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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RIMFROST AS,
Petitioner,

v.

AKER BIOMARINE ANTARCTIC AS,
Patent Owner.

IPR2018-01178
Patent 9,375,453 B2

Before ERICA A. FRANKLIN, TINA E. HULSE, and JOHN E. SCHNEIDER, *Administrative Patent Judges.*

FRANKLIN, *Administrative Patent Judge.*

JUDGMENT

Final Written Decision
Determining All Challenged Claims Unpatentable
Denying Patent Owner's Motion to Amend
35 U.S.C. § 318(a)

I. INTRODUCTION

This is a Final Written Decision in an *inter partes* review challenging the patentability of claims 1–32 ("the challenged claims") of U.S. Patent No. 9,375,453 B2 ("the '453 patent," Ex. 1001). We have jurisdiction under 35 U.S.C. § 6, and enter this Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons set forth below, we determine that Rimfrost AS ("Petitioner") has shown, by a preponderance of the evidence, that the challenged claims are unpatentable. *See* 35 U.S.C. § 316(e) (2012). Additionally, we deny the contingent Motion to Amend filed by Aker Biomarine Antarctic AS ("Patent Owner").

A. Procedural History

Petitioner filed a Petition for an *inter partes* review of the challenged claims under 35 U.S.C. § 311. Paper 2 ("Pet."). Petitioner supported the Petition with the Declaration of Stephen J. Tallon, Ph.D. (Ex. 1006). Patent Owner declined to file a Preliminary Response to the Petition.

On January 14, 2019, pursuant to 35 U.S.C. § 314(a), we instituted trial to determine whether any challenged claim of the '453 patent is unpatentable based on the grounds raised in the Petition:

Claim(s) Challenged	35 U.S.C. §	References
1–3, 5–10, 12, 14–17, 19–20, 23–26, 28, 30–32	103(a)	Breivik II[1], Catchpole[2], Bottino II[3], Sampalis I[4]
4	103(a)	Breivik II, Catchpole, Bottino II, Sampalis I, Sampalis II[5]
11, 18, 21, 27	103(a)	Breivik II, Catchpole, Bottino II, Sampalis I, Fricke[6]
13, 22, 29	103(a)	Breivik II, Catchpole, Bottino II, Sampalis I, Randolph[7]

Paper 7 ("Institution Decision" or "Inst. Dec.").

Patent Owner filed a Patent Owner Response to the Petition. Paper 12 ("PO Resp."). Patent Owner supported the Response with the Declaration of Nils Hoem, Ph.D. Ex. 2001. Petitioner filed a Reply to the Patent Owner

[1] Breivik, WO 2008/060163 A1, published May 22, 2008 ("Breivik II") (Ex. 1037).
[2] Catchpole, WO 2007/123424 A1, published Nov. 1, 2007 ("Catchpole") (Ex. 1009).
[3] Bottino, *Lipid Composition of Two Species of Antarctic Krill: Euphausia superba and E. crystallorophias*, 50B COMP. BIOCHEM. PHYSIOL. 479–484 (1975) ("Bottino II") (Ex. 1038).
[4] Sampalis et al., *Evaluation of the Effects of Neptune Krill Oil™ on the Management of Premenstrual Syndrome and Dysmenorrhea*, 8(2) ALT. MED. REV. 171–179 (2003) ("Sampalis I") (Ex. 1012).
[5] Sampalis, WO 03/011873 A2, published Feb. 13, 2003 ("Sampalis II") (Ex. 1013).
[6] Fricke et al., *Lipid, Sterol and Fatty Acid Composition of Antarctic Krill (Euphausia superba Dana)*, 19(11) LIPIDS 821–827 (1984) ("Fricke") (Ex. 1010).
[7] Randolph, US 2005/0058728 A1, published Mar. 17, 2005 ("Randolph") (Ex. 1011).

Response. Paper 18 ("Pet. Reply"). Patent Owner filed a Sur-Reply to Petitioner's Reply. Paper 22 ("PO Sur-Reply").

Patent Owner filed a Contingent Motion to Amend. Paper 11 ("MTA"). Patent Owner supports the motion with the Reply Declaration of Nils Hoem, Ph.D. Ex. 2025. Petitioner filed an Opposition to the motion. Paper 19 ("MTA Opp."). Petitioner supports the Opposition to the motion with the Reply and Opposition Declaration of Stephen J. Tallon, Ph.D. Ex. 1086. Patent Owner filed a Reply to Petitioner's Opposition to the Motion to Amend. Paper 21 ("MTA Reply"). Petitioner filed a Sur-Reply to Patent Owner's Reply to Opposition to Motion to Amend. Paper 30 ("MTA Sur-Reply").

On October 16, 2019, the parties presented arguments at an oral hearing. Paper 31. The hearing transcript has been entered in the record. Paper 33 ("Tr.").

B. Real Parties in Interest

Petitioner identifies its real parties in interest as Olympic Holding AS, Emerald Fisheries AS, Rimfrost USA, LLC, Rimfrost New Zealand Limited, Bioriginal Food and Science Corp., and Petitioner, Rimfrost AS. Pet. 1. Additionally, Petitioner asserts that, based upon a majority ownership interest in those entities, and in an abundance of caution, it also names Stig Remøy, SRR Invest AS, Rimfrost Holding AS, and Omega Protein Corporation as real parties in interest. *Id.* at 2. Patent Owner identifies its real party in interest as Aker BioMarine Antarctic AS. Paper 4, 1.

C. Related Matters

Petitioner and Patent Owner provide notice that two related patents, U.S. Patent Nos. 9,028,877 B2 ("the '877 patent") and 9,078,905 B2 ("the

’905 patent”), have been asserted in *Aker Biomarine Antarctic AS v. Olympic Holding AS*, Case No. 1:16-CV-00035-LPS-CJB (D. Del.) (stayed). Pet. 2; Paper 4, 1. The parties note that the ’453 patent was asserted, along with related patents, including U.S. Patent No. 9,320,765 B2 (“the ’765 patent”), in *In the Matter of Certain Krill Oil Products and Krill Meal for Production of Krill Oil Products*, Investigation No. 337-TA-1019 (USITC). Pet. 2; Paper 4, 1. According to the parties, that matter has been “effectively terminated.” Pet. 2; Paper 4, 1.

The Board has issued Final Written Decisions addressing challenges to claims of: (a) the ’877 patent (IPR2017-00746, Paper 23, claims 1–19 shown to be unpatentable; IPR2017-00748, Paper 23, claims 1–19 not shown to be unpatentable); (b) the ’905 patent (IPR2017-00745, Paper 24, claims 1–20 shown to be unpatentable; IPR2017-00747, Paper 24, claims 1–20 not shown to be unpatentable); and (c) the ’765 patent (IPR2018-00295, Paper 35, claims 1–48 shown to be unpatentable). The Federal Circuit has affirmed the Board’s determination that the challenged claims of the ’877 patent and ’905 patent would have been obvious based upon the grounds set forth in IPR2017-00746 and IPR2017-00745, respectively. *Aker Biomarine Antarctic AS v. Rimfrost AS*, 786 F. App’x 251 (Fed. Cir. Oct. 3, 2019).

Petitioner has challenged, and we have instituted *inter partes* review of, claims 33–61 of the ’453 patent in IPR2018-01179.

D. The ’453 Patent

The ’453 patent describes extracts from Antarctic krill that include bioactive fatty acids. Ex. 1001, 1:19–20. The Specification states that the patent “discloses novel krill oil compositions characterized by containing

high levels of astaxanthin, phospholipids, includ[ing] enriched quantities of ether phospholipids, and omega-3 fatty acids." *Id*. at 9:28–31.

The '453 patent explains that "[k]rill oil compositions have been described as being effective for decreasing cholesterol, inhibiting platelet adhesion, inhibiting artery plaque formation, preventing hypertension, controlling arthritis symptoms, preventing skin cancer, enhancing transdermal transport, reducing the symptoms of premenstrual symptoms or controlling blood glucose levels in a patient." Ex. 1001, 1:46–52. In addition, the '453 patent recognizes that krill oil compositions, including compositions having up to 60% w/w phospholipid content and as much as 35% w/w EPA/DHA content, were known in the art prior to the time of invention. *Id*. at 1:52–57. The '453 patent also indicates that supercritical fluid extraction with solvent modifier was known to be a useful method for extracting marine phospholipids from salmon roe. *Id*. at 1:65–67.

According to the '453 patent, the solvent extraction methods used in the prior art to isolate krill oil from the krill "rely on the processing of frozen krill that are transported from the Southern Ocean to the processing site," which transportation is expensive and may result in the degradation of the krill starting material. *Id*. at 2:3–6. Such methods have included steps of placing the material into a ketone solvent, such as acetone, to extract the lipid soluble fraction, and recovering the soluble lipid fraction from the solid contents using a solvent such as ethanol. *Id*. at 1:32–40. To overcome the above limitations, the '453 patent discloses "methods for processing freshly caught krill at the site of capture and preferably on board a ship." *Id*. at 10:18–20.

The ’453 patent describes producing krill oil by first subjecting the krill to a protein denaturation step to avoid the formation of enzymatically decomposed oil constituents. *Id.* at 9:44–50. The Specification explains that the invention is “not limited to any particular method of protein denaturation. In some embodiments, the denaturation is accomplished by application of chemicals, heat, or combinations thereof.” *Id.* at 10:26–31. The Specification describes an embodiment wherein the krill oil is subsequently extracted using, e.g., a polar solvent and use of supercritical carbon dioxide. *Id.* at 9:51–54.

In Example 7 of the ’453 patent, “[k]rill lipids were extracted from krill meal (a food grade powder) using supercritical fluid extraction with co-solvent.” *Id.* at 31:45–46.

> Initially, 300 bar pressure, 333°K and 5% ethanol (ethanol:CO_2, w/w) were utilized for 60 minutes in order to remove neutral lipids and astaxanthin from the krill meal. Next, the ethanol content was increased to 23% and the extraction was maintained for 3 hours and 40 minutes. The extract was then evaporated using a falling film evaporator and the resulting krill oil was finally filtered.

Id. at 31:47–53.

