

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RIMFROST AS,
Petitioner,

v.

AKER BIOMARINE ANTARCTIC AS,
Patent Owner.

Case IPR2017-00748
Patent 9,028,877 B2

Before ERICA A. FRANKLIN, TINA E. HULSE, and
JACQUELINE T. HARLOW, *Administrative Patent Judges*.

HARLOW, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
Determining That Claims 1–19 Have Not Been Shown to Be Unpatentable
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

Rimfrost AS (“Petitioner”) filed a Petition requesting an *inter partes* review of claims 1–19 of U.S. Patent No. 9,028,877 B2 (Ex. 1001, “the ’877 patent”). Paper 2 (“Pet.”). Aker Biomarine Antarctic AS (“Patent Owner”) declined to file a Preliminary Response.

On August 16, 2017, we instituted an *inter partes* review of all challenged claims on all grounds asserted. Paper 8. On November 8, 2017, Patent Owner filed a Patent Owner Response to the Petition. Paper 13 (“PO Resp.”). On January 24, 2018, Petitioner filed a Reply to the Patent Owner Response. Paper 16 (“Reply”).

We issue this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. Having considered the record before us, we determine that Petitioner has not shown by a preponderance of the evidence that claims 1–19 of the ’877 patent are unpatentable. See 35 U.S.C. § 316(e).

A. Related Matters

The ’877 patent is asserted in *Aker Biomarine Antarctic AS v. Olympic Holding AS*, Case No. 1:16-CV-00035-LPS-CJB (D. Del.). Pet. 2; Paper 7, 2–3. In addition, Petitioner has challenged, and we have instituted *inter partes* review of the claims of the ’877 patent in IPR2017-00746. Paper 5, 2.

Petitioner also challenges U.S. Patent No. 9,078,905 B2 (“the ’905 patent”) in IPR2017-00745 and IPR2017-00747. Pet. 3. Both the ’877 patent and the ’905 patent are continuations of U.S. Patent Application

No. 12/057,775, filed March 28, 2008.

The parties have not identified any further, currently pending, related proceedings concerning the '877 patent.¹

B. The '877 Patent

The '877 patent, titled “Bioeffective Krill Oil Compositions,” issued May 12, 2015, with Inge Bruheim, Snorre Tilseth, and Daniele Mancinelli as the listed co-inventors. Ex. 1001, [54], [45], [72].

The '877 patent describes extracts from Antarctic krill, small shrimp-like animals, that include bioactive fatty acids. Ex. 1001, 1:19–20. In particular, the '877 patent discloses krill oil compositions having “high levels of astaxanthin, phospholipids, includ[ing] enriched quantities of ether phospholipids, and omega-3 fatty acids.” *Id.* at 9:28–31.

The '877 patent states that myriad health benefits have been attributed to krill oil in the prior art. For example, the '877 patent states 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 '877 patent recognizes that krill oil

¹ The '877 patent was also asserted in *In the Matter of Certain Krill Oil Products and Krill Meal for Production of Krill Oil Products*, Investigation No. 337-TA-1019 (USITC) (Pet. 2–3; Paper 3, 1); however, Petitioner states that the investigation has been “effectively terminated.” Paper 21, 3.

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 '877 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 '877 patent, however, 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 '877 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 '877 patent explains that the krill may be first subject to a protein denaturation step, such as a heating step, to avoid the formation of enzymatically decomposed oil constituents. *Id.* at 9:43–50; 10:26–31. Subsequently, the “oil can be extracted by an optional selection of nonpolar and polar solvents including use of supercritical carbon dioxide.” *Id.* at 9:51–54.

In Example 7 of the '877 patent, “[k]rill lipids were extracted from krill meal (a food grade powder) using supercritical fluid extraction with co-solvent.” *Id.* at 31:15–16.

Initially, 300 bar pressure, 333°K and 5% ethanol (ethanol:CO₂, 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 31:17–23.

Example 8 of the '877 patent prepared krill oil using the same method described in Example 7, from the same krill meal used in that example.

Ex. 1001, 31:46–47. The krill oil was then analyzed using ³¹P NMR analysis to identify and quantify the phospholipids in the oil. *Id.* at 31:47–49. Table 22² shows the phospholipid profiles for the raw material, the final product, and a commercially available krill oil, Neptune Krill Oil (“NKO”). *Id.* at 32:6–9. Table 22 is reproduced below:

² We view reference in the '877 patent to “table 25” (Ex. 1001, 32:6–9) to be an inadvertent typographical error, as the specification does not include a table 25. We understand Example 8 of the specification to refer, instead, to Table 22, which sets forth the described phospholipid profiles.

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 '877 patent teaches that the “main polar ether lipids of the krill meal are alkylacylphosphatidylcholine (AAPC) at 7–9% of total polar lipids, lyso-alkylacylphosphatidylcholine (LAAPC) at 1% of total polar lipids (TPL) and alkylacylphosphatidyl-ethanolamine (AAPE) at <1% of TPL.”

Id. at 32:9–14.

C. Illustrative Claim

Of the challenged claims, claims 1 and 11 are independent. Claim 1, reproduced below, is illustrative of the claimed subject matter.

1. A method of production of krill oil comprising:
 - a) providing krill;
 - b) treating said krill to denature lipases and phospholipases in said krill to provide a denatured krill product; and
 - c) extracting oil from said denatured krill product with a polar solvent to provide a krill oil with from about 3% to about 10% w/w ether phospholipids; from about 27% to 50% w/w non-ether phospholipids so that the amount of total phospholipids in said krill oil is about 30% to 60% w/w; and from about 20% to 50% w/w triglycerides, wherein said steps a and b are performed on a ship.

Ex. 1001, 34–59–35:2. Claim 11 requires that the krill oil produced by the method recited includes amounts of phospholipid components and triglycerides within the same ranges as claim 1. *Id.* at 35:23–36:7.

