

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RIMFROST AS
Petitioner,

v.

AKER BIOMARINE ANTARCTIC AS
Patent Owner.

Case IPR2018-00295

U.S Patent No. 9,320,765

Patent Owner's Sur-Reply to Petitioner's Reply

Mail Stop Patent Board
Patent Trial and Appeal Board
U.S. Patent and Trademark Office
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I. Introduction

When assessing obviousness, the claimed subject matter must be considered as a whole. Pre-AIA 35 U.S.C. 103(a). The pending claims require specific amounts of each of ether phospholipids (>3%), total phospholipids (30-60%) and triglycerides (20-50%) among other components. Petitioner alleges that these are natural components of krill that could be extracted within predictable ranges by modifying conventional techniques. Petitioner's Reply ("Pet. Reply"), Paper 19 at 2. To arrive at the claimed composition, Petitioner takes the triglyceride and total phospholipid ranges from Fricke and the ether phospholipid range from Catchpole. However, the krill oils described in those references were extracted by very different techniques. *Id.* at 6. Fricke utilized a non-selective Folch extraction which is intended to extract total lipids, including both neutral and polar lipids, from the source material. Ex. 1010 at 0001. Catchpole utilized a two-step supercritical fluid extraction. Ex. 1009 at 0024. In the first step, neat CO₂ is used to selectively extract neutral lipids. *Id.* In the second step, catchpole using CO₂ in combination with ethanol to selectively extract polar lipids. *Id.* As will be shown by the evidence below, the rationale advanced by Petitioner to explain why the ranges for total phospholipids and triglycerides from Fricke can be simply combined with the ether phospholipid range from Catchpole is fatally flawed. Thus, a person having ordinary skill in the art (POSITA): 1) would not combine

the cited to arrive at the claimed krill oil with specific claimed levels of components; and 2) recognize there is no reasonable expectation of success in obtaining a composition with the claimed components.

II. There is no motivation to combine the references

A. The ranges from Fricke and Catchpole are not interchangeable

Petitioner alleges that “[b]ased on the teaching of Catchpole in view of Fricke, it clearly would have been well within the ability of a POSITA to obtain a krill oil composition” with the defined amounts of ether phospholipids, total phospholipids and triglycerides. Pet. Reply at 6, citing Tallon Decl. Ex. 1086 ¶¶49&25-50. In ¶40-46 of his Reply Decl. (Ex. 1086), Dr. Tallon states that Extract 2 of Catchpole must contain a significant proportion of triglycerides and purports to calculate the triglyceride content of Extract 2 of Catchpole by applying the triglyceride and other neutral lipid ranges from Fricke. However, evidence obtained from cross-examination of Dr. Tallon demonstrates that this rationale for combination is fatally flawed and further demonstrates why a POSITA would not be motivated to combine Catchpole and Fricke (or the other cited references).

Example 18 of Catchpole teaches a two-step extraction process. In Step 1, the starting freeze-dried krill material was “extracted continuously with supercritical CO₂” until “no further extract was contained.” Ex. 1009, p. 0024. A

total of 650 g of that extract (Extract 1) was obtained and reported to contain “substantially all neutral lipids” and “no phospholipids.” *Id.* In Step 2, the residual powder, containing the phospholipids and lacking neutral lipids, was then extracted with CO₂ and 11% ethanol to provide Extract 2 which has an alleged ether phospholipid content of 4.8%.

Petitioner argues that Extract 2 must contain triglycerides and that “Patent Owner’s suggestion that the initial extraction in the Example 18 process would have removed all triglycerides lacks foundation and is wrong.” Pet. Reply at 8, citing Tallon Dec. Ex. 1086 ¶¶37,25-46. This is incorrect.

First, Catchpole itself clearly teaches that the “feed material can be processed using pure CO₂ before the co-solvent is introduced to remove much or all of neutral lipids.” Ex. 1009, p. 11, l. 23-24. In a general description of the process, Catchpole further teaches the extractions are “optionally carried out using only CO₂ until all of the compounds soluble in CO₂ only, such as neutral lipids, were extracted.” *Id.*, p. 13, l. 2-22. Thus, Catchpole clearly teaches that the Step 1 extraction can remove all neutral lipids, including triglycerides. This is consistent with Example 18 which indicates that Step 1 was continued until no further extract was obtained.

Second, evidence obtained during cross-examination of Dr. Tallon establishes that when his methodology for calculation of the triglyceride content

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