Example 8 of the ’453 patent prepared krill oil using the same method described in Example 7, from the same krill meal used in that example. Ex. 1001, 32:16–17. The krill oil was then analyzed using ^{31}P NMR analysis to identify and quantify the phospholipids in the oil. *Id.* at 32:17–19. Table 22[8] shows the phospholipid profiles for the raw material, the final

[8] A reference in Example 8 of the ’453 patent to “table 25” (Ex. 1001, 32:45) appears to be a typographical error, as the Specification does not include a

product, and a commercially available krill oil, Neptune Krill Oil ("NKO"). *Id.* at 32:44–47. Table 22 is reproduced below:

TABLE 22

Phospholipid profiles

	Type B krill powder	NKO	Krill Oil obtained in Example 7
PC	66.0	68.6	75.3
AAPC	12.0	7.0	13.0
PI			
1LPC	1.2	1.3	0.4
PS			
2LPC	7.4	13.8	2.9
LAAPC	2.2	1.2	0.9
PE	6.0	3.4	3.4
AAPE			1.5
SM			
GPC		1.3	
DHSM			
NAPE		3.4	
CL	5.3		2.1
LPE			0.5
LCL			
% PL in powder or lipid sample	8.3	30.0	47.9

Id. at 32:53–33:15.

The '453 patent teaches that the "main polar ether lipids of the krill meal are alkylacylphosphatidylcholine (AAPC) at 7–9% of total polar lipids, lyso-alkylacylphosphatidylcholine (LAAPC) at 1% of total polar lipids (TPL) and alkylacylphosphatidyl-ethanolamine (AAPE) at <1% of TPL." *Id.* at 32:47–52.

E. Illustrative Claim

Of the challenged claims, claim 1, reproduced below, is the only independent claim and is illustrative of the claimed subject matter.

Table 25. We understand that reference to "table 25" to instead mean "Table 22," which sets forth the relevant phospholipid profiles.

> 1. A method of production of polar krill oil from *Euphausia superba* comprising:
> a) treating the *Euphasia superba* to denature lipases and phospholipases to provide a denatured krill product;
> b) contacting the denatured krill product with a polar solvent to extract a polar krill oil comprising phospholipids, said polar krill oil comprises greater than about 3% ether phospholipids w/w of said polar krill oil; from about 27% to 50% non-ether phospholipids w/w of said polar krill oil so that the amount of total phospholipids is from about 30% to 60% w/w of said polar krill oil; from about 20% to 50% triglycerides w/w of said polar krill oil, and astaxanthin esters in amount greater than about 100 mg/kg of said polar krill oil; and
> c) formulating said polar krill oil with a carrier for oral consumption.

Ex. 1001, 35:43–58.

II. PATENTABILITY ANALYSIS

A. Principles of Law

To prevail in its challenges to the patentability of all claims of the '453 patent, Petitioner must demonstrate by a preponderance of the evidence that the claims are unpatentable. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d) (2017). "In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid. Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016); *see also* 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify "with particularity . . . the evidence that supports the grounds for the challenge to each claim"). That burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015); *see also In re Magnum Oil Tools*

Int'l, Ltd., 829 F.3d 1364, 1375–78 (Fed. Cir. 2016) (discussing the burden of proof in *inter partes* review).

A claim is unpatentable for obviousness if, to one of ordinary skill in the pertinent art, "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made." 35 U.S.C. § 103(a) (2006); *see also 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 the scope and content of the prior art, any differences between the claimed subject matter and the prior art, the level of ordinary skill in the art, and objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). A petitioner cannot satisfy its burden of proving obviousness by employing "mere conclusory statements." *Magnum Oil*, 829 F.3d at 1380. Moreover, a decision on the ground of obviousness must include "articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR*, 550 U.S. at 418 (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)).

"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)). "The reasonable expectation of success requirement refers to the likelihood of success in combining references to meet the limitations of the claimed invention." *Intelligent Bio-Sys., Inc.*, 821 F.3d at

1367. A reasonable expectation of success "does not require absolute predictability of success . . . *all that is required is a reasonable expectation of success*." *In re Kubin*, 561 F.3d 1351, 1360 (Fed. Cir. 2009) (quoting *In re O'Farrell*, 853 F.2d 894, 903–04 (Fed. Cir. 1988)).).

We analyze Petitioner's asserted grounds of unpatentability in accordance with the above-stated principles.

B. Level of Ordinary Skill in the Art

We consider the asserted grounds of unpatentability in view of the understanding of a person of ordinary skill in the art, and thus we begin by addressing the level 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)).

According to Petitioner, a person of ordinary skill in the art at the time of the invention would have

> held an advanced degree in marine sciences, biochemistry, organic (especially lipid) chemistry, chemical or process engineering, or associated sciences with complementary understanding, either through education or experience, of organic chemistry and in particular lipid chemistry, chemical or process engineering, marine biology, nutrition, or associated sciences; and knowledge of or experience in the field of extraction. In addition, a POSITA would have had at least five years applied experience.

Pet. 6 (citing Ex. 1006 ¶¶ 30–31).

At institution, we preliminarily adopted Petitioner's definition of an ordinarily skilled artisan, and determined that the prior art itself was

sufficient to demonstrate the level of ordinary skill in the art at the time of the invention. Inst. Dec. 9. We note that Patent Owner states that it "accepts [Petitioner's] definition of a POSITA." PO Resp. 16. Accordingly, for this Decision, we adopt Petitioner's definition, while maintaining that the prior art demonstrates the appropriate level of ordinary skill in the art. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (the prior art, itself, can reflect appropriate level of ordinary skill in art).

Moreover, we have reviewed the credentials of Drs. Tallon and Hoem, and consider each of them to be qualified to provide their opinion on the level of skill and the knowledge of a person of ordinary skill in the art at the time of the invention.

C. Claim Construction

Having defined the ordinarily skilled artisan, we now turn to claim construction. For petitions filed before November 13, 2018—as here—the Board interprets claims in an unexpired patent using the "broadest reasonable construction in light of the specification of the patent." 37 C.F.R. § 42.100(b) (2017);[9] *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under that standard, we presume that a claim term carries its "ordinary and customary meaning," which "is the meaning that the term would have to a person of ordinary skill in the art in question" at the time of

[9] The amendment to this rule does not apply here because the Petition was filed before November 13, 2018. *See* Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340 (Oct. 11, 2018) (amending 37 C.F.R. § 42.100(b) effective November 13, 2018).

the invention. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007) (citation omitted). We need not explicitly interpret every claim term for which the parties propose a construction. *See* 35 U.S.C. § 314(a); *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) ("[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy."); *see also Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (applying *Vivid Techs.* in the context of an *inter partes* review).

"greater than about 5% w/w ether phospholipids"

Dependent claim 23 requires the polar krill oil to comprise "greater than about 5% w/w ether phospholipids." Ex. 1001, 36:54–55. The parties offer different claim constructions for that phrase. Pet. 27–31; PO Resp. 14–15. Petitioner asserts that the broadest reasonable interpretation of the phrase "greater than about 5% w/w" is "greater than 4.5% ether phospholipids." Pet. 31 (citing Ex. 1006 ¶ 158). According to Petitioner, the whole number values referenced in the Specification for the ether phospholipid content of krill oil "are accurate only to within the rounding values," such that a person of ordinary skill in the art would have understood that "because the claimed ether phospholipid values are modified by the word 'about,' those values encompass a range extending 0.5% below the claimed numerical limitation, e.g., 4.5% which is rounded up to 5%." *Id.* at 30–31.

Patent Owner notes that Petitioner's declarant, Dr. Tallon, acknowledges in his declaration that the values for total phospholipids and ether phospholipids provided in Examples 7 and 8 of the Specification "are accurate to a tenth of a percent." PO Resp. 14–15 (citing Ex. 1006 ¶ 75).

Patent Owner asserts that based on that testimony, and "applying the rounding rationale proposed by Petitioner, the actual rounding should be from the tenth of a percent. Thus, 4.95% would round up to 5.0% and be included in the term 'about 5%.'" *Id.* at 15. Accordingly, Patent Owner contends that the broadest reasonable interpretation of the phrase "greater than about 5% w/w" is "greater than 4.95% ether phospholipids w/w of said krill oil." *Id.* (citing Ex. 2001 ¶ 37).

As noted by Petitioner, the Board construed the phrase "greater than about 5% w/w" as meaning "greater than 4.5% w/w" in a Final Written Decision addressing similar claims of a related patent. Pet. Reply 12. Specifically, in IPR2018-00295, the Board's analysis of the claim phrase "greater than about 5% w/w" of krill oil in the Final Written Decision reads as follows:

> Such broadening usages as 'about' must be given reasonable scope; they must be viewed by the decision maker as they would be understood by persons experienced in the field of the invention. Although it is rarely feasible to attach a precise limit to 'about,' the usage can usually be understood in light of the technology embodied in the invention." *Modine Mfg. Co. v. U.S. Int'l Trade Comm'n*, 75 F.3d 1545, 1554 (Fed. Cir. 1996).
>
> After considering the parties' arguments and reviewing the Specification of the '765 patent, we conclude that Petitioner's proposed construction is consistent with the intrinsic evidence. Although the '765 patent does not explicitly address the issue of "about," the meaning of the term can be discerned from a careful reading of the Specification. Example 8 of the '765 patent reports the analysis of phospholipid fractions of a product of the invention and a commercially available Krill product. Ex. 1001, col. 31, l, 46–col. 32, l. 42. Table 22, reproduced above, reports the calculated values for the various phospholipids in values to a tenth of a percent. *Id.* at col. 32, ll. 18–38. In the discussion of the table, the values are rounded to the nearest whole number,

> not the nearest tenth. *Id.* at col. 32, ll. 11–15. This is consistent with the approach advanced by Petitioner.

IPR2018-00295, Paper 35, 12.[10] Similarly here, we find that although the Specification does not explicitly define the term "about," its meaning may be discerned from the manner by which the Specification refers to reported values for phospholipid profiles of krill oil. Ex. 1001, 32:55–67 (Table 22). In the discussion of the lipids reported in Table 22, the values are rounded to the nearest whole number, not the nearest tenth. *Id.* at 32:47–52. This is more consistent with the approach advanced by Petitioner than by Patent Owner. Thus, as determined in that Final Written Decision, and for the reasons set forth therein, "the term 'greater than about 5% w/w' shall be construed to mean 'greater than 4.5% w/w.'" IPR2018-00295, Paper 35, 13. Similarly, we construe the recitation in claim 1 requiring "greater than about 3% ether phospholipids" as meaning "greater than 2.5% ether phospholipids," and we construe the recitation in claim 14 of "greater than 4% ether phospholipids" as meaning "greater than 3.5% phospholipids."

Although Petitioner and Patent Owner propose additional claim constructions, we determine that explicit construction of those additional claim terms is not necessary for purposes of this Decision.

D. Overview of Asserted References

Before turning to Petitioner's asserted grounds of unpatentability, we provide a brief summary of the asserted references.

