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

Pending before the Court in this patent infringement case filed by Bausch & Lomb Incorporated and PF Consumer Healthcare 1 LLC ("Plaintiffs") is Defendant SBH Holdings LLC's ("SBH" or "Defendant") "Motion for Judgment on the Pleadings[,]" filed pursuant to Federal Rule of Civil Procedure 12(c) (the "Motion"). (D.I. 63) For the reasons set forth below, the Court recommends that SBH's Motion be DENIED.[1]

I. BACKGROUND

A. Factual Background

In this case, Plaintiffs allege that SBH's MacularProtect® products (the "accused products") infringe 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"). (D.I. 1 at ¶¶ 15, 28) The asserted patents are both entitled "Nutritional Supplement to Treat Macular Degeneration"

[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 expert discovery matters, pursuant to 28 U.S.C. § 636(b). (D.I. 40)

and share a common specification. (D.I. 1, exs. A-C)[2] The inventions 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)[3]

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 September 2007, a request for an *inter partes* reexamination of the '297 patent was filed with the United States Patent and Trademark Office ("PTO"). (D.I. 1 at ¶ 12) On April 30, 2013, the PTO issued an *Inter Partes* Reexamination Certificate determining that: (1) claims 1-4, 10, 18 and 19 were patentable as amended; (2) claims 5, 6, 8, 9, 11, 12 and 14-17 were patentable; (3) new claims 22-32 were patentable; and (4) claims 20 and 21 were cancelled. (*Id.*, ex. B ("'297 patent, reexamination certificate"))[4] The majority of the claims of the '297 patent are directed to compositions, though a few are directed to methods of manufacturing such compositions. ('297 patent, cols. 9:54-12:11; '297 patent, reexamination certificate at cols. 1:26-2:61; *see also* D.I. 79 at 4) The '297 patent expired on March 23, 2021. (*See* '297 patent at 1; D.I. 63 at 4)

The '522 patent issued from a continuation of the '284 Application on December 10, 2013. ('522 patent at 1) The '522 patent was granted a statutory patent-term adjustment ("PTA") of 1,775 days under 35 U.S.C. § 154(b), and thus expires on January 31, 2026. (*Id.*; *see also* D.I.

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[2] 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.

[3] AMD is the leading cause of blindness in individuals in the United States who are over the age of 55. ('297 patent, col. 1:27-30)

[4] Claims 7 and 13 were not reexamined. ('297 patent, reexamination certificate)

73 at 4) The claims of the '522 patent are directed to methods of using the claimed formulations. ('522 patent, cols. 9:58-11:20; *see also* D.I. 79 at 4)

Any further relevant facts will be set out as needed in Section III.

B. Procedural History

Plaintiffs filed this action on October 28, 2020. (D.I. 1) In lieu of filing an answer, SBH filed a motion to dismiss the complaint pursuant to Federal Rule of Civil Procedure 12(b)(6), or alternatively a request for a more definite statement pursuant to Federal Rule of Civil Procedure 12(e) (the "motion to dismiss"). (D.I. 8) The District Judge then assigned to the case, Judge Leonard P. Stark, subsequently denied SBH's motion to dismiss on March 23, 2022. (D.I. 15)

On April 1, 2022, SBH filed its Answer to the Complaint and Counterclaims. (D.I. 19) On April 4, 2023, SBH filed the instant Motion, (D.I. 63), which was fully briefed as of May 5, 2023, (D.I. 76). On May 25, 2023, SBH filed a Notice of Supplemental Authority in support of the Motion. (D.I. 82)

II. LEGAL STANDARD

In evaluating a motion for judgment on the pleadings brought pursuant to Rule 12(c), the Court uses the same standard that applies to a motion to dismiss filed pursuant to Federal Rule of Civil Procedure 12(b)(6). *See Wolfington v. Reconstructive Orthopaedic Assocs. II PC*, 935 F.3d 187, 195 (3d Cir. 2019). It must view all factual allegations in a complaint in the light most favorable to the non-moving party, and it may not grant the motion "unless the movant clearly establishes that no material issue of fact remains to be resolved and that he is entitled to judgment as a matter of law." *Id.* (internal quotation marks and citation omitted). In deciding such a motion, the Court may consider only the pleadings, the exhibits attached thereto, matters of public record and undisputedly authentic documents integral to the pleadings. *Id.*

III. DISCUSSION

With its Motion, SBH argues that the patents are invalid. Its arguments regarding invalidity are different for each patent; thus, the Court will take the patents up in turn.[5] For the reasons discussed below, the Court recommends that SBH's Motion be denied because the arguments raised therein are premature.

A. '522 Patent

SBH asserts that it is entitled to judgment in its favor with respect to Plaintiffs' claims regarding the '522 patent; it argues this is so because the '522 patent claims amount to obvious-type double patenting ("OTDP") over the claims of the '297 patent and are therefore invalid. (D.I. 63 at 4-11; D.I. 76 at 3-8) OTDP "is a judicially-created doctrine designed to prevent claims in separate applications or patents that do not recite the 'same' invention, but nonetheless claim inventions so alike that granting both exclusive rights would effectively extend the life of patent protection." *In re Hubbell*, 709 F.3d 1140, 1145 (Fed. Cir. 2013) (internal quotation marks and citation omitted).[6] Under the OTDP doctrine, a patentee is prohibited "from obtaining an extension of the right to exclude through claims in a later patent that are not patentably distinct from claims in a commonly owned earlier patent." *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 967 (Fed. Cir. 2001). "A later patent claim is not patentably distinct from an earlier claim if the later claim is obvious over, or anticipated by, the earlier claim." *Id.* at 968.

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[5] SBH's briefing often included case citations without pin cites, or it quoted certain material without including a citation indicating where that material was drawn from. (*See, e.g.*, D.I. 63 at 12, 18) This made it more difficult to follow SBH's arguments and to resolve the Motion.

[6] There is a second type of double patenting known as statutory double patenting, which stems from 35 U.S.C. § 101 and prohibits a later patent from covering identical subject matter (or the "same invention") as an earlier patent. *Takeda Pharm. Co. v. Doll*, 561 F.3d 1372, 1375 (Fed. Cir. 2009) (internal quotation marks and citation omitted).

SBH's argument relies on decisions from the United States Court of Appeals for the Federal Circuit, such as that in *Sun Pharm. Indus., Ltd. v. Eli Lilly & Co.*, 611 F.3d 1381 (Fed. Cir. 2010). In *Sun Pharm. Indus.*, the Federal Circuit explained that OTDP "encompasses any use for a compound that is disclosed in the specification of an earlier patent claiming the compound and is later claimed as a method of using that compound." *Sun Pharm. Indus.*, 611 F.3d at 1386 (*cited in* D.I. 63 at 5-6); *see also* (D.I. 76 at 2 ("[T]his patent claim scenario, a composition in the first patent (explaining the use of that composition), and a method of use of that same composition in the second patent, is very firmly and consistently laid out as OTDP by the Federal Circuit.")). Here, SBH argues that the '297 patent claims are directed to "composition claims on a treatment for AMD" and the "'522 patent claims are directed to a method of use of those same compositions in treating AMD." (D.I. 63 at 2; *see also id.* at 6)

Plaintiffs respond by arguing that, on the record here, it would be improper to resolve the issue of whether OTDP applies to the '522 patent via a Rule 12(c) motion.[7] (D.I. 73 at 9-12) The Court agrees.

As noted above, the OTDP analysis requires a determination of whether a later patent claim is obvious over, or anticipated by, the earlier claim; for such determination, a two-step

[7] Plaintiffs also argue that, as a matter of law and equity, OTDP should not apply to the '522 patent because courts have recognized that when there is a difference in expiration dates between two patents due to one patent receiving a statutorily authorized time extension (such as a PTA under 35 U.S.C. § 154(b) or a patent-term extension ("PTE") pursuant to 35 U.S.C. § 156), then OTDP does not apply. (D.I. 73 at 7-9 (citing cases)) Here, as noted above, the '522 patent was granted a PTA. ('522 patent at 1) At the time of briefing, the United States Court of Appeals for the Federal Circuit had declined to invalidate a drug patent due to OTDP whose term had been extended pursuant to PTE, *Novartis AG v. Ezra Ventures LLC*, 909 F.3d 1367, 1373-75 (Fed. Cir. 2018), but the Court had not yet determined how PTAs interact with the OTDP doctrine, (*see* D.I. 73 at 8 n.3). Subsequently, the Federal Circuit has concluded that OTDP can invalidate a patent that claims overlapping subject matter with another patent but that has a different expiration date because of PTA. *In re Cellect, LLC*, 81 F.4th 1216, 1227-28 (Fed. Cir. 2023). Thus, this argument of Plaintiffs' is not well-taken.

