

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

BAUSCH & LOMB INCORPORATED &	)	
PF CONSUMER HEALTHCARE 1 LLC,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civil Action No. 20-1463-GBW-CJB
	)	
SBH HOLDINGS LLC,	)	
	)	
Defendant.	)	

**REPORT AND RECOMMENDATION**

In this patent action filed by Plaintiffs Bausch & Lomb Incorporated and PF Consumer Healthcare 1 LLC (“Plaintiffs”) against Defendant SBH Holdings LLC (“SBH” or “Defendant”), Plaintiffs allege infringement of United States Patent Nos. 6,660,297 (the “’297 patent”) and 8,603,522 (the “’522 patent” and collectively with the ’297 patent, “the asserted patents”). Presently before the Court is the matter of claim construction. (D.I. 55; D.I. 56) The Court recommends that the District Court adopt the constructions set forth below.

**I. BACKGROUND**

The asserted patents relate to “an antioxidant and high-dosage zinc nutritional or dietary supplement composition that decreases visual acuity loss by reducing the risk of developing late stage or advanced age-related macular degeneration [(“AMD”)].” (’297 patent, col. 1:17-22)<sup>1</sup> The Court hereby incorporates by reference the portion of its December 29, 2023 Report and Recommendation (“December R&R”) in which it set out this case’s factual background. (D.I. 102 at 1-3) Further details regarding the asserted patents will be provided below in Section III.

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<sup>1</sup> The asserted patents appear on the docket in this action more than once. Further citations to the patents will simply be to their patent number. The Court will cite below only to the ’297 patent, unless otherwise noted.

On May 25, 2023, the parties filed their joint claim construction brief. (D.I. 79) The Court conducted a *Markman* hearing on September 26, 2023. (D.I. 97 (hereinafter, “Tr.”))<sup>2</sup>

## **II. STANDARD OF REVIEW**

The Court has often set out the relevant legal standards for claim construction, including in *Vytacera Bio, LLC v. CytomX Therapeutics, Inc.*, Civil Action No. 20-333-LPS-CJB, 2021 WL 4621866, at \*2-3 (D. Del. Oct. 7, 2021). The Court hereby incorporates by reference its discussion in *Vytacera Bio* of these legal standards and will follow them herein. To the extent that consideration of the disputed terms here necessitates discussion of other, related legal principles, the Court will address those principles in Section III below.

## **III. DISCUSSION**

The parties set out four terms or sets of terms for the Court’s review. The Court will take up the terms in the order in which they were argued.

### **A. “approximately” terms**

The claims of the asserted patents are directed to compositions as well as methods of manufacturing and administering compositions that contain “approximately” certain amounts of various ingredients—such as vitamin A in the form of beta-carotene, vitamin C, vitamin E, zinc, copper, lutein, zeaxanthine and/or lutein-zeaxanthine combination (the “approximately terms”). (See, e.g., '297 patent, reexamination certificate at col. 2:6-15, 49-59; '522 patent, cols. 9:58-67, 10:21-32, 10:40-51, 10:65-11:6) The parties address the construction of the approximately terms in two categories: (1) “approximately” with respect to the amounts of vitamin C, vitamin E, zinc, copper, lutein, zeaxanthine and lutein-zeaxanthine combination (i.e., all ingredients other

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<sup>2</sup> This case has been referred to the Court by United States District Judge Gregory B. Williams to resolve all pre-trial matters up to and including expert discovery matters, pursuant to 28 U.S.C. § 636(b). (D.I. 40)

than vitamin A in the form of beta-carotene); and (2) “approximately” with respect to the amounts of vitamin A in the form of beta-carotene. (D.I. 79 at 7-8) And so below, the Court will do the same.

**1. “approximately”: All Ingredients Other Than Vitamin A in the Form of Beta-Carotene**

The term “approximately” with respect to the amounts of vitamin C, vitamin E, zinc, copper, lutein and lutein-zeaxanthine combination is found in claims 19 and 31 of the '297 patent and claims 1, 8, 11 and 16 of the '522 patent. Exemplary claim 31 of the '297 patent recites:

**31.** A retina stabilizing composition comprising on a daily dosage basis:  
*approximately* 7 to 10 times the RDA of vitamin C;  
*approximately* 13 to 18 times the RDA of vitamin E;  
*approximately* 1 mg to 40 mg of lutein;  
*approximately* 0.04 mg to 40 mg of zeaxanthine;  
*approximately* 4 to 7 times the RDA of zinc; and  
 not less than 1.6 mg and not more than 2.4 mg copper as a suitable dosage form for the stabilization of visual acuity loss in persons with early age-related macular degeneration.

(’297 patent, reexamination certificate at col. 2:49-59 (certain emphasis omitted)) The parties’ competing proposed constructions for “approximately” are set out in the chart below:

<b>Term</b>	<b>Plaintiffs’ Proposed Construction</b>	<b>Defendant’s Proposed Construction</b>
“approximately” (with respect to the amounts of vitamin C, vitamin E, zinc, copper, lutein, zeaxanthine and lutein-zeaxanthine combination)	No construction necessary.  Plain and ordinary meaning which is, “reasonably close to.”	No latitude or deviation from numerical ranges stated in the claims. However, if any latitude in claimed amount ranges were permitted, it would be limited to a half integer variation in stated [recommended daily allowance, or] RDA multiples.
“approximately 1 mg to 40 mg of lutein; approximately	No construction necessary.	If claims valid, they require beta-carotene (or Reex.

0.04 mg to 40 mg of zeaxanthine”	Plain and ordinary meaning which is, “reasonably close to 1 mg to 40 mg of lutein; reasonably close to 0.04 mg to 40 mg of zeaxanthine”	claims are broader than issued '297 patent claims). Total replacement of beta-carotene by lutein/zeaxanthine not a possible interpretation of these claims.
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(D.I. 79 at 8 (emphasis omitted)) The parties’ primary dispute with respect to “approximately” is whether the term should be given its plain and ordinary meaning, which is “reasonably close to” (Plaintiffs’ position), or whether the word “approximately” must be limited, at most, to a half-integer variation from those limits (Defendant’s position). (*Id.* at 8, 17-18, 29; Tr. at 13-14)<sup>3</sup>

For the reasons that follow, the Court agrees with Plaintiffs.

In support of its position, Defendant asserts that prosecution history disclaimer<sup>4</sup> limits the construction of the “approximately” terms. It says this is so because during the prosecutions of

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<sup>3</sup> In its briefing, Defendant also asserted that the claims could be construed such that Plaintiffs would be “entitled no latitude beyond the actual range stated in each of the claims”—meaning that the Court should “ignor[e] the word ‘approximately[.]’” (D.I. 79 at 12) However, during the *Markman* hearing, Defendant ultimately conceded that *some* latitude beyond the actual range stated in each of the claims would be permissible. (Tr. at 51-52) This was a wise concession; as the Court has previously noted, courts have generally rejected constructions that would render terms of degree (such as “approximately” or “about”) meaningless. *See Integra LifeScis. Corp. v. HyperBranch Med. Tech., Inc.*, Civil Action No. 15-819-LPS-CJB, 2017 WL 3731244, \*6 (D. Del. Aug. 30, 2017) (citing cases); *see also Anchor Wall Sys., Inc. v. Rockwood Retaining Walls, Inc.*, 340 F.3d 1298, 1310-11 (Fed. Cir. 2003) (“[W]ords of approximation . . . are descriptive terms commonly used in patent claims to avoid a strict numerical boundary to the specified parameter.”) (internal quotation marks and citation omitted).

