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 FAUSTINUS YEBOAH, PH.D. UNDER 37 C.F.R. § 1.132

I, Faustinus Yeboah, declare as follows:

1. I am a Canadian citizen.

2. I am the Director of KABS Laboratories, Inc., a company that offers a broad range of product development services to the bio-pharmaceutical industry worldwide. The services offered include strategic planning, pre-clinical development, analytical testing, formulation development, manufacturing of prototypes and clinical supplies, distribution of clinical supplies to clinical sites, and chemistry, manufacturing and controls (CMC) aspects of regulatory affairs. I am also the Founder and Principal Consultant of PDMC Pharma Consulting.

3. I obtained my Ph.D., concentrating on protein and carbohydrate chemistry, and my M.Sc., concentrating on food chemistry, from McGill University in Montréal, Québec. I was a post-doctoral fellow at the Biotechnology Research Institute of the National Research Council in Canada.

4. I have authored twenty five papers, many of which concern mass spectrometry and extraction of biomolecules, and I am an inventor of one U.S. patent and six patent applications. I

am a Faculty Lecturer at McGill University in the Department of Food Science, and I serve as a Journal Reviewer for the *Journal of Food Composition and Analysis*, the *Journal of Agriculture and Food Chemistry*, and the *Journal of Environmental Toxicology*. I also serve as a Grant Reviewer for the National Science and Engineering Research Council of Canada (NSERC). My Curriculum Vitae is enclosed as **Appendix A**.

5. I am considered an expert in the area of mass spectrometry and extraction of biomolecules.

6. I was engaged by counsel for Neptune Technologies and Bioressources, Inc. ("Neptune") of Québec, Canada to analyze the Corrected Request for Reexamination (U.S. 95/001,774) filed by Aker Biomarine ASA ("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 U.S. Patent 8,030,348 ("the '348 patent") or any continuation application from the '348 patent.

7. Specifically, I was asked to review the Declaration of Thomas Gundersen, which was filed in support of the Request for Reexamination filed by Aker and the Declaration of Earl L. White, Ph.D., which was submitted by Neptune in the prosecution of the '348 patent, and to opine on the validity of the results provided therein. Further, I was asked to express an opinion on quantitative aspects of the data discussed herein.

Gundersen Presents Incomplete and Unreliable Data

8. I have read and reviewed the Declaration of Thomas Gundersen submitted by Aker, and it is my opinion that it suffers from considerable technical deficiencies and errors which render its conclusions completely unreliable. I summarize these deficiencies and errors below.

Gundersen Presents Clearly Erroneous Data

9. My review of the Gundersen Declaration leads me to conclude that it contains incomplete and unreliable data. Gundersen erroneously presents data as distinct when it is merely an exact copy of another chromatogram. In my opinion, there is clear error in the Gundersen Declaration

and, whether reflective of a sloppy study marred by negligence or a fraudulent study submitted with deceitful intent, one cannot rely on this data at all.

10. Specifically, referring to Appendix B of the Gundersen Declaration, the chromatograms labeled "Sample P308-8" and "Sample P308-9" are identical (*see* Gundersen Declaration, Appendix B, pp. 18-19). Similarly, the chromatograms labeled "Sample P308-10," "Sample P308-11," and "Sample P308-12" are identical (*see* Gundersen Declaration, Appendix B, pp. 19-20).

11. Gundersen provided Table 1, which states that "Sample P308-8," "Sample P308-9," "Sample P308-10," "Sample P308-11," and "Sample P308-12" are distinctly different samples (*see* page 3 of the report appended to the Gundersen Declaration). Below, I reproduce, in part, Table 1 (emphasis added, note the "Marking of Sample" Column):

Vitas ID	Fraction number	Temperature treatment (°C)	Time (min)	Marking of sample
P308-8	IIa	70	5	**E.superba Fraction IIa 70 degr 5 min**
P308-9	IIa	125	15	**E.superba Fraction IIa 125 degr 15 min**
P308-10	IIb	-	-	**E.superba Fraction IIb not heated**
P308-11	IIb	70	85	**E.superba Fraction IIb 70 degr 5 min**
P308-12	IIb	125	15	**E.superba Fraction IIb 125 degr 15 min**

