

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ONYX THERAPEUTICS, INC.,

Plaintiff,

v.

AMNEAL PHARMACEUTICALS OF NEW
YORK, LLC and AMNEAL EU, LIMITED,

Defendants.

Civil Action No. 25-1107-GBW

MEMORANDUM OPINION

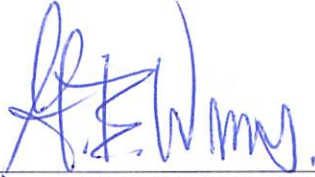
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Counsel for Defendants

October 6, 2026
Wilmington, Delaware


GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE

Before the Court is a single claim construction dispute. (D.I. 69). The Court has considered the parties' briefing. (D.I. 69). Upon consideration of the full record, the Court construes the disputed term as described below.

I. BACKGROUND

A. Plaintiff's New Drug KYPROLIS®

"On July 20, 2012, the FDA granted . . . approval to [Plaintiff] to market KYPROLIS® (carfilzomib) for injection to treat relapsed or refractory multiple myeloma, a type of cancer, and more specifically a type of hematopoietic cancer." (D.I. 2 ¶ 15). Plaintiff holds New Drug Application ("NDA") No. 202714 for KYPROLIS® for injection, and "is the authorized agent for matters related to NDA No. 202714 in the United States." (*Id.* ¶ 20). Plaintiff believes that KYPROLIS® for injection is "covered by one or more claims" of U.S. Patent No. 7,737,112 ("the '112 Patent"). (*Id.* ¶ 21). Therefore, Plaintiff listed the '112 Patent in the FDA's Publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book"). (*Id.*).

B. Procedural History

"On or About July 22, 2025, [Plaintiff] received a letter from [Defendants] dated July 21, 2025 ('the Notice Letter'), notifying [Plaintiff] that [Defendants] seek[] approval" to manufacture, use, sell, and offer for sale a generic carfilzomib product through Defendants' NDA No. 220712 ("Defendants' generic carfilzomib product"). (D.I. 2 ¶¶ 26, 34). "Included in NDA No. 220712 is a certification pursuant to 21 U.S.C. § 355(b)(2)(A)(iv) ('Paragraph IV Certification') that the '112 Patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use,

importation, sale, or offer for sale of” Defendants’ proposed generic carfilzomib product. (*Id.* ¶ 26).

On September 4, 2025, Plaintiff filed the instant lawsuit, alleging that Defendants’ generic carfilzomib product is “covered by at least Claims 1-9, 14, 18-24, and 29-31 of the ’112 Patent [(the ‘Asserted Claims’)], either literally or under the doctrine of equivalents.” (D.I. 2 ¶ 40). On November 6, 2025, Defendants filed their Answer, Affirmative Defenses, and Counterclaim, attaching as exhibits the Notice Letter and selected portions of Defendants’ NDA No. 220712. (D.I. 12). Defendants subsequently moved for Judgment on the Pleadings the same day. (D.I. 14). On February 3, 2026, the Court denied Defendants’ Motion for Judgment on the Pleadings. (D.I. 38). The parties have submitted their Joint Claim Construction Brief. (D.I. 69). The Court heard oral argument on claim construction on September 2, 2026. (D.I. 75).

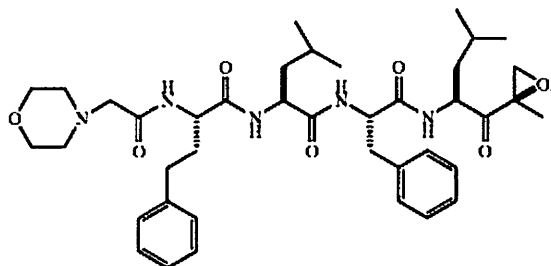
C. The ’112 Patent

The ’112 Patent is directed toward “[c]ompositions comprising one or more practically insoluble proteasome inhibitors and a cyclodextrin, particularly a substituted cyclodextrin, substantially increase the solubility of these proteasome inhibitors and facilitate their administration.” (’112 Patent at Abstract). The Complaint asserts that Defendants’ proposed generic carfilzomib product would infringe several of the ’112 Patent’s claims, three of which are independent claims. (D.I. 2 ¶ 40). The first independent claim asserted in the Complaint is Claim 1, which recites:

1. A pharmaceutical composition comprising a practically insoluble peptide epoxy ketone proteasome inhibitor or a pharmaceutically acceptable salt thereof and a substituted cyclodextrin selected from hydroxypropyl beta-cyclodextrin and sulfobutyl ether beta-cyclodextrin (SBECD).