D. Prior Art Relied Upon

Petitioner relies upon the following as prior art references (Pet. 8):

Randolph	US 2005/0058728 A1	Mar. 17, 2005	(Ex. 1011)
Sampalis	WO 03/011873 A2	Feb. 13, 1003	(“Sampalis II”) (Ex. 1013)

Bottino, *The Fatty Acids of Antarctic Phytoplankton and Euphausiids. Fatty Acid Exchange Among Trophic Levels of the Ross Sea*, 27 MARINE BIOLOGY, 197–204 (1974) (Ex. 1007).

Fricke et al., *Lipid, Sterol and Fatty Acid Composition of Antarctic Krill (Euphausia superba Dana)*, 19(11) LIPIDS 821–827 (1984) (Fricke 1984) (Ex. 1010).

Grantham, *The Utilization of Krill*, UNDP/FAO Southern Ocean Fisheries Survey Programme (1977) (Ex. 1032).

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).

Tanaka et al., *Platelet-Activating Factor (PAF)-Like Phospholipids Formed During Peroxidation of Phosphatidylcholines from Different Foodstuffs*, 59(8) BIOSCI. BIOTECH. BIOCHEM. 1389–1393 (1995) (“Tanaka I”) (Ex. 1014).

Tanaka et al., *Extraction of Phospholipids from Salmon Roe with Supercritical Carbon Dioxide and an Entrainer*, 53(9) J. Oleo Science 417–424 (2004) (“Tanaka II”) (Ex. 1015).

Petitioner also relies on the Declaration of Stephen J. Tallon, Ph.D. (Ex. 1006), and the Reply Declaration of Dr. Tallon (Ex. 1086).

Patent Owner relies on the Declaration of Nils Hoem, Ph.D. (Ex. 2001).

E. Instituted Challenges

We instituted trial based on each challenge to the patentability of the '877 patent presented in the Petition (Pet. 7):

Claim(s)	Basis	References
1–3, 8, 9, 11, 12, 17, and 18	§ 103(a)	Grantham, Fricke 1984, and Tanaka I
4, 5, 13, and 14	§ 103(a)	Grantham, Fricke 1984, Tanaka I, and Bottino
6 and 15	§ 103(a)	Grantham, Fricke 1984, Tanaka I, and Tanaka II
7 and 16	§ 103(a)	Grantham, Fricke 1984, Tanaka I, and Sampalis I
10 and 19	§ 103(a)	Grantham, Fricke 1984, Tanaka I, and Sampalis II

II. ANALYSIS

A. Level of Ordinary Skill in the Art

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

Petitioner asserts that a person of ordinary skill in the art at the time of the invention of the '877 patent would have had “an advanced degree in marine sciences, biochemistry, organic (especially lipid) chemistry, chemical or process engineering, or associated sciences,” as well as a complementary understanding 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 to “at least five years applied experience.” Pet. 6; Ex. 1006 ¶ 27.

Patent Owner does not address the level of ordinary skill in its Response; however, Patent Owner’s declarant, Dr. Hoem opines that the definition proposed by Petitioner “is consistent with the literature, credentials of individuals working on lipid extractions, and the skill necessary to perform these extractions and interpret their results” Ex. 2001 ¶ 15. Based on that assessment, Dr. Hoem adopts the definition of the level of ordinary skill in the art advanced by Petitioner. *Id.*

We agree with Petitioner, Dr. Tallon, and Dr. Hoem, and find that Petitioner’s description of the level of ordinary skill in the art at the time of invention of the ’877 patent is consistent with the type of problems encountered in the art, prior art solutions to those problems, rapidity with which innovations are made, sophistication of the technology, and educational level of active workers in the field. *See In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). For purposes of this Decision, therefore, we adopt Petitioner’s description. 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).

In addition, we recognize each of Petitioner’s and Patent Owner’s declarants as qualified to provide the proffered opinions on the level of skill and the knowledge of a person of ordinary skill in the art at the time of the invention. The relative weight that we assign such testimony, however, is subject to additional factors. *See, e.g.*, 37 C.F.R. § 42.65(a) (“Expert

testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.”); Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,763 (Aug. 14, 2012) (same).

B. 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. § 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). 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 the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Only those terms that are in controversy need be construed, and only to the extent necessary to resolve the controversy. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (citing *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

Although both Petitioner (Pet. 19–29) and Patent Owner (PO Resp. 11–14) offer several claim constructions, we determine that no explicit construction of any claim term is necessary for purposes of this Decision. In reaching this conclusion, we observe that the parties’ proposed constructions are largely coextensive with each other, and to the extent those constructions differ, they do so in ways that do not impact our analysis. For example, our

analysis below remains the same irrespective of whether we apply Petitioner's construction of "krill oil" as meaning "lipids extracted from krill" (Pet. 21) or Patent Owner's interpretation, "oil produced from krill" (PO Resp. 11). Similarly, our analysis is unaffected by whether we apply Petitioner's definition of "to denature lipases and phospholipases," i.e., "to alter the conformational structure of lipases and phospholipases to reduce lipid and phospholipid decomposition" (Pet. 24), or Patent Owner's construction, "to treat the lipases and phospholipases to rupture hydrogen bonds thereby changing the molecular structure of the lipases and phospholipases" (PO Resp. 12–13).³

C. Overview of the Prior Art

Petitioner relies on combinations including Grantham, Fricke 1984, Tanaka I, Tanaka II, Bottino, Sampalis I, and/or Sampalis II, to support its contention that claims 1–19 of the '877 patent would have been obvious. Pet. 7. Pertinent to our discussion below, Patent Owner asserts that Fricke 1986⁴ supports its argument that the cited combination fails to disclose the

³ Patent Owner expressly accepts, for purposes of this proceeding, Petitioner's proposed constructions of "polar solvent," "freshly harvested krill," and "polar entrainer," the remaining terms for which the parties propose constructions. PO Resp. 13–14.

⁴ Fricke et al., *1-O-Alkylglycerolipids in Antarctic Krill (Euphasia Superba Dana)*, 85B COMP. BIOCHEM. PHYSIOL. 131–134 ("Fricke 1986") (Ex. 2006).

claimed ranges of ether phospholipid content. PO Resp. 14–16. We provide an overview of each reference.

1. *Grantham*

Grantham is a report published by the Food and Agriculture Organization of the United Nations, United Nations Development Programme, regarding the utilization of krill. Ex. 1032. Grantham teaches that most commercial catches of krill appear to consist mainly of *Euphasia superba*. *Id.* at 3.

