

Materials Considered by Thomas A. Baillie, Ph.D., D.Sc.

Case: IPR2015-01836

Patent No. 7,932,268

Doc. No.	Nickname	Description
Paper 1	CFAD Pet.	Petition for <i>Inter Partes</i> Review of U.S. Patent No. 8,618,135, dated August, 28, 2015.
Paper 7	Institution Decision	Institution of <i>Inter Partes</i> Review, IPR2015-01835, dated March 7, 2016.
Ex. 1001	'268 Patent	U.S. Patent No. 7,932,268
Ex. 1001 ¹	'135 Patent	U.S. Patent No. 8,618,135
Ex. 1002	Zusman Dec.	Declaration of Randall J. Zusman, M.D.
Ex. 1003	Mayersohn Dec.	Declaration of Michael Mayersohn, Ph.D.
Ex. 1006	'915 Provisional	U.S. Provisional Patent Application No. 60/550,915
Ex. 1013	Pink Sheet 2004	"Bayer/PPD Implipitapide Development Follows Zetia Model", THE PINK SHEET, Vol. 66, No. 7, p. 17 (2004)
Ex. 1014	Stein	Evan Stein, "Microsomal Triglyceride Transfer Protein (MTP) Inhibitor (implipitapide) program", Presentation Given at PPD's Analyst Day (February 5, 2004)
Ex. 1015	Chang	Chang, <i>et al.</i> , "Microsomal triglyceride transfer protein (MTP) inhibitors: Discovery of clinically active inhibitors using high-throughput screening and parallel synthesis paradigms", CURRENT OPINION IN DRUG DISCOVERY & DEV., Vol. 5, No. 4, pp. 562-570 (2002)
Ex. 1018	Wetterau	Wetterau, <i>et. al.</i> , "An MTP Inhibitor That Normalizes Atherogenic Lipoprotein Levels in WHHL Rabbits," SCIENCE, Vol. 282, pp. 751-754 (1998)
Ex. 1031	Shiomi	Shiomi & Ito, "MTP inhibitor decreases plasma cholesterol levels in LDL receptor-deficient WHHL

¹ This exhibit appears in the docket for related case IPR2015-01835.

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		rabbits by lowering the VLDL secretion,” European Journal of Pharmacology, Vol. 431, pp. 127-131 (2001)
Ex. 2002	Lomitapide NDA	NDA No. 203858, Sponsor’s Background Package (October 17, 2012)
Ex. 2007	Cutchel	Cuchel, <i>et. al</i> , “Efficacy and safety of a microsomal triglyceride transfer protein inhibitor in patients with homozygous familial hypercholesterolaemia: a single-arm, open-label, phase 3 study,” THE LANCET, Vol. 381, pp. 40-46 (2013)
Ex. 2011	Pink Sheet 2000	“MTP inhibitor research discontinued”, THE PINK SHEET (2000)
Ex. 2020	Robl	Robl, <i>et. al</i> , “A Novel Series of Highly Potent Benzimidazole-Based Microsomal Triglyceride Transfer Protein Inhibitors,” JOURNAL OF MEDICINAL CHEMISTRY, Vol. 44, pp. 851-56 (2001) (Penn Ex. 2020, “Robl”)
Ex. 2028	n/a	<i>Curriculum Vitae</i> for Thomas A. Baillie, Ph.D., D.Sc.
Ex. 2034	Rowland	Rowland & Tozer, <i>Clinical Pharmacokinetics: Concepts and Applications</i> , William and Wilkins (1995)
Ex. 2035	Huang	Huang & Lie, “Phosphodiesterase-5 (PDE ₅) Inhibitors in the Management of Erectile Dysfunction”, PHARMACY AND THERAPEUTICS, Vol. 38, No. 7, pp. 407-419 (2013)
Ex. 2036	Lüllmann	Lüllmann, <i>et. al</i> , “Lipidosis Induced by Amphiphilic Cationic Drugs”, Biochemical Pharmacology, Vol. 27, pp. 1103-08 (1978)
Ex. 2037	Ploemen	Ploemen, <i>et. al</i> , “Use of physicochemical calculation of pKa and CLogP to predict phospholipidosis-inducing potential: A case study with structurally related piperazines,” EXPERIMENTAL AND TOXIC PATHOLOGY, Vol. 55, pp. 347-55 (2004)
Ex. 2038	Cavalli	Cavalli, <i>et. al</i> , “Toward a pharmacophore for drugs inducing the long QT syndrome: insights from a CoMFA study of HERG K(+) channel blockers,”

Doc. No.	Nickname	Description
		JOURNAL OF MEDICINAL CHEMISTRY, Vol. 45, pp. 3844-53 (2002) (Penn Ex. 2038, "Cavalli")
Ex. 2039	Walsh	Walsh, <i>et. al.</i> , "The Metabolic Activation of Abacavir by Human Liver Cytosol and Expressed Human Alcohol Dehydrogenase Isozymes," CHEMICO-BIOLOGICAL INTERACTIONS, Vol. 142, pp. 135-54 (2002)
Ex. 2040	Le Bigot	Le Bigot, <i>et. al.</i> , "Metabolism of Ketotifen by Human Liver Microsomes," DRUG METABOLISM AND DISPOSITION, Vol. 11, pp. 585-89 (1983)
Ex. 2041	Aegerion Press Release	Aegerion Pharmaceuticals, Press Release: "FDA Advisory Committee Recommends Approval of Lomitapide for Treatment of Homozygous Familial Hypercholesterolemia (HoFH)" (October 17, 2012)
Ex. 2042	PPD 10-K	Pharmaceutical Product Development, Inc., Annual Report for the Fiscal Year Ending December 31, 2005, SEC Form 10-K (2006)
Ex. 2054	Adams	Adams, <i>et al.</i> , "Studies on the biotransformation of ketamine. I - Identification of metabolites produced in vitro from rat liver microsomal preparations," BIOMEDICAL MASS SPECTROMETRY, Vol. 8, pp. 527-38 (1981)