

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BAUSCH & LOMB, INCORPORATED,
Petitioner,

v.

ZEAVISION, LLC,
Patent Owner.

IPR2022-01029
Patent 11,045,431 B1

Before ZHENYU YANG, TINA E. HULSE, and ROBERT A. POLLOCK,
Administrative Patent Judges.

HULSE, *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 1–20 of U.S. Patent No. 11,045,431 B1 (Ex. 1001, “the ’431 patent”). Paper 2 (“Pet.”). ZeaVision, LLC (“Patent Owner”) has not filed a Preliminary Response to the Petition.

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 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a). Upon considering the argument and evidence presented in the papers, we determine that Petitioner has established 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 1–20 of the ’431 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 3–4.

Patent Owner identifies itself as the real party-in-interest. Paper 4, 2.

B. *Related Proceedings*

The parties state that the ’431 patent has been asserted against Petitioner in a pending case 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). Pet. 4; Paper 4, 2.

The parties also identify IPR2022-00089 (“the -089 IPR”) as related. Pet. 4; Paper 4, 2. The -089 IPR was instituted on April 18, 2022, and involves U.S. Patent No. 10,307,384 B2, which is the great-grandparent of the ’431 patent. IPR2022-00089, Paper 7 (PTAB Apr. 18, 2022). Petitioner notes the district court case has been stayed pending the -089 IPR. Pet. 4.

Petitioner also identifies pending U.S. Patent Application Nos. 16/949,955 and 17/656,825 as matters that may be affected by a decision in this proceeding. Pet. 5.

C. The ’431 Patent

The ’431 patent, entitled “Zeaxanthin Formulations with Additional Ocular-active Nutrients, for Protecting Eye Health and Treating Eye Disorders” was filed on February 24, 2021, and claims the benefit of a series of continuation applications, the earliest of which is U.S. Patent Application No. 10,746,403 (“the ’403 application”) filed on December 23, 2003.¹ Ex. 1001, codes (54), (22), (63).

The ’431 patent “relates to orally-ingested formulations for treating or preventing eye diseases and vision problems.” Ex. 1001, 1:28–30. The ’431 patent explains that it has been known since 1985 that there are two carotenoid pigments—lutein and zeaxanthin—that exist naturally in the retina, which is crucial for clear vision. *Id.* at 2:31–40. Carotenoids are

¹ Petitioner asserts the ’431 patent is not entitled to claim priority to the ’403 application, because the ’403 application fails to provide adequate § 112 support for the ’431 patent claims. Pet. 13–18. Regardless, Petitioner notes that the claims are unpatentable over the cited references, because they qualify as prior art as of the earliest potential effective filing date. *Id.* at 17–18, n.3. Because we agree, on this record, that the cited references qualify as prior art as of December 23, 2003, we need not address Petitioner’s priority argument for purposes of this Decision.

important because they can absorb ultraviolet (“UV”) and blue light. *Id.* at 4:33–35. Carotenoids are effective anti-oxidants that neutralize oxygen free radicals that result from UV radiation damage. *Id.* at 5:30–46. Carotenoids, however, cannot be synthesized by humans, who must therefore obtain carotenoids in food or dietary supplements. *Id.* at 4:36–39.

Zeaxanthin and lutein are the only two carotenoids found in the macula, which is in the center of the retina. *Id.* at 6:31–35. The macula is responsible for fine resolution and must therefore be healthy for good vision. *Id.* at 9:18–22. The macula deposits the highest concentration of zeaxanthin in the center, which is the most crucial part of the macula, and deposits lutein in a ring around the zeaxanthin. *Id.* at 10:1–5. Macular degeneration is the leading cause of blindness among the elderly. *Id.* at 9:25–27. Studies have shown that people with below-normal concentrations of zeaxanthin in their macula have higher risks and rates of macular degeneration than those with normal levels. *Id.* at 9:47–51.

