

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RIMFROST AS

Petitioner

v.

AKER BIOMARINE ANTARCTIC AS

Patent Owner

Case No.: IPR2018-01178

U.S. Patent No. 9,375,453

Issue Date: June 28, 2016

Title: Bioeffective Krill Oil Compositions

**PETITIONER'S SUR-REPLY TO PATENT OWNER'S
MOTION TO AMEND**

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I. INTRODUCTION

Patent Owner does not dispute that the steps of “grinding, cooking and drying” krill were known in the art. Nor does Patent Owner dispute that Yoshitomi expressly discloses these steps, and teaches the benefits of denaturing krill. Nevertheless, by pointing to three values taken from Yoshitomi’s specification, and relying on Dr. Hoem’s unsupported speculation regarding acid and peroxide values, Patent Owner attempts to limit Yoshitomi’s disclosure to a single krill powder it names “YKP.” Patent Owner also tries to rewrite the proposed claims to recite a method of producing a “phospholipid-rich krill oil” extracted from krill meal that is not subjected to any hydrolytic or oxidative degradation. Contrary to Patent Owner’s arguments, Yoshitomi expressly discloses and teaches grinding, cooking and drying fresh krill which, in combination with the other prior art of record, renders claims 62-74 unpatentable.¹

II. THE PROPOSED CLAIMS FAIL TO COMPLY WITH SECTION 112

It is not contested that the term “grinding” can only be found in a single sentence, branded as one of over 175 so-called “embodiments” supposedly

¹ Patent Owner refuses to address why Yoshitomi was not mentioned in its MTA or why that omission did not violate its duty of candor. 37 C.F.R. § 42.11; *see* Petitioner’s Opposition (Paper 19) (“Opp.”), p. 2, n.2.

described in the '162 application. The only reason Patent Owner offers why this isolated reference satisfies the written description requirement of Section 112 is that the proposed “grinding, cooking and drying” steps were known in the art. PO Reply, 3. That the steps of “grinding, cooking and drying” krill were known and obvious, however, is insufficient to satisfy Section 112’s written description requirement. *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1352 (Fed. Cir. 2010) (“a description that merely renders the invention obvious does not satisfy” the written description requirement). Patent Owner has failed to meet its burden with respect to the written description requirement and the proposed “grinding, cooking and drying” limitation. Patent Owner’s MTA should be denied.

Patent Owner feigns uncertainty as to why the proposed claims are also indefinite under Section 112. PO Reply, 3, n.1.² Since the recited ether phospholipid and non-ether phospholipid values only add up to a minimum of 31% and a maximum of 58% (*i.e.*, 4-8% ether phospholipids + 27-50% non-ether phospholipids), it is mathematically impossible to achieve either the minimum or maximum total phospholipid limitation. The proposed claims are also indefinite.

² Patent Owner wrongly avers that collateral estoppel bars Petitioner from arguing that proposed claims 62-74 are indefinite. Petitioner, however, never raised, and the Board never addressed, the issue of indefiniteness in IPR2018-00295.

III. THE PROPOSED CLAIMS ARE UNPATENTABLE

A. A POSITA Would Have Motivated To Use The “Grinding, Cooking And Drying” Process Described In Yoshitomi

Patent Owner tries to limit the scope of Yoshitomi’s disclosure to a single “krill powder” it names “YKP,” and then maintains that YKP is an unacceptable product because it was purportedly subject to excessive hydrolytic and oxidative degradation and has an abnormally low level of lipids, relying on Dr. Hoem’s unsupported suppositions regarding the acid and peroxide values and “course fat” values found in Tables 3 and 5, respectively; values that are acceptable for commercial krill oil products. PO Reply, 4; *infra*, p. 7. Patent Owner concludes that a “POSITA would not choose to combine Yoshitomi with the other cited references for the production of a krill oil.” PO Reply, 6. Patent Owner’s arguments are meritless.

