

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RIMFROST AS

Petitioner

v.

AKER BIOMARINE ANTARCTIC AS

Patent Owner

Case: PGR2018-00033

U.S. Patent No. 9,644,170 B2

DECLARATION OF DR STEPHEN J. TALLON

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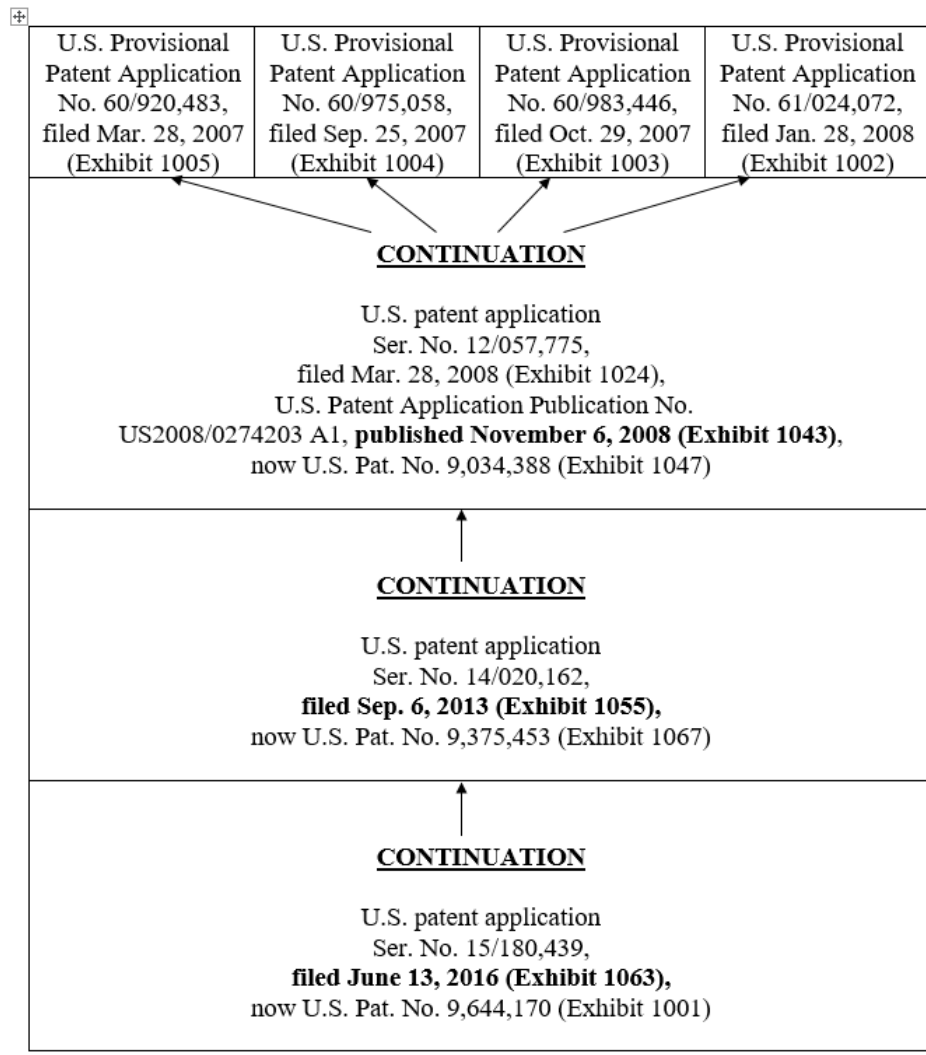
I, Dr Stephen J. Tallon, do hereby make the following declaration:

AGREEMENT TO PROVIDE EXPERT TESTIMONY

1. I have agreed to provide expert testimony in support of Rimfrost AS's Petition for Post Grant Review of U.S. Patent No. 9,644,170 B2. My *Curriculum Vitae* is attached hereto as Appendix D.
2. I understand that this proceeding involves U.S. Patent No. 9,644,170 B2 ("the '170 Patent") entitled "Bioeffective Krill Oil Compositions," (Exhibit 1001).
3. I also understand that the '170 Patent states that it is a continuation of application of No. 14/020,162, now U.S. Patent No. 9,375,453 ("the '453 Patent", Exhibit 1067) , which is a continuation application of No. 12/057,755, now U.S. Patent No. 9,034,388 B2 ("the '388 Patent", Exhibit 1047), which claims the benefit of US Provisional Application No. 60/920,483, filed on March 28, 2007 ("the '483 Provisional Application", Exhibit 1005), US Provisional Application No. 60/975,058, filed on September 25, 2007 ("the '058 Provisional Application", Exhibit 1004), US Provisional Application No. 60/983,446, filed on October 29, 2007 ("the '446 Provisional Application", Exhibit 1003), and US Provisional Application No. 61/024,072, filed on January 28, 2008 ("the '072 Provisional Application", Exhibit 1002).

The '170 Patent Family Chart

4. As I understand it, the chain of applications forming the '170 family history is provided in the chart below (arrows show claims for priority). See also '170 Patent, 1:7-17, for priority claims.



5. I was asked to review and did review the chain of applications referred to in the '170 Patent ('170 Patent, 1:7-17) for disclosures relating to krill oil compositions containing (a) 3% to 10% and 3% to 15% ether phospholipid w/w krill oil, (b) astaxanthin esters greater than about 100 mg/kg [0.01% w/w] krill oil, and (c) TMA in amounts less than 1 mg/kg krill oil. In my opinion, as discussed below, none of the Provisional Applications, Exhibits 1002-1005, the '388 Patent (Exhibit 1047), the '388 File History (Exhibit 1024), the '453 Patent (Exhibit 1067), the '453 file history (Exhibit 1055) provide written, enabling, support for the entire scope of the claimed ranges, that is: a) 3% to 10% and 3% to 15% ether phospholipid w/w krill oil, (b) astaxanthin esters greater than about 100 mg/kg [0.01% w/w] krill oil, and (c) TMA in amounts less than 1 mg/kg krill oil.

6. Based on my review the chain of applications referred to in the '170 Patent, see above, including the '170 Patent and the '170 Patent application, the descriptions in the '453 Patent and the '388 Patent and their respective applications, except for their claims, are substantively the same as the '170 Patent and its application.

7. I have been asked to provide my opinion regarding whether one of ordinary skill in the art at the relevant time would have understood that certain prior art

references, alone or in combination, disclose or teach each of the elements and limitations recited in the claims of the '170 Patent. I have also been asked to provide my opinion regarding whether a person of ordinary skill in the art (a "POSITA") would have been motivated or had a rationale or reason to modify or combine those certain prior art references to arrive at the elements recited in the claims of the '170 Patent. In my opinion, as discussed below, the references discussed below disclose or teach each of the elements and limitations recited in the claims of the '170 Patent and a POSITA would have had a strong rationale to combine them.

BASES FOR OPINIONS GIVEN

8. In forming my opinion, I have relied on my own education, work experiences and knowledge and my review of the following documents:
- a. U.S. Patent No. 9,644,170 B2, filed June 13, 2016, issued May 9, 2017 (the ‘170 Patent) (Exhibit 1001);
 - b. File History of U.S. Patent No. 9,644,170 B2, filed June 13, 2016 (Exhibit 1063);
 - c. U.S. Provisional Patent Application No. 61/024,072, filed January 28, 2008 (the ‘072 Provisional Application) (Exhibit 1002);
 - d. U.S. Provisional Patent Application No. 60/983,446, filed October 29, 2007 (the ‘446 Provisional Application) (Exhibit 1003);
 - e. U.S. Provisional Patent Application No. 60/975,058, filed September 25, 2007 (the ‘058 Provisional Application) (Exhibit 1004);
 - f. U.S. Provisional Patent Application No. 60/920,483, filed March 28, 2007 (the ‘483 Provisional Application) (Exhibit 1005);
 - g. File History of U.S. Patent Application Serial No. 12/057,755, filed March 28, 2008 (Exhibit 1024);

- h. U.S. Patent Application Publication US2008/0274203 A1, Serial No. 12/057,755, published November 6, 2008 ('388 Pat.Appl.Pub., Exhibit 1043);
- i. U.S. Patent No. 9,034,388 B2, Serial No. 12/057,755, filed March 28, 2008, issued May 19, 2015 ("the '388 Patent", Exhibit 1047)
- j. File History of U.S. Patent Application Serial No. 14/020,162, filed September 6, 2013 (Exhibit 1055);
- k. U.S. Patent No. 9,375,453 B2, Serial No. 14/020,162, filed September 6, 2013, issued June 28, 2016 ("the '453 Patent", Exhibit 1067);
- l. 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 or Bottino I) (Exhibit 1007);
- m. Catchpole and Tallon, WO 2007/123424, published November 1, 2007, "Process for Separating Lipid Materials," (Catchpole) (Exhibit 1009);
- n. Randolph, et al., U.S. Patent Application Publication No. US/2005/0058728 A1, "Cytokine Modulators and Related Method of Use" (Randolph) (Exhibit 1011);

- o. Grynbaum, M., *et al.* “Unambiguous detection of astaxanthin and astaxanthin fatty acid esters in krill (*Euphausia superba Dana*)”, J. Sep. Sci., 28, 1685–1693 (2005) (Grynbaum) (Exhibit 1039);
- p. U.S. Patent Application Publication No. 2012/0149867 A1, Serial No. 13,342,664, filed January 3, 2012, published June 14, 2012 (Bruheim, Exhibit 1085);
- q. U.S. Patent No. 8,557,297 B2, Serial No. 13,342,664, filed January 3, 2012, issued October 15, 2013 (Exhibit 1074);
- r. Krill Bill Bottle and Capsules from IRL (Exhibit 1069).
- s. Krill Bill Online Purchase Order and Specification Pages from 2006 (<https://web.archive.org/web/20060715103715/http://www.krillbill.com:80/purchase.htm>; <https://web.archive.org/web/20060715103809/http://www.krillbill.com/profile.htm>) (Exhibit 1070).
- t. Antarctica Select Krill Oil Online Literature and Purchase Order Form and linked FDA webpage from 2006 (<https://web.archive.org/web/20060816050841/http://www.aquasourceproducts.com:80/store/>; https://web.archive.org/web/20060816051010/http://www.aquasourceproducts.com:80/krill_oil.html;

<https://web.archive.org/web/20060506115548/>

<http://www.aquasourceproducts.com:80/resources.html?osCsid=aee4bb3df08470be3a75bc598448dabc>) (Exhibit 1071);

- u. Affidavit of Christopher Butler, Office Manager of Internet Archive, dated November 8, 2017 regarding Krill Bill, Aquasource and FDA related webpages from 2006 (see Exhibit 1070 and Exhibit 1071);
- v. Kochian et al, “Agricultural Approaches to Improving Phytonutrient Content in Plants: An Overview”, Nutrition Reviews, Vol. 57, No. 9, September 1999: S13-S18 (Exhibit 1018);
- w. 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) (Exhibit 1012);
- x. 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) (Exhibit 1013);

- y. Sampalis [III] et al., WO 2009/132463, published November 5, 2009, “New Deodorization Method And Organoleptic Improvement Of Marine Oil Extracts” (Sampalis III) (Exhibit 1064);
- z. 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) (Exhibit 1020);
- aa. Neptune, GRAS Notice [No. GRN 000242] for “High Phospholipid Krill Oil” <https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm269133.pdf>, dated January 18, 2008 and filed by the FDA February 4, 2008 (Neptune’s GRAS) (Exhibit 1075);
- bb. Aker GRAS [No. GRN 000371], “Notification of GRAS Determination of Krill Oil”, December 14, 2010. <https://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices&id=371> (Exhibit 1089);
- cc. Affidavit of Christopher Butler, Office Manager of Internet Archive, dated November 8, 2017 regarding Krill Bill and Aquasource webpages from 2006, Exhibit 1070 and Exhibit 1071 (Exhibit 1076);
- dd. Neptune GRAS Agency Response Letter GRN 000242 (Exhibit 1091).

NO FINANCIAL INTEREST IN PROCEEDING

9. For my work related to this Post Grant Review, my employer, Callaghan Innovation, receives compensation for my time. I am not directly compensated by either Hoffmann and Baron, LLP or the Petitioner. I have no financial interest in this proceeding, and the potential for any future financial benefit is unaffected by the content of my testimony or the outcome of this proceeding. My compensation from my employer, Callaghan Innovation, is not in any way related to the outcome of the case.

QUALIFICATIONS AND RELEVANT EXPERIENCE

10. I am currently employed as Team Manager of the Processing Team within the Integrated Bioactive Technologies Group of Callaghan Innovation, at the Gracefield Research Centre in Lower Hutt, New Zealand (an agency of the Government of New Zealand). The Integrated Bioactive Technologies group specializes in near to market research and development in the field of processing of biologically-derived raw materials to make high value nutraceuticals, food ingredients and biopharmaceuticals. My research and expertise has helped to enable a number of industries in New Zealand to make such products, including a

range of plant and marine derived extracts, including lipid extracts that are produced using a supercritical fluid extraction process.

11. Consequently, I have knowledge and expertise regarding methods of making or extracting oils from crustaceans such as krill, including lipid oils, and of their composition, including various extraction methods involving the use of supercritical fluids both with, and without, polar solvents; and the polar solvent extraction of marine biomasses to achieve the same aims. These methods are now a matter of public knowledge. See my CV attached Appendix D.

12. I began developing supercritical CO₂ + polar co-solvent extraction and fractionation processes around 2003 with my colleague Dr Catchpole, and applied them to biomasses containing phospholipids around 2004, and in particular to marine and dairy biomasses. Around this time I also investigated the use of dimethyl ether (DME) for extracting phospholipids, again mainly from marine and dairy biomasses.

13. Around this time, 2003-2004, Dr Andrew Mackenzie, also part of the Integrated Bioactive Technologies group, developed an NMR-based method for analyzing and quantifying phospholipids, based on the ³¹P isotope. This analysis method was able to distinguish between very closely related phospholipids, such as

phosphatidylcholine (PC) and its ether-lipid analogue alkylacylphosphatidylcholine (AAPC); and phosphatidylethanolamine (PE) and its ether analogues phosphatidylethanolamine plasmalogen and alkylacylphosphatidylethanolamine (AAPE).

14. Prior to the use of ^{31}P NMR to determine the ether phospholipid content of phospholipid lipids, and though other methods for analyzing same were available, it was common industry practice to report only the total phospholipid content for the phosphatidylcholine (PC) and phosphatidylethanolamine (PE) lipid components. Thus, when the amount of the PC lipid component was reported, the number reported included not only PC, but its ether-lipid analogue alkylacylphosphatidylcholine (AAPC). The total then reported being the sum of the non-ether phospholipids and ether phospholipids. In a like manner, when the amount of the phosphatidylethanolamine (PE) component was reported, the number reported included not only PE, but its ether analogues phosphatidylethanolamine plasmalogen (PE plasmalogen) and alkylacylphosphatidylethanolamine (AAPE) as well.

15. When the industry began to accept the ^{31}P NMR standard for the first time the ether-phospholipid components started to be consistently reported as separate constituents.

16. In 2006 the Integrated Bioactive Technologies group of Callaghan Innovation (of which I am a part), began to work collaboratively with Nutrizeal Ltd (founded 1995), now operating as Pharmalink Extracts, Ltd. (Nelson, New Zealand) on the extraction of dry krill powder to produce krill lipid extracts enriched in phospholipids, and to provide a detailed compositional analysis of those extracts.

17. The work of the Integrated Bioactive Technologies group on the extraction of phospholipids using CO_2 and CO_2 + polar co-solvent led us to discover that we could separate different types of phospholipids based on their solubility. Work was performed on a variety of biomasses including krill, which demonstrated that a phospholipid-rich extract containing both ether and non-ether phospholipids was obtained. This work is described in WO 2007/123424, published November 2007, based on International Application Number PCT/NZ/2007/000087, Catchpole and Tallon, International Filing Date April 20, 2007 (Catchpole, Example 18 and Table 16, p. 24, Exhibit 1009, p. 0024).

18. The ³¹P-NMR analysis method used in Catchpole (pp. 14 & 24, Exhibit 1009, pp. 0014 & 0024) demonstrated that ether phospholipids were an intrinsic constituent of the lipid composition of many marine organisms, including krill and krill meal and provided a direct determination of the amounts of ether phospholipids present.

19. We also performed lipid analysis work on existing commercial krill lipid products that were supplied to us by Nutrizel in 2006. Upon information and belief, these products were Neptune Krill Oil (NKO), a.k.a. “Krill Bill”, with the krill oil in the form of gelatine capsules as taken from a Krill Bill bottle shown below (see Exhibit 1069); and Aquasource Krill Oil (Antarctica Select), again with the krill oil in the form of gelatine capsules (see Exhibit 1071 for online Aquasource Antarctica Krill Oil disclosures). In 2006, the product specification for Krill Bill krill oil disclosed the krill oils content as having greater than 40% phospholipids and greater than 1500 mg/kg astaxanthin esters. See Exhibit 1070. (See Exhibit 1076 from Internet Archive regarding contents of Exhibit 1070 and Exhibit 1071.)

20. The encapsulated krill oils were analyzed and found to contain, among the phospholipids, both non-ether phospholipids and ether phospholipids, and high

levels of omega-3 fatty acids (polyunsaturated fatty acids which have an unsaturated bond at the third carbon from the terminal end, commonly reported as ω -3, *n*-3, or omega-3) including eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) attached to the phospholipids.

21. By 2006 and even before, EPA, DHA and phospholipids were associated with beneficial health and were recognized to be important compounds for use in the nutraceutical industry and they remain so today. *See, e.g.,* Aquasource Antarctica Select Krill Oil published literature from 2006 shown in Exhibit 1071.

22. Since 2006 I have continued to work with, among other things, krill and krill oils, including analysis of the components, development of extraction processes for further fractionation of the components, and product concepts thereof.

RELEVANT CONSIDERATIONS

23. I provide my opinions in this declaration as informed below.

24. I have been informed that to be entitled to an earlier priority date each claim limitation must be expressly, implicitly, or inherently supported in the originally filed disclosure, in this case in the Provisional Applications Exhibits 1002-1005, the '388 File History (Exhibit 1024), the '388 Patent (Exhibit 1047), the '453 File History (Exhibit 1055), and the '453 Patent (Exhibit 1067).

25. I have been informed that to benefit from a claim of priority to an originally filed disclosure, the originally filed disclosure must contain a written description of the invention as claimed in the later application, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person of ordinary skill in the art to make and use the invention as claimed. When a range is claimed, there must be reasonable enablement of the entire scope of the range.

26. I have been further informed that for a later application to receive the benefit of an earlier filed application or patent, a person of ordinary skill in the art would have to recognize that the applicant possessed what is claimed in the later filed application as of the filing date of the earlier filed application or patent. The disclosure as originally filed in the earlier applications or patent must convey with reasonable clarity to those skilled in the art that the inventor was in possession of the invention. That is, one skilled in the art, reading the original disclosure, must immediately discern the limitation at issue in the claims. A disclosure in a parent application that merely renders the later-claimed invention obvious is not sufficient to meet the written description requirement; the disclosure must describe the claimed invention with all its limitations.

27. I have been informed that these requirements for written support, possession of the invention and enablement, are referred to as § 112(a) requirements. I have further been informed that if a patent's claims do not have § 112(a) support, it is unpatentable and invalid.

28. I have been informed that if a patent claim is not new, that is, all of the claim elements are found in a single prior art reference, it is invalid as anticipated under 35 U.S.C. § 102.

29. I have further been informed as follows: a claimed invention is not new if it was previously disclosed in a single patent, published patent application or publication; to establish anticipation in light of a printed publication or a patent, the printed publication or patent must disclose each element of the claim, either explicitly or inherently; and when a claim covers a range of compositions the claim is anticipated if any of the compositions within the scope of the claim is disclosed in the prior art.

30. I have been informed that a claimed invention is unpatentable if the differences between the invention and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having ordinary skill in the art to which the subject matter pertains. I

have also been informed that an obviousness analysis takes into account factual inquiries including the level of a person of ordinary skill in the art, the scope and content of the prior art, and the differences between the prior art and the claimed subject matter.

31. I have been informed that there are several accepted rationales for combining references or modifying a reference to show obviousness of the claimed subject matter. Some of these rationales include the following: combining prior art elements according to known methods to yield predictable results; simple substitution of one known element for another to obtain predictable results; a predictable use of prior art elements according to their established functions; applying a known technique to a known device to yield predictable results; choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; and some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

32. I have been informed that “a person of ordinary skill in the art”, a POSITA, is not a specific, real individual, but rather a hypothetical individual or team of

individuals working closely together, who is presumed to have known the relevant art at the time of the invention. In defining the POSITA, I have been informed to consider factors such as the educational level and years of experience not only of the person or persons who have developed the invention that is the subject of the case, but also others working in the pertinent art at the time of the invention; the types of problems encountered in the art; the teachings of the prior art; patents and publications of other persons or companies; and the sophistication of the technology.

33. I have been informed that claim terms are interpreted according to their broadest reasonable construction in light of the specification of the '170 Patent in which they appear and that the patent claim terms are also given their ordinary and customary meaning as would be understood by a POSITA in the context of the entire disclosure.

LEVEL OF ORDINARY SKILL IN THE ART & THE POSITA

34. I have assessed the level of ordinary skill in the art based upon my review of the '170 Patent, the prior art, my own long standing career of working in the field of producing oils from various biomasses, including marine and other aquatic

biomass, with extensive leadership roles managing projects in marine organism processing, oil extraction and compositional analysis.

35. In my opinion, as of the earliest priority date the '170 Patent is entitled to, 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.

THE '170 PATENT (EXHIBIT 1001)

36. The '170 Patent relates to a krill oil composition "characterized by having high amounts of phospholipids, astaxanthin esters and/or omega-3 contents."

Abstract, Exhibit 1001, p. 0001. The patent describes methods for preparing krill oil extracts, their composition, methods for formulating them, and their bioactivity.

37. The '170 Patent discloses that it was well known that krill needs to be processed while fresh to minimize decomposition of the krill products while it is

transported. If these measures are not taken then the krill products would become degraded during transit resulting in decomposed phospholipids and high levels of free fatty acids.

The 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. 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(1): 51-55 (1986). The products offered also contain high levels of free fatty acids.

‘170 Patent at 2:5-15, Exhibit 1001, p. 0026.

38. The processing methods disclosed in the ‘170 Patent include denaturing the enzymes (i.e., inactivating the enzymes) that can cause lipid decomposition in fresh krill prior to extraction using polar and nonpolar solvents.¹

¹ The ‘170 Patent acknowledges prior use of polar solvents, for example, a ketone solvent such as acetone. ‘170 Patent, 1:33-37, Exhibit 1001, p. 0026.

The present invention provides methods to avoid decomposition of glycerides and phospholipids in krill oil and compositions produced by those methods. The product obtained by these new methods is virtually free of enzymatically decomposed oil constituents. 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 nonpolar and polar solvents including use of supercritical carbon dioxide.

‘170 Patent at 9:61 – 10:5, Exhibit 1001, p. 0030.

39. The denaturation step is carried out shortly after harvesting of the krill, preferably on board the ship. “Fresh krill was pumped from the harvesting trawl directly into an indirect steam cooker, and heated to 90 C.”

‘170 Patent at 31:51-52, Exhibit 1001, p. 0041. After denaturing, the krill meal is more stable and further processing can be carried out at a later time.

‘170 Patent at 10:37-44, Exhibit 1001, p. 0030.

40. The ‘170 Patent describes a process to extract the krill oil which uses combinations of supercritical CO₂ and CO₂ plus a co-solvent, typically ethanol, to selectively extract different lipid classes in order to produce extracts that are respectively concentrated in neutral lipids and in

phospholipids (i.e., polar lipids). See, e.g., '170 Patent, 9:49-60, Exhibit 1001, p. 0030; and '170 Patent, Examples 3, 4 and 7 Exhibit 1001, pp. 0036 - 0042.

41. The bioactivity of the krill oil extracts is compared to that of an existing commercial krill oil extract (NKO, Neptune Krill Oil). Assays include Zucker rat trials to demonstrate the possible effect of the extracts on obesity and metabolism (Example 9, p. 0042); blood urea nitrogen trials to indicate benefits to renal function (Example 11, p. 0042); and studies on mitigating the effects of high fat diets (Example 12, p. 0043).

42. The patent claims of the '170 Patent relate to the composition of the krill oil as encapsulated, including specification of a range of ether phospholipid content in each of the independent claims which require either "krill oil comprising from 3% to 15% w/w ether phospholipids w/w of said krill oil" or "krill oil further compris[ing] from about 3% to about 10% w/w ether phospholipids". The only amounts of ether phospholipids disclosed in the '170 Patent are those found in Table 22 and in the text at 32:67 – 33:4. The independent claims also include elements related to encapsulation and the amount of astaxanthin esters.

43. The remaining (dependent) claims in the '170 patent add further requirements related to levels and ratios of individual and total lipids, encapsulation of the oil, and addition of a phytonutrient, etc.

44. From my experience and knowledge and as is apparent from the literature cited here, the lipid components described in the '170 Patent, are the natural lipid components in the krill oil that can be extracted using any of a selection of suitable, conventional solvents.² The relative proportions can be varied in predictable ways by applying a single solvent or combination of solvents including super critical fluid extraction to selectively extract specific groups of lipid components based on their different solubility, and by blending these selective extracts in known and predictable ways to produce a desired composition. These methods and solvents were well known to the POSITA prior to the earliest priority date to which the '170 Patent is entitled.

45. The '170 Patent relates to a krill oil composition "characterized by having high amounts of phospholipids, astaxanthin esters and/or omega-3 contents."

² The relative proportions of the lipid components in krill also vary depending on stage in its life cycle as well as environmental factors.

Abstract, Exhibit 1001, p. 0001. The patent describes methods for preparing krill oil extracts, their composition, methods for formulating them, and their bioactivity.

46. From my experience and knowledge, and as is apparent from the literature cited here, the krill oil lipid components described in the '170 Patent are the natural lipid components in the krill oil that can be extracted using any of a number of conventional solvents known to a POSITA. The method of denaturing the lipases and phospholipases of krill to provide a denatured krill product in which the decomposition of the krill product by the action of lipases and phospholipases was reduced or eliminated was also well known to a POSITA. Moreover, a POSITA would have known that the relative proportions of krill oil constituents could be varied in predictable ways by applying a single solvent or combination of solvents including super critical fluid extraction to selectively extract specific groups of lipid components based on their different solubility, and by blending these selective extracts in known and predictable ways to produce a desired krill oil composition. These denaturation, extraction and blending methods were well known to the POSITA prior to the earliest priority date to which the '170 Patent is entitled.

47. The '170 Patent has two independent claims, claims 1 and 11. Both independent claims require a krill oil composition comprising: "from 3% to 15% ether phospholipids w/w of said krill oil"; and "astaxanthin esters in an amount greater than about 100 mg/kg of said krill oil".

48. Therefore, among other things, as all the dependent claims of the '170 Patent incorporate by reference all the independent claim limitations, all the claims require krill oil compositions having "greater than about 3% ether phospholipids w/w of said krill oil" and "astaxanthin esters in an amount greater than about 100 mg/kg of said krill oil".

49. Moreover, the application for the '170 Patent, had an original claim 1 which required not only the amounts of ether phospholipids and astaxanthin recited in claims 1 and 11 of the '170 Patent but also "trimethyl amine in an amount of less than 1 mg/kg of said krill oil." See '170 Patent File History, p. 0420. ll. 4-7, Exhibit 1063.

50. Finally, the '170 Patent specification discloses, without details or explanations, hundreds of entries for several of the krill oil components claimed without providing any guidance as to which to use or why. For example, see the discussion below regarding the over 75 times the specification provides, without

explanation, various amounts and ranges for astaxanthin ester and astaxanthin components of krill oil.

51. Independent claims 1 and 11 of the '170 Patent simply specify the amounts of components naturally found in krill to be extracted as a krill oil and placed in a capsule. A POSITA would expect that the components extracted would fall somewhere within the ranges claimed.

CLAIM TERMS

ITC Claim Construction.

52. I have been informed that in a proceeding before the U.S. International Trade Commission ("ITC"), *In the Matter of Certain Krill Oil Products and Krill Meal for Production of Krill Oil Products*, Inv. No. 337-TA-1019, Patent Owner asserted patents in the '170 Patent family (all continuations, with the same specifications)³ against Petitioner and others. I have also been informed that, in

³ I am informed that Patent Owner asserted the following patents in the 337-ITC-1019 Investigation, namely U.S. Patent Nos.: 9,028,877; 9,078,905; 9,072,752; 9,320,765; and 9,375,453.

response to Patent Owner's complaint, Petitioner and the other ITC respondents alleged, among other things, that the patents were invalid.

53. I have been informed that the Administrative Law Judge ("ALJ"), shortly after issuing her claim construction order ("Markman Order"), issued initial determinations terminating the investigation against Petitioner and all the others. On May 23, 2017, the ITC determined that it would not review the ALJ's initial determinations terminating the investigation, therefore, I am informed that ITC Investigation No. 337-TA-1019 has been concluded without any determination as to the merits of the investigation.

54. I have been informed that the ALJ construed certain claim terms as follows:

The term "krill oil" has its plain and ordinary meaning, which is oil produced from krill.

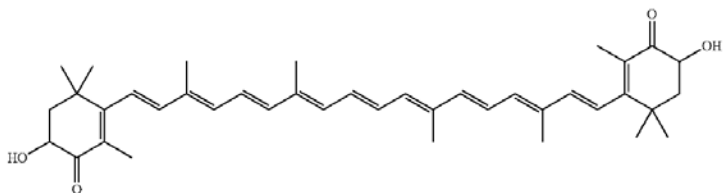
The term "polar krill oil" is construed to mean krill oil containing polar lipids.

The terms "krill" and "*Euphausia superba*" do not require construction.

The term "denatured krill product" does not require construction.⁴

⁴ I have been informed that the ALJ did provide some guidance in her Markman Order as to the nature of "denatured krill product", namely:

The term “astaxanthin” is construed to mean the *trans*-astaxanthin molecule having the following structure:



55. As noted above, I have been informed that claim terms are interpreted according to their broadest reasonable construction in light of the specification of the ‘170 Patent in which they appear and that the patent claim terms are also given their ordinary and customary meaning as would be understood by a POSITA in the context of the entire disclosure.

