2] Zydus argues that the specification and claim language provide no description or indication of what components are to be considered as part of the "extended release pharmaceutically-acceptable polymeric blend" besides "(i) a water insoluble polymer/ethylcellulose and (ii) a pore-forming polymer/[hydroxypropylmethyl cellulose]." Joint Br. at 25–26. Plaintiff asserts that Zydus fails to meet its burden to show indefiniteness, Zydus' proposed alternative construction undermines its indefiniteness argument, and a person of ordinary skill in the art would understand that the disputed term means "a coating that extends the release of the pharmaceutical composition and includes pharmaceutically-acceptable polymers and optionally other excipients." Id. at 21–22.

The Parties both discuss Example 1 from the specification, which provides an embodiment of the patented invention. Id. at 17–19, 27–28. Example 1 is titled "Manufacturing of Core-Shell Composition" and describes the preparation of budesonide beads. '719 Patent at 33:3–4, 33:43–46. An extended release polymer

[2] Step one of Claim 7 recites "an extended release pharmaceutically-acceptable polymeric blend comprising ethylcellulose in an amount of from about 47 wt. % to about 56 wt. % of the extended release pharmaceutically-acceptable polymeric blend and hydroxypropylmethyl cellulose in an amount from 32 wt. % to about 22 wt. % of the extended release pharmaceutically-acceptable polymeric blend" and step two recites that "the extended release pharmaceutically-acceptable polymeric blend is present in an amount of from about 5 wt. % to about 18 wt. % of the total coated core weight . . . ." '719 Patent at 64:48–63.

coating is applied onto the budesonide beads. Id. at 34:13–15. Example 1 names a dry powder polymer blend, "Opadry OY-7240" ("Opadry"), a polymer dispersion, "Surelease," and lists the components within both substances. Id. at 33:6–37. An extended release coating solution is prepared by adding Opadry to purified water, and mixing Surelease into the solution. Id. at 34:6–10. The "resulting polymer blend of the extended release coating on the beads" is comprised of about "27.3 wt. % [hydroxypropylmethyl cellulose] of the total blend and about 51.8 wt. % ethycellulose of the total blend." Id. at 34:20–23. "The ethylcellulose is a water-insoluble polymer" and "the [hydroxypropylmethyl cellulose] acts as the pore forming polymer." Id. at 34:23–25.

The specification states that the extended release coating "may comprise a pharmaceutically-acceptable polymeric blend comprising a water-insoluble polymer and a pore-forming polymer[,]" identifies hydropropylmethyl cellulose as the preferred pore-forming polymer, and provides a series of examples comprising pharmaceutically-acceptable polymeric blends. '719 Patent at 26:59–61, 27:41–42, 28:4–49. The specification's examples include polymeric blends comprised of a fatty acid, a medium-chain triglyceride, or a further water-soluble polymer, all with specific weight percentages. See id. at 28:4–49. Zydus claims that the intrinsic evidence does not provide sufficient guidance to reasonably ascertain what components form the polymeric blend because the specification provides

alternative descriptions, but the Court disagrees. See Joint Br. at 50. A patent does not satisfy the definiteness requirement of 35 U.S.C. § 112 simply because "a court can ascribe some meaning to a patent's claims." Interval Licensing LLC v. AOL, Inc., 766 F.3d 1364, 1371 (Fed. Cir. 2014) (quoting Nautilus Inc., 572 U.S. at 911) (emphasis omitted). "The claims, when read in light of the specification and the prosecution history, must provide objective boundaries for those of skill in the art." Id. The claim language recites an explanation of "an extended release pharmaceutically-acceptable polymeric blend" that is further supported by explanations and examples in the specification to instruct what properties form the invention's polymeric blend. The claim term "an extended release pharmaceutically-acceptable polymeric blend," when read in conjunction with the specification, does not leave a person skilled in the art without reasonable certainty as to the scope of the invention. Nautilus, Inc., 572 U.S. at 901. Given the claim language and intrinsic evidence on the record, the Court concludes that the disputed term is not indefinite pursuant to 35 U.S.C. § 112(b).

