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PAR PHARMACEUTICAL, INC.
Petitioner

v.

JAZZ PHARMACEUTICALS, INC.
Patent Owner

CASE IPR: Unassigned
Patent 8,772,306

PAR PHARMACEUTICAL, INC.'S EXHIBIT LIST
PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,772,306

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Exhibit #	Description
1001	Eller, M., U.S. Patent No. 8,772,306 (filed Apr. 29, 2013; issued Jul. 8, 2014)
1002	File History for U.S. Patent No. 8,772,306 (filed Apr. 29, 2013; issued Jul. 8, 2014)
1003	Declaration of John W. Winkelman, M.D., Ph.D.
1004	Curriculum Vitae of John W. Winkelman, M.D., Ph.D.
1005	Orange Book Patent Exclusivity Listing for XYREM (http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=021196&Product_No=001&table1=OB_Rx)
1006	Jazz Pharmaceuticals, Inc., Prescribing Information and Medication Guide for XYREM (sodium oxybate) (Nov. 18, 2005)
1007	Abbvie, Inc., Prescribing Information and Medication Guide for DEPAKOTE (divalproex sodium) (Oct. 7, 2011)
1008	Cagnin, A. et al., *γ-Hydroxybutyric Acid-Induced Psychosis and Seizures*, 21(2) Epilepsy Behav. 203–05 (2011) ("Cagnin")
1009	Waszkielewicz, *A. et al.*, *γ-Hydrobutyric Acid (GHB) and Its Chemical Modifications: A Review of the GHBergic System*, 56(1) Pol. J. Pharmacol. 43–49 (2004) ("Waszkielewicz")
1010	Weiss, T. et al., *Gamma-Hydroxybutyrate (GHB) and Topiramate—Clinically Relevant Drug Interaction Suggested by a Case of Coma and Increased Plasma GHB Concentration*, 69(5) Eur. J. Clin. Pharmacol. 1193–94 (2013) ("Weiss")
1011	FDA's Center for Drug Evaluation and Research, *Guidance for Industry: Drug Interaction Studies—Study Design, Data Analysis, Implications for Dosing, and Labeling Recommendations* (Feb. 2012) ("FDA Guidance")
1012	Vayer, P. et al., *Is the Anticonvulsant Mechanism of Valproate Linked to Its Interaction with the Cerebral γ-Hydroxybutyrate System?*, 9(4) Trends Pharmacol. Sci. 127–29 (1988) ("Vayer")

Exhibit #	Description
1013	Shinka, T. et al., *Effect of Valproic Acid on the Urinary Metabolic Profile of a Patient with Succinic Semialdehyde Dehydrogenase Deficiency*, 792(1) J. Chromatogr. B 99–106 (2003) ("Shinka")
1014	Hechler, V. et al., *γ-Hydroxybutyrate Conversion into GABA Induces Displacement of GABAB Binding That Is Blocked by Valproate and Ethosuximide*, 281(2) J. Pharmacol. Exp. Ther. 735–60 (1997)
1015	Kaufman, E. et al., *An Overview of γ-Hydroxybutyrate Catabolism: The Role of the Cytosolic $NADP^+$-Dependent Oxidoreductase EC 1.1.1.19 and of a Mitochondrial Hydroxyacid-Oxoacid Transhydrogenase in the Initial, Rate-Limiting Step in This Pathway*, 16(9) Neurochem. Res. 965–74 (1991)
1016	Draft Guidance for Industry on Drug Interaction Studies—Study Design, Data Analysis, Implications for Dosing, and Labeling Recommendations, 77 Fed. Reg. 9,946 (Feb. 21, 2012)
1017	FDA Approval Letter for Xyrem (Nov. 18, 2005)
1018	FDA Approval Letter for Depakote Label (Oct. 7, 2011)
1019	Bhattacharya, I. et al., *Potential γ-Hydroxybutyric Acid (GHB) Interactions Through Blood–Brain Barrier Transport Inhibition: A Pharmacokinetic Simulation-Based Evaluation*, 33(5) J. Pharmacokinetics & Pharmacodynamics 657–81 (2006) ("Bhattacharya")
1020	Swann, A., *Major System Toxicities and Side Effects of Anticonvulsants*, 62(Suppl. 14) J. Clin. Psychiatry 16–21 (2001) ("Swann")
1021	European Medicines Agency, *Scientific Discussion: Sodium Oxybate* (Aug. 9, 2006)
1022	European Medicines Agency, *Find medicine – Xyrem – Assessment History* (last visited Oct. 5, 2015), *available at* http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000593/human_med_001163.jsp&mid=WC0b01ac058001d124