“Respondents have proposed a more natural reading of the term denatured krill product, as ‘the result of treating krill to denature lipases and phospholipases.’ The parties seem to agree that this is the meaning of the term ‘denatured krill product’- a product that results from denaturing lipases and phospholipases in krill. See Markman Hearing Tr. at 90 (‘The parties have agreed what that means is you unfold those lipases and -phospholipases; causing them to lose their biological activity without changing the primary structure.’).”

56. I have also been informed that because the claims in a PGR are construed according to their broadest reasonable interpretation, while claims in the ITC (and district courts) are given the meaning a term would have to a POSITA at the time of the invention, claims may be construed differently and more narrowly at the ITC than at the PTO in an PGR.

57. For example, I have been informed that in the ITC investigation Petitioner argued that “astaxanthin” should be construed as limited to the *trans*-astaxanthin molecule, while herein it is my opinion that the term “astaxanthin”, under the broadest reasonable construction in light of the specification of the ‘170 Patent in which it appears and as given its ordinary and customary meaning as would be understood by a POSITA includes both the *cis*- and *trans* forms of astaxanthin. In part, because both the *cis*- and *trans* forms of astaxanthin are naturally present when astaxanthin and astaxanthin esters are extracted from krill. Finally, the ‘170 Patent does not ever identify or differentiate any specific isomers (it only ever refers to just “astaxanthin”) which also supports the broader interpretation of including both the *cis*- and *trans*- forms of astaxanthin. See further discussion below.

“krill oil” means “lipids extracted from krill”

58. In the context of the ‘170 Patent and prior art, as discussed below, “krill oil” is a lipid-rich extract of krill that comprises phospholipids, as well as a lipid-rich extract of krill that comprises a blend of polar lipids (phospholipids) and neutral lipids in different proportions. The ‘170 Patent repeatedly refers to the krill oil composition as comprising a blend of lipid fractions. “In some embodiments, krill oil composition comprises a blend of lipid fractions obtained from krill” (‘170 Patent, 3:31-33, Exhibit 1001, p. 0027). “In further embodiments, the present invention provides a blended krill oil composition comprising: from about 45% to 55% w/w phospholipids; from about 20% to 45% w/w triglycerides; and from about 400 to about 2500 mg/kg astaxanthin” (‘170 Patent, 5:45-49, Exhibit 1001, p. 0028). “In some embodiments, the blended krill oil product comprises a blend of lipid fractions obtained from *Euphausia superba*” (‘170 Patent, 5:49-51, Exhibit 1001, p. 0028). “In some embodiments, the krill oil composition comprises a blend of lipid fractions obtained from *Euphausia superba*” (‘170 Patent, 6:60-62, 7:28-31, Exhibit 1001, pp. 0028, 0029). Thus, as further discussed below, “krill oil” means “lipids and blends of lipid fractions obtained from krill”.

59. The methods of extraction are not limited. They include using, singularly and in combination, among others, polar solvents, neutral solvents, and more specifically ketone solvents, neat supercritical carbon dioxide, and supercritical carbon dioxide with a solvent modifier (co-solvent or entrainer). See, for example, in the '170 Patent, 1:35-42, 1:62-2:4, 4:42-52, 4:65-5:6, 5:21-31, 6:6-19, 11:23-49, Exhibit 1001, pp. 0026-0028, 0031.

60. The '170 Patent discloses a well-known two-step extraction process using supercritical CO₂, in combination with ethanol, to extract two lipid fractions; a neutral lipid fraction and a polar lipid fraction.

The krill oils are extracted from the krill meal in two stages, in step 1 the neutral fraction is extracted using neat supercritical CO₂ or in combination with 5% ethanol. The neutral fraction consisted mostly of triglycerides and cholesterol. In stage 2, the polar lipids (phospholipids) are extracted by adding at least 20% ethanol to the supercritical CO₂ extraction medium.

'170 Patent, 9:54-60, Exhibit 1001, p. 0030.

61. The '170 Patent also discloses combinations of extraction methods.

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.

‘170 Patent, 11:23-32, Exhibit 1001, p. 0031.

62. The krill oil by this disclosure is a lipid extract produced in either a single or a two stage (step) process with solvents including ethanol, ketone solvents, and supercritical fluids with and without a polar entrainer. Two types of krill oil lipid fractions are also described, namely ‘neutral krill oil’ and ‘polar krill oil’, depending on the solvent or combination of solvents used to extract them.

63. The abstract of the ‘170 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 CO₂ or CO₂ plus approximately 5% of a co-solvent. Stage 2 extracts the *actual krill oils* by using supercritical CO₂ in combination with approximately 20% ethanol.

‘170 Patent, Abstract, Exhibit 1001, p. 0001, emphasis added.

64. Furthermore, the '170 Patent states that:

In some embodiments, the krill 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 CO₂ supplemented with a low amount of a polar co-solvent (e.g., from about 1% to about 10%, preferably about 5%) such as a C₁-C₃ monohydric alcohol, preferably ethanol, followed by extraction with CO₂ supplemented with a high amount of a polar co-solvent (from about 10% to about 30%, preferably about 23%) such as such a C₁-C₃ monohydric alcohol, preferably ethanol, or vice versa. Surprisingly, it has been found that use of a low amount of polar solvent in the CO₂ 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.

See '170 Patent, 11:32-49, Exhibit 1001, p. 0031.

65. The krill oil by this disclosure is a lipid extract produced in two stages by removing some or much of the triglyceride and other neutral lipids, and then extracting the polar lipids.

66. Elsewhere, the ‘170 Patent also confirms that krill oil may be produced by blending two or more different lipid fractions, which are then encapsulated. In particular, at 6:12-13 (p. 0028) the ‘170 Patent describes “combining said polar extract and said neutral extract to provide *Euphausia superba* krill oil...”.

67. To elaborate, the ‘170 Patent states that:

In some embodiments, the present invention provides methods of making a *Euphausia superba* krill oil composition comprising: contacting *Euphausia superba* with a polar solvent to provide a polar extract comprising phospholipids; contacting *Euphausia superba* with a neutral solvent to provide a neutral extract comprising triglycerides and astaxanthin; combining said polar extract and said neutral extract to provide *Euphausia superba* krill oil 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. In some embodiments, the methods further comprise the step of encapsulating the *Euphausia superba* krill oil. In some embodiments, the present invention provides a *Euphausia superba* krill oil produced by the methods described above.

See ‘170 Patent, 6:6-23, Exhibit 1001, p. 0028.

68. The krill oil by this disclosure again includes a lipid extract produced by combining or blending two different fractions, e.g., a polar extract and a neutral extract.

69. The neutral lipids, discussed above, are mainly comprised of triglycerides, partial glycerides, free fatty acids, and sterols. The krill oil also contains astaxanthin esters and the nitrogen containing compounds trimethylamine (TMA) and trimethylamine oxide (TMAO).

70. In quality krill oil, the phospholipids are highly enriched in the omega-3 fatty acids EPA and DHA, while the neutral lipids have very low levels of these fatty acids. In an oil decomposed through the action of lipases and phospholipases, which are naturally present in the krill, the overall composition will have a high level of free fatty acids and a portion of the phospholipids will have been degraded to lyso-phospholipids (one or both fatty acids have been lysed from the molecule), such as lysophosphatidylcholine (LPC), and lysoalkylacylphosphatidylcholine (LAAPC). The free fatty acid fraction of the oil will have elevated levels of omega-3 fatty acids including EPA and DHA, as these will have been cleaved from the parent phospholipid. The final composition of the krill oil is dependent upon

the solvent combinations used, the extent of extraction carried out, and the ratios in which different fractions are mixed or blended together.

71. Therefore, “krill oil” in accordance with the ‘170 Patent means “lipids extracted from krill”.

“phytonutrient” means “plant-derived compound that has a positive impact on human health or nutrition”

72. My understanding of a phytonutrient is a plant derived compound associated with proper health function. Kochian (Exhibit 1018) describes phytonutrients as follows:

A literal definition for the term phytonutrient is “a nutrient derived from plants.” Thus, we would be talking about a plant-based substance essential for proper metabolism and function in humans. This would include proteins, lipids, and carbohydrates as well as essential minerals and vitamins. However, the term is generally used much more loosely to include any organic or inorganic compound in plant foods that has a positive impact on human health or nutrition. This would include the true essential nutrients and vitamins such as vitamin E, pro-vitamin A carotenoids, iron, zinc, calcium, and selenium for which there is solid evidence as to their importance in human health and nutrition from research in animal model systems as well as from clinical and

epidemiologic studies.^{3,4} Also included under this umbrella term would be the broad classes of secondary compounds such as phytoestrogens, isoflavonoids, anthocyanins, polyphenols, and glucosinolates that can improve human nutrition and health by mechanisms that are not, or are only partially, defined. A better term for these secondary plant products might be “accessory health factors” (GF Combs, personal communication). This term indicates that although not essential for humans, these compounds could play an important role in improving human health by reducing the impact of certain chronic diseases (e.g., heart disease, cancer) and the effects of aging.

See pages S13-S14 of Kochian, Exhibit 1018, p. 0001-0002.

73. The term “phytonutrient” is not expressly defined in the ‘170 Patent, but it is described as the ‘170 patent provides examples of compounds that are phytonutrients, including a non-limiting list of sources of plant phytonutrients.

74. In particular, the ‘170 patent states:

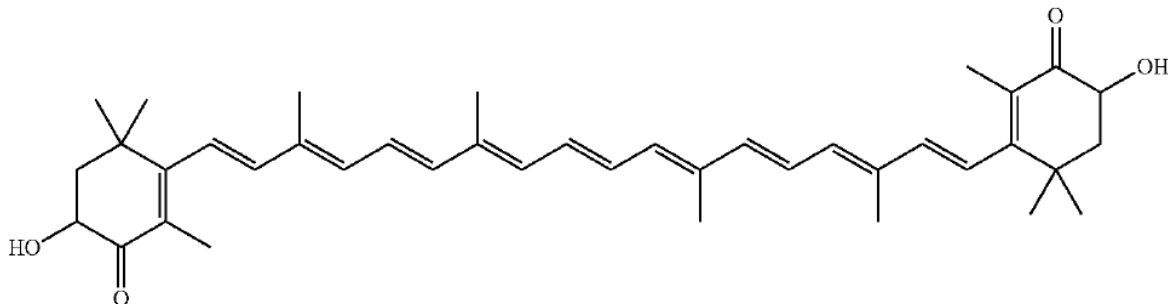
In still further embodiments, the compositions comprise at least one phytonutrient (e.g. soy isoflavonoids, oligomeric proanthocyanidins, indol 3 carbinol [sic], sulforaphane, fibrous ligands [sic], **plant phytosterols**, ferulic acid, anthocyanocides [sic], triterpenes, omega 3/6 fatty acids, conjugated fatty acids such as conjugated linoleic acid and conjugated linolenic acid, polyacetylene, quinones, terpenes, catechins [sic], gallates, and quercitin). **Sources of plant**

phytonutrients include, but are not limited to, soy lecithin, soy isoflavones, brown rice germ, royal jelly, bee propolis, acerola berry juice powder, Japanese green tea, grape seed extract, **grape skin extract [resveratrol, which is a grape skin extract]**, carrot juice, bilberry, flaxseed meal, bee pollen, ginkgo biloba, primrose (evening primrose oil), red clover, burdock root, dandelion, parsley, **rose hips**, milk thistle, ginger, Siberian ginseng, rosemary, curcumin, garlic, lycopene, grapefruit seed extract, spinach, and broccoli.

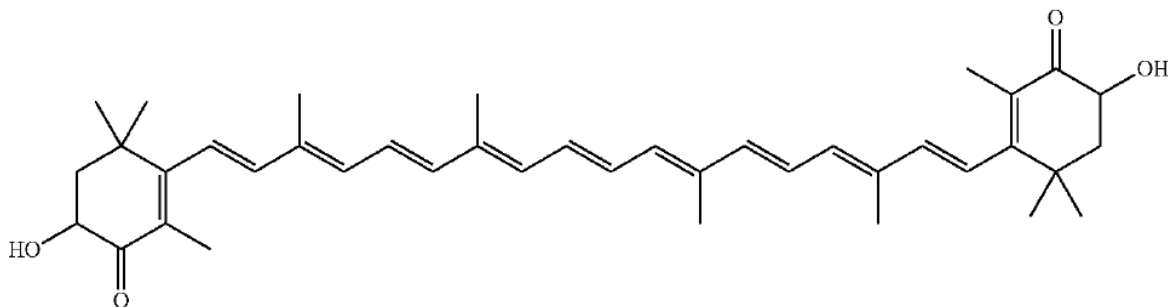
See '170 Patent, 16:8-23, Exhibit 1001, p. 0033 (emphasis added).

75. Therefore, in accordance with the '170 Patent and my understanding of the term phytonutrient, a "phytonutrient" is a "plant-derived compound that has a positive impact on human health or nutrition". Furthermore, examples of compounds that are phytonutrients include: ferulic acid, resveratrol (which is derived from grape skin extract), and quercetin, and compounds derived from grape seed extract, grape skin extract, and rose hips.

“astaxanthin” means “the astaxanthin molecule having the structure shown below, and includes both *cis*- and *trans* forms of the molecule:



76. “Astaxanthin” is defined in the ‘170 Patent (9:17-32, Exhibit 1001, p. 0030.) as referring “to the following chemical structure:



”.

77. I understand the above definition, represented as a 2-dimensional structure, to include both the *cis*- and *trans* forms of astaxanthin having that structure. As discussed above in the ITC Claim Construction section, I have been informed that in the ITC investigation counsel for Petitioner argued that “astaxanthin” should be

construed as limited to the trans-astaxanthin molecule, while herein it is my opinion that the term “astaxanthin”, under the broadest reasonable construction in light of the specification of the ‘170 Patent in which it appears and as given its ordinary and customary meaning as would be understood by a POSITA includes both the cis- and trans forms of astaxanthin. In part, because both the cis- and trans forms of astaxanthin are naturally present when astaxanthin and astaxanthin esters are extracted from krill. Additionally, the ‘170 Patent does not ever identify or differentiate any specific isomers (it only ever refers to just “astaxanthin”) which also supports the broader interpretation of including both the cis- and trans-forms of astaxanthin. In any event, as discussed below and in Grynbaum, Exhibit 1039, astaxanthin extracted from krill naturally contains both the cis- and trans-form of the molecule, with the trans- form of astaxanthin predominating.

78. The ‘170 Patent discusses the extraction of astaxanthin and astaxanthin esters from krill.

79. Krill naturally contains astaxanthin in the cis- and *trans*-forms, and as free and esterified astaxanthin. See disclosure in Grynbaum (Exhibit 1039) discussed below and the following summary from Grynbaum:

HPLC atmospheric pressure chemical ionization (APCI)/MS, GC MS, HPLC diode array detection (DAD), and NMR were used for the

identification of astaxanthin and astaxanthin fatty acid esters in krill (*Euphausia superba Dana*). . . . (13-*cis*) Astaxanthin (70 µg/g), 542 µg/g (all-*E* [*trans*]) astaxanthin, 36 µg/g unidentified astaxanthin isomer, 62 µg/g (9-*cis*) astaxanthin, and 7842 µg/g astaxanthin fatty acid esters were found.

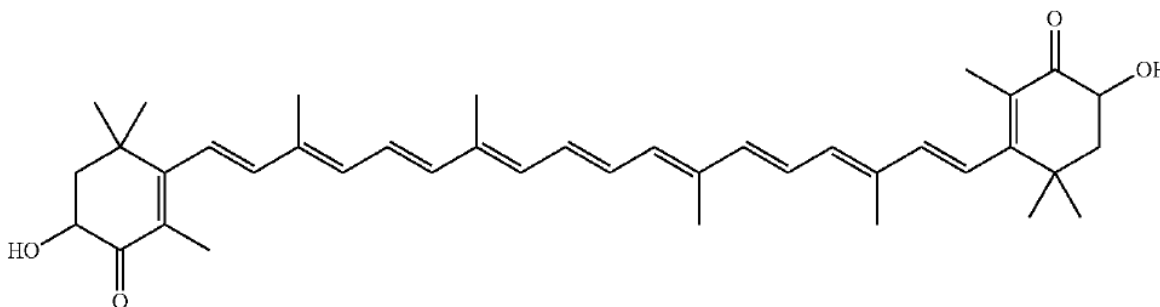
Grynbaum, p. 1685, Exhibit 1039, p. 0001. Moreover, as discussed below, while astaxanthin, including its astaxanthin esters may vary in amount “the relative composition of astaxanthin, its monoesters and diesters remains constant at 5, 49, and 40%, respectively”. (Grynbaum, p. 1686, 1st col., Exhibit 1039, p. 0002.)

80. As the ‘170 Patent does not identify or differentiate any specific isomers (it only ever refers to just “astaxanthin”) and does not disclose any method for preferentially extracting *trans*-astaxanthin from krill, and because both the *cis*- and *trans* forms of astaxanthin are naturally present when astaxanthin and antaxanthin esters are extracted from krill, it is my opinion that when the ‘170 Patent refers to astaxanthin in the specification and in the claims it means both the *cis*- and *trans*-forms of astaxanthin.

81. Moreover, as the *trans*- form of astaxanthin is the most prevalent form of astaxanthin extracted from krill, disclosures relating to astaxanthin as extracted

from krill would be expected to have the *trans*- form of astaxanthin as well as the *cis*- form.

82. Therefore, “astaxanthin” means “the astaxanthin molecule having the structure shown below” and includes both cis- and trans- forms of the molecule:

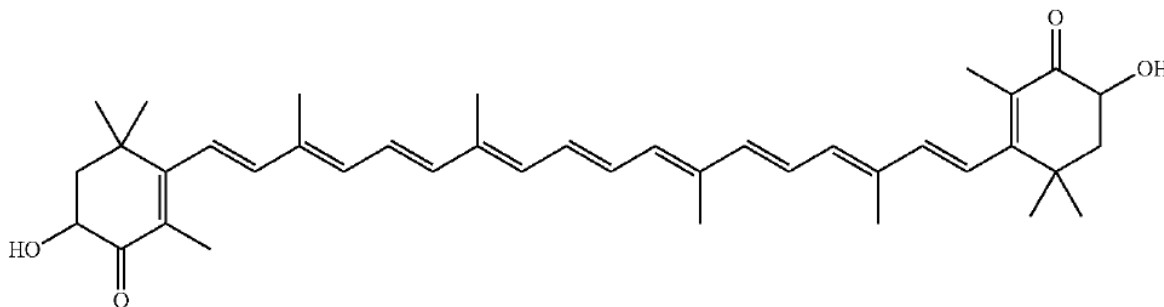


“astaxanthin esters” means “astaxanthin molecules in which one or both of the hydroxyl groups are replaced by a fatty acid tail connected to the astaxanthin molecule through an ester bond.”

83. “Astaxanthin esters” are defined in the ‘170 Patent (9:32-33, Exhibit 1001, p. 0030) as referring to “the fatty acids esterified to OH group in the astaxanthin molecule.” As discussed above, and as described by Grynbaum (Exhibit 1039), astaxanthin is a molecule naturally found in krill in both “free” and “esterified” forms, both of which are discussed in the ‘170 Patent. The “free” form, shown

below and in the '170 Patent, has a hydroxyl (OH) group on either end. The esterified form consists of both mono-esters (in which one of the hydroxyl groups is replaced by a fatty acid) and di-esters (in which both of the hydroxyl groups are replaced by fatty acids), see for example Grynbaum (Exhibit 1039)

84. Therefore, “astaxanthin esters” means “astaxanthin molecules in which one or both of the hydroxyl groups are replaced by a fatty acid tail connected to the astaxanthin molecule through an ester bond.”



**THE ‘170 PATENT IS ENTITLED TO A PRIORITY
DATE NO EARLIER THAN JUNE 13, 2016**

85. I have read and understood the ‘170 Patent (Exhibit 1001), the ‘483 Provisional Application (Exhibit 1005), the ‘058 Provisional Application” (Exhibit 1004), the ‘446 Provisional Application (Exhibit 1003), the ‘072 Provisional Application (Exhibit 1002), the ‘388 Patent (Exhibit 1047), the ‘453 File History (Exhibit 1055), and the ‘453 Patent (Exhibit 1067). Set forth in the Table below, are three claim limitations that fail to have adequate Section 112(a) support in the ‘170 Patent, and thus necessarily find no § 112(a) support in the ‘388 Patent. Additionally, with respect to the ether phospholipid and astaxanthin esters claim limitations, the ‘170 Patent provides no description or explanation as to why the claimed range is important or whether it provides for any form of benefit or unexpected results, nor does the ‘170 Patent describe any critical reason for choosing any of the ranges claimed in these claim limitations. Furthermore, the ‘170 Patent does not describe any method for achieving the ranges claimed for any of the three claim limitations.

Claims Limitations	Claim Ranges/Amounts Not Supported
(i) “from 3% to 15% ether phospholipids w/w of said krill oil” ‘170 Patent, claims 1 and 11 “from about 3% to about 10% w/w ether phospholipids” ‘170 Patent, claims 7 and 18, which depend directly from claims 1 and 11, respectively One of these two limitations is present in all the claims of the ‘170 Patent.	There is no support for ether phospholipids w/w of said krill oil greater than or equal to 8%. Patent Owner argued that difference between 2.46% and 3%, <i>i.e.</i>, 0.54% was patentable enablement difference. There is no 112(a) support for 8%, 9%, 10%, 11%, 12%, 13%, 14% and 15% ether phospholipids.
(ii) “astaxanthin esters in amount of greater than about 100 mg/kg [0.01%] of said krill oil” ‘170 Patent, claims 1 and 11 This claim includes astaxanthin esters in amounts from 100 mg/kg (0.01%) to at least 850,000 mg/kg (85%) of said krill oil. This limitation is present in all the claims of the ‘170 Patent.	There is no disclosure for astaxanthin esters in amounts greater than 2,500 mg/kg = 2.5 g/kg = .0025 kg/kg [0.25%]. There is no 112(a) support for the portion of the claimed ranges of astaxanthin esters from about 0.25% to 85% or 97%.
(iii) “trimethylamine in an amount of less than 1 mg/kg of said krill oil” ‘170 Patent application’s original claim 1 (Exhibit 1063, p. 0420).	There is no enabling support for trimethylamine in an amount less than about 42.2 mg/kg. There is no 112(a) support for less than 1 mg/kg trimethylamine

There is no § 112(a) support for ether phospholipids in the upper portion of the recited range of 3% to 15% w/w krill oil i.e., 8% to 15%, as required at least by '170 Patent claims 1 and 11.

86. Independent claims 1 and 11 of the '170 Patent recite “from 3% to 15% *ether phospholipids* w/w of said krill oil”. However, there is insufficient Section 112(a) support for this broad range in the '170 Patent or any of the applications it relies upon for priority.

87. The highest percentage of ether phospholipids of a krill oil composition in the '170 Patent is disclosed in Table 22, 33:6-27, Exhibit 1001, p. 0042 (reproduced below), and is less than 8% w/w.

TABLE 22			
Phospholipid profiles			
	Type B krill powder	NKO	Krill Oil obtained in Example 7
PC	66.0	68.6	75.3
AAFC	12.0	7.0	13.0
PI			
1LPC	1.2	1.3	0.4
PS			
2LPC	7.4	13.8	2.9
LAAPC	2.2	1.2	0.9
PE	6.0	3.4	3.4
AAPE			1.5
SM			
GPC		1.3	
DHSM			
NAPE		3.4	
CL	5.3		2.1
LPE			0.5
LCL			
% PL in powder or lipid sample	8.3	30.0	47.9

88. Table 22 of the '170 Patent identifies three krill products containing ether phospholipids: Type B krill powder; NKO (commercially available Neptune Krill Oil); and Patent Owner's Krill oil obtained from Example 7.

89. Type B krill powder contains 14.2% ether phospholipids (12.0% (AAPC) + 2.2% (LAAPC)) as a percentage by weight of phospholipids. However, the '170 Patent discloses that phospholipids constitute 8.3% of the krill powder. Thus, ether phospholipids in accordance with the '170 Patent constitute **1.2%** by weight of the krill powder ($14.2\% \times .083 = 1.18\%$).

90. The commercial NKO product (Neptune Krill Oil) contains 8.2% ether phospholipids (7.0% (AAPC) + 1.2 (LAAPC)) as a percentage by weight of phospholipids. However, Patent Owner represents that phospholipids constituted only 30.0% of the NKO product. Thus, the '170 Patent discloses that ether phospholipids constitute only **~2.5%** by weight of the NKO product ($8.2\% \times .300 = 2.46\%$).

91. Example 7 krill oil contains 15.4% ether phospholipids (13.0% (AAPC) + 0.9% (LAAPC) + 1.5% (AAPE)) as a percentage by weight of phospholipids. However, because phospholipids only make up 47.9% of the Patent Owner's Krill

oil obtained from Example 7, ether phospholipids comprise only ~7.4% by weight of the Patent Owner's Krill oil obtained from Example 7 ($15.4\% \times .479 = 7.38\%$).

92. Thus the '170 Patent discloses that its claimed invention can produce krill oil extracts with an ether phospholipid content up to a maximum of 7.4% by weight of krill oil. But this disclosure of an ether phospholipid content of 7.4% does not establish that the '170 Patent applicants were in possession of, or enabled higher percentages of ether phospholipid (*e.g.*, 8-15%). The patent does not disclose higher levels of ether phospholipid in a krill oil, nor does it describe any methods by which the ether phospholipid levels might be increased.

93. Each of the challenged claims of the '170 Patent include an ether phospholipids range that includes $\geq 8\%$ w/w krill oil. However, none of the referenced priority documents with a filing date before March 16, 2013 (Exhibits 1002, 1003, 1004, 1005, 1024) contain any written description of the complete range, or even a substantial portion of the range of ether phospholipid percentages by w/w of krill oil claimed (*e.g.*, percentages $\geq 8\%$).

94. Thus, lacking a sufficient written enabling disclosure for ranges $\geq 8\%$, the '170 Patent is not entitled to a priority date any earlier than filing of date of the application that issued as the '170 Patent, namely June 13, 2016.

95. Importantly, the difference between 8% and 9% or 10-15% is substantial. During prosecution, to overcome prior art rejections and secure issuance of the challenged claims, Patent Owner represented that the prior art Neptune Krill Oil and the Sampalis/Beaudoin references disclosed krill oil compositions having only 2.46% ether phospholipids. The Patent Owner then successfully argued that a mere 0.54% difference between the cited prior art (2.46%) and the claimed lower limit (3%) was a patentable difference. Response To Office Action, October 12, 2016, '170 Patent File History, Exhibit 1063, pp. 0438-0447, see p. 0446. *See also*, Applicant-Initiated Interview Summary, October 20, 2016, '170 Patent File History, Exhibit 1063, pp. 0582-0584.⁵

96. Fundamentally, Patent Owner's argument that this 0.54% difference was sufficient to overcome the Examiner's rejections, demonstrates that slight differences in ether phospholipid content are significant for possession and enablement requirements under Section 112(a).

⁵ I am informed that Patent Owner made this same argument to overcome prior art references in the prosecution of several other members of its patent family.

97. Three of the '170 Patent's priority documents⁶ included an original "Table 17" indicating that the commercial NKO product has a phospholipid content of 43.0%⁷, which is consistent with the published literature for NKO.⁸ Yet in presenting arguments to overcome the prior art, applicants relied solely upon Table 22, maintaining that the phospholipid content of the commercial Neptune Krill Oil product was only 30%.

⁶ Table 17, '072 Provisional, p. 33, Exhibit 1002, p. 0036; and Table 17, '058 Provisional, Exhibit 1004, p. 0034; and Table 17, '483 Provisional, p. 28, Exhibit 1005, p. 0036.

⁷ Since 2.1% (Lyso-PC) + 38.7% (PC) + 0.18% (PS) + 1.8% (PE) + 0.18 (PI) = 42.96% phospholipids in the Neptune Krill Oil (Neptune KO) composition. See Table 17, '072 Provisional, p. 33, Exhibit 1002, p. 0036, copied below.

Table 17. Lipid class distribution of the different krill oil materials.

	DG	FFA	TG	Lyso- PC	PC	PS	PE	PI
Neutral KO	5,8	5,5	87,4	0	0,2	0,2	0,1	0,8
Polar KO	0,4	0,6	1,1	6,4	84,9	0,2	0,5	2
Neptune KO	2,6	6,8	47,6	2,1	38,7	0,18	1,8	0,18
Ethanol extracted KO	3,3	16,0	31,1	6,2	25,3	0	2,7	0

98. Curiously, Table 17 was omitted in the '170 Patent and its application file history and not disclosed to the Examiner during the prosecution of the '170 Patent despite being included in three of the four provisional applications. Interestingly, the ether phospholipid content of the prior art NKO product increases to 3.5% ($43.0\% \times 8.2\%$) when the Table 17 phospholipid content is used to calculate the level of ether phospholipids. While 3.5% is clearly within the 3% to 15% claim range for purposes of anticipation and obviousness, it still fails to provide sufficient written description or enablement for 8% or greater ether phospholipids.

99. In view of the limited disclosure in the patent specification and the 0.54% patentable distinction arguments advanced to secure issuance of the '170 patent, Patent Owner cannot legitimately assert that the patent's disclosure of 7.4% ether phospholipids⁹ is an enabling disclosure for 8% or any higher percentage ether

⁸ See, *e.g.*, Krill Bill NKO 2006 Advertisement, Exhibit 1070.

⁹ Again, even adding Patent Owner's alleged patentable difference of 0.54% to its highest ether PL content of 7.4%, from the '170 Patent's Example 7, does not support an ether PL content of $\geq 8\%$. (Because $7.4\% + 0.54\% = 7.94\%$ which is still $< 8\%$.)

phospholipids, this includes (i) the 8-15% range as required by the 3% to 15% claim limitation of the challenged claims, and (ii) the 8-10% range as required by the 3% to 10% claim limitation of the challenged claims 7 and 18. See further discussion below.

100. In my opinion, the '170 Patent applicants failed to provide adequate written description showing any criticality or reason for the ether phospholipid ranges claimed, and the '170 Patent applicants failed to enable a POSITA to make the claimed krill oil composition having 8% or greater ether phospholipids, as applicants argued that a 0.54% difference in ether phospholipid content was a patentable distinction. In my opinion, the '170 Patent does teach how to make a krill oil composition containing an ether phospholipids content greater than about 8% w/w krill oil.

