

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS VIII, LLC
Petitioner

v.

TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA
Patent Owner, based on Electronic Records of PTO
U.S. Patent No. 8,618,135 B2 to Rader
Filing Date: March 11, 2011
Issue Date: December 31, 2013

TITLE: METHODS FOR TREATING DISORDERS OR DISEASES ASSOCIATED
WITH HYPERLIPIDEMIA AND HYPERCHOLESTEROLEMIA WHILE
MINIMIZING SIDE EFFECTS

Inter Partes Review Trial No. TBD

**Declaration of Michael Mayersohn, Ph.D. in Support of Coalition for
Affordable Drugs' Petition for
Inter Partes Review of U.S. Patent No. 8,618,135 B2**

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TABLE OF EXHIBITS

Exhibit	Title
CFAD 1001	Certified U.S. Patent No. 8,618,135.
CFAD 1002	Declaration of Randall M. Zusman, M.D.
CFAD 1005	<p>Affidavit of Christopher Butler, Office Manager, Internet Archive, authenticating Internet Archive URLs (June 12, 2015) (attaching as Ex. A:</p> <p><i>PPD News Releases(2004/02/13)</i> (available at https://web.archive.org/web/20040213233245/http://www.ppd.com/PPD_U6.htm?ID=126662);</p> <p><i>PPD News & IR Presentations(2003/12/12)</i> (available at https://web.archive.org/web/20031212193444/http://ppdi.com/PPD_6_12.htm);</p> <p><i>PPD News & IR Presentations (2004/06/04)</i> (available at https://web.archive.org/web/20040604203252/http://www.ppd.com/PPD_6_12.htm)).</p>
CFAD 1006	Certified U.S. Provisional Patent Application No. 60/550,915.
CFAD 1007	U.S. Patent No. 8,618,135 (highlighting dosing information not present in U.S. Provisional Patent Application No. 60/550,915).
CFAD 1013	<i>Bayer/PPD Implitapide Development Follows Zetia Model As Statin Add-On</i> , 66 THE PINK SHEET 17 (Feb. 16, 2004).
CFAD 1014	Evan Stein, CEO & President, MRL Int'l (Division of PPD), Presentation Given at PPD's Analyst Day, <i>Microsomal Triglyceride [sic] