UNITED STATES DISTRICT COURT
FILED
JUL 25 2016
MARY C. LOEWENGUTH, CLERK
WESTERN DISTRICT OF NY

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

BAUSCH & LOMB INCORPORATED and
WYETH LLC,

Plaintiffs,

v.

VITAMIN HEALTH, INC.,

Defendant.

DECISION & ORDER
13-CV-6498

PRELIMINARY STATEMENT

Plaintiffs Bausch & Lomb Incorporated and Wyeth LLC (collectively "Bausch & Lomb") bring this action under federal patent law, claiming that defendant Vitamin Health, Inc. ("Vitamin Health") infringed two patents owned by Bausch & Lomb. Specifically, Bausch & Lomb contends that Vitamin Health has infringed United States patent numbers 6,660,297 ("the '297 patent") and 8,603,522 ("the '522 patent"), both of which disclose a nutritional supplement intended to promote retinal health, by making and selling a vitamin supplement that utilizes, either literally or through the use of equivalent formulations, the inventions described in the patents. Bausch & Lomb also contends that Vitamin Health has engaged in false advertising and unfair competition in violation of the Lanham Act, codified at 15 U.S.C. § 1125(a).

By motion dated May 6, 2016, Bausch & Lomb now seeks summary judgment[1] of infringement against Vitamin Health, arguing that eight of Vitamin Health's accused products infringe the '297 patent. See Docket # 260. Vitamin Health submitted a response in opposition, see Docket # 296, and Bausch & Lomb has submitted a reply in further support of its motion. Docket # 305. After considering the parties' submissions and hearing argument on the motion, the Court now renders its decision. For the reasons that follow, Bausch & Lomb's motion for summary judgment of infringement, Docket # 260, is **granted**.

FACTUAL BACKGROUND

Familiarity with the facts of this case, as set forth more fully in the Court's claim construction and its decision on Vitamin Health's previous motions for summary judgment, is presumed. See Docket ## 130, 143. To summarize, the patents at issue are both titled "Nutritional Supplement to Treat Macular Degeneration." The '297 patent is a composition patent[2] which,

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[1] In accordance with the provisions of 28 U.S.C. § 636(c), the parties have consented to the jurisdiction of this Court for all dispositive matters, including trial.

[2] A composition patent includes "all compositions of two or more substances and all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids." Diamond v. Chakrabarty, 447 U.S. 303, 308 (1980) (quotation omitted).

according to its abstract, discloses a "nutritional or dietary supplement composition that strengthens and promotes retinal health through the prevention, stabilization, reversal and/or treatment of visual acuity loss by reducing the risk of developing late stage or advanced age-related macular degeneration in persons with early age-related macular degeneration." Exhibit 1, '297 patent, annexed to Docket # 260 (Docket # 260-4) (hereinafter "'297 patent"). The '522 patent is a method patent[3] that arose from the application that led to the '297 patent. The abstract for the '522 patent, in language almost identical to the '297 patent's, discloses a "daily nutritional or dietary supplement composition that strengthens and promotes retinal health through the prevention, stabilization, reversal and/or treatment of visual acuity loss by reducing the risk of developing late stage or advanced age-related macular degeneration in persons with early age-related macular degeneration." Exhibit 2, '522 patent, annexed to Docket # 296 (Docket # 296-5) (hereinafter "'522 patent").

The disclosed inventions stem from a ten-year research study sponsored by the National Eye Institute ("NEI") of the

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[3] A method patent is "a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing." See Gottschalk v. Benson, 409 U.S. 63, 70 (1972) (citing Cochrane v. Deener, 94 U.S. 780, 787-88 (1877)).