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[10] Patent Owner has requested a rehearing in response to the Final Written Decision entered in IPR2018-00295. *Id.* at Paper 36. However, the rehearing request is limited to issues involving the denied motion to amend claims, and does not challenge the Board's construction of any claim term.

1. Breivik II

Breivik II "relates to a process for preparing a substantially total lipid fraction from fresh krill, and a process for separating phospholipids from the other lipids." Ex. 1037, 1:8–10.[11] According to Breivik II, approximately 50% of the lipids in *E. superba* are phospholipids, and oil extracted from *E. superba* contains lower amounts of environmental pollutants than traditional fish oils. *Id.* at 1:32–33, 2:3–4. Breivik II explains that krill lipases remain active after the krill is dead, and, thus, krill oil may contain an undesired amount of free fatty acids, making it desirable to use a process that will provide for a low degree of hydrolysis of the krill lipids. *Id.* at 2:6–13.

Breivik II teaches that its extraction process provides a substantially total lipid fraction from fresh krill, without using organic solvents like acetone. *Id.* at 3:29–31. That lipid fraction contains triglycerides, astaxanthin and phospholipids. *Id.* at 3:19–20. According to Breivik II, the process includes an optional heat pre-treatment of the krill to inactivate enzymatic decomposition of the lipids, ensuring a product with a low level of free fatty acids. *Id.* at 4:3–6.

Breivik II describes an extraction process in which fresh krill is washed with ethanol, and the ethanol washed krill is then extracted with supercritical CO_2 containing 10% ethanol. *Id.* at 7:31–8:3 (Example 2). Breivik II also discloses a process in which the raw material is pre-treated with heat at 80ºC for 5 minutes before the first wash with ethanol. *Id.* at 9:5–11 (Example 6). According to Breivik II, "heat-treatment gives an

[11] Unless otherwise noted, the cited page numbers refer to those supplied by the original reference, and not the page numbers added by Petitioner.

increased yield of lipids compared to the same treatment with no heating." *Id.* at 9:33–34 (emphasis omitted).

Breivik II explains that "[a] lipid fraction or lipid product, derived from the process according to the invention may have some additional advantages related to quality compared to known krill oil products (produced by conventional processes), such as for instance a krill oil from Neptune Biotechnologies & Bioresources extracted from a Japanese krill source" having ≥ 40.0% total phospholipids and ≥ 1.0 mg/g esterified astaxanthin. *Id.* at 11:23–36. Breivik II states that a lipid fraction or product according to the invention would be expected, among other things, to "contain substantially less hydrolysed and/or oxidised lipids than lipid produced by conventional processes" and have "less deterioration of the krill lipid antioxidants from conventional processing." *Id.* at 12:1–9 (emphasis omitted).

2. Catchpole

Catchpole discloses "a process for separating lipid materials containing phospholipids," Ex. 1009, 1:5–6, in order to produce a product containing "desirable levels of particular phospholipids," *id*. at 3:27–28. Catchpole states that phospholipids "have been implicated in conferring a number of health benefits including brain health, skin health, eczema treatment, anti-infection, wound healing, gut microbiota modifications, anti-cancer activity, alleviation of arthritis, improvement of cardiovascular health, and treatment of metabolic syndromes. They can also be used in sports nutrition." *Id*. at 1:29–2:2. Catchpole further discloses that products having high levels of particular phospholipids "may be employed in a

number of applications, including infant formulas, brain health, sports nutrition and dermatological compositions." *Id*. at 25:9–13.

Catchpole describes, in Example 18, the fractionation of krill lipids from krill powder using a process that employs supercritical CO_2 in a first extraction, and a CO_2 and absolute ethanol mixture in a second. *Id*. at 24:1–16. Table 16, reproduced below, reports the phospholipid concentrations present in the krill oil extract obtained by Catchpole. *Id*. at Table 16.

Table 16

	Yield % of feed	Composition, %							
		PC	PI	PS	PE	CL	AAPC	AAPE	Other compounds
Feed		6.6	0.0	0.0	0.4	0.1	0.6	0.1	78.6
Extract 2	4.3	39.8	0.0	0.0	0.3	0.2	4.6	0.2	53.7
Residue	79.2	3.6	0.0	0.0	0.3	0.2	0.5	0.1	93.4

As shown in Table 16, the composition of Extract 2 includes 39.8% phosphatidylcholine ("PC"). *Id*. The ether phospholipids alkylacylphosphatidylcholine ("AAPC") and alkylacylphosphatidyl-ethanolamine ("AAPE") were also present in Extract 2, representing 4.6% and 0.2%, respectively, of the extracted composition. *Id*. In addition, summing each of the reported phospholipid amounts reported for Extract 2 yields a total phospholipid concentration of 45.1%. *See id*.

3. Bottino II

Bottino II characterizes the lipids of two Antarctic euphausiids, *Euphausia superba* and *Euphasia crystallorophias*. Ex, 1038, Abstr. Bottino II explains, "when one refers to Antarctic krill, one generally means *Euphausia superba*, which is the most abundant and far better known species of krill in the Antarctic Oceans." *Id*. at 479.

Bottino II explains that the euphausiids were collected and, once on board the ship, the samples were rapidly sorted by hand and extracted with a

"chloroform:[methanol] (2:1, v/v) mixture." *Id.* Fatty acid compositions were determined by gas-liquid chromatography. *Id.* at 480.

Table 1 of Bottino II is reproduced below.

Table 1. Fatty acids of Antarctic krill*

	E. superba		*E. crystallorophias*	
Fatty acid	Station 8	Station 11	Station 13	Station 16
		weight %		
12:0	0·3	0·2	0·2	tr
14:0	14·9	14·3	2·3	2·4
15:0 br†	0·3	0·2	0·1	
15:0	0·5	0·2	0·2	0·1
16:0	21·2	24·7	13·8	14·8
18:0	0·7	1·4	1·2	1·3
22:0	0·1	0·1		
14:1 (*n*−?)	0·3	0·2		
15:1 (*n*−?)	tr	0·1		
16:1 (*n*−7)	9·0	8·9	8·4	10·8
17:1 (*n*−8)	0·7	0·3	0·4	0·4
18:1 (*n*−9)	18·2	21·7	47·5	45·2
20:1 (*n*−9)	0·6	0·9	0·2	0·5
18:2 (*n*−6)	0·3	0·1		
18:2 (*n*−3)	2·6	2·0	3·3	2·7
20:2 (*n*−3)			0·1	
18:3 (*n*−6)	0·3	0·2	0·2	0·3
18:3 (*n*−3)	1·1	1·0	0·9	0·9
20:3 (*n*−3)	0·6	0·5	0·5	
18:4 (*n*−3)	2·2	3·3	1·5	0·9
20:4 (*n*−6)	0·5	0·4		0·7
20:4 (*n*−3)	0·5	0·2		0·1
22:4 (*n*−6)	0·2	0·3		
20:5 (*n*−3)	16·0	11·4	11·8	13·4
22:5 (*n*−3)	0·3	0·1	0·1	
22:6 (*n*−3)	8·6	7·3	7·3	5·5

* Data from Bottino (1974).
† br, Branched-chain fatty acids.

Ex. 1038, Table 1. Table 1 discloses the fatty acid content of *E. superba* and *E. crystallorophias* obtained from different locations (i.e., stations) as a weight percent of total fatty acids. *Id.* at 480.

Table 2 of Bottino II is reproduced below.

Table 2. The lipids of Antarctic krill

	E. superba		*E. crystallorophias*	
	Station 8 (1)*	Station 11 (2)	Station 13 (4)	Station 16 (2)
		weight %		
Waxes	—	—	44±10‡	20±1
Steroid esters	—	—	2±3	27±9
Triglycerides	8	36±6	—	—
Diglycerides	17	4±5	—	4±1
Complex lipids	54	58±14	53±8	42±8
PC†		48	46	
PE†		8	6	
Lyso PC		1	1	
PG†		1	—	
Unknown§	21	2±22	1±2	7±1

* Number of determinations in parentheses.
† PC, Phosphatidylcholine; PE, phosphatidylethanolamine; PG, phosphatidylglycerol.
‡ Weight per cent plus or minus the standard deviation.
§ R_f between those of triglycerides and diglycerides. The recovered amount of this fraction was too small for further characterization.

Ex. 1038, Table 2. Table 2 reports the identity and amount of each lipid present in the *E. superba* and *E. crystallorophias* samples analyzed as a weight percent of total lipids. *Id.* at 480–481.

4. Sampalis I

Sampalis I describes a clinical trial "[t]o evaluate the effectiveness of Neptune Krill Oil™ (NKO™) for the management of premenstrual syndrome and dysmenorrhea." Ex. 1012, 171. Sampalis I explains that NKO is "extracted from Antarctic krill also known as *Euphausia superba*. *Euphausia superba*, a zooplankton crustacean, is rich in phospholipids and triglycerides carrying long-chain omega-3 polyunsaturated fatty acids, mainly EPA and DHA, and in various potent antioxidants including vitamins A and E, astaxanthin, and a novel flavonoid." *Id*. at 174.

Sampalis I discloses that each patient in the clinical trial was "asked to take two 1-gram soft gels of either NKO or omega-3 18:12 fish oil (fish oil containing 18% EPA and 12% DHA) once daily with meals during the first

month of the trial." *Id.* Sampalis I reports that "[t]he final results of the present study suggest within a high level of confidence that Neptune Krill Oil can significantly reduce the physical and emotional symptoms related to premenstrual syndrome, and is significantly more effective for the management of dysmenorrhea and emotional premenstrual symptoms than fish oil." *Id*. at 178.

5. Sampalis II

Sampalis II discloses a "phospholipid extract from a marine or aquatic biomass [that] possesses therapeutic properties. The phospholipid extract comprises a variety of phospholipids, fatty acid, metals and a novel flavonoid." Ex. 1013, Abstr. Sampalis II explains that the disclosed phospholipid and its components "are useful in the prevention or treatment of a variety of disease states and for the aesthetic enhancement of an animal, including human, body. Pharmaceutical, nutraceutical and cosmetic compositions containing the extract and uses thereof are also within the invention." *Id.* at 3:6–11.

Sampalis II further discloses that

> [t]he phospholipid extract of the present invention may be extracted from a variety of marine or aquatic biomass sources. Preferred sources of the phospholipid composition are crustaceans, in particular, zooplankton. A particularly preferred zooplankton is Krill. Krill can be found in any marine environment around the world. For example, the Antarctic Ocean (where the krill is *Euphasia superba*), the Pacific Ocean (where the krill is *Euphasia pacifica*), the Atlantic Ocean and the Indian Ocean all contain krill habitats.

