amount for use in a skin moisturizer, nutraceutical composition or other product envisioned by the specification.

Examiner's Rejections and Objections

25. Claims 22, 23, 26, 40, 41 and 46-148 are rejected under 35 U.S.C. 112 (pre-AIA), first paragraph, because the best mode contemplated by the inventor has not been disclosed. Evidence of concealment of the best mode is based upon the Sampalis declaration.

The claims are drawn to a krill oil extract containing an "effective amount" of phospholipids having two EPA and/or DHA groups. Patent Owner has argued that the prior art krill extracts do not contain an effective amount of the claimed phospholipids due to high temperatures used to evaporate extraction solvents. If Patent Owner's theory is correct, then removal of solvent at low temperature is clearly the best mode for practicing the invention and has not been disclosed in the specification.

A proper best mode analysis has two components: Determine (A) whether at the time the application was filed, the inventor knew of a mode of practicing the claimed invention that the inventor considered to be better than any other and (B) whether the disclosure is adequate to enable one skilled in the art to practice the best mode. See MPEP 2165.03.

The Sampalis declaration clearly indicates that the inventor considered solvent evaporation at temperatures below 5 ˚C to be critical for producing an extract with "effective amounts" of the claimed phospholipids (¶¶ 8-11), satisfying requirement (A). With regard to requirement (B), the specification does not enable the skilled artisan to practice the best mode. This conclusion is based on the state of the art and the absence of guidance in the specification. The expert declarants for Requester and Patent Owner agree that it was standard practice to remove solvents from oil extracts using temperatures substantially higher than 5 ˚C. The specification directs the reader to Beaudoin I for the extraction procedure (col. 18). The only deviations from the Beaudoin I procedure are the proportions of solvents used for extraction. The

specification states that acetone is removed by flash evaporation or spray drying (col. 18, lines 58-59) and ethanol is simply "evaporated" (col. 18, lines 63-64). No mention is made of solvent evaporation temperature. Since the Sampalis declaration states that the key to the invention was changing the Beaudoin I method, the specification, by directing to follow the Beaudoin I method, actually teaches away from the best mode. Therefore the disclosure does not enable one skilled in the art to practice the best mode.

26. Claims 129 and 145 are rejected under 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claims 129 and 145 are indefinite in their recitation of "composition," which lacks antecedent in the claims from which they depend.

27. Claims 108, 125 and 142 are objected to because they fail to further limit claims 100, 117 and 134, respectively.

Response to Patent Owner's Arguments

Patent Owner's response, Requester's comments and all declarations submitted by both parties have been considered.

Rejections 1 and 22

Patent Owner argues (response, pp. 34-40) that Haugsgjerd and Gundersen do not show that extracts made by the Beaudoin I procedure contain the claimed phospholipids. This argument is based on the declarations submitted with the response, which have been analyzed and not found persuasive for the reasons stated above. With regard to the alleged errors made by Haugsgjerd in producing the extracts, Haugsgjerd repeated the extractions as "instructed" by Patent Owner's experts and van Breemen definitively showed that the extracts contained the claimed phospholipids.

Patent Owner argues that Beaudoin I heated the extracts to remove solvents and further argues that Beaudoin I discloses solvent residues in excess of what is suitable for human consumption (response, pp. 41-44 and 44-46, respectively). These two lines of argument are not consistent; it is not clear how both can be correct. It may be that Beaudoin I removed an aliquot of extract and heated it to 125 ˚C for 15 minutes prior to analysis, as suggested in the Storrø declaration (¶ 27). But Patent Owner's position seems to be that Beaudoin I heated the extract to 125 ˚C to remove "traces of solvents," yet the extracts still contained large amounts of solvent.

With regard to heating, Patent Owner's arguments are not persuasive. As discussed at length above, Patent Owner's declarants rely on studies of very different compositions subjected to very different conditions to support the theory that heating destroys the claimed phospholipids. The only direct experimental evidence is provided by Requester's declarants, who conclude that the claimed phospholipids are present in the extract regardless of heat treatment (e.g. van Breemen, ¶ 15). With regard to solvent residue, as discussed above, 1) the residue was not analyzed, so the chemical composition thereof is a matter of speculation; 2) solvents were removed at 125 ˚C, so at least the portion of the composition that was heated to this temperature should be free of solvents; 3) ethanol is suitable for human consumption; 4) acetone is suitable for use in cosmetic compositions; 5) the GRAS data for other products says nothing about whether the Beaudoin extract is suitable for human consumption; 6) Beaudoin I teaches how to remove solvents and 7) Beaudoin actually consumed his composition.

