

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BAUSCH & LOMB INCORPORATED,
Petitioner,

v.

ZEAVISION, LLC,
Patent Owner.

IPR2022-01440
Patent 11,173,133 B2

Before ERICA A. FRANKLIN, TINA E. HULSE, and ROBERT A.
POLLOCK, *Administrative Patent Judges*.

FRANKLIN, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Bausch & Lomb Incorporated (“Petitioner”) filed a Petition requesting an *inter partes* review of claims 1–19 of U.S. Patent No. 11, 173, 133 B2 (Ex. 1001, “the ’133 patent”). Paper 2 (“Pet.”). Zeavision, LLC. (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 6. (“Prelim. Resp.”).

We have authority under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted unless there is a reasonable likelihood that the petitioner would prevail with respect to at least one of the claims challenged in the petition. 35 U.S.C. § 314(a). Upon considering the parties’ arguments and evidence, we determine that Petitioner has demonstrated a reasonable likelihood that it would prevail in showing the unpatentability of at least one claim challenged in the Petition. Accordingly, we institute an *inter partes* review of claims 1–19 of the ’133 patent.

A. *Real Parties-in-Interest*

Petitioner identifies itself as the real party-in-interest. Pet. 3. Petitioner also states that Bausch + Lomb Netherlands B.V., Bausch + Lomb Corporation, and Bausch Health Companies Inc. may also have an interest because Petitioner is a subsidiary of Bausch + Lomb Netherlands B.V., which is a subsidiary of Bausch + Lomb Corporation, which is a subsidiary of Bausch Health Companies Inc. *Id.* at 4.

Patent Owner identifies itself as the real party-in-interest. Paper 5, 2.

B. *Related Matters*

The parties explain that the ’133 patent has been asserted in two pending cases before the U.S. District Court for the Eastern District of Missouri: *ZeaVision LLC v. Bausch & Lomb Inc.*, No. 4:21-cv-00739 (E.D.

Mo.) and *Bausch & Lomb Incorporated, et al. v. ZeaVision, LLC*, No. 4:22-cv-00914 (E.D. Mo.). See Pet. 4–5; Paper 5, 2.

The parties also identify IPR2022-00089 (“the -0089 IPR”) and IPR2022-01029 (“the -1029 IPR”) as related. Pet. 4; Paper 5, 2. The -0089 IPR was instituted on April 18, 2022, and involves U.S. Patent No. 10,307,384 B2 (“the ’384 patent”). IPR2022-00089, Paper 7. The -1029 IPR was instituted on November 17, 2022, and involves U.S. Patent No. 11,045,431. IPR2022-01029, Paper 6.

The parties refer to pending U.S. Patent Application No. 17/656,825 as a matter that may be affected by a decision in this proceeding. Pet. 5; Paper 5, 2.

C. *The ’133 Patent*

The ’133 patent is directed to “orally-ingested formulations for treating or preventing eye diseases and vision problems.” Ex. 1001, 1:29–31. The Specification explains that the use of zeaxanthin for treating and preventing macular degeneration is described in several United States patents, including Garnett.¹ *Id.* at 4:19–24. Additionally, a number of articles discuss “the roles and the assumed, purported, or likely effects of zeaxanthin and lutein, in mammalian eyes.” *Id.* at 4:27–29.

“Zeaxanthin and lutein both belong to a class of molecules called carotenoids, which are created by plants.” *Id.* at 4:32–33. Carotenoids are important in nature and nutrition because they are “very good at absorbing ultraviolet (UV) and blue light” and “cannot be synthesized inside the cells or bodies of humans, or other mammals.” *Id.* at 4:36–40.

¹ Garnett et al., US 5,747,544, issued May 5, 1998 (Ex. 1012, “Garnett”).

According to the Specification, in addition to the potential benefits of zeaxanthin, “in recent years it also has become clear that high dosages of vitamin A or its precursor, beta carotene, offer little or no serious hope for providing any significant protection against macular degeneration, or any other serious eye disorders among people who receive minimal baseline levels of vitamin A.” Ex. 1001, 2:3–9. The Specification includes the following quote from Jampol²:

In view of previous studies suggesting that beta-carotene might be harmful in smokers and may be associated with a greater risk of lung cancer, beta carotene should probably not be used by smokers and recent ex-smokers. An argument could be made that another carotenoid, lutein or zeaxanthin, could be substituted for beta carotene, but the values and risk of other carotenoids [apparently referring again to lutein and zeaxanthin] is unknown at this time.

