

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AKER BIOMARINE AS

Petitioner

v.

NEPTUNE TECHNOLOGIES AND BIORESOURCES INC.

Patent Owner

CASE IPR: Unassigned

Declaration of Dr. Richard B. van Breemen

Petition for Inter Partes Review
Of U.S. Patent 8,278,351
Exhibit

ENZYMOTEC - 1040

I, Richard B. van Breemen, Ph.D., hereby declare and say:

1. I, Dr. Richard B. van Breemen, have been retained by counsel for Petitioner Aker BioMarine AS to provide an expert declaration in 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).

3. As part of my engagement by the Respondents, I have been asked to provide analysis and opinions on the following:

- whether certain krill extracts analyzed by Earl L. White on behalf of the Patentee contain the Claimed Phospholipids of the '351 patent; and
- whether any of the Claims of the '351 patent are invalid under 35 U.S.C. § 102 as anticipated or under 35 U.S.C. § 103 as being rendered obvious.

4. I hold a B.A. degree in Chemistry from Oberlin College (1980) and a Ph.D. in Pharmacology from the Johns Hopkins University School of Medicine (1985).

5. From 1986 to 1993, I was an Assistant Professor of Chemistry at North Carolina State University. During that time, I also served as Director of the Mass Spectrometry Laboratory for Biotechnology Research. In 1994, I joined the faculty of the University of Illinois at Chicago (UIC) as an Associate Professor of Medicinal Chemistry at the College of Pharmacy. In 2000, I was promoted to the position of Professor of Medicinal Chemistry and Pharmacognosy at the UIC College of Pharmacy, and I hold that position today.

6. Since 1999, I have also worked at the UIC/NIH Center for Botanical Dietary Supplements Research (UIC Botanical Center). The UIC Botanical Center focuses on the study of the safety and efficacy of dietary supplements used by women. I was initially a Co-Director at the UIC Botanical Center when it was founded in 1999, and my primary responsibilities were supplement safety and all analytical aspects of supplements, including chemical standardization. Since 2011, I have been the Director of the UIC Botanical Center. In this role, I have been responsible for extraction and standardization of all botanical supplements for study. Since 1999, we have completed three Phase-1 trials and one Phase-2 clinical trial at the UIC Botanical Center.

7. Since 2001, I have also held the administrative position of Assistant to the Director of the Research Resources Center at the University of Illinois at Chicago. In this position, I provide advice regarding campus needs in the area of mass spectrometry, and my laboratory serves as a central campus resource in mass spectrometry.

8. Since 2010, I have been the leader of the Mass Spectrometry, Metabolomics and Proteomics Facility (MMPF) for the University of Illinois Cancer Center. MMPF provides analytical mass spectrometry support for cancer researchers for all branches of the University of Illinois. For examples, MMPF supports drug discovery, drug metabolism, pharmacokinetics, and clinical trials.

9. I have done analytical work regarding materials of marine origin. Beginning in the 1990s, I performed research on carotenoids that included astaxanthin of marine origin utilizing tandem mass spectrometry (MS/MS). My publications stemming from that work include:

- van Breemen RB, Schmitz HH, Schwartz SJ. Fast atom bombardment tandem mass spectrometry of carotenoids. *J. Agric. Food Chem.* **43**, 384-389 (1995); and
- van Breemen RB, Dong L, Pajkovic ND. Atmospheric pressure chemical ionization tandem mass spectrometry of carotenoids. *Int. J. Mass Spectrom.* **312**, 163-172 (2012)

From 2006-2011, as a project leader on a program project grant entitled, “Natural inhibitors of carcinogenesis,” from the National Cancer Institute of the National Institutes of Health, I carried out drug discovery research utilizing mass spectrometry focused exclusively on natural products from marine sediment microorganisms. My publications stemming from that work include:

- Choi Y, Jermihov K, Nam S-J, Sturdy M, Maloney K, Qiu X, Chadwick LR, Main M, Chen S-N, Mesecar AD, Farnsworth NR, Pauli GF, Fenical W, Pezzuto JM, van Breemen RB. Screening natural products for inhibitors of quinone reductase-2 using ultrafiltration LC-MS. *Anal. Chem.* **83**, 1048-1052 (2011). PMC3034444; and
- Kondratyuk TP, Park E-J, Yu R, van Breemen RB, Asolkar RN, Murphy BT, Fenical W, Pezzuto JM. Novel marine phenazines as potential cancer chemopreventive and inflammatory agents. *Mar. Drugs*, 10, 451-464 (2012). PMC3297008

I have also done work in the field of lipid chemistry. For example, between 1990-1995, I carried out early mass spectrometry-based structural studies of phosphatidylinositols (PI) including:

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