The Parties' competing constructions focus on whether the polymeric blend is a coating and whether it contains non-polymers. Joint Chart at A-1. Plaintiff's construction begins by defining the term as "a coating that extends the release of the pharmaceutical composition" to reflect the claim language that recites that "cores comprising budesonide" are "coated with an extended release

pharmaceutically-acceptable polymeric blend . . . ." '719 Patent at 63:61–65; Joint Br. at 16. By identifying that the polymeric blend is a coating, this construction acknowledges how the claim language and specification describe the term. See '719 Patent at 26:59–62 ("The extended release coating may comprise a pharmaceutically-acceptable polymeric blend . . . ."). Next, Plaintiff's construction states that the blend "includes pharmaceutically-acceptable polymers and optionally other excipients." Joint Chart at A-1. Defendants define the blend as "a water-insoluble polymer, a pore-forming polymer, and optionally a fatty acid, medium chain triglyceride, or further water soluble polymer." Id.

Plaintiff claims that the prosecution history and Example 1 in the specification support construing the disputed term to include all excipients in the extended-release coating. Joint Br. at 21. Defendants argue that Plaintiff's inclusion of "optionally other excipients" introduces ambiguity as to whether non-polymeric components could be included in the claim term. Id. at 34–35. The specification details different examples of a pharmaceutically-acceptable polymeric blend such as one comprised of a fatty acid, medium-chain triglyceride, or water-soluble polymer. '719 at 28:4–31. Defendants' proposed construction includes these examples as options for the blend, which Defendants argue is supported by lexicography. Joint Br. at 31.

The intrinsic evidence supports defining the disputed term as "a coating that

extends the release of the pharmaceutical composition" and the claim's use of "comprising" indicates that the coating can include more than only polymers. '719 Patent at 63:65; see Joint Br. at 16. Defendants' construction would read into the claim language the exemplary excipients listed in the specification, which is unnecessarily limiting. See Phillips, 415 F.3d at 1323. The Court adopts Plaintiff's construction and concludes that the claim term "an extended release pharmaceutically-acceptable polymeric blend" means "a coating that extends the release of the pharmaceutical composition and includes pharmaceutically-acceptable polymers and optionally other excipients."

B. "pore-forming polymer"

Plaintiff asserts that the Asserted Patents include an express definition for the term "pore-forming polymer" and propose construing the term as the express definition: "polymers which have higher water solubility than the water-insoluble polymer and are, therefore, capable of dissolving first leaving pores in the coating." Joint Br. at 54. Zydus' proposed construction is "a water soluble polymer, when in a polymeric blend with a further water soluble polymer, is different from the further water soluble polymer." Joint Chart at A-5. The Court should not depart from the plain meaning of the claims, "absent lexicography or disavowal[.]" Alcon Rsch., Ltd. v. Watson Lab'ys, Inc., No. 16129-LPS-SRF, 2018 WL 1805530, at *4 (D. Del. Apr. 17, 2018) (quoting Luminara Worldwide,

LLC v. Liown Elecs. Co., 814 F.3d 1343, 1353 (Fed. Cir. 2016)). "To act as its own lexicographer, a patentee must 'clearly set forth a definition of the disputed claim term,' and 'clearly express an intent to define the term.'" GE Lighting Sols. LLC, 750 F.3d at 1309 (quoting Thorner, 669 F.3d at 1365). Claim 1 of the '882 Patent recites in part:

> 1. A method of treating IgA nephropathy in a subject in need thereof, comprising administering to the subject a pharmaceutical composition comprising one or more cores comprising budesonide;
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> wherein the one or more cores are coated with an extended release pharmaceutically-acceptable polymeric blend comprising a water-insoluble polymer having a solubility in water (at 25 [degrees Celsius]) of less than about 0.1 mg/mL and a pore-forming polymer having a solubility in water (at 25 [degrees Celsius]) of at least 10 mg/mL;
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> wherein the water-insoluble polymer is present in an amount of from about 47 wt. % to about 56 wt. % of the extended release pharmaceutically-acceptable polymeric blend and the pore-forming polymer is present in an amount of from about 32 wt. % to about 22 wt. % of the extended release pharmaceutically-acceptable polymeric blend . . . .

