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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 IPR2015-01572
Patent 8,058,238 B2

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

TORNQUIST, *Administrative Patent Judge*.

DECISION
Denying 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 20, 45–47, 49–52, 54–91, 108–111, 147–150, 168–175, 178, 180–183, and 190–192 of U.S. Patent No. 8,058,238 B2 ("the '238 patent"). On September 15, 2015, we granted the parties' joint motion to limit the Petition to claim 91. 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 not demonstrated a reasonable likelihood of prevailing with respect to claim 91. Accordingly, we do not institute an *inter partes* review.

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, 2–3; Paper 19, 1. The '238 patent is also at issue in *inter partes* review proceedings: IPR2015-01566, IPR2015-01570, and IPR2015-01571. 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, 1:58–61. 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. The '238 patent indicates that ultrafiltration is preferred for purifying lipopeptides using this size separation technique. *Id.* at 6:11–13.

C. Illustrative Claims

Claim 91 depends from claim 85, which in turn depends from independent claim 49. Claims 49, 85, and 91 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, 40:33–37.

> 85. A method for preparing a pharmaceutical composition comprising combining the composition of claim 49 with a pharmaceutically acceptable carrier or excipient.

Id. at 42:54–56.

> 91. The method of claim 85 wherein the composition is daptomycin that is essentially free of each of impurities 1 to 14 defined by peaks 1-14 shown in FIG. 12.

Id. at 43:4–6.

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").

U.S. Patent No. 5,912,226, issued June 15, 1999 (Ex. 1010, "the '226 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").

E. Asserted Ground of Unpatentability

Petitioner contends that claim 91 would have been obvious under 35 U.S.C. § 103 over '843 patent, the '226 patent, Mulligan, Lin II, and Lakey. Pet. 5; Paper 15, 2.

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).

Upon review of Petitioner's and Patent Owner's arguments, as well as the recited prior art references, we conclude that no claim terms require construction for purposes of this Decision. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (noting that only those claim terms that are in dispute and necessary to resolve the controversy need be construed).

B. Obviousness of Claim 91 over the '843 patent, the '226 patent, Mulligan, Lin II, and Lakey

Petitioner asserts that claim 91 would have been obvious over the '843 patent, the '226 patent, Mulligan, Lin II, and Lakey. Pet. 14–31. In support of this argument, Petitioner relies upon the declaration testimony of Dr. Tarantino. Ex. 1005. Patent Owner opposes. Prelim. Resp. 6–11.

1. The '843 Patent

The '843 patent issued October 17, 1989, and is prior art under 35 U.S.C. § 102(b). Pet. 7. The '843 patent is directed to a "new chromatographic process for purifying fermentation products, particularly the antibiotic LY146032 [(daptomycin)], from fermentation broths by use of a non-functional resin in reverse mode." Ex. 1007, 1:5–8. This "reverse method" removes impurities from daptomycin and "improves the final purity

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