

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 IPR: Unassigned
Patent 8,731,963

**PAR PHARMACEUTICAL, INC. AND
AMNEAL PHARMACEUTICALS LLC'S EXHIBIT LIST
PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,731,963**

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*Inter Partes Review of USPN 8,731,963
Par and Amneal Exhibit List*

PAR Exhibit #	Description
1001	Reardan <i>et al.</i> , U.S. Patent No. 8,731,963 (filed Aug. 22, 2012; issued May 20, 2014)
1002	File History for U.S. Patent No. 8,731,963 (filed Aug. 22, 2012; issued May 20, 2014)
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	Curriculum Vitae 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	INTENTIONALLY LEFT BLANK
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)

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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. 24,391
1016	File History for U.S. Patent No. 7,668,730 (filed Dec. 17, 2002; issued Feb. 23, 2010)
1017	INTENTIONALLY LEFT BLANK
1018	INTENTIONALLY LEFT BLANK
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)
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)

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PAR Exhibit #	Description
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, Jazz Pharms., Inc. v. Amneal Pharms. LLC, 2:15-cv-01043 (D.N.J. Feb. 6, 2015)
1026	Complaint, Jazz Pharms., Inc. v. Par Pharm., Inc., 2:14-cv-05139 (D.N.J. Aug. 15, 2014)
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 1/
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)
1033	INTENTIONALLY LEFT BLANK
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1035	INTENTIONALLY LEFT BLANK
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PAR Exhibit #	Description
1037	Korfhage, R.R., "Information Storage and Retrieval," (1997) ("Korfhage")
1038	INTENTIONALLY LEFT BLANK
1039	September 16, 2014 Email from A. Burgy to G. Brier, re: Jazz v. Par, Civil Action No. 14-5139
1040	Declaration of Barry Gilman (May 26, 2015)

Respectfully Submitted,



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