Rimfrost USA, LLC, Rimfrost New Zealand Limited and Bioriginal Food & Science Corp. (Exhibit 1023). On January 27, 2017, Petitioner filed IPR2017-0745 and IPR2017-0747 seeking *inter partes* review of Claims 1-20 of U.S. Patent No. 9,078,905.

C. Counsel (37 C.F.R. §§ 42.8(b)(3) and 42.10(a))

Petitioner designates the following individuals as its lead counsel and back-up lead counsel:

Lead Counsel	Back-up Lead Counsel
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D. Service information (37 C.F.R. §42.8(b)(4))

Service on Petitioner may be made electronically by using the following email address: 877ipr1@hbiplaw.com and the email addresses above. Service on Petitioner may be made by Postal Mailing or Hand-delivery addressed to Lead and Back-up Lead Counsel at the following address, but electronic service above is requested:

Hoffmann & Baron, LLP
6900 Jericho Turnpike
Syosset, New York 11791

This document, together with all exhibits referenced herein, has been served on the patent owner at its corporate headquarters, Oskenøyveien 10 No-1327, 1366 Lysaker, Norway, as well as the correspondence address of record for the '877 patent: Casimir Jones, S.C., 2275 Deming Way, Suite 310, Middleton, Wisconsin 53562, and the address of Patent Owner's litigation counsel: Andrew F. Pratt, Esq. Venable LLP, 575 Seventh Street NW, Washington, DC 20004.

III. PAYMENT OFFICE FEES

Pursuant to 37 C.F.R. §§ 42.103 and 42.15(a), the requisite filing fee of $24,600 (request fee of $9,000, post-institution fee of $14,000 and excess claims

fee of $1,600) for a Petition for *Inter Partes* Review is submitted herewith. Claims 1-19 of the '877 patent are being reviewed as part of this Petition. The undersigned further authorizes payment from Deposit Account No. 08-2461 for any additional fees or refund that may be due in connection with the Petition.

IV. ADDITIONAL REQUIREMENTS FOR *INTER PARTES* REVIEW

A. Grounds for Standing (37 C.F.R. § 42.104(a))

Petitioner hereby certifies that the '877 patent is available for *Inter Partes* Review and that Petitioner is not barred or estopped from requesting *Inter Partes* Review challenging the claims of the '877 patent on the grounds identified herein. This Petition is timely filed under 35 U.S.C. §315(b) because it is filed within one year of the service of the Complaint alleging infringement of the '877 patent by Aker. *See* Exhibits 1021-1022.

B. Level or Ordinary Skill in the Art

As of the earliest priority date the '877 Patent is entitled to, (*i.e.*, January 28, 2008), a POSITA would have held an advanced degree in marine sciences, biochemistry, organic (especially lipid) chemistry, chemical or process engineering, or associated sciences with complementary understanding, either

through education or experience, of organic chemistry and in particular lipid chemistry, chemical or process engineering, marine biology, nutrition, or associated sciences; and knowledge of or experience in the field of extraction. In addition, a POSITA would have had at least five years' applied experience. (Tallon Decl. ¶27).

C. Identification of Challenge and Relief Requested (37 C.F.R. § 42.104(b) and 37 C.F.R. § 42.22(a)(1))

The precise relief requested by Petitioner is that Claims 1-19 are found unpatentable and cancelled from the '877 patent.

1. Claims for which Inter Partes Review is Requested(37 C.F.R. §42.104(b)(2))

Petitioner requests *Inter Partes* Review of Claims 1-19 of the '877 patent.

2. Specific Statutory Grounds on which the Challenge is Based (37 C.F.R. § 42.104(b)(2))

The specific statutory grounds for the challenge are as follows:

Ground	References	Basis	Claims Challenged
1	Breivik, Catchpole, and Fricke	35 U.S.C. §103(a)	1-3, 6, 8-9, 11-12, 15 and 17-18
2	Breivik, Catchpole, Fricke, and Bottino	35 U.S.C. §103(a)	4-5 and 13-14

Ground	References	Basis	Claims Challenged
3	Breivik, Catchpole, Fricke, and Sampalis I	35 U.S.C. §103(a)	7 and 16
4	Breivik, Catchpole, Fricke, and Sampalis II	35 U.S.C. §103(a)	10 and 19

Petitioner also relies on the expert declaration of Dr. Stephen Tallon (Exhibit 1006).

3. Earliest Effective Priority Date

All of the issued claims in the '877 patent require the element that the krill oil comprise from about 3% to about 10% w/w ether phospholipids. Support for the claim element "ether phospholipid" was not introduced until the filing of U.S. Application No. 61/024,072, filed on January 28, 2008. (*See* Exhibits 1002-1005). Consequently, the earliest effective priority date for the claims of the '877 patent is January 28, 2008. (*See* Tallon Dec. ¶ 34).

4. Prior Art References

Other than Catchpole and Breivik, all prior art references utilized herein were published more than one year prior to the earliest possible priority date of January 28, 2008, and, therefore, qualify as prior art under 35 U.S.C. §102(b). Catchpole has an international filing date of April 20, 2007 and was published on

November 1, 2007 and, therefore, qualifies as a prior art reference under 35 U.S.C. §102(e)[1]. Breivik claims priority to U.S. provisional application No. 60/859,289 (Exhibit 1036) filed November 16, 2006 and was filed as a PCT application on November 15, 2007 (Exhibit 1037).

§102(b) Reference	Publication Date	Exhibit No.
Fricke	April 30, 1984	1010
Sampalis I	May 2003	1012
Bottino	June 28, 1974	1007
Sampalis II	February 13, 2003	1013

§102(e) Reference	Effective Filing Date	Exhibit No.
Catchpole	April 20, 2007	1009
Breivik	November 16, 2006	1035

[1] Catchpole is also a prior art reference under 35 U.S.C. § 102(a).

D. Claim Construction - Broadest Reasonable Interpretation ("BRI") (37 C.F.R. § 42.104(b)(3))

In an *inter partes* review, claim terms 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. 48756 and 48766 (Aug. 14, 2012).

Solely for this proceeding, the Section V. D. contains the proposed terms for construction and Petitioner's proposed constructions. All other terms, not presented below, should be given their plain and ordinary meaning. Petitioner reserves the right to address any claim construction issue raised by Patent Owner.

V. SUMMARY OF THE '877 PATENT (EXHIBIT 1001)

A. State of the Art

All of the claims issued in the '877 Patent are directed to methods of producing krill oil. The steps of the methods include providing and treating krill (*e.g.*, by heating) to denature lipases and phospholipases and extracting oil using a polar solvent. Independent Claim 1 requires the denaturation step to be performed "on a ship," while independent Claim 11 requires the denaturation be performed on "freshly harvested krill." However, such steps were well known in the art as of

the earliest effective filing date.

For example, Budziński (Exhibit 1008) recognized the need to process freshly harvested krill to ensure the optimum product quality. "Due to its technological properties, the raw material should be processed as soon as possible after capture. The only way to meet this requirement is to install processing facilities on board the vessel." (Exhibit 1008, p. 0031, sec. 4.9, lines 2-4.) (Tallon Decl. ¶ 81.).

Budziński further discloses cooking and pressing krill on board the ship to produce a denatured product—krill meal. (Exhibit 1008, p. 002620, sec. 4.5.1, lines 1-2, 6-8, 15-17, and 21-23.) (*See* Tallon Decl. ¶ 84). Budziński also discloses extracting oil with a polar solvent ("[k]rill oil was only obtained by extraction with the help of various organic solvents." (Exhibit 1008, p. 0030, sec. 4.7, line 12.) (Tallon Decl., ¶ 86).

Similarly, Grantham discloses the problem of krill's instability after catching and describes methods for processing (cooking) on board the ship before extracting krill lipids. (Exhibit 1032, p. 0026, section 3.1; pp. 0033-0034, section 3.4.4; p. 0035, section 3.4.5; p. 0036, sec. 3.4.6.; p. 0039, section 3.4.8). (Tallon

Decl., ¶¶ 158-166).

The claims of the '877 patent also specify percentages of components in the resulting krill oil. However, the krill oil components were well known to be naturally present in krill oil in the amounts specified using standard extraction techniques. (*See, e.g.*, Section VI, *infra*; Exhibit 1034, Kolakowska (1991)).

B. Background of '877 Patent

The '877 patent "provides methods of production of krill oil comprising: a) providing fresh krill; b) treating said fresh krill to denature lipases and phospholipases in said fresh krill to provide a denatured krill product; and c) extracting oil from said denatured krill product," wherein steps (a) and (b) are performed on board a ship. (Exhibit 1001, col. 4, lines 47-52). The Patentee of the'877 patent also states that, "The present invention provides a *Euphausia superba* krill oil composition comprising: from about 30% to 60% w/w phospholipids; from about 20% to 50% triglycerides; from about 400 to about 2500 mg/kg astaxanthin; and from about 20% to 35% omega-3 fatty acids as a percentage of total fatty acids in said composition, wherein from about 70% to 95% of said omega-3 fatty acids are attached to said phospholipids." (Exhibit

1001, col. 5, lines 49-56).

However, as acknowledged in the Background of the Invention:

> In order to isolate the krill oil from the krill, solvent extraction methods have been used. See, e.g., WO 00/23546. Krill lipids have been extracted by placing the material in a ketone solvent (e.g. acetone) in order to extract the lipid soluble fraction. This method involves separating the liquid and solid contents by evaporation. Further processing steps include extracting and recovering by evaporation the remaining soluble lipid fraction from the solid contents by using a solvent such as ethanol. See e.g., WO 00/23546."

(Exhibit 1001, 1:31-40).

Patentee also acknowledges that, "[t]he methods described above rely on the processing of frozen krill that are transported from the Southern Ocean to the processing site. This transportation is both expensive and can result in degradation of the krill starting material." (Exhibit 1001, col. 2, lines 3-6).

Patentee also states, "[s]upercritical fluid extraction with solvent modifier has previously been used to extract marine phospholipids from salmon roe, but

has not been previously used to extract phospholipids from krill meal. *See, e.g.*, Tanaka et al., J. Oleo. Sci. (2004), 53(9), 417-424." (Exhibit 1001, col. 1, line 65 to col. 2, line 2). However, this statement is demonstrably false in view of the disclosure of Catchpole (Exhibit 1009) discussed further below. *See also*, Halliday, Jess, "Neptune-Degussa Deal to Develop Phospholipids, Adapt Krill Oil," http://www.nutraingredients-usa.com/Suppliers2/Neptune-Degussa-deal-to-develop-phospholipids-adapt-krill-oil, December 12, 2005. (Exhibit 1031, p. 0002, "Degussa is renowned for its expertise in supercritical CO_2 extraction.").

With regard to krill compositions, Patentees admit, "[a] krill oil composition has been disclosed comprising a phospholipid and/or a flavonoid. The phospholipid content in the krill lipid extract could be as high as 60% w/w and the EPA/DHA content as high as 35% (w/w). *See, e.g.*, WO 03/011873." (Exhibit 1001, col. 1, lines 53-56).

The analysis of the extracted krill oil is disclosed in the '877 patent in Table 21, which shows the amount of phospholipids, triglycerides and omega-3 fatty acids in the extract. Tables 22 and 23 provide the only ether phospholipid data in the entire specification. Example 8 of the '877 patent concludes:

> The main polar ether lipids of the krill meal are alkylacylphosphatidylcholine (AAPC) at 7-9% of total polar lipids, lysoalkylacylphosphatidylcholine (LAAPC) at 1% of total polar lipids (TPL) and alkylacylphosphatidyl-ethanolamine (AAPE) at <1% of TPL.

(Tallon Decl. ¶ 210).

All of the issued claims include the ***"from about 3% to about 10% w/w"*** ether phospholipid limitation and it appears to be the element that Patentee relies upon for novelty. However, as demonstrated herein, krill oil containing ether phospholipid levels between about 3% and about 10% was known in the prior art.

C. Prosecution History of the '877 Patent

The '877 patent issued on May 12, 2015 from U.S. Application No. 14/490,176, filed September 18, 2014. The '877 patent is a continuation of U.S. Patent Application No. 12/057,775, filed on March 28, 2008 and claims the benefit of four U.S. provisional applications: 61/024,072, filed on January 28, 2008; 60/983,446, filed on October 29, 2007; 60/975,058, filed on September 25, 2007; and 60/920,483, filed on March 28, 2007. Support for the claim element

"ether phospholipid" – required by each '877 claim – was not introduced until the filing of the U.S. Application No. 61/024,072. (*See* Exhibits 1002-1005). Consequently, "the earliest priority date" for the claims of the '877 patent is January 28, 2008.

During the prosecution of the '877 patent (Exhibit 1025), a final Office Action was mailed on January 13, 2015 in which all of the claims were rejected. Exhibit 1025, Part 1, pp. 0091-0097. After a telephone interview with the Applicant's attorney on March 13, 2015, the Examiner issued a Notice of Allowance on April 6, 2015 with an Examiner's Amendment. In the Examiner's Amendment, claim 1 was amended to require *steps (a) and (b) of the method to be performed on board a ship*. Prior to the Examiner's Amendment, Claim 1 did not require step (a) (providing krill) and step (b) (treating the krill) to be performed on board a ship. Thus, the Examiner only found Claim 1 to be allowable over the prior art if steps (a) and (b) were performed on board a ship. (Exhibit 1025, Part 1, pp. 0011-0017).

All of the claims of the '877 patent have the claim limitation of "from about 3% to about 10% w/w ether phospholipids." Applicant relied on this limitation in

asserting patentability of the claims.

In parent application no. 12/057,775, which issued as U.S. Patent No. 9,034,388, Applicant amended the claims to add the limitation "about 3% to about 10% ether phospholipid" and argued that the cited references do not teach extraction of a krill oil having the amended limitations. (*See* Response to Office Action dated September 7, 2012.) The claims are directed to "a method of producing krill oil….from about 3% to about 10% w/w ether phospholipids". (Exhibit 1024, Part 2, pp. 00633-0650).

Furthermore, it is noted that in the prosecution history of U.S. Patent Application No. 9,078,905 (U.S. Patent Application No. 14/490,221), Applicants rely on the limitation of ether phospholipid levels in asserting patentability of the claims therein. (*See* Exhibit 1026).

In particular, a Non-Final Office Action was mailed November 17, 2014 (Exhibit 1026, part 1, pp. 0168-0177) that rejected all the as-filed claims. The Examiner asserted two United States Patents as prior art arguing that the disclosures these patents made the as-filed claims obvious: Beaudoin (Exhibit 1016); and Porzio (Exhibit 1019). Beaudoin was characterized as disclosing krill

oil components including phospholipids and triglycerides at similar concentrations as presented in the claims. This was combined with Porzio, which teaches how to encapsulate lipid compositions. A Response to the Non-Final Office Action was filed on December 19, 2014 (Exhibit 1026, part 1, pp. 0242-0251) with no claim amendments. The cited art was distinguished on the basis that it did not disclose a krill oil comprising "from about 3% - 15% ether phospholipids." It was argued that Beaudoin's '299 patent extraction method was virtually identical to the NKO (Neptune Krill Oil) extraction process and would therefore be less than 3%.

An analysis was presented of the NKO composition in the '877 patent (Example 8 and Table 22), showing that NKO has 7% AAPC and 1.2% LAAPC, *i.e.,* a total ether phospholipid content of 8.2% of total phospholipids. It was argued that this percentage corresponded to an actual 2.46% value[2] when relative to the krill oil (*e.g.,* based upon a 30% measurement of total NKO phospholipids). It was argued, "[a]pplicant respectfully submits that this demonstrates that krill oil made by the Beaudoin method does not contain the claimed range of 3% to 15%

[2] This is an admission that Beaudoin describes krill oil having just below 3% ether phospholipids.

ether phospholipids as a percentage of the total krill oil composition." (Exhibit 1026, part 1 pp. 0242 - 0251).

A Final Rejection was mailed on February 17, 2015 (Exhibit 1026, part 1, pp. 0168 - 0177) where the non-statutory double patenting and obviousness rejections were maintained. The Examiner maintained that the calculated 2.46% ether phospholipid concentration in Beaudoin was close enough to the claimed range such that it would be obvious for one of ordinary skill in the art to optimize the extraction process through routine means to increase the ether phospholipid content to the claimed 3% concentration because of the known health benefits of ether phospholipids.

A Response to the Final Office Action was filed on April 16, 2015 (Exhibit 1026, part 1, pp. 0159 - 0164) with no claim amendments. Instead, an argument concerning alleged unexpected results was made in which the Applicants directed the examiner's attention to Example 9 and some selected figures referred to therein that allegedly compares the claimed krill oil (designated Superba or PL2) to prior art krill oil (designated NKO or PL1).

While Applicants relied on the above-quoted statement that "greater than

3% ether phospholipids have superior activity," there is no evidence of superior activity art and, in fact, the only disclosure of ether phospholipid amounts is in Table 22 and Table 23. (Tallon Decl. ¶ 165). Moreover, the claims specify "about 3%" – not "greater than 3%." Nevertheless, it appears that this "superior results" argument convinced the Examiner, since a Notice of Allowance followed on May 20, 2015 (with no written reasons for the allowance).

Accordingly, throughout the prosecution of the '877 patent family, Applicants repeatedly stressed the importance of krill oil compositions with greater than 3% ether phospholipids in gaining allowance of the claims.

D. Construction of the '877 Patent Claim Terms

As discussed above, a claim in *inter partes* review is given the "broadest reasonable construction in light of the specification." *See* 37 C.F.R. § 42.100(b).

Petitioner sets forth herein its recommended interpretation of certain claim terms, the scope of the claims being unclear on their face.

1. Claims 1 and 11 - "krill oil"

The term "krill oil" is found in all of the independent claims, i.e., Claims 1 and 11. The meaning of "krill oil" can be determined from the specification. The

'877 specification states:

> In order to isolate the krill oil from krill, solvent extraction methods have been used. See, e.g., WO 00/23564. Krill lipids have been extracted by placing the material in a ketone solvent (e.g., acetone) in order to extract the lipid soluble fraction. (Exhibit 1001, Col. 1, lines 31-34).

Accordingly, patentees equate krill oil with the lipids extracted from krill.

The '877 Patent further describes "krill oil" is a lipid-rich extract of krill. This extract can primarily include phospholipids and neutral lipids in varying proportions. The abstract of the '877 Patent describes the "actual krill oils" as the oil extracted using a polar solvent after using a non-polar solvent to remove neutral lipids: "The krill oils are obtained from krill meal using supercritical fluid extraction in a two stage process. Stage 1 removes the neutral lipid by extracting with neat supercritical CO_2 or CO_2 plus approximately 5% of a co-solvent. Stage 2 extracts the *actual krill oils* by using supercritical CO_2 in combination with approximately 20% ethanol" (Exhibit 1001, Abstract, emphasis added). The '877 patent therefore also discloses krill oil as a phospholipid rich extract produced by removing some or much of the triglyceride and other neutral oils. In addition, the

'877 Patent describes "combining said polar extract and said neutral extract to provide *Euphausia superba* krill oil…" (Exhibit 1001, Col. 5, line 55- Col. 6, line 11; *see also* Tallon Dec. ¶ 37).

Additionally, in the context of the '877 Patent, "krill oil" is a lipid-rich extract of krill that comprises phospholipids, as well as a lipid-rich extract of krill that comprises blends of polar lipids (phospholipids) and neutral lipids in varying proportions. The '877 Patent repeatedly refers to the krill oil composition as comprising blend of lipid fractions. "In some embodiments, krill oil composition comprises a blend of lipid fractions obtained from krill" ('877 Patent, 3:26-27, Exhibit 1001, p. 0025). "In some embodiments, the blended krill oil product comprises a blend of lipid fractions obtained from *Euphausia superba*" ('877 Patent, 5:43-45 and 6:50-52, Exhibit 1001, p. 0027; Exhibit 1001, 7:18-20, p. 0028). (*See* Tallon Decl. ¶¶ 35-48).

Thus, the proper construction of "krill oil" is "lipids extracted from krill." (See Tallon Decl. ¶ 48.)

2. Claims 1 and 11 – "denature lipases and phospholipases"

Claims 1 and 11 include the step of treating "to denature lipases and

phospholipases in said krill." The term "denature" is not expressly defined in the specification, but is described.

In the Detailed Description of the '877 patent, patentees explain,

> The present invention provides methods to avoid decomposition of glycerides and phospholipids in krill oil and compositions produced by those methods....The solution to the problem is to incorporate a protein denaturation step on fresh krill prior to use of any extraction technology. Denaturation can be achieved by thermal stress or by other means. After denaturation the oil can be extracted by an optional selection of non-polar and polar solvents including use of supercritical carbon dioxide.

(Exhibit 1001, 9: 44-54).

Patentees also explain:

> In some preferred embodiments, freshly caught krill is first subjected to a protein denaturation step. The present invention is not limited to any particular method of protein denaturation. In some embodiments, the denaturation is accomplished by application of chemicals, heat, or combinations thereof. In some embodiments, freshly caught krill is wet pressed to obtain oil and meal. In some embodiments, the meal is then heated to

> a temperature of about 50°C to about 100°C for about 20 minutes to about an hour, preferably about 40 minutes to denature the proteins. In some embodiments, this material is then pressed to yield a pressed cake. When this method is used on krill, only a small amount of oil is released. Most of the oil is still present in the denatured meal.

(Exhibit 1001, 10:26-40).

This disclosure is consistent with the extrinsic evidence. Hawley's Condensed Chemical Dictionary defines "denaturation" as "a change in the molecular structure of globular proteins that may be induced by bringing a protein solution to its boiling point or by exposing it to acids or alkalies, or to various detergents….It involves rupture of hydrogen bonds so that the highly ordered structure of the native protein is replaced by a looser and more random structure…." (Exhibit 1028, pp. 003-004.) (Tallon Decl. ¶ 58).

Proteins are like ribbons that coil to form more stable structures, for example, alpha helices and pleated sheets. The final three-dimensional structure of the protein is formed by non-covalent interactions between the amino acids of the protein. A quaternary structure is formed when multiple three-dimensional

proteins bind to form a single larger protein. (Tallon Decl. ¶ 59). Thus, the "looser and more random structure" from denaturation causes proteins, such as enzymes, to lose their activity because the substrates can no longer bind to the active site of the enzyme. (Tallon Decl. ¶ 60).

It is well known that active lipases and phospholipases, enzymes present in krill, if not deactivated, will cause triglycerides (triacylglycerols) and glycerol-based phospholipids (phosphoglycerides) present in the krill to decompose and form free fatty acids. (*See* for example, Saether, p. 51, Exhibit 1027, p. 0001.) (Tallon Decl. ¶ 60). It is also well known that an effective method to denature enzymes is to apply heat. (*See, e.g.*, Yoshitomi, Exhibit 1033, p. 0001, Abstract, "The [krill] product is produced by a process including only heating as means for denaturing protein and disabling the proteolytic enzymes originally contained in krill materials.") (Tallon Decl. ¶ 167).

Thus, "to denature lipases and phospholipases" means "to alter the conformational structure of lipases and phospholipases to reduce lipid and phospholipid decomposition." (Tallon Decl. ¶¶ 55-62).

3. Claims 1 and 11 – "polar solvent"

The element of "polar solvent" as set forth in Claim 1 and 11 is not explicitly defined in the specification, but is described. In the Krill Processing section of the Detailed Description, applicants disclose methods of making a *Euphausia superba* krill oil by contacting a *Euphausia superba* preparation, such as *Euphausia superba* krill meal with a polar solvent, such as ethanol to extract lipids. (Exhibit 1001, col. 12, lines 24-36). (Emphasis supplied). Applicants also disclose, "In some embodiments, krill oil is extracted from denatured krill meal. In some embodiments, the krill oil is extracted by contacting the krill meal with ethanol." (Exhibit 1001, Col. 11, lines 3-5).

In the Background of the Invention, patentees admit:

> In order to isolate the krill oil from the krill, solvent extraction methods have been used. See, e.g., WO 00/23546. Krill lipids have been extracted by placing the material in a ketone solvent (e.g., acetone) in order to extract the lipid soluble fraction. .... Further processing steps include extracting and recovering by evaporation the remaining soluble lipid fraction from the contents by using a solvent such as ethanol. *See, e.g.*, WO 00/23546.

(Exhibit 1001, l: 31-40).

In the Detailed Description, patentees disclose:

> In some embodiments, krill oil is extracted from the denatured krill meal. In some embodiments, the krill oil is extracted by contacting the krill meal with ethanol. In some embodiments, krill is then extracted with a ketone solvent such as acetone. In other embodiments, the krill oil is extracted by one or two step supercritical fluid extraction. In some embodiments, the supercritical fluid extraction uses carbon dioxide and neutral krill oil is produced. In some embodiments, the supercritical fluid extraction uses carbon dioxide with the addition of a polar entrainer, such as ethanol, to produce a polar krill oil. In some embodiments, the krill oil meal is first extracted with carbon dioxide followed by carbon dioxide with a polar entrainer, or vice versa. In some embodiments, the krill meal is first extracted with CO_2 supplemented with a low amount of a polar co-solvent (e.g., from about 1% to about 10%, preferably about 5%) such a C_1-C_3 monohydric alcohol, preferably ethanol, followed by extraction with CO_2 supplemented with a high amount of a polar co-solvent (from about 10% to about 30%, preferably about 23%) such as such a C_1-C_3 monohydric alcohol, preferably ethanol, or vice versa.

(Exhibit 1001, 11:3-24).

Thus, the '877 Patent contemplates extraction with a polar solvent or supercritical CO_2 in the presence of a polar solvent or entrainer. (*See* Tallon Decl. ¶ 52.)

The solvent must also be able to extract lipids that include phospholipids. The '877 patent explains, "[i]n some embodiments, the present invention provides a method of making a *Euphausia superba* krill oil composition comprising contacting *Euphausia superba* with a polar solvent to provide an polar extract comprising phospholipids." (Exhibit 1001, Col. 6, lines 12-16). Typical polar organic solvents (pure or mixtures) used in industrial practice that meet these criteria include alcohols (e.g., methanol, ethanol, and isopropyl alcohol), ketones (particularly acetone), and esters (*e.g.* ethyl acetate). (*See* Tallon Decl. ¶ 53.)

Thus, the proper construction of "polar solvent" is "solvent or a mixture of solvents capable of extracting polar lipids comprising phospholipids." (Tallon Decl. ¶¶ 49-54).

4. Claims 3 and 11 - "freshly harvested krill"

The specification does not include the term "freshly harvested" with regard to the krill. The specification does refer to "freshly caught" krill, but does not

define the term or define how long the krill remains fresh after being caught. The only disclosure by the Patentee of the time lapse between harvesting and processing of the "freshly harvested" krill is found in the specification at col. 9, lines 33-36:

> The krill meal has been processed on board a ship in Antarctica using live krill as starting material in order to ensure the highest possible quality of the krill meal.

and Example 6 (col. 30), which states:

> Fresh krill was pumped from the harvesting trawl directly into an indirect steam cooker, and heated to 90C.

Patentees further explain, "[t]he methods described above rely on the processing of frozen krill that are transported from the Southern Ocean to the processing site. This transportation is both expensive and can result in degradation of the krill starting material." (Exhibit 1001, p. 0025, 2:5-7). (Tallon Decl. ¶ 63).

With regard to krill, it is well known that proteases and lipases naturally found within krill begin to digest the krill soon after catching. The '877 Patent explains that krill can quickly degrade between the time it is caught and the time it is processed:

> Data in the literature showing a rapid decomposition of the oil in krill explains why some krill oil currently offered as an omega-3 supplement in the marketplace contains very high amounts of partly decomposed phosphatidylcholine and also partly decomposed glycerides. Saether *et al.*, Comp. Biochem Phys. B 83B(l): 51-55 (1986)[Exhibit 1027, pp. 0001-0005]. The products offered also contain high levels of free fatty acids.

(Exhibit 1001, 2:2-13, p. 0025 (emphasis added). (Tallon Decl. ¶ 64).

This explanation is consistent with the extrinsic evidence. Webster's New Universal Unabridged Dictionary defines "fresh" in relevant part to mean, "not spoiled, rotten, or stale; as fresh milk." (Exhibit 1029, p. 0003.) (Tallon Decl. ¶ 65).

Thus, the proper construction of the term "freshly harvested krill" is "recently caught krill that has not significantly degraded." (Tallon Decl. ¶¶ 63-67).

5. Claim 6 - "polar entrainer"

The specification does not specifically define the term "polar entrainer" but the Patentee discloses that ethanol is an example of a polar entrainer (col. 11,

line 12) and that:

> Surprisingly, it has been found that use of a low amount of polar solvent in the CO_2 as an entrainer facilitates the extraction of neutral lipid components and astaxanthin in a single step. Use of the high of polar solvent as an entrainer in the other step facilitates extraction of ether phospholipids, as well as non-ether phospholipids.

(Exhibit 1001, 11:23-28)

Thus, the proper construction of "polar entrainer" is "a polar solvent additive to aid in extraction." (Tallon Decl. ¶¶ 68-70).

VI. EACH GROUND PROVIDES MORE THAN A REASONABLE LIKELIHOOD THAT EACH CLAIM OF THE '877 PATENT IS UNPATENTABLE

A detailed discussion of each ground for claim invalidation, i.e., Grounds 1-4, is set forth below. In support of the invalidity arguments, Petitioner relies upon the Declaration of Dr. Stephen Tallon (Exhibit 1006) and the opinions and analyses set forth therein.

A. Ground 1: §103(a) – Breivik, Catchpole, and Fricke [Claims 1-3, 6, 8-9, 11-12, 15 and 17-18]

1. Claims 1 and 11

The '877 patent includes two (2) independent claims (claims 1 and 11) and a total of nineteen (19) claims, all directed to methods for producing krill oil.

(a) The three steps in the method of claim 1 are disclosed

Steps (a) and (b) of claim 1 require "krill" be provided for processing into a denatured krill product.

(i) providing krill

Breivik (Exhibit 1035) is entitled "Process for Production of Omega-3 Rich Marine Phospholipids From Krill." Breivik states in the Abstract "The present disclosure relates to a process for preparing a substantially total lipid fraction from fresh krill, a process for separating phospholipids from other lipids, and a process for producing krill meal." (Exhibit 1035, p. 0001). Breivik further states, "It is a main object of the present invention to provide a process for preparing a substantial total lipid fraction from fresh krill…." (Exhibit 1035, p. 0004, ¶ [0014]). (Tallon Decl., ¶¶ 184-185, 189). Fricke (Exhibit 1010) also discloses

obtaining lipids from krill. (Exhibit 1035, p. 0001, 2nd col.). (Tallon Decl. ¶ 98-100). Thus, both Breivik and Fricke disclose providing krill for lipid extraction.

(ii) Treating the krill to provide a denatured product

Claim 1 requires, "treating said krill to denature lipases and phospholipases in said krill to provide a denatured krill product."

Breivik discloses, "The optional pre-treatment involving short-time heating of the fresh krill will also give an inactivation of enzymatic decomposition of the lipids, thus ensuring a product with very low levels of free fatty acids." (Exhibit 1035, pp. 0004-0005, ¶ [0015]). Breivik further discloses, "Fresh *E. superba* (200 g) was washed with ethanol (1:1) as in example 2, but with the difference that the raw material had been pre-treated at 80°C for 5 minutes." (Exhibit 1035, p. 0006, ¶ [0047]). Breivik also teaches, "The heat treatment gives a[n] additional result that the highly active krill digestive enzymes are inactivated, reducing the potential lipid hydrolysis." (Exhibit 1035, p. 0007, ¶ [0053]). Breivik also teaches that "pre-heating to 95°C tended to increase the yield of lipids in step a) even higher than pre-heating to 80°C." (Exhibit 1035, p. 0007, ¶ [0052]). (Tallon Decl. ¶¶ 191, 193-194, 199-200, 227).

In Fricke (Exhibit 1010), lipid extraction from the krill samples was performed according to the method of Folch et al., (J. Biol. Chem. 226:497-509 (1957). That is, "the lipides were extracted by homogenizing the tissue with 2:1 chloroform-methanol (v/v) [a polar solvent], and filtering the homogenate" (Folch, Exhibit 1017, p. 0001). The krill samples used by Fricke for extraction and analysis were taken from the Scotia Sea (those caught in December 1977) and from the Gerlache Strait (those caught in March 1981). Fricke noted that, in the 1977 sample, the free fatty acid (FFA) content is about twice that of the 1981 sample. Fricke speculates that the high value could be caused by the longer storage time of the 1977 sample (Exhibit 1010, p. 0002, col, 2). Therefore, samples of the same haul were *cooked (i.e., heated) on board immediately after hauling* and stored under the same conditions. As expected, they showed a FFA content ranging from 1% - 3% of total lipids, which was much lower than the non-cooked samples. Furthermore, Fricke noted that the low FFA content of freshly caught krill had been confirmed by others. (Exhibit 1010, 1st col. p. 0003). (Tallon Decl. ¶¶ 99-100, 228.)

Thus, both Breivik and Fricke disclose denaturing using heat. (Tallon Decl.

¶¶ 227-229).

(iii) Extracting krill oil with a polar solvent

Extracting krill oil with a polar solvent is well known. Breivik discloses:

> In a preferred embodiment of the invention it is provided a process for extracting a substantially total lipid fraction from fresh krill, comprising the steps of:
>
> a) reducing the water content of the krill raw material;
>
> a-1) extracting the water reduced krill material from step a) with CO_2 containing ethanol, the extraction taking place at supercritical pressure; and
>
> b) isolating the lipid fraction from the ethanol.

(Exhibit 1035, p. 0005, ¶ [0021]). Breivik also discloses, "A second extraction with CO_2 containing 10% ethanol resulted in an extract of 100 g/kg (calculated from starting sample weight). ^{31}P NMR showed that the product contained phospholipids. The extract contained a sum of EPA plus DHA of 33.5%." (Exhibit 1035, p. 0006, ¶ [0034]). Breivik also teaches, "Fresh *E. superba* (200 g) was washed with ethanol (1:1) as in example 2, but with the difference that the raw material had been pre-treated at 80°C for 5 minutes. This gave an ethanol extract

of 7.3%. Supercritical fluid extraction with CO_2 containing 10% ethanol gave an additional extract of 2.6% calculated from the fresh raw material." (Exhibit 1035, p. 0006, ¶ [0047]). (See Tallon Decl. ¶¶ 192, 195-196, 198, 199, 230).

Catchpole (Exhibit 1009) also discloses using a polar organic solvent (ethanol) with SC-CO_2 to extract phospholipids from krill. Catchpole expressly discloses, "The residual powder was then extracted with CO_2 and absolute ethanol, using a mass ration of ethanol to CO_2 of 11%." (Exhibit 1009, *see e.g.*, p. 0024, lines 1-18). (See Tallon Decl. ¶¶ 87, 91, 96, 231.) The '877 patent discloses ethanol as a preferred solvent. (See Section V.D.3).

Fricke also describes lipid extraction from krill samples with a polar solvent. Fricke teaches, "Krill samples of 5kg were quick-frozen and stored at -35C until analyzed. Subsamples prepared from the core of the 5kg samples were homogenized in a mortar under liquid nitrogen, and lipid extraction was performed according to Folch *et al.* (15)." (Exhibit 1010, p. 0001, 2nd col.). Folch, in turn, teaches extracting the lipids using 2:1 chloroform-methanol mixture (v/v). (Folch, Exhibit 1017, p. 0001). (See Tallon Decl. ¶¶ 99, 232).

Thus, it would be obvious to a POSITA to extract oil from a denatured krill product with a polar solvent as set forth in Claim 1. (*See* Tallon Decl. ¶ 233).

(b) The two steps in the method of claim 11 are disclosed

(i) obtaining a denatured krill product produced by treating freshly harvested krill

Although step (a) in Claim 11 is stated as one step, subsumed in step (a) is the catching of krill insofar as that is how krill is "obtained." The "freshly harvested" element is discussed further below.

Breivik discloses denaturing by heating (*e.g.,* 80ºC for 5 minutes) to avoid enzymatic decomposition of the krill lipids and provide a product with a low level of free fatty acids. (Exhibit 1035, pp. 0004-0005, ¶ [0015]; p. 0006, ¶ [0047]; p. 0007, ¶ [0053]; p. 0007, ¶ [0052]). (Tallon Decl. ¶¶ 191, 193-194, 199-200, 227).

Also, as discussed above, Fricke discloses cooking the krill on board the ship immediately after hauling to reduce the level of free fatty acids in the extracted krill oil. (Exhibit 1010, p. 0003), (Tallon Decl. ¶¶ 99-100, 228).

Thus, the cooking of freshly harvested krill by Fricke also discloses the treating to denature lipases and phospholipases of freshly harvested krill in step

(a) of claim 11. (Tallon Decl. ¶ 227-229.)

(ii) a polar solvent is used to extract krill oil from the denatured krill product

As demonstrated in connection with Claim 1, Breivik teaches extracting krill oil using ethanol, a well-known polar solvent. (Exhibit 1035, p. 0005, ¶ [0021]; p. 0006, ¶ [0034]; p. 0006, ¶ [0047]). (See Tallon Decl. ¶¶ 192, 195, 198, 199, 230).

Catchpole (Exhibit 1009) also discloses using a polar organic solvent (ethanol) with SC-CO_2 to extract phospholipids from krill (Exhibit 1009, *see e.g.*, p. 0024, lines 1-18) (*See* Tallon Decl. ¶¶ 87, 91, 96, 231).

Fricke also describes lipid extraction from krill samples with a polar solvent ("Krill samples of 5kg were quick-frozen and stored at -35C until analyzed. Subsamples prepared from the core of the 5kg samples were homogenized in a mortar under liquid nitrogen, and lipid extraction was performed according to Folch *et al.* (15)." (Exhibit 1010, p. 0001, 2nd col.) (*See* Tallon Decl. ¶¶ 99, 232).

Thus, it would be obvious to a POSITA to treat freshly harvested krill to obtain a denatured krill product and extract krill oil using a polar solvent. (Tallon

Decl. ¶ 227-229.)

(c) Claim 1 requires denaturing "on a ship" and Claim 11 requires denaturing "freshly harvested krill"

Claim 1 requires treating krill to denature the krill and form a denatured krill product on board a ship before a polar solvent is used to extract krill oil from the denatured krill product. Claim 11 is directed to a similar method but, instead of requiring the krill to be denatured on board a ship, claim 11 requires a method that treats "freshly harvested krill" to denature the krill and obtain a denatured krill product before a polar solvent is used to extract krill oil from the denatured krill product.

Claim 11 combines steps (a) and (b) of claim 1 into step (a) of claim 11. Step (a) of claim 11 requires "freshly harvested krill" be provided for processing into a denatured krill product. Thus, the only difference between claim 1 and claim 11 is that claim 1 requires krill to be processed "on board" and claim 11 requires "freshly harvested krill" to be processed.

Breivik teaches both possibilities, stating "[a]s the process according to the invention requires a minimum of handling of the raw materials, and is well suited

to be used on *fresh* [krill], for example *onboard the fishing vessel*, the product according to the invention is expected to contain substantially less hydrolysed and/or oxidised lipids than lipid produced by conventional processes. This also means that there is expected to be less deterioration of the krill lipid antioxidants than from conventional processing." (Exhibit 1035, ¶ [0015] p. 0004-0005,). Breivik also teaches, "In the following, *'fresh krill'* is defined as krill that is treated immediately after harvesting or sufficiently short time after harvesting to avoid quality deterioration like hydrolysis or oxidation of lipids, or krill that is frozen immediately after harvesting." (Exhibit 1035, p. 0005, ¶ [0030]) (Emphasis supplied) (Tallon Decl. ¶¶191, 197, 219).

Fricke teaches, "Samples of the same haul which were *cooked on board immediately after hauling* and stored under the same conditions showed a FFA content which was much lower, ranging from 1% to 3% of total lipids." (Exhibit 1010, pp. 0002-0003, 1st col.) (Tallon Decl. ¶¶100, 220).

Thus, it would be obvious to a POSITA to treat "freshly harvested krill" (Claim 11) "on a ship" (Claim 1) to obtain a denatured krill product. (Tallon Decl., ¶¶ 219, 220, 233).

(d) Claim 1 and Claim 11 require the same krill oil components which are disclosed

Claims 1 and 11 are directed to three and ostensibly two-step methods for providing krill oil. Both claims require the krill oil to have "from about 3% to about 10% w/w ether phospholipids; from about 27% to 50% w/w non-ether phospholipids; from about 30% to 60% w/w total phospholipids; and from about 20% to 50% w/w triglycerides." All of the components are well-known components of lipids extracted from krill.

(i) total phospholipids

Table 16 of Example 18 of Catchpole (Exhibit 1009) discloses Extract 2 includes ***45.1% total phospholipids*** (PC+PI+PS+PE+CL+AAPC+AAPE).

Table 16

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

(Exhibit 1017, p. 24). Thus, Catchpole discloses "from about 30% to 60% w/w" total phospholipids as required by the Patentee's Claims 1and 11. (Tallon Decl.

¶¶ 95, 96, 234, 235).

(ii) ether phospholipids

Catchpole (Exhibit 1009) discloses in Table 16 (p. 0024) that Extract 2 had total phospholipid concentrations of 45.1% extracted from krill powder; including two ether phospholipids—4.6% AAPC and 0.2% alkylacylphosphatidylethanolamine ("AAPE")—having a total concentration of ***4.8% ether phospholipids***.

Table 16

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

Both AAPC and AAPE are ether phospholipids. Thus, both ether phospholipids would total 4.8% which is within the 3% of 10% range required by Claim 1 and Claim 11. (Tallon Decl. ¶¶ 95, 96, 234, 235).

(iii) non-ether phospholipids

Catchpole (Exhbit 1009) shows the fractionation of krill lipids extracted from krill powders in Table 16 (p. 24). The composition in Extract 2 has 45.1% total phospholipids, including 4.8% ether phospholipids (4.6% AAPC + 0.2%

AAPE). Therefore, Catchpole discloses the remaining phospholipids are ***40.3% non-ether phospholipids*** (i.e., 45.1% - 4.8%). Thus, the "from about 27% to 50% w/w non-ether phospholipids" element required by the Patentee's Claim 1 is disclosed by Catchpole. (Tallon Dec. ¶¶ 95, 96, 234, 235).

(iv) triglycerides

Table 1 (Exhibit 1010, Table 1, p. 0002, col. 2) of Fricke shows the lipid composition of the Antarctic krill for both the 1977 and 1981 samples. Fricke reports levels of triacylglycerols (triglycerides) of 33.3 +/- 0.5 and 40.4 +/- 0.1 for both the 1977 and 1981 samples, respectively.

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

Thus, Fricke discloses the "from about 20% to 50% w/w triglycerides" required by claims 1 and 11. (Tallon Dec. ¶¶ 101, 236, 238).

Thus, in view of Breivik, Fricke, and Catchpole, a POSITA would find

claims 1 and 11 to be obvious. (Tallon Dec. ¶¶ 219-239, 261).

2. Claims 2 and 12

Claims 2 and 12 require the ***heat treatment*** of krill. As discussed above, Breivik discloses denaturing by heating (*e.g.* 80°C for 5 minutes) to avoid enzymatic decomposition of the krill lipids and provide a product with a low level of free fatty acids. (Exhibit 1035 p. 0004-0005, ¶ [0015]; p. 0006, ¶ [0047]; p. 0007, ¶ [0053]; p. 0007, ¶ [0052). (Tallon Decl. ¶¶ 191, 199, 200).

Also, as discussed above, Fricke discloses cooking the krill on board the ship immediately after hauling to reduce the level of free fatty acids in the extracted krill oil. (Exhibit 1010, p. 0003). (Tallon Decl. ¶¶ 100, 243).

Thus, Breivik and Fricke both describe the additional requirements of claims 2 and 12 of treating by heating. Accordingly, in view of the disclosures in Breivik, Fricke, and Catchpole, a POSITA would find the krill methods and compositions of claims 2 and 12 to be obvious. (Tallon Decl. ¶¶ 240-245, 261).

3. Claim 3

Claim 3 requires the krill to be ***freshly harvested***. Breivik teaches processing "onboard the fishing vessel" to reduce deterioration of the krill lipid.

(Exhibit 1035, ¶ [0015] p. 0004-0005). Breivik also teaches, treating "fresh krill" which is "defined as krill that is treated *immediately after harvesting* or sufficiently short time after harvesting to avoid quality deterioration like hydrolysis or oxidation of lipids, or krill that is frozen immediately after harvesting." (Emphasis supplied). (Exhibit 1035, p. 0005, ¶ [0030]) (Tallon Decl., ¶¶ 191, 196, 197).

Moreover, Fricke discloses that freshly harvested krill were cooked on board the ship immediately after they were caught (Exhibit 1010, pp. 0002-0003). (Tallon Decl., ¶¶ 100, 248).

Thus, in view of Breivik and Fricke in combination with Catchpole, a POSITA would find claim 3 to be obvious. (Tallon Dec. ¶¶ 246-248, 261.)

4. Claims 6 and 15

Claims 6 and 15 require that the extracting comprises the use of ***supercritical fluid extraction with a polar entrainer***. As mentioned above (Section V.D.5), the '877 patent states, "[T]he supercritical fluid extraction uses carbon dioxide with the addition of a polar entrainer, such as ethanol, to produce a polar krill oil." (Exhibit 1001, 11:12-13). This element is disclosed by both

Breivik and Catchpole.

Breivik discloses "extracting…with CO_2 containing 10% ethanol…."(Exhibit 1035, p. 0005, ¶ [0021]). Breivik also discloses, "A second extraction with CO_2 containing 10% ethanol resulted in an extract of 100 g/kg (calculated from starting sample weight)." (Exhibit 1035, p. 0006, ¶ [0034]). Breivik also teaches, "[s]upercritical fluid extraction with CO_2 containing 10% ethanol gave an addition extract of 2.6% calculated from the fresh raw material." (Exhibit 1035, p. 0006, ¶ [0047]) (Tallon Decl. ¶¶ 192, 198, 199, 250).

Catchpole discloses extracting phospholipids from freeze dried krill powder. Catchpole describes in Example 18 the extraction of krill lipids with CO_2 and absolute ethanol using a mass ratio of ethanol to CO_2 of 11%. (Exhibit 1009, p. 0024, lines 8-9) (Tallon Decl. ¶¶ 92, 251). Catchpole explains, "Supercritical fluid extraction processes using CO_2 are becoming increasingly popular because of a number of processing end consumer benefits. CO_2 can be easily removed from the final product by reducing the pressure, whereupon CO_2 reverts to a gaseous state, giving a completely solvent product. The extract is considered to be more 'natural' than extracts produced using other solvents…." (Exhibit 1009,

p. 0002, lines 18-25) (Tallon Decl. ¶ 87). Also, Catchpole discloses that it is an object of the invention described therein to provide a process for producing a product that contains desirable levels of particular phospholipids. (Exhibit 1009, p. 0003, lines 28-29) (Tallon Decl. ¶ 88).

Therefore, a POSITA would find the extraction of krill oil using a supercritical fluid and polar solvent (such as ethanol) in claims 6 and 15 to be obvious in view of Breivik and Catchpole in combination with Fricke. (Tallon Decl. ¶¶ 249-252, 261).

5. Claims 8 and 17

Claims 8 and 17 require that the krill is Antarctic krill. Breivik states, "[k]rill are small, shrimp-like animals, containing relatively high concentrations of phospholipids. In the group *Euphasiids*, there is more than 80 species, of which the Antarctic krill is one of these. The current greatest potential for commercial utilization is the Antarctic *Euphausia superba*….Another Antarctic krill species is *E. crystallorphias*." (Exhibit 1035, p. 0004, ¶ [0005]). Breivik further discloses, "The approximate composition of lipids from the two main species of Antarctic krill is given in Table 1." (Exhibit 1035, p. 0004, ¶ [0006]). Breivik also teaches,

"Furthermore, Antarctic krill has lower level of environmental pollutants than traditional fish oils." (Exhibit 1035, p. 0004, ¶ [0007]). (Tallon Decl. ¶¶ 187, 254).

Table 1 of Fricke is titled "Lipid Composition of Antarctic Krill (*Euphausia superba* Dana)" (Exhibit 1010, p.0002).

Thus, in view of Breivik, in combination with Catchpole and Fricke, a POSITA would find claims 8 and 17 to be obvious. (Tallon Dec. ¶¶ 253-255, 261).

6. Claims 9 and 18

Claims 9 and 18 depend on claims 8 and 17, respectively, and require the Antarctic krill in claims 8 and 17 to be *Euphausia superba*.

Breivik discloses, "In the group *Euphasiids*, there is more than 80 species, of which the Antarctic krill is one of these. The current greatest potential for commercial utilization is the *Euphausia superba*…."(Exhibit 1035, p. 0004, ¶ [0005]; see also [0006]). (Tallon Decl. ¶ 257, 258).

Table 1 of Fricke is titled "Lipid Composition of Antarctic Krill (*Euphausia superba* Dana)" (Exhibit 1010, p. 0002, Table 1).

Thus, in view of Breivik and Fricke in combination with Catchpole, a

POSITA would find claims 9 and 18 to be obvious. (Tallon Decl. ¶¶ 256-261).

Reason to Combine

A POSITA would have possessed a reason and motivation to combine the teachings found in Breivik, Catchpole, and Fricke. As indicated above, Breivik expressly discloses processing freshly captured krill on board the ship by heat treating (i.e., cooking) to produce a denatured krill product, and extracting krill oil using organic solvents. (Exhibit 1035, pp. 0004-0005, ¶ [0015]; p. 0006, ¶ [0047]; p. 0007, ¶ [0053]; p. 0005, ¶ [0021]; p. 0006, ¶ [0034]; p. 0006, ¶ [0047]). Breivik also acknowledges the well-known fact that "[m]arine phospholipids are useful in medical products, health food and human nutrition…" and that "[o]mega-3 fatty acids bound to marine phospholipids are assumed to have particularly useful properties." (Exhibit 1035, pp. 0004, ¶¶ [0002-0003]). Catchpole also discloses that phospholipids have been implicated in conferring a number of health benefits. Catchpole and Breivik disclose methods of extracting lipids from krill using conventional polar solvents and extraction techniques. (Exhibit 1009, p. 0001, lines 11-21, p. 0002, lines 1-6, and p. 0025, lines 9-13). Catchpole further discloses that the extract obtained from the methods disclosed therein are

considered to be more "natural" than extracts produced by other solvents. (Exhibit 1009, p. 0023, lines 18-19). Fricke indicates there were a number of prior publications that investigated the "lipid composition of this pelagic euphausiid." (Exhibit 1010, p. 0001, 1st col.) Fricke further noted the importance of prompt reduction of lipolytic enzymes to preserve phospholipids and their associated fatty acids, e.g. omega-3. (Exhibit 1010, pp. 0002-0003).

Additionally, as of the earliest effective filing date of the '877 patent it was demonstrated that phospholipids and, phosphatidlycholine in particular, were associated with beneficial health effects. (*See, e.g.*, Sampalis II, 1013, pp. 0017-0022). The health benefits of omega-3 fatty acids, particularly in connection with cardiovascular disease, was also well established. (*See, e.g.*, Bunea, Exhibit 1020, pp. 0001-0002). Moreover, it was known that "[k]rill oil has a unique biomolecular profile of phospholipids naturally rich in omega-3 fatty acids and diverse antioxidants significantly different than fish oil" and that "[t]he association between phospholipids and long-chain omega-3 fatty acids highly facilitates the passage of fatty acid molecules through the intestinal wall, increasing bioavailability…." (Bunea, Exhibit 1020, p. 0002, col. 1-2.)

Accordingly, a POSITA, performing the treatment and extraction steps disclosed in Breivik, would have been motivated to look to other references such as Fricke and Catchpole to ascertain the components of the krill oil and their amounts as obtained by standard extraction methods. (Tallon Decl. ¶¶ 28-32, 261).

B. Ground 2: §103(a) – Breivik, Fricke, Bottino, and Catchpole [Claims 4-5, and 13-14]

The discussions above regarding the obviousness of claims 1 and 11 are incorporated herein.

1. Claims 4 and 13

Claims 4 and 13 require that the ***krill oil comprises from about 20% to 35% omega-3 fatty acids*** as a percentage of total fatty acids in said krill oil. Bottino (Exhibit 1007) discloses krill oil having about 20% to 35% (30.5%, 26.8%, 25.0%, and 28.6 %) omega-3 fatty acids as a percentage of total fatty acids in the composition as required by claims 4 and 13. (Tallon Decl. ¶ 264.)

Bottino analyzed the fatty acid content of Antarctic phytoplankton and Euphausiids, in particular *Euphausia superba* and *Euphausia crystllorophias*. *E.*

superba is the better known species found in the Southern Oceans and has been considered almost a synonym for krill. (Exhibit 1007, 1st col., p. 0001). The *E. superba* samples were collected from various locations (stations) and lipids were extracted "immediately after capture" using a chloroform:methanol 2:1 v/v mixture as described in Folch *et al* (1957). The fatty acids were analyzed using chromatography. (Exhibit 1007, 2nd col., pp. 0001-0002).

Table 1 set forth below shows the fatty acid content in *E. superba* from 3 different stations as a weight percent of total fatty acids. The percentage of omega-3 fatty acids are circled in the chart and add up to 30.5%, 26.8%, and 25.0%, respectively. Thus, all three samples had an omega-3 fatty acid content of between 20% to 35% omega-3 fatty acids as a percentage of total fatty acids, as required by Claims 4 and 13. (Tallon Decl. ¶¶ 120, 121.)

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

Footnote c of Table 1 indicates "[o]nly those fatty acids present at a level of 1% or more are included." Table 3 from Bottino identifies all of the fatty acids identified from the various species tested as a weight percent of total fatty acids. The fatty acid content from *E. superba* is provided as an average of the 3 stations. The omega-3 fatty acid content from *E. superba* in Table 3 are circled below.

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

Fatty acid													*Euphausia superba* (average of 3 stations)	
18:2(n-3)	3.7	3.3	3.4	3.1	3.3	3.0	2.7	2.1	7.1	12.0	1.2	1.7	2.4	3.1
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	2.8	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)	3.0	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	0.6	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	8.2	7.0	6.4	1.7	2.1	5.3	6.0	2.1	18.4	23.6	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	4.8	7.9	8.4	5.5	0.9	0.8	2.1	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	6.4

When all of the omega-3 fatty acids are added, including those less than 1% omitted in Table 1, the total is 28.6%. (Tallon Decl. ¶¶ 120, 121).

Therefore, Bottino discloses the element wherein the krill oil further includes from about 20% to 35% omega-3 fatty acids as a percentage of total fatty acids in the composition as set forth in Claims 4 and 13. Thus, in view of Bottino in combination with Breivik, Fricke, and Catchpole, a POSITA would find Claims 4 and 13 to be obvious. (Tallon Decl. ¶¶ 263-264, 268).

2. Claims 5 and 14

The discussions above regarding the obviousness of Claims 1 and 11, and Claims 4 and 13 are incorporated herein.

Claims 5 and 14 require that ***from about 70% to 95% of the omega-3 fatty acids are attached to the total phospholipids***.

Table 1 in Fricke (Exhibit 1010, p. 0002) provides the amount of each lipid class in the total lipid composition. Tables 4 and 5 provide the omega-3 fatty acid composition of each phospholipid class (Exhibit 1010, p. 0004-0005). The omega-3 fatty acids in Tables 4 and 5 are identified as 18:3(n-3), 18:4(n-3), 20:5(n-3), 21:5(n-3), 22:5(n-3), and 22:6(n-3). (Tallon Decl. ¶ 106, n. 3).

TABLE 4

Fatty Acid Analysis of Polar Lipid Classes of *Euphausia superba* Dana

Polar lipid	PC		PE		LPC		PI		PA + CI	
Sample	12/1977	3/1981	12/1977	3/1981*	12/1977	3/1981*	12/1977	3/1981*	12/1977	3/1981*
14:0	4.5 ± 1.1	2.8 ± 1.1	2.9 ± 1.1	–	9.1 ± 5.4	4.2	3.5 ± 0.3	3.2	6.0 ± 1.4	–
15:0	–	–	–	–	–	–	–	1.6	–	–
16:0	43.7 ± 7.2	25.7 ± 1.4	42.7 ± 9.3	24.2	40.5 ± 8.9	18.7	33.9 ± 5.9	24.9	39.3 ± 6.3	23.7
16:1(n-7)	3.7 ± 0.4	2.2 ± 0.3	2.0 ± 1.0	1.9	4.4 ± 2.3	2.8	2.2 ± 0.9	1.2	3.6 ± 0.8	4.3
18:0	1.8 ± 0.5	1.5 ± 0.2	3.2 ± 1.0	2.9	2.1 ± 0.3	1.5	6.1 ± 1.0	7.3	2.5 ± 0.1	2.6
18:1(n-7)	7.7 ± 0.8	6.1 ± 0.8	15.0 ± 3.9	16.3	9.7 ± 3.7	4.0	11.6 ± 3.3	10.9	12.3 ± 0.6	14.7
18:1(n-9)	9.2 ± 1.7	5.4 ± 1.1	5.4 ± 2.1	6.8	10.3 ± 3.3	7.3	6.5 ± 0.4	7.9	4.9 ± 1.5	8.7
18:2(n-6)	1.6 ± 0.1	1.1 ± 0.1	1.0 ± 0.6	1.0	1.1 ± 0.8	1.6	1.7 ± 0.7	1.7	1.4 ± 0.1	1.5
18:3(n-3)	–	0.8 ± 0.2	–	–	–	1.1	–	0.6	–	1.6
18:3(n-6)	–	2.7 ± 0.4	–	0.7	–	3.8	–	–	–	1.7
18:4(n-3)	–	–	–	–	–	–	–	–	–	0.8
20:1(n-7)	–	–	–	–	–	–	–	–	–	–
20:1(n-9)	0.6 ± 0.1	0.9 ± 1.1	–	0.8	–	0.8	–	1.1	–	1.1
20:5(n-3)	10.7 ± 0.6	29.9 ± 2.2	10.5 ± 4.9	21.1	2.6 ± 0.1	31.2	8.1 ± 0.1	20.1	1.9 ± 1.0	19.7
21:5(n-3)	1.0 ± 0.7	1.1 ± 0.0	–	0.7	–	1.6	–	1.9	–	0.8
22:1(n-7)	–	0.9 ± 0.1	–	–	–	1.0	–	–	–	–
22:1(n-9)	–	1.7 ± 0.2	–	–	–	1.5	–	1.4	–	–
22:5(n-3)	0.9 ± 0.6	0.6 ± 0.2	–	0.9	–	1.1	–	1.8	–	–
22:6(n-3)	6.2 ± 0.6	11.5 ± 1.0	7.6 ± 2.3	19.2	1.2 ± 0.2	12.2	1.8 ± 0.7	10.1	1.1 ± 0.3	15.5
Phytanic acid	0.7 0.6	–	–	–	–	–	–	–	–	–

TABLE 5

Fatty Acid Analysis of Neutral Lipid Classes of *Euphausia superba* Dana

Neutral lipid	TAG		FFA		DG		MG		WE + SE	
Sample	12/1977	3/1981	12/1977	3/1981	12/1977*	3/1981*	12/1977*	3/1981*	12/1977*	3/1981*
12:0	0.5 ± 0.1	–	–	0.8 ± 0.2	–	–	–	–	3.7	–
14:0	23.3 ± 0.2	21.8 ± 2.0	7.9 ± 1.0	5.1 ± 0.7	4.5	6.1	2.1	3.8	14.8	8.8
15:0	0.5 ± 0.1	–	–	–	–	0.5	–	1.2	–	–
16:0	29.9 ± 1.6	21.8 ± 1.8	32.5 ± 1.1	12.1 ± 2.2	19.4	16.9	9.6	10.3	25.1	37.8
16:1(n-7)	8.9 ± 1.9	13.1 ± 0.3	4.8 ± 1.0	4.9 ± 0.5	5.6	7.1	2.0	6.6	10.8	8.8
18:0	1.5 ± 0.2	1.8 ± 0.3	1.5 ± 0.2	0.7 ± 0.1	2.1	2.0	–	2.1	2.2	2.6
18:1(n-7)	5.9 ± 1.1	6.6 ± 3.1	12.9 ± 2.7	8.5 ± 2.2	14.7	7.5	73.7	10.9	15.8	17.5
18:1(n-9)	11.9 ± 3.6	12.1 ± 2.5	7.1 ± 0.6	4.7 ± 1.3	6.5	10.4	2.3	14.5	14.3	11.9
18:2(n-6)	0.7 ± 0.5	1.0 ± 0.2	1.5 ± 0.3	0.9 ± 0.7	3.1	1.3	0.8	1.3	1.9	–
18:3(n-3)	–	–	–	0.7 ± 0.2	–	0.8	–	–	–	–
18:3(n-6)	–	4.1 ± 1.0	–	1.5 ± 0.7	0.7	3.0	–	1.8	–	–
18:4(n-3)	–	–	0.6 ± 0.2	3.5 ± 1.2	–	–	–	–	–	–
20:1(n-7)	0.5 ± 0.1	–	–	–	0.5	–	–	–	–	–
20:1(n-9)	0.8 ± 0.2	1.3 ± 0.9	0.5 ± 0.1	1.0 ± 0.3	0.8	0.8	–	0.6	–	–
20:5(n-3)	1.0 ± 0.1	3.3 ± 0.5	11.8 ± 2.2	30.0 ± 2.1	15.8	28.8	2.9	26.8	5.1	11.9
21:5(n-3)	–	–	0.5 ± 0.4	0.9 ± 0.2	–	0.7	–	1.4	–	–
22:1(n-7)	–	–	0.8 ± 0.3	–	2.0	–	–	–	–	–
22:1(n-9)	–	0.5 ± 0.2		0.9 ± 0.4	1.5	1.3	–	0.8	–	–
22:5(n-3)	–	–	0.5 ± 0.3	0.5 ± 0.1	2.5	–	–	1.0	–	–
22:6(n-3)	–	0.7 ± 0.2	6.3 ± 2.4	12.1 ± 1.5	7.0	8.2	1.7	12.8	–	–
Phytanic acid	5.6 ± 0.8	4.1 ± 0.6	1.5 ± 0.6	1.3 ± 0.7	1.5	1.6	1.4	1.3	0.8	0.7

Therefore, the amount of omega-3 and each lipid class relative to the total lipid can be calculated by multiplying the amount of omega-3 fatty acids for each lipid class by the amount of the particular lipid class in the total lipid composition.

This provides the amount of omega-3 associated with each lipid class. The total amount of omega-3 fatty acids associated with the lipid classes that constitute phospholipids can then be added. The total amount of omega-3 associated with phospholipids can then divided by the amount of omega-3 in the total lipid from all lipid classes to provide the percentage of omega-3 fatty acid attached to phospholipid. For the March 1981 sample, 74.81% of the omega-3 fatty acids are attached to phospholipids assuming the 3% free fatty acid content disclosed in Fricke. The calculation for the December 1977 sample is 82.03%. (Tallon Decl. ¶107-118).[3]

Thus, a POSITA would find the element "from about 70% to 95% of the omega-3 fatty acids are attached to the total phospholipids" required in Claims 5 and 14 to be obvious in view of Breivik, Catchpole, Fricke, and Bottino. (Tallon Decl. ¶¶ 265-268).

[3] Even if one assumes a 1% FFA content disclosed as the low end of Fricke or 4% FFA as disclosed in Budzinski, the values of omega 3 fatty acids attached to phospholipids as calculated all fall between the 70%-95%. (Tallon Decl. ¶¶ 117-118).

Reasons to Combine

A POSITA would have possessed a reason to combine the teachings found in Bottino with the references set forth in Ground 1 because Bottino discloses the fatty acid levels naturally found in a lipid extract of *Euphausia superba*. Bottino explains that the study of krill at the time of the article (1974) had become intensive as a result of its potential importance as food. (Exhibit 1007, p. 0001, 1st col.). The health benefits of omega-3 fatty acids, particularly in connection with cardiovascular disease, was also well established. (See, e.g., Bunea, Exhibit 1020, pp. 0001-0002). Moreover, it was known that "[k]rill oil has a unique biomolecular profile of phospholipids naturally rich in omega-3 fatty acids and diverse antioxidants significantly different than fish oil" and that "[t]he association between phospholipids and long-chain omega-3 fatty acids highly facilitates the passage of fatty acid molecules through the intestinal wall, increasing bioavailability…." (Bunea, Exhibit 1020, p. 0002, col. 1-2.) As described above, Catchpole describes the benefits of using CO_2 extraction. Accordingly, a POSITA would have been motivated to look to the omega-3 fatty acid levels disclosed in Bottino, along with the components found in krill oil as

disclosed in Fricke and Catchpole, to determine the components naturally found in the krill oil extracted by the methods taught in Breivik, Catchpole, and Fricke. (Tallon Decl. ¶ 28-32, 268).

C. Ground 3: §103(a) to Breivik, Fricke, Sampalis I, and Catchpole [Claims 7 and 16]

The discussions above regarding the obviousness of claims 1 and 11 are incorporated herein.

Claims 7 and 16 require that the method further includes ***encapsulating the krill oil***. Sampalis I describes NKO (Neptune Krill Oil)—an encapsulated krill oil in the form of soft gel capsules (Exhibit 1012, p. 0004, col. 2, first full paragraph).

Sampalis I discloses "Neptune Krill Oil (NKO) is a natural health product 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…" The authors further explain, "each patient 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." (Exhibit 1012, p.0004). The study determined that NKO significantly reduces the physical and emotional symptoms of premenstrual syndrome and was significantly more effective for managing PMS symptoms than fish oil. (Exhibit 1012, p. 0004, col. 2) Thus, Sampalis I discloses an encapsulated krill oil that includes a capsule containing an effective amount of krill oil. (Tallon Decl. ¶¶ 72-75.)

Thus, in view of Sampalis I in combination with Breivik, Fricke, and Catchpole, a POSITA would find the encapsulating of the krill oil required by claims 7 and 16 to be obvious. (Tallon Decl. ¶¶ 271-272.)

Reason to Combine

Sampalis I discloses a convenient method of administering an encapsulated krill oil to a person in need thereof in the form of a soft gel capsule. A POSITA, in view of the method or treating, processing and extracting oil from a denatured krill product as taught by Breivik, Fricke and Catchpole, would have been motivated to administer that krill oil compound in a convenient dosage form as described. Thus, a POSITA would have a reason to combine Sampalis I with the references in Ground 1. (Tallon Decl. ¶ 28-32, 273).

D. Ground 4: §103(a) – Breivik, Fricke, Catchpole, and Sampalis II [Claims 10 and 19]

The discussions above regarding the obviousness of claims 1 and 11 are incorporated herein.

Claims 10 and 19 require that the krill is Euphausia pacifica, which are also known as Pacific krill.

Sampalis II teaches that Pacific krill, including *Euphasia pacifica* are all appropriate sources of krill for its krill oil extract. "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*)…." (Exhibit 1013, p. 0027, lines 2-10). (Tallon Decl. ¶¶ 151, 276.)

In view of Sampalis II's disclosure that Pacific krill (i.e., *Euphausia pacifica*) could be exploited as a source of krill oil, a POSITA would find it obvious to use *Euphausia pacifica* in a method for the production of krill oil. Thus, the use of *Euphausia pacifica* –Pacific Ocean krill– in claims 10 and 19

would be obvious in view of the disclosure in Sampalis II in combination with Breivik, Fricke and Catchpole. (Tallon Decl. ¶¶ 277-278).

Reason to Combine

A POSITA would be motivated to combine Sampalis II with the references of Ground 1 because, as discussed above, Breivik and Fricke disclose processing freshly captured krill on board the ship by heat treating (*i.e.*, cooking) to produce a denatured krill meal, and extracting krill oil using organic solvents. Sampalis II teaches that *Euphausia pacifica*, a Pacific krill, is a suitable krill for extraction. Catchpole also discloses methods of extracting lipids from krill, and further discloses the fractionation of extracts of such lipids. Breivik, Catchpole, and Sampalis II further disclose that phospholipids have been implicated in conferring a number of health benefits. Fricke indicates there were a number of prior publications that investigated krill. Thus, a POSITA would have a reason to use the Pacific krill as disclosed in Sampalis II in the method disclosed in Breivik, Fricke, and Catchpole to produce a krill oil composition. (Tallon Decl. ¶¶ 28-32, 277).

E. CLAIM CHART

CLAIMS	REFERENCES
1. A method of production of krill oil comprising:	**Catchpole (Exhibit 1009)** P. 0024, Example 18, Table 16. "This example shows the fractionation of **krill lipids from krill powder** . . ." **Breivik (Exhibit 1035)** P. 0001, (Abstract) "The present disclosure relates to a **process for preparing** a substantially **total lipid fraction from fresh krill**, a process for separating phospholipids from other lipids, and a process for producing krill meal." P. 0004, ¶ [0014] "It is a main object of the present invention to provide a **process for preparing** a substantial **total lipid fraction from fresh krill**." **Fricke (Exhibit 1010)** P. 0001, 2nd col. "Krill samples of 5kg were quick-frozen and stored at -35 C until analyzed. Subsamples prepared from the core of the 5 kg samples were homogenized in a mortar under liquid nitrogen,

CLAIMS	REFERENCES
	and **lipid extraction was performed** according to Folch *et al.* (15)."[4]
a) providing krill;	**Breivik (Exhibit 1035)** P. 0001, (Abstract) "The present disclosure relates to a process for preparing a substantially total lipid fraction **from fresh krill**, a process for separating phospholipids from other lipids, and a process for producing krill meal." P. 0004, ¶ [0014] "It is a main object of the present invention to provide a process for preparing a substantial total lipid fraction **from fresh krill**." **Fricke (Exhibit 1010)** P. 0002-0003, 1st col. "Samples of the same haul which were **cooked on board immediately after hauling** and stored under the same conditions showed a FFA content which was much lower, ranging from 1% to 3% of total lipids."
b) treating said krill to denature lipases and phospholipases in said	**Breivik (Exhibit 1035)** Pp. 0004-0005, ¶ [0015]

[4] Folch et al., "A simple method for the isolation and purification of total lipides from animal tissues," J Biol Chem. 1957 May; 226(1):497-509, 497 ("the lipides were extracted by homogenizing the tissue with 2:1 chloroform-methanol (v/v)…."). See Exhibit 1017, p. 0001.

CLAIMS	REFERENCES
krill to provide a denatured krill product;	"The optional pre-treatment involving short-time **heating of the fresh krill** will also give an inactivation of enzymatic decomposition of the lipids, thus ensuring a product with very low levels of free fatty acids." P. 0006, ¶ [0047] "**Fresh *E. superba*** (200 g) was washed with ethanol (1:1) as in example 2, but with the difference that the raw material had been **pre-treated at 80°C** for 5 minutes." P. 0007, ¶ [0052] "Experiments showed that pre-heating to 95°C tended to increase the yield of lipids . . . even higher than pre-heating to 80°C." P. 0007, ¶ [0053] "The heat treatment gives a[n] additional result that the highly active **krill digestive enzymes are inactivated**, reducing the potential lipid hydrolysis." **Fricke (Exhibit 1010)** Pp. 0002-0003. See claim 1a above.

CLAIMS	REFERENCES
c) extracting oil from said denatured krill product with a polar solvent;	**Breivik (Exhibit 1035)** P. 0007, ¶ [0053] "The heat treatment gives a[n] additional result that the highly active **krill digestive enzymes are inactivated**, reducing the potential lipid hydrolysis." P. 0005, ¶ [0021] "In a preferred embodiment of the invention it is provided a process for extracting a substantially total lipid fraction from fresh krill, comprising the steps of : c) reducing the water content of the krill raw material; a-1) extracting the water reduced krill material from step a) with **CO2 containing ethanol**, the extraction taking place at supercritical pressure; and d) isolating the lipid fraction from the ethanol." P. 0006, ¶ [0034] "A second extraction with **CO_2 containing 10% ethanol** resulted in an extract of 100 g/kg (calculated from starting sample weight). ^{31}P NMR showed that the product contained phospholipids. The extract contained a sum of EPA plus DHA of 33.5%." P. 0006, ¶ [0047] "Fresh *E. superba* (200 g) was washed with ethanol (1:1) as in example 2, but with the difference that the raw material had been pre-treated at 80ºC for 5

CLAIMS	REFERENCES
	minutes. This gave an ethanol extract of 7.3%. Supercritical fluid extraction with **CO_2 containing 10% ethanol** gave an addition extract of 2.6% calculated from the fresh raw material." **Fricke (Exhibit 1010)** P. 0001, 2nd col. *See* claim 1 above. **Catchpole (Exhibit 1009)** P. 0024, lines 8-12. "The residual powder was then **extracted with CO_2 and absolute ethanol**, using a mass ratio of ethanol to CO_2 of 11 %. The CO_2 and ethanol extract phase was passed through two sequential separators in which the pressure was 95 and 60 bar respectively. The bulk of the phospholipids-rich extract (extract 2) was obtained in the first separator, and the bulk of the co-solvent in the second separator (extract 3). The composition of extract 2 and residual powder are shown in table 16."

CLAIMS	REFERENCES
d) to provide a krill oil with from about 3% to about 10% w/w ether phospholipids;	**Catchpole (Exhibit 1009)** P. 0024, Example 18, Table 16. "This example shows the fractionation of krill lipids from krill powder and demonstrates concentration of AAPC in the extract, and AAPE in the residue." Extract 2 includes 4.6% AAPC and 0.2% AAPE, totaling **4.8% ether phospholipid**.
e) from about 27% to 50% w/w non-ether phospholipids;	**Catchpole (Exhibit 1009)** P. 0024, Example 18, Table 16. **Total phospholipids include 45.1%** of the extract, and ether phospholipids include 4.8%. Therefore, **non-ether phospholipids include 39.7%**.

CLAIMS	REFERENCES
f) so that the amount of total phospholipids in said krill oil is from about 30% to 60% w/w; and	**Catchpole (Exhibit 1009)** P. 0024, Example 18, Table 16. Total phospholipids include **45.1%** of the extract. **Fricke (Exhibit 1010)** P. 0002, 2nd col., Table 1. Lipid Composition of Antarctic Krill (*Euphausia superba*) Phospholipids **45.7 % +/-** 1.6 (12/1977 sample) **44.0 % +/-** 2.0 (3/1981 sample) **Breivik (Exhibit 1035)** P. 0008, ¶ [0070] "Moreover, examples of a lipid compositions obtained by the process according to the invention are presented in the tables below, and also included herein." TABLE 2 Lipid composition Phospholipids >30-40% by weight EPA >5-15% by weight DHA >5-15% by weight

CLAIMS	REFERENCES
g) and from about 20% to 50% w/w triglycerides,	**Fricke (Exhibit 1010)** P. 0002, Table 1. Lipid Composition of Antarctic Krill (*Euphausia superba*) Triacylglycerols **33.3 %** +/- 0.5 (12/1977 sample) **40.4 %** +/- 0.1 (3/1981 sample)

CLAIMS	REFERENCES
h) wherein said steps a and b are performed on a ship.	**Breivik (Exhibit 1035)** Pp. 0004-0005, ¶ [0015] "As the process according to the invention require a minimum of handling of the raw materials, and is well suited to be used on fresh [krill], for example **onboard the fishing vessel**, the product according to the invention is expected to contain substantially less hydrolysed and/or oxidised lipids than lipid produced by conventional processes. This also means that there is expected to be less deterioration of the krill lipid antioxidants than from conventional processing." P. 0005, ¶ [0030] "In the following, 'fresh krill' is defined as krill that is **treated immediately after harvesting or sufficiently short time after harvesting** to avoid quality deterioration like hydrolysis or oxidation of lipids, or krill that is frozen immediately after harvesting." **Fricke (Exhibit 1010)** Pp. 0002-0003, 1st column. *See* claim 1a above.

CLAIMS	REFERENCES
2. The method of claim 1, wherein said treating comprises heating.	**Breivik (Exhibit 1035)** Pp. 0004-0005, ¶ [0015]. *See* claim 1b above P. 0006, ¶ [0047]. *See* claim 1b above P. 0007, ¶ [0052]. *See* claim 1b above P. 0007, ¶ [0053]. *See* claim 1b above **Fricke (Exhibit1010)** P. 0003, 1st column. *See* claim 1b above.
3. The method of claim 1, wherein said krill is freshly harvested.	**Breivik (Exhibit 1035)** Pp. 0004-0005, ¶ [0015]. *See* claim 1h above P. 0005, ¶ [0030]. *See* claim 1h above **Fricke (Exhibit 1010)** Pp. 0002-0003. *See* claim 1b above.

CLAIMS	REFERENCES
4. The method of claim 1, wherein said krill oil further comprises from about 20% to 35% omega-3 fatty acids as a percentage of total fatty acids in said krill oil.	**Bottino (Exhibit 1007)** P. 0002 Table 1. Omega-3 fatty acids[5] (as weight percent of total acids of Euphausia superba) of whole krill: Station 8--**30.5%** Station 9--**26.8%** Station 11--**25.0%** Pp. 0004-0005 Table 3. Omega-3 fatty acids[6] as weight percent of total acids of Euphausia superba: **28.6%**
5. The method of claim 4, wherein from about 70% to 95% of said omega-3 fatty acids are attached to said total phospholipids.	**Fricke (Exhibit 1010)** Pp. 0002, 0004-0005, and Tables 1, 4, and 5; Table 1 provides the amount of each lipid class in the total lipid. Tables 4 and 5 provide the omega-3 fatty acid composition of each phospholipid class. Therefore, the amount of omega-3 in each lipid class relative to the total lipid can be calculated by multiplying the amount of omega-3 fatty acid for each lipid class by the amount of the particular lipid class in the total lipid composition. This is done for each lipid class.

[5] Omega-3 fatty acids include 18:2(n-3), 18:3(n-3), 18:4(n-3), 20:5(n-3), and 22:6(n-3).
[6] Omega-3 fatty acids include 18:2(n-3), 22:2(n-3), 18:3(n-3), 20:3(n-3), 18:4(n-3), 20:4(n-3), 22:4(n-3), 22:5(n-3), and 22:6(n-3).

CLAIMS	REFERENCES
	The amount of omega-3 associated with phospholipid is then divided by the total amount of omega-3 in the total lipid to provide the percentage of omega-3 fatty acid attached to phospholipid. Using this calculation, **74.81%** (3/1981 sample) and **82.03%** (12/1977 sample) of the omega-3 fatty acids are attached to phospholipids. (Exhibit 1006, Tallon Appendix B.)
6. The method of claim 1, wherein said extracting comprises supercritical fluid extraction with a polar entrainer.	**Catchpole (Exhibit 1009)** P. 0024, lines 7-12. *See* claim 1c above. **Breivik (Exhibit 1035)** P. 0005, ¶ [0021]. *See* claim 1c above P. 0006, ¶ [0034]. *See* claim 1c above P. 0006, ¶ [0047]. *See* claim 1c above
7. The method of claim 1, further comprising encapsulating said krill oil.	**Sampalis I (Exhibit 1012)** P. 0004, 2nd column. "Each patient was asked to take two 1-gram **soft gels** of either **NKO**[7] 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."
8. The method of claim 1,	**Breivik (Exhibit 1035)**

[7] "NKO" is Neptune Krill Oil.