National Institutes of Health known as the Age-Related Eye Disease Study ("AREDS" or "AREDS 1"). '297 patent at col. 3, lines 39-46; '522 patent at col. 3, lines 42-49. The results of AREDS 1 indicate that a nutritional supplement containing particular doses of vitamins A (or certain substitutes thereof), C, and E, along with copper and zinc, had a "protective effect" on eye health. '297 patent at col. 3, lines 39-46; '522 patent at col. 3, lines 42-49. Based on NEI research, the inventors of the '297 and '522 patents developed a dietary supplement comprised of those ingredients that was designed to protect the visual acuity in persons suffering from early age-related macular degeneration by "reducing the risk of developing late stage or advanced age-related macular degeneration." '297 patent at col. 2, lines 22-36; '522 patent at col. 2, lines 26-43.

Following the conclusion of AREDS 1, the NEI published the results of the study and recommended a formula of ingredients for a nutritional supplement that would effectively treat early age-related macular degeneration. The NEI additionally allowed manufacturers of supplements utilizing the recommended formulations to use the term "AREDS," which is trademarked by the NEI, in the marketing and labeling of those supplements.

After AREDS 1 was completed, the NEI began a second study ("AREDS 2") in which researchers experimented with different

amounts and combinations of vitamins A (or certain substitutes thereof), C, and E, and zinc, copper, omega-3 fatty acids, and other ingredients to treat age-related eye conditions. The findings of AREDS 2 were published in 2013.

The '297 Patent Claims: At issue in the instant motion are claims 1, 19, and 31 of the '297 patent. Each of these claims discloses a composition of nutrients, quantified in terms of the recommended dietary allowance ("RDA"), intended to be taken daily. For example, claim 1, which was amended following a period of reexamination of the '297 patent, discloses

> [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; approximately 4 to 7 times the RDA of zinc; and at least 1.6 mg and not more than approximately 2.4 mg copper into a suitable dosage form.

Amended '297 patent at col. 1, lines 26-33. Bausch & Lomb alleges that four of Vitamin Health's AREDS-based products - Viteyes AREDS, Viteyes AREDS Advanced, Viteyes AREDS Plus Lutein, and Viteyes AREDS Powder - contain amounts of vitamin A, vitamin C, vitamin E, zinc, and copper that fall within the ranges disclosed in claim 1 and, thus, literally infringe Bausch & Lomb's '297 patent. See Docket # 260-1 at 6-8.

Similarly, after being reexamined and amended, claim 19 of the '297 patent discloses

> [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 and not more than approximately 2.4 mg copper into a suitable dosage form.

Amended '297 patent at col. 2, lines 6-14. Bausch & Lomb contends that one of Vitamin Health's products, Viteyes AREDS Lutein BC Free, contains amounts of vitamins C, vitamin E, zinc, copper, and lutein that fall within the ranges provided by claim 19 and, thus, literally infringes Bausch & Lomb's '297 patent. See Docket # 260-1 at 10-12.

Finally, with respect to claim 31, the amended '297 patent discloses

> [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.

Amended '297 patent at col. 2, lines 49-59. Bausch & Lomb contends that three of Vitamin Health's AREDS-2-based products - Viteyes AREDS 2, Viteyes AREDS 2 + Omega 3, and Viteyes Advanced BC Free - contain amounts of vitamin C, vitamin E, zinc, copper,

lutein, and zeaxanthine that fall within the ranges provided by claim 31 and, thus, literally infringe Bausch & Lomb's '297 patent. See Docket # 260-1 at 8-10.

On January 15, 2015, the Court issued a decision pursuant to Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996) ("Markman") construing the disputed terms of the '297 and '522 patents. Docket # 130. With respect to the instant motion, there are only two relevant disputed terms: "on a daily dosage basis," which the Court construed to mean "the total amount to be ingested in a day"; and "approximately 6 to 10 times the RDA of vitamin A in the form of beta-carotene," which the Court 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." Docket # 130 at 19, 20-22.

