

(Ex. 1054; March 16, 2012 Declaration of Faustinus Yeboah, '348 Reexamination at ¶ 36.) Another Neptune declarant, Dr. Shahidi, also acknowledged that extractions resulting from the Beaudoin process contain the claimed phospholipids:

As Beaudoin reports an oil potentially with a small amount of the phospholipid containing two of EPA and DHA (i.e. about 0.1 to 1%), it is my opinion that this is not a biologically effective amount. As the claims of the '348 patent are directed to biologically effective amounts of this composition, they are distinct from Beaudoin.

(Ex. 1056; March 16, 2012 Declaration of Fereidoon Shahidi, '348 Reexamination, at ¶ 22.)

4.1.2.4. Conclusion on Obviousness

(i) Claims 1-94 of the '351 patent are obvious over Beaudoin I (Ex. 1002) in view of Bergelson (Ex. 1017)

384. Claims 1-94 are obvious over Beaudoin I in view of Bergelson.

385. As established above, Beaudoin I provides each element of claims 1-94 either expressly or inherently. The declaratory evidence conclusively

establishes the inherent presence of the claimed phospholipids in Beaudoin I extracts from both *E. pacifica* and *E. superba*.

386. There are no data in the '351 patent that compares the biological effectiveness of the claimed phospholipids to phospholipids with only one EPA or DHA attached. Likewise, there are no data that establishes the criticality of any of the other components listed in the independent and dependent claims. The extraction methods described in '351 patent are essentially the same as described in Table 19 of Beaudoin I. Thus, the extracts disclosed in Beaudoin I would be very similar in composition to the '351 extracts and necessarily include the components listed in the independent and dependent claims. To the extent there are any differences, it would have been routine optimization to provide the claimed amounts of extract components absent a showing of criticality.

387. Patentee has also argued that the Beaudoin I extracts are not suitable for human consumption because of the solvent content in the extracts. Bergelson discloses that is well known to remove solvent from lipid extracts under gentle conditions by rotary evaporation.

388. Beaudoin I is directed to the production of phospholipid extracts from marine sources, including krill, for human consumption. Beaudoin I contains a detailed protocol for extraction in Table 19, specifying that solvent may be removed under reduced pressure. Bergelson teaches that solvent can be removed

by rotary evaporation (i.e., under reduced pressure) under mild temperature conditions. Ex. 1002, p. 10-11. Thus, there is a motivation to combine the references. A person of ordinary skill in the art would be motivated to remove solvent from the krill extracts of Beaudoin I by rotary evaporation as described in Bergelson to provide a krill extract with a desired content of phospholipids, EPA and DHA as well as other components naturally present in krill and presented in the claims. The person of skill in the art would be motivated to remove solvent to levels suitable for human consumption as Beaudoin clearly teaches the desirability of krill oil for both oral administration and topical administration as a cosmetic. The person of skill in the art would likewise be motivated to process the extracts so as to maintain the phospholipid content (i.e., avoid phospholipid degradation) because Beaudoin I teaches the desirability of the recovery of total lipids.

389. A person of skill in the art would have a reasonable expectation of success in arriving at the claimed invention because the methods of Beaudoin I are essentially the same as those described in the '351 patent. Thus, the concentration of lipids in the extracts resulting from the Beaudoin I extraction process would be essentially the same as the concentrations specified in the claims. The extracts could easily be made suitable for human consumption by rotary evaporation as described in Bergelson.

(ii) Claims 1-94 are unpatentable under 35 USC 103(a) over Beaudoin I (Ex. 1002) in view of the 2001 Prospectus (Ex. 1011), 2001 Press Release (Ex. 1012) and Bergelson (Ex. 1017)

390. Claims 1- 94 are obvious over Beaudoin I in view of the 2001 Prospectus, 2001 Press Release and Bergelson. As discussed above, Beaudoin I provides each element of claims 1-94 either expressly or inherently. The declaratory evidence conclusively establishes the inherent presence of the claimed phospholipids in Beaudoin I extracts from both *E. pacifica* and *E. superba*.

391. In addition to its arguments that the Beaudoin I extracts do contain meaningful amounts the claimed phospholipids, Patentee has argued that the claimed phospholipids are absent in the Beaudoin I extracts because they were degraded by heating. The citation of the 2001 Prospectus and 2001 Press release address this alleged deficiency as they describe the Beaudoin I process is a “cold extraction” process. Following the Beaudoin I protocol and using solvent evaporation techniques known in the art (e.g., as described in Bergelson) would produce an undegraded krill oil. The 2001 Prospectus states that the Beaudoin I/OceanExtract™ process is a cold extraction process that preserves the biological activity of the lipid substances, results in minimal alterations to the lipids, and is suitable for human consumption. Ex. 1011 at 13. The 2001 Press Release states that the Beaudoin I/OceanExtract™ process is a “cold process that

preserves the biological activity and stability of the nutritional qualities intrinsic to the most highly sought substances of Krill, such as its powerful antioxidants, phospholipids and Omega-3-6-9 fatty acids” and produces a krill extract suitable for human consumption. Ex. 1012 at 1. Thus, krill phospholipid extracts produced according to the Beaudoin I/OceanExtract™ process would be in all aspects identical to those claimed in the ‘351 patent. The disclosure of the 2001 Prospectus and Press Release is entirely consistent with the protocols in Beaudoin I which describe the preferred extraction process which a) does not include a heating step and b) specifies cold conditions for extraction (i.e., 4°C).

392. Beaudoin I is directed to the production of phospholipid extracts from marine sources, including krill, for human consumption. Beaudoin I contains a detailed protocol for extraction in Table 19, specifying that solvent may be removed under reduced pressure. The 2001 Prospectus and 2001 Press release state that the process disclosed in Beaudoin I and licensed from the University of Sherbrooke by Patentee is a cold extraction process. Bergelson teaches that solvent can be removed by rotary evaporation (i.e., under reduced pressure) under mild temperature conditions. Ex. 1017, p. 10-11. A person of ordinary skill in the art would be motivated to conduct extraction from krill under cold conditions and to remove solvent from the krill extracts of Beaudoin I by rotary evaporation as described in Bergelson to provide a krill extract with a desired content of

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