Yoshitomi repeatedly and unambiguously describes grinding (*i.e.*, chopping or coarsely crushing), cooking (*i.e.*, heating) and drying fresh *Euphausia superba* krill to produce a denatured krill powder containing “all the components” of fresh krill. *See, e.g.*, Exhibit 1033, Abstract; ¶¶ 0009, 0021-0023, 0025, 0029, 0032-0034, 0037, 0041, 0049, 0051, 0055. It is noted that excessive cooking and drying temperatures “reduces astaxanthin . . . present in krill, reduces vitamins and oxidizes lipids.” *Id.*, ¶ 0034. Yoshitomi, however, discloses that one of the benefits associated with grinding or chopping krill into smaller pieces is improved

thermal efficiency during the subsequent denaturing (*i.e.*, cooking and drying) steps. *Id.*, ¶ 0032. Because of the improved thermal efficiency associated with a ground krill starting material, Yoshitomi discloses that the cooking and drying steps need not be performed “at overly high temperatures [or] for an overly long time,” resulting in an “improvement in product quality.” *Id.*, ¶ 0037.³

“A reference must be considered for everything it teaches by way of technology and is not limited to the particular invention it is describing and attempting to protect.” *EWP Corp. v. Reliance Universal Inc.*, 755 F.2d 898, 907 (Fed. Cir. 1985); *see Medichem, S.A. v. Rolabo, S.I.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) (“[a] given course of action often has simultaneous advantages and disadvantages and this does not necessarily obviate motivation to combine”).

Yoshitomi unequivocally discloses grinding, cooking and drying fresh *Euphausia superba* krill to produce a denatured krill product with “all the components” of fresh krill. *Supra*, pp. 3-4. Ignoring this clear mandate, Patent Owner asserts that the acid and peroxide values reported in Table 3 and the course fat value in Table 5 of Yoshitomi demonstrate that grinding results in a krill product having unacceptable levels of hydrolytic and oxidative degradation. PO

³ Catchpole also discloses that grinding feed material improves the efficiency of solvent extraction. *See* Exhibit 1009, p. 0011, lines 30-32.

Reply, 5-6. Patent Owner's argument, however, is predicated on the very antithesis of Yoshitomi's stated purpose; producing a denatured krill product in which "the enzymes in krill [are] perfectly disabled." Exhibit 1033, ¶ 0022; *supra*, pp. 3-4. Notably, Dr. Hoem could not identify a single reference supporting his conclusion that the specific acid and peroxide values reported in Table 3 disclose that a krill product was subjected to unacceptable levels of hydrolytic and oxidative degradation. *See, e.g.*, Hoem Dep. (Exhibit 1151), 50:14-24; 82:9-83:24. Patent Owner's attempt to dismiss the entirety of Yoshitomi's disclosure based on three values from Tables 3 and 5 fails for a number of reasons.

As an initial matter, Patent Owner's arguments based on its comparison of the specific krill meal identified in Yamaguchi and the denatured krill products encompassed by Yoshitomi are inapt. In particular, Patent Owner asserts that Yamaguchi teaches away from grinding krill because the specific krill meal in Yamaguchi "was deteriorated by oxidation or polymerization," and that two values from Table 3 indicates all products encompassed by Yoshitomi have a quality similar to "conventional krill meals such as disclosed in Yamaguchi." PO Reply, 7-9. However, other than noting the krill meal was purchased, Yamaguchi provides absolutely no details regarding, *inter alia*, how the krill meal was processed or the meal's acid and peroxide values; precluding even the most cursory comparison with Yoshitomi. *See* Yamaguchi (Exhibit 2002), p. 1. The

irrelevance of Patent Owner's strained comparison is further underscored by the fact that Yoshitomi describes a process to denature and perfectly disable the enzymes present in fresh krill. *Supra*, pp. 3-4. In contrast, the krill meal used by Yamaguchi produced an "undenatured oil." Exhibit 2002, at p. 2. As Dr. Hoem confirmed, once a product is denatured, the product stays denatured. Hoem Dep. (Exhibit 1151), 139:10-19. Thus, it would be impossible to extract "undenatured oil" from Yoshitomi's denatured krill product. Patent Owner's arguments, predicated on its attempt to infer from Yamaguchi's krill meal that the denatured krill product described in Yoshitomi has poor lipid quality should be rejected.

Patent Owner's comparison of the peroxide values from Table 3 of Yoshitomi and the NKO GRAS Notice is also a non-starter. PO Reply, 5-6. Patent Owner's attempt to draw a distinction between the peroxide values of the denatured krill powders or meals encompassed by Yoshitomi and a commercial krill oil product is "comparing apples to oranges." *See* Hoem Dep. (Exhibit 1151), 48:5-9. Even if such a comparison was appropriate, Enzymotec's GRAS reports that acceptable peroxide values for krill extracts are less than 5. Exhibit 1048, p. 7; *see* Tallon Decl. (Exhibit 1006), ¶ 55, n.3. This is consistent with peroxide values of 1.8 and 4.1 reported in Table 3. In fact, Dr. Hoem admitted that krill oil with peroxide values less than 5 is acceptable. Hoem Dep. (Exhibit 1151), 19:4-11; *see* 17:14-21:2.