Requester notes that solvent extraction has been used for decades to obtain phospholipids such as lecithin from biological material, and that solvents are routinely removed under reduced pressure to yield products suitable for human consumption (see Storrø ¶ 24). This is (indirectly) supported by the documents submitted with the Bimbo declaration. For example, the GRAS notice for Enzymotec (Bimbo appendix K) states, "The raw material to be extracted, krill meal, is a biomass composed of lipids, sugars and proteins. By using a solvent extraction process, the proteins and free sugars are removed so that only lipids are left. Various solvents may be used for the extraction process, all of which are of food-grade quality and are used and removed from the

product in accordance with current good manufacturing practice" (p. 10). Similarly, the GRAS notice for Aker Biomarine (Bimbo appendix I) simply states that krill meal is subjected to ethanol extraction and the "ethanol-oil solution is then concentrated by evaporation and stored" (p. 6). The fact that regulatory agencies do not require more detailed information than "solvents are removed" or "concentrated by evaporation" supports the notion that these methods are well known in the art. Therefore it is concluded that, when Beaudoin I states that the krill oil extract is intended as a dietary supplement (p. 1) and the protocol for its production includes solvent "evaporation under reduced pressure" (Table 19), one skilled in the art would know how to remove substantially all solvent to yield a product suitable for human consumption.

Patent Owner argues that krill meat does not anticipate the claims because the claims are limited to an extract (response, pp. 46-47). For claims drawn to a "composition" rather than an extract, this argument is not persuasive for the reasons discussed above. The specification describes a "composition" as well as an "extract." The claimed phospholipids are natural products. Therefore a composition comprising krill lipids is anticipated by krill meat, just as a composition comprising vitamin C is anticipated by orange juice.

Patent Owner argues that the Beaudoin I extracts contain a "de minimis" amount of the claimed phospholipids (response, pp. 47-52). This argument is not persuasive for the reasons discussed at length above. In brief, 1) there is no quantitative data regarding the level of the phospholipids in the Beaudoin I extract or in the '348 patent extract. There is no basis for concluding that the '348 patent extract contained more of these lipid species. 2) There is no evidence regarding what constitutes an "effective amount" of the claimed lipids, for any intended use contemplated in the specification. 3) It is not known what White's detection limits for the claimed species were, because he did not use a reference standard for those species. 4) None of Patent Owner's evidence distinguishes between the biological effects of the claimed phospholipids and the effects of other lipids in the extract, such as phospholipids having a single DHA or EPA group, which are also biologically active. Patent Owner's declarants also do not discuss the effective levels of phospholipids for cosmetic and nutraceutical

compositions as contemplated in the specification (and encompassed by the claims). Moreover, Patent Owner's reliance on *In re Seaborg* is misplaced. In that case, a radioactive isotope was present at a level of 6.15 ng in 88,000 kg, or 0.000000000000007%. Since Dr. Shahidi opines (¶ 22) that the "Beaudoin extract" analyzed by White contains 0.1 to 1.0% of the claimed phospholipids (about a quadrillion times higher than in *Seaborg*), the instant case clearly does not present the same fact situation.

Rejections 2 and 23

Patent Owner traverses the rejections over Beaudoin II on essentially the same grounds as rejection 1 (response, pp. 52-57), and these arguments are not persuasive for the same reasons noted above. Patent Owner further argues that the extract of Beaudoin II would contain even more solvent because it was heated to only 60 or 70 ˚C rather than 125 ˚C. This argument is not persuasive because, like Beaudoin I, Beaudoin II directs the skilled artisan to remove solvents by "evaporation under reduced pressure" (Table 11) and the skilled artisan knew how to remove substantially all solvent residue from food products, such procedures being routinely used in the art for decades.

Rejection 3

Patent Owner's traversal (response, pp. 57-63) is based on the premise that the claims are drawn to an extract. This argument is not persuasive because the claims are drawn to a composition, as discussed above.

Patent Owner argues that Maruyama does not disclose how ethanol was removed from the krill lipid extract, leading to speculation that either the extract was heated (thereby destroying phospholipids) or that it contained so much residual ethanol that it was not suitable for human consumption. These arguments are not persuasive. In working example 1, Maruyama obtained 239 g phosphatidylcholine and 45 g phosphatidylethanolamine from 2 kg dried krill (equivalent to 18.2 kg fresh krill, since 20 kg fresh krill yielded 2.2 kg dried). Therefore these two classes of phospholipid made

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