Ex. 1013, 25:2–10.

6. Fricke

Fricke discloses the "lipid classes, fatty acids of total and individual lipids and sterols of Antarctic krill (*Euphausia superba* Dana) from two areas of the Antarctic Ocean" as determined by thin layer chromatography, gas liquid chromatography, and gas liquid chromatography/mass spectrometry analyses. Ex. 1010, Abstr. According to Fricke, krill were collected and were quick frozen, and lipids were extracted using the method of Folch.[12] *Id.* at 821. Fricke teaches further that samples were also cooked on board "immediately after hauling," and were stored under the same condition. *Id.* at 822–23.

Table 1 of Fricke is reproduced below.

TABLE 1

Lipid Composition of Antarctic Krill (*Euphausia superba* Dana)

Sample	12/1977	3/1981
Total lipid content (% wet weight)	2.7 ± 0.2	6.2 ± 0.3
Phospholipids		
Phosphatidylcholine	35.6 ± 0.1	33.3 ± 0.5
Phosphatidylethanolamine	6.1 ± 0.4	5.2 ± 0.5
Lysophosphatidylcholine	1.5 ± 0.2	2.8 ± 0.4
Phosphatidylinositol	0.9 ± 0.1	1.1 ± 0.4
Cardiolipin	1.0 ± 0.4	1.6 ± 0.2
Phosphatidic acid	0.6 ± 0.4	
Neutral lipids		
Triacylglycerols	33.3 ± 0.5	40.4 ± 0.1
Free fatty acids[a]	16.1 ± 1.3	8.5 ± 1.0
Diacylglycerols	1.3 ± 0.1	3.6 ± 0.1
Sterols	1.7 ± 0.1	1.4 ± 0.1
Monoacylglycerols	0.4 ± 0.2	0.9 ± 0.1
Others[b]	0.9 ± 0.1	0.5 ± 0.1
Total	98.9	99.3

[12] Folch et al., *A Simple Method for the Isolation and Purification of Total Lipides from Animal Tissues*, 266 J. BIOL. CHEM. 497–509 (1957) (Ex. 1017).

Table 1 shows the total lipid content and the lipid composition data for the two krill samples analyzed by Fricke. *Id*. at 822. As indicated in Table 1, the krill samples respectively included approximately 33.3% +/- 0.5% w/w and 40.4% +/- 0.1% w/w triacylglycerols. *Id*.

7. Randolph

Randolph discloses compositions for modulating cytokines to regulate an inflammatory or immunomodulatory response including, *inter alia*, rosehips and krill oil. Ex. 1011 ¶ 8. With regard to rosehips, Randolph discloses that the composition may include one or more rosehip ingredients, such as "dried rosehips, rosehip oil, and rosehip extracts." *Id.* ¶ 24. Concerning krill oil, Randolph discloses that

> [a] composition of the invention can include krill oil. Krill oil can be obtained from any member of the *Euphausia* family, for example *Euphausia superba*. Conventional oil producing techniques can be used to obtain the krill oil. In addition, krill oil can be obtained commercially from Neptune Technologies and Bioresources of Quebec, Canada.

Id. ¶ 39. Randolph further explains that "[a] composition can contain any amount of krill oil," but will typically contain "between about 300 mg and about 3000 mg of a krill oil ingredient." *Id.* ¶ 40. Additionally, Randolph teaches

> A composition can contain any amount of an astaxanthin ingredient. For example, at least about 1 percent (e.g., at least about 2, 3, 4, 5, 10, 15, 20, 25, 30, 35, 40, 50, 60, 70, 80, or 90 percent) of a dietary supplement can be astaxanthin. Typically, a composition contains between about 0.5 mg and about 50 mg of an astaxanthin ingredient.

Ex. 1011 ¶ 44.

Randolph also discloses that "[t]he ingredients of the composition can be processed into forms having varying delivery systems. For example, the ingredients can be processed and included in capsules, tablets, gel tabs, lozenges, strips, granules, powders, concentrates, solutions, lotions, creams or suspensions." Ex. 1011 ¶ 46. Randolph further discloses that "[a] soft gel capsule of the composition can be manufactured to include krill oil. This capsule can be manufactured using conventional capsule manufacturing techniques. The amount of krill oil in each capsule is about 300 mg." *Id.* ¶ 52.

E. Obviousness over Breivik II, Catchpole, Bottino II, and Sampalis I.

Petitioner asserts that claims 1–3, 5–10, 12, 14–17, 19–20, 23–26, 28, and 30–32 would have been obvious over the combined teachings of Breivik II, Catchpole, Bottino II, and Sampalis I. Pet. 33–56. Patent Owner disagrees. PO Resp. 17–35.

1. Teachings of Breivik II, Catchpole, Bottino II, and Sampalis I

According to Petitioner, Breivik II teaches a method of producing polar krill oil from *E. superba*, as recited by independent claim 1, because the reference is directed to "preparing a substantially total lipid extract from fresh krill," and explains that "[t]he current greatest potential for commercial utilisation is the Antarctic *Euphausia superba*." Pet. 34 (quoting Ex. 1037, 1:25–28). Petitioner also references an example in Breivik II describing the extraction of lipids from fresh *E. superba*. *Id.* at 36–37 (citing Breivik II Example 6).

Petitioner asserts that Breivik II describes the "application of heat to denature krill resulting in a denatured krill product," as required by claim 1, by teaching, among other things, an "optional pre-treatment involving short-

term heating of the fresh krill will also give an inactivation of enzymatic decomposition of the lipids, thus ensuring a product with very low levels of free fatty acids." *Id.* at 35 (citing Ex. 1037, 4:3–6, 9:5–6, 10:6–8 and 11–12). Dr. Tallon explains that, in Brevik II, heating the fresh krill inactivates the krill's enzymes, including lipases, thereby preventing decomposition of the krill lipids. Ex. 1006 ¶ 196.

As for the next claimed step of contacting the denatured krill product with a polar solvent to extract polar krill oil, Petitioner asserts that such process was well known in the art at the time of the invention and Breivik II expressly discloses this processing step for *E. superba* by teaching an extraction step at supercritical pressure using CO_2 containing 10% ethanol, and isolating the lipid fraction from the ethanol. Pet. 35–36 (citing Ex. 1037, 4:28–33). As further support, Petitioner also refers to Breivik II's example using a "[s]upercritical fluid extraction with CO_2 containing 10% ethanol." *Id.* at 36–37 (quoting Ex. 1037, 9:5–8).

For the last step of the method of claim 1, requiring formulating the polar krill oil with a carrier for oral consumption, Petitioner asserts that "[t]he prior art expressly discloses the formulation of krill oil in capsule and soft get capsule dosage forms suitable for oral administration." Pet. 37. As an example, Petitioner refers to a disclosure in Sampalis I of administering krill oil to patients in the form of a soft gel. *Id.* at 37–38 (citing Ex. 1012, 174).

With respect to the recited composition of the extracted krill oil in claim 1, Petitioner and Dr. Tallon assert that "each of the recited constituents is naturally present in live krill, and were known to be present in lipid fractions extracted from krill using conventional extraction techniques and

solvents." Pet. 38 (citing Ex. 1006 ¶¶ 102, 106, and 110). In support of that position, Petitioner and Dr. Tallon refer to Catchpole. In particular, for the recitation that the polar krill oil comprises "greater than about 3% ether phospholipids," Petitioner and Dr. Tallon assert that Catchpole is directed to methods for separating lipid materials from materials, including krill, and describes the extracted phospholipids as being "implicated in conferring a number of health benefits." *Id.* at 39–40 (citing Ex. 1006 ¶¶ 214–225, Ex. 1009, 1:29–2:2, 7:5–6, 24:1–9).

More particularly, Petitioner and Dr. Tallon rely upon Catchpole's disclosure in Example 18 of the fractionation of krill lipids from krill powder, and the reported concentrations of extracted phospholipids in Table 16. Pet. 40 (citing Ex. 1006 ¶¶ 219–225, Ex. 1009, 24:1–19). Dr. Tallon explains that the ether phospholipids fractions analyzed were alkylacyl-phosphatidylcholine (AAPC) and alkylacylphospatidylethanolamine (AAPE). Ex. 1006 ¶¶ 221–222; Ex. 1009, 14:7–11. Petitioner and Dr. Tallon draw our attention to the composition of Extract 2 in Table 16 reported as having 4.8% ether phospholipids (4.6% AAPC and 0.2% AAPE), thus comprising greater than about 3% ether phospholipids as required by claim 1. Pet. 41.

Petitioner and Dr. Tallon also refer to Catchpole's Extract 2 in Example 18 as disclosing "from about 27% to 50% w/w non-ether phospholipids so that the amount of total phospholipids in the krill oil is from about 30% to 60% [w/w]," as required in claim 1. Pet. 41–42 (citing Ex. 1006 ¶¶ 219–225, 414, Ex. 1009, 24). Specifically, they rely upon Catchpole's disclosure in Table 16 that Extract 2 has 45.1% total phospholipids (39.8% PC, 0.3% PE, 0.2% CL, 4.6% AAPC, 0.2% AAPE),

and thus, has 40.3% non-ether phospholipids by deduction, i.e., total phospholipids (45.1%) minus ether phospholipids (4.8%). *Id.* at 42 (citing Ex. 1006 ¶¶ 212–225, 414).

Concerning the claim 1 recitation that the krill extract include "from about 20% to 50% triglycerides w/w of said polar krill oil," Petitioner asserts that "[i]t would have been recognized that triglycerides represent one of the most abundant constituents in krill oil, and a POSITA would have . . . looked to other polar krill extracts for the relative amount present." Pet. 42 (citing Ex. 1006 ¶¶ 100, 414). As an example of such relative amounts, Petitioner and Dr. Tallon refer to the details provided in Bottino II's study of the lipids extracted from two species of Antarctic krill, including *E. superba*, using a polar solvent. *Id*. (citing Ex. 1038, 479–482). According to Petitioner and Dr. Tallon, Bottino's report that "in *Euphausia superba* the complex lipids were mostly phosphatidylcholine at 48-49%, followed by triglycerides at 36%" demonstrates that it was known in the art at the time of the invention that "oil extracted from krill using conventional solvent extraction techniques and solvents contained triglyceride levels within 20%-50% the limitation of claim 1." *Id*. at 42–43 (quoting Ex. 1006 ¶¶ 182–187 and citing Ex. 1038, 481 (Table 2) and 479–482)).