<sup>4</sup> Defendant’s briefing actually refers to the concept of “file history estoppel” instead of prosecution history disclaimer. (*See, e.g.*, D.I. 79 at 13) However, the doctrine of file history estoppel (more commonly known as prosecution history estoppel) applies as part of an infringement analysis under the doctrine of equivalents; it is the doctrine of prosecution history disclaimer that affects claim construction, and it applies where a patentee’s assertions during the prosecution proceedings narrow the literal scope of an otherwise broader claim limitation. *See, e.g., Trading Techs. Int’l, Inc. v. Open E Cry, LLC*, 728 F.3d 1309, 1322 (Fed. Cir. 2013); *Abiomed, Inc. v. Maquet Cardiovascular LLC*, 566 F. Supp. 3d 59, 70 (D. Mass. 2021); *Almirall, LLC v. Torrent Pharms., Ltd.*, 548 F. Supp. 3d 443, 453 (D. Del. 2021); *see also TD Pro. Servs.*

the asserted patents, “Plaintiff[s] repeatedly argued the criticality of the specific formulas in the claims[.]” (D.I. 79 at 13-14; *see also id.* at 26-28)<sup>5</sup> For example, Defendant points out that:

- Early in the prosecution of the '297 patent, in an October 15, 2002 response to a rejection, the patentee sought to distinguish its claimed formula from United States Patent No. 6,103,756 (“Gorsek”).<sup>6</sup> In doing so, the patentee noted that its invention “is directed to a[] unique . . . formulation” that “differs significantly” from Gorsek. (D.I. 80, Defendant’s Exhibits at ex. 14 at 99) The patentee explained that its formulation comprised the claimed ingredients, and it recited the claimed numerical ranges in bold, largely without reciting “approximately”: i.e., “[t]he subject formulation . . . comprises **6 to 10** times the RDA of vitamin A, **7 to 10** times the RDA of vitamin C, **13 to 18** times the RDA of vitamin E, **4 to 7** times the RDA of zinc and approximately the RDA of copper.” (*Id.* (emphasis in original)) The patentee then stated that the subject formulation as compared to Gorsek comprises “approximately a 2 to 3 times **greater** amount of vitamin A, approximately **half** the amount of vitamin C, approximately within the **same** range of vitamin E, approximately 2 to 3 times **greater** amount of zinc and approximately **double** the amount of copper.” (*Id.* at 99-100 (emphasis in original)) In sum, according to the patentee, Gorsek “teaches away from the importance of the subject five ingredients and the essential formulation amounts disclosed and claimed in the subject application.” (*Id.* at 100) The patentee then went on to make a

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*v. Truyo Inc.*, No. CV-22-00018-PHX-MTL, 2023 WL 1767203, at \*17 n.16 (D. Ariz. Feb. 3, 2023) (“Although the parties argue that the similar concept of prosecution history estoppel is at issue here, the Court notes that the proper analysis at the claim construction stage is under the doctrine of prosecution disclaimer.”).

<sup>5</sup> Defendant notes that while its argument applies to all ingredients, it is particularly concerned with the quantity of vitamin C used in the claimed invention. (D.I. 79 at 12-13) This is because its formula allegedly contains a vitamin C content of 750 mg, which is 12.5 times the RDA—whereas the claims at issue require approximately 7 to 10 times the RDA of vitamin C. (*Id.* at 17)

<sup>6</sup> Gorsek taught a formula for treating macular degeneration that also included as essential ingredients vitamin C, vitamin E, vitamin A, copper and zinc (as well as some additional vitamins and minerals). (D.I. 80, Defendant’s Exhibits at ex. 14 at 99) Gorsek’s formulation recited 3.5 times the % Daily Value (or “%DV”) of vitamin A, 16.7 times the %DV of vitamin C, 17 times the %DV of vitamin E, 0.5 times the %DV of copper and 1.6 times the %DV of zinc. (*Id.*)

similar argument to distinguish its claims from United States Patent No. 5,075,116 (“LaHaye”), again emphasizing the ranges of its “unique” formulation in bold without using “approximately.” (*Id.* at 100-01) The patentee also asserted that the subject formulation “differs significantly” from the formulation claimed in LaHaye, in that the subject formulation as compared to LaHaye comprised approximately “**3 to 5 times less** vitamin C, approximately **6 to 9 times more** vitamin E, approximately within the **same range** of zinc and approximately **half** the amount of copper.” (*Id.* at 101-02 (emphasis in original))

- In March 11, 2003 remarks, the patentee again argued that the claimed invention “comprises **6 to 10** times the RDA of vitamin A as beta carotene, **7 to 10** times the RDA of vitamin C, **13 to 18** times the RDA of vitamin E, **4 to 7** times the RDA of zinc and approximately the RDA of copper” and that Gorsek and LaHaye teach away from the invention. (*Id.* at ex. 15 at 105-08 (emphasis in original))
- In remarks on May 30, 2003, June 2, 2003 and July 30, 2003, the patentee repeated these arguments that its “unique” formulation, including the bolded numerical ranges of ingredients, was distinguishable from the prior art including Gorsek—and did so without using the word “approximately” to describe these ranges. The patentee noted that “Gorsek does not teach the present invention or the surprising beneficial effects achieved by the *specific formulation* of vitamin A as beta carotene, vitamin C, vitamin E, zinc and copper of the present invention.” (*Id.* at ex. 16 at 113-17 (emphasis added); *id.* at ex. 17 at 122-26 (emphasis added); *id.* at ex. 10 at 72-76 (emphasis added))
- The Examiner’s August 26, 2003 statement of reasons for allowance provided that the prior art failed to teach “a composition that contains the recited five essential components, vitamins A, C, E, zinc and copper *in their recited concentrations* on a daily dosage basis wherein the synergism between the 5 components provides a beneficial effect for treating macular degeneration. The prior art did not show this particular combination in these[] *particular concentrations* on a daily basis to have a synergistic effect on treating macular degeneration.” (*Id.* at ex. 18 at 131 (emphasis added))

(D.I. 79 at 14-17) Defendant asserts that in light of Plaintiffs' "repeated emphatic arguments that its formula was unique and specific, with repeated emphasis on the specific numerical ranges as distinct from the prior art[.]" Plaintiffs are "absolutely preclude[d] . . . from now stating, in this litigation, that [they are] entitled to a significant range of equivalents." (*Id.* at 17; *see also id.* at 28-29; Tr. at 53-54)

As for Defendant's proposal that any deviation from the claimed numerical ranges should be limited to a half integer, there it relies on the patentee's statements during the '297 patent's reexamination proceedings. (D.I. 79 at 17-18, 30-31; Tr. at 44-45) During those proceedings, the third party requester argued that "approximately" should be ignored when it comes to the numerical ranges recited for vitamin C, vitamin E and zinc, but should be relied upon to extend the range of vitamin A. (D.I. 80, Defendant's Exhibits at ex. 20 at 149) In support, the third party contended that during the original prosecution, the patentee "had repeatedly characterized the range of the amount of each ingredient" without reference to the term "approximately." (*Id.* at 150 (internal quotation marks and citation omitted)) In response, the patentee asserted that "approximately" should be construed "to extend the recited range to at least the next half integer" (while also noting that the term "would not extend to the next adjacent *whole* integer"). (*Id.* at 149-50 (emphasis added))

As an initial matter, the Court disagrees with Defendant's position that Plaintiffs disclaimed the plain and ordinary meaning of "approximately" during prosecution of the '297 patent. The United States Court of Appeals for the Federal Circuit has explained that "because the prosecution history represents an ongoing negotiation between the [United States Patent Office ('PTO')] and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Phillips*

*v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005). In order for a statement to constitute prosecution history disclaimer, the statement must amount to a “*clear and unmistakable*” disclaimer. *Aylus Networks, Inc. v. Apple Inc.*, 856 F.3d 1353, 1359 (Fed. Cir. 2017) (internal quotation marks and citations omitted, emphasis added). The Federal Circuit has explained that “when a prosecution argument is subject to more than one reasonable interpretation, it cannot rise to the level of a clear and unmistakable disclaimer.” *Id.* at 1363 (internal quotation marks and citation omitted).

