

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Mylan Laboratories Ltd.
Petitioner,

v.

Janssen Pharmaceutica NV
Patent Owner.

U.S. Patent No. 9,439,906 to Vermeulen *et al.*
Issue Date: September 13, 2016
Title: Dosing Regimen Associated with Long
Acting Injectable Paliperidone Esters

Inter Partes Review No.: IPR2020-00440

PETITIONER'S EXHIBIT LIST AS OF JUNE 30, 2020

Exhibit #	Description
1001	U.S. Patent No. 9,439,906 (“the ’906 patent”)
1002	Declaration of Dr. Mansoor M. Amiji, Ph.D and Accompanying Exhibits
1003	Abstracts of the Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics, 83 Supp. 1 Clin. Pharmacol. & Therapeutics S31, PI-74 and PI-75 (Mar. 2008) (“Cleton”)
1004	L. Citrome, Paliperidone: quo vadis?, Int. J. Clin. Pract. 61(1):653662 (Apr. 2007) (“Citrome”)
1005	U.S. Patent No. 6,555,544 (“the ’544 patent”)
1006	Formulary Drug Reviews – Paliperidone, Hospital pharmacy 42(7):637-647 July 2007 (“Paliperidone Formulary”)
1007	N. Washington, C. Washington, C. Wilson. Physiological Pharmaceutics: Barriers to Drug Absorption. (2001), pages 26-29 (“Physiological Pharmaceutics”)
1008	U.S. Patent No. 6,495,534 (“the ’534 patent”)
1009	J.M. Kane, et al. Guidelines for depot antipsychotic treatment in schizophrenia. B. Eur. Neuropharmacol. 8(1):55-65 (1995) (“Kane”)
1010	N. Marder, et al. Pharmacokinetics of long-acting injectable neuroleptic drugs: clinical implications. Psychopharmacology. 98:433-439 (1989) (“Marder”)
1011	M.E. Aulton. Pharmaceutics: The Science of Dosage Form Design (2002), Chapter 19 (“Aulton”)
1012	Comparison of the ’276 and the ’918 provisional application specifications (“Specification Comparison”)
1013	U.S. Patent No. 5,254,556 (“the ’556 patent”)

Exhibit #	Description
1014	U.S. Patent No. 7,449,184 (“the ’184 patent”)
1015	R. Urso, P. Blardi, G. Giorgi. A short introduction to pharmacokinetics, Rev. Med. Pharmacol. Sci. 6: 33-44 (2002) (“Urso”)
1016	U.S. Provisional Application No. 61/014,918 (“the ’918 provisional”)
1017	U.S. Provisional Application No. 61/120,276 (“the ’276 provisional”)
1018	Excerpt of ’906 Patent Prosecution History (“6-12-2016 Amendment and Response”)
1019	’906 Patent Prosecution History
1020	L. Ereshefsky, et al., Future of Depot Neuroleptic Therapy: Pharmacokinetic and Pharmacodynamic Approaches. J. Clin. Psychiatry, 45(5):50-59 (1984) (“Ereshefsky”)
1021	Goodman & Gilman’s, The Pharmacological Basis of Therapeutics (2001), Chapter 1 (“Goodman & Gilman”)
1022	D. Waller & A. Renwick, Principles of Medical Pharmacology (1994) (“Principles of Medical Pharmacology”)
1023	U.S. Patent No. 6,818,633 (“the ’633 patent”)
1024	Ansel <i>et al.</i> , Pharmaceutical Dosage Forms and Drug Delivery Systems 8th ed. (2005) (“Added Substances”)
1025	Orange Book Entry for Invega Sustenna®
1026	Excerpt of ’906 Patent Prosecution History (“11-11-2015 IDS”)
1027	Curriculum Vitae of Dr. Mansoor Amiji
1028	<i>Janssen Pharmaceuticals, Inc. et al v. Teva Pharmaceuticals USA, Inc. et al.</i> , 2-18-cv-00734 (D.N.J.) (“Joint Claim Construction”)

Exhibit #	Description
1029	<i>Janssen Pharmaceuticals, Inc. et al v. Teva Pharmaceuticals USA, Inc. et al.</i> , 2-18-cv-00734 (D.N.J.) (“Claim Construction Agreement”)
1030	INVEGA SUSTENNA® Label (“INVEGA LABEL”)
1031	ClinicalTrials.gov , A Safety and Tolerability Study of Paliperidone Palmitate Injected in the Shoulder or the Buttock Muscle in Patients With Schizophrenia (July 2006), https://clinicaltrials.gov/ct2/history/NCT00119756?V_10=View#StudyPageTop (“NCT00119756”)
1032	ClinicalTrials.gov , A Study to Evaluate the Effectiveness and Safety of 3 Doses of Paliperidone Palmitate in Treating Subjects With Schizophrenia (October 2006), https://clinicaltrials.gov/ct2/history/NCT00210548?V_11=View#StudyPageTop (“NCT00210548”)
1033	ClinicalTrials.gov , Safety and Efficacy of an Anti-Psychotic Versus Placebo in Subjects With Schizophrenia (November 2005), https://clinicaltrials.gov/ct2/history/NCT00101634?V_4=View#StudyPageTop (“NCT00101634”)
1034	ClinicalTrials.gov , A Study to Compare the Effectiveness and Safety of Flexibly Varied Doses of Paliperidone Palmitate and Risperidone in Treating Patients With Schizophrenia (July 2006), https://clinicaltrials.gov/ct2/history/NCT00210717?V_10=View#StudyPageTop (“NCT00210717”)
1035	ClinicalTrials.gov , Intramuscular Injections of Paliperidone Palmitate in the Arm or Buttock of Subjects With Schizophrenia (June 2005), https://clinicaltrials.gov/ct2/history/NCT00073320?V_1=View#StudyPageTop (“NCT00073320”)

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1036	ClinicalTrials.gov , Evaluate the Efficacy in the Prevention of Recurrence of the Symptoms of Schizophrenia (April 2006), https://clinicaltrials.gov/ct2/history/NCT00111189?V_3=View#StudyPageTop (“NCT00111189”)
1037	Guarino, Richard A. “Clinical research protocols.” New Drug Approval Process. CRC Press, 2004, pages 257-61
1038	Bishara, Delia, and David Taylor. “Upcoming agents for the treatment of schizophrenia.” <i>Drugs</i> 68.16 (2008): 2269-2292
1039	Kramer, M., et al. “322–Efficacy/tolerability of paliperidone palmitate: 9-week, placebo-controlled study in schizophrenia patients.” <i>Schizophrenia Research</i> 98 (2008): 165-166
1040	’906 Patent Specification as Filed
1041	Kramer M, Litman R, Lane R, et al. “908. Efficacy and tolerability of two fixed dosages of paliperidone palmitate in the treatment of schizophrenia: results of a 9-week placebo-controlled trial.” <i>Biol Psychiatry</i> 2008;63:1S-319S
1042	Declaration of Laboratory Research Analyst Alys Tryon
1043	Nankivell, Brian J. Creatinine clearance and the assessment of renal function. <i>Australian Prescriber</i> , 2001
1044	Perry, Paul J., ed. <i>Psychotropic drug handbook</i> . Lippincott Williams & Wilkins, 2007, pages 74-77
1045	Traynor, Jamie, et al. How to measure renal function in clinical practice. <i>Bmj</i> 333.7571 (2006): 733-737
1046	Janicak, Philip G., and Elizabeth A. Winans. Paliperidone ER: a review of the clinical trial data. <i>Neuropsychiatric disease and treatment</i> 3.6 (2007):869

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