PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

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

ORDER NO. 13: MARKMAN ORDER

(April 13, 2017)

A *Markman* hearing was held in this investigation on March 2, 2017. Counsel for Complainants Aker BioMarine Antarctic AS and Aker BioMarine Manufacturing, LLC and Respondents Olympic Holding AS, Rimfrost AS, Emerald Fisheries AS, Avoca, Inc., Rimfrost USA, LLC, Rimfrost New Zealand Limited, and Bioriginal Food & Science Corp. appeared at the hearing. In advance of the hearing, Complainants and Respondents filed initial and rebuttal *Markman* briefs.[1,2]

[1] Complainants filed a corrected initial brief pursuant to Order No. 9 (Feb. 10, 2017).

[2] Complainants' initial and rebuttal briefs are referenced herein as "CIB" and "CRB," and Respondents' initial and rebuttal briefs are referenced herein as "RIB" and "RRB."

Table of Contents

I. PROCEDURAL HISTORY

This investigation was instituted to determine whether there is a violation of section 337 of the Tariff Act of 1930, as amended, in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain krill oil products and krill meal for production of krill oil products by reason of infringement of certain claims of U.S. Patent No. 9,028,877 (the "'877 patent"); U.S. Patent No. 9,078,905 (the "'905 patent"); U.S. Patent No. 9,072,752 (the "'752 patent"); U.S. Patent No. 9,320,765 (the "'765 patent"); and U.S. Patent No. 9,375,453 (the "'453 patent"). Notice of Investigation, 81 Fed. Reg. 63805-06 (2016). Pursuant to Order No. 5, the '905 patent was withdrawn from the investigation. Order No. 5 (Oct. 17, 2016), *not reviewed by* Comm'n Notice (Nov. 7, 2016).

The asserted claims in the four remaining patents are claims 1-4, 7-9, 11-13, and 16-18 of the '877 patent; claims 1, 7, and 11-13 of the '752 patent; claims 1-5, 7, 9-12, 14-15, 19-21, 23, 25-29, 31, 33-36, 38-39, 43-45, and 47 of the '765 patent; and claims 1, 5-10, 12, 14-17, 19-20, 24-26, 28, 30-32, 33-36, 39-43, 46-49, 51-52, 56-58, and 60 of the '453 patent. All of the asserted patents claim priority to the same parent application and share a common specification. The parties' *Markman* briefing addresses six disputed claim terms, each of which appears in the claims of several of the asserted patents.

II. LEGAL STANDARD

"The construction of claims is simply a way of elaborating the normally terse claim language[] in order to understand and explain, but not to change, the scope of the claims." *Embrex, Inc. v. Serv. Eng'g Corp.*, 216 F.3d 1343, 1347 (Fed. Cir. 2000) (alterations in original) (quoting *Scripps Clinic v. Genentech, Inc.*, 927 F.2d 1565, 1580 (Fed. Cir. 1991)). "[O]nly those [claim] terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy." *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed.

Cir. 1999).

Claim construction focuses mainly on the intrinsic evidence, which consists of the claims themselves, the specification, and the prosecution history. *See generally Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*). The Federal Circuit in *Phillips* explained that, in construing terms, courts must analyze each of these components to determine the "ordinary and customary meaning of a claim term," which is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Id.* at 1313.

"It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" *Id.* at 1312. "Quite apart from the written description and the prosecution history, the claims themselves provide substantial guidance as to the meaning of particular claim terms." *Id.* at 1314. For example, "the context in which a term is used in the asserted claim can be highly instructive," and "[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment as to the meaning of a claim term." *Id.*

"[T]he specification 'is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'" *Id.* at 1315 (quoting *Vitronics Corp. v. Conceptronic*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). "The longstanding difficulty is the contrasting nature of the axioms that (a) a claim must be read in view of the specification and (b) a court may not read a limitation into a claim from the specification." *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1117 (Fed. Cir. 2004). The Federal Circuit has explained that there are certain instances when the specification may limit the meaning of the claim language. For example, "the specification may reveal a special definition given to a claim term by the patentee that differs from the

meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Phillips,* 415 F.3d at 1316. The specification also "may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor." *Id.* In such cases, "the inventor has dictated the correct claim scope, and the inventor's intention, as expressed in the specification, is regarded as dispositive." *Id.*

In addition to the claims and the specification, the prosecution history should be examined if in evidence. "The prosecution history . . . consists of the complete record of the proceedings before the PTO and includes the prior art cited during the examination of the patent. Like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent." *Id.* at 1317. "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

If the intrinsic evidence does not establish the meaning of a claim, then extrinsic evidence may be considered. Extrinsic evidence "consists of all evidence external to the patent and the prosecution history, including inventor and expert testimony, dictionaries, and learned treatises." *Id.* at 1317. Extrinsic evidence is generally viewed "as less reliable than the patent and its prosecution history in determining how to read claim terms." *Id.* at 1318. "The court may receive extrinsic evidence to educate itself about the invention and the relevant technology, but the court may not use extrinsic evidence to arrive at a claim construction that is clearly at odds with the construction mandated by the intrinsic evidence." *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 977 (Fed. Cir. 1999).

III. ASSERTED PATENTS

The four asserted patents claim priority to the same parent application and share a

common specification. The parent application, U.S. Patent Application No. 12/057,775, was filed on March 28, 2008, naming inventors Inge Bruheim, Snorre Tilseth, and Daniele Mancinelli of Aker Biomarine Antarctic AS. The '877 patent, entitled "Bioeffective Krill Oil Compositions," issued on May 12, 2015, with two independent claims for methods of production of krill oil. The '453 patent, entitled "Methods for Producing Bioeffective Krill Oil Compositions," issued on June 28, 2016, with two independent claims for methods of production of polar krill oil. The '752 patent, entitled "Bioeffective Krill Oil Compositions," issued on July 7, 2015, with two independent claims for specific compositions of krill oil. The '765 patent, also entitled "Bioeffective Krill Oil Compositions," issued on April 26, 2016, with two independent claims for specific compositions of krill oil.