As described in the ’431 patent, “human retinas have developed and evolved with a notable and substantial preference for zeaxanthin, over lutein.” *Id.* at 10:33–35. Zeaxanthin, however, is scarce in dietary sources, whereas lutein is relatively abundant. *Id.* at 10:13–15. The Specification states that the only isomer of zeaxanthin that is present in dietary sources is the 3R, 3'R stereoisomer (or R—R isomer). *Id.* at 10:42–47. Although the human retina can convert lutein into zeaxanthin, it cannot convert lutein into the same isomer of zeaxanthin that is present in the natural diet. *Id.* at 10:36–42. Rather, the retina can only convert lutein into the S—R stereoisomer, or meso-zeaxanthin, which has not been shown to exist in any known dietary sources. *Id.* at 10:49–54.

Accordingly, it is an object of the invention to disclose oral formulations for mammals that “contain zeaxanthin as an essential and critical ingredient, and which also contain at least two or more other agents that have been proven . . . to act in a synergistic and potentiating manner with zeaxanthin, to provide improved efficacy in preventing or treating eye diseases.” *Id.* at 15:47–55.

D. Illustrative Claims

Petitioner challenges claims 1–20 of the ’431 patent, of which claims 1, 13, and 20 are independent. Claim 1 is illustrative and reproduced below:

1. A nutritional supplement for eye health, comprising:
a capsule or tablet for oral ingestion that comprises a composition comprising
 - (a) at least 0.5 mg of zeaxanthin, the zeaxanthin being present in the 3R-3R' stereoisomer form and is substantially free of meso-zeaxanthin stereoisomers,
 - (b) zinc in an amount that does not exceed 40 mg,
 - (c) vitamin E, and
 - (d) vitamin C.

Ex. 1001, claim 1. Independent claim 13 differs from claim 1 in that it recites “an oily carrier material” and “vitamin C in the form of ascorbic acid.” *Id.*, claim 13. Independent claim 20 is identical to claim 13, but recites “omega-3 fatty acids including docosa-hexaenoic acid (DHA) and eicosa-pentaenoic acid (EPA)” instead of “an oily carrier material.” *Id.*, claim 20.

Dependent claims 2–12 and 14–19 recite additional components of the nutritional supplement; dependent claim 10 recites a supplement with at least 10 mg of zeaxanthin; and dependent claims 9 and 19 recite that the

ingredients of the supplement are released over a span of at least 3 hours. *Id.* at 36:58–38:15.

E. The Asserted Grounds of Unpatentability

Petitioner asserts that claims 1–20 are unpatentable on the following grounds:

Claims Challenged	32 U.S.C. § ²	Reference(s)
1, 5, 7, 8, 11–13, 16–18	102(b)	Lang ³
1, 2, 5–8, 11, 13, 14, 17, 18	102(a)	Barker ⁴
1, 5, 7, 8, 10–13, 16–18	103	Lang, Garnett ⁵
2–4, 6, 14, 15, 20	103	Lang, Garnett, Brown ⁶
1, 5, 7, 8, 11–13, 16–18	103	Lang, Roche ⁷
2–4, 6, 14, 15, 20	103	Lang, Roche, Brown
9, 19	103	Lang, Roche, Remington ⁸

² The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. §§ 102–103, effective March 16, 2013. Because the ’431 patent has an effective filing date before March 16, 2013, the pre-AIA versions of §§ 102 and 103 applies.

³ Lang, WO 01/019383 A1, published Mar. 22, 2001 (“Lang”) (Ex. 1009).

⁴ Barker, et al., WO 03/064318 A1, published Aug. 7, 2003 (“Barker”) (Ex. 1011).

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

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

⁷ FDA Docket No. 95S-0316, 75-Day Premarket Notification for New Dietary Ingredient Zeaxanthin by Roche Vitamins, Inc. (opened for public inspection June 2001) (“Roche”) (Ex. 1020).

⁸ Remington’s Pharmaceutical Sciences (18th ed.) (1990) (“Remington”) (Ex. 1040).

Petitioner also relies on the Declaration of Elizabeth J. Johnson, PhD., FACN, FICS. Ex. 1024.

II. ANALYSIS

A. *Person of Ordinary Skill in the Art*

Petitioner contends that a person of ordinary skill in the art at the time of the invention 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 degeneration, and background information. And to the extent needed, the POSITA would have collaborated with others having ordinary skill in the areas pertinent to the subject matter of the ’431 Patent.