101. None of the claims of the '170 Patent find adequate § 112(a) support in the priority documents or the '170 Patent.

There is no Section 112(a) support for astaxanthin esters for almost the entire claim limitation range for astaxanthin esters of about 100 mg/kg of said krill oil to 85% or 97% w/w of krill oil as required by at least '170 Patent claims 1 and 11.

Claim1. A krill oil composition comprising a capsule containing *Euphausia superba* krill oil suitable for oral administration, said krill oil comprising from 3% to 15% ether phospholipids w/w of said krill oil and **astaxanthin esters in amount of greater than about 100 mg/kg [0.01%] of said krill oil.**

Claim 11. A composition comprising a soft gel capsule containing *Euphausia superba* krill oil suitable for oral administration, said krill oil comprising from 3% to 15% ether phospholipids w/w of said krill oil and **astaxanthin esters in amount of greater than about 100 mg/kg [0.01%] of said krill oil.**

The '170 Patent, 35:49-53, Exhibit 1001, p. 0001.

102. The '170 Patent does not enable a POSITA to make a krill oil composition containing the entire range of astaxanthin esters specified in the challenged claims. The ranges claimed by the '170 Patent for astaxanthin esters do not recite an upper bound. As discussed below the claimed amount of astaxanthin esters ranges from

100 mg/kg to as high as 85% or 95% w/w krill oil. Yet, at most, the '170 Patent discloses astaxanthin esters in an amount $\leq 0.25\%$ (2,500 mg/kg).

103. As discussed above, independent claims 1 and 11 of the '170 Patent recite a composition containing a 3% to 15% ether PL (phospholipid) krill oil component and a greater than about 100 mg/kg krill oil component. The claim uses the transition "comprising" so, it may, I am informed, but is not required to have any other components.

104. As a percentage, $100 \text{ mg/kg} = .1 \text{ g/kg} = .0001 \text{ kg/kg} = .01\% \text{ w/w}$.

Therefore, claim 1 recites astaxanthin esters in amounts of greater than about 0.01% w/w krill oil.

105. Based upon the '170 Patent disclosure, the teachings in the art and the breadth of the astaxanthin esters limitation, there is nothing that would inform a POSITA how to make and use the scope of claimed invention and obtain a krill oil composition having an astaxanthin content more than 0.25% and certainly not anywhere approaching 85-97%.

106. In claims 1 and 11 other than ether phospholipids in amounts from 3% up to 15% w/w krill oil, astaxanthin esters is the only claimed component. Thus, claims

1 and 11 provide that up to 85% to 97% of the krill oil composition can be astaxanthin esters. (100% - 15% = 85%. 100% - 3% = 97%.)

107. As recited in claims 1 and 11 of the '170 Patent, the range of "astaxanthin esters in amount of greater than about 100 mg/kg of said krill oil" is equivalent to astaxanthin esters in an amount greater than about 100 mg/kg of said krill oil up to 85% or 97% w/w of the krill oil composition. Alternatively, e.g., 85% w/w krill oil is the same as 850,000 mg/kg krill oil.¹⁰ Consequently, claims 1 and 11 require astaxanthin esters in the range of greater than about **0.01% up to 85% or 97% of the krill oil composition.**

108. Claims 7 and 18, depend from claims 1 and 11, respectively, and additionally provide for two additional components: non-ether phospholipids, with a minimum total phospholipid content of 30% w/w, and a minimum triglycerides content of 20% w/w. Thus, claims 7 and 18 provide that 50% of the krill oil composition can be astaxanthin esters. (100% - 30% - 20% = 50%.)

109. Additionally, claims 7 and 18, which allow for the lowest upper limit of astaxanthin esters of any of the '170 Patent's claims, still sets that amount at 50%

¹⁰ 85% w/w = .85 kg/kg = 850 g/kg = 850,000 mg/kg.

w/w krill oil composition. Alternatively, 50% w/w krill oil is the same as 500,000 mg/kg krill oil. Consequently, claims 7 and 18 require at a minimum astaxanthin esters in the range of greater than about **0.01% to 50% krill oil composition**.

110. The upper limit for astaxanthin esters in the remaining dependent claims all fall above the 50% of claims 7 and 18 and less than or equal to the 85% and 97% of claims 1 and 11.

111. However, the disclosures in the '170 Patent only describe krill oil up to a maximum of 2,500 mg/kg (0.25%) astaxanthin esters, which is not commensurate with the range of astaxanthin esters recited in the claims. For example:

(i) astaxanthin esters less than or about 2,200, *e.g.*, “at least 500, 100, 1500, 2000, 2100, or 2200 mg/kg astaxanthin esters,” 3:64-65;

(ii) astaxanthin esters less than or about 2,500 mg/kg in ranges, *e.g.*, “from about 50, 100, 200, or 500 to about 750, 1000, 1500 or 2500 mg/kg astaxanthin esters”, 13:26-28; and

(iii) miniscule amounts of astaxanthin esters, “less than about 5 micrograms/kilogram [.005 mg/kg] (w/w) astaxanthin esters” (5:39-40).

See Appendix B, for a complete listing of all disclosed amounts of astaxanthin esters and astaxanthin.

112. The '170 Patent provides 4 tables disclosing the range of astaxanthin esters it obtained – Tables: 16, 17C, 19C, 20C. See Astaxanthin Section, Appendix A.

In many cases the '170 Patent refers separately to different forms of astaxanthin, including free astaxanthin and mono- and di-esters. Even if all forms of astaxanthin were taken together there is still no additional support for higher levels of astaxanthin. Those tables are discussed below as well. None show that the '170 Patent processes provided any astaxanthin content higher than 2091 mg/kg (0.21%, see Table 21, Exhibit 1001, p. 0044, and discussions below).

113. Table 1, “Composition of products from the processing line”, Exhibit 1001, p. 0034: total astaxanthin – krill – 53.3, 81.3, 145, and 126 mg/kg.

TABLE 1

Composition of products from the processing line				
	Round frozen krill	After decanter	After drier	Konstruktor Koshkin (Ukrainian vessel)
Protein	13.5 g/100 g	20.9 g/100 g	58.5 g/100 g	60.2 g/100 g
Moisture	76.3 g/100 g	65.6 g/100 g	9.1 g/100 g	9.6 g/100 g
Lipid (Folch)	8.6 g/100 g	10 g/100 g	21.8 g/100 g	21.4 g/100 g
Free fatty acids	29.8 g/100 g	25.3 g/100 g	24.8 g/100 g	23.3 g/100 g
Total astaxanthin	53.3 mg/kg	81.3 mg/kg	145 mg/kg	126 mg/kg

114. Table 4, “Compositions and quality parameters of asta oil”, Exhibit 1001, p. 0035: astaxanthin – asta oil – 1245 mg/kg.

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TABLE 4-continued

Composition and quality parameters of asta oil.	
Phospholipids	575 mg/kg
Astaxanthin	1245 mg/kg

115. Table 7, “Composition and properties of the krill meal and products after extraction”, Exhibit 1001, p. 0036: astaxanthin esters – 144, 10, 117 mg/kg.

TABLE 7

Composition and properties of the krill meal and products after extraction			
	Krill meal	Delipidated krill meal	EtOH extracted krill oil
Crude protein	586 g/kg	735 g/kg	
Fat (Folch)	250 g/kg	30 g/kg	
Moisture/ethanol	71 g/kg	134 g/kg	85 g/kg
Astaxanthin esters	144 mg/kg	10 mg/kg	117 mg/kg
Dieters	110 mg/kg	8.5 mg/kg	117 mg/kg
Monoesters	33 mg/kg	1.8 mg/kg	37 mg/kg
Biological digestible protein	854 g/kg protein	870 g/kg protein	
Flow number	4.8	1.9	
NH3	9 mg N/100 g	0	3 mg N/100 g
TMA	2 mg N/100 g	0	70 mg N/100 g
TMAO	125 mg N/100 g	0	456 mg N/100 g

116. Table 16, “Compositional data for the novel krill oil composition obtained and NKO krill oil”, Exhibit 1001, p. 0039: astaxanthin esters 472, 117, 580, and 98 mg/kg; astaxanthin free – 11, <1, <1, and <1 mg/kg.

TABLE 16

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Compositional data for the novel krill oil composition obtained and NKO krill oil.				
Compounds	Neptune KO	Ethanol extracted KO	Polar KO	Neutral KO
25 Astaxanthin esters	472 mg/kg	117 mg/kg	580 mg/kg	98 mg/kg
Astaxanthin free	11 mg/kg	<1 mg/kg	<1 mg/kg	<1 mg/kg
Total cholesterol	1 g/100 g	12 g/100 g	<0.5 g/100 g	5.7 g/100 g

117. Table 17C, “Miscellaneous analysis of the extract in S1”, Exhibit 1001, p.

0040: astaxanthin esters – 462 mg/kg; free astaxanthin – 4.3 mg/kg.

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TABLE 17C

Miscellaneous analysis of the extract in S1.		
Compound	Unit	Amount
Free astaxanthin	mg/kg	4.3
Astaxanthin esters	mg/kg	462
Trimethylamin	mg N/100 g	<1
Trimethylamineoxide	mg N/100 g	2

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118. Table 19C, “Miscellaneous analysis of the final blended product obtained in example 4”, Exhibit 1001, p. 0040: astaxanthin esters - 151 mg/kg; free astaxanthin – 1.1 mg/kg.

TABLE 19C

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Miscellaneous analysis of the final blended product obtained in example 4.		
Compound	Unit	Amount
Free astaxanthin	mg/kg	1.1
Astaxanthin esters	mg/kg	151
Trimethylamin	mg N/100 g	109
Trimethylamineoxide	mg N/100 g	80

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119. Table 20C, “Miscellaneous analysis of the final blended product obtained in Example 5”: astaxanthin esters - 1302 mg/kg; free astaxanthin – 12 mg/kg.

TABLE 20C

Miscellaneous analysis of the final blended product obtained in Example 5			
Compound	Unit	Amount	
Free astaxanthin	mg/kg	12	
Astaxanthin esters	mg/kg	1302	40
Trimethylamin	mg N/100 g	193	
Trimethylamineoxide	mg N/100 g	1.7	45

120. Table 21, “Analysis of the krill oil obtained using supercritical fluid extraction”, Exhibit 1001, p. 0041: astaxanthin - 2091 mg/kg.

TABLE 21

Analysis of the krill oil obtained using supercritical fluid extraction.	
Parameter	Value
Ethanol	1.11% w/w
Water Content	2.98% w/w
C20:5 n-3 (EPA)	19.9
C22:6 n-3 (DHA)	11.3
Total Omega 3	35.7
Total Omega 6	3.0
Total Phospholipids	50.55 wt %
Ratio Omega3-PL/Total Omega 3	77.6% w/w
Ratio EPA-PL/Total EPA	84.4% w/w
Ratio DHA-PL/Total DHA	74.7% w/w
Triglycerides	25.9 g/100 g
Astaxanthin	2091 mg/kg
Peroxide Value	<0.1

121. Importantly, the '170 Patent specification, while disclosing specific amounts of astaxanthin esters over 50 times,¹¹ fails to teach or disclose any amount greater than 2,500 mg/kg. But $2,500 \text{ mg/kg} = 2.5 \text{ g/kg} = .0025 \text{ kg/kg} = 0.25\% \text{ w/w}$ astaxanthin esters, comprises a minuscule portion of the entire claimed ranges for astaxanthin esters content required by the all the claims of the '170 Patent.¹² This

¹¹ The '170 Patent specification discloses an additional 25 times separate amounts for astaxanthin, each less than 2,500 mg/kg as well. See also Appendix A, below.

¹² The prior art reference Grynbaum, with the highest disclosed amount of astaxanthin esters obtained from krill only discloses $7842 \text{ mg/kg} = 7.8 \text{ g/kg} = .0078 \text{ kg/kg} = 0.78\% \text{ w/w}$. This is still nowhere near the upper limits of 85-97%

highlights the inventors' failure to possess the full scope of the patent claim as well as their failure to provide an enabling description.

122. The '170 Patent also shows the inventors lacked possession of their invention when they disclosed numerous time amounts for astaxanthin esters greater than 100 mg/kg, and then side-by-side with such disclosures, and without explanation, claim that their invention also encompasses krill oil compositions whose astaxanthin esters is required to be less than some miniscule amount (e.g., less than 0.05 mg/kg w/w krill oil).

In some embodiments, the present invention provides a composition comprising krill oil containing less than about 70 micrograms/kilogram [0.070 mg/kg] (w/w) astaxanthin esters. In some embodiments, the compositions comprise less than about 50 micrograms/kilogram [0.050 mg/kg] (w/w) astaxanthin esters. In some embodiments, the compositions comprise less than about 20 micrograms/kilogram [0.020 mg/kg] (w/w) astaxanthin esters. In some embodiments, the compositions comprise less than about 5 micrograms/kilogram [0.005 mg/kg] (w/w) astaxanthin esters.

w/w recited in claims 1 and 11. See Grynbaum, p. 1692, 2nd col., Exhibit 1039, p. 0008.

‘170 Patent, 5:32-40, Exhibit 1001, p. 0028 (emphasis added).¹³

In some embodiments, the present invention provides krill oil containing less than about 70, 60, 50, 40, 30, 20, 10, 5 or 1 micrograms/kilogram (w/w) astaxanthin esters.

‘170 Patent, 13:34-36, Exhibit 1001, p. 0032 (emphasis added).

123. Neither the independent claims nor the dependent claims have an upper limit of the amount of astaxanthin esters below 50%, much less below 0.25%. In my opinion, the ‘170 Patent does not teach how to make a krill oil composition containing an astaxanthin esters content greater than about 0.25% w/w krill oil. Thus, none of the claims of the ‘170 Patent can find § 112(a) support in the priority documents or the ‘170 Patent itself.

¹³ 1 microgram/kg = 0.001 mg/kg = .000000001 kg/kg = .0000001%

There is no § 112(a) support for '170 Patent Application's Original claim 1's "trimethylamine in an amount of less than 1 mg/kg of said krill oil".

124. Original independent claim 1¹⁴ of the '170 Patent Application, Exhibit 1063, p. 0420, recites in pertinent part:

krill oil comprising from **3% to 15% ether phospholipids** w/w of said krill oil, **astaxanthin esters in amount of greater than about 100 mg/kg** of said krill oil, and **trimethylamine in an amount of less than 1 mg/kg** of said krill oil.

125. The lack of sufficient Section 112(a) support for the upper ranges of both ether phospholipids and astaxanthin esters were discussed previously.

126. Additionally, original claim 1 further recites krill oil comprising **"trimethylamine in an amount of less than 1 mg/kg [0.0001%] of said krill oil"** (1 mg/kg = .001 g/kg = .000001 kg/kg = 0.0001% w/w).

127. However, neither the '170 Patent nor any of its priority documents enable one of ordinary skill to make a krill oil composition having trimethylamine in an amount of less than 1 mg/kg [0.0001%] of said krill oil. See also Appendix B, below.

¹⁴ Original patent claim 11 also recites the same three components.

128. The '170 Patent does reference trimethylamine, TMA, as follows:

“In some embodiments, the odorless krill oil comprises less than about 10 mg/kg (w/w) trimethylamine.” ‘170 Patent, 5:21-23.

“In some embodiments, the substantially odorless krill oil comprises less than about 10, 5 or 1 milligrams/kilogram trimethylamine. . . .” ‘170 Patent, 13:54-61.

129. However, none of the examples support such low amounts. In the tables and examples of the '170 Patent, TMA is reported in units of “mg N/100 g”. In contrast, the '170 Patent specification and original '170 Patent application claim 1 reports TMA in units of “mg/kg”. Importantly, 1 mg/kg TMA equals 0.0237 mg N/100g TMA.¹⁵ Accordingly, sufficient support for TMA of <1 mg/kg requires a

¹⁵ TMA of <1 mg/kg of said krill oil = <1 (mg TMA)/(kg krill oil) = <0.237 (mg N)/(kg krill oil) = TMA in an amount of <0.0237 (mg N)/(100g krill oil) (based on molecular mass of TMA = 59.11, with the molecular mass of (the single atom of) Nitrogen in TMA = 14.01).

disclosure of TMA in amounts <0.0237 mg N/100g.¹⁶ However, such amounts are not disclosed in any example or table of the '170 Patent.

130. In fact, the lowest amount of TMA reported in any example or table is for a neutral extract having <1 mg N/100g of said krill oil = <42 mg/kg of said krill oil.

Furthermore, a neutral extract would not be expected to have the claimed amount of the polar ether phospholipids. See Table 17C ('170 Patent, 29:26-35). There is no question that <42 mg/kg TMA fails to demonstrate possession or enablement of a krill oil extract having <1 mg/kg TMA.

131. The '170 Patent discloses amounts of TMA for its neutral extracts (**<42 mg/kg**), see above, it also discloses amounts of TMA for its polar extracts (**17,808 mg/kg TMA**), combinations of polar and neutral extracts (**4,599 mg/kg TMA**), combinations of asta and polar extracts (**8,145 mg/kg TMA**), and an EtOH extract (**2,954 mg/kg TMA**). See Appendix B. However, the patent fails to disclose TMA in the claimed amount of **<1 mg/kg** of said krill oil.

¹⁶ A disclosure of TMA of 1 mg N/100g equals 42 mg/kg of TMA (1 mg N/100g = 42 mg/kg).

132. In my opinion, the ‘170 Patent does not disclose, nor teach, how to make a krill oil composition containing TMA in amounts less than 1 mg/kg. Thus, the ‘170 Patent shows neither possession nor enablement of the TMA claim limitation of <1 mg/kg and thus satisfy § 112(a).

MOTIVATION TO COMBINE – OVERVIEW

133. The market for nutraceutical products has been a growing and commercially important market since long before 2007. An important segment of that market is based on the benefits of omega-3 fatty acids and other lipid compounds, including phospholipids, triglycerides and astaxanthin for use in providing a positive impact on health or nutrition. This was true in 2007 and before, and is true now with substantially similar “new” lipid products constantly being brought to the marketplace. See for example, Sampalis I (Exhibit 1012, p. 0004), and Sampalis II (Exhibit 1013). Sampalis II disclosed the many known beneficial health aspects of phospholipids (pp. 15-20, Exhibit 1013, pp. 0017-0022) and associated omega-3s such as DHA and EPA (p. 0036), specifically pointed out the benefits of phosphatidylcholine (p. 0017) and provided a laundry list of reasons why a POSITA seeking a superior source of phospholipids would have been motivated to

extract them from krill. Randolph teaches that astaxanthin may be added to krill oil obtained from *Euphausia superba* to provide a krill oil composition in a capsule with health benefits. Randolph, Exhibit 1011, Abstract, ¶¶ [0007], [0008], [0021], [0024], [0039], [0040], [0043], [0046], [0049], pp. 0001, 0004-0007.

134. The prior art disclosed fish, fish extracts, krill and krill extracts as a starting source for many of these lipid compounds. Moreover, prior art krill and krill extract literature also disclosed that the krill extracts could be combined with other compounds such as phytonutrients to provide additional health or nutritional benefits to the omega-3 lipid compounds. See for example, Randolph (Exhibit 1011).

135. The health benefits of omega-3 fatty acids, particularly in connection with cardiovascular disease, were also well known. See for example Bunea, pp. 421, 426, Exhibit 1020, pp. 0002, 0007. Further, it was also well known to a POSITA that krill lipids contain high levels of phospholipids, and that a high proportion of the omega-3 fatty acids are attached to these phospholipids. Further still, 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 from the usual profile of fish oils. The association between phospholipids and long-chain

omega-3 fatty acids highly facilitates the passage of fatty acid molecules through the intestinal wall, increasing bioavailability and ultimately improving the omega-3:omega-6 fatty acid ratio”. See Bunea, p. 421, Exhibit 1020, p. 0002, col. 1-2.

Krill oil’s phospholipid and ether phospholipid content was of no concern to the POSITA, because krill oil had been found to be safe, effective and without adverse effect on human subjects. Bunea reported no adverse effects in the patients who were administered Neptune Krill Oil, rich in phospholipids, in doses of from 1500 mg/day to 500 mg/day for months. See Bunea, Exhibit 1020. Sampalis I reported that the administration of 2000 mg/day of Neptune Krill Oil over months to human subjects was safe. See, ¶¶ 228-229, below. Catchpole expressly reported that krill oil had levels of phospholipids and ether phospholipids falling within the ranges claimed in the ‘170 Patent. See ¶¶ 202-204, below.

136. Thus, considering the ever increasing commercial market for nutraceuticals, the POSITA would have had a strong motivation or rationale to try and combine various well known lipid processing methods to obtain nutraceutical products containing omega-3 lipids and other beneficial constituents. A POSITA would have been aware of the various krill lipid constituents that had already been successfully extracted. Additionally, it was known that extracts obtained by

supercritical fluid extraction processes using CO₂ were considered to be “more ‘natural’ than extracts produced using other solvents”. Catchpole (Exhibit 1009). Additionally, a POSITA would have been further motivated to differentiate these products by combining not only the products of the various krill lipid processing methods and extracts with each other, but also to add additional beneficial compounds to the krill extracts as was disclosed in the prior art, e.g., phytonutrients, so as to be able to promote and advertise an even broader range of benefits for any final product.

137. Additionally, blending can be used to manage the characteristics of the final krill oil, such as viscosity, which is important in the manufacturing of an encapsulated krill oil product. For example, a POSITA would know that adding a triglyceride krill oil extract to a very high phospholipid, highly viscous krill oil extract, or by extracting less of the triglycerides in a two-step extraction process, would result in a krill oil with a lower viscosity and thus different handling characteristics.

138. Finally, the POSITA already knew, and the prior art krill and krill extracts literature disclosed, the use of capsules and encapsulation as safe and convenient means for administering these beneficial krill extracts and additional compounds.

See for example, Randolph (Exhibit 1011), Sampalis I (Exhibit 1012), and Sampalis II (Exhibit 1013). Krill oil products containing high levels of phospholipids encapsulated in capsules ('gel caps') were also manufactured and commercially available before at least 2006, see for example Exhibit 1070.

139. Importantly, at least as early as 2006, sellers of krill oil were touting its many health benefits based on the components it naturally contains. For example, Krill Bill advertised its krill oil on the Internet in 2006 as "Krill Bill 100% Neptune Krill Oil - the purest combination of phospholipids, antioxidants, omega-3, omega-6, and omega-9 fatty acids 'Get Krilling and Start Living Again'". Exhibit 1070, p. 0001.

140. Krill Bill provided the composition of its krill oil, noting that its krill oil contained many of the krill oil components claimed by the '170 Patent, for example: (i) >40% by weight phospholipids; (ii) >30% by weight phosphatidylcholine; (iii) >30% by weight omega-3 fatty acids; and (iv) >150 mg/100 gm esterified astaxanthin (>1500 mg/kg astaxanthin esters). See Krill Bill Order Form and Specifications, Exhibit 1070, p. 0003.

141. For another example, Antarctica Select krill oil sold by AquaSource Products, Inc. was advertised in 2006 on the Internet as being "high in antioxidants

to help fight the aging process contains unique phospholipids rich source of Omega 3 fatty acids.” Exhibit 1071, p. 0001. Its advertising noted that “Krill oil has a higher content of Omega 3 fatty acids than fish oils and some antioxidants that are not found in other products. It will not cause gastrointestinal difficulty or aftertaste. It is suggested that the mercury content in fish oil may cancel out any benefits derived from it, but krill oil is free of all toxic elements.” Exhibit 1071, p. 0002.

The 2006 Internet advertisement goes on at p. 0003, Exhibit 1071:

Krill is a small shimp-like crustacean. It is the most important zooplankton species associated with the sea ice and plays a key role in the Antarctic food web. Each krill consists of about 15% high quality protein containing vital amino acids and about 3% fat and vitamins. It also supplies minerals such as iron, phosphorus, and calcium. It is very nutritious and a natural source of energy.

Krill are caught in the clear Antarctic Ocean and are processed within one hour and packed onboard specially equipped ships to ensure freshness, taste and superlative quality.

Antarctica Select is guaranteed to contain 100% antarctic krill oil. Krill oil contains high levels of astaxanthin, a powerful antioxidant, as indicated by the deep ruby color. It also contains higher quantities of fatty acids, notably EPA and DHA, than other fish oils.

What are some of the health benefits of Krill Oil?

- May prevent heart disease
- Boosts Immune system
- Increases body energy
- Lowers bad cholesterol
- Increases concentration
- Reduces arthritis symptoms
- Reduces joint pain
- Helps digestive functions (liver, intestines)

Exhibit 1071, p. 0003.

142. POSITAs were aware that ether phospholipids were recognized as offering health benefits through their enhanced delivery of DHA to the brain. See Chen, “Mixtures of and Methods of Use for Polyunsaturated Fatty Acid-Containing Phospholipids and Alkyl Ether Phospholipids Species”. Exhibit 1072. “DHA-containing ether phospholipid species and DHA-containing lysophospholipid species can be delivered smoothly into the brain as carriers of DHA, resulting in the uptake of free DHA after brain phospholipase hydrolyses of the phospholipids species [Ross et al., Characterization of a novel phospholipase A2 activity in human brain. J. Neurochem. 64, 2213 (1995)].” Chen, [0011], p. 2, Exhibit 1072, p. 0006; see also Chen, [0001], [0048], pp. 1, 5, Exhibit 1072, pp. 0005, 0006.

Chen thus claims methods of providing a health benefit using compositions containing ether phospholipids. *See, e.g.*, claims 26-37. Chen, pp. 14-15, Exhibit 1072, pp. 0018-0019. Thus, a POSITA would have recognized that components cited in the claims of the '170 Patent are both beneficial and readily obtainable in view of the prior art. A POSITA would have been motivated to, and at most, simply been combining prior art elements according to known methods to yield predictable results to arrive at the processes and products claimed in the '170 Patent. See discussion below.

PRIOR ART

'388 Pat.Appl.Pub. (Exhibit 1043)

143. The '388 Patent Application Publication, Exhibit 1043 is substantially exactly the same as the '170 Patent. It discloses every claim limitation range and provides examples of amounts for specified components falling within the ranges. See discussion below, the '170 Patent Claim Chart, Appendix C, below and see '170 Patent section above at ¶¶ 36-52.

144. The '388 Patent Application Publication is directed, as is the '170 Patent, to a krill oil composition "characterized by having high amounts of phospholipids, astaxanthin esters and/or omega-3 contents." Both Exhibit 1001 ('170 Patent) and Exhibit 1043 ('388 PatAppPub), Abstract, p. 0001. The patent describes methods for preparing krill oil extracts, their composition, methods for formulating them, and their bioactivity.

145. Exhibit 1043 discloses in the Detailed Description of the Invention that its krill oil products include enriched quantities of ether phospholipids.

[0064] This invention discloses novel krill oil compositions characterized by containing high levels of astaxanthin, phospholipids, included an enriched quantities of ether phospholipids, and omega-3

fatty acids. The krill oils compositions are extracted from krill meal using supercritical fluid extraction (SFE) with a co-solvent modifier. 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. The krill oils are extracted from the krill meal in two stages, in step 1 the neutral fraction is extracted using neat supercritical CO₂ or in combination with 5% ethanol. The neutral fraction consisted mostly of triglycerides and cholesterol. In stage 2, the polar lipids (phospholipids) are extracted by adding at least 20% ethanol to the supercritical CO₂ extraction medium.

‘388 PatAppPub, [0064], p. 5, Exhibit 1043, p. 0025.

146. Exhibit 1043 discloses that its krill oil composition is a blend of lipid factions obtained preferably from *Euphausia superba* krill.

[0034] In some embodiments, the present invention provides methods of making a *Euphausia superba* krill oil composition comprising: contacting *Euphausia superba* with a polar solvent to provide a polar extract comprising phospholipids; contacting *Euphausia superba* with a neutral solvent to provide a neutral extract comprising triglycerides and astaxanthin; combining said polar extract and said neutral extract to provide *Euphausia superba* krill oil 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. In some embodiments, the methods further comprise the step of encapsulating the *Euphausia superba* krill oil. In some embodiments, the present invention provides a *Euphausia superba* krill oil produced by the methods described above.

‘388 PatAppPub, ¶ [0034], p. 3, Exhibit 1043, p. 0023.

147. Exhibit 1043 discloses that its krill oil compositions, which are for oral administration, are preferably in the form of a capsule, and preferably a soft gel capsule.

“B. Compositions Containing Krill Oil

In some embodiments, *the compositions of this invention (such as those described in the preceding sections) are contained in acceptable excipients and/or carriers for oral consumption.* The actual form of the carrier, and thus, the composition itself, is not critical. *The carrier may be a liquid, gel, gelcap, capsule, powder, solid tablet (coated or non-coated), tea, or the like.* The composition is preferably in the form of a tablet or capsule and most preferably in the form of a soft gel capsule.”

‘388 PatAppPub, ¶ [0078], p. 7, Exhibit 1043, p. 0027 (emphasis supplied).

148. Moreover, the krill oil composition comprises a blend of fractions obtained from *Euphausia superba*. “In some embodiments, krill oil composition comprises a blend of lipid fractions obtained from krill. In some preferred embodiments, krill is *Euphausia superba*” ‘388 PatAppPub, ¶ [0018], p. 2, Exhibit 1043, p. 0022 (emphasis supplied).

149. Exhibit 1043 discloses that the main ether phospholipid components of its krill meal are AAPC, LAAPC, and AAPE. “The main polar ether lipids [extracts] of the krill meal are alkylacylphosphatidylcholine (AAPC) at 7-9% of total polar lipids, lyso-alkylacylphosphatidylcholine (LAAPC) at 1% of total polar lipids (TPL) and alkylacylphosphatidyl-ethanolamine (AAPE) at <1% of TPL.” ‘388 PatAppPub, ¶ [0105], p. 19, Exhibit 1043, p. 0039. See Table 22, below.

TABLE 22

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

‘388 PatAppPub, ¶ [0105], p. 19, Exhibit 1043, p. 0039 (emphasis supplied).

150. Table 22 discloses a krill oil extract obtained from Example 7, with the following compositional content:

PC = 75.3% w/w PL;

AAPC = 13% w/w PL;

LAAPC = 0.9% w/w PL;

AAPE = 1.5% w/w PL;

PL = 47.9% w/w Krill oil lipids.