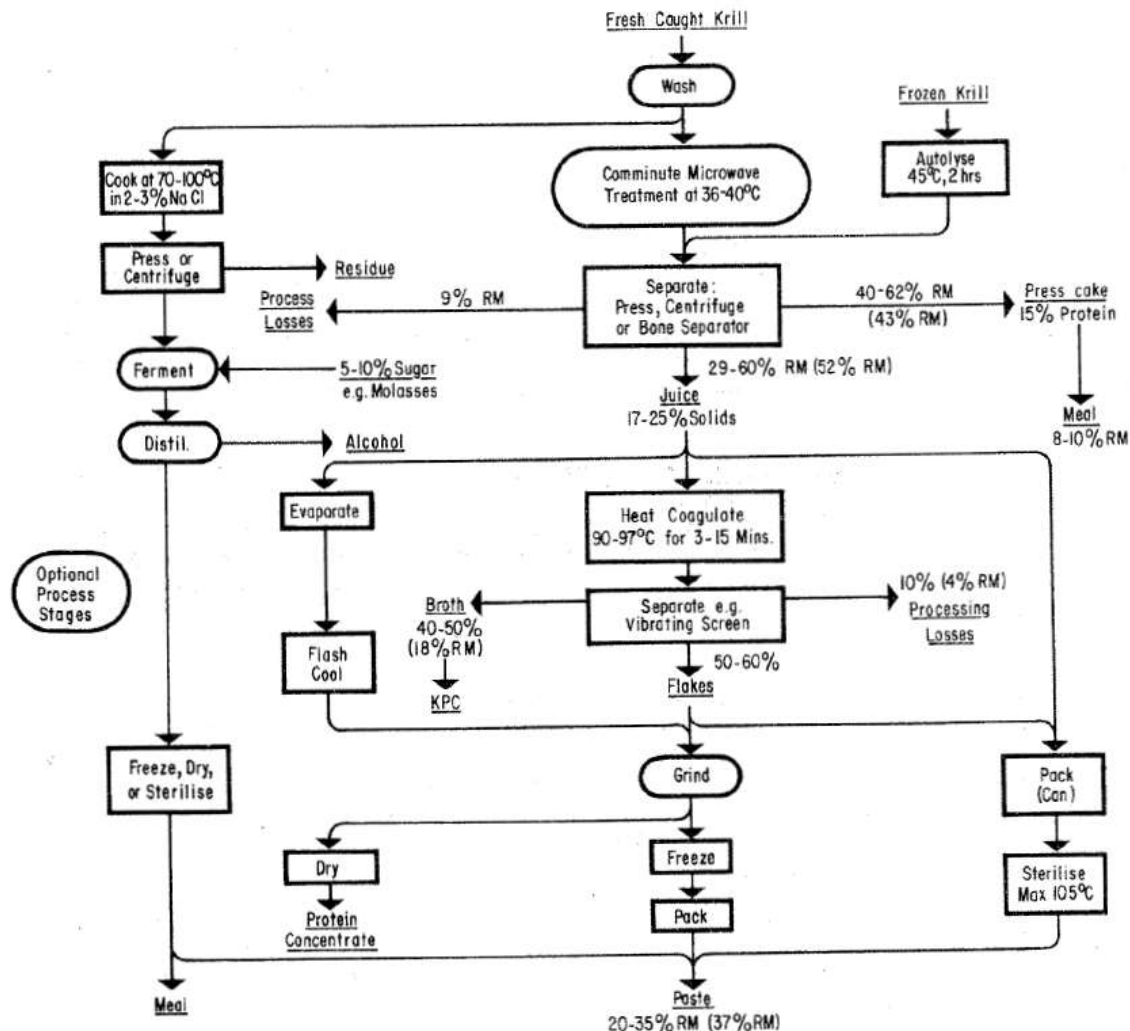
According to Grantham:

Although the fat content of krill varies markedly, its composition would seem to remain fairly constant. It is characterized by its high content of complex (phospho) lipids (50%, mainly lecithins (phosphatidyl-choline) and cephalins (phosphatidyl ethanolamine)), about 30–40% neutral fats (glycerides), and about 8% unsaponifiable elements. . . . Unlike other Antarctic zooplankters, it contains no waxes. Cholesterol is the only major sterol found, although traces of vitamin D and appreciable quantities of the pro-vitamin are also present. . . . Most of the common fatty acids are present, notably oleic, C_{20:5}, palmitic and myristic. The three ‘essentials’ are found, totalling 5%. The erucic acid content is low. Several unusual species are also evident. The occasional reports of high free fatty acid content (high acid value) are probably due to lipolysis during frozen storage of samples.

Id. at 19 (internal citations omitted).

Grantham notes that once harvested, krill spoil rapidly, particularly because the liver and stomach contain highly active enzymes, resulting in autolysis. *Id.* at 18. Thus, Grantham teaches, “krill can be held at ambient temperatures for only very limited periods before being preserved by one

means or another, and that (apart from any physical damage that may ensue) it is not practicable to transfer the catch under these conditions from one ship to another factory vessel.” *Id.* at 19. Grantham discloses the following method for processing krill on a ship (*id.* at 33):



Grantham discloses that the processing method depicted in the above flow chart, which produces a krill paste that may be stored at -18° to -20°C for up to a year, can be performed on a freezer trawler or on land. *Id.* at 32–33. As

illustrated in the flow chart, that process includes a cooking (i.e., heating) step. *Id.* at 33.

Grantham teaches further that most krill products are unstable during storage, whether that storage be by freezing, drying, or sterilization and, thus, benefit from some method of stabilization prior to final preservation. *Id.* at 36. According to Grantham, heat treatment is the most common such method, and “[b]oiling krill and krill products has been shown to inactivate the proteolytic, lipolytic and pigment degrading enzymes.” *Id.* Grantham teaches that solvent extraction has been used to remove the fats from the boiled krill. *Id.* at 39.

