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 pending before the Court is Plaintiffs' motion for summary judgment no. 3 of no invalidity under 35 U.S.C. § 112 and broadening during reexamination (the "Motion"). (D.I. 155; *see also* D.I. 247 at 1) Defendant opposes the Motion. For the reasons set forth below, the Court recommends that the Motion be GRANTED-IN-PART and DENIED-IN-PART.

I. BACKGROUND

Plaintiffs filed this action on October 28, 2020. (D.I. 1) 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 summary judgment motions, pursuant to 28 U.S.C. § 636(b). (D.I. 40; D.I. 143)

Plaintiffs filed the instant Motion on September 6, 2024. (D.I. 155) The Motion was fully briefed as of November 7, 2024. (D.I. 227) A trial is set to begin on April 21, 2025. (D.I. 241)

The Court here writes primarily for the parties, and so any facts relevant to this Report and Recommendation will be discussed in Section III below.

II. STANDARD OF REVIEW

The Court incorporates by reference the standard of review for summary judgment motions, which it set out in its March 17, 2025 Report and Recommendation. (D.I. 270 at 2-3)

III. DISCUSSION

Plaintiffs assert that Defendant infringes claims 19, 24 and 31-32 of the '297 patent[1] and claims 1, 4-6, 8, 11, 15-16 and 20 (collectively, the "asserted claims") of the '522 patent[2] by making and selling its MacularProtect® products (the "accused products"). (D.I. 166, ex. 4 at ¶¶ 44, 47, 50-51) The asserted patents are both entitled "Nutritional Supplement to Treat Macular Degeneration" and share a common specification.

As relevant to this Motion: (1) claims 19 and 24 of the '297 patent recite a composition that includes "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[;]" and (2) claims 11 and 15 of the '522 patent recite a method for treating visual acuity loss in persons with early age-related macular degeneration ("AMD") by administering a composition that includes this same language (the "substituted or supplemented" term). ('297 patent,

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[1] The '297 patent issued on December 9, 2003 from Application No. 09/816,284 (the "'284 Application"), which was filed on March 23, 2001. ('297 patent at 1) In October 2007, a request for an *inter partes* reexamination of the '297 patent was filed with the United States Patent and Trademark Office ("PTO"). (*See* D.I. 150, ex. 20 at 147) On April 30, 2013, the PTO issued an *Inter Partes* Reexamination Certificate determining that, *inter alia*, claim 19 was patentable as amended and that new claims 24, 31 and 32 were patentable. ('297 patent, reexamination certificate)

[2] The '522 patent issued from a continuation of the '284 Application on December 10, 2013. ('522 patent at 1)

reexamination certificate at col. 2:9-12, 19; '522 patent, col. 10:45-48, 61) During claim construction, Defendant argued that beta-carotene, in some amount, is required in these claims—and that "substituted" in the substituted or supplemented term therefore must mean that beta-carotene can only be substituted *in part* with lutein, zeaxanthine or a raw material combination thereof. (D.I. 108 at 16) Plaintiffs, meanwhile, asserted that "substituted" means that beta-carotene can be completely replaced by lutein, zeaxanthine or a raw material combination thereof. (*Id*.) Guided by the intrinsic evidence, the Court sided with Plaintiffs regarding that dispute. It thus construed the substituted or supplemented term 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." (*Id.* at 16-24; D.I. 189 at 7-8)

Claims 31 and 32 of the '297 patent are also relevant to the Motion. Those two claims were added as a result of *inter partes* reexamination proceedings, and they recite a composition that includes "approximately 1 mg to 40 mg of lutein" and "approximately 0.04 mg to 40 mg of zeaxanthine[.]" ('297 patent, reexamination certificate at col. 2:53-54, 60) These claims do not recite beta-carotene. (*Id.*)[3]

In its Final Invalidity Contentions ("Contentions"), Defendant alleged that claims 19 and 24 of the '297 patent are invalid because the substituted or supplemented term is indefinite and fails to enable the person of skill in the art ("POSITA") to make and use the invention. (D.I. 166, ex. 3 at 3-7)[4] And Defendant argues in its Contentions that claims 31 and 32 of the '297 patent are invalid for improperly broadening the scope of the patent. (*Id.* at 7-8)

