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Paper 104

Entered: March 23, 2015

## UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

AKER BIOMARINE AS and ENZYMOTEC LTD. and ENZYMOTEC USA, INC., Petitioner,

v.

NEPTUNE TECHNOLOGIES AND BIORESSOURCES INC., Patent Owner.

Case IPR2014-00003<sup>1</sup> Patent 8,278,351 B2

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

SNEDDEN, Administrative Patent Judge.

FINAL WRITTEN DECISION 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

<sup>1</sup> Case IPR2014-00556 has been joined with this proceeding.



### I. INTRODUCTION

The parties in the case are Aker Biomarine AS ("Aker") and Enzymotec Ltd. and Enzymotec USA, Inc. ("Enzymotec") (collectively, "Petitioner"), and Neptune Technologies and Bioressources, Inc. ("Patent Owner"). Aker filed a first Petition to institute an *inter partes* review of claims 1–27 (Paper 8; "Pet. I") of Patent No. 8,278,351 B2 (Ex. 1001; "the '351 patent"). We instituted trial as to the challenged claims on the following grounds of unpatentability asserted by Aker:

Reference(s)	Basis	Claims challenged
Beaudoin <sup>2</sup>	§ 102(b)	1, 3–6, 9, 12, 13, 19–24, 26–29, 32, 35, 36, and 42–46
Fricke, <sup>3</sup> Bergelson, <sup>4</sup> Yasawa, <sup>5</sup> Itano, <sup>6</sup> and WHO Bulletin <sup>7</sup>	§ 103	1–6, 9, 12, 13, 19–29, 32, 35, 36, and 42–46

Decision to Institute, 18 (Paper 22 ("Dec. I")).

<sup>&</sup>lt;sup>7</sup> WHO News and Activities, Bulletin of the World Health Organization, 73(4), pp. 547-51 (1995). Ex. 1018.



<sup>&</sup>lt;sup>2</sup> Beaudoin et al., WO 00/23546, published April 27, 2000. Ex. 1002.

<sup>&</sup>lt;sup>3</sup> Fricke et al., Lipid, Sterol and Fatty Acid Composition of Antarctic Krill, 19(11) LIPIDS 821-827 (1984). Ex. 1006.

<sup>&</sup>lt;sup>4</sup> Lipid Biochemical Preparation, LD Bergelson (ed.), Elsevier/North-Holland Biomedical Press (1980). Ex. 1017.

<sup>&</sup>lt;sup>5</sup> Yasawa et al., JP H8-231391, published September 10, 1996. The certified translation, Japanese language document, and translation certificate for Yasawa are provided as Exs. 1015, 1076 and 1077, respectively. We reference Ex. 1015 in this Decision.

<sup>&</sup>lt;sup>6</sup> Itano Refrigerated Food Co., Ltd., Bio & High Technology Announcement and Natural Astaxanthin & Krill Lecithin, 1–16. Ex. 1009.

After institution, Neptune Technologies and Bioressources, Inc. ("Patent Owner"), filed its Patent Owner's Response. Paper 66 ("Resp. I").

Within a month of our Decision to Institute in the first case, Enzymotec filed a second Petition and Motion for Joinder. IPR2014-00556, Paper 1 ("Pet. II"), Paper 4. We then instituted *inter partes* review of the '351 patent in IPR2014-00556 based on the second Petition, and granted Enzymotec's Motion to join IPR2014-00556 with IPR2014-00003. Paper 72 ("Dec. II"). In IPR2014-00556, we instituted trial on the identical alleged grounds of unpatentability previously instituted in IPR2014-00003, and in addition, on the alleged anticipation of claims 2 and 25 over Beaudoin. *Id.* Patent Owner filed its second Patent Owner's Response to address the added ground involving claims 2 and 25. Paper 77 ("Resp. II").

Petitioner filed a Reply, which was responsive to both of the Patent Owner Responses. Paper 84 ("Reply"). Patent Owner did not file a motion to amend claims.

Petitioner relies upon the declarations of Drs. Van Breemen ("Van Breemen" Ex. 1040), Brenna ("Brenna" Ex. 1042) Storrø ("Storrø" Ex. 1044), Budge ("Budge" Ex. 1041); Welch ("Welch" Ex. 1043); Moore ("Moore" Ex. 1044), Lee ("Lee" Ex. 1045), Haugsgjerd ("Haugsgjerd" Ex. 1047, Ex. 1048, and Ex. 1080), and Gundersen ("Gundersen" Ex. 1049 and Ex. 1050).

<sup>&</sup>lt;sup>8</sup> In this paper, we refer to solely: Paper 66, Patent Owner's Response ("Resp. I"); Paper 84, the Reply filed by Aker; and Paper 22, our Decision to Institute in IPR2014-00003. To the extent that there are differences in arguments and issues raised in the joined case, IPR2014-00556, we refer to the second Petition filed by Enzymotec (IPR2014-00556, Paper 1, "Pet. II") and Paper 72, our Decision to Institute in IPR2014-00556.



Patent Owner relies upon the declaration of Dr. Jacek Jaczynski ("Jaczynski Declaration") (Ex. 2059) in support of its Response.

Patent Owner filed a Motion to Exclude certain of Petitioner's evidence. Paper 89. Petitioner filed an Opposition (Paper 95), and Patent Owner filed a Reply. Paper 97.

Oral argument was conducted on October 31, 2014. A transcript is entered as Paper 103 ("Tr.").

This Final Written Decision addresses challenges to the patentability of claims 1–6, 9, 12, 13, 19–29, 32, 35, 36, and 42–46. Petitioner has established by a preponderance of the evidence that claims 1–4, 6, 9, 12, 13, 19–27, 29, 32, 35, 36, and 42–46 of the '351 patent are unpatentable. Petitioner has failed to demonstrate by a preponderance of the evidence that claims 5 and 28 of the '351 patent are unpatentable.

### A. Related Matters

The parties represent that the '351 patent is the subject of patent infringement lawsuits in the U.S. District Court for the District of Delaware: *Neptune Technologies and Bioressources Inc.*, v. Aker Biomarine ASA, et al., No. 12-cv-1252 (filed October 2, 2012) and *Neptune Technologies and Bioressources Inc.*, v. Enzymotec Limited, et al., No. 12-cv-1253 (filed October 2, 2012). Pet. I, 2; Paper 10.

The parties represent that the '351 patent is the subject of an International Trade Commission investigation, entitled *Certain Omega-3 Extracts from Marine or Aquatic Biomass and Products Containing the Same*, Investigation No. 337-TA-877. *Id*.



The parties represent that the '351 patent is the subject of an *Ex Parte* Reexamination, Control No. 90/012,698. *Id*.

Petitioner Aker represents that the '351 patent is a continuation of U.S. Pat. 8,030,348 (the "'348 patent"; Ex. 1069), which is currently subject to an *Inter Partes* Reexamination, Control No. 95/001,774. Pet. I, 2. The '348 patent is also the subject a patent infringement lawsuit filed by Neptune Bioressources & Technologies against Aker Biomarine in the United States District Court of Delaware (1:11-cv-00894-GMS). *Id.* The '351 patent (Ex. 1001)

## 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, 4:41–56. 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



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