Pet. 8–9 (citing Ex. 1024 ¶ 16) (citations omitted).

We adopt Petitioner’s definition as it appears to be consistent with the prior art’s demonstration of the level of ordinary skill in the art at the time of the invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required “where the prior art itself reflects an appropriate level and a need for testimony is not shown” (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985))).

Moreover, we find on this record that Dr. Johnson is qualified to opine from the perspective of a skilled artisan as she is a person of at least ordinary skill in the art. *See* Ex. 1024 ¶¶ 2–11, App’x A.

B. Claim Construction

In an *inter partes* review, 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).

1. “substantially free of meso-zeaxanthin stereoisomers”

Petitioner contends the term “substantially free of meso-zeaxanthin stereoisomers” should have its plain and ordinary meaning, and a person of ordinary skill in the art would have understood this 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. 20–22 (citing Ex. 1024 ¶ 62; Ex. 1031, 3). The Board adopted this construction in the -089 IPR. -089 IPR, Paper 7 at 9–10.

2. “mixed tocopherols”

Petitioner contends the term “mixed tocopherols” should be construed to mean “a mixture of tocopherols such as alpha-, beta-, gamma-, and delta-tocopherols.” Pet. 23–24 (citing Ex. 1024 ¶ 69). The Board adopted this construction in the -089 IPR. -089 IPR, Paper 7 at 10.

3. Conclusion

At this stage of the proceeding, we adopt Petitioner’s proposed constructions as consistent with the plain and ordinary meaning of the terms

and our prior decision in the -089 IPR. *See Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) (“[C]laim terms need only be construed ‘to the extent necessary to resolve the controversy.’” (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))).

C. Alleged Anticipation over Lang

Petitioner argues that Lang anticipates claims 1, 5, 7, 8, 11–13, and 16–18. Pet. 25–36. On this record, we determine that Petitioner has established a reasonable likelihood that it would prevail in showing that the challenged claims are anticipated by Lang.

1. Lang (Ex. 1009)

Lang relates to beadlet formulations for including 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 “the enhancement of ocular health and the prophylaxis of retinal disorders, including age-related macular degeneration.” *Id.* at 4:17–18.

Lang further states that examples of xanthophylls include lutein and zeaxanthin. *Id.* at 8:7–9. Lang states that “[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 teaches that xanthophylls may be obtained from various dietary sources, such as corn and leafy green vegetables. *Id.* at 8:3–4. Lang also teaches that 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 lutein, zeaxanthin, and tocopherol(s). *Id.* at 12:19. Lang also provides examples of dietary supplement gelatin capsules that incorporate beadlets, such as that of Example 3, along with other nutrients such as vitamin E and zinc to treat various ocular diseases. *See, e.g., id.* at 21 (Example 10).

2. *Analysis*

Anticipation requires that “each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (citation omitted). “To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.’” *Id.* (citation omitted). Moreover, to anticipate, a prior art reference must “disclose[] within the four corners of the document not only

all of the limitations claimed but also all of the limitations arranged or combined in the same way as recited in the claim.” *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008).

Petitioner asserts that Lang discloses each limitation of independent claims 1 and 13. Pet. 26–33. Specifically, Petitioner asserts that Example 10, which incorporates the beadlets of Examples 1–6, anticipates the claims. Example 10 (as reproduced in the Petition) is shown below:

Example 10

A preferred dietary supplement gelatin capsule of the present invention incorporating any of the beadlets of Example 1-6, or mixtures thereof:

Ingredient	Amount		
Beadlets	80-120 mg	Pantothenic Acid	6 mg
Other nutrients:		Selenium	0.07 mg
Thiamin (Vitamin B-1)	1.4 mg	Bilberry Herb Powder	40 mg
Riboflavin (Vitamin B-2)	1.6 mg	Citrus Bioflavonoid Complex Powder	250 mg
Pyridoxine (Vitamin B-6)	2 mg	Grape Seed Extract with Leucoanthocyanins	10 mg
Cyanocobalamin	0.001 mg	Taurine	50 mg
Niacin	18 mg	Polyphenol Catechins of Green Tea Extract	50 mg
Ascorbic Acid	60 mg	Spinach Leaf Powder	50 mg
Vitamin E (d-alpha-tocopherol succinate)	9 IU	n-Acetyl L-Cysteine (Anhydrous)	50 mg
Copper (as copper gluconate)	0.5 mg	Excipients:	
Zinc (as zinc acetate)	5 mg	Vegetable Derived Magnesium Stearate	13 mg
Manganese (as citrate)	1 mg	Fine Silica Powder	10 mg
Folate	0.2 mg	Croscarmellose Sodium	20 mg
Biotin	0.15 mg	White Opaque Gelatin Capsule	115 mg
		Ancillary Excipients	0-100 mg