Patent Owner's "acid value" argument also fails to detract from Yoshitomi's disclosure of grinding, cooking and drying fresh krill. Dr. Hoem conceded the acid value of a krill extract equals about twice the extract's free fatty acid content. *Id.*, 6:21-7:19. Notably Table 2 of the '453 patent reports that krill meal produced in accordance with the patent's teachings had a free fatty acid content of 9.0. Exhibit 1001, 18:48-65. Based on Dr. Hoem's testimony, this corresponds to an acid value of 18 which is comparable to the acid values in Table 3 of Yoshitomi (*e.g.*, 18.1 and 19.2). Dr. Hoem even confirmed that the acceptable acid value for krill oil pursuant to a current "Codex" standard is less than 45; twice the values reported in Table 3. Hoem Dep. (Exhibit 1151), 42:9-22; 44:23-45:16; *see* Exhibit 1147.⁴

Patent Owner's naked assertion that the course fat content 7% in Table 5 of Yoshitomi was abnormal and was consistent with lipid degradation is unavailing. PO Reply, 6. For example, other than the documents disclosed in his declaration, Dr. Hoem could not point to any document expressly disclosing that 7% fat or lipid content evidenced lipid degradation. Hoem Dep. (Exhibit 1151), 82:9-83:24.

⁴ Dr. Hoem testified that krill has a higher free fatty acid content than fish. Exhibit 1151, 6:21-7:19; 49:10-50:13; 136:9-18. A POSITA would have expected that the acid value for a quality krill product would have been higher than that for fish oil which Dr. Hoem seems to have been referencing. *See* Exhibit 1147, §§ 3.3.1-3.3.2.

Tellingly, Dr. Hoem agreed that phospholipids and neutral lipids could be extracted from Yoshitomi's 7% course fat krill product. *Id.*, 108:7-109:16.

Finally, Yoshitomi emphatically discloses that the recited grinding, cooking and drying steps results in a denatured krill product, and further describes the benefits associated with grinding fresh krill. *Supra*, pp. 5-6. This unambiguous disclosure cannot be disregarded, even assuming Yoshitomi's grinding, cooking and drying steps results in a krill product with some degree of hydrolytic and oxidative degradation as proposed by Patent Owner. *See Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1349 n.8 (Fed. Cir. 2000) ("that the motivating benefit comes at the expense of another benefit, however, should not nullify its use as a basis to modify the disclosure of one reference with the teachings of another").

B. NKO, Randolph And Sampalis II Each Disclose Krill Oil Satisfying The 100-700 mg/kg Astaxanthin Esters Limitation

Patent Owner's argument regarding the specific commercial NKO krill oil formulation identified in the '453 patent is factually and legally wrong.

Petitioner has never argued that **every** commercial NKO formulation inherently possessed 100-700 mg/kg astaxanthin esters as Patent Owner suggests. PO Reply, 10. Rather, Petitioner has steadfastly maintained that **the specific NKO formulation** identified in Table 16 of the '453 patent that **Patent Owner admitted had 472 mg/kg astaxanthin esters** and represented was the "**closest prior art**,"

satisfies the proposed astaxanthin esters limitation. *See, e.g.*, Petitioner’s Opp., 13; Tallon Reply/Opp. (Exhibit 1086), ¶¶ 303-304.

Additionally, Patent Owner’s argument that these admissions were “not known to a POSITA,” and therefore cannot be considered by the Board in accessing the patentability of the proposed claims is legally wrong. PO Reply, 10. Specifically, the Federal Circuit has held “[a]dmissions in the specification regarding the prior art are binding on the patentee for purposes of a later inquiry into obviousness.” *Pharmastem Therapeutics v. Viacell*, 491 F.3d 1343, 1362 (Fed. Cir. 2007); *see, e.g., In re Nomiya*, 509 F.2d 566, 570-71 (CCPA 1975) (representations in specification are admissions for purposes of obviousness). While both of these cases were cited by Petitioner, Opp., 13, Patent Owner chose to ignore this controlling precedent. In sum, Patent Owner cannot run from its “binding admissions” that a specific prior art NKO formulation with 472 mg/kg astaxanthin esters was the “closest prior art.” This NKO formulation, in combination with the prior art of record, renders claims 62-74 obvious.

