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Paper 20
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

JAZZ PHARMACEUTICALS, INC.,
Patent Owner.

Case IPR2015-00551 (Patent 8,457,988 B1)
Case IPR2015-00554 (Patent 7,668,730 B2)[1]

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

[1] This Decision addresses common issues raised in both cases. The patents at issue in Case IPR2015-00551 and Case IPR2015-00554 are related, and the arguments by Petitioners and Patent Owner are largely the same in each case. Therefore, we issue one Decision to be entered in each case. The parties are not authorized to use this caption without prior authorization of the Board.

I. INTRODUCTION

Par Pharmaceutical, Inc. ("Par Inc."), and Amneal Pharmaceuticals, LLC ("Amneal") (together, "Petitioner") filed a Petition requesting an *inter partes* review of claims 1–11 (all claims) of U.S. Patent No. 7,668,730 B2 (Ex. 1001, "the '730 patent"). Paper 1 ("Petition" or "Pet."). Jazz Pharmaceuticals, Inc. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 10 ("Prelim. Resp."). Petitioner also filed a Petition requesting an *inter partes* review of claims 1–15 (all claims) of U.S. Patent No. 8,457,988 B1 ("the '988 patent"). IPR2015-00551, Paper 1 ("the '551 Petition" or "'551 Pet."). Patent Owner filed a Preliminary Response to the Petition. IPR2015-00551, Paper 9 ("'551 Prelim. Resp."). Because the challenged claims in these two cases are very similar, with the exception of preambles, we consider the two cases together in this Decision. For clarity and expediency, we treat IPR2015-00554 as representative of both cases. 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 1–11 of the '730 patent as unpatentable under 35 U.S.C. § 103(a). Pet. 11–12.[2] 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

[2] As noted above, for clarity and expediency, we treat IPR2015-00554 as representative of both cases. All citations are to IPR2015-00554 unless otherwise noted. Petitioner also challenges claims 1–15 of the '988 patent as unpatentable under 35 U.S.C. § 103(a). '551 Pet. 2.

challenged in the Petition and the '551 Petition. Therefore, we institute *inter partes* review of claims 1–11 of the '730 patent and claims 1–15 of the '988 patent.

A. Related Proceedings

The parties identify the following as related district court proceedings regarding the '730 patent: *Jazz Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*, 2:10-cv-6108 (D.N.J.); *Jazz Pharmaceuticals, Inc. v. Amneal Pharmaceuticals, LLC*, 2:13-cv-391(consolidated) (D.N.J.); *Jazz Pharmaceuticals, Inc. v. Ranbaxy Laboratories Ltd.*, 2:14-cv-4467 (D.N.J.); and *Jazz Pharmaceuticals, Inc. v. Watson Laboratories, Inc.*, 2:14-cv-7757 (D.N.J). Pet. 58; Paper 8, 1. Patent Owner identifies two other district court proceedings concerning patents related to the '730 patent: *Jazz Pharmaceuticals, Inc. v. Amneal Pharmaceuticals, LLC*, 2:14-cv-3235 (D.N.J.) and *Jazz Pharmaceuticals, Inc. v. Par Pharmaceutical, Inc.*, 2:14-cv-5139 (D.N.J.). Paper 8, 2.

The parties identify the following as petitions for *inter partes* review of patents related to the '730 patent: IPR2015-00545 (Patent 8,589,182); IPR2015-00546 (Patent 7,765,106); IPR2015-00547 (Patent 7,765,107); IPR2015-00548 (Patent 7,895,059); and IPR2015-00551 (Patent 8,457,988. Pet. 58–59; Paper 8, 2. The parties also identify the following as petitions for covered business method patent review regarding the '730 patent and related patents: CBM2014-00149 (Patent 7,895,059); CBM2014-00150 (Patent 8,457,988); CBM2014-00151 (the '730 patent); CBM2014-00153 (Patent 8,589,182); CBM2014-00161 (Patent 7,765,106); and CBM2014-00175 (Patent 7,765,107). Pet. 58; Paper 8, 2–3.

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 U.S. Patent No. 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 '730 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 '730 patent and the '988 patent (IPR2015-00551): [3]

[3] Petitioner advances additional grounds of unpatentability for obviousness of claims 2 and 10 of the '988 patent, addressed separately below in Section II. G.

Reference[s]	Statutory Basis	Challenged Claims
Advisory Committee Art (Exs. 1003–1006), including FDA Advisory Committee Transcript and Slides (Ex. 1003),[4] Preclinical Safety Review (Ex. 1004),[5] Briefing Booklet (Ex. 1005),[6] and Xyrem Video and Transcript (Ex. 1006)[7]	§ 103(a)	1–11 of the '730 patent
Talk About Sleep (Ex.1033)[8] in view of Honigfeld (Ex. 1034),[9] Elsayed (Ex. 1035),[10] and Lilly (Ex. 1010)[11]	§ 103(a)	Same as above

[4] FDA Peripheral & Central Nervous System Drugs Advisory Committee, Transcript and Slides ("Advisory Committee Transcript and Slides") (July 13, 2001) (Ex. 1003).
[5] 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).
[6] FDA Peripheral & Central Nervous System Drugs Advisory Committee, Briefing Information, Briefing Booklet ("Briefing Booklet") (July 13, 2001) (Ex. 1005).
[7] 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).
[8] 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).
[9] 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).
[10] Elsayed et al., U.S. Patent No. 6,045,501, filed Aug. 28, 1998, issued Apr. 4, 2000 ("Elsayed") (Ex. 1035).
[11] Lilly et al., U.S. Patent Appl. Pub. No. 2004/0176985, filed Mar. 18, 2004, published Sept. 9, 2004 ("Lilly") (Ex. 1010).

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