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Paper 25
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAR PHARMACEUTICAL, INC. and AMNEAL PHARMACEUTICALS, LLC,
Petitioner,

v.

JAZZ PHARMACEUTICALS, INC.,
Patent Owner.

Case IPR2015-00547
Patent 7,765,107 B2

Before JACQUELINE WRIGHT BONILLA, SUSAN L. C. MITCHELL, and BRIAN P. MURPHY, *Administrative Patent Judges.*

BONILLA, *Administrative Patent Judge*.

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

I. INTRODUCTION

Amneal Pharmaceuticals, LLC, and Par Pharmaceutical, Inc. ("Par Inc.") (together, "Petitioner"), filed a Petition requesting an *inter partes* review of claims 1–6 (all claims) of U.S. Patent No. 7,765,107 B2 (Ex. 1001, "the '107 patent"). Paper 4 ("Petition" or "Pet."). Jazz Pharmaceuticals, Inc. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 10 ("Prelim. Resp."). We have statutory authority 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."

Petitioner challenges claims 1–6 of the '107 patent as unpatentable under 35 U.S.C. § 103(a). Pet. 9. Based on the information presented in the Petition and Preliminary Response, we are persuaded there is a reasonable likelihood Petitioner would prevail with respect to the claims challenged in the Petition. Thus, we institute *inter partes* review of claims 1–6 of the '107 patent.

A. Related Proceedings

The parties identify the following as related district court proceedings regarding the '107 patent: *Jazz Pharms, Inc. v. Par Pharm., Inc.*, 2:13-cv-07884 (D.N.J. Dec. 27, 2013); *Jazz Pharms, Inc. v. Amneal Pharms., LLC*, 2:13-cv-00391 (consolidated) (D.N.J. Jan. 18, 2013); *Jazz Pharms, Inc. v. Roxane Labs., Inc.*, 2:10-cv-06108 (consolidated) (D.N.J. Nov. 22, 2010); *Jazz Pharms., Inc. v. Ranbaxy Labs. Ltd.*, 2:14-cv-4467 (D.N.J. July 15, 2014); *Jazz Pharms., Inc. v. Watson Labs., Inc.*, 2:14-cv-7757 (D.N.J). Pet. 59–59; Paper 8, 1–2.

The parties also identify the following as Petitions for *inter partes* review of patents related to the '107 patent: IPR2015-00545 (Patent 8,589,182); IPR2015-00546 (Patent 7,765,106); IPR2015-00548 (Patent 7,895,059); IPR2015-00551 (Patent 8,457,988); and IPR2015-00554 (Patent 7,668,730). Pet. 59; Paper 8, 2. The parties also identify the following as Petitions for covered business method patent review ("CBM") regarding the '106 patent and related patents: CBM2014-00149 (Patent 7,895,059); CBM2014-00150 (Patent 8,457,988); CBM2014-00151 (Patent 7,668,730, "the '730 patent"); CBM2014-00153 (Patent 8,589,182); CBM2014-00161 (Patent 7,765,106); and CBM2014-00175 (the '107 patent). Pet. 59; Paper 8, 2.

We note that the Board has denied institution in all six of the above-mentioned CBM cases. In addition, a different petitioner has filed a Petition for *inter partes* review of related Patent 7,895,059 in IPR2015-01018.

Patent Owner identifies the following pending U.S. patent applications claiming priority benefit from U.S. Patent Application No. 10/322,348—the application from which the '107 patent issued, U.S. Patent Application No. 14/196,603, filed March 4, 2014; U.S. Patent Application No. 14/219,904, filed March 19, 2014; and U.S. Patent Application No. 14/219,941, filed March 19, 2014. Paper 8, 3.