[3] The accused products do not contain beta-carotene. (D.I. 152 at ¶ 3; D.I. 193 at ¶ 3)

With the Motion, Plaintiffs take the position that Defendant "has provided no evidence in support" of these invalidity arguments. Plaintiffs request that summary judgment of no invalidity based on indefiniteness and non-enablement be granted with respect to claims 19 and 24 of the '297 patent and claims 11 and 15 of the '522 patent, and that summary judgment of no invalidity based on improper broadening should be granted with respect to claims 31 and 32 of the '297 patent. (D.I. 165 at 12 & n.3) Below, the Court recommends that: (1) Plaintiffs' portion of the Motion seeking summary judgment of no invalidity based on improper broadening be granted for the reasons set out below; (2) Plaintiffs' portion of the Motion seeking summary judgment of no invalidity based on non-enablement be denied for the reasons set out below; and (3) Plaintiffs' portion of the Motion seeking summary judgment of no invalidity based on indefiniteness be denied, in light of Judge Williams' ranking procedures. *See Lindis Biotech, GmbH v. Amgen, Inc.*, Civil Action No. 22-35-GBW, D.I. 292 at 10 (D. Del. Nov. 22, 2024).[5]

A. Improper Broadening Through Reexamination

A patentee may not enlarge the scope of a patent claim during reexamination. 35 U.S.C. § 305 ("Section 305"); *Network-1 Techs., Inc. v. Hewlett-Packard Co.*, 981 F.3d 1015, 1028

[4] Since claims 11 and 15 of the '522 patent also contain the substituted or supplemented term, Plaintiffs assume that Defendant is making the same invalidity assertion as to those claims too, even though Defendant did not explicitly state this in its Contentions. (D.I. 165 at 12 n.3) The Court will assume the same thing here as well.

[5] Plaintiffs filed one summary judgment motion—the instant Motion—covering all three of these grounds. (D.I. 155) However, while it is true that these defenses "can overlap at times," they are separate and distinct concepts that are governed by different legal standards. *Orexo AB v. Actavis Elizabeth LLC*, 371 F. Supp. 3d 175, 186 (D. Del. 2019); *see also See Vas–Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1560-62 (Fed. Cir. 1991). Plaintiffs really should have filed three separate motions regarding these three grounds, and the Court therefore is construing the Motion as three separate motions. Nevertheless, for ease of reference, the Court may sometimes below refer to each of the three motions as a "portion" of the "Motion" at issue here.

(Fed. Cir. 2020). Claims that are improperly broadened during reexamination are invalid as a matter of law. *Quantum Corp. v. Rodime, PLC*, 65 F.3d 1577, 1583-84 (Fed. Cir. 1995). The broadening inquiry involves two steps: (1) "analyz[ing] the scope of the claim prior to reexamination" and (2) "compar[ing] it with the scope of the claim subsequent to reexamination." *Creo Prods., Inc. v. Presstek, Inc.*, 305 F.3d 1337, 1344 (Fed. Cir. 2002). A claim "is broader in scope than the original claims if it contains within its scope any conceivable apparatus or process which would not have infringed the original patent." *Medtronic, Inc. v. Guidant Corp.*, 465 F.3d 1360, 1374 (Fed. Cir. 2006) (internal quotation marks and citations omitted); *see also Predicate Logic, Inc. v. Distributive Software, Inc.*, 544 F.3d 1298, 1303 (Fed. Cir. 2008). Thus, the United States Court of Appeals for the Federal Circuit has explained that the question of "[w]hether amendments made during reexamination enlarge the scope of a claim is a matter of claim construction[.]" *Network-1 Techs.*, 981 F.3d at 1028 (internal quotation marks and citation omitted).

