

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

**COALITION FOR AFFORDABLE DRUGS VIII, LLC**

Petitioner,

v.

**THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA**

Patent Owner

**Case: IPR2015-01835**

Patent No. 8,618,135

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**UPDATED LIST OF PATENT OWNER'S EXHIBITS**

## PATENT OWNER'S LIST OF EXHIBITS

Ex. 2001	University of Pennsylvania Patent License Agreement (May 19, 2006)
Ex. 2002	NDA #203858, Sponsor's Background Package For the Endocrinologic and Metabolic Drugs Advisory Committee Meeting, Advisory Committee Briefing Materials (Oct. 17, 2012)
Ex. 2003	ClinicalTrials.gov: Safety, Tolerability, and Efficacy of Microsomal Triglyceride Protein (MTP) Inhibitor, available at <a href="https://clinicaltrials.gov/ct2/show/NCT01556906?term=NCT01556906&amp;rank=1">https://clinicaltrials.gov/ct2/show/NCT01556906?term=NCT01556906&amp;rank=1</a>
Ex. 2004	Marina Cuchel <i>et al.</i> , <i>Inhibition of Microsomal Triglyceride Transfer Protein in Familial Hypercholesterolemia</i> , 356 (2) N. ENG. J. MED. 148-56 (Jan. 11, 2007).
Ex. 2005	U.S. Appl. No. 14/075,483, Amendment and Response to Final Office Action (Nov. 30, 2015)
Ex. 2006	FDA News Release, FDA approves new orphan drug for rare cholesterol disorder, available at <a href="http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm333285.htm">http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm333285.htm</a> (Dec. 26, 2012)
Ex. 2007	Marina Cuchel <i>et al.</i> , <i>Efficacy and safety of a microsomal triglyceride transfer protein inhibitor in patients with homozygous familial hypercholesterolemia: a single-arm, open-label, phase 3 study</i> , 381 THE LANCET 40-46 (Jan. 5, 2013)
Ex. 2008	Joseph Walker <i>et al.</i> , <i>New Hedge Fund Strategy: Dispute the Patent, Short the Stock</i> , THE WALL STREET JOURNAL, available at <a href="http://www.wsj.com/articles/hedgefundmanagerkylebasschallengesjazzpharmaceuticalspatent1428417408">http://www.wsj.com/articles/hedgefundmanagerkylebasschallengesjazzpharmaceuticalspatent1428417408</a> (Apr. 7, 2015)
Ex. 2009	U.S. Appl. No. 13/046,118: Information Disclosure Statement (IDS) (Sept. 28, 2011)
Ex. 2010	Patentee's Observations in reply to the Notice of Opposition by Dr. Evan Stein, European Patent No. 1 725 234

Ex. 2011	The Pink Sheet, <i>MTP inhibitor research discontinued</i> (July 31, 2000)
Ex. 2012	Aegerion Pharmaceuticals, Inc., U.S. Securities and Exchange Commission, Form 10-K (March 2, 2015)
Ex. 2013	Aegerion Pharmaceuticals, Inc., U.S. Securities and Exchange Commission, Form 10-K (March 18, 2013)
Ex. 2014	Aegerion Pharmaceuticals, Inc., Third Quarter 2015 Earnings Conference Call, available at <a href="http://files.shareholder.com/downloads/AEGR/0x0x860375/8F9C1576-D084-454D-BBCF-C656C341E238/AEGR_Q3_15_Slides_Final.pdf">http://files.shareholder.com/downloads/AEGR/0x0x860375/8F9C1576-D084-454D-BBCF-C656C341E238/AEGR_Q3_15_Slides_Final.pdf</a> (Nov. 9, 2015)
Ex. 2015	JUXTAPID label (2012)
Ex. 2016	Center For Drug Evaluation And Research, Application Number 203858Orig1s00, Summary Basis for Regulatory Action (Dec. 21, 2012)
Ex. 2017	Declaration of Nicholas K. Mitrokostas in support of Patent Owner's Motion for <i>Pro Hac Vice</i> Admission of Nicholas K. Mitrokostas Under 37 C.F.R. § 42.10(c)
Ex. 2018	Michael Mayersohn, <i>Designing a Dosage Regimen: Drug Therapy</i> , CLIN. THER., Vol. 10, No. 10 (Oct. 1980).
Ex. 2019	Peter Jones <i>et al.</i> , <i>Comparative Dose Efficacy Study of Atorvastatin Versus Simvastatin, Pravastatin, Lovastatin, and Fluvastatin in Patients With Hypercholesterolemia (The CURVES Study)</i> , AM. J. CARDIOL., Vol. 81 (Mar. 1, 1998).
Ex. 2020	Jeffrey A. Robl <i>et al.</i> , <i>A Novel Series of Highly Potent Benzimidazole-Based Microsomal Triglyceride Transfer Protein Inhibitors</i> , J. MED. CHEM., Vol. 44, No. 6 (Mar. 15, 2001).
Ex. 2021	Deposition Transcript of Michael Mayersohn, Ph. D. (May 16, 2016).
Ex. 2022	Deposition Transcript of Randall M. Zusman, M.D. (May 19, 2016).
Ex. 2023	Declaration of Dr. Frank Sacks, M.D.