B. Proposed Grounds of Unpatentability

Petitioner advances two grounds of unpatentability under 35 U.S.C. § 103(a) in relation to all challenged claims in the '107 patent (Pet. 9–10):

Reference[s]	Statutory Basis	Challenged Claims
Advisory Committee Art (Exs. 1003–1006), including FDA Advisory Committee Transcript and Slides (Ex. 1003),[1] Preclinical Safety Review (Ex. 1004),[2] Briefing Booklet (Ex. 1005),[3] and Xyrem Video and Transcript (Ex. 1006)[4]	§ 103(a)	1–6
Talk About Sleep (Ex.1033)[5] in view of Honigfeld (Ex. 1034),[6] Elsayed (Ex. 1035),[7] and Lilly (Ex. 1010)[8]	§ 103(a)	1–6

In addition, Petitioner supports its challenges with a Declaration by Robert J. Valuck, Ph.D., R.Ph. ("Valuck Decl.") (Ex. 1007). Pet. 9.

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[1] FDA Peripheral & Central Nervous System Drugs Advisory Committee, Transcript and Slides ("Advisory Committee Transcript and Slides") (July 13, 2001) (Ex. 1003).

[2] FDA Peripheral & Central Nervous System Drugs Advisory Committee, Briefing Information, Division of Neuropharmacological Drug Products Preliminary Clinical Safety Review of NDA 21-196 ("Preclinical Safety Review") (July 13, 2001) (Ex. 1004).

[3] FDA Peripheral & Central Nervous System Drugs Advisory Committee, Briefing Information, Briefing Booklet ("Briefing Booklet") (July 13, 2001) (Ex. 1005).

[4] FDA Peripheral & Central Nervous System Drugs Advisory Committee, Briefing Information, Xyrem Prescription and Distribution Process Video and Transcript ("Xyrem Video and Transcript") (July 13, 2001) (Ex. 1006)

[5] Talk About Sleep, "An Interview with Orphan Medical about Xyrem®," available at http://www.talkaboutsleep.com/an-interview-with-orphan-medical-about-xyrem/ ("Talk About Sleep") (Feb. 12, 2001) (Ex. 1033).

[6] Honigfeld et al., "Reducing Clozapine-Related Morbidity and Mortality: 5 Years of Experience with the Clozaril National Registry," J. Clin. Psych. 59 (suppl. 3): 3-7 (1998) ("Honigfeld") (Ex. 1034).

[7] Elsayed et al., U.S. Patent No. 6,045,501, filed Aug. 28, 1998, issued Apr. 4, 2000) ("Elsayed") (Ex. 1035).

[8] Lilly et al., U.S. Patent Appl. Pub. No. 2004/0176985, filed Mar. 18, 2004, published Sept. 9, 2004 ("Lilly") (Ex. 1010).

C. The '107 Patent

The '107 patent, titled "Sensitive Drug Distribution System and Method," issued July 27, 2010, from an application of a divisional application filed December 17, 2002. Ex. 1001. The '107 patent is directed to a method for controlling access to a sensitive prescription drug prone to potential abuse or diversion, by utilizing a central pharmacy and database to track all prescriptions for the sensitive drug. *Id.* at Abstract, 1:44–50. Information regarding all physicians authorized to prescribe the drug and all patients receiving the drug is maintained in the database. *Id.* Abuses are identified by monitoring the database for prescription patterns by physicians and prescriptions obtained by patients. *Id.* at Abstract, 1:48–50.

Figures 2A, 2B, and 2C comprise flow charts representing "an initial prescription order entry process for a sensitive drug." *Id.* at 4:13–14. In overview, a physician submits prescriber, patient, and prescription information for the sensitive drug to a pharmacy team, which enters the information into a computer database. *Id.* at 4:13–31, Fig. 2A (steps 202–210). The pharmacy team then engages in "intake reimbursement" (Fig. 2A), which includes verification of insurance coverage or the patient's willingness and ability to pay for the prescription drug. *Id.* at 4:32–34. Steps 226–230, 234–238 of Figure 2A are reproduced below:

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