Under the circumstances here, the patentee’s statements referenced above—i.e., its statements that the claimed formulation comprises the claimed numerical ranges (without always using the word “approximately” when saying so)—does not amount to a clear and unmistakable statement that the claims cannot cover approximation in those ranges. (*See* D.I. 79 at 20-24) This is so for three reasons.

First, in the prosecution statements at issue, the patentee was asserting that the claimed amounts of the relevant ingredients differed *significantly* in nearly all cases from those in references like Gorsek and LaHaye. In other words, as to nearly all relevant ingredients at issue, it is not as if the ingredient amounts claimed in Gorsek or LaHaye came *very close* to the claimed ranges in the '297 patent—such that the patentee would have needed to distinguish its own claimed ranges by repeatedly emphasizing the specific nature of the claimed numerical boundaries. (*See* Tr. at 40, 65) To take just one example, when the patentee was comparing the claimed amounts of vitamin C in its patent and in Gorsek, the claimed range in the '297 patent was 7 to 10 times the RDA, while the corresponding claimed vitamin C range in Gorsek was almost two times larger (i.e., 16.7 times the %DV). (D.I. 80, Defendant’s Exhibits at ex. 14 at 99) If instead Gorsek had claimed 10.1 times the RDA of vitamin C (or something close to it),



then perhaps one might think that the patentee would have needed to note the *precise* boundaries of its claimed ranges (including its upper end of 10 times the RDA) in distinguishing the reference. But that is not what happened here. (Tr. at 40-41, 54-55) Thus, the patentee's failure to use "approximately" at various points cannot be read to be clearly and unmistakably disclaiming the plain and ordinary meaning of "approximately." *See, e.g., Cohesive Techs., Inc. v. Waters Corp.*, 543 F.3d 1351, 1370 (Fed. Cir. 2008) (rejecting the defendant's argument that the claim term "greater than about 30  $\mu\text{m}$ " should be construed to mean "greater than 30  $\mu\text{m}$ " in light of "various statements in the prosecution history that refer to 30  $\mu\text{m}$  particles" without the modifier "about," where "the word 'about' appears in each of the claims" and "[s]imply using the phrase '30  $\mu\text{m}$  particles' without the qualifier 'about' during prosecution is not such a clear and unmistakable disavowal"); *Amgen Inc. v. Mylan Inc.*, 2:17-cv-01235, 2018 WL 6061213, at \*24 (W.D. Pa. Nov. 20, 2018) ("To secure the issuance of that claim, the patentee would have only needed to surrender concentrations pertaining to those salt pairs. The Court will not extend the scope of the disavowal beyond what was surrendered in order to secure the patent.").

Second, at certain points during prosecution, the patentee *did* make clear that the claimed amounts were approximations. For example, in its October 15, 2002 remarks, immediately after noting that the claimed formulation comprises numerical ranges of the claimed ingredients without using "approximately," the patentee then turned to Gorsek. (D.I. 80, Defendant's Exhibits at ex. 14 at 99) There, it noted that as compared to Gorsek, the claimed formulation comprises "*approximately* a 2 to 3 times greater amount of vitamin A, *approximately* half the amount of vitamin C, *approximately* within the same range of vitamin E, *approximately* 2 to 3

times greater amount of zinc and *approximately* double the amount of copper.”<sup>7</sup> (*Id.* at 99-100 (certain emphasis omitted and certain emphasis added)); *see also, e.g., id.*, ex. 16 at 116 (the patentee noting in June 2, 2003 remarks that its invention “requires *approximately* 6 to 10 times . . . the RDA of vitamin A”) (emphasis added); *id.*, ex. 17 at 125 (same in the May 30, 2003 remarks))

Third, it is also notable that during the reexamination proceedings, the Examiner concluded that in the original prosecution the patentee did not “clearly and unambiguously disclaim[] or disavow[] any interpretation of the term ‘approximately’ in order to distinguish the recited ranges of the claimed components from the ranges [in] the prior art.” (D.I. 54, ex. E1 at 8) The Examiner’s view here, of course, is not binding on the Court. But it is noteworthy that this knowledgeable source, looking at the same prosecution history as the Court does now, found nothing clear or unmistakable about the patentee’s wording in this regard.

Nor does the Court agree with Defendant that “approximately” must be construed to limit any deviation from the claimed ranges to “a half integer variation in stated RDA multiples”—in light of the patentee’s statements during the '297 patent reexamination proceedings. (D.I. 79 at 25-26) Importantly, in the reexamination, the Examiner rejected the argument that the patentee was making with those statements. Instead, the Examiner concluded that the term “approximately” should be interpreted more broadly than the patentee suggested, in line with the term’s ordinary and customary meaning: “comes near” or “nearly exact.” (D.I. 54, ex. E1 at 8-10) Courts have refused to find prosecution history disclaimer where the alleged disclaimer was not accepted by the PTO. *See, e.g., Galderma Lab’ys, L.P. v. Amneal Pharms. LLC*, 806 F.

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<sup>7</sup> In Gorsek, the relevant claim recites ranges of ingredients without the use of “approximately.” (United States Patent No. 6,103,756, col. 4:8-16)

App’x 1007, 1010-11 (Fed. Cir. 2020) (“While clear and limiting statements made by the patent owner can give rise to disclaimer, they do not in this case where those statements were clearly and expressly rejected by the Patent Office.”); *see also Zoho Corp. v. Sentius Int’l, LLC*, Case No. 4:19-cv-0001-YGR, 2020 WL 3128910, at \*11 (N.D. Cal. June 12, 2020) (citing cases); *Vertical Tank, Inc. v. BakerCorp*, Case No. 1:18-CV-00145-LJO-JLT, 2019 WL 2207668, at \*11 (E.D. Cal. May 22, 2019) (citing cases); *see also* (Tr. at 48-49).<sup>8</sup> Indeed, in another case involving the same patents-in-suit that Plaintiffs filed against a third party, the United States District Court for the Western District of New York (the “*Vitamin Health Court*”) was presented with this same argument (i.e., that the patentee narrowed the meaning of “approximately” during the reexamination proceedings by asserting that it would not extend to the next adjacent whole integer, and the term should instead be construed to extend the recited range to at least the next half integer). The *Vitamin Health Court* likewise concluded that “because Bausch and Lomb’s purported disclaimer was not accepted, and indeed was rejected by the patent office, there can be no finding that the disclaimer was made for the purpose of obtaining the '297 patent.” *Bausch & Lomb Inc. v. Vitamin Health, Inc.*, 13-CV-6498T, 2015 WL 13574354, at \*7 (W.D.N.Y. Jan. 15, 2015) (citing cases).