('112 Patent at Claim 1). The second independent claim asserted in the Complaint is Claim 29, which recites:

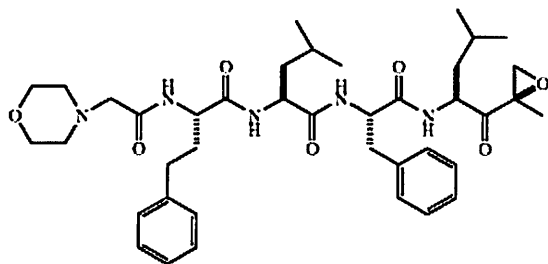
29. A pharmaceutical composition comprising a compound having a structure



or a pharmaceutically acceptable salt thereof, and a substituted cyclodextrin selected from hydroxypropyl beta-cyclodextrin and sulfobutyl ether beta-cyclodextrin (SBECD).

('112 Patent at Claim 29). The third (and final) independent claim asserted in the Complaint is Claim 31, which recites:

31. A pharmaceutical composition comprising a compound having a structure



or a pharmaceutically acceptable salt thereof, in an aqueous solution containing 10% (w/v) SBECD and 10 mM citric acid adjusted to pH 3.5.

('112 Patent at Claim 31).

II. LEGAL STANDARD

A. Claim Construction

“It is a ‘bedrock principle’ of patent law that ‘the claims of a patent define the invention to which the patentee is entitled the right to exclude.’” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312

(Fed. Cir. 2005) (en banc) (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)); see also *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989) (“A claim in a patent provides the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using, or selling the protected invention.”). “[T]here is no magic formula or catechism for conducting claim construction.” *Phillips*, 415 F.3d at 1324. The Court is free to attach the appropriate weight to appropriate sources “in light of the statutes and policies that inform patent law.” *Id.* The ultimate question of the proper construction of a patent is a question of law, although subsidiary fact-finding is sometimes necessary. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 326 (2015); see also *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 378, 388-91 (1996).

“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*, 415 F.3d at 1313). A person of ordinary skill in the art “is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification.” *Phillips*, 415 F.3d at 1313.

“When construing claim terms, [the court] first look[s] to, and primarily rel[ies] on, the intrinsic evidence, including the claims themselves, the specification, and the prosecution history of the patent, which is usually dispositive.” *Sunovion Pharms., Inc. v. Teva Pharms. USA, Inc.*, 731 F.3d 1271, 1276 (Fed. Cir. 2013). “Other claims of the patent in question, both asserted and unasserted, can . . . be valuable” in discerning the meaning of a disputed claim term, because “claim terms are normally used consistently throughout the patent” and so “the usage of a term in one claim can often illuminate the meaning of the same term in other claims.” *Phillips*, 415 F.3d

at 1314 (citations omitted). In addition, “[d]ifferences among claims can also be a useful guide in understanding the meaning of particular claim terms.” *Id.* (citing *Laitram Corp. v. Rexnord, Inc.*, 939 F.2d 1533, 1538 (Fed. Cir. 1991)). “For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim.” *Id.* at 1314-15 (citing *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 910 (Fed. Cir. 2004)).

In addition to the claims, the court should analyze the specification, which “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 (citing *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002)). “[E]ven 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) (quoting *Liebel-Flarsheim*, 358 F.3d at 906). Furthermore, the specification “is not a substitute for, nor can it be used to rewrite, the chosen claim language.” *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004).

The 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), *aff’d*, 517 U.S. 370 (1996) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 33 (1966)). The 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” *Phillips*, 415 F.3d at 1317 (citations omitted).

In some cases, the court “will need to look beyond the patent’s intrinsic evidence and to 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 (citing *Seymour v. Osborne*, 20 L.Ed. 33 (1871)). 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. Overall, while extrinsic evidence may be useful, it is “less significant than the intrinsic record in determining the legally operative meaning of claim language.” *Phillips*, 415 F.3d at 1317 (cleaned up).

