Trials@uspto.gov
Tel: 571-272-7822

Paper 104
Entered: March 23, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AKER BIOMARINE AS and ENZYMOTEC LTD. and
ENZYMOTEC USA, INC.,
Petitioner,

v.

NEPTUNE TECHNOLOGIES AND BIORESSOURCES INC.,
Patent Owner.

Case IPR2014-00003[1]
Patent 8,278,351 B2

Before LORA M. GREEN, JACQUELINE WRIGHT BONILLA, and SHERIDAN K. SNEDDEN, *Administrative Patent Judges.*

SNEDDEN, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

[1] Case IPR2014-00556 has been joined with this proceeding.

I. INTRODUCTION

The parties in the case are Aker Biomarine AS ("Aker") and Enzymotec Ltd. and Enzymotec USA, Inc. ("Enzymotec") (collectively, "Petitioner"), and Neptune Technologies and Bioressources, Inc. ("Patent Owner"). Aker filed a first Petition to institute an *inter partes* review of claims 1–27 (Paper 8; "Pet. I") of Patent No. 8,278,351 B2 (Ex. 1001; "the '351 patent"). We instituted trial as to the challenged claims on the following grounds of unpatentability asserted by Aker:

Reference(s)	**Basis**	**Claims challenged**
Beaudoin[2]	§ 102(b)	1, 3–6, 9, 12, 13, 19–24, 26–29, 32, 35, 36, and 42–46
Fricke,[3] Bergelson,[4] Yasawa,[5] Itano,[6] and WHO Bulletin[7]	§ 103	1–6, 9, 12, 13, 19–29, 32, 35, 36, and 42–46

Decision to Institute, 18 (Paper 22 ("Dec. I")).

[2] Beaudoin et al., WO 00/23546, published April 27, 2000. Ex. 1002.

[3] Fricke et al., Lipid, Sterol and Fatty Acid Composition of Antarctic Krill, 19(11) LIPIDS 821-827 (1984). Ex. 1006.

[4] Lipid Biochemical Preparation, LD Bergelson (ed.), Elsevier/North-Holland Biomedical Press (1980). Ex. 1017.

[5] Yasawa et al., JP H8-231391, published September 10, 1996. The certified translation, Japanese language document, and translation certificate for Yasawa are provided as Exs. 1015, 1076 and 1077, respectively. We reference Ex. 1015 in this Decision.

[6] Itano Refrigerated Food Co., Ltd., Bio & High Technology Announcement and Natural Astaxanthin & Krill Lecithin, 1–16. Ex. 1009.

[7] WHO News and Activities, Bulletin of the World Health Organization, 73(4), pp. 547-51 (1995). Ex. 1018.

After institution, Neptune Technologies and Bioressources, Inc. ("Patent Owner"), filed its Patent Owner's Response. Paper 66 ("Resp. I").

Within a month of our Decision to Institute in the first case, Enzymotec filed a second Petition and Motion for Joinder. IPR2014-00556, Paper 1 ("Pet. II"), Paper 4. We then instituted *inter partes* review of the '351 patent in IPR2014-00556 based on the second Petition, and granted Enzymotec's Motion to join IPR2014-00556 with IPR2014-00003. Paper 72 ("Dec. II"). In IPR2014-00556, we instituted trial on the identical alleged grounds of unpatentability previously instituted in IPR2014-00003, and in addition, on the alleged anticipation of claims 2 and 25 over Beaudoin.[8] *Id.* Patent Owner filed its second Patent Owner's Response to address the added ground involving claims 2 and 25. Paper 77 ("Resp. II").

Petitioner filed a Reply, which was responsive to both of the Patent Owner Responses. Paper 84 ("Reply"). Patent Owner did not file a motion to amend claims.

Petitioner relies upon the declarations of Drs. Van Breemen ("Van Breemen" Ex. 1040), Brenna ("Brenna" Ex. 1042) Storrø ("Storrø" Ex. 1044), Budge ("Budge" Ex. 1041); Welch ("Welch" Ex. 1043); Moore ("Moore" Ex. 1044), Lee ("Lee" Ex. 1045), Haugsgjerd ("Haugsgjerd" Ex. 1047, Ex. 1048, and Ex. 1080), and Gundersen ("Gundersen" Ex. 1049 and Ex. 1050).

[8] In this paper, we refer to solely: Paper 66, Patent Owner's Response ("Resp. I"); Paper 84, the Reply filed by Aker; and Paper 22, our Decision to Institute in IPR2014-00003. To the extent that there are differences in arguments and issues raised in the joined case, IPR2014-00556, we refer to the second Petition filed by Enzymotec (IPR2014-00556, Paper 1, "Pet. II") and Paper 72, our Decision to Institute in IPR2014-00556.

Patent Owner relies upon the declaration of Dr. Jacek Jaczynski ("Jaczynski Declaration") (Ex. 2059) in support of its Response.

Patent Owner filed a Motion to Exclude certain of Petitioner's evidence. Paper 89. Petitioner filed an Opposition (Paper 95), and Patent Owner filed a Reply. Paper 97.

Oral argument was conducted on October 31, 2014. A transcript is entered as Paper 103 ("Tr.").

This Final Written Decision addresses challenges to the patentability of claims 1–6, 9, 12, 13, 19–29, 32, 35, 36, and 42–46. Petitioner has established by a preponderance of the evidence that claims 1–4, 6, 9, 12, 13, 19–27, 29, 32, 35, 36, and 42–46 of the '351 patent are unpatentable. Petitioner has failed to demonstrate by a preponderance of the evidence that claims 5 and 28 of the '351 patent are unpatentable.

A. Related Matters

The parties represent that the '351 patent is the subject of patent infringement lawsuits in the U.S. District Court for the District of Delaware: *Neptune Technologies and Bioressources Inc., v. Aker Biomarine ASA, et al.*, No. 12-cv-1252 (filed October 2, 2012) and *Neptune Technologies and Bioressources Inc., v. Enzymotec Limited, et al*., No. 12-cv-1253 (filed October 2, 2012). Pet. I, 2; Paper 10.

The parties represent that the '351 patent is the subject of an International Trade Commission investigation, entitled *Certain Omega-3 Extracts from Marine or Aquatic Biomass and Products Containing the Same*, Investigation No. 337-TA-877. *Id.*

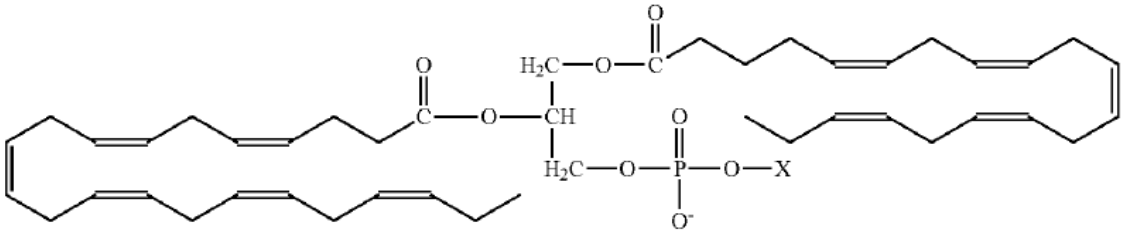
The parties represent that the ’351 patent is the subject of an *Ex Parte* Reexamination, Control No. 90/012,698. *Id.*