‘388 PatAppPub, ¶ [0105], p. 19, Exhibit 1043, p. 0039.

151. Exhibit 1043 discloses in Table 22 a krill oil extract with an ether phospholipid content of 7.38% w/w krill oil extract. To calculate the percentage of ether phospholipids in the krill oil, we first determine the amount of ether phospholipids as a percentage of phospholipids (PL). Total ether PL is 15.4% (13.0 (AAPC) + 0.9 (LAAPC) + 1.5 (AAPE)) w/w PL. Next, we note the phospholipid content of the krill oil. It is given as = 47.9%. Finally, multiplying the ether phospholipid content of the PL by the PL content of the krill oil results in an ether phospholipid content w/w krill oil of **7.38%** (15.4 x 47.9 = 7.38%). ‘388 PatAppPub, ¶ [0105], p. 19, Exhibit 1043, p. 0039.

152. Exhibit 1043 discloses in Table 22 a krill oil extract with a Phosphatidylcholine (PC) content of 36.1% w/w krill oil lipid extract. PC as a percentage of PL = 75.3% multiply that by percentage of PL in krill oil lipid composition, namely 47.9%, results in a PC content w/w krill oil of 36.1% (75.3 x 47.9). See ‘388 PatAppPub, [0105], Exhibit 1043, p. 0039.

153. Exhibit 1043 also discloses in Table 18B a polar extract of krill with a PC content of 67% w/w lipids, while in Table 19B Exhibit 1043 discloses a 50/50 blend of the polar and neutral extracts with a PC content of 42%. ‘388 PatAppPub, [0100], Exhibit 1043, pp. 0036- 0037. Tables 18B and 19B are copied below. *Id.*

TABLE 18B

Lipid class composition of the extract collected after CO ₂ and 20% ethanol in S1.		
Lipid	Unit	Amount
Triacylglycerol	g/100 g	<0.5
Cholesterol	g/100 g	<0.5
Phosphatidylethanolamine	g/100 g	1.6
Phosphatidylcholine	g/100 g	67
Lyso-phosphatidylcholine	g/100 g	4.4

TABLE 19B

Lipid class composition of the final blended product obtained in Example 4.		
Lipid	Unit	Amount
Triacylglycerol	g/100 g	53
Diacylglycerol	g/100 g	1.3
Free fatty acids	g/100 g	0.5
Cholesterol	g/100 g	0.6
Cholesterol esters	g/100 g	<0.5
Phosphatidylethanolamine	g/100 g	<1
Phosphatidylcholine	g/100 g	42
Lyso-phosphatidylcholine	g/100 g	5.9

154. Exhibit 1043 discloses in Table 22 a krill oil extract with a non-ether phospholipid content of 40.5% w/w krill oil extract. First, the non-ether phospholipids as a percentage of phospholipids = 84.6% (75.3 (PC) + 0.4 (1LPC) + 2.9 (2LPC) + 3.4 (PE) + 2.1 (CL) + 0.5 (LPE)). Then, the non-ether PL content as a percentage of krill oil lipids is the % PL in krill oil composition = 47.9% multiplied by the % non-ether phospholipids in krill oil composition = 84.6 x 47.9 = 40.5%.

155. Exhibit 1043 discloses in Table 16 krill oil with an astaxanthin esters content of 580 mg/kg.

TABLE 16

Compositional data for the novel krill oil composition
obtained and NKO krill oil.

Compounds	Neptune KO	Ethanol extracted KO	Polar KO	Neutral KO
Astaxanthin esters	472 mg/kg	117 mg/kg	580 mg/kg	98 mg/kg
Astaxanthin free	11 mg/kg	<1 mg/kg	<1 mg/kg	<1 mg/kg
Total cholesterol	1 g/100 g	12 g/100 g	<0.5 g/100 g	5.7 g/100 g

‘388 PatAppPub, ¶ [0099], p. 16, Exhibit 1043, p. 0036. (emphasis supplied).

Other tables also disclose amounts for astaxanthin esters in krill oil compositions greater than 100 mg/kg. Table 21 of the ‘388 Pat. App. Pub. discloses an astaxanthin level obtained in the krill oil from Example 7 of 2091 mg/kg. Table 20C of the ‘388 Pat. App. Pub. discloses an astaxanthin esters level obtained in the krill oil from Example 5 of 1302 mg/kg. See, ‘388 PatAppPub, Tables 22 and 20C, [0101], [0105], pp. 18-19, Exhibit 1043, pp. 0038 -0039.

156. Exhibit 1043 discloses in Table 20B a krill oil extract with a triglyceride (triacylglycerol) content of 41% w/w krill oil extract and a PC content of 51% w/w krill oil (plus a lyso-phosphatidylcholine content of <0.5%).

TABLE 20B

Lipid class composition of the final blended product obtained in Example 5.		
Lipid	Unit	Amount
Triacylglycerol	g/100 g	41
Diacylglycerol	g/100 g	0.8
Free fatty acids	g/100 g	1.2
Cholesterol	g/100 g	0.4
Cholesterol esters	g/100 g	0.3
Phosphatidylethanolamine	g/100 g	0.6
Phosphatidylcholine	g/100 g	51
Lyso-phosphatidylcholine	g/100 g	<0.5
Total polar lipids	g/100 g	52.4
Total neutral lipids	g/100 g	43.6

‘388 PatAppPub, ¶ [0102], p. 38, Exhibit 1043, p. 0038 (emphasis supplied).

157. Exhibit 1043 discloses in Table 21 a krill oil extract with a triglycerides content 25.9% w/w krill oil extract.

TABLE 21

Analysis of the krill oil obtained using supercritical fluid extraction.	
Parameter	Value
Ethanol	1.11% w/w
Water Content	2.98% w/w
C20:5 n-3 (EPA)	19.9
C22:6 n-3 (DHA)	11.3
Total Omega 3	35.7
Total Omega 6	3.0
Total Phospholipids	50.55 wt %
Ratio Omega3-PL/Total Omega 3	77.6% w/w
Ratio EPA-PL/Total EPA	84.4% w/w
Ratio DHA-PL/Total DHA	74.7% w/w
Triglycerides	25.9 g/100 g
Astaxanthin	2091 mg/kg
Peroxide Value	<0.1

‘388 PatAppPub, ¶ [0103], p. 38, Exhibit 1043, p. 0038 (emphasis supplied).

158. Exhibit 1043 discloses that in some embodiments its krill oil “compositions comprise from about 20% to 35%, preferably from about 25% to 35%, omega-3 fatty acids as a percentage of total fatty acids in the composition . . .”. ‘388 PatAppPub, [0072], p. 6, Exhibit 1043, p. 0026.

159. Exhibit 1043 discloses an odorless krill oil. “In some embodiments, the present invention provides [*sic*] composition comprising odorless krill oil.” ‘388 PatAppPub, ¶ [0028], p. 3, Exhibit 1043, p. 0023.

160. Exhibit 1043 also discloses a substantially odorless krill oil.

[0076] In some embodiments, the present invention provides krill oil that is substantially odorless. By substantially odorless it is meant that the krill oil lacks an appreciable odor as determined by a test panel. In some embodiments, the substantially odorless krill oil comprises less than about 10, 5 or 1 milligrams/kilogram trimethylamine. In some preferred embodiments, the odorless krill oil is produced by first subjecting krill material to supercritical fluid extraction with neat carbon dioxide to remove odor causing compounds such as trimethylamine, followed by extraction with carbon dioxide with a polar entrainer such as ethanol.

‘388 PatAppPub, ¶ [0076], p. 7, Exhibit 1043, p. 0027.

161. Exhibit 1043 discloses that its krill oil compositions can contain phytonutrients.

In still further embodiments, the compositions comprise at least one phytonutrient (e.g., soy isoflavonoids, oligomeric proanthcyanidins, indol 3 carbinol, sulforaphane, fibrous ligands, plant phytosterols, ferulic acid, anthocyanocides, triterpenes, omega 3/6 fatty acids, conjugated fatty acids such as conjugated linoleic acid and conjugated linolenic acid, polyacetylene, quinones, terpenes, catechins, gallates, and quercetin). Sources of plant phytonutrients include, but are not limited to, soy lecithin, soy isoflavones, brown rice germ, royal jelly, bee propolis, acerola berry juice powder, Japanese green tea, grape seed extract, grape skin extract, carrot juice, bilberry, flaxseed meal, bee pollen, ginkgo biloba, primrose (evening primrose oil), red clover, burdock root, dandelion, parsley, rose hips, milk thistle, ginger, Siberian ginseng, rosemary, curcumin, garlic, lycopene, grapefruit seed extract, spinach, and broccoli.

‘388 PatAppPub, ¶ [0083], p. 8, Exhibit 1043, p. 0028.

162. Exhibit 1043 also discloses embodiments of the invention with less than about 0.45% arachidonic acid (w/w). “In some embodiments, the composition comprises less than about 0.45% arachidonic acid (w/w).” ‘388 PatAppPub, ¶ [0020], p. 2, Exhibit 1043, p. 0022.

Bruheim (Exhibit 1085)

163. Bruheim discloses “a method for processing crustaceans (i.e., for example, krill) rich in lipids to produce low fluoride compositions comprising phospholipids, proteinaceous nutrients and oil (i.e., for example, neutral lipids and/or triglycerides).” Bruheim [0001], Exhibit 1085, p. 0006.

164. Bruheim focuses on Antarctic Krill, *Euphausia superba*. Noting that “these small crustaceans, which live in the cold waters around the Antarctic, are interesting as a source for proteins, lipids such as phospholipids, poly-unsaturated fatty acids etc., chitin/chitosan, astaxanthin and other carotenoids, enzymes and other materials.” Bruheim [0002], Exhibit 1085, p. 0006.

165. Bruheim discloses that krill oil is a valuable krill product. “The krill oil is one the valuable products made from krills. It contains inter alia phospholipids, triglycerides and carotenoid astaxanthin while being essentially free of protein, carbohydrates and minerals.” Bruheim [0006], Exhibit 1085, p. 0006.

166. Bruheim discloses certain krill oil compositions having 40% to 50% phospholipids.

In one embodiment, the present invention contemplates an oil composition comprising approximately 400-500 grams/Kg [40%-50%] phospholipids, approximately 200-260 grams/Kg [20%-26%] Omega-

3 fatty acids, less than 0.5 mg/Kg fluoride, approximately 15 grams/Kg lysophosphatidic acid, and less than approximately 8 grams/Kg free fatty acids.

Bruheim, [0010], Exhibit 1085, p. 0006.

167. Bruheim in Example I discusses the production of a low fluoride krill oil in great detail. Bruheim's Example I krill oil is extracted from krill meal using CO₂ as a solvent and ethanol as a polar co-solvent.

EXAMPLE I

Production of Low Fluoride Krill Oil

5 kg batches of PPC feed material in granular faun [sic] was processed using CO₂ as solvent and azeotropic food grade ethanol as co-solvent, the weight of the ethanol being 23% of the weight of CO₂. The plant was pre-pressurised to operating pressure with CO₂ only, and ethanol was added when CO₂ circulation started. Solvent to feed material ratio was 25:1 or greater and co-solvent to feed material ratio was 5:1. Runs were carried out under two extraction conditions; 300 bar at 60° C., and 177 bar at 40° C. See, Table II.

TABLE II

Extraction conditions		
	Run 1	Run 2
Feed Mass (g, as received)	5000.5	5000.9
Extraction pressure (bar)	300	177
Extraction temperature (° C.)	60	33
First separator pressure (bar)	90	90
First separator temperature (° C.)	41	41
Second separator pressure (bar)	48-50	48-50
Second separator temperature (° C.)	39	39
CO ₂ used with ethanol co-solvent (kg)	132.6	134.9
Additional CO ₂ at end of run (kg)	33.1	44.5
Total ethanol used (kg)	31.65	32.19

The extracted material was passed through two separation vessels in series, held at 90 bar and 45-50 bar respectively. Material collected from both separators was pooled together for evaporation of ethanol.

Bruheim, Example I, [0108], Exhibit 1085, p. 0015.

168. Bruheim Table IV discloses the phospholipid profiles of its lipid extracts.

Phospholipid profiles of the lipid extracts are given in Table IV. First column shows the phospholipid profile of the feed material (PPC or ‘Olymeg®’) and the last two columns show the phospholipid profiles of the extracted PPC residue sampled from top and bottom of the extraction column. In the lipid extracts the major phospholipid is phosphatidyl choline (PC) with proportion ranging from 72.7% to 80.4% including alkyl acyl phosphatidyl choline (AAPC) and lyso forms of the PCs (LPC and LAAPC). Smaller amounts of phosphatidyl ethanolamine (PE) are present in the feed material (5.3%) and in the

lipid extracts (3.5-4.5%). Alkyl acyl and lyso forms of PE (AAPE, LPE) are also present in the feed material and lipid extracts. Phosphatidyl inositol (PI) and phosphatidyl serine are present in the feed material (PPC), but because they are poorly soluble in ethanol, these phospholipids are concentrated in the PPC residue.

Bruheim, [0111], Exhibit 1085, p. 0016.

169. In connection with the phospholipid profiles of the lipid extracts obtained in Example I, Table IV provides the ether phospholipid profile as well. These ether phospholipids include alkyl acyl phosphatidylcholine (AAPC) and its lyso form (LAAPC) and alkyl acyl phosphatidyl ethanolamine (AAPE).

TABLE IV

Phospholipid Profiles Of Lipid Extracts (run 1)									
Sample	Olymeg 10071199	Extract 1	Extract 2	Extract 3	Extract 4	Extract 5	Extract 6	Residue (Top)	Residue (Bottom)
Wt % of total PL									
PC	70.1	80.4	77.1	76.9	75.9	73.5	72.7	40.2	32.5
AAPC	8.5	8.0	9.0	9.8	9.1	10.6	9.0	7.5	7.8
PI	1.8				0.7	0.6	0.6	6.2	10.1
PS	1.0							5.5	8.1
LPC	6.9	4.6	5.6	5.7	6.0	6.8	7.5	13.4	8.9
LAAPC	1.7	1.2	1.2	1.0	1.3	1.2	1.4	3.2	2.6
PE	5.3	3.6	4.0	3.5	3.8	3.5	4.5	9.4	9.4
EPLAS	0.6	0.0	0.5	0.5	0.5	0.5	0.3	1.0	2.2
AAPE	2.0	1.1	1.5	1.3	1.6	1.6	2.0	4.4	4.9
LPS								0.7	1.9
CL/NAPE	1.0	0.9	0.7	0.8	0.8	1.2	1.6	4.2	5.7
LPE	0.8	0.3	0.4	0.4	0.4	0.4	0.4	3.2	4.5
Total PL	40.88							81.46	80.96
(wt % of lipid)									
Lipid yield	44.7							4.9	5.9
(wt %)									
Total PL	18.3	26.68	46.03	57.94	71.34	76.13	78.50	4.0	4.8
(wt % of sample)									
Ether PL w/w KO		2.7%	5.4%	7.0%	8.6%	10.2%	9.7%		

Table IV (Bruheim, p. 11, Exhibit 1085, p. 0016 (The row after the lowest horizontal line and beginning with “Ether PL w/w KO” was added.).

170. Thus, Bruheim discloses that, for example with respect to Extract 2, the phospholipid (“PL”) portion of the krill oil extract had 77.1% w/w phosphatidylcholine (“PC”). However, the total PL by weight of the Extract 2 sample was 46.03%. Thus, the phosphatidylcholine content of Extract 2 is 35.5% (77.1% PC/PL x 46.03% PL/Total Lipids) w/w krill oil. In a like manner, the phosphatidylcholine content of Extract 3 is 44.6% (76.9% PC/PL x 57.94% PL/Total Lipids). See Bruheim, Table IV, p. 11, Exhibit 1085, p. 0016. Table IV is copied above.

171. Thus, Bruheim also discloses that, for example, with respect to Extract 2, the phospholipid portion of the krill oil extract has 11.7% w/w ether phospholipids.¹⁷ Again, for Extract 2, the total PL by weight of the sample was 46.03%. Thus, the ether phospholipid content of Extract 2 is 5.4% (11.7 Ether PL/PL x 46.03% PL/Total Lipids) w/w krill oil. In the same manner, the ether phospholipid content of Extract 3 is 7.0% (12.1% Ether PL/PL x 57.94% PL/Total Lipids) w/w krill oil. See Bruheim, Table IV, p. 11, Exhibit 1085, p. 0016. Table IV is copied above. As

¹⁷ Ether PL = 9.0% (AAPC) + 1.2% (LAAPC) + 1.5% (AAPE) = 11.7% w/w total PL.

noted under the copied Table IV above, the ether phospholipid content for these and the remaining extracts are given in the added text provided in the row after the lowest horizontal line and beginning with “Ether PL w/w KO” in the copy of Table IV above.

172. Bruheim also discloses that, for example, with respect to Extract 2, the phospholipid portion of the krill oil extract has 88.3% w/w non-ether phospholipids.¹⁸ Again, for Extract 2, the total PL by weight of the sample was 46.03%. Thus, the non-ether phospholipid content of Extract 2 is 40.6% (88.3 x 46.03%) w/w krill oil. See Bruheim, Table IV, p. 11, Exhibit 1085, p. 0016. Table IV is copied above.

173. Bruheim summarizes additional information for its extracts in Table V. Noting that triglycerides ranged between 40.3% and 42.1% w/w krill oil lipid extracts. While polar lipids were present in amounts ranging from 46.9% to 50.2% w/w lipid extracts, and astaxanthins were present at a 0.05% w/w, or 500 mg/kg lipid extracts.

¹⁸ Non-ether PL = 77.1% (PC) + 5.6% (LPC) + 4.0 (PE) + 0.5 (EPLAS) + 0.7% (CL/NAPE) + 0.4 (LPE) = 88.3% w/w total PL.

The results presented in Table V (below) show that no free fatty acids (FFAs) are present in the lipid extracts. Sterols are present at levels of 2% or less in the extract. Triglycerides (TAGs) were measured at around 40 wt % and phospholipids (e.g., polar lipids) at around 50% in the extracts. See, Table V.

TABLE V

Main Components Of The Lipid Extracts						
	TAG	Polar Lipid	Sterols	FFA	Astaxanthin	Total Lipid
Run 1	40.3	46.9	1.9	ND	0.05	92.2
Run 2	42.1	50.2	2	ND	0.05	95.3

Bruheim, [0111], and Table V, Exhibit 1085, p. 0017.

174. Bruheim discloses that its krill oil has astaxanthin at levels varying from 50 mg/kg to 1500 mg/kg.¹⁹ “Krill oil has typically a strong red colour arising from the carotenoid astaxanthin present in the oil at levels varying from 50 ppm to 1500 ppm.” Bruheim, [0120], Exhibit 1085, p. 0017.

¹⁹ 1 ppm = 1 mg/kg.

Neptune's GRAS (GRN 242, Exhibit 1075)

175. Exhibit 1075 is a GRAS Notice exemption claim (GRN 242), submitted on behalf of Neptune Technologies & Bioresources (“Neptune”) to the U.S. Food and Drug Administration (“FDA”), for “High Phospholipid Krill Oil” in January 2008. The Neptune GRAS Agency Response Letter to GRN 000242 states that “[b]ased on the information provided by Neptune, and other information available to FDA, the agency has no questions at this time regarding Neptune's conclusion that krill oil is GRAS” Exhibit 1091, p. 0004.

176. Neptune claims its high phospholipid oil is Generally Recognized as Safe (“GRAS”) for human consumption. Neptune's GRAS, Exhibit 1075, p. 0003.

177. Neptune Krill Oil (NKO) is a whole lipid extract derived from *Euphasia superba*, a marine organism harvested in from Antarctic waters, that is intended for use as a dietary ingredient as a source of phospholipid-bound omega-3 fatty acids. The major components of NKO are triglycerides and phospholipids.

NKO™ is refined krill oil which is derived from the marine organism, *Euphasia superba*, which is harvested from Antarctic waters. Krill is recognized as a vital part of the marine food chain for baleen whales, mantas, whale sharks, crabeater seals and other seals, and a few seabird species.

* * * *

NKO™ is a whole lipid extract and is an opaque reddish oil with a seafood odor. The major components of NKO™ are triglycerides and phospholipids which are rich in eicosapentaenoic acid (EPA, C20:5 n-3 fatty acid) and docosahexaenoic acid (DHA, C22:6 n-3 fatty acid). NKO™ is an oil intended for use as a dietary ingredient as a source of omega-3 fatty acids, which as noted are found in NKO™ in their phospholipid form. No processing aids or additives are included in the final NKO™ product due to naturally occurring antioxidants that aid in NKO™'s preservation.

Neptune's GRAS, Chemistry and Manufacture of NKO™, Exhibit 1075, p. 0005.

178. Table 2, Neptune's GRAS, is entitled Batch Analysis of Three Lots of NKO™ and provides information on, *inter alia*, the amounts of total phospholipids and esterified astaxanthin (astaxanthin esters) present in 3 batches of the NKO product. Total phospholipids for the commercial NKO product range from 43.8 g/100g to 47.3 g/100g or from 43.8% to 47.3% w/w of the NKO krill oil product. Astaxanthin esters range from 154.0 mg/100g to 162.6 mg/100g or from 1540 mg/kg to 1626 mg/kg.

TABLE 2. BATCH ANALYSES OF THREE LOTS OF NKO™
Assessing the Compositional Guidelines for NKO™

Requirement	Specifications	Lot Number		
		060116	060519	060224
Total Phospholipids	≥ 40.0 g/100g	47.3 g/100 g	44.8 g/100 g	43.8 g/100 g
Esterified Astaxanthin	≥ 150.0 mg/100 g	162.6 mg/100 g	160.7 mg/100 g	154.0 mg/100 g

Neptune's GRAS, Table 2, Exhibit 1075, p. 0010 (this is a partial copy of the table).

179. Table 9, Neptune's GRAS, is entitled Fatty Acid Content of NKO™ and provides information on, *inter alia*, the amount of arachidonic fatty acid (C20:4 n-6) present in 4 lots of the NKO product. The amount of arachidonic acid ranged from 0.24% to 0.43% w/w total lipid, with a mean arachidonic acid content of 0.33% w/w total lipid.

TABLE 9. FATTY ACID CONTENT OF NKO™

Fatty Acid	Fatty Acid Content Of NKO™ Lots (%of total lipid)				Mean Fatty Acid Content (Standard Deviation)
	050117	050201	050223	050909	
C20 :4 n-6 (arachidonic)	0.37	0.24	0.37	0.43	0.33 (0.10)

Neptune's GRAS, Table 9, Exhibit 1075, p. 0016 (this is a partial copy of the table).

180. Neptune discloses that its NKO krill oil product is sold as a dietary supplement in 300 and 500 mg capsules, and that softgels containing its NKO krill oil, had been on the market in North America since 2002 and based on the ingestion of 120,000 kg of NKO by humans is safe. Thus, the NKO krill oil product is suitable for oral administration. Finally, note the interchangeability of "capsule" with "softgel" and with "softgel capsule" in the material quoted below.

Neptune submitted a notification to FDA in 2002 for use of krill oil in dietary supplements. FDA did not object to this use (FDA, 2002a). The *supplement is sold in 300 and 500 mg capsules* with a recommended dose of 1 - 2 capsules per day.

Softgels containing the NKO™ have been available as dietary supplements in North America for several years; in Canada and the US, NKO™ has been commercially available since October of 2002, and in Japan, Korea, Singapore, and Hong Kong, NKO™ has been available since December of 2004. A total of 120,000 kg of Neptune krill oil, which is equivalent to 60,000,000 [sic] individual 500 mg *softgel capsules*, has been ingested by consumers. Throughout this time no serious adverse effects have been reported.

Neptune's GRAS, Current Usage of NKO™ in the Diet, Exhibit 1075, p. 0019 (emphasis added).

Sampalis III (Exhibit 1064)

181. Sampalis III is a PCT publication, entitled “New deodorization method and organoleptic improvement of marine oil extracts”, WO 2009/132463 A1, published November 5, 2009. The Sampalis III invention relates to a process for deodorizing fish or marine oil for use in the food industry. Sampalis III, [0001], Exhibit 1064, p. 0001. Sampalis III discloses that its marine oil is a lipid extract that may be extracted from a variety of marine or aquatic biomass sources. Noting further that, preferred sources of the oil extract are crustaceans, in particular, zooplankton and the preferred zooplankton is krill. Sampalis III, [0020] – [0023], Exhibit 1064, pp. 0005-0006.

[0023] 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.

182. Sampalis III then discusses, inter alia, the process by which undesirable odors are removed or further removed from the marine oils, including krill oil. The process involves one or more washing steps to “completely eliminate or remove DMS [dimethyl-sulfide] and odor-causing amines such as trimethylamine (TMA)” from the krill oil extract.

[0027] Undesirable odours and taste of marine/krill oils can be removed or further removed by washing with HCl, preferably dilute 0.1 N HCl, and/or NaCl preferably from 0.1-1M, (more preferably at 0.1mM or 0.5mM or 0.75mM), and if desired, followed by activated carbon treatment and vacuum distillation. The wash can also be followed by a second wash with water, preferably distilled water. The wash is preferably done with one part NaCl (10 mM – 1000 mM and preferred washing with 100mM or 500mM, or 750mM and further preferred with 100mM) for one part oil followed by a second wash with one or two parts water for one part oil. The NaCl or HCl wash can be replaced by a run down of the extracted oil on Ammonia Removing Ion Exchange Resin. These additional steps completely eliminate or remove DMS and odor-causing amines such as trimethylamine (TMA) from the extract. No appreciable weight loss or color loss occurs in the oil following this treatment. After the deodorization process, a slightly fruity odour appears indicating a distinct decrease in the extract odour and its improvement in palatability. Appearance of a slightly fruity odour originates from the reduced carbonyl and TMA like compounds in the

oil. Table 2 describes the improved stability indexes of the marine extract after complete treatment (inhibition of autolysis and elimination of volatiles and amines.

Samplis III, [0027], Exhibit 1064, pp. 0007.

183. Sampalis III starts off its description of its deodorization processes as follows:

[0076] The data reported herein detail the analytical chemistry documentation of the deodorization processing on krill oil. Comparison of the aroma and flavor profile of krill oil without treatment and after various deodorization strategies and accelerated aging was made and designed to predict a one-year shelf life at room temperature.

Samplis III, [0076], Exhibit 1064, pp. 0021.

Sampalis III provides the following description of its analysis of the krill oil before and after deodorization:

[0083] The volatile and semi-volatile aroma/flavor profiles of the KO samples as measured by Headspace-CC[sic GC]-MS and Purge & Trap-Thermal Desorption- GC-MS are presented in Tables 5 - 14. Each Table lists the MS Scan # of the peaks detected, the peak area integration values, the peak assignment and the concentration of each component calculated in parts per million on a weight to weight basis

(PPM w/w). The volatile aroma compounds (compounds w/ boiling points < toluene) are reported in the Headspace data in Tables 5, 7, 9, 11 and 12. The semi-volatiles flavor compounds (compounds w/ boiling points > toluene) are reported in the P&T-TD-GC-MS data in Tables 5, 7, 9, 11 and 13.

Samplis III, [0083], Exhibit 1064, pp. 0024.

184. Sampalis III notes the foul, fishy smell of pre-treated krill oil due to the presence of TMA.

[0084] Most noteworthy in the volatile aroma profile of KO before treatment (See Table 5) is the presence of trimethylamine (TMA). TMA is very strongly fishy smell and this and several of the other amines found at lesser concentration are primarily responsible for the fishy odor of the sample.

Samplis III, [0084], Exhibit 1064, pp. 0025.

185. The amount of TMA is disclosed in the Headspace GC-MS Volatile Odor Profiles given in Tables 5, 7, 9, 11, and 13. Sampalis III, pp. 0027-0034.

Table 5 (Krill oil without treatment: TMA = 84.67 ppm (mg/kg));

Table 7 (acid washed and distilled krill oil: TMA = 0 (absent, not reported in the table);

Table 9 (krill oil treated with ammonia, etc.: TMA = 18.85 ppm (mg/kg));

Table 11 (krill oil treated with AMMO Chips, etc.: TMA = 93.36 ppm (mg/kg));

Table 13 (krill oil acid washed, etc.: TMA = 0 (absent, not reported in the table).

186. Thus, Sampalis III discloses that at least two of its methods for deodorizing krill oil, shown in Tables 7 and 13, provided a krill oil with a zero (ie not measured) amount of TMA. This observation is supported, in part, when Sampalis III notes that the Table 13 process completely removed the TMA (trimethylamine) and as well as other odor causing agents, N,N-dimethylformamide (DMF) and N-methylpyrrolidinone (NMP) present in Tables 5 and 6.

In any event, deodorization processing by washing with dilute HCl (See Tables 5, 6, 12 & 13) completely removes DFM [sic], NMP and odor-causing amines such as TMA from the samples.

Sampalis III, [0086], Exhibit 1064, pp. 0025 (emphasis supplied).

Bottino I (Exhibit 1007)

187. Bottino I discusses how the “study of krill has become intensive in recent times, perhaps as a result of its potential importance as food” and discloses a study of the fatty acids of phytoplankton and krill including *Euphausia Superba*. *E. superba* is the better known species found in the Southern Oceans and has been considered almost “a synonym for krill”. See Bottino I, p.197, 1st col, Exhibit 1007, p. 0001. The krill was collected from 3 locations in the Ross Sea, Antarctica. The lipids were extracted immediately after capture using a chloroform:methanol 2:1 v/v mixture utilizing the methods of Folch *et al.*, 1957. (Bottino I, p. 197, 2nd col., and p. 198, 2nd col., Exhibit 1007, pp. 0001 & 0002) . In particular, Bottino I states “[of] all samples of *Euphausia superba* studied so far, only those [krill samples] of the present study were extracted immediately after capture.” See Bottino I, page 197, 2nd col., Exhibit 1007, p. 0001.