DISCUSSION

I. Legal Standard

As always, summary judgment in a patent infringement case is appropriate where "the movant shows that there is no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); see also Union Carbide Corp. v. American Can Co., 724 F.2d 1567, 1571 (Fed. Cir. 1984) ("[T]he statutory purposes of the grant of

summary judgment under Fed. R. Civ. P. 56 are without question intended to be effectuated in patent litigation as in any other type of suit and in accordance with the same standard." (citation omitted)). "By its very terms, the standard provides that the mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-48 (1986) (emphasis in original). A genuine issue of material fact exists "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Id. at 248. When deciding whether a genuine issue of material fact exists, the court must resolve all inferences and ambiguities in favor of the party against whom summary judgment is sought. Thompson v. Gjivoje, 896 F.2d 716, 720 (2d Cir. 1990); Donahue v. Windsor Locks Bd. of Fire Comm'rs, 834 F.2d 54, 57 (2d Cir. 1987).

The burden of showing the absence of any issue of material fact rests with the moving party. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). "Once this showing is made, the non-moving party may not rely solely on conclusory allegations, conjecture, and speculation, but must come forward with specific facts demonstrating that there is a genuine issue for trial." Lee v. Accessories by Peak, 705 F. Supp. 2d 249, 253 (W.D.N.Y.

2010) (citation and quotation omitted). If, after considering the evidence in the light most favorable to the non-moving party, the court determines that no rational jury could find in favor of that party, a grant of summary judgment is appropriate. See Scott v. Harris, 550 U.S. 372, 380 (2007) (citing Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586-87 (1986)).

II. Patent Infringement

Patent infringement occurs when an individual "without authority, makes, uses or sells any patented invention . . . during the term of the patent." 35 U.S.C. § 271(a). "An infringement analysis entails two steps." Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc) (citation omitted), aff'd 517 U.S. 370 (1996). First, the Court must construe the meaning and scope of the asserted claims. Id. Second, the claims, as construed by the Court, must be compared to the accused products. Id. While the first step is a question of law, infringement is a question of fact. See Frank's Casing Crew & Rental Tools, Inc. v. Weatherford Intern., Inc., 389 F.3d 1370, 1376 (Fed. Cir. 2004) (citing RF Del., Inc. v. Pac. Keystone Techs., Inc., 326 F.3d 1255, 1266 (Fed. Cir. 2003)). After the court construes the disputed terms of a patent, "[a]n infringement issue is properly decided upon

summary judgment when no reasonable jury could find that every limitation recited in the properly construed claim either is or is not found in the accused device . . . ." Gart v. Logitech, Inc., 254 F.3d 1334, 1339 (Fed. Cir. 2001) (citation omitted).

III. Infringement of the '297 Patent

This Court has already performed the first step of the above analysis, construing the disputed terms of the '297 patent on January 15, 2015. See Docket # 130. Now, based on the Court's Markman decision, Bausch & Lomb moves for summary judgment of infringement on the grounds that eight of Vitamin Health's accused products - Viteyes AREDS, Viteyes AREDS Advanced, Viteyes AREDS Plus Lutein, Viteyes AREDS Powder, Viteyes AREDS Lutein BC Free, Viteyes AREDS 2, Viteyes AREDS 2 + Omega 3, and Viteyes Advanced BC Free - literally infringe either claims 1, 19, or 31 in the '297 patent. See Docket # 260-1; see also Ghaly v. Hasbro, Inc., 112 F. App'x 7, 10 (Fed. Cir. 2004) ("Where there is no dispute surrounding the relevant facts regarding the accused devices, the only inquiry a court must engage in is a legal one that is amenable to resolution on summary judgment." (citation omitted)); General Mills, Inc. v. Hunt-Wesson, Inc., 103 F.3d 978, 983 (Fed. Cir. 1997) ("Where the parties do not dispute any relevant facts regarding the accused product . . . but disagree over possible claim

interpretations, the question of literal infringement collapses into claim construction and is amenable to summary judgment." (citation omitted)).

While each claim will be addressed in turn, as a preliminary matter, this Court must determine whether Vitamin Health's products meet the term "on a daily dosage basis," which appears in all of the asserted claims. See Amended '297 patent at col. 1, line 26, col. 2, lines 6 and 49.