The common specification of the asserted patents describes the extraction of krill oil from Antarctic krill. In the prior art, frozen krill was transported over long distances for processing. '877 patent at 2:3-16. The patents describe the downsides of this transportation, which "is both expensive and can result in degradation of the krill starting material." *Id.* at 2:5-6. To avoid these problems, the patents describe a process where krill meal is "processed on board a ship in Antarctica using live krill as starting material." *Id.* at 9:33-36. This processing includes a "protein denaturation step" followed by the extraction of krill oil. *Id.* at 9:48-54. This extraction can proceed in two stages, with the neutral lipids being extracted in the first stage and the polar lipids being extracted in the second stage. *Id.* at 9:36-42. The result of the process is krill oil "characterized by containing high levels of astaxanthin, phospholipids, includ[ing] enriched quantities of ether phospholipids and omega-3 fatty acids." *Id.* at 9:28-31.

IV. LEVEL OF ORDINARY SKILL IN THE ART

Complainants contend that a person of ordinary skill in the relevant art would have a Bachelor's degree in chemical engineering, chemistry, biology, or food science, plus 1-3 years'

experience related to the analysis of organic compounds. CIB at 15. Respondents contend that a person of ordinary skill in the art would have held an advanced degree in a relevant scientific field,[3] knowledge of or experience in the field of extraction, and at least five years' post-graduate experience. RIB at 11. Although Respondents propose a more advanced standard for ordinary skill in the art, this dispute between the parties does not affect the construction of any of the disputed terms, and it is not resolved at this time.

V. DISPUTED TERMS

The parties briefed six disputed terms from the asserted patents, and five of these terms remain disputed.[4]

A. "krill oil"

The term "krill oil" appears in all of the asserted independent claims.

Term	Complainants' Construction	Respondents' Construction
"krill oil"	oil produced from krill	oil virtually free of enzymatically decomposed oil constituents that are obtained from krill following protein denaturation

Complainants propose that this term has its plain and ordinary meaning. In Complainants' view, the patents use the term "krill oil" in accordance with its plain and ordinary meaning, and there is no definition or disclaimer in the specification. CIB at 16-18.

[3] Respondents identify marine sciences, biochemistry, organic (especially lipid) chemistry, nutritional sciences, chemical or process engineering, or associated sciences with complementary understanding, either through education or experience, of biochemistry, organic chemistry and in particular lipid chemistry, nutrition, chemical or process engineering, marine biology, or associated sciences. RIB at 11.

[4] The parties previously disputed the terms "freshly harvested" and "freshly caught," but during the *Markman* hearing, the parties agreed that the claim language itself was more clear than any of the parties' proposed constructions, and accordingly, no construction is adopted at this time. Tr. at 115:21-116:19.

Respondents base their proposed construction on a description of the invention in the specification, pointing to the second paragraph of the "Detailed Description of the Invention," which states:

> 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 . . . . Surprisingly, it has been found that the use of mild denaturation conditions can greatly enhance the quality of krill oil.

'877 patent at 9:43-60. Respondents argue that this description of the "present invention" limits the claims to krill oil that is virtually free of enzymatically decomposed oil constituents that are obtained from krill following protein denaturation. RIB at 12-16; RRB at 1-7. Respondents argue that the specification consistently distinguishes the claimed krill oil from the prior art that contained decomposed phospholipids. RIB at 15 (citing '877 patent at 10:51-64).

I agree with Complainants that the term "krill oil" in the asserted patents has its plain and ordinary meaning, which is oil produced from krill. *See Phillips*, 415 F.3d at 1313 ("[T]he words of a claim are generally given their ordinary and customary meaning."). The specification uses the term "krill oil" generally, to refer to both the prior art and the claimed invention. *See, e.g.,* '877 patent at 1:31-32 ("In order to isolate the krill oil from the krill, solvent extraction methods have been used."), 1:46-52 ("Krill oil compositions have been described as being effective for decreasing cholesterol . . . ."), 9:43-45 ("The present invention provides methods to avoid decomposition of glycerides and phospholipids in krill oil and compositions produced by those methods."), 9:58-60 ("Surprisingly, it has been found that the use of mild denaturation conditions can greatly enhance the quality of krill oil."). There is no indication that the patentee

acted as his own lexicographer when using the term "krill oil" or disclaimed the full scope of the term "krill oil" in the specification or during prosecution. *See Thorner v. Sony Computer Entertainment America LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012).

At the *Markman* hearing, Respondents cited case law emphasizing the importance of patent language referencing the "present invention," but the Federal Circuit has held that such language "is not always so limiting, such as where the references to a certain limitation as being the 'invention' are not uniform, or where other portions of the intrinsic evidence do not support applying the limitation to the entire patent." *Absolute Software, Inc. v. Stealth Signal, Inc.*, 659 F.3d 1121, 1136-37 (Fed. Cir. 2011). That is the case here, where the paragraph referencing decomposed oil constituents is only one of many descriptions of the "invention" and the "present invention" in the specification. When these statements are read in the context of the entire specification, it is clear that avoiding decomposition is only one of many benefits of the invention. It would be inappropriate to read such a limitation into every claim that uses the term "krill oil."