Petitioner Aker represents that the ’351 patent is a continuation of U.S. Pat. 8,030,348 (the “’348 patent”; Ex. 1069), which is currently subject to an *Inter Partes* Reexamination, Control No. 95/001,774. Pet. I, 2. The ’348 patent is also the subject a patent infringement lawsuit filed by Neptune Bioressources & Technologies against Aker Biomarine in the United States District Court of Delaware (1:11-cv-00894-GMS). *Id.* The ’351 patent (Ex. 1001)

B. The ’351 patent (Ex. 1001)

Phospholipids are made up of two chains of fatty acids attached to a chemical backbone made up of phosphoric acid, glycerol and nitrogenous bases (e.g., choline). Ex. 1001, 4:41–56. Phospholipids having choline as the nitrogenous base are referred to as phosphatidylcholines. *Id.*

The ’351 patent relates to certain phospholipids and compositions containing phospholipids. The ’351 patent discloses a phospholipid including two fatty acids chains of eicosapentanoic acid (“EPA”) and docosahexanoic acid (“DHA”) simultaneously. The general formula for the phospholipid is:



,

wherein X represents a moiety normally found in a phospholipid such as

phosphatidylcholine (PC), phosphatidylethanolamine (PE) and phosphatidylinositol (PI). *Id.* at 2:46–3:2, 21:1–25.

The phospholipids are derived from natural marine or aquatic sources. *Id.* at 1:19–22. Krill is described as the preferred source of the disclosed phospholipids, which includes krill found in the Antarctic Ocean (*Euphasia superba*) and in the Pacific Ocean (*Euphasia pacifica*). *Id.* at 15:8–21. The '351 patent describes the preparation of krill extracts that preferably contain 40% weight per weight (w/w) phospholipid. *Id.* at 15:42–45. Polyunsaturated fatty acids, in particular omega-3 fatty acids, preferably make up at least 15% w/w of the total lipids in the extract. *Id.* at 16:47–51. DHA or EPA may account for at least 32% w/w of the total lipid content of the extract. *Id.* at 16:51–54.

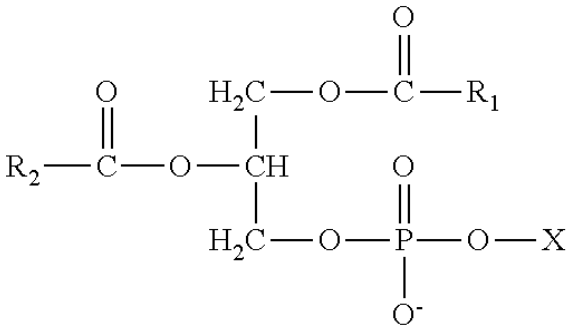
C. Challenged Claims

Claims 1 and 24 are the only independent claims among the challenged claims, and are reproduced below:

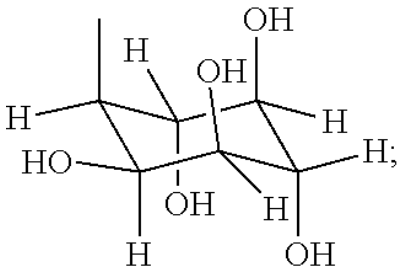
1. A krill extract comprising:

a phospholipid of the general formula (I),

(I)



wherein R1 and R2, each together with the respective carboxyl groups to which each is attached, each independently represents a docosahexaenoic acid (DHA) or an eicosapentanoic acid (EPA) residue, and X is —$CH_2CH_2NH_3$, —$CH_2CH_2N(CH_3)_3$, or

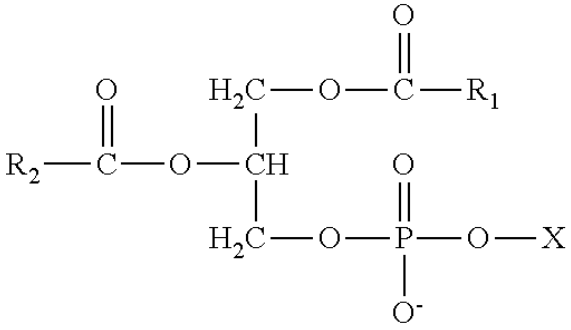


and wherein the extract is suitable for human consumption.

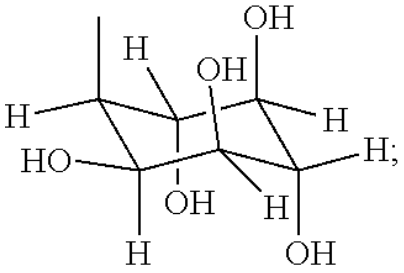
24. A capsule, tablet, solution, syrup, or suspension comprising a krill extract comprising:

a phospholipid of the general formula (I),

(I)



wherein R1 and R2, each together with the respective carboxyl groups to which each is attached, each independently represents a docosahexaenoic acid (DHA) or an eicosapentanoic acid (EPA) residue, and X is —$CH_2CH_2NH_3$, —$CH_2CH_2N(CH_3)_3$, or



and wherein the extract is suitable for human consumption.

Claims 2–6, 9, 12, 13, and 19–23 depend from claim 1, either directly or indirectly. Claims 25–29, 32, 35, 36, and 42–46 depend from claim 24, either directly or indirectly.

II. DISCUSSION

A. Claim Interpretation

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012); *In re Cuozzo Speed Techs., LLC*, No. 2014-1301, 2015 WL 448667, at *5–*8 (Fed. Cir. Feb. 4, 2015). Claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc*., 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

We expressly interpret below only those claim terms that require analysis to resolve arguments related to the patentability of the challenged claims.

1. Construction of the phrase "suitable for human consumption"

Petitioner suggests that "suitable for consumption" broadly covers "any form of consumption by a human (e.g., oral or topical administration)." Pet. I, 9.

Patent Owner contends that any interpretation of "suitable for human consumption" must cover extracts intended for oral ingestion. Resp. I, 9–10. To support this argument, Patent Owner cites to those passages of the '351 patent that disclose compositions intended for oral consumption such as foods, beverages, energy bars, sports drinks, and supplements. *Id.* (citing Ex. 1001, 20:34-36, 20:42-57, and Examples 2 and 3).

Patent Owner's analysis does not address the disclosure of "topical cosmetic products" in the '351 patent. *See e.g.*, Ex. 1001, 20:38–41 ("[T]the phospholipid extract of the invention is also useful in cosmetic preparations, e.g., moisturizing creams, sun-block products and other topical cosmetic products as known in the art."). In light of that disclosure in the '351 patent, we agree with Petitioner that "suitable for consumption" broadly covers any form of human consumption (e.g., oral or topical administration).

2. Construction of the phrase "capsule, tablet, solution, syrup, or suspension"

Under a broadest reasonable interpretation, words of the claim must be given their plain meaning unless the plain meaning is inconsistent with the specification. *In re Zletz*, 893 F.2d 319, 321 (Fed. Cir. 1989). Limitations from the specification are not to be read into the claims. *In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993); *see also Superguide Corp. v. DirecTV Enterprises, Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004) ("Though understanding the claim language may be aided by explanations contained in the written description, it is important not to import into a claim limitations that are not part of the claim. For example, a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment."); *cf. Merck*

& Co. v. Teva Pharm. USA, Inc., 395 F.3d 1364, 1372 (Fed. Cir. 2005) (reversing the district court's construction of the term "about" because the interpretation was inconsistent with the specification).