Grantham additionally teaches:

Krill fat, while difficult to remove by traditional means, has been seen to be of unusual composition in several respects. The high content of poly-unsaturated fatty acids, the presence of unusual fatty acid species, the absence of waxes, and the composition of the non-glyceride fractions suggest possible applications additional to the food and industrial outlets presently found for fish oils. A full assessment is recommended of the possibilities for krill fat in the areas of pharmaceuticals, cosmetics, perfumery, dietetics and other specialised fields.

Id. at 57.

2. *Fricke 1984*

Fricke 1984 discloses the “lipid classes, fatty acids of total and individual lipids and sterols of Antarctic krill (*Euphausia superba* Dana) from two areas of the Antarctic Ocean” as determined by thin layer chromatography, gas liquid chromatography, and gas liquid chromatography/mass spectrometry analyses. Ex. 1010, Abstract. According to Fricke 1984, krill were collected and were quick frozen, and lipids were extracted using the method of Folch.⁵ *Id.* at 1. Fricke 1984 teaches further that samples were also cooked on board “immediately after hauling,” and were stored under the same condition. *Id.* at 2–3.

⁵ Folch et al., *A Simple Method for the Isolation and Purification of Total Lipids From Animal Tissues*, 266 J. BIOL. CHEM. 497–509 (1957) (Ex. 1017).

Table 1 of Fricke 1984 is reproduced below.

TABLE 1		
Lipid Composition of Antarctic Krill (<i>Euphausia superba</i> Dana)		
Sample	12/1977	3/1981
Total lipid content (% wet weight)	2.7 ± 0.2	6.2 ± 0.3
<u>Phospholipids</u>		
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	
<u>Neutral lipids</u>		
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

Table 1 shows the total lipid content and the lipid composition data for the two krill samples analyzed by Fricke 1984. *Id.* at 2. As indicated in Table 1, the krill samples respectively included approximately 33.3% +/- 0.5% w/w and 40.4% +/- 0.1% w/w triacylglycerols. *Id.*

3. Tanaka I

Tanaka I examines the “PAF-like lipids formed during peroxidation of [phosphatidylcholines (“PCs”)] from hen egg yolk, salmon roe, sea urchin eggs, and krill in an FeSO₄/EDTA/ascorbate system.” Ex. 1004, Abstract. Tanaka I discloses the PC subclasses, and their relative amounts, present in Antarctic krill (*Euphausia superba*) extract. Ex. 1014, 2, 3. Tanaka I explains that PC was purified from crude krill lipid extract using column chromatography and thin layer chromatography. *Id.* at 2. Successive

degradations of the purified extract using alkaline and acid hydrolysis were then performed to measure the percentages of PC subclasses in the extract.

Id.

Table 1 of Tanaka I is reproduced below.

Table I. Subclass Composition of PCs from Food Stuffs

PC	Diacyl	Alkylacyl	Alkenylacyl
		%	
Hen egg yolk	99.2 ± 0.2	0.8 ± 0.1	< 0.1
Salmon roe	98.8 ± 0.2	1.2 ± 0.2	< 0.1
Sea urchin egg	57.5 ± 1.1	41.5 ± 0.3	1.0 ± 0.8
Krill	77.0 ± 1.2	23.0 ± 1.2	< 0.1

Values are means ± SE for four experiments.

Ex. 1014, Table 1. Table 1 shows that the ether phospholipid AAPC accounted for 23.0% +/- 1.2% of the total PC present in Antarctic krill extract. *Id.* at 3.

Tanaka I concludes that although the study “demonstrated the formation of PAF-like phospholipids during peroxidation of PCs from different foodstuffs[,] . . . the occurrence of PAF-like lipids in some stored foods is still speculative and requires further investigation.” Ex. 1014, 5.

4. Tanaka II

Tanaka II describes the extraction of phospholipids from salmon roe using supercritical carbon dioxide and the polar entrainer ethanol. Ex. 1015, Abstract, 1. Tanaka II reports the effect of ethanol concentration, extraction time, and extraction temperature on phospholipid yield. *Id.* at Abstract.

Tanaka II discloses:

Many researchers have already reported since a pure carbon dioxide does not dissolve [phospholipids (“PLs”)]

effectively, extraction of PLs might be achieved by the addition of a polar entrainer to SC-CO₂. An entrainer is a substance of medium volatility added to a mixture of compressed gas and a low volatility substance. As the solubility in SC-CO₂ at the same extracting conditions (temperature and pressure) is drastically enhanced, extraction can be conducted at a lower pressure. The logical choice for a co-solvent in the food industry would be ethanol. The authors used ethanol as the entrainer to extract PLs in SC-CO₂ because: (i) It is suitable for food use; and (ii) the phase behavior of CO₂/ethanol mixes at high pressure is available.

Ex. 1015, 3 (internal citations omitted). Tanaka II additionally explains that “[b]ecause CO₂ is stable chemically, it does not react with other materials in treatment. Easy separation and removal of CO₂ from the products eliminates any problem related to toxic residual solvents.” *Id.* at 1.

5. Bottino

Bottino observes that “[t]he study of krill has become intensive in recent times, perhaps as a result of its potential importance as food,” and explains that “[a] variety of organisms [are] usually included under that generic name, but in the Southern Oceans the name *Euphausia superba* has been considered almost a synonym for krill.” Ex. 1007, 1.

Bottino describes the fatty acid profiles for *E. superba*, *E. crystallorophias*, and phytoplankton. Ex. 1007, Abstract. Bottino explains that, in contrast to prior studies, lipids were extracted from *E. superba* “immediately after capture.” *Id.* at 2. Euphausiids lipid extraction was performed “with a chloroform:methanol (2:1, v/v) mixture,” as previously described by Folch, and the fatty acids were analyzed using chromatography. *Id.* at 1.

Table 1 of Bottino is reproduced below.