Respondents' arguments focus on the description of the "present invention" in the second paragraph of the "Detailed Description of the Invention," but the preceding paragraph emphasizes different features of the invention: "This invention discloses novel krill oil compositions characterized by containing high levels of astaxanthin, phospholipids, included [*sic*] an enriched quantities of ether phospholipids, and omega-3 fatty acids." '877 patent at 9:28-31. These components of the claimed krill oil are consistently referenced more prominently in the specification than the decomposed oil constituents cited by Respondents, appearing in the first sentence of the Abstract and the first several paragraphs of the "Summary of the Invention. *See id.* at Abstract ("This invention discloses new krill oil compositions characterized by having

high amounts of phospholipids, astaxanthin esters and/or omega-3 contents."), 2:20-41 (describing levels of phospholipids, omega-3 fatty acids, and astaxanthin esters). Notably, these limitations regarding the amount of phospholipids, astaxanthin esters, and/or triglycerides are explicitly claimed in the independent claims of the asserted patents. *See, e.g.,* '765 patent at claim 1, 34:64-35:5 ("A krill oil composition comprising *Euphausia superba* krill oil suitable for oral administration, said krill oil comprising greater than about 3% ether phospholipids w/w of said krill oil; from about 27% to 50% non-ether phospholipids w/w of said krill oil so that the amount of total phospholipids in the composition is from about 30% to 60% w/w of said krill oil; from about 20% to 50% triglycerides w/w of said krill oil, and astaxanthin esters in amount of greater than about 100 mg/kg of said krill oil.").[5] When read in the context of these other statements in the specification and the claims, the avoidance of decomposed oil constituents is at best a secondary feature of the invention.

Respondents' arguments regarding the significance of the "present invention" language are undercut by the numerous instances of this phrase in the specification. In the "Summary of the Invention," the phrase "the present invention" is invoked more than forty times, describing different aspects of the invention such as the health benefits, phospholipid content, astaxanthin levels, species of krill, capsule form, fat content, extraction steps, and methods for administering

[5] *See also* '877 patent at claim 1, 34:64-35:2 ("a krill oil with from about 3% to about 10% w/w ether phospholipids; from about 27% to 50% w/w non-ether phospholipids so that the amount of total phospholipids in said krill oil is from about 30% to 60% w/w; and about 20% to 50% w/w triglycerides"); '453 patent at claim 1, 35:48-56 ("a polar krill oil comprising phospholipids, said polar krill oil comprises greater than about 3% ether phospholipids w/w of said polar krill oil; from about 27% to 50% non-ether phospholipids w/w of said polar krill oil so that the amount of total phospholipids is from about 30% to 60% w/w of said polar krill oil; from about 20% to 50% triglycerides w/w of said polar krill oil, and astaxanthin esters in amount of greater than about 100 mg/kg of said polar krill oil"); '752 patent at claim 1, 34:65-67 ("A polar krill oil comprising greater than about 40% phosphatidylcholine w/w of said krill oil and greater than about 5% ether phospholipids w/w of said krill oil.").

krill oil. '877 patent at 2:42-7:52. The "Detailed Description of the Present Invention" similarly includes more than thirty references to the "present invention," describing the same variety of benefits, processing steps, and specific contents of the krill oil. *Id.* at 9:43-14:46. Respondents have failed to make a compelling argument for importing a "decomposed oil constituents" limitation into the claims while ignoring the many other features of the "present invention" referenced in the specification. Providing higher phospholipid content, avoiding decomposition, and improving health outcomes may all be important benefits of the invented krill oil, but the Federal Circuit has warned that "not every benefit flowing from an invention is a claim limitation." *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 843 (Fed. Cir. 2010), *aff'd*, 564 U.S. 91 (2011).

Other claim language in the asserted patents further counsels against the incorporation of Respondents' proposed limitation into the construction for "krill oil." In the method claims, there is an explicit denaturation step, which is the patent's claimed solution to the problem of decomposition. *Compare* '877 patent at 9:48-50 ("The solution to the problem is to incorporate a protein denaturation step on fresh krill prior to use of any extraction technology.") *with id.* at claim 1, 34:61-62 ("treating said krill to denature lipases and phospholipases in said krill to provide a denatured krill product"); *see also* '453 patent at claim 1, 35:45-46 ("treating the *Euphausia superba* to denature lipases and phospholipases to provide a denatured krill product"). The patentees are entitled to claim this feature by reference to a denaturation step rather than by specifying the content of decomposed oil constituents. *See Phillips*, 415 F.3d at 1312 ("It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'") (quoting *Innova*, 381 F.3d at 1115).

In addition, there are unasserted dependent claims with explicit limitations on the

proportion of attached fatty acids, which relates to the feature of avoiding decomposition. Dependent claims 5 and 14 of the '877 patent, claims 11, 18, 27, 44, and 59 of the '453 patent, and claims 6, 13, 22, 30, 37, and 40 of the '765 patent claim percentages of attached fatty acids. *See, e.g.,* '877 patent at claim 5, 35:10-12 ("wherein from about 70% to 95% of said omega-3 fatty acids are attached to said total phospholipids"); '453 patent at claim 27 ("wherein from about 70% to 95% of said omega-3 fatty acids are attached to said total phospholipids"); '765 patent at claim 13 ("wherein from about 70% to 95% of said omega-3 fatty acids are attached to said total phospholipids"). By requiring a high percentage of attached fatty acids, these limitations limit the percentage of unattached "free" fatty acids, which is the limitation that Respondents propose to incorporate into their construction.[6] The presence of this limitation in dependent claims "gives rise to a presumption that the limitation in question is not present in the independent claim." *Phillips*, 415 F.3d at 1315. The language of the dependent claims thus further counsels against the adoption of Respondents' proposed construction.

