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Paper 18

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ENZYMOTEC LTD. and ENZYMOTEC USA, INC. Petitioner

v.

NEPTUNE TECHNOLOGIES & BIORESSOURCES, INC. Patent Owner

Case IPR2014-00556 Patent 8,278,351

Before LORA M. GREEN, JACQUELINE WRIGHT BONILLA, and SHERIDAN K. SNEDDEN, *Administrative Patent Judges*.

SNEDDEN, Administrative Patent Judge.

DECISION Institution of *Inter Partes* Review 37 C.F.R. § 42.108



I. INTRODUCTION

Petitioners Enzymotec Ltd. and Enzymotec USA, Inc. (collectively, "Enzymotec") filed a Petition (Paper 1; "Pet.") requesting an *inter partes* review of claims 1–6, 9, 12, 13, 19–29, 32, 35, 36, and 42–46 of U.S. Patent No. 8,278,351 ("the '351 patent"). Neptune Technologies and Bioressources, Inc. ("Neptune") filed a Patent Owner Preliminary Response. Paper 11 ("Prelim. Resp.").

We have jurisdiction under 35 U.S.C. § 314. The standard for instituting an *inter partes* review is set forth in 35 U.S.C. § 314(a), which states:

THRESHOLD.—The Director may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.

Upon consideration of the above-mentioned Petition and Preliminary Response, we conclude that Enzymotec has established that there is a reasonable likelihood that it would prevail with respect to at least one of the challenged claims. We grant the Petition and institute an *inter partes* review as to claims 1–6, 9, 12, 13, 19–29, 32, 35, 36, and 42–46.

A. Related Matters

The '351 patent is also the subject of an *inter partes* review in IPR2014-00003. Aker Biomarine AS ("Aker") is the Petitioner in IPR2014-00003. Enzymotec filed a Motion for Joinder (Paper 4) requesting joinder of the current proceeding with IPR2014-00003. We have granted Enzymotec's Motion for Joinder in an Order decided concurrently with this Decision.



B. The '351 Patent (Ex. 1001)

Phospholipids are made up of two chains of fatty acids attached to a chemical backbone made up of phosphoric acid, glycerol and nitrogenous bases (e.g., choline). Ex. 1001, col. 4, ll. 41–56. Phospholipids having choline as the nitrogenous base are referred to as phosphatidylcholines. *Id*.

The '351 patent relates to certain phospholipids and compositions containing phospholipids. The '351 patent discloses a phospholipid including two fatty acids chains of eicosapentanoic acid ("EPA") and docosahexanoic acid ("DHA") simultaneously. The general formula for the phospholipid is:

wherein X represents a moiety normally found in a phospholipid such as phosphatidylcholine (PC), phosphatidylethanolamine (PE) and phosphatidylinositol (PI). *Id.* at col. 2, l. 46 to col. 3, l. 2 and col. 21, ll. 1–25.

The phospholipids are derived from natural marine or aquatic sources. *Id.* at col. 1, ll. 19–22. Krill is described as the preferred source of the disclosed phospholipids, which includes krill found in the Antarctic Ocean (*Euphasia superba*) and in the Pacific Ocean (*Euphasia pacifica*). *Id.* at col. 15, ll. 8–21. The '351 patent describes the preparation of krill extracts that preferably contain 40% weight per weight (w/w) phospholipid. *Id.* at col. 15, ll. 42–45. Polyunsaturated fatty acids, in particular omega-3 fatty acids, preferably make up at least 15% w/w of the total lipids in the extract. *Id.* at col. 16, ll. 47–51. DHA or EPA may account for at least 32% w/w of the total lipid content of the extract. *Id.*



at col. 16, ll. 51–54

C. Illustrative Claims

Claims 1 and 24 are the only independent claims among the challenged claims and are reproduced below:

1. A krill extract comprising:

a phospholipid of the general formula (I),

wherein R1 and R2, each together with the respective carboxyl groups to which each is attached, each independently represents a docosahexaenoic acid (DHA) or an eicosapentanoic acid (EPA) residue, and X is —CH₂CH₂NH₃, —CH₂CH₂N(CH₃)₃, or

and wherein the extract is suitable for human consumption.

24. A capsule, tablet, solution, syrup, or suspension comprising a krill extract comprising:

a phospholipid of the general formula (I),



wherein R1 and R2, each together with the respective carboxyl groups to which each is attached, each independently represents a docosahexaenoic acid (DHA) or an eicosapentanoic acid (EPA) residue, and X is —CH₂CH₂NH₃, —CH₂CH₂N(CH₃)₃, or

and wherein the extract is suitable for human consumption.

Claims 2–6, 9, 12, 13, and 19–23 depend from claim 1, either directly or indirectly. Claims 25–29, 32, 35, 36, and 42–46 depend from claim 24, either directly or indirectly.

D. The Prior Art and Supporting Evidence

Enzymotec relies on the following prior art:

Beaudoin et al., WO 00/23546 A1, published April 27, 2000 (Ex. 1002) ("Beaudoin I").

Fricke et al., Lipid, Sterol and Fatty Acid Composition of Antarctic Krill (*Euphausia superba* Dana), 19(11) LIPIDS 821–827 (1984) (Ex. 1006) ("Fricke").

Itano Refrigerated Food Co., Ltd., Bio & High Technology Announcement



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