Table 1. *Euphausia superba*. Fatty acids (as weight per cent of total acids)

Fatty acid ^a	Station 8		Station 9	Station 11		
	Whole krill	HP+S ^b	Whole krill	Whole krill	HP+S	Remaining carcass
14:0	14.9	10.7	12.9	14.3	12.9	13.5
16:0	21.2	21.2	20.9	24.7	22.3	23.4
18:0	0.7	1.2	0.9	1.4	1.3	1.4
16:1(n-7)	9.0	6.7	10.7	8.9	8.2	8.0
18:1(n-9)	18.2	17.1	22.8	21.7	21.8	21.5
20:1(n-9)	0.6	0.9	1.1	0.9	1.2	1.1
18:2(n-3)	2.6	2.5	2.7	2.0	2.1	1.9
18:3(n-3)	1.1	1.2	1.4	1.0	1.0	1.1
18:4(n-3)	2.2	1.9	2.6	3.3	3.6	3.8
20:5(n-3)	16.0	22.2	11.8	11.4	13.9	11.6
22:6(n-3)	8.6	9.4	8.3	7.3	8.1	9.4
Minor fatty acids ^c	4.9	5.0	3.9	3.1	3.6	3.3

^aThe number preceding the colon gives the number of carbon atoms in the chain, the number following the colon the number of double bonds; (n-x): number of carbons in the chain minus number of carbons between the methyl end and the nearest double bond.

^bHepatopancreas plus stomach.

^cOnly those fatty acids present at a level of 1% or more are included.

Ex. 1007, Table 1. Table 1 discloses the fatty acid content of *E. superba* obtained from three different locations (i.e., stations) as a weight percent of total fatty acids. *Id.* at 2. Notably, only those fatty acids present at 1% or more as a weight percent of total fatty acids are included in Table 1. *Id.* Table 1 n.c.

Table 3 of Bottino is reproduced below.

Table 3. Fatty acids of Antarctic phytoplankton and euphausiids (as weight per cent of total acids)

Fatty acid	Phytoplankton at Stations ^a												<i>Euphausia superba</i> (average of 3 stations)	<i>Euphausia crystallographica</i> (average of 7 stations)
	8	9a	9b	11a	11b	13	14	15a	15b	15c	18a	18b		
8:0	-	-	-	0.4	-	1.2	1.0	-	-	0.7	-	-	-	-
9:0	0.2	0.3	2.9	0.9	0.2	1.4	2.5	1.5	0.1	1.7	-	-	-	0.2
10:0	-	1.5	-	1.7	-	0.9	4.0	2.4	0.1	2.2	-	-	-	-
11:0	-	-	-	0.7	1.3	1.2	1.9	1.1	trace	0.3	-	-	-	-
12:0	1.3	2.3	2.3	1.9	0.4	2.0	2.2	2.5	0.4	0.8	0.2	-	0.2	0.1
13:0	-	1.1	-	-	-	0.4	3.0	0.8	-	-	-	-	-	0.1
14:0	9.7	22.5	11.5	15.9	22.9	25.5	20.7	17.4	19.3	5.1	13.0	9.5	14.0	2.4
15:0	1.9	0.3	1.6	2.6	1.7	2.6	-	3.4	0.7	1.1	0.3	-	0.4	0.1
16:0	20.4	20.1	19.9	16.0	18.8	21.7	18.5	18.7	17.2	16.1	17.3	14.9	22.3	14.6
18:0	7.0	2.1	3.3	2.0	2.0	2.6	2.2	1.9	1.8	5.2	1.7	1.5	1.0	0.5
10:1(n-7)	0.6	2.2	2.5	-	0.8	-	-	-	-	-	0.2	-	-	-
11:1(n-7)	-	-	-	0.7	-	1.9	2.0	1.3	0.1	0.9	-	-	-	-
12:1(n-7)	-	2.8	1.5	1.6	2.4	0.7	1.2	1.6	0.2	0.9	1.5	0.3	-	-
13:1(n-7)	-	0.5	-	1.0	-	0.6	1.8	1.4	0.1	1.1	-	-	-	-
15:1(n-7)	0.5	0.7	0.6	1.3	0.6	1.2	1.0	2.7	0.4	0.7	1.8	-	trace	-
16:1(n-7)	12.4	8.3	7.5	6.2	5.7	5.3	3.4	7.8	3.6	3.2	13.1	10.3	9.5	7.9
17:1(n-7)	1.6	0.3	0.9	0.6	0.3	0.2	-	0.3	0.3	trace	1.4	0.9	0.5	0.3
18:1(n-9)	12.1	16.0	15.6	16.2	18.3	16.3	24.8	11.4	20.2	12.5	17.3	18.7	20.8	46.2
20:1(n-9)	0.4	-	0.8	trace	-	1.7	-	0.1	trace	-	0.3	0.3	0.9	0.2
18:2(n-6)	2.1	0.1	0.3	0.2	0.1	-	-	-	0.1	-	4.1	3.8	0.2	-
18:2(n-3)	3.7	3.3	2.4	3.1	3.3	3.0	2.7	2.1	7.1	12.0	1.2	1.7	2.4	2.1
22:2(n-6)	-	-	-	-	-	0.8	0.9	1.6	2.0	-	-	-	-	-
22:2(n-3)	-	0.6	0.7	1.4	1.4	-	-	-	-	-	-	-	-	-
18:3(n-6)	0.3	0.3	0.3	0.2	0.2	-	-	-	0.2	0.3	0.2	0.3	0.2	0.1
18:3(n-3)	0.9	0.7	0.6	0.7	0.7	0.7	0.3	0.2	0.1	0.2	0.2	0.3	1.2	0.9
20:3(n-6)	0.4	0.2	-	trace	0.9	trace	-	0.3	2.6	0.1	-	0.1	-	-
20:3(n-3)	0.2	0.2	0.3	-	-	-	-	trace	0.9	1.0	-	0.2	0.5	0.3
16:4(n-1)	-	-	0.5	-	-	-	-	-	-	6.3	-	-	-	-
18:4(n-3)	2.0	3.1	3.5	5.2	6.0	3.0	2.7	3.2	6.2	0.9	2.2	2.5	2.7	1.2
20:4(n-6)	-	-	-	0.4	-	-	-	-	-	4.7	-	-	0.4	0.4
20:4(n-3)	0.2	-	0.3	0.2	-	-	-	0.1	trace	-	-	0.2	0.4	0.1
22:4(n-6)	-	-	-	-	-	-	-	-	-	trace	-	-	0.2	-
22:4(n-3)	1.3	-	trace	-	-	-	-	trace	-	trace	-	-	-	-
20:5(n-3)	11.4	4.8	9.2	7.0	6.4	1.7	2.1	5.3	6.0	2.1	18.4	23.4	13.1	14.4
22:5(n-6)	1.1	-	-	-	-	-	-	-	-	-	-	-	-	-
22:5(n-3)	0.3	0.3	-	-	-	-	-	0.1	-	2.1	-	-	0.2	-
22:6(n-3)	6.1	4.9	7.9	8.4	5.5	0.9	0.8	7.1	7.8	16.5	5.5	11.0	8.1	7.5
Minor fatty acids ^b	3.3	1.5	4.3	4.6	1.0	3.2	0.6	4.0	2.8	1.8	0.5	0.9	0.8	0.4