CLAIMS	REFERENCES
wherein said krill is Antarctic krill.	P. 0004, ¶ [0005] "Krill are small, shrimp-like animals, containing relatively high concentrations of phospholipids. In the group *Euphasiids*, there is more than 80 species, of which the **Antarctic krill** is one of these. The current greatest potential for commercial utilization is the *Euphausia superba*….Another **Antarctic krill** species is *E. crystallorphias*." P. 0004, ¶ [0006] "The approximate composition of lipids from the two main species of **Antarctic krill** is given in Table 1." P. 0004, ¶ [0007] "Furthermore, **Antarctic krill** has lower level of environmental pollutants than traditional fish oils." **Fricke (Exhibit 1010)** P. 0002, Table 1 "Lipid Composition of Antarctic Krill (*Euphausia superba Dana).*"

CLAIMS	REFERENCES
9. The method of claim 8, wherein said Antarctic krill is *Euphausia superba*.	**Fricke (Exhibit 1010)** P. 0002, Table 1. *See* claim 8 above. **Breivik (Exhibit 1035)** P. 0004, ¶ [0005]. *See* claim 8 above. P. 0004, ¶ [0006]. *See* claim 8 above.
10. The method of claim 1, wherein said krill is *Euphausia pacifica*.	**Sampalis II (Exhibit 1013)** P. 0027, lines 2-10. "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."

CLAIMS	REFERENCES
11. A method of production of krill oil comprising:	**Breivik (Exhibit 1035)** P. 0001, (Abstract). *See* claim 1 above. P. 0004, [0014]. *See* claim 1 above. **Catchpole (Exhibit 1009)** P. 0024, Example 18, Table 16. *See* claim 1 above. **Fricke (Exhibit 1010)** P. 0001, 2nd col. *See* claim 1 above.
a) obtaining a denatured krill product produced by treating freshly harvested krill to denature lipases and phospholipases in said krill;	**Breivik (Exhibit 1035)** P. 0001, (Abstract). *See* claim 1a above. P. 0004, ¶ [0014]. *See* claim 1a above. Pp. 0004-0005, ¶ [0015]. *See* claim 1b above. P. 0007, ¶ [0052]. *See* claim 1b above. P. 0007, ¶ [0053]. *See* claim 1b above. Pp. 0004-0005, ¶[0015]. *See* claim 1h above. P. 0005, ¶[0030]. *See* claim 1h above. **Fricke (Exhibit 1010)** Pp. 0002-0003. *See* claim 1a above.

CLAIMS	REFERENCES
b) extracting oil from said denatured krill product with a polar solvent;	**Breivik (Exhibit 1035)** P. 0005, ¶[0021]. *See* claim 1c above. P. 0006, ¶[0034]. *See* claim 1c above. P. 0006, ¶[0047]. *See* claim 1c above. **Fricke (Exhibit 1010)** P. 0001, 2nd col. *See* claim 1 above. **Catchpole (Exhibit 1009)** P. 0024, lines 7-12. *See* claim 1c above.
c) to provide a krill oil with from about 3% to about 10% w/w ether phospholipids;	**Catchpole (Exhibit 1009)** P. 0024, Example 18, Table 16. *See* claim 1d above.
d) from about 27% to 50% w/w non-ether phospholipids;	**Catchpole (Exhibit 1009)** P. 0024, Example 18, Table 16. *See* claim 1e above.

CLAIMS	REFERENCES
e) so that the amount of total phospholipids in the krill oil is from about 30% to 60% w/w; and	**Breivik (Exhibit 1035)** P. 0008, ¶[0070]. *See* claim 1f above. **Catchpole (Exhibit 1009)** P. 0024, Example 18, Table 16. *See* claim 1f above. **Fricke (Exhibit 1010)** P. 0002, 2nd col., Table 1. *See* claim 1f above.
f) from about 20% to 50% w/w triglycerides.	**Fricke (Exhibit 1010)** P. 0002, Table 1. *See* claim 1g above.
12. The method of claim 11, wherein said treating comprises heating.	**Fricke (Exhibit 1010)** Pp. 0002-0003. *See* claim 1a above. **Breivik (Exhibit 1035)** Pp. 0004-0005, ¶ [0015]. *See* claim 1b above P. 0006, ¶ [0047]. *See* claim 1b above P. 0007, ¶ [0052]. *See* claim 1b above P. 0007, ¶ [0053]. *See* claim 1b above

CLAIMS	REFERENCES
13. The method of claim 11, wherein said krill oil further comprises from about 20% to 35% omega-3 fatty acids as a percentage of total fatty acids in said krill oil.	**Bottino (Exhibit 1007)** P. 0002 Table 1. *See* claim 4 above. Pp. 0004-0005 Table 3. *See* claim 4 above.
14. The method of claim 13, wherein from about 70% to 95% of said omega-3 fatty acids are attached to said total phospholipids.	**Fricke (Exhibit 1010)** Pp. 0002, 0004-0005, and Tables 1, 4, and 5. *See* claim 5 above.
15. The method of claim 11, wherein said extracting comprises supercritical fluid extraction with a polar entrainer.	**Catchpole (Exhibit 1009)** P. 0024, lines 7-12. *See* claim 1c. **Breivik (Exhibit 1035)** P. 0005, ¶ [0021]. *See* claim 1c above P. 0006, ¶ [0034]. *See* claim 1c above P. 0006, ¶ [0047]. *See* claim 1c above
16. The method of claim 11, further comprising encapsulating said krill oil.	**Sampalis I (Exhibit 1012)** P. 0004, 2nd column. *See* claim 7 above.

CLAIMS	REFERENCES
17. The method of claim 11, wherein said krill is Antarctic krill.	**Fricke (Exhibit 1010)** P. 0002, Table 1. *See* claim 8 above. **Breivik (Exhibit 1035)** P. 0004, ¶ [0005]. *See* claim 8 above. P. 0004, ¶ [0006]. *See* claim 8 above. P. 0004, ¶ [0007]. *See* claim 8 above.
18. The method of claim 17, wherein said Antarctic krill is *Euphausia superba*.	**Fricke (Exhibit 1010)** P. 0002, Table 1. *See* claim 8 above. **Breivik (Exhibit 1035)** P. 0004, ¶ [0005]. *See* claim 8 above. P. 0004, ¶ [0006]. *See* claim 8 above.
19. The method of claim 11, wherein said krill is *Euphausia pacifica*.	**Sampalis II (Exhibit 1013)** P. 0027, lines 7-10. *See* claim 10 above.

VII. CONCLUSION

For the above reasons, Petitioner respectfully requests institution of *Inter Partes* Review of Claims 1-20 of U.S. 9,078,877, followed by a grant of this Petition canceling Claims 1-20 of the '877 patent on the grounds detailed herein.

Dated: February 3, 2017

Respectfully submitted,

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VIII. CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. §42.24(d), the undersigned certifies that this Petition complies with the type-volume limitation of to 37 C.F.R. §42.24(a). The word count application of the word processing program used to prepare this Petition indicates that the Petition contains 12,725 words, excluding the parts of the brief exempted by to 37 C.F.R. §42.24(a) (that is, the word count does not include the table of contents, the exhibit list, mandatory notices under §42.8, the certificate of service or the certificate of compliance).

Dated: February 3, 2017

Respectfully,

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CERTIFICATE OF SERVICE

I hereby certify that on this 3rd day of February, 2017, the foregoing PETITION FOR *INTER PARTES* REVIEW UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.1 *ET SEQ.*, including all Exhibits and the Power of Attorney, were served pursuant to 37 C.F.R. §§ 42.6 and 42.105, via Federal Express® (Domestic - next day delivery, International – priority), on the following:

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RIMFROST AS

Petitioner

v.

AKER BIOMARINE ANTARCTIC AS

Patent Owner

Case No.: IPR2017-00748

U.S. Patent 9,028,877

Issue Date: May 12, 2015

Title: Bioeffective Krill Oil Compositions

PETITION FOR *INTER PARTES* REVIEW

UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.1 *ET SEQ.*

TABLE OF CONTENTS

I. THE PETITION 1

II. MANDATORY NOTICES 1

A. Real parties-in-interest 1

B. Related matters (37 C.F.R. § 42.8(b)(2)) 2

C. Counsel (37 C.F.R. §§ 42.8(b)(3) and 42.10(a)) 3

D. Service information (37 C.F.R. §42.8(b)(4)) 4

III. PAYMENT OFFICE FEES 5

IV. ADDITIONAL REQUIREMENTS FOR *INTER PARTES* REVIEW 5

A. Grounds for Standing (37 C.F.R. § 42.104(a)) 5

B. Level of Ordinary Skill in the Art 5

C. Identification of Challenge and Relief Requested (37 C.F.R. § 42.104(b) and 37 C.F.R. § 42.22(a)(1)) 6

1. Claims for which Inter Partes Review is Requested (37 C.F.R. § 42.104(b)(2)) 6

2. Specific Statutory Grounds on which the Challenge is Based (37 C.F.R. § 42.104(b)(2)) The specific statutory grounds for the challenge are as follows: 7

3. Earliest Effective Priority Date 7

4. Prior Art References 8

D. Claim Construction - Broadest Reasonable Interpretation ("BRI") (37 C.F.R. § 42.104(b)(3)) 8

V. SUMMARY OF THE '877 PATENT (EX 1001) 9

A. State of the Art 9

B. Background of '877 Patent....10

C. Prosecution History of the '877 Patent 14

D. Construction of the '877 Patent Claim Terms....18

1. Claims 1 and 11 - "krill oil"..... 19

2. Claims 1 and 11 – "denature lipases and phospholipases"..... 21

3. Claims 1 and 11 – "polar solvent" 24

4. Claims 3 and 11 - "freshly harvested krill" 27

5. Claim 6 - "polar entrainer" 29

VI. EACH GROUND PROVIDES MORE THAN A REASONABLE LIKELIHOOD THAT EACHCLAIM OF THE '877 PATENT IS UNPATENTABLE....29

A. Ground 1: §103(a) – Grantham, Fricke, and Tanaka I [Claims 1-3, 8-9, 11-12, and 17-18] 30

1. Claims 1 and 11..... 30

2. Claims 2 and 12..... 46

3. Claim 3 47

4. Claims 8 and 17..... 48

5. Claims 9 and 18..... 48

B. Ground 2: § 103(a) – Grantham, Fricke, Bottino, and Tanaka I [Claims 4, 5, 13 and 14] 51

1. Claims 4 and 13..... 51

2. Claims 5 and 14 55

C. Ground 3: § 103(a) to Grantham, Fricke, Tanaka II, and Tanaka I [Claims 6 and 15] 58

D. Ground 4: § 103(a) to Grantham, Fricke, Sampalis I, and Tanaka I [Claims 7 and 16] 60

E. Ground 5: § 103(a) – Grantham, Fricke, Tanaka I and Sampalis II [Claims 10 and 19] 61

VII. CONCLUSION 83

VIII. Certificate of Compliance 84

APPENDIX OF EXHIBITS

Exhibit Number	Exhibit Description
1001	U.S. Patent No. 9,028,877 B2, filed September 18, 2014 ('877)
1002	U.S. Provisional Patent Application No. 61/024,072, filed January 28, 2008 ('072 Provisional)
1003	U.S. Provisional Patent Application No. 60/983,446, filed October 29, 2007 ('446 Provisional)
1004	U.S. Provisional Patent Application No. 60/975,058, filed September 25, 3007 ('058 Provisional)
1005	U.S. Provisional Patent Application No. 60/920,483, filed March 28, 2007 ('483 Provisional)
1006	Declaration of Dr. Stephen Tallon
1007	Bottino, N.R., "The Fatty Acids of Antarctic Phytoplankton and Euphausiids. Fatty Acid Exchange among Trophic Levels of the Ross Sea", Marine Biology, 27, 197-204 (1974) (Bottino)
1008	Budziński, E., P. Bykowski and D. Dutkiewicz, 1985, "Possibilities of processing and marketing of products made from Antarctic krill", FAO Fish. Tech. Pap., (268):46 (Budzinski)
1009	Catchpole and Tallon, WO 2007/123424, published November 1, 2007, "Process for Separating Lipid Materials" (Catchpole)
1010	Fricke et al., "Lipid, Sterol and Fatty Acid Composition of Antarctic Krill (Euphausia superba Dana)", LIPIDS 19(11):821-827 (1984) (Fricke)

1011	Randolph, et al., U.S. Patent Application Publication No. US/2005/0058728 A1, "Cytokine Modulators and Related Method of Use"(Randolph)
1012	Sampalis [I] *et al.*, "Evaluation of the Effects of Neptune Krill Oil™ on the Management of Premenstrual Syndrome and Dysmenorrhea", Altern. Med. Rev. 8(2):171-179 (2003) (Sampalis I)
1013	Sampalis [II] *et al.*, WO 2003/011873, published February 13, 2003, "Natural Marine Source Phospholipids Comprising Flavonoids, Polyunsaturated Fatty Acids and Their Applications" (Sampalis II)
1014	Tanaka [I] et al., "Platelet – Activating Factor (PAF) – Like Phospholipids Formed During Peroxidation of Phosphatidylcholines from Different Foodstuffs", Biosci. Biotech. Biochem., 59(8) 1389-1393 (1995) (Tanaka I).
1015	Tanaka [II] et al., "Extraction of Phospholipids from Salmon Roe with Supercritical Carbon Dioxide and an Entrainer", Journal of Oleo Science Vol. 53 (2004) No. 9, p.17-424 (Tanaka II)
1016	Beaudoin et al., "Method of Extracting Lipids From Marine and Aquatic Animal Tissues," U.S. Patent No. 6,800,299 B1 filed July 25, 2001 (Beaudoin)
1017	Folch et al., "A simple method for the isolation and purification of total lipides from animal tissues", J. Biol. Chem. (1957) 226: 497-509 (Folch).
1018	Kochian et al, "Agricultural Approaches to Improving Phytonutrient Content in Plants: An Overview," Nutrition Reviews", Vol. 57, No. 9, September 1999: S13-S18 (Kochian)

1019 Porzio et al., "Encapsulation Compositions and Processes for Preparing the Same", U.S. Patent No. 7,488,503 B1 filed March 31, 2004 (Porzio)

1020 Bunea, et al., "Evaluation of The Effects Of Neptune Krill Oil On The Clinical Course of Hyperlipidemia", Altern Med Rev. 2004; 9:420–428 (Bunea).

1021 Complaint filed in *Aker Biomarine Antarctic AS v. Olympic Holding AS, et al.,* 1:16-CV-00035-LPS-CJB (D. Del)

1022 Affidavits of Service Filed in *Aker Biomarine Antarctic AS v. Olympic Holding AS, et al.,* No. 1:16-CV-00035 LPS-CJB (D. Del)

1023 Federal Register Notice of Institution of Investigation 337-TA-1019 on September 16, 2016 by the ITC (81 Fed. Reg. pages 63805-63806)

1024 File History to U.S. Patent No. 9,034,388 B2, Serial No, 12/057,775 ('388 File History)

1024 Part 1 - Pages 1-450
1024 Part 2 - Pages 451-900
1024 Part 3 - Pages 901-1350
1024 Part 4 - Pages 1351-1800
1024 Part 5 - Pages 1801-2250
1024 Part 6 - Pages 2251-2700
1024 Part 7 - Pages 2701-3083

1025 File History to U.S. Patent No. 9,028,877 B2, Serial No, 14/490,176 ('877 File History)

1025 Part 1 - Pages 1-375
1025 Part 2 - Pages 376-724

1026	File History to U.S. Patent No. 9,078,905 B2, Serial No, 14/490,221 ('905 File History) 1026 Part 1 - Pages 1-450 1026 Part 2 - Pages 451-882
1027	Saether et al., "Lipolysis post mortem in North Atlantic krill", Comp. Biochem. Physiol. Vol. 83B, No. 1, pp. 51-55, 1986 (Saether).
1028	Hawley's Condensed Chemical Dictionary, p. 893, 13th ed., 1997 (Hawley's)
1029	Webster's New Universal Unabridged Dictionary, 2nd ed., p. 732, 1983 (Webster's)
1030	Tehoharides, U.S. Patent Application Publication No. US/2006/0013905 A1, "Anti-Inflammatory Compositions For Treating Multiple Sclerosis" (Tehoharides)
1031	Halliday, Jess, "Neptune-Degussa Deal to Develop Phospholipids, Adapt Krill Oil," http://www.nutraingredients-usa.com/Suppliers2/Neptune-Degussa-deal-to-develop-phospholipids-adapt-krill-oil, December 12, 2005 (Neptune-DeGussa)
1032	Grantham, G.J., "The Utilization Of Krill", UNDP/FAO Southern Ocean Fisheries Survey Programme (1977) (Grantham)
1033	Yoshitomi, U.S. Patent Application Publication No. US/2003/0113432 A1, "Process For Making Dried Powdery and Granular Krill" (Yoshitomi).
1034	Kolakowska, A., "The influence of sex and maturity stage of krill (*Euphausia superba* Dana) upon the content and composition of its lipids", 1991, Pol. Polar Res. 12: 73-78 (Kolakowska).

1035	Breivik, U.S. Patent Application Publication No. US 2010/0143571 A1, "Process for Production of Omega-3 Rich Marine Phospholipids from Krill" (Breivik).
1036	Breivik, U.S. Provisional Patent Application No. 60/859,289, "Processes for production of omega-3 rich marine phospholipids from krill", filed November 16, 2006 (Breivik '289 Provisional)
1037	Breivik, WO 2008/060163 A1, "Process for Production of Omega-3 Rich Marine Phospholipids from Krill," International filing date November 15, 2007 (Breivik PCT).

I. THE PETITION

Petitioner, real party-in-interest, Rimfrost AS, a Norwegian corporation with its principal place of business at Vågsplassen, 6090, Fosnavåg, Norway, hereby petitions the Patent Trial and Appeal Board (the "Board" or the "PTAB") of the United States Patent and Trademark Office ("PTO"), pursuant to 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42.1 *et seq*., to institute an *inter partes* review and to find unpatentable and cancel Claims 1-19 of U.S. Patent No. 9,028,877, entitled "Bioeffective Krill Oil Compositions," issued May 12, 2015 (Serial No. 14/490,176, filed September 18, 2014) ("the '877 patent"), assigned to Aker Biomarine Antarctic AS ("Aker"). The '877 patent is submitted herewith as Exhibit 1001. There is a reasonable likelihood that Petitioner will prevail with respect to at least one claim challenged in this petition.

II. MANDATORY NOTICES

As set forth below and pursuant to 37 C.F.R. § 42.8(a)(1), the following mandatory notices are provided as part of this petition.

A. Real parties-in-interest

Pursuant to 37 C.F.R. § 42.8(b)(1), Olympic Holding AS, Emerald Fisheries

AS, Avoca Inc., Rimfrost USA, LLC, Rimfrost New Zealand Limited, Bioriginal Food and Science Corp., and Petitioner, Rimfrost AS, are identified as the real parties-in-interest. Several other entities have a majority ownership interest in the above-identified real parties-in-interest. Based upon those ownership interests, and in an abundance of caution, Petitioner also names Stig Remøy, SRR Invest AS, Rimfrost Holding AS, Pharmachem Laboratories, Inc., and Omega Protein Corporation as real parties-in-interest.

B. Related matters (37 C.F.R. § 42.8(b)(2))

Aker has asserted two patents – U.S. Patent Nos. 9,078,905 and 9,028,877 in a lawsuit captioned *Aker Biomarine Antarctic AS v. Olympic Holding AS; Rimfrost AS; Emerald Fisheries AS, Rimfrost USA, LLC; Avoca Inc.;* and *Bioriginal Food & Science Corp.* Case No. 1:16-CV-00035-LPS-CJB (D. Del.). (Complaint, Exhibit 1021). The litigation is presently pending, although it has been stayed in view of Investigation No. 337-TA-1019 instituted by the United States International Trade Commission on September 16, 2016 as noticed in the Federal Register. The ITC proceeding is entitled In the Matter of Certain Krill Oil Products and Krill Meal for Production of Krill Oil Products and concerns U.S. Patent Nos. 9,028,877;

9,078,905; 9,072,752; 9,320,765; and 9,375,453. The ITC investigation lists as respondents Olympic Holding AS, Rimfrost AS, Emerald Fisheries AS, Avoca Inc., Rimfrost USA, LLC, Rimfrost New Zealand Limited and Bioriginal Food & Science Corp. (Exhibit 1023). On January 27, 2017, Petitioner filed IPR2017-0745 and IPR2017-0747 seeking *inter partes* review of Claims 1-20 of U.S. Patent No. 9,078,905.

C. Counsel (37 C.F.R. §§ 42.8(b)(3) and 42.10(a))

Petitioner designates the following individuals as its lead counsel and back-up lead counsel:

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D. Service information (37 C.F.R. §42.8(b)(4))

Service on Petitioner may be made electronically by using the following email address: 877ipr2@hbiplaw.com and the email addresses above. Service on Petitioner may be made by Postal Mailing or Hand-delivery addressed to Lead and Back-up Lead Counsel at the following address, but electronic service above is requested:

Hoffmann & Baron, LLP

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Syosset, New York 11791

This document, together with all exhibits referenced herein, has been served on the patent owner at its corporate headquarters, Oskenøyveien 10 No-1327, 1366 Lysaker, Norway, as well as the correspondence address of record for the '877 patent: Casimir Jones, S.C., 2275 Deming Way, Suite 310, Middleton, Wisconsin 53562, and the address of patent owner's litigation counsel: Andrew F. Pratt,

Venable LLP, 575 Seventh Street NW, Washington, DC 20004.

III. PAYMENT OFFICE FEES

Pursuant to 37 C.F.R. §§ 42.103 and 42.15(a), the requisite filing fee of $24,600 (request fee of $9,000, post-institution fee of $14,000 and excess claims fee of $1,600) for a Petition for *Inter Partes* Review is submitted herewith. Claims 1-19 of the '877 patent are being reviewed as part of this Petition. The undersigned further authorizes payment from Deposit Account No. 08-2461 for any additional fees or refund that may be due in connection with the Petition.

IV. ADDITIONAL REQUIREMENTS FOR *INTER PARTES* REVIEW

A. Grounds for Standing (37 C.F.R. § 42.104(a))

Petitioner hereby certifies that the '877 patent is available for *Inter Partes* Review and that Petitioner is not barred or estopped from requesting *Inter Partes* Review challenging the claims of the '877 patent on the grounds identified herein. This Petition is timely filed under 35 U.S.C. §315(b) because it is filed within one year of the service of the Complaint alleging infringement of the '877 patent by Aker. *See* Exhibits 1021-1022.

B. Level of Ordinary Skill in the Art

As of the earliest priority date the '877 Patent is entitled to, that is January

28, 2008, a POSITA would have held an advanced degree in marine sciences, biochemistry, organic (especially lipid) chemistry, chemical or process engineering, or associated sciences with complementary understanding, either through education or experience, of organic chemistry and in particular lipid chemistry, chemical or process engineering, marine biology, nutrition, or associated sciences; and knowledge of or experience in the field of extraction. In addition, a POSITA would have had at least five years' applied experience. (Tallon Decl. ¶ 27).

C. Identification of Challenge and Relief Requested (37 C.F.R. § 42.104(b) and 37 C.F.R. § 42.22(a)(1))

The precise relief requested by Petitioner is that Claims 1-19 are found unpatentable and cancelled from the '877 patent.

1. Claims for which Inter Partes Review is Requested (37 C.F.R. § 42.104(b)(2))

Petitioner requests *Inter Partes* Review of Claims 1-19 of the '877 patent.

2. Specific Statutory Grounds on which the Challenge is Based (37 C.F.R. § 42.104(b)(2)) The specific statutory grounds for the challenge are as follows:

Ground	References	Basis	Claims Challenged
1	Grantham, Fricke, and Tanaka I	35 U.S.C. §103(a)	1-3, 8-9, 11-12, and 17-18
2	Grantham, Fricke, Bottino, and Tanaka I	35 U.S.C. §103(a)	4-5 and 13-14
3	Grantham, Fricke, Tanaka II, and Tanaka I	35 U.S.C. §103(a)	6 and 15
4	Grantham, Fricke, Sampalis I, and Tanaka I	35 U.S.C. §103(a)	7 and 16
5	Grantham, Fricke, Tanaka I, and Sampalis II	35 U.S.C. §103(a)	10 and 19

Petitioner also relies on the expert declaration of Dr. Stephen Tallon (Exhibit 1006).

3. Earliest Effective Priority Date

All of the issued claims in the '877 patent require the element that the krill oil comprise from about 3% to about 10% w/w ether phospholipids. Support for the claim element "ether phospholipid" was not introduced until the filing of U.S. Application No. 61/024,072, filed on January 28, 2008. (See Exhibits 1002 –

1005). Consequently, the earliest effective priority date for the claims of the '877 patent is January 28, 2008.

4. Prior Art References

All prior art references utilized herein were published more than one year prior to the earliest possible priority date of January 28, 2008, and, therefore, qualify as prior art under 35 U.S.C. §102(b).

§102(b) Reference	Publication Date	Exhibit No.
Grantham	1977	1032
Fricke	April 30, 1984	1010
Tanaka I	August 23, 1995	1014
Tanaka II	August 12, 2004	1015
Sampalis I	May 2003	1012
Bottino	June 28, 1974	1007
Sampalis II	February 13, 2003	1013

D. Claim Construction - Broadest Reasonable Interpretation ("BRI") (37 C.F.R. § 42.104(b)(3))

In an *inter partes* review, claim terms 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. 48756, 48766 (Aug. 14, 2012Solely for this proceeding, the following list contains the proposed terms for construction and Petitioner's proposed constructions. All other terms, not presented below, should be given their plain and ordinary meaning. Petitioner reserves the right to address any claim construction issue raised by Patent Owner.

V. SUMMARY OF THE '877 PATENT (EX 1001)

A. State of the Art

All of the claims issued in the '877 Patent are directed to methods of producing krill oil. The steps of the methods include treating krill (*e.g.,* by heating) to denature lipases and phospholipases and extracting oil from the denatured krill product using a polar solvent. Claim 1 (but not Claim 11) requires the denaturation step to be performed "on a ship." However, such steps were well known in the art as of the earliest effective filing date.

For example, Budziński (Exhibit 1008) recognized the need to process freshly harvested krill to ensure the optimum product quality. (Tallon Decl. ¶¶ 76-86). "Due to its technological properties, the ***raw material should be processed as soon as possible after capture***. The only way to meet this requirement is to ***install***

processing facilities on board the vessel." (Exhibit 1008, p. 0031) (Tallon Decl. ¶ 81).

Budziński further taught cooking and pressing krill on board the ship to produce a denatured product - krill meal. (Exhibit 1008, pp. 0016, 0018, 0026) (*See* Tallon Decl. ¶ 84). Budziński also disclosed extracting oil with a polar solvent ("[k]rill oil was only obtained by extraction with the help of various organic solvents." (Exhibit 1008, p. 0030) (Tallon Decl. ¶ 86).

Breivik also discloses denaturing krill by heat treatment onboard the fishing vessel to reduce degradation of the lipids, and subsequent extraction using supercritical CO2 with ethanol. (Exhibit 1035, pp. 0004-0005, ¶ [0015]; p. 0005, ¶ [0021]; p. 0006, ¶ [0034]; p. 0006, ¶ [0047]; p. 0007, ¶ [0053]).

The claims of the '877 patent also specify percentages of components in the resulting krill oil. However, the krill oil components were well known to be naturally present in krill oil in the amounts specified using standard extraction techniques. (*See, e.g.,* Section II *infra*; *see also* Kolakowska (1991) (Exhibit 1034).

B. Background of '877 Patent

The '877 patent "provides methods of production of krill oil comprising: a)

providing fresh krill; b) treating said fresh krill to denature lipases and phospholipases in said fresh krill to provide a denatured krill product; and c) extracting oil from said denatured krill product," wherein steps (a) and (b) are performed on board a ship. (Exhibit 1001, 4:47-52). The '877 patent also states that "the present invention provides a *Euphausia superba* krill oil composition comprising: from about 30% to 60% w/w phospholipids; from about 20% to 50% triglycerides; from about 400 to about 2500 mg/kg astaxanthin; and from about 20% to 35% omega-3 fatty acids as a percentage of total fatty acids in said composition, wherein from about 70% to 95% of said omega-3 fatty acids are attached to said phospholipids." (Exhibit 1001, 5:49-56).

However, as acknowledged in the Background of the Invention:

> In order to isolate the krill oil from the krill, solvent extraction methods have been used. See, e.g., WO 00/23546. Krill lipids have been extracted by placing the material in a ketone solvent (e.g. acetone) in order to extract the lipid soluble fraction. This method involves separating the liquid and solid contents by evaporation. Further processing steps include extracting and recovering by evaporation the remaining soluble lipid fraction from the solid contents by using a solvent such

as ethanol. See e.g., WO 00/23546. (Exhibit 1001, 1:31-40).

The '877 patent also acknowledges that, "[t]he methods described above rely on the processing of frozen krill that are transported from the Southern Ocean to the processing site. This transportation is both expensive and can result in degradation of the krill starting material." (Exhibit 1001, 2:3-6).

The '877 patent also states, "Supercritical fluid extraction with solvent modifier has previously been used to extract marine phospholipids from salmon roe, but has not been previously used to extract phospholipids from krill meal. See, e.g., Tanaka *et al.*, J. Oleo. Sci. (2004), 53(9), 417-424." (Exhibit 1001, 1:65-2:2). However, this statement is demonstrably false. *See, e.g.,* Catchpole (Exhibit 1009 p. 0024, lines 1-19) (Tallon Decl. ¶¶ 87-96); Halliday, Jess, "Neptune-Degussa Deal to Develop Phospholipids, Adapt Krill Oil," http://www.nutraingredients-usa.com/Suppliers2/Neptune-Degussa-deal-to-develop-phospholipids-adapt-krill-oil, December 12, 2005. (Exhibit 1031, p. 0002) ("Degussa is renowned for its expertise in supercritical CO2 extraction.").

With regard to krill compositions, the '877 patent concedes "[a] krill oil composition has been disclosed comprising a phospholipid and/or a flavonoid. The

phospholipid content in the krill lipid extract could be as high as 60% w/w and the EPA/DHA content as high as 35% (w/w). *See, e.g.*, WO 03/011873." (Exhibit 1001, 1:53-56).

The analysis of the extracted krill oil disclosed in the '877 patent in Table 21, reports that the amount of phospholipids, triglycerides and omega-3 fatty acids in the extract. Tables 22 and 23 provide the only ether phospholipid data in the entire specification and was the element relied upon in all of the claims issued in the '877 patent. Example 8 of the '877 patent concludes:

> The main polar ether lipids of the krill meal are alkylacylphosphatidylcholine (AAPC) at 7-9% of total polar lipids, lysoalkylacylphosphatidylcholine (LAAPC) at 1% of total polar lipids (TPL) and alkylacylphosphatidyl-ethanolamine (AAPE) at <1% of TPL. (Exhibit 1001, 32:9-4)

All of the issued claims include the **"from about 3% to about 10% w/w ether phospholipid"** limitation and appears to be the limitation that applicants relied upon in arguing novelty. However, as demonstrated herein, krill oil containing ether phospholipid levels between about 3% and about 10% was well known in the prior art.

C. Prosecution History of the '877 Patent

The '877 patent issued on May 12, 2015 from U.S. Application No. 14/490,176, filed September 18, 2014. The '877 patent is a continuation of U.S. Patent Application No. 12/057,775, filed on March 28, 2008 and claims the benefit of four U.S. provisional applications: 61/024,072, filed on January 28, 2008; 60/983,446, filed on October 29, 2007; 60/975,058, filed on September 25, 2007; and 60/920,483, filed on March 28, 2007. Support for the claim limitation "ether phospholipid" – required by each '877 claim – was not introduced until the filing of the U.S. Application No. 61/024,072. (See Exhibits 1002 – 1005). Consequently, "the earliest priority date" for the claims of the '877 patent is January 28, 2008.

During the prosecution of the '877 patent, a final Office Action was mailed on January 13, 2015 in which all pending claims were rejected. (*See* Exhibit 1025, part 1, pp. 91-97). After a telephone interview with applicants' attorney on March 13, 2015, the Examiner issued a Notice of Allowance on April 6, 2015 with an Examiner's Amendment. In the Examiner's Amendment, claim 1 was amended to require that steps (a) and (b) of the claimed method must be performed *"on a ship."* (*See* Exhibit 1025, part 1, pp. 9-17) (emphasis added). Prior to the

Examiner's Amendment, claim 1 did not require step (a) (providing krill) and step (b) (treating the krill) to be performed on a ship. Thus, the Examiner found that claim 1 was allowable over the prior art only if claimed steps (a) and (b) were performed on a ship.

All of the claims of the '877 patent also have the claim limitation of "from about 3% to about 10% w/w ether phospholipids." Applicants relied on this limitation in asserting patentability of the claims.

In parent application no. 12/057,775, which issued as U.S. Patent No. 9,034,388, applicants amended the claims to include the limitation "about 3% to about 10% ether phospholipids" and argued that the cited references did not teach extraction of a krill oil having this limitation. (*See* Response to Office Action dated June 7, 2012). (Exhibit 1024, part 2, pp. 633-50). In particular, applicants urged that "[n]one of the references, alone or in combination, teach…krill oil with the claimed phospholipids content…." (p. 648).

Further, in the prosecution history of U.S. Patent Application No. 9,078,905 (U.S. Patent Application No. 14/490,221), applicants again relied on the ether phospholipid limitation in asserting patentability of the claims therein. In

particular, a Non-Final Office Action dated November 17, 2014 (Exhibit 1026, part 1, pp. 168-77) rejected all as-filed claims. The Examiner asserted two U.S. Patents were prior art and maintained that these patents made the as-filed claims obvious: Beaudoin (Exhibit 1016) and Porzio (Exhibit 1019). The Examiner observed that Beaudoin disclosed krill oil components including phospholipids and triglycerides at similar concentrations as presented in the claims. This disclosure was combined with Porzio, which taught how to encapsulate lipid compositions. (Exhibit 1026, part I, p. 175). In a Response to the Non-Final Office Action dated December 19, 2014 (Exhibit 1026, part 1, pp. 242-51), applicants argued, *inter alia*, that the cited references failed to disclose a krill oil composition comprising "from about 3% - 15% ether phospholipids." (pp. 248, 250). In particular, applicants maintained that Beaudoin's '299 patent extraction method was virtually identical to the NKO (Neptune Krill Oil) extraction process and would therefore be less than 3%. (p. 250).

An analysis was presented of the composition of the NKO product in the '877 patent (Example 8 and Table 22), purportedly showing that this commercial krill oil product had 7% AAPC and 1.2% LAAPC, *i.e.,* a total ether phospholipid

content of 8.2% of total phospholipids. Applicants maintained that this percentage corresponded to an actual 2.46% value[1] when relative to the krill oil (*e.g.,* based upon a 30% measurement of total NKO phospholipids). It was argued, "[a]pplicant respectfully submits that this demonstrates that krill oil made by the Beaudoin method does not contain the claimed range of 3% to 15% ether phospholipids as a percentage of the total krill oil composition." (Exhibit 1026, part 1 p. 250).

A Final Rejection, mailed on February 17, 2015 (Exhibit 1026, part 1, pp. 168-77), maintained the non-statutory double patenting and obviousness rejections. The Examiner contended that 2.46% of ether phospholipid applicants argued was found in Neptune's commercial NKO krill oil product was "very close" to the claimed range, and therefore it would have been obvious for one of ordinary skill in the art to optimize the extraction process through routine means to increase the ether phospholipid content to the claimed 3% concentration because of the known health benefits of ether phospholipids. (p. 176).

Applicants filed a Response to the Final Office Action on April 16, 2015 (Exhibit 1026, part 1, pp. 159-64) and argued that the claimed range of about 3-

[1] This is an admission that Beaudoin describes krill oil having just below 3% ether phospholipids.

15% ether phospholipids purportedly provided unexpected results, relying upon Example 9 and selected figures referred to therein that allegedly compares the claimed krill oil (designated Superba or PL2) to prior art krill oil (designated NKO or PL1). (pp. 163-64).While urging that "greater than 3% ether phospholipids have superior activity," there was no evidence in the specification for ether phospholipid amounts other than those reported in Table 22 and Table 23. (Tallon Decl. ¶ 190). Moreover, the claims recite "about 3%" – not "greater than 3%." Nevertheless, it appears that applicants' "superior results" argument convinced the Examiner to allow the pending claims, since a Notice of Allowance followed on May 20, 2015 (with no written reasons for the allowance).

Accordingly, throughout the prosecution of the '877 patent family, applicants repeatedly stressed the importance of krill oil compositions having greater than 3% ether phospholipids in gaining allowance of the claims.

D. Construction of the '877 Patent Claim Terms

As discussed above, a claim in *inter partes* review is given the "broadest reasonable construction in light of the specification." *See* 37 C.F.R. § 42.100(b).

Petitioner sets forth herein its recommended interpretation of certain claim

terms, the scope of the claims being unclear on their face.

1. Claims 1 and 11 - "krill oil"

The term "krill oil" is found in all of the independent claims, *i.e.*, Claims 1 and 11. The meaning of "krill oil" can be ascertained from the specification. The '877 specification states:

> In order to isolate the krill oil from krill, solvent extraction methods have been used. See, e.g., WO 00/23564. Krill lipids have been extracted by placing the material in a ketone solvent (e.g., acetone) in order to extract the lipid soluble fraction. (Exhibit 1001, 1:31-35).

Accordingly, the '877 patent equates "krill oil" with the lipids extracted from krill.

The '877 patent further describes "krill oil" as a lipid-rich extract of krill. This extract can primarily include phospholipids and neutral lipids in varying proportions. The Abstract of the '877 patent describes the "actual krill oils" as the oil extracted using a polar solvent after using a non-polar solvent to remove neutral lipids: "The krill oils are obtained from krill meal using supercritical fluid extraction in a two stage process. Stage 1 removes the neutral lipid by extracting with neat supercritical CO_2 or CO_2 plus approximately 5% of a co-solvent. Stage 2

extracts the *actual krill oils* by using supercritical CO_2 in combination with approximately 20% ethanol" (Exhibit 1001, Abstract) (emphasis added). The '877 patent therefore also describes krill oil as a phospholipid rich extract produced by removing some or much of the triglyceride and other neutral oils. In addition, the '877 patent discloses "combining said polar extract and said neutral extract to provide *Euphausia superba* krill oil…". ('877 patent, 5:55-6:11, Exhibit 1001, p. 0027; *see also* Tallon Dec. ¶ 35).

Additionally, in the context of the '877 patent, "krill oil" is characterized as a lipid-rich extract of krill that comprises phospholipids, as well as a lipid-rich extract of krill that comprises blends of polar lipids (phospholipids) and neutral lipids in varying proportions. The '877 patent repeatedly refers to the krill oil composition as comprising blend of lipid fractions. "In some embodiments, krill oil composition comprises a blend of lipid fractions obtained from krill" ('877 patent, 3:26-27, Exhibit 1001, p. 0025). "In some embodiments, the blended krill oil product comprises a blend of lipid fractions obtained from *Euphausia superba*" ('877 patent, 5:43-45, 6:50-52, 7:18-20, Exhibit 1001, pp. 0027, 0028; *see* Tallon Decl. ¶¶ 35-48).

