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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FRESENIUS KABI USA LLC,
Petitioner,

v.

CUBIST PHARMACEUTICALS LLC,
Patent Owner.

Case IPR2015-01571
Patent 8,058,238 B2

Before BRIAN P. MURPHY, JON B. TORNQUIST, and TINA E. HULSE, *Administrative Patent Judges*.

TORNQUIST, *Administrative Patent Judge*.

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

I. INTRODUCTION

Fresenius Kabi USA LLC ("Petitioner") filed a corrected Petition (Paper 7, "Pet.") requesting institution of *inter partes* review of claims 1–19, 21–44, 48–51, 53, 92–107, 112–146, 151–167, 176, 177, 179, and 183–189 of U.S. Patent No. 8,058,238 B2 (Ex. 1001, "the '238 patent"). On September 15, 2015, we granted the parties' joint motion to limit the Petition to claims 98 and 187. Paper 15, 3. Cubist Pharmaceuticals LLC (f/k/a Cubist Pharmaceuticals, Inc., "Patent Owner") timely filed a Preliminary Response (Paper 18, "Prelim. Resp.") to the limited Petition.

We have jurisdiction under 35 U.S.C. § 314(a), which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." For the reasons given below, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing with respect to claims 98 and 187. Accordingly, pursuant to 35 U.S.C. § 314, we authorize an *inter partes* review to be instituted as to these claims on the ground set forth below.

A. Related Proceedings

The parties indicate that the '238 patent is at issue in: *Cubist Pharms., Inc. v. Hospira, Inc.*, 1:12-cv-00367-GMS (D. Del.); *Cubist Pharms., Inc. v. Agila Specialties Inc. and Mylan Laboratories Limited*, 1:13-cv-01679-GMS (D. Del); *Cubist Pharms., Inc. v. Fresenius-Kabi USA LLC*, 1:14-cv-00914-GMS (D. Del.) and *Cubist Pharmaceuticals, Inc. v. Hospira, Inc.*, 805 F.3d 1112 (Fed. Cir. 2015) (pending request for rehearing). Pet. 3–4; Paper 5, 2; Paper 19, 1. The '238 patent is also at issue

in *inter partes* review proceedings: IPR2015-01566, IPR2015-01570, and IPR2015-01572. Pet. 4; Paper 5, 3.

B. The '238 Patent

The '238 patent, titled "High Purity Lipopeptides," discloses a highly purified form of daptomycin (also known as LY146032), "a lipopeptide antibiotic with potent bactericidal activity against gram-positive bacteria." Ex. 1001, 1:21–24, 58–61. More particularly, the '238 patent is directed to "providing commercially feasible methods to produce high levels of purified lipopeptides," such as daptomycin. *Id.* at 3:50–52.

The '238 patent describes several methods of purifying lipopeptides, and daptomycin in particular, to achieve a highly pure composition. One method involves a size separation technique, where a lipopeptide is converted from a monomer to a micelle (aggregate) and back to a monomer during the purification process, in order to separate the lipopeptide from low molecular weight and high molecular weight impurities. *Id.* at 5:56–6:10. Ultrafiltration is preferred for purifying lipopeptides using this size separation technique. *Id.* at 6:11–13.

C. Illustrative Claims

Dependent claims 98 and 187 are the only claims challenged in this proceeding. Claims 98 and 187, as well as the independent and dependent claims from which these claims depend, are reproduced below:

> 49. A purified daptomycin composition comprising daptomycin of greater than or about 93% purity relative to impurities 1–14 defined by peaks 1–14 shown in FIG. 12, the daptomycin being obtained by a process comprising the step of forming an aggregate comprising daptomycin.

Ex. 1001, 40:34–38.

92. The composition of claim 49, wherein the purity of daptomycin is at least 93%.

93. The composition of claim 92, wherein the daptomycin is obtained by a process comprising:

a) subjecting a daptomycin solution to conditions forming a daptomycin aggregate;
b) separating the daptomycin aggregate from low molecular weight contaminants; and
c) subjecting the daptomycin aggregate to conditions in which the daptomycin aggregate dissociates into daptomycin monomers.

94. The composition of claim 93, wherein the daptomycin aggregate of step b) is separated from the low molecular weight contaminants by a size selection technique.

95. The composition of claim 94, wherein the size selection technique is ultrafiltration or size exclusion chromatography.

96. The composition of claim 95 further comprising separating the daptomycin monomers obtained from step c) from high molecular weight contaminants.

97. The composition of claim 96, wherein the daptomycin monomers are separated from the high molecular weight contaminants by a size selection technique.

98. The composition of claim 97, wherein the size selection technique is ultrafiltration or size exclusion chromatography.

Id. at 43:7–30

183. A purified daptomycin composition of greater than or about 93% purity relative to impurities 1-14 defined by peaks 1-14 shown in FIG. 12, wherein the percent purity is measured by HPLC analysis, and the purified daptomycin composition is obtained from a lipopeptide aggregate comprising daptomycin.

187. The composition of claim 183, wherein the daptomycin composition is at least or about 97% pure.

Id. at 48:54–59, 49:6–7.

D. Prior Art Relied Upon

Petitioner relies upon the following prior art references, as well as the declaration testimony of Dr. Ralph Tarantino (Ex. 1005):

U.S. Patent No. 4,874,843, issued October 17, 1989 (Ex. 1007, "the '843 patent).

Catherine N. Mulligan & Bernard F. Gibbs, *Recovery of Biosurfactants by Ultrafiltration*, 47 J. CHEM. TECH. BIOTECHNOLOGY 23–29 (1990) (Ex. 1013, "Mulligan");

Lin et. al., *General Approach for the Development of High-performance Liquid Chromatography Methods for Biosurfactant Analysis and Purification*, 825 JOURNAL OF CHROMATOGRAPHY A 149–159 (1998) (Exhibit 1015, "Lin II"); and

Jeremy H. Lakey and Marius Ptak, *Fluorescence Indicates a Calcium-Dependent Interaction Between the Lipopeptide Antibiotic LY146032 and Phospholipid Membranes*, BIOCHEMISTRY 27, 4639–4645 (1988) (Exhibit 1033, "Lakey").

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, "[a] claim in an unexpired patent shall be given its broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100(b); *In re Cuozzo Speed Tech., LLC*, 793 F.3d 1268, 1275 (Fed. Cir. 2015). Under this standard, we may take into account definitions or other explanations provided in the written description of applicant's specification. *See In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

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