When the patent claims and specification are read as a whole, it is clear that the term "krill oil" is used in accordance with its plain and ordinary meaning, and it would be inappropriate to import Respondents' proposed limitation into this claim term.

B. "polar krill oil"

The term "polar krill oil" appears in the asserted claims of the '453 and '752 patents.

Term	Complainants' Construction	Respondents' Construction
"polar krill oil"	krill oil containing polar lipids	krill oil containing polar lipids obtained from supercritical extraction with polar entrainer

[6] As described during the tutorial, one of the advantages of krill is that the fatty acids are "attached" to phospholipids, and a problem that the invention was trying to solve is that these fatty acids detach and become "free" in the decomposition process. Tutorial Tr. at 36-37; '877 patent at 2:3-13.

The parties agree that the specification uses the term "polar krill oil" to refer to krill oil containing polar lipids, pointing to Example 3 of the specification. CIB at 19-20; RIB at 16-17 (citing '453 patent at 21:64-22:14). Complainants contend that it is sufficient to construe polar krill oil as "krill oil containing polar lipids," but Respondents argue that construction of this term requires a limitation on how the krill oil is extracted—specifying that polar krill oil must be "obtained from supercritical extraction with polar entrainer."[7]

The embodiment in Example 3 of the specification is consistent with both Complainants' and Respondents' proposed constructions. This embodiment describes a method for extracting krill oil using "a supercritical fluid extraction method in two stages." '453 patent at 21:64-65. In the first stage, "neutral krill oil" is removed using carbon dioxide. *Id.* at 21:65-67. In the second stage, ethanol is added, and the specification states: "This resulted in further extraction of 9% polar fat which hereafter is called polar krill oil." *Id.* at 22:2-3. The specification further provides several tables describing the contents of the neutral krill oil and the polar krill oil in comparison to prior art krill oil. *Id.* at 22:15-27:60. The term "polar krill oil" is also referenced earlier in the specification, including a statement that "[i]n 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." '453 patent at 11:10-14. In another part of the specification, there is an embodiment of "extracting a polar krill oil from said deodorized krill material by supercritical fluid extraction with a polar entrainer to provide an essentially odorless krill oil." *Id.* at 5:22-25. Respondents argue that the specification consistently describes the extraction of polar krill oil using supercritical fluid extraction with ethanol, a polar entrainer, and that these limitations must

[7] The claim language in the '453 patent uses the term "polar solvent," '453 patent at 35:47-48, and Respondents confirmed that there is no difference between a "polar entrainer" and a "polar solvent." Markman Tr. at 57:18-24.

be imported into the construction for "polar krill oil." RIB at 16-18.

In the context of Example 3, Respondents argue that the specification distinguishes polar krill oil from neutral krill oil by combining the use of supercritical fluid extraction and polar entrainer (ethanol). RRB at 7-10. Supercritical fluid extraction is used for both neutral krill oil and polar krill oil. '453 patent at 21:64-22:14. Respondents are correct that in Example 3, ethanol is not used for the extraction of neutral krill oil but only for polar krill oil. *Id.* at 21:65-22:3. The use of ethanol is only one of many distinctions between these two types of krill oil described in Example 3, however, which includes eight detailed tables showing differences in the contents of neutral krill oil and polar krill oil. *Id.* at 22:3-27:60. In addition, Example 3 describes differences in the pressure and length of time for the extraction of neutral krill oil and polar krill oil. *Compare id.* at 21:65-67 ("During stage 1, 12.1% fat (neutral krill oil) was removed using neat CO2 only at 300 bars, 60° C, and for 30 minutes.") *to id.* at 21:67-22:2 ("In stage 2, the pressure was increased to 400 bar and 20% ethanol was added (v/v) for 90 minutes."). The specification also indicates that the order of the steps is important, with neutral lipids extracted in the first stage and polar lipids further extracted in the second stage. *Id.* at 21:64-22:3 ("This resulted in *further* extraction of 9% polar fat which hereafter is called polar krill oil." (emphasis added)); *see also id.* at 11:7-8 ("In other embodiments, the krill oil is extracted by one or two step supercritical fluid extraction."). There is nothing in the specification to suggest that Respondents' two proposed limitations, supercritical fluid extraction and polar entrainer, are the defining features of polar krill oil in the asserted patents. Respondents have not identified any definitions or disclaimers in the specification, and these two features of polar krill oil do not appear to be any more significant than other aspects of the embodiments described in the specification.

Another part of the specification provides intrinsic evidence that contradicts Respondents' proposed construction: In Example 7, neutral lipids are extracted using supercritical fluid extraction with a polar entrainer. '453 patent at 31:44-54. In Example 7, both stages of a two-stage extraction process are performed "using supercritical fluid extraction with co-solvent." *Id.* at 31:44-45. This includes a first extraction stage using 5% ethanol to "remove neutral lipids and astaxanthin from the krill meal," and a second stage where "the ethanol content was increased to 23%." *Id.* at 31:44-54. This embodiment is referenced in another part of the specification, stating: "Surprisingly, it has been found that use of a low amount of polar solvent in the CO_2 as an entrainer facilitates the extraction of neutral lipid components and astaxanthin in a single step." *Id.* at 11:24-27. When the specification is read as a whole, there is no consistent definition of polar krill oil that comports with Respondents' proposed construction.