188. Bottino I, Tables 1 and 3 present the fatty acids of the Antarctic krill (*Euphausia superba*) as a weight percentage of total fatty acids. (pp. 198, 200-201, Exhibit 1007, pp. 0002, 0004, 0005). The fatty acids were analyzed using chromatography (Bottino I, p. 197, 2nd col., Exhibit 1007, p. 0001). Table 1 shows

that the omega-3 fatty acids²⁰ constitute 30.5% (station 8 whole krill), 26.8% (station 9 whole krill), and 25.0% (station 11 whole krill) of total fatty acids.²¹ Bottino I, p. 198, Exhibit 1007, p. 0002, Table 3 shows that omega-3 fatty acids²² constitute 28.6 % of total fatty acids.²³ Table 3 further shows that arachadonic acid²⁴ [20:4 (n-6)] constitutes 0.4% of total fatty acids. Bottino I, pp. 200-201, Exhibit 1007, pp. 0004-0005.

²⁰ Omega-3 fatty acids shown in Table 1 include: 18:2(n-3), 18:3(n-3), 18:4(n-3), 20:5(n-3), and 22:6(n-3).

²¹ Table 1 only shows those fatty acids that are present at a level of 1% or more.

²² Omega-3 fatty acids shown in Table 3 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).

²³ The values in Table 3 represent the average from data collected at the three stations described in Table 1.

²⁴ Arachadonic acid and arachidonic acid, are different spellings of the same fatty acid, also known as 20:4 (n-6), an omega 6 fatty acid. Therefore, “arachadonic acid” is the same as “arachadonic acid, arachidonic acid and/or 20:4 (n-6)”.

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

189. Thus Bottino I discloses krill oil within 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.

190. Since fatty acids constitute only a limited percentage of total lipids, the amounts of arachadonic acid recorded by Bottino I would be even less than 0.4% when calculated as a percentage of total lipids, and substantially less than 0.45% w/w.

Catchpole (Exhibit 1009)

191. Catchpole and Tallon filed a PCT in April 2007 on the extraction and fractionation of phospholipids from various feedstocks using supercritical CO₂ with a polar co-solvent. The polar co-solvent is a polar entrainer. It was noted that supercritical fluid extraction processes using CO₂ were becoming increasingly popular because of processing and consumer benefits. For example, CO₂ can be easily removed from the final product by reducing the pressure, whereupon CO₂ reverts to a gaseous state giving a completely solvent free product. The extract is considered to be “more ‘natural’ than extracts produced using other solvents”. See Catchpole, p. 2, lines 18-22, Exhibit 1009, p. 0002.

192. Catchpole also 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. See Catchpole, p. 3, lines 27-29, Exhibit 1009, p. 0003.

193. Catchpole further discloses that the described compositions and methods may be employed in a number of applications including infant formulas, brain health, sports nutrition and dermatological compositions. Many of these

applications by their nature include oral administration. See Catchpole, p. 25, lines 9-13, Exhibit 1009, p. 0025.

194. Furthermore, Catchpole notes that phospholipids have been implicated in conferring a number of health benefits including brain health, skin health, eczema treatment, anti-infection, wound healing, gut microbiota modifications, anti-cancer activity, alleviation of arthritis, improvement of cardiovascular health, and treatment of metabolic syndromes. Catchpole, p. 1, line 11 to p. 2, line 2, see also p. 25, lines 9-13, Exhibit 1009, pp. 0001, 0002, 0025.

195. The polar co-solvent comprises at least 10 % of the CO₂ by mass and preferably consists of a C₁ – C₃ mono-hydric alcohol (most preferably ethanol) optionally containing a small amount of water (0 – 40 %) (see, for example, Catchpole, p. 4, lines 11-15, Exhibit 1009, p. 0004). The solvent mixture of CO₂ and polar co-solvent (polar entrainer) constitutes a polar solvent. The feedstocks containing phospholipids included dairy and marine biomasses, and krill. See Catchpole, p. 7, lines 11-14, Exhibit 1009, p. 0007.

196. The invention of Catchpole is the description of means for fractionating a mixture of phospholipids, based on their differential solubility in supercritical CO₂ + polar co-solvent. The most soluble phospholipids are extracted into the mixed

solvent, whilst the least soluble phospholipids are concentrated in the residue.

Dried krill powder in “Example 18: Fractionation of Krill Lipids” of Catchpole (p. 24, Exhibit 1009, p. 0024) was extracted with supercritical CO₂ to firstly extract neutral lipids (mainly triglycerides) and then with a CO₂ + ethanol mixture, ‘the residual powder was then extracted with CO₂ and absolute ethanol, using a mass ratio of ethanol to CO₂ of 11 %’, to produce a second extract labelled ‘Extract 2’, and a residual un-extracted fraction labelled ‘Residue’. Catchpole, p. 24, lines 3-19, Exhibit 1009, p. 0024.

197. The krill powder was a freeze-dried powder (Catchpole, p. 24, lines 1-4, Exhibit 1009, p. 0024).

198. Extract and residue fractions were analyzed for phospholipid content and profiled by ³¹P-NMR. Phospholipids that were able to be measured using this technique included “phosphatidylchoine (PC), phosphatidylinositol (PI), phosphatidylethanolamine (PE), plasmalogens (PL), phosphonolipids (PP), alkylacylphospholipids (ALP), sphingomyelin (SM), ceramide aminoethylphosphonate (CAEP), phosphatidyl-serine (PS), and cardiolipin (CL). Catchpole, p. 14, lines 7-11, Exhibit 1009, p. 0014.

199. The composition of the resulting krill oil from the second extraction using CO₂ + ethanol mixture (Extract 2) is disclosed in Table 16 (Exhibit 1009, p. 24) as containing 4.6% AAPC (an ether phospholipid), 0.2% AAPE (an ether phospholipid), 39.8% PC, 0.3% PE and 0.2% CL giving a total phospholipid content of 45.1%, a phosphatidylcholine (PC) level of 39.8%, and an ether phospholipid (AAPC+AAPE) content of 4.8%.

Table 16

	Yield % of feed	Composition, %							Other compounds
		PC	PI	PS	PE	CL	AAPC	AAPE	
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

Catchpole, “Example 18: Fractionation of krill lipids”, ll. 1-16 & Table 16, p. 24, Exhibit 1009, p. 0024. By far the most predominant phospholipid is phosphatidylcholine, amounting to 80% of the phospholipids in Extract 2 krill oil ($PC/(PC + PE + AAPC + AAPE + CL) = 39.8\%/45.1\% = 39.8\%/(39.8 + 0.3 + 4.6 + 0.2 + 0.2)$). Catchpole also discloses 4.8% (or about 5%) as the amount of ether phospholipids by weight Extract 2 polar krill oil (Total Ether PL = AAPC (4.6%) + AAPE (0.2%) = 4.8% = 5%).

200. Catchpole also discloses that 10.6%, which can be rounded to 11%, is the proportion of ether phospholipids (Ether PL) content to total phospholipids (PL) content in the krill oil extract:²⁵

Total PL = PC (39.8) + AAPC (4.6) + PE (0.3) + AAPE (0.2) + CL (0.2) = 45.1%;

Total Ether PL = AAPC (4.6) + AAPE (0.2) = 4.8%;

Total Ether PL/Total PL = 4.8/45.1 = 10.6% = 11%.

Catchpole, "Example 18: Fractionation of krill lipids", ll. 1-16 & Table 16, p. 24, Exhibit 1009, p. 0024.

201. Thus, Catchpole discloses in Extract 2 alone (a) a polar krill oil obtained by polar solvent extraction, (b) the polar krill oil having an ether phospholipid content of 4.8% or about 5% by weight of the krill oil, (c) the polar krill oil containing about 30% to 60% (45.1%) total phospholipids by weight of krill oil, (d) the polar

²⁵ The 10.6% ratio of ether phospholipids to total phospholipids in krill oil agrees nicely with the 9.9% ratio of ether phospholipids to total phospholipids in the krill meal/powder (the Feed). Total PL in Feed = 6.6% (PC) + 0.4% (PE) + 0.1% (CL) = 7.1% Total PL. Total Ether PL = 0.6% (AAPC) + 0.1% (AAPE) = 0.7%. Total Ether PL/Total PL = 0.7/7.1 = 9.9%.

krill oil containing about 39.8% or about 40% phosphatidylcholine by weight of krill oil, and (e) the polar krill oil containing 40.3% non-ether phospholipids (45.1% - 4.8%) by weight. The composition of the remaining 53.7% of Extract 2 is not disclosed but one skilled in the art would have expected the remaining components to comprise mainly triglycerides, and smaller amounts of free fatty acids, partial glycerides and other minor lipid and lipid-soluble compounds – with the amount of triglycerides likely to be less than 50% by weight of krill oil.

Randolph (Exhibit 1011)

202. Randolph describes compositions for modulating cytokines to regulate an inflammatory or immunomodulatory response which include at least one of rosehips, grape seed extract, resveratrol [grape skin extract], **krill oil**, at least one type of xanthophyll (e.g., **astaxanthin**) and ferulic acid. “Based on the cytokine modulation and cytokine response inhibition of the composition, it can be used to regulate an immunomodulatory and/or inflammatory response, and subsequently treat diseases and/or abnormal conditions associated with inflammatory response, for example, cardiovascular conditions, arthritis, osteoporosis and Alzheimer's

disease.” Randolph, Abstract, Exhibit 1011, p. 0001, see also ¶ [0021], Exhibit 1011, p. 0006.

203. Randolph teaches that “treatments have been developed to regulate the release of inflammatory cytokines, or the signaling of inflammatory cytokines, specifically the interleukin-1 (IL-1) cytokine from macrophages.” Randolph, p. 1, ¶ [0007], Exhibit 1011, p. 0004.

204. Randolph discloses that the composition “regulates interleukin cytokines and/or regulates a physiological response caused by interleukin cytokines. This regulation is effective in controlling an immune response and/or an inflammatory condition.” See Randolph, p. 1, ¶ [0008], Exhibit 1011, p. 0004.

205. In disclosing the composition, Randolph discloses that the composition includes “rosehips and at least one of blackberry, blueberry and elderberry. *In another aspect, the composition can comprise rosehips and krill oil.* In yet another aspect, *the composition can comprise rosehips, blackberry, blueberry, elderberry and krill oil.*” Randolph, p. 1, ¶ [0008], Exhibit 1011, p. 0004 (emphasis added).

206. In further describing rosehips, Randolph states “[e]xamples of rosehip ingredients include, without limitation, dried rosehips, rosehip oil, and rosehip extracts.” Randolph, p. 2, ¶ [0024], Exhibit 1011, p. 0005.

207. Randolph further describes that “[a] composition of the invention can include krill oil. Krill oil can be obtained from any member of the *Euphausia* family, for example *Euphausia superba*. Conventional oil producing techniques can be used to obtain the krill oil. In addition, krill oil can be obtained commercially from Neptune Technologies and Bioresources of Quebec, Canada.” Randolph, p. 3, ¶ [0039], Exhibit 1011, p. 0006.

208. In further disclosing the krill oil in the composition, Randolph discloses that the composition may “contain any amount of krill oil. For example, at least about 1 percent (e.g., at least about 2, 3, 4, 5, 10, 15, 20, 25, 30, 35, 40, 50, 60, 70, 80, or 90 percent) of a dietary supplement can be a krill oil. Typically, a composition contains between about 300 mg and about 3000 mg of a krill oil ingredient.” Randolph, p. 3, ¶ [0040], Exhibit 1011, p. 0006, see also Table III, pp. 6-7, Exhibit 1011, pp. 0009-0010.

209. Further, Randolph teaches that the composition may include resveratrol which can be obtained from grape skin. “Where the composition includes resveratrol, *the resveratrol can be obtained from an extract of grape skin* or other grape components. Resveratrol can be present in the composition in one or more

different forms, for example, extract form and powder form.” Randolph, p. 3, ¶ [0041], Exhibit 1011, p. 0006 (emphasis added).

210. Randolph further notes that the delivery system for the compositions includes capsules. In particular, “[t]he ingredients of the composition can be processed into forms having varying delivery systems. For example, *the ingredients can be processed and included in capsules*, tablets, gel tabs, lozenges, strips, granules, powders, concentrates, solutions, lotions, creams or suspensions.” Randolph, p. 4, ¶ [0046], Exhibit 1011, p. 0007 (emphasis added), see also Randolph, p. 4, ¶ [0049], Exhibit 1011, p. 0007 (rosehips in capsule form).

211. Randolph also notes that the delivery system for the compositions may include soft gels. In particular, “[a] soft gel capsule of the composition can be manufactured to include krill oil. This capsule can be manufactured using conventional capsule manufacturing techniques. The amount of krill oil in each capsule is about 300 mg.” Randolph, p. 4, ¶ [0052], Exhibit 1011, p. 0007.

212. Randolph also discloses “the composition can comprise at least one ingredient chosen from . . . *krill oil*, at least one type of xanthophyll (e.g., *astaxanthin*), . . . and ferulic acid.” Randolph, p. 1, ¶ [0009], Exhibit 1011, p. 0004 (emphasis added); see also, p. 2, ¶ [0021], Exhibit 1011, p. 0005. “Astaxanthin can

be obtained from natural sources or synthesized. For example, *astaxanthin* can be obtained from algae, fungi and/or *crustaceans*. ” Randolph, p. 4, ¶ [0043], Exhibit 1011, p. 0007 (emphasis added). “A composition can contain any amount of an astaxanthin ingredient. For example, at least about 1 percent (e.g., at least about 2, 3, 4, 5, 10, 15, 20, 25, 30, 35, 40, 50, 60, 70, 80, or 90 percent) of a dietary supplement can be astaxanthin. Typically, a composition contains between about 0.5 mg and about 50 mg of an astaxanthin ingredient.” Randolph, p. 4, ¶ [0044], Exhibit 1011, p. 0007. ²⁶

²⁶ For safe and effective amounts of krill oil, that is, 0.2 grams to 10 grams of krill oil disclosed in the ‘170 Patent, the 0.5 mg to 50 mg amounts of astaxanthin disclosed in Randolph inherently requires astaxanthin in amounts including **2500 mg/kg and 5000 mg/kg of astaxanthin w/w krill oil composition**. See calculation below:

(a) $0.5\text{mg}/0.2 \text{ grams} = 2.5 \text{ mg/gm} = 2500 \text{ mg/kg}$;

(b) $50\text{mg}/0.2 \text{ grams} = 250 \text{ mg/gm} = 250,000 \text{ mg/kg}$;

(c) $0.5\text{mg}/10 \text{ grams} = 0.05 \text{ mg/gm} = 50 \text{ mg/kg}$; and

(d) $50\text{mg}/10\text{grams} = 5 \text{ mg/gm} = 5000 \text{ mg/kg}$.

Grynbaum (Exhibit 1039)

213. Grynbaum is entitled “Unambiguous detection of astaxanthin and astaxanthin fatty acid esters in krill (*Euphausia superba* Dana)”. Grynbaum starts off by discussing the importance of carotenoids. “Carotenoids are one of the most important groups of natural pigments occurring in plants and animals. . . . Animals seem to be incapable of synthesizing carotenoids de novo; those carotenoids which are present are of dietary source. *Carotenoids* provide animals with bright coloration and *serve as antioxidants and radical scavengers*.” Grynbaum, p. 1685, Exhibit 1039, p. 0001. Thus, Grynbaum teaches that carotenoids, astaxanthin and astaxanthin esters, serve as *antioxidants and radical scavengers*.

214. Grynbaum describes the presence of *trans*-astaxanthin (all-E) and *cis*-astaxanthin and astaxanthin esters specifically, and gives quantification of astaxanthin ester content up to high levels (3921µg/0.5g krill, which is 7842 mg/kg krill, which gives >>7800 mg/kg of extracted krill oil). Thus, Grynbaum discloses the astaxanthin ester content of its krill oil was greater than 7800 mg/kg of krill oil. Grynbaum states that *trans*-astaxanthin is the main isomer (in relation to the astaxanthin esters).

215. Grynbaum summarizes their work as follows:

HPLC atmospheric pressure chemical ionization (APCI)/MS, GC MS, HPLC diode array detection (DAD), and NMR were used for the identification of astaxanthin and astaxanthin fatty acid esters in krill (*Euphausia superba* Dana). Matrix solid phase dispersion was applied for the extraction of the carotenoids. This gentle and expeditious extraction technique for solid and viscous samples leads to distinct higher enrichment rates than the conventional liquid–liquid extraction. . . . C14:0, C16:0, C16:1, C18:1, C20:0, C20:5, and C22:6 were found in astaxanthin monoesters and in astaxanthin diesters. (all-E) Astaxanthin was identified as the main isomer in six fatty acid ester fractions by NMR. Quantitation was carried out by the method of internal standard. (13-cis) Astaxanthin (70 µg/g), 542 µg/g (all-E) astaxanthin, 36 µg/g unidentified astaxanthin isomer, 62 µg/g (9-cis) astaxanthin, and 7842 µg/g astaxanthin fatty acid esters were found.

Grynbaum, p. 1685, Exhibit 1039, p. 0001.

216. Grynbaum notes, based on a reference regarding *E. pacifica*, that in krill the “relative composition of astaxanthin, its monoesters and diesters remains constant at 5, 49, and 40%, respectively, but the total amount of astaxanthin varies with the season and the stage of sexual maturity”. (Grynbaum, p. 1686, 1st col., Exhibit 1039, p. 0002.)

217. Grynbaum reports their results as follows:

In 0.5 g krill (mean of five extracts), 35 µg (13-cis) astaxanthin, 271 µg (all-E) astaxanthin, 18 µg unidentified astaxanthin isomer, 31 µg (9-cis) astaxanthin, and 3921 µg astaxanthin fatty acid esters were found. These concentrations differ from those reported in previous studies. The fact that we found 3–17 times more astaxanthin might be due to the higher efficiency of MSPD extraction compared to liquid–liquid extraction.

Grynbaum, p. 1692, 2nd col., Exhibit 1039, p. 0008.

218. Grynbaum reports the trans-astaxanthin as 271 µg (all-E) astaxanthin in a 0.5 g sample of ground *Euphausia superba* Dana krill, thus the amount of trans-astaxanthin was 542 µg/g (all-E) astaxanthin = 542 mg/kg trans-astaxanthin.

Grynbaum, p. 1692, 1st col., Exhibit 1039, p. 0008.

219. Grynbaum reports the astaxanthin fatty acids as 3921 µg astaxanthin in a 0.5 g sample of ground *Euphausia superba* Dana krill, thus the amount of astaxanthin esters was 7842 µg/g astaxanthin fatty acid esters = 7842 mg/kg astaxanthin esters.

Grynbaum, p. 1692, 1st col., Exhibit 1039, p. 0008.

Sampalis I (Exhibit 1012)

220. Sampalis I, published in 2003, discloses a human clinical trial study on the use of Neptune Krill Oil™ (NKO™) in comparison to an 18:12 EPA:DHA fish oil (which ostensibly contains no phospholipids) to ameliorate the symptoms of PMS and dysmenorrhea. See, e.g., Sampalis I, Abstract, p. 171 (Exhibit 1012, p. 0001).

221. Sampalis I notes on page 174 (Exhibit 1012, p. 0004, left column) that “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 . . .” (emphasis added). This inherent composition of the krill lipid extract is consistent with the compositions variously reported for NKO with Examples 2, 3, and 8 in the ‘170 Patent, see also the tables associated with these examples.

222. In further describing Neptune Krill Oil, Sampalis I describes the krill oil as being rich in potent antioxidants, including vitamins A and E, and astaxanthin, and a novel flavonoid. See Sampalis I, p. 174, left col., Exhibit 1012, p. 0004.

223. Sampalis I evaluates the effectiveness of Neptune Krill Oil™, a product rich in phospholipids and triglycerides carrying long-chain omega-3 polyunsaturated fatty acids, for the management of premenstrual syndrome and dysmenorrhea (p. 174, right column, Exhibit 1012, page 0004), after first disclosing previous studies that reinforce the theory that one of the main causes of PMS is inflammation and noting the beneficial effect of omega-3 fatty acid on reducing inflammation.

The balance of polyunsaturated (essential) fatty acids in the body is critical for the maintenance of healthy cell membranes and hormone regulation. During the last several decades, the average Western diet has shifted to much higher levels of omega-6 and less omega-3 fatty acid intake. Long-chain omega-6 fatty acids, such as arachidonic acid, predominating in the phospholipids of cell membranes can encourage the production of pro-inflammatory type-2 prostaglandins (PGE₂), *while omega-3 fatty acids promote the production of anti-inflammatory prostaglandins.*

Sampalis I, (p. 173, left column, Exhibit 1012, page 0003, emphasis added).

224. Sampalis I further discloses on page 174, right column (Exhibit 1012, p. 0004) that “[e]ach 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.” Sampalis I concludes on page 178

(Exhibit 1012, p. 0008) that “The final results of the present study suggest within a high level of confidence that Neptune Krill Oil can significantly reduce the physical and emotional symptoms related to premenstrual syndrome....”

225. Thus, an encapsulated krill oil comprising a soft gel capsule containing an effective amount of krill oil obtained from the Antarctic krill *Euphausia superba* is disclosed in Sampalis I. The effective amount described by Sampalis I is the equivalent of 2g (two 1-gram soft gels) of krill oil, taken daily. This is within the range of 0.2g to 10g described in the ‘170 Patent (see for example, ‘170 Patent, 7:12-14, p. 0029).

226. The krill oil was also found to be safe and effective in oral administration. Sampalis I discloses at p. 174, right column (Exhibit 1012, p. 0004), that “[e]ach patient was asked to take two 1-gram soft gels of either NKO [krill oil] or omega-3 18:12 fish oil . . . once daily”, and it was *Euphausia superba* krill oil that was safely and effectively administered to the patients in those amounts. See, for example, Sampalis I, Exhibit 1012, p. 0004, left column (“Neptune Krill Oil™ (NKO™) is a natural health product extracted from Antarctic krill also known as *Euphausia superba*”).

227. The krill oil was administered safely over a long term “...three cycles of 45 and 90 days of treatment” (Exhibit 1012, Abstract). Sampalis I also reports that “*No serious adverse events were reported during the duration of the trial. . .* Patients taking NKO did not experience any gastrointestinal difficulties such as regurgitation, while 64 percent of the women in the fish oil group complained of unpleasant reflux. On the contrary, the NKO subjects reported an increase of alertness, energy, and well-being.” Sampalis I, p. 177, left column, Exhibit 1012, page 0007 (emphasis added). Thus, krill oil (NKO), when administered to humans in doses of 2000 mg/day for months, was found to be safe in humans.

Sampalis II (Exhibit 1013)

228. Sampalis II is entitled, “Natural Marine Source Phospholipids Comprising Flavonoids, Polyunsaturated Fatty Acids and Their Applications” and discloses as set forth in the Abstract, “A phospholipid extract from a marine or aquatic biomass possesses therapeutic properties. The phospholipid extract comprises a variety of phospholipids, fatty acid, metals and a novel flavonoid.” Exhibit 1013, p. 0001.

229. In the Background of the Invention, Sampalis II describes how it was known to extract phospholipids from krill using a polar solvent.

JP 2215351, published on August 28, 1990, discloses a method for extracting and purifying phospholipids from fresh krill. Krill is lyophilized [freeze dried] and then extracted with ethanol to produce an extract which is fractionated by absorption column chromatography to produce high purity phosphatidyl choline and phosphatidyl ethanolamine.

Sampalis II, 1:22-27, Exhibit 1013, p. 0003.

230. In the Summary of the Invention, Sampalis II states:

There is also provided a phospholipid extract comprising the above noted phospholipids and flavonoid compound derived from a marine or aquatic biomass [including krill]. The extract and the components are useful in the prevention or treatment of a variety of disease states and for the aesthetic enhancement of an animal, including human, body. Pharmaceutical, nutraceutical and cosmetic compositions containing the extract and uses thereof are also within the invention, as are commercial packages contain the compositions of the invention.

Sampalis II, 3:4-12, Exhibit 1013, p. 0005.

231. Sampalis II teaches that Antarctic krill, including *Euphasia superba* and Pacific krill, including *Euphasia pacifica* are all appropriate sources of krill for its krill oil extract.

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

Sampalis II, 25:2-10, Exhibit 1013, p. 0027.

232. Sampalis II teaches that the freshly harvested krill is extracted using polar solvents. “Preferably, freshly harvested and finely divided marine and aquatic animal material is subjected to acetone extraction, for at least about two hours and preferably overnight.” Sampalis II, 32:1-4, Exhibit 1013, p. 0034. “The extraction is generally carried out by successive acetone and alcohol treatments [both polar solvents]. For the extraction of the instant application, the preferred treatment involves the use of >60% acetone in the first extraction followed by extraction with a mixture of organic solvents at 65-95%/45-50% preferably acetone, ethyl acetate/ethanol mixture [again polar solvents].” Sampalis II, 31:17-23, Exhibit 1013, p. 0033.

233. Like the extraction methods, the recovery methods are well known in the art.

The solubilized lipid fraction is separated from the solid starting material by known techniques, for example, by filtration, centrifugation or sedimentation. Filtration is preferred. The residue is optionally washed with acetone to recover more lipid and the acetone removed by flash evaporation or spray drying. Water residue is allowed to separate from the lipid extract at low temperature.

The solid residue left on the filter from the initial extraction is suspended and extracted with 95/5 ethyl acetate/ethanol, preferably two volumes (original volume of material). The filtrate is evaporated yielding a second fraction of lipids. Extraction period is not critical although it is preferred to extract for about 30 minutes at a temperature below about 5 degrees Celsius.

Sampalis II, 32:11-24, Exhibit 1013, p. 0034.

234. Sampalis II's krill oil extract contains from 40% to 60% phospholipids.

Phospholipids are generally present in the extract in an amount of at least 40% w/w, preferably at least 45% w/w. More preferably, the amount of phospholipid is from about 45-60% w/w. A variety of types of phospholipids may be present in the extract. These include phosphatidylethanolamine, phosphatidylinositol, phosphatidylserine, phosphatidylcholine and sphingomyelin.

Sampalis II, 26:3-9, Exhibit 1013, p. 0028. Moreover, the omega-3s, such as DHA and EPA present in the krill phospholipids, contribute to health benefits.

“DHA and EPA are the two most active polyunsaturated fatty acids in the human body, contributing to all health benefits associated with omega-3 fatty acids.”

Sampalis II, 34:16-18, Exhibit 1013, p. 0036.

235. Sampalis II discloses the many known beneficial health aspects of phospholipids (15:5 – 20:46, Exhibit 1013, pp. 0017-0022), specifically pointed out the benefits of phosphatidylcholine (17:1-14, Exhibit 1013, p. 0019) and provided a laundry list of reasons why POSITAs seeking a superior source of phospholipids would be motivated to extract them from krill.

“Compared to phospholipids existing in the market today, the [krill] extract phospholipids:

- a. achieve a superior profile;
- b. have the highest quantities of polyunsaturated fatty acids;
- c. have the highest quantities of DHA;
- d. are the only phospholipids that contain EPA; and
- e. are the only phospholipids that contain a combination of EPA and DHA on the same molecule.”

Sampalis II, 27:8-16, Exhibit 1013, p. 0029.

236. As discussed above at ¶ 231, Sampalis II discloses that the polar krill oil containing phospholipids may be extracted from *Euphausia superba* and krill is a preferred source. Sampalis II, 25:2-10, Exhibit 1013, p. 0027 (emphasis added).

237. Sampalis II noted in its disclosure of the fatty acid content of the krill extract that omega-3 fatty acids make up between 15% w/w and 45% w/w of the krill oil lipids, while the omega-3 fatty acids DHA and EPA account for at least 32% w/w, more preferably at least 35% or 37%, of the total lipid content of the extracted krill oil.

Free fatty acids are present in the extract in an amount of at least 4% w/w and preferably at least 5% w/w. Polyunsaturated fatty acids, *in particular omega-3 fatty acids*, preferably *make up* at least 15% w/w, more preferably at least 40% w/w, and even more preferably *at least 45% w/w, of the total lipids in the extract*. DHA and EPA are generally the largest component of the fatty acids and *preferably account for* at least 32% w/w, more preferably *at least 35% or 37%*, of the total lipid content of the extract.

Sampalis II, 28:6-14, Exhibit 1013, p. 0030 (emphasis added).

238. Sampalis II Table IV provides that the fatty acid composition of the extract included Omega-3 in amounts equal to or greater than 30% w/w of the krill oil lipids. Sampalis II, 28:6-14, Exhibit 1013, p. 0030. Sampalis II discloses that its

krill oil preferably contains at least 45% omega-3 fatty acids w/w of the total krill oil. As fatty acids are a subset of the total krill oil, a krill oil containing 45% omega-3 fatty acids w/w of total krill oil cannot constitute less than 45% omega-3 fatty acids w/w of fatty acids. Therefore, Sampalis II inherently discloses that in its krill oil, the omega-3 fatty acids w/w of total fatty acids must be greater than at least 45%. That is, Sampalis II discloses at least 45% omega-3 fatty acids w/w of total fatty acids.

239. Sampalis II teaches that the krill oil extract may contain astaxanthin, both free (i.e., non-esterified) and esterified.

Antioxidants present in the extract may include vitamin A (for example, all-trans retinol), vitamin E (for example, alpha-tocopherol), beta-carotene, astaxanthin (mainly esterified but non-esterified may be present), canthaxanthin and/or flavonoids. Antioxidants are preferably present in the extract in an amount of at least 20 and preferably at least 200 mg/100 ml.

Sampalis II, 30:1-7, Exhibit 1013, p. 0032.

240. Sampalis II notes that the means of preparing the carrier for the krill phospholipid extract product was well known in the art.

The phospholipid extract of the present invention may be used with or without other additives. Preferably, no other additives are used. However, if other additives are used, pharmaceutical or nutraceutical formulations may be made by methods known in the art. For example, the compositions of the present invention may be formulated in a conventional manner using one or more pharmaceutically or nutraceutically acceptable carriers. *Thus, the extract may be formulated for oral administration. For oral administration, the pharmaceutical or nutraceutical compositions may take the form of, for example, tablets or capsules prepared by conventional means* with pharmaceutically or nutraceutically acceptable excipients such as binding agents

Sampalis II, 34:26 - 35:9, Exhibit 1013, pp. 0036-0037 (emphasis added).

241. Sampalis II notes that “Neptune Krill Oil™ (the present invention) phospholipids contain high quantities of eicosapentanoic acid -EPA (20:5) and docosahexanoic acid -DHA (22:6). Their fatty acid profile closely resembles that of human brain phospholipids.” Sampalis II, Exhibit 1013, p. 0036, ll. 3-7.