^aMicroscopic examination indicated that the following genera predominated in each station. Station 9: *Endorina*, *Pandorina*; Station 10: *Thalassiosira*, *Fragilaria*, *Nitzschia*, *Corethron*, *Silicoflagellates*; Station 11: *Corethron*, *Fragilaria*, *Chaetoceros*, *Silicoflagellates*; Station 12: *Corethron*, *Fragilaria*, *Nitzschia*, *Tintinnids*; Station 13: Complex mixture; Station 14: *Phaeocystis*; Station 15: *Phaeocystis*, *Chaetoceros*, *Nitzschia*, *Thalassiosira*, *Fragilaria*; Stations 17 and 18: *Fragilaria*, *Nitzschia*, *Coccolithoides*, *Dinoflagellates*, *Tintinnids*.

^bOnly those fatty acids present at a level of 1% or more are included. See footnotes to Tables 1 and 2 for further explanation.

Ex. 1007, Table 3. Table 3 reports the identity and average amount of each fatty acid present in the *E. superba* samples analyzed as a weight percent of total fatty acids.

6. *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, 1. Sampalis I explains that Neptune Krill Oil 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 4.

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 8.

7. *Sampalis II*

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

Sampalis II further discloses that

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

Ex. 1013, 25:2–10.

8. *Fricke 1986*

Fricke 1986 teaches that “[s]mall amounts of alkoxy lipids, commonly referred to as glyceryl ethers or ether lipids, are present in the lipids of many marine animals.” Ex. 2006, 1. Fricke notes that “[w]hile investigating the complete lipid composition of Antarctic Krill” in the study reported in Fricke 1984, “there was some evidence for the presence of 1-O-

alkylglycerolipids in trace amounts,” which suggested “that some degradation processes had taken place during storage.” *Id.* Fricke 1986 explains that the samples analyzed in Fricke 1984 “were frozen on board a research vessel in 1977 and 1981 and could only be investigated after some months of frozen storage.” *Id.* Accordingly, Fricke 1986 set out to verify the findings of Fricke 1984, using lipid extracts from freshly caught krill that were prepared on-board during an expedition in 1985. *Id.*

According to Fricke 1986, 1-O-alkylglycerolipids “were found as minor lipid components,” and “ranged from 0.3 to 0.6% of total lipid content of Antarctic Krill” (Ex. 2006, 2) as shown in Table 1, reproduced below.

Table 1. Lipid content and 1-O-alkylglycerol content in total lipids of Antarctic Krill (*Euphausia superba* Dana). Data are expressed as wt % and represent means and standard deviation of at least three separate experiments

	A*	B†	C‡	D‡	E‡	F‡§
Lipid content S	2.7 ± 0.2	6.2 ± 0.3	9.2 ± 0.3	8.3 ± 0.7	10.3 ± 0.4	5.7 ± 0.3
1-O-Alkylglycerol-content	0.43 ± 0.04	0.50 ± 0.02	0.53 ± 0.01	0.65 ± 0.03	0.58 ± 0.03	0.58 ± 0.01

*Krill caught in December 1977.

†Krill caught in March 1981.

‡Krill caught in March/April 1985. Krill samples extracted immediately after catching.

§Krill muscle analyzed.

||On a wet weight basis.

*†Krill samples stored at -30°C.

Id. at Table 1.

With regard to the preparation of the 1977 and 1981 samples, Fricke 1986 teaches that alkylglycerolipids were isolated after stepwise hydrolysis of total lipids. Ex. 2006, 1. Phospholipids and neutral lipids were separated using thin layer chromatography, and phospholipids were incubated with phospholipase C. *Id.* Fricke 1986 teaches that the alkylglycerols were prepared from the phospholipids and neutral lipids by concentrated methanolic hydrochloric acid, and the alkylglycerols were isolated using thin layer chromatography. *Id.* at 1–2. Concerning the 1985 samples, Fricke 1986 explains that those “samples were treated “according

to Snyder et al. (1971) with Vitride (sodium-di-hydro-bis-(2-methoxyethoxy)-aluminate) to form the free alkylglycerols.” *Id.*

*D. Obviousness Based on
Grantham, Fricke 1984, and Tanaka I*

Petitioner asserts that claims 1–3 8, 9, 11, 12, 17, and 18 are unpatentable under § 103(a) as obvious in view of Grantham, Fricke 1984, and Tanaka I. Pet. 30–51. Patent Owner disagrees. PO Resp. 14–19.

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). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and, where presented, (4) objective evidence of nonobviousness. *Graham*, 383 U.S. at 17–18.

Although *inter partes* review may be instituted where it has been shown that “there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition” (35 U.S.C. § 314(a)), “the burden of persuasion is on the petitioner to prove ‘unpatentability by a preponderance of the evidence,’ 35 U.S.C. § 316(e), and that burden never shifts to the patentee.” *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). It is, therefore,

of the utmost importance that petitioners “adhere to the requirement that the initial petition identify ‘with particularity’ the ‘evidence that supports the grounds for the challenge to each claim.’” *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016) (quoting 35 U.S.C. § 312(a)(3)).