Claim 1 also requires "astaxanthin esters in amount of greater than about 100 mg/kg of said polar krill oil." Ex. 1001, 35:55–56. For this element, Petitioner relies upon Breivik II's disclosure that "Neptune's commercial krill oil product has ≥ 40% total phospholipids and ≥ 1.0 mg/g esterified astaxanthin (*i.e.*, ≥ 1000 mg/kg)." Pet. 43. Based on that disclosure, Petitioner asserts that "the astaxanthin element of claim 1 is expressly disclosed in the prior art." *Id*.

Based upon our review of the cited evidence, and the record as a whole, we find that Petitioner's characterization of Breivik II, Catchpole, Bottino II, and Sampalis I, as well as Dr. Tallon's testimony as to the knowledge in the art are supported by the evidence in terms of demonstrating that Breivik II teaches or suggests the claimed method steps for producing polar krill oil from *E. superba* by providing a denatured krill product and extracting polar krill oil from that product using a polar solvent, Catchpole discloses the claimed components of polar krill oil and the amounts of ether and total phospholipids therein, Bottino II discloses the triglyceride content of polar krill oil, and Sampalis I discloses polar krill oil formulated for oral consumption. Accordingly, we adopt those characterizations as our findings.

As for the claim element requiring the polar krill oil from *E. superba* to comprise astaxanthin esters in an amount of greater than about 100 mg/kg, Petitioner relies upon Breivik II. Petitioner asserts that Breivik II discloses a commercial krill oil from Neptune Biotechnologies & Bioresources containing ≥ 40% total phospholipids and ≥ 1.0 mg/g esterified astaxanthin (i.e., ≥ 1000 mg/kg). Pet. 43 (citing Ex. 1037, 11:23–30). We agree. Breivik II also discloses a general teaching that the lipid fraction from krill oil "contained triglycerides, astaxanthin and phospholipids," Ex. 1037, 3:19–20, and a specific example wherein a polar krill oil extract from *E. superba* was "rich in phospholipids, and also contained triglycerides and astaxanthin," *id.* at 9:4–11 (Example 6). Additionally, we note that Bottino II explains "when one refers to Antarctic krill, one generally means *Euphausia superba*, which is the most abundant and far better known species of krill in the Antarctic Oceans." Ex. 1038, 479. Thus, based upon

our consideration of Breivik II, as a whole, along with the unrefuted evidence that a person of skill in the art would have understood a reference to Antarctic krill to mean *E. superba*, and Dr. Tallon's testimony that a skilled artisan would expect "a lipid product or fraction made by Breivik [II's] method would have an even higher level of astaxanthin esters, a known antioxidant, than the 1000 mg/kg astaxanthin esters disclosed for the Neptune product," Ex. 1006 ¶ 208, we find that Breivik II suggests the astaxanthin claim limitation, i.e., that the polar krill oil from *E. superba* comprises astaxanthin esters in an amount of greater than about 100 mg/kg.

Patent Owner does not challenge Petitioner's characterization of the separate teachings of Breivik II, Catchpole, Bottino II, and Sampalis I. Rather, Patent Owner asserts that a person of ordinary skill in the art would not have had a reason to combine those teachings, with a reasonable expectation of successfully arriving at the claimed inventions by doing so.

In the Reply, Petitioner asserts that collateral estoppel precludes Patent Owner from advancing arguments Petitioner contends were previously rejected in Final Written Decisions by the Board. Pet. Reply 4. Accordingly, we address those issues in the following analysis.

2. Motivation to Combine and Reasonable Expectation of Success

According to Petitioner, an ordinarily skilled artisan would have had a reason to combine the teachings of Breivik II, Catchpole, Bottino II and Sampalis I because they each relate to the same field of endeavor, i.e., extracting krill oil using conventional polar solvents and extraction techniques, characterizing krill oil components, and discussing health benefits associated with such components. *See* Pet. 53–55. For example, Petitioner notes that Breivik II and Catchpole disclose methods of such

extraction, Catchpole discloses phospholipid and triglyceride contents of polar krill oil, Bottino II discloses the esterified astaxanthin content of a commercial krill oil, and Sampalis I discloses polar krill oil formulated for oral consumption. *Id.*

According to Petitioner,

> Thus, a POSITA, following the treatment and extraction steps taught by Breivik II, would have been motivated to look to other references such as Catchpole and Bottino II to ascertain the other constituents naturally present in the krill oil extracts and their respective amounts, and to administer the resulting polar krill oil in the form of a soft-gel capsule as taught by Sampalis I.

Pet. 56 (citing Ex. 1006 ¶¶ 85–110, 438).

Based on those prior art teachings, Petitioner asserts that the ordinarily skilled artisan also would have had a "reasonable expectation of producing a polar krill oil having the percentage of constituents as recited in the claims." *Id*. at 53. Likewise, Dr. Tallon testifies that a person of ordinary skill in the art "would have known that the relative proportions of the natural krill and hence the natural krill oil constituents could be varied in predictable ways by applying a single solvent or combination of solvents . . . to selectively extract specific groups of lipid components . . . , and by blending these selective extracts in known and predictable ways to produce a desired krill oil composition," indicating that an ordinarily skilled artisan would have had a reason to combine the teachings of the cited references and a reasonable expectation of success in doing so in a manner that yields the claimed invention. Ex. 1006 ¶ 104.

Based on our review of the record as a whole, we determine that a preponderance of the evidence supports Petitioner's contention that an

ordinarily skilled artisan would have had reason to combine the teachings of Breivik II, Catchpole, Bottino II, and Sampalis I, with a reasonable expectation of successfully arriving at the inventions of claims 1–3, 5–10, 12, 14–17, 19–20, 23–26, 28, and 30–32. Next, we address Patent Owner's arguments and Petitioner's assertion of collateral estoppel.

3. Collateral Estoppel

"Collateral estoppel protects a party from having to litigate issues that have been fully and fairly tried in a previous action and adversely resolved against a party-opponent." *Ohio Willow Wood Co. v. Alps South, LLC*, 735 F.3d 1333, 1342 (Fed. Cir. 2013) (citing *Pharmacia & Upjohn Co. v. Mylan Pharm., Inc.*, 170 F.3d 1373, 1379 (Fed Cir. 1999)). "It is well established that collateral estoppel, also known as issue preclusion, applies in the administrative context." *MaxLinear, Inc. v. CF CRESPE LLC*, 880 F.3d 1373, 1376 (Fed. Cir. 2018) (citations omitted); *Webpower, Inc. v. WAG Acquisition, LLC*, IPR2016-01239, Paper 21 at 26–28 (PTAB Dec. 26, 2017) (Final Written Decision). The application of collateral estoppel is not limited to patent claims that are identical. *Ohio Willow Wood*, 735 F.3d at 1342. "Rather, it is the identity of the *issues* that were litigated that determines whether collateral estoppel should apply. . . . If the differences between the unadjudicated patent claims and the adjudicated patent claims do not materially alter the question of invalidity, collateral estoppel applies." *Id.*

As our reviewing court has explained, collateral estoppel precludes a party from relitigating an issue if:

> (1) prior action presents an identical issue; (2) the prior action actually litigated and adjudged that issue; (3) the judgment in that prior action necessarily required determination of the identical

> issue; and (4) the prior action featured full representation of the estopped party.

VirnetX Inc. v. Apple, Inc., 909 F.3d 1375, 1377 (Fed. Cir. 2018) (quoting *Stephen Slesinger, Inc. v. Disney Enters., Inc.*, 702 F.3d 640, 644 (Fed. Cir. 2012)).

Petitioner asserts that collateral estoppel precludes Patent Owner from advancing the same patentability arguments rejected in the Board's Final Written Decisions in IPR2019-00295, IPR2017-00745, and IPR2017-00746. Pet. Reply 4. Although those decisions addressed different patents and claims,[13] Petitioner asserts that the challenged claims "recite many of the same limitations, and are materially identical" to the claims found to be unpatentable in those earlier Final Written Decisions. *Id.* For example, Petitioner asserts that the challenged claims shown to be unpatentable in the '765, '877, and '905 patents "recite krill oil with materially identical ranges of ether phospholipids, triglycerides and astaxanthin esters." *Id.* Further, Petitioner notes that the '453 patent is in the same family and shares the same specification and priority date as the '765, '877, and '905 patents. *Id.* at 4 n.2. Additionally, Petitioner asserts that the same prior art asserted here was previously relied upon by the Board to conclude that the claims of the related patents are unpatentable. *Id.* at 5. According to Petitioner, "[g]iven the substantially identical claim limitations and the same prior art, this

[13] As mentioned above in section I. C., "Related Matters," challenged claims of the '765 patent were shown to be unpatentable in IPR2018-00295, challenged claims of the '905 patent were shown to be unpatentable in IPR2017-00745, and challenged claims of the '877 patent were shown to be unpatentable in IPR2017-00746.

proceeding implicates at least two of the same patentability arguments that were fully considered, and expressly rejected by the Board." *Id.*

a. "No triglycerides" and "PAF teaching away" Arguments

In particular, Petitioner asserts that Patent Owner's argument that the combined references do not provide a reasonable expectation of arriving at the claimed methods of producing and formulating a krill oil comprising greater than about 3% (e.g., claim 1), 4% (e.g., claim 14) or 5% (e.g., claim 23) ether phospholipids, and the amount of total phospholipids and triglycerides required by the claims because Catchpole's Extract 2 "contains no triglycerides" should be precluded because the Board rejected the "no triglycerides" argument regarding Catchpole's Extract 2 in the IPR2018-00295 Final Written Decision. Pet. Reply 5 (citing IPR2018-00295, Paper 35, 35–39).

Additionally, Petitioner asserts that Patent Owner's argument that the prior art teachings that ether lipids such as those found in krill could be converted to compounds having potent inflammatory Platelet Activating Factor ("PAF") activity would have led an ordinarily skilled artisan away from producing a krill oil composition for oral consumption comprising the recited amounts of ether phospholipids should be precluded because the Board rejected that "PAF teaching away" argument in the Final Written Decision in IPR2018-00295, Paper 35, 39–47, IPR2017-00746, Paper 23, 53–61, and IPR2017-00745, Paper 24, 29–38. Pet. Reply 5–6.