Pet. 27 (reproducing Ex. 1009, 21). Example 10 discloses a preferred dietary supplement gelatin capsule. Relying on Example 3 as the incorporated beadlet, Petitioner refers to the embodiment as “Lang 10-3.” Pet. 27. Lang 10-3 is an example of a preferred dietary supplement gelatin capsule that includes the zeaxanthin-containing beadlets of Example 3 and other nutrients such as vitamin C (ascorbic acid), zinc, and vitamin E. Ex. 1009, 14, 21.

Petitioner asserts that Lang reads on the preambles of claims 1 and 13 because Lang 10-3 discloses a gelatin capsule for promoting eye health. Pet. 28 (citing Ex. 1009, 4:16–19, Example 10, 10:1–4; Ex. 1024 ¶ 84). Petitioner also asserts that Lang discloses at least 0.5 mg of zeaxanthin in 3R-3R' form because Lang 10-3 contains 80–120 mg of Example 3 beadlets, which include 1.5% w/w zeaxanthin, and a person of ordinary skill in the art would understand that amounts to about 1.2–1.8 mg of zeaxanthin. *Id.* at 28–29 (citing Ex. 1009, Examples 3, 10; Ex. 1024 ¶ 85). Moreover, Petitioner asserts a skilled artisan would have understood that the zeaxanthin in Lang 10-3 discloses the 3R-R' form of zeaxanthin that is substantially free of meso-zeaxanthin because Lang teaches obtaining zeaxanthin from corn, and a person of ordinary skill in the art would have understood that the 3R-3R' stereoisomer is the only zeaxanthin present in dietary sources and any such preparation from corn would be substantially free of meso-zeaxanthin stereoisomers. Pet. 29–30 (citing Ex. 1009, Examples 3, 10, 8:3–7; Ex. 1024 ¶¶ 86–88; Ex. 1016 at 122, table 1; Ex. 1001 at 10:42–45, 10:65–66; Ex. 1023 at 3). Petitioner further notes the '431 patent states that “[t]he only isomer of zeaxanthin that is present in dietary sources is the 3R, 3'R stereoisomer” and that “meso-zeaxanthin has never been shown to exist in any food sources that humans eat.” *Id.* (quoting Ex. 1001, 10:42–45, 65–66). Finally, Petitioner asserts that Lang 10-3 discloses 5 mg zinc, vitamin E, vitamin C (i.e., ascorbic acid), and vegetable oil/oleoresin as an oily carrier material (for claim 13). Pet. 32–33 (citing Ex. 1009, Example 10, 11:12–19; Ex. 1024 ¶¶ 89–93).

Petitioner also asserts that Lang anticipates dependent claims 5, 7, 8, 11, 12, and 16–18, providing a claim chart and discussion identifying how

Lang 10-3 discloses each limitation of the claims. Pet. 33–36 (citing Ex. 1009, Examples 3, 10; Ex. 1024 ¶¶ 95–99).

On this record at this stage of the proceeding, we are persuaded that Petitioner has shown sufficiently that Lang anticipates claims 1, 5, 7, 8, 11–13, 17, and 18 for the reasons stated by Petitioner, which we adopt for purposes of this Decision. *See* Pet. 25–36; Ex. 1009, Examples 3, 10; Ex. 1029 ¶¶ 81–99.

3. Conclusion

Accordingly, we determine that Petitioner has demonstrated a reasonable likelihood that it would prevail in showing claims 1, 5, 7, 8, 11–13, and 16–18 are anticipated by Lang.