Moreover, as quoted above, “DHA and EPA are the two most active polyunsaturated fatty acids in the human body, contributing to all health benefits associated with omega-3 fatty acids. Sampalis II, Exhibit 1013, p. 0036, ll. 16-18.”

242. Sampalis II also teaches many beneficial uses of the krill oil extract. In one example, a 7 year old was given 2g of the krill oil extract a day for a month and a half at which point she was showing a marked improvement in her condition.

“Example 3

This example illustrates the use of the present krill extract in improving dyslexia and abnormal motor function in a 7 year old girl.

2g per day of the krill extract were given to a 7 year old girl suffering from dyslexia and abnormal motor function. After 1.5 months, she showed:

- Increased learning ability (blind observation by psychologist)
- Improved motor function (moderate ice skating)
- Improved social skills
- Improved speech

Accordingly, the krill extract has beneficial neurological properties.”

Sampalis II, 46:15-28, Exhibit 1013, p. 0048.

Bunea (Exhibit 1020)

243. Bunea is entitled “Evaluation of the Effects of Neptune Krill Oil on the Clinical Course of Hyperlipidemia.” The stated objective of the evaluation was “To assess the effects of krill oil on blood lipids, specifically total cholesterol, triglycerides, low-density lipoprotein (LDL), and high-density lipoprotein (HDL).” The overall results reported by Bunea were that within high levels of confidence “krill oil is effective for the management of hyperlipidemia by significantly reducing total cholesterol, LDL, and triglycerides, and increasing HDL levels. At lower and equal doses, krill oil was significantly more effective than fish oil for the reduction of glucose, triglycerides, and LDL levels.” Bunea, p. 420, Exhibit 1020, p. 0001.

244. The krill oil used in Bunea’s study was Neptune Krill Oil (NKO). Bunea, p. 420, Exhibit 1020, p. 0001.

245. Bunea explained why omega-3s were important in ameliorating inflammation due to omega-6s.

Omega-6 fatty acids, mainly arachidonic acid, have been shown to initiate an inflammatory process by triggering a flux of inflammatory PGs and LTs. Omega-3 fatty acids, mainly eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), compete with the omega-6 species for the

enzyme prostaglandin synthetase. Omega-3 fatty acids trigger secretion of less potent 5-series LTs and anti-inflammatory PGs of the 3 series (PE3, PI3 and thromboxanes-A3). Consequently, supplementation with EPA and DHA promotes the production of less potent PGs and LTs, resulting in a decrease in the formation of inflammatory mediators.

Bunea, p. 421, Exhibit 1020, p. 0002.

246. Bunea further notes that human studies have revealed the ability of omega-3's such as EPA and DHA to provide other significant health benefits, for example, by favorably modifying cardiovascular disease and associated disorders, perhaps by reducing circulating levels of blood triglyceride and very low-density lipoprotein. Bunea, p. 421, Exhibit 1020, p. 0002.

247. Bunea's krill oil was extracted from Antarctic krill, *Euphausia superba*.

Bunea noting that the extracted phospholipids present in krill oil are naturally rich in the beneficial omega-3 fatty acids, such as EPA and DHA.

Krill oil is extracted from Antarctic krill, *Euphausia superba*, a zooplankton crustacean rich in phospholipids carrying long-chain omega-3 PUFAs, mainly EPA and DHA. Krill oil also contains various potent antioxidants, including vitamins A and E, astaxanthin, and a novel flavonoid similar to 6,8-di-c-glucosylluteolin, but with two or more glucose molecules and one aglycone.

Krill oil has a unique biomolecular profile of phospholipids naturally rich in omega-3 fatty acids and diverse antioxidants significantly different from the usual profile of fish oils. The association between phospholipids and long-chain omega-3 fatty acids highly facilitates the passage of fatty acid molecules through the intestinal wall, increasing bioavailability and ultimately improving the omega-3:omega-6 fatty acid ratio.

Bunea, p. 421, Exhibit 1020, p. 0002 (emphasis added), see also, p. 426, Exhibit 1020, p. 0007.

248. Bunea evaluated the effects of the administration of krill oil at three different dosages, namely 1 to 3 grams per day, finding them to be beneficial. Bunea, pp. 421, 427, Exhibit 1020, pp. 0002, 0008.

249. Bunea's evaluation demonstrated the superiority of krill oil to fish oil, and its safe use in long-term treatment.

The results of this clinical trial demonstrate that daily doses of 1-3 g krill oil are significantly more effective than 3 g EPA/DHA fish oil in the management of hyperlipidemia. Furthermore, a maintenance dose of 500 mg krill oil is significantly effective for long-term regulation of blood lipids. The unique molecular composition of krill oil, which is rich in phospholipids, omega-3 fatty acids, and diverse antioxidants, surpasses the profile of fish oils and offers a superior approach toward the reduction of risk for cardiovascular disease.

Bunea, p. 427, Exhibit 1020, p. 0008 (emphasis added).

THE '170 PATENT CLAIM CHART

250. I have reviewed the '170 Patent Claim Chart attached hereto as Tallon Appendix C²⁷ in light of the prior art discussed above and as further discussed below. It is my opinion that a POSITA would have been motivated to combine the various disclosures found in the discussed prior art to arrive at the subject matter of each and every claim of the '170 Patent. Therefore, the '170 Claim Chart supports a finding that all the claims of the '170 Patent would have been obvious to one skilled in the art. My opinions are discussed in more detail in the Grounds for obviousness set forth below.

²⁷ I have been informed by counsel that the attached claim chart (Tallon Appendix C) prepared by counsel, is the same claim chart found in the Petition.

'170 PETITION GROUNDS

Ground	Reference(s)	Basis	Claims Challenged
1		35 U.S.C. §112(a) Lack of possession / enablement / written description	1-20
2		35 U.S.C. §101 Product of Nature	1-20
3		35 U.S.C. §101 Lack of Inventorship	1-20
4	'388 Patent Application Publication, Serial No. 12/057,775 ('388 Pat.Appl.Pub.) (Exhibit 1043)	35 U.S.C. §102(a)	1-20
5	Bruheim (Exhibit 1085) and Neptune's GRAS (Exhibit 1075)	35 U.S.C. §103(a)	1, 3-5, 7, 9- 11, 13-16, 18 and 20
6	Neptune's GRAS, Bruheim and Sampalis III (Exhibit 1064)	35 U.S.C. §103(a)	2 and 12
7	Neptune's GRAS, Bruheim and Randolph (Exhibit 1011)	35 U.S.C. §103(a)	6 and 17
8	Neptune's GRAS, Bruheim and Bottino (Exhibit 1007)	35 U.S.C. §103(a)	8 and 19

GROUND 1CLAIMS 1-20[Lack of possession / enablement / written description]

251. See discussion above (¶¶ 85-132) and below, regarding lack of possession, enablement and written description.

252. There is no § 112(a) support for ether phospholipids in the upper half of the claimed range of “from about 3% to 15% w/w krill oil (i.e., 8% to 15%), as required by both of the independent ‘170 Patent claims 1 and 11. This lack of support applies to all the dependent claims as well, and for that reason claims 1-20 lack § 112(a) support for ether phospholipids in the upper half of the claimed range of 3% to 15% w/w krill oil. See ¶¶ 102-107, 111-123, above.

253. There is no Section 112(a) support for astaxanthin esters for the majority of the claimed range for “astaxanthin esters in amount greater than about 100 mg/kg of said krill oil”, which can include up to 85% or 97% w/w of krill oil, depending on the ether phospholipid content (3% to 15%), as required by at least ‘170 Patent claims 1 and 11. See ¶¶ 108-123, above.

254. There is no Section 112(a) support for astaxanthin esters for almost the entire claim limitation range for “astaxanthin esters in amount greater than about 100 mg/kg of said krill oil”, which includes up to 50% w/w of krill oil, as required

by '170 Patent claims 7 and 18. These claims depend from claims 1 and 11, respectively, and additionally provide for two additional components: non-ether phospholipids, with a minimum total phospholipid (ether + non-ether) content of 30% w/w, and a minimum triglycerides content of 20% w/w. Thus, claims 7 and 18 provide that up to 50% of the krill oil composition can be astaxanthin esters. $100\% - 30\% - 20\% = 50\%$. See ¶¶ 108-110, above.

255. As the '170 Patent provides no arguable support for astaxanthin esters content greater than about even 0.25% (i.e., 2,500 mg/kg), see discussion above at ¶¶ 111-122, this limited support for astaxanthin esters content applies to all the other claims as well. Thus, claims 1-20, which all require astaxanthin esters in amounts much greater than about 0.25% (i.e., 2,500 mg/kg), lack § 112(a) support for astaxanthin esters. See ¶¶ 102, 111-123, above.

256. In my opinion, all the claims of the '170 Patent lack § 112(a) support and thus, based on my understanding that absent § 112(a) support patent claims are invalid, claims 1-20 of the '170 Patent are invalid.

GROUND 2
CLAIMS 1-20
[Product of Nature]

257. See discussion above regarding the ‘170 Patent (¶¶ 36-51)

258. Independent claims 1 and 11 of the ‘170 Patent simply recite a krill oil composition containing amounts of the naturally occurring components present in krill (*i.e.*, ether phospholipids and astaxanthin esters) that are extracted from the natural krill and placed in a capsule or soft gel capsule.

259. Dependent claims 3-5, 7- 8, 10, 13-16 and 18-20 likewise simply recite a krill oil composition containing amounts of the naturally occurring components present in krill (*i.e.*, ether phospholipids, astaxanthin esters, phospholipids, non-ether phospholipids, phosphatidylcholine, triglycerides, fatty acids including omega-3 fatty acids and arachadonic acid) that are extracted from the natural krill and placed in a capsule or soft gel capsule.

260. Dependent claims 2 and 12 require that the extracted krill oil of claims 1 and 11 be “substantially odorless”. Basically, that is another way of saying that the odor causing components naturally found in krill and krill oil (e.g., trimethylamine or TMA) are not present in the krill oil in substantial levels. The components

present in the krill oil remain those extracted from the natural krill and placed in a capsule or soft gel capsule.

261. Dependent claims 6 and 17 require that the extracted krill oil of claims 1 and 11 be encapsulated with a phytonutrient that comes from a source other than krill. Simply adding a natural phytonutrient (such as those described in the '170 Patent, see, e.g., '170 Patent, 15:52-67, Exhibit 1001, p. 0033) to a natural krill oil extract does not transform the nature of the combined product, it is still a mixture of components naturally present in krill that have been extracted from a natural krill biomass and combined with a naturally occurring phytonutrient and placing the mixture in a capsule or soft gel capsule.

262. Dependent claim 9 requires that the capsule be a soft gel capsule. Simply placing the natural components of the krill oil composition in a conventional capsule or soft gel capsule is not novel or transformative. In fact, prior art krill oil extracts such as Neptune's NKO and Krill Bill's krill oil products were encapsulated in soft gel capsules. See Sampalis I, page 174, right column, Exhibit 1012, p. 0004, and Krill Bill Order Form and Specification, Exhibit 1070, p. 0001.

263. Thus, claims 1-20 of the '170 Patent recite a krill oil composition containing naturally occurring components naturally present in krill, that are extracted from

the natural krill biomass, and sometimes adding a natural phytonutrient, and placing those naturally occurring components in a capsule or soft gel capsule. It is my understanding that claims 1-20 are not patentable on this basis.

GROUND 3
CLAIMS 1-20
[Lack of Inventorship]

264. Individuals from Industrial Research Limited, New Zealand, (IRL, now known as Callaghan Innovation, New Zealand), developed methods of extracting krill oil from krill and analyzing the resulting krill oil product during the period of at least 2003-2006. The extraction methods used involved CO₂ extraction with and without a polar entrainer. The work was for a third party. This work includes the results reported in the '170 Patent in Tables 22 and 23, and in the text of the patent (see, e.g., '170 Patent, Example 8, 32:67-33:5, Exhibit 1001, pp. 0041-0042). Additional results are reported in the '072 Provision Application. See, e.g., '072 Provisional Application, pp. 44-52, Exhibit 1002, pp. 0047-0055. The '170 Patent does not identify individuals at IRL who conceived and developed this work as inventors of the '170 Patent, even though all the claims require that the krill oil compositions have an ether phospholipid component, a component whose presence the applicants for the '170 Patent argued distinguished it from the prior art NKO krill oil product. See discussion above at ¶¶ 95-96.

GROUND 4CLAIMS 1-20

[The '388 Patent Application Publication (Exhibit 1043)]

266. As discussed above, the '388 Patent Application Publication, Exhibit 1043 is substantially exactly the same as the '170 Patent and discloses not only every claim limitation, but also provides examples of specific amounts falling within the claimed ranges for each claimed components. Therefore, it anticipates each of the '170 Patent claims. See Claim Chart, Appendix C below, and discussion above, '388 PatAppPub Section, ¶¶ 143-161.

Claims 1, 11 and 9

1. A krill oil composition comprising a capsule containing *Euphausia superba* krill oil suitable for oral administration, said krill oil comprising from 3% to 15% ether phospholipids w/w of said krill oil and astaxanthin esters in amount of greater than about 100 mg/kg of said krill oil.
11. A composition comprising a soft gel capsule containing *Euphausia superba* krill oil suitable for oral administration, said krill oil comprising from 3% to 15% ether phospholipids w/w of said krill oil and astaxanthin esters in amount of greater than about 100 mg/kg of said krill oil.

9. The krill oil composition of claim 1, wherein said capsule is a soft gel capsule.

267. Claims 1 and 11 are both directed to *Euphausia superba* krill oil compositions having exactly the same components in the same claimed ranges. The only difference between claim 1 and claim 11 is that the krill oil composition of claim 1 comprises a capsule containing krill oil, while claim 11's comprises a soft gel capsule containing krill oil.

268. Claim 9 depends from claim 1 and adds the limitation that the capsule is a soft gel capsule. A soft gel capsule is a capsule, and in my opinion the disclosure of either one to a POSITA would be a disclosure of the other. They are used interchangeably in the literature. See, e.g., Neptune's GRAS, Current Usage of NKO™ in the Diet, Exhibit 1075, p. 0019, and discussion above at ¶ 180.

269. Claims 1 and 11 (and 9 which depends from claim 1) recite a *Euphausia superba* krill oil, suitable for oral administration, with an ether phospholipids content of from 3% to 15% w/w of krill oil, and an astaxanthin esters content of greater than about 100 mg/kg of said krill oil.

270. The ‘388 PatAppPub discloses a krill oil composition “characterized by containing high levels of astaxanthin, phospholipids, included an enriched quantities of ether phospholipids, and omega-3 fatty acids” (Exhibit 1043, ¶ [0064]), in some preferred embodiments, the krill oil is extracted from krill is *Euphausia superba* (see. e.g., (Exhibit 1043, ¶¶ [0034], [0018]), and the krill oil compositions “are contained in acceptable . . . carriers for oral consumption . . . preferably in the form of a tablet or capsule and most preferably in the form of a soft gel capsule” (Exhibit 1043, ¶ [0078]). See discussion at ¶¶ 145-148, above.

271. Table 22 discloses a krill oil composition made in accordance with Example 7, which has an ether phospholipid content of 7.38% w/w krill oil. See ‘388 PatAppPub, ¶ [0105], p. 19, Exhibit 1043, p. 0039, and see also discussion at ¶ 151, above. 7.38% w/w krill oil clearly falls within the ether phospholipid claimed range of 3% to 15% ether phospholipids w/w of krill oil.

272. Table 21 of the ‘388 Pat. App. Pub. discloses an astaxanthin level obtained in the krill oil from Example 7 of 2091 mg/kg, while Table 20C of the ‘388 Pat. App. Pub. discloses an astaxanthin esters level obtained in the krill oil from Example 5 of 1302 mg/kg. See, ‘388 PatAppPub, Tables 22 and 20C, [0101], [0105], pp. 18-19, Exhibit 1043, pp. 0038-0039. Table 16 discloses a polar krill oil

composition made in accordance with Example 3 having an astaxanthin esters content of 580 mg/kg of krill oil. ‘388 PatAppPub, ¶ [0099], p. 16, Exhibit 1043, p. 0036. See also discussion at ¶ 155, 157 (for copy of Table 21), above. 2091 mg/kg, 1302 mg/kg and 580 mg/kg of krill oil each clearly fall within the claimed range of astaxanthin esters in amount of greater than about 100 mg/kg of krill oil.

Claims 2 and 12

2. The krill oil composition of claim 1, wherein said krill oil composition is substantially odorless.

12. The composition of claim 11, wherein said krill oil composition is substantially odorless.

273. Claims 2 and 12 depend from claims 1 and 11, respectively, and add the limitation that the krill oil composition is “substantially odorless”.

274. Exhibit 1043 discloses that some embodiments of its krill oil compositions are “substantially odorless”. In some embodiments, the present invention provides krill oil that is substantially odorless. ‘388 PatAppPub, ¶ [0076], p. 7, Exhibit 1043, p. 0027. See discussion at ¶¶ 159-160, above.

Claims 3 and 13

3. The krill oil composition of claim 1, wherein said krill oil contains astaxanthin esters in an amount of greater than about 200 mg/kg of said krill oil.

13. The composition of claim 11, wherein said krill oil contains astaxanthin esters in an amount of greater than about 200 mg/kg of said krill oil.

275. Claims 3 and 13 depend from claims 1 and 11, respectively, and add the limitation that “said krill oil contains astaxanthin esters in an amount of greater than about 200 mg/kg of said krill oil”.

276. Table 21 of the ‘388 Pat. App. Pub. discloses an astaxanthin level obtained in the krill oil from Example 7 of 2091 mg/kg, while Table 20C of the ‘388 Pat. App. Pub. discloses an astaxanthin esters level obtained in the krill oil from Example 5 of 1302 mg/kg. See, ‘388 PatAppPub, Tables 22 and 20C, [0101], [0105], pp. 18-19, Exhibit 1043, pp. 0038 -0039. Table 16 discloses a polar krill oil composition made in accordance with Example 3 having an astaxanthin esters content of 580 mg/kg of krill oil. ‘388 PatAppPub, ¶ [0099], p. 16, Exhibit 1043, p. 0036. See also discussion at ¶ 155, 157 (for copy of Table 21), above. 2091

mg/kg, 1302 mg/kg and 580 mg/kg of krill oil each clearly fall within the claimed range of astaxanthin esters in amount of greater than about 200 mg/kg of krill oil.

Claims 4 and 14

4. The krill oil composition of claim 1, wherein said krill oil comprises at least 30% total phospholipids w/w of said krill oil.

14. The composition of claim 11, wherein said krill oil comprises at least 30% total phospholipids w/w of said krill oil.

277. Claims 4 and 14 depend from claims 1 and 11, respectively, and add the limitation that “said krill oil comprises at least 30% total phospholipids w/w of said krill oil”. The at least 30% total phospholipids necessarily includes the amount of ether phospholipids recited in the independent claims.

278. Table 22 discloses a krill oil composition made in accordance with Example 7 having a phospholipid content w/w krill oil of 47.9%. ‘388 PatAppPub, Table 22, ¶ [0105], p. 19, Exhibit 1043, p. 0039 and see discussion at ¶¶ 149-151, above. A phospholipid content of 47.9% w/w krill oil clearly falls within the claimed range of at least 30% total phospholipids w/w of krill oil.

Claims 5, 15 and 16

5. The krill oil composition of claim 1, wherein said krill oil comprises at least 30% phosphatidylcholine w/w of said krill oil.

15. The composition of claim 11, wherein said krill oil comprises at least 30% phosphatidylcholine w/w of said krill oil.

16. The composition of claim 11, wherein said krill oil comprises at least 40% phosphatidylcholine w/w of said krill oil.

279. Claims 5 and 15 depend from claims 1 and 11, respectively, and add the limitation that “said krill oil comprises at least 30% phosphatidylcholine w/w of said krill oil”.

280. Claim 16 depends from independent claim 11 and adds the limitation that “said krill oil comprises at least 40% phosphatidylcholine w/w of said krill oil”.

281. As discussed above, ¶ 152, Exhibit 1043 discloses in Table 22 a krill oil extract made in accordance with Example 7 that has a phosphatidylcholine (PC) content of 36.1% w/w krill oil. ‘388 PatAppPub, [0105], Exhibit 1043, p. 0038. A PC content of 36.1% w/w krill oil complies with the claimed, at least 30% phosphatidylcholine w/w of said krill oil, of claims 5 and 15.

282. As discussed above, ¶ 153, Exhibit 1043 discloses in Table 18B a polar extract of krill with a PC content of 67% w/w lipids, while in Table 19B Exhibit 1043 discloses a 50/50 blend of the polar and neutral extracts with a PC content of 42%. ‘388 PatAppPub, [0100], Exhibit 1043, pp. 0036- 0037. PC content of 67% and 42% both comply with the claimed, at least 40% phosphatidylcholine w/w of said krill oil, of claims 5, 15 and 16.

Claims 6 and 17

6. The krill oil composition of claim 1, wherein said capsule contains a phytonutrient derived from a source other than krill.

17. The composition of claim 11, wherein said capsule contains a phytonutrient derived from a source other than krill.

283. Claims 6 and 17 depend from claims 1 and 11, respectively, and add the limitation that “said capsule contains a phytonutrient derived from a source other than krill”.

284. As discussed above at ¶ 161, Exhibit 1043 discloses that its krill oil compositions can contain phytonutrients derived from a source other than krill. “In still further embodiments, the compositions comprise at least one phytonutrient . .

.. [derived from] plant phytonutrients . . . ” See ‘388 PatAppPub, ¶ [0083], p. 8, Exhibit 1043, p. 0028.

Claims 7 and 18

7. The krill oil composition of claim 1, wherein said krill oil further comprises from about 3% to about 10% w/w ether phospholipids; from about 27% to 50% w/w non-ether phospholipids so that the amount of total phospholipids in the composition is from about 30% to 60% w/w; and from about 20% to 50% w/w triglycerides.

18. The composition of claim 11, wherein said krill oil further comprises from about 3% to about 10% w/w ether phospholipids; from about 27% to 50% w/w non-ether phospholipids so that the amount of total phospholipids in the composition is from about 30% to 60% w/w; and from about 20% to 50% w/w triglycerides.

285. Claims 7 and 18 depend from independent claims 1 and 11, respectively, and add the limitations of (i) from about 3% to about 10% w/w ether phospholipids; (ii) from about 27% to 50% w/w non-ether phospholipids so that the amount of total

phospholipids in the composition is from about 30% to 60% w/w; and (iii) from about 20% to 50% w/w triglycerides.

286. As discussed above at ¶ 151, Table 22 discloses a krill oil composition, made in accordance with Example 7, which has an ether phospholipid content of 7.38% w/w krill oil. See '388 PatAppPub, ¶ [0105], p. 19, Exhibit 1043, p. 0039. 7.38% w/w krill oil clearly falls within the ether phospholipid claimed range of 3% to 10% ether phospholipids w/w of krill oil.

287. As discussed above at ¶ 154, Exhibit 1043 discloses in Table 22 a krill oil composition, made in accordance with Example 7, with a non-ether phospholipid content of 40.5% w/w krill oil extract, which complies with non-ether phospholipids claimed range of from about 27% to 50% w/w krill oil.

288. As discussed above at ¶¶ 149-151, Exhibit 1043 discloses in Table 22 closes a krill oil composition, made in accordance with Example 7, having a phospholipid content w/w krill oil of 47.9%. '388 PatAppPub, Table 22, ¶ [0105], p. 19, Exhibit 1043, p. 0039. A phospholipid content of 47.9% w/w krill oil clearly falls within the claimed range of total phospholipids from about 30% to 60% w/w of krill oil.

289. As discussed above at ¶ 157, Exhibit 1043 discloses in Table 21 closes a krill oil composition, made in accordance with Example 7, having a 25.9% triglycerides w/w krill oil. ‘388 PatAppPub, ¶ [0103], p. 38, Exhibit 1043, p. 0038. 25.9% w/w triglycerides w/w krill oil clearly falls within the claimed from about 20% to 50% w/w triglycerides.

Claims 8 and 19

8. The krill oil composition of claim 7, wherein said krill oil further comprises from about 20% to 35% omega-3 fatty acids as a percentage of total fatty acids in said composition.

19. The composition of claim 18, wherein said krill oil further comprises from about 20% to 35% omega-3 fatty acids as a percentage of total fatty acids in said composition.

290. Claims 8 and 19 depend from dependent claims 7 and 18, respectively, and add the limitation that “said krill oil further comprises from about 20% to 35% omega-3 fatty acids as a percentage of total fatty acids in said composition”.

291. As discussed above at ¶ 158, Exhibit 1043 discloses that in some embodiments its krill oil “compositions comprise from about 20% to 35% . . .

omega-3 fatty acids as a percentage of total fatty acids in the composition . . .”.

‘388 PatAppPub, [0072], p. 6, Exhibit 1043, p. 0026.

Claims 10 and 20

10. The krill oil composition of claim 1, wherein said krill oil comprises less than about 0.45% w/w arachadonic acid.

20. The composition of claim 11, wherein said krill oil comprises less than about 0.45% w/w arachadonic acid.

292. Claims 10 and 20 depend from independent claims 1 and 11, respectively, and add the limitation that “said krill oil comprises less than about 0.45% w/w arachadonic acid”.

293. As discussed above at ¶ 162, Exhibit 1043 also discloses embodiments of the invention with less than about 0.45% arachidonic acid (w/w). ‘388 PatAppPub, ¶ [0020], p. 2, Exhibit 1043, p. 0022.

294. The ‘388 PatAppPub, Exhibit 1043, discloses each of the claimed elements of all of the ‘170 Patent claims in one reference, and thus anticipates each of claims 1-20.

295. Thus, claims 1-20, that is, all the claims of the '170 Patent are anticipated by '388 PatAppPub, Exhibit 1043 and thus are invalid and unpatentable.

GROUND 5CLAIMS 1, 3-5, 7, 9-11, 13-16, 18 and 20[BRUHEIM (Exhibit 1085) and NEPTUNE'S GRAS (Exhibit 1075)]Claims 1, 11 and 9

1. A krill oil composition comprising a capsule containing *Euphausia superba* krill oil suitable for oral administration, said krill oil comprising from 3% to 15% ether phospholipids w/w of said krill oil and astaxanthin esters in amount of greater than about 100 mg/kg of said krill oil.

11. A composition comprising a soft gel capsule containing *Euphausia superba* krill oil suitable for oral administration, said krill oil comprising from 3% to 15% ether phospholipids w/w of said krill oil and astaxanthin esters in amount of greater than about 100 mg/kg of said krill oil.

9. The krill oil composition of claim 1, wherein said capsule is a soft gel capsule.

296. Claims 1 and 11 are both directed to *Euphausia superba* krill oil compositions having exactly the same components in the same claimed ranges.

The only difference between claim 1 and claim 11 is that the krill oil composition of claim 1 comprises a capsule containing krill oil, while claim 11's comprises a soft gel capsule containing krill oil.

297. Claim 9 depends from claim 1 and adds the limitation that the capsule is a soft gel capsule. A soft gel capsule is a capsule, and in my opinion the disclosure of either one to a POSITA would be a disclosure of the other. They are used interchangeably in the literature. See, e.g., Neptune's GRAS, Current Usage of NKO™ in the Diet, Exhibit 1075, p. 0019, and discussion above at ¶ 180.

298. Claims 1 and 11 (and 9 which depends from claim 1) recite a *Euphausia superba* krill oil, suitable for oral administration, with an ether phospholipids content of from 3% to 15% w/w of krill oil, and an astaxanthin esters content of greater than about 100 mg/kg of said krill oil.

299. Bruheim teaches the use of *Euphausia superba* krill for use in extracting krill oil. See Bruheim [0002], Exhibit 1085, p. 0006, and ¶ 163, above. Neptune's GRAS discloses that its commercial krill oil product made for oral administration is made from *Euphausia superba* krill. Neptune's GRAS, Exhibit 1075, p. 0005, and see ¶¶ 177, 180, above.

300. Bruheim teaches that its krill oil Extract 2, with a total phospholipid content of 46.03%, had an ether phospholipid content of 5.4% w/w krill oil. Bruheim also teaches that its krill oil Extract 3, with a total phospholipid content of 57.94%, had an ether phospholipid content of 7.0% w/w krill oil. See Bruheim, Table IV, p. 11,

Exhibit 1085, p.0016, and ¶¶ 169-170, above. Thus, clearly falling within the 3% to 15% ether phospholipid content claimed.

301. Bruheim discloses that their krill oil contains astaxanthin at levels varying from 50 mg/kg to 1500 mg/kg. Bruheim, [0120], Exhibit 1085, p. 0017, and see ¶ 174, above. Neptune's GRAS discloses that across three batches of its commercial NKO krill oil, the astaxanthin esters content ranged from 1540 mg/g to 1626 mg/kg. Neptune's GRAS, Exhibit 1075, p. 0010, and see ¶ 178, above. Thus, both clearly complying with the > 100 mg/kg astaxanthin esters content claimed.

302. Thus, claims 1, 11 and 9 are obvious in view of Bruheim and Neptune's GRAS.

Claims 3 and 13

3. The krill oil composition of claim 1, wherein said krill oil contains astaxanthin esters in an amount of greater than about 200 mg/kg of said krill oil.

13. The composition of claim 11, wherein said krill oil contains astaxanthin esters in an amount of greater than about 200 mg/kg of said krill oil.

303. Claims 3 and 13 depend from claims 1 and 11, respectively, and add the limitation that “said krill oil contains astaxanthin esters in an amount of greater than about 200 mg/kg of said krill oil”.

304. Bruheim discloses that their krill oil contains astaxanthin at levels varying from 50 mg/kg to 1500 mg/kg. Bruheim, [0120], Exhibit 1085, p. 0017, and see ¶ 174, above. Neptune’s GRAS discloses that across three batches of its commercial NKO krill oil, the astaxanthin esters content ranged from 1540 mg/g to 1626 mg/kg. Neptune’s GRAS, Exhibit 1075, p. 0010, and see ¶ 178, above. Thus, both clearly complying with the > 200 mg/kg astaxanthin esters content claimed.

305. Thus, claims 3 and 13 are obvious in view of Bruheim and Neptune’s GRAS.

Claims 4 and 14

4. The krill oil composition of claim 1, wherein said krill oil comprises at least 30% total phospholipids w/w of said krill oil.

14. The composition of claim 11, wherein said krill oil comprises at least 30% total phospholipids w/w of said krill oil.

