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Paper No. 7
Date: May 29, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS LLC,
Petitioner,

v.

CUBIST PHARMACEUTICALS LLC,
Patent Owner.

IPR2020-00193
Patent 9,138,456 B2

Before SUSAN L. C. MITCHELL, TINA E. HULSE, and TIMOTHY G. MAJORS, *Administrative Patent Judges*.

MAJORS, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Amneal Pharmaceuticals LLC ("Petitioner"),[1] on November 27, 2019, filed a Petition to institute *inter partes* review of claims 1, 2, and 7–11 of U.S. Patent No. 9,138,456 B2 (Ex. 1001, "the '456 patent"). Paper 2 ("Pet." or "Petition"). Cubist Pharmaceuticals LLC ("Patent Owner")[2] filed a Preliminary Response to the Petition. Paper 6 ("Prelim. Resp.").

Under 35 U.S.C. § 314(a), *inter partes* review may not be instituted unless the Petition "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." Petitioner has not established a reasonable likelihood of prevailing on its assertion that claims 1, 2, and 7–11 are unpatentable based on the grounds advanced here. Thus, for reasons explained below, we do not institute *inter partes* review of claims 1, 2, and 7–11 of the '456 patent.

A. *Related Patents & Proceedings*

The '456 patent issued September 22, 2015, from U.S. Patent Application No. 14/096,346 ("the '346 Application"), filed December 4, 2013. Ex. 1001, (21), (22), (45). The '346 Application is a division of U.S. Patent Application No. 13/511,246, which was filed November 23, 2010 and issued as U.S. Patent No. 8,835,382 B2. *Id.* at (62). The '346 Application

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[1] Petitioner identifies Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals Company GmbH, Amneal Pharmaceuticals of NY LLC, and Amneal Pharmaceuticals Company (India) Private Limited as the real parties-in-interest. Pet. 1.

[2] Patent Owner identifies Cubist Pharmaceuticals LLC, Merck & Co., Inc., and Merck Sharp & Dohme Corp. as the real parties-in-interest. Paper 4, 1.

also claimed priority to U.S. Provisional Application No. 61/263,784, filed November 23, 2009 ("the '784 Application"). *Id.* at (60).

Petitioner identifies the following lawsuits involving the '456 patent: *Cubist Pharmaceuticals LLC v. Amneal Pharmaceuticals, LLC*, No. 3:19-cv-15439, filed July 16, 2019, in the United States District Court for the District of New Jersey; and *Cubist Pharmaceuticals LLC v. Cipla USA, Inc.*, No. 3:19-cv-12920-BRM, filed May 25, 2019, in the United States District Court for the District of New Jersey. Pet. 1–2. Patent Owner states that those lawsuits have been consolidated. Paper 4, 1.

B. *Asserted Grounds of Unpatentability*

Petitioner asserts two grounds of unpatentability in this Petition (Pet. 3–4), which are provided in the table below:

Claims Challenged	35 U.S.C. §	Reference(s)/Basis
1, 2, 7–11	103(a)[3]	The Cubicin® label,[4] Neururkar,[5] Mittal,[6] Sawai[7]
1, 2, 7–11	103(a)	Inman,[8] Neururkar, Mittal, Sawai

[3] The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) ("AIA"), amended 35 U.S.C. §§ 102 and 103. Based on the putative effective filing date of the '456 patent, we refer to the pre-AIA versions of 35 U.S.C. §§ 102 and 103 in this Decision.
[4] Cubicin® label (downloaded December 7, 2018, from https://www.accessdata.fda.gov/drugsatfda_docs/nda/2003/21-572_Cubicin_Prntlbl.pdf) (Ex. 1004, "The Cubicin® label").
[5] Neururkar, US 6,136,783, issued Oct. 24, 2000 (Ex. 1005, "Neururkar").
[6] Mittal, US 2010/0137197 A1, publ. June 3, 2010 (Ex. 1007, "Mittal").
[7] Sawai, US 7,112,565 B2, issued Sept. 26, 2006 (Ex. 1006, "Sawai").
[8] Inman, EP 0 386 951 A2, publ. Sept. 12, 1990 (Ex. 1008, "Inman").

Petitioner also relies on the declaration of Raj Suryanarayanan, Ph.D., among other evidence. Ex. 1003.

C. *The '456 Patent*

According to the '456 patent, the patent relates to "novel powder daptomycin formulations which have improved chemical stability and faster reconstitution times when in the solid state," and exemplary formulations "comprise daptomycin and sucrose." Ex. 1001, Abstr.

The '456 patent explains that "[d]aptomycin is a cyclic lipopeptide antibiotic indicated for the treatment of complicated skin and skin structure infections and bacteremia, including bacteremia with suspected or proven infective endocarditis." *Id.* at 1:26–31 (describing treatment of infections caused by susceptible gram-positive bacteria including methicillin-resistant *Staphylococus aureus* (MRSA)). The '456 patent notes, as background, that daptomycin is "supplied as a lyophilized powder that is reconstituted and compounded as a pharmaceutical composition for parenteral administration." *Id.* at 1:33–37 (identifying "[d]aptomycin for injection (CUBICIN®, Cubist Pharmaceuticals, Inc., Lexington, Mass.), [which] is supplied as a lyophilized powder").

According to the '456 patent, daptomycin "can be derived from the fermentation product of the microorganism *Streptomyces roseosporus* with a feed of n-decanoic acid." *Id.* at 1:47–49. The '456 patent explains, however, that other structurally similar components are also present in the fermentation product. *Id.* at 1:51–2:19 (describing degradation products including anhydro-daptomycin). One measure of chemical stability of

daptomycin in the lyophilized form is described in the '456 patent as the amount of daptomycin present in the reconstituted composition relative to the amount of structurally similar degradation compounds. *Id.* at 2:20–26.

The '456 patent describes "a need for solid daptomycin compositions with improved chemical stability in the solid and/or reconstituted form (i.e., higher total percent daptomycin purity over time), providing advantages of longer shelf life, increased tolerance for more varied storage conditions (e.g., higher temperature or humidity) and increased chemical stability after reconstitution." *Id.* at 2:51–58.

The '456 patent discloses that "[s]olid pharmaceutical daptomycin preparations can be obtained by converting an aqueous solution including daptomycin and a non-reducing sugar (e.g., 15-20% sucrose w/v in the solution) at a pH above the isoelectric point of daptomycin (e.g., a pH of about 3.7 or greater)." *Id.* at 4:33–39. The solid, lyophilized composition can later be reconstituted in a suitable diluent for injection. *Id.* at 3:1–4. Pharmaceutically-acceptable diluents "include sterile Water for Injection (sWFI), 0.9% sterile sodium chloride injection (sSCl), bacteriostatic water for injection (bWFI), and Ringer's solution." *Id.* at 8:16–21.

The '456 patent teaches that the time for reconstituting the solid daptomycin compositions can be "unexpectedly reduced" by increasing the pH of the aqueous solution (preferably to a pH of about 6.5–7.5, most preferably about 7.0) prior to lyophilizing the solution. *Id.* at 3:5–10. The '456 patent also teaches that "[t]he molar ratio of the lipopeptide to the total amount of glycine and/or one or more sugars can be selected to obtain solid compositions with more rapid reconstitution rates in aqueous solvents" with

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