Respondents argue that adopting Complainants' construction without any additional limitations would remove any distinction between the claimed polar krill oil and other krill oil, RRB at 7-10, but this ignores the other limitations in the asserted claims. The claim language of the '453 patent and '752 patent explicitly incorporates other limitations that distinguish polar krill oil from other krill oil. Independent claims 1 and 33 of the '453 patent require the use of "a polar solvent to extract polar krill oil" and "astaxanthin esters in amount of greater than about 100 mg/kg of said polar krill oil." '453 patent at 35:47-56, 37:13-22. These limitations correspond directly to distinctions between neutral krill oil and polar krill oil described in Example 3 in the specification. *See* '453 patent at 21:67-22:3 (describing the use of a polar solvent, ethanol), 27:50-60 (Table 16 showing astaxanthin esters for neutral krill oil below 100 mg/kg and much higher amounts for polar krill oil). Claim 1 of the '752 patent requires "about 40% phosphatidylcholine w/w," which corresponds to an analysis of polar lipids in Example 4 in

the specification. *See* '752 patent at 27:58-64, 29:1-12 (Table 18B showing 67 g/100g of phosphatidylcholine). The limitations that characterize the claimed polar krill oil are thus specified in the claim language itself, and it would be improper to import additional unclaimed limitations from the specification.

The prosecution history further confirms that Respondents' proposed construction is incorrect. The original claims of the '453 patent included an explicit limitation requiring "supercritical fluid extraction," but this language was removed from the claims during prosecution in favor of, *inter alia*, the limitations discussed above requiring a "polar solvent" and a minimum level of astaxanthin esters:

> 1. (Currently amended) A method of production of polar krill oil from *Euphausia superba* ~~krill~~ comprising:
>
> a) Treating denaturing the *Euphausia superba* ~~krill~~ to denature lipases and phospholipases to provide a denatured krill product; and
>
> b) ~~extracting~~ contacting the denatured krill product with ~~supercritical fluid extraction~~ a polar solvent to extract ~~provide~~ a polar krill oil comprising phospholipids, wherein said polar krill oil comprising phospholipids is further characterized in comprising greater than about 3% ether phospholipids w/w of said polar krill oil; from about 27% to 50% non-ether phospholipids w/w of said polar krill oil so that the amount of total phospholipids is from about 30% to 60% w/w of said polar krill oil; from about 20% to 50% triglycerides w/w of said polar krill oil, and astaxanthin esters in amount of greater than about 100 mg/kg of said polar krill oil;

CIB, Ex. H ('453 patent file history), Applicant's Resp. to Office Action at 2 (Jan. 8, 2016); *see also* RIB Ex. 14 at 21. The Federal Circuit has held that it is improper to read a limitation back into the claims that was deleted by the applicant during prosecution. *Laryngeal Mask Co. Ltd. v. Ambu*, 618 F.3d 1367, 1372-73 (Fed. Cir. 2010). Reading a "supercritical fluid extraction" limitation back into the claims would be particularly inappropriate here because the applicants chose to amend their claims to remove this limitation in favor of other limitations defining the

claimed polar krill oil.

Accordingly, the term "polar krill oil" shall be construed to mean krill oil containing polar lipids.

C. "krill" and "*Euphausia superba*"

The terms "krill" and "*Euphausia superba*" appear in claims of all the asserted patents in the context of "krill oil," but the parties' dispute focuses on the references to "krill" and "*Euphausia superba*" in the denaturation step in the method claims of the '877 and '453 patents.

Term	Complainants' Construction	Respondents' Construction
"krill" / "*Euphausia superba*"	organisms of the order *Euphausiacea*/ organisms of the species *Euphausia superba*	small shrimplike plankton of the order *Euphausiacea*/ small shrimplike plankton of the species *Euphausia superba*

There is no dispute about the meaning or technical scope of the term krill. The parties both describe krill in biological terms as organisms of the order *Euphausiacea* and the species *Euphausia superba*. The term krill thus denotes biological organisms, and *Euphausia superba* are a species of that biological organism that live in Antarctic waters, as set forth in the patent specifications. *E.g.*, '877 patent at 1:24-26.[8]

Complainants maintain, however, that "the plain and ordinary meaning of krill includes krill parts," CRB at 10, while Respondents argue that "[t]he specification indicates that krill and *Euphausia superba* are animals, not processed pieces or parts." RIB at 20. This disagreement arises from the parties' differing interpretations of the "treating said krill" claim limitations, *e.g.*, '877 patent at 34:61-62 (claim 1), in which the term krill appears, but not from any disagreement

[8] The patents mention other species of krill, but nothing in these references indicates that the term krill means anything other than a variety of living organism known by the biological names, *e.g., E. pacifica, E. frigida, E. longirostris, E. triacantha, E. vallentini, Meganyctiphanes norvegica, Thysanoessa raschii,* and *Thysanoessa inermis*. *See, e.g.*, '877 patent at 2:65-3:2.

as to the meaning of the word krill. Construing the word krill as it is used in the patent does not resolve the parties' dispute concerning the correct interpretation of these "treating said krill" claim limitations. To resolve their dispute, the parties could have sought construction of the term "said krill" or of the term "treating said krill," but the parties have not proposed a claim term for construction that resolves this issue.[9]

Given that the meaning of the term krill is undisputed, there is no need to construe the term further. *See Vivid Techs.*, 200 F.2d at 803 ("[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.").

D. "denatured krill product"

The term "denatured krill product" appears in the extraction step in the method claims of the '877 and '453 patents.

Term	Complainants' Construction	Respondents' Construction
"denatured krill product"	a product derived in whole or in part from krill, wherein lipases and phospholipases have been denatured	the result of treating krill to denature lipases and phospholipases

On the surface, there appears to be a dispute concerning the construction of the term "denatured krill product." In particular, Complainants add to the term the concept of a product "derived *in whole or in part from krill* (emphasis added)." Nothing in the term denatured krill product, however, indicates how the denatured krill product is derived. Complainants have simply appended this element to the plain words.