Thus, the broadest reasonable construction of "krill oil" is "lipids extracted from krill."

2. Claims 1 and 11 – "denature lipases and phospholipases"

Claims 1 and 11 include the step of treating "to denature lipases and phospholipases in said krill." The term "denature" is not expressly defined in the specification, but is described. For example, the Detailed Description of the '877 patent states:

> The present invention provides methods to avoid decomposition of glycerides and phospholipids in krill oil and compositions produced by those methods….the solution to the problem is to incorporate a protein denaturation step on fresh krill prior to use of any extraction technology. Denaturation can be achieved by thermal stress or by other means. After denaturation the oil can be extracted by an optional selection of non-polar and polar solvents including use of supercritical carbon dioxide. (9:44-54, Exhibit 1001, p. 0029).

The specification further explains:

> In some preferred embodiments, freshly caught krill is first subjected to a protein denaturation step. The present

> invention is not limited to any particular method of protein denaturation. In some embodiments, the denaturation is accomplished by application of chemicals, heat, or combinations thereof. In some embodiments, freshly caught krill is wet pressed to obtain oil and meal. In some embodiments, the meal is then heated to a temperature of about 50°C to about 100°C for about 20 minutes to about an hour, preferably about 40 minutes to denature the proteins. In some embodiments, this material is then pressed to yield a pressed cake. When this method is used on krill, only a small amount of oil is released. Most of the oil is still present in the denatured meal. ('877 patent, 10:26-40, Exhibit 1001, p. 0029).

These disclosures are consistent with the extrinsic evidence. For example, Hawley's Condensed Chemical Dictionary defines "denaturation" as "a change in the molecular structure of globular proteins that may be induced by bringing a protein solution to its boiling point or by exposing it to acids or alkalies, or to various detergents…. It involves rupture of hydrogen bonds to that the highly ordered structure or the native protein is replaced by a looser and more random

structure…." (Hawley's, p. 339-340, Exhibit 1028, pp. 0003-0004; *see* Tallon Decl. ¶ 58).

Proteins are like ribbons that coil to form more stable structures, for example, alpha helices and pleated sheets. The final three-dimensional structure of the protein is formed by non-covalent interactions between the amino acids of the protein. A quaternary structure is also formed when multiple three-dimensional proteins bind to form a single larger protein. (Tallon Decl. ¶ 59). Denaturation results in a "looser and more random structure, " and that "looser and more random structure" causes proteins, such as enzymes, to lose their activity because the substrates can no longer bind to the active site of the enzyme. (Tallon Decl. ¶ 60).

It was well known that active lipases and phospholipases, enzymes present in krill, if not deactivated, will cause triglycerides (triacylglycerols) and glycerol-based phospholipids (phosphoglycerides) present in the krill to decompose and form free fatty acids. (*See, e.g.,* Saether, p. 51, Exhibit 1027, p. 0001; Tallon Decl. ¶ 60). It was also well recognized that an effective method to denature enzymes was to apply heat. For example, Yoshitomi teaches that a krill product "is produced by a process including only heating as means for denaturing protein and disabling

the proteolytic enzymes originally contained in krill materials." (Abstract, Exhibit 1033, p. 0001; Tallon Decl. ¶¶ 167, 170, 172, 174).

Thus, "to denature lipases and phospholipases" means "to alter the conformational structure of lipases and phospholipases to reduce lipid and phospholipid decomposition." (Tallon Decl. ¶¶ 55-62).

3. Claims 1 and 11 – "polar solvent"

The term "polar solvent" recited in Claims 1 and 11 is not explicitly defined in the specification, but is described. In the "Krill Processing" section of the Detailed Description, applicants disclose methods of making a *Euphausia superba* krill oil by contacting a *Euphausia superba* preparation, such as *Euphausia superba* krill meal with a *polar solvent, such as ethanol* to extract lipids. ('877 patent, 12:24-36, Exhibit 1001, p. 0030) (emphasis added). Applicants also disclose, "In some embodiments, krill oil is extracted from denatured krill meal. In some embodiments, the krill oil is extracted by contacting the krill meal with ethanol." ('877 patent, 11:3-5, Exhibit 1001, p. 0030).

In the Background of the Invention, it was admitted:

> In order to isolate the krill oil from the krill, solvent extraction methods have been used. See, e.g., WO

> 00/23546. Krill lipids have been extracted by placing the material in a ketone solvent (e.g., acetone) in order to extract the lipid soluble fraction. …Further processing steps include extracting and recovering by evaporation the remaining soluble lipid fraction from the contents by using a solvent such as ethanol. See, e.g., WO 00/23546. ('877 patent, 1:31-40, Exhibit 1001, p. 0025).

In the Detailed Description, it was also noted:

> In some embodiments, krill oil is extracted from the denatured krill meal. In some embodiments, the krill oil is extracted by contacting the krill meal with ethanol. In some embodiments, krill is then extracted with a ketone solvent such as acetone. In other embodiments, the krill oil is extracted by one or two step supercritical fluid extraction. In some embodiments, the supercritical fluid extraction uses carbon dioxide and neutral krill oil is produced. In some embodiments, the supercritical fluid extraction uses carbon dioxide with the addition of a polar entrainer, such as ethanol, to produce a polar krill oil. In some embodiments, the krill oil meal is first extracted with carbon dioxide followed by carbon dioxide with a polar entrainer, or vice versa. In some embodiments, the krill meal is first extracted with CO_2

> supplemented with a low amount of a polar co-solvent (e.g., from about 1% to about 10%, preferably about 5%) such a C_1-C_3 monohydric alcohol, preferably ethanol, followed by extraction with CO_2 supplemented with a high amount of a polar co-solvent (from about 10% to about 30%, preferably about 23%) such as such a C_1-C_3 monohydric alcohol, preferably ethanol, or vice versa. " ('877 patent, 11:3-24, Exhibit 1001, p. 0030)).

Thus, the '877 patent contemplates extraction using either a polar solvent or a mixture of a polar solvent and supercritical CO_2. (*See* Tallon Decl. ¶¶ 49-52.)

The solvent must also be able to extract lipids that include phospholipids, and the '877 patent explains "[i]n some embodiments, the present invention provides a method of making a *Euphausia superba* krill oil composition comprising contacting *Euphausia superba* with a polar solvent to provide an polar extract comprising phospholipids." ('877 patent, 6:12-16, Exhibit 1001, p. 0027). Typical polar organic solvents (pure or mixtures) used in industrial practice that meet these criteria include alcohols (*e.g.,* methanol, ethanol, and isopropyl alcohol), ketones (particularly acetone), and esters (*e.g.* ethyl acetate) (*See* Tallon Decl. ¶ 53).

Thus, the broadest reasonable construction of "polar solvent" is "solvent or a mixture of solvents capable of extracting polar lipids comprising phospholipids." (Tallon Decl. ¶¶ 49-54.)

4. Claims 3 and 11 - "freshly harvested krill"

The '877 patent specification does not include the term "freshly harvested" with regard to the krill. The specification does, however, refer to "freshly caught" krill, but does not define the term or define how long the krill remains fresh after being caught. The only disclosure in the '877 patent of the time between harvesting and processing of the "freshly harvested" krill is as follows:

> The krill meal has been processed on board a ship in Antarctica using live krill as starting material in order to ensure the highest possible quality of the krill meal. ('877 patent, 9:33-36, Exhibit 1001, p. 0021).

Example 6 further notes:

> Fresh krill was pumped from the harvesting trawl directly into an indirect steam cooker, and heated to 90C. ('877 patent, 30:62-63, Exhibit 1001, p. 0039).

The '877 patent further explains that "[t]he methods described above rely on the processing of frozen krill that are transported from the Southern Ocean to the

processing site. This transportation is both expensive and can result in degradation of the krill starting material." ('877 patent, 2:5-7, Exhibit 1001, p. 0025).

It was well known that proteases and lipases naturally found in krill begin to digest the krill soon after being caught. In fact, the '877 patent acknowledges that krill can quickly degrade between the time it is caught and the time it is processed:

> Data in the literature showing a rapid decomposition of the oil in krill explains why some krill oil currently offered as an omega-3 supplement in the marketplace contains very high amounts of partly decomposed phosphatidylcholine and also partly decomposed glycerides. Saether *et al.*, Comp. Biochem Phys. B 83B(l): 51-55 (1986)[Exhibit 1027, pp. 0001-0005]. The products offered also contain high levels of free fatty acids. ('877 patent, 2:2-13, Exhibit 1001, p. 0025; *see* Tallon Decl. ¶¶ 64, 66).

This explanation is consistent with the extrinsic evidence. For example, Webster's New Universal Unabridged Dictionary defines "fresh" in relevant part to mean, "not spoiled, rotten, or stale; as *fresh* milk." (Exhibit 1029, p. 0003; *see* Tallon Decl. ¶ 65).

Thus, the proper construction of the term "freshly harvested krill" is

"recently caught krill that has not significantly degraded." (Tallon Decl. ¶¶ 63-67).

5. Claim 6 - "polar entrainer"

The specification does not expressly define "polar entrainer" but applicants disclosed that ethanol is an example of a polar entrainer and that:

> Surprisingly, it has been found that use of a low amount of polar solvent in the CO_2 as an entrainer facilitates the extraction of neutral lipid components and astaxanthin in a single step. Use of the high of polar solvent as an entrainer in the other step facilitates extraction of ether phospholipids, as well as non-ether phospholipids. ('877 patent, 1:23-28, Exhibit 1001, p. 0025).

Thus, the proper construction of "polar entrainer" is "a polar solvent additive to aid in extraction." (Tallon Decl. ¶¶ 68-70).

VI. EACH GROUND PROVIDES MORE THAN A REASONABLE LIKELIHOOD THAT EACHCLAIM OF THE '877 PATENT IS UNPATENTABLE

A detailed discussion of each ground for claim invalidation, *i.e.*, Grounds 1-5, is set forth below. In support of the invalidity arguments, Petitioner relies upon the Declaration of Dr. Stephen Tallon (Exhibit 1006) and the opinions and analyses set forth therein.

A. Ground 1: §103(a) – Grantham, Fricke, and Tanaka I [Claims 1-3, 8-9, 11-12, and 17-18]

The '877 patent includes two (2) independent claims (claims 1 and 11) and a total of nineteen (19) claims. The two independent claims are directed to methods for producing krill oil. However, extracting oil from krill was well known (*See, e.g.,* Grantham, Exhibit 1032, p. 0039, Fricke, Exhibit 1010, p. 0001; *see* Budziński, Exhibit 1008 *infra* pp. 20-23.

Claim 1 recites a method that requires treating krill to denature the krill to form a denatured krill product on board a ship before a polar solvent is used to extract oil from the denatured krill product. Claim 11 is directed to a similar method but, instead of requiring the krill to be denatured on board a ship, claim 11 requires a method that treats "freshly harvested krill" to denature the krill and obtain a denatured krill product before a polar solvent is used to extract krill oil from the denatured krill product.

1. Claims 1 and 11

Claim 11 combines steps (a) and (b) of claim 1 into step (a) of claim 11. Steps (a) and (b) of claim 1 require that "krill" be is processed into a denatured krill product. Step (a) of claim 11 requires that "freshly harvested krill" be

processed into a denatured krill product. During prosecution, after applicants' attorney conducted a telephone interview with the Examiner, an Examiner's Amendment was mailed with the Notice of Allowance, requiring the addition of the limitation that "steps a and b [of claim 1] are performed on a ship." (*see supra*, pp. 22-23) Thus, the only difference between claim 1 and claim 11 is that claim 1 requires that krill be processed "on board" while claim 11 requires that "freshly harvested krill" be processed. Both the "on board" and "freshly harvested" limitations of claims 1 and 11, respectively are expressly taught by Grantham. (Tallon Decl. ¶¶ 160-162, 164-165).

Grantham was prepared by the Food and Agriculture Organization of the United Nations ("FAO") to gather together the then current (1977) knowledge on the biochemistry, processing, and marketing of Antarctic krill. (Exhibit 1032, p. 0010) (Tallon Decl. ¶¶ 158-159).Grantham focused on *Euphausia superba* and observed that "[t]he predominant type of commercially caught krill, and biochemical composition of krill will determine its technological and nutritional properties and thus directly influence the selection of processing and product options. Commercial catches of krill would seem to consist predominantly of

Euphausia superba. Therefore the biochemical composition of the catch will be characterized by the euphausiid . . .". (Exhibit 1032, pp. 0011) (Tallon Decl. ¶ 159).

Grantham also discussed the krill's highly active enzymes which breaks down the krill's proteins so that storage of krill was problematic: "The inherent instability of krill after catching has profound implications for processing and pre-processing, product type and quality, storage regimes, vessel design and fleet structure. Once landed, krill spoil rapidly because their organs - particularly the liver (hepatopancreas) and stomach - contain highly active enzymes which cause the rapid development of autolysis…. The Russian consensus would seem to be that krill should not be held for more than one hour at 10°C before processing, or for 3 - 4 hours at 0 – 7°C, and in depths of not greater than 30 cm . . . ." (Exhibit 1032, pp. 0026-0027) (Tallon Decl. ¶ 160).

Grantham repeatedly refers to the production of krill meal on board ship.

- The production of krill meal and KPC type B can be **undertaken on board ship**, using packaged units on catcher-processors or large scale plants on factory vessels. (Exhibit 1032, p. 0036) (emphasis added)

(Tallon Decl. ¶ 162).

- "**Cooking has been traditionally achieved on board ship** by immersion in tanks of boiling sea-water; a recent Japanese krill patent (Kyokuyo 1976) describes a continuous boiling process at 90°C for 3 to 15 minutes, where improved temperature control is said to improve product quality." (Exhibit 1032, pp. 00036, 0038) (emphasis added) (Tallon Decl. ¶ 164).
- "The krill is generally **boiled at sea** before freezing." (Exhibit 1032, p. 0043) (emphasis added) (Tallon Decl. ¶ 165).

Thus, Grantham expressly teaches "treating" krill "on a ship" as set forth in claim 1 and "treating freshly harvested krill" as set forth in claim 11. (Tallon Decl. ¶¶ 160-164).

Furthermore, Grantham notes that by-products of the processing of krill that that may be of interest, to include "fat, chitin, pigment and enzymes. They will be generated in varying degrees of purity by several of the processes described previously." (Exhibit 1032, p. 0039); Tallon Decl. ¶ 166).

(a) Grantham and Fricke disclose the three steps recited in claim 1

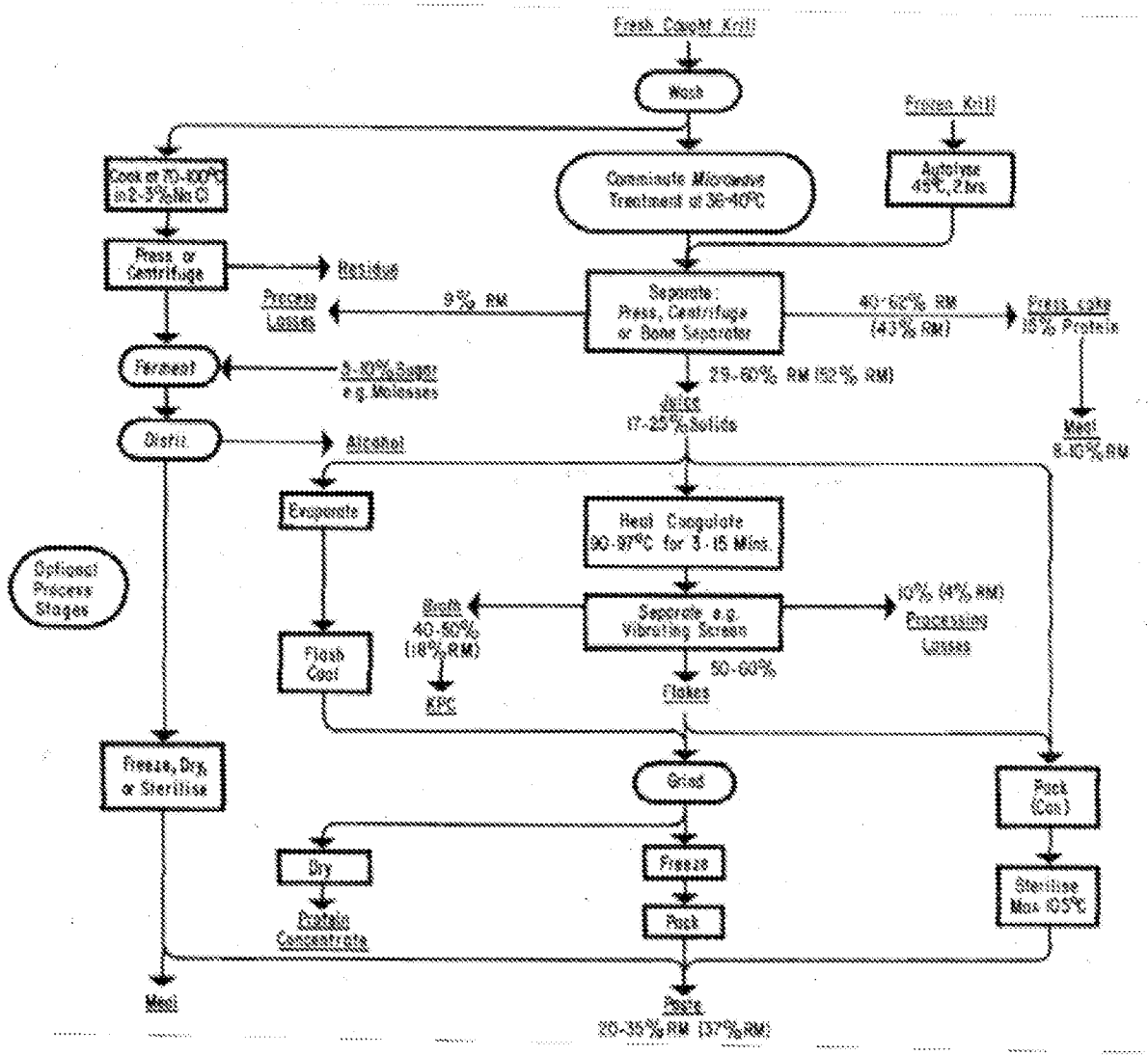
(i) providing krill

Grantham states "[o]nce the krill are caught, the catch should be utilized in a manner that maximizes their food potential and justifies the substantial efforts expended in their harvesting." (Exhibit 1032, p. 0026). Further, the "providing krill" step is subsumed in the "treating" step discussed below since one would need to first provide krill in order to treat it.

(ii) treating the krill to provide a denatured product

Grantham expressly discloses that "**[h]eat treatment** is the most commonly used technique for frozen krill products. Boiling krill and krill products has been shown to **inactivate** the proteolytic, **lipolytic** and pigment degrading **enzymes**…." (Exhibit 1032, p. 0036) (emphasis added) (Tallon Decl. ¶ 164).

In fact Grantham illustrates a shipboard processes -- a Norwegian process for the production of krill meal which includes the stages of catching krill (the freshly caught krill), washing the krill, then cooking the krill at 70-100°C and provides a flow chart for this process:



(Exhibit 1032, pp. 0033-0034) (Tallon Decl. ¶ 161).

Grantham also specifically teaches a krill meal by type that can be produced by cooking fresh krill on board ship, namely KPC type B (Krill Protein Concentrate type B) that "involves cooking, pressing and drying to hygienic krill

meal". Another krill product described by Grantham uses "proteolysis, separation and drying to produce a hydrolysate (KPC type A)." (Exhibit 1032, p. 0035) (Tallon Decl. ¶¶ 162-163).

Similarly, Fricke discloses that krill can be "cooked on board immediately after hauling and stored" (Exhibit 1010, pp. 0002-0003). (Tallon Decl. ¶ 100.)

(iii) extracting krill oil with a polar solvent

Grantham discloses that **"[s]olvent extraction** has also been reported as a means of **removing fat** and pigment from whole boiled krill or shell waste (Nippon Suisan 1976); solvent mixes include **acetone** and petroleum ether, iso-propanol and n-hexane, and chloroform." (Exhibit 1032, p. 0039) (emphasis added) (Tallon Decl. ¶ 166). A POSITA would have been readily familiar with the solvents listed above for extraction processes and would have understood that polar solvents, including acetone, may be used to extract fats [lipids]. *See* Tallon Decl. ¶ 86.

Fricke (1010) also discloses this claim element. In Fricke, lipid extraction from the krill was performed according to the method of Folch (1957) (Exhibit 1010, p. 0001). That is, "the lipides were extracted by homogenizing the tissue with 2:1 chloroform-methanol (v/v) [a polar solvent], and filtering the

homogenate" (Folch, Exhibit 1017, p. 0001) (Tallon Decl. ¶ 99).

Thus, it would have been obvious to a POSITA to treat krill on board a ship to provide a denatured product and then extract krill oil using a polar solvent as recited in Claim 1. (Tallon Decl. ¶¶ 199-200).

(b) Grantham and Fricke disclose the two steps in the method of claim 11:

(i) a denatured krill product produced by treating freshly harvested krill.

As discussed above, Grantham illustrates that producing a denatured krill product by treating freshly harvested krill was well known in the art. For example, Grantham observes that "**[h]eat treatment is the most commonly used technique** for frozen krill products. Boiling krill and krill products has been shown to **inactivate** the proteolytic, **lipolytic** and pigment degrading **enzymes**…." (Exhibit 1032, p. 0036 (emphasis added) (Tallon Decl. ¶ 164).

Grantham describes processing krill on board ships was a common practice. *See supra*, pp. 32-33; Tallon Decl. ¶¶ 161-165. In fact, Grantham specifically discloses a krill meal that was produced by cooking on board ship that "involves cooking, pressing and drying to hygienic krill meal (KPC type B)," as well as another krill meal product that uses proteolysis, separation and drying to produce a

hydrolysate (KPC type A)." (Exhibit 1032, p. 0035) (Tallon Decl. ¶ 163).

Similarly, Fricke (Exhibit 1010) also teaches that lipids were extracted from the krill samples caught in the Scotia sea (December 1977) and in the Gerlache Strait (March 1981) was performed using a polar solvent and that some of those krill samples were cooked (*i.e.*, heated) on board immediately after being caught. hauling and stored under the same conditions. Exhibit 1010, p. 0002-0003; *see* Tallon Decl. ¶¶ 97-99).

Thus, cooking of freshly harvested krill as expressly described by both Fricke Grantham also disclose treating to denature lipases and phospholipases of freshly harvested krill in step (a) of claim 11. (Tallon Decl. ¶¶ 221-223).

(ii) a polar solvent is used to extract krill oil from the denatured krill product

Grantham discloses that **"[s]olvent extraction** has also been reported as a means of **removing fat** and pigment from whole boiled krill or shell waste (Nippon Suisan 1976); solvent mixes include **acetone** and petroleum ether, iso-propanol and n-hexane, and chloroform." (Exhibit 1032, p. 0039) (Tallon Decl. ¶ 166). Fricke also describes lipid extraction from krill samples with a polar solvent (Exhibit 1010, p. 0001) (*See* Tallon Decl. ¶ 99).

Thus, it would have been obvious to a POSITA to treat freshly harvested krill to obtain a denatured krill product and extract krill oil using a polar solvent. (Tallon Decl., ¶¶ 200, 208-210).

(c) Claim 1 and claim 11 require extracted krill oil with the same composition

Claims 1 and 11 are directed to three and two-step methods for providing krill oil. Both claims require the krill oil to have "from about 3% to about 10% w/w ether phospholipids; from about 27% to 50% w/w non-ether phospholipids; from about 30% to 60% w/w total phospholipids; and from about 20% to 50% w/w triglycerides."

Grantham discloses various components of extracted krill oil, including phospholipids, fatty acids, triglycerides (*e.g.,* Exhibit 1032, p. 0020, Table 6). Moreover, other prior art references provide greater detail as to the natural components extracted from krill. Grantham discloses the steps in claims 1 and 11, the use of freshly harvested krill for heat processing into a denatured krill product and the extraction of krill oil using a solvent, while the other references provide an analysis of the natural components found in krill oil.

(i) Total phospholipids

Table 1 of Fricke (Exhibit 1010, p. 0002), reproduced below, details the levels of the phospholipid classes. By adding all of the listed phospholipids in Table 1, the total phospholipid level for the 12/1977 sample is 45.7 weight % of total lipids; and for the 3/1981 sample, the total phospholipid level is 44.0 weight %. (*E.g.,* Tallon Decl. ¶ 104).

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.

Thus, Fricke expressly teaches total phospholipids within the "from about 30% to 60% w/w" range recited by claims 1 and 11. (Tallon Decl. ¶¶ 104, 213-214).

(ii) Ether phospholipids

Tanaka I investigated the effects of oxidation of phosphatidlycholines (PCs), which have been associated with cytotoxicity. The subclasses of phosphatidylcholine were measured by Tanaka and the quantities of alkylacyl-phosphatidylcholine (AAPC, an ether phospholipid), and other phosphatidylcholine subtypes were reported. (Exhibit 1014, p. 0002). The proportion of AAPC in the total phosphatidylcholine extracted from krill is reported in Table 1 of Tanaka I is 23.0 ±1.2 %. See below, Tanaka I, 'Alkylacyl' col. ('Subclass Composition of PCs from Food Stuffs') (Exhibit 1014, p. 0003) (*See, e.g,* Tallon Decl. ¶ 135).

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.

Table 1 of Fricke reproduced below shows the lipid composition of the Antarctic krill for both samples. Table 1 shows the PC level for both samples as approximately 34% (35.6 +/- 0.1 for 1977 sample and 33.3 +/- 0.5 for 1981 sample). (Exhibit 1010, Table 1, p. 0002.) (Tallon Decl. ¶ 102).

TABLE I

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 ± 1.9
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.

Since Tanaka I demonstrates that AAPC is 23.0 +/- 1.2% of krill phosphatidylcholine and Fricke 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%),*** which is between the 3% and 10% required by Claim 1. (Tallon Decl. ¶ 102).

Accordingly, Tanaka I discloses an ether phospholipids level of 7.8% which is within the 3% of 10% range required by Claims 1 and 11. (Tallon Decl. ¶¶ 211-212).

(iii) Non-ether phospholipids

Fricke also provides a detailed analysis of lipid classes, fatty acids of total and individual lipids and sterols found in Antarctic krill and discloses a total phospholipids amount of 44.0 +/- 2.0 % w/w in a lipid composition of Antarctic krill (Exhibit 1010, Table 1, p. 0002) (Tallon Decl. ¶ 104). Tanaka I, in combination with Fricke, discloses that ether phospholipids make up about 7.8% of the total phospholipids in Fricke's Antarctic krill. Therefore, the lipid composition in the krill analyzed by Fricke contains **about 36.2% non-ether phospholipids** (*i.e.,* 44.0% - 7.8%). (Tallon Decl. ¶ 104). Thus, the "from about 27% to 50% w/w non-ether phospholipids" required by claim 1 is disclosed by Fricke in combination

with Tanaka I. (Tallon Decl. ¶ 213-215).

(iv) Triglycerides

Table 1 (Exhibit 1010, p. 0002) of Fricke also reports levels of triacylglycerols (triglycerides) of 33.3 +/- 0.5 and 40.4 +/- 0.1 for both the 1977 and 1981 krill samples, respectively. (Tallon Decl. ¶ 101).

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.

Thus, Fricke discloses triglycerides in the "from about 20% to 50% w/w" range

required by claims 1 and 11. (Tallon Decl. ¶¶ 216-217).

Accordingly, in view of the disclosures in Fricke and Tanaka I in combination with Grantham, a POSITA would find the krill compositions and claims 1 and 11 to be obvious. (*See* Tallon Decl. ¶¶ 199-218)

2. Claims 2 and 12

Claims 2 and 12 require the **heat treatment** of krill. As discussed above in connection with Claim 1, well known techniques were disclosed in both Grantham and Fricke. For example, Grantham discloses "**[h]eat treatment is the most commonly used technique** for frozen krill products. Boiling krill and krill products has been shown to ***inactivate*** the proteolytic, ***lipolytic*** and pigment degrading ***enzymes***…" (Exhibit 1032, p. 0036) (emphasis added) (Tallon Decl. ¶ 160). Grantham also teaches that it was well known that "krill is generally **boiled at sea**" (Exhibit 1032, p. 0043) (Tallon Decl. ¶ 105).

Likewise, Fricke discloses that freshly harvested krill was "cooked on board" the ship "immediately" after being caught (Exhibit 1010, pp. 0002-0003). (Tallon Decl. ¶ 100).Thus, Grantham and Fricke both describe the additional requirements of claims 2 and 12 of treating krill by heating. Accordingly, in view of the disclosures in Grantham, Fricke and Tanaka I, a POSITA would have found

krill methods and krill compositions of claims 2 and 12 to be obvious. (Tallon Decl. ¶¶ 219-224).

3. Claim 3

Claim 3 requires that the krill be ***freshly harvested***. However, this claim limitation was well known in the art. For example, Grantham discussed the known problem of storing krill because of the effect of the krill's highly active enzymes breaking down the krill's proteins and observed that the " inherent instability of krill after catching has profound implications for processing and pre-processing, product type and quality, storage regimes, vessel design and fleet structure. Once landed, krill spoil rapidly because their organs - particularly the liver (hepatopancreas) and stomach - contain highly active enzymes which cause the rapid development of autolysis…. The Russian consensus would seem to be that krill should not be held for more than one hour at 10°C before processing, or for 3 - 4 hours at 0 – 7°C, and in depths of not greater than 30 cm . . . ." (Exhibit 1032, pp. 0026-0027) (Tallon Decl. ¶ 160).

Similarly, Fricke described freshly harvested krill was "cooked on board" the ship "immediately" after being caught (Exhibit 1010, pp. 0002-0003) (Tallon Decl. ¶ 100).

Accordingly, in view of the disclosures in Grantham, Fricke and Tanaka I, a POSITA would have found the methods and krill compositions of claim 3 to be obvious. (Tallon Dec. ¶¶ 225-227).

4. Claims 8 and 17

Claims 8 and 17 require that the krill is Antarctic krill. Again, details regarding the composition and processing of Antarctic krill was well known for years. For example, Grantham was prepared to gather together current knowledge on the biochemistry, processing and marketing of **Antarctic krill**." (Exhibit 1032, p.0009, Abstract). Further, Table 1 of Fricke (Exhibit 1010, p. 0002) is entitled, "Lipid Composition of Antarctic Krill." (Tallon Decl. ¶ 229.).

Therefore, in view of the teachings of Grantham and Fricke in combination with Tanaka I, a POSITA would find the use of Antarctic krill required by claims 8 and 17 obvious.

5. Claims 9 and 18

Claims 9 and 18 depend on claims 8 and 17, respectively, and require the Antarctic krill in claims 8 and 17 to be *Euphausia superba*.

Grantham affirmatively states that "[c]ommercial catches of krill would seem to consist predominantly of ***Euphausia superba***." (Exhibit 1032, p.0011)

(Tallon Decl. ¶ 159). Grantham also discloses that the introduction of whole krill as a food source in Japan was "plausible as ***E. superba*** has a similar appearance, taste and texture" to other established crustacea. (Exhibit 1032, p.0042) (Tallon Decl. ¶ 159). Grantham further states that in Japan "Euphausiids have been eaten for many centuries, thus assuring both their palatability and their lack of toxicity (Parsons 1972). Several series of biological tests on **E. superba** have confirmed its nutritional quality." (Exhibit 1032, p.0051). (Tallon Decl. ¶ 159).

Likewise, Fricke discloses that "[k]rill (*Euphausia superba* Dana) lives exclusively in cold Antarctic waters." (Exhibit 1010, p. 0001).

Therefore, in view of Grantham and Fricke in combination with Tanaka I, a POSITA would find the use of *Euphausia superba* krill in claims 9 and 18 to be obvious. (Tallon Decl. ¶¶ 22-24, 228-230).

Reason to Combine

A POSITA would have possessed motivation and reason to combine Grantham, Fricke and Tanaka I. As detailed above, Grantham discloses that it was well known to use available heat treatment or cooking techniques to process freshly captured krill on board the ship to produce krill meal, and then to extract

krill oil from that denatured krill product using conventional organic solvents. In particular, Grantham stresses the importance of the reduction in lipolytic enzymes to avoid decomposition early in krill processing through, for example, heat treating or cooking. (*See supra*, pp. 32-37). Fricke also noted the importance of prompt reduction of lipolytic enzymes to preserve phospholipids and their associated fatty acids, *e.g.,* omega-3. (*See supra*, p. 39). Fricke describes that there were a number of prior publications that investigated the "lipid composition" that is naturally found in krill. (Exhibit 1010, p. 0001). Tanaka I provides the level of PC and various subclasses, including ether-PC for krill. As of the earliest effective filing date of the '877 patent it was well recognized that phospholipids and, phosphatidlycholine in particular, were associated with beneficial health effects. (*See, e.g.*, Sampalis II, 1013, pp. 0017-0022) (Tallon Decl. ¶ 155). Further, the health benefits of omega-3 fatty acids, particularly in connection with cardiovascular disease, was also well established. (Exhibit 1032, p. 0036) (Tallon Decl. ¶ 179). Accordingly, a POSITA performing the treatment and extraction steps disclosed in Grantham would be motivated to look to other references such as Fricke and Tanaka I to ascertain the components of the krill oil and their amounts

that were obtained by standard extraction methods. (Tallon Decl. ¶ 235).

B. Ground 2: § 103(a) – Grantham, Fricke, Bottino, and Tanaka I [Claims 4, 5, 13 and 14]

The discussions above regarding the obviousness of claims 1 and 11 are incorporated herein.

1. Claims 4 and 13

Claims 4 and 13 require that the krill oil comprises from about 20% to 35% omega-3 fatty acids as a percentage of total fatty acids in said krill oil. Bottino discloses an extract of phospholipids having an omega-3 fatty acid content of "at least 15% w/w, more preferably at least 40% w/w." Bottino discloses krill oil having about 20% to 35% (30.5%, 26.8%, 25.0%, and 28.6 %) omega-3 fatty acids as a percentage of total fatty acids in the composition as required by claims 4 and 13. (Bottino, Exhibit 1007, p. 0002) (Tallon Decl. ¶¶ 120-121).

Specifically, Bottino analyzed the fatty acid content of Antarctic phytoplankton and Euphausiids, in particular *Euphausia superba* and *E. crystallorophias*. *E. superba* is the better-known species found in the Southern Oceans and has been considered almost a synonym for krill. (Exhibit 1007, p. 0001). The *E. superba* samples were collected from various locations (stations) and

lipids were extracted "immediately after capture" using a chloroform:methanol 2:1 v/v mixture as described in Folch. The fatty acids were analyzed using chromatography. (Exhibit 1007, pp. 0001-0002).

Table 1, reproduced below, details the fatty acid content in *E. superba* from 3 different stations as a weight percent of total fatty acids. The percentage of omega-3 fatty acids are circled in the chart and total 30.5%, 26.8%, and 25%, respectively. (Tallon Decl. ¶¶ 120.) Thus, all three samples had an omega-3 fatty acid content of between 20% to 35% omega-3 fatty acids as a percentage of total fatty acids, as required by Claims 4 and 13. (Tallon Decl. ¶¶ 119-120).

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

Footnote c of Table 1 indicates "[o]nly those fatty acids present at a level of 1% or more are included."

Table 3 of Bottino, reproduced below, further identifies all of the fatty acids identified from the various species tested as a weight percent of total fatty acids. The fatty acid content from *E. superba* is provided as an average of the 3 stations. The omega-3 fatty acid content from *E. superba* in Table 3 are circled below.

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

Fatty acid												Euphausia superba (average of 3 stations)	
18:2(n-3)	3.7	3.3	2.4	3.1	3.3	3.0	2.7	2.1	7.1	10.0	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	0.2	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)	2.6	3.1	3.5	5.2	6.0	3.0	2.7	3.2	6.2	0.9	3.2	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	0.3
22:4(n-6)	-	-	-	-	-	-	-	-	-	trace	-	-	0.2	-
22:4(n-3)	1.3	-	trace	-	-	-	-	trace	-	trace	-	-	-	-
20:5(n-3)	11.4	6.8	8.2	7.6	6.4	1.7	2.1	5.3	6.0	2.1	16.4	23.6	13.1	16.6
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	8.6	5.5	0.9	0.8	2.1	7.8	16.3	5.5	11.0	8.1	7.5
Minor fatty acids[b]	3.3	1.5	4.3	4.8	1.0	3.2	0.6	4.0	2.8	1.8	0.5	0.9	0.8	0.4

Bottino teaches that all omega-3 fatty acids, including those less than 1% omitted in Table 1, total 28.6%. (Tallon Decl. ¶¶ 120-121).

Therefore, Bottino discloses that the krill oil includes from about 20% to 35% omega-3 fatty acids as a percentage of total fatty acids in the composition which is well within the range of "about 20% to 35%" recited in Claims 4 and 13.

Accordingly, the teaching of Bottino in combination with Grantham, Fricke, and Tanaka I, renders claims 4 and 13 obvious to a POSITA. (Tallon Decl. ¶¶ 236-239).

2. Claims 5 and 14

Claims 5 and 14 require that **from about 70% to 95% of the omega-3 fatty acids are attached to the total phospholipids**.

Table 1 in Fricke (Exhibit 1010, p. 0002) details the amount of each lipid class in the total lipid composition of krill. Tables 4 and 5, reproduced below, provide the omega-3 fatty acid composition of each phospholipid class (Exhibit 1010, pp. 0004-0005). The omega-3 fatty acids in Tables 4 and 5 are identified as 18:3(n-3), 18:4(n-3), 20:5(n-3), 21:5(n-3), 22:5(n-3), and 22:6(n-3). (Tallon Decl. ¶ 106, n. 3).