D. Ground 2: Alleged Anticipation over Barker

Petitioner argues claims 1, 2, 5–8, 11, 13, 14, 17, and 18 of the ’431 patent are anticipated by Barker. Pet. 36–44. On this record, we determine Petitioner has shown a reasonable likelihood that it would prevail in showing the challenged claims are anticipated by Barker.

1. Barker (Ex. 1011)

Barker relates to “administration of a colorant that is capable of being incorporated into eye tissue and/or causing yellowing of eye tissue[, which] results in an improvement of visual performance.” Ex. 1011, 1:10–12. Barker explains that such colorants, when deposited in the retina, provide a yellow filter that absorbs potentially damaging blue light. *Id.* at 1:12–15. As examples of colorants that can be used, Barker lists carotenoids such as lutein, zeaxanthin, and mesozeaxanthin, and compounds having Vitamin A activity. *Id.* at 1:21–26. Barker also states that the colorants may be used in combination with an antioxidant such as Vitamin E, Vitamin C, and zinc. *Id.* at 1:31–2:5.

An example of a soft gelatin capsule according to the invention is shown in Example 6, reproduced below:

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

Example 6 shows a soft gelatin capsule with ingredients including lutein, zeaxanthin, Vitamin E, and soybean oil. *Id.* at 6:2.

2. Analysis

Petitioner asserts that Barker discloses each limitation of claims 1 and 13. Pet. 37–40. Specifically, Petitioner asserts that Example 6 discloses a gelatin capsule for promoting eye health containing 6 mg of zeaxanthin in the 3R-3R' form that is substantially free of meso-zeaxanthin, 7.5 mg zinc, vitamin E, vitamin C, and soybean oil as an oily carrier material. *Id.* (citing Ex. 1011, Example 6; Ex. 1024 ¶¶ 112–119). Petitioner also provides a claim chart and discussion identifying how Example 6 of Barker discloses each limitation of dependent claims 2, 5, 6–8, 11, 14, 17, and 18. *Id.* at 41–44 (citing Ex. 1011, Example 6; Ex. 1024 ¶¶ 121, 123).

On this record at this stage of the proceeding, we are persuaded that Petitioner has shown sufficiently that Barker anticipates claims 1, 2, 5–8, 11, 13, 14, 17, and 18 for the reasons stated by Petitioner, which we adopt for

purposes of this Decision. *See* Pet. 37–40; Ex. 1011, Example 6; Ex. 1024 ¶¶ 110–123.

3. *Conclusion*

Having considered the arguments and evidence presented by the parties, we find Petitioner has shown a reasonable likelihood that it would prevail on its assertion that claims 1, 2, 5–8, 11, 13, 14, 17, and 18 are unpatentable as anticipated by Barker.

E. Remaining Obviousness Grounds

Petitioner asserts that claims 1, 5, 7, 8, 10–13, and 16–18 would have been obvious over Lang and Garnett (Pet. 44–54); claims 2–4, 6, 14, 15, and 20 would have been obvious over Lang, Garnett, and Brown (Pet. 54–59); claims 1, 5, 7, 8, 11–13, and 16–18 would have been obvious over Lang and Roche (Pet. 59–69); claims 2–4, 6, 14, 15, and 20 would have been obvious over Lang, Roche, and Brown (Pet. 69–74); and claims 9 and 19 would have been obvious over Lang, Roche, and Remington (Pet. 74–76).

On this record, we determine Petitioner has shown a reasonable likelihood that it would prevail in showing the challenged claims would have been unpatentable as obvious over the cited art. We incorporate here our earlier findings and discussion regarding Lang.