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

[9] If the parties continue to dispute the application of this claim limitation to products or prior art at issue, this dispute may be further addressed at the hearing.

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.").

Neither party's construction, however, addresses the matter that is actually in dispute, which is the meaning of the claim term "said denatured krill products" in element c of claim 1. '877 patent at 34:59-63. The actual dispute seems to be whether denatured krill product is covered by the claim if it undergoes further treatment after it is denatured. *See* Markman Hearing Tr. at 99 (Complainants: "[I]t's our position that the denatured krill product covers a spectrum of krill in various states of treatment"); 104 (Respondents: "The property of what is treated and it being a denatured krill product, by the language of the claim, must be the same for what you extract.")

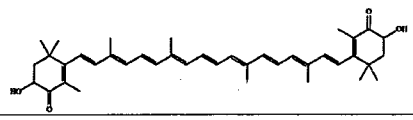
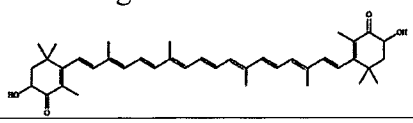
Thus, even if the Respondents' construction of the term "denatured krill product" is adopted, it does not resolve the parties' dispute. In such circumstances, claim construction of the term "denatured krill product" is unnecessary. *See Vivid Techs.,* 200 F.2d at 803.

To resolve their dispute, the parties could have sought construction of the term "said denatured krill product" or of the term "comprising," which is used in the preamble to Claim 1. In general, as Complainants assert, the use of the term "comprising" does not preclude additional steps. "The well-established meaning of "'comprising' in a method claim indicates that the claim is open-ended and allows for additional steps.'" *Solvay, S.A. v. Honeywell International Inc.,* 742 F.3d 998, 1005 (Fed. Cir. 2014) (quoting *Invitrogen Corp. v. Biocrest Mfg.,* L.P. 327 F.3d 1364, 1368 (Fed. Cir. 2003) (citing *Vivid Techs*)). The question then would have been whether anything "in the claims or specification overcomes the well-established meaning of 'comprises' as a transitional term allowing for additional steps." *Id.* The parties have not

proposed a claim term for construction that resolves this issue;[10] meanwhile, their agreement as to what constitutes "denatured krill product" makes construction of that term unnecessary.

E. "astaxanthin"

The term "astaxanthin" appears in dependent claim 7 of the '752 patent, and it also appears in the claims of the '765 patent and '453 patent as part of the phrase "astaxanthin esters."

Term	Complainants' Construction	Respondents' Construction
"astaxanthin"	the structure shown including stereoisomers 	the molecule having the following structure: 

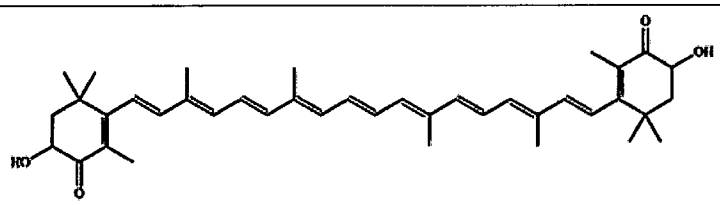
The parties' dispute concerns whether the term "astaxanthin" should be construed to encompass both the *cis* and *trans* stereoisomers of astaxanthin, or whether it should be construed to encompass only the *trans* stereoisomers of astaxanthin. Stereoisomers are molecules that have the same molecular formula and sequence of atoms, but different three-dimensional structures. Declaration of Dr. Eric Decker ("Decker Declaration").[11] Astaxanthin consists of two carbon rings connected by a chain of 18 carbon atoms linked together through a series of alternating double and single bonds. Each ring has a hydroxyl (-OH) group.

The stereoisomers of astaxanthin are characterized by the orientation of the hydroxyl groups and the orientation of the carbon chain. Each hydroxyl group is oriented so that it is either extending into or out of the page. Depending on the orientation of the hydroxyl group, the molecule is either an *R* or *S* stereoisomer. In addition, depending on the orientation of certain of the double bonds, the carbon chain connecting the two carbon rings can form either a zig-zag

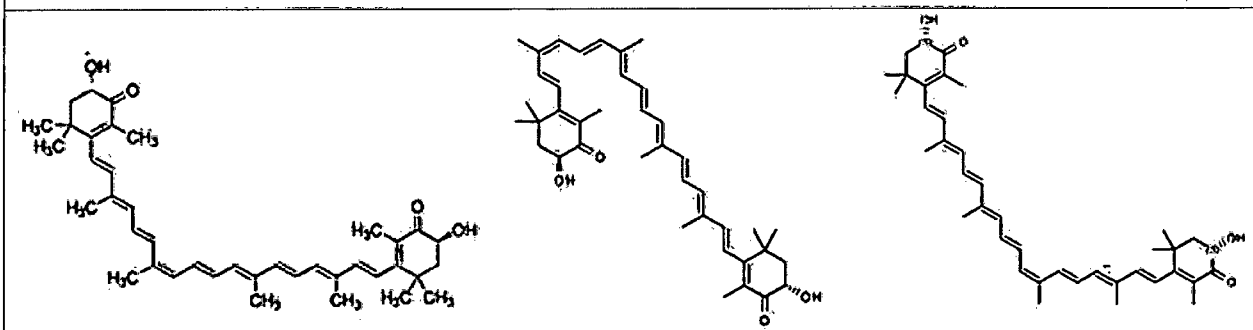
[10] If the parties continue to dispute the application of this claim limitation to products or prior art at issue, this dispute may be further addressed at the hearing.

