

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 IPR2015-01570
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 Petition (Paper 2, “Pet.”) requesting institution of *inter partes* review of claims 3–7, 21–25, 27–33, 35–44, 48–52, 55–57, 61–63, 66, 85, 87–89, 92–109, 113, 115–121, 123–151, 153–159, 161, 162, 164–167, 175–184, 189, and 190 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 claim 98. Paper 12, 3. Cubist Pharmaceuticals, LLC. (f/k/a Cubist Pharmaceuticals, Inc., “Patent Owner”) timely filed a Preliminary Response (Paper 15, “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 claim 98. Accordingly, pursuant to 35 U.S.C. § 314, we authorize an *inter partes* review to be instituted as to claim 98 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 16, 1. The ’238 patent is also at issue

in *inter partes* review proceedings: IPR2015-01566, IPR2015-01571, 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, 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 3:50–54.

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.

In Example 15 of the '238 patent, daptomycin is purified by repeated column chromatography on HP-20 and HP-20ss resin. Ex. 1001, 36:42–45. The resulting product is 93% pure, but contains “visible impurities on HPLC chromatographs and measurable pyrogen.” *Id.* at 36:46–47. The 93% pure daptomycin is then passed through a 10,000 NMW ultrafiltration membrane in monomeric form. *Id.* at 36:50–53. According to the '238 patent, “[t]he resulting product remains 93% pure, but several impurities that had been present at 0.1-0.2% are removed by the ultrafiltration membrane” and “pyrogen content is reduced to undetectable levels.” *Id.* at 36:52–55.

C. Illustrative Claims

Claim 98 depends from claims 49 and 92–97. These claims 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.

D. Asserted Ground of Unpatentability

Petitioner contends that claim 98 of the '238 patent is unpatentable under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 4,874,843, issued October 17, 1989 (Ex. 1007, “the ’843 patent). Pet. 5, 14–19, 23–24. In support of its patentability challenge, Petitioner relies upon the declaration testimony of Dr. Ralph Tarantino (Ex. 1005).

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). Only those terms that are in controversy need be construed, and only to the extent necessary to resolve the controversy. *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

Product-by-Process Limitations

The parties agree that challenged claim 98 is a product-by-process claim. Pet. 14–17; Prelim. Resp. 8–11. The general rule when determining

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.