TABLE 4

Fatty Acid Analysis of Polar Lipid Classes of *Euphausia superba* Dana

Polar lipid	PC		PE		LPC		PI		PA + CI	
Sample	12/1977	3/1981	12/1977	3/1981*	12/1977	3/1981*	12/1977	3/1981*	12/1977	3/1981*
14:0	4.5 ± 1.1	2.8 ± 1.1	2.9 ± 1.1	–	9.1 ± 5.4	4.2	3.5 ± 0.3	3.2	6.0 ± 1.4	–
15:0	–	–	–	–	–	–	–	1.6	–	–
16:0	43.7 ± 7.2	25.7 ± 1.4	42.7 ± 9.3	24.2	40.5 ± 8.9	18.7	33.9 ± 5.9	24.9	39.3 ± 6.3	23.7
16:1(n-7)	3.7 ± 0.4	2.2 ± 0.3	2.0 ± 1.0	1.9	4.4 ± 2.3	2.8	2.2 ± 0.9	1.2	3.6 ± 0.8	4.3
18:0	1.8 ± 0.5	1.5 ± 0.2	3.2 ± 1.0	2.9	2.1 ± 0.3	1.5	6.1 ± 1.0	7.3	2.5 ± 0.1	2.6
18:1(n-7)	7.7 ± 0.8	6.1 ± 0.8	15.0 ± 3.9	16.3	9.7 ± 3.7	4.0	11.6 ± 3.3	10.9	12.3 ± 0.6	14.7
18:1(n-9)	9.2 ± 1.7	5.4 ± 1.1	5.4 ± 2.1	6.8	10.3 ± 3.3	7.3	6.5 ± 0.4	7.9	4.9 ± 1.5	8.7
18:2(n-6)	1.6 ± 0.1	1.1 ± 0.1	1.0 ± 0.6	1.0	1.1 ± 0.8	1.6	1.7 ± 0.7	1.7	1.4 ± 0.1	1.6
18:3(n-3)	–	0.8 ± 0.2	–	–	–	1.1	–	0.6	–	1.6
18:3(n-6)	–	2.7 ± 0.4	–	0.7	–	3.8	–	–	–	1.7
18:4(n-3)	–	–	–	–	–	–	–	–	–	0.8
20:1(n-7)	–	–	–	–	–	–	–	–	–	–
20:1(n-9)	0.6 ± 0.1	0.9 ± 1.1	–	0.8	–	0.8	–	1.1	–	1.1
20:5(n-3)	10.7 ± 0.6	29.9 ± 2.2	10.5 ± 4.9	21.1	2.6 ± 0.1	31.2	8.1 ± 0.1	20.1	1.9 ± 1.0	19.7
21:5(n-3)	1.0 ± 0.7	1.1 ± 0.0	–	0.7	–	1.6	–	1.9	–	0.8
22:1(n-7)	–	0.9 ± 0.1	–	–	–	1.0	–	–	–	–
22:1(n-9)	–	1.7 ± 0.2	–	–	–	1.5	–	1.4	–	–
22:5(n-3)	0.9 ± 0.6	0.6 ± 0.2	–	0.9	–	1.1	–	1.8	–	–
22:6(n-3)	6.2 ± 0.6	11.5 ± 1.0	7.6 ± 2.3	19.2	1.2 ± 0.2	12.2	1.8 ± 0.7	10.1	1.1 ± 0.3	15.5
Phytanic acid	0.7 0.6	–	–	–	–	–	–	–	–	–

TABLE 5

Fatty Acid Analysis of Neutral Lipid Classes of *Euphausia superba* Dana

Neutral lipid	TAG		FFA		DG		MG		WE + SE	
Sample	12/1977	3/1981	12/1977	3/1981	12/1977*	3/1981*	12/1977*	3/1981*	12/1977*	3/1981*
12:0	0.5 ± 0.1	–	–	0.8 ± 0.2	–	–	–	–	3.7	–
14:0	23.3 ± 0.2	21.8 ± 2.0	7.9 ± 1.0	5.1 ± 0.7	4.5	6.1	2.1	3.8	14.8	8.8
15:0	0.5 ± 0.1	–	–	–	–	0.5	–	1.2	–	–
16:0	29.9 ± 1.6	21.8 ± 1.8	32.5 ± 1.1	12.1 ± 2.2	19.4	16.9	9.6	10.3	25.1	37.8
16:1(n-7)	8.9 ± 1.9	13.1 ± 0.3	4.8 ± 1.0	4.9 ± 0.5	5.6	7.1	2.0	6.6	10.8	8.8
18:0	1.5 ± 0.2	1.8 ± 0.3	1.5 ± 0.2	0.7 ± 0.1	2.1	2.0	–	2.1	2.2	2.6
18:1(n-7)	5.9 ± 1.1	6.6 ± 3.1	12.9 ± 2.7	8.5 ± 2.2	14.7	7.5	73.7	10.9	15.8	17.5
18:1(n-9)	11.9 ± 3.6	12.1 ± 2.5	7.1 ± 0.6	4.7 ± 1.3	6.5	10.4	2.3	14.5	14.3	11.9
18:2(n-6)	0.7 ± 0.5	1.0 ± 0.2	1.5 ± 0.3	0.9 ± 0.2	3.1	1.3	0.8	1.3	1.9	–
18:3(n-3)	–	–	–	0.7 ± 0.2	–	0.8	–	–	–	–
18:3(n-6)	–	4.1 ± 1.0	–	1.5 ± 0.7	0.7	3.0	–	1.8	–	–
18:4(n-3)	–	–	0.6 ± 0.2	3.5 ± 1.2	–	–	–	–	–	–
20:1(n-7)	0.5 ± 0.1	–	–	–	0.5	–	–	–	–	–
20:1(n-9)	0.8 ± 0.2	1.3 ± 0.0	0.5 ± 0.1	1.0 ± 0.3	0.8	0.8	–	0.6	–	–
20:5(n-3)	1.0 ± 0.1	3.3 ± 0.5	11.8 ± 2.2	30.0 ± 2.1	15.8	28.8	2.9	26.8	5.1	11.9
21:5(n-3)	–	–	0.5 ± 0.4	0.9 ± 0.2	–	0.7	–	1.4	–	–
22:1(n-7)	–	–	0.8 ± 0.3	–	2.0	–	–	–	–	–
22:1(n-9)	–	0.5 ± 0.2		0.9 ± 0.4	1.5	1.3	–	0.8	–	–
22:5(n-3)	–	–	0.5 ± 0.3	0.5 ± 0.1	2.5	–	–	1.0	–	–
22:6(n-3)	–	0.7 ± 0.2	6.3 ± 2.4	12.1 ± 1.5	7.0	8.2	1.7	12.8	–	–
Phytanic acid	5.6 ± 0.8	4.1 ± 0.6	1.5 ± 0.6	1.3 ± 0.7	1.5	1.6	1.4	1.3	0.8	0.7

Therefore, the amount of omega-3 and each lipid class relative to the total lipid can be easily determined by multiplying the amount of omega-3 fatty acids for each lipid class by the amount of the particular lipid class in the total lipid composition. This provides the amount of omega-3 associated with each lipid class. The total amount of omega-3 fatty acids associated with the lipid classes that constitute phospholipids can then be calculated. The total amount of omega-3 associated with phospholipids can then divided by the amount of omega-3 in the total lipid from all lipid classes to provide the percentage of omega-3 fatty acid attached to phospholipid. In particular, for the March 1981 sample, 74.81% of the omega-3 fatty acids are attached to phospholipids assuming the 3% free fatty acid content disclosed in Fricke. The calculation for the December 1977 sample

resulted in 82.03%. (*See, e.g.,* Tallon Decl. ¶¶ 107-116)[2].

Thus, in view of the teachings of Fricke in combination with Grantham, Bottino and Tanaka I, a POSITA would find the element "from about 70% to 95% of the omega-3 fatty acids are attached to the total phospholipids" required in Claims 5 and 14 to be obvious. (Tallon Decl. ¶¶ 22-24, 240-243).

Reason to Combine

A POSITA would have possessed reasons and motivation to combine Bottino with the disclosures found in Grantham, Fricke and Tanaka I. Bottino discloses the fatty acid levels of a lipid extract of *Euphausia superba*, and explains that the study of krill at the time of the article (1974) had become intensive as a result of its potential importance as food. (Exhibit 1019, p. 0001). The health benefits of omega-3 fatty acids, particularly in connection with cardiovascular disease, were also well established. (*See, e.g.,* Bunea, Exhibit 1020, pp. 0001-0002) (Tallon Decl. ¶ 179). Moreover, it was known that "[k]rill oil has a unique

[2] Even if one assumes a 1% FFA content disclosed as the low end of Fricke or 4% FFA as disclosed in Budzinski, the values of omega 3 fatty acids attached to phospholipids as calculated all fall between the 70%-95%. (Tallon Decl. ¶¶ 117-118).

biomolecular profile of phospholipids naturally rich in omega-3 fatty acids and diverse antioxidants significantly different than fish oil" and that "[t]he association between phospholipids and long-chain omega-3 fatty acids highly facilitates the passage of fatty acid molecules through the intestinal wall, increasing bioavailability…." (Bunea, Exhibit 1020, p. 0002.) (Tallon Decl. ¶ 181.) Accordingly, a POSITA would have been motivated to consider Bottino to ascertain the omega-3 fatty acids naturally found in krill oil, along with the disclosures of Fricke and Tanaka I detailing other the components found in the krill oil that could be extracted using the processing and extraction methods taught in Grantham and Fricke. (Tallon Decl. ¶ 240-243).

C. Ground 3: § 103(a) to Grantham, Fricke, Tanaka II, and Tanaka I [Claims 6 and 15]

The discussions above regarding the obviousness of claims 1 and 11 are incorporated herein.

Dependent Claims 6 and 15 require that the extraction of krill oil comprises the use of **supercritical fluid extraction with a polar entrainer**. Tanaka II discloses the extraction of phospholipids from salmon roe using supercritical carbon dioxide ("SC-CO_2") and an entrainer . (Exhibit 1015, Abstract, p. 0001).

Tanaka II also discloses the advantages of using SC-CO_2 for extraction including the fact that it is stable and does not react with other materials, and is easily separated and removed. (Exhibit 1015, p. 0001) (Tallon Decl. ¶¶ 137-138). Tanaka II also describes the addition of a polar entrainer to SC-CO_2 for extraction of phospholipids, and that the **preferred polar entrainer is ethanol**, (Exhibit 1015, p. 0003), a highly polar organic solvent. (Tallon Decl. ¶ 138-140).

A POSITA would have found it obvious to extract krill oil from denatured krill product disclosed in Grantham and Fricke using the SC-CO_2 with a polar entrainer (such as ethanol) extraction fluid as disclosed in Tanaka II. A POSITA would have understood that the extraction of phospholipids from salmon roe disclosed in Tanaka II would also be analogous to the extraction of phospholipids from krill meal. (Tallon Decl. ¶ 142).

Thus, a POSITA would find the extraction of krill oil using a supercritical fluid and polar solvent in claims 6 and 15 to be obvious in view of Tanaka II in combination with Grantham, Fricke and Tanaka I. (Tallon Decl. ¶¶ 22-24, 244-246.)

Reason to Combine

Tanaka II describes the benefits of adding a polar entrainer to SC-CO_2 for extraction of phospholipids. Accordingly, a POSITA would have been motivated to combine Tanaka II with the teachings of Grantham, Fricke and Tanaka I, to arrive at the method and krill oil composition recited in Claims 6 and 15. In view of these teachings claims 6 and 15 are obvious.

D. Ground 4: § 103(a) to Grantham, Fricke, Sampalis I, and Tanaka I [Claims 7 and 16]

The discussions above regarding the obviousness of claims 1 and 11 are incorporated herein.

Dependent Claims 7 and 16 require that the method further includes encapsulated krill oil.

Sampalis I describes the administration of a commercial encapsulated krill oil product that is in the form of soft gel capsules -- Neptune Krill Oil™ (NKO™). (Exhibit 1012, p. 0004). Sampalis I explains that Neptune's commercial krill oil product "is a natural health product 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." Sampalis I further details the administration of krill oil encapsulated in soft gels. (Exhibit 1012, p. 0004.) Thus, Sampalis I expressly describes the administration of encapsulated krill oil. (Tallon Decl. ¶¶ 71-75).

Accordingly, a POSITA would have found that krill oil obtained by the processing and extraction techniques described by Grantham in combination with the analysis of the components naturally occurring in krill and krill oil as disclosed by Fricke and Tanaka I could have been encapsulated as described by Sampalis I to be obvious. (Tallon Decl. ¶¶ 22-24, 247-251.)

Reason to Combine

Sampalis I discloses the well-known and convenient use of an encapsulated soft gel capsule for administering krill oil to a person. Thus, a POSITA would have been motivated to combine the methods and krill oil compositions taught by Grantham, Fricke and Tanaka I with the dosage form of Sampalis I, thus rendering claims 7 and 16 obvious. (Tallon Decl. ¶ 227, 228).

E. Ground 5: § 103(a) – Grantham, Fricke, Tanaka I and Sampalis II [Claims 10 and 19]

The discussions above regarding the obviousness of claims 1 and 11 are

incorporated herein.

Claims 10 and 19 require that the krill is Euphausia pacifica, which are also known as Pacific krill.

Grantham notes that "[s]mall whole shrimp and zooplankters are traditional items in the diet of Japan and several other Indo-Pacific courrtries.1/ (Subba Rao 1976). The Japanese introduction of whole krill was, therefore, plausible as ***E. superba*** has a similar appearance, taste and texture to these established crustacea. [1/ Mainly *Sergestes lucens* and *Euphausia pacifica*.]" (Exhibit 1032, p.0042). (Tallon Decl. ¶ 159). Sampalis II also teaches that Pacific krill, including *Euphasia pacifica* are all appropriate sources of krill for its krill oil extract: "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*) . . .". (Exhibit 1013, p. 0027) (Tallon Decl. ¶ 151).

A POSITA would have found it obvious to catch *Euphausia pacifica* krill, and in view of the disclosures found in in Sampalis II and Grantham, that Pacific

krill (*i.e., Euphausia pacifica*) could be processed. Thus, the use of *Euphausia pacifica* – Pacific Ocean krill – in claims 10 and 19 would have been obvious in view of the disclosure in Sampalis II in combination with Grantham, Fricke and Tanaka I.

A POSITA would have been motivated to combine Sampalis II with the references of Ground 1 because, as discussed above, Grantham discloses processing freshly captured krill, including Pacific krill, on board the ship by heat treating (i.e., cooking) to produce krill meal, and extracting krill oil using organic solvents. Sampalis II teaches that *Euphausia pacifica* a Pacific krill is a suitable additional source of krill for extraction. Tanaka I provides the level of PC and various subclasses, including ether-PC for krill. Fricke indicates there were a number of prior publications that investigated krill. (Tallon Decl. ¶¶ 22-24, 252-256).

CLAIM CHART

CLAIMS	REFERENCES
1. A method of production of krill oil comprising:	**Grantham (Exhibit 1032)** P. 0039, sec. 3.4.8. "Four krill processing by-products are of potential interest; **fat**, chitin, pigment and enzymes. They will be generated in varying degrees of purity by several of the processes described previously." **Fricke (Exhibit 1010)** P. 0001, 2nd col. "Krill samples of 5kg were quick-frozen and stored at -35 C until analyzed. Subsamples prepared from the core of the 5 kg samples were homogenized in a mortar under liquid nitrogen, and **lipid extraction was performed** according to Folch *et al.* (15)."[3]
a) providing krill;	**Grantham (Exhibit 1032)** P. 0033, section 3.4.4. Figure 1, showing processing of freshly caught krill. P. 0036, sec. 3.4.6. "**Heat treatment [cooking]** is the most commonly used technique for frozen krill products. **Boiling krill** and

[3] Folch et al., "A simple method for the isolation and purification of total lipides from animal tissues," J Biol Chem. 1957 May; 226(1):497-509 ("The lipids were extracted by homogenizing the tissue with 2: 1 chloroform-methanol (v/v)."

CLAIMS	REFERENCES
	krill products has been shown to **inactivate** the proteolytic, **lipolytic** and pigment degrading **enzymes**." Pp. 0033-0034, section 3.4.4. "The original Russian plant used for this process, produced by AKP - VNIR01 has been installed both on freezer trawlers and on land. . . . The Norwegian firm of Rieber & Son has developed a continuously recycling loop coagulator and a downstream flash cooler for incorporation in the Russian process, with the option of flash evaporation as an alternative to separation. It gives improved process control and results in higher product quality. A pilot plant has been installed on a Russian trawler. Yields vary with the age and size of the raw material. . . . The full yields at the various process stages are given in Figure 1, together with other reported options [the Norwegian] for the paste process. Another Norwegian paste method [optional process stages] involves the **rapid heating of fresh krill to 70 - 100°C** with 2 - 3% sodium chloride in water. The hot mass is then pressed or centrifuged to remove the water, treated with 5 -10% sugar (e.g. molasses), and optionally fermented with yeasts. The alcohol is removed by distillation to give a material that can be frozen, sterilised or dried and is suited to human consumption or to the production of meal. The process is said to remove the unpleasant odour that can prevent the use of krill in human foods." P. 0035, section 3.4.5. "**cooking**, pressing and drying to hygienic krillmeal (KPC type B). …proteolysis, separation and drying to produce a hydrolysate (KPC type A)." P. 0038, sec. 3.4.6.

CLAIMS	REFERENCES
	"**Cooking has been traditionally achieved on board ship** by immersion in tanks of boiling sea-water; a recent Japanese krill patent (Kyokuyo 1976) describes a **continuous boiling process at 90°C** for 3 to 15 minutes, where improved temperature control is said to improve product quality." P. 0043, sec. 4.2. "The krill is generally **boiled at sea** before freezing." **Fricke (Exhibit 1010)** P. 0001, 1st col. " **cooked on board immediately after hauling** and stored"
b) treating said krill to denature lipases and phospholipases in said krill to provide a denatured krill product;	**Grantham (Exhibit 1032)** P. 0036, sec. 3.4.6. See element 1a above. Pp. 0033-0034, section 3.4.4. See element 1a above. P. 0035, section 3.4.5. See element 1a above. **Fricke (Exhibit 1010)** Pp. 0003, 1st column. See element 1a above.

CLAIMS	REFERENCES
c) extracting oil from said denatured krill product with a polar solvent;	**Grantham (Exhibit 1032)** P. 0039, sec. 3.4.8. "**Solvent extraction** has also been reported as a means of removing fat and pigment from whole **boiled krill** or shell waste (Nippon Suisan 1976); solvent mixes include acetone and petroleum ether, iso-propanol and n-hexane, and chloroform." **Fricke (Exhibit 1010)** P. 0001, 2nd col. See claim 1 above.
d) to provide a krill oil with from about 3% to about 10% w/w ether phospholipids;	**Fricke (Exhibit 1010)** P. 0002, Table 1. Phosphatidylcholine is ~34% of krill lipids. and **Tanaka I (Exhibit 1014)** P. 0003, Table I, left column. 23.0 +/- 1.2% of krill phosphatidylcholine are alkylacylphosphatidylcholine (AAPC). AAPC is present at **7.8%.** (23% x .34 = 7.82%)

CLAIMS	REFERENCES
e) from about 27% to 50% w/w non-ether phospholipids;	**Fricke (Exhibit 1010)** P. 0002, Table 1. **Total phospholipids =** 45.7 % +/- 1.6 12/1977 PC is 35.6% of krill lipids Ether phospholipids = 7.8% See 1(d) Subtract total lipids from ether phospholipid to get non-ether phospholipid 45.7% - 7.8%=**37.9 %** Therefore, non-ether phospholipid would be around **37.9%.** **Total phospholipids =** 44.0% +/- 2.0 3/1981 PC is 33.3% of krill lipids Ether phospholipids = 7.8% See 1(d) Subtract total lipids from ether phospholipid to get non-ether phospholipid 44.0%-7.8%=**36.2%** Therefore, non-ether phospholipid would be around **36.2%.**

CLAIMS	REFERENCES
f) so that the amount of total phospholipids in said krill oil is from about 30% to 60% w/w; and	**Fricke (Exhibit 1010)** P. 0002, Table 1. Total phospholipids = **45.7 %** +/- 1.6 (12/1977 sample) **44.0 %** +/- 2.0 (3/1981 sample)
g) and from about 20% to 50% w/w triglycerides,	**Fricke (Exhibit 1010)** P. 0002, Table 1. Lipid Composition of Antarctic Krill (*Euphausia superba*) Triacylglycerols (*i.e.*, triglycerides) **33.3 %** +/- 0.5 (12/1977 sample) **40.4 %** +/- 0.1 (3/1981 sample)

CLAIMS	REFERENCES
wherein said steps a and b are performed on a ship.	**Grantham (Exhibit 1032)** Pp. 0033-0034, section 3.4.4. See element 1a above. P. 0036, sec. 3.4.5. "The **production of krill** meal and KPC type B can be **undertaken on board ship**, using packaged units on catcher-processors or large scale plants on factory vessels. Solvent extracted KPC type A could be produced on a mother ship similar to the Swedish vessel 'Astra' - custom fitted for the purpose…." P. 0038, sec. 3.4.6. See element 1a above. P. 0043, sec. 4.2. See element 1a above. **Fricke (Exhibit 1010)** Pp. 0002-0003. See element 1b above.

CLAIMS	REFERENCES
2. The method of claim 1, wherein said treating comprises heating.	**Grantham (Exhibit 1032)** P. 0036, sec. 3.4.6. See element 1a above. P. 0043, sec. 4.2. See element 1a above. Pp. 0033-0034, section 3.4.4. See element 1a above. P. 0035, section 3.4.5. See element 1a above. P. 0038, sec. 3.4.6. See element 1a above. and **Fricke (Exhibit 1010)** P. 0003, 1st column. See element 1b above.

CLAIMS	REFERENCES
3. The method of claim 1, wherein said krill is freshly harvested.	**Grantham (Exhibit 1032)** Pp. 0026-0027, section 3.2. "The inherent instability of krill after catching has profound implications for processing and pre-processing, product type and quality, storage regimes, vessel design and fleet structure. Once landed, krill spoil rapidly because their organs - particularly the liver (hepatopancreas) and stomach - contain highly active enzymes which cause the rapid development of autolysis….The Russian consensus would seem to be that **krill should not be held for more than one** hour at 10°C before processing, or for 3 - 4 hours at 0 – 7°C, and in depths of not greater than 30 cm . . . ." **Fricke (Exhibit 1010)** Pp. 0003, 1st column. See element 1b above.

CLAIMS	REFERENCES
4. The method of claim 1, wherein said krill oil further comprises from about 20% to 35 % omega-3 fatty acids as a percentage of total fatty acids in said krill oil.	**Bottino (Exhibit 1007)** P. 0002 Table 1 Omega-3 fatty acids[4] (as weight percent of total acids of Euphausia superba) of whole krill: Station 8--**30.5%** Station 9--**26.8%** Station 11--**25.0%** Pp. 0004-0005 Table 3 Omega-3 fatty acids[5] as weight percent of total acids of Euphausia superba: **28.6%**
5. The method of claim 4, wherein from about 70% to 95% of said omega-3 fatty acids are attached to said total phospholipids.	**Fricke (Exhibit 1010)** Pp. 0002, 0004-0005, and Tables 1, 4, and 5; Table 1 provides the amount of each lipid class in the total lipid. Tables 4 and 5 provide the omega-3 fatty acid composition of each phospholipid class. Therefore, the amount of omega-3 in each lipid class relative to the total lipid can be calculated by multiplying the amount of omega-3 fatty acid for each

[4] Omega-3 fatty acids include 18:2(n-3), 18:3(n-3), 18:4(n-3), 20:5(n-3), and 22:6(n-3).

[5] Omega-3 fatty acids include 18:2(n-3), 22:2(n-3), 18:3(n-3), 20:3(n-3), 18:4(n-3), 20:4(n-3), 22:4(n-3), 22:5(n-3), and 22:6(n-3).

CLAIMS	REFERENCES
	lipid class by the amount of the particular lipid class in the total lipid composition. This is done for each lipid class. The amount of omega-3 associated with phospholipid is then divided by the total amount of omega-3 in the total lipid to provide the percentage of omega-3 fatty acid attached to phospholipid. Using this calculation, **74.81%** (3/1981 sample) and **82.03%** (12/1977 sample) of the omega-3 fatty acids are attached to phospholipids. (Exhibit 1006, Tallon Appendix B)

CLAIMS	REFERENCES
6. The method of claim 1, wherein said extrqacting comprises supercriticval fluid extraction with a polar entrainer.	**Tanaka II (Exhibit 1015)** P. 0003, 2nd column. "Many researchers have already reported since a pure carbon dioxide does not dissolve PLs effectively, extraction of PLs might be achieved by the addition of a polar entrainer to SC-CO_2. An entrainer is a substance of medium volatility added to a mixture of compressed gas and a low volatility substance (20). As the solubility in SC-CO_2 at the same extracting conditions (temperature and pressure) is drastically enhanced, extraction can be conducted at a lower pressure (25). 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-CO_2 because: (i) It is suitable for food use; and (ii) the phase behavior of CO_2/ethanol mixes at high pressure is available (26, 27)**." P. 0001, 1st column. "Because CO_2 is stable chemically, it does not react with other materials in treatment. Easy separation and removal of CO_2 from the products eliminates any problem related to toxic residual solvents."

CLAIMS	REFERENCES
7. The method of claim 1, further comprising encapsulating said krill oil.	**Sampalis I (Exhibit 1012)** P. 0004, 2nd column. "Each patient was asked to take two 1-gram **soft gels** of either **NKO**[6] 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."
8. The method of claim 1, wherein said krill is Antarctic krill.	**Grantham (Exhibit 1032)** P. 0009, Abstract. "This report is one of a series prepared by FAO under the preparatory phase of the Programme. It gathers together current knowledge on the biochemistry, processing and marketing of **Antarctic krill**." **Fricke (Exhibit 1010)** P. 0002, Table 1. "Lipid Composition of **Antarctic Krill**"
9. The method of claim 8, wherein said Antarctic krill is *Euphausia superba*.	**Grantham (Exhibit 1032)** P. 0011, sec. 2.1. "Commercial catches of krill would seem to consist predominantly of ***Euphausia superba***." P. 0042, sec. 4.2. "Small whole shrimp and zooplankters are traditional

[6] "NKO" is Neptune Krill Oil.

CLAIMS	REFERENCES
	items in the diet of Japan and several other Indo-Pacific courrtries.1/ (Subba Rao 1976). The Japanese introduction of whole krill was, therefore, plausible as ***E. superba*** has a similar appearance, taste and texture to these established crustacea." "[1/ Mainly Sergestes lucens and Euphausia pacifica.]" P. 0051, sec. 4.8. "In Japan, Euphausiids have been eaten for many centuries, thus assuring both their palatability and their lack of toxicity (Parsons 1972). Several series of biological tests on ***E. superba*** have confirmed its nutritional quality." **Fricke (Exhibit 1010)** P. 0001, Introduction, lines 1-2. "Krill (***Euphausia superba*** Dana) lives exclusively in cold Antarctic waters."

CLAIMS	REFERENCES
10. The method of claim 1, wherein said krill is *Euphausia pacifica*.	**Sampalis II** P. 0027, lines 4-10. "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." **Grantham (Exhibit 1032)** P. 0042, sec. 4.2. "Small whole shrimp and zooplankters are traditional items in the diet of Japan and several other Indo-Pacific courrtries.1/ (Subba Rao 1976). The Japanese introduction of whole krill was, therefore, plausible as *E. superba* has a similar appearance, taste and texture to these established crustacea." "[1/ Mainly *Sergestes lucens* and ***Euphausia pacifica***.]"
11. A method of production of krill oil comprising:	**Fricke (Exhibit 1010)** P. 0001, 2nd col. See claim 1 above. **Grantham (Exhibit 1032)** P. 0039, sec. 3.4.8. See claim 1 above.

CLAIMS	REFERENCES
a) obtaining a denatured krill product produced by treating freshly harvested krill to denature lipases and phospholipases in said krill;	**Grantham (Exhibit 1032)** P. 0036, sec. 3.4.6. See element 1a above. Pp. 0033-0034, section 3.4.4. See element 1a above. P. 0036, sec. 3.4.5. See claim 1 above. P. 0035, section 3.4.5. See element 1a above. P. 0038, sec. 3.4.6. See element 1a above. P. 0043, sec. 4.2. See element 1a above. and **Fricke (Exhibit 1010)** Pp. 0002-0003. See element 1b above.
b) extracting oil from said denatured krill product with a polar solvent;	**Grantham (Exhibit 1032)** P. 0039, sec. 3.4.8. See claim 1 above. **Fricke (Exhibit 1010)** P. 0001, 2nd col. See claim 1 above.

CLAIMS	REFERENCES
c) to provide a krill oil with from about 3% to about 10% w/w ether phospholipids;	**Fricke (Exhibit 1010)** P. 0002, Table 1. See element 1d above. **Tanaka I (Exhibit 1014)** P. 1391, Table I, left column. See element 1d above.
d) from about 27% to 50% w/w non-ether phospholipids;	**Fricke (Exhibit 1010)** P. 0002, Table 1. See element 1e above.
e) so that the amount of total phospholipids in the krill oil is from about 30% to 60% w/w; and	**Fricke (Exhibit 1010)** P. 0002, Table 1.See element 1f above.
f) from about 20% to 50% w/w triglycerides.	**Fricke (Exhibit 1010)** P. 0002, Table 1. See element 1g above.

CLAIMS	REFERENCES
12. The method of claim 11, wherein said treating comprises heating.	**Fricke (Exhibit 1010)** Pp. 0002-0003. See element 1b above. **Grantham (Exhibit 1032)** P. 0036, sec. 3.4.6. See element 1a above. P. 0043, sec 4.2. See element 1a above. Pp. 0033-0034, section 3.4.4. See element 1a above. P. 0035, section 3.4.5. See element 1a above. P. 0038, sec. 3.4.6. See element 1a above.
13. The method of claim 11, wherein said krill oil further comprises from about 20% to 35% omega-3 fatty acids as a percentage of total fatty acids in said krill oil.	**Fricke (Exhibit 1010)** Pp. 0002, 0004-0005, and Tables 1, 4, and 5. See claim 5 above.
14. The method of claim 13, wherein from about 70% to 95% of said omega-3 fatty acids are attached to said total phospholipids.	**Fricke (Exhibit 1010)** Pp. 0002, 0004-0005, and Tables 1, 4, and 5 See claim 5 above.

CLAIMS	REFERENCES
15. The method of claim 11, wherein said extracting comprises supercritical fluid extraction with a polar entrainer.	**Tanaka II (Exhibit 1015)** P. 0003, 2nd column. See claim 6 above. P. 0001, 1st column. See claim 6 above.
16. The method of claim 11, further comprising encapsulating said krill oil.	**Sampalis I (Exhibit 1012)** P. 0004, 2nd column. See claim 7 above.
17. The method of claim 11, wherein said krill is Antarctic krill.	**Fricke (Exhibit 1010)** P. 0002, Table 1. See claim 8 above. **Grantham (Exhibit 1032)** P. 0009, Abstract. See claim 8 above.
18. The method of claim 17, wherein said Antarctic krill is *Euphausia superba*.	**Grantham (Exhibit 1032)** P. 0011, sec. 2.1. See claim 9 above. P. 0042, sec. 4.2. See claim 9 above. P. 0051, sec. 4.8. See claim 9 above. **Fricke (Exhibit 1010)** P. 0001, Introduction, lines 1-2. See claim 9 above.

CLAIMS	REFERENCES
19. The method of claim 11, wherein said krill is *Euphausia pacifica*.	**Sampalis II** P. 0027, lines 7-10. See claim 10 above. **Grantham (Exhibit 1032)** P. 0042, sec. 4.2. See claim 10 above.

VII. CONCLUSION

For the above reasons, Petitioner respectfully requests institution of *Inter Partes* Review of Claims 1-20 of U.S. 9,078,877, followed by a grant of this Petition canceling Claims 1-20 of the '877 patent on the grounds detailed herein.

Dated: February 3, 2017

Respectfully submitted,

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VIII. CERTIFICATE OF COMPLIANCE

Pursuant to 37 C.F.R. §42.24(d), the undersigned certifies that this Petition complies with the type-volume limitation of to 37 C.F.R. §42.24(a). The word count application of the word processing program used to prepare this Petition indicates that the Petition contains 12,792 words, excluding the parts of the brief exempted by to 37 C.F.R. §42.24(a) (that is, the word count does not include the table of contents, the exhibit list, mandatory notices under §42.8, the certificate of service or the certificate of compliance).

Dated: February 3, 2017

Respectfully,

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CERTIFICATE OF SERVICE

I hereby certify that on this 3rd day of February, 2017, the foregoing PETITION FOR *INTER PARTES* REVIEW UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.1 *ET SEQ.*, including all Exhibits and the Power of Attorney, were served pursuant to 37 C.F.R. §§ 42.6 and 42.105, via Federal Express® (Domestic - next day delivery, International – priority), on the following:

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UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, DC

Honorable Dee Lord, Administrative Law Judge

In the Matter of	
CERTAIN KRILL OIL PRODUCTS AND KRILL MEAL FOR PRODUCTION OF KRILL OIL PRODUCTS	Investigation No. 337-TA-1019

RESPONDENTS' NOTICE OF PRIOR ART

Respondents Olympic Holding AS, Rimfrost AS, Emerald Fisheries AS, Avoca Inc., Rimfrost USA, LLC, Rimfrost New Zealand Limited, and Bioriginal Food & Science Corp. (collectively "Respondents"), hereby respectfully submit this Notice of Prior Art. Respondents may rely on the prior art set forth in Appendices A-E to establish invalidity or unenforceability of the asserted claims of the patents-in-suit. Discovery is ongoing in this Investigation, including discovery from third parties, and Complainants have yet to provide their contentions for the patents at issue. Accordingly, Respondents reserve the right to supplement and/or amend this Notice as additional information or prior art is discovered. In particular, Respondents reserve the right to amend this Notice as necessary based on further discovery and investigation, review of newly or yet-to-be produced documents, the disclosures of witnesses not yet disclosed and to cite to witness deposition testimony.

To the extent any file history (including patent and/or reexamination and/or other U.S. or foreign patent office pre- or post-grant opposition file histories) below includes expert declarations, Respondents may rely upon those expert declarations, any documents cited therein, and all underlying testing data. Respondents also expressly reserve the right to rely on expert declarations and all testing data associated with any future reexaminations and/or other U.S. or

foreign patent office pre- or post-grant oppositions concerning the Asserted Patents or related patents or applications. To the extent any of the references below is in a language other than English, Respondents may also rely upon any English translation thereof. Respondents may also rely upon any product described in a printed publication described below.

Respondents also reserve the right to rely on the documents identified in Appendices A-E as printed publications that either anticipate or render obvious the asserted patents, or to establish the functionality, public use, sale, offer for sale, or prior invention of the identified system before the alleged invention of the relevant asserted patent.

Additionally, Appendices A-E also do not include information, material, or documents that will be used to establish motivation to combine, public availability of the products and/or publications listed in this chart. Respondents expressly reserve their rights to use any documents, information, or testimony produced in this case for such purposes.

Finally, Respondents may rely upon prior art (1) identified or produced by Complainants, (2) included on any party's hearing exhibit list, or (3) cited in any expert report served during this Investigation, and expressly incorporates by reference all of this art herein.

Dated: February 1, 2017

Respectfully submitted,

/s/ Doris Johnson Hines

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Appendix A: Patents and Published Patent Applications

ISSUING COUNTRY	NUMBER	DATE	FIRST NAMED INVENTOR OR APPLICANT
Australia	AU 2002322233	7/27/2001	Sampalis
Australia	AU 2008231570	10/2/2008	Bruheim
Australia	AU 2008291978	3/5/2009	Hostmark
Australia	AU 2013205514	7/27/2001	Sampalis
Australia	AU 2013205516	7/27/2001	Sampalis
Australia	AU 2013227998	9/26/2013	Bruheim
Australia	AU 2014256345	11/20/2014	Bruheim
Australia	AU 657969	1/8/1993	Larrson-Backstrom
Australia	AU 671329	8/22/1996	Horrobin
Brazil	BR 8701265	12/29/1987	Rene, Guillot Bernard
Canada	CA 1098900	4/7/1981	Rogozhin
Canada	CA 2115571	12/23/1993	Kohn
Canada	CA 2251265	4/21/2000	Beaudoin
Canada	CA 2362663	6/14/2001	Lee
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Canada	CA 2694492	7/11/2008	Kralovec
Chile	CL 102-95	1/24/1995	Guerra
China	CN 200880112125	1/15/2014	Tilseth
Europe	EP 0209037	2/28/1990	Bombardelli
Europe	EP 0209038	3/27/1996	Bruno Gabetta
Europe	EP 0275005	8/11/1993	Bombardelli
Europe	EP 0275224	7/21/1993	Bombardelli
Europe	EP 0519916	12/22/1993	Sola
Europe	EP 0609078	8/3/1994	Horrobin
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USA	US Application No, No. 11/458,451	7/19/2006	Chen

USA	US Application No. 14/968,183	4/7/2016	Bruheim
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USA	US Application No. 15/180,439	9/29/2016	Bruheim
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PCT	WO 00/38708	7/6/2000	Franklin
PCT	WO 01/28526	4/26/2001	Seneci
PCT	WO 01/76385	10/18/2001	Hruschka
PCT	WO 01/82928 A1	11/8/2001	Henderson
PCT	WO 01/82928 A9	6/15/2006	Henderson
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PCT	WO 98/34498	8/13/1998	Saxby
PCT	WO 99/39589	8/12/1999	Saxby

Appendix B: File Histories

NUMBER	FILE HISTORY TYPE
AU Application No. 2014256345	Prosecution history and Third Party Submissions filed Oct. 12, 2015 and Dec. 22, 2015
WO 2003/011873	Prosecution history
AU 2002322233	Prosecution history
AU 2008231570	Prosecution history
AU 2008291978	Prosecution history
AU 2013227998	Prosecution history and Third Party Submissions and Correspondences filed Oct. 12 2015, June 29, 2016, July 15, 2016 and Sept. 15, 2016
CA 2493888	Prosecution history
EP 1417211	Prosecution history
EP 1997498	Prosecution history
EP 2144618	Prosecution history and EP Opposition filed by Olympic Seafood AS, including but not limited to Declaration of Risa Enge
EP Application No. 08 718 910.6	EP Opposition filed by Olympic Seafood AS
EP Application No. EP12187516	Prosecution history, including but not limited to European Search Report mailed Jun. 10, 2013
CN 200880112125.6	Prosecution history, including but not limited to CN Office Action mailed Apr. 27, 2012
KR Application No. 10-2010-700689	Prosecution history, including but not limited to Dec. 8, 2011 Office Action and its English translation.
JP Application No. 2010-522444	Prosecution history, including but not limited to JP Office Action mailed Feb. 23, 2012 and its English translation
PCT/GB2008/002934	Prosecution history, including but not limited to International Search Report and Written Opinion for dated Mar. 11, 2009.
PCT/IB2007/000098	Prosecution history, including but not limited to International Search Report dated Jun 26, 2007
PCT/IB2010/000512	Prosecution history, including but not limited to International Search Report and Written Opinion dated Jun. 24, 2010
PCT/IB2014/002130	Prosecution history, including but not limited to International Search Report and Written Opinion mailed Feb. 3, 2015
US 5,527,533	Prosecution history
US 6,800,299	Prosecution history
US 8,030,348	Prosecution history, including but not limited to Action Closing Prosecution, '348 patent, Oct. 21, 2011, May 31, 2011 Declaration of Dr. Earl White

US 8,030,348	Inter Partes Reexamination filed Oct. 19, 2011, including but not limited to Oct. 4, 2011 Declaration of Bjorn Ole Haugsgjerd, Declaration of Dr. Chong Lee, Declaration of Dr. Jacek Jaczynsk, Mar. 29, 2016 Declaration of Dr. Shahidi, Oct. 4, 2011 Declaration of Dr. Thomas Gundersen, Mar. 16, 2012 Declaration of Dr. Tina Sampalis, Apr. 17, 2012 Declaration of Dr. Van Breemen, Mar. 16, 2012 Declaration of Dr. Yeboah, Mar. 16, 2012 Supplemental Declaration of Dr. Earl White, Apr. 18, 2012 Supplemental Declaration of Dr. Thomas Gundersen, Apr. 16, 2012 Supplemental Declaration of Bjorn Ole Haugsgjerd
US 8,057,825	Prosecution history
US 8,278,351	Prosecution history, including but not limited to Jan. 5, 2012 Office Action, Apr. 2, 2012 Response to Office Action, Mar. 29, 2012 Declaration of Dr. Shahidi, Mar. 16, 2012 Declaration of Dr. Yeboah, Mar. 29, 2012 Supplemental Declaration of Dr. Earl White
US 8,278,351	Inter Partes Review filed 10/1/13, including but not limited to Oct. 4, 2011 Declaration of Bjorn Ole Haugsgjerd, Oct. 14, 2013 Declaration of Albert Lee, Declaration of Dr. Ivar Storro, Mar. 29, 2012 Declaration of Dr. Jaczynski, Declaration of Dr. Jeff Moore, Declaration of Dr. Richard van Breemen, Declaration of Dr. Suzanne Budge, Declaration of Dr. Thomas Brenna
US 8,278,351	Ex Parte Reexamination filed Oct. 2, 2012, including but not limited to Dec. 21, 2012 Grant of Request for Ex parte Reexamination, Oct. 1 2012 Declaration of Dr. Van Breemen
US 8,383,675	Prosecution history, including but not limited to Oct. 24, 2012 Office Action
US 8,383,675	Inter Partes Review filed 11/7/13, including but not limited to Declaration of Dr. Ivar Storro, Oct. 2013 Declaration of Dr. Jeff Moore, Declaration of Dr. Richard van Breemen, Declaration of Dr. Suzanne Budge, Oct. 17, 2013 Declaration of Dr. Thomas Brenna
US 8,697,138	Prosecution history
US 9,028,877	Prosecution history
US 9,034,388	Prosecution history
US 9,072,752	Prosecution history
US 9,078,905	Prosecution history
US 9,119,864	Prosecution history
US 9,220,735	Prosecution history
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US 9,375,453	Prosecution history
US Application No. 14/968,183	Prosecution history
US Application No. 15/180,431	Prosecution history
US Application No. 15/180,439	Prosecution history
US Application No. 60/920,483	Prosecution history
US Application No. 60/975,058	Prosecution history
US Application No. 60/983,446	Prosecution history
US Application No. 61/024,072	Prosecution history
US Application No. 61/181,743	Prosecution history
US Application No. 90/012,698	Prosecution history - Ex Parte reexam filed 10/2/12
US Application No. 95/001,774	Prosecution history - Interpartes reexam filed 10/19/11
US Application No. 95/001,819	Prosecution history - Interpartes reexam filed 12/16/11
WO 2000/23546, EP 1123368	Prosecution history
WO 2008117062	Prosecution history
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US 2010/0143571	Prosecution history

