

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

JAZZ PHARMACEUTICALS, INC.,
Patent Owner.

Case IPR2015-00554 ¹
Patent 7,668,730

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

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¹ Case IPR2015-01818 has been joined with this proceeding.

IPR2015-00554
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Petitioners' Exhibit List

PAR Exhibit #	Description
1001	Reardan <i>et al.</i> , U.S. Patent No. 7,895,059 (filed Feb. 11, 2010; issued Feb. 22, 2011)
1002	File History for U.S. Patent No. 7,895,059 (filed Feb. 11, 2010; issued Feb. 22, 2011)
1003	FDA Peripheral & Central Nervous System Drugs Advisory Committee, Transcript and Slides
1004	FDA Peripheral & Central Nervous System Drugs Advisory Committee, Briefing Information, Division of Neuropharmacological Drug Products Preliminary Clinical Safety Review of NDA 21-196
1005	FDA Peripheral & Central Nervous System Drugs Advisory Committee, Briefing Information, Briefing Booklet
1006	FDA Peripheral & Central Nervous System Drugs Advisory Committee, Briefing Information, Xyrem Video and Transcript
1007	Declaration of Dr. Robert J. Valuck, 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	Spurgeon, D., "Advent of Mail-Order Pharmacy Causes Concern Among Some Pharmacists," <i>Can. Med. Assoc. J.</i> , 152:1485-1486 (1995)
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)
1012	Burleson, K., "Review of computer applications in institutional pharmacy—1975-1981," <i>Am. J. Hosp. Pharm.</i> , 39:53-70 (1982)

PAR Exhibit #	Description
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	INTENTIONALLY LEFT BLANK
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	Internet Archive Wayback Machine, FDA Peripheral & Central Nervous System Drugs Advisory Committee, Briefing Information for Xyrem NDA 21-196, <i>available at</i> https://web.archive.org/web/20010701233052/http://www.fda.gov/ohrms/dockets/ac/01/briefing/3754b1.htm (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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1021	Orange Book Entries for Xyrem®, <i>available at</i> 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, <i>available at</i> http://www.accessdata.fda.gov/drugsatfda_docs/nda/2002/21-196_Xyrem_prntlbl_P1.pdf
1024	INTENTIONALLY LEFT BLANK
1025	Complaint, <i>Jazz Pharms., Inc. v. Roxane Labs., Inc.</i> , 2:11-cv-02523 (D.N.J. May 5, 2011)
1026	Complaint, <i>Jazz Pharms., Inc. v. Par Pharm., Inc.</i> , 2:13-cv-07884 (D.N.J. Dec. 27, 2013)
1027	FDA's Center for Drug Evaluation and Research, Advisory Committees CDER 2001 Meeting Documents, <i>available at</i> 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., "A Pregnancy-Prevention Program in Women of Childbearing Age Receiving Isotretinoin," <i>The New England Journal of Medicine</i> , 333:101-106 (1995)
1030	Moradi <i>et al.</i> , U.S. Patent Appl. Pub. No. 2004/0019794 (filed Jul. 29, 2002; published Jan. 29, 2004)

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1031	Lilly <i>et al.</i> , U.S. Patent Appl. Pub. No. 2003/0093295 (filed Jan. 31, 2002; published May 15, 2003)
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," available at http://www.talkaboutsleepp.com/an-interview-with-orphan-medical-about-xyrem/ (last visited Dec. 15, 2014) (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>Journal of Clinical Psychiatry</i> 59 (suppl. 3): 3-7 (1998)
1035	Elsayed <i>et al.</i> , U.S. Patent No. 6,045,501 (filed Aug. 28, 1998; issued Apr. 4, 2000)
1036	Lilly <i>et al.</i> , U.S. Patent Application No. 2004/0176985 A1 (filed Mar. 18, 2004 and claiming priority to U.S. Patent Application No. 10/062,251, filed Jan. 31, 2002; published Sep. 9, 2004)
1037	U.S. Provisional Patent Application Ser. No. 60/332,807 ("807 application) filed November 14, 2001.
1038	INTENTIONALLY LEFT BLANK
1039	January 13, 2014 Email from A. Burgy to G. Brier, re: Jazz v. Par, Civil Action No. 13-7884
1040	Declaration of Barry Gilman
1041	Jazz Pharmaceuticals SEC Form 10-K (February 24, 2015)
1042	INTENTIONALLY LEFT BLANK

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