IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re *Inter Partes* Reexamination of U.S. Patent No. 8,057,825

Entitled: Krill Extracts for Treatment of Cardiovascular Diseases

Issued: 15 November 2011 to Sampalis

DECLARATION BY DR. NILS HOEM IN SUPPORT OF REQUEST FOR INTER PARTES REEXAMINATION OF U.S. PATENT NO. 8,057,825

EFS WEB Filed

Mail Stop Inter Partes Reexam
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I, Dr. Nils Hoem, state as follows:

1. My present position is Chief Scientist of Aker Biomarine ASA. My Curriculum Vitae is attached hereto as Exhibit 1.

2. I have reviewed the following references which are cited in this re-examination proceeding:

- Makuta et al, Application of Eicosapentaenoic Acid to Health Food, Japan Fudo Saiensu (1986), 25:1, 29-35 (Makuta)
- Gordeev et al., Chemistry of Natural Compounds (1990) 26(2) 143-147 (Gordeev)
- Kuroda et al., Comparison of Hypocholesterolemic Effect among Three Phospholipids Containing Different Fatty Acid and the Related Oils in Rats, Jap. J. Nutr. (1990), 48(5):213-20 (Kuroda)
- Canadian Application 2,251,265 (Beaudoin)
- WO 00/23546 (Sherbrooke)
- Japanese Laid Open Publication S63-23819 (Murata).

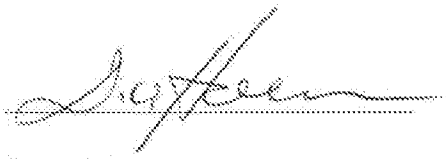
In this Declaration, I also refer to Fricke et al., Lipid, Sterol and Fatty Acid Composition of Antarctic Krill (Euphausia superba Dana)(1984) Lipids 19(11):821-827 (attached as Exhibit 2).

3. Krill are rich in a variety of liposoluble compounds including phospholipids, carotenoids such as astaxanthin, and vitamin E (α-tocopherol). This fact is supported by Canadian Application 2,251,265 at p. 5 and WO 00/23546 at p. 9-11. Astaxanthin and α-tocopherol are antioxidants. *Id.* The phospholipid fraction of krill contains phosphatidylcholine and phosphatidylethanolamine as well as other phospholipid species. See Fricke et al., p. 822, Table 1; See also WO 00/23546, p. 9-11 and Tables 14-18. A variety of fatty acids are attached to the phospholipids. These include docosahexaenoic acid, eicosahexaenoic acid, oleic acid, and linoleic acid among many others. WO 00/23546, p. 9-11 and Tables 14-18; Fricke et al., Tables 2-6.

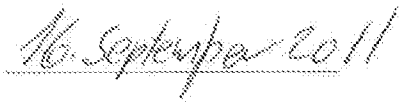
4. Lipid extracts from krill have common characteristics. This is demonstrated by the fact that the different extraction protocols employed in WO 00/23546 (Tables 14-18), Fricke et al. (Tables 2-6), and Gordeev (Table 1) all produce lipid fractions containing phosphatidylcholine and phosphatidylethanolamine as well as other phospholipid species, docosahexaenoic acid, eicosahexaenoic acid, and oleic acid as well as many other fatty acids. The phospholipid fractions utilized by Kuroda (Tables 1 and 2) and described in Makuta (Tables 9 and 10) also contain these phospholipids and fatty acids. In each instance, liposoluble substances such as astaxanthin and α-tocopherol would be present in the various krill lipid extracts and phospholipid fractions as demonstrated in WO 00/23546 at p. 9-11 and Tables 14-18. This means that the phospholipid fractions and krill lipid extracts in each of the references listed in Paragraph 2 above would contain phosphatidylcholine and phosphatidylethanolamine as well as other phospholipid species, docosahexaenoic acid, eicosahexaenoic acid, linoleic acid and oleic acid as well as many other fatty acids as listed in the various Tables, astaxanthin and α-tocopherol. The phospholipid fractions and krill lipid extracts would also contain triglycerides and free fatty acids.

5. I further declare that all statement 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 issued thereon.

Respectfully submitted,



Dr. Nils Hoem



Date

EXHIBIT 1

Curriculum Vitae

Nils Ove Hoem, M.Sc.(Pharm), Ph. D.

PROFESSIONAL BACKGROUND

Academic Appointments	1985-1989	Research Assistant, Department of Pharmacology, School of Pharmacy, University of Oslo.
	1989-1990	Assistant Professor, Department of Pharmacology, School of Pharmacy, University of Oslo.
	1990-1998	Associate Professor, Department of Pharmacology, School of Pharmacy, University of Oslo.
	2000-2002	Associate Professor, Department of Pharmacology, School of Pharmacy, University of Oslo
	2001-present	Associated member of Laboratory of Applied Pharmacokinetics, USC, Los Angeles
Non-Academic appointments	1979-1980	Teacher (Ellingsoy Junior High School)
	1984 - 2004	Several shorter periods (1-4 weeks) as community Pharmacist in Norway
	1992-1996	Project manager: Development and implementation of a Post Graduate one-year continuing education program for Pharmacists.
	1999	Senior Regulatory Advisor, Smerud Medical Research Group, Oslo, Norway.
	2003	Senior Scientific Consultant, Smerud Medical Research Group, Oslo, Norway.
	2003-2004	Running own consultancy business. Hoem Pharma Consult in Oslo Norway. Consulting in Pharmacokinetics and in more general aspects of early drug development.
	2004-2007	Director PK/PD (Europe) MDS Pharma Services, Hamburg, Germany and Belfast Northern-Ireland
	2007-2007	Director R&D Pronova Biocare AS, Lysaker, Norway
	2008-2010	Vice President Research and Development Aker BioMarine, Norway
	2011-present	Chief Scientist Aker BioMarine, Norway

LICENSURE

1983 - present	Certified to Dispense Drugs in Norway.

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