

Materials Considered by S. David Kimball, Ph.D.

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. 1016	Chandler	Chandler, <i>et. al.</i> , "CP-346086: an MTP inhibitor that lowers plasma cholesterol," JOURNAL OF LIPID RESEARCH, Vol. 44, pp.1887-1901 (2003)
Ex. 2002	Lomitapide NDA	NDA No. 203858, Sponsor's Background Package (October 17, 2012)
Ex. 2011	Pink Sheet	"MTP inhibitor research discontinued", THE PINK

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

Doc. No.	Nickname	Description
	2000	SHEET (2000)
Ex. 2018	Mayersohn 1980	Mayersohn, "Designing a dosing regimen," DRUG THERAPY, Vol. 10, No. 10, pp. 99-102 (1980)
Ex. 2019	Jones	Jones, <i>et. al.</i> , "Comparative Dose Efficacy Study of Atorvastatin Versus Simvastatin, Pravastatin, Lovastatin, and Fluvastatin in Patients With Hypercholesterolemia (The CURVES Study)," THE AMERICAN JOURNAL OF CARDIOLOGY, Vol. 81, pp. 582-87 (1998)
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)
Ex. 2029	n/a	<i>Curriculum Vitae</i> for S. David Kimball, Ph.D.
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 physiochemical 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," JOURNAL OF MEDICINAL CHEMISTRY, Vol. 45, pp. 3844-53 (2002) (Penn Ex. 2038, "Cavalli")
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. 2059	Albert	Albert, <i>Xenobiosis: Food, Drugs and Poisons in the Human Body</i> , Chapman & Hall (1987)
Ex. 2060	Goodman	Goodman, <i>et. al.</i> , <i>Goodman & Gilman's The Pharmacological Basis of Therapeutics</i> , MacMillan (1985) (Penn Ex. 2060, "Goodman")
Ex. 2061	van de Waterbeemd	van de Waterbeemd & Gifford "ADMET in silico modelling: towards prediction paradise?", NATURE

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		REVIEWS DRUG DISCOVERY, Vol 2, No. 3, pp. 192-204 (2003)
Ex. 2062	Failed Drugs	“35 FDA-Approved Prescription Drugs Later Pulled from the Market”, http://prescriptiondrugs.procon.org/view.resource.php?resourceID=005528 , Last updated January 30, 2014
Ex. 2063	Halliwell	Halliwell, “Cationic Amphiphilic Drug-Induced Phospholipidosis,” TOXICOLOGIC PATHOLOGY, Vol. 25, pp. 53-60 (1997)
Ex. 2064	Fischer	Fischer <i>et. al</i> , “CAFCA: A Novel Tool for the Calculation of Amphiphilic Properties of Charged Drug Molecules,” CHIMIA, Vol. 54, pp. 640-45 (2000)
Ex. 2065	Mason	Mason, <i>et. al</i> , “Reevaluating Equilibrium and Kinetic Binding Parameters for Lipophilic Drugs Based on a Structural Model for Drug Interaction with Biological Membranes,” JOURNAL OF MEDICINAL CHEMISTRY, Vol. 34, pp. 869-77 (1991)
Ex. 2066	Tristiani-Firouzi	Tristiani-Firouzi, <i>et. al</i> , “Molecular Biology of K ⁺ Channels and Their Role in Cardiac Arrhythmias,” AMERICAN JOURNAL OF MEDICINE, Vol. 110, pp. 50-59 (2001)
Ex. 2067	Curran	Curran, <i>et. al</i> , “A Molecular Basis for Cardiac Arrhythmia: HERG Mutations Cause Long QT Syndrome,” CELL, Vol. 80, pp. 795-803 (1995)
Ex. 2068	Fermini	Fermini & Fossa, “Pre-Clinical Assessment of Drug-Induced QT Interval Prolongation, Current Issues and Impact on Drug Discovery,” ANNUAL REPORTS IN MEDICINAL CHEMISTRY, Vol. 39, pp. 323-33 (2004)
Ex. 2069	Crumb	Crumb & Cavero, “QT Interval Prolongation by Non-cardiovascular Drugs: Issues and Solutions for Novel Drug Development,” PHARMACEUTICAL SCIENCE & TECHNOLOGY TODAY, Vol. 2, pp. 270-80 (1999)
Ex. 2070	Lo	Lo, <i>et. al</i> , “Pharmacokinetics of losartan, an angiotensin II receptor antagonist, and its active

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		metabolite EXP3174 in humans,” CLINICAL PHARMACOLOGY & THERAPEUTICS, Vol. 58, No. 6, pp. 641-49 (1995)
Ex. 2071	Wilson	Block & Beale, eds., <i>Wilson and Grisvold’s Textbook of Organic Medicinal and Pharmaceutical chemistry</i> , 11 th Ed., Lippincott Williams & Wilkins, pp. 65-66 (2004)