Id. at 3:15–24 (quoting Ex. 1043, 1534) (alteration in original). The Specification also recognizes that “various general and specific benefits of vitamins C and E, and of zinc, are well known and solidly proven, especially among elderly people and people with poor diets.” *Id.* at 17:20–23.

D. Illustrative Claim

Petitioner challenges claims 1–19 in the ’133 patent, of which claims 1, 14, and 19 are independent. Claim 1 is illustrative of the challenged claims and reads as follows:

1. A nutritional supplement for eye health in the form of a capsule or tablet for oral ingestion, comprising:
zeaxanthin and lutein, the zeaxanthin being present in the 3R-3R' stereoisomer form and being substantially free of meso-zeaxanthin stereoisomers, the zeaxanthin being present in an amount that is at least 0.5 mg;

² Jampol, *Antioxidants, Zinc, and Age-Related Macular Degeneration*, 119 ARCH. OPHTHALMOL. 1533–1534 (2001) (Ex. 1043, “Jampol”).

zinc in an amount that does not exceed 40 mg;
vitamin E;
vitamin C; and
wherein the nutritional supplement is free of beta-carotene.

Ex. 1001, claim 1.

Independent claim 14 differs from claim 1 in that it recites that the nutritional supplement is for eye health is “for users having macular degeneration,” is formulated with an oil-based carrier, comprises vitamin C in the form of ascorbic acid, and further comprises selenium and riboflavin. *Id.* at claim 14. Independent claim 19 differs from claim 1 in that it recites that the nutritional supplement is “for reducing the risk of progression of macular degeneration for the user,” comprises vitamin C in the form of ascorbic acid, and further comprises “omega-3 fatty acids comprising docosa-hexaenoic acid (DHA) and eicosa-pentaenoic acid (EPA).” *Id.* at claim 19.

E. Asserted Grounds of Unpatentability

Petitioner asserts four grounds of unpatentability in the Petition, see Pet. 7, which are provided in the table below:

Claims Challenged	35 U.S.C. §³	Reference(s)/Basis
1, 2, 5, 9–12	102(a), 102(e)	Barker ⁴
1, 2, 5, 9–12	103	Barker, Garnett

³ The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112–29, 125 Stat. 284 (2011), amended 35 U.S.C. §§ 102–103, effective March 16, 2013. Because the ’133 patent has an effective filing date after March 16, 2013, the AIA versions of §§ 102 and 103 apply.

⁴ Barker, et al., WO 03/063848 A1, published Aug. 7, 2003 (Ex. 1011, “Barker”).

Claims Challenged	35 U.S.C. § ³	Reference(s)/Basis
1, 4–14, 16–18	103	Lang, ⁵ Garnett, Jampol
2, 3, 15, 19	103	Lang, Brown, ⁶ Garnett, Jampol

Petitioner additionally relies on the declaration of Elizabeth J. Johnson, Ph.D. Ex. 1024. Among other evidence, Patent Owner relies on the declaration of Kathleen Dorey, Ph.D. Ex. 2001.

II. ANALYSIS

A. *Person of Ordinary Skill in the Art*

The level of skill in the art is a factual determination that provides a primary guarantee of objectivity in an obviousness analysis. *Al-Site Corp. v. VSI Int’l Inc.*, 174 F.3d 1308, 1324 (Fed. Cir. 1999) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966); *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991)).

Petitioner contends that a person of ordinary skill in the art (“POSA” or “POSITA”) would have had:

a Masters or a Ph.D. degree in nutritional science, chemistry, biology, biochemistry, or a related discipline or an M.D. or doctor of optometry (“O.D.”), and a few years of practical experience in the nutritional supplement area, including an understanding of formulations that could be considered for promoting eye health, including preventing or treating eye disorders such as macular degeneration. Alternatively, such a person could have been a person with a Bachelor’s degree with a greater number of years of experience. The POSITA would have, or would have access to, general information regarding eye health and eye disorders, the convenience and needs of patients who suffer from eye disorders[,] such as macular

⁵ Lang, WO 01/19383 A1, published Mar. 22, 2001 (Ex. 1009, “Lang”).