III. AGREED-UPON TERMS

The parties submitted agreed-upon constructions for claim terms below.

Claim Term	Agreed-Upon Construction
“practically insoluble” (’112 Patent, claims 1-5, 10-14, 29-31)	“solubility of less than 0.1 mg/mL”
“buffer” (’112 Patent, claims 10-13)	“a substance that assists in regulating the pH of a composition”

“pharmaceutically acceptable” (’112 Patent, claims 1-5, 10-14, 29-31)	“within the scope of sound medical judgment, suitable for use in contact with the tissues of human beings and animals without excessive toxicity, irritation, allergic response, or other problem or complication, commensurate with a reasonable benefit/risk ratio”
“carrier” (’112 Patent, claim 14)	“material, composition, or vehicle, such as a liquid or solid filler, diluent, excipient, solvent or encapsulating material, that is compatible with the other ingredients of the formulation and not injurious to the patient”

(D.I. 69 at 1). The Court will adopt these agreed-upon constructions.

IV. DISPUTED TERM

A. “a substituted cyclodextrin selected from hydroxypropyl beta-cyclodextrin and sulfobutyl ether beta-cyclodextrin (SBECD)”

Disputed Term	Plaintiff’s Construction	Defendants’ Construction	The Court’s Construction
“a substituted cyclodextrin selected from hydroxypropyl beta-cyclodextrin and sulfobutyl ether beta-cyclodextrin (SBECD)” (’112 Patent, claims 1-5, 10-14, 29-30)	The term requires no construction. Should the Court construe the term, the term should be afforded its plain and ordinary meaning as understood by a person of ordinary skill in the art, which is: “hydroxypropyl betacyclodextrin (HPBCD) or sulfobutyl ether betacyclodextrin (SBECD)”	“either hydroxypropyl betacyclodextrin (HPBCD) or sulfobutyl ether betacyclodextrin (SBECD) only”	Plain and ordinary meaning, which is: “hydroxypropyl betacyclodextrin (HPBCD) or sulfobutyl ether betacyclodextrin (SBECD)”

The dispute before the Court is a narrow one. The parties dispute whether the claim term reciting “a substituted cyclodextrin selected from hydroxypropyl beta-cyclodextrin and sulfobutyl ether beta-cyclodextrin (SBECD)” (the “disputed claim term”), present in some Asserted Claims¹, should be construed as its plain and ordinary meaning or whether it should be construed to mean “either hydroxypropyl betacyclodextrin (HPBCD) or sulfobutyl ether betacyclodextrin (SBECD) **only**.” (D.I. 69 at 1 (emphasis added)). The only difference between the two parties’ proposed construction is the word “only.” (D.I. 69 at 1). For the reasons set forth below, the Court will construe “a substituted cyclodextrin selected from hydroxypropyl beta-cyclodextrin and sulfobutyl ether beta-cyclodextrin (SBECD)” according to its plain and ordinary meaning, which is: “hydroxypropyl betacyclodextrin (HPBCD) or sulfobutyl ether betacyclodextrin (SBECD).”

1. The Court Declines to Limit the Disputed Claim Term Based on Defenses to the Doctrine of Equivalents

As an initial matter, the Court finds that many of Defendants’ arguments in favor of their proposed construction concern potential defenses to Plaintiff’s assertion of infringement pursuant to the doctrine of equivalents. Although Defendants do not *explicitly* argue against the doctrine of equivalents, Defendants nonetheless proffer that the parties disagree on the scope of the disputed claim term. (D.I. 69 at 31). However, both parties’ proposed constructions appear to be identical in scope: one requires that the claimed “substituted cyclodextrin” to be selected from “hydroxypropyl betacyclodextrin (HPBCD) or sulfobutyl ether betacyclodextrin (SBECD),” and

