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Paper 70
Entered: July 27, 2016

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

Before JACQUELINE WRIGHT BONILLA, BRIAN P. MURPHY, and JON B. TORNQUIST, *Administrative Patent Judges.*

MURPHY, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

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[1] This Final Written Decision addresses common issues raised in both cases. The patents at issue in IPR2015-00551 and IPR2015-00554 are related, and the arguments by Petitioner and Patent Owner are largely the same in each case. Therefore, we issue one Final Written 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"). IPR2015-00554, Paper 1 ("Petition" or "Pet."). [2] Jazz Pharmaceuticals, Inc. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 10.[3] As authorized (Paper 11), Petitioner filed a response directed solely to real party in interest issues raised in the Preliminary Response (Paper 13), and Patent Owner filed a reply to that paper (Papers 17/18). Upon considering those submissions, we instituted *inter partes* review of claims 1–11 of the '730 patent and claims 1–15 of the '988 patent. Paper 20 ("Dec. on Inst.").

After institution, Patent Owner filed a Response (Paper 39, "PO Resp."), and Petitioner filed a Reply (Paper 46, "Reply"). Petitioner supports its challenge with a Declaration by Robert J. Valuck, Ph.D., R.Ph. ("Valuck Declaration") (Ex. 1007) and the Affidavit of Christopher Butler ("Butler First Affidavit") (Ex. 1028). Pet. 11, 17–18. Petitioner also presents another Affidavit of Mr. Butler (Ex. 1058, "Butler Third Affidavit") with its Reply. Reply 7.

With its Response, Patent Owner presents the Declarations of Joseph T. DiPiro, Pharm.D. (Ex. 2046, "DiPiro Declaration"), Bryan Bergeron,

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[2] For clarity and expediency, we treat IPR2015-00554 as representative of both cases. All citations are to IPR2015-00554 unless otherwise noted.
[3] 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 that Petition. IPR2015-00551, Paper 9.

MD, FACMI (Ex. 2047, "Bergeron Declaration"), Craig F. Kirkwood, Pharm.D. (Ex. 2053, "Kirkwood Declaration"), David A. Holdford, Ph.D., FAPhA (Ex. 2056, "Holdford Declaration"), and Lyndsey J. Przybylski (Ex. 2057, "Przybylski Declaration"). PO Resp. 18–22, 27–36, 39–49, 53–57. Patent Owner also presents a responsive Affidavit of Christopher Butler dated November 4, 2015 (Ex. 2052, "Butler Second Affidavit"). PO Resp. 8.

Petitioner filed a Motion to Exclude seeking to exclude certain evidence (Paper 54), along with a Motion to Allow Late Filing of Evidence Objections (Paper 57). Patent Owner filed an Opposition to Petitioner's Motion to Exclude (Paper 61) and an Opposition to Petitioner's Motion to Allow Late Filing of Evidence Objections (Paper 59). Petitioner filed a Reply to Patent Owner's Opposition to the Motion to Exclude (Paper 63). In addition, Patent Owner filed a Notice Regarding New Arguments and Evidence in Petitioner's Reply (Paper 50), to which Petitioner filed a Response (Paper 51).

A combined oral hearing in Cases IPR2015-00545, IPR2015-00546, IPR2015-00547, IPR2015-00548, IPR2015-00551, and IPR2015-00554 was held on April 19, 2016; a transcript of the hearing is included in the record. (Paper 67, "Tr.").

We have jurisdiction under 35 U.S.C. § 6(c). We issue this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons that follow, we determine Petitioner has shown by a preponderance of the evidence that claims 1–11 of the '730 patent and claims 1–15 of the '988 patent are unpatentable. We also dismiss Petitioner's Motions to Allow Late Filing of Objections and Motions to

Exclude as moot.

A. Ground of Unpatentability at Issue

Petitioner contends that claims 1–11 of the '730 patent and claims 1, 3–9, and 11–15 of the '988 patent are unpatentable under 35 U.S.C. § 103 as obvious over Advisory Committee Art (Exs. 1003–1006, collectively called "the ACA"), including the Food and Drug Administration ("FDA") Advisory Committee Transcript and Slides (Ex. 1003),[4] FDA Preliminary Clinical Safety Review (Ex. 1004),[5] Briefing Booklet (Ex. 1005),[6] and Xyrem Video and Transcript (Ex. 1006).[7] Pet. 1, 9–33, 56–58. Petitioner further contends that claims 2 and 10 of the '988 patent are unpatentable under 35 U.S.C. § 103 as obvious over the Advisory Committee Art in view of Korfhage.[8]

B. Related Proceedings

The parties identify the following as related district court proceedings:

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[4] FDA Peripheral & Central Nervous System Drugs Advisory Committee, Transcript and Slides (June 6, 2001) ("Advisory Committee Transcript and Slides") (Ex. 1003).

[5] Ranjit B. Mani, FDA Peripheral & Central Nervous System Drugs Advisory Committee, Division of Neuropharmacological Drug Products, Preliminary Clinical Safety Review of NDA 21-196 (May 3, 2001) ("Preliminary Clinical Safety Review") (Ex. 1004).

[6] Xyrem® (sodium oxybate) oral solution NDA #21-196: Briefing Booklet for the FDA Peripheral & Central Nervous System Drugs Advisory Committee (May 3, 2001) ("Briefing Booklet") (Ex. 1005).

[7] FDA Peripheral & Central Nervous System Drugs Advisory Committee, Briefing Information, Xyrem Prescription and Distribution Process Video and Transcript (Feb. 2, 2001) ("Xyrem Video and Transcript") (Ex. 1006)

[8] Korfhage, Information Storage and Retrieval (John Wiley & Sons, Inc. 1997) ("Korfhage") (IPR2015-00551, Ex. 1037).

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: *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 cases as involving petitions for *inter partes* review of patents related to the '730 and '988 patents: IPR2015-00545 (Patent 8,589,182); IPR2015-00546 (Patent 7,765,106); IPR2015-00547 (Patent 7,765,107); and IPR2015-00548 (Patent 7,895,059). Pet. 58–59; Paper 8, 2. The parties also identify the following cases as involving petitions for covered business method patent review regarding the '730, '988 and related patents: CBM2014-00149 (Patent 7,895,059); CBM2014-00150 (the '988 patent); 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. The Board has denied institution in all six of the above-mentioned CBM cases.

In addition, a different Petitioner, Wockhardt Bio AG ("Petitioner Wockhardt"), filed petitions for *inter partes* review of the '730 and '988 patents in IPR2015-01818 and IPR2015-01814, respectively, as well as four additional petitions challenging claims in the other patents at issue in the related *inter partes* review proceedings noted above. Petitioner Wockhardt also filed Motions for Joinder in all six cases in relation to the corresponding

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