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Paper 7
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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.

Case 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.*

DECISION
Institution of *Inter Partes* Review
35 U.S.C. § 314(a)

I. INTRODUCTION

Rimfrost AS ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–32 of U.S. Patent No. 9,375,453 B2 (Ex. 1001, "the '453 patent"). Paper 2 ("Pet."). Aker Biomarine Antarctic AS ("Patent Owner") declined to file a Preliminary Response to the Petition.

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314(b); 37 C.F.R. § 42.4(a). Upon considering the Petition, we determine that Petitioner has shown a reasonable likelihood that it would prevail in showing the unpatentability of at least one challenged claim. Accordingly, we institute an *inter partes* review of all challenged claims based upon all grounds raised in the Petition.

A. Related Proceedings

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, in *In the Matter of Certain Krill Oil Products and Krill Meal for Production of Krill Oil Products*, Investigation No. 337-TA-1019 (USITC). *Id.* According to the parties, that matter has been "effectively terminated." *Id.*

The Board has issued Final Written Decisions addressing challenges to claims of 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), and challenges to claims of 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).

Petitioner has concurrently filed a petition for *inter partes* review of claims 33–61 of the ’453 patent in IPR2018-01179.

B. 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 having 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 9:43–50. 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[1] shows the phospholipid profiles for the raw material, the final 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 32:15–39.

The '453 patent teaches that the "main polar ether lipids of the krill meal are alkylacylphosphatidylcholine (AAPC) at 7–9% of total polar lipids,

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

lyso-alkylacylphosphatidylcholine (LAAPC) at 1% of total polar lipids (TPL) and alkylacylphosphatidyl-ethanolamine (AAPE) at <1% of TPL." *Id.* at 32:47–52.

C. Illustrative Claim

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

> 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.

D. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–32 of the '453 patent on the following grounds:

Claim(s)
1–3, 5–10, 12, 14–17, 19–20, 23–26, 28, 30–32
4
11, 18, 21, 27
13, 22, 29

Petitioner also relies upon the Declaration of Stephen J. Tallon, Ph.D. (Ex. 1006).

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, the Board interprets claim terms in an unexpired patent according to the broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R.

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[2] Breivik, WO 2008/060163 A1, published May 22, 2008 ("Breivik II") (Ex. 1037).
[3] Catchpole, WO 2007/123424, published Nov. 1, 2007 ("Catchpole) (Ex. 1009).
[4] 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).
[5] 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).
[6] Sampalis, WO 03/011873 A2, published Feb. 13, 2003 ("Sampalis II) (Ex. 1013).
[7] Fricke et al., *Lipid, Sterol and Fatty Acid Composition of Antarctic Krill (Euphausia superba Dana)*, 19(11) LIPIDS 821–827 (1984) ("Fricke") (Ex. 1010).
[8] Randolph, US 2005/0058728 A1, published Mar. 17, 2005 ("Randolph") (Ex. 1011).

§ 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142 (2016) (affirming applicability of broadest reasonable construction standard to *inter partes* review proceedings).[9] Under that standard, and absent any special definitions, we give claim terms their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007); *Trivascular, Inc. v. Samuels*, 812 F.3d 1056, 1062 (Fed. Cir. 2016) ("Under a broadest reasonable interpretation, words of the claim must be given their plain meaning, unless such meaning is inconsistent with the specification and prosecution history.").

Any special definitions for claim terms must be set forth with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Petitioner asserts proposed claim constructions for a number of claim terms. Pet. 16–32. We determine that construction of those claim terms are not necessary for purpose of this Decision. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (only terms that are in controversy need to be construed, and only to the extent necessary to resolve the controversy).

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[9] The Office recently changed the claim construction standard to be employed in an *inter partes* review. *See Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board*, 83 Fed. Reg. 51340 (October 11, 2018). However, based on the filing date of the Petition in this proceeding, the applicable claim construction standard remains as set forth in 37 C.F.R. § 42.100(b) (2016).

B. 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 this stage in the proceeding, we determine that Petitioner's description of the level of ordinary skill in the art is sufficiently supported by the current record. Moreover, we have reviewed the credentials of Dr. Tallon and, at this stage in the proceeding, consider him to be qualified to provide his opinion on the level of skill and the knowledge of a person of ordinary skill in the art at the time of the invention. We also note that the applied prior art reflects the appropriate level of skill at the time of the claimed invention. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001).

C. 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.

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.[10] 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

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

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

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 (species not specified)" 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.

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%. *Id*.

3. Bottino II

Bottino II characterizes the lipids of two Antarctic euphausiids, *Euphasia supercar* and *Euphasia crystallorophias*. 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.

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. 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 said subject matter pertains. *KSR Int'l Co. v. Teleflex Inc*., 550 U.S. 398, 406 (2007). "An obviousness determination requires finding both 'that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.'" *CRFD Research, Inc. v. Matal*, 876 F.3d 1330, 1340 (Fed. Cir. 2017) (quoting *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367–1368 (Fed. Cir. 2016)). "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, 903–904 (Fed. Cir. 1988)).