1. *Garnett (Ex. 1012)*

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 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, the purified R—R isomer of zeaxanthin can

be taken orally as a nutritional supplement by patients suffering from macular degeneration or who want to reduce their risk of macular degeneration. *Id.*

2. *Brown (Ex. 1014)*

Brown is a review article regarding “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.*

3. *Roche (Ex. 1020)*

Roche is an FDA premarket notification of a new dietary ingredient, zeaxanthin. Ex. 1020, 1. Roche describes that zeaxanthin is a dietary ingredient for dietary supplements, which belongs to a class of carotenoids called xanthophylls. *Id.* at 14. Roche teaches that three isomers of zeaxanthin are normally present in the retina of which the most abundant isomer is “(3R,3’R)-zeaxanthin.” *Id.* Roche also states that “[t]he presently described dietary ingredient contains almost exclusively (3R,3’R)-zeaxanthin, as well as very small amounts of (3R,3’S)-(meso)-zeaxanthin and (3S,3’S)-zeaxanthin.” *Id.* Roche states that the “product will be available as a bulk ingredient in a beadlet formulation containing 5% zeaxanthin (Zeaxanthin 5% TG), for the manufacture of dietary supplements.” *Id.* at 12.

4. *Remington (Ex. 1040)*

Remington is a chapter from “Remington’s Pharmaceutical Sciences” entitled “Sustained-Release Drug Delivery Systems.” Ex. 1040 at 1676. Remington discusses sustained-release drug therapy, including the advantages, relevant drug properties, oral dosage forms, parenteral dosage forms, and targeted delivery systems for such therapy. *Id.* at 1677–93.

5. *Analysis*

A patent claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, 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 subject matter pertains. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations, including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

“[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *KSR*, 550 U.S. at 418. “[I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” *Id.* Moreover, a person of ordinary skill in the art must have had a reasonable expectation of success of doing so. *PAR Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1193 (Fed. Cir. 2014).

We note that because we find above that Petitioner has shown sufficiently that claims 1, 5, 7, 8, 11–13, and 16–18 are anticipated by Lang,

we find Petitioner has also shown a reasonable likelihood of succeeding on its assertions that the combination of Lang and Garnett and the combination of Lang and Roche render those claims obvious, as well, as it is well settled that anticipation is the epitome of obviousness. *See Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1373 (Fed. Cir. 2019) (“[I]t is well settled that a disclosure that anticipates under § 102 also renders the claim invalid under § 103, for anticipation is the epitome of obviousness.”) (internal quotations and citations omitted).

As for the remaining dependent claims, we have considered Petitioner’s arguments and evidence, and find each of the limitations is taught by the combinations of references cited for the reasons stated by Petitioner. Pet. 46–76 (citing Ex. 1024 ¶¶ 134–250). We are also persuaded that Petitioner has shown sufficiently that a person of ordinary skill in the art would have been motivated to combine the references with a reasonable expectation of success. For example, Petitioner additionally relies on the 3R-3R' zeaxanthin formulations of Garnett and Roche as teaching formulations that are substantially free of meso-zeaxanthin stereoisomers. Pet. 62–63 (citing Ex. 1020, 14). Petitioner notes that Lang (and the ’431 patent) teaches that zeaxanthin was available from various manufacturers (such as Roche) and the references are directed to the same problem of promoting eye health using formulations comprising zeaxanthin. *Id.* at 49–50, 64–65 (citing Ex. 1001, 20:15–22; Ex. 1009, 4:7–18, 8:3–7; Ex. 1012, Abstract, 16:28–51, 22:13–41; Ex. 1020, 17–33; Ex. 1024 ¶¶ 148–149, 209–210). Thus, Petitioner asserts that it would have been obvious for a person of ordinary skill in the art to use the highly purified zeaxanthin taught by Garnett or Roche in the formulations taught by Lang. Pet. 63 (citing Ex. 1024 ¶¶ 198–204).

For dependent claims 2, 6, and 14, which additionally recite “the composition further comprises omega-3 fatty acids,” Petitioner relies on Brown’s teachings of the benefits of omega-3-fatty acids that are found in fish oil for eye health. Pet. 55 (citing Ex. 1014, 130–31; Ex. 1024 ¶ 167). Similarly, independent claim 20⁹ and dependent claim 15 recite “omega-3 fatty acids including docosa-hexaenoic acid (DHA) and eicosa-pentaenoic acid (EPA).” Ex. 1001, claims 15, 20. Petitioner asserts that a person of ordinary skill in the art would have known from the teachings of Brown and the art that fish oil contains omega-3 fatty acids such as DHA and EPA. Pet. 57, 59 (citing Ex. 1014, 131; Ex. 1039, 1; Ex. 1024 ¶¶ 177–178, 185). Petitioner asserts that a person of ordinary skill would have been motivated to incorporate the omega-3 fatty acids of Brown into the zeaxanthin formulations of Lang (or Lang and Garnett or Lang and Roche) because both teach nutrients that are beneficial for eye health and compositions comprising lutein, zeaxanthin, and omega-3 fatty acids have been disclosed in the art. Pet. 55–56, 70–71 (citing Ex. 1024 ¶¶ 168–170, 176–178, 226–228; Ex. 1013 at 22, 30).