Appendix C: Non-Patent Publications

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Ali-Nehari et al., Comparative Study of Digestive Enzymes of Krill (Euphausia superba) After Supercritical Carbon Dioxide and Organic Solvent Extraction, International program of fisheries Sciences, Faculty of Fisheries Sciences Pukyong National University	undated	not numbered
Ali-Nehari et al., Digestive enzymes characterization of krill (Euphausia superba) residues deoiled by supercritical carbon dioxide and organic solvents, Journal of Industrial and Engineering Chemistry 18, pp. 1314–1319 (2012)	2010	1314-1319
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Appendix D: Prior Use Products

PRODUCT or TM NAME	DESCRIPTION	MANUFACTURER	APPOXIMATE DATE
Tri-Shield	Omega-3 fatty acids from Neptune Krill Oil	Herbalife International	12-May-05
Krill Essentials	Containing Neptune Krill Oil	ISI Brands Inc.	9-Mar-05
AquaSource Products Inc.	AquaSource Krill Oil, including but not limited to Lot#OK206T and any other lots tested by or on behalf of Aker	AquaSource Products Inc. in Canada	17-Feb-05
Antarctica Select	Aqua Source Krill oil, including but not limited to lot # 20508121	AquaSource Products Inc. in Canada	Prior to July 2004
Neptune Krill Oil or NKO	Neptune Krill Oil, including but not limited to Lot # 1660CM8843, 060116, 060519, 060224, 730612, JW-0304-04, 72439, 23376000609, product tested for Table 22 in the Asserted patents, product disclosed on page 11 line 26 of WO2008060163, and any other lots tested by or on behalf of Aker	Neptune Technologies & Bioresources Inc.	25-Feb-03
Nissui Global Links	Edible fish oils, fish oil for foodstuffs, sauces made of krill	Nippon Suisan Kabushiki Kaisha TA Nippon Suisan Kaisha, Ltd. In Japan	20-Jan-04
Nissui Krill Oil	Nissui Krill Oil, including but not limited to Lot # 09100R	Nippon Suisan	
NLK	Lyophilised krill; Neptune LyO-Krill	Neptune Technologies & Bioresources Inc.	31-Mar-03
Okiami Plus	Krill oil	AquaSource Products Inc. in Canada	29-Mar-07
KriaXanthin	Krill oil	Cyvex Nutrition, Inc	19-May-06
Krilex	Pure, concentrated krill	Gryd Inc. in Canada	4-Jun-01
King Krill	Krill products, including oil	Top Ocean, Inc.	12-Nov-99
Biokrill	Processed and unprocessed krill	Biocean, Inc.	4-Apr-02
Krillipid		Azantis, LLC	12-Mar-08
Better Than Krill Oil		Weider Global Nutrition, LLC	27-Aug-08
Better Than Krill		Weider Global Nutrition, LLC	3-Sep-08
Krilliant		Vivenzio, John	22-Oct-08
Total Krill	Containing Neptune Krill Oil	WellnessPartners.com, Total Krill	Prior to 3/1/08

Neptune Krill Oil	Neptune Krill Oil, including but not limited to Lot # 6053, and any other lots tested by or on behalf of Aker	Klabin Marketing	Prior to 3/1/08
Neptune Krill Oil	Neptune Krill Oil, including but not limited to Lot # 3597500 0310, and any other lots tested by or on behalf of Aker	DaVinci Laboratories of Vermont	Prior to 3/1/08
PhosphOmega	Neptune Krill Oil, including but not limited to Lot # 15351H7 and any other lots tested by or on behalf of Aker	Jarrow Formulas	Prior to 3/1/08
Neptune Krill Oil	Containing Neptune Krill Oil, including but not limited to Lot # 3824100 0310 and any other lots tested by or on behalf of Aker	Mountain Naturals of Vermont	Prior to 3/1/08
Efa Gold Krill Oil	Krill oil, including Lot #526368 and any other lots tested by or on behalf of Aker		Prior to 3/1/08
Krill Bill	Containing Neptune Krill Oil, including but not limited to Lot# 2395000 0609, and any other lots tested by or on behalf of Aker		Prior to 2006
Krill oil	Krill oil produced from Examples 1-8 of WO2008060163, or made by or on behalf of Pronova	Pronova Biopharma Norge AS	Prior to 3/1/08
Astax-1700	"Astaxanthin from Antartic Krill"	Itano Refrigerated Food Co., LTD	Prior to 1996

Appendix E: Person With Knowledge About Prior Use Products

NAME	ADDRESS
Fotini Sampalis	Children's Health & Wellness Center 3230 Boulevard Curé-Labelle Suite 305 Laval, QC H7P OH9
Risa Enge	Conspac Enterprises Ltd. 2-3237 King George Blvd SURREY, British Columbia V4P 1B7
David Ko	Viva Pharmaceuticals 13880 Viking Place RICHMOND, British Columbia V6V 1K8
Owen Catchpole	Callahan Innovation Auckland Research Centre Brooke House, 24 Balfour Road, Parnell PO Box 2225 Auckland 1140 New Zealand
Stephen Tallon	Callaghan Innovation 69 Gracefield Road Lower Hutt 5010 New Zealand
Andrew MacKenzie	Callaghan Innovation 69 Gracefield Road Lower Hutt 5010 New Zealand
Bill Ziese	Solutions Unlimited 871 Engleville Road Sharon Springs, NY 13459
Jay Sperco	Solutions Unlimited 871 Engleville Road Sharon Springs, NY 13459
Arlene D. Hanks	Suite 500 430 Davis Drive Morrisville, NC 27560

CERTAIN KRILL OIL PRODUCTS AND KRILL MEAL FOR PRODUCTION OF KRILL OIL PRODUCTS **Inv. No. 337-TA-1019**

CERTIFICATE OF SERVICE

I, Jeremy Miller, hereby certify that on February 1, 2017, copies of the foregoing were filed with and served upon the following as indicated:

The Honorable Lisa R. Barton Secretary, Office of the Secretary U.S. INTERNATIONAL TRADE COMMISSION 500 E Street, S.W., Room 112-F Washington, DC 20436 (202) 205-2000	☐ Via First Class Mail ☐ Via Courier (FedEx) ☐ Via Hand Delivery ☐ Via Email (PDF File) ☒ Via EDIS
The Honorable Dee Lord Administrative Law Judge U.S. INTERNATIONAL TRADE COMMISSION 500 E Street, S.W., Room 317 Washington, DC 20436 edward.jou@usitc.gov	☐ Via First Class Mail ☒ Via Courier (FedEx) ☐ Via Hand Delivery ☒ Via Email (PDF File)
COUNSEL FOR COMPLAINANTS AKER BIOMARINE ANTARCTIC AS and AKER BIOMARINE MANUFACTURING, LLC Andrew F. Pratt VENABLE LLP 575 Seventh Street NW Washington, DC 20004 Aker-1019@venable.com	☐ Via First Class Mail ☐ Via Courier (FedEx) ☐ Via Hand Delivery ☒ Via Email (PDF File)

/s/ Jeremy Miller
Jeremy Miller, Legal Assistant

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2 March 2017

Pizzeys Patent and Trade Mark Attorneys Pty Ltd
PO Box 291
WODEN ACT 2606
Australia

Patent Oppositions - Notice of Opposition

Application Number: 2014256345

Applicant Name: Aker BioMarine Antarctic AS

Applicant Ref: 44183AKE/TMB

Opponent: Enzymotec Ltd.

Opponent Ref: M50162661:TPG:JY:aa

Dear Madam/Sir

We acknowledge a Notice of Opposition for the above patent application under Section 59 of the Patents Act, on 01 March 2017. A copy is attached for the Applicant.

This will be advertised in the Australian Official Journal of Patents Supplement, dated 16 March 2017.

The parties are required to provide an e-mail address for filing and receiving documents relating to this opposition electronically via Objective Connect.

Please provide this information within ten (10) days of the date of this letter.

The Opponent's Statement of Grounds and Particulars is due to be filed in Objective Connect by 1 June 2017.

Yours Faithfully

Dave Murphy
Senior Opposition Officer
Patent Oppositions
Phone: 02 6283 2679

FPA Patent Attorneys

1 March 2017

The Commissioner of Patents
IP Australia

FPA ref: M50162661:TPG:JY:aa
Principal: Tom Gumley PhD

Dear Commissioner

Enzymotec Ltd.
Opposition to
Australian patent application no 2014256345
Bio effective krill oil compositions
in the name of Aker BioMarine Antarctic AS

We enclose:

1 Notice of Opposition; and

2 the prescribed fee of $600.

Our nominated address for Objective Connect is info@fpapatents.com.

Yours sincerely

Damian Slizys
Principal
FPA Patent Attorneys Pty Ltd

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Notice of Opposition

We Enzymotec Ltd.

of Sagi 2000 Industrial Park
Kfar Baruch 36584
Israel

give notice that we oppose the grant of a patent in respect of application no. 2014256345 in the name of Aker BioMarine Antarctic AS.

Address for service in Australia

FPA Patent Attorneys Pty Ltd — Attorney Code: FM

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Telephone no.	Facsimile no.	Reference
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Signature

1 March 2017

Tom Gumley PhD

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2 March 2017

Pizzeys Patent and Trade Mark Attorneys Pty Ltd
PO Box 291
WODEN ACT 2606
Australia

Patent Oppositions - Notice of Opposition

Application Number: 2014256345

Applicant Name: Aker BioMarine Antarctic AS

Applicant Ref: 44183AKE/TMB

Opponent: Rimfrost AS

Dear Madam/Sir

We acknowledge a Notice of Opposition for the above patent application under Section 59 of the Patents Act, on 01 March 2017. A copy is attached for the Applicant.

This will be advertised in the Australian Official Journal of Patents Supplement, dated 16 March 2017.

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Please provide this information within ten (10) days of the date of this letter.

The Opponent's Statement of Grounds and Particulars is due to be filed in Objective Connect by 1 June 2017.

Yours Faithfully

Dave Murphy
Senior Opposition Officer
Patent Oppositions
Phone: 02 6283 2679

The Commissioner of Patents
PO Box 200
WODEN ACT 2606

1 March 2017

Our Ref: 94350AUQ00

Speed Dial: 508

CCN: 3710000352

Contact:
Michael Zammit

Dear Commissioner

Australian Patent Application No. 2014256345
Title: Bio Effective Krill Oil Compositions
In the Name of: Aker BioMarine Antarctic AS
- and -
Opposition by: Rimfrost AS

We enclose a Notice of Opposition to the grant of a patent on the above application.

We understand that the Commissioner will give the applicant a copy of the notice as soon as practicable.

Our nominated address for Objective Connect is: email@SheIstonIP.com

Yours sincerely
Shelston IP

Michael Zammit, PhD
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Shelston IP Pty Ltd and Shelston IP Lawyers Pty Ltd are members of Xenith IP Group Limited.

Section 59
Regulation 5.3

AUSTRALIA

PATENTS ACT 1990

NOTICE OF OPPOSITION

We, Rimfrost AS, of PO Box 234, N-6099, Fosnavag, Norway, give notice that we oppose the grant of a patent in respect of Australian Patent Application No. 2014256345, in the name of Aker BioMarine Antarctic AS.

Address for Service is:

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DATED this 1st day of March 2017
Rimfrost AS

Michael Zammit, PhD
Fellow, Institute of Patent and Trade Mark
Attorneys of Australia of Shelston IP Pty Ltd

To: The Commissioner of Patents
WODEN ACT 2606

File: 94350AUQ00

Fee: $600

CONTAINS CONFIDENTIAL BUSINESS INFORMATION
SUBJECT TO PROTECTIVE ORDER

UNITED STATES INTERNATIONAL TRADE COMMISSION WASHINGTON, D.C.

Before the Honorable Dee Lord Administrative Law Judge

In the Matter of **CERTAIN KRILL OIL PRODUCTS AND KRILL MEAL FOR PRODUCTION OF KRILL OIL PRODUCTS**	**Inv. No. 337-TA-1019**

RESPONDENTS' MOTION FOR LEAVE TO AMEND THEIR RESPONSE TO THE COMPLAINT AND NOTICE OF INVESTIGATION

Respondents Olympic Holding AS, Rimfrost AS, Emerald Fisheries AS, Avoca, Inc., Rimfrost USA, LLC, Rimfrost New Zealand Limited, and Bioriginal Food & Science Corp. (collectively, Respondents), move for leave to amend their Response to the Complaint and Notice of Investigation (Amended Response) to include an affirmative defense of inequitable conduct based on facts acquired in discovery from Aker BioMarine Antarctic AS and Aker BioMarine Manufacturing, LLC (Aker or Complainants). Respondents move pursuant to 19 C.F.R. §§ 210.14(b)(2), 210.15 and Order No. 1019-008, at 7. Respondents' Motion to Amend is Submitted herewith and their proposed affirmative defense of inequitable conduct is detailed in Confidential Exhibit No. 1 thereto. Respondents' proposed Amended Response replaces the previously-pled affirmative defense of inequitable conduct that was addressed in Order 8.

Good cause supports Respondents' motion, as detailed in the Motion to Amend filed herewith. In particular, the specifically-pled facts support allegations of inequitable conduct; Respondents are promptly seeking leave to amend their Response just a few days after the deposition of attorney Jones, who Respondents allege committed inequitable conduct; no party

will suffer prejudice as the information supporting Respondents' inequitable conduct defense comes from Aker and Jones; and information supporting Respondents' inequitable conduct defense, including the testimony of Jones on March 9, 2017, was not previously available to Respondents.

Ground Rule 3.2 Certification

Respondents hereby certify that they contacted counsel for Complainants at least two (2) business days before filing this motion for leave and motion to amend, as required by Ground Rule 3.2. Complainants' counsel indicated that Complainants would take a position after reviewing the papers.

Date: March 14, 2017

Respectfully submitted,

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Counsel for Respondents Olympic Holding AS, Rimfrost AS, Emerald Fisheries AS, Avoca Inc., Rimfrost USA, LLC, Rimfrost New Zealand Limited, and Bioriginal Food & Science Corp

CONTAINS CONFIDENTIAL BUSINESS INFORMATION
SUBJECT TO PROTECTIVE ORDER

UNITED STATES INTERNATIONAL TRADE COMMISSION WASHINGTON, D.C.

Before the Honorable Dee Lord Administrative Law Judge

In the Matter of **CERTAIN KRILL OIL PRODUCTS AND KRILL MEAL FOR PRODUCTION OF KRILL OIL PRODUCTS**	**Inv. No. 337-TA-1019**

RESPONDENTS' MOTION TO AMEND THEIR RESPONSE TO THE COMPLAINT AND NOTICE OF INVESTIGATION

Respondents Olympic Holding AS, Rimfrost AS, Emerald Fisheries AS, Avoca, Inc., Rimfrost USA, LLC, Rimfrost New Zealand Limited, and Bioriginal Food & Science Corp. (collectively, Respondents), move to amend their Response to the Complaint and Notice of Investigation to include an affirmative defense of inequitable conduct based on facts acquired from discovery provided by Aker BioMarine Antarctic AS and Aker BioMarine Manufacturing, LLC (Aker or Complainants) and their patent attorney J. Mitchell Jones. Respondents move pursuant to 19 C.F.R. §§ 210.14(b)(2), 210.15 and Order No. 1019-008, at 7. In moving to amend, Respondents seek to specifically plead inequitable conduct resulting from actions taken by Jones in filing and prosecuting applications related to the asserted patents before the U.S. Patent and Trademark Office (PTO).

I. GOOD CAUSE EXISTS FOR ALLOWING AMENDMENT

Commission Rule 210.14(b)(2) provides that "[i]f disposition of the issues in an investigation on the merits will be facilitated, or for good cause shown, the presiding administrative law judge may allow appropriate amendments to pleadings other than the

complaint upon such conditions as are necessary to avoid prejudicing the public and the rights of the parties to the investigation." It is well established that a respondent may amend the response to the complaint under Commission Rule 210.14(b)(2). *See, e.g., Certain Cold Cathode Fluorescent Lamp ("CCFL") Inverter Circuits and Products Containing the Same*, Inv. No. 337-TA-666, Order No. 9 (May 13, 2009) (granting respondent's motion to amend the response to add a recently discovered allegation pertaining to respondent's inequitable conduct affirmative defense); *Certain Electronic Devices, Including Mobile Phones, Portable Music Players, and Computers*, Inv. No. 337-TA-701, Order No. 28 (July 30, 2010) (granting in part respondent's motion to amend their response to the complaint to conform the pleadings to evidence obtained during discovery).

Exhibit 1 to this Motion is a proposed Amended Response to the Complaint and Notice of Investigation, which includes a Fourth Affirmative Defense of Inequitable Conduct, which replaces the Fourth Affirmative Defense originally plead by Respondents and addressed in Order No. 8.

Good cause exists to allow this amendment. Through discovery, including the deposition of Jones on March 9, 2017, Respondents learned facts supporting their inequitable conduct defense and diligently filed this motion thereafter. Respondents have sufficiently pled their defense and have demonstrated, per *Exergen*, the who, what, when, where, and how details required to specifically plead inequitable conduct. Further, Complainants are not prejudiced by this amendment because the facts surrounding the inequitable conduct are in their possession and control. Consistent with Rule 210.14(b)(2) and Commission precedent and for the reasons stated below, good cause exists to grant leave for Respondents to file their proposed Amended Response.

II. AMENDMENT OF THE RESPONSE TO THE COMPLAINT AND NOTICE OF INVESTIGATION IS APPROPRIATE

Respondents' proposed Amended Response satisfies the pleading standard set forth in 19 C.F.R. §210.13(b) and Federal Rule of Civil Procedure 9(b), as described in *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1327 (Fed. Cir. 2009). The proposed Amended Response includes the *Exergen* who, what, when, where, and how specifics the ALJ held were required to plead inequitable conduct. Order No. 8.

A. The Pleading Standard for Inequitable Conduct / Unclean Hands

Inequitable conduct is an equitable defense that arises out of a patent applicant's "duty of candor and good faith to the United States Patent and Trademark Office." *Monsanto Co. v. Bayer Bioscience NV*, 514 F. 3d 1229, 1234 (Fed. Cir. 2008). An applicant breaches its duty of candor and good faith "by failing to disclose material information . . . with an intent to deceive the PTO." *Id.* Thus, an inequitable conduct determination requires a finding that the applicant failed to disclose material information and that the applicant had the intent to deceive the PTO. Furthermore, the knowledge and intent of the applicant's attorney who is prosecuting the application is chargeable to the applicant. *See id.* at 1241 (affirming inequitable conduct determination when prosecuting attorney had "intentionally withheld the material [information] with the intent to deceive the PTO"); *FMC Corp. v. Manitowoc Co., Inc.*, 835 F. 2d 1411, 1415 n.8 (Fed. Cir. 1987) (in the inequitable conduct context, "the knowledge and actions of applicant's attorney are chargeable to applicant").

The Commission's pleading standard for affirmative defenses is set out in Rule 210.13(b) ("Affirmative defenses shall be pleaded with as much specificity as possible in the response."). Commission Rule 210.13(b) provides that "[a]ffirmative defenses shall be pleaded with as much

specificity *as possible* in the response." 19 C.F.R. § 210.13(b) (emphasis added). The Rule also provides that respondents are "encouraged" to make the following showing when appropriate:

> If the claims of any involved U.S. patent are asserted to be invalid or unenforceable, the basis for such assertion, including, when prior art is relied on, a showing of how the prior art renders each claim invalid or unenforceable and a copy of such prior art.

Further, Commission Rule 210.13(b)(3) authorizes the Administrative Law Judge to waive or add pleading requirements relating to unenforceability. As a result, Commission Rule 210.13(b) is a flexible standard, allowing the Administrative Law Judge discretion to tailor the pleading requirements according to what information is available and to determine whether the pleadings are adequate given the stage of the proceeding. In fact, as noted by Judge Luckern:

> Commission Rule 210.13 requires a respondent to plead affirmative defenses with "as much specificity as possible." *Id.* If a respondent asserts that the claims of a U.S. patent are unenforceable, then the respondent is "encouraged" to make a showing of "how the prior art renders each claim . . . . unenforceable." *Id.* at § 210.13(b)(3). The Rule also states that the administrative law judge may waive any of the substantive requirements of the Rule or may impose additional requirements. *Id.* However, because Commission Rule 210.13(b)(3) authorizes an administrative law judge to waive or add pleading requirements relating to unenforceability, it is largely within the administrative law judge's discretion to determine whether the pleadings at issue in [complainant's] motion are adequate.

Certain Integrated Circuits, Chipsets, and Products Containing Same Including Televisions, Media Players, and Cameras, 337-TA-709, Order No. 32 (Dec. 9, 2010).

Following the ALJ's holding "agree[ing] with administrative law judges who have applied heightened pleading standards for inequitable conduct," (Order No. 8, at 3), Respondents have included in their proposed Amended Response facts recently discovered from Aker and its attorney Jones that satisfy the heightened pleading requirements of Federal Rule of Civil Procedure 9(b). *See Exergen*, 575 F.3d at 1327 (requiring specific pleading of the "who, what, when, where, and how" of the inequitable conduct).

To plead inequitable conduct, so long as the facts are pled with particularity and with sufficient relationship to the equity sought, no particular formula is required. *See Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240, 245-46 (1933) (explaining that courts of equity "are not bound by a formula or a restraint by any limitation that tends to trammel the free and just exercise of discretion."). Respondents do not need to plead sufficient facts to show "litigation misconduct or any other variety of unconscionable behavior by Complainants or anyone acting for them." *Id.*

In addition, a "finding of inequitable conduct can spread from a single patent to render unenforceable other related patents and applications in the same technology family. Thus, a finding of inequitable conduct may endanger a substantial portion of a company's patent portfolio. *Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F.3d 1276, 1288 (Fed. Cir. 2011) (citations omitted); *Fox Indus., Inc. v. Structural Preservation Sys., Inc.*, 922 F.2d 801, 803-04 (Fed. Cir. 1990) ("In determining inequitable conduct, a trial court may look beyond the final claims to their antecedents. . . . [A] breach of the duty of candor early in the prosecution may render unenforceable all claims which eventually issue from the same or a related application" (citations omitted)); *Consolidated Aluminum Corp. v. Foseco Int'l, Ltd.*, 910 F.2d 804, 811-12 (Fed. Cir. 1990) (inequitable conduct in prosecuting one patent had the "immediate and necessary relation" to the equity sought be the patentee, namely the enforcement of the other patents-in-suit, to render them similarly unenforceable).

B. Respondents Have Met the Standard for Pleading Inequitable Conduct

1. IPR Declarations

In 2013, on behalf of Aker, Jones filed a Petition for Inter Partes Review of U.S. Patent No. 8,383,675, in the PTO. The IPR sought to invalidate a claim of a patent assigned to one of

Aker's competitors, Neptune Technologies & Bioressources, Inc. Jones submitted declarations with that IPR, including data showing that krill oil extracted using the prior art Beaudoin method had ether phospholipid levels of greater than 3%, greater than 4%, and greater than 5%. Amended Response, ¶¶ 30-46.

In 2014, 2015, and 2016, during prosecution of applications related to the asserted patents, Jones repeatedly distinguished the pending claims (and those now asserted in this Investigation) from prior art Neptune Krill Oil (NKO) made by the Beaudoin method on the grounds that it supposedly had less than 3% ether phospholipids. *Id.* at ¶¶ 47-73. Jones's arguments were misleading, incorrect, and directly contradicted by the declarations Jones submitted to the PTO in 2013 in the IPR when Aker was trying to invalidate the patent of its competitor Neptune. *Id.* at ¶¶ 74, 76, 78, 80-82, 84. But for Jones's misleading and incorrect arguments distinguishing the prior art NKO made by the Beaudoin method during prosecution of the applications related to the asserted patents, which were directly contradicted by the declarations Jones submitted in Aker's Neptune IPR, *none* of Aker's asserted patent claims would have issued. *Id.* at ¶¶ 75, 77, 79, 83, 85-86.

Not only did Jones owe a duty of good faith and candor to the PTO under 37 CFR §1.56, *id.* at ¶¶ 88, 96, Jones knew about the information in the IPR declarations he filed in 2013 when he made directly contradictory arguments in 2014-16. *Id.* at ¶ 91. Jones provided no reasonable explanation for failing to specifically point out that information to the PTO in 2014-16 while making arguments distinguishing the prior art NKO made by the same Beaudoin method, *id.* at ¶¶ 92-95, 97-99. The only reasonable inference is that Jones concealed the contradictory declaration evidence he himself had obtained with the specific intent to deceive the PTO. *Id.* at ¶¶ 96, 100.

2. Table 17

In 2007 and 2008, Jones filed provisional patent applications for the asserted patents including Table 17, which reported 42.96% total phospholipids for the closest prior art krill oil, Neptune Krill Oil (NKO). Amended Response, ¶¶ 102-107. Later in 2008, Jones suppressed this data and did not include it with data in the original non-provisional application and it is not included in the asserted patents. Instead, Table 22 in the asserted patents identifies the prior art NKO as having a total phospholipid level of 30%. During prosecution, Jones repeatedly distinguished claims reciting a lower limit of ether phospholipids of 3% from the prior art NKO, using Table 22 to argue that the prior art NKO contained only 2.46% ether phospholipids based on a total phospholipid level of 30%. Jones did so without identifying or considering the data in Table 17. *Id.* at ¶¶ 107-112, 114. Jones secured allowance of numerous claims of the asserted patents, called Aker's 3% claims in the proposed Amended Response, by repeatedly presenting this argument. *Id.* at ¶¶ 118, 120. However, considering the data in Table 17 in conjunction with the data in Table 22, one would conclude that the prior art NKO in Table 17 had 3.52% ether phospholipids, within the range in Aker's 3% claims, and directly contradicted by the arguments made by Jones and accepted by the PTO that the prior art NKO had only 2.46% ether phospholipids. *Id.* at ¶¶ 115-117, 119, 130.

Aker's 3% claims recite a range of ether phospholipids with a low end of 3%. *Id.* at ¶ 111. The arguments presented by Jones were therefore incomplete, incorrect, and misleading because they omitted information showing that the prior art NKO had an ether phospholipid level greater than 3%, *id.* at ¶¶ 112, 115, 117, 119, and they were material to the PTO's determination of patentability. *Id.* at ¶¶ 118, 120, 132. But for Jones' failure to disclose this material information, the PTO would not have issued Aker's 3% claims. *Id.* at ¶¶ 121, 132.

Jones not only owed a duty of good faith and candor the to the PTO under 37 CFR §1.56, *id.* at ¶¶ 123, 137, his selective copying and deleting of information in the non-provisional patent application demonstrate that he was aware that the information he was submitting was incorrect and misleading. *Id.* at ¶¶ 119-120, 127, 139. Jones nevertheless concealed the information from the PTO in order to obtain issuance of Aker's 3% claims. *Id.* at ¶¶ 122, 128-129, 139. Jones provided no reasonable explanation for failing to tell the PTO that the data in Table 17 indicated an ether phospholipid level of greater than 3% in the prior art NKO. *Id.* at ¶¶ 133-136, 138. The only reasonable inference is that Jones suppressed this information with the specific intent to deceive the PTO. *Id.* at ¶ 140.

3. Nutrizeal/IRL

Aker retained the technical services of two companies, Nutrizeal and IRL to design, develop and optimize the technology that Aker now asserts it invented. Amended Response, ¶¶ 142-143, 145-150, 152, 155. Jones was aware of the substantial work of Nutrizeal and IRL, *id.* at ¶¶ 142, 144, 154, 156, 158, 160, 161, as well as IRL's previously existing IP rights related to the work. *Id.* at ¶¶ 151, 153. Jones copied large portions of the work of Nutrizeal and IRL in drafting provisional patent applications, *id.* at ¶¶ 156-157, 160-161, including a caution raised by IRL with regard to uncertainty in the possible underreporting of the amount of ether phospholipids in past testing. *Id.* at ¶¶ 155-158.

Jones knew that information as to who actually derived the claimed inventions, as well as information about the uncertainty of relevant prior art testing was directly relevant to the claimed inventions and would be material to the patentability of all of the asserted claims. *Id.* at ¶¶ 163-164. Nevertheless, Jones concealed this information from the PTO when filing the original non-provisional application and subsequently the asserted patents that claim priority to it. *Id.* at ¶¶

162-164. But for Jones' acts of concealment, the PTO would not have issued the asserted claims to Aker. Instead, the Nutrizeal/IRL information showed the substantial involvement of these entities and called into question whether the asserted patents are the property of Aker. *Id.* at ¶¶ 163-165.

Jones not only owed a duty of good faith and candor the to the PTO under 37 CFR §1.56, *id.* at ¶¶ 167, 173, he provided no reasonable explanation for failing to disclose information about the involvement of Nutrizeal and IRL to the PTO during prosecution of the asserted patents, *id.* at ¶¶ 168-172, 175. The only reasonable inference is that Jones concealed this information with the specific intent to deceive the PTO because Jones did not want to call into question whether any other entity beside Aker, like Nutrizeal or IRL, actually owned rights in the subject matter disclosed and claimed in the asserted patents. *Id.* at ¶¶ 158, 163-66, 174, 176.

C. The Proposed Amended Response is Timely

The proposed Amended Response is timely because it is based on documents and other information that were largely unavailable to Respondents until they were produced by Aker and Jones, including (i) documents Aker produced in January and February 2017, (ii) documents produced in February 2017 from a subpoena Respondents served on Jones, and (iii) documents Aker produced in February 2017 in response to Respondents' Motion to Compel Production of Project Mail Files (Motion No. 1019-0006). The Amended Response is particularly timely because it alleges inequitable conduct by Jones in filing and prosecuting the asserted patents. It was thus necessary to depose Jones regarding his actions and intentions. Jones was deposed on March 9, 2017, after which Respondents worked diligently to file this motion and to prepare their proposed Amended Response. This motion is therefore timely.

D. There is no Prejudice to Complainants

Consistent with Commission Rule 210.14(b)(2), the proposed Amended Response would not prejudice either the public interest or any of the rights of the parties to the Investigation, as allowing Respondents to amend their Response to include specific information that Aker already knew and that was within its own possession, will neither prejudice Aker or alter discovery or the trial schedule. Additionally, the proposed amendment will result in a more accurate and complete record facilitating disposition of the issues in this Investigation on the merits, as required by Commission Rule 210.14(b)(2).

III. CONCLUSION

Respondents thus request leave to file an Amended Response to the Complaint, as set forth in the attached Amended Response to the Complaint and Notice of Investigation.

Date: March 14, 2017

Respectfully submitted,

/s/Doris Johnson Hines

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Counsel for Respondents Olympic Holding AS, Rimfrost AS, Emerald Fisheries AS, Avoca Inc., Rimfrost USA, LLC, Rimfrost New Zealand Limited, and Bioriginal Food & Science Corp

Confidential
Exhibit 1

UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

Before the Honorable Dee Lord
Administrative Law Judge

In the Matter of **CERTAIN KRILL OIL PRODUCTS AND KRILL MEAL FOR PRODUCTION OF KRILL OIL PRODUCTS**	**Inv. No. 337-TA-1019**

AMENDED RESPONSE TO THE COMPLAINT AND NOTICE OF INVESTIGATION

RESPONDENTS

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PRELIMINARY STATEMENT

Pursuant to 19 C.F.R. § 210.13, Respondents Olympic Holding AS, Rimfrost AS, Emerald Fisheries AS, Avoca Inc., Rimfrost USA, LLC, Rimfrost New Zealand Limited, and Bioriginal Food & Science Corp. (collectively "Respondents"), by their undersigned counsel, submit the following Response to the Verified Complaint of Aker BioMarine Antarctic AS and Aker BioMarine Manufacturing, LLC under Section 337 of the Tariff Act of 1930, as amended, and the Notice of Institution of Investigation.

Respondents respond based on personal knowledge as to their own activities and on information and belief as to the activities of others. Respondents deny each and every allegation contained in the Complaint that is not expressly admitted herein. Where only certain, not all, of the Respondents have knowledge sufficient to respond to a particular contention, the Respondents responding and not responding are separately identified. Any factual allegation admitted in this Response is admitted only as to any specifically admitted fact, and not as to any purported conclusion, characterization, implication, or speculation arguably following from such admitted fact.

The Complaint and supporting documentation lack clarity and are insufficient to demonstrate that any of Respondents' products or processes infringe any claim of the patents asserted against Respondents. Because discovery has only recently started, Respondents provide this Response without the benefit of complete discovery, including contention discovery, necessary to fully understand the nature and scope of Aker BioMarine Antarctic AS and Aker BioMarine Manufacturing, LLC's (collectively "Complainants") allegations. Respondents therefore reserve the right to supplement their responses to the allegations in the Complaint and

Notice of Investigation because they have had insufficient time and opportunity to collect and review the entirety of information that may be needed to fully respond to the Complaint.

RESPONSE TO NOTICE OF INSTITUTION OF INVESTIGATION

The Commission issued a Notice of Investigation on September 12, 2016, which was published in the Federal Register on September 16, 2016 (81 Fed. Reg. 63,805). Pursuant to Commission Rule 210.13, Respondents hereby respond to the Notice of Investigation as follows:

Respondents admit that such an Investigation exists, and that Olympic Holding AS, Rimfrost AS, Emerald Fisheries AS, Avoca Inc., Rimfrost USA, LLC, Rimfrost New Zealand Limited, and Bioriginal Food & Science Corp. are the named Respondents. Respondents otherwise deny the existence of the predicates and requirements for liability under such Investigation, and therefore deny the allegations in the Notice of Institution of Investigation, to the extent such allegations exist and relate to Respondents. Respondents lack sufficient information to admit or deny the remaining allegations in the Notice of Institution of Investigation and therefore deny them.

RESPONSE TO COMPLAINT

Except as expressly and specifically admitted herein, Respondents deny all allegations of the Complaint.

I. INTRODUCTION[1]

1. Responding to paragraph 1, Respondents admit that Complainants requested that the United States International Trade Commission institute an investigation under Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337. Respondents assert that

[1] The section headers in this Response correspond to the section headers in the Complaint and are included only for clarity. They are not admissions of any allegations contained in such section headers. All allegations in the Complaint that are not specifically admitted as set forth below, including any allegations in the Complaint's section headers, are hereby denied.

Complainants' assertion of the '905 patent was improper because Complainants knew or should have known that the '905 patent was unenforceable. Respondents deny the remaining allegations of paragraph 1.

2. Respondents admit that Antarctic krill (*Euphausia superba*) is found in the Antarctic Ocean, although the estimated amounts vary, krill can be a source for proteins, lipids such as phospholipids, poly-unsaturated fatty acids, chitin/chitosan, astaxanthin and other carotenoids, enzymes, and other material and that it was well known that krill can degrade after being caught. Respondents lack sufficient information to admit or deny the remaining allegations of Paragraph 2 and therefore deny them.

3. Responding to paragraph 3, Respondents lack sufficient information to admit or deny the allegations and therefore deny them.

4. Responding to paragraph 4, Respondents lack sufficient information to admit or deny the allegations and therefore deny them.

5. Responding to paragraph 5, Respondents deny the allegations.

6. Responding to paragraph 6, Respondents admit that Complainants purport to assert the asserted claims set out in the chart of paragraph 6. Except as so admitted, Respondents deny the remaining allegations of paragraph 6.

7. Responding to paragraph 7, Respondents have not had discovery regarding the facts of Complainants' alleged domestic industry. Further, the proper construction of the asserted claims has not yet been determined. Therefore, Respondents deny the existence of a domestic industry. Respondents deny any remaining allegations of paragraph 7.

8. Respondents deny the allegations of paragraph 8.

9. Responding to paragraph 9, Respondents admit that Complainants seek the stated relief. Respondents deny the existence of the predicates and requirements of such relief and deny that Complainants are entitled to such relief. Respondents deny any remaining allegations of paragraph 9.

II. THE PARTIES

A. Complainants

i. Aker BioMarine Antarctic AS

10. Responding to paragraph 10, Respondents lack sufficient information to admit or deny the allegations and therefore deny them.

11. Responding to paragraph 11, Respondents lack sufficient information to admit or deny the allegations and therefore deny them.

12. Responding to paragraph 12, Respondents lack sufficient information to admit or deny the allegations and therefore deny them.

13. Responding to paragraph 13, Respondents lack sufficient information to admit or deny the allegations and therefore deny them.

14. Responding to paragraph 14, Respondents lack sufficient information to admit or deny the allegations and therefore deny them.

ii. Aker BioMarine Manufacturing LLC

15. Responding to paragraph 15, Respondents lack sufficient information to admit or deny the allegations and therefore deny them.

16. Responding to paragraph 16, Respondents lack sufficient information to admit or deny the allegations and therefore deny them.

17. Responding to paragraph 17, Respondents lack sufficient information to admit or deny the allegations and therefore deny them.

B. Respondents and Their Relationships

i. Olympic Holding AS

18. Responding to paragraph 18, Respondent Olympic Holding AS ("Olympic Holding") admits that it is a Norwegian corporation with its principal place of business at Fosnavåg Brygge Holmsildgata 12, N-6099, Fosnavåg, Norway, and that it is the parent corporation of Rimfrost AS. Olympic Holding denies any remaining allegations of this paragraph. Respondents Rimfrost AS, Emerald Fisheries AS ("Emerald"), Avoca Inc. ("Avoca"), Rimfrost USA, LLC ("Rimfrost USA"), Rimfrost New Zealand Limited ("Rimfrost NZ"), and Bioriginal Food & Science Corp. ("Bioriginal") each reference Olympic Holding's response.

19. Responding to paragraph 19, Olympic Holding admits that Stig Rune Remøy is a majority shareholder, chairman, and only member of the board of Olympic Holding, and that Mr. Remøy is a member of the board of Rimfrost AS and of Emerald. Olympic Holding denies any remaining allegations of this paragraph. Rimfrost AS, Emerald, Avoca, Rimfrost USA, Rimfrost NZ, and Bioriginal each reference Olympic Holding's response.