Petitioner asserts that the method of independent claim 1 would have been obvious to a person of skill in the art over the combined teachings of Breivik II, Catchpole, Bottino II, and Sampalis I. Pet. 33–44. To begin, Petitioner asserts that Breivik II teaches a method of producing polar krill oil from *E. superba* 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 claimed method 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, 4).

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 (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. 43.

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." 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*.

According to Petitioner, the ordinary 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 the prior art teachings, Petitioner asserts that the ordinarily skilled artisan would have also 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 upon our review of the current record, we determine 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 adequately supported 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 disclosed the components of polar krill oil and the amounts thereof, Bottino II discloses the triglyceride content of polar krill oil, and Sampalis I discloses polar krill oil formulated for oral consumption.

Based on the current record, we do not agree with Petitioner's assertion that Breivik II "expressly disclosed" 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. Pet. 43. For that assertion, Petitioner relies upon a disclosure in Breivik II relating to a commercial krill oil from Neptune Biotechnologies & Bioresources containing ≥ 40% total phospholipids and ≥ 1.0 mg/g esterified astaxanthin (i.e., ≥ 1000 mg/kg). *Id*. (citing (Ex. 1037, 11:23–30). While the amount of astaxanthin in the Neptune krill oil appears to be more than adequate to meet the claim recitation, we note that Breivik II describes that particular Neptune krill oil as "extracted from Japanese krill source (species not specified)." Ex. 1037, 11:25–27. Thus, at this stage in the proceeding, based on the current record, we are unable to appreciate that the Neptune krill oil is a polar krill oil from *E. superba*.

We do, however, recognize that Breivik II discloses a general teaching that the lipid fraction from krill oil "contained triglycerides, astaxanthin and phospholipids," *id.* at 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). We note also 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. Based upon our consideration of Breivik II as a whole, including Breivik II's teaching that a lipid product or fraction according to Breivik II's method is expected to involve "less deterioration of the krill lipid antioxidants than from conventional processing," *id.* at 12:1–7, 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 determine that, at this stage of the proceeding, the current record supports finding that Breivik II suggests the astaxanthin claim limitation.

Thus, based on the information presented at this stage of the proceeding, we determine that Petitioner has shown sufficiently that there is a reasonable likelihood that it would prevail in showing the unpatentability of independent claim 1 as obvious over the combination of Breivik II, Catchpole, Bottino II, and Sampalis I. We have also reviewed Petitioner's evidence and arguments as to the dependent claims and determine, at this stage in the proceeding that such evidence and arguments are supported by the current record. Based on that showing, Petitioner has demonstrated a reasonable likelihood that those claims are also rendered obvious by the combined references. Accordingly, we determine that Petitioner has demonstrated a reasonable likelihood that claims 1–3, 5–10, 12, 14–17, 19–20, 23–26, 28, and 30–32 are rendered obvious by the combination of Breivik II, Catchpole, Bottino II, and Sampalis I.

D. Remaining Grounds

The remaining grounds rely upon similar combinations of Breivik II, Catchpole, Bottino II, and Sampalis I, as set forth in the ground analyzed and instituted above, in Section II. C. Pet. 7, 56–66. The remaining grounds combine additional references to address various limitations of certain dependent claims. *Id.* We have considered those combined teachings along with Petitioner's arguments and Dr. Tallon's testimony and, based on the

current record, we determine that Petitioner has established a reasonable likelihood of prevailing on those grounds, as well. Moreover, on April 24, 2018, the Supreme Court held that a decision to institute under 35 U.S.C. § 314 may not institute on less than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018). Accordingly, we institute an *inter partes* review of all challenged based upon all grounds raised in the Petition.

III. CONCLUSION

For the foregoing reasons, we conclude that the information presented in the Petition establishes a reasonable likelihood that Petitioner would prevail in showing that at least one of the challenged claims of the '453 patent is unpatentable.

At this stage of the proceeding, the Board has not made a final determination as to the construction of any claim term or the patentability of any challenged claim.

ORDER

Accordingly, it is hereby:

ORDERED that pursuant to 35 U.S.C. § 314, an *inter partes* review is instituted as to claims 1–32 of the '453 patent on the following grounds of unpatentability:

Claims 1–3, 5–10, 12, 14–17, 19–20, 23–26, 28, and 30–32 under 35 U.S.C. § 103(a) as obvious over Breivik II, Catchpole, Bottino II, and Sampalis I;

Claim 4 under 35 U.S.C. § 103(a) as obvious over Breivik II, Catchpole, Bottino II, Sampalis I, and Sampalis II;

Claims 11, 18, 21, and 27 under 35 U.S.C. § 103(a) as obvious over Breivik II, Catchpole, Bottino II, Sampalis I, and Fricke;

Claims 13, 22, and 29 under 35 U.S.C. § 103(a) as obvious over Breivik II, Catchpole, Bottino II, Sampalis I, and Randolph; 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 commencing on the entry date of this Decision.

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