¹ In the parties’ Joint Claim Construction brief, the parties state that the disputed claim term is present in Claim 31 of the ’112 Patent. (D.I. 69 at 1 (“a substituted cyclodextrin selected from hydroxypropyl beta-cyclodextrin and sulfobutyl ether beta-cyclodextrin (SBECD)” (’112 Patent, claims 1-5, 10-14, 29-31))). However, Claim 31 of the ’112 Patent does not contain the disputed claim term. (’112 Patent at Claim 31 (“A pharmaceutical composition comprising a compound having a structure . . . or a pharmaceutically acceptable salt thereof, in an aqueous solution containing 10% (w/v) SBECD and 10 mM citric acid adjusted to pH 3.5.”)).

the other requires that the claimed “substituted cyclodextrin” to be selected from “hydroxypropyl betacyclodextrin (HPBCD) or sulfobutyl ether betacyclodextrin (SBECD) only.” (D.I. 69 at 1). Plaintiff does not suggest that the scope of the claim language encompasses more than HPBCD or SBECD. (*Id.* at 23). In fact, Plaintiff concedes that the claim term “is clear and unambiguous on its face: it literally means HPBCD or SBCED.” (*Id.*). Thus, the parties agree that the disputed claim term, as properly construed, require that the claimed “substituted cyclodextrin” to be selected from either “hydroxypropyl betacyclodextrin (HPBCD) or sulfobutyl ether betacyclodextrin (SBECD)” exclusively.

Because both parties agree that the literal scope of the disputed claim term is confined to a “substituted cyclodextrin” selected from HPBCD or SBECD, Defendants’ assertion that the parties disagree on the scope of the disputed claim term must refer to the applicability of the doctrine of equivalents. However, the Federal Circuit has made clear that “[d]etermination of infringement under the doctrine of equivalents occurs *after* the claims have been construed as a matter of law.” *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1480 (Fed. Cir. 1998) (emphasis added). In determining whether a claim is infringed under the doctrine of equivalents, “[t]he trier of fact, applying the claims *as construed*, finds whether the accused device, element by element, is equivalent to that which has been patented.” *Id.* (emphasis added). At that stage, “[t]he court also determines whether there is any estoppel derived from the prosecution history that bars remedy even when there is technologic equivalency, for the patentee is precluded from reaching, under the doctrine of equivalents, subject matter that was disclaimed in order to obtain the patent.” *Id.*

At Oral Argument, Defendants asserted that their proposed construction of the disputed claim term was not about claim meaning or an attempt to foreclose application of the doctrine of

equivalents, but instead concerned disclaimer. (D.I. 78 at 9:24-25). Defendants, in contending that the disputed claim term presents an issue of disclaimer, rely on *Astrazeneca AB, Aktiebolaget Hassle, KBI-E, Inc. v. Mut. Pharm. Co.*, 384 F.3d 1333 (Fed. Cir. 2004). In *Astrazeneca*, the Federal Circuit found that the claim term “solubilizer” should not be afforded its plain and ordinary meaning, but instead should be limited to surface active agents. 384 F.3d at 1340. The Federal Circuit explained that the specification and prosecution history of the patent-in-suit showed a disavowal of the plain and ordinary meaning of the claim term “solubilizer,” and that the proper meaning of “solubilizer” as used in the patent-in-suit was only surface active agents. Furthermore, the Federal Circuit declined to remand *Astrazeneca* to the district court to address the doctrine of equivalents, as “[t]he specification’s clear disavowal of nonsurfactant solubilizers precludes the application of the doctrine of equivalents to recapture the disavowed solubilizers.” 384 F.3d at 1342.

Unlike *Astrazeneca*, the instant case does not present a difference in the scope of the disputed term. All parties agree that the scope of the disputed claim term encompasses either HPBCD or SBECD. Contrast *Astrazeneca*, 384 F.3d at 1335-40 (discussing whether the proper scope of “solubilizer” encompasses surfactants only, or surfactants, co-solvents, and complexation agents), with D.I. 69 at 6-7 (“Onyx’s proposed plain meaning construction appropriately recognizes that the literal scope of the claims encompasses a substituted cyclodextrin that can be either of the two recited types . . .”). Thus, it appears that Defendants’ reliance on *Astrazeneca* in support of their disclaimer argument is an attempt to foreclose the application of the doctrine of equivalents, which the Court will not do at the *Markman* stage. Instead, the Court will determine the literal scope of the disputed claim term. *O2 Micro Int’l Ltd. v. Beyond Innovation Tech. Co.*,

521 F.3d 1351, 1362 (Fed. Cir. 2008) (“When the parties present a fundamental dispute *regarding the scope of a claim term*, it is the court’s duty to resolve it.” (emphasis added)).