analysis applies. "First, the court construes the claim[s] in the earlier patent and the claim[s] in the later patent and determines the differences. Second, the court determines whether those differences render the claims patentably distinct." *AbbVie Inc. v. Mathilda & Terence Kennedy Inst. of Rheumatology Trust*, 764 F.3d 1366, 1374 (Fed. Cir. 2014) (internal quotation marks omitted). A later claim that is not patentably distinct from an earlier claim is invalid for OTDP. *Id.* OTDP is an issue of law premised on underlying factual inquiries. *Otsuka Pharm. Co. v. Sandoz, Inc.,* 678 F.3d 1280, 1290 (Fed. Cir. 2012).[8]

The Court has not yet construed the claims of the asserted patents, and so it cannot even begin to engage in the first step of the OTDP analysis, let alone the second step.[9] Indeed, SBH itself provides no real analysis with regard to this two-step process. Instead, in its opening brief, SBH simply pasted the text of claim 11 of the '522 patent and claim 19 of the '297 patent next to each other "[a]s an example[,]" (D.I. 63 at 7-8), but "offer[ed] no OTDP analysis of those claims[,]" (D.I. 73 at 10). In its reply brief, SBH attached a chart setting out certain of the claims of the asserted patents side-by-side and invited the Court "to make a five-minute comparison" of the respective claims. (D.I. 76 at 3 & ex. 1) In doing so, SBH baldly asserts that "[n]o factual issues exist regarding double patenting, since as a matter of law the claims are nearly verbatim, and in legal effect completely equivalent . . . . Only a reading of the legally identical and

[8] A patent granted by the United States Patent and Trademark Office ("PTO") is presumed to be valid. 35 U.S.C. § 282(a); *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 100-03 (2011). The burden of proving invalidity rests with the patent challenger at all times, who must establish a patent's invalidity by clear and convincing evidence in order to prevail. *Microsoft Corp.*, 564 U.S. at 100-14; *see also Abbvie Inc.*, 764 F.3d at 1372. Clear and convincing evidence places in the fact finder "an abiding conviction that the truth of [the] factual contentions are highly probable." *Procter & Gamble Co. v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 994 (Fed. Cir. 2009) (quoting *Colorado v. New Mexico*, 467 U.S. 310, 316 (1984)).

[9] The Court held a *Markman* hearing on September 26, 2023. (D.I. 97) A Report and Recommendation regarding claim construction will be issued in the future.

equivalent language of the two patents' claims is required to conform OTDP as to the '522 patent[.]" (*Id.* at 2)

The Court is not prepared to agree with SBH and invalidate all 20 claims of the '522 patent on this minimalist record. To give just one example as to why, the Court notes SBH's apparent assertion that composition claim 31 of the '297 patent is equivalent to method claims 1, 8 and 16 of the '522 patent. (*Id.*, ex. 1 at 1) Claim 1 of the '522 patent requires a "lutein-zeaxanthine combination"—a limitation that is not present in claim 31 of the '297 patent. (*See id.*; *see also* D.I. 79 at 33) Claim 8 of the '522 patent recites "reducing the risk of developing late stage or advanced age-related macular degeneration"—another limitation not present in claim 31 of the '297 patent. Yet the Court has no record indicating that these differences do not render the claims patentably distinct.