Patent Owner contends that that recitation of "solution, syrup, or suspension" in claim 24 refers to liquid preparations for oral administration. Resp. I, 14 (citing Ex. 2059 ¶ 40; Ex. 2037, 245:20–246:2; Ex. 1001, 20:10–22 ("Liquid preparations for oral administration may take the form of, for example, solutions, syrups or suspensions . . . ."). Although we agree that that recitation of "solution, syrup, or suspension" encompasses liquid preparations for oral administration, we decline to interpret the phrase to be limited to liquid preparations for oral administration. Claim 24 recites, for example, solutions comprising a krill extract that are suitable for human consumption. The claim is absent any language that limits "consumption" to oral consumption and we must take care to not import limitations from the specification into the claim. *Superguide Corp.*, 358 F.3d at 875.

3. Construction of the term "about"

The term "about" is defined in the '351 patent as follows:

> As used herein and in the claims, where the term "about" is used with a numerical value, the numerical value may vary by at least ±50%. Preferably, the variation will be ±40% or ±30% and more preferably ±20% or ±10%. Even more preferred variations are in the range ±5%, ±4%, ±3% or ±2%. Most preferably, the variation is in the range of ±1%.

Ex. 1001, 21:61–63.

Patent Owner contends that "±50%" would not be understood by a person of ordinary skill in the art to mean plus or minus an absolute value of 50%, because it would be nonsensical as it would include negative values for

lower numerical numbers such as 5% (i.e., indicating a range of -45% to 55%). Resp. I, 11–12 (citing Ex. 2059 ¶ 37). Rather, a person of ordinary skill in the art would have interpreted "±50%" to be determined from the numerical value used with the variation. *Id.* Thus, for example, about 5% ± 50% means plus or minus 50% of 5%, and therefore indicates a range of 2.5% (5% minus 2.5%) to 7.5% (5% plus 2.5%). *Id.*

Petitioner contends that the broadest reasonable interpretation of "about," in view of the express definition set forth in the specification, is to read "±50%" as an absolute value. Reply 3–4. Petitioner contends that negative values would not render such an interpretation nonsensical as the term "about" is used in the context of amounts of compositional elements, which are not negative. *Id.* Thus, for example, claims 5 and 28 require free fatty acids and therefore would not encompass a negative amount.

Upon consideration of the claims, Specification, other evidence, and the arguments summarized above, we conclude that a person of ordinary skill in the art would have interpreted "±50%" in the Specification, and thus the broadest reasonable interpretation of "about" in claims (lacking any other definition in the claims) in view of the Specification, to mean ±50% as determined from the numerical value used with the variation. Ex. 2059 ¶ 37. Thus, for example, "about 5% w/w" in claim 5 refers to a range of 2.5% to 7.5% w/w.

Patent Owner's proposed claim construction does not address the presence of the phrase "at least" in the express definition of the term "about," which provides that "the numerical value may vary by at least ±50%." Ex. 1001, 21:61–63. In this regard, we read the phrase "at least 50%" in the context of the entire definition of the term "about," set forth in

the above paragraph, to mean ±50%, but may be less if indicated otherwise (e.g., ±40% or ±30%) %) in the claim. Thus, if "about" is defined in a claim with a particular percentage, that percentage is determined from the numerical value used with the variation. For example, "about 45% w/w, wherein about represents ±20%" in claim 3 refers to the range of 36% to 54% w/w. As another example, claim 7 recites that the "extract further comprises polyunsaturated fatty acids which comprise at least 40% w/w of the lipids in the extract;" the "at least 40%" represents 40% or more.

B. The Prior Art

a. Summary of Beaudoin (Ex. 1002)

Beaudoin relates to the extraction of lipid fractions from marine and aquatic animals such as krill. Ex. 1002, 1:5–6. Lipids are extracted from freshly collected marine and aquatic material with a ketone, such as acetone. *Id.* at 4:29–30. Beaudoin discloses that krill lipid fractions have various uses, including medical and nutritional applications. *Id.* at 1:11–26.

Beaudoin provides a description of the general extraction method used to prepare extracts from marine and aquatic animal material. *Id.* at 5:21–6:20. Beaudoin discloses that the starting material is subjected to acetone extraction, under inert atmosphere, and at a temperature of about 5°C or less for about two hours, and preferably overnight. *Id.* Table 19 of Beaudoin is reproduced below.

TABLE 19. OPTIMAL CONDITIONS FOR LIPID EXTRACTION OF AQUATIC ANIMAL TISSUES (suggested procedure)

STEP	CONDITIONS
Grinding (if particles > 5mm)	4°C
Lipid extraction	sample-acetone ratio of 1:6 (w/v) 2h (including swirling 20 min) 4°C
Filtration	organic solvent resistant filter under reduced pressure
Washing	sample-acetone ratio of 1:2 (w/v) pure and cold acetone
Filtration	organic solvent resistant filter under reduced pressure
Evaporation	under reduced pressure
Oil-water separation	4°C
Lipid extraction	sample: ethyl acetate ratio of 1:2 (w/v)[a)] pure ethyl acetate 30 min 4°C [b)]
Filtration	organic solvent resistant filter under reduced pressure
Evaporation	under reduced pressure

[a)]: Ethanol can be replaced by isopropanol, *t*-butanol or ethyl acetate.
[b)]: 25 °C when using *t*-butanol.

Id. at 28:1–36. Table 19 is disclosed as providing the suggested procedure and optimal conditions for lipid extraction of aquatic animal tissues. *Id.*

Beaudoin discloses the preparation of krill oil using various solvents. *Id.* at 8:4–19; *see also id.* at 21:39–55 (Table 12). The characteristics of certain lipid fractions of the krill oil were analyzed and the results are provided in Table 13 of Beaudoin. *Id.* at 22. In the paragraph summarizing Table 13, Beaudoin discloses that the krill oil fractions were heated to about 125°C for about 15 minutes to remove traces of solvents. *Id.* at 10:6–20.

As stated in the reference, the inventor of Beaudoin, Dr. Adrien Beaudoin, ingested lipid fractions of krill, and no side effect profile was observed. *Id.* at 12:13–14.

b. Summary of Fricke (Ex. 1006)

Fricke discloses the preparation of lipid extractions from Antarctic krill (*E. superba*). Ex. 1006, 821. 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

Data are expressed as wt % of total lipids and represent means ± standard deviation of 3 separate experiments.

[a]Probably mostly artifacts.

[b]Traces of lysophosphatidylethanolamine, phosphatidylserine, sphingomyelin, glycolipids, sterol esters, waxes and carotenoids were detected.

Id. at 822 (Table 1). Table 1 discloses the total lipid content and the lipid composition data of two krill samples obtained from krill caught in December 1977 and March 1981. *Id.*

Table 6 of Fricke is reproduced below.

TABLE 6

Fatty Acid Positional Analysis in Phosphatidylcholine (PC) and Phosphatidylethanolamine (PE) of *Euphausia superba* Dana (1977 Sample)

Phospholipid	PC		PE	
sn-position	*sn*-1	*sn*-2	*sn*-1	*sn*-2
14:0	3.5	2.3	0.7	0.8
16:0	60.8	4.7	45.4	3.3
16:1(n-7)	1.5	5.4	0.7	0.5
18:0	1.9	0.8	5.6	1.5
18:1(n-7)	11.1	tr.	24.0	0.9
18:1(n-9)	3.5	22.0	4.8	2.9
18:2(n-6)	0.6	4.8	0.6	0.6
20:5(n-3)	5.6	27.7	5.7	31.3
22:6(n-3)	2.1	11.1	3.5	41.3
Others	9.4	21.2	9.0	16.9

Data are expressed as wt % of fatty acids in one position from one experiment.

