

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re *Inter Partes* Review of:)
U.S. Patent No. 9,138,432 B2)
Issued: Sept. 22, 2015)
Application No.: 14/150,575)
Filing Date: Jan. 8, 2014)

For: **Methods for the Administration of Iloperidone**

FILED VIA PRPS

**PETITION FOR *INTER PARTES* REVIEW
OF U.S. PATENT NO. 9,138,432**

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Exhibit List

- 1001 U.S. Patent No. 9,138,432 (the “’432 Patent”)
- 1002 File History for the ’432 Patent (from the USPTO public Patent Application Information Retrieval (PAIR) database, www.uspto.gov, excluding foreign references)
- 1003 Declaration of David Fogelson, M.D. in Support of Petition for *Inter Partes* Review of U.S. Patent No. 9,138,432
- 1004 Curriculum Vitae of David Fogelson, M.D.
- 1005 U.S. Department of Health and Human Services, Food and Drug Administration (“FDA”), *Guidance for Industry, In Vivo Drug Metabolism/Drug Interaction Studies – Study Design, Data Analysis, and Recommendations for Dosing and Labeling* (November 1999) (available at <http://www.fda.gov/OHRMS/DOCKETS/98fr/994718gd.pdf>) (accessed February 22, 2016) (“FDA Guidance 1999”)
- 1006 A.E. Mutlib *et al.*, *Application of Liquid Chromatography/Mass Spectrometry in Accelerating the Identification of Human Liver Cytochrome P450 Isoforms Involved in the Metabolism of Iloperidone*, 286 J. PHARM. & EXPERIMENTAL THERAPEUTICS 1285-93 (September 1998) (“Mutlib”)
- 1007 K. Brøsen, *Differences in Interactions of SSRIs*, 13 INT’L CLINICAL PSYCHOPHARM. S45-47 (September 1998) (“Brøsen”)
- 1008 *Physicians’ Desk Reference* (58th ed. 2004) (Montvale, NJ; Thompson PDR, November 2003) (“PDR 2004”), comprising: Abilify Official Labeling, Bristol-Myers Squibb Company (revised May 2003) at 1034-38, and Otsuka America Pharmaceutical, Inc. (revised May 2003) at 2496-500 (the “PDR Abilify Label”); and Strattera Official Labeling, Eli Lilly and Company (revised March 5, 2003) at 1850-54 (the “Strattera Label”)
- 1009 FDA Official Website, Drug Approval Package: Abilify (Aripiprazole) NDA #21-436, November 15, 2002 (the “Abilify Approval Package”) (available at http://www.accessdata.fda.gov/drugsatfda_docs/nda/2002/21-436_Abilify.cfm) (webpage created March 7, 2003), linking to: “Approval Letter(s),” November 15, 2002 Letter from FDA to Otsuka

- Pharmaceutical Co., Ltd. (the “Abilify Approval Letter”) (*available at* http://www.accessdata.fda.gov/drugsatfda_docs/nda/2002/21-436_Abilify_Approv.pdf); and “Printed Labeling,” Final Printed Labeling (the “FPL Abilify Label”) (*available at* http://www.accessdata.fda.gov/drugsatfda_docs/nda/2002/21436_Abilify_prntlbl.pdf) (accessed February 23, 2016)
- 1010 N.E. Mealy *et al.*, *Annual Review 2002: Psychopharmacologic Drugs*, 27 DRUGS OF THE FUTURE 995-1027 (October 2002) (“Mealy”)
- 1011 K.K. Jain, *An Assessment of Iloperidone for the Treatment of Schizophrenia*, 9 EXPERT OPINION ON INVESTIGATIONAL DRUGS 2935-43 (December 2000) (“Jain”)
- 1012 U.S. Patent Publication No. 2003/0144220, “Use of CYP2D6 Inhibitors in Combination Therapies,” filed March 21, 2000, published July 31, 2003 (“Obach”)
- 1013 S.M. Cheer *et al.*, *Fluoxetine, A Review of its Therapeutic Potential in the Treatment of Depression Associated with Physical Illness*, 61 DRUGS 81-110 (January 2001) (“Cheer”)
- 1014 International Publication No. WO 01/79554, “Genetic Diagnosis for QT Prolongation Related Adverse Drug Reactions,” filed April 13, 2001, published October 25, 2001 (“Woosley”)
- 1015 U.S. Department of Health and Human Services, Food and Drug Administration (“FDA”), *Guidance for Industry, Drug Metabolism/Drug Interaction Studies in the Drug Development Process: Studies In Vitro* (April 1997) (*available at* <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/UCM142439.pdf>) (accessed February 22, 2016) (“FDA Guidance 1997”)
- 1016 R.R. Shah, *Pharmacogenetic Aspects of Drug-Induced Torsade de Pointes: Potential Tool for Improving Clinical Drug Development and Prescribing*, 27 DRUG SAFETY 145-72 (March 2004) (“Shah”)
- 1017 *Physicians’ Desk Reference* (56th ed. 2002), Prozac Official Labeling, Dista Products Company (revised February 28, 2001, product information prepared June 2001) at 1238-43 (the “Prozac Label”)
- 1018 FDA Official Website, Drugs@FDA: FDA Approved Drug Products,

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