At some later point in the case, when the record is fully developed, it could be that SBH will have a viable OTDP argument with respect to at least some of the claims at issue. After all, some of the wording of certain '522 patent claims does seem pretty similar to some of the wording of certain '297 patent claims. But of course, there are some linguistic differences between those claims too. And at this early stage, for the reasons set out above, the Court recommends that SBH's Motion as it relates to the '522 patent be denied. *See, e.g.*, *Kove IO, Inc. v. Amazon Web Servs., Inc.*, Case No. 18 C 8175, 2021 WL 4515413, at *2 (N.D. Ill. Mar. 26, 2021) (declining to resolve the defendant's Rule 12(c) motion until at least after a claim construction hearing, where the defendant argued that OTDP applied, because, *inter alia*, "neither side's briefing is sufficiently instructive on either step of the O[T]DP analysis" and the Court was not prepared to decide the issue by taking defendant's suggestion to simply "compar[e] quoted claim language from the '978 Patent to quoted claim language from the

reference patents and . . . conclude that the language has the same meaning"); *Novartis AG v. Ezra Ventures, LLC*, C.A. No. 15-150-LPS, 2016 WL 5334464, at *3 (D. Del. Sept. 22, 2016) ("[T]he Court is not in a position to make [an OTDP] determination at the judgment on the pleadings stage of this case. Both the 'same invention' and 'obviousness' inquiries appear to raise fact issues (potentially requiring discovery and claim construction to resolve). At the appropriate time, Defendant may seek leave to file a motion for summary judgment based on double patenting should it have a good faith basis to do so."), *aff'd*, 909 F.3d 1367 (Fed. Cir. 2018).

B. '297 patent

SBH advances a few different arguments regarding the '297 patent, which the Court will take up in turn.

SBH's first argument relates to claims 19 and 24 of the '297 patent. Independent claim 19 recites, *inter alia*, "vitamin A in the form of beta-carotene, substituted or supplemented with lutein, zeaxanthine or a raw material combination thereof[,]" (the "substituted or supplemented term"); claim 24, which is dependent on claim 19, necessarily includes the substituted or supplemented term as well. ('297 patent, reexamination certificate at col. 2:6-14, 19-20; D.I. 63 at 11-12) SBH asserts that the substituted or supplemented term requires the use of beta-carotene in all instances. Its argument as to why this is so is a multi-step one, and goes as follows: (1) the original independent claims of the '297 patent application all required beta-carotene; while (2) certain dependent claims in the application only included the substituted or supplemented term; (3) because a dependent claim cannot remove a limitation from an independent claim, this meant that *in the application*, even those dependent claims that used the substituted or supplemented term still *required* the use of beta-carotene; and (4) therefore, even

though the substituted or supplemented term was later moved into independent claim 19 of the issued '297 patent, the use of the beta-carotene is still *required* in that claim and dependent claim 24 of the patent (such that the claims' use of the word "substituted" cannot mean that beta-carotene is *entirely removed* from the claimed composition). (D.I. 63 at 11-12; D.I. 76 at 8-9) SBH also argues that Plaintiffs disclaimed formulas not including beta-carotene during prosecution of the '297 patent and that the specification confirms that beta-carotene is required by the claims. (D.I. 63 at 17-19) And since SBH states that its accused products lack beta-carotene, this purportedly means that SBH cannot infringe these claims of the '297 patent. (*Id.* at 11)

As Plaintiffs point out, (D.I. 73 at 2 n.1), SBH makes this identical argument in the context of claim construction. Indeed, the substituted or supplemented term is a disputed claim construction term, and SBH's claim construction briefing is virtually identical to much of its Rule 12(c) opening brief with respect to this issue. (*Compare* D.I. 63 at 11-12, *with* D.I. 79 at 37-38) SBH is essentially asking the Court to construe "substituted with or supplemented with" to mean "something is added, not removed" or "substituted in part." (D.I. 63 at 12; D.I. 73 at 15) That is premature to do on a Rule 12(c) Motion.[10] The Court will take up this issue in its claim construction opinion.

[10] SBH's own briefing demonstrates that this issue is premature. For example, in asserting that the patent specification demonstrates that the claims require beta-carotene, SBH argues that the specification teaches that "[a] carotenoid proform of vitamin A is *required*" but that "[l]utein and zeaxanthine *ARE NOT* carotenoid proforms of vitamin A[.]" (D.I. 63 at 18 (emphasis in original)) But SBH includes no citations in support of these statements. Instead, it simply asserts that these facts are "[c]ommon knowledge readily verifiable." (*Id.*) But attorney argument cannot win the day here, and it would not be appropriate for the Court to engage in an attempt to independently "verifi[y]" such arguments, especially not in the context of a Rule 12(c) Motion.