"On A Daily Dosage Basis": Bausch & Lomb first argues that each of Vitamin Health's eight accused products meet the Court's construction of the "on a daily dosage basis" limitation in claims 1, 19, and 31 of the '297 patent. See Docket # 260-1 at 4-5. The Court construed that term to mean "the total amount to be ingested in a day." Docket # 130 at 20-22 ("Because the term 'on a daily dosage basis' used in claims 1, 2, 19, and 31 simply clarifies that the disclosed supplement is claimed in a quantity intended for a daily dosage, I find that the term should be construed in accordance with the plain meaning of the words as the total amount to be ingested in day."). Now, Bausch & Lomb points to Vitamin Health's products' labels and its website, which contain instructions on the amount of the products to be taken daily, and argues that this meets the "daily dosage" term in the '297 patent. See Docket # 260-1 at 4-5. Additionally, Bausch & Lomb contends that Vitamin Health's expert witness on

this issue, Dr. George Williams, "applied his own interpretation of the term because he did not agree with the Court's construction." Id. at 5.

Vitamin Health's response is four-pronged. First, Vitamin Health argues that the Court's construction of the "daily dosage" term renders the claims containing it indefinite. See Docket # 296 at 4. Second, because the Court's construction of "daily dosage" includes the words "to be," Vitamin Health asserts that Bausch & Lomb must prove that consumers of Vitamin Health's products actually ingest the composition claimed by the '297 patent on a daily basis. Id. at 4-5. Third, Vitamin Health argues that Bausch & Lomb violated the printed matter doctrine by relying on the labels of Vitamin Health's products to determine the amount intended to be taken daily. Id. at 5. Finally, Vitamin Health contends that its expert witness properly applied the Court's construction of "daily dosage" to conclude that the asserted claims are invalid. Id. at 6.

Consistent with this Court's construction of the "daily dosage" term, I conclude that no reasonable jury could find that the claim term is not found in Vitamin Health's eight products. As Bausch & Lomb highlights, the accused products all contain labels instructing consumers on the amount of the product to be taken daily. See Docket # 260-1 at 4 (citations to exhibits omitted). This fits squarely into the Court's construction of

"on a daily dosage basis," which I determined "disclose[s] the amount of the supplement that is to be ingested daily" and "clarifies that the disclosed supplement is claimed in a quantity intended for daily dosage . . . ." Docket # 130 at 20-22. Thus, as to the "daily dosage" limitation in claims 1, 19, and 31, the Court finds that Bausch & Lomb has satisfied its burden of proving that the term is present in the accused products. See TechSearch, L.L.C. v. Intel Corp., 286 F.3d 1360, 1371 (Fed. Cir. 2002) ("To establish literal infringement, all of the elements of the claim, as correctly construed, must be present in the accused system." (citation omitted)).

Moreover, Vitamin Health has failed to sufficiently demonstrate that the accused products are not literally within the scope of the claims' language. To start, the undersigned finds no basis for Vitamin Health's contention that the printed matter doctrine bars this Court from contemplating the accused products' labels to assess infringement. See Docket # 296 at 4. The case on which Vitamin Health relies for this proposition, AstraZeneca LP v. Apotex, Inc., makes no mention of whether printed matter can inform a court as to how an accused product is intended to be used; instead, it instructs that printed matter - like a label providing dosage instructions - receives patentable weight to distinguish a product from prior art only where it functionally changes that product. 623 F. Supp. 2d