Based upon our review of those prior Final Written Decisions, we find persuasive Petitioner's contention that Patent Owner's "no triglycerides" and "PAF teaching away" arguments were presented, litigated, and adjudged in one or more of those proceedings. As noted above in sections I. B. and C.,

two of those Final Written Decisions have been affirmed by the Federal Circuit. Further, we find that the patentability analysis in the prior Final Written Decisions necessarily required determination of the "no triglycerides" and "PAF teaching away" issues raised by Patent Owner, who was fully represented in each of those proceedings. Thus, we agree with Petitioner that collateral estoppel applies so as to preclude Patent Owner from relitigating here its assertions that a person of ordinary skill in the art would not have had a reason to combine the cited art with a reasonable expectation of success based upon its "no triglycerides" or "PAF teaching away" arguments. Moreover, we consider Patent Owner to have conceded the issue by declining to dispute whether collateral estoppel applies with regard to the "no triglycerides" and "PAF teaching away" arguments in its Sur-Reply. *See* PO Sur-Reply 2 (Patent Owner asserting instead that it "will not dispute whether collateral estoppel applies to issues related to the Board's findings regarding ranges for these components").

b. Combining Extraction Techniques Argument

In the Reply, Petitioner does not raise the issue of collateral estoppel regarding Patent Owner's remaining argument that a person of ordinary skill in the art would not combine ranges for specific lipid components in an extract from references that use different extraction techniques. *See* Pet. Reply 5 (identifying specifically the "no triglycerides/dilution" and "PAF teaching away" arguments as subject to issue preclusion). Although Patent Owner presented a similar argument in IPR2018-00295, which the Board rejected in the Final Written Decision, IPR2018-00295, Paper 35, 34–39, Patent Owner asserts that a distinction between the claims in the patent addressed there and here cause the issue to not be "identical" so as to

implicate collateral estoppel. PO Sur-Reply 2; Tr. 23:3–7. In particular, Patent Owner asserts that unlike in IPR2018-00295, the challenged claims here are directed to method claims and require contacting the krill material with a polar solvent. PO Sur-Reply 2, 9–10.

Based upon our review of the arguments, however, it does not appear that those differences between the claims analyzed in IPR2018-00295 and the challenged claims are material to the issue presented by Patent Owner regarding whether a person of ordinary skill in the art would combine ranges for specific lipid components in an extract from references that use different extraction techniques. Indeed, a side-by-side comparison of the argument set forth in Patent Owner's Response filed in IPR2018-00295 and the Patent Owner's Response filed here reveals that the same, virtually verbatim, arguments were made in both cases, absent changes in, e.g., citations and referring to Bottino II instead of Frick 1984 as disclosing a "non-selective" Folch extraction of krill. *Compare* IPR2018-00295, Paper 14, 14–22, *with* IPR2018-01178, Paper 12, 24–31. In the Final Written Decision, Patent Owner's arguments, repeated here, were rejected. IPR2018-00295, Paper 35, 34–39. In any event, we do not apply collateral estoppel to this issue, as the parties have not fully briefed their positions in this proceeding. However, we determine that the analysis in the Final Written Decision for IPR2018-00295 regarding whether a skilled artisan would have been motivated to combine ranges for specific lipid components in an extract from references using different, i.e., "selective and non-selective" extraction techniques is applicable here.

In particular, for the same reasons discussed in the IPR2018-00295 Final Written Decision, we accord persuasive weight to Dr. Tallon's testimony that

> a POSITA would have known that the relative proportions of natural krill and hence the natural krill oil constituents could be varied in predictable ways by applying a single solvent or combination of solvents including super critical fluid extraction to selectively extract specific groups of lipid components based on their different solubility, and by blending these selective extracts in known and predictable ways to produce a desired krill oil composition.

Ex. 1006 ¶¶ 104, 106, 110; *see* IPR2018-00295, Paper 35, 37–39. We note that Dr. Tallon provided similar testimony in IPR2017-00746, Ex. 1006 ¶ 212, which the Board also credited in determining that the claims of the '877 patent, directed to a *method* of producing krill oil comprising extracting oil from denatured krill product with a *polar solvent*, IPR2017-00746, Paper 23, 47–48, are unpatentable. Indeed, the Federal Circuit affirmed that Final Written Decision and the Board's finding that "the lipid components of krill oil can be extracted using any number of suitable solvents, that the proportions of the components could be varied in predictable ways, and that the resulting extracts could be blended to produce a final krill oil product." *Aker Biomarine Antarctic*, 786 F. App'x at 254.

Moreover, as discussed in the IPR2018-00295 Final Written Decision, the '765 patent, which shares the same Specification as the challenged patent, describes the compositions of the invention as being prepared by "blending the neutral and polar lipid extracts." IPR2018-00295, Paper 35, 39, Ex. 1001, 12:34–35. As explained there, "[t]he Specification provides no further guidance regarding the blending step but instead relies on the

knowledge of those skilled in the art. This supports Dr. Tallon's conclusion that one skilled in the art would have known how to combine the different lipid fractions to achieve the claimed composition." IPR2018-00295, Paper 35, 39.

Accordingly, we disagree with Patent Owner that the evidence demonstrates that a person having ordinary skill in the art would not have combined the teachings of the cited references to yield the claimed compositions, with a reasonable expectation of successfully doing so.

Based on the foregoing, we conclude that Petitioner has established by a preponderance of the evidence that claims 1–3, 5–10, 12, 14–17, 19–20, 23–26, 28, and 30–32 are unpatentable over the combined teachings of Breivik II, Catchpole, Bottino II, and Sampalis I.

F. Obviousness of Remaining Grounds Based upon Combinations including Breivik II, Catchpole, Bottino II and Sampalis I

Each of the three remaining grounds rely upon similar combinations of Breivik II, Catchpole, Bottino II, and Sampalis I, as set forth in the ground analyzed above, in Section II. E. Pet. 7, 56–66. The remaining grounds combine additional references to address various limitations of dependent claims 4, 11, 13, 18, 21, 22, 27, and 29. *Id.* Patent Owner challenges those additional grounds only by relying on its arguments presented with respect to the ground based upon Breivik II, Catchpole, Bottino II, and Sampalis I. PO Resp. 33–35. According to Patent Owner, the additional references relied upon in the remaining grounds do not "cure the deficiencies noted above for the core four references." *Id.*

We have considered the combined teachings of the cited references for each of the remaining grounds, along with Petitioner's arguments and Dr.

Tallon's testimony and, based on the record as a whole, we determine that Petitioner has established by a preponderance of the evidence that claims 4, 11, 13, 18, 21, 22, 27, and 29 are unpatentable over those combined teachings for the reasons discussed herein regarding the combination of Breivik II, Catchpole, Bottino II, and Sampalis I, and based upon Petitioner's additional evidence and arguments in each of the remaining grounds, which we adopt as our own. *See* Pet. 56–66; Ex. 1006 ¶¶ 439–457.

III. MOTION TO AMEND

Patent Owner's motion to amend is contingent on the Board's finding of unpatentability of the challenged claims. MTA 1. Because we conclude that Petitioner has demonstrated that the challenged claims are unpatentable, we proceed to consider Patent Owner's Motion to Amend the claims of the '453 patent. Proposed amended claims are set forth in Appendix A of the motion. Patent Owner supports its motion with the Reply Declaration of Dr. Nils Hoem (Ex. 2025) and the original disclosure of the '453 patent (U.S. Appl. No. 14/020,162) (Ex. 2012). MTA 1, 3. For the reasons discussed below, Patent Owner's motion is denied.

The Federal Circuit has explained that the Board must assess "the patentability of the proposed substitute claims without placing the burden of persuasion on the patent owner." *Aqua Prods., Inc. v. Matal*, 872 F.3d 1290, 1296 (Fed. Cir. 2017). As for procedural requirements regarding motions to amend, the Court stated that "the patent owner must satisfy the Board that the statutory criteria in [35 U.S.C.] § 316(d)(1)(a)–(b) and § 316(d)(3) are met and that any reasonable procedural obligations imposed by the Director are satisfied before the amendment is entered into the IPR." *Aqua Prods.*,

872 F.3d at 1305–06. In view of *Aqua Products*, the Board has issued guidance explaining,

> [A] patent owner still must meet the requirements for a motion to amend under 37 C.F.R. § 42.121 or § 42.221, as applicable. That is, a motion to amend must set forth written description support and support for the benefit of a filing date in relation to each substitute claim, and respond to grounds of unpatentability involved in the trial. Likewise, under 37 C.F.R. § 42.11, all parties have a duty of candor, which includes a patent owner's duty to disclose to the Board information that the patent owner is aware of that is material to the patentability of substitute claims, if such information is not already of record in the case.

See Memorandum "Guidance on Motions to Amend in view of *Aqua Products*" (Nov. 21, 2017) (https://www.uspto.gov/sites/default/files/documents/guidance_on_motions_to_amend_11_2017.pdf) ("Memorandum") at 2; *see also Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 15 at 4 (PTAB Feb. 25, 2019) (precedential).

A. Reasonable Number of Substitute Claims

"A motion to amend may . . . propose a reasonable number of substitute claims. The presumption is that only one substitute claim would be needed to replace each challenged claim, and [that presumption] may be rebutted by a demonstration of need." 37 C.F.R. § 42.121(a)(3). Patent Owner's proposed claims 62–74 represent a one-for-one substitution for original claims 1–13, respectively.[14] MTA App'x A, ii–v. Thus, those proposed substitutions satisfy 37 C.F.R. § 42.121(a)(3).

[14] Patent Owner does not propose substitute claims for original claims 14–32. MTA App'x A, v.

B. No Broadening of Scope

Proposed substitute claims in an *inter partes* review "may not enlarge the scope of the claims of the patent." 35 U.S.C. § 316(d)(3); *see* 37 C.F.R. § 42.121(a)(2)(ii). In the Motion to Amend, each of proposed substitute claims adds limitations to each corresponding original claim. MTA 2–3. Accordingly, we determine that Patent Owner has met the requirements of 35 U.S.C. § 316(d)(3) and 37 C.F.R. § 42.121(a)(2)(ii) by not enlarging the scope of the original claims in the proposed substitute claims.

C. Written Description Support

Pursuant to 37 C.F.R. § 42.121(b), a motion to amend in an *inter partes* review must set forth "[t]he support in the original disclosure of the patent for each claim that is added or amended," and "[t]he support in an earlier-filed disclosure for each claim for which benefit of the filing date of the earlier filed disclosure is sought." In particular, the limitations added to the challenged claims must be supported *individually* by the application, from which Patent Owner claims priority, and the substitute claims also must be supported *as a whole* by that application. *Lectrosonics*, Paper 15 at 7–8.