2. The Court Will Give the Disputed Claim Term its Plain and Ordinary Meaning

Plaintiff asserts that the disputed claim term should be given its plain and ordinary meaning. (D.I. 69 at 3). Plaintiff contends that its proposed construction “appropriately recognizes that the literal scope of the claims encompasses a substituted cyclodextrin that can be either of the two recited types” (*Id.* at 7). In Plaintiff’s view, adding the word “only” to the construction of the disputed claim term is unnecessary and inserts needless ambiguity into the construction of the disputed claim term. (*Id.*).

Defendants disagree. Defendants assert that Plaintiff “disclaimed non-cyclodextrin solubilizing agents, disparaged non-substituted cyclodextrins, and disavowed cyclodextrins other than HPBCD and SBECD.” (*Id.* at 16). In Defendants’ view, the claim language, specification, and prosecution history of the Asserted Patent all support including the word “only” in the construction of the disputed claim term. (*See id.* at 16-22).

The Court agrees with Plaintiff. “Claim terms are generally given their plain and ordinary meaning.” *Magēmā Tech. LLC v. Phillips* 66, 153 F.4th 1248, 1260 (Fed. Cir. 2025) (citing *Phillips*, 415 F.3d at 1313-14). None of Defendants’ arguments that the Court should stray from the plain and ordinary meaning of the disputed claim term are persuasive.

First, Defendants assert that the disputed claim term, which recites “a substituted cyclodextrin selected from hydroxypropyl beta-cyclodextrin and sulfobutyl ether beta-cyclodextrin (SBECD),” is a Markush group that requires the claimed substituted cyclodextrin to be selected from either HPBCD or SBECD only. The Court agrees. “Claims that set forth a list of alternatives from which a selection is to be made are typically referred to as Markush claims

...” MPEP ¶ 2173.05(H)(I) (9th ed. Rev. 8, Jan. 2024). Although the MPEP states that “[c]laim language defined by a Markush grouping requires selection from a closed group ‘consisting of’ the alternative members,” (MPEP ¶ 2117(I)), it goes on to explain that “[t]reatment of claims reciting alternatives is not governed by the particular format used” MPEP ¶ 2173.05(H)(I); *see also Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp.*, 831 F.3d 1350, 1357 n.2 (Fed. Cir. 2016) (“No precise linguistic formula is required to create a Markush claim.”). Importantly, the MPEP gives an example of a Markush claim that does not use the phrase “consisting of.”² MPEP ¶ 2173.05(H)(I) (“wherein the material is A, B, or C”).

However, as discussed *supra*, Plaintiff’s proposed construction does not include any substituted cyclodextrins not explicitly mentioned. (D.I. 69 at 1). The Court agrees with both parties that the literal meaning of the disputed claim term is limited to HPBCD and SBECD. Thus, inserting the word “only” into the proposed construction would be unnecessary. Plaintiff’s proposed construction of the disputed claim term, which is its plain and ordinary meaning, adequately limits the disputed claim term and is identical in scope to Defendants’ proposed construction. Thus, the Court need not construe the disputed claim term further than its plain and ordinary meaning.³ *Apple Inc. v. Masimo Corp.*, C.A. No. 22-1377-JLH, 2024 WL 4441741, at

² The Court notes that, even if the disputed claim term were not a Markush group, a POSA would be able to determine the disputed claim term: HPBCD and SBECD. *See Lexington Luminance LLC v. Amazon.com Inc.*, 601 F. App’x 963, 968-96 (Fed. Cir. 2015) (holding a claim term not indefinite and that intrinsic evidence properly informed the scope of the claim term when the disputed claim term used the phrase “comprising,” rather than “consisting of,” in listing alternatives from which a selection is made.).

³ The Court notes that the doctrine of equivalents is still available to Markush groups. *Amgen Inc. v. Aurobindo Pharma Ltd.*, C.A. No. 16-853-GMS, 2018 WL 1061369, at *4 (D. Del. Feb. 27, 2018) (“Thus, it appears that a patentee may still rely on the doctrine of equivalents to prove infringement of an element containing a closed Markush group.”), *rev’d on other grounds sub nom. Amgen Inc. v. Amneal Pharms. LLC*, 945 F.3d 1368 (Fed. Cir. 2020).