⁶ Brown et al., *Nutrition Supplements and the Eye*, 12 EYE 127–33 (1998) (Ex. 1014, “Brown”).

degeneration, and background information. To the extent needed, the POSITA would have collaborated with others having ordinary skill in the areas pertinent to the subject matter of the '133 Patent.

Pet. 8–9 (citing Ex. 1024 ¶¶ 15–16) (citations omitted). This definition by Petitioner is uncontested on the current record. *See* Prelim. Resp. 7–8. Because we find Petitioner’s definition to be reasonable and consistent with the '133 patent and the cited art, we adopt it for purposes of this Decision.

B. Claim Construction

The Board applies the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b). *See* 37 C.F.R. § 100(b) (2022). Under that standard, claim terms “are generally given their ordinary and customary meaning” as understood by a person of ordinary skill in the art at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc) (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). “In determining the meaning of the disputed claim limitation, we look principally to the intrinsic evidence of record, examining the claim language itself, the written description, and the prosecution history, if in evidence.” *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1014 (Fed. Cir. 2006) (citing *Phillips*, 415 F.3d at 1312–17).

Petitioner asserts proposed constructions for the two claim terms: “substantially free of meso-zeaxanthin stereoisomers” and “mixed tocopherols.” Pet. 25–29. Patent Owner does not challenge Petitioner’s proposed constructions and does not submit any proposed constructions for additional claim terms. *See* Prelim. Resp. 7. Accordingly, we address Petitioner’s proposed claim constructions in the following discussion.

1. “*substantially free of meso-zeaxanthin stereoisomers*”

Independent claims 1, 14, and 19 recite that the zeaxanthin is “present in the 3R-3R' stereoisomer form and is *substantially free of meso-zeaxanthin stereoisomers*.” Claims 1, 14, 19 (emphasis added). Petitioner contend that the term “*substantially free of meso-zeaxanthin stereoisomers*” should have its plain and ordinary meaning, and a POSA would have understood the term to mean that the zeaxanthin that is present in the 3R-3R' stereoisomer form is “largely but not wholly free of meso-zeaxanthin stereoisomers.” Pet. 25–26 (emphasis removed) (citing Ex. 1024 ¶ 70; Ex. 1031, 3). The Board adopted, preliminarily, this construction by Petitioner in the Institution Decisions in the -0089 IPR and -1029 IPR. -0089 IPR, Paper 7 at 9–10; -1029 IPR, Paper 6 at 8–9.

At this stage of the proceeding, we adopt Petitioner’s proposed construction as consistent with the plain and ordinary meaning of the term and the prior decisions in the -0089 IPR and -1029 IPR.

2. “*mixed tocopherols*”

Dependent claim 5 recites that the nutritional supplement of claim 1 “further comprises *mixed tocopherols*.” Claim 5 (emphasis added). Petitioner contends that the term “mixed tocopherols” appears to be a term of art and that a POSA would understand it to mean “a mixture of tocopherols such as alpha-, beta-, gamma-, and delta-tocopherols.” Pet. 28 (emphasis removed) (citing Ex. 1024 ¶ 77). The Board adopted, preliminarily, this construction by Petitioner in the Institution Decisions in the -0089 IPR and -1029 IPR. -0089 IPR, Paper 7 at 10; -1029 IPR, Paper 6 at 8–9.

At this stage of the proceeding, we adopt Petitioner’s proposed construction as consistent with the plain and ordinary meaning of the term and the prior decisions in the -0089 IPR and -1029 IPR.

C. Anticipation by Barker

Petitioner asserts that claims 1, 2, 5, and 9–12 are anticipated by Barker. Pet. 30–37. Patent Owner disagrees. Prelim. Resp. 9–14.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Schering Corp. v. Geneva Pharms*, 339 F.3d 1373, 1379 (Fed. Cir. 2003) (quoting *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987)).

1. Barker

Barker relates to a method of improving visual performance by administering “a colorant that is capable of being incorporated into eye tissue and/or causing yellowing of eye tissue.” Ex. 1011, 1:10–12. Barker explains that, when deposited in the eye tissue, the colorant provides a yellow filter that absorbs potentially damaging blue light. *Id.* at 1:13–15.

