

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 JULY 10, 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):653-662 (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	<a href="https://clinicaltrials.gov">ClinicalTrials.gov</a> , A Safety and Tolerability Study of Paliperidone Palmitate Injected in the Shoulder or the Buttock Muscle in Patients With Schizophrenia (July 2006), <a href="https://clinicaltrials.gov/ct2/history/NCT00119756?V_10=View#StudyPageTop">https://clinicaltrials.gov/ct2/history/NCT00119756?V_10=View#StudyPageTop</a> (“NCT00119756”)
1032	<a href="https://clinicaltrials.gov">ClinicalTrials.gov</a> , A Study to Evaluate the Effectiveness and Safety of 3 Doses of Paliperidone Palmitate in Treating Subjects With Schizophrenia (October 2006), <a href="https://clinicaltrials.gov/ct2/history/NCT00210548?V_11=View#StudyPageTop">https://clinicaltrials.gov/ct2/history/NCT00210548?V_11=View#StudyPageTop</a> (“NCT00210548”)
1033	<a href="https://clinicaltrials.gov">ClinicalTrials.gov</a> , Safety and Efficacy of an Anti-Psychotic Versus Placebo in Subjects With Schizophrenia (November 2005), <a href="https://clinicaltrials.gov/ct2/history/NCT00101634?V_4=View#StudyPageTop">https://clinicaltrials.gov/ct2/history/NCT00101634?V_4=View#StudyPageTop</a> (“NCT00101634”)
1034	<a href="https://clinicaltrials.gov">ClinicalTrials.gov</a> , A Study to Compare the Effectiveness and Safety of Flexibly Varied Doses of Paliperidone Palmitate and Risperidone in Treating Patients With Schizophrenia (July 2006), <a href="https://clinicaltrials.gov/ct2/history/NCT00210717?V_10=View#StudyPageTop">https://clinicaltrials.gov/ct2/history/NCT00210717?V_10=View#StudyPageTop</a> (“NCT00210717”)
1035	<a href="https://clinicaltrials.gov">ClinicalTrials.gov</a> , Intramuscular Injections of Paliperidone Palmitate in the Arm or Buttock of Subjects With Schizophrenia (June 2005), <a href="https://clinicaltrials.gov/ct2/history/NCT00073320?V_1=View#StudyPageTop">https://clinicaltrials.gov/ct2/history/NCT00073320?V_1=View#StudyPageTop</a> (“NCT00073320”)

Exhibit #	Description
1036	<a href="https://clinicaltrials.gov">ClinicalTrials.gov</a> , Evaluate the Efficacy in the Prevention of Recurrence of the Symptoms of Schizophrenia (April 2006), <a href="https://clinicaltrials.gov/ct2/history/NCT00111189?V_3=View#StudyPageTop">https://clinicaltrials.gov/ct2/history/NCT00111189?V_3=View#StudyPageTop</a> (“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

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.