

Materials Considered by Frank M. Sacks
In Support of the Patent Owner Response

Case: IPR2015-01836
Patent No. 7,932,268

Doc. No.	Description
Paper 1	Petition for <i>Inter Partes</i> Review of U.S. Patent No. 7,932,268, dated August, 28, 2015
Paper 7	Institution of <i>Inter Partes</i> Review, IPR2015-01836, dated March 7, 2016
Ex. 1001 ¹	U.S. Patent No. 8,618,135
Ex. 1001	U.S. Patent No. 7,932,268
Ex. 1002	Declaration of Randall J. Zusman, M.D
Ex. 1003	Declaration of Michael Mayersohn, Ph.D.
Ex. 1006	U.S. Provisional Patent Application No. 60/550,915
Ex. 1010	Declaration of William Sasiela, Ph.D., Under 37 C.F.R. 1.132 (Apr. 8, 2010)
Ex. 1013	“Bayer/PPD Implitapide Development Follows Zetia Model”, THE PINK SHEET, Vol. 66, No. 7, p. 17 (2004)
Ex. 1014	Evan Stein, “Microsomal Triglyceride Transfer Protein (MTP) Inhibitor (implitapide) program”, Presentation Given at PPD’s Analyst Day (February 5, 2004)
Ex. 1015	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	Charles E. Chandler et al., <i>CP-346086: an MTP inhibitor that lowers plasma cholesterol and triglycerides in experimental animals and in humans</i> , 44 J. OF LIPID RES. 1887 (2003)
Ex. 1018	Wetterau, <i>et. al.</i> , “An MTP Inhibitor That Normalizes Atherogenic Lipoprotien Levels in WHHL Rabbits,” SCIENCE, Vol. 282, pp. 751-754 (1998)

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

Doc. No.	Description
Ex. 1021	THOMPSON PDR, PHYSICIANS' DESK REFERENCE 506-09, 1101-06, 1813-21, 2036-41, 2126-31, 2547-51, 2729-31, 2865-68 (57th ed. 2003) (excerpting product information for Tricor®, Pravachol®, Advicor®, Niaspan®, Mevacor®, Zocor®, Lipitor®, Colestid®, and Lescol®)
Ex. 1022	THOMPSON PDR, PHYSICIANS' DESK REFERENCE 2118-23, 3085-89 (58th ed. 2004) (excerpting product information for Zetia®)
Ex. 1031	Shiomi & Ito, <i>MTP inhibitor decreases plasma cholesterol levels in LDL receptor-deficient WHHL rabbits by lowering the VLDL secretion</i> , European Journal of Pharmacology, Vol. 431, pp. 127-131 (2001)
Ex. 2011	"MTP inhibitor research discontinued", THE PINK SHEET (2000)
Ex. 2015	JUXTAPID label (2012)
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. 2027	Dr. Frank Sacks, M.D., <i>curriculum vitae</i>
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. 2053	Marc A. Pfeffer <i>et al.</i> , <i>Safety and tolerability of pravastatin in long-term clinical trials. Prospective Pravastatin Pooling (PPP) Project</i> , CIRC. (May 21, 2002)
Ex. 2072	Christopher P. Cannon <i>et al.</i> , <i>Intensive versus Moderate Lipid Lowering with Statins after Acute Coronary Syndromes</i> , N. ENG. J. MED., Vol. 350, No. 15 (Apr. 8, 2004)
Ex. 2073	List of Prior Art Reviewed by Frank Sacks, M.D. for Motion to