Examples of such colorants include “carotenoids, such as lutein, zeaxanthin, mesozeaxanthin, astaxanthin, or esters thereof, or canthaxanthin, or mixtures of the foregoing, as well as compounds having vitamin A activity, or precursors thereof.” *Id.* at 1:15–18. According to Barker, administration of lutein and zeaxanthin has been found to lower the risk of developing age-related macular disease (“AMD”). *Id.* at 1:18–19. Barker states that “[e]xamples of compounds having vitamin A- activity or precursors thereof are retinol and esters thereof, such as retinyl palmitate; α - and β -carotene, β -cryptoxanthin, and lycopene.” Ex. 1011, 2:11–13.

Barker illustrates its invention with examples, including Example 7, set forth below:

Example 7

A soft gelatin capsule may be prepared comprising the following ingredients:

Ingredient	Amount per Capsule
Lutein	6 mg
Zeaxanthin	6 mg
Vitamin E (α -d,l-tocopherol)	200 mg
Vitamin C	500 mg
Vitamin A	1000 Int. Units
Zinc (as orotate)	7.5 mg
Lecithin	50 mg
Soy bean oil	200 mg

Example 7 shows the ingredient list per capsule for a soft gelatin capsule comprising, among other ingredients, lutein, zeaxanthin, and Vitamin A. *Id.* at 6:14–24.

2. *Discussion*

Petitioner identifies the disclosures in Barker that Petitioner asserts disclose each element of claim 1. *See* Pet. 31–34. Specifically, Petitioner asserts that Barker’s disclosure of a soft gelatin capsule in Example 7 is anticipatory, as it is a nutritional supplement, in the form of a capsule for oral administration, to promote eye health, which comprises zeaxanthin, lutein, zinc, and vitamins E and C, as required by claim 1. *Id.* at 31–34. Petitioner alleges that a POSA would at once envisage that the zeaxanthin in

Example 7 would be in the stereoisomer form recited by claim 1, and would be substantially free of meso-zeaxanthin stereoisomers. *Id.* at 33. Petitioner asserts also that the amounts of the zeaxanthin and zinc in Example 7 meet the limitations for those ingredients in claim 1. *Id.* at 33–34.

Regarding the limitation in claim 1 that the nutritional supplement is free of beta-carotene, Petitioner asserts that Barker meets this limitation because Example 7 does not include beta-carotene. *Id.* at 34 (citing Ex. 1011, Example 7; Ex. 1024 ¶ 101).

Further, Petitioner identifies the disclosures in Barker that Petitioner asserts disclose each additional element of dependent claims 2, 5, and 9–12. *Id.* at 35–37.

Patent Owner contends that Petitioner has failed to demonstrate that the challenged claims are anticipated by Barker because Barker’s Example 7 includes Vitamin A. Prelim. Resp. 9. According to Patent Owner, “a POSITA would understand that supplements free of beta-carotene must also be free of Vitamin A” because: (a) beta-carotene, a precursor to Vitamin A, converts to Vitamin A in the human body; and (b) “nutritional supplements include beta-carotene as Vitamin A equivalent.” *Id.* at 9–11 (citing Ex. 2001 19).

At this stage in the proceeding, there is no dispute that Barker discloses the remaining claim elements for each of the challenged claims. Thus, we focus the remainder of our discussion on the one element of the claims challenged by Patent Owner.

We begin by noting that the challenged claims do not recite that the nutritional supplements are “free of Vitamin A” or “free of all sources of Vitamin A.” Rather, independent claim 1 expressly recites that the supplement is “free of beta-carotene.” See Claim 1. Patent Owner urges us

to expand the exclusion of beta-carotene to all forms of Vitamin A. That argument, however, lacks support on the current record.

In particular, the support asserted by Patent Owner and its expert, Dr. Dorey, that “nutritional supplements include beta-carotene as Vitamin A equivalent,” see Prelim. Resp. 9–10 (citing Ex. 2001 ¶ 19), establishes little, on its own. Barker does not require the use of beta-carotene as its source of Vitamin A, nor does it limit the source or form of Vitamin A used. Rather, Barker discloses that several “[e]xamples of compounds having vitamin A-activity or precursors thereof are retinol and esters thereof, such as retinyl palmitate; α - and β -carotene, β -cryptoxanthin, and lycopene.” Ex. 1011, 2:11–13. Thus, Barker discloses a number of exemplary compounds to supply Vitamin A to its nutritional supplement that are not beta-carotene.