Ex. 2024	Declaration of Dr. Thomas A. Baillie, Ph.D., D.SC.
Ex. 2025	Declaration of S. David Kimball, Ph.D.
Ex. 2026	Declaration of Daniel J. Rader, M.D.
Ex. 2027	Dr. Frank Sacks, M.D., <i>curriculum vitae</i>
Ex. 2028	Dr. Thomas A. Baillie, Ph.D., D.SC., <i>curriculum vitae</i>
Ex. 2029	S. David Kimball, Ph.D., <i>curriculum vitae</i>
Ex. 2030	Daniel J. Rader, M.D., <i>curriculum vitae</i>
Ex. 2031	Dr. Frank Sacks, M.D., Materials Considered
Ex. 2032	Dr. Thomas A. Baillie, Ph.D., D.SC., Materials Considered
Ex. 2033	David Kimball, Ph.D., Materials Considered
Ex. 2034	Malcolm Rowland <i>et al.</i> , CLINICAL PHARMACOKINETICS: Concepts and Applications, William and Wilkins (1995).
Ex. 2035	Sharon A. Huang <i>et al.</i> , <i>Phosphodiesterase-5 (PDE5) Inhibitors In the Management of Erectile Dysfunction</i> , P T, Vol. 38, No. 7, pp. 407-419 (Jul. 2013).
Ex. 2036	Heinz Lüllmann <i>et al.</i> , <i>Lipidosis Induced by Amphiphilic Cationic Drugs</i> , BIOCHEM. PHARMACOL., Vol. 27, pp. 1103-08 (1978).
Ex. 2037	Jan-Peter H. T. M. Ploemen <i>et al.</i> , <i>Use of physiochemical calculation of pKa and CLogP to predict phospholipidosis-inducing potential: A case study with structurally related piperazines</i> , EXP. TOXIC PATHOL., Vol. 55, pp. 347-55 (2004).
Ex. 2038	Andrea Cavalli <i>et al.</i> , <i>Toward a pharmacophore for drugs inducing the long QT syndrome: insights from a CoMFA study of HERG K(+) channel blockers</i> , J. MED. CHEM., Vol. 45, pp. 3844-53 (2002).

Ex. 2039	John S. Walsh <i>et al.</i> , <i>The Metabolic Activation of Abacavir by Human Liver Cytosol and Expressed Human Alcohol Dehydrogenase Isozymes</i> , CHEM. BIOL. INTERACT., Vol. 142, pp. 135-154 (2002).
Ex. 2040	Jean F. Le Bigot <i>et al.</i> , <i>Metabolism of Ketotifen by Human Liver Microsomes</i> , DRUG METAB. DISPOS., Vol. 11, pp. 585-589 (1983).
Ex. 2041	Press Release, Aegerion Pharmaceuticals, FDA Advisory Committee Recommends Approval of Lomitapide for Treatment of Homozygous Familial Hypercholesterolemia (HoFH) (Oct. 17, 2012).
Ex. 2042	Pharmaceutical Product Development, Inc., Annual Report (Form 10-K) (Dec. 31, 2005).
Ex. 2043	Frank M. Sacks <i>et al.</i> , <i>Severe Hypertriglyceridemia With Pancreatitis: Thirteen Years' Treatment With Lomitapide</i> , JAMA INTERN. MED., Vol. 174, No. 3 (Mar. 2014).
Ex. 2044	Internet Archive WayBack, Machine Error Message (June 6, 2016).
Ex. 2045	Internet Archive WayBack Machine, PPD Analyst/Investor Day: Dapoxetine
Ex. 2046	Internet Archive WayBack Machine, PPD Analyst/Investor Day: DP4 Inhibitor
Ex. 2047	U.S. Patent No. 5,739,135
Ex. 2048	U.S. Patent No. 5,883,109
Ex. 2049	U.S. Patent No. 6,582,698
Ex. 2050	Patent Owner's Motion to Amend Under 37 C.F.R. § 42.121
Ex. 2051	Marjel van Dam <i>et al.</i> , <i>Efficacy and Safety of Implipitapide (Bay 13-9952), a Microsomal Triglyceride Transfer Protein Inhibitor, in Patients with Primary Hypercholesterolemia, Stein Phase I Study</i> (2001).

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