[11] The Decker Declaration was attached as Exhibit I to Complainants' initial brief.

line that runs straight, or it can form a zig-zag line that doglegs or kinks. *Trans*-astaxanthin has a carbon chain that runs straight, while the *cis* stereoisomers have a carbon chain that is kinked or doglegged:

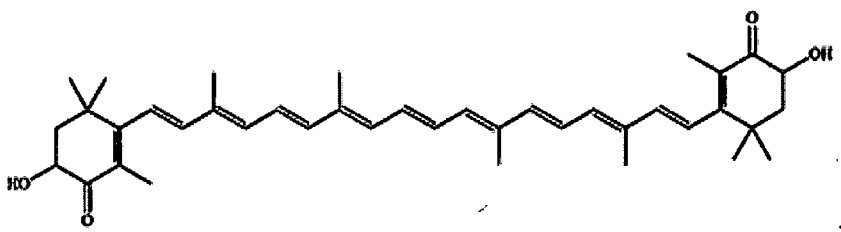


***Trans* stereoisomer of Astaxanthin**



***Cis* stereoisomers of Astaxanthin**

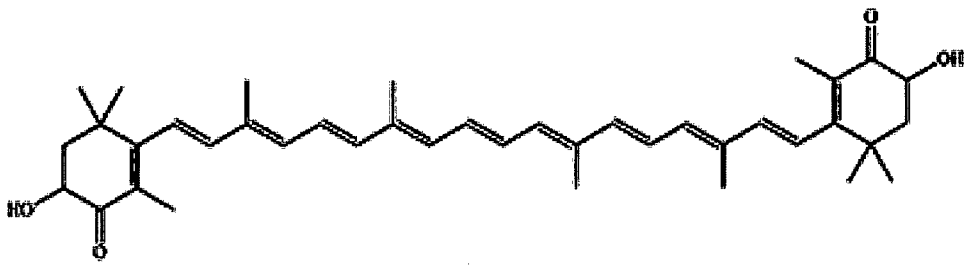
In a section of the patent entitled "Definitions," the specification expressly defines "astaxanthin" as "the following chemical structure":



'752 patent, col. 9:1-15. The image does not specify the orientations of the hydroxyl groups and there is no dispute that the patentees' definition encompasses both the *R* and the *S* stereoisomers. RIB at 30-31. Furthermore, there is no dispute that the image depicts *trans*-astaxanthin. CIB at 29 ("While the image used in the specification is a *trans* form . . . ."). Complainants, however,

argue that one of ordinary skill in the art would have understood the image as referring to *cis*-astaxanthin, as well as to *trans*-astaxanthin.

For the reasons set forth below, Complainants' arguments are unpersuasive and I find that the term "astaxanthin" means the *trans*-astaxanthin molecule having the following structure:



1. The patentees expressly defined "astaxanthin" to be *trans*-astaxanthin.

Complainants argue that "astaxanthin" should be construed to include the *cis* stereoisomers of astaxanthin, because the patentees did not distinguish between the *trans* and *cis* forms in the specification or the claims, but instead opted to use the "generic" term astaxanthin. The references to "astaxanthin" in the claims and the specification are not to "astaxanthin" generically, however, but to "astaxanthin" as the patentees expressly defined it. As discussed above, in the section of the specification entitled "Definitions," the patentees defined astaxanthin using an image of *trans*-astaxanthin. The patentees' express definition of the term "astaxanthin" governs. *Braintree Laboratories, Inc. v. Novel Laboratories, Inc.*, 749 F.3d 1349, 1355-56 (Fed. Cir. 2014) ("Under our precedent, the patentee's lexicography must govern the claim construction analysis."); *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1380–82 (Fed. Cir. 2009 ("When a patentee explicitly defines a claim term in the patent specification, the patentee's definition controls.").

Complainants argue that one of ordinary skill in the art would have understood that the patentees' definition encompassed both *cis*- and *trans*-astaxanthin, because the image of *trans*-

astaxanthin is customarily used to "generically" illustrate astaxanthin and all of its stereoisomers. Complainants' argument is unpersuasive. Assuming *arguendo* that Complainants are correct and the image of *trans*-astaxanthin is used to illustrate astaxanthin in general, it is also used to illustrate *trans*-astaxanthin in particular. For instance, the National Center for Biotechnology Information maintains the PubChem database, which contains an entry for astaxanthin.[12] As pointed out by Complainants, the PubChem entry illustrates astaxanthin using an image of *trans*-astaxanthin. PubChem entry at 1. The entry also sets forth two sets of synonyms for the image. The synonyms show that the image is used to illustrate *trans*-astaxanthin specifically. *Id.*

The first set of synonyms was obtained from the "Medical Subject Headings" ("MeSH") and the second set was obtained from "depositors" who contributed information to the PubChem database. PubChem entry at 7-8.[13] MeSH "is a controlled vocabulary thesaurus of medical terms" compiled and maintained by the National Library of Medicine. MeSH identifies three synonyms for the image of *trans*-astaxanthin: "astaxanthin," "astaxanthine," and "*E*-astaxanthin." *Id.* *E*-astaxanthin is the *trans* form of astaxanthin.[14] The "Depositor-Supplied Synonyms" for astaxanthin also show that the image of *trans*-astaxanthin is used to illustrate *trans*-astaxanthin. *Id.* at 7-8 (listing synonyms for the image of *trans*-astaxanthin, including "*trans*-Astaxanthin," "all-*trans*-Astaxanthin," "(3S, 3'S)-all-*trans*-Astaxanthin," "Astaxanthin, all-*trans*-," "all-*trans*-3,3'-dihydroxy-b-Carotene-4," "all-*trans*-4'-dione (8CI)," and "all-*trans*-3,3'-dihydroxy-beta-Carotene-4, 4'-dione (8CI)").