Accordingly, based on the current record, we disagree with Patent Owner’s argument that the challenged claims exclude all forms of Vitamin A and that Barker, therefore fails to anticipate those claims. Having considered the arguments and evidence at this stage in the proceeding, we are persuaded that Petitioner has shown sufficiently for institution that Barker discloses a nutritional supplement that is “free of beta-carotene.” Therefore, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing in showing that claims 1, 2, 5, and 9–12 are anticipated by Barker.

D. Obviousness over Barker and Garnett

Petitioner asserts that claims 1, 2, 5, and 9–12 would have been obvious over the combined teachings of Barker and Garnett. Pet. 38–46. Patent Owner disagrees. Prelim. Resp. 14–15.

A patent claim is unpatentable under 35 U.S.C. § 103 if the differences between the claimed invention and the prior art are such that the

claimed invention, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the claimed invention pertains. *See KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). “An obviousness determination requires finding both ‘that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.’” *CRFD Research, Inc. v. Matal*, 876 F.3d 1330, 1340 (Fed. Cir. 2017) (quoting *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367–1368 (Fed. Cir. 2016)).

Notwithstanding what the teachings of the prior art would have suggested to one with ordinary skill in the art at the time of the patent’s invention, the totality of the evidence submitted, including objective evidence of nonobviousness, may lead to a conclusion that the challenged claims would not have been obvious to one with ordinary skill in the art. *In re Piasecki*, 745 F.2d 1468, 1471–72 (Fed. Cir. 1984); *see also Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966); *Leapfrog Enters., Inc. v. Fisher–Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007).⁷

We incorporate our description and discussion of Barker in Section II.C here.

1. *Garnett*

Garnett relates to a method “for treating or preventing macular degeneration . . . by administering a preparation of zeaxanthin which contains the 3R-3'R stereoisomer as a sole or heavily dominant

⁷ At this stage of the proceeding, Patent Owner does not assert evidence of objective indicia supporting nonobviousness of the challenged claim.

stereoisomer.” Ex. 1012, Abstract. Garnett further teaches that zeaxanthin is naturally present in macular cells and “absorbs blue and near-ultraviolet light radiation, thereby protecting retinal cells against phototoxic damage.” *Id.* Thus, according to Garnett, “[t]he purified R-R isomer of zeaxanthin can be taken orally . . . by anyone who wants to reduce his or her risk of macular degeneration, which is widespread among people over the age of about 50 or 60.” *Id.*

2. Discussion

Petitioner contends that Barker anticipates, and therefore renders obvious each limitation of the challenged claims. Pet. 38–46. Petitioner identifies the disclosures in Barker that Petitioner asserts disclose each element of the challenged claims. *See id.* Additionally, Petitioner combines Garnett’s disclosure of a “highly purified zeaxanthin” to further address the recitation in independent claim 1 requiring the zeaxanthin to be “present in the 3R-3'R stereoisomer form” and “substantially free of meso-zeaxanthin stereoisomers.” *Id.* at 40 (quoting Claim 1). According to Petitioner, a POSA would have been motivated to formulate the nutritional supplement disclosed as Barker’s Example 7 using Garnett’s “highly purified zeaxanthin,” which contains no detectable quantities of meso-zeaxanthin stereoisomers, with a reasonable expectation of success. *Id.* at 40–42.

Patent Owner contends only that the combination of Barker and Garnett does not render the challenged claims obvious because Barker contains Vitamin A. Prelim. Resp. 14–15. At this stage in the proceeding, Patent Owner does not dispute that the combination of Barker and Garnett teaches or suggests the remaining limitations of the challenged claims. *See id.*

As discussed for the anticipation ground, we do not find, based on the current record, that the challenged claims exclude all forms of Vitamin A. Rather, in this regard, the claims require only that the supplement is “free of beta-carotene.” Having considered the arguments and evidence, we are persuaded that Petitioner has shown sufficiently for institution that a person of skill in the art would have been motivated with a reasonable expectation of success in combining the teachings of Barker and Garnett, and that such combination discloses each recited limitation of the challenged claims, including a nutritional supplement that is “free of beta-carotene.”