306. Claims 4 and 14 depend from claims 1 and 11, respectively, and add the limitation that “said krill oil comprises at least 30% total phospholipids w/w of said krill oil”. The at least 30% total phospholipids necessarily includes the amount of ether phospholipids recited in the independent claims.

307. Bruheim discloses krill oil compositions having 40% to 50% phospholipids. Bruheim, [0010], Exhibit 1085, and see ¶ 165, above. Bruheim’s Extract 2, discloses a total phospholipid content of 46.03% w/w lipid extracts. Bruheim, Table IV, p. 11, Exhibit 1085, p. 0016, and see ¶¶ 168-169, above. Neptune’s GRAS discloses that across three batches of its NKO krill oil product, total phospholipids ranged in content from 43.8% to 47.3% w/w NKO. Neptune’s GRAS, Table 2, Exhibit 1075, p. 0010, and see ¶ 178, above.

308. Thus, both Bruheim and Neptune’s GRAS report krill oils with total phospholipids comprising at least 30% w/w krill oil, clearly complying with the amount of phospholipids claimed.

309. Thus, claims 4 and 14 are obvious in view of Bruheim and Neptune’s GRAS.

Claims 5, 15 and 16

5. The krill oil composition of claim 1, wherein said krill oil comprises at least 30% phosphatidylcholine w/w of said krill oil.

15. The composition of claim 11, wherein said krill oil comprises at least 30% phosphatidylcholine w/w of said krill oil.

16. The composition of claim 11, wherein said krill oil comprises at least 40% phosphatidylcholine w/w of said krill oil.

310. Claims 5 and 15 depend from claims 1 and 11, respectively, and add the limitation that “said krill oil comprises at least 30% phosphatidylcholine w/w of said krill oil”.

311. Claim 16 depends from independent claim 11 and adds the limitation that “said krill oil comprises at least 40% phosphatidylcholine w/w of said krill oil”.

312. Bruheim’s Table IV discloses that the phosphatidylcholine w/w of Extract 2’s krill oil is 35.5% (77.1% PC/PL x 46.03% PL/Total Lipids). Bruheim’s Table IV discloses that the phosphatidylcholine w/w of Extract 3’s krill oil is 44.6% (76.9% PC/PL x 57.94% PL/Total Lipids). Bruheim, Table IV, p. 11, Exhibit 1085, p. 0016, and ¶ 169 above.

313. Bruheim's 35.5% phosphatidylcholine w/w of Extract 2's krill oil is > 30% and thus complies with the phosphatidylcholine content as claimed in claims 5 and 15. Bruheim's 44.6% phosphatidylcholine w/w of Extract 3's krill oil is > 40% and thus complies with the phosphatidylcholine content as claimed in claims 5, 15 and 16.

314. Thus, claims 5, 15 and 16 are obvious in view of Bruheim and Neptune's GRAS.

Claims 7 and 18

7. The krill oil composition of claim 1, wherein said krill oil further comprises from about 3% to about 10% w/w ether phospholipids; from about 27% to 50% w/w non-ether phospholipids so that the amount of total phospholipids in the composition is from about 30% to 60% w/w; and from about 20% to 50% w/w triglycerides.

18. The composition of claim 11, wherein said krill oil further comprises from about 3% to about 10% w/w ether phospholipids; from about 27% to 50% w/w non-ether phospholipids so that the amount of total phospholipids in the composition is from about 30% to 60% w/w; and from about 20% to 50% w/w triglycerides.

315. Claims 7 and 18 depend from independent claims 1 and 11, respectively, and add the limitations of (i) from about 3% to about 10% w/w ether phospholipids; (ii) from about 27% to 50% w/w non-ether phospholipids so that the amount of total phospholipids in the composition is from about 30% to 60% w/w; and (iii) from about 20% to 50% w/w triglycerides

316. Bruheim teaches that its krill oil Extract 2, with a total phospholipid content of 46.03%, has an ether phospholipid content of 5.4% w/w krill oil. Bruheim also teaches that its krill oil Extract 3, with a total phospholipid content of 57.94%, has an ether phospholipid content of 7.0% w/w krill oil. See Bruheim, Table IV, p. 11, Exhibit 1085, p.0016, and ¶¶ 169-170, above.

317. Bruheim's Extract 2 has a non-ether phospholipid content of 40.6% (46.03% PL – 5.4% Ether PL). See ¶ 172, above. Bruheim's Extract 3 has a non-ether phospholipid content of 50.9% (57.94% PL – 7.0% Ether PL). Bruheim Extract 2's 40.6% non-ether PL content complies with the 27% to 50% w/w non-ether phospholipids content claimed. Bruheim's Extract 3's 50.9% non-ether PL content complies with the about 27% to 50% w/w non-ether phospholipids content claimed.

318. Bruheim also discloses that its krill oil lipid extracts have triglycerides as one of the major component of both krill oil extraction runs. The triglyceride content ranges from 40.3% to 42.1% w/w krill oil. The triglyceride content for Run 1, whose phospholipid profiles appear in Table IV) is disclosed as 40.3% w/w krill oil. See Bruheim, [0111], and Tables IV and V, Exhibit 1085, pp. 0016-0017 and ¶ 173, above. Thus, clearly falling within the about 20% to 50% w/w triglycerides as claimed.

319. Thus, Bruheim discloses (i) from about 3% to about 10% w/w ether phospholipids; (ii) from about 27% to 50% w/w non-ether phospholipids so that the amount of total phospholipids in the composition is from about 30% to 60% w/w; and (iii) from about 20% to 50% w/w triglycerides

320. Thus, claims 7 and 18 are obvious in view of Bruheim and Neptune's GRAS.

Claims 10 and 20

10. The krill oil composition of claim 1, wherein said krill oil comprises less than about 0.45% w/w arachadonic acid.

20. The composition of claim 11, wherein said krill oil comprises less than about 0.45% w/w arachadonic acid.

321. Claims 10 and 20 depend from independent claims 1 and 11, respectively, and add the limitation that “said krill oil comprises less than about 0.45% w/w arachadonic acid”.

322. Neptune’s GRAS discloses NKO krill oil product with between 0.24% and 0.43% arachadonic acid w/w krill oil and a mean arachadonic acid content across four lots of 0.33% w/w krill oil. Neptune’s GRAS, Table 9, Exhibit 1075, p.0016 and ¶ 179, above. Thus, disclosing arachadonic acid levels in the krill oil as claimed.

323. Thus, claims 10 and 20 are obvious in view of Bruheim and Neptune’s GRAS.

324. A POSITA would have been motivated to combine Neptune’s GRAS and Bruheim for the reasons given in the Motivation to Combine – Overview section above, ¶¶ 133-142, and because, *inter alia*, a POSITA developing an encapsulated krill oil supplement as taught in Neptune’s GRAS would have been motivated to look to other references such as Bruheim for methods of manufacturing such a krill oil and to ascertain the components of the krill oil and their amounts that could be obtained using conventional extraction techniques.

325. Thus, claims 1, 3-5, 7, 9-11, 13-16, 18 and 20 of the '170 Patent would have been obvious to a POSITA.

GROUND 6CLAIMS 2 and 12

[NEPTUNE'S GRAS, BRUHEIM and SAMPALIS III (Exhibit 1064)]

326. The discussions above regarding the obviousness of claims 1, 3-5, 7, 9-11, 13-16, 18 and 20 are incorporated herein.

Claims 2 and 12

2. The krill oil composition of claim 1, wherein said krill oil composition is substantially odorless.

12. The composition of claim 11, wherein said krill oil composition is substantially odorless.

327. Claims 2 and 12 depend from claims 1 and 11, respectively, and add the limitation that the krill oil composition is “substantially odorless”.

328. Sampalis III discloses processes for deodorizing krill oil, by among other things, reducing or eliminating odor causing components, such as TMA, from the krill oil. See discussion above at ¶¶ 181-186.

329. Thus, it would have been obvious for a POSITA to use Sampalis III's processes, which eliminated odor causing components, on the krill oil extracts

disclosed by Bruheim and Neptune's GRAS. In addition to the motivation to combine Bruheim and Neptune's GRAS given above in connection with Ground 5, and the Motivation to Combine Overview section, at ¶¶ 133-142 above, a POSITA would have been motivated to use the processes disclosed in Sampalis III to reduce or eliminate any fishy smell associated with the odor causing components which may be found in krill oil.

330. Thus, claims 2 and 12 are obvious in view of Bruheim, Neptune's GRAS, and Sampalis III.

GROUND 7CLAIMS 6 and 17[NEPTUNE'S GRAS, BRUHEIM and RANDOLPH (Exhibit 1011)]

331. The discussions above regarding the obviousness of claims 1, 3-5, 7, 9-11, 13-16, 18 and 20 are incorporated herein.

332.

Claims 6 and 17

6. The krill oil composition of claim 1, wherein said capsule contains a phytonutrient derived from a source other than krill.

17. The composition of claim 11, wherein said capsule contains a phytonutrient derived from a source other than krill.

333. Claims 6 and 17 depend from claims 1 and 11, respectively, and add the limitation that "said capsule contains a phytonutrient derived from a source other than krill".

334. As discussed above, ¶¶ 202-212, Randolph discloses encapsulated compositions of krill oil (including effective amounts of Neptune krill oil) and rose hips, including rose hips extracts, to modulate inflammatory cytokines. Randolph, Exhibit 1011, at Abstract, paragraphs 7, 8, 21, 24, 39, 40, 41, 46, 49, 52, and Table

III. Thus, it would have been obvious to a POSITA to use this combination of krill oil and rosehips, a plant phytonutrient, to moderate inflammatory response in humans.

335. Randolph further discloses krill oil plus nutrients encapsulated in a soft gel, capable of being administered in safe and effective amounts to provide a health benefit. See ¶¶ 202, 204, 205-208, 210-211, above.

336. Randolph also discloses compositions of krill oil with ferulic acid and with resveratrol (which is derived from grape skin extract). This is another example of an encapsulated krill oil composition with plant phytonutrients. See ¶¶ 202 and 212, above.

337. Finally, Randolph also discloses the combination of krill oil, astaxanthin and plant phytonutrients, namely “the composition can comprise at least one ingredient chosen from . . . *krill oil*, at least one type of xanthophyll (e.g., *astaxanthin*), . . . and *ferulic acid*.” Randolph, p. 1, ¶ [0009], Exhibit 1011, p. 0004 (emphasis added); see also ¶ 212, above.

338. As explained above, the ‘170 Patent expressly identifies grape skin extract and rose hips as sources of plant phytonutrients. See ¶¶ 73-74, above. Thus,

Randolph discloses combinations of krill oil, astaxanthin and plant phytonutrient in krill oil encapsulated in a soft gel capsule, as set forth in claims 6 and 17.

339. In addition to the motivation to combine Bruheim and Neptune's GRAS given above in connection with Ground 5, and the Motivation to Combine Overview section, at ¶¶ 133-142 above, a POSITA would have been motivated to include a phytonutrient together with krill oil as taught by Randolph, for at least to be able to get the benefit of Randolph's disclosures that its compositions which include phytonutrients are effective in controlling an immune response and/or an inflammatory condition. See Randolph, p. 1, ¶ [0008], Exhibit 1011, p. 0004, and ¶¶ 202-205, above.

340. Thus, claims 6 and 17 are obvious in view of Bruheim, Neptune's GRAS, and Randolph.

GROUND 8
CLAIMS 8 and 19
[NEPTUNE'S GRAS, BRUHEIM and BOTTINO (Exhibit 1007)]

341. The discussions above regarding the obviousness of claims 1, 3-5, 7, 9-11, 13-16, 18 and 20 are incorporated herein.

Claims 8 and 19

8. The krill oil composition of claim 7, wherein said krill oil further comprises from about 20% to 35% omega-3 fatty acids as a percentage of total fatty acids in said composition.

19. The composition of claim 18, wherein said krill oil further comprises from about 20% to 35% omega-3 fatty acids as a percentage of total fatty acids in said composition.

342. Claims 8 and 19 depend from dependent claims 7 and 18, respectively, and add the limitation that “said krill oil further comprises from about 20% to 35% omega-3 fatty acids as a percentage of total fatty acids in said composition”.

343. As discussed above at ¶¶ 188-189, Bottino I 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 8 and 19.

Bottino I, pp. 200-201, Exhibit 1007, pp. 0004-0005.

344. In addition to the motivation to combine Bruheim and Neptune's GRAS given above in connection with Ground 5, and the Motivation to Combine Overview section, at ¶¶ 133-142 above, a POSITA would have been motivated to look to Bottino I which discusses how the "study of krill has become intensive in recent times, perhaps as a result of its potential importance as food", see ¶ 187 above, and discloses a study of the fatty acids of phytoplankton and krill including *Euphausia Superba*, teaching that krill oil has about 20% to 35% (30.5%, 26.8%, 25.0%, and 28.6 %) omega-3 fatty acids as a percentage of total fatty acids. This, would motivate a POSITA, who would have known that omega-3 fatty acids provided significant health benefits (see, e.g., Bunea, Exhibit 1020, p. 0002 and ¶¶ 243-249, above), to include the omega-3 fatty acid levels disclosed in Bottino I.

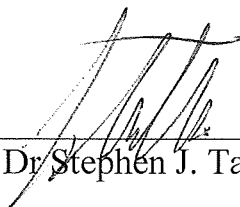
345. Thus, claims 6 and 17 are obvious in view of Bruheim, Neptune's GRAS, and Bottino I.

CONCLUDING OPINION

346. Based on the foregoing, it is my opinion that the '170 Patent and all of its claims are unpatentable and invalid on the grounds presented above.

347. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on this the 9th day of February, 2018.



Dr. Stephen J. Tallon

TALLON APPENDIX A

Listing of all references to the amounts of astaxanthin esters and astaxanthin in the '170 Patent specification.

Below is a listing of all the references to astaxanthin esters, as well as astaxanthin, in the '170 Patent specification, along with citations by column and line numbers (column:line), unless otherwise noted.

Astaxanthin references to the prior art

Astaxanthin references to the prior art:

“at least 75 $\mu\text{g/g}$ [75 mg/kg] astaxanthin, preferably 90 $\mu\text{g/g}$ [90 g/kg] astaxanthin” – 1:44-45;

“at least 250 $\mu\text{g/g}$ [250 mg/kg] canastaxanthin, preferably 270 $\mu\text{g/g}$ [270 mg/kg] canastaxanthin” – 1:46-47.

Astaxanthin references in connection with the invention

Astaxanthin references in connection with the invention:

astaxanthin esters

“at least 100 mg/kg astaxanthin esters”

“at least 580 mg/kg astaxanthin esters” – 2:37; 2:40-14; 2:44-45; 3:56-57;
3:58; 5:17;

“at least 500, 100, 1500, 2000, 2100, or 2200 mg/kg astaxanthin esters” –
3:64-65;

“at least 500, 1000, 1500, 2000, 2100, or 2200 mg/kg astaxanthin esters” –
13:13-14;

“greater than about 90, 100, 500, 1000, 1500, 200, 2100 or 2200 mg/kg
astaxanthin esters” – 4:11-12;

“greater than about 100, 200, 300, 400, or 500 mg/kg astaxanthin esters” –
13:10-11;

“from about 50, 100, 200, or 500 to about 750, 1000, 1500 or 2500 mg/kg
astaxanthin esters” – 13:26-28;

“from about 50 to about 2500 mg/kg astaxanthin esters” – 13:24-25;

“less than about 50 micrograms/kilogram [.050 mg/kg] (w/w) astaxanthin
esters” – 5:35-36;

“than about 20 micrograms/kilogram [.020 mg/kg] (w/w) astaxanthin esters”

- 5:37-38;

“less than about 5 micrograms/kilogram [.005 mg/kg] (w/w) astaxanthin esters” - 5:39-40;

“less than about 70, 60, 50, 40, 30, 20, 10, 5 or 1 micrograms/kilogram (w/w) astaxanthin esters”²⁸ = – 13:35-36;

astaxanthin

“the astaxanthin content was 500 ppm” [.05% = 500 mg/kg **check**] – 35:27;

“from about 300 mg/kg astaxanthin to about 2500 mg/kg astaxanthin” – 11:66-67;

“from about 400 to about 2500 mg/kg astaxanthin” – 2:57; 3:15-16; 5:48-49; 5:59-60; 6:1; 6:15-16; 6:33-34; 6:59-60; 7:1-2; 7:27-28; 7:37-38; 12:25-26;

“from about 1000 to about 2200 mg/kg astaxanthin” - 12:1;

“from about 1500 to about 2200 mg/kg astaxanthin” – 12:2-3;

²⁸ 1 microgram/kg = .000000001 kg/kg = .0000001%
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“greater than about 1000, 1500, 1800, 1900, 2000, or 2100 mg/kg
astaxanthin” – 12:4-5;

Astaxanthin in the ‘170 Patent Tables

Astaxanthin in the ‘170 Patent Tables:

Table 1 – total astaxanthin – krill – 53.3, 81.3, 145, and 126 mg/kg;

Table 4 – astaxanthin – asta oil – 1245 mg/kg;

Table 7 – astaxanthin esters – 144, 10, 117 mg/kg;

Table 16 - astaxanthin esters – 472, 117, 580, and 98 mg/kg;

Table 16 – astaxanthin free – 11, <1, <1, and <1 mg/kg;

Table 17C – astaxanthin esters – 462 mg/kg;

Table 17C – free astaxanthin – 4.3 mg/kg;

Table 18C – polar krill oil extract - no astaxanthin entry at all;

Table 19C – astaxanthin esters - 151 mg/kg;

Table 19C – free astaxanthin – 1.1 mg/kg;

Table 20C – astaxanthin esters - 1302 mg/kg;

Table 20C – free astaxanthin – 12 mg/kg;

Table 21 – astaxanthin - 2091 mg/kg;

TABLE 1

Composition of products from the processing line					
	Round frozen krill	After decanter	After drier	Konstruktor Koshkin (Ukranian vessel)	
Protein	13.5 g/100 g	20.9 g/100 g	58.5 g/100 g	60.2 g/100 g	
Moisture	76.3 g/100 g	65.6 g/100 g	9.1 g/100 g	9.6 g/100 g	
Lipid (Folch)	8.6 g/100 g	10 g/100 g	21.8 g/100 g	21.4 g/100 g	
Free fatty acids	29.8 g/100 g	25.3 g/100 g	24.8 g/100 g	23.3 g/100 g	
Total astaxanthin	53.3 mg/kg	81.3 mg/kg	145 mg/kg	126 mg/kg	

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TABLE 4-continued

Composition and quality parameters of asta oil.	
Phopspholipids	575 mg/kg
Astaxanthin	1245 mg/kg

TABLE 7

Composition and properties of the krill meal and products after extraction			
	Krill meal	Delipidated krill meal	EtOH extracted krill oil
Crude protein	586 g/kg	735 g/kg	
Fat (Folch)	250 g/kg	30 g/kg	
Moisture/ethanol	71 g/kg	134 g/kg	85 g/kg
Astaxanthin esters	144 mg/kg	10 mg/kg	117 mg/kg
Diesters	110 mg/kg	8.5 mg/kg	117 mg/kg
Monoesters	33 mg/kg	1.8 mg/kg	37 mg/kg
Biological digestable protein	854 g/kg protein	870 g/kg protein	
Flow number	4.8	1.9	
NH3	9 mg N/100 g	0	3 mg N/100 g
TMA	2 mg N/100 g	0	70 mg N/100 g
TMAO	125 mg N/100 g	0	456 mg N/100 g

TABLE 16

Compositional data for the novel krill oil composition obtained and NKO krill oil.				
Compounds	Neptune KO	Ethanol extracted KO	Polar KO	Neutral KO
Astaxanthin esters	472 mg/kg	117 mg/kg	580 mg/kg	98 mg/kg
Astaxanthin free	11 mg/kg	<1 mg/kg	<1 mg/kg	<1 mg/kg
Total cholesterol	1 g/100 g	12 g/100 g	<0.5 g/100 g	5.7 g/100 g

TABLE 17C

Miscellaneous analysis of the extract in S1.		
Compound	Unit	Amount
Free astaxanthin	mg/kg	4.3
Astaxanthin esters	mg/kg	462
Trimethylamin	mg N/100 g	<1
Trimethylamineoxide	mg N/100 g	2

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TABLE 18C

Miscellaneous analysis of the extract in S1.		
Compound	Unit	Amount
Trimethylamin	mg N/100 g	422
Trimethylamineoxide	mg N/100 g	239

TABLE 19C

Miscellaneous analysis of the final blended product obtained in example 4.		
Compound	Unit	Amount
Free astaxanthin	mg/kg	1.1
Astaxanthin esters	mg/kg	151
Trimethylamin	mg N/100 g	109
Trimethylamineoxide	mg N/100 g	80

TABLE 20C

Miscellaneous analysis of the final blended product obtained in Example 5		
Compound	Unit	Amount
Free astaxanthin	mg/kg	12
Astaxanthin esters	mg/kg	1302
Trimethylamin	mg N/100 g	193
Trimethylamineoxide	mg N/100 g	1.7

TABLE 21

15	Analysis of the krill oil obtained using supercritical fluid extraction.	
	Parameter	Value
20	Ethanol	1.11% w/w
	Water Content	2.98% w/w
	C20:5 n-3 (EPA)	19.9
	C22:6 n-3 (DHA)	11.3
	Total Omega 3	35.7
	Total Omega 6	3.0
25	Total Phospholipids	50.55 wt %
	Ratio Omega3-PL/Total Omega 3	77.6% w/w
	Ratio EPA-PL/Total EPA	84.4% w/w
	Ratio DHA-PL/Total DHA	74.7% w/w
	Triglycerides	25.9 g/100 g
	Astaxanthin	2091 mg/kg
30	Peroxide Value	<0.1

TALLON APPENDIX B

TMA and Trimethylamine in the '170 Patent Tables (mg N/100 g)

Example 2 - EtOH Extracted Krill Oil (70 mg N/100g)

Example 2 - EtOH Extracted Krill Oil (70 mg N/100g):

“The krill meal obtained in example 1 was then ethanol extracted according to the method disclosed in JP02215351. The results showed that around 22% fat from the meal could be extracted, somewhat lower than was extracted using Folch (25%). Table 6 shows the fatty acid composition of the krill meal and the krill oil extracted from the meal using ethanol. **Table 7** shows the composition and properties of the krill meal and products before and after extraction, whereas table 8 shows the lipid composition.”

'170 Patent, 20:49-58, Exhibit 1001, p. 0035 (emphasis supplied).

TABLE 7

Composition and properties of the krill meal and products after extraction				50
	Krill meal	Delipidated krill meal	EtOH extracted krill oil	
Crude protein	586 g/kg	735 g/kg		55
Fat (Folch)	250 g/kg	30 g/kg		
Moisture/ethanol	71 g/kg	134 g/kg	85 g/kg	
Astaxanthin esters	144 mg/kg	10 mg/kg	117 mg/kg	
Diesters	110 mg/kg	8.5 mg/kg	117 mg/kg	60
Monoesters	33 mg/kg	1.8 mg/kg	37 mg/kg	
Biological digestable protein	854 g/kg protein	870 g/kg protein		
Flow number	4.8	1.9		
NH ₃	9 mg N/100 g	0	3 mg N/100 g	65
TMA	2 mg N/100 g	0	70 mg N/100 g	
TMAO	125 mg N/100 g	0	456 mg N/100 g	

‘170 Patent, 21:45-66, Exhibit 1001, p. 0036 (emphasis supplied).

Example 4 – SFE with CO₂ Neat, CO₂ 20% Ethanol, & a 50%/50% Blend

SFE with CO₂ Neat, Neutral Lipids:

Neutral Lipids (<1 mg N/100 g)

Neutral lipids were extracted from krill meal (138 kg) using SFE with neat CO₂ (solvent ratio 25 kg/kg) at 500 bar and 75° C. The neutral lipids were fractionated at 200 bar (75° C.) and at 60 bar (35° C.) at separator S1 and S2, respectively. The extract obtained in S1 (19.6 kg) were characterized and the results can be found in Tables 17A-C.”

‘170 Patent, 28:32-38, Exhibit 1001, p. 0039 (emphasis supplied).

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TABLE 17C

Miscellaneous analysis of the extract in S1.		
Compound	Unit	Amount
Free astaxanthin	mg/kg	4.3
Astaxanthin esters	mg/kg	462
Trimethylamin	mg N/100 g	≤1
Trimethylamineoxide	mg N/100 g	2

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‘170 Patent, 29:26-35, Exhibit 1001, p. 0040 (emphasis supplied).

SFE with CO₂ 20% Ethanol – Polar Lipids:

Polar Lipids (422 mg N/100 g)

“The extract in table S2 (0.4 kg) were rich in water and were not further used. Next, the polar lipids were extracted using CO₂ at 500 bar, 20% ethanol and at a temperature of 75° C. Using a solvent ratio of 32 (kg/kg) and collecting an extract of 18.2 kg using a separator at 60 bars and 35° C. *The polar lipids were collected and analyzed (Tables 18A-C).*”

‘170 Patent, 28:38-43, Exhibit 1001, p. 0039 (emphasis supplied).

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TABLE 18C

Miscellaneous analysis of the extract in S1.		
Compound	Unit	Amount
Trimethylamin	mg N/100 g	422
Trimethylamineoxide	mg N/100 g	239

‘170 Patent, 30:1-8, Exhibit 1001, p. 0040 (emphasis supplied).

50/50 Polar Lipids/Neutral Lipid:

50/50 Polar Lipids/Neutral Lipids (109 mg N/100 g)

*Next, the polar lipids were mixed in a 50/50 ratio with the neutral lipids collected from S1 before finally the ethanol was removed carefully by evaporation. The product obtained was red and transparent. If the ethanol is removed before the mixing if the fractions a transparent product is not obtained. The composition of the 50/50 red and transparent product can be found in **Tables 19A-C.***

‘170 Patent, 28:43-51, Exhibit 1001, p. 0039 (emphasis supplied).

TABLE 19C

Miscellaneous analysis of the final blended product obtained in example 4.		
Compound	Unit	Amount
Free astaxanthin	mg/kg	1.1
Astaxanthin esters	mg/kg	151
Trimethylamin	mg N/100 g	109
Trimethylamineoxide	mg N/100 g	80

‘170 Patent, 30:44-53, Exhibit 1001, p. 0040 (emphasis supplied).

Example 5 - Asta oil/Polar Lipids Blend (193 mg N/100 g)

Astor Oil/Polar Lipids Blend:

“The asta oil obtained in example 1 was blended with the polar lipids obtained in example 4 in a ratio of 46:54 (v/v). Next the ethanol was removed by evaporation and a dark red and transparent product was obtained. The product was analyzed and the results can be found in **Tables 20A-C**. Furthermore, the product was encapsulated into soft gels successfully. During the encapsulation it was observed that any further increase in phospholipids and thereby viscosity will make it very difficult to encapsulate the final product.”

‘170 Patent, 30:56-67, Exhibit 1001, p. 0040 (emphasis supplied).

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TABLE 20C

Miscellaneous analysis of the final blended product obtained in Example 5			40
Compound	Unit	Amount	
Free astaxanthin	mg/kg	12	45
Astaxanthin esters	mg/kg	1302	
Trimethylamin	mg N/100 g	193	
Trimethylamineoxide	mg N/100 g	1.7	

‘170 Patent, 31:36-45, Exhibit 1001, p. 0041 (emphasis supplied).

TALLON APPENDIX C

‘170 PATENT INVALIDITY GROUNDS

Ground	Reference(s)	Basis	Claims Challenged
1		35 U.S.C. §112(a) Lack of possession / enablement / written description	1-20
2		35 U.S.C. §101 Product of Nature	1-20
3		35 U.S.C. §101 Lack of Inventorship	1-20
4	‘388 Patent Application Publication, Serial No. 12/057,775 (‘388 Pat.Appl.Pub.) (Exhibit 1043)	35 U.S.C. §102(a)	1-20
5	Bruheim (Exhibit 1085) and Neptune’s GRAS (Exhibit 1075)	35 U.S.C. §103(a)	1, 3-5, 7, 9- 11, 13-16, 18 and 20
6	Neptune’s GRAS, Bruheim and Sampalis III (Exhibit 1064)	35 U.S.C. §103(a)	2 and 12
7	Neptune’s GRAS, Bruheim and Randolph (Exhibit 1011)	35 U.S.C. §103(a)	6 and 17
8	Neptune’s GRAS, Bruheim and Bottino (Exhibit 1007)	35 U.S.C. §103(a)	8 and 19

'170 PATENT CLAIM CHART

CLAIMS	REFERENCES
1. A krill oil composition comprising	<u>'388 Pat.App.Pub. (Exhibit 1043)</u> P. 0025, 1st col., ¶ [0064]. “This invention discloses novel krill oil compositions characterized by containing high levels of astaxanthin, phospholipids, included an enriched quantities of ether phospholipids, and omega-3 fatty acids.” <u>OR</u> ----- <u>Bruheim (Exhibit 1085)</u> P. 0006, 2nd col., ¶ [0010]. “The krill oil is one the valuable products made from krills. It contains inter alia phospholipids, triglycerides and carotenoid astaxanthin while being essentially free of protein, carbohydrates and minerals.” <u>Neptune GRAS (Exhibit 1075)</u> P. 0005. “NKO™ is refined krill oil which is derived from the marine organism, Euphasia superba, which is harvested from Antarctic waters.”

CLAIMS	REFERENCES
1(a) a capsule containing <i>Euphausia superba</i> krill oil suitable for oral administration,	<u>'388 Pat.App.Pub. (Exhibit 1043)</u> P. 0026, 1st col., ¶ [0071]. “In some embodiments, krill oil composition comprises a blend of lipid fractions obtained from krill. In some preferred embodiments, krill is Euphausia superba, although other krill species also find use in the present invention.” P. 0027, 2nd col. ¶ [0078]. “In some embodiments, the compositions of this invention (such as those described in the preceding sections) are contained in acceptable excipients and/or carriers for oral consumption... The composition is preferably in the form of a tablet or capsule and most preferably in the form of a soft gel capsule.” <u>OR</u> ----- <u>Neptune GRAS (Exhibit 1075)</u> P. 0005. “NKO™ is refined krill oil which is derived from the marine organism, Euphausia superba, which is harvested from Antarctic waters.”