20. Responding to paragraph 20, Olympic Holding admits that it owns Emerald Fisheries AS. Olympic Holding denies any remaining allegations of this paragraph. Rimfrost AS, Emerald, Avoca, Rimfrost USA, Rimfrost NZ, and Bioriginal each reference Olympic Holding's response.

21. Responding to paragraph 21, Olympic Holding denies the allegations. Rimfrost AS, Emerald, Avoca, Rimfrost USA, Rimfrost NZ, and Bioriginal each reference Olympic Holding's response.

22. Responding to paragraph 22, Olympic Holding denies the allegations. Rimfrost AS, Emerald, Avoca, Rimfrost USA, Rimfrost NZ, and Bioriginal each reference Olympic Holding's response.

ii. Rimfrost AS

23. Responding to paragraph 23, Rimfrost AS admits that it is a Norwegian corporation with its principal place of business at Vågsplassen, 6090 Fosnavåg, Norway, that it was formerly known as Olympic Seafood AS, and that it is a wholly owned subsidiary of Olympic Holding. Rimfrost AS denies any remaining allegations of this paragraph. Olympic Holding, Emerald, Avoca, Rimfrost USA, Rimfrost NZ, and Bioriginal each reference Rimfrost AS's response.

24. Responding to paragraph 24, Rimfrost AS admits that Inge Bruheim is the first named inventor of each Asserted Patent, that Dr. Bruheim was hired by Rimfrost AS in 2011, and that Dr. Bruheim currently holds the title of Research Director at Rimfrost AS. Rimfrost AS denies any remaining allegations of paragraph 24. Olympic Holding, Emerald, Avoca, Rimfrost USA, Rimfrost NZ, and Bioriginal each reference Rimfrost AS's response.

25. Responding to paragraph 25, Rimfrost AS denies that "After Dr. Bruheim was hired, Rimfrost AS ultimately transitioned from processing denatured krill product with a supercritical fluid extraction process in New Zealand to an ethanol extraction process in North Carolina by Avoca and Rimfrost USA." Regarding the remaining allegations of paragraph 25, Rimfrost AS lacks sufficient information to admit or deny the allegations and therefore denies

them. Olympic Holding, Emerald, Avoca, Rimfrost USA, Rimfrost NZ, and Bioriginal each reference Rimfrost AS's response.

26. Responding to paragraph 26, Rimfrost AS admits that Complaint Exhibits 26, 27, 41, and 42 include the statements appearing as quotations in paragraph 26. Rimfrost AS admits that Exhibit 27 purports to be a transcript of a May 2014 YouTube video. Rimfrost AS denies any remaining allegations of paragraph 26. Olympic Holding, Emerald, Avoca, Rimfrost USA, Rimfrost NZ, and Bioriginal each reference Rimfrost AS's response.

27. Responding to paragraph 27, Rimfrost AS admits that Exhibit 25 of the Complaint is a document that on its face appears to identify Olympic Seafood AS as its source and that includes the graphic inserted into paragraph 27. Rimfrost AS denies any remaining allegations of paragraph 27. Olympic Holding, Emerald, Avoca, Rimfrost USA, Rimfrost NZ, and Bioriginal each reference Rimfrost AS's response.

28. Responding to paragraph 28, Respondents deny the allegations.

29. Responding to paragraph 29, Rimfrost AS denies the allegations. Olympic Holding, Emerald, Avoca, Rimfrost USA, Rimfrost NZ, and Bioriginal each reference Rimfrost AS's response.

iii. Emerald Fisheries AS

30. Responding to paragraph 30, Emerald admits that it is a Norwegian corporation with its principal place of business at Fosnavåg Brygge, 6090 Fosnavåg, Norway, that it is a wholly owned subsidiary of Rimfrost AS, and that it is the registered owner of the Juvel. Emerald denies any remaining allegations of paragraph 30. Olympic Holding, Rimfrost AS, Avoca, Rimfrost USA, Rimfrost NZ, and Bioriginal each reference Emerald's response.

31. Responding to paragraph 31, Emerald admits that Complaint Exhibit 34 includes the statements appearing as quotations in paragraph 31. Emerald denies any remaining allegations of paragraph 31. Olympic Holding, Rimfrost AS, Avoca, Rimfrost USA, Rimfrost NZ, and Bioriginal each reference Emerald's response.

iv. Avoca, Inc.

32. Responding to paragraph 32, Avoca admits that it is a North Carolina corporation with its principal place of business at 841 Avoca Farm Rd, Merry Hill, North Carolina 27957. Avoca denies any remaining allegations of paragraph 32. Olympic Holding, Emerald, Rimfrost AS, Rimfrost USA, Rimfrost NZ, and Bioriginal each reference Avoca's response.

v. Rimfrost USA, LLC

33. Responding to paragraph 33, Rimfrost USA admits that it is a Delaware limited liability company with its principal place of business at 841 Avoca Farm Rd, Merry Hill, North Carolina 27957 and that it is a joint venture between Rimfrost AS and Avoca. Olympic Holding, Emerald, Rimfrost AS, Avoca, Rimfrost NZ, and Bioriginal each reference Rimfrost USA's response.

34. Responding to paragraph 34, Rimfrost USA admits that Complaint Exhibit 34 includes the statements appearing as quotations in paragraph 34. Rimfrost USA denies any remaining allegations of paragraph 34. Olympic Holding, Emerald, Rimfrost AS, Avoca, Rimfrost NZ, and Bioriginal each reference Rimfrost USA's response.

vi. Rimfrost New Zealand Limited

35. Responding to paragraph 35, Rimfrost NZ admits that it is a New Zealand corporation with its principal place of business at 20 Oxford Street, Richmond, Nelson, NZ

7020, that it was formerly known as Olympic Biotech Limited, and that it is a wholly owned subsidiary of Rimfrost AS. Rimfrost NZ denies any remaining allegations of paragraph 35. Olympic Holding, Emerald, Rimfrost AS, Avoca, Rimfrost USA, and Bioriginal each reference Rimfrost NZ's response.

vii. Bioriginal Food & Science Corp.

36. Responding to paragraph 36, Bioriginal admits that it is a Canadian corporation with its principal place of business at 102 Melville Street, Saskatoon, Saskatchewan, Canada S7J 0R1. Bioriginal denies any remaining allegations of paragraph 36. Olympic Holding, Emerald, Rimfrost AS, Avoca, Rimfrost USA, and Rimfrost NZ each reference Bioriginal's response.

III. THE PRODUCTS AT ISSUE

37. Responding to paragraph 37, Respondents deny Complainants' characterization of the products at issue and therefore deny the allegations.

38. Responding to paragraph 38, Respondents deny the allegations.

39. Responding to paragraph 39, Respondents deny the allegations.

IV. THE ASSERTED PATENTS AND NONTECHNICAL DESCRIPTIONS OF THE INVENTIONS

A. Non-Technical Description of the Asserted Patents

40. Responding to paragraph 40, Respondents admit that the asserted patents, on their faces, are identified as continuations of the same parent application. Respondents deny any remaining allegations of paragraph 40.

B. Identification of the Asserted Patents and Ownership by Complainant

41. Responding to paragraph 41, Respondents admit that the '877 patent, on its face, is entitled "Bioeffective Krill Oil Compositions" and was issued on May 12, 2015, identifying Aker BioMarine Antarctic AS as the assignee.

42. Responding to paragraph 42, Respondents admit that the '905[2] patent, on its face, is entitled "Bioeffective Krill Oil Compositions" and was issued on July 14, 2015, identifying Aker BioMarine Antarctic AS as the assignee.

43. Responding to paragraph 43, Respondents admit that the '752 patent, on its face, is entitled "Bioeffective Krill Oil Compositions" and was issued on July 7, 2015, identifying Aker BioMarine Antarctic AS as the assignee.

44. Responding to paragraph 44, Respondents admit that the '765 patent, on its face, is entitled "Bioeffective Krill Oil Compositions" and was issued on April 26, 2016, identifying Aker BioMarine Antarctic AS as the assignee.

45. Responding to paragraph 45, Respondents admit that the '453 patent, on its face, is entitled "Bioeffective Krill Oil Compositions" and was issued on June 28, 2016, identifying Aker BioMarine Antarctic AS as the assignee.

46. Responding to paragraph 46, Respondents admit that the asserted patents are each assigned on their face to Aker BioMarine Antarctic AS. Respondents lack sufficient information to admit or deny the remaining allegations of paragraph 46 and therefore deny them.

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[2] Complainants filed a Motion for Partial Termination of This Investigation as to Certain Claims, Motion No. 1019-0002, on October 5, 2016, requesting termination of the investigation as to the '905 patent. Respondents filed their response on October 6, 2016, stating they agreed to termination of the '905 patent because that patent is unenforceable because it was terminally disclaimed from a non-commonly-owned patent. The Motion is pending.

47. Responding to paragraph 47, Respondents admit that Exhibit 6 purports to be a copy of the assignment history of the '877 patent, that Exhibit 7 purports to be a copy of the assignment history of the '905 patent, that Exhibit 8 purports to be a copy of the assignment history of the '752 patent, that Exhibit 9 purports to be a copy of the assignment history of the '765 patent, and that Exhibit 10 purports to be a copy of the assignment history of the '453 patent.

48. Responding to paragraph 48, Respondents admit that Appendices A through J purport to include certified copies of the asserted patents, their prosecution histories, and each technical reference cited in said prosecution histories.

C. Foreign Counterparts to the Asserted Patents

49. Responding to paragraph 49, Respondents lack sufficient information to admit or deny the allegations and therefore deny them. On information and belief, Exhibit 11 is not a complete listing of foreign patents and foreign patent applications corresponding to the asserted patents. On information and belief, Exhibit 11 does not provide the correct status of all foreign patents and foreign patent applications, as required under Commission Rule 210.12(a)(9)(v).

D. Licenses

50. Responding to paragraph 50, Respondents lack sufficient information to admit or deny the allegations and therefore deny them. On information and belief, Complainants' allegation that "[t]he Asserted Patents have never been licensed to any third parties" is not accurate. Aker announced on October 3, 2016, the purported licensing of its krill oil-related patent portfolio to Neptune Technologies and Bioressources. When Complainants licensed the asserted patents to Neptune, they knew or should have known that the '905 patent was not enforceable.

V. THE DOMESTIC INDUSTRY

51. Responding to paragraph 51, Respondents lack sufficient information to admit or deny the allegations and therefore deny them.

A. Complainants' Investment in the Domestic Industry

52. Responding to paragraph 52, Respondents lack sufficient information to admit or deny the allegations and therefore deny them.

53. Responding to paragraph 53, Respondents lack sufficient information to admit or deny the allegations and therefore deny them.

54. Responding to paragraph 54, Respondents lack sufficient information to admit or deny the allegations and therefore deny them.

55. Responding to paragraph 55, Respondents lack sufficient information to admit or deny the allegations and therefore deny them.

56. Responding to paragraph 56, Respondents lack sufficient information to admit or deny the allegations and therefore deny them.

57. Responding to paragraph 57, Respondents lack sufficient information to admit or deny the allegations and therefore deny them.

58. Responding to paragraph 58, Respondents lack sufficient information to admit or deny the allegations and therefore deny them.

59. Responding to paragraph 59, Respondents lack sufficient information to admit or deny the allegations and therefore deny them.

B. Complainants' Practice of the Asserted Patents

60. Responding to paragraph 60, Respondents deny the allegations.

VI. SPECIFIC INSTANCES OF IMPORTATION AND SALE

61. Responding to paragraph 61, Respondents deny the allegations.

62. Responding to paragraph 62, Respondents deny the allegations.

63. Responding to paragraph 63, Respondents admit that Exhibit 33 purports to show importation of Olymeg into the United States as late as December 2015. Respondents note that two of the asserted patents, namely the '765 and '453 patents, did not issue until 2016. Respondents admit Exhibit 35 purports to be an account in "nutrition insight." Respondents note that the URL at the end of Exhibit 35 is no longer an active link and indicates, "Article not found!" Respondents deny the remaining allegations of paragraph 63.

64. Responding to paragraph 64, Respondents deny the allegations.

65. Responding to paragraph 65, Respondents admit that Exhibit 28 includes pictures of a product apparently manufactured in February 2016 labeled Swanson EFAs Superior Essential Fatty Acids Rimfrost Krill Oil. Exhibit 28 Respondents deny any remaining allegations of paragraph 65.

66. Responding to paragraph 66, Respondents deny the allegations.

VII. UNLAWFUL AND UNFAIR ACTS COMMITTED BY RESPONDENTS

67. Responding to paragraph 67, Respondents deny the allegations.

68. Responding to paragraph 68, Respondents deny the allegations.

69. Responding to paragraph 69, Respondents deny the allegations. Further, the allegations of paragraph 69 are moot because the '905 patent was terminally disclaimed from a non-commonly-owned patent and is thus unenforceable and in view of Complainants' Motion for Partial Termination of This Investigation as to Certain Claims, Motion No. 1019-002.

70. Responding to paragraph 70, Respondents deny the allegations.

71. Responding to paragraph 71, Respondents deny the allegations.

72. Responding to paragraph 72, Respondents deny the allegations.

73. Responding to paragraph 73, Respondents deny the allegations.

74. Responding to paragraph 74, Respondents deny the allegations.

75. Responding to paragraph 75, Respondents deny the allegations.

76. Responding to paragraph 76, Olympic Holding denies the allegations. Rimfrost AS, Emerald, Avoca, Rimfrost USA, Rimfrost NZ, and Bioriginal each reference Olympic Holding's response.

77. Responding to paragraph 77, Rimfrost AS denies the allegations. Olympic Holding, Emerald, Avoca, Rimfrost USA, Rimfrost NZ, and Bioriginal each reference Rimfrost AS's response.

78. Responding to paragraph 78, Rimfrost NZ denies the allegations. Olympic Holding, Emerald, Rimfrost AS, Avoca, Rimfrost USA, and Bioriginal each reference Rimfrost NZ's response.

79. Responding to paragraph 79, Emerald denies the allegations. Olympic Holding, Rimfrost AS, Avoca, Rimfrost USA, Rimfrost NZ, and Bioriginal each reference Emerald's response.

80. Responding to paragraph 80, Avoca denies the allegations. Olympic Holding, Emerald, Rimfrost AS, Rimfrost USA, Rimfrost NZ, and Bioriginal each Avoca's response.

81. Responding to paragraph 81, Bioriginal denies the allegations. Olympic Holding, Emerald, Rimfrost AS, Avoca, Rimfrost USA, and Rimfrost NZ each reference Bioriginal's response.

82. Responding to paragraph 82, Respondents deny the allegations.

83. Responding to paragraph 83, Respondents admit that Aker BioMarine Antarctic AS filed a Complaint for Patent Infringement in the United States District Court for the District of Delaware ("Delaware Complaint") on January 22, 2016, naming Olympic Holding, Rimfrost AS, Emerald, Rimfrost USA, Avoca, and Bioriginal as defendants and alleging infringement of the '877 and '905 patents. Respondents' response to paragraph 83 is not an admission as to any allegations made in the Delaware Complaint. Additionally, Respondents admit that Exhibit 39 and Exhibit 40 purport to be correspondence dated immediately before the Complaint in this Investigation was filed. Respondents deny any remaining allegations of paragraph 83.

84. Responding to paragraph 84, Rimfrost AS admits that Inge Bruheim is the first named inventor of each Asserted Patent, that Dr. Bruheim was hired by Rimfrost AS in 2011, that Dr. Bruheim currently holds the title of Research Director at Rimfrost AS, and that Dr. Bruheim contacted Aker regarding inventor compensation for certain patents. Rimfrost AS denies any remaining allegations of paragraph 84. Olympic Holding, Emerald, Avoca, Rimfrost USA, Rimfrost NZ, and Bioriginal each reference Rimfrost AS's response.

85. Responding to paragraph 85, Respondents deny the allegations.

86. Responding to paragraph 86, Respondents deny the allegations.

87. Responding to paragraph 87, Respondents admit that Aker BioMarine Antarctic AS filed the Delaware Complaint on January 22, 2016, naming Olympic Holding, Rimfrost AS, Emerald, Rimfrost USA, Avoca, and Bioriginal as defendants and alleging infringement of the '877 and '905 patents, that the corresponding case number is 1:16-cv-0035-LPS-CJB.

IX. RELIEF REQUESTED

88. Respondents deny that Complainants have any valid cause of action against Respondents pursuant to Section 337 of the Tariff Act of 1930, as amended. Respondents deny

that Complainants are entitled to obtain, or that the U.S. International Trade Commission should issue, Complainants' requested relief, including any kind of exclusion order, cease and desist order, or any other form of relief. The allegations contained in Complainants' Relief Requested are not factual allegations that call for a response from Respondents. To the extent that the allegations call for a response, Respondents deny them.

89. To the extent that any allegation of the Complaint is not specifically admitted in the numbered paragraphs above, Respondents deny such allegation.

INFORMATION REQUIRED UNDER COMMISSION RULE 210.13(b)

See **Confidential Exhibit Nos. 1 and 2** for information required under 19 C.F.R. § 210.13(b). By providing the information contained in Exs. 1 and 2, Respondents intend only to supply data required by 19 C.F.R. § 210.13(b). Respondents specifically deny that any of this information or data relates to or supports any allegations of infringement against Respondents or any violation of 19 U.S.C. § 1337.

AFFIRMATIVE DEFENSES

In addition to the defenses set forth above as denials regarding infringement, validity, importation, and domestic industry, as well as the affirmative defenses below, Respondents specifically reserve the right to modify their defenses and allege additional affirmative defenses as they become known through the course of discovery.

FIRST AFFIRMATIVE DEFENSE
(Non-Infringement)

1. Respondents do not, and have not, directly and/or indirectly infringed, contributed to the infringement, or induced the infringement of any valid and enforceable asserted claim of the asserted patents, either literally or under the doctrine of equivalents, and has not otherwise committed any acts in violation of 19 U.S.C. § 1337 or 35 U.S.C. § 271, et seq.

2. Although the asserted claims have yet to be construed, Complainants are not entitled to any construction that would cover any product made, used, sold, offered for sale, or imported into the United States, or any process used, by any Respondent. Respondents expect that the planned *Markman* hearing will narrow the issues and establish that Respondents do not infringe any asserted claim. Respondents reserve the right to amend their responses, including adding additional bases of non-infringement, after further discovery into this matter.

3. Complainants are estopped from construing the claims of the asserted patents to cover any of Respondents' accused products or processes because representations, omissions, and/or concessions made during prosecution of the asserted patents , and/or related U.S. or foreign patents and patent applications, and/or the prior art, limit the scope of the claims of the asserted patents.

4. Prosecution history estoppel bars Complainants from asserting infringement under the doctrine of equivalents because of representations, omissions, and/or concessions made during prosecution of the asserted patents, and/or related U.S. or foreign patents and patent applications.

5. Complainants' allegations of infringement of the '905 patent are moot because the '905 patent was terminally disclaimed from a non-commonly-owned patent and is thus unenforceable and in view of Motion No. 1019-0002 filed by Complainants, requesting termination of this Investigation as to the '905 patent.

6. Respondents' analysis of the asserted patents, the asserted claims, and their prosecution histories is just beginning and Respondents reserve the right to alter, amend, or supplement this affirmative defense as the Investigation proceeds.

SECOND AFFIRMATIVE DEFENSE
(Invalidity)

7. The asserted claims of the asserted patents are invalid for failure to meet the conditions of patentability set forth in Title 35 of the United States Code, including but not limited to §§ 101, 102, 103, 112, 115, and/or 116, and judicially-created doctrines of invalidity.

8. Respondents reference all the reasons for invalidity advanced in the prosecution histories of the asserted patents and all related U.S. and foreign patents and patent applications, including all oppositions thereto.

9. Complainants' asserted claims directed to krill oil and/or any krill oil composition recite patent ineligible subject matter and are invalid under 35 U.S.C. § 101.

10. The asserted claims of the asserted patents are invalid under 35 U.S.C. §§ 102 and/or 103 in view of the prior art of record in the prosecution of the asserted patents, and at least the following prior art, either alone or in combination:

Document Number	First Listed Inventor	Publication or Issue Date
CA 2251265	Beaudoin	04-21-2000
EP 1004245	Bork	05-31-2000
EP 1127497	Shigematu	08-29-2001
JP 2909508	Maruyama	06-23-1999
JP H4-57853	Tokumori	02-25-1992
NZ 500824	Bork	09-28-2001
US 4,119,619	Rogozhin	10-10-1978
US 6,800,299	Beaudoin	10-05-2004
US 7,488,503	Porzio	02-10-2009
US 7,666,447	Rockway	02-23-2010
US 7,763,717	Jaczynski	07-27-2010
US 7,803,413	van Lengerich	09-28-2010
US 8,030,348	Sampalis	10-04-2011
US 8,057,825	Sampalis	11-15-2011
US 8,278,351	Sampalis	10-02-2012
US 2005-0192634	Beaudoin	09-01-2005
WO 2000/023546	Beaudoin	04-27-2000
WO 2000/025608	Yoshitomi	05-11-2000
WO 2002/102394	Sampalis	12-27-2002
WO 2003/011873	Sampalis	02-13-2003

WO 2007/123424	Catchpole	11-01-2007

Publication	Date
Balassa et al., *Microencapsulation in the food industry*, CRC Critical Reviews in Food Technology, 2:2, 245-265	1971
Bunea et al., *Evaluation of the Effects of Neptune Krill Oil on the Clinical Course of Hyperlipidemia*, Altern. Med. Rev. 9(4):420-428	2004
Bottino, *The Fatty Acids of Antarctic Phytoplankton and Euphausiids*, Marine Biology 27, 197-204	1974
Budzinski et al., *Possibilities of processing and marketing of products made from Antarctic krill*, FAO Fish. Tech. Pap., 268:46	1985
Chen et al., *Polysaccharidase And Glycosidase Activities Of Antarctic Krill Euphausia Superba*, Journal of Food Biochemistry 5.1: 63-68.	1981
Dunford et al., *Supercritical CO_2 extraction of oil and residual proteins from Atlantic mackerel (Scomber scombrus) as affected by moisture content*, Journal of Food Science, 62.2: 289-294	1997
Folch et al., *A simple method for the isolation and purification of total lipids from animal tissues*, J. Biol. Chem., 226:497-509	1957
Fricke et al., *Lipid, Sterol and Fatty Acid Composition of Antarctic Krill*, Lipids, Vol. 19, No. 11, 821-827	1984
Fricke et al., *1-O-Alkylglycerolipids in Antarctic krill*, Comp. Biochem. 59:8, 1389-93	1986
Grantham et al., *The Southern Ocean: The Utilization Of Krill*, Southern Oceans Fisheries Survey Programme, Food And Agriculture Organization Of The United Nations GLO/S0/77/3	1977
Jiang et al., *Comparison of protein precipitation methods for sample preparation prior to proteomic analysis*, J. Chromatography A 1023:2, 317-320	2004
Joseph, et al., *Products for human consumption from Antarctic krill*, Fishery Technology 36:1	1999
Kolakowska et al., *Winter season krill (Euphasia superba D.) as a source of n-3 polunsaturated fatty acids*, Die Nahrung, 38, 2:128-134	1994
Kolakowski, et al., *Endogenous enzymes in Antarctic krill: control of activity during storage and utilization*, FOOD SCIENCE AND TECHNOLOGY, New York (MARCEL DEKKER), 505-530	2000
Kolakowski, et al., *Application of partial autoproteolysis to extraction of protein from Antarctic krill (Euphasia superba) Part 1. Effect of pH on protein extraction intensity*, Food/Nahrung 24:6, 499-506	1980
Kolakowski et al., *Application of partial autoproteolysis to extraction of protein from Antarctic krill (Euphasia superba). Part 2. Influence of temperature on protein extraction intensity*, Food/Nahrung 24:6, 507-512	1980
Kolakowski et al., *Optimization of autoproteolysis to obtain an edible product 'precipitate' from Antarctic krill (Euphausia superba Dana)*, Seafood science and technology, Oxford UK (Fishing News Books) 331-336	1992
Kubota et al., *Autolysis of Antarctic krill protein and its inactivation by combined effects of temperature and pH*, Transactions of the Tokyo University of Fisheries, 2:53-63	1978

Kusumoto et al., "Lipid Profile of Krill *Euphausia pacifica* Collected in the Pacific Ocean near Funka Bay, Hokkaido, Japan" J. Oleo Sci. 53(1):45-51.	2004
Marathe et al., *Inflammatory Platelet-activating Factor-like Phospholipids in Oxidized Low Density Lipoproteins are Fragmented Alkyl Phosphatidylcholines*, J. Bio. Chem 274:28395-28404	1999
Martin, *Krill as a protein source-methods of recovery, potential uses, and problems*, Food Technology, January 46-51.	1979
Nagayama, F., et al. *Lipase, carboxylesterase and catechol oxidase of the Antarctic krill*, Transactions of the Tokyo University of Fisheries, 3:153-159	1979
Nicol, et al., *Products derived from krill*, Krill: Biology, Ecology and Fisheries, 6: 262-283	2000
Osnes, et al., *On the purification and characterization of exopeptidases from Antarctic krill, Euphausia superba,* Comparative Biochemistry and Physiology Part B: Comparative Biochemistry 83.2: 445-458	1986
Osnes, et al., *Peptide hydrolases of Antartic krill, Euphausia superba*, Comparative Biochemistry and Physiology Part B: Comparative Biochemistry 82.4: 599-606	1985
Osnes, et al., *On the purification and characterization of three anionic, serine-type peptide hydrolases from Antarctic krill, Euphausia superba*, Comparative Biochemistry and Physiology Part B: Comparative Biochemistry 82.4: 607-619	1985
Phleger et al., *Interannual and between species comparison of the lipids, fatty acids and sterols of Antarctic krill from the US AMLR Elephant Island survey area*, Comp. Biochem. and Phys. Part B, 131:733-747	2002
Saether, et al., *Lipolysis post mortem in North Atlantic krill*, Comparative Biochemistry and Physiology Part B: Comparative Biochemistry, 83.1:51-55.	1986
Saether et al., "Proteolysis *Post Mortem* in North Atlantic Krill" Comp. Biochem. Physiol. Vol. 88B(1):165-176.	1987
Sampalis et al., *Evaluation of the Effects of Neptune Krill Oil on the Management of Premenstrual Syndrome and Dysmenorrhea*, Alt. Med. Review, Vol. 8, No. 2, 171-179	2003
Sizer et al., *Kinetics as a function of temperature of lipase, trypsin, and invertase activity from -70 to 50 C (-94 to 122 F)*, Journal of Food Science 7.3: 201-209	1942
Storebakken, *Krill as a potential feed source for salmonids*, Aquaculture 70 193-205	1988
Suzuki, et al., *Fish and krill protein: processing technology*. No. 637.33 SUZf.	1982
Suzuki et al., *The utilization of Antarctic krill for human food*, Food Reviews Int'l, 6:1, 119-147	1990
Takaichi et al., "Fatty acids of astaxanthin esters in krill determined by mild mass spectrometry" Comparative Biochemistry and Physiology Part B 136 317-322.	2003
Tanaka et al., *Platelet-activating factor (PAF)-like phospholipids formed during peroxidation of phosphatidylcholines from different foodstuffs*, Bioscience, Biotechnology, and Biochemistry, 59:8, 1389-1393	1995
Tanaka et al., *Extraction of Phospholipids from Salmon Roe with Supercritical Carbon Dioxide and an Entrainer*, J. Oleo Sci. 53(9):417-424	2004
Tanaka et al., *Extraction of Phospholipids from Unused Natural Resources with Supercritical Carbon Dioxide and an Entrainer*, Journal of Oleo Science, 54.11: 569-576	2005

Tou et al., *Krill for human consumption: nutritional value and potential health benefits*, Nutrition Reviews, 65:2, 63-77	2007
Turkiewicz et al., *Lipolytic activity of Antarctic krill, Euphasia superba Dana*, Polish Polar Research, 16:3-4, 185-189	1995
Yamaguchi et al., *Supercritical carbon dioxide extraction of oils from Antarctic krill*, Journal of Agricultural and Food Chemistry 34.5: 904-907	1986
Yanase, M., *Chemical composition of Antarctic krill Euphausia superba by raw freezing and precooked freezing*, Bulletin of Tokai Regional Fisheries Research Laboratory, 77, 97	1974

Respondents' investigation is continuing Respondents may rely on additional or different invalidating prior art.

11. Complainants are estopped from construing the claims of the asserted patents to overcome invalidating prior art references because representations, omissions, and/or concessions made during prosecution of the asserted patents, and/or related U.S. or foreign patents and patent applications, define the scope of the claims of the asserted patents.

12. On information and belief, the asserted claims are invalid under 35 U.S.C. §§ 102 and/or 103 in view of prior art krill oil products known, used, offered for sale, and/or on sale in the United States more than one year prior to the earliest U.S. filing date to which the claims are entitled to claim priority. On information and belief, a Krill Bill krill oil product was on sale in the U.S. before the priority date of the asserted claims. On information and belief, a Neptune Krill Oil product was on sale in the U.S. before the priority date of the asserted claims. On information and belief, an Antarctica Select krill oil product was on sale in the U.S. before the priority date of the asserted claims. On information and belief, the asserted claims are invalid in view of the Krill Bill, Neptune Krill Oil, and/or Antarctica Select products.

13. Each of the asserted patents claims benefit under 35 U.S.C. § 119(e) to four provisional applications, U.S. Provisional Patent Application Nos. 60/920,483; 60/975,058; 60/983,446; and 60/024,072. The asserted claims are not supported by at least the '483, '058, and

'446 provisional applications under 35 U.S.C. § 112, ¶ 1, and are thus not entitled to the filing dates of these provisional applications.

14. The specifications of the asserted patents fail to sufficiently describe the subject matter recited in the asserted claims, and fail to show that the named inventors actually invented what is claimed. Because the named inventors failed to convey with reasonable clarity to those skilled in the art, as of the filing date of each of the asserted patents, that the named inventors were in possession of any claimed invention(s) and demonstrate that by what is actually disclosed in the patent specifications, the asserted claims are invalid under 35 U.S.C. § 112.

15. The asserted claims, read in light of their corresponding specifications and prosecution histories, fail to inform, with reasonable certainty, those skilled in the art the scope and bounds of the purported inventions claimed, and accordingly the asserted claims are invalid under 35 U.S.C. § 112, ¶ 2 for indefiniteness.

16. The asserted patents fail to disclose sufficient information to enable or teach a person skilled in the art, at the time each corresponding application was filed, how to make and use the full scope of the subject matter recited in each of the patents, without undue experimentation. Accordingly, the asserted claims are invalid under 35 U.S.C. 112, ¶ 1, for lack of enablement.

17. Respondents' analysis of the asserted patents, the asserted claims, and the applicable prior art is just beginning and Respondents reserve the right to alter, amend, or supplement this affirmative defense as the Investigation proceeds.

THIRD AFFIRMATIVE DEFENSE
(Unenforceability and Lack of Standing)

18. The '905 patent is unenforceable based on the Terminal Disclaimer filed by Aker during prosecution, which states that the '905 patent "shall be enforceable only for and during

such period that it and any patent granted on [U.S. Patent Application No. 13/856,642, issued as U.S. Patent No. 9,068,142] are commonly owned." *See* Complaint Appendix B at AKBM00002266-70. The '905 patent and the '142 patent are not now, and never have been, commonly owned. As stated in Complaint paragraph 42, the '905 patent is owned by Aker BioMarine Antarctic AS. The '142 patent is owned by Respondent Rimfrost AS. Because the '905 patent and the '142 patent are not commonly owned, the '905 patent is unenforceable. Complainants knew or should have known the '905 patent was unenforceable when the Complaint in this Investigation was filed.

19. Complainants do not have standing to assert the '905 patent. Section 337 authorizes the U.S. International Trade Commission to act against "[t]he importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee of articles that— (i) infringe a valid and *enforceable* United States patent . . . ; or (ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and *enforceable* United States patent." 19 U.S.C. § 337(a)(1)(B) (emphasis added). Articles or activities alleged to infringe an unenforceable patent are not violations of § 337. Accordingly, the owner of an unenforceable patent does not have standing to seek relief from the Commission for alleged infringement of such a patent. Complainants lack standing to bring this action as to the '905 patent because that patent is not enforceable.

FOURTH AFFIRMATIVE DEFENSE
(Inequitable Conduct)

20. Respondents contend that all asserted claims of the asserted patents are unenforceable for inequitable conduct and Complainants' assertions of infringement are thus barred.

21. The asserted patents share a common specification and are all continuations of and claim priority to the same non-provisional application Aker filed on March 28, 2008: U.S. Patent Application No. 12/057,775. Complaint ¶¶ 40-45.

22. The original '775 application claims priority to four provisional patent applications filed between March 28, 2007 and January 28, 2008: No. 60/920,483 filed March 28, 2007; No. 60/975,058 filed September 25, 2007; No. 60/983,446, filed October 29, 2007; and No. 61/024,072 filed January 28, 2008. Complaint Ex. 1 at cover.

23. Each of the provisional applications is incorporated by reference into the common specification of the original '775 application. Ex. 1 to Complaint, '877 patent at 1:15; Ex. 3 to Complaint, '752 patent at 1:14-15; Ex. 4 to Complaint, '765 patent at 1:14-15; and Ex. 5 to Complaint, '453 patent at 1:15.

24. Each asserted patent is a continuation application from the original '775 application. Complaint Exs. 1 and 3-5.

25. The application that issued as the '765 patent was filed on September 6, 2013. Complaint Ex. 4 at cover.

26. The application that issued as the '453 patent was filed on September 6, 2013. Complaint Ex. 5 at cover.

27. The application that issued as the '877 patent was filed on September 18, 2014. Complaint Ex. 1 at cover.

28. The application that issued as the '752 patent was filed on December 12, 2015. Complaint Ex. 3 at cover.

29. Each of the applications that issued as the asserted patents was filed and prosecuted on behalf of Aker by patent attorney J. Mitchell Jones. Complaint Exs. 1 and 3-5;

Jones Tr. 14:1-15:22; AKBM0000076-1039 ('877 file history); AKBM00002513-6760 ('765 file history); AKBM0001040-1385 ('752 file history); and AKBM00006761-11403 ('453 file history).

IPR Declarations

30. In November 2013, attorney Jones, on behalf of Aker, filed a Petition for Inter Partes Review of U.S. Patent No. 8,383,675, which was assigned to Neptune Technologies & Bioressources, Inc (hereafter called, "Aker's Neptune IPR").

31. Attorney Jones was identified as lead counsel for Aker Biomarine AS in Aker's Neptune IPR. Jones Dep. Ex. 10; Jones Tr. 93:5-20.

32. In Aker's Neptune IPR, Aker noted that Neptune's '675 patent was the subject of a patent infringement lawsuit filed on March 1, 2012 in the United States District Court of Delaware (1:13-cv-00340-GMS) and International Trade Commission (ITC) Action, Investigation No. 337-TA-877.

33. In Aker's Neptune IPR, Aker sought cancellation of claim 1 of Neptune's '675 patent.

34. In conjunction with Aker's Neptune IPR, Jones submitted various declarations on behalf of Aker. AKBM00012934-41; AKBM00016127-65.

35. One declarant, Dr. Suzanne Budge, explained in a declaration dated October 14, 2013 that she obtained blocks of frozen krill and prepared sample krill oil extractions using the methods described in PCT Patent publication, WO 00/23546, ("Beaudoin I") and in its priority document Canadian Patent Application No. CA 2,251,265 ("Beaudoin II"). AKBM00012934-41.

36. In her declaration, Dr. Budge stated that after performing the extractions of krill oil according to the Beaudoin method, she sent the samples to various labs for testing. One of the labs was Avanti Polar Lipids. AKBM00012939-40.

37. In a declaration dated October 14, 2013, Dr. Jeff Moore stated that he was the Director of Analytical Technologies for Avanti Polar Lipids and provided a report including data reporting, among other things, total phospholipid content in the krill extracts he received from Dr. Budge. AKBM00016127-65.

38. The report of Dr. Moore included an analysis of "Total Phospholipid Content." AKBM00016139.

39. The data provided by Dr. Moore identified the level of ether phosphatidylcholine (ether PC) in the krill oil extract samples provided by Dr. Budge. AKBM00016139-44.

40. Ether PC is a type of ether phospholipid. Jones Tr. 109:20-110:2.

41. Four of the krill oil samples extracted by Dr. Budge by the Beaudoin method and tested by Dr. Moore had an ether PC level of greater than 3%. AKBM00016142-43.

42. Because those four samples had an ether PC level of greater than 3%, they had an ether phospholipid level of greater than 3%. Jones Tr. 109:11-110:2.

43. One of the samples extracted by Dr. Budge by the Beaudoin method and tested by Dr. Moore had an ether PC level of 4.91% with a standard deviation of 0.17. AKBM00016142.

44. The test results showing an ether PC level of 4.91% with a standard deviation of 0.17 would include an ether phospholipid level of greater than 5%. *Id.*; Jones Tr. 99:22-101:2.

45. The Budge and Moore declarations submitted by Jones show that kill oil extracted by the Beaudoin method contains ether phospholipids greater than 3%, greater than 4%, and greater than 5%. AKBM00003649-51. AKBM00012934-41; AKBM00016127-65.

46. Aker's Neptune IPR was terminated in January 2014 based on a settlement between Aker and Neptune.

Arguments Made During Prosecution of Applications Related to the Asserted Patents

47. During prosecution of applications related to the asserted patents, Aker, through attorney Jones, distinguished prior art Neptune krill oil, called NKO, from the claims.

48. Jones understood, and stated to the PTO, that the prior art NKO was prepared by the Beaudoin method. Jones Tr. 78:11-79:9.

'905 Patent Prosecution

49. During prosecution of the '905 patent, which was a continuation application from the original '775 application, the PTO Examiner rejected claims reciting a lower limit of 3% ether phospholipids as unpatentable over U.S. Patent No. 6,800,299 issued to Beaudoin et al. in view of U.S. Patent No. 7,488,503 issued to Porzio et al. AKBM00002251.

50. In responding to the PTO rejection, Jones stated that, "[t]he combined references do not teach encapsulated krill oil with from 3% to 15% ether phospholipids." AKBM00002254.

51. Jones stated that "U.S. Pat. No. 8,030,348 discloses that the Beaudoin method is used to make Neptune Krill Oil™" and that "[t]he Beaudoin process used to make Neptune Krill Oil™" is described in "PCT publication number WO 00/23546." AKBM00002251-52.

52. PCT publication number WO 00/23546 is the same PCT publication identified in the Budge declaration as disclosing the Beaudoin method. *See* AKBM00002252 and AKBM00012936-37.

53. Jones stated that "[t]he present Applicant analyzed Neptune Krill Oil™ for the presence of ether phospholipids. This data is disclosed in Example 8 and Table 22. The data for NKO (Neptune Krill Oil) shows that the phospholipid fraction of the Neptune Krill Oil contained

8.2% ether phospholipids (7.0% AAPC + 1.2% LAAPC). The Neptune Krill Oil analyzed contained 30% total phospholipids. To give the percent ether phospholipids in the Neptune Krill Oil as a whole, this 8.2% value for the ether phospholipids present in the phospholipid fraction of the krill oil is thus multiplied by 30% to give a percent total of 2.46% ether phospholipids in the Neptune Krill Oil." AKBM00002253.

54. Jones argued that "this demonstrates that kill oil made by the Beaudoin method does not contain the claimed range of 3% to 15% ether phospholipids as a percentage of the total krill oil composition." *Id.*

55. Based on this argument, Jones requested that the PTO's prior art "rejection be withdrawn and the claims passed to issue." *Id.*

56. Jones presented this argument to the PTO in December 2014, not long after he submitted the Budge and Moore declarations to the PTO in Aker's Neptune IPR in 2013. AKBM00002245-54; AKBM00012934-41; AKBM00016127-65.

