

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TEVA PHARMACEUTICALS USA, INC.

Petitioner

v.

RB PHARMACEUTICALS LTD.

Patent Owner

U.S. Patent No. 8,475,832

Case IPR2016: Unassigned

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,475,832

PETITIONER EXHIBIT LIST

Exhibit No.	Reference
1001	U.S. Patent No. 8,475,832 (filed August 7, 2009)
1002	File History, U.S. Patent No. 8,475,832
1003	Expert Declaration of Nandita Das, Ph.D., Relating to U.S. Patent No. 8,475,832
1004	U.S. Patent Application Publication 2005/0085440 (published April 21, 2005) (“Birch”)
1005	WO 2008/025791 (published March 6, 2008) (“Oksche”)
1006	U.S. Patent No. 7,357,891 (published December 23, 2004) (issued April 15, 2008) (“Yang”)
1007	WO 2008/040534 (published April 10, 2008) (“LabTec”)
1008	Suboxone® Label
1009	Suboxone® Tablet Summary Basis of Approval (“SBOA”)
1010	U.S. Patent Application Publication No. 2005/0037055 (“the ’055 publication”)
1011	European Medicines Agency Initial Marketing-Authorisation Document, Scientific Discussion, Oct. 19, 2006 for Suboxone sublingual tablets (“EMA”)
1012	J.P. Cassidy et al., <i>Controlled Buccal Delivery of Buprenorphine</i> , 25 J. Controlled Release 21 (1993)
1013	Rex M. C. Dawson et al., <i>Data for Biochemical Research</i> (3d ed. 1986)
1014	Domenic A. Ciraulo et al., <i>Pharmacokinetics and Pharmacodynamics of Multiple Sublingual Buprenorphine Tablets in Dose-Escalation Trials</i> , 46 J. Clinical Pharmacology 179 (2006)

Exhibit No.	Reference
1015	C. Nora Chiang & Richard L. Hawks, <i>Pharmacokinetics of the Combination Tablet of Buprenorphine and Naloxone</i> , 70 <i>Drug & Alcohol Dependence</i> S39 (2003)
1016	Campbell et al., <i>The History of the Development of Buprenorphine as an Addiction Therapeutic</i> , 1248 <i>Ann. N.Y. Acad. Sc.</i> (Issue: <i>Addiction Reviews</i>), 124 (2012) (“Campbell”)
1017	Bullingham et al., <i>Sublingual Buprenorphine Used Postoperatively: Clinical Observations and Preliminary Pharmacokinetic Analysis</i> , 12 <i>Br. J. Clinical Pharmacology</i> 117 (1981)
1018	U.S. Patent App. No. US 2010/0087470
1019	U.S. Patent No. 4,582,835
1020	Center for Drug Evaluation and Research, Approval Package for App. No. 22-410/S006/S007 (approval date 8/10/12) (“Film Approval Package”)
1021	Encyclopedia of Pharmaceutical Technology, 2 nd ed., Vol. I, Drug Delivery—Buccal Route (McElnay et al.) (“McElnay”)
1022	U.S. Patent No. 5,288,497 (“Stanley”)
1023	Declaration by Maureen Reitman, SC.D. (“Reitman Decl.”)
1024	Parkhurst A. Shore et al., <i>The Gastric Secretion of Drugs: A pH Partition Hypothesis</i> , 119 <i>J. Pharmacology Exp. Ther.</i> 361 (1957)
1025	Curriculum Vitae of Nandita Das, Ph.D.
1026	List of Materials Considered by Nandita Das, Ph.D.

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