

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 IPR2015-00547

Patent 7,765,107

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

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Patent Trial and Appeal Board

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<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)

<i>Exhibit #</i>	<i>Description</i>
<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%201/</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>
<b>1031</b>	INTENTIONALLY LEFT BLANK
<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 about Xyrem®,” <i>available at</i> <a href="http://www.talkaboutsleee.com/an-interview-with-orphan-medical-about-xyrem/">http://www.talkaboutsleee.com/an-interview-with-orphan-medical-about-xyrem/</a> (“ <b>Talk About Sleep</b> ”) (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>J. Clin. Psych.</i> 59 (suppl. 3): 3-7 (“ <b>Honigfeld</b> ”) (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>Elsayed</b> ”)
<b>1036</b>	U.S. Provisional Appl. No. 60/332,807 (filed Nov. 14, 2001)
<b>1037</b>	Jazz Pharmaceuticals Form 10-K, (Annual Report) for the period ending December 31, 2014
<b>1038</b>	Complaint for Patent Infringement, <i>Jazz Pharmaceuticals, Inc., v. Par Pharmaceuticals, Inc.</i> , 2:13-cv-07884 (December 27, 2013)
<b>1039</b>	Declaration of Barry Gilman

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