*1 (D. Del. Oct. 8, 2024) (“The Court only needs to construe a claim term if there is a dispute over its meaning, and it only needs to be construed to the extent necessary to resolve the dispute.”).

Second, Defendants contend that the specification supports the inclusion of the word “only” in the construction of the disputed claim term. Specifically, Defendants assert that, as of the alleged priority date of the Asserted Patent, “a POSA was aware of numerous techniques to improve the solubility of poorly aqueous drugs,” but that the Asserted Patent teaches that such approaches were not suitable for peptide epoxy ketones. (D.I. 69 at 17). According to Defendants, the specification taught that cyclodextrins, and particularly substituted cyclodextrins, did succeed in increasing the solubility of peptide epoxy ketones. (*Id.*). Defendants also contend that the specification of the Asserted Patent identifies HPBCD and SBECD as cyclodextrins “that are ‘particularly suitable’ for the invention.” (*Id.* at 18 (citation omitted)). Thus, in Defendants’ view, the disputed claim term is appropriately limited to HPBCD and SBECD only.

Importantly, however, Plaintiff’s proposed construction does not include any solubilizing agent other than HPBCD and SBECD. (D.I. 69 at 1); *see also Apple*, 2024 WL 4441741, at *1 (“The Court only needs to construe a claim term if there is a dispute over its meaning, and it only needs to be construed to the extent necessary to resolve the dispute.”). Thus, Defendants’ assertion that the specification precludes solubilizing agents other than HPBCD and SBECD appears to be in reference to any *equivalents* of HPBCD and SBECD, which the Court will not consider at the claim construction stage. *See supra* Section IV.A.1. Furthermore, the Court has previously found that the specification of the Asserted Patent does not preclude any theory of equivalence for HPBCD and SBECD. (D.I. 37 at 18-20).

In assessing whether the specification necessitates that the word “only” be included in the construction of the disputed claim term, the Court finds *Abraxis Bioscience, Inc. v. Mayne Pharma*

(USA) Inc., 467 F.3d 1370 (Fed. Cir. 2006) instructive. In *Abraxis*, the Federal Circuit rejected the district court’s construction of a claim term that recited a pharmaceutical composition that “comprises an amount of edetate [(“EDTA”)] sufficient to prevent a no more than 10-fold increase in growth” 467 F.3d at 1375. The district court had construed “edetate” to mean “EDTA as well as compounds structurally related to EDTA regardless of how they are synthesized.” *Id.* The Federal Circuit, however, held that the proper construction of “edetate” was “EDTA and derivatives of EDTA, such as salts, but not including structural analogs.” *Id.* at 1378. The Federal Circuit subsequently found infringement under the doctrine of equivalents. *Id.* at 1379.

The Court will take the same approach here that the Federal Circuit took in *Abraxis*. The Court will construe the disputed claim term according to its literal scope, and make a doctrine of equivalents determination at the appropriate time. Inserting the word “only” into the construction of the disputed claim term, particularly when the parties agree on the literal scope of said term, is unnecessary. Thus, the Court finds that the specification of the Asserted Patent does not warrant deviating from the plain and ordinary meaning of the disputed claim term.

Third, Defendants contend that the prosecution history of the Asserted Patent requires that the disputed claim term be limited to HBPCD and SBECD “only.” (D.I. 69 at 19-22). Specifically, Defendants point to a series of amendments made during prosecution of U.S. Patent Application No. 11/299,265 (“the ’265 Application”), which would ultimately become the ’112 Patent, that Defendants assert support construing the Asserted Claims to HBPCD and SBECD “only.” (*Id.* at 19-22). Importantly, in ruling on Defendants’ Motion for Judgment on the Pleadings (D.I. 14), the Court has already described the prosecution history that Defendants cite. (D.I. 37 at 11-12).