12. I have also attached the incomplete and unreliable chromatograms as enumerated above as a series of figures to make this point clear (*see* Figures 1-5). By reviewing Figures 1 and 2 side by side (on pages 14-15 of this Declaration), it is apparent that the retention times, areas under the curve, and sample identification information are exactly the same. For convenience, I have magnified the bottom peak of each of the chromatograms labeled "Sample P308-8" and "Sample P308-9" and displayed them in Figures 1 and 2. The bottom chromatograms both have

areas under the curve of 124384 and retention times of 3.758 minutes. It is my opinion that it would be impossible for two distinct samples to provide the exact same data. Even if "Sample P308-8" and "Sample P308-9" were merely repeats of each other, which they are not according to Gundersen's Table 1 (above), the data would have *at least some deviation*. The unreliability of this data is further underscored by the fact that the same sample identification number appears on the chromatograms labeled "Sample P308-8" and "Sample P308-9" and displayed in Figures 1 and 2 (on pages 15-16 of this Declaration). Both chromatograms have the following sample identifier: "MSD1 826. EIC=825.7.826.7 (C:\PAD\AKER BIOMARIN\P308\AB 110929\AB 110929\AB 110929 2011-09-29 10-35-22\004-0401D) ES." By providing the exact same data twice yet referring to the data as originating from two different experimental samples, Gundersen himself firmly demonstrates that his data is not credible. This is summarized below:

Vitas ID	Marking of sample	Retention Time	Area Under the Curve
P308-8	"E.superba Fraction IIa 70 degr 5 min"	3.758	124384
P308-9	"E.superba Fraction IIa 125 degr 15 min"	3.758	124384

13. The chromatograms labeled "Sample P308-10," "Sample P308-11," and "Sample P308-12" also present identical data for allegedly distinct samples and therefore provide further incomplete and unreliable data. By reviewing Figures 3, 4, and 5 (on pages 16-18 of this Declaration) side by side, it is apparent that the retention times, areas under the curve, and sample identification information are exactly the same. For convenience, I have magnified the bottom peak of each of the chromatograms labeled "Sample P308-10," "Sample P308-11," and "Sample P308-12" and displayed them in Figures 3, 4, and 5. The bottom chromatograms of all three have areas under the curve of 58821.8 and retention times of 3.770 minutes. It is my opinion that it would be impossible for three distinct samples to provide the exact same data. Even if "Sample P308-10," "Sample P308-11," and "Sample P308-12" were merely repeats of each other, which they are not according to Gundersen's Table 1 (above), the data would have *at least some deviation*. The unreliability of this data is further underscored by the appearance of the same sample identification number on the chromatograms labeled "Sample P308-10," "Sample P308-11," and "Sample P308-12" and displayed in Figures 3-5. All three chromatograms carry the following sample identifier: "MSD1 826. EIC=825.7.826.7 (C:\PAD\AKER BIOMARIN\P308\AB 110929\AB 110929\AB 110929 2011-09-29 10-35-

22006-D601 D) ES." As with the samples discussed in Paragraph 12 above, by providing the exact same data three times yet referring to it as three different experimental samples, Gundersen establishes that his data is not credible. This is summarized below:

Vitas ID	Marking of sample	Retention Time	Area Under the Curve
P308-10	"E.superba Fraction IIb not heated"	3.770	58821.8
P308-11	"E.superba Fraction IIb 70 degr 5 min"	3.770	58821.8
P308-12	"E.superba Fraction IIb 125 degr 15 min"	3.770	58821.8

14. I note that I limited my review in this section to data presented in Appendix A of the Gundersen Declaration, as the data presented in Appendix B of the Gundersen Declaration is so poorly reproduced that I cannot discern most of the alleged peaks that are presented. For example, I cannot see any data on the chromatograms labeled "p308-4" to "p308-7" and can only make out faint images on the remainder of the figures presented in Appendix B of the Gundersen Declaration.

Gundersen's Results are Highly Variable and Reflective of a Rushed Experiment.

15. Besides the incomplete and unreliable data presented, there is a puzzling complete absence of data in the Gundersen Declaration for the ethyl acetate extract of *E. superba* krill lipid samples (*see* Gundersen Declaration ¶ 5). The fact that no data was generated for these experimental samples suggests that the experiment was not conducted carefully (*see* Gundersen Declaration, Appendix B, pp. 16-17 for chromatograms labeled "Sample P308-4," "Sample P308-5," and "Sample P308-6"). In fact, Gundersen himself states that the experiment "should have been repeated but there was not enough time for this" (*see* Gundersen Declaration ¶ 5; emphasis added). Further, on page 2 of Exhibit 2 of the Gundersen Declaration, Gundersen states that "the analysis of the samples took place between 28 September and 4 October 2011." Therefore, all within the span of just five business days, the data was acquired, the data was analyzed, a report was generated, and a declaration regarding analysis of the data was written. A

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