57. Following Jones's December 2014 response, the PTO Examiner again rejected the claims as unpatentable over U.S. Patent No. 6,800,299 issued to Beaudoin et al. in view of U.S. Patent No. 7,488,503 issued to Porzio et al. AKBM00002353.

58. Jones responded, stating that, [a]s previously pointed out, Applicant analyzed Neptune Krill Oil™ for the presence of ether phospholipids. Neptune Krill Oil ™ contained 2.46% ether phospholipids as opposed to the presently claimed lower limit of 3.0%." *Id.*

59. In response to the PTO Examiner's statement that "[t]he amount of 2.46 percent of ether phospholipids contained in the Neptune Oil is very close to 3% ether phospholipid," Jones argued that "a person of skill in the art would not have sought to increase the ether phospholipid content of prior art krill oil" and that "Applicants obtained unexpected results

which demonstrate that the claims [sic, claimed] krill oil compositions with greater than 3% ether phospholipids have superior activity to the prior art krill oils with lower ether phospholipid levels." AKBM00002354.

60. Based on these arguments, Jones requested that the "rejection be withdrawn and the claims passed to allowance." AKBM00002354.

61. Jones filed an additional submission, stating that "one of skill in the art would not have expected that increasing the ether phospholipid content of krill oil would lead to increased health benefits." AKBM00002371.

62. Immediately after Jones's submissions, the PTO allowed claims reciting an ether phospholipid level with a lower limit of 3%. AKBM00002457.

'765 Patent Prosecution

63. In October 2015, in responding to a rejection over Sampalis US2004/0241249 during prosecution of application serial number 14/020,155, which was a continuation of the original '775 application, and which issued as the asserted '765 patent, Jones amended the claims to recite an ether phospholipid content of "greater than about 3%," and argued "that the claims as amended are distinguished over Sampalis, which discloses Neptune Krill Oil™." AKBM00006287-95.

64. Jones argued that "[a]s previously pointed out in the related cases which the Examiner has allowed, Applicant analyzed Neptune Krill Oil™ for the presence of ether phospholipids. Neptune Krill Oil™ contained 2.46% ether phospholipids as opposed to the presently claimed lower limit of 3.0%." AKBM00006294.

65. Jones argued there were "unexpected results which demonstrate that the claims [sic, claimed] krill oil compositions with greater than 3% ether phospholipids have superior activity to the prior art krill oils with lower ether phospholipid levels," pointing to Example 9's

comparison of "the claimed krill oils" to the prior art NKO as supporting the alleged unexpected results. AKBM0006294-95.

66. After Jones made those arguments, the PTO allowed the claims and the '765 patent issued. AKBM00006678.

Application Serial No. 15/180,439

67. Application serial number 15/180,439 is a continuation application from the '453 asserted patent. During prosecution of that application, Jones distinguished krill oil made by the Beaudoin method from claims reciting a lower limit of 3% ether phospholipids. CJ0008097-110.

68. An "Applicant-Initiated Interview Summary" reporting on an interview between the PTO Examiner and Jones on October 11, 2016, states that "the Beaudoin method for production of krill oil cannot be expected to produce krill oil containing the same range of ether phospholipids as a percentage of the total krill oil composition" and that "Applicants can show that the ether phospholipid content [of krill oil made by the Beaudoin method] is only 2.46% which is below the claimed range." CJ0008098.

69. The day after the October 11, 2016 applicant-initiated Examiner interview, Jones submitted a response. The pending claims all recited a lower limit of 3% ether phospholipids. CJ0008101-10 at 02-04.

70. Jones argued that the prior art rejection was improper because "[i]n particular, the combined referenced [sic, references] do not teach an encapsulated krill oil with from 3% to 15% ether phospholipids." CJ0008105.

71. Jones argued that "Sampalis (US 2004/0241249) is yet another application directed to the use of Neptune Krill Oil™, which Applicant has tested and shown to contain less than the claimed amounts of ether phospholipids as discussed in more detail below." Jones stated that the "method used to make the krill oil in Sampalis (US 2004/0241249) is virtually identical

to the method disclosed in Beaudoin (US6800299; PCT 00/23546)" which the Examiner relied on in rejecting the claims that issued as the related '905 patent. CJ0008106.

72. Jones argued that "krill oil made by the Beaudoin method used in Sampalis (US 2004/0241249) and Sampalis (US 8,030,348) does not contain the claimed range of 3% to 15% ether phospholipids as a percentage of the total krill oil composition." CJ0008109.

73. Following Jones's arguments, the claims were allowed, each of which recites a lower limit of 3% ether phospholipids.

Materiality

74. The data presented by Jones in the declarations he submitted with Aker's Neptune IPR show that krill oil made with the Beaudoin method had ether phospholipid levels of greater than 3%, greater than 4%, and greater than 5%. Jones's repeated arguments during prosecution of the applications related to the asserted patents that prior art NKO made with the Beaudoin method had an ether phospholipid level of less than 3% were thus false, misleading, and directly contradicted by the data he procured and submitted to the PTO for Aker's Neptune IPR.

75. Asserted claims 1-4, 7-9, 11-13, and 16-18 of the '877 patent (including asserted independent claims 1 and 11); asserted claims 1-5, 7, 25-29, and 31 of the '765 patent (including asserted independent claims 1 and 25); and asserted claims 1, 5-10, 12, 30-32, 33-36, and 39-43 of the '453 patent (including asserted independent claims 1 and 33) each recite a lower limit of ether phospholipids of 3% (hereafter called "Aker's 3% claims"). Complaint ¶ 6; Complaint Exs. 1, 4 and 5.

76. But for Jones's misleading and false arguments, which were directly contradicted by the data Jones presented in Aker's Neptune IPR, Aker's 3% claims would not have issued.

77. Asserted claims 9-12, 14, 15, 23, 33-36, 38, and 39 of the '765 patent; and asserted claims 14-17, 19, 20, 46-49, 51, and 52 of the '453 patent each recite a lower limit of ether phospholipid of 4% (hereafter called "Aker's 4% claims"). Complaint ¶ 6; Complaint Exs. 4 and 5.

78. But for Jones's misleading and false arguments, which were directly contradicted by the data Jones presented in Aker's Neptune IPR, Aker's 4% claims would not have issued.

79. Asserted claims 19-21, 43-45, and 47 of the '765 patent; claims 1, 7, and 11-13 of the '752 patent (including asserted independent claim 1); and claims 24-26, 28, 56-58, and 60 of the '453 patent each recite a lower limit of ether phospholipid of 5% (hereafter called "Aker's 5% claims"). Complaint ¶ 6; Complaint Exs. 3, 4 and 5.

80. But for Jones's misleading and false arguments, which were directly contradicted by the data Jones presented in Aker's Neptune IPR, Aker's 5% claims would not have issued.

81. In an attempt to invalidate another competitor's patent, Aker, through Jones, obtained declarations in 2013 showing that krill oil extracted by the Beaudoin method had ether phospholipid levels of greater than 3%, greater that 4%, and greater than 5%. Despite those declarations, Jones repeatedly argued to the PTO between 2014 and 2016 that prior art NKO made by the Beaudoin method had an ether phospholipid level of 2.46%, less than 3%.

82. The arguments that Jones repeatedly made to secure allowance of Aker's 3% claims, Aker's 4% claims and Aker's 5% claims were directly contradicted by the declarations and data that Jones submitted to the PTO in Aker's Neptune IPR.

83. The arguments that Jones made to the PTO to distinguish prior art NKO made by the Beaudoin method were material to the patentability of all asserted claims of all asserted

patents, which recite a lower limit of one of 3%, 4%, or 5% ether phospholipid. Complaint ¶ 6; Complaint Exs. 1 and 3-5.

84. The arguments that Jones made to the PTO to secure allowance of claims with a low end level of ether phospholipids of 3%, 4%, and 5% were misleading and wrong.

85. The arguments that Jones made to the PTO to secure allowance of claims with a low end level of ether phospholipids of 3%, 4%, and 5% were critical to the PTO allowing those claims.

86. But for Jones's misleading and incorrect arguments to the PTO, the PTO would not have allowed Aker's 3% claims, Aker's 4% claims, or Aker's 5% claims.

Intent

87. Jones's misconduct resulted in the unfair benefit of Aker receiving unwarranted claims reciting ether phospholipid levels with lower limits of 3%, 4%, and 5%.

88. Jones recognized his duty of good faith and candor to the PTO. Jones Tr. 151:6-152:9.

89. Jones testified that he is involved in this litigation, Jones Tr. 44:17-45:2, and the testing data that Aker relied on in its Complaint to allege infringement and domestic industry was sent to him. Complaint Exs. 30 and 38; Jones Tr. 48:13-49:7.

90. Jones is, therefore, not just prosecution counsel; he is interested in and aware of the proof Aker needs in this litigation and was instrumental in procuring the patent claims Aker is now asserting in this Investigation.

91. In arguing the invalidity of a patent claim of Aker's competitor Neptune, Jones knew that he submitted declarations on behalf of Aker in Aker's Neptune's IPR, showing that the

Beaudoin method resulted in krill oil with an ether phospholipid content of greater than 3%, greater than 4%, and greater than 5%.

92. When asked at his deposition, attorney Jones had no reasonable explanation for repeatedly arguing during prosecution of applications related to the asserted patents that prior art NKO made by the Beaudoin method had an ether phospholipid level of 2.46% when the declarations he procured and submitted in Aker's Neptune IPR showed that krill oil made by the Beaudoin method had ether phospholipid levels of greater than 3%, greater than 4%, and greater 5%. Jones Tr. 101:20-103:2; Jones Tr. 105:9-14.

93. The best explanation Jones offered at his deposition was that "knowing precisely what is in everything being able to categorize that in your mind is somewhat difficult." Jones Tr. 184:7-186:21.

94. Jones's explanation is not reasonable.

95. Jones's duty of candor and good faith required him to know what was in the IPR declarations and data he submitted to the PTO in 2013 on behalf of Aker when Aker was seeking to invalidate a patent claim of its competitor Neptune, when he presented arguments to the PTO in 2014-2016 for the patentability of Aker's claims directly contradicted by those declarations.

96. Jones's duty of candor and good faith required him to tell the PTO that data he procured and submitted in another PTO proceeding directly contradicted the only arguments he presented for patentability during prosecution of applications related to the asserted patents.

97. Jones's submission of the IPR declarations to the PTO during prosecution of the asserted patents (and his reliance on that submission) does not negate and cannot explain away his intent to deceive the PTO. Jones Tr. 185:5-21. Nor does his self-serving testimony elicited by Aker's counsel that he had no intent to deceive. Jones Tr. 188:22-190:08.

98. As attorney Jones conceded, he submitted the IPR declarations and data with hundreds of other pieces of information listed on the faces of the asserted patents. Jones Tr. 186:2-8; Complaint Exs. 1 and 3-5 (listing over 300 pieces of information).

99. Jones submitted the IPR declarations and data during prosecution of the asserted patents with no explanation to the PTO that the information in the IPR declarations and data directly contradicted his arguments for patentability.

100. The single most reasonable inference to be drawn is that Jones specifically intended to deceive the PTO by not telling the PTO that the data and declarations he procured and submitted on behalf of Aker in Aker's Neptune IPR directly contradicted arguments he made to the PTO to secure allowance of all asserted claims of the asserted patents.

101. Based on Jones's material misconduct with respect to the IPR declarations and data, all asserted claims of the asserted patents are unenforceable for inequitable conduct.

Table 17

102. On March 28, 2007, Jones, filed the earliest of the provisional patent applications. CJ0008685-731.

103. Table 16 of the March 2007 provisional application was titled "Compositional data for the novel krill oil composition and the closest prior art krill oil." CJ0008720.

104. The "closest prior art krill oil" in Table 16 is referred to as "Neptune KO" and was also known as NKO. CJ0008720; Jones Tr. 64:3-16.

105. Table 17 of the March 2007 provisional application was titled "Lipid class distribution of the different krill oil materials" and shows a percentage lipid class distribution for various oils, including the same prior art "Neptune KO" referred to in Table 16 CJ0008720.

106. Table 17 was also included in the provisional applications filed in September 2007, CJ0027149-208 at 182, and January 2008. CJ0008732-815 at 767.

107. Table 17 of the provisional applications reports that prior art NKO has a total phospholipid level of 42.96%. CJ0008720; Jones Tr. 67:15-68:17 (combining values for PC, PS, PE and PI).

108. Table 22 of the asserted patents report the total phospholipid level of the prior art NKO as 30%. Complaint, Ex. 4 at 32:17-39; Jones Tr. 50:18-51:1, 68:18-20.

109. Table 22 of the asserted patents reports that the prior art NKO contains 8.2% ether phospholipids in its phospholipid fraction (Jones Tr. 138:6-10), thus containing 2.46% ether phospholipids overall (8.2 x .30 = 2.46%). Complaint, Ex. 4 at 32:17-39.

110. Assuming that the percentage of ether phospholipids in the phospholipid fraction in the prior art NKO in Table 17 of the provisional applications is the same as the percentage of ether phospholipids in the phospholipid fraction in the prior art NKO in Table 22 of the asserted patents, the prior art NKO in Table 17 contained 3.52% ether phospholipids (8.2 x .4296 = 3.52%).

111. Aker's 3% claims all recite an ether phospholipid content with a low end of 3%.

112. Based on the percentage of ether phospholipids in the phospholipid fraction in the prior art NKO in Table 22, the prior art NKO reported in Table 17 of the provisional applications had an ether phospholipid amount of 3.52%, which is within the claimed range in each of Aker's 3% claims.

Materiality

113. Jones had to have been aware that the prior art "Neptune KO" reported in Table 17 of the provisional applications had a higher level of total phospholipids than reported for the

same prior art NKO in Table 22 of the asserted patents because he filed the provisional applications on behalf of Aker.

114. As detailed above, attorney Jones made arguments to the PTO that the prior art NKO reported in Table 22 of the asserted patents had a total ether phospholipid content of 2.46%.

115. The higher level of total phospholipid in the prior art NKO reported in Table 17 called into question the arguments Jones made distinguishing the prior art NKO from the claims with a low end level of ether phospholipids of 3%.

116. Jones must have been aware that based on the percentage of ether phospholipids in the phospholipid fraction in the prior art NKO in Table 22, the prior art NKO reported in Table 17 of the provisional applications would have an ether phospholipid amount of 3.52%.

117. The existence of prior art NKO with an ether phospholipid amount greater than 3% contradicted Jones's repeated arguments that the prior art NKO had a total ether phospholipid level less than 3%.

118. The data in Table 17 was material to the arguments Jones made in distinguishing the prior art NKO from the claims and to the PTO's decision to allow Aker's 3% claims.

119. Jones's repeated arguments distinguishing the prior art NKO from claims reciting a lower limit of 3% ether phospholipids were inconsistent with Table 17, which when read in conjunction with Table 22, discloses that the prior art NKO had an ether phospholipid level of 3.52%. Nevertheless, Aker and its attorney Jones did not include Table 17 in the common specification of the original '775 application filed in March 2008. In addition, Jones did not tell the PTO that considering Table 17 and Table 22 together showed that the prior art NKO had an ether phospholipid level greater than 3%.

120. Based on attorney Jones' representations regarding the ether phospholipid level of the prior art NKO as below 3% and his failure to advise the PTO that Table 17 in conjunction with Table 22 showed that prior art NKO had an ether phospholipid level greater than 3%, the PTO issued Aker's 3% claims.

121. But for Jones's failure to advise the PTO that Table 17 was inconsistent with the arguments Jones made to distinguish the prior art NKO from claims reciting a low end limit of 3% ether phospholipid, Aker's 3% claims would not have issued.

Intent

122. Jones intended that the PTO accept his repeated arguments that the prior art NKO had less than 3% ether phospholipids. Jones excluded Table 17 from the original '775 application and failed to tell the PTO that Table 17 in conjunction with Table 22 contradicted arguments he made to have claims with a 3% lower limit of ether phospholipids allowed.

123. Jones recognized his duty of good faith and candor to the PTO. Jones Tr. 151:5-152:9.

124. Jones testified that he is involved in this litigation, Jones Tr. 44:17-45:2, and the testing data that Aker relied on in its Complaint to allege infringement and domestic industry was sent to him. Complaint Exs. 30 and 38. Jones Tr. 48:13-49:7

125. Jones, therefore, is not just prosecution counsel; he is interested in and aware of the proof Aker needs in this litigation and was instrumental in procuring the patent claims Aker is now asserting in this Investigation.

126. Table 22 of the asserted patents report the total phospholipid level of the prior art NKO as 30%. Complaint, Ex. 4 at 32:17-39; Jones Tr. 50:18-51:1, 68:18-20.

127. Jones was aware that the prior art "Neptune KO" reported in Table 17 of the provisional applications had a much higher level of total phospholipids (over 40%) than reported for the same prior art NKO in Table 22 of the asserted patents (30%).

128. Jones did not include the data for prior art NKO from Table 17 in the March 2008 original '775 application. Jones Tr. 68:18-69:4.

129. Jones did not bring to the PTO's attention the fact that there was testing data showing NKO with over 40% total phospholipid content. Jones Tr. 71:3-72:18.

130. The existence of the commercially available krill oil NKO with a total phospholipid content greater than 30% contradicted Jones's arguments to the PTO that the prior art NKO had a total phospholipid content of 30%.

131. In addition, it would be reasonable to assume that NKO with a higher total phospholipid content over 40% would have had a higher ether phospholipid content than that reported on in Table 22 and relied on by Jones when distinguishing the prior art.

132. But for Jones's failure to advise the PTO that Table 17 was inconsistent with the arguments Jones made to distinguish the prior art NKO from claims reciting a lower limit of 3% ether phospholipids, Aker's 3% claims would not have issued.

133. Jones testified that he did not consider the data in Table 17. Jones Tr. 71:3-13.

134. When asked at his deposition, Jones had no reasonable explanation for failing to tell the PTO about the data in Table 17 and its impact on the arguments he made to secure allowance of Aker's 3% claims. Jones Tr. 182:10-184:6.

135. The best explanation Jones offered at his deposition was that "to try to, you know, match something that, you know, that gapped -- what you're asking me about responses that we made in 2014, the time frame compared to something that was in a provisional application in

2007, you know, I don't know that, you know, you can quite be charged with -- you know, in other words, yeah." Jones Tr. 183:18-184:2.

136. Jones's explanation is not reasonable.

137. Jones's duty of candor and good faith required him to know what was in Table 17 of the provisional applications he submitted to the PTO when he made arguments to the PTO supporting the patentability of Aker's 3% claims that were contradicted by the data in Table 17.

138. Jones's submission of Table 17 in the provisional applications and its incorporation by reference into the asserted patents does not negate and cannot explain away his intent to deceive the PTO. Jones Tr. 183:4-184:6. Nor does his self-serving testimony elicited by Aker's counsel that he had no intent to deceive. Jones Tr. 188:22-190:8.

139. Jones concealed the data in Table 17 and failed to provide an explanation of it to the PTO Examiner because it directly contradicted his arguments for patentability.

140. The single most reasonable inference to be drawn is that Jones specifically intended to deceive the PTO by not telling the PTO that Table 17 directly contradicted arguments he made to secure allowance of Aker's 3% claims.

141. Based on Jones's material misconduct with respect to Table 17, Aker's 3% claims are unenforceable for inequitable conduct.

Nutrizeal/IRL

August 2007 Reports

142. In August 2007, Nutrizeal Limited and Industrial Research Limited (IRL) prepared reports regarding work they were doing for Aker on extracting krill oil. Those reports were in the files of attorney Jones. CJ0048490-531; Jones Tr. 178:14-179:14. Attorney Jones

was thus aware of the work of Nutrizeal and IRL reflected in the August 2007 IRL/Nutrizeal Reports.

September 2007 Technical Services Agreement

143. Aker entered into a Technical Services Agreement with Nutrizeal in September 2007, titled "Agreement for a Second Phase in the Development of Processes for the Extraction of Oil Fractions from Aker Krill Powder," hereafter called the September 2007 Technical Services Agreement. CJ0048619-29.

144. The September 2007 Technical Services Agreement was in the files of attorney Jones. Jones Tr. 141:1-11. Jones was thus aware of the work of Nutrizeal and IRL reflected in the September 2007 Technical Services Agreement.

145. The September 2007 Technical Services Agreement describes earlier activities between May and July 2007, stating that Aker used the technical services of Nutrizeal and IRL for a "programme of work" "to investigate methods of processing krill meal with supercritical fluid extraction," and "the laboratory and pilot plant work involved in this project." CJ0048619-29, at 20 and 27.

146. The September 2007 Technical Services Agreement describes the earlier activities: "IRL's research for Nutrizeal/Aker Biomarine in Project 35012508 'Extraction of Krill Lipids using Supercritical CO_2 + Ethanol' established that a two stage extraction process using firstly CO_2 + 5% ethanol and then 20+% ethanol resulted in four fractions that go some way towards meeting the initially articulated requirement for the range of products that Aker are desiring." CJ0048619-29 at 21.

147. Through the September 2007 Technical Services Agreement, Aker further retained Nutrizeal and IRL for a second phase of work with the objective of "[s]pecify[ing]

analytical methods for the analysis of krill oil based on established methods and the learning from the previous development program" and "[d]evelop[ing] and optimiz[ing] an extraction and blending protocol with the aim of producing a human grade krill oil product according to the product specification attached [to] this agreement." CJ0048619-629 at 20.

148. The September 2007 Technical Services Agreement describes the work to be performed as: "[q]uantification of polar ether lipids in the Aker krill oil product and in Neptune krill oil. A sample of the Neptune product will be provided by Aker Biomarine." CJ0048621. It calls for preparation of another report "which contains detailed description of all analytical method used and the quantification of the polar ether lipids to Aker Biomarine" and calls for technology development to be carried out by IRL and Nutrizeal in IRL's own laboratories in Wellington, New Zealand. CJ0048621-22.

149. The September 2007 Technical Services Agreement states that: "[q]uantification of polar ether lipids" work "will be carried out in part using some new IP [intellectual property] IRL has under development for the separation of polar ether phospholipids from other phospholipids. IRL is in the process of filing a provisional patent on this separation process, and so a condition of performing the work will be that IRL does not describe the process until a PCT has been published, and that IRL retains the IP rights to this process." *Id.*

150. The September 2007 Technical Services Agreement provides payment terms from Aker to Nutrizeal, CJ0048623, and states that "Nutrizeal/IRL will attempt to achieve the Aker Biomarine specifications for the products to be manufactured as per the supplied specification document 'Superba 090707.doc'." CJ0048619-629 at 23.

151. Section 7.3 of the September 2007 Technical Services Agreement provided that improvements to previously existing IP rights that relate to IRL's or Nutrizeal's tools of trade do not transfer from Nutrizeal or IRL, to Aker. CJ0048627.

152. The September 2007 Technical Services Agreement thus indicates that Nutrizeal and IRL were intimately involved in developing krill oil processes and testing methodologies for Aker at around the same time that Jones was filing Aker's provisional patent applications. CJ0048619-29; Complaint Ex. 1 at cover (provisional applications filed between March 2007 and January 2008).

153. The September 2007 Technical Services Agreement also indicates that IRL may have had IP rights to its development work. CJ0048621-22 and 27.

The December 2007 Report and Testing Difficulties

154. IRL provided a progress report to Aker in December 2007. The December 2007 IRL report was in the files of Aker's attorney Jones. CJ0048552-569. Attorney Jones reviewed the December 2007 IRL report for his deposition. Jones Tr. 162:1-11.

155. The December 2007 IRL report included statements about uncertainties in identifying polar ether lipids via NMR. In particular, the December 2007 Report states that it is difficult to resolve glycerophosphatidylcholine (GPC) from alkylacylphosphatidylcholine (AAPE), and in some cases AAPE has been identified as GPC "by around 1-2 % by mass[.]" CJ0048552-569, at 55.

156. When Jones filed the January 2008 provisional application, he copied IRL's language from the December 2007 IRL report into Example 14. Jones was thus aware of IRL's statements about the unreliability of measuring krill generally, and even made spelling and punctuation changes to it. Jones then removed these statements when he filed the original '775

application two months later in March 2008, which omission carried through to the asserted patents. CJ0048552-569 at 55; CJ0008732-815 at 776; Complaint Ex. 1 at col. 32:9-43.

157. The statements in the December 2007 IRL report are material to patentability because they suggest that prior art phospholipid profiles could reflect misidentification of AAPE and GPC and thus have a higher amount of ether phospholipids. The uncertainties expressed by IRL to Aker in December 2007, which were copied and edited by Jones in January 2008, who then removed them from the March 2008 parent application, would have demonstrated to the PTO underreporting of the percentage of ether phospholipids in the prior art as well as uncertainty in the mechanism of such reporting. Jones Tr. at 168:1-19 (recognizing possible historical underreporting of ether phospholipids by 1-2%).

158. Given the centrality of the particular percentage of ether phospholipids in the asserted claims to gaining issuance of the asserted patents, as detailed above, Jones would have known that the uncertainty reported by IRL was material to patentability of the asserted claims. The suppression of this material information, at the same time Aker and attorney Jones incorporated so much other information verbatim from the same December 2007 IRL report, evidences the specific intention of Jones to deceive the PTO.

159. On January 28, 2008, Jones filed U.S. provisional patent application No. 61/024,072. CJ0008732-815 at 809.

160. The January 2008 provisional application reproduced large portions of the December 2007 IRL report, including numerous figures and examples, such as Examples 14 and 15. Table 2 of the December 2007 IRL report is identical to Table 23 of the January 2008 provisional application. Table 22 from the asserted patent contains information from Table 2 of the December 2007 IRL report. CJ008732-815; CJ0048552-569; Complaint Ex. 1 at Table 22.

161. Jones was aware of the involvement of and contribution from IRL and Nutrizeal to the development of the subject matter disclosed in the asserted patents when he filed the January 2008 provisional application and when he filed the original '775 application in March 2008. Jones was aware of the December 2007 IRL report because it was in his files and it is reasonable to assume that he used it to draft the January 2008 provisional application and the March 2008 original '775 application.

162. The January 2008 provisional application identifies Nutrizeal and its employee Andy Herbert. CJ0008732-815 at 779:18 and 780:17. Jones removed reference to Nutrizeal and Andy Herbert from the original '775 application in March 2008.

Materiality

163. Jones filed the January 2008 provisional application and the March 2008 non-provisional application but never advised the PTO of (1) the substantial involvement of Nutrizeal and IRL in developing the extraction processes and test methodologies described in the asserted patents; (2) the fact that Nutrizeal and IRL optimized the superfluid extraction process to develop krill oil described in the asserted patents; (3) the fact that Nutrizeal had "detected ether linked omega-3 phospholipids" that were used to distinguish the claims of the asserted patents from the prior art; (4) the substantial involvement of Nutrizeal and IRL in analyzing the resulting krill oil and the prior art Neptune krill oil reported in Table 2 of the December 2007 IRL report, Table 23 of the January 2008 provisional patent application, and Table 22 of the asserted patents; (5) IRL's pre-existing intellectual property rights to the extraction processing described and claimed in the asserted patents; (6) IRL's rights to additional intellectual property rights; and (7) testing uncertainties in identifying polar ether lipids via NMR. AKBM00143799-800; AKBM00091057-58; CJ0048621-22; CJ0048627.

164. Jones's actions lead to the issuance of the asserted patents without the PTO: (1) questioning inventorship of the asserted patents; (2) questioning whether the processes and products that Aker now asserts as its own were actually derived from the work of others, namely Nutrizeal and IRL; (3) questioning whether IRL's IP rights affected Aker's claims; or (4) questioning whether uncertainties in identifying polar ether lipids via NMR impacted any prior art analysis.

165. But for Jones's intentionally concealing material information relating to the substantial involvement of Nutrizeal and IRL and the information in the reports provided to Jones, none of the asserted claims of any of the asserted patents would have issued to Aker.

Intent

166. Jones intended that the PTO accept that the work identified in the asserted patents was Aker's and not question whether it was the work of Nutrizeal or IRL.

167. Jones recognized his duty of good faith and candor to the PTO. Jones Tr. 151:6-152:9.

168. Jones testified that he is involved in this litigation, Jones Tr. 44:17-45:2. Jones, therefore, is not just prosecution counsel; he is aware of the particular interest Aker has in maintaining the ownership of and the ability to enforce the asserted patents.

169. Jones testified that he did not consider whether IRL had IP rights to any of the technology it developed when working with Aker. Jones Tr. 156:22-157:15.

170. Jones had no reasonable explanation for failing to tell the PTO the about the involvement of Nutrizeal and IRL. He testified that he didn't know if he ever considered it. Jones Tr. 157:12-15.

171. Jones testified that the testing inconsistencies with respect to GPC and reporting lower phospholipid levels would not be relevant. Jones Tr. 171:3-20.

172. Jones's explanations are not reasonable.

173. Jones's duty of candor and good faith required him to advise the PTO what other entities were developing the methods and products disclosed and claimed in Aker's patent applications, whether they had IP interests in that work, and whether there were previous testing irregularities that would implicate the prior art.

174. Jones' suppression of information about and from Nutrizeal and IRL, including the August 2007 IRL/Nutrizeal Reports, the September 2007 Technical Services Agreement, and the December 2007 IRL report demonstrates his specific intent to deceive the PTO.

175. Jones's self-serving testimony elicited by Aker's counsel that he had no intent to deceive does not negate and cannot explain away his intent to deceive. Jones Tr. 188:22-190:8.

176. The single most reasonable inference to be drawn is that Jones specifically intended to deceive the PTO by not telling the PTO that Nutrizeal and IRL were substantially involved in the development of the work in the asserted patents because that would have risked Aker's ownership rights in the patents.

177. Based on Jones's material misconduct conduct in failing to disclose information about Nutrizeal and IRL to the PTO, including the August 2007 IRL/Nutrizeal Reports, the September 2007 Technical Services Agreement, and the December 2007 IRL report, all asserted claims of all asserted patents are unenforceable for inequitable conduct.

178. But for the intentional misconduct by Jones, none of the asserted claims of any of the asserted patents would have issued to Aker. As a result, the asserted patents are unenforceable for inequitable conduct.

FIFTH AFFIRMATIVE DEFENSE
(Lack of Domestic Industry)

179. No protectable industry exists or is being established in the United States as defined under Section 337 with respect to any valid and enforceable claim of any of the asserted patents.

SIXTH AFFIRMATIVE DEFENSE
(Patent Misuse)

180. Complainants have committed patent misuse by asserting patents they know or reasonably should have known are unenforceable.

SEVENTH AFFIRMATIVE DEFENSE
(No Importation)

181. Complainants do not sell and have not sold for importation into the United States, imported into the United States, or sold after importation into the United States any article or use any process that infringes a valid and enforceable asserted claim of any of the asserted patents.

EIGHTH AFFIRMATIVE DEFENSE
(No Jurisdiction to Issue Remedy)

182. The Commission lacks statutory authority to issue a remedy as to the Accused Products because they do not contain at least one element of a valid and enforceable asserted claim at the time of any sale for importation, importation, or sale after importation.

Date: March 14, 2017

Respectfully submitted,

/s/ Doris Johnson Hines

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CERTAIN KRILL OIL PRODUCTS AND KRILL MEAL FOR PRODUCTION OF KRILL OIL PRODUCTS **Inv. No. 337-TA-1019**

CERTIFICATE OF SERVICE

I, Jeremy Miller, hereby certify that on March 14, 2017, copies of the foregoing were filed with and served upon the following as indicated:

The Honorable Lisa R. Barton Secretary, Office of the Secretary U.S. INTERNATIONAL TRADE COMMISSION 500 E Street, S.W., Room 112-F Washington, DC 20436 (202) 205-2000	☐ Via First Class Mail ☐ Via Courier (FedEx) ☐ Via Hand Delivery ☐ Via Email (PDF File) ☒ Via EDIS
The Honorable Dee Lord Administrative Law Judge U.S. INTERNATIONAL TRADE COMMISSION 500 E Street, S.W., Room 317 Washington, DC 20436 edward.jou@usitc.gov	☐ Via First Class Mail ☒ Via Courier (FedEx) ☐ Via Hand Delivery ☒ Via Email (PDF File)
COUNSEL FOR COMPLAINANTS AKER BIOMARINE ANTARCTIC AS and AKER BIOMARINE MANUFACTURING, LLC Andrew F. Pratt VENABLE LLP 575 Seventh Street NW Washington, DC 20004 Aker-1019@venable.com	☐ Via First Class Mail ☐ Via Courier (FedEx) ☐ Via Hand Delivery ☒ Via Email (PDF File)

/s/ Jeremy Miller
Jeremy Miller, Legal Assistant

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

72960 7590 12/22/2016
Casimir Jones, S.C.
2275 DEMING WAY, SUITE 310
MIDDLETON, WI 53562

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(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/180,439	06/13/2016	Inge Bruheim	AKBM-14409/US-13/CON	4687

TITLE OF INVENTION: BIOEFFECTIVE KRILL OIL COMPOSITIONS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$960	$0	$0	$960	03/22/2017

EXAMINER	ART UNIT	CLASS-SUBCLASS
WARE, DEBORAH K	1651	424-520000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Casimir Jones, S.C.
2
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: AKER BIOMARINE ANTARCTIC AS

(B) RESIDENCE: (CITY and STATE OR COUNTRY): Stamsund, Norway

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:
- ☒ Issue Fee
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- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
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- ☐ Applicant asserting small entity status. See 37 CFR 1.27
  NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
- ☐ Applicant changing to regular undiscounted fee status.
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NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature /J. Mitchell Jones/ Date March 21, 2017

Typed or printed name J. Mitchell Jones Registration No. 44,174

Electronic Patent Application Fee Transmittal

Application Number:	15180439
Filing Date:	13-Jun-2016
Title of Invention:	BIOEFFECTIVE KRILL OIL COMPOSITIONS
First Named Inventor/Applicant Name:	Inge Bruheim
Filer:	John Mitchell Jones
Attorney Docket Number:	AKBM-14409/US-13/CON

Filed as Large Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
UTILITY APPL ISSUE FEE	1501	1	960	960

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**960**

Electronic Acknowledgement Receipt

EFS ID:	28689120
Application Number:	15180439
International Application Number:	
Confirmation Number:	4687
Title of Invention:	BIOEFFECTIVE KRILL OIL COMPOSITIONS
First Named Inventor/Applicant Name:	Inge Bruheim
Customer Number:	72960
Filer:	John Mitchell Jones/Mallory Checkett
Filer Authorized By:	John Mitchell Jones
Attorney Docket Number:	AKBM-14409/US-13/CON
Receipt Date:	21-MAR-2017
Filing Date:	13-JUN-2016
Time Stamp:	12:44:50
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	DA
Payment was successfully received in RAM	$960
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Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30484 cb5f739bace1a4d3144d1513644c583dff2e820b	no	2
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National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/180,439	06/13/2016	Inge Bruheim	AKBM-14409/US-13/CON	4687

7590 03/23/2017

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EXAMINER	
WARE, DEBORAH K	

ART UNIT	PAPER NUMBER
1651	

NOTIFICATION DATE	DELIVERY MODE
03/23/2017	ELECTRONIC

NOTICE OF NON-COMPLIANT INFORMATION DISCLOSURE STATEMENT

An Information Disclosure Statement (IDS) filed 3/17/2017 in the above-identified application fails to meet the requirements of 37 CFR 1.97(d) for the reason(s) specified below. Accordingly, the IDS will be placed in the file, but the information referred to therein has not been considered.

The IDS is not compliant with 37 CFR 1.97(d) because:

☒ The IDS lacks a statement as specified in 37 CFR 1.97(e).

☐ The IDS lacks the fee set forth in 37 CFR 1.17(p).

☐ The IDS was filed after the issue fee was paid. Applicant may wish to consider filing a petition to withdraw the application from issue under 37 CFR 1.313(c) to have the IDS considered. See MPEP 1308.

/[illegible]/

571-272-4200 or 1-888-786-0101
Application Assistance Unit
Office of Data Management

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	
Filing Date	2016-06-13
First Named Inventor	Inge Bruheim
Art Unit	
Examiner Name	
Attorney Docket Number	AKBM-14409/US-13/CON

	11	20140107072		2014-04-17	Snorre Tilseth et al.	
	12	20090061067		2009-03-05	Snorre Tilseth et al.	
Change(s) applied to document, /SXS/ 12/30/2016	13	20140010888		2014-01-09	Bruheim, et al. ~~AKER BIOMARINE ANTARCTIC~~ AS	

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	1	Takahashi et al., Prediction of Relative Retention Value of the Individual Molecular Species of Diacyl Glycerolipid on High Performance Liquid Chromatography, Bull. Fac. Fish. Hokkaido Univ. 38(4), 398-404. 1987	
	2	Tanaka, Biosynthesis of 1,2-dieicosapentaenoyl-sn-glycero-3-phosphocholine in Caenorhabditis elegans, Eur. J. Biochem. 263, 189±194 (1999)	
	3	Tocher, Chapter 6, Glycerophospholipid metabolism, Biochemistry and molecular biology of fishes, vol. 4, Hochachka and Mommsen (eds.)(1995)	

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	
Filing Date	2016-06-13
First Named Inventor	Inge Bruheim
Art Unit	
Examiner Name	
Attorney Docket Number	AKBM-14409/US-13/CON

Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
Change(s) applied to document, /S.X.S./ 12/30/2016	1	20140274968		2014-09-18	Berge, et al. ~~AKER BIOMARINE ANTARCTIC AS~~	
	2	20150030718		2015-01-29	Saebo ~~AKER BIOMARINE ANTARCTIC AS~~	
	3	20140088043		2014-03-27	Hoem, et al. ~~AKER BIOMARINE ANTARCTIC AS~~	
	4	20140088047		2014-03-27	Hoem, et al. ~~AKER BIOMARINE ANTARCTIC AS~~	
	5	20140080791		2014-03-20	Berge, et al. ~~AKER BIOMARINE ANTARCTIC AS~~	
	6	20150164841		2015-06-18	Hoem, et al. ~~AKER BIOMARINE ANTARCTIC AS~~	
	7	20140363517		2014-12-11	Bruheim, et al. ~~AKER BIOMARINE ANTARCTIC AS~~	
	8	20100226977		2010-09-09	Snorre Tilseth et al.	
	9	20150050403		2015-02-19	Tilseth, et al. ~~AKER BIOMARINE ANTARCTIC AS~~	
	10	20140005421		2014-01-02	Bruheim, et al. ~~AKER BIOMARINE ANTARCTIC AS~~	

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (03-15)
Approved for use through 07/31/2016. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	
Filing Date	2016-06-13
First Named Inventor	Inge Bruheim
Art Unit	
Examiner Name	
Attorney Docket Number	AKBM-14409/US-13/CON

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
Change(s) applied to document, /S.X.S./ 12/30/2016	1	9119864		2015-09-01	Bruheim, et al. ~~AKER BIOMARINE ANTARCTIC AS~~	
	2	9072752		2015-07-07	Bruheim, et al. ~~AKER BIOMARINE ANTARCTIC AS~~	
	3	9034388		2015-05-19	Inge Bruheim et al.	
	4	9028877		2015-05-12	Bruheim, et al. ~~AKER BIOMARINE ANTARCTIC AS~~	
	5	9078905		2015-07-14	Bruheim, et al. ~~AKER BIOMARINE ANTARCTIC AS~~	
	6	8372812		2013-02-12	Snorre Tilseth et al.	
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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/180,439	05/09/2017	9644170	AKBM-14409/US-13/CON	4687

72960 7590 04/19/2017

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ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

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