

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: SAMPALIS, Fotini Confirmation No.: 1767
Serial No.: 13/189,714 Group Art Unit: 1629
Filed: July 25, 2011 Examiner: POLANSKY, Gregg

FOR: NATURAL MARINE SOURCE PHOSPHOLIPIDS COMPRISING
POLYUNSATURATED FATTY ACIDS AND THEIR APPLICATIONS

Mail Stop Declaration

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF FEREDOON SHAHIDI, PH.D. UNDER 37 C.F.R. § 1.132

I, Fereidoon Shahidi, declare as follows:

1. I am a tenured University Research Professor at Memorial University of Newfoundland in St. John's, Canada. My appointment is in the Department of Biochemistry, with a cross-appointment with the Aquaculture Program, Biology Department and Ocean Sciences Centre. I have been a professor at Memorial University since 1987. I am also an Honorary Professor at Chung Shan Medical University in Taichung, Taiwan; a Chair Professor in the Department of Food Science at National Chung Hsing University in Taichung, Taiwan; and an Adjunct Professor at Dalhousie University in Halifax, Nova Scotia, Canada and the Nova Scotia Agricultural College in Truro, Nova Scotia, Canada. Prior to being at Memorial, I was in the Department of Chemistry and the Department of Chemical Engineering at the University of Toronto.
2. I earned a Ph.D. in 1977 in Physical Organic Chemistry from the Department of Chemistry at McGill University in Montréal, Canada. Prior to that, I earned a Bachelors of Science, with

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Exhibit

Honours, from the Department of Chemistry at Shiraz (Pahlavi) University in Shiraz, Iran. After my doctoral work, I was a Postdoctoral Fellow in the Department of Chemistry at McGill University.

3. I have been a scientist for almost 40 years, as outlined in my Curriculum Vitae (Appendix A).
4. I have been recognized with a variety of awards, including, for example: European Lipid Technology Award, Eurofed Lipid (2010); Fellow, American Chemical Society (2010); Distinguished Service Award, Agricultural and Food Chemistry Division, American Chemical Society (2008); Fellow, American Oil Chemists' Society (2008); Outstanding Division Member, Nutraceutical and Functional Food Division, Institute of Food Technologists (2008); Advancement of Application of Agricultural and Food Chemistry, American Chemical Society (2007); Fellow, International Academy of Food Science and Technology (2006); Stephen S. Chang Award, Institute of Food Technologists (2005); Fellow, Institute of Food Technologists (2005); Fellow, Royal Society of Chemistry (UK) (1998); Earl P. McFee Award, Atlantic Fisheries Technological Society (1998); Fellow, Chemical Institute of Canada (1996); William J. Eva Award, Canadian Institute of Food Science and Technology (1996); Fellow, Agricultural and Food Chemistry Division, American Chemical Society (1994); Platinum Award, American Chemical Society (1994); Fellow, Canadian Institute of Food Science and Technology (1993).
5. I have published about 450 peer reviewed articles, about 260 book chapters and conference proceedings, and about 60 books. I have been recognized as the ISI most published author (1st) in the area of Food, Nutrition and Agricultural Science for the period of 1996-2006; the ISI most cited (4th) author in Food, Nutrition and Agricultural Science for the period of 1997-2007; the ISI most cited (7th) author in the area of Food, Nutrition and Agricultural Science for the period of 1996-2006; the ISI most cited (3rd) author in the area of Agricultural Science for the period of 2001-2011; and author of the American Oil Chemists Society, Best Paper Award for 1995, 1997, 1998, 1999, 2002, and 2003.
6. I am the Editor-in-Chief of the *Journal of Functional Foods*. I am also an Editor of *Food Chemistry*, and I am or have been on the Editorial Board of: *Journal of Food Science*,

International Journal of Food Properties, Nutraceuticals and Food, Current Nutrition and Food Science, Inform, and the Journal of Aquatic Food Product Technology, and on the Editorial Advisory Board of the *Journal of Agricultural and Food Chemistry*. I was the Editor-in-Chief of the *Journal of Food Lipids* from 1993 to 2009.