Accordingly, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing in showing that claims 1, 2, 5, and 9–12 are rendered obvious over the combination of Barker and Garnett.

E. Obviousness over Lang, Garnett, and Jampol

Petitioner asserts that claims 1, 4–14, and 16–18 would have been obvious over the combination of Lang, Garnett, and Jampol. Pet. 46–67.

We incorporate our description and discussion of Garnett in Section II.D. here.

1. Lang

Lang relates to beadlet formulations for inclusion in dietary supplements comprising “one or more xanthophylls; one or more carotenes, retinoids, or combinations thereof; one or more antioxidants; and excipients.” Ex. 1009, 4:7–10. Lang discloses that the dietary supplements are used for “enhancement of ocular health and the prophylaxis of retinal disorders, including age-related macular degeneration.” *Id.* at 4:17–18.

Lang teaches that examples of xanthophylls include lutein and zeaxanthin. *Id.* at 8:7–9. According to Lang, “[i]t has been suggested that the particular xanthophylls, zeaxanthin and its isomer lutein, may be

beneficial in improving the health of the macula and the clarity of the lens.” *Id.* at 2:17–19. Lang explains that xanthophylls may be obtained from various dietary sources, such as corn and leafy green vegetables. *Id.* at 8:3–4. Examples of natural antioxidants and related derivatives include alpha-, beta-, gamma-, delta- and epsilon-tocopherol, as well as vitamin C. *Id.* at 9:23–10:2.

An example of a beadlet composition is shown in Example 3, reproduced below:

Example 3

Ingredient	Amount (% w/w)
Beta Carotene (natural)	3
Lutein	1.5
Zeaxanthin	1.5
Hydrolyzed Gelatin	30
Vegetable Oil/Oleoresin	23
Sucrose	14.6
Food Grade Corn Starch	17
Ascorbyl Palmitate	2.7
Tocopherol(s)	1.7
Water	5

Example 3 shows a beadlet composition including beta carotene, lutein, zeaxanthin, and tocopherol(s). *Id.* at 12:19, 13 (Example 3). In Example 10, Lang exemplifies dietary supplement gelatin capsules that incorporate beadlets, such as that of Example 3, along with other ingredients, including zinc, Vitamin C, and Vitamin E. *See id.* at 21 (Example 10).

2. Discussion

Independent claim 1 is set forth above, in Section I.D. As noted there, independent claim 14 differs from claim 1 in that it recites that the

nutritional supplement is for eye health is “for users having macular degeneration,”⁸ is formulated with an oil-based carrier, comprises vitamin C in the form of ascorbic acid, and further comprises selenium and riboflavin. Ex. 1001, claim 14.

Petitioner contends that Lang discloses each limitation of claims 1 and 14, except for the recitation that “the composition is free of beta-carotene.” See Pet. 49–61. Petitioner asserts, however, that it would have been obvious for a POSA to formulate Lang’s combined formulation of Examples 3 and 10, i.e., “Lang 10-3,” without beta-carotene for use in smokers, based on Jampol’s teaching that beta-carotene “should probably not be used by smokers and recent ex-smokers” as it “might be harmful in smokers and may be associated with a greater risk of lung cancer.” *Id.* at 55 (quoting Ex. 1043, 1534). According to Petitioner, a POSA would have understood from Jampol that, “at the very least, beta-carotene should be excluded from ocular supplements for current or former smokers.” *Id.* at 55–56 (citing Ex. 1024 ¶ 160).

Additionally, Petitioner combines Garnett’s disclosure of a “highly purified zeaxanthin” to further address the recitation in independent claim 1 requiring the zeaxanthin to be “present in the 3R-3'R stereoisomer form” and “substantially free of meso-zeaxanthin stereoisomers.” *Id.* at 52 (quoting Claim 1). According to Petitioner, a POSA would have been motivated to formulate Lang 10-3 using Garnett’s “highly purified zeaxanthin,” which contains no detectable quantities of meso-zeaxanthin stereoisomers, with a reasonable expectation of success. *Id.* at 52, 58–61.