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1023	FDA Approval Letter for Xyrem (Jul. 17, 2002)
1024	Jazz Pharmaceuticals, Inc., Prescribing Information and Medication Guide for XYREM (sodium oxybate) (2014)
1025	Cipraini, A. et al., *Valproic Acid, Valproate and Divalproex in the Maintenance Treatment of Bipolar Disorder (Review)*, 10 Cochrane Database Syst. Rev. CD003196 (2013)
1026	Bhattacharya, I. et al., *GHB (γ-Hydroxybutyrate) Carrier-Mediated Transport across the Blood-Brain Barrier*, 311(1) J. Pharmacol. Exp. Ther. 92–98 (2004)
1027	Cui, D. et al., *The Drug of Abuse γ-Hydroxybutyrate Is a Substrate for Sodium-Coupled Monocarboxylate Transporter (SMCT) 1 (SLC5A8): Characterization of SMCT-Mediated Uptake and Inhibition*, 37(7) Drug Metab. Dispos. 1404–10 (2009)
1028	Eller, M. et al., *Evaluation of Drug–Drug Interactions of Sodium Oxybate with Divalproex: Results from a Pharmacokinetic/Pharmacodynamics Study*, 14S Abs. Sleep Med. e302–e303 (2013)
1029	Harvey, P. et al., *The Inhibitory Effect of Sodium* n*-Dipropyl Acetate on the Degradative Enzymes of the GABA Shunt*, 52(2) FEBS Lett. 251–54 (1975)
1030	Kaufman, E. et al., *Oxidation of γ-Hydroxybutyrate to Succinic Semialdehyde by a Mitochondrial Pyridine Nucleotide-Independent Enzyme*, 51(4) J. Neurochem. 1079–84 (1988)
1031	Kaufman, E. et al., *Evidence of the Participation of a Cytosolic $NADP^+$-Dependent Oxidoreductase in the Catabolism of γ-Hydroxybutyrate in Vivo*, 48(6) J. Neurochem. 1935–41 (1987)
1032	Kennedy, G. et al., *CNS Adverse Events Associated with Antiepileptic Drugs*, 22(9) CNS Drugs 739–60 (2008)
1033	Löscher, W., *Basic Pharmacology of Valproate: A Review after 35 Years of Clinical Use for the Treatment of Epilepsy*, 16(10) CNS Drugs 669–42 (2002)
1034	Morris, M. et al., *Overview of the Proton-Coupled MCT (SLC16A) Family of Transporters: Characterization, Function and Role in the Transport of the Drug of Abuse γ-Hydroxybutyric Acid*, 10(2) AAPS J. 311–21 (2008)

Exhibit #	Description
1035	Rumigny, J. et al., *Specific and Non-Specific Succinic Semialdehyde Reductases from Rat Brain: Isolation and Properties*, 117(1) FEBS Lett. 111–16 (1980)
1036	Schep, L. et al., *The Clinical Toxicology of Gamma-Hydroxybutyrate, Gamma-Butyrolactone and 1,4-Butanediol*, 50(6) Clin. Toxicol. (Phila). 458–70 (2012)
1037	Thompson, P.J. et al., *Sodium Valproate and Cognitive Functioning in Normal Volunteers*, 12(6) Br. J. Clin. Pharmacol. 819–24 (1981)
1038	Van der Laan, J.W. et al., *Di-n-Propylacetate and GABA Degradation: Preferential Inhibition of Succinic Semialdehyde Dehydrogenase and Indirect Inhibition of GABA-Transaminase*, 32(4) J. Neurochem. 1769–80 (1979)
1039	Vayer, P. et al., *3'-5' Cyclic-Guanosine Monophosphate Increase in Rat Brain Hippocampus after Gamma-Hydroxybutyrate Administration: Prevention by Valproate and Naloxone*, 41(5) Life Sci. 605–10 (1987)
1040	Whittle, S. et al., *Effects of Anticonvulsants on the Formation of γ-Hydroxybutyrate from γ-Aminobutyrate in Rat Brain*, 38(3) J. Neurochem. 848–51 (1982)

Respectfully Submitted,

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