of polyunsaturated fatty acids and a person of ordinary skill in the art reading Table 4 would understand that they are included in the polyunsaturated fatty acids.

59. The specification states that "Table 5 … details the lipids and other compounds (non-metal) of the extract." '351 Patent at col.17 l.49-col.18 l.7. Table 5 lists lipid classes as "≥ X g/100g extract." The way Table 5 is reported indicates that the lipids are measured as g/100g of the extract, meaning that this is a quantitative measure of the lipid classes in the extract.

60. Although not clear what type of analysis was conducted in the specification, the fatty acid composition (also known in the art as fatty acid profile) of total lipids is typically measured by conducting a fatty acid methyl ester ("FAME") analysis. To do so lipids are dissolved in a suitable solvent and an acid or based catalyzed reaction or set of reactions is performed to remove all fatty acyl groups from their respective esterified positions in triacylglycerols, phospholipids, cholesterol esters and all other lipid classes, and together with native free fatty acids, they are esterified to methyl groups to yield free fatty acids. FAME mixtures are then subjected to gas liquid chromatography which produces a series of mostly separated FAME peaks corresponding to the original fatty acids in the lipid, which must then be calibrated for differential response with an external standard of containing representative FAME. Once calibrated the relative areas under the FAME peaks are proportional to their abundance in the original lipid.

Areas are integrated and normalized to (divided by) the sum of all areas to yield proportions of each fatty acid in the lipid; the sum of all FAME in a sample added to 100%, and this is considered a weight-for-weight (w/w) of total fatty acids percentage. For instance, DHA might be 10% w/w of fatty acids in the mixture. Quantitative analysis is often performed as an additional measure. Normally an internal standard will be added quantitatively (on the basis of milligrams per milliliter) to the FAME mixture prior to analysis. Once responses are calibrated, the internal standard can be used to calculate the concentration of each particular fatty acid per unit weight of a sample. For instance, 100 mg of a lipid might contain 8 mg of DHA, and the concentration of DHA would be said to be 80 mg per gram lipid. These procedures both presume proper identification of the identity of fatty acids which requires separate criteria.

61. Example 1 of the '351 Patent purports to be an analysis that "illustrates the isolation and molecular characterization of the phospholipids from the extract." This analysis does not demonstrate a particular phospholipid molecular species exists in the sample tested. Any chemically definable class of lipids within a lipid sample can be analyzed for their fatty acid composition (profile). For instance, free fatty acids can be purified and then their fatty acid profile can be determined. When a fatty acid profile is performed on a phospholipid such as phosphatidylcholine the profile does not distinguish between

fatty acids on the sn-1 and sn-2 positions; this can be accomplished using additional analysis steps, such as phospholipase A2 to selectively cleave the sn-2 position with subsequent separation and profiling of the free fatty acids and 1-monoglycerols. In special cases the results of a fatty acid analysis of phosphatidylcholine can be used to unambiguously drawn chemical conclusions about fatty acids bound to the sn-1 and sn-2 positions. For instance, if DHA was found to be between 51 and 100% of the fatty acids on a phosphatidylcholine, then at least some phosphatidylcholine molecules must have DHA on both positions.

62. It is not clear from the specification whether the same samples were tested in Tables 3, 4, and 5, or in any other Tables in the '351 Patent. Nor is there any information about how these samples were prepared.

63. The specification identifies an extraction method that is "similar to the one described in commonly owned PCT publication number WO 00/23546" ("Beaudoin I"; Ex. 1002), which is incorporated by reference. ('351 Patent col.18.) No variation of this extraction procedure is mentioned or described. The table below compares the extraction process in Beaudoin I and the '351 Patent. The methods are virtually identical.

Beaudoin I **Beaudoin '299 patent**	**'351 Patent ('351 Patent col.18 l.32-col.19 l.9)**
The starting material consisting of freshly harvested and preferably finely divided marine and aquatic animal material is subjected to acetone extraction, for at about two hours and preferably overnight. p. 5, l. 21-25.	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. Col. 18, l. 53-55.
However extraction time is not critical to the yield of lipid extraction. To facilitate extraction, it is preferable to use particles of less than 5mm in diameter. Extraction is preferably conducted under inert atmosphere and at a temperature in the order of about 5°C or less. p. 5, l. 25-29.	However, extraction time is not critical to the yield of lipid extracted. Particle sizes of comminuted crustacean less than 5 mm are preferred. The extraction is preferably conducted under an inert atmosphere and at a temperature of about 5 degrees Celsius or less. Col. 18, l. 55-60.
Preferably, the beginning of the	The mixture may be agitated

Beaudoin I **Beaudoin '299 patent**	**'351 Patent ('351 Patent col.18 l.32-col.19 l.9)**
extraction will be conducted under agitation for about 10 to 40 minutes, preferably 20 minutes. Although extraction time is not critical, it was found that a 2 hour extraction with 6:1 volume ratio of acetone to marine and aquatic animal material is best. p. 6, l. 30 – p. 6, l. 2.	during extraction and a volume ratio of about 6:1 of acetone to biomass is generally most preferred. Col. 18, l. 60-62.
The solubilized lipid fractions are separated from the solid material by standard techniques including, for example, filtration, centrifugation or sedimentation. Filtration is preferably used. p. 6, l. 6-7.	The solubilized lipid fraction is separated from the solid starting material by known techniques, for example, by filtration, centrifugation or sedimentation. Filtration is preferred. Col. 18, l. 63-66.
After separation by filtration on	The residue is optionally washed

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