Id. at 826 (Table 6). Table 6 discloses the fatty acid positional analysis in PC and PE detected in the December 1977 *E. superba* sample. *Id.*

c. Summary of Itano (Ex. 1009)

Itano describes the nutritional value of krill extracts. Ex. 1009, 7–15. Specifically, Itano discloses as follows:

> Phospholipid, a structural component of organic membranes, contributes to enzyme- activation and is said to be effective in lowering the concentration of cholesterol in human blood.
>
> Krill lecithin (phospholipid found in krill) is more effective in decomposing peroxides than ordinary soybean or vitellinephospholipid, and is equally effective in lowering cholesterol levels. A further characteristic of krill lecithin that

> has been the focus of considerable attention in recent years is the high content of the highly unsaturated fatty acids, EPA (20:5) and DHA (22:6), both of which are considered to be effective in preventing and treating adult diseases such as myocardial infarction and thrombosis.
>
> Itano's krill lecithin has the potential to make maximum use of these Characteristics through application to promising health foods and "functional foods."

Id. at 15.

d. Summary of Yasawa (Ex.1015)

Yasawa discloses the administration of DHA for improving dementia symptoms. Ex. 1015, Abstract. Yasawa discloses the use of krill oil as a carrier for DHA. Specifically, Yasawa discloses as follows:

> The DHA used in the present invention is an isolated acid, and refers to salt, ester, glyceride, phospholipids, choline compounds, ascorbic acid compounds, amino acid compounds. As for the oil that includes the DHA, an inclusion ratio of 10% or more DHA (as an isolated acid) within general fatty acids. As an example of such an oil, the fish oil extracted from blue backed fish such as Japanese pilchard, mackerel, horse mackerel, salmon, and Pacific saury, the fish oil from large ocean fish eye oil, such as that of the tuna or the shipjack tuna, oil coming from microorganisms, krill oil, and oil from industrial products extracted from the livers of Pacific cod and dolphins.

Id. ¶ 8.

e. Summary of Bergelson (Ex. 1017)

Bergelson discloses techniques for the preparing lipid extracts from natural sources using various solvents, such as chloroform and methanol. Ex. 1017, 2–4. Bergelson discloses to remove solvent from lipid extracts by

rotary evaporation using mild conditions (e.g., 35° C) or under nitrogen to avoid auto-oxidation. *Id.* at 10–11.

f. Summary of WHO Bulletin (Ex. 1018)

The WHO Bulletin describes the nutritional value of Antarctic krill (*Euphausia superba*). Ex. 1018, 551. The WHO Bulletin identifies krill as a source of EPA, DHA, zinc, and selenium. *Id.*

C. Analysis

1. Anticipation of Claims 1, 4–6, 9, 12, 13, 19–24, 27–29, 32, 35, 36, and 42–46 by Beaudoin (Ex. 1002)

a. Claims 1 and 24

Claims 1 and 24 are directed to a krill extract and solution, respectively, containing a phospholipid of the general formula (I) that is suitable for human consumption. Petitioner contends that Beaudoin discloses lipid extracts from krill that necessarily contain the phospholipids recited in claims 1 and 24. Pet. I, 15–19. Although Beaudoin does not identify the lipid composition of the *E. pacifica* krill extracts, Petitioner provides extensive declaration evidence, related to the reproduction and testing of krill extracts made according to the disclosure of Beaudoin, to show that the *E. pacifica* krill extracts disclosed in Beaudoin necessarily contained the claimed phospholipids. Van Breemen (Ex. 1040) ¶¶ 73–85, 93–98; Budge (Ex. 1041) ¶¶ 7–10; Haugsgjerd (Ex. 1048) ¶¶ 2–5; Lee (Ex. 1045), Table 7. Krill extract samples were prepared by Dr. Budge and Dr. Haugsgjerd and certain tests on the krill extract samples were performed by Drs. Lee and van Breeman. *Id.* The Van Breemen Declaration, in particular, provides mass spectrometry evidence that *E. pacifica* krill acetone

extracts contain PC-EPA/EPA, PC-DHA/DHA, and PC-EPA/DHA. Ex. 1040 ¶¶ 73–85, 93–98.

With regard to the suitability-for-human-consumption element of claims 1 and 24, Beaudoin discloses that extract fractions were consumed with no side effect. Ex. 1002, 12:13–14.

With regard to the recitation of a krill solution in claim 24, Beaudoin krill oil extracts are solutions encompassed by claim 24, as the phospholipids and other components are dissolved in the extracts. Ex. 1042 ¶ 202.

Patent Owner argues that Beaudoin fails to disclose expressly all elements of any patented claims. This argument is premised on the understanding that Beaudoin requires a heating step to obtain krill extracts. Resp. I, 17–24. In this regard, Patent Owner contends that "the testimony of Dr. Jaczynski, Dr. Budge, and Dr. Brenna makes clear that the heating step is a required, or at least 'optional', part of Beaudoin's process." *Id.* at 22. Patent Owner further contends that:

> Dr. Budge clarified that while Table 19 does not recite the heating step, Beaudoin's heating procedure is a "postextraction step," not a part of the extraction procedure itself. Dr. Jaczynski concurred with Dr. Budge's analysis, testifying that one of skill would view the heating step as a post-extraction step required to refine the oil, and therefore not expect to find it in the "optimal" extraction steps summarized in Table 19.

Resp. I, 18 (citing Ex. 2039, 154:20–155:11, 90:20–91:3; Ex. 2059 ¶¶ 55–56). Patent Owner contends also that "the heating step is not an alternate embodiment that differs from the 'optimal' extraction method of Table 19; it is a required post-extraction step of Beaudoin's method." *Id.* (citing Ex. 2059 ¶ 62; Ex. 2038, 200:2–9; Ex. 2028, 1).

Patent Owner contends that this heating step distinguishes Beaudoin from the '351 patent because the "heating step would result in both heat-induced and acid-induced hydrolysis due to the high level of water and free fatty acids in Beaudoin's extracts, as disclosed in Tables 13 and 14." *Id.* at 22–23 (citing Ex. 2059 ¶ 61). Patent Owner further contends that the heating step would oxidize and degrade EPA and DHA present in the extract into a variety of undesirable intermediate by-products. *Id.* at 23 (citing Ex. 2059 ¶ 61).

Patent Owner contends that because Dr. Budge and Dr. Haugsgjerd do not perform the heating step properly according to the extraction process disclosed in Beaudoin, their attempts to recreate samples of the krill extract obtained by Beaudoin fail. Resp. I, 26–29.

Patent Owner further contends that the claimed phospholipid was not detected in all heated and unheated recreation samples. *Id.*

We first address the question of whether the extraction process disclosed in Beaudoin requires a heating step. We find it does not. The only mention of a heating step in Beaudoin is made in conjunction with compositional analysis of the extracts. Ex. 1002, 10:6–20. That method differed from methods used to prepare the krill extracts in the first instance, before any preparation of the sample for analysis (to be analyzed). For example, Beaudoin expressly discloses that the krill extracts were purified by standard techniques, such as filtration and evaporation. Ex 1002, 6:4–13, Furthermore, Table 19 of Beaudoin, entitled "Optimal Conditions for Lipid Extraction of Aquatic Animal Tissue," summarizes the steps involved in a lipid extraction process, and does not provide for a heating step. *Id.* at 28. Rather, Table 19 suggests the use of an organic solvent resistant filter for the

filtration step of the process. *Id.* Accordingly, we are not persuaded by Patent Owner's arguments or the testimony of Dr. Jaczynski that Beaudoin requires a heating step.