579, 591-92 (D.N.J. 2009); see also In re Distefano, 808 F.3d 845, 848 (Fed. Cir. 2015) ("[W]e have long held that if a limitation claims (a) printed matter that (b) is not functionally or structurally related to the physical substrate holding the printed matter, it does not lend any patentable weight to the patentability analysis.") (citation omitted)). On appeal, the Federal Circuit confirmed this and further noted that label instructions, while not patentable, may simply "explain how to use [a] known drug." AstraZenenca LP v. Apotex, Inc., 633 F.3d 1042, 1064-65 (Fed. Cir. 2010) (citing In re Ngai, 367 F.3d 1336, 1339 (Fed. Cir. 2004)). In fact, seemingly in contrast to Vitamin Health's suggestion, the Federal Circuit in AstraZeneca recognized that an accused product's label can be used to determine whether the product's inventor intended to induce infringement of a method claim. See id. at 1059-60 ("The pertinent question is whether the proposed label instructs users to perform the patented method. If so, the proposed label may provide evidence of [appellant's] affirmative intent to induce infringement." (citation omitted)). In any event, here, the Court has no intention of reading the accused products' labels into any method claims or assessing Vitamin Health's intention to induce infringement. Rather, the Court is simply relying on the labels in the same manner in which it relied on the "daily dosage" term in the '297 patent: to provide the context in which

Vitamin Health intends the accused products to be used. Accordingly, Vitamin Health's printed matter argument is unpersuasive.

Additionally, at this juncture, the Court rejects Vitamin Health's indefiniteness argument. It is well-established that "infringement and invalidity are separate and distinct issues." Pandrol USA, LP v. Airboss Ry. Prods., Inc., 320 F.3d 1354, 1365 (Fed. Cir. 2003) (citing Cardinal Chemical Co. v. Morton Int'l, Inc., 508 U.S. 83, 102-03 (1993)). Indeed, "whether [a claim] is infringed is an entirely separate question capable of determination without regard to its validity." Id. (citation and quotation omitted). While invalidity "can preclude enforcement of a patent against otherwise infringing conduct," it is not a defense to infringement itself. Commil USA, LLC v. Cisco Systems, Inc., ___ U.S. ___, 135 S. Ct. 1920, 1928 (2015). Accordingly, because the instant motion deals exclusively with infringement, the Court declines to consider Vitamin Health's invalidity defense as to the "daily dosage" term in claims 1, 19, and 31.

With regard to Vitamin Health's remaining arguments, the Court finds them equally unavailing. Nothing in the Court's construction of the "daily dosage" term requires proof that consumers actually ingest the claimed composition on a daily basis. Instead, as noted above, the Court construed "on a daily

dosage basis" to be an explanatory term - one that "establishes context for understanding the claim composition" and reveals "the total amount to be ingested in a day." Docket # 130 at 22. The term is present to recite the capabilities of the claimed compositions, not to require actual administration. Id. at 20-22. Thus, Vitamin Health's arguments regarding proof of actual use and the testimony of Dr. Williams - who opined that the claim both was invalid and required proof of daily use - are based on an incorrect reading of the Court's claim construction. Accordingly, I find that each of Vitamin Health's accused products meet the "daily dosage" term in the '297 patent as construed by this Court.

Claim 1: Bausch & Lomb next argues that four AREDS-based accused products - Viteyes AREDS, Viteyes AREDS Advanced, Viteyes AREDS Plus Lutein, and Viteyes AREDS Powder - infringe claim 1 of the '297 patent.[4] Bausch & Lomb asserts that these four products contain amounts of vitamin A in the form of beta-carotene, vitamin C, vitamin E, zinc, and copper that fall within the limitations disclosed in claim 1. See Docket # 260-1

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[4] Claim 1 discloses "[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; approximately 4 to 7 times the RDA of zinc; and at least 1.6 mg and not more than approximately 2.4 mg copper into a suitable dosage form." Amended '297 patent at col. 1, lines 26-33.

at 6-8. In response, Vitamin Health concedes that the accused products meet the limitations as to vitamin C, vitamin E, zinc, and copper, but argues that they do not infringe the vitamin A limitation. See Docket # 296 at 6-8.