For these reasons, Defendant’s arguments that “approximately” should be limited in the manner it suggests are not persuasive. For their part, Plaintiffs propose that the term either not be construed or be construed in accordance with the plain and ordinary meaning of

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<sup>8</sup> This makes sense, in that “rejected arguments do not implicate the policies served by prosecution disclaimer: they pose no risk that claims will be construed one way to obtain allowance and another for purposes of infringement, and the PTO’s rejection defeats any reasonable reliance on the statements by competitors.” *Droplets, Inc. v. Yahoo! Inc.*, Case No. 12-cv-03733-JST, 2021 WL 9038501, at \*7 (N.D. Cal. July 2, 2021).

“approximately,” which is “reasonably close to.” (D.I. 79 at 8-9); *see also, e.g., SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004) (claim terms are to be given their ordinary and accustomed meaning unless the patentee redefined the term or otherwise disavowed claim scope). The *Vitamin Health* Court construed “approximately” in this way, citing in support to a dictionary definition of “approximately.” *Bausch & Lomb Inc.*, 2015 WL 13574354, at \*6. Defendant does not seem to dispute that the plain and ordinary meaning of “approximately” is “reasonably close to.” (D.I. 79 at 6, 29-30)<sup>9</sup>

Therefore, the Court recommends that “approximately” with respect to the amounts of vitamin C, vitamin E, zinc, copper, lutein, zeaxanthine and lutein-zeaxanthine combination be construed to mean “reasonably close to.”<sup>10</sup>

## 2. “approximately”: Vitamin A in the Form of Beta-Carotene

Claim 19 of the '297 patent and claim 11 of the '522 patent are directed to a composition and method of administering a composition that includes, *inter alia*, “approximately 6 to 10 times the RDA of vitamin A in the form of beta-carotene[.]” ('297 patent, reexamination certificate at col. 2:6-14; '522 patent, col. 10:40-51) Plaintiffs treat this term slightly differently than the approximately term above, because this one was specifically addressed in the context of the '297 patent reexamination proceedings. (D.I. 79 at 8) The parties’ competing constructions are set out below:

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<sup>9</sup> Plaintiffs do not see a real distinction between “reasonably close to” and the Examiner’s construction for “approximately” (“comes near” or “nearly exact”). (Tr. at 14-15)

<sup>10</sup> As seen in the chart above, Defendant also identified the phrase “approximately 1 mg to 40 mg of lutein; approximately 0.04 mg to 40 mg of zeaxanthine” as one requiring construction, but it offers no construction for this term. Instead, Defendant asserts that if the claims containing this phrase are valid, they require beta-carotene. (*See* D.I. 79 at 8, 10) Defendant makes the same argument with respect to subsequent claim terms, and the Court will take it up there. (*See* Tr. at 60-61)

<b>Term</b>	<b>Plaintiffs' Proposed Construction</b>	<b>Defendant's Proposed Construction</b>
"approximately" (with respect to the amounts of vitamin A in the form of beta-carotene)	"an amount of Vitamin A in the form of beta-carotene that comes reasonably close to 6 to 10 times the RDA for vitamin A, but not less than 5 times the RDA for Vitamin A"	No latitude or deviation from numerical ranges stated in the claims. However, if any latitude in claimed amount ranges were permitted, it would be limited to a half integer variation in stated RDA multiples.

(*Id.* at 11) Plaintiffs point out that during the reexamination proceedings, the Examiner, citing to relevant evidence in support, interpreted this term to embrace a lower limit of 5 times the RDA of vitamin A (which is 25,000 IU).<sup>11</sup> (D.I. 54, ex. E1 at 8, 20-22; *id.*, ex. E3 at 3-4; *id.*, ex. E4 at 11; *id.*, ex. E5 at 8; *id.*, ex. E6 at 10-11; Tr. at 38, 59) Thus, they propose that the term be construed in accordance with its plain and ordinary meaning (i.e., "reasonably close to"), while also including this lower limit. (D.I. 79 at 11-12, 24) Defendant, for its part, makes no unique or specific argument with respect to the term. Instead it simply asserts that all approximately terms should be narrowed, such that any deviation from the claimed ranges would be limited to a half integer variation. (*See id.* at 24)

In the absence of any new contrary argument from Defendant, and for the reasons expressed above regarding the use of the term "approximately," the Court recommends that "approximately" with regard to the amounts of vitamin A in the form of beta-carotene be construed to mean "an amount of vitamin A in the form of beta-carotene that comes reasonably

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<sup>11</sup> The '297 patent specification teaches that the RDA of vitamin A is 5,000 IU, so 5 times the RDA of vitamin A is 25,000 IU. ('297 patent, col. 6:13-14)

close to 6 to 10 times the RDA for vitamin A, but not less than 5 times the RDA for vitamin A.”<sup>12</sup>

**B. “0.04 mg to 40 mg lutein-zeaxanthine combination”**

The next disputed term, “0.04 mg to 40 mg lutein-zeaxanthine combination,” appears in claims 1 and 8 of the '522 patent. Exemplary claim 1 recites:

1. A method for stabilizing visual acuity loss in persons with early age-related macular degeneration comprising:  
administering a daily dosage of not less than approximately 420 mg and not more than approximately 600 mg vitamin C, not less than approximately 400 IU and not more than approximately 540 IU vitamin E, *approximately 0.04 mg to 40 mg of lutein-zeaxanthine combination*, not less than approximately 60 mg and not more than approximately 100 mg zinc and at least 1.6 mg and not more than approximately 2.4 mg copper.

('522 patent, col. 9:58-67 (emphasis added)) The parties propose the following constructions:

<b>Term</b>	<b>Plaintiffs’ Proposed Construction</b>	<b>Defendant’s Proposed Construction</b>
“0.04 mg to 40 mg lutein-zeaxanthine combination”	“0.04 mg to 40 mg lutein-zeaxanthine achieved deliberately because of normal composition or through raw material contamination”	Claims require beta-carotene. Claims require vitamin A or a precursor to vitamin A.

(D.I. 79 at 32) While Defendant is the party that identified this term for construction, Defendant did not actually propose a construction for the term. (*Id.* at 2, 32-33; Tr. at 67) Instead, Defendant argues that the claims at issue require beta-carotene—even though these claims do not, on their face, include beta-carotene as a required aspect of the methods. (D.I. 79 at 33; Tr. at 69-70) In its briefing on this term, the whole of Defendant’s argument was: “[t]his term is

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<sup>12</sup> The *Vitamin Health* Court also construed the term to include this lower limit, in light of the Examiner’s interpretation of the term during the reexamination proceedings. *Bausch & Lomb Inc.*, 2015 WL 13574354, at \*7.

effectively dealt with above, regarding beta-carotene as required, and in the discussion of ‘approximately.’ Because beta-carotene is required in all claims of the '297 patent, no further construction of this term is necessary.” (D.I. 79 at 33)

As we will get to in a moment below regarding the next term, there Defendant is making an argument that certain claims require the inclusion of beta-carotene. But at the *Markman* hearing, the Court explained to Defendant’s counsel that it did not understand exactly how that beta-carotene argument would apply to claims 1 and 8 of the '522 patent (which are at issue here as to this term). (Tr. at 70-72) Defendant’s counsel’s explanation did not make things any clearer for the Court. (*Id.*) In any event, Defendant’s counsel at least confirmed that whatever argument Defendant is making here rises and falls with the beta-carotene argument it makes as to the next term addressed below. And as the Court will explain below, it does not agree with Defendant’s argument in that regard. Thus, as to this term, the Court will not adopt Defendant’s proposed construction.