Doc. No.	Description
	Amend
Ex. 2086	Visioli, F., "Microsomoal triglyceride transfer protein inhibitors," <i>Current Opinion in Cardiovascular, Pulmonary & Renal Investigational Drugs</i> 2000 2(3):292-293
Ex. 2087	Williams, S. et al., "Novel microsomal triglyceride transfer protein inhibitors," <i>Expert Opin. Ther. Patents</i> (2003) 13(4): 479-488
Ex. 2088	Funatsu, T. et al. "Atorvastatin Increases Hepatic Fatty Acid Beta-Oxidation in Sucrose-Fed Rats: Comparison with an MTP Inhibitor" <i>European Journal of Pharmacology</i> 455 (2002) 161- 167
Ex. 2089	Barclay, L., "Hyperlipidemia", <i>NMT Briefs</i> , 2003, 1-4
Ex. 2090	Evans, M., et al., "Medical Lipid-Regulating Therapy: Current Evidence, Ongoing Trials and Future Developments," <i>Drugs</i> 2004: 64 (11): 1181-1196
Ex. 2091	US5760246A Biller S. et al., 1998
Ex. 2092	Intentionally left blank
Ex. 2093	WO 98/03069, Gregg R. et al.
Ex. 2094	US6057339A, Gregg R., 2000
Ex. 2095	US6066653A, Gregg R. et al., 2000
Ex. 2096	WO1998031367, Gregg R. et al.
Ex. 2097	US6620821B2, Robl J., 2003
Ex. 2098	US6627636B2 –Robl, J. 2003
Ex. 2099	US6812345B2 – Robl, J. et al. 2004
Ex. 2100	US7358254B2 – Robl, J. et al., 2008
Ex. 2101	US5990110A, Firestone R., 1999
Ex. 2102	WO 2005/097131, Engelen, M. et al.
Ex. 2103	van Dam, M.J., Dyslipidemia; diagnosis and treatment, <i>Dissertation, UvA-DARE</i> , 2001, 147-157
Ex. 2104	U.S. National Institutes of Health, Implitapide in Patients With Hypertriglyceridemia on Maximal, Concurrent Triglyceride-Lowering Therapy, <i>NIH Clinical Trials.gov</i> , NT0008013, 2004, 1-3
Ex. 2105	U.S. National Institutes of Health, Implitapide in Patients With Homozygous Familial Hypercholesterolemia on Maximal Concurrent Lipid-Lowering Therapy, <i>NIH Clinical Trials.gov</i> , NCT00079846, 2003, 1-3
Ex. 2106	Baddour, L. et al., <i>PPD to Hold Analyst Day on February 5, 2004</i> (Jan. 15, 2004)

Doc. No.	Description
Ex. 2107	Gruetzmann R., et al., "Impitapide inhibits secretion of apoB-associated lipoproteins by inhibition of the MTP," <i>Eur. Heart J.</i> 2000, 21 (Suppl), Abst 3271, p. 600.
Ex. 2108	Bischoff, H., et al., Bay 13-9952 (implitapide): pharmacodynamic effects of a new MTP inhibitor on plasma lipids and adipose tissue in animals, <i>Eur. Heart J.</i> 2000, 21 (Suppl), Abst P3501, p. 636
Ex. 2109	Zaiss, S., et al., 194, Bay 13-9952 (Implitapide), an inhibitor of the MTP, inhibits atherosclerosis and prolongs lifetime in apo-E knockout mice, <i>Eur. Hert J.</i> 2000, 21 (Suppl), Abst 194, p. 16
Ex. 2110	Bayes, M., et al., Gateways to Clinical Trials, <i>Methods Find Exp Clin Pharmacol</i> 2002, 24(1): 37-55
Ex. 2111	Sorbera, L.A., et al., Implitapide, <i>Drugs of the Future</i> , 2000, 25(11): 1138-1144
Ex. 2112	US20060135460A1, Widder K. et al., 2006
Ex. 2113	WO 2006/063128, Widder K. et al.
Ex. 2114	US20060153913A1, Yamane S. et al., 2006
Ex. 2115	WO 2006/046623, Yamane S. et al.
Ex. 2116	US20060211762A1, Rongen, R. et al., 2006
Ex. 2117	WO 2006/062748, Rongen, R. et al.
Ex. 2118	US20070098778A1, Borsadia S., 2007
Ex. 2119	WO 2005/084666, Borsadia S.
Ex. 2120	WO 96/26205, Wetterau, J. et al.
Ex. 2121	WO 98/03174, Firestone, R.
Ex. 2122	WO 98/27979, Tino, J.
Ex. 2123	Aguilar-Salinas, C., et al., Efficacy and safety of atorvastatin in hyperlipidemic, type 2 diabetic patients. A 34-week, multicenter, open-label study, <i>Eslevier, Atherosclerosis</i> , 2000, 489-496
Ex. 2124	Capuzzi, D., et al., Niacin Dosing: Relationship to Benefits and Adverse Effect, <i>Current Atherosclerosis Reports</i> , 2000, 2, 64-71
Ex. 2125	Teramoto T. et al.; Effect of large dose of niceritrol (Percyit) on hypercholesterolemia –by administering Gradually Increasing Doses, <i>Hardening of the arteries</i> (1991), 199-208
Ex. 2126	Reference 4 cited in JPA No. 2007-502093, Vol. 40, 3389-3397.
Ex. 2127	Knopp R., Treatment of Lipid Disorders, <i>New England Journal of Medicine</i> , August, 1999, Vol. 341:498-511
Ex. 2128	Bays, H. et al., Pharmacotherapy for dyslipidaemia - current