Patent Owner maintains that Randolph’s disclosure of compositions containing “any amount” of astaxanthin, and in particular, 0.5-50 mg, is “not related to,” and somehow inapplicable to the krill oil compositions disclosed in Randolph. Patent Owner further contends that the proposed astaxanthin esters limitation is obtained by “cherry picking” the ranges disclosed in Randolph. PO

Reply, 11. It cannot be legitimately disputed that Randolph expressly teaches compositions containing “between about **0.5 mg** and about 50 mg” of astaxanthin, and “between about 300 mg and **about 3000 mg [.003 kg]**” of krill oil. Randolph, Exhibit 1011, ¶¶ 0040, 0044 (emphasis added). Dr. Tallon used the endpoint values for astaxanthin and krill oil and calculated that Randolph discloses krill oil compositions having 167 mg/kg of astaxanthin (*i.e.*, 0.5 mg/.003 kg), which is equivalent to 158 mg/kg astaxanthin esters. Tallon Reply/Opp. (Exhibit 1086), ¶¶ 306-311. Relying on Dr. Tallon’s calculation, the Board previously found that Randolph describes compositions with amounts of astaxanthin esters that “overlap with the range recited in the substitute claims.” IPR2018-00295 (Paper 35) (Exhibit 1129), 67-68; *In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003).

“A reference must be considered for everything it teaches.” *In re Applied Materials, Inc.*, 692 F.3d 1289, 1298 (Fed. Cir. 2012). Patent Owner ignores both this fundamental precept and the breadth of Sampalis II’s disclosure in arguing that a “POSITA would not derive the claimed astaxanthin range from Sampalis II.” PO Reply, 11. Sampalis II is directed to phospholipid extracts “from a marine or aquatic biomass.” Exhibit 1013, p. 1 (Abstract); p. 3, lines 9-12; p. 5, lines 1-3. Sampalis II also states the recited extracts are preferably extracted from krill, such as *Euphausia superba*, *id.*, p. 0027, lines 2-9, and notes that antioxidants, such as astaxanthin esters are present in amounts of at least 20 mg/100 ml. *Id.*, p. 0032,

lines 1-7; Tallon Reply/Opp. (Exhibit 1086), ¶¶ 312-316. Dr. Hoem confirmed 20 mg/100 ml astaxanthin is equivalent to 200 mg/kg astaxanthin and 190 mg/kg astaxanthin esters. Hoem Dep. (Exhibit 1128), 207:13-209:9.

Patent Owner's suggestion that a POSITA would "discredit" Sampalis II's disclosure and teachings of krill extracts having at least 200 mg/kg astaxanthin because Table 5 lists components found in both marine and aquatic biomass extracts is meritless. First, Patent Owner asserts that a POSITA would recognize that it is "impossible" for a krill extract to contain canthaxanthin by misrepresenting Grynbaum as confirming "the only carotenoid present in krill is astaxanthin." PO Reply, 12. While Grynbaum notes that its analysis shows that "astaxanthin was the sole carotenoid identified," the very next sentence states: "This is also inconsistent with the literature." Exhibit 1039, p. 0008. With that important caveat, a POSITA would not "discredit" the teachings of Sampalis II as averred by Patent Owner. Second, since Sampalis II is directed to phospholipid extracts "from a marine or aquatic biomass," it is not surprising that Table 5 identifies flavonoids as being present in the various extracts encompassed by the teachings of Sampalis II. Finally, Patent Owner's assertion that Sampalis II "discloses the same production process as used in the NKO GRAS submission" is simply unsupported attorney argument. PO Reply, 12.

At bottom, the astaxanthin esters disclosures of NKO, Randolph or Sampalis II in combination with the prior art of record renders claims 62-74 obvious.

IV. CONCLUSION

A preponderance of evidence demonstrates that claims 62-74 are disclosed and taught by the prior art of record and are unpatentable.

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CERTIFICATE OF SERVICE

I hereby certify that on this 23rd day of September, 2019, **PETITIONER’S SUR-REPLY TO PATENT OWNER’S MOTION TO AMEND** was served in its entirety on the following counsel of record by e-mail at the address provided in the Patent Owner’s Mandatory Notice Information as set forth below:

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