“from about 3% to about 10% w/w ether phospholipids”

Each challenged claim requires that the krill oil produced according to the claimed method include “from about 3% to about 10% w/w ether phospholipids.” Ex. 1001, 34:64–65, 36:2–3. Petitioner asserts that Tanaka I, in view of Fricke 1984, satisfies these claim requirements. Pet. 42–44 (citing Ex. 1086 ¶¶ 102, 135, 211–212).

In support of its position, Petitioner states that Fricke teaches that phosphatidylcholine makes up approximately 34% w/w of Antarctic krill lipids (35.6% +/- 0.1% w/w and 33.3% +/- 0.5% w/w, respectively, for the samples tested). Pet. 43 (citing Ex. 1006 ¶ 102; Ex. 1010, Table 1). Petitioner further explains that Tanaka I discloses that 23.0% +/- 1.2% w/w of the phosphatidylcholine content of Antarctic krill is AAPC. *Id.* at 42 (citing Ex. 1006 ¶ 135; Ex. 1014, Table I). Relying on its declarant, Dr. Tallon, Petitioner, therefore, asserts that an ordinarily skilled artisan would have understood that Antarctic krill oil includes approximately 7.8% w/w of the ether phospholipid AAPC. *Id.* at 44. In particular, Petitioner reasons that “[s]ince Tanaka I demonstrates that AAPC is 23.0 +/- 1.2% of krill phosphatidylcholine and Fricke [1984] demonstrates that PC is approximately 34% of krill lipids, it can be concluded that AAPC, *an ether*

phospholipid, is present at approximately 7.8% of krill oil (34% x .23 = 7.8%).” *Id.* (citing Ex. 1006 ¶ 102).

With regard to the rationale for, and reasonable expectation of success in making the proposed combination, Petitioner asserts, relying on its declarant, Dr. Tallon, that it was well-known, prior to the invention of the ’877 patent, that “phospholipids and, phosphatidylcholine in particular, were associated with beneficial health effects. Further, the health benefits of omega-3 fatty acids, particularly in connection with cardiovascular disease, was also well established.” Pet. 50 (internal citations omitted). Petitioner, therefore, reasons that an ordinarily skilled artisan “performing the treatment and extraction steps disclosed in Grantham would be motivated to look to other references such as Fricke [1984] and Tanaka I to ascertain the components of the krill oil and their amounts that were obtained by standard extraction methods.” Pet. 50–51 (citing Ex. 1006 ¶ 235).

Patent Owner responds that the proffered combination does not disclose a krill oil having an ether phospholipid content within the ranges required by the challenged claims. PO Resp. 14–16. In particular, Patent Owner contends that Fricke 1986, which discloses krill ether phospholipid levels obtained using the krill extracts examined in Fricke 1984 (Ex. 2006, 1, Table 1), contradicts Petitioner’s declarant’s calculations. *Id.* at 16. Patent Owner, therefore, asserts that “[t]he combined references do not teach or suggest the claim element of from 3% to 10% ether phospholipids in the extracted oil as evidenced by Fricke 1986.” *Id.* at 19. Patent Owner additionally contends that an ordinarily skilled artisan would not have had

reason for, nor a reasonable expectation of success in, combining Sampalis I, Tanaka I, and Fricke 1984 to arrive at the claimed invention. *Id.* at 16–19.

On Reply, Petitioner asserts that an ordinarily skilled artisan “would have understood that the ether phospholipid levels reported in Fricke [1986] are anomalies that are significantly lower than the typical ether lipid content observed in krill.” Reply 7 (citing Ex. 1086 ¶¶ 67–69, 76). For example, according to Petitioner, because Fricke 1986 does not directly measure krill ether phospholipid levels, but rather, depends on successive degradation of those phospholipids in its analysis, “[t]here are numerous steps . . . in which losses of the final quantifiable compound could occur.” *Id.* at 6. In addition, Petitioner contends that the molecular mass of the degradation product measured by Fricke 1986 is much lower than that of the ether phospholipids present in krill, and thus, the weight percentage results for the degradation product will necessarily be lower than the results would have been had the krill ether phospholipids been measured directly. *Id.* at 5–6 (citing Ex. 1086 ¶¶ 67, 69).

Petitioner further contends that an ordinarily skilled artisan would have recognized that the method of ether phospholipid analysis employed in Fricke 1986 was inaccurate and obsolete. Reply 7–8. Specifically, Petitioner asserts that an ordinarily skilled artisan would have had a “compelling reason to rely upon the results obtained using a more precise analytical technique, such as NMR, and disregard Fricke [1986]’s outdated and imprecise method which failed to directly measure ether phospholipid content or differentiate between ether phospholipids and other possible sources of ether lipids in the samples analyzed.” *Id.* at 8 (citing Ex. 1086

¶ 71). Petitioner also characterizes Tanaka I as disclosing “a direct and more precise technique for measuring krill ether phospholipid[s].” *Id.* at 9. According to Petitioner, Tanaka I involves fewer degradation steps than Fricke 1986. *Id.* (citing Ex. 1086 ¶ 79). Petitioner additionally addresses Patent Owner’s rationale to combine and reasonable expectation of success arguments. Reply 10–14.

We agree with Patent Owner that Petitioner has not carried its burden to establish by a preponderance of the evidence that the combination of Grantham, Fricke 1984, and Tanaka I teaches or suggests a krill oil “with from about 3% to about 10% w/w ether phospholipids” (Ex. 1001, 34:64–65, 36:2–3), as required by the challenged claims.

Petitioner does not rely on a direct measurement of the ether phospholipids present in krill oil to satisfy this claim element. Instead, as explained above, Petitioner’s declarant, Dr. Tallon estimates the amount of ether phospholipids present in the krill extract of Fricke 1984 based on Tanaka I’s disclosure that 23% of the total phosphatidylcholine extracted from krill is AAPC, and Fricke 1984’s disclosure that phosphatidylcholine comprises approximately 34% w/w of krill oil extract. Ex. 1006 ¶ 102. But Petitioner does not adequately explain why an ordinarily skilled artisan would have turned to Tanaka I to discern the ether phospholipid content of Fricke 1984, when Tanaka I did not use the then-preferred method for ether phospholipid analysis, and when more accurate measurements of krill oil ether phospholipid content were known in the art.