The Court instead recommends that Plaintiffs’ proposal be adopted. The specification supports it, teaching that “[l]utein-zeaxanthine raw material combinations achieved deliberately, because of normal composition, or through raw material contamination may likewise be added to the subject composition as desired.” ('522 patent, col. 8:15-18 (*cited in* D.I. 79 at 32))

**C. “vitamin A in the form of beta-carotene, substituted or supplemented with lutein, zeaxanthine or a raw material combination thereof”**

The next disputed term, “vitamin A in the form of beta-carotene, substituted or supplemented with lutein, zeaxanthine or a raw material combination thereof[,]” (the “substituted or supplemented with” term) appears in claim 19 of the '297 patent and claim 11 of the '522 patent. Exemplary claim 19 of the '297 patent recites:

**19.** A composition comprising on a daily dosage basis:

approximately 7 to 10 times the RDA of vitamin C;  
 approximately 13 to 18 times the RDA of vitamin E;  
 approximately 6 to 10 times the RDA of *vitamin A in the form of beta-carotene, substituted or supplemented with lutein, zeaxanthine or a raw material combination thereof*;  
 approximately 4 to 7 times the RDA of zinc; and  
 at least 1.6 mg [of copper] and not more than approximately 2.4 mg copper into a suitable dosage form.

(’297 patent, reexamination certificate at col. 2:6-14 (certain emphasis omitted, certain emphasis added)) The parties’ positions regarding this term are set out in the chart below:

<b>Term</b>	<b>Plaintiffs’ Proposed Construction</b>	<b>Defendant’s Proposed Construction</b>
“vitamin A in the form of beta-carotene, substituted or supplemented with lutein, zeaxanthine or a raw material combination thereof”	No construction necessary.  Plain and ordinary meaning which is, “lutein, zeaxanthine, or a raw material combination thereof, may be used instead of, or in addition to, vitamin A in the form of beta-carotene”	Claims require beta-carotene. Claims require vitamin A or a precursor of vitamin A. Total replacement of beta-carotene by lutein/zeaxanthine not a possible interpretation of this term.

(D.I. 79 at 34) The crux of the dispute with respect to this term is really over the meaning of the word “substituted.” Plaintiffs assert that “substituted” means that vitamin A in the form of beta-carotene (i.e., “beta-carotene”) can be *completely replaced* by lutein, zeaxanthine or a raw material combination thereof, while Defendant argues that “substituted” instead means that beta-carotene can only be *substituted in part* with lutein, zeaxanthine or a raw material combination thereof—i.e., that the beta-carotene cannot be completely replaced. (*Id.* at 35, 38, 47, 50; Tr. at 88) For the reasons discussed below, the Court sides with Plaintiffs.

First, and importantly, the plain language of the claims aligns with Plaintiffs’ position. The claims use the phrase “substituted *or* supplemented with,” which tells us that “substituted” and “supplemented with” are two different choices. The parties agree that “supplemented with” means that lutein, zeaxanthine or a combination thereof can be *added with* the beta-carotene in



the claimed composition. (D.I. 79 at 35; Tr. at 88) And the plain meaning of “substitute”—which has to mean something different from “supplemented with”—is “replace (a person or thing) with another[.]” (D.I. 80, Plaintiffs’ Exhibits at ex. C at 1390 (*cited in* D.I. 79 at 36)) The claims do not say “substituted in part”—instead, they recite “substituted,” full stop, which requires complete replacement. (D.I. 79 at 36, 47)<sup>13</sup> Defendant’s contrary view—that “[t]he only way to make sense of the expression ‘beta-carotene, substituted or supplemented with . . .’ is to interpret this as meaning lutein and/or zeaxanthine, in some desired amount, can be added to the required amount of beta carotene[.]” (*id.* at 45)—would essentially read “substituted” out of the claims.

The specification also supports Plaintiffs’ position. (*Id.* at 35-36, 47; Tr. at 75-76) It teaches that for each of lutein, zeaxanthine and lutein-zeaxanthine, each tablet of a four-tablet-per-day dosage regime could provide approximately a range of each ingredient, “depending upon whether [lutein, zeaxanthine or lutein-zeaxanthine] is used to supplement or substitute beta-carotene [and/or zeaxanthine or lutein][.]” (‘297 patent, cols. 7:55-8:25) It uses the same language as the claims, and it does not suggest that what is *really* meant by this phraseology is that lutein, zeaxanthine or lutein-zeaxanthine can only be used to substitute *in part* beta-carotene (or that at least some amount of beta-carotene *must always be* included in the composition).

Defendant advances four arguments in support of its position. None are compelling.

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<sup>13</sup> The Court notes that the *Vitamin Health* Court construed this claim term in line with the above-referenced meaning of “substitute.” (*See* D.I. 79 at 36) There, the defendant contended that the claim term was indefinite (or alternatively that, if beta-carotene was not present in the composition, the term required that certain amounts of lutein, zeaxanthine or a combination of lutein and zeaxanthine be present). *Bausch & Lomb Inc.*, 2015 WL 13574354, at \*9. The *Vitamin Health* Court concluded that “where the claim discloses a first ingredient that may be substituted or supplemented with an alternative ingredient or combination of ingredients, the term ‘supplemented or substituted with’ means that the alternative ingredient, or ingredients, may be used *instead of*, or in addition to, the first ingredient.” *Id.* (emphasis added).

Defendant's first (and primary) argument is based on the originally drafted claims of Plaintiffs' applications. The argument, which takes some time to explain, goes as follows: (1) all of the independent claims of the three relevant patent applications expressly required the use of beta-carotene; (2) the "substituted or supplemented with" claim term was present only in several dependent claims in those applications; (3) the law requires a dependent claim to incorporate all limitations of an independent claim from which it depends; (4) therefore all of these originally-drafted claims, including the dependent claims reciting the "substituted or supplemented with" language, had to have required the use of beta-carotene in some amount; (5) although the "substituted or supplemented with" claim language was later moved from the dependent claims into certain independent claims in the issued patents, the meaning of "substituted or supplemented with" "was established with the original claims, the intent of the drafter being clear[;]" and (6) therefore all claims, including the independent claims now reciting the "substituted or supplemented with" language, require beta-carotene in some amount. (D.I. 79 at 37-38 (citing 35 U.S.C. § 112(d)), 54; Tr. at 89-91)

The Court is not persuaded. As just noted, the originally drafted claims in the '297 patent application included: (1) an independent claim (then-claim 1) requiring "approximately 6 to 10 times the RDA of vitamin A in the form of beta-carotene" and (2) dependent claims (the former claims 10 and 17) specifying that "said beta-carotene is substituted or supplemented with lutein, zeaxanthine or a raw material combination thereof." (D.I. 54, ex. F at 25, 29-30) The Examiner subsequently made suggestions that "would place the case in condition for allowance"—including cancelling the then-dependent claim 17 or writing it "as an independent claim because [] the language relating to substituting the beta-carotene with an additional substance does not further limit the parent claim from which it depends." (D.I. 80, Defendant's Exhibits at ex. 9 at