In the originally-filed ’265 Application, claim 1 contained a limitation requiring that the claimed “pharmaceutical composition” include “a cyclodextrin.” (D.I. 16, Ex. A at Claim 1). In

an Office Action dated May 19, 2008, the United States Patent and Trademark Office (“USPTO”) rejected the then-pending claim 1 of the ’265 Application under 35 U.S.C. § 103, citing to prior art that disclosed, among other things, cyclodextrins and their purported benefits in pharmaceutical compositions. (D.I. 16, Ex. B). Plaintiff responded to the May 19, 2008 Office Action on August 14, 2008, amending claim 1 of the ’265 Application, but keeping the “cyclodextrin” limitation unchanged. (D.I. 16, Ex. C). In a subsequent Office Action dated December 2, 2008, the USPTO again rejected claim 1 on obviousness grounds, citing to prior art that disclosed, among other things, cyclodextrins and their purported benefits in pharmaceutical compositions. (D.I. 16, Ex. D). Plaintiff responded to the December 2, 2008 Office Action on April 29, 2009, amending the “cyclodextrin” limitation of the then-pending claim 1 to require a “substituted cyclodextrin.” (D.I. 16, Ex. E, at Claim 1). The USPTO, in a subsequent Office Action dated July 17, 2009, again rejected claim 1, citing to prior art that showed the purported benefits of cyclodextrins, with the examiner appearing to find that requiring the cyclodextrin to be a “substituted cyclodextrin” does not materially limit that claim element. (D.I. 16, Ex. H, at 4 (“In response, the examiner would point out that claim 1 is drawn to a mixture of **any** epoxy ketone and **any** cyclodextrin.”)). In response to the July 17, 2009 Office Action, Plaintiff amended claim 1 of the ’265 Application to require that the substituted cyclodextrin be “selected from hydroxypropyl beta-cyclodextrin and sulfobutyl ether beta-cyclodextrin (SBECD),” which was the claim that ultimately issued. (D.I. 16, Ex. I at Claim 1).

“[E]xplicit statements made by a patent applicant during prosecution to distinguish a claimed invention over prior art may serve to narrow the scope of a claim.” *Spectrum Int’l, Inc. v. Sterilite Corp.*, 164 F.3d 1372, 1378 (Fed. Cir. 1998). However, Plaintiff’s proposed construction does not attempt to broaden the Asserted Claims to include other cyclodextrins, or even non-

cyclodextrins. (D.I. 69 at 25). Plaintiff *concedes* that its proposed construction is limited to HPBCD or SBECD. (*Id.*).

Defendants' cited authority is not persuasive. Defendants cite to *Rheox, Inc. v. Entact, Inc.*, 276 F.3d 1319 (Fed. Cir. 2002) and *CAE Screenplates Inc. v. Heinrich Fiedler GmbH & Co. KG*, 224 F.3d 1308 (Fed. Cir. 2000) to support their prosecution disclaimer argument. (D.I. 69 at 21). However, both *Rheox* and *Entact* concerned constructions. *Rheox*, 276 F.3d at 1326 (excluding "TSP or monocalcium orthophosphate" from the literal scope of the claims); *CAE*, 224 F.3d at 1328 (excluding certain embodiments from the literal scope of the claims based on prosecution history). Unlike the plaintiffs in *Rheox* and *CAE*, Plaintiff does not attempt to bring additional solubilizing agents other than HPBCD and SBECD into the literal scope of the claims. (D.I. 69 at 1). Thus, both *Rheox* and *CAE* are distinguishable.

There is no real dispute over the literal scope of the claim language, and the Court will not deviate from the claim term's plain and ordinary meaning. *Apple*, 2024 WL 4441741, at *1 ("The Court only needs to construe a claim term if there is a dispute over its meaning, and it only needs to be construed to the extent necessary to resolve the dispute."). Therefore, the Court will construe the disputed claim: "a substituted cyclodextrin selected from hydroxypropyl beta-cyclodextrin and sulfobutyl ether beta-cyclodextrin (SBECD)," according to its plain and ordinary meaning, which is "hydroxypropyl betacyclodextrin (HPBCD) or sulfobutyl ether betacyclodextrin (SBECD)."

V. CONCLUSION

The Court will adopt the parties' agreed-upon constructions and construe the disputed claim terms as described above. The Court will issue an Order consistent with this Memorandum Opinion.