The language of the proposed substitute claims does not need to be described *in ipsis verbis* in the original disclosure to support the proposed substitute claims. *Id.*; *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000); *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1570 (Fed. Cir. 1996). However, if the original disclosure does not use the precise terminology recited in a proposed claim, "mere citation to the original disclosure without any explanation as to why a person of ordinary skill in the art would have recognized that the inventor possessed the claimed subject

matter as a whole may be similarly inadequate." *Nichia Corp.*, Paper 27 at 4. In other words, in such case, the question remains whether the disclosure reasonably would lead persons of ordinary skill in the art to the subject matter recited in the proposed claims. *See Fujikawa*, 93 F.3d at 1570.

Patent Owner asserts that each proposed claim finds written description support in the disclosure of U.S. Application No. 14/020,162 (Ex. 2012) ("the original disclosure") that later issued as the '453 patent. MTA 4–8. Petitioner disagrees. MTA Opp. 5–6. Proposed substitute claim 62 is presented as an independent claim, from which proposed claims 63–74 depend. The parties dispute only whether the added limitation in substitute claim 62 requiring "grinding, cooking and drying" the *E. superba* to provide dried krill meal finds support in the original disclosure. We focus our analysis on that dispute. Patent Owner asserts,

> The '162 application provides detailed support for producing a dried krill meal by grinding, cooking and drying *E. superba*. *See, e.g.*, Ex. 2012 at p. 6, l. 12-21, p. 14, l. 8-18; Examples at p. 25, l. 7-8, p. 44, l. 10 – p. 45, l. 2; Tallon Decl. (Ex. 1006) at ¶170; Ex. 2001 (Hoem Decl.) ¶107. For example, the '162 application teaches that with respect to the denatured krill product used for extraction: "In some embodiments, the denaturation step comprises heating said fresh krill after grinding." Ex. 2012 at p. 6, l. 13-14. As taught in the Examples, meal for extraction was produced as follows: "Fresh krill was pumped from the harvesting trawl directly into an indirect steam cooker, and heated to 90C. Water and a small amount of oil were removed in a screw press before ethoxyquin (antioxidant) was added and the denatured meal was dried under vacuum at a temperature not exceeding 80C." Ex. 2012 at p. 44, l. 10 – p. 45, l. 2. The lipases and phospholipases in the meal are described to be denatured. Ex. 2012 at p. 6, l. 10-11 and 20; p. 14, l. 8-14; Ex. 2001 (Hoem Decl.) ¶108.

MTA 5. Petitioner asserts that only one of the excerpts from the original disclosure relied upon by Petitioner actually uses the term "grinding." MTA Opp. 5 (citing Ex. 2012, p. 6, ll. 12–14). According to Petitioner, "the single isolated use of the term 'grinding in the [original disclosure] does not demonstrate that applicants were sufficiently aware of the proposed 'grinding, cooking and drying' step as inventive to satisfy 35 U.S.C. §112 (b)." *Id.* at 6.

Patent Owner responds by asserting that the original disclosure "specifically describes production of the meal by steps including grinding, cooking and drying." MTA Reply 3 (citing Ex. 2012, p. 6, ll. 9–21; p. 15, ll. 5–21; p. 44, Example 6). Patent Owner asserts also that "Petitioner's expert admits that these steps were known in the art." *Id.* (citing Ex. 1086 ¶¶ 253–259). According to Patent Owner, "given the existing knowledge in the field and the content of the prior art, a person of ordinary skill in the art ('POSITA') would readily recognize that the inventors were in possession of a method of making krill meal by cooking, grinding and drying and [then] using that krill meal for extraction of krill oil as claimed." *Id.* (citing Ex. 2025 ¶ 6). Petitioner replies that Patent Owner inappropriately relies only on an obviousness rationale to support why an isolated reference to a grinding step satisfies the written description requirement for the step of "grinding, cooking and drying" by relying on the fact that those steps were known in the art. MTA Sur-Reply 1–2.

We agree with Petitioner that Patent Owner's reference to what was known in the art suggests an obviousness rationale rather than an appropriate basis for satisfying the written description requirement. However, contrary to Petitioner's assertions, we find that Patent Owner has otherwise

adequately shown that the original disclosure itself provides support for the added "grinding, cooking and drying" limitation. In particular, Patent Owner directs us to disclosures in the original specification describing heating fresh krill after grinding, Ex. 2012, p. 6, ll. 13–14, and drying krill after heating/cooking, *id.* at 44, Example 6. Based upon those descriptions, we find that a person of ordinary skill in the art would have understood from the original disclosure that the inventors were in possession of a method of treating fresh krill comprising "grinding, cooking and drying," as recited in proposed claim 62. Accordingly, we determine that Patent Owner has met the requirements of 37 C.F.R. § 42.121(b) by setting forth the support in the original disclosure for that added claim limitation.

D. Patentability Analysis of Substitute Claims 62–74

"The Board determines whether substitute claims are unpatentable by a preponderance of the evidence based on the entirety of the record, including any opposition made by petitioner." *Lectrosonics*, Paper 15 at 4.

Proposed claims 62 recites,

> A method of production of polar krill oil from *Euphausia superba* comprising:
>
> a) treating freshly caught *Euphasia superba* by grinding, cooking and drying the *Euphasia superba* to provide a dried krill meal, wherein lipases and phospholipases in the *Euphasia superba* are denatured by said treating;
>
> b) contacting the dried krill meal with a polar solvent to extract a polar krill oil comprising phospholipids,
>
> said polar krill oil comprising from 4% to 8% ether phospholipids w/w of said polar krill oil; from about 27% to 50% non-ether phospholipids w/w of said polar krill oil so that the amount of total phospholipids is from about 30% to 60% w/w of said polar krill oil; from about 20% to 50% triglycerides w/w of said polar krill oil, and astaxanthin esters in amount of from 100 mg/kg to 700 mg/kg of said polar krill oil; and

c) formulating said polar krill oil with a carrier for oral consumption.

See MTA, App'x A ii–iii.

Proposed claims 62–74 are based upon original claims 1–13, respectively, wherein the proposed claims "further specify how the *E. superba* is treated to provide a material (dried krill meal with denatured lipases and phospholipases) for extraction and adds upper limits to the ranges of two different components of the krill oil extracted from the dried krill meal." MTA 12, App'x A, ii–v. Petitioner asserts that substitute claims 62–71, and 73 are unpatentable as obvious over the combination of Yoshitomi, Catchpole, Bottino II, Sampalis I, Randolph, Sampalis II, and NKO. MTA Opp. 18–23. Petitioner asserts that substitute claim 72 is unpatentable as obvious over the combination of Yoshitomi, Catchpole, Bottino II, Sampalis I, Fricke, Randolph, Sampalis II, and NKO. *Id.* at 23–24. Petitioner asserts that substitute claim 74 is unpatentable as obvious over Yoshitomi, Catchpole, Bottino II, Sampalis I, Sampalis II, Randolph, and NKO. *Id.* at 24–25.

In support of those contentions, Petitioner reiterates its arguments presented to challenge the original claims, and introduces additional arguments and evidence to address the amended elements of the substitute claims. Patent Owner also reiterates its arguments raised regarding the original claims and introduces new arguments regarding the amended limitations of the substitute claims. Based on our analysis in Section II, above, we determined that Petitioner has shown by a preponderance of the evidence that claims 1–32 are unpatentable as obvious over combinations including Breivik II, Catchpole, Bottino II, and Sampalis I. Accordingly, we

incorporate our prior analysis, findings and conclusions relating to arguments presented regarding the original claims and reiterated here with respect to the proposed substitute claims. Below, we focus on the parties' disputes regarding the amended limitations of the substitute claims.

"grinding, cooking and drying"

Petitioner contends that "treating fresh krill by 'grinding, cooking and drying' to obtain a denatured krill product has been known for years and encompasses conventional processing techniques." MTA Opp. 4. Thus, Petitioner asserts that simply adding that limitation to the proposed claims does not confer patentability. *Id.* In support of its contention, Petitioner directs us to Yoshitomi[15] and Grantham[16]. *Id.* (citing Exs. 1033 and 1032). In particular, Petitioner asserts that Yoshitomi discloses producing a "'dried powdery and granular krill product which contains all components' of freshly captured *Euphasia superba* krill." *Id.* at 6 (citing Ex. 1033 ¶¶ 2, 9, 55). Petitioner asserts that in Yoshitomi's process, "krill is 'first chopped into pieces . . . and then put into a heating and drying machine.'" *Id.* at 7 (citing Ex. 1033 ¶¶ 37 and 49, Example 1). Additionally, Petitioner asserts that Yoshitomi explains that chopping or grinding krill "improve[s] thermal efficiency" during the cooking and drying steps and that lipids extracted from the krill contain fewer degradation by-products. *Id.* at 18 (citing Ex. 1033 ¶¶ 32). Petitioner asserts that Yoshitomi teaches that heating krill

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[15] Yoshitomi, US 2003/0113432 A1, published Jun. 19, 2003 ("Yoshitomi") (Ex. 1033).
[16] Grantham, *The Utilization of Krill* (Southern Ocean Fisheries Survey Programme) (1977) ("Grantham") (Ex. 1032).

"will 'perfectly disable' the proteolytic enzymes which would also denature the lipases and phospholipases." *Id.* at 7.

Patent Owner's position is that Breivik II and Yamaguchi[17] teach away from "utilizing krill meal made by processes such as grinding, cooking and drying *E. superba* for extraction of krill oil," by teaching that "polymerized and oxidized material in krill meal limits extraction of oil from krill meal." MTA 14 (citing Ex. 2002, 905; Ex. 1037, 2). Patent Owner acknowledges that Breivik II teaches that "krill meal made by a 'mild' procedure can be used for extraction." *Id.* (citing Ex. 1037, 11). Although Patent Owner and Dr. Hoem note that Breivik II does not identify what method is a "mild" procedure, they assert that "such a method would not involve grinding, cooking and drying *E. Superba* to provide a dried krill meal." *Id.* at 15 (citing Ex. 2001 ¶ 126).