68) In other words, the Examiner understood that when “substitute” was used in then-claim 17, that term required the complete replacement of beta-carotene—and this meant that the claim was in improper form, because it would not further limit the independent claim (in that then-claim 17 could require the use of a completely different substance than what was referenced in then-claim 1). (Tr. at 78-79) Thus, the Examiner directed the patentee to cancel then-claim 17 or rewrite it as an independent claim. The patentee ultimately did so as to both then-claims 10 and 17 (which thereafter became, at the time, independent claims 26 through 28). (D.I. 80, Defendant’s Exhibits at ex. 8 at 61-62, 64) Eventually, then-independent claim 26, with its “substituted or supplemented with” language, became independent claim 19 of the '297 patent (i.e., the claim of the '297 patent that now contains the substituted or supplemented with term). (*See id.*, ex. 18; D.I. 79 at 49) And so as Plaintiffs point out, by converting these once dependent claims into independent claims (in line with the Examiner’s suggestion), the patentee “made clear that the language ‘supplemented or substituted with’ was not limited to requiring the presence of beta-carotene, i.e., the beta-carotene can be ‘supplemented or substituted with’ lutein, zeaxanthine or a raw material combination thereof.” (D.I. 79 at 49)<sup>14</sup>

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<sup>14</sup> Defendant does not clearly point to any caselaw that teaches otherwise. It mainly relies on *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867 (Fed. Cir. 1988). (*Id.* at 54; *see also id.* at 38) But in *Kingsdown*, in the context of reviewing a district court’s finding of inequitable conduct, the Federal Circuit merely recited the unremarkable proposition that “[e]ach [claim] is related to other claims . . . and often, as here, to earlier or later versions of itself in light of amendments made to it[.]” 863 F.2d at 874. Defendant also cites in support to *Jonsson v. The Stanley Works*, 903 F.2d 812 (Fed. Cir. 1990) (unfortunately without a pincite) and to *E.I. DuPont De Nemours & Co. v. Unifrax I LLC*, 921 F.3d 1060, 1069-70 (Fed. Cir. 2019). It asserts that those cases stand for the proposition that “the meaning of a claim term, established in the prosecution history, remains the same in a continuation application.” (D.I. 79 at 38) But even if it is true that the patentee originally intended “substituted” to mean “substituted in part” (and it is not clear that the patentee *did* intend this), nothing in cases like *Jonsson* or *DuPont* suggests that the term must necessarily retain that meaning in a scenario like this one—i.e., where the Examiner disagreed that the term had such a meaning, and then suggested that the patentee should amend its claims as a result. *Cf. 3M Innovative Props. Co. v.*

Defendant's second argument relates to statements that the patentee made during the prosecution of the '297 application; Defendant asserts that these statements further demonstrate that "substituted" cannot mean total replacement of beta-carotene. (*Id.* at 42-43, 55; Tr. at 94-97) As described above, the Examiner had rejected certain claims as unpatentable over Gorsek. In July 2003, the patentee distinguished the invention from Gorsek by explaining that it "use[d] *beta-carotene*, not the six component natural carotenoid mixture of Gorsek; furthermore, applicants use a much higher concentration of *beta-carotene*[" (D.I. 80, Defendant's Exhibits at ex. 10 at 76 (certain emphasis in original, certain emphasis omitted)) The patentee similarly pointed out that "Gorsek does not teach the present invention or the surprising beneficial effects achieved by the specific formulation of vitamin A as beta carotene, vitamin C, vitamin E, zinc and copper of the present invention." (*Id.* at 73; *see also id.* at 74-76) The patentee made arguments like these to distinguish Gorsek and other references at other points in the prosecution history as well. (*See, e.g., id.*, ex. 14 at 99, 101; *id.*, ex. 15 at 105-08; *id.*, ex. 16 at 112-17) According to Defendant, Plaintiffs' "securing of these claims plainly relied on the presence of beta-carotene, instead of any carotenoid substitute" and therefore Plaintiffs disclaimed formulas that do not include beta-carotene. (D.I. 79 at 43)

In the Court's view, the statements that Defendant highlights do not amount to a clear and unmistakable disclaimer to the effect that the substituted or supplemented with term cannot allow for total replacement of beta-carotene. During oral argument, Plaintiffs asserted that at the time the patentee was making these above-referenced arguments, the only independent claims to the

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*Avery Dennison Corp.*, 350 F.3d 1365, 1372 (Fed. Cir. 2003) ("The fact that 3M broadened its claims in response to an indefiniteness rejection and dropped the sequential limitation is perhaps unusual, but it is entirely permissible, *and the plain language of the claim as issued must control.*") (emphasis added).

compositions that existed *did* require beta-carotene—i.e., the independent claims did not yet contain the “substituted or supplemented with” language. (Tr. at 82-83) And this seems to be mostly correct. As described above, the patentees converted the dependent claims that included this language into independent claims (then-claims 26-28) in June 2003. (See D.I. 80, Defendant’s Exhibits at ex. 8 at 61-62) And nearly all of the arguments that Defendant highlights above were made by the patentee *before* June 2003. The one exception is the patentee’s July 2003 remarks referenced above. (*Id.*, ex. 10 at 73, 75) But even those remarks were about “[c]laims 1-25[,]” which had then been rejected as unpatentable over Gorsek and other references; the remarks were *not* about claims 26-28 (i.e., the new claims containing the substituted or supplemented with language). And so in these July 2003 remarks, the patentee was not specifically addressing this language either. Therefore, the patentee’s statements referenced above do not clearly and unmistakably disclaim a composition that utilizes lutein, zeaxanthine or a combination thereof in place of beta-carotene.

Defendant’s third argument focuses on the specification; it argues that the written description confirms that beta-carotene is required in the claims at issue. (D.I. 79 at 43-46) Again, though, the Court disagrees.

In support of this argument, Defendant starts by pointing to the specification’s descriptions of lutein, zeaxanthine and lutein-zeaxanthine, and how the patent notes that each tablet of a four-tablet-per-day dosage regime could provide approximately a range of each ingredient, “depending upon whether [lutein, zeaxanthine or lutein-zeaxanthine] is used to supplement or substitute beta-carotene [and/or zeaxanthine or lutein][.]” (*Id.* at 43 (citing ‘297 patent, cols. 7:55-8:25)) Defendant then points out that when the specification describes beta-carotene, it does not include similar phraseology, which to Defendant “adds further confirmation

that beta-carotene is *required*[.]” (*Id.* (emphasis in original) (citing '297 patent, col. 6:9-42)) Defendant next points to a second statement, also found in the specification’s description of beta-carotene, which notes that “[b]eta-carotene is preferred in the subject composition due to its ready commercial availability although alternative carotenoid proforms of vitamin A could likewise be used.” ('297 patent, col. 6:41-43 (*cited in* D.I. 79 at 44)) Lastly, Defendant focuses on a third statement, wherein the patent teaches that “[a] safe and effective method of preventing, stabilizing, reversing and/or treating macular degeneration” consists of providing a daily dosage of approximate amounts of vitamin C, vitamin E, beta-carotene, zinc and copper, as well as to a subsequent reference to these as “essential ingredients[.]” (*Id.*, col. 9:10-20, 32-33 (*cited in* D.I. 79 at 44))

Defendant’s assertions, however, do not move the needle. None of the cited portions of the specification clearly say something like “The invention must, at all times, utilize beta-carotene.” Indeed, the second statement Defendant relies on actually demonstrates that beta-carotene is *not* required—instead, it is just a “preferred” ingredient. *See, e.g., Frac Shack Inc. v. Fuel Automation Station, LLC*, 300 F. Supp. 3d 1333, 1356 (D. Colo. 2018) (where specification stated that “[e]ach cap . . . preferably comprises a fuel level sensor [ ] mounted in port[.]” finding that “while the preferred embodiment places the sensor in the cap, such placement is only preferred and not required”) (internal citation omitted, emphasis in original). Similarly, with respect to the third statement, it is located in the “Detailed Description” section of the specification; earlier in that section, the patent notes that “[t]he *preferred* nutritional or dietary supplement composition of the present invention is a formulation of five essential ingredients[.]” ('297 patent, col. 3:23-25 (emphasis added); Tr. at 80) The specification therefore does not

dictate that beta-carotene cannot be totally replaced; it *prefers* that beta-carotene be used, but does not require it.