Defendant's broadening theory is that: (1) all original claims of the '297 patent required beta-carotene; (2) claims 31 and 32, added during reexamination, do not require beta-carotene (instead, they recite lutein and zeaxanthine); (3) claims 31 and 32 are thus broader than all the original claims of the '297 patent, since they are to compositions that are not covered by any of those original claims; and (4) therefore claims 31 and 32 are invalid as a matter of law. (D.I. 207 at 28; *see also* D.I. 151 at 28; D.I. 166, ex. 3 at 7)[6] This argument, however, is clearly foreclosed by the Court's claim construction. (*See* D.I. 165 at 21) As explained above, the Court construed

[6] Relatedly, Defendant's motion for summary judgment no. 8 requests summary judgment that claims 31 and 32 of the '297 patent are invalid because they are broader than the original claims of the '297 patent. (D.I. 173; *see also* D.I. 151 at 28)

the substituted or supplemented term in claims 19 and 24 of the '297 patent to mean that lutein and/or zeaxanthine, or a raw material combination thereof, can be used *instead of* beta-carotene (and that beta-carotene is thus not *required* in these claims). (D.I. 108 at 16-24; D.I. 189 at 7-8) Indeed, later in its briefing here, Defendant acknowledges that its argument against summary judgment on this score (i.e., that all of the original claims of the '297 patent required beta-carotene) "is contrary to the finding in the" Court's claim construction. (D.I. 207 at 34; *see also* D.I. 227 at 11)

In light of all of this, it is clear that claims 31 and 32 do not "encompass any subject matter beyond that encompassed by the original claim[19.]" *Hockerson-Halberstadt, Inc. v. Converse Inc.*, 183 F.3d 1369, 1375 (Fed. Cir. 1999). And so the Court recommends that this portion of Plaintiffs' Motion be granted.

B. Enablement

The Court next turns to Plaintiffs' portion of the Motion seeking summary judgment of no invalidity based on non-enablement. This argument implicates claims 19 and 24 of the '297 patent and claims 11 and 15 of the '522 patent.

To meet the enablement requirement, a patent specification must enable one skilled in the art to practice the full scope of the claimed invention without undue experimentation. *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1244 (Fed. Cir. 2003). "The scope of the claims must be less than or equal to the scope of the enablement to ensure that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims." *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 999 (Fed. Cir. 2008) (internal quotation marks, citation and brackets omitted). The enablement requirement is a question of law based on underlying factual inquiries, and is determined as of the filing date of the patent application. *In*

re '318 Patent Infringement Litig., 583 F.3d 1317, 1323 (Fed. Cir. 2009). An enablement analysis is considered from the vantage point of the POSITA. *See Sitrick*, 516 F.3d at 1000. There are a number of factors, known as the "*Wands* factors," that can be used when assessing whether a disclosure would require undue experimentation:

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

A patent claim is presumed enabled. *Pharm. Res., Inc. v. Roxane Lab'ys, Inc.*, 253 F. App'x 26, 28 (Fed. Cir. 2007). "The party alleging invalidity for lack of enablement bears the burden of proving by clear and convincing evidence that the specification of a challenged patent fails to teach one of ordinary skill in the art how to make the invention." *Ormco Corp. v. Align Tech., Inc.*, 498 F.3d 1307, 1318 (Fed. Cir. 2007).

Defendant argues that the claims containing the substituted or supplemented term are not enabled because at the time that the asserted patents were filed in March 2001, a POSITA would not be able to figure out—without undue experimentation—what amounts of lutein, zeaxanthine and/or beta-carotene would be effective to treat AMD. (D.I. 207 at 22, 24; D.I. 151 at 27) To that end, Defendant asserts that the specification does not provide a single example of lutein or zeaxanthine amounts that would be effective for the purpose of treating AMD, nor provide any guidance as to what combinations of beta-carotene, lutein and/or zeaxanthine would be so effective "among millions of possible combinations" disclosed in the specification. (D.I. 207 at

22, 24-25)[7] Defendant also contends that Plaintiffs' own evidence demonstrates that the purpose of the AREDS 2 study was to determine whether lutein and zeaxanthine would further decrease the risk of developing advanced AMD. Defendant notes that the AREDS 2 study began in 2006—five years *after* the filing date of the patents—and lasted for *six years*, thus underscoring