CLAIMS	REFERENCES																																																																												
	P. 0005. “NKO™ is an oil intended for use as a dietary ingredient as a source of omega-3 fatty acids, which as noted are found in NKO™ in their phospholipid form.” P. 0019 “The supplement is sold in 300 and 500 mg capsules with a recommended dose of 1-2 capsules per day. Softgels containing the NKO™ have been available as dietary supplements in North America for several years.”																																																																												
1(b) said krill oil comprising from 3% to 15% ether phospholipids w/w of said krill oil and	<u>‘388 Pat.App.Pub. (Exhibit 1043)</u> P. 0039, 1st col., ¶[0105]. TABLE 22 <table><tr><th colspan="4">Phospholipid profiles</th></tr><tr><th></th><th>Type B krill powder</th><th>NKO</th><th>Krill Oil obtained in Example 7</th></tr><tr><td>PC</td><td>66.0</td><td>68.6</td><td>75.3</td></tr><tr><td>AAPC</td><td>12.0</td><td>7.0</td><td>13.0</td></tr><tr><td>PI</td><td></td><td></td><td></td></tr><tr><td>1LPC</td><td>1.2</td><td>1.3</td><td>0.4</td></tr><tr><td>PS</td><td></td><td></td><td></td></tr><tr><td>2LPC</td><td>7.4</td><td>13.8</td><td>2.9</td></tr><tr><td>LAAPC</td><td>2.2</td><td>1.2</td><td>0.9</td></tr><tr><td>PE</td><td>6.0</td><td>3.4</td><td>3.4</td></tr><tr><td>AAPE</td><td></td><td></td><td>1.5</td></tr><tr><td>SM</td><td></td><td></td><td></td></tr><tr><td>GPC</td><td></td><td>1.3</td><td></td></tr><tr><td>DHSM</td><td></td><td></td><td></td></tr><tr><td>NAPE</td><td></td><td>3.4</td><td></td></tr><tr><td>CL</td><td>5.3</td><td></td><td>2.1</td></tr><tr><td>LPE</td><td></td><td></td><td>0.5</td></tr><tr><td>LCL</td><td></td><td></td><td></td></tr><tr><td>% PL in powder or lipid sample</td><td>8.3</td><td>30.0</td><td>47.9</td></tr></table>	Phospholipid profiles					Type B krill powder	NKO	Krill Oil obtained in Example 7	PC	66.0	68.6	75.3	AAPC	12.0	7.0	13.0	PI				1LPC	1.2	1.3	0.4	PS				2LPC	7.4	13.8	2.9	LAAPC	2.2	1.2	0.9	PE	6.0	3.4	3.4	AAPE			1.5	SM				GPC		1.3		DHSM				NAPE		3.4		CL	5.3		2.1	LPE			0.5	LCL				% PL in powder or lipid sample	8.3	30.0	47.9
Phospholipid profiles																																																																													
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PS																																																																													
2LPC	7.4	13.8	2.9																																																																										
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AAPE			1.5																																																																										
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GPC		1.3																																																																											
DHSM																																																																													
NAPE		3.4																																																																											
CL	5.3		2.1																																																																										
LPE			0.5																																																																										
LCL																																																																													
% PL in powder or lipid sample	8.3	30.0	47.9																																																																										

CLAIMS	REFERENCES
	Ether phospholipids as a percentage of phospholipids (PL) = 13.0 (AAPC) + 0.9 (LAAPC) + 1.5 (AAPE) = 15.4% % PL in krill oil composition = 47.9% % Ether phospholipids in krill oil composition = 15.4 x 47.9 = 7.38% <u>OR</u> ----- <u>Bruheim (Exhibit 1085)</u> P. 0016, Table IV, extract 2. AAPC 9.0; LAAPC 1.2; AAPE 1.5; and Total PL 46.03 (wt% of sample). Total ether phospholipid= 11.7 of PL. If PL is 46.03 % of total sample, then ether phospholipid is 5.4% of lipid extract.
1(c) astaxanthin esters in amount of greater than about 100 mg/kg of said krill oil.	<u>'388 Pat.App.Pub. (Exhibit 1043)</u> P. 0038, 1st col., ¶[0101].

CLAIMS	REFERENCES															
	TABLE 20C Miscellaneous analysis of the final blended product obtained in Example 5 <table><tr><th>Compound</th><th>Unit</th><th>Amount</th></tr><tr><td>Free astaxanthin</td><td>mg/kg</td><td>12</td></tr><tr><td>Astaxanthin esters</td><td>mg/kg</td><td>1302</td></tr><tr><td>Trimethylamin</td><td>mg N/100 g</td><td>193</td></tr><tr><td>Trimethylamineoxide</td><td>mg N/100 g</td><td>1.7</td></tr></table> % astaxantin esters=1302 mg/kg. <u>OR</u> ----- <u>Bruheim (Exhibit 1085)</u> P. 0017, 2nd col., ¶ [0120]. “Krill oil has typically a strong red colour arising from the carotenoid astaxanthin present in the oil at levels varying from 50 ppm to 1500 ppm.” [50 mg/kg-1500 mg/kg (ester not specified)] <u>Neptune GRAS (Exhibit 1075)</u> P. 0010, Table 2. Batch Analysis of Three Lots of NKO™. Esterified Astaxanthin 154.0-162.6 mg/100g. [1540 mg/kg-1626 mg/kg]	Compound	Unit	Amount	Free astaxanthin	mg/kg	12	Astaxanthin esters	mg/kg	1302	Trimethylamin	mg N/100 g	193	Trimethylamineoxide	mg N/100 g	1.7
Compound	Unit	Amount														
Free astaxanthin	mg/kg	12														
Astaxanthin esters	mg/kg	1302														
Trimethylamin	mg N/100 g	193														
Trimethylamineoxide	mg N/100 g	1.7														

CLAIMS	REFERENCES
2. The krill oil composition of claim 1, wherein said krill oil composition is substantially odorless.	<u>'388 Pat.App.Pub. (Exhibit 1043)</u> P. 0027, 2nd col., ¶ [0076]. “In some embodiments, the present invention provides krill oil that is substantially odorless.” <u>OR</u> ----- <u>Sampalis III (Exhibit 1064)</u> P. 7, ¶ [0027]. “Undesirable odours and taste of marine/krill oils can be removed or further removed by washing ... These additional steps completely eliminate or remove DMS and odor-causing amines such as trimethylamine (TMA) from the extract[krill oil].”
3. The krill oil composition of claim 1, wherein said krill oil contains astaxanthin esters in an amount of greater than about 200 mg/kg of said krill oil.	See claim 1(c).
4. The krill oil composition of claim 1, wherein said krill oil comprises at least 30% total phospholipids w/w of said krill oil.	<u>'388 Pat.App.Pub. (Exhibit 1043)</u> P. 0039, 1st col., [0105].

CLAIMS	REFERENCES																																																																												
	TABLE 22 <table><tr><th colspan="4">Phospholipid profiles</th></tr><tr><th></th><th>Type B krill powder</th><th>NKO</th><th>Krill Oil obtained in Example 7</th></tr><tr><td>PC</td><td>66.0</td><td>68.6</td><td>75.3</td></tr><tr><td>AAPC</td><td>12.0</td><td>7.0</td><td>13.0</td></tr><tr><td>PI</td><td></td><td></td><td></td></tr><tr><td>1LPC</td><td>1.2</td><td>1.3</td><td>0.4</td></tr><tr><td>PS</td><td></td><td></td><td></td></tr><tr><td>2LPC</td><td>7.4</td><td>13.8</td><td>2.9</td></tr><tr><td>LAAPC</td><td>2.2</td><td>1.2</td><td>0.9</td></tr><tr><td>PE</td><td>6.0</td><td>3.4</td><td>3.4</td></tr><tr><td>AAPE</td><td></td><td></td><td>1.5</td></tr><tr><td>SM</td><td></td><td></td><td></td></tr><tr><td>GPC</td><td></td><td>1.3</td><td></td></tr><tr><td>DHSM</td><td></td><td></td><td></td></tr><tr><td>NAPE</td><td></td><td>3.4</td><td></td></tr><tr><td>CL</td><td>5.3</td><td></td><td>2.1</td></tr><tr><td>LPE</td><td></td><td></td><td>0.5</td></tr><tr><td>LCL</td><td></td><td></td><td></td></tr><tr><td>% PL in powder or lipid sample</td><td>8.3</td><td>30.0</td><td>47.9</td></tr></table> % PL in krill oil composition=47.9% OR <u>Bruheim (Exhibit 1085)</u> P. 0006, 2nd col., ¶ [0010]. “In one embodiment, the present invention contemplates an oil composition comprising approximately 400-500 grams/Kg phospholipids [40%-50%], approximately 200-260 grams/Kg Omega-3 fatty acids, less than 0.5 mg/Kg fluoride, approximately 15 grams/Kg lysophosphatidic acid, and less than approximately 8 grams/Kg free fatty acids.”	Phospholipid profiles					Type B krill powder	NKO	Krill Oil obtained in Example 7	PC	66.0	68.6	75.3	AAPC	12.0	7.0	13.0	PI				1LPC	1.2	1.3	0.4	PS				2LPC	7.4	13.8	2.9	LAAPC	2.2	1.2	0.9	PE	6.0	3.4	3.4	AAPE			1.5	SM				GPC		1.3		DHSM				NAPE		3.4		CL	5.3		2.1	LPE			0.5	LCL				% PL in powder or lipid sample	8.3	30.0	47.9
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	P. 0017, 1st col., ¶ [0111]. “Triglycerides (TAGs) were measured at around 40 wt % and phospholipids (e.g., polar lipids) at around 50% in the extracts. See, Table V.” <u>Neptune GRAS (Exhibit 1075)</u> P. 0010, Table 2. Batch Analysis of Three Lots of NKO™. Total Phospholipids 43.8-47.3 g/ 100g. [43.8%-47.3%]																					
5. The krill oil composition of claim 1, wherein said krill oil comprises at least 30% phosphatidylcholine w/w of said krill oil.	<u>‘388 Pat.App.Pub. (Exhibit 1043)</u> P. 0037, 1st col. TABLE 18B <table><tr><th colspan="3">Lipid class composition of the extract collected after CO₂ and 20% ethanol in S1.</th></tr><tr><th>Lipid</th><th>Unit</th><th>Amount</th></tr><tr><td>Triacylglycerol</td><td>g/100 g</td><td><0.5</td></tr><tr><td>Cholesterol</td><td>g/100 g</td><td><0.5</td></tr><tr><td>Phosphatidylethanolamine</td><td>g/100 g</td><td>1.6</td></tr><tr><td>Phosphatidylcholine</td><td>g/100 g</td><td>67</td></tr><tr><td>Lyso-phosphatidylcholine</td><td>g/100 g</td><td>4.4</td></tr></table> Phosphatidylcholine having a level of 67% (67 g / 100g)	Lipid class composition of the extract collected after CO ₂ and 20% ethanol in S1.			Lipid	Unit	Amount	Triacylglycerol	g/100 g	<0.5	Cholesterol	g/100 g	<0.5	Phosphatidylethanolamine	g/100 g	1.6	Phosphatidylcholine	g/100 g	67	Lyso-phosphatidylcholine	g/100 g	4.4
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	P. 0037, 2nd col. <table><tr><th colspan="3">TABLE 19B</th></tr><tr><th colspan="3">Lipid class composition of the final blended product obtained in Example 4.</th></tr><tr><th>Lipid</th><th>Unit</th><th>Amount</th></tr><tr><td>Triacylglycerol</td><td>g/100 g</td><td>53</td></tr><tr><td>Diacylglycerol</td><td>g/100 g</td><td>1.3</td></tr><tr><td>Free fatty acids</td><td>g/100 g</td><td>0.5</td></tr><tr><td>Cholesterol</td><td>g/100 g</td><td>0.6</td></tr><tr><td>Cholesterol esters</td><td>g/100 g</td><td><0.5</td></tr><tr><td>Phosphatidylethanolamine</td><td>g/100 g</td><td><1</td></tr><tr><td>Phosphatidylcholine</td><td>g/100 g</td><td>42</td></tr><tr><td>Lyso-phosphatidylcholine</td><td>g/100 g</td><td>5.9</td></tr></table> Phosphatidylcholine having a level of 42% (42 g / 100g) OR ----- <u>Bruheim (Exhibit 1085)</u> P. 0016, Table IV, extract 2. 77.1% of phospholipid content is PC and 46.03 % of the extract is PL; 35.5% of lipid extract is PC. P. 0016, Table IV, extract 3. 76.9% of phospholipid content is PC and 57.94 % of the extract is PL; 44.6% of lipid extract is PC.	TABLE 19B			Lipid class composition of the final blended product obtained in Example 4.			Lipid	Unit	Amount	Triacylglycerol	g/100 g	53	Diacylglycerol	g/100 g	1.3	Free fatty acids	g/100 g	0.5	Cholesterol	g/100 g	0.6	Cholesterol esters	g/100 g	<0.5	Phosphatidylethanolamine	g/100 g	<1	Phosphatidylcholine	g/100 g	42	Lyso-phosphatidylcholine	g/100 g	5.9
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CLAIMS	REFERENCES
6. The krill oil composition of claim 1, wherein said capsule contains a phytonutrient derived from a source other than krill.	<u>'388 Pat.App.Pub. (Exhibit 1043)</u> P. 0028, 2nd col., ¶ [0083]. “In still further embodiments, the compositions comprise at least one phytonutrient ... Sources of plant phytonutrients include...rose hips...” <u>OR</u> ----- <u>Randolph (Exhibit 1011)</u> P. 0004, 1st col., ¶ [0008]. “In another aspect, the composition can comprise rosehips and krill oil. In yet another aspect, the composition can comprise rosehips, blackberry, blueberry, elderberry and krill oil.”
7. The krill oil composition of claim 1, wherein said krill oil further comprises	
7(a) from about 3% to about 10% w/w ether phospholipids;	<u>'388 Pat.App.Pub. (Exhibit 1043)</u> P. 0039, 1st col., ¶[0105].

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	TABLE 22 <table><tr><th colspan="4">Phospholipid profiles</th></tr><tr><th></th><th>Type B krill powder</th><th>NKO</th><th>Krill Oil obtained in Example 7</th></tr><tr><td>PC</td><td>66.0</td><td>68.6</td><td>75.3</td></tr><tr><td>AAPC</td><td>12.0</td><td>7.0</td><td>13.0</td></tr><tr><td>PI</td><td></td><td></td><td></td></tr><tr><td>1LPC</td><td>1.2</td><td>1.3</td><td>0.4</td></tr><tr><td>PS</td><td></td><td></td><td></td></tr><tr><td>2LPC</td><td>7.4</td><td>13.8</td><td>2.9</td></tr><tr><td>LAAPC</td><td>2.2</td><td>1.2</td><td>0.9</td></tr><tr><td>PE</td><td>6.0</td><td>3.4</td><td>3.4</td></tr><tr><td>AAPE</td><td></td><td></td><td>1.5</td></tr><tr><td>SM</td><td></td><td></td><td></td></tr><tr><td>GPC</td><td></td><td>1.3</td><td></td></tr><tr><td>DHSM</td><td></td><td></td><td></td></tr><tr><td>NAPE</td><td></td><td>3.4</td><td></td></tr><tr><td>CL</td><td>5.3</td><td></td><td>2.1</td></tr><tr><td>LPE</td><td></td><td></td><td>0.5</td></tr><tr><td>LCL</td><td></td><td></td><td></td></tr><tr><td>% PL in powder or lipid sample</td><td>8.3</td><td>30.0</td><td>47.9</td></tr></table> Ether phospholipids as a percentage of phospholipids (PL) = 13.0 (AAPC) + 0.9 (LAAPC) + 1.5 (AAPE) = 15.4% % PL in krill oil composition = 47.9% % Ether phospholipids in krill oil composition = 15.4 x 47.9 = 7.38% OR <u>Bruheim (Exhibit 1085)</u> P. 0016, Table IV, extract 2. AAPC 9.0; LAAPC 1.2; AAPE 1.5; and Total PL 46.03 (wt% of sample). Total ether phospholipid= 11.7 of PL.	Phospholipid profiles					Type B krill powder	NKO	Krill Oil obtained in Example 7	PC	66.0	68.6	75.3	AAPC	12.0	7.0	13.0	PI				1LPC	1.2	1.3	0.4	PS				2LPC	7.4	13.8	2.9	LAAPC	2.2	1.2	0.9	PE	6.0	3.4	3.4	AAPE			1.5	SM				GPC		1.3		DHSM				NAPE		3.4		CL	5.3		2.1	LPE			0.5	LCL				% PL in powder or lipid sample	8.3	30.0	47.9
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	If PL is 46.03 % of total sample, then ether phospholipid is 5.4% of lipid extract.																																																																												
7(b) from about 27% to 50% w/w non-ether phospholipids	<u>'388 Pat.App.Pub. (Exhibit 1043)</u> P. 0039, 1st col., ¶[0105]. TABLE 22 <table><tr><th colspan="4">Phospholipid profiles</th></tr><tr><th></th><th>Type B krill powder</th><th>NKO</th><th>Krill Oil obtained in Example 7</th></tr><tr><td>PC</td><td>66.0</td><td>68.6</td><td>75.3</td></tr><tr><td>AAPC</td><td>12.0</td><td>7.0</td><td>13.0</td></tr><tr><td>PI</td><td></td><td></td><td></td></tr><tr><td>1LPC</td><td>1.2</td><td>1.3</td><td>0.4</td></tr><tr><td>PS</td><td></td><td></td><td></td></tr><tr><td>2LPC</td><td>7.4</td><td>13.8</td><td>2.9</td></tr><tr><td>LAAPC</td><td>2.2</td><td>1.2</td><td>0.9</td></tr><tr><td>PE</td><td>6.0</td><td>3.4</td><td>3.4</td></tr><tr><td>AAPE</td><td></td><td></td><td>1.5</td></tr><tr><td>SM</td><td></td><td></td><td></td></tr><tr><td>GPC</td><td></td><td>1.3</td><td></td></tr><tr><td>DHSM</td><td></td><td></td><td></td></tr><tr><td>NAPE</td><td></td><td>3.4</td><td></td></tr><tr><td>CL</td><td>5.3</td><td></td><td>2.1</td></tr><tr><td>LPE</td><td></td><td></td><td>0.5</td></tr><tr><td>LCL</td><td></td><td></td><td></td></tr><tr><td>% PL in powder or lipid sample</td><td>8.3</td><td>30.0</td><td>47.9</td></tr></table> Ether phospholipids as a percentage of phospholipids (PL) = 13.0 (AAPC) + 0.9 (LAAPC) + 1.5 (AAPE) = 15.4% % PL in krill oil composition = 47.9% % Non-ether phospholipids in krill oil composition = 84.6 x 47.9 = 40.5% OR	Phospholipid profiles					Type B krill powder	NKO	Krill Oil obtained in Example 7	PC	66.0	68.6	75.3	AAPC	12.0	7.0	13.0	PI				1LPC	1.2	1.3	0.4	PS				2LPC	7.4	13.8	2.9	LAAPC	2.2	1.2	0.9	PE	6.0	3.4	3.4	AAPE			1.5	SM				GPC		1.3		DHSM				NAPE		3.4		CL	5.3		2.1	LPE			0.5	LCL				% PL in powder or lipid sample	8.3	30.0	47.9
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7(c) so that the amount of total phospholipids in the composition is from about 30% to 60% w/w; and	<u>'388 Pat.App.Pub. (Exhibit 1043)</u> P. 0039, 1st col., [0105]. TABLE 22 <table><tr><th colspan="4">Phospholipid profiles</th></tr><tr><th></th><th>Type B krill powder</th><th>NKO</th><th>Krill Oil obtained in Example 7</th></tr><tr><td>PC</td><td>66.0</td><td>68.6</td><td>75.3</td></tr><tr><td>AAPC</td><td>12.0</td><td>7.0</td><td>13.0</td></tr><tr><td>PI</td><td></td><td></td><td></td></tr><tr><td>1LPC</td><td>1.2</td><td>1.3</td><td>0.4</td></tr><tr><td>PS</td><td></td><td></td><td></td></tr><tr><td>2LPC</td><td>7.4</td><td>13.8</td><td>2.9</td></tr><tr><td>LAAPC</td><td>2.2</td><td>1.2</td><td>0.9</td></tr><tr><td>PE</td><td>6.0</td><td>3.4</td><td>3.4</td></tr><tr><td>AAPE</td><td></td><td></td><td>1.5</td></tr><tr><td>SM</td><td></td><td></td><td></td></tr><tr><td>GPC</td><td></td><td>1.3</td><td></td></tr><tr><td>DHSM</td><td></td><td></td><td></td></tr><tr><td>NAPE</td><td></td><td>3.4</td><td></td></tr><tr><td>CL</td><td>5.3</td><td></td><td>2.1</td></tr><tr><td>LPE</td><td></td><td></td><td>0.5</td></tr><tr><td>LCL</td><td></td><td></td><td></td></tr><tr><td>% PL in powder or lipid sample</td><td>8.3</td><td>30.0</td><td>47.9</td></tr></table> % PL in krill oil composition=47.9% OR	Phospholipid profiles					Type B krill powder	NKO	Krill Oil obtained in Example 7	PC	66.0	68.6	75.3	AAPC	12.0	7.0	13.0	PI				1LPC	1.2	1.3	0.4	PS				2LPC	7.4	13.8	2.9	LAAPC	2.2	1.2	0.9	PE	6.0	3.4	3.4	AAPE			1.5	SM				GPC		1.3		DHSM				NAPE		3.4		CL	5.3		2.1	LPE			0.5	LCL				% PL in powder or lipid sample	8.3	30.0	47.9
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	----- <u>Bruheim (Exhibit 1085)</u> P. 0016, Table IV, extract 2. Total PL (wt% of sample) is 46.03% <u>Neptune GRAS (Exhibit 1075)</u> P. 0010, Table 2. Batch Analysis of Three Lots of NKO™. Total Phospholipids 43.8-47.3 g/ 100g. [43.8%-47.3%]																														
7(d) from about 20% to 50% w/w triglycerides.	<u>'388 Pat.App.Pub. (Exhibit 1043)</u> P. 0038, 2nd col., ¶[0103]. TABLE 21 <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="2" style="text-align: center;">Analysis of the krill oil obtained using supercritical fluid extraction.</th></tr> <tr> <th style="text-align: left;">Parameter</th><th style="text-align: left;">Value</th></tr> </thead> <tbody> <tr> <td>Ethanol</td><td>1.11% w/w</td></tr> <tr> <td>Water Content</td><td>2.98% w/w</td></tr> <tr> <td>C20:5 n-3 (EPA)</td><td>19.9</td></tr> <tr> <td>C22:6 n-3 (DHA)</td><td>11.3</td></tr> <tr> <td>Total Omega 3</td><td>35.7</td></tr> <tr> <td>Total Omega 6</td><td>3.0</td></tr> <tr> <td>Total Phospholipids</td><td>50.55 wt %</td></tr> <tr> <td>Ratio Omega3-PL/Total Omega 3</td><td>77.6% w/w</td></tr> <tr> <td>Ratio EPA-PL/Total EPA</td><td>84.4% w/w</td></tr> <tr> <td>Ratio DHA-PL/Total DHA</td><td>74.7% w/w</td></tr> <tr> <td>Triglycerides</td><td>25.9 g/100 g</td></tr> <tr> <td>Astaxanthin</td><td>2091 mg/kg</td></tr> <tr> <td>Peroxide Value</td><td><0.1</td></tr> </tbody> </table> % triglycerides in krill oil 25.9g/100g =25.9% <u>OR</u>	Analysis of the krill oil obtained using supercritical fluid extraction.		Parameter	Value	Ethanol	1.11% w/w	Water Content	2.98% w/w	C20:5 n-3 (EPA)	19.9	C22:6 n-3 (DHA)	11.3	Total Omega 3	35.7	Total Omega 6	3.0	Total Phospholipids	50.55 wt %	Ratio Omega3-PL/Total Omega 3	77.6% w/w	Ratio EPA-PL/Total EPA	84.4% w/w	Ratio DHA-PL/Total DHA	74.7% w/w	Triglycerides	25.9 g/100 g	Astaxanthin	2091 mg/kg	Peroxide Value	<0.1
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Peroxide Value	<0.1																														

CLAIMS	REFERENCES
	----- <u>Bruheim (Exhibit 1085)</u> P. 0017, 1st col., ¶ [0111]. “Triglycerides (TAGs) were measured at around 40 wt % ... in the extracts. See, Table V.” P. 0016, 1st col., Table V, Main Components Of The Lipid Extracts 40.3-42.1 % of lipid extract is TAG [triglycerides].
8. The krill oil composition of claim 7, wherein said krill oil further comprises from about 20% to 35% omega-3 fatty acids as a percentage of total fatty acids in said composition.	<u>‘388 Pat.App.Pub. (Exhibit 1043)</u> P. 0026, 2nd col., ¶[0072]. “In some embodiments, the compositions comprise from about 20% to 35%, preferably from about 25% to 35%, omega-3 fatty acids as a percentage of total fatty acids in the composition,” <u>OR</u> ----- <u>Bottino (Exhibit 1007)</u> P. 0002, Table 1.

CLAIMS	REFERENCES
	Omega-3 fatty acids²⁹ (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 acids³⁰ as weight percent of total acids of Euphausia superba: 28.6%
9. The krill oil composition of claim 1, wherein said capsule is a soft gel capsule.	<u>‘388 Pat.App.Pub. (Exhibit 1043)</u> P. 0027, 2nd col., ¶ [0078]. “The composition is preferably in the form of a tablet or capsule and most preferably in the form of a soft gel capsule.” <u>OR</u> -----

²⁹ 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).

³⁰ 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
	<u>Neptune GRAS (Exhibit 1075)</u> P. 0019. “The supplement is sold in 300 and 500 mg capsules with a recommended dose of 1-2 capsules per day.”; “Softgels containing the NKO™ have been available as dietary supplements in North American for several years...”
10. The krill oil composition of claim 1, wherein said krill oil comprises less than about 0.45% w/w arachadonic acid.	<u>‘388 Pat.App.Pub. (Exhibit 1043)</u> P. 0022, 1st col., ¶ [0020]. “In some embodiments, the composition comprises less than about 0.45% arachidonic acid (w/w).” <u>OR</u> ----- <u>Neptune GRAS (Exhibit 1075)</u> P. 0016 Table 9 fatty acid content of NKO™ C20:4 n-6 (arachidonic) 0.24-0.43 (% of total lipid)
11. A composition comprising a soft gel capsule containing	See claim 9.

CLAIMS	REFERENCES
11(a) Euphausia superba krill oil suitable for oral administration,	See claim 1(a).
11(b) said krill oil comprising from 3% to 15% ether phospholipids w/w of said krill oil and	See claim 1(b).
11(c) astaxanthin esters in amount of greater than about 100 mg/kg of said krill oil.	See claim 1(c).
12. The composition of claim 11, wherein said krill oil composition is substantially odorless.	See claim 2.
13. The composition of claim 11, wherein said krill oil contains astaxanthin esters in an amount of greater than about 200 mg/kg of said krill oil.	See claim 1(c).

CLAIMS	REFERENCES
14. The composition of claim 11, wherein said krill oil comprises at least 30% total phospholipids w/w of said krill oil.	See claim 4.
15. The composition of claim 11, wherein said krill oil comprises at least 30% phosphatidylcholine w/w of said krill oil.	See claim 5.
16. The composition of claim 11, wherein said krill oil comprises at least 40% phosphatidylcholine w/w of said krill oil.	See claim 5.
17. The composition of claim 11, wherein said capsule contains a phytonutrient derived from a source other than krill.	See claim 6.
18. The composition of claim 11, wherein said krill oil further comprises	
18(a) from about 3% to about 10% w/w ether phospholipids;	See claim 1(b).
18(b) from about 27% to 50% w/w non-ether phospholipids	See claim 7(b).

CLAIMS	REFERENCES
18(c) so that the amount of total phospholipids in the composition is from about 30% to 60% w/w;	See claim 7(c).
18(d) and from about 20% to 50% w/w triglycerides.	See claim 7(d).
19. The composition of claim 18, wherein said krill oil further comprises from about 20% to 35% omega-3 fatty acids as a percentage of total fatty acids in said composition.	See claim 8.
20. The composition of claim 11, wherein said krill oil comprises less than about 0.45% w/w arachadonic acid.	See claim 10.

TALLON APPENDIX D

Curriculum Vitae – Dr Stephen Tallon

PART 1

1a. Personal details			
Present position	Principal Research Scientist		
Organisation/Employer	Callaghan Innovation		
Contact Address	69 Gracefield Rd, Lower Hutt, New Zealand		
		Post code	5040
Work telephone		Mobile	
Email	Stephen.Tallon@callaghaninnovation.govt.nz		

1b. Academic qualifications

PhD (Chemical and Materials Engineering) 2001, Auckland University, Auckland, New Zealand

M.E (Chemical and Process Engineering, with distinction), 1995, Canterbury University, Christchurch, New Zealand

B.E (Chemical and Process Engineering, Honours), 1993, Canterbury University, Christchurch, New Zealand

1c. Professional positions held

1992-Present: Principle Research Scientist, Callaghan Innovation, Lower Hutt, New Zealand.

1d. Present research/professional speciality

Natural product extraction and fractionation
Processing operations using supercritical fluid and compressed gas solvents
Engineering process design and evaluation

1e. Professional distinctions and memberships (including honours, prizes, scholarships, boards or governance roles, etc)

Chemeca 2012 organising committee member

Member of the American Institute of Chemical Engineers

Programme leader, MBIE (FRST) High Value Lipids contract CO8X0709
Intermediate Outcome 2, 2007-2013

Honorary research associate, Massey University, 2004.

AIChE Particle Technology Forum 2003 award for best PhD thesis in the particle technology field, sponsored by Proctor and Gamble.

John A Brodie Medal, 9th Asia Pacific Confederation of Chemical Engineers Congress, Christchurch, New Zealand, 2002, Certificate of Merit.

Auckland University Best Doctoral Thesis Award, 2002.

Engineering Foundation Conference Fellowship, Fluidization IX, Durango, Colorado, USA, May 17-22, 1998

Du Pont de Nemours award, best postgraduate paper, Chemeca Conference, Adelaide, Australia, September, 1996.

PART 2

Research publications and patents

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