Defendant’s fourth and final argument is that the substituted or supplemented with language is vague and unintelligible. This, according to Defendant, “mandate[s] that the claim must be construed as limited to requiring vitamin A in the form of beta-carotene.” (D.I. 79 at 38-42) This argument is confusing, unpersuasive and (in any event) surely premature.

Defendant first asserts here that the patent gives no guidance as to how much lutein or zeaxanthine would be required to partially replace the beta-carotene, nor any guidance as to how much of these components would be required to completely replace beta-carotene—such that claim 19 of the '297 patent is therefore invalid as indefinite. (*Id.* at 38-39) Defendant then later says that if the claims at issue are to be considered valid, they must be construed to require, at a minimum, that one of other ingredients be at least substituting for only part of the beta-carotene. (*Id.* at 46 (“If its *validity can be saved*, claim 19 literally requires vitamin A in the form of beta-carotene, with ‘substituted’ at most meaning substituting *part* of the beta-carotene.”) (certain emphasis in original, certain emphasis added), 55-56; Tr. at 86-87)<sup>15</sup> But this latter argument does not make sense to the Court, because it is Defendant’s view that whether the beta-carotene is completely or only partially replaced, the patent fails to inform the person of ordinary skill in the art how much lutein or zeaxanthine must be used in both cases. Regardless, Defendant’s arguments about indefiniteness otherwise are: (1) premature, because the parties expressly

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<sup>15</sup> The Federal Circuit has explained that “claims should be [] construed, if possible, as to sustain their validity” in circumstances where “the court concludes, after applying all the available tools of claim construction, that the claim is . . . ambiguous.” *Horizon Pharma, Inc. v. Dr. Reddy’s Lab’ys Inc.*, 839 F. App’x 500, 504 (Fed. Cir. 2021) (internal quotation marks and citations omitted).

agreed “to reserve argument and briefing on definiteness for trial[,]” (D.I. 54 at 2), and (2) rife with attorney argument that “is not evidence” and cannot serve to meet an accused infringer’s burden of proof with respect to invalidity, *see Taction Tech., Inc. v. Apple Inc.*, Case No.: 21-CV-812 TWR (JLB), 2022 WL 18781398, at \*18 (S.D. Cal. Sept. 28, 2022) (quoting *Icon Health & Fitness, Inc. v. Strava, Inc.*, 849 F.3d 1034, 1043 (Fed. Cir. 2017)); *see also* (December R&R at 11; D.I. 79 at 39-42 & n.7).<sup>16</sup>

For these reasons, the Court recommends that “vitamin A in the form of beta-carotene, substituted or supplemented with lutein, zeaxanthine or a raw material combination thereof” be construed to mean “lutein, zeaxanthine, or a raw material combination thereof, may be used instead of, or in addition to, vitamin A in the form of beta-carotene.”<sup>17</sup>

#### **D. “early age-related macular degeneration”**

The final disputed term, “early age-related macular degeneration[,]” (the “early AMD term”), is found in claim 31 of the '297 patent and claims 1, 11 and 16 of the '522 patent. These claims are directed to a composition (claim 31) and methods (claims 1, 11 and 16) used to treat “early age-related macular degeneration.” ('297 patent, reexamination certificate at col. 2:49-59;

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<sup>16</sup> Defendant also briefly argues that the claims fail to enable one to make and use the invention without undue experimentation. (D.I. 79 at 41, 56-57) Claim construction is not the time for such an argument, and the Court will not consider it here. *See, e.g., Idenix Pharms., Inc. v. Gilead Scis., Inc.*, Civil Action No. 13-1987-LPS, 2015 WL 9048010, at \*4 (D. Del. Dec. 16, 2015); *see also* (Tr. at 100-01).

<sup>17</sup> In this section of its briefing, Defendant also argues that claims 31 and 32 of the '297 patent, which were added during the reexamination proceeding, are invalid because they do not recite beta-carotene (and instead recite lutein and zeaxanthine) and therefore are “broader than every claim of the '297 patent as originally issued[.]” (D.I. 79 at 46-47; Tr. at 97) Again, this is the claim construction phase of the case, where the Court’s job is to construe disputed claim terms; it is not the time for the Court to be assessing such invalidity arguments.



'522 patent, cols. 9:58-67, 10:40-51, 10:65-11:6) The parties propose the following constructions:

<b>Term</b>	<b>Plaintiffs' Proposed Construction</b>	<b>Defendant's Proposed Construction</b>
"early age-related macular degeneration"	"early AMD, intermediate AMD, and advanced AMD in one eye only"	Plain meaning of the words, encompassing treatment of persons only with early age-related macular degeneration.

(D.I. 79 at 57) Both sides agree here that the term, as its literal wording suggests, encompasses "early" AMD. The dispute is whether the term also encompasses *other* forms of AMD "prior to advanced or late AMD, which in post-AREDS terminology<sup>[18]</sup> includes 'early/intermediate stage' AMD (and also advanced AMD in one eye only)[,]" as Plaintiffs contend. (*Id.*) Defendant says it does not. (*Id.* at 62)

Why do Plaintiffs argue for a broader construction with respect to the early AMD term? They begin with the well-settled principle that a claim term is to be given "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention[.]" *Phillips*, 415 F.3d at 1312-13; *see also Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998) (explaining that a claim should be construed in line with "what the inventors actually invented and intended to envelop with the claim"). Here, the relevant "time of the invention" is March 2001, which is when the application resulting in the '297 patent was filed. ('297 patent at 1; *see also* D.I. 79 at 59; Tr. at 105) From there, Plaintiffs' multi-step argument goes as follows:

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<sup>18</sup> AREDS refers to a 10-year Age-Related Eye Disease Study sponsored by the National Eye Institute of the National Institute of Health, which demonstrated that particular formulations of vitamins and minerals including vitamin C, vitamin E, beta-carotene, zinc and copper safely and effectively reduced the progression of vision loss due to AMD. (D.I. 80, Plaintiffs' Exhibits at ex. A at ¶¶ 6, 38, 41; '297 patent, cols. 3:18-45, 8:65-9:4; D.I. 79 at 1)