Based on a review of the parties' submissions and the record before this Court, I find that no outstanding issue of material fact exists as to infringement of the vitamin A limitation. Claim 1 provides that the disclosed supplement contains "approximately 6 to 10 times the RDA of vitamin A in the form of beta-carotene." Amended '297 patent at col. 1, line 29-30. In its Markman decision, the Court construed this term 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." Docket # 130 at 19. Both parties concede that the accused products contain five times the RDA of vitamin A in the form of beta-carotene,[5] see Docket # 260-1 at 6-7; Docket # 296 at 2, 6-8, but Vitamin Health argues that the Court's claim construction does not encompass that exact amount. Id. at 6-8. Instead, because the first limiting phrase in the Court's construction included

[5] According to the '297 patent, the RDA of vitamin A in the form of beta-carotene is 5,000 international units ("IU"). '297 patent at col.6, lines 13-14. Each of the accused products contains 25,000 IU vitamin A in the form of beta-carotene – exactly five times the RDA specified in the '297 patent. See Docket # 296 at 2.

the language "comes reasonably close to 6 to 10 times the RDA for vitamin A," Vitamin Health argues that the subsequent limiting phrase - "not less than 5 times the RDA for vitamin A" - does not extend to the explicitly-stated lower limit. Id.

Vitamin Health's interpretation of the Court's construction defies logic and, more importantly, is belied by the construction's unambiguous language. Indeed, in its Markman decision, the Court rejected Vitamin Health's efforts to set a floor of 5.5 times the RDA and recognized that, upon reexamination, the '297 patent was found to specifically "embrace a lower limit of 5 times the RDA for vitamin A." Docket # 130 at 19. Vitamin Health's present attempts to parse the language of the Court's construction are unsuccessful; put simply, there is no language to parse. If the Court were seeking to carve out a range of vitamin A disclosed by the limitation that did not include 5 times the RDA of vitamin A, the Court had a number of options to choose from: for example, "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 greater than 5 times the RDA for vitamin A," or "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 or equal to 5 times the RDA for vitamin A." Instead, the Court construed the limitation to explicitly include 5 times the RDA

of vitamin A in the form of beta-carotene – the exact amount of vitamin A found in the accused products. Accordingly, the Court finds that Vitamin Health's AREDS-based products literally infringe the '297 patent and Bausch & Lomb's motion for summary judgment of infringement as to claim 1 is **granted**.

Claim 31: Bausch & Lomb next argues that the three AREDS-2-based accused products – Viteyes AREDS 2, Viteyes AREDS 2 + Omega 3, and Viteyes Advanced BC Free – infringe claim 31[6] of the '297 patent. See Docket # 260-1 at 8-10. According to Bausch & Lomb, these three products contain amounts of vitamin C, vitamin E, zinc, copper, lutein, and zeaxanthine that meet the disclosed limitations. Id. Vitamin Health again concedes that the accused products meet the limitations as to vitamin C, vitamin E, zinc, and copper, but asserts that they do not infringe the lutein and zeaxanthine limitations. See Docket # 296 at 9-13.

Consistent with this Court's claim construction, I find that Vitamin Health's three AREDS-2-based products literally infringe claim 31 of the '297 patent. At its core, Vitamin

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[6] Claim 31 discloses "[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." Amended '297 patent at col. 2, lines 49-59.

Health's argument on this issue goes to invalidity. Id. at 9-10. Vitamin Health contends that, based on the statement in the '297 patent's specifications that the amount of lutein or zeaxanthine required to create the claimed composition "depend[s] upon" whether the lutein or zeaxanthine substitutes or supplements vitamin A, claim 31 is invalid for lack of written description and enablement. Id. For purposes of the instant motion, the Court need not address Vitamin Health's invalidity contentions. See Medtronic, Inc. v. Cardiac Pacemakers, Inc., 721 F.2d 1563, 1583 (Fed. Cir. 1983) ("Though an invalid claim cannot give rise to liability for infringement, whether it is infringed is an entirely separate question capable of determination without regard to its validity."). Instead, to adjudicate Bausch & Lomb's summary judgment motion, the Court must simply "compar[e] the properly construed claims to the [products] accused of infringing." Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc) (citation omitted), aff'd 517 U.S. 370 (1996). In so doing, it is clear to the Court that Vitamin Health's three AREDS-2-based products, which contain 10 milligrams of lutein and either 2 or 3.5 milligrams of zeaxanthine, meet the "approximately 1 to 40 milligrams of lutein" and "approximately 0.04 to 40 milligrams of zeaxanthine" limitations in claim 31.