As we are not persuaded that the Beaudoin extraction process requires a heating step, we conclude that the adequacy of the heating steps in the preparation of test samples is not relevant to the analysis of whether or not the Beaudoin extracts prepared by either the disclosed general extraction method or the optimal extraction method inherently comprise the claimed phospholipids. The preponderance of evidence on the record suggests that the *E. pacifica* krill extracts disclosed in Beaudoin necessarily contained the claimed phospholipids. Ex. 1040 ¶¶ 73–85, 93–98

Moreover, even if we were to agree that Beaudoin requires a post-extraction heating step to "refine the oil," such a conclusion would not render the claims patentable over Beaudoin. Resp. I, 18. An intermediate product can anticipate a claimed product even if the intermediate product is merely a stage in the final production. *In re Mullin*, 481 F.2d 1333, 1335–36 (CCPA 1973) (*citing In re Herbert*, 461 F.2d 1390, 1394 (CCPA 1972)). In that regard, Patent Owner does not contend that the unheated extraction product produced by the Beaudoin extraction process is distinguishable from a product encompassed by the claims. Resp. I, 17–31.

Finally, Patent Owner contends that Beaudoin does not disclose an extract "suitable for human consumption" as required by claims 1 and 24. *Id.* at 31–36. We are not persuaded. Beaudoin expressly discloses that the krill extracts were purified by standard techniques, such as filtration and evaporation (Ex 1002, 6:4-13, 28 (Table 19), and consumed by a human (*id.* at 12:13-14). We are not persuaded that the evidence relied on by Patent

Owner supports a finding that the amounts of solvent remaining after removal efforts renders the extracts unsuitable for human consumption in any form. As discussed above, we decline to interpret the phrase "suitable for human consumption" to require oral ingestion.

In view of the above, we conclude that Petitioner has established by a preponderance of the evidence that Beaudoin anticipates claims 1 and 24 of the '351 patent.

a. Claims 2, 3, 25, and 26

Dependent claims 2 and 25 require the claimed extract or solution to comprise a total phospholipid concentration in an amount of about 40% w/w, wherein "about represents ±10%." We interpret claims 2 and 25 to recite a total phospholipid concentration range of 36% to 44% w/w.

Dependent claims 3 and 26 require the claimed extract or solution to have a total phospholipid concentration in an amount of about 45% w/w, wherein about represents ±20%. We interpret claims 3 and 26 to recite a total phospholipid concentration range of 36% to 54% w/w.

Petitioner contends that Beaudoin discloses 54.1±6.1% phospholipids and polar material w/w in Fraction I extracts, which falls within or touches the claimed ranges. Pet. II, 18–19 (citing Ex. 1002, 23 (Table 14)). Beaudoin's description of concentration percentages of "[p]hospholipids or other polar material" in Table 14, however, does not disclose explicitly a total phospholipid concentration, as recited in the challenged claims. Rather, Table 14 in Beaudoin describes percentages, in krill oil Fractions I and II, of material having phospholipids (at some undisclosed concentration) plus "other polar material" (at some undisclosed concentration). Thus, Petitioner does not explain sufficiently in its Petition how one can ascertain the total

phospholipid concentration of Fraction I by looking at Table 14 or elsewhere in Beaudoin.

Petitioner further directs our attention to the testimony of Patent Owner's declarant, Dr. Yeboah. *Id.* at 19. Petitioner contends that Dr. Yeboah has explained that the Beaudoin extracts tested by Dr. White contain about 40% phospholipids. *Id.* (citing Ex. 1054 ¶ 36). Dr. Yeboah, however, makes no such statement in the cited paragraph. Rather, in the passage relied on by Petitioner, Dr. Yeboah refers to general teachings in the scientific literature that discuss the phospholipid content of oil extracted from *E. superba*, which is not the same species of krill examined in Beaudoin. Ex. 1054, n. 7. Accordingly, we do not consider the statement of Dr. Yeboah to be material to the phospholipid concentration of the krill oil compositions disclosed by Beaudoin.

Petitioner also relies on declarations from Drs. Budge, Moore, and Brenna to demonstrate that the *E. pacifica* krill extracts disclosed in Beaudoin necessarily contained the phospholipids concentrations recited in claims 2, 3, 25 and 26. Pet. II, 18–19 (citing Budge (Ex. 1041) ¶ 10; Moore (Ex 1044) at Exhibit A, Table 11; Brenna (Ex. 1042) ¶¶ 180–81). Dr. Budge testifies that he prepared acetone extracts of *E. pacifica* krill following the method of Beaudoin in all relevant steps, and sent the samples to Dr. Moore. Ex. 1041, 4–7 (citing Ex. 1002, 5–6, Table 19). Dr. Moore conducted compositional analysis on the samples. Ex. 1044. The results obtained by Dr. Moore indicated that the unheated *E. pacifica* krill extracts prepared by Dr. Budge (SB1-8/19/2013-BEA-P0, SB5-8/19/2013-BEA-P1, and SB9-8/19/2013-BEA-P2) contained phospholipids concentrations of 31.02 ± 0.07

%, 31.51 ± 0.12 %, and 44.40 ± 0.48 %. Thus, only one of the three samples fell within the ranges recited in claims 2, 3, 25 and 26.

Claims are not inherently anticipated where the prior art process occasionally yields the claimed element. *In re Crish*, 393 F.3d 1253, 1259 (Fed. Cir. 2004) (*citing Glaxo Inc. v. Novopharm Ltd*., 52 F.3d 1043, 1047 (Fed. Cir. 1995)). Thus, the evidence before us does not persuaded us that the Beaudoin samples inherently, i.e., necessarily, contained the phospholipid w/w percentages recited in claims 2, 3, 25, and 26.

In view of the above, we conclude that Petitioner has failed to establish that Beaudoin anticipates claims 2, 3, 25 and 26 of the ’351 patent.

b. Claims 4 and 27

Dependent claims 4 and 27 require the claimed extract or solution to have an additional lipid, such as a free fatty acid. In its Response, Patent Owner does not address specifically the merits of Petitioner’s proposed ground with regard to claims 4 and 27.

As Petitioner notes, the Beaudoin extracts contain free fatty acids at a concentration of 23.7 ±1.1% and 20.3±0.3%. Pet. I, 20; Ex. 1002, 23 (Table 14). Accordingly, we find that the preponderance of evidence shows that Beaudoin discloses the elements of claims 4 and 27.

In view of the above, we conclude that Petitioner has established by a preponderance of the evidence that Beaudoin anticipates claims 4 and 27 of the ’351 patent.

a. Claims 5 and 28

Dependent claims 5 and 28 require a concentration of free fatty acids of about 5% w/w of the lipids in the recited krill extract. As Petitioner notes, the Beaudoin extracts contain free fatty acids at a concentration of 23.7

±1.1% and 20.3 ±0.3%. Pet. I, 20; Ex. 1002, 23 (Table 14). Petitioner contends that 23.7 ±1.1% is within the range of "about 5%," as defined in the '351 patent. Pet. I, 20.