- (1) The specification of the '522 patent tells us that the inventions claimed in the asserted patents cover what AREDS demonstrated to be effective. ('522 patent, col. 9:1-7);
- (2) The specification also tells us that the results of AREDS were shown to be effective in patients with “early” AMD. (*Id.*, col. 9:12-16);
- (3) In March 2001 when the patents were filed, AMD was only classified as either “early” AMD or “late stage” AMD—no one was using the phraseology “intermediate AMD” at that time. (D.I. 80, Plaintiffs’ Exhibits at ex. A at ¶¶ 52, 57);<sup>19</sup>
- (4) Several months later, in October 2001, the phrase “intermediate” AMD was first used in a press release related to AREDS, and an AREDS report used the term beginning in 2003. (*Id.* at ¶ 52; *see also id.*, ex. A5 at 2; *id.*, ex. A3 at Abstract);
- (5) AREDS demonstrated that the claimed compositions were effective in treating what was later referred to as “intermediate” AMD and “unilateral advanced” AMD where the fellow eye is at risk. (*Id.* at ¶ 61); and
- (6) Because the patents “cover what AREDS found to be effective . . . the claim term ‘early’ AMD includes intermediate AMD.” (D.I. 79 at 61 (citing D.I. 80, Plaintiffs’ Exhibits at ex. A at ¶ 61))

(D.I. 79 at 57-61, 63; Tr. at 104-07)

In order for Plaintiffs’ argument to be persuasive, we need to see evidence that what the patents refer to as “early” AMD has the same meaning in March 2001 as what is now understood

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<sup>19</sup> In 1999 and 2001, when AMD was only classified as either early or late stage, publications relating to AREDS explained that the study had placed participants into one of four categories. (D.I. 80, Plaintiffs’ Exhibits at ex. A15 at 4-5; *id.*, ex. A2 at 1418) Category 1 contained individuals without AMD, while category 4 contained individuals with advanced AMD; Categories 2 and 3 contained individuals with different levels of AMD-related features such as number and size of drusen. (*Id.*, ex. A15 at 4-5)

to encompass early AMD, intermediate AMD, and advanced AMD in one eye only. Plaintiffs point to a few portions of the intrinsic record to make this link:

- (1) During prosecution of the '297 patent, in 2003, one of the inventors submitted a declaration with respect to claims for the treatment of “persons with early age-related macular degeneration” explaining that the invention would help millions of Americans “with intermediate age-related macular degeneration or advanced age-related macular degeneration in one eye.” (D.I. 80, Plaintiffs’ Exhibits at ex. A6 at 2; *id.*, ex. A at ¶ 53); and
- (2) In 2009, during prosecution of the '522 patent, in response to a rejection, the patentee noted that the claims related to “a very specific ocular disease referred to in the art as early/intermediate-stage age-related macula[r] degeneration.” (*Id.*, ex. A9 at 7; *id.*, ex. A at ¶ 54)

(D.I. 79 at 59-60)

Extrinsic evidence in the record also helps to demonstrate this link. (Tr. at 109-10) For example, Plaintiffs’ expert, Susan B. Bressler, M.D., explains that “[w]hat is now known as intermediate AMD is typically characterized by at least 1 large druse . . . or many (extensive number) medium drusen . . . or areas of non-central GA.” (D.I. 80, Plaintiffs’ Exhibits at ex. A at ¶ 34) From there, Defendant’s own chart—in which it compiles quotes from “articles from well-known scientific journals and prestigious medical journals, many from large clinical trials or cited as references in AREDS” that define “early and late” AMD “as these terms were understood in the time leading up to March 2001[.]” (D.I. 79 at 61-62 (emphasis omitted))—shows that patients with drusen (including “intermediate- and large- size drusen”) were characterized as having early AMD, (D.I. 80, Defendant’s Exhibits at ex. 22 at 1-3). Dr. Bressler also notes that what later became known as intermediate AMD corresponds to Category 3 of AREDS. (*Id.*, Plaintiffs’ Exhibits at ex. A at ¶ 61) Category 3, as noted above, *supra* note 19, did not include patients with advanced or late stage AMD. And she represents that “[o]ften the

categories of early and intermediate AMD are collapsed and referred to as ‘early AMD.’” (*Id.* at ¶ 29) In light of the intrinsic and extrinsic evidence, the Court is persuaded that at the time of the invention, the meaning of early AMD would encompass what is now known as intermediate AMD.<sup>20</sup>

In pushing back against this conclusion, Defendant asserts that: (1) early AMD cannot be reasonably defined to include all such degeneration other than late stage macular degeneration and (2) there was no clear later subdivision of early AMD. (D.I. 79 at 62) But it does not explain why this is so, or back up these assertions with specific citations to record evidence. (*Id.*) During oral argument, when asked what in the record demonstrates that Plaintiffs are wrong (and that what is now understood to be intermediate AMD was understood to be something different than early AMD as of March 2001), Defendant’s counsel could say only that he did not “have the proof, but we spoke to our clients or our experts and they said it falls somewhere in the middle, that what was called early then would pick up maybe half of what they call intermediate now. It’s not black and white.” (Tr. at 117-18) Mere attorney argument is not evidence, of course. Thus, Plaintiffs’ evidence that aligns with their proposal stands unrebutted.

For these reasons, the Court recommends that “early age-related macular degeneration” be construed to mean “early AMD, intermediate AMD, and advanced AMD in one eye only[.]”<sup>21</sup>

#### **IV. CONCLUSION**

For the foregoing reasons, the Court recommends that the District Court adopt the

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<sup>20</sup> The *Vitamin Health* Court reached the same conclusion. *Bausch & Lomb Inc. v. Vitamin Health, Inc.*, 13-CV-6498, 2016 WL 3703071, at \*3-4 (W.D.N.Y. July 7, 2016).

<sup>21</sup> The Court also recommends that the District Court adopt the parties’ agreed-upon constructions for “comprising on a daily dosage” and “administering a daily dosage[.]” (D.I. 79 at 7 & n.3; Tr. at 11)

following constructions:

1. “approximately” with respect to the amounts of vitamin C, vitamin E, zinc, copper, lutein, zeaxanthine and lutein-zeaxanthine combination should be construed to mean “reasonably close to” and “approximately” with respect to the amounts of vitamin A in the form of beta-carotene should be construed to mean “an amount of vitamin A in the form of beta-carotene that comes reasonably close to 6 to 10 times the RDA for vitamin A, but not less than 5 times the RDA for vitamin A”

2. “0.04 mg to 40 mg lutein-zeaxanthine combination” should be construed to mean “0.04 mg to 40 mg lutein-zeaxanthine achieved deliberately because of normal composition or through raw material contamination”

3. “vitamin A in the form of beta-carotene, substituted or supplemented with lutein, zeaxanthine or a raw material combination thereof” should be construed to mean “lutein, zeaxanthine, or a raw material combination thereof, may be used instead of, or in addition to, vitamin A in the form of beta-carotene”

4. “early age-related macular degeneration” should be construed to mean “early AMD, intermediate AMD, and advanced AMD in one eye only”

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b)(2). The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the district court. *See Sincavage v. Barnhart*, 171 F. App’x 924, 925 n.1 (3d Cir. 2006); *Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987).

The parties are directed to the Court's Standing Order for Objections Filed Under Fed. R. Civ. P. 72, dated March 7, 2022, a copy of which is available on the District Court's website, located at <http://www.ded.uscourts.gov>.

Dated: February 8, 2024

  
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Christopher J. Burke  
UNITED STATES MAGISTRATE JUDGE