

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 IPR2015-00545
Patent 8,589,182 B1

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

I. INTRODUCTION

Amneal Pharmaceuticals, LLC (“Amneal”) and Par Pharmaceutical, Inc. (“Par Inc.”) (together, “Petitioner”) filed a Petition requesting an *inter partes* review of claims 1–26 (all claims) of U.S. Patent No. 8,589,182 B1 (Ex. 1001, “the ’182 patent”). Paper 4 (“Petition” or “Pet.”). Jazz Pharmaceuticals, Inc. (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 10. As authorized (Paper 11), Petitioner filed a response directed solely to real party in interest issues raised in the Preliminary Response (Paper 12), and Patent Owner filed a reply to that paper (Papers 17/18). Upon considering those submissions, we instituted *inter partes* review of claims 1–26 of the ’182 patent. Paper 25 (“Dec. on Inst.”).

After institution, Patent Owner filed a Response (Paper 46, “PO Resp.”), and Petitioner filed a Reply (Paper 50, “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. 9, 15. 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, 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. 17–22, 27–29. Patent Owner also presents a responsive Affidavit of Christopher Butler dated November 4, 2015 (Ex. 2052, “Butler Second Affidavit”). PO Resp. 7–8.

Petitioner filed a Motion to Exclude seeking to exclude certain evidence (Paper 56), along with a Motion to Allow Late Filing of Evidence Objections (Paper 58). Patent Owner filed an Opposition to Petitioner's Motion to Exclude (Paper 63) and an Opposition to Petitioner's Motion to Allow Late Filing of Evidence Objections (Paper 61). Petitioner filed a Reply to Patent Owner's Opposition to the Motion to Exclude (Paper 64). In addition, Patent Owner filed a Notice Regarding New Arguments and Evidence in Petitioner's Reply (Paper 52), to which Petitioner filed a Response (Paper 53).

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 68, "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 1–26 of the '182 patent are unpatentable. Petitioner's Motion to Allow Late Filing of Evidence Objections and Motion to Exclude are dismissed as moot.

A. Ground of Unpatentability at Issue

Petitioner contends that claims 1–26 of the '182 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),¹ FDA Preliminary Clinical Safety Review (Ex. 1004),² Briefing Booklet (Ex. 1005),³ and Xyrem Video and Transcript (Ex. 1006).⁴ Pet. 1, 9–37, 56–58.

B. Related Proceedings

The parties identify the following as related district court proceedings regarding the '182 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. Par Pharmaceutical, Inc.*, 2:13-cv-07884 (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. 59; Paper 7, 1–2. Patent Owner identifies two other district court proceedings concerning patents related to the '182 patent: *Jazz Pharmaceuticals, Inc. v. Amneal Pharmaceuticals, LLC*, 2:14-cv-3235

¹ FDA Peripheral & Central Nervous System Drugs Advisory Committee, Transcript and Slides (June 6, 2001) (“Advisory Committee Transcript and Slides”) (Ex. 1003).

² 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).

³ 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).

⁴ FDA Peripheral & Central Nervous System Drugs Advisory Committee, Briefing Information, Xyrem Prescription and Distribution Process Video and Transcript (February 2, 2001) (“Xyrem Video and Transcript”) (Ex. 1006).

IPR2015-00545
Patent 8,589,182 B1

(D.N.J.) and *Jazz Pharmaceuticals, Inc. v. Par Pharmaceutical, Inc.*, 2:14-cv-5139 (D.N.J.). Paper 7, 2.

The parties identify the following as Petitions for *inter partes* review of patents related to the '182 patent: IPR2015-00546 (Patent 7,765,106); IPR2015-00547 (Patent 7,765,107); IPR2015-00548 (Patent 7,895,059); IPR2015-00551 (Patent 8,457,988); and IPR2015-00554 (Patent 7,668,730). Pet. 59; Paper 7, 2. The parties also identify the following as Petitions for covered business method patent review regarding the '182 patent and related patents: CBM2014-00149 (Patent 7,895,059); CBM2014-00150 (Patent 8,457,988); CBM2014-00151 (Patent 7,668,730); CBM2014-00153 (the '182 patent); CBM2014-00161 (Patent 7,765,106); and CBM2014-00175 (Patent 7,765,107). Pet. 59; Paper 7, 2. 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 a Petition for *inter partes* review of the '182 patent in IPR2015-01813, as well as five 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 earlier filed Petitions. We originally instituted review in those cases and granted Petitioner Wockhardt’s Joinder Motions. *See, e.g.*, Paper 44 (granting institution and Petitioner Wockhardt’s Motion for Joinder in IPR2015-01813, in relation to the '182 patent). After the oral hearing took place, however, upon the parties’ joint request (Paper 65), we ordered the termination of all six proceedings as to Petitioner Wockhardt, and granted the parties’ joint request to treat the

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.