7. I am or have been a member of the following exemplary professional organizations: International Society for Nutraceuticals and Functional Foods, International Union of Food Science and Technology, International Commission on Natural Health Products, American Oil Chemists' Society, American Meat Science Association, Chemical Institute of Canada, Groupe Polyphenol International, Canadian Meat Science Association, Institute of Food Technologists, Canadian Institute of Food Science and Technology, American Chemical Society, and the Royal Chemical Society.
8. I have been a preceptor for 25 post-doctoral fellows/research assistants/associates and 50 graduate-level thesis students.
9. I have been a member of various food standards committees, including being an Expert Advisory Committee member for the U.S. Pharmacopeia (USP), Food Ingredients (2010-present); Member, Expert Advisory Panel, Health Canada, Standards of Evidence for Health Claims for Foods (1999-2010); and Member, Standards Council of Canada (2000-2010).
10. I was a technical expert witness in a patent infringement lawsuit concerning the pharmaceutical Lovaza, a drug that contains ethyl esters of omega 3 fatty acids, namely DHA and EPA (*Pronova BioPharma Norge AS v. Apotex Corp.*, 1:09-cv-00304-SLR -MPT).
11. I am an inventor of 4 U.S. Patents (5,443,852, 5,425,956, 5,230,915, and 4,559,234), a European Patent (0,554,283), as well as other patent applications.
12. In December of 2011, I was engaged by counsel for Neptune Technologies and Bioresources ("Neptune") to review U.S. Patent 8,030,348 ("the '348 patent") and its substantive prosecution history, including the Declaration of Dr. Earl L. White; the Corrected Request for Reexamination filed by Aker Biomarine ("Aker"), listed as U.S.S.N. 95/001,714, including the Declaration of Mr. Bjorn Ole Haugsgjerd and the Declaration of Dr. Thomas Gundersen and WO 00/23546 ("Beaudoin I"); and supporting materials, and to provide my

expert scientific opinion. I have had no prior direct involvement with either Neptune or Aker. I am being compensated at my customary hourly rate for my time spent on developing, forming, and expressing the facts and opinions in this declaration. I have no personal interest in the ultimate outcome of the reexamination proceedings involving the '348 patent or any continuation applications filed from this patent.

13. I have carefully read the information provided. Below I provide my expert scientific opinion.

The '348 Patent Discloses and Claims a Biologically Effective Amount of an Extract With a Phospholipid Containing Two of EPA and DHA.

14. I have read the disclosure and claims of the '348 patent and understand them to be directed to a biologically effective amount of an extract containing a phospholipid composition bearing two of EPA and DHA. That is, amounts of phospholipid compositions containing two of EPA and DHA that would allow these compositions to be active ingredients. Therefore, it is my understanding that the '348 patent is not directed to nor encompasses *de minimis* amounts of the phospholipid composition.

15. Specifically, claim 1 includes the phrase "wherein the composition is suitable for human consumption." This strongly suggests that the claim is directed to a biologically effective amount of the composition. My reading of the '348 patent's specification supports this point. Under "Field of the Invention," Patentee states that "[t]he present invention is directed to nutraceutical, pharmaceutical or cosmetic compositions." '348 Patent, Column 1, lines 22-25. Claim 1 would not cover "nutraceutical, pharmaceutical or cosmetic compositions" if it encompassed preparations containing *de minimis* amounts of the recited composition. Further, Column 4, lines 3-5, states: "[t]he composition . . . [is] useful in the prevention or treatment of a variety of disease states." Again, biologically effective amounts of the composition, and not *de minimis* levels, would be needed to have a medical effect with the claimed phospholipids as the active ingredient. Further, Examples 2 and 3 show the medical uses of this composition, underscoring the need for biologically effective quantities. This is also seen in Column 19, line 63 to Column 21, line 31, which recites, among others, various

pharmaceutical and medical uses of the composition, based on the assumption that the composition is in biologically active amounts. Therefore, it is my opinion that this patent is directed to a biologically effective amount of the composition.

The White Declaration of May 31, 2011 Concludes that Beaudoin I Does Not Contain a Biologically Effective Amount of a Phospholipid Containing Two of EPA and DHA.

16. I have read the Declaration of Earl L. White submitted on May 31, 2011 in support of the '348 patent. My scientific opinion of this declaration is that Dr. White properly concluded that Beaudoin I does not contain a biologically effective amount of a phospholipid containing two of EPA and DHA.
17. This reading is necessitated by not only Dr. White's statements but also a reasonable interpretation by a scientist in the field.
18. As to the latter, I do not, nor would any other scientist, interpret Dr. White's conclusion to mean that trace amounts of the phospholipid containing two of EPA and DHA are not present in Beaudoin oil. As a veteran scientist, Dr. White would not make such a definitive statement, nor would a typical scientist draw such a conclusion. On the contrary, a scientist would look at the White data and understand that his conclusion was that, on the whole, and limited by the instrumental caveats that come with every experiment, biologically effective amounts of the composition were not detected.
19. Dr. White explicitly states this as he reports his "opinion that the Beaudoin Oil Fractions received and tested by [Dr. White] do not contain PLs [phospholipids] which have attached to them DHA and DHA, EPA and EPA, DHA and EPA, or EPA and DHA, at the detection limits described above in paragraph 7 [outlining LC/MS and MS/MS techniques]." White Declaration of May 31, 2011, ¶ 13 (emphasis added).
20. Therefore, the only reasonable reading of the Earl L. White Declaration of May 31, 2011 is that Dr. White concluded that Beaudoin I does not contain a biologically effective amount of a phospholipid containing two of EPA and DHA.

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