Patent Owner contends that a person of skill in the art would interpret "about 5%" as used in claims 5 and 28 to refer to 2.5–7.5% w/w, and thus, Beaudoin discloses extracts having free fatty acids concentrations outside of the claimed range. Resp. I, 36–37.

Petitioner responds that Patent Owner's expert, Dr. Jaczynski, testified that a phospholipid concentration of 40% or 45% would correspond to free fatty acid levels of 2.5–7.5% w/w. Reply 11–12; Ex. 1097, 322:8–16, 285:20–286:7. We have reviewed the cited portions of Dr. Jaczynski's testimony, and are not persuaded that Dr. Jaczynski stated that a phospholipid concentration of 40% or 45% would correspond to free fatty acid levels of 2.5–7.5% w/w. Dr. Jaczynski may have agreed to a general relationship between phospholipid concentration and free fatty acid levels, but the evidence fails to inform us of the specific relationship, which is necessary to support a conclusion that a phospholipid concentration of 40% or 45% corresponds to free fatty acid levels of 2.5–7.5% w/w.

As noted above, we interpret "about 5%" as used in claims 5 and 28 to indicate a range of 2.5–7.5% w/w. Beaudoin discloses extracts having free fatty acids concentrations of 23.7 ±1.1% and 20.3 ±0.3%, which are outside of the claimed range. Accordingly, we conclude that Petitioner has failed to establish that Beaudoin anticipates the subject matter of claims 5 and 28.

b. Claims 6, 9, 29, and 32

Dependent claims 6 and 29 require the claimed extract or solution to have polyunsaturated fatty acids (PUFAs) at a concentration of at least 15%

w/w. Dependent claims 9 and 32 require the PUFAs to be omega-3 fatty acids.

In its Response, Patent Owner does not address specifically the merits of Petitioner's proposed ground with regard to claims 6, 9, 29, and 32.

As Petitioner notes, Beaudoin discloses that its extracts contain 54.4% PUFAs, a portion of which are omega-3 fatty acids. Pet I, 21; Ex. 1002, 23–24 (Table 15). Accordingly, Beaudoin discloses the elements of claim 6, 9, 29, and 32.

In view of the above, we conclude that Petitioner has established sufficiently that Beaudoin anticipates claims 6, 9, 29, and 32 of the '351 patent.

c. Claims 12, 13, 35, and 36

Dependent claims 12 and 35 require the claimed extract or solution to comprise a metal. Dependent claims 13 and 36 require the metal to be zinc, selenium, or a mixture thereof. Petitioner relies on testimony from Drs. Brenna, Budge, and Lee to demonstrate that *E. pacifica* extracts inherently contain metal such as zinc. Pet. I, 21 (citing Ex. 1042 ¶¶ 191–192; Ex. 1045, Exhibit A (Table 7)). Dr. Lee confirmed the presence of zinc in the unheated sample of an *E. pacifica* acetone extract prepared by Dr. Budge. Ex. 1045, Exhibit A (Sample "S6," corresponding to sample "SB2 8/19/2013 BEA-P0" prepared by Dr. Budge (Ex. 1041)).

In its Response, Patent Owner does not address specifically the merits of Petitioner's proposed ground with regard to claims 12, 13, 35, and 36.

In view of the above, we find that the preponderance of evidence of record shows that Beaudoin discloses the elements of claims 12, 13, 35, and

36. Accordingly, we conclude that Petitioner has established sufficiently that Beaudoin anticipates claims 12, 13, 35, and 36 of the '351 patent.

d. Claims 19, 20, 21, 42, 43, and 44

Dependent claims 19, 20, 21, 42, 43, and 44 require the claimed extract to have PC-EPA/DHA (claims 19 and 42), PC-EPA/EPA (claims 20 and 43), and PC-DHA/DHA (claims 21 and 44). Petitioner relies on testimony from Drs. Brenna, Haugsgjerd, and Van Breemen to demonstrate that *E. pacifica* extracts inherently contain the recited EPA and DHA species. Pet. I, 22. Dr. Haugsgjerd prepared acetone extractions of *E. pacifica* and sent the samples to Dr. Van Breemen, of the University of Illinois, for analysis. Ex. 1048 ¶¶ 2–3. Petitioner contends that Dr. Van Breemen detected the presence of all of the species (PC-EPA/EPA, PC-DHA/DHA, and PC-EPA-DHA) in the tested *E. pacifica* extracts. Pet. I, 22; Ex. 1040 ¶¶ 57, 73, 93.

In its Response, Patent Owner does not address specifically the merits of Petitioner's proposed ground with regard to claims 19, 20, 21, 42, 43, and 44.

In view of the above, we find that the preponderance of evidence on record shows that Beaudoin discloses the elements of claims 19, 20, 21, 42, 43, and 44. Accordingly, we conclude that Petitioner has established sufficiently that Beaudoin anticipates claims 19, 20, 21, 42, 43, and 44 of the '351 patent.

e. Claims 22, 23, 45, and 46

Dependent claims 22, 23, 45, and 46 require the claimed extract to have an antioxidant such as astaxanthin. In its Response, Patent Owner does

not address specifically the merits of Petitioner's proposed ground with regard to claims 22, 23, 45, and 46.

As Petitioner notes, Beaudoin expressly discloses that the extracts described in that reference contain astaxanthin. Pet. I, 22; Ex. 1002, 27 (Table 18). Accordingly, the preponderance of evidence on record shows that Beaudoin discloses the elements of claims 22, 23, 45, and 46.

In view of the above, we conclude that Petitioner has established sufficiently that Beaudoin anticipates claims 22, 23, 45, and 46 of the '351 patent.

2. Obviousness of Claims 1–6, 9, 12, 13, 19–29, 32, 35, 36, and 42–46 Over the Combination of Fricke (Ex. 1006), Bergelson (Ex. 1017), Yasawa (Ex.1015), Itano (Ex. 1009), and the WHO Bulletin (Ex. 1018)

a. Claims 1, 19, 20, 21, 24, 42, 43, and 44

Claims 1 and 24 are directed to a krill extract and solution, respectively, containing a phospholipid of the general formula (I) that is suitable for human consumption. Dependent claims 19–21 and 42–44 require the claimed extract to have PC-EPA/DHA (claims 19 and 42), PC-EPA/EPA (claims 20 and 43) and PC-DHA/DHA (claims 21 and 44). None of claims 1, 19, 20, 21, 24, 42, 43, and 44 require a minimal concentration of the recited phospholipid to be present in the krill extract or solution.

Fricke prepared lipid extracts from *E. superba*, an Antarctic krill, according to the Folch method. Ex. 1006, 821–822, Table 1. The Folch method uses chloroform and methanol as solvents. Ex. 1006, 821.