[7] To this, Plaintiffs initially retort that claims 19 and 24 of the '297 patent are composition claims that do not recite any particular purpose (e.g., the purpose of *effectively treating AMD*), thus rendering Defendant's argument irrelevant as to those claims. (D.I. 165 at 16-17) "Enablement requires only that the specification impart to a [POSITA] the ability to practice 'the invention *as defined by its claims.*'" *Janssen Pharms., Inc. v. Tolmar, Inc.*, 718 F. Supp. 3d 394, 434-35 (D. Del. 2024) (emphasis in original) (quoting *Amgen Inc. v. Sanofi*, 598 U.S. 594, 610 (2023)); *see also McRO, Inc. v. Bandai Namco Games Am. Inc.*, 959 F.3d 1091, 1100 (Fed. Cir. 2020) ("Section 112 requires enablement of only the claimed invention, not matter outside the claims.") (internal quotation marks and citations omitted); *INVISTA N. Am. S.a.r.l. v. M & G USA Corp.*, 951 F. Supp. 2d 626, 653 (D. Del. 2013) ("The enablement . . . requirement[is] based on the invention *as claimed.*") (emphasis in original). Plaintiffs' argument here seems to be that Defendant is wrongly assuming that composition claims 19 and 24 of the '297 patent require that only certain amounts of lutein and/or zeaxanthine can be substituted or supplemented into the composition—that is, only those amounts that, when part of the composition, render that composition as *effective in treating AMD* as the composition would be if it contained only "approximately 6 to 10 times the RDA of vitamin A in the form of beta-carotene[.]" And Plaintiffs seem to be saying that such a position is off base, because claims 19 and 24 *do not require that the composition be effective in doing anything at all*. (D.I. 165 at 16-17)

Plaintiffs' argument is effectively a claim construction argument. That is, Plaintiffs are asserting that the scope of the claims is such that they do not require *any particular amount* of lutein or zeaxanthine or a combination thereof. But Plaintiffs have not provided the Court with the tools to make a good claim construction call as to this issue. For example, Plaintiffs do not suggest what claim term the Court should construe (or further construe). Nor do Plaintiffs perform anything like a typical claim construction analysis in their portion of the briefing here. Plaintiffs had the burden to demonstrate why their Motion should be granted. And since they failed to sufficiently tee up the above-referenced claim construction dispute, the Court will not assume—for purposes of this Motion—that claims 19 and 24 of the '297 patent have any different claim scope than claims 11 and 15 of the '522 patent (i.e., claims that do claim a "method *for treating visual acuity* in persons with early [AMD]")) with respect to the substituted or supplemented term. ('522 patent, col. 10:40, 10:61)

that undue experimentation would have been required to practice the claimed invention back in *2001*. (*Id.* at 22, 27; *see also* D.I. 151 at 27-28)[8]

Plaintiffs' Motion is premised on the view that Defendant has introduced "no evidence or expert testimony" showing that a POSITA would require undue experimentation to make and use the claimed invention. (D.I. 165 at 18-20; *see also* D.I. 227 at 7-8) But while it is true that Defendant has not introduced any testimony from an expert as to the lack of enablement issue, Defendant *does* point to other evidence of record relating to this topic. That evidence, in the Court's view, is sufficient to establish a genuine issue of material fact precluding summary judgment in Plaintiffs' favor.[9]

The Court thus turns to the record. To start, the Court notes that although Plaintiffs criticize Defendant for relying "on only two" *Wands* factors to argue that the claims are not enabled (i.e., the "presence or absence of working examples" factor and the "quantity of

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[8] AREDS 2 followed the first AREDS study, which was a 10-year Age-Related Eye Disease Study sponsored by the National Eye Institute of the National Institutes of Health; the first AREDS study 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)

[9] To the extent that Plaintiffs suggest that Defendant's failure to engage an expert to opine on enablement alone dooms the defense, (*see* D.I. 227 at 7), the Court does not agree, *see, e.g.*, *Lear Corp. v. NHK Seating of Am. Inc.*, Case No. 13-12937, 2022 WL 876021, at *13-14 (E.D. Mich. Mar. 23, 2022) (rejecting the notion that a lack of enablement defense fails as a matter of law without expert testimony, as while the defense involves "how a person having ordinary skill in the art would interpret the patent specification or its claims" none of the defendant's cases "state that expert testimony is the only way for a juror or this Court to understand how an ordinary practitioner would interpret Lear's patents"); *Bos. Sci. Corp. v. Johnson & Johnson Inc.*, 679 F. Supp. 2d 539, 556-57 & n.34 (D. Del. 2010) (granting summary judgment of non-enablement even where the patent challenger had not adduced any expert testimony regarding the defense, in light of the "lack of any prophetic examples (or other description) in the 1997 patents' specification regarding the claimed analogs").

experimentation necessary" factor), in the Court's view, Defendant also at least invokes a third factor in support of its argument: the "amount of direction or guidance presented."[10] (*See* D.I. 227 at 7) Those three factors—and Defendant's evidence relating thereto—do enough work to warrant denial of this portion of the Motion.

