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

RIMFROST AS Petitioner

v.

AKER BIOMARINE ANTARCTIC AS Patent Owner

CASE IPR: IPR2018-01178 and CASE IPR: IPR2018-01179

U.S. Patent No. 9,375,453 B2

Reply Declaration of Dr. Nils Hoem in Support of Patent Owner's Motion to Amend



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I. <u>Introduction</u>

- I, Dr. Nils Hoem, state as follows:
- 1. I make this declaration in support of Patent Owner's Contingent Motion to Amend the Claims (Papers No. 11) in both IPR2018-01178 and IPR2018-01179 ("MTA1178" and "MTA1179") and in Reply to Petitioner's Opposition of the Contingent Motion to Amend the Claims.
- 2. I have reviewed and considered, in the preparation of this report, the documents below in addition to the documents identified in my first declaration (Ex. 2001). In providing this declaration, I have also used the legal standards set forth in my first declaration.

EXHIBIT NO.	EXHIBIT DESCRIPTION
1086	Reply and Opposition Declaration of Dr Stephen J. Tallon
	(IPR2018-01178 & IPR2018-01179)
1121	Declaration by Nils Hoem in Support of Request for Inter Partes
	Reexamination of U.S. Patent No. 8,057,825, Control No.
	95/001,819, executed September 16, 2011.
1122	Japanese Laid Open Publication S63-23819 (Murata).
1124	Itano Refrigerated Food Co., Ltd., Bio & High Technology
1127	Announcement and Natural Astaxanthin & Krill Lecithin, pp. 1-
	/ 11
	16, Exhibit 1124 ("Itano").



EXHIBIT	EXHIBIT DESCRIPTION
NO.	
2024	Transcript of Deposition of Dr. Stephen Tallon, August 29, 2018

A. The Contingent Amended Claims are Supported by an Adequate Written Description

5. I have been informed that the written description must convey clearly to those skilled in the art, that, as of the filing date sought, the applicant was in possession of the invention claimed. The level of detail required to satisfy the written description requirement depends on (i) the nature and scope of the claims and (ii) the complexity and predictability of the relevant technology.

Factors to be taken under consideration include the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, and the predictability of the aspect at issue.

6. As stated in my previous declaration (Hoem Decl., Ex. 2001) at ¶89, the specification provides a written description for producing a krill meal from freshly caught *Euphausia superba* by grinding, cooking and drying the *Euphausia superba* to provide a dried krill meal. I stand by this statement. The specification refers repeatedly to use of krill meal as the source material for extraction. One need look no further than the summary of the invention (Ex. 2012, p. 2-9) and the



Examples confirm that the krill meal is made by steps including cooking, grinding and drying the freshly caught krill. For example, the specification provides the following:

In some embodiments, the present invention provides methods of production of krill oil comprising: a) providing fresh krill; b) treating said fresh krill to denature lipases and phospholipases in said fresh krill to provide a denatured krill product; and c) extracting oil from said denatured krill product. In some embodiments, the denaturation step comprises heating of said fresh krill. In some embodiments, the denaturation step comprises heating said fresh krill after grinding. In some embodiments, the methods further comprise storing said denatured krill product at room temperature or below between the denaturation step and the extraction step. In some embodiments, the enzyme denaturation step is achieved by application of heat. In some embodiments, the extraction step comprises use of supercritical carbon dioxide, with or without use of a polar modifier. In some embodiments, the extraction step is comprises ethanol extraction followed by acetone to precipitation of phospholipids. In some embodiments, the denatured krill product is a meal. In some embodiments, the present invention provides oil produced by the foregoing method.

Ex. 2012, p. 6. The specification further provides working examples, such as the following excerpt from Example 6:

EXAMPLE 6

Fresh krill was pumped from the harvesting trawl directly into an indirect steam cooker, and heated to 90C. Water and a small amount of oil were removed in a screw press before

ethoxyquin (antioxidant) was added and the denatured meal was dried under vacuum at a temperature not exceeding 80C. After 19 months storage in room temperature, a sample of the denatured meal was extracted in two steps with supercritical CO₂ in laboratory scale at a flow rate of 2ml/min at 100C and a pressure of 7500 psi. In the second step 20% ethanol was added to the CO₂. The two fractions collected were combined and analyzed by HPLC using ELS detection.



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