The Van Breemen Declaration summarizes the results of a compositional analysis of *E. superba* krill extracts. The data shows that PC-EPA/EPA, PC-DHA/DHA, and PC-EPA/DHA are found in certain *E.*

superba krill extracts (i.e., acetone extracts, ethanol extracts, and ethyl acetate extracts) and thus establishes *E. superba* krill as a source of PC-EPA/EPA, PC-DHA/DHA, and PC-EPA/DHA. Ex. 1040 ¶¶ 73–85, 93–98. Dr. Van Breemen did not test a sample prepared using the Folch method, which is an extraction method using chloroform and methanol used in Fricke. Nonetheless, the evidence of record establishes that the Folch method is "considered the classic and most reliable means for quantitatively extracting lipids" (Ex. 1105, 1283) and thus capable of extracting phospholipids from *E. superba* krill, which, in view of the Van Breemen Declaration, inherently contain PC-EPA/EPA, PC-DHA/DHA, and PC-EPA/DHA. Accordingly, on this record, we find that the preponderance of evidence establishes that the *E. superba* krill extracts disclosed in Fricke inherently contained EPA/EPA, PC-DHA/DHA, and PC-EPA/DHA.

With regard to suitability for human consumption, Itano and WHO Bulletin recognize krill as valuable for human consumption and thus provide a reason to modify the extracts disclosed in Fricke for human consumption. In that regard, Bergelson teaches removal of chloroform/methanol solvents from lipids by rotary evaporation. Ex. 1017, 10–11.

Patent Owner contends that the combination of Fricke, Bergelson, Yasawa, Itano, and the WHO Bulletin fail to suggest a krill extract that is suitable for human consumption. Resp I, 42–46. Patent Owner contends that Fricke and Bergelson disclose krill extracts obtained with toxic solvents, chloroform and methanol, and that such techniques are intended to produce an extract only for laboratory analysis, not human consumption. *Id.* at 38–42. Patent Owner further contends that Bergelson's extraction process uses benzene, an additional toxic substance. *Id.* at 43 (citing Ex. 1017, 23).

Patent Owner contends that the toxicity of the Folch method solvents where known as: 1) Beaudoin teaches that the Folch method "is not commercially feasible because of the toxicity of the solvents" (*id.*, citing Ex. 1002, 5; Ex. 2059 ¶ 83); 2) Maruyama teaches that use of chloroform is unacceptable because it "entails the fear that harmful substances might remain, no matter how the [extracts] are refined and fractionated, making it difficult to use this in food products" (*id.* at 44, citing Ex. 1004, 2; Ex. 2059 ¶ 83); and 3) Fujita teaches that extracts intended for use in human food products should be obtained with non-toxic organic solvents (*id.* at 44, citing Ex. 1005, 14; Ex. 2059 ¶ 83).

We are not persuaded that the evidence relied on by Patent Owner supports a finding that the use of methanol and chloroform renders the extracts of Fricke unsuitable for human consumption in the amounts that remain after removal efforts. Rather, the evidence relied on by Patent Owner suggests that these solvents, in the amounts that remain after removal efforts, are undesirable, because of toxicity in larger amounts, and therefore commercially infeasible. *See, e.g.*, Ex. 1004, 2 ("The method using chloroform ethanol . . . entails the fear that harmful substances might remain, no matter how the [extracts] are refined and fractionated, making it difficult to use this in food products, which is a problem"). Specifically, as noted by Petitioner, FDA guidelines contemplate ingestion of chloroform or methanol. Reply 13 (citing Ex. 1095, 6). Moreover, as further noted by Petitioner, an ordinary artisan would have known that such solvents could have been removed by evaporation. *Id.* (citing Ex. 2059 ¶ 89; Ex. 1097, 304:6–22).

In view of the above, we conclude that Petitioner has demonstrated by a preponderance of the evidence that claims 1, 19, 20, 21, 24, 42, 43, and 44 would have been obvious over the combination of Fricke, Bergelson, Yasawa, Itano, and the WHO Bulletin.

b. Claims 2, 3, 25, and 26

As discussed above, we interpret claims 2 and 25 to recite a total phospholipid concentration in the range of 36% to 44% w/w, and interpret claims 3 and 26 to recite a total phospholipid concentration in the range of 36% to 54% w/w.

Petitioner contends that Fricke discloses krill extracts containing 39.6% to 42.5% phospholipids, which falls within the range recited in claims 2, 3, 25, and 26. Pet. I, 40 (citing Ex. 1006, 822 (Table 1)).

Patent Owner contends that the data in Table 1 of Fricke is expressed in weight percentage of total lipids, not as a weight percentage of the components of the extract as a whole, and, as such, Fricke Table 1 does not disclose the recited weight percent of the phospholipid component. Resp. I, 47–50 (citing Ex. 2037, 178:18–18, 187:4–9, 188:5–19; Ex. 2059 ¶¶ 110, 112–115). Patent Owner further contends that an analogous extraction method, referred to as the Bligh & Dyer method, produces total lipid content of concentrations as low as 92.3 and 90% of the total weight of the extract, thus the data presented in Fricke Table 1 would not have informed a person of ordinary skill in the art as to the total phospholipid concentrations as a weight percent of the extract as a whole. *Id.* at 49, Ex. 2059, Jaczynski Decl. ¶ 112; Ex. 2020

Petitioner contends that the Folch extraction method used by Fricke would produce an extract containing only lipids. Reply, 14 (citing Ex. 1078,

502 ("One washing was sufficient for removing all the non-lipide contaminants from the crude extract.")). Petitioner further contends that the Bligh & Dyer extraction method is not the equivalent of the Folch extraction method and has been found to be less efficient than Folch. *Id.* (citing Ex. 1105); *see also,* Ex. 1105, 1286 ("[F]or samples containing >2% lipid (n = 34), the Bligh and Dyer estimates of lipid content were significantly lower than those of Folch ($P < 0.0001$).").

Petitioner further contends that, even assuming Patent Owner is correct in their contention that that there are about 8–10% non-lipid materials in the Fricke extracts, both extracts in Fricke's Table 1 would still fall within the claimed ranges. Specifically, Petitioner contends that "[e]ven assuming only 90% are lipids, the phospholipid concentrations would be 41.13% and 39.6% for the 1977 and 1981 samples, respectively." Reply, 14 n. 4 (citing Ex. 1006 at Table 1).

In view of the arguments and evidence summarized above, we find that the data summarized in Fricke's Table 1 would have represented at least 90% of the components of the disclosed extracts. As such, the data shows that the Fricke extracts contained the claimed amounts of total phospholipids. Accordingly, we conclude that Petitioner has demonstrated by a preponderance of the evidence that claims 2, 3, 25, and 26 would have been obvious over the combination of Fricke, Bergelson, Yasawa, Itano, and the WHO Bulletin.

c. Claims 4 and 27

Dependent claims 4 and 27 require the claimed extract or solution to have an additional lipid, such as a free fatty acid.

In its Response, Patent Owner does not specifically address the merits of Petitioner's proposed ground with regard to claims 4 and 27.

As Petitioner notes, Fricke discloses krill extracts containing from 8.5% to 16.1% free fatty acids. Pet. I, 42, 57; Ex. 1006, 822 (Table 1). Accordingly, we conclude that Petitioner has demonstrated that claims 4 and 27 are unpatentable as obvious over the combination of Fricke, Bergelson, Yasawa, Itano, and the WHO Bulletin.

a. Claims 5 and 28

Dependent claims 5 and 28 require a concentration of free fatty acids of about 5% w/w of the lipids in the recited krill extract.

Petitioner contends that Fricke discloses krill extracts containing from 8.5% to 16.1% free fatty acids, which is encompassed by about 5%, as defined in the '351 patent. Pet. I, 42 (citing Ex. 1006, 822 (Table 1)).

As noted above, we interpret "about 5%" as used in claims 5 and 28 to indicate a range of 2.5–7.5% w/w. Thus, we find the Fricke extracts having free fatty acids concentrations of 8.5% to 16.1% to be outside of the claimed range.

