

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. Suzanne Budge in Support of Inter Partes
Review of U.S. Pat. No. 8,278,351**

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

Exhibit

ENZYMOTEC - 1041

I. QUALIFICATIONS

1. My name is Dr. Suzanne Budge. I have been retained by counsel for Respondents Aker BioMarine AS to testify as an expert in this inter partes review.

2. I am currently an Associate Professor in the Food Science Program, in the Department of Process Engineering and Applied Science at Dalhousie University. I obtained a B.Sc. in Chemistry from Acadia University in 1993 and a Ph.D. in Analytical and Marine Chemistry from Memorial University of Newfoundland in 1999. My Ph.D. research primarily involved preparing extracts of marine animals and analyzing the components of these extracts using various analytical techniques. Upon obtaining my Ph.D., I joined Dalhousie University as a Post-Doctoral Fellow, and in 2004 became an Assistant Professor. In 2009, I was promoted to Associate Professor.

3. Throughout my career, I have published numerous papers and given numerous presentations related to the chemistry of marine animals, including many related to marine oil extraction. As an Associate Professor, my research is focused primarily on the preparation and analysis of marine oils. I have more than fifteen years of experience in performing extractions of marine animals, and analyzing marine extracts. I consider myself an expert in this field. My *curriculum vitae* is attached as Exhibit A.

4. In forming my opinions, I have considered and relied upon my education, background, and experience in marine chemistry, as well as the documents and information cited herein.

II. INTRODUCTION

5. I have been asked to review PCT Publication No. WO 00/23546 (“Beaudoin I”) and Canadian Patent Application No. CA 2,251,265 (“Beaudoin II”) and to prepare krill extracts in accordance with the extraction procedure described in those references, .

6. I reviewed Beaudoin I and Beaudoin II from the perspective of a person of ordinary skill in the art as of July 27, 2001. I understand that Respondents have proposed that a person of ordinary skill in the art as of that date is:

A person with an advanced degree in a field such as chemical engineering, food engineering, pharmacology, analytical chemistry, biochemistry, organic chemistry, biology, marine biology, or food chemistry, and at least (i) several years of experience in preparing lipid extracts from biological or natural products, for example in an industrial or research setting and/or (ii) several years of experience in analytical chemistry. A person of ordinary skill in the art may consist of a team of individuals with the foregoing education and experience. The more education one has, for example post-

graduate degrees and/or study, the less industry experience is needed to attain an ordinary level of skill.

I interpreted Beaudoin I and Beaudoin II from the perspective of a person or team who meets this criteria, and carried out the extractions described in this report based on my understanding of Beaudoin I and Beaudoin II's disclosures as viewed from this perspective. I note that based on my education and experience, I met the above criteria as of July 27, 2001.¹

III. EXTRACTIONS

7. I received two blocks of frozen krill identified as *Euphausia pacifica* and *Euphausia superba*, on or about August 13, 2013, and August 16, 2013, respectively. I received a third block of frozen krill, identified as *Euphausia superba*, on September 6, 2013. Upon receipt, each of these lots was stored in a freezer at -30°C until the extraction was performed.

8. I repeated the Beaudoin I (pages 5-6 and Table 19) and Beaudoin II (page 2 and Table 11) acetone extractions. Separate extractions were conducted for the *Euphausia pacifica* sample and for the *Euphausia superba* samples. I used the following procedure:

¹ I understand that Complainants have proposed that a person of ordinary skill in the art is "a person with at least a bachelor's degree (or equivalent) who has studied or worked in the life sciences for at least 5 years and who has concentrated for at least 1 year on natural marine products." As of July 27, 2001, I met this criteria as well.

1. The frozen krill were removed from storage and ground in a blender at 4°C to reduce particle size to < 5 mm.
2. Approximately 300 g of ground krill was placed in a 4 L Erlenmeyer flask and 1800 mL of cold acetone (0°C) was added. The Erlenmeyer flask was placed in an ice water bath at 0°C and swirled for 20 min. The flask was then left to sit in the ice water bath for an additional 100 min, for a total of two hours.
3. The acetone-krill mixture was filtered through an 18 cm diameter Buchner funnel containing filter paper using a partial vacuum created with an aspirator. After filtration, 600 mL of cold acetone (0°C) was added to the Erlenmeyer flask. The flask was then gently swirled and the acetone was used to rinse the krill material remaining on the filter. A partial vacuum was again applied. The filtration was considered complete when filtrate no longer dripped from the funnel.
4. The filtrate was transferred to a 3 L round bottom flask and attached to a rotary evaporator. A partial vacuum was applied using an aspirator and the sample was heated to 38°C in

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