With regard to the "presence or absence of working examples" factor and the "amount of direction or guidance presented" factor, Defendant's evidence in part comes from the patent itself. The specification describes lutein and zeaxanthine as carotenoids that are also antioxidants found in the retinas of healthy eyes. ('297 patent, cols. 7:52-55, 7:66-8:2) It teaches that with respect to lutein, preferably each tablet of a four tablet per day dosage regime "could provide approximately 0.25 to 10 mg of lutein for a total daily dosage of 1 to 40 mg depending upon whether lutein is used to supplement or substitute beta-carotene and/or zeaxanthine[.]" (*Id.*, col. 7:55-59) And with respect to zeaxanthine, the specification states that preferably each tablet of a four tablet per day dosage regime "could provide approximately 0.01 to 10 mg of zeaxanthine for a total daily dosage of approximately 0.04 to 40 mg depending upon whether zeaxanthine is used to supplement or substitute beta-carotene and/or lutein." (*Id.*, col. 8:2-7)[11]

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[10] A party is not required to analyze all eight *Wands* factors in order to raise a genuine dispute of fact regarding enablement. *See, e.g.*, *Streck, Inc. v. Rsch. & Diagnostic Sys., Inc.,* 665 F.3d 1269, 1288 (Fed. Cir. 2012) ("[I]t is not necessary that a court review all the *Wands* factors to find a disclosure enabling. They are illustrative, not mandatory.") (internal quotation marks and citation omitted); *Wyeth v. Mylan Pharms., Inc.*, Civil Action No. 1:07CV91, 2009 WL 3335062, at *13 (N.D.W. Va. Oct. 14, 2009) ("Given that genuine questions of fact remain as to at least two of the *Wands* factors, the Court need not consider any remaining factors at this time" to "determine[] that genuine questions of material fact are in dispute as to the issue of enablement[.]").

[11] Similarly, with respect to lutein-zeaxanthine, the specification states that preferred ratios of lutein-zeaxanthine include "90 to 99 percent lutein and 1 to 10 percent zeaxanthine or 90 to 99 percent zeaxanthine and 1 to 10 percent lutein" and that each tablet of a four tablet per day dosage regime "could provide approximately 0.01 to 10 mg of lutein-zeaxanthine for a total

But Defendant asserts that what the patent does *not* do is provide an example for "an effective formula using zeaxanthine or lutein"; instead, it provides "extremely wide ranges" of possible amounts of the relevant components, with possible combinations from the quantities set out numbering in the millions. (D.I. 207 at 21 n.2, 24; *see also* D.I. 151 at 27 (asserting that "Plaintiff had no idea what quantities or combinations would be effective, which is the reason for the claimed quantity range being vastly wide as to cover every possible combination: a 40-fold range for lutein, and a 1000-fold range for zeaxanthine"))

Defendant also points to the declaration of its employee, Zac Denning, when addressing these two *Wands* factors.[12] Mr. Denning supports Defendant's assertions, when he opines that:

> - "At the time of the '297 patent filing in 2001 I knew there were many unanswered questions concerning lutein and zeaxanthine. To my recollection, zeaxanthine in supplement form, was not commercially available until around or just after the time of the filing of the '297 patent, which means there would have been insufficient time for research to confirm an effective dose for reducing AMD risk." (D.I. 206 at ¶ 8; *see also id*. at ¶ 18 (noting that prior to the filing of the '297 patent application, "zeaxanthine hadn't been tested in clinical trials sufficient to assess efficacy, or even to any meaningful degree, as a high potency, purified supplement apart from diet"));[13]

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daily dosage of approximately 0.04 to 40 mg depending upon whether lutein-zeaxanthine is used to supplement or substitute beta-carotene." ('297 patent, col. 8:17-25)

[12] Plaintiffs successfully moved to strike certain portions of Mr. Denning's declaration, and the Court therefore relies only on opinions therein that have not been stricken. (D.I. 252) With a Bachelor's Degree in Science and decades of experience in promoting macular products to doctors with a focus in particular on the scientific rationale behind nutritional ingredients for the eye, (D.I. 206 at ¶¶ 2-3), Mr. Denning appears to meet the parties' definition of a POSITA, (*see* D.I. 259 at 4-5).