Finally, dependent claims 9 and 19 further recite “wherein the capsule [or tablet] provides a daily dosage of the ingredients to the user that is released over a span of at least 3 hours following the oral ingestion.” Ex. 1001, claims 9, 19. Petitioner asserts that Lang teaches the beadlets may comprise additional excipients such as “timed-release polymer coating agents useful in prolonging dissolution of the beadlet in the digestive tract.” Pet. 75 (citing Ex. 1009, 11:20–25). Petitioner further asserts that

⁹ Claim 20 is identical to independent claim 13, but replaces the “oily carrier material” of (a) with the “omega-3 fatty acids including docosa-hexaenoic acid (DHA) and eicosa-pentaenoic acid (EPA)” limitation.

Remington teaches sustained- and controlled-dosage forms that release drug over extended periods of time (e.g., over 12 hours). *Id.* (citing Ex. 1040 at 1677–82; Ex. 1024 ¶ 250). Given the teachings of Lang and Remington, Petitioner argues that a person of ordinary skill in the art would have been motivated to incorporate sustained-release dosage forms into the capsule formulations of Lang 10-3 and would have expected to be able to release the ingredients over a span of at least 3 hours. *Id.* at 75–76 (citing Ex. 1024 ¶¶ 246, 250).

On this record at this stage of the proceeding, we are persuaded that Petitioner has shown sufficiently that claims 1–20 would have been unpatentable as obvious over the cited art for the reasons stated by Petitioner, which we adopt for purposes of this Decision. *See* Pet. 44–76; Ex. 1024 ¶¶ 124–251.

6. Conclusion

Having considered the arguments and evidence presented by the parties, we find Petitioner has shown a reasonable likelihood that it would prevail on its assertions that claims 1, 5, 7, 8, 10–13, and 16–18 would have been obvious over Lang and Garnett; claims 2–4, 6, 14, 15, and 20 would have been obvious over Lang, Garnett, and Brown; claims 1, 5, 7, 8, 11–13, and 16–18 would have been obvious over Lang and Roche; claims 2–4, 6, 14, 15, and 20 would have been obvious over Lang, Roche, and Brown; and claims 9 and 19 would have been obvious over Lang, Roche, and Remington.

III. CONCLUSION

For the foregoing reasons, we determine that Petitioner has established a reasonable likelihood of prevailing on its assertion that at least one of the challenged claims of the '431 patent is unpatentable.

Accordingly, we institute an *inter partes* review of claims 1–20 of the ’431 patent on each of the grounds raised in the Petition.

Our determination in this Decision is not a final determination on the construction of any claim term or the patentability of any challenged claim and, thus, leaves undecided any factual issues necessary to determine whether sufficient evidence supports Petitioner’s contentions by a preponderance of the evidence in the final written decision. *See TriVascular, Inc. v. Samuels*, 812 F.3d 1056, 1068 (Fed. Cir. 2016) (noting that “there is a significant difference between a petitioner’s burden to establish a ‘reasonable likelihood of success’ at institution, and actually proving invalidity by a preponderance of the evidence at trial”) (quoting 35 U.S.C. § 314(a) and comparing § 316(e)).

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 1–20 of U.S. Patent No. 11,045,431 B1 is instituted with respect to all challenged claims and all grounds set forth in the Petition; 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 a trial, which will commence on the entry date of this decision.

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For PETITIONER:

Scott Reed
Prajakta Sonalker
VENABLE LLP
bauschptab@venable.com
psonalker@venable.com

For PATENT OWNER:

Anthony G. Simon
Anthony R. Friedman
SIMON LAW FIRM, P.C.
asimon@simonlawpc.com
afriedman@simonlawpc.com