In response to Patent Owner’s contention that the ether phospholipid levels reported in Fricke 1986 establish that the krill oil disclosed by

Fricke 1984 had ether phospholipid levels well below those required by the challenged claims, Petitioner argues that ^{31}P NMR spectroscopy is “much more reliable and accurate” than other methods for quantifying ether phospholipid levels that were known at the time of invention of the ’877 patent, including the method used in Fricke 1986. Reply 8–9 (citing Ex. 1086 ¶¶ 72–74). In particular, Petitioner avers that

^{31}P -NMR provides a direct, sensitive, and selective method of analysis, allowing phospholipids to be analyzed in their natural intact state, without the additional uncertainty of chemical modification steps that convert them into another form for analysis. (Exhibit 1079, p. 0012). This analytical technique also directly responds to the presence of the characteristic phosphorous nucleus that is present in the phospholipids, making the results much more reliable and accurate.

Id. (citing Ex. 1086 ¶¶ 72–74). According to Petitioner, an ordinarily skilled artisan would have had a “compelling reason to rely upon the results obtained using a more precise analytical technique, such as NMR, and disregard Fricke [1986]’s outdated and imprecise method which failed to directly measure ether phospholipid content or differentiate between ether phospholipids and other possible sources of ether lipids in the samples analyzed.” *Id.* at 8 (citing Ex. 1086 ¶ 71). In addition, Petitioner’s declarant, Dr. Tallon testifies that, prior to the invention of the ’877 patent, Catchpole disclosed a krill oil having an ether phospholipid content of 4.8% by weight, based on ^{31}P NMR spectroscopy. Ex. 1006 ¶¶ 94–95.

We find Petitioner’s arguments concerning the superior accuracy and reliability of ^{31}P NMR relative to other ether phospholipid quantification techniques persuasive. We likewise credit Petitioner’s assertions that an

ordinarily skilled artisan would have had “compelling reason” to use NMR to measure krill oil ether phospholipid content. Indeed, Dr. Hoem, Patent Owner’s declarant, also recognizes NMR as the preferred method for analyzing the components of krill oil. Ex. 1079, 1, 3–4, 11; Ex. 1090, 97:23–98:5; Ex. 1086 ¶¶ 72–74). Moreover, as set forth in the accompanying Final Written Decision in IPR2017–00746, we determine that claims 1–19 of the ’877 patent would have been obvious over combinations that rely on Catchpole, which discloses the use of ³¹P NMR to quantify krill oil ether phospholipids as disclosing a krill oil extract that meets the required ether phospholipid ranges.

In view of the “enhanced accuracy of NMR” (Reply 8 (citing Ex. 1086 ¶¶ 72–73)), and the fact that NMR measurements of krill oil ether phospholipid content were known in the art (*id.* at 7 (citing Ex. 1009, 14; Ex. 1006 ¶ 94)), however, we are not persuaded that an ordinarily skilled artisan would have looked to Tanaka I to determine the phospholipid content of Fricke 1984 (Reply 9 (citing Ex. 1006 ¶¶ 134–136)). Tanaka I measures the percentages of the PC subclasses present in krill oil using a process of “successive degradations of PC with mild alkali and acid.” Ex. 1014, 2. Petitioner fails to adequately explain why an ordinarily skilled artisan would have turned to Tanaka I, which, like Fricke 1986, discloses a degradation process for measuring ether phospholipid levels, when more reliable NMR analyses were available. Even if, as Petitioner contends, the method of Tanaka I is more accurate than that of Fricke 1986 because it involves fewer degradation steps (Reply 9), Petitioner has not sufficiently established the reliability of Tanaka I’s degradation analysis for purposes of this Decision.

In particular, Petitioner does not adequately explain how the results obtained by Tanaka I compare to results acquired using other methods, such as ^{31}P NMR, or why an ordinarily skilled artisan would have relied on Tanaka I when NMR analyses of krill oil ether phospholipid levels were available. The absence of evidence sufficient to establish the reliability of Tanaka I is of particular importance where, as here, Petitioner and its declarant, Dr. Tallon, go to great lengths both to tout the superiority of a quantification technique different from that used by Tanaka I—NMR (Reply 7–9; Ex. 1086 ¶¶ 71–74)—as well as to disparage the accuracy of other degradation-based analyses—namely, that used by Fricke 1986 (Reply 5–7; Ex. 1086 ¶¶ 67, 69).

Accordingly, having reviewed Petitioner’s evidence and arguments, we determine that Petitioner has failed to demonstrate by a preponderance of the evidence that independent claims 1 and 11 are rendered obvious by the combination of Grantham, Fricke 1984, and Tanaka I. We have also reviewed Petitioner’s evidence and arguments as to dependent claims 2, 3, 8, 9, 11, 12, 17, 18, and determine, for the reasons set forth with respect to the independent claims, that Petitioner has failed to demonstrate by a preponderance of the evidence that those claims are rendered obvious by the combination of Grantham, Fricke 1984, and Tanaka I. Thus, Petitioner has failed to demonstrate by a preponderance of the evidence that claims 1–3, 8, 9, 11, 12, 17, and 18 are rendered obvious by the combination of Grantham, Fricke 1984, and Tanaka I.

*E. Obviousness Based on
Grantham, Fricke 1984, Tanaka I, Tanaka II,
Bottino, Sampalis I, and/or Sampalis II*

The remaining asserted grounds of unpatentability address dependent claims 4–7, 10, 13–16, and 19. As Petitioner does not rely on Tanaka II, Bottino, Sampalis I, or Sampalis II to remedy the deficiencies of Grantham, Fricke 1984, and Tanaka I discussed above, we determine that Petitioner has not demonstrated the unpatentability of dependent claims 4–7, 10, 13–16, and 19 by a preponderance of the evidence.

III. CONCLUSION

After considering Petitioner’s and Patent Owner’s arguments and evidence, we conclude that Petitioner has failed to demonstrate by a preponderance of the evidence that claims 1–19 of the ’877 patent are unpatentable.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner has failed to demonstrate by a preponderance of the evidence that claims 1–19 of the ’877 patent are unpatentable under 35 U.S.C. § 103(a); 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.

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