Accordingly, we conclude that Petitioner has failed to establish that claims 5 and 28 are unpatentable as obvious over the combination of Fricke, Bergelson, Yasawa, Itano, and the WHO Bulletin.

b. Claims 6, 9, 29, and 32

Dependent claims 6 and 29 require the claimed extract or solution to comprise polyunsaturated fatty acids (PUFAs) at a concentration of at least 15% w/w. Dependent claims 9 and 32 require the PUFAs to be omega-3 fatty acids.

Petitioner contends that Fricke discloses krill extracts containing 21.42% omega-3 fatty acids. Pet I, 43 (citing Ex. 1006, 823 (sum of n-3s in Table 2)).

In its Response, Patent Owner does not address specifically the merits of Petitioner's proposed ground with regard to claims 6 and 29.

With regard to claim 9 and 32, Patent Owner contends that Fricke Table 2 shows particular fatty acids as a percentage of the weight of total fatty acids, not as a percentage of the weight of the total lipids of the extract. Resp. I, 50–51 (citing Ex. 2037, 196:8–15; Ex. 2059 ¶ 117).

Petitioner contends that, even assuming Table 2 of Fricke shows fatty acids as a weight percentage of total fatty acids, not as weight percentage of total lipids in the extract, Fricke still discloses extracts containing at least 15% omega-3 fatty acids, which can be derived from calculations using the data presented in Fricke Tables 1 and 2. Reply 14–15 (citing Ex. 2037, 196:16–198:14, 267:22–269:21). However, the record does not show that these calculations were completed, and Petitioner does not direct us to sufficient evidence establishing that the Fricke extracts contained the recited amounts of omega-3 fatty acids. Accordingly, we find that Petitioner has failed to adequately explain how it can be determined that the Fricke extracts contained at least 15% w/w omega-3 fatty acids.

In view of the above, we conclude that Petitioner has demonstrated that claims 6 and 29 are unpatentable as obvious over the combination of Fricke, Bergelson, Yasawa, Itano, and the WHO Bulletin. We conclude that Petitioner has failed to show that claims 9 and 32 are unpatentable as obvious over the combination of Fricke, Bergelson, Yasawa, Itano, and the WHO Bulletin

c. Claims 12, 13, 35, and 36

Dependent claims 12 and 35 require the claimed extract or solution to have a metal. Dependent claims 13 and 36 require the metal to be zinc, selenium, or a mixture thereof.

Petitioner contends that krill extracts disclosed in the prior art inherently would contain zinc ("Zn") and selenium ("Se"). Pet. I, 58 (citing Ex. 1018, 551). This conclusion is supported by the declaration of Dr. Lee, which presents evidence that zinc and selenium may be extracted successfully from *E. superba*. Ex. 1045, Exhibit A (Samples "S9," "S10," "S18," "S19," "S20," and corresponding samples prepared by Dr. Budge (Ex. 1041)).

Patent Owner contends that the WHO Bulletin discloses that krill meat is known to contain Zn and Se, but does not suggest that a krill extract would contain Zn and/or Se. Resp. I, 52–53. Patent Owner further contends that "[e]ven if the Board agreed that Petitioner's recreation testing data show that Zn and Se are inherently present in krill extracts, this does not prove obviousness unless one of ordinary skill would have recognized it at the time of the patented inventions. *Id.* (citing *In re Rijckaert*, 9 F.3d 1531 (Fed. Cir. 1993); M.P.E.P. § 2141.02).

We are not persuaded. The preponderance of evidence shows that zinc and selenium are present inherently in krill (Ex. 1018, 551) and in krill extracts (Ex. 1045, Exhibit A). The identification of an inherent property does not render a product nonobvious. *PAR Pharm., Inc. v. TWI Pharm., Inc.*, 773 F.3d 1186, 1195 (Fed. Cir. 2014) (stating that, in an obviousness context, inherency is present "when the limitation at issue is the "natural result" of the combination of prior art elements"); *see also In re Kao*, 639

F.3d 1057, 1070 (Fed. Cir. 2011) ("[The prior art's] express teachings render the claimed . . . formulation obvious, and the claimed [blood concentration] adds nothing of patentable consequence.").

In view of the above, we conclude that Petitioner has demonstrated by a preponderance of the evidence that claims 12, 13, 35 and 36 would have been obvious over the combination of Fricke, Bergelson, Yasawa, Itano, and the WHO Bulletin.

d. Claims 22, 23, 45, and 46

Dependent claims 22, 23, 45, and 46 require the claimed extract or solution to have an antioxidant such as astaxanthin.

Petitioner points us to where Fricke discloses krill extracts containing carotenoids, which are antioxidants. Pet. I, 43 (citing Ex. 1006, 821 (Table 1, note b)).

In its Response, Patent Owner does not specifically address the merits of Petitioner's proposed ground with regard to claims 22, 23, 45, and 46.

In view of the above, we conclude that Petitioner has demonstrated by a preponderance of the evidence that claims 22, 23, 45, and 46 would have been obvious over the combination of Fricke, Bergelson, Yasawa, Itano, and the WHO Bulletin.

3. Conclusion

In view of the above, we conclude that Petitioner has established by a preponderance of the evidence that claims 1, 4, 6, 9, 12, 13, 19–24, 27, 29, 32, 35, 36, and 42–46 of the '351 patent are unpatentable as anticipated by Beaudoin.

We conclude that Petitioner has established by a preponderance of the

evidence that claims 1–4, 6, 12, 13, 19–27, 29, 35, 36, and 42–46 are unpatentable as obvious over the combination of Fricke, Bergelson, Yasawa, Itano, and the WHO Bulletin.

We conclude that Petitioner has failed to establish by a preponderance of the evidence that claims 2, 3, 5, 25, 26, and 28 of the '351 patent are unpatentable as anticipated by Beaudoin.

We conclude that Petitioner has failed to establish by a preponderance of the evidence that claims 5, 9, 28, and 32 are unpatentable as obvious over the combination of Fricke, Bergelson, Yasawa, Itano, and the WHO Bulletin.

III. PATENT OWNER'S MOTION TO SEAL

Patent Owner filed a Motion to Seal certain information contained in Ex. 2059, which Petitioner Aker has designated as confidential. Paper 67. The portions of Ex. 2059 that Patent Owner seeks to file under seal appear, on their face, to contain confidential research, development, or commercial information. Accordingly, Patent Owner's motion is granted.

IV. PATENT OWNER'S MOTION TO EXCLUDE

Patent Owner seeks to exclude Ex. 1107 as irrelevant. Paper 89. Because we do not rely on Ex. 1107 to reach this Final Decision, we dismiss Patent Owner's Motion to Exclude as moot.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–4, 6, 9, 12, 13, 19–27, 29, 32, 35, 36, and 42–46 of the '351 patent have been shown to be unpatentable;

FURTHER ORDERED that claims 5 and 28 of the ’351 patent have not been shown to be unpatentable;

FURTHER ORDERED that Patent Owner’s Motion to Seal is granted;

FURTHER ORDERED that Patent Owner’s Motion to Exclude is dismissed as moot; and

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

For PETITIONER:

Amanda Hollis
KIRKLAND & ELLIS
amanda.hollis@kirkland.com

For PATENT OWNER:

J. Dean Farmer
COOLEY LLP
dfarmer@cooley.com