

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

SUPPLEMENTAL DECLARATION OF EARL L. WHITE, PH.D.

UNDER 37 C.F.R. § 1.132

I, Earl L. White, declare as follows:

1. I am a U.S. citizen.
2. I am currently the President and CEO of MDx BioAnalytical Laboratory, Inc. in College Station, TX, which offers, among other things, expert analytical services for the identification of biosubstances.
3. I have a Ph.D. in analytical chemistry specializing in mass spectrometry from the University of North Carolina at Chapel Hill. Since 1985, I have worked professionally in the area of analytical chemistry and mass spectrometry (around 27 years). I was appointed and served as Adjunct Professor of Chemistry, Wake Forest University, Department of Chemistry and have published more than 27 peer reviewed journal articles. I currently serve as a Peer Reviewer for *J. Chromatographic Science* and *J. Chromatography*. I am a member of the American Chemical Society (CNCS-Section Chairman '93, Chair-Elect/Program Chair '92, Secretary '91 and Treasurer '90), Mississippi Academy of Science, Society of Analytical Chemists of Pittsburgh, Applied Spectroscopy Society, Phi Lambda Upsilon Honorary

Chemical Society, America Society for Mass Spectrometry, National Technical Association and Alpha Phi Alpha Fraternity, Inc., Triangle Area Mass Spectrometry Discussion Group, National Organization of Black Chemists and Chemical Engineers (NOBChCE), Bay Area Mass Spectrometry Discussion group (BAMS) and the SF Bay Area Proteome Society. My Curriculum Vitae is attached as Appendix A.

4. I am considered an expert in the area of identification of biomolecules using analytical techniques in general, and mass spectrometry, specifically.
5. 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 filings from the ‘348 patent.
6. In 2011, MDx BioAnalytical Laboratory, Inc. was contracted by Neptune Technologies and Bioresources, Inc. of Québec, Canada to analyze certain phospholipid samples (the “Beaudoin Oil Fractions”) and report which fatty acid phospholipids are present. Furthermore, I was asked to opine on whether certain fatty acid phospholipids were present or absent in the Beaudoin Oil Fractions, within the levels of detection of a conventional mass spectrometry experiment. The results of this analysis were submitted in a Declaration dated May 31, 2011 in U.S.S.N. 10/485,094 (now the ‘348 patent). There, I stated that “it is my opinion that the Beaudoin Oil Fractions received and tested by me 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 liquid chromatography/mass spectrometry (LC/MS) and tandem mass spectrometry (MS/MS) techniques].” White Declaration of May 31, 2011, ¶ 13.
7. I have been informed that Aker BioMarine filed a Request for Reexamination (U.S.S.N. 95/001,774) which questions the accuracy of the data that I presented in the Declaration of May 31, 2011. Aker also filed a Corrected Request for Reexamination, which I have read.
8. I specifically note that Aker’s Corrected Request for Reexamination states, at pages 20-21 (emphasis added):

“Requestors further note that the analysis by Dr. White was incomplete because Dr. White apparently did not utilize any reference standards or positive controls in his analysis. This raises

the questions of whether: 1) the conditions used by Dr. White were sufficient to detect the claimed phospholipid species; and 2) the assumptions by Dr. White in the interpretation of the MS data were correct. Both of these issues could have been addressed by the use of reference standards to validate the detection techniques. From an analytical standpoint, it is important to use reference standards and positive controls to verify that the analytical procedures are working and will perform their intended purpose. It is especially important to optimize mass spectrometric parameters using reference compounds. See the Declaration by Dr. Thomas Gundersen in Support of Request for Inter Partes Reexamination of U.S. Patent No. 8,030,348.”

9. I clarify herein that, as is standard in the industry, I contemporaneously ran adequate controls when I conducted the experiments that were reported in the Declaration of May 31, 2011.
10. I submit herewith controls, which were analyzed at the same time the experiments were analyzed, that were reported in the Declaration of May 31, 2011. Specifically, I ran the following controls that are summarized in detail below:
 - a. a series of *positive* controls in the form of a commercial phospholipid standard set which contains four phospholipids of various weights; and
 - b. a solvent-only *negative* control of 20% acetonitrile, which was run at the beginning of the experiment and between each run that involved a species that differed from the previous. As discussed below, such a control is crucial to correct for the contamination of data from other samples (the so-called “memory effect” or “carry-over effect”).
11. It is necessary to run positive controls to demonstrate experimental sensitivity and validity of data generated. It is well known in the field that such controls must be run, and therefore I, having over 25 years in the field, ran adequate *positive* controls in generating the data reported in my Declaration of May 31, 2011.
12. Specifically, I ran a series of positive controls in the form of a commercial phospholipid standard set (see Figure 1). This standard set is commercially available from Sigma-Aldrich (Catalog No. P3817-1VL). This standard set includes four different common phospholipid species of different molecular masses, such as L- α -lysophosphatidylcholine, L- α -phosphatidylcholine, L- α -phosphatidylethanolamine, and L- α -phosphatidylinositol sodium salt.
13. Further, a sound and experimentally viable mass spectrometry experiment requires solvent “blank” or “negative control” samples at the beginning of a series of runs and between different experimental runs, specifically when the chemical species to be studied are different

between runs. Such standards correct for the "memory effect," *i.e.*, contamination from the chemical carryover from prior samples. Blank controls in the form of 20% acetonitrile were run first thing each day, between every sample set (which would wash out carry over species), and at the end of a day as a column-cleaning technique. A representative solvent-only run is included as Figure 2. Note that the signal intensity is at least one order of magnitude lower than in the positive control (6.06×10^4 in Figure 1 versus 1.5×10^3 in Figure 2). The small peak at 22.22 minutes is a contaminant in the solvent blank. The noise level is indicative of the low level of this contaminant. The baseline rise at 26 minutes is due to high concentration of acetonitrile used to clean the column. It is well known in the field that *negative* controls must be run and therefore I, having over 25 years in the field, ran adequate negative controls in generating the data reported in the Declaration of May 31, 2011.

14. Accordingly, I contemporaneously ran adequate controls (*i.e.*, positive and negative controls) when I conducted the experiments that were reported in the Declaration of May 31, 2011.

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15. I further declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

By:



Earl L. White, Ph.D.

Dated: March 29, 2012

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