

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 IPR2015-00547
Patent 7,765,107

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

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*Amneal Pharmaceuticals LLC and
Par Pharmaceutical, Inc. Exhibit List*

<i>Exhibit #</i>	<i>Description</i>
1001	Reardan <i>et al.</i> , U.S. Patent No. 7,765,107 (filed Apr. 1, 2005; issued Jul. 27, 2010)
1002	File History for U.S. Patent No. 7,765,107 (filed Apr. 1, 2005; issued Jul. 27, 2010)
1003	FDA Peripheral & Central Nervous System Drugs Advisory Committee, Transcript and Slides (“ Advisory Committee Transcript and Slides ”) (July 13, 2001)
1004	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)
1005	FDA Peripheral & Central Nervous System Drugs Advisory Committee, Briefing Information, Briefing Booklet (“ Briefing Booklet ”) (July 13, 2001)
1006	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)
1007	Declaration of Dr. Robert J. Valcuk, Ph.D., R.Ph.
1008	<i>Curriculum Vitae</i> of Dr. Robert J. Valuck, Ph.D., R.Ph.
1009	Shulman, S., “The Broader Message of Accutane,” <i>Am. J. of Public Health</i> , 79:1565-1568 (1989)
1010	Lilly <i>et al.</i> , U.S. Patent Appl. Pub. No. 2004/0176985 (filed Mar. 18, 2004; published Sep. 9, 2004) (“ Lilly ”)
1011	Honigfeld, G., “Effects of the Clozapine National Registry System on Incidence of Deaths Related to Agranulocytosis,” <i>Psychiatric Services</i> , 47:52-56 (1996)

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1012	Burleson, K., "Review of computer applications in institutional pharmacy—1975-1981," <i>Am. J. Hosp. Pharm.</i> , 39:53-70 (1982)
1013	Zeldis, J., <i>et al.</i> , "S.T.E.P.S. TM : A Comprehensive Program for Controlling and Monitoring Access to Thalidomide," <i>Clin. Therapeutics</i> , 21:319-330 (1999)
1014	"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)
1015	66 Fed. Reg. 24391
1016	File History for U.S. Patent No. 7,668,730 (filed Dec. 17, 2002; issued Feb. 23, 2010)
1017	FDA Center for Drug Evaluation and Research, 2001 FDA Advisory Committee's Meeting Documents by Center, <i>available at</i> http://www.fda.gov/ohrms/dockets/ac/01docsbc.htm
1018	Internet Archive Wayback Machine, Center for Drug Evaluation and Research 2001 Meeting Documents, <i>available at</i> https://web.archive.org/web/20010617210030/http://www.fda.gov/ohrms/dockets/ac/cder01.htm (dated June 17, 2001)
1019	Peripheral and Central Nervous System Drugs Advisory Committee, Briefing Information, from FDA Central Website (dated July 1, 2001)
1020	Internet Archive Wayback Machine, Center for Drug Evaluation and Research 2001 Meeting Documents, <i>available at</i> https://web.archive.org/web/20011004081740/http://www.fda.gov/ohrms/dockets/ac/cder01.htm (dated Oct. 4, 2001)


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Par Pharmaceutical, Inc. Exhibit List*

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1021	Orange Book Entries for Xyrem®, available at http://www.accessdata.fda.gov/scripts/cder/ob/docs/obdetail.cfm?Appl_No=021196&TABLE1=OB_Rx ; and http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=021196&Product_No=001&table1=OB_Rx
1022	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)
1023	FDA, Center for Drug Evaluation and Research, NDA 21-196, Approved Labeling, available at http://www.accessdata.fda.gov/drugsatfda_docs/nda/2002/21-196_Xyrem_prntlbl_P1.pdf
1024	INTENTIONALLY LEFT BLANK
1025	INTENTIONALLY LEFT BLANK
1026	INTENTIONALLY LEFT BLANK
1027	FDA’s Center for Drug Evaluation and Research, Advisory Committees CDER 2001 Meeting Documents, available at http://www.fda.gov/ohrms/dockets/ac/cder01.htm#Peripheral%20&%20Central%20Nervous%201/
1028	Affidavit from the Internet Archive Wayback Machine
1029	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)
1030	INTENTIONALLY LEFT BLANK
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)

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Par Pharmaceutical, Inc. Exhibit List*

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1033	Talk About Sleep, “An Interview with Orphan Medical about Xyrem®,” available at http://www.talkaboutslee.com/an-interview-with-orphan-medical-about-xyrem/ (“ 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

Respectfully Submitted,



Dennies Varughese
Registration No. 61,868
Attorney for Petitioner

Date: July 28, 2015
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600

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