SBH's second argument with respect to the '297 patent also focuses on the substituted or supplemented term. Here, SBH argues that if the claims at issue permitted lutein and/or zeaxanthine to replace the beta-carotene in some way, then the patent provides no guidance as to how much of those substances would be needed to do so, such that claim 19 would therefore be "indefinite and non-enabling[.]" (D.I. 63 at 13-16)

These issues are also premature for a Rule 12(c) Motion. "[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). Definiteness is to be evaluated from the perspective of a person of ordinary skill in the art ("POSITA") at the time the patent was filed. *Id.* at 908. Indefiniteness is a question of law that may involve underlying factual disputes. *Otsuka Pharm. Co. v. Zenara Pharma Private Ltd.*, C.A. No. 19-1938-LPS, 2021 WL 3172017, at *3 (D. Del. July 27, 2021). To meet the enablement requirement, a patent specification must enable the POSITA 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) (citation omitted).[11] Like indefiniteness, the enablement requirement is a question of law based on underlying factual inquiries, *In re '318*

[11] Factors for assessing whether a disclosure would require undue experimentation include:

> (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).

Patent Infringement Litig., 583 F.3d 1317, 1323 (Fed. Cir. 2009) (citation omitted), and is considered from the vantage point of the POSITA, *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 1000 (Fed. Cir. 2008). Clear and convincing evidence is required to show that a patent is invalid for indefiniteness and for lack of enablement. *Shure Inc. v. Clearone, Inc.*, Civil Action No. 19-1343-RGA-CJB, 2020 WL 6074233, at *10 (D. Del. Oct. 15, 2020).

SBH's briefing falls far short of meeting its burden on this score. (*See* D.I. 73 at 15-18) It is rife with attorney argument. For example, SBH states that the specification "gives not a clue" regarding how much lutein and/or zeaxanthine would be required to perform the function of the beta-carotene, and baldly asserts (without citations in support) that "at the time of the '297 filing, no one in the industry knew how much lutein and/or zeaxanthine could replace a milligram of beta-carotene." (D.I. 63 at 13, 17 n.6; *see also id.* at 16 ("[N]o clue exists as to how much other carotenoid is needed to achieve the result or effectiveness of beta-carotene.")) But "[a]ttorney argument is not evidence" and cannot serve to meet an accused infringer's burden of proof with respect to invalidity. *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, e.g.*, *Venkee Commc'ns, LLC v. Ubiquiti Networks, Inc.*, Case No. SACV 21-1009 PSG (DFMx), 2022 WL 2288078, at *8 (C.D. Cal. May 23, 2022) ("The Court finds that Defendant has not carried its burden by clear and convincing evidence to show that this limitation is indefinite. . . . Defendant supports its indefiniteness contention with attorney argument only, which is not persuasive."); *Vaxcel Int'l Co. v. Heathco LLC*, C.A. No. 20-224-LPS, 2021 WL 7209508, at *7 (D. Del. Nov. 22, 2021) (same). The Court therefore recommends that this portion of SBH's Motion be denied.

Finally, SBH argues that claims 31 and 32 of the '297 patent, added during reexamination, are invalid. (D.I. 63 at 19-20) SBH states that (in its view) claim 19 of the '297 patent requires beta-carotene; it notes that claims 31 and 32 do not recite beta-carotene and instead recite, *inter alia*, "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) SBH asserts that these claims are thus "broader than every claim of the '297 patent as originally issued" which is "contrary to law." (D.I. 63 at 20)

This argument, however, is premised on SBH's assertion that claim 19 of the '297 patent in fact requires beta-carotene in all instances. As explained above, the Rule 12(c) stage is not the appropriate time to take up such an argument. Thus, the Court recommends that SBH's Motion be denied on this ground too.

IV. CONCLUSION

SBH's filing of the instant Motion led to the inefficient use of Court resources. The time the Court had to reserve for assessing the Motion could have been better spent working on and issuing the pending claim construction decision—the opinion in which at least some of the issues discussed herein should first be properly assessed. In any event, for the foregoing reasons, the Court recommends that SBH's Motion be DENIED.

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 October 9, 2013, a copy of which is available on the District Court's website, located at http://www.ded.uscourts.gov.

Dated: December 29, 2023

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