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[12] A printout of the PubChem entry for astaxanthin is attached as Exhibit K to the Complainants' initial brief.

[13] https://pubchem.ncbi.nlm.nih.gov/docs/subcmpd_summary_page_help.html (Medical Subject Headings (MeSH)).

[14] In chemistry, the *trans* form is indicated by the letter "*E*" and the *cis* form is indicated by the letter "*Z*."

In defining astaxanthin, the patentees do not indicate that they are using the image in any sense other than to mean *trans*-astaxanthin. For example, in defining astaxanthin, the patentees did not explicitly indicate, as they could have, that their definition encompassed stereoisomers of the molecule depicted in the image. To the extent that the image is susceptible to being interpreted by one of ordinary skill to mean all stereoisomers of astaxanthin, it is also as susceptible, if not more so, to being interpreted to mean only *trans*-astaxanthin. Where two constructions are equally plausible, the narrower construction governs. *Athletic Alternatives, Inc. v. Prince Mfg., Inc.*, 73 F.3d 1573, 1581 (Fed. Cir. 1996) ("Where there is an equal choice between a broader and a narrower meaning of a claim, and there is an enabling disclosure that indicates that the applicant is at least entitled to a claim having the narrower meaning, we consider the notice function of the claim to be best served by adopting the narrower meaning."). Accordingly, I find that the patentees defined the term "astaxanthin" to mean *trans*-astaxanthin.

2. The prosecution history does not support broadening the patentees' express definition to encompass *cis*-astaxanthin.

Complainants argue that the examiner's rejection of application claims 5, 9, and 10 showed that the examiner and the patentees understood that the term "astaxanthin" encompassed all of the stereoisomers of astaxanthin. In particular, application claims 5, 9, and 10 are directed to polar krill oil containing astaxanthin. Application for '765 Patent, 48.[15] Finding that they were unpatentable in view of U.S. Patent Application Publication No. 2004/0241249 to Sampalis ("Sampalis"), the examiner rejected the application claims. Office Action (Jun. 18, 2015) at 5. While Sampalis discloses polar krill oil containing astaxanthin, it does not specify that the

[15] Complainants submitted a certified copy of the prosecution history of the '765 patent in support of their complaint as Appendix D.

disclosed astaxanthin is *trans*-astaxanthin. Sampalis, ¶¶ 18-20, 65, 100.[16] According to Complainants, the examiner did not specifically cite art disclosing *trans*-astaxanthin, because she understood that the claim term "astaxanthin" encompassed all forms of astaxanthin. CIB at 32.

Complainants' argument is unpersuasive. First, the argument is extremely attenuated, because it requires divining the examiner's thought processes on an issue that was not expressly addressed during prosecution. Second, although Sampalis does not describe the polar krill oil as containing *trans*-astaxanthin, the *trans* form is the "most dominant form" of astaxanthin. J. Runco & R. Chen, *Quantitative Analysis of Astaxanthin in Dietary Supplements by UltraPerformance Convergence Chromatography (UPC2)* ("*Quantitative Analysis of Astaxanthin*") at 3.[17] Accordingly, Sampalis's disclosure of "astaxanthin" in general is a disclosure of *trans*-astaxanthin in particular.

3. Extrinsic evidence cannot be used to change the patentees' express construction.

Complainants rely upon extrinsic evidence in support of their proposed construction. Extrinsic evidence cannot be used to vary or alter the patentees' express and unambiguous definition of astaxanthin. *Phillips*, 415 F.3d at 1324 ("Nor is the court barred from considering any particular sources or required to analyze sources in any specific sequence, as long as those sources are not used to contradict claim meaning that is unambiguous in light of the intrinsic evidence."). Moreover, as discussed below, the extrinsic evidence cited by Complainants does not support their proposed claim construction. The extrinsic evidence at issue can be divided into three categories.

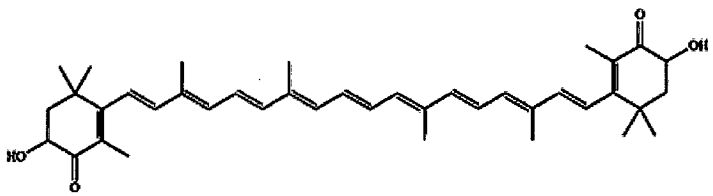
The first category of extrinsic evidence consists of four references that allegedly use the

[16] Sampalis is attached as Exhibit O to Complainants' initial brief.

[17] Quantitative Analysis of Astaxanthin is attached as Exhibit R to Complainants' initial brief.

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

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



Hereafter, discovery and briefing in this Investigation shall be governed by the construction of the claim terms herein.

SO ORDERED.

Dee Lord

Dee Lord
Administrative Law Judge

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

PUBLIC CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the attached **ORDER** has been served upon the following parties as indicated, on **April 13, 2017**.

Lisa R. Barton, Secretary
U.S. International Trade Commission
500 E Street, SW, Room 112
Washington, DC 20436

On Behalf of Complainants Aker BioMarine Antarctic AS and Aker BioMarine Manufacturing LLC:

Andrew F. Pratt, Esq.
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☐ Via Hand Delivery
☑ Via Express Delivery
☐ Via First Class Mail
☐ Other:_____

On Behalf of Respondents Olympic Holding AS, Rimfrost AS, Emerald Fisheries AS, Avoca Inc., Rimfrost USA, LLC, Rimfrost New Zealand Limited, and Bioriginal Food & Science Corp.:

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