

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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AMNEAL PHARMACEUTICALS, LLC and  
PAR PHARMACEUTICAL, INC  
Petitioners

v.

JAZZ PHARMACEUTICALS, INC.  
Patent Owner

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CASE IPR2015-00554  
Patent 7,668,730

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**PETITIONERS' EXHIBIT LIST  
(REPLY REGARDING THE IDENTIFICATION OF  
REAL PARTIES IN INTEREST)**

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**IPR2015-00554 (Patent 7,668,730)**  
**Petitioners' Exhibit List**

<b>PAR Exhibit #</b>	<b>Description</b>
<b>1001</b>	Reardan, <i>et al.</i> , U.S. Patent No. 7,668,730 (filed Dec. 17, 2002; issued Feb. 23, 2010)
<b>1002</b>	File History for U.S. Patent No. 7,668,730 (filed Dec. 17, 2002; issued Feb. 23, 2010)
<b>1003</b>	FDA Peripheral & Central Nervous System Drugs Advisory Committee, Transcript and Slides (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 (July 13, 2001)
<b>1005</b>	FDA Peripheral & Central Nervous System Drugs Advisory Committee, Briefing Information, Briefing Booklet (July 13, 2001)
<b>1006</b>	FDA Peripheral & Central Nervous System Drugs Advisory Committee, Briefing Information, Xyrem Video and Transcript
<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>	Spurgeon, D., "Advent of Mail-Order Pharmacy Causes Concern Among Some Pharmacists," <i>Can. Med. Assoc. J.</i> , 152:1485-1486 (1995)
<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)

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<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>	INTENTIONALLY LEFT BLANK
<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>	Internet Archive Wayback Machine, FDA Peripheral & Central Nervous System Drugs Advisory Committee, Briefing Information for Xyrem NDA 21-196, <i>available at</i> <a href="https://web.archive.org/web/20010701233052/http://www.fda.gov/ohrms/dockets/ac/01/briefing/3754b1.htm">https://web.archive.org/web/20010701233052/http://www.fda.gov/ohrms/dockets/ac/01/briefing/3754b1.htm</a> (dated July 1, 2001)
<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)

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<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>	Complaint, <i>Jazz Pharms., Inc. v. Roxane Labs., Inc.</i> , 2:11-cv-02523 (D.N.J. May 5, 2011)
<b>1026</b>	Complaint, <i>Jazz Pharms., Inc. v. Par Pharm., Inc.</i> , 2:13-cv-07884 (D.N.J. Dec. 27, 2013)
<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%201/</a>
<b>1028</b>	Affidavit from the Internet Archive Wayback Machine
<b>1029</b>	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)
<b>1030</b>	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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<b>1031</b>	Lilly <i>et al.</i> , U.S. Patent Appl. Pub. No. 2003/0093295 (filed Jan. 31, 2002; published May 15, 2003)
<b>1032</b>	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).
<b>1033</b>	Talk About Sleep, "An Interview with Orphan Medical," 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> (last visited Dec. 15, 2014) (Feb. 12, 2001)
<b>1034</b>	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)
<b>1035</b>	Elsayed <i>et al.</i> , U.S. Patent No. 6,045,501 (filed Aug. 28, 1998; issued Apr. 4, 2000)
<b>1036</b>	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) ("Lilly")
<b>1037</b>	U.S. Provisional Patent Application Ser. No. 60/332,807 ("807 application) filed November 14, 2001.
<b>1038</b>	INTENTIONALLY LEFT BLANK
<b>1039</b>	January 13, 2014 Email from A. Burgy to G. Brier, re: Jazz v. Par, Civil Action No. 13-7884
<b>1040</b>	Declaration of Barry Gilman
<b>1041</b>	Jazz Pharmaceuticals SEC Form 10-K (February 24, 2015)

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