⁸ At this stage in the proceeding, the parties take no position on whether this preamble is limiting.

Petitioner also identifies the disclosures in Lang that Petitioner asserts further disclose each additional element of dependent claims 4–13 and 16–18. *Id.* at 61–67.

Patent Owner contends that Petitioner’s combined references do not render the challenged claims obvious because Lang does not exclude beta-carotene and teaches away from doing so. Prelim. Resp. 15–17. Patent Owner asserts that “Lang cites to a study describing the implications of use of beta-carotene by smokers” and “still chose to include beta-carotene in every one of its examples.” *Id.* at 16 (citing Ex. 1009, 3:16–18). According to Patent Owner, “Lang considered issues with beta-carotene and *rejected* the opportunity to exclude it.” *Id.* Patent Owner contends that “[a] POSITA would not have been motivated to remove beta-carotene from the Lang formulation based on the teachings of Jampol” and would not have had a reasonable expectation of success “because Jampol excludes an ingredient that Lang explicitly includes,” i.e., beta-carotene. *Id.* At this stage in the proceeding, Patent Owner does not dispute that the combined references teach or suggest the remaining limitations of the challenged claims. *See id.* at 15–16.

Having considered the parties’ arguments and evidence, we are persuaded that Petitioner has shown sufficiently at this stage in the proceeding that Jampol provides motivation for excluding beta-carotene from the Lang 10-3 formulation, i.e., to protect smokers from the potential harmful effects of a formulation comprising beta-carotene. *See* Pet. 54–57; Ex. 1043, 1534; Ex. 1024 ¶¶ 159–164. Patent Owner’s argument to the contrary is unsupported on the current record because it fails to demonstrate that Lang considered the potential harm that beta-carotene may have on smokers. In particular, Patent Owner has not shown, nor do we find that

Hammond,⁹ cited by Lang, addresses beta-carotene's potential adverse effects in smokers. *See* Prelim. Resp. 16 (citing Ex. 1009, 3:16–19); Ex. 1044. Instead, Hammond's discussion focuses on how smoking might increase the probability of developing age-related macular degeneration and how smoking depresses the concentrations of carotenoids in the blood, and perhaps affects retinal carotenoids as well. Ex. 1044, 3003–3008.

According to Hammond, “[h]igh intake of food rich in carotenoids and antioxidant vitamins might help some hopelessly addicted smokers become less susceptible to tobacco-associated diseases.” *Id.* at 3007–3008.

Accordingly, we presently understand Hammond to support Lang's addition of carotenoids generally to its nutritional supplement without acknowledging the harm that a particular carotenoid, beta-carotene, may cause the smokers, as taught by Jampol.

Based on our consideration of the current record, we determine that Petitioner has shown sufficiently for institution that, at the time of the invention, a person of skill in the art would have been motivated with a reasonable expectation of success in combining the teachings of Lang, Garnett, and Jampol and that doing so would have provided a nutritional supplement that meets each element of the challenged claims, including being “free of beta-carotene.” *See* Pet. 49–67 (citing Ex. 1024 ¶¶ 140–193).

Accordingly, based on the information presented at this stage of the proceeding, we determine that Petitioner has shown sufficiently that there is a reasonable likelihood that it would prevail in showing that claims 1, 4–14,

⁹ Hammond, et al., *Cigarette Smoking and Retinal Carotenoids: Implications for Age-related Macular Degeneration*, 36 VISION RES. 3003-3009 (1996) (Ex. 1044, “Hammond”).

and 16–18 are rendered obvious by the combination of Lang, Garnett, and Jampol.

F. Obviousness over Lang, Brown, Garnett, and Jampol

Petitioner asserts that claims 2, 3, 15, and 19 would have been obvious over the combination of Lang, Brown, Garnett, and Jampol. Pet. 67–76.

We incorporate our description and discussions of Lang, Garnett, and Jampol in Sections II.D. and II.E. here.

