

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

AMNEAL PHARMACEUTICALS LLC, PAR PHARMACEUTICAL,  
INC., and WOCKHARDT BIO AG,  
Petitioners,

v.

JAZZ PHARMACEUTICALS, INC.  
Patent Owner.

---

IPR2015-00547<sup>1</sup>  
Patent 7,765,107

---

**AMNEAL PHARMACEUTICALS LLC and  
PAR PHARMACEUTICAL, INC.'S EXHIBIT LIST**

***Mail Stop "PATENT BOARD"***  
Patent Trial and Appeal Board  
U.S. Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450

---

<sup>1</sup> Case IPR2015-01820 has been joined with this proceeding.

<i>Exhibit #</i>	<i>Description</i>
<b>1001</b>	Reardan <i>et al.</i> , U.S. Patent No. 7,765,107 (filed Apr. 1, 2005; issued Jul. 27, 2010)
<b>1002</b>	File History for U.S. Patent No. 7,765,107 (filed Apr. 1, 2005; issued Jul. 27, 2010)
<b>1003</b>	FDA Peripheral & Central Nervous System Drugs Advisory Committee, Transcript and Slides (“ <b>Advisory Committee Transcript and Slides</b> ”) (July 13, 2001)
<b>1004</b>	FDA Peripheral & Central Nervous System Drugs Advisory Committee, Briefing Information, Division of Neuropharmacological Drug Products Preliminary Clinical Safety Review of NDA 21-196 (“ <b>Preclinical Safety Review</b> ”) (July 13, 2001)
<b>1005</b>	FDA Peripheral & Central Nervous System Drugs Advisory Committee, Briefing Information, Briefing Booklet (“ <b>Briefing Booklet</b> ”) (July 13, 2001)
<b>1006</b>	FDA Peripheral & Central Nervous System Drugs Advisory Committee, Briefing Information, Xyrem Prescription and Distribution Process Video and Transcript (“ <b>Xyrem Video and Transcript</b> ”) (July 13, 2001)
<b>1007</b>	Declaration of Dr. Robert J. Valcuk, Ph.D., R.Ph.
<b>1008</b>	<i>Curriculum Vitae</i> of Dr. Robert J. Valuck, Ph.D., R.Ph.
<b>1009</b>	Shulman, S., “The Broader Message of Accutane,” <i>Am. J. of Public Health</i> , 79:1565-1568 (1989)
<b>1010</b>	Lilly <i>et al.</i> , U.S. Patent Appl. Pub. No. 2004/0176985 (filed Mar. 18, 2004; published Sep. 9, 2004) (“ <b>Lilly</b> ”)

<i>Exhibit #</i>	<i>Description</i>
<b>1011</b>	Honigfeld, G., "Effects of the Clozapine National Registry System on Incidence of Deaths Related to Agranulocytosis," <i>Psychiatric Services</i> , 47:52-56 (1996)
<b>1012</b>	Burleson, K., "Review of computer applications in institutional pharmacy—1975-1981," <i>Am. J. Hosp. Pharm.</i> , 39:53-70 (1982)
<b>1013</b>	Zeldis, J., <i>et al.</i> , "S.T.E.P.S. <sup>TM</sup> : A Comprehensive Program for Controlling and Monitoring Access to Thalidomide," <i>Clin. Therapeutics</i> , 21:319-330 (1999)
<b>1014</b>	"Managing the Risks from Medical Product Use: Creating a Risk Management Framework," Report to the FDA Commissioner from the Task Force on Risk Management, U.S. Dept. of Health and Human Services, Food and Drug Administration (1999)
<b>1015</b>	66 Fed. Reg. 24391
<b>1016</b>	File History for U.S. Patent No. 7,668,730 (filed Dec. 17, 2002; issued Feb. 23, 2010)
<b>1017</b>	FDA Center for Drug Evaluation and Research, 2001 FDA Advisory Committee's Meeting Documents by Center, <i>available at</i> <a href="http://www.fda.gov/ohrms/dockets/ac/01docsbc.htm">http://www.fda.gov/ohrms/dockets/ac/01docsbc.htm</a>
<b>1018</b>	Internet Archive Wayback Machine, Center for Drug Evaluation and Research 2001 Meeting Documents, <i>available at</i> <a href="https://web.archive.org/web/20010617210030/http://www.fda.gov/ohrms/dockets/ac/cder01.htm">https://web.archive.org/web/20010617210030/http://www.fda.gov/ohrms/dockets/ac/cder01.htm</a> (dated June 17, 2001)
<b>1019</b>	Peripheral and Central Nervous System Drugs Advisory Committee, Briefing Information, from FDA Central Website (dated July 1, 2001)