Vitamin Health raises three additional arguments in opposition to plaintiff's summary judgment motion: (1) that a letter from Bausch & Lomb's director of global finance to the NEI's chief of monitoring and enforcement raises a genuine issue of material fact; (2) that Vitamin Health's experts believe that the accused products are not covered by the limitations in the '297 patent; and (3) that vitamin A in the form of beta-carotene is an essential ingredient to the claimed composition. See Docket # 296 at 9-13. These arguments are without merit. With regard to the first two, neither raises a genuine issue of fact that could persuade a reasonable jury to find in Vitamin Health's favor on infringement. The conclusion that 10 milligrams of lutein falls within 1 to 40 milligrams and that 2 and 3.5 milligrams of zeaxanthine fall within 0.04 to 40 milligrams is inescapable. The third argument, which requires an analysis of whether vitamin A is a necessary ingredient to create the claimed composition, goes to invalidity, not infringement. Accordingly, Bausch & Lomb's motion for summary judgment of infringement is **granted** as to claim 31.

Claim 19: Lastly, Bausch & Lomb argues that Vitamin Health's Viteyes Plus Lutein BC Free product infringes claim 19[7]

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[7] Claim 19 discloses "[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

of the '297 patent. See Docket # 260-1 10-12. Noting that the product contains amounts of vitamin C, vitamin E, zinc, copper, and lutein that meet the limitations disclosed in claim 19, Bausch & Lomb contends that summary judgment is appropriate. Id. In response, Vitamin Health concedes that its product infringes claim 19 as to the vitamin C, vitamin E, zinc, and copper limitations, but argues that the amount of lutein contained in its product is not covered by the patent. Docket # 296 at 13-14. Vitamin Health's argument mirrors its previous one: because claim 19 calls for "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 because the patent's specifications state that the amount of lutein, zeaxanthine, or combination thereof required to create the claimed composition "depend[s] upon" whether vitamin A is being supplemented or substituted, Vitamin Health believes that claim 19 is invalid for lack of written description and enablement. Id.

For the reasons stated above, the Court rejects Vitamin Health's invalidity defense as to Bausch & Lomb's motion for

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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 and not more than approximately 2.4 mg copper into a suitable dosage form." Amended '297 patent at col. 2, lines 6-14.

summary judgment of infringement. See Medtronic, Inc. v. Cardiac Pacemakers, Inc., 721 F.2d 1563, 1583 (Fed. Cir. 1983) ("Though an invalid claim cannot give rise to liability for infringement, whether it is infringed is an entirely separate question capable of determination without regard to its validity."). Moreover, and in accordance with the Court's claim construction, I find that Vitamin Health's product literally infringes claim 19. In its claim construction, the Court denied Vitamin Health's "request to hold that in any case where vitamin A in the supplement is less than 6 times the RDA of that vitamin, then 40 mg of lutein, zeaxanthine, or a combination of lutein and zeaxanthine, must be included." Docket # 130 at 37. Instead, the Court found that "[t]here is no basis in the claims or specification for precisely defining the amount of lutein or zeaxanthine that can or must be used to substitute for or supplement vitamin A in the form of beta-carotene." Id. The only construction required, I concluded, was to find that "substituted" means "instead of" and "supplemented" means "in addition to." Accordingly, I find that Vitamin Health's product, which contains 6 milligrams of lutein instead of Vitamin A in the form of beta-carotene literally infringes Bausch & Lomb's patent. Therefore, Bausch & Lomb's motion for summary judgment of infringement is **granted** as to claim 19.

Conclusion

For the reasons stated, Bausch & Lomb's motion for summary judgment of infringement with respect to claims 1, 19, and 31 of the '297 patent is **granted.**

SO ORDERED.

JONATHAN W. FELDMAN
United States Magistrate Judge

Dated: July 25, 2016
Rochester, New York