1. Brown

Brown provides “[a] review of the role of vitamins, minerals, carotenoids and essential fatty acids in relation to eye health.” Ex. 1014, Abstract. Brown describes that “[t]he omega-3 fatty acids are essential for the normal development of the eye and brain in the infant.” *Id.* at 131. Brown further describes that “[o]mega-3 fatty acids are essential to retinal function at all ages and are found in the receptor outer segments.” *Id.* As further taught by Brown, “[c]onsumption of omega-3 fatty acids has been shown to reduce the incidence of cardiovascular disease, so that they can be considered to have a role of promoting general health with an indirect benefit to the eye.” *Id.* Brown notes that omega-3 long-chain polyunsaturated essential fatty acids, such as docosahexaenoic acid (DHA), are present in oils of animal origin, especially in those from oily fish. *Id.*

2. Discussion

Claims 2 and 3 depend from independent claim 1. Claim 2 recites that the nutritional supplement of claim 1 further comprises omega-3 fatty acids. Claim 3 recites the nutritional supplement of claim 2, “wherein the omega-3 fatty acids comprise docosa-hexaenoic acid (DHA) and eicosa-pentaenoic acid (EPA).” Claim 15 depends from independent claim 14, and recites that

the composition further “comprises omega-3 fatty acids.” Independent claim 19 recites “[a] nutritional supplement is for eye health in the form of a capsule or tablet for oral ingestion . . . for reducing the risk of progression of macular degeneration for the user, the nutritional supplement comprising: omega-3 fatty acids comprising docosa-hexaenoic acid (DHA) and eicosa-pentaenoic acid (EPA),” along with the same components recited in claim 1, except that Vitamin C must be in the form of ascorbic acid.

Petitioner asserts that each limitation of the challenged claims are rendered obvious by the Lang 10-3 formulation as modified to use Garnett’s “highly purified” 3R-3R' form of zeaxanthin and to exclude beta-carotene as taught by Jampol, as discussed in Section II.E. *See* Pet. 68–76.

Additionally, Petitioner relies on Brown to further modify the Lang 10-3 formulation to include omega-3, as required by the challenged claims. *See id.* According to Petitioner, “[a] POSITA would have known from the teachings of Brown and the art that fish oil contains omega-3 fatty acids such as DHA and EPA.” *Id.*; Ex. 1024 ¶ 202. Based on the teachings of Brown, Petitioner asserts that a POSITA would have been motivated to add omega-3 fatty acids from fish oil to the modified zeaxanthin formulations of Lang that exclude beta-carotene in view of Jampol, to provide a beneficial formulation for eye health with a reasonable expectation of success. Pet. 68–69 (citing Ex. 1013, 22; Ex. 1024 ¶¶ 204–205).

Patent Owner contends only that Petitioner’s combined references do not render the challenged claims obvious because Lang does not exclude beta-carotene and teaches away from doing so. Prelim. Resp. 16–17. At this stage in the proceeding, Patent Owner does not dispute that the combined references teach or suggest the remaining limitations of the challenged claims. *See id.*

As discussed for the above, in Section II.E., we determine at this stage in the proceeding, based on the current record, that Jampol provides motivation for excluding beta-carotene from the Lang 10-3 formulation, i.e., to protect smokers from the potential harmful effects of a formulation comprising beta-carotene. Having considered the arguments and evidence, we are persuaded that, at the time of the invention, a person of skill in the art would have been motivated with a reasonable expectation of success in combining the teachings of Lang, Brown, Garnett, and Jampol, as asserted by Petitioner, *see* Pet. 67–76 (citing Ex. 1024 ¶¶ 198–238), and that such combination discloses each recited limitation of the challenged claims, including that the nutritional supplement that is “free of beta-carotene.”

Accordingly, based on the information presented at this stage of the proceeding, we determine that Petitioner has shown sufficiently that there is a reasonable likelihood that it would prevail in showing that claims 2, 3, 15, and 19 are rendered obvious by the combination of Lang, Brown, Garnett, and Jampol.

III. CONCLUSION

For the foregoing reasons, we conclude that Petitioner has established a reasonable likelihood of prevailing in its assertion that claims 1–19 of the ’133 patent are unpatentable. Accordingly, we institute an *inter partes* review of all of the challenged claims on all of the asserted grounds.

Our determination in this Decision is not a final determination on either the patentability of any challenged claims or the construction of any claim.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 1–19 of the '133 patent on all grounds set forth in the Petition is instituted, commencing on the entry date of this decision; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of review.

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