<b><i>Exhibit #</i></b>	<b><i>Description</i></b>
<b>1020</b>	Internet Archive Wayback Machine, Center for Drug Evaluation and Research 2001 Meeting Documents, <i>available at</i> <a href="https://web.archive.org/web/20011004081740/http://www.fda.gov/ohrms/dockets/ac/cder01.htm">https://web.archive.org/web/20011004081740/http://www.fda.gov/ohrms/dockets/ac/cder01.htm</a> (dated Oct. 4, 2001)
<b>1021</b>	Orange Book Entries for Xyrem®, <i>available at</i> <a href="http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl_No=021196&amp;TABLE1=OB_Rx">http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl_No=021196&amp;TABLE1=OB_Rx</a> ; and <a href="http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=021196&amp;Product_No=001&amp;table1=OB_Rx">http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=021196&amp;Product_No=001&amp;table1=OB_Rx</a>
<b>1022</b>	Rome, E., "It's a rave new world: Rave culture and illicit drug use in the young," <i>Cleveland Clinic J. of Med.</i> , 68:541-550 (2001)
<b>1023</b>	FDA, Center for Drug Evaluation and Research, NDA 21-196, Approved Labeling, <i>available at</i> <a href="http://www.accessdata.fda.gov/drugsatfda_docs/nda/2002/21-196_Xyrem_prntlbl_P1.pdf">http://www.accessdata.fda.gov/drugsatfda_docs/nda/2002/21-196_Xyrem_prntlbl_P1.pdf</a>
<b>1024</b>	INTENTIONALLY LEFT BLANK
<b>1025</b>	INTENTIONALLY LEFT BLANK
<b>1026</b>	INTENTIONALLY LEFT BLANK
<b>1027</b>	FDA's Center for Drug Evaluation and Research, Advisory Committees CDER 2001 Meeting Documents, <i>available at</i> <a href="http://www.fda.gov/ohrms/dockets/ac/cder01.htm#Peripheral%20&amp;%20Central%20Nervous%201/">http://www.fda.gov/ohrms/dockets/ac/cder01.htm#Peripheral%20&amp;%20Central%20Nervous 1/</a>
<b>1028</b>	Affidavit from the Internet Archive Wayback Machine
<b>1029</b>	Mitchell, A., <i>et al.</i> , "A Pregnancy-Prevention Program in Women of Childbearing Age Receiving Isotretinoin," <i>The New England Journal of Medicine</i> , 333:101-106 (1995)
<b>1030</b>	INTENTIONALLY LEFT BLANK

<i>Exhibit #</i>	<i>Description</i>
1031	INTENTIONALLY LEFT BLANK
1032	Scrima, L., <i>et al.</i> , "Efficacy of Gamma-Hydroxybutyrate versus Placebo in Treating Narcolepsy-Cataplexy: Double-Blind Subjective Measures," <i>Biol. Psychiatry</i> , 26:331-343 (1989)
1033	Talk About Sleep, "An Interview with Orphan Medical about Xyrem®," available at <a href="http://www.talkaboutsleepp.com/an-interview-with-orphan-medical-about-xyrem/">http://www.talkaboutsleepp.com/an-interview-with-orphan-medical-about-xyrem/</a> ("Talk About Sleep") (Feb. 12, 2001)
1034	Honigfeld, G., <i>et al.</i> , "Reducing Clozapine-Related Morbidity and Mortality: 5 Years of Experience with the Clozaril National Registry," <i>J. Clin. Psych.</i> 59 (suppl. 3): 3-7 ("Honigfeld") (1998)
1035	Elsayed <i>et al.</i> , U.S. Patent No. 6,045,501 (filed Aug. 28, 1998; issued Apr. 4, 2000) ("Elsayed")
1036	U.S. Provisional Appl. No. 60/332,807 (filed Nov. 14, 2001)
1037	Jazz Pharmaceuticals Form 10-K, (Annual Report) for the period ending December 31, 2014
1038	Complaint for Patent Infringement, <i>Jazz Pharmaceuticals, Inc., v. Par Pharmaceuticals, Inc.</i> , 2:13-cv-07884 (December 27, 2013)
1039	Declaration of Barry Gilman
1040	Declaration of Steven A. Maddox In Support of <i>Pro Hac Vice</i> Motion
1041	INTENTIONALLY LEFT BLANK
1042	INTENTIONALLY LEFT BLANK
1043	INTENTIONALLY LEFT BLANK

# 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.