Doc. No.	Description
	therapies and future agents, <i>Expert Opin. Pharmacother.</i> (2003) 4(11), 1901-38
Ex. 2129	Bruckert, E., New lipid-modifying therapies, <i>Expert Opin. Invescig. Drugs</i> (2003) 12(3): 325-335
Ex. 2130	Kastelein, J., What future for combination therapies? <i>Int. J. Clin. Pract. Suppl. Mar. 2003</i> , (134), 45-50
Ex. 2131	US4686237A, Anderson, P., 1987
Ex. 2132	WO 98 31366, Behounek, E. et al.
Ex. 2133	US6194454B1, Dow, R., 2001
Ex. 2134	US20020035064A1, Robl, J. et al, 2002
Ex. 2135	US20080248070A1, Tunac J, 2008
Ex. 2136	US20050101561A, Tunac J., 2005
Ex. 2137	WO 98/31225, Gregg, R.
Ex. 2138	WO 98/50028, Gregg, R. et al.
Ex. 2139	US6875782B2, Cheng, P. et al., 2005
Ex. 2140	US20030109543A1, Ogletree, M., 2003
Ex. 2141	US20040058908A1, Keller, B, et al., 2004
Ex. 2142	WO 00/38725, Keller, B, et al.
Ex. 2143	US20070099884A1, Erondur, N, et al., 2007
Ex. 2144	WO 2004/110375, Erondur, N, et al.
Ex. 2145	WO 2005/000217, Erondur, N, et al.
Ex. 2146	Microsomal Triglyceride Transfer Protein, 1-6
Ex. 2147	Wetterau, J., et al., Microsomal triglyceride transfer protein, <i>Biochimica et Biophysica Acta</i> 1345 (1997) 136-150
Ex. 2148	Thomas, L., Alleviation of MTP inhibitor-induced hepatic steatosis in hyperlipidemic fa/fa rats by fenofibrate, Department of Metabolic Diseases and Dept. of Chemical Research, <i>Boehringer Ingelheim</i> , 1 page
Ex. 2149	Wierzbicki, A., New lipid-lowering agents, <i>Expert Opin. Emerging Drugs</i> (2003) 8(2): 365-376
Ex. 2150	Atzel, A., et al., Mechanism of Microsomal Triglyceride Transfer Protein Catalyzed Lipid Transport, <i>Biochemistry</i> 1993, 32, 10444-10450
Ex. 2151	Bakillah, A., et al., Decreased Secretion of ApoB Follows Inhibition of ApoB-MTP Binding by a Novel Antagonist, <i>Biochemistry</i> 2000, 39, 4892-4899

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.