[13] Plaintiffs and their expert, Dr. Johnson, opined to the contrary that zeaxanthine was commercially available as of and prior to March 2001. (D.I. 227 at 9; D.I. 166, ex. 10 at ¶ 25) The 1997 document that they cite in this regard references commercial products containing lutein, while noting that one such product, which contained 20 mg of lutein, also contained an

- "In 2001 when the '297 patent application was filed, and during the ensuing years until the publication of the AREDS 2 findings in 2013, I recall there was a high degree of uncertainty about how much lutein and zeaxanthin was an optimal dose to treat or effectively combat AMD—and even whether these ingredients would be effective at all." (*Id.* at ¶ 9; *see also id.* at ¶ 16); and

- "In 2001, it was not known to me or the industry in general, that lutein and zeaxanthine or a combination *could* be used in the place of beta-carotene. Beta-carotene was already known at this time to be very different from lutein and zeaxanthine in its structure, metabolism and effects on the human body. Given this knowledge, in 2001, I would not have been able to determine any amount of lutein and zeaxanthine or a combination that could replace beta-carotene in accordance with the patent and its claims." (*Id.* at ¶ 12 (emphasis in original); *see also id.* at ¶ 16).

(D.I. 207 at 27)

Additionally, with respect to the "quantity of experimentation necessary" factor, Defendant points to the fact that a six-year, 4,200+ participant clinical trial (AREDS 2) was needed in order to discover an effective combination of lutein and zeaxanthine. (*Id.* at 22, 27; *see also* D.I. 151 at 26-27) In support of this argument, Defendant highlights the report of Plaintiffs' expert Dr. Susan Bressler. Dr. Bressler explains that the purpose of the AREDS 2 study "was to determine whether adding oral supplements containing lutein and zeaxanthin [among others] would further decrease the risk of developing advanced AMD" and to "explore the effects of removing beta-carotene from the formula entirely[.]" (D.I. 203, ex. 1 at ¶ 36)

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undisclosed amount of zeaxanthin. (D.I. 228, ex. 5 (*cited in* D.I. 227 at 9)) Plaintiffs also cite to internal memos from 1996, in which groups at Plaintiffs discussed conducting a study using "lutein/zeaxanthine[.]" (*Id.*, ex. 6 (*cited in* D.I. 227 at 9); *see also id.*, ex. 7 at 2 (*cited in* D.I. 227 at 9)) But in the Court's view, these documents do not necessarily show that zeaxanthine—on its own—was commercially available as a supplement. Indeed, one such memo noted that manufacturing *of lutein* had begun recently. (*Id.*, ex. 7 at 2)

According to Defendant, the AREDS 2 study demonstrates that in March 2001, a POSITA "would have had no idea of what quantitative combination of lutein and zeaxanthine would be effective" and would have required undue experimentation to learn this information. (D.I. 151 at 27; *see also* D.I. 207 at 27)

This all seems like sufficient evidence to generate a material dispute of fact on the enablement issue. In arguing to the contrary, Plaintiffs make three primary arguments. Below, the Court explains why none are persuasive.

