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Paper 10
Entered: March 25, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

JAZZ PHARMACEUTICALS, INC.,
Patent Owner.

Case IPR2015-01903
Patent 8,731,963 B1

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

MURPHY, *Administrative Patent Judge*.

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

I. INTRODUCTION

Amneal Pharmaceuticals, LLC ("Amneal") and Par Pharmaceutical, Inc. ("Par Inc.") (together "Petitioner"), filed a Petition requesting an *inter partes* review of claims 1–28 (all claims) of U.S. Patent No. 8,731,963 B1 (Ex. 1001, "the '963 patent"). Paper 1 ("Petition" or "Pet."). Jazz Pharmaceuticals, Inc. ("Patent Owner") did not file a Preliminary Response to the Petition. 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 1–28 of the '963 patent as unpatentable under 35 U.S.C. § 103(a). Pet. 9–10. Based on the information presented in the Petition, we are persuaded there is a reasonable likelihood Petitioner would prevail with respect to claims 24, 26, and 27 of the '963 patent. Therefore, we institute *inter partes* review of the '963 patent, limited to the single ground of obviousness asserted against claims 24, 26, and 27.

A. Related Proceedings

Petitioner identifies the following as related district court proceedings regarding the '963 patent: *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. Wockhardt Bio AG.*, Inc., 2:14-cv-05619 (D.N.J. July 17, 2015); and *Jazz Pharms., Inc. v. Lupin Ltd.*, 2:2015-cv-6548 (D.N.J. Sept. 1, 2015). Pet. 59.

Petitioner identifies the following as petitions for *inter partes* review of patents related to the '963 patent: U.S. Patent Nos. 7,668,730 (IPR2015-00554); 7,765,106 (IPR2015-00546); 7,765,107 (IPR2015-00547); 7,895,059 (IPR2015-00548); 8,457,988 (IPR2015-00551); and 8,589,182 (IPR2015-00545). *Id.* The Board has instituted *inter partes* reviews in all six of the aforementioned proceedings.

B. Proposed Grounds of Unpatentability

Petitioner advances two grounds of unpatentability under 35 U.S.C. § 103(a) in relation to the challenged claims in the '963 patent:

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)	1–7 and 9–23

[1] FDA Peripheral & Central Nervous System Drugs Advisory Committee, Transcript and Slides ("Advisory Committee Transcript and Slides"). Ex. 1003. Petitioner refers to Exhibits 1003–1006 collectively as the "Advisory Committee Art" or "ACA."

[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"). Ex. 1004.

[3] Peripheral & Central Nervous System Drugs Advisory Committee, Briefing Booklet, Orphan Medical, Inc. Presentation, Food and Drug Administration (June 2001), ("Briefing Booklet"). 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"). Ex. 1006.

Reference[s]	Statutory Basis	Challenged Claims
Advisory Committee Art (Exs. 1003–1006) and Korfhage (Ex. 1037)[5]	§ 103(a)	8 and 24–28

Petitioner supports its challenge with a Declaration by Robert J. Valuck, Ph.D., R.Ph. ("Valuck Decl.") (Ex. 1007).

C. The '963 Patent

The '963 patent, titled "Sensitive Drug Distribution System and Method," issued May 20, 2014, from an application filed August 22, 2012. Ex. 1001.[6] The '963 patent is directed to a computer-implemented system for controlling access to an abuse-prone prescription drug by using a central pharmacy and computer database to track all prescriptions, patients, and prescribers. *Id.* at Abstract, 1:48–52. 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, 1:52–54.

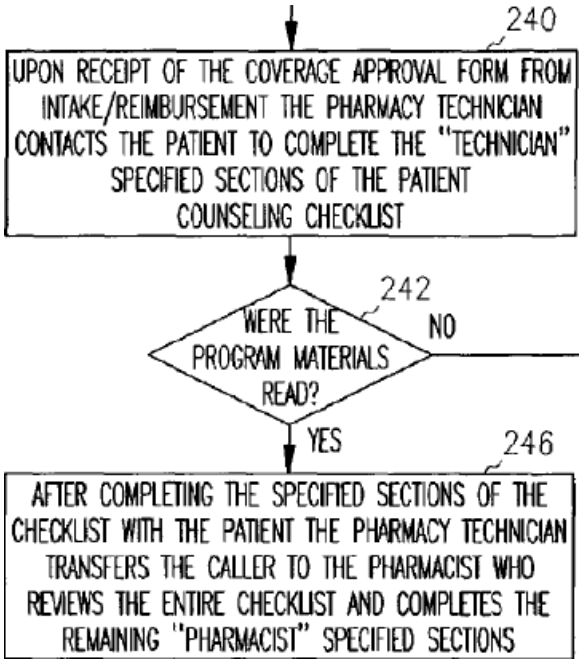
Figures 2A, 2B, and 2C comprise flow charts representing "an initial prescription order entry process for a sensitive drug." *Id.* at 4:17–18. In overview, a physician submits prescriber, patient, and prescription information for the sensitive drug to a pharmacy team, which enters the information into a computer database. *Id.* at 4:17–35, Fig. 2A (steps 202–

[5] Korfhage, Robert R., *Information Storage and Retrieval*, Wiley Computer Publishing (1997). Ex. 1037.

[6] The '963 patent issued from a series of continuation applications, the earliest of which is U.S. Patent Application No. 10/322,348 ("the '348 application") filed December 17, 2002. Ex. 1001.

210). Figure 9 is an example of the information to be provided by the physician in a prescription and enrollment form. *Id.* at 8:6–9. The pharmacy team then engages in "intake reimbursement," which includes verification of insurance coverage or the patient's willingness and ability to pay for the prescription drug. *Id.* at 4:36–38, Fig. 2A.

The "pharmacy" workflow also includes verification of the prescribing physician's credentials. *Id.* at 5:19–36, Fig. 2B (steps 274–280). Filling the prescription includes confirming the patient has read educational materials regarding the sensitive drug, confirming the patient's receipt of the sensitive drug, and daily cycle counting and inventory reconciliation. *Id.* at 5:37–6:7. Steps 240, 242, 246, and 258–266 of Figure 2C, are reproduced below.



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