'882 Patent at 64:50–67. Plaintiff refers to the following specification language as the express definition of pore-forming polymer:

> As used herein, the term 'pore-forming polymer' refers to polymers which have a higher water solubility than the water-insoluble polymer and are, therefore, capable of dissolving first leaving pores in the coating, thus allowing a certain amount of water to penetrate towards the core.

'719 Patent at 27:14–17. Zydus argues that the Asserted Patents explicitly distinguish a further water-soluble polymer from the pore-forming polymer. Joint

Br. at 56. Zydus refers to the following specification language to support this argument:

> The pharmaceutically-acceptable blend of the extended release coating may comprise a further water-soluble polymer in an amount of from about 1 wt. % to about 5 wt. % such as from about 2 wt. % to about 3 wt. % of the total extended release coating. For the avoidance of doubt, the further water-soluble polymer is different to the pore-forming polymer. Preferably, the further water-soluble polymer is poly(ethylene glycol) having a molecular weight in the range of from about 200 to about 1000 g/mol.

'719 Patent at 28:27–35. Defendants claim that the specification explains that the "further water-soluble polymer" is not considered "the pore-forming polymer." Joint Br. at 57. Additionally, Defendants refer to the prosecution history of the '719 Patent as foreclosing Plaintiff from arguing that the pore-forming polymer is a further water-soluble polymer. Id. Zydus argues that Plaintiff surrendered any claim that a further water-soluble polymer is part of a pore-forming polymer because Calliditas only argued that the invention was not obvious over prior art based on the "weight percentage amounts of the water insoluble polymer (ethylcellulose) and pore-forming polymer (HPMC) . . . ." Joint Br. at 57 (citing Ex. 23 Oct. 27, 2023 Amendment, File History for U.S. 11,896,719 (ECF No. 80-1, 87) at 9). Defendants claim that lexicography requires that a patent have defined specific terms "with reasonable clarity, deliberateness, and precision," and argue that the specification is ambiguous as to this claim term. Joint Br. at 59–60.

"When a patentee defines a claim term, the patentee's definition governs,

even if it is contrary to the conventional meaning of the term." Honeywell Int'l, Inc. v. Universal Avionics Sys. Corp., 493 F.3d 1358, 1361 (Fed. Cir. 2007). A term can be defined in a "particular manner for purposes of a patent even without an explicit statement of redefinition." Id. at 1362 (internal citations omitted). The specification may also reveal an intentional disclaimer, or disavowal, of claim scope by the inventor. Phillips, 415 F.3d at 1316. "In that instance as well, the inventor has dictated the correct claim scope, and the inventor's intention, as expressed in the specification, is regarded as dispositive." Id. (citing SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1343–44 (Fed. Cir. 2001)).

The specification provides a definition for how the term "pore-forming polymer" is used within the context of the patent. See '719 Patent at 27:14–19. The definition in its entirety states that the term refers to "polymers which have a higher water solubility than the water-insoluble polymer and are, therefore, capable of dissolving first leaving pores in the coating, thus allowing a certain amount of water to penetrate towards the core."[3] Id. This definition does not require the inclusion of further water-soluble polymers, and thus is not in contrast with the

[3] Plaintiff omitted the phrase "thus allowing a certain amount of water to penetrate the core" from its proposed construction. See Joint Chart at A-5. The Court notes that this omitted phrase is included in the definition provided by the patent and, in construing the claim term as the patentee defined it, will incorporate this phrase into the construction.

specification language distinguishing further water-soluble polymers from pore-forming polymers. See id. at 28:27–35. In accordance with language defining the term in the specification, the Court concludes that the claim term "pore-forming polymer" means "polymers that have a higher water solubility than the water-insoluble polymer and are, therefore, capable of dissolving first leaving pores in the coating, thus allowing a certain amount of water to penetrate towards the core."