First, Plaintiffs retort that the existence of a clinical study like AREDS 2 doesn't have any bearing on whether a POSITA would be able to make and use the invention without undue experimentation. (D.I. 227 at 8, 10) Now, it is true that the Federal Circuit has held (on the facts of the particular case before it) that where a district court found the asserted patents to be invalid for lack of enablement following a bench trial, "[t]he mere potential need for clinical work, without more, is not dispositive." *Cephalon, Inc. v. Watson Pharms., Inc.*, 707 F.3d 1330, 1339 (Fed. Cir. 2013). Nevertheless, evidence relating to clinical trials like these—i.e., a study that started five years after the effective date of the patent, and that purportedly aims to assess a question discussed in the patent—surely can at least be *considered* in determining whether extensive experimentation would be required to practice an invention. *See, e.g.*, *Teva Pharms. Int'l GmbH v. Eli Lilly & Co.*, Civil Action No. 18-12029-ADB, 2022 WL 10489059, at *3 (D. Mass. Oct. 17, 2022) ("[T]he Court finds that evidence of Lilly's clinical trials is relevant to the enablement inquiry because it may offer insight into the extent of experimentation necessary to practice the claimed methods."); *cf. Intel Corp. v. Tela Innovations, Inc.*, Case No. 3:18-cv-02848-WHO, 2021 WL 1222622, at *10 (N.D. Cal. Feb. 11, 2021) ("[T]he evidence as a whole paints a clear picture that the 'experimentation' required to reach each progressively smaller size

is 'undue[]'" where it shows that reaching each smaller process node has "historically taken *two years*[.]") (emphasis in original).

Second, Plaintiffs dispute Defendant's position (i.e., that the POSITA would not know, from reading the patent or otherwise, how much lutein or zeaxanthine should be included in a relevant effective composition) by pointing to the opinion of their expert, Dr. Elizabeth Johnson. Plaintiffs note Dr. Johnson's testimony that the specification "discloses effective amounts of lutein, zeaxanthine, or a raw material combination thereof" to be used in the claimed invention. (D.I. 227 at 8 (citing D.I. 166, ex. 10 at ¶ 25); *id*. at 9; *see also* D.I. 165 at 19 ("[T]he inventors provided details in the patent specifications about why lutein and zeaxanthine are healthy for the eyes and how much of these ingredients can be used in the claimed compositions.")) But again, Defendant's point is that the patent only identifies wide ranges of lutein, zeaxanthine or a combination thereof that may be utilized—and is unclear as to what precise amount(s) of these components should be used, depending upon whether they are being utilized to supplement or substitute beta-carotene. (D.I. 151 at 27 (Defendant noting that "the claimed quantity range [is] vastly wide as to cover every possible combination: a 40-fold range for lutein, and a 1000-fold range for zeaxanthine"); D.I. 207 at 25 ("The point is, no one would find any hint as to how much lutein or zeaxanthine should be included.)) At most then, Dr. Johnson's testimony suggests that there is a *factual dispute* as to whether the patent enabled the full scope of the inventive solution.

Third, Plaintiffs contend that actual working examples are not required in a patent specification. (D.I. 165 at 19; D.I. 227 at 8) Even so, the "presence or absence of working examples" is undoubtedly a *Wands* factor that can at least be taken into account when assessing whether experimentation would be undue. *In re Wands*, 858 F.2d at 737; *see also, e.g.*,

Orthopaedic Hosp. v. Encore Med. L.P., Case No.: 19-CV-970 JLS (AHG), 2022 WL 254956, at *13-14 (S.D. Cal. Jan. 27, 2022) (finding that the broad scope of the claims and the alleged extended period of time before reduction to practice, as well the lack of working examples, *inter alia*, were "sufficient to raise a genuine issue of material fact as to the amount and type of experimentation required").

In sum, Defendant has pointed to enough evidence of record to demonstrate a genuine dispute of material fact on the enablement question. For that reason, the Court recommends that Plaintiffs' Motion requesting summary judgment of no invalidity based on non-enablement be denied.

IV. CONCLUSION

For the foregoing reasons, the Court recommends that: (1) Plaintiffs' Motion be granted to the extent it seeks summary judgment of no invalidity based on improper broadening; and (2) Plaintiffs' Motion be denied to the extent it seeks summary judgment of no invalidity based on non-enablement. And the Court also recommends that Plaintiffs' Motion be denied to the extent it seeks summary judgment of no invalidity based on indefiniteness, in light of Judge Williams' ranking procedures.

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. Any objections to this Report and Recommendation should be filed by **April 3, 2025**; any responses should be filed by **April 10, 2025**. 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: March 27, 2025

Christopher J. Burke
Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE