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. Jeff D. Moore

I, Dr. Jeff D. Moore, state as follows:

1. I am the director of Analytical Technologies for Avanti Polar Lipids, Inc. I have been retained by counsel for Petitioner Aker BioMarine AS to testify as an expert in this inter partes review.

2. My report concerning analysis of total lipid content, free fatty acid content and total phospholipid content in krill extracts is attached hereto.

3. 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,

Jeff D. Moore

Dr. Jeff D. Moore

9-27-13

Date: September 27, 2013

Introduction

Avanti Polar Lipids, Incorporated is a Bulk Pharmaceutical Manufacturer licensed by the U.S. Food and Drug Administration . The analytical laboratory provides quality control testing of processes, raw materials and final products under current good manufacturing practices (cGMP). The quality control laboratory resources to include instrumentation and personnel are also utilized to provide fee for service laboratory testing under the Analytical Services Division. All instrumentation is maintained, calibrated, operationally and performance qualified (OQ/PQ). All personnel are professionally qualified by education and experience as well as maintain documented training.

Samples of krill extract were provided for analysis to determine total lipid content, free fatty acid content and total phospholipid content. The samples were assayed by methods developed at Avanti. Each sample was assayed in triplicate and one sample was fortified with a relevant compound to determine suitability of respective methodology, i.e. precision and accuracy. The instrumentation, sample preparation, instrument settings, chemicals, calculations and results for the three assays are described herein.

Samples and Receipt

Samples were received by courier at Avanti Polar Lipids and unpacked for storage. All samples were stored at 2-8° C until time of preparation and returned to such storage between uses.

Received: August 13, 2013
Condition: no dry ice cool to touch, intact and legibly labeled
VB 1 8/8/13 FH
VB 7 8/9/13 FHE

Received: August 21, 2013
Condition: dry ice and frozen, intact and legibly labeled
SB1 BEA-P0
SB5 BEA-P1
SB9 BEA-P2
SB 13 BEA-S0
SB 17 BEA-S1
SB 21 BEA-S2

Received: September 10, 2013
Condition: dry ice and frozen, intact and legibly labeled

Total Lipid Content

The VB and SB1 thru 21 series of samples above were assayed by gravimetrical weighing upon extraction and drying. The total lipid content is expressed as weight % of original sample weight used in the assay.

Principle:

Lipids are fats or oils which are not soluble in water. They must be extracted and dissolved into non-polar solvents to form solutions. Lipid extraction techniques utilize the layering of the water and non-polar solvents to separate lipids from a sample. The water soluble compounds dissolve into the upper layer and lipids into the lower layer. Lipids extracted into the lower layer can be recovered by evaporating the solvent and weighing the dried residue. The weight percentage of lipid can be determined by the ratio of recovered lipid weight to the original sample weight. The Folch extraction technique (*Folch et al., J Biol Chem 1957, 226, 497*) is universally accepted as a means to extract lipid.

Reagents:

Fisher Scientific HPLC grade chloroform, lot # 133740, exp. 08-08-14
Fisher Scientific HPLC grade methanol, lot #132577, exp. 08-12-14
Fisher Scientific HPLC grade water, lot #133911, exp. 08-12-14

Instrumentation:

Sartorius CP124S analytical balance (4 place), ser. #22650193.
Calibration date: 02-27-13 / Calibration due: 02-28-14 / Suitability tested: passed 08-15-13.

Sample Extraction:

1. Each sample was removed from 2-8° C storage and allowed to equilibrate to ambient temperature.

2. Each sample was weighed in triplicate into separate 12 mL, 16 X 100 mm glass test tubes with screw cap at 500 ± 3 milligram.

3. Sample VB 7 8/9/13 FHE was weighed and transferred again in triplicate for fortification with

weights and solvent volumes are provided in table 1.

Table 1: Sample weights and solution volumes.

Sample	Sample Weight (mg)	$CHCl_3$ (mL)	CH_3OH (mL)	H_2O (mL)	Oleic acid (mL)
VB 1 8/8/13 FH	503.0	6.5	3.25	2.0	
VB 1 8/8/13 FH	501.4	6.5	3.25	2.0	
VB 1 8/8/13 FH	499.9	6.5	3.25	2.0	
VB 7 8/9/13 FHE	501.6	6.5	3.25	2.0	
VB 7 8/9/13 FHE	499.2	6.5	3.25	2.0	
VB 7 8/9/13 FHE	502.2	6.5	3.25	2.0	
VB 7 8/9/13 FHE-SPIKE	502.0	5.5	3.25	2.0	1.0
VB 7 8/9/13 FHE-SPIKE	502.2	5.5	3.25	2.0	1.0
VB 7 8/9/13 FHE-SPIKE	499.4	5.5	3.25	2.0	1.0
BEA SB1 P0	500.7	6.5	3.25	2.0	
BEA SB1 P0	501.1	6.5	3.25	2.0	
BEA SB1 P0	500.0	6.5	3.25	2.0	
BEA SB5 P1	499.3	6.5	3.25	2.0	
BEA SB5 P1	501.0	6.5	3.25	2.0	
BEA SB5 P1	499.8	6.5	3.25	2.0	
BEA SB9 P2	500.3	6.5	3.25	2.0	
BEA SB9 P2	499.6	6.5	3.25	2.0	
BEA SB9 P2	500.2	6.5	3.25	2.0	
BEA SB13 S0	500.0	6.5	3.25	2.0	
BEA SB13 S0	501.0	6.5	3.25	2.0	
BEA SB13 S0	499.3	6.5	3.25	2.0	
BEA SB17 S1	500.6	6.5	3.25	2.0	
BEA SB17 S1	500.6	6.5	3.25	2.0	
BEA SB17 S1	499.5	6.5	3.25	2.0	
BEA SB21 S2	499.3	6.5	3.25	2.0	
BEA SB21 S2	500.4	6.5	3.25	2.0	
BEA SB21 S2	500.0	6.5	3.25	2.0	

4. The samples were extracted using a Folch extraction technique whereby approximately 20

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