

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ROXANE LABORATORIES, INC. and PAR PHARMACEUTICAL, INC.
Petitioners

v.

JAZZ PHARMACEUTICALS, INC.
Patent Owner

CASE CBM: Unassigned
Patent 7,765,107

**ROXANE LABORATORIES, INC. and PAR PHARMACEUTICAL, INC.’S
EXHIBIT LIST (COVERED BUSINESS METHOD PATENT REVIEW OF
U.S. PATENT NO. 7,765,107)**

Mail Stop “PATENT BOARD”
Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

***Covered Business Method Patent Review of USPN 7,765,107
Roxane and Par 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
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)
1013	Zeldis, J., et al., "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)

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<i>Exhibit #</i>	<i>Description</i>
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	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)
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	Complaint, <i>Jazz Pharms., Inc. v. Roxane Labs., Inc.</i> , 2:10-cv-06108 (D.N.J. Nov. 22, 2010)

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Roxane and Par Exhibit List**

<i>Exhibit #</i>	<i>Description</i>
1025	Complaint, <i>Jazz Pharms., Inc. v. Par Pharm., Inc.</i> , 2:13-cv-07884 (D.N.J. Dec. 27, 2013)
1026	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/
1027	Affidavit from the Internet Archive Wayback Machine
1028	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)
1029	Moradi <i>et al.</i> , U.S. Patent Appl. Pub. No. 2004/0019794 (filed Jul. 29, 2002; published Jan. 29, 2004)
1030	Lilly <i>et al.</i> , U.S. Patent Appl. Pub. No. 2003/0093295 (filed Jan. 31, 2002; published May 15, 2003)
1031	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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***Covered Business Method Patent Review of USPN 7,765,107
Roxane and Par Exhibit List***

CERTIFICATION OF SERVICE (37 C.F.R. §§ 42.6(e), 42.105(a))

The undersigned hereby certifies that the above-captioned “Roxane Laboratories, Inc. and Par Pharmaceutical, Inc.’s Exhibit List (Covered Business Method Patent Review of U.S. Patent No. 7,765,107),” including its supporting evidence (EXHIBITS 1001-1031), was served in its entirety on August 18, 2014, upon the following parties via EXPRESS MAIL:

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