# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD

## AKER BIOMARINE AS Petitioner

 $\mathbf{v}_{\bullet}$ 

# NEPTUNE TECHNOLOGIES AND BIORESOURCES INC. Patent Owner

**CASE IPR: Unassigned** 

**Declaration of Dr. J. Thomas Brenna** 



- I, Dr. J. Thomas Brenna, state as follows:
- 1. I have been retained by counsel for Petitioner Aker BioMarine AS to provide an expert declaration this action.
- 2. I have reviewed U.S. Patent 8,278,351 (hereinafter '351 patent; Ex. 1001) and the claims contained therein. It is my understanding that the '351 patent contains claims to krill extracts (claims 1-23); capsules, tablets, solutions, syrups or suspensions comprising the krill extracts (claims 24-46); foods, beverages or nutritional supplements comprising the krill extracts (claims 47-69); cosmetics comprising the krill extracts (claims 70-93); and Antarctic krill extracts (claim 94). The common feature of the independent claims (claims 1, 24, 47, 70 and 94) is the requirement of



a phospholipid of the formula (I),

wherein R1 and R2, each together with the respective carboxyl groups to which each is attached, each independently represents a docosahexaenoic acid (DHA) or an eicosapentaenoic acid (EPA) residue, and X is —CH<sub>2</sub>CH<sub>2</sub>NH<sub>3</sub>, —CH<sub>2</sub>CH<sub>2</sub>N(CH<sub>3</sub>)<sub>3</sub>, or

The dependent claims add limitations on other components of the composition such as omega-3 content, polyunsaturated fatty acid content, content of other lipid classes, metal content and antioxidant content.

3. I have been asked to provide analysis and expert opinions on the following: whether any prior art reference teaches every element of any of the Claims of the '351; whether any single prior art reference or combination of references, renders any of the Claims of the '351 patent obvious.



- 4. In connection with providing my opinions, I have further been asked to provide an overview of the technology of the '351 Patent.
- 5. I hold a B.S. degree in Nutritional Biochemistry from the University of Connecticut (1980), an M.S. degree in Chemistry from Cornell University (1982), and a Ph.D. in Chemistry from Cornell University (1985).
- 6. From 1985 to 1989, I served as a staff scientist in the Advanced Technology Development Laboratory at IBM Corporation, Endicott, New York, where I was the Founding Director of the Fourier Transform Mass Spectrometry Laboratory. From 1988 to 1989, I served as a faculty member at Binghamton University, Binghamton, New York, where I held the title of Adjunct Assistant Professor of Chemistry. From 1989 to 2000, I served as a faculty member in the Division of Nutritional Sciences at Cornell University, Ithaca, New York, where I held the titles of Assistant Professor and Associate Professor. In 2000, I became Professor of Human Nutrition and Professor of Chemistry and Chemical Biology at Cornell University. In 2006, I was appointed Adjunct Professor in the Department of Public Health Sciences at the University of Rochester College of Medicine and Dentistry, Rochester, New York.
- 7. I have been principal investigator for over \$15 million in sponsored Research Funding Awards to investigate the various aspects of nutrition and



metabolism using techniques of molecular biology and genetics, mass spectrometry, and high precision isotope ratio mass spectrometry in antidoping science. I am currently a member of the 2015 Dietary Guidelines Advisory Committee appointed jointly by US Secretary of Health and Human Services Kathleen Sebelius and Secretary of Agriculture Tom Vilsack. I was the 2013 recipient of the American Society for Nutrition Robert H. Herman Award, given each year to a clinical investigator whose research work has contributed importantly to the advancement of clinical nutrition, particularly the biochemical and metabolic aspects of human nutrition. I have also been selected to advise a number of scientific organizations, including:

- panelist and author for the FAO/WHO Expert Consultation on Fats and Fatty Acids in Human Nutrition (2008–2011);
- research proposal review on behalf of the National Institutes of Health for: Regional Comprehensive Metabolomics Resource Core program (2013, 2012); Enabling Biomedical Technologies-Shared Research Instrumentation (2010; Study Section Chairman); NIGMS Large Scale Collaboration (2008); Biological Chemistry and Macromolecular Biophysics Study Section (2001–2007); Metabolomics Panel, NIH Director's Roadmap (2004); NCI Innovative



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