C. "about" or "about [value] wt. %"

Plaintiff asserts that the Asserted Patents include an express definition for the term "about" or "about [value] wt. %" and proposes construing the term as the express definition: "may vary by ±10%, even if such numbers are presented as percentages in the first place." Joint Br. at 73. Zydus' proposed construction is "[value] wt. % (±2 of the value)." Id. Following the claim construction hearing, the Parties filed a letter clarifying for the Court that the Parties seek construction of both "about [value] wt. %" and "about." Letter (Aug. 19, 2026) (D.I. 99). The Parties clarified that their proposed constructions "apply in the contexts of weight percentage and other recited values[.]" Id. at 1. Defendants specified that their proposals include construing "about [value] wt. %" as "[value] wt. % (±2% of the value)," and "about" as "±2% of the value." Id. at 2.

Plaintiff refers to the following specification language as an express definition of the disputed term:

> Wherever the word 'about' is employed herein in the context of amounts, for example absolute amounts, such as weights, volumes, sizes, diameters, etc., or relative amounts (e.g. percentages) of individual constituents in a composition or a component of a composition (including concentrations and ratios), timeframes, and parameters such as temperatures, etc., it will be appreciated that such variables are approximate and as such may vary by ±10%, for example ±5% and preferably ±2% (e.g. ±1%) from the actual numbers specified herein. This is the case even if such numbers are presented as percentages in the first place (for example 'about 10%' may mean ±10% about the number 10, which is anything between 9% and 11%).

'719 patent at 32:54–67; Joint Br. at 74. Plaintiff argues that construing the term as "may vary by ±10%, even if such numbers are presented as percentages in the first place" aligns with the specification and claims that Defendants' construction improperly limits the term. Joint Br. at 76. According to Plaintiff, Zydus requests that the Court violate claim differentiation principles by proposing the construction "[value] wt. % (±2% of the value)," which would render certain dependent claims superfluous. Id. Plaintiff claims that Claim 26 of the '719 Patent recites the claim term in conjunction with Defendants' proposed construction of "±2%," which demonstrates claim differentiation because it would be redundant for "about" to mean "±2%" in the claim's context. Id. at 77; see '719 Patent at 66:30–38.

Zydus claims that the prosecution history of the '719 Patent demonstrates that Calliditas relied on the importance of specific weight percentage amounts to overcome prior art. Joint Br. at 81. Defendants argue that by narrowing the claims during prosecution, Plaintiff cannot propose construing the term as broader than

previously argued before the USPTO. Id. at 82. Plaintiff contends that the specification's definition of the disputed term is clear and unambiguous, and the Court agrees. See Joint Br. at 84. The specification describes that variables "may vary by ±10%" and the inclusion of plus or minus demonstrates the "may" or possibility of variety. See '719 Patent at 32:54–67. Zydus fails to provide sufficient evidence of disavowal to support an argument to stray from the language provided by the patentee. The Court concludes that the claim term "about" or "about [value] wt. %" means "may vary by ±10%, even if such numbers are presented as percentages in the first place." Accordingly, the Court adopts Plaintiff's construction for the claim term "about" or "about [value] wt. %."

CONCLUSION

For the foregoing reasons, the Court construes the disputed claim terms in the Asserted Patents as follows:

1. "an extended release pharmaceutically-acceptable polymeric blend" means "a coating that extends the release of the pharmaceutical composition and includes pharmaceutically-acceptable polymers and optionally other excipients;"
2. "pore-forming polymer" means "polymers that have a higher water solubility than the water-insoluble polymer and are, therefore, capable of dissolving first leaving pores in the coating, thus allowing a certain amount

of water to penetrate towards the core;" and

3. "about" or "about [value] wt. %" means "may vary by ±10%, even if such numbers are presented as percentages in the first place."

IT IS SO ORDERED this 2nd day of November, 2026.

/s/ Jennifer Choe-Groves
Jennifer Choe-Groves
U.S. District Court Judge*

*Judge Jennifer Choe-Groves, of the United States Court of International Trade, sitting by designation.