Additionally, Patent Owner asserts that a skilled artisan would not have combined Yoshitomi with other prior art cited by Petitioner because (1) the data in Yoshitomi demonstrate that the lipids in its krill powder (YKP) were subject to hydrolytic and oxidative degradation, and (2) the lipids levels in the YKP were at abnormally low due to oxidative degradation. MTA Reply 4–5. Specifically Patent Owner asserts that Table 3 of Yoshitomi reports that the acid value of YKP without antioxidant immediately after manufacture was 18.1, and 19.2 with antioxidant. *Id.* at 5. Patent Owner asserts that the "[a]cid value is a general indicator of

[17]Yamaguchi et al., *Supercritical Carbon Dioxide Extraction of Oils from Antarctic Krill*, J. AGRIC. FOOD CHEM. 34, 904–07 (1986) ("Yamaguchi") (Ex. 2002).

hydrolytic rancidity of lipids in which krill can be caused by both enzymatic and non-enzymatic processes." *Id.* According to Patent Owner, Yoshitomi's reported acid value levels are "consistent with hydrolytic degradation of the lipids in YKP and are similar to or higher than conventional krill meals such as those described in Yamaguchi." *Id.*

Further, Patent Owner asserts that Yoshitomi's Table 3 also reports that the starting peroxide value, an early indicator of oxidative degradation, is 1.8, with the antioxidant, and 4.1 without the antioxidant. *Id.* According to Patent Owner, those values are high for a product that has just been manufactured and indicate that the lipids in YKP were subject to oxidative degradation. *Id.* Patent Owner asserts that the crude fat content reported for YKP in Yoshitomi Table 5 is abnormally low, in comparison to the lipid content reported in Catchpole for its freeze-dried krill powder. *Id.* at 6. According to Patent Owner, YKP's low lipid content is consistent with lipid degradation. *Id.*

Petitioner's position is that instead of teaching away, Breivik II teaches that "cooking denatures krill lipases, thus permitting grinding without hydrolysis concerns," MTA Opp. 8 (citing Ex. 1037, 4), and that Yamaguchi states that "SC-CO2 extraction is a suitable method to obtain undenatured oils from meals of marine origin." *Id.* (citing Ex. 2002, 905).

Regarding Patent Owner's arguments regarding Yoshitomi, Petitioner counters that "Yoshitomi repeatedly and unambiguously describes grinding (i.e., chopping or coarsely crushing), cooking (i.e., heating) and drying fresh *Euphasia superba* krill to produce a denatured krill powder containing 'all the components' of fresh krill." MTA Sur-Reply 3 (citing Ex. 1033, Abstr., ¶¶ 9, 21–23, 25, 32–34, 37, 41, 49, 51, and 55). Further, Petitioner asserts

that Patent Owner's contentions regarding Yoshitomi's krill product "is predicated on the very antithesis of Yoshitomi's stated purpose; producing a denatured krill product in which 'enzymes in krill [are] perfectly disabled.'" *Id.* at 5. Petitioner notes that Patent Owner and Dr. Hoem have not identified support for concluding that the acid and peroxide values reported in Yoshitomi's Table 3 disclose a krill product that was subjected to unacceptable levels of hydrolytic and oxidative degradation. *Id.* Petitioner asserts that Patent Owner's comparison of Yoshitomi's product with Yamaguchi's product, to relate Yoshitomi with Yamaguchi's alleged teaching away from grinding krill due to oxidation and polymerization of the krill meal, based upon acid and peroxide values is precluded as "Yamaguchi provides absolutely no details regarding, *inter alia*, how the krill meal was processed or the meal's acid and peroxide values." *Id.* (citing Ex. 2002, 904). Further, Petitioner asserts that Patent Owner and Dr. Hoem have not demonstrated that the 7% course fat content reported in Yoshitomi's Table 5 for its krill powder represents unacceptable lipid degradation. *Id.* at 7.

Based upon our review of the record as a whole, we agree with Petitioner that Patent Owner and Dr. Hoem have not sufficiently supported their assertions that a person of ordinary skill in the art would have considered the acid and peroxide values reported in Yoshitomi's Table 3, and the fat content reported in Table 5 as disclosures that the lipids in its krill powder were subject to unacceptable levels of hydrolytic and oxidative degradation. We are also not persuaded that that such data reported by Yoshitomi would lead a skilled artisan to disregard Yoshitomi's unambiguous teaching to grind, cook and dry krill, as required by the added claim limitation, or not to combine such teaching with the other prior art

teachings relied upon by Petitioner to demonstrate obviousness. Moreover, we credit Dr. Tallon's testimony that, in addition to the undisputed fact that making krill meal by grinding, cooking, and drying was known in the art, means for doing so without the degradation effects asserted by Patent Owner were well known also. Ex. 1086 ¶¶ 24, 261–262, 265, 268.

"from 4% to 8% ether phospholipids w/w"

Petitioner asserts that the limitation of "from 4% to 8%" ether phospholipids would have been obvious over the teachings of Catchpole. MTA Opp. 8. As with the original claims, Petitioner relies upon Catchpole's disclosure in Example 18 of a process to obtain krill extract having at least 4.8% ether phospholipids. *Id.* Patent Owner's position is the same as presented regarding the original claims, i.e., that Extract 2 in Example 18 did not contain triglycerides, and that adding the required amount of triglycerides would dilute the disclosed ether phospholipid content in Example 18 from 4.8% to less than 4%. MTA 16–18. Regarding the original claims, we determined that collateral estoppel precluded this argument, as the same issue was presented and rejected in the Final Written Decision in IPR2018-00295. We preclude and reject the argument here for the same reason. *See supra*, Section II. E. 3.

"astaxanthin esters in amount of from 100 mg/kg to 700 mg/kg"

Petitioner asserts that, as the Board found in the Final Written Decision in IPR2018-00295, Randolph describes compositions comprising about 300 mg to about 3000 mg krill oil having at least 158 mg/kg of astaxanthin esters. MTA Opp. 12. Patent Owner's position is that none of Petitioner's cited prior art discloses astaxanthin esters within the recited range. MTA 19–20.

Based upon our review of the evidence and arguments, we find that Petitioner and Dr. Tallon have demonstrated persuasively that Randolph teaches krill oil comprising "astaxanthin esters in amount of from 100 mg/kg to 700 mg/kg." To begin, Randolph explains,

> A composition can contain any amount of an astaxanthin ingredient. For example, at least about 1 percent (e.g., at least about 2, 3, 4, 5, 10, 15, 20, 25, 30, 35, 40, 50, 60, 70, 80, or 90 percent) of a dietary supplement can be astaxanthin. Typically, a composition contains between about 0.5 mg and about 50 mg of an astaxanthin ingredient.

Ex. 1011 ¶ 44. Randolph also teaches that the composition typically contains about 300 mg to about 3000 mg of krill oil. *Id.* ¶ 40. Sampalis II teaches that the astaxanthin in krill oil is mainly present as esterified astaxanthin. Ex. 1013, 30; Ex. 1006 ¶ 298. Dr. Tallon explained persuasively that a person of ordinary skill in the art "would have understood that at least 95% of the astaxanthin [present in Randolph's composition] would be in the esterified form and thus Randolph discloses a typical krill oil composition containing 158 mg/kg esterified astaxanthin (166 mg/kg x 0.95)." Ex. 1086 ¶ 311.

Based on the foregoing, we determine that it would have been obvious to one of ordinary skill in the art to prepare krill oil comprising between 100 mg/kg and 700 mg/kg of astaxanthin esters.[18] *See In re Peterson*, 315 F.3d

[18] We agree with Petitioner that this issue was presented and decided in the Final Written Decision in IPR2018-00295. As mentioned above in footnote 10, Patent Owner has requested a rehearing in response to that Final Written Decision regarding issues involving the denied motion to amend claims, including the astaxanthin limitation. We note that our independent analysis

1325, 1329 (Fed. Cir. 2003) ("A prima facie case of obviousness typically exists when the ranges of a claimed composition overlap the ranges disclosed in the prior art."); *see also E.I. DuPont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996, 1006–08 (Fed. Cir. 2018) (determining that the presumption of obviousness based upon overlapping range scheme applies in the context of an *inter partes* review).

Having considered the amended limitations of the substitute claims, and incorporating our analysis and conclusions regarding for the reiterated arguments regarding a motivation to combine and reasonable expectation of success from our discussion of the original claims, we conclude that the preponderance of the evidence demonstrates that substitute claims 62–71, and 73 are unpatentable as obvious over the combination of Yoshitomi, Catchpole, Bottino II, Sampalis I, Randolph, Sampalis II, and NKO; substitute claim 72 is unpatentable as obvious over the combination of Yoshitomi, Catchpole, Bottino II, Sampalis I, Fricke, Randolph, Sampalis II, and NKO; and substitute claim 74 is unpatentable as obvious over Yoshitomi, Catchpole, Bottino II, Sampalis I, Sampalis II, Randolph, and NKO. Accordingly, Patent Owner's contingent Motion to Amend is denied.

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of this issue here is consistent with what was decided in that Final Written Decision.

IV. CONCLUSION

For the foregoing reasons, we conclude that Petitioner has established by a preponderance of the evidence that claims 1–3, 5–10, 12, 14–17, 19–20, 23–26, 28, and 30–32 are unpatentable as obvious over Breivik II, Catchpole, Bottino II, and Sampalis I; claim 4 is unpatentable as obvious over Breivik II, Catchpole, Bottino II, Sampalis I, and Sampalis II; claims 11, 18, 21, and 27 are unpatentable as obvious over Breivik II, Catchpole, Bottino II, Sampalis I, and Fricke; and claims 13, 22, and 29 are unpatentable as obvious over Breivik II, Catchpole, Bottino II, Sampalis I, and Randolph. Additionally, we deny Patent Owner's contingent Motion to Amend.

V. ORDER

Accordingly, it is hereby:

ORDERED that based on a preponderance of the evidence, claims 1–32 of the '453 patent are unpatentable;

FURTHER ORDERED, Patent Owner's Motion to Amend is denied; and

FURTHER ORDERED, because this is a final written decision, the parties to this proceeding seeking judicial review of our Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

In summary:

Claims	35 U.S.C. §	References	Claims Shown Unpatentable	Claims Not shown Unpatentable
1–3, 5–10, 12, 14–17, 19–20, 23–26, 28, 30–32	103	Breivik II, Catchpole, Bottino II, Sampalis I	1–3, 5–10, 12, 14–17, 19–20, 23–26, 28, 30–32	
4	103	Breivik II, Catchpole, Bottino II, Sampalis I, Sampalis II	4	
11, 18, 21, 27	103	Breivik II, Catchpole, Bottino II, Sampalis I, Fricke	11, 18, 21, 27	
13, 22, 29	103	Breivik II, Catchpole, Bottino II, Sampalis I, Randolph	13, 22, 29	
Overall Outcome			1–32	

Motion to Amend Outcome	Claims
Original Claims Cancelled by Amendment	
Substitute Claims Proposed in the Amendment	62–74
Substitute Claims: Motion to Amend Granted	
Substitute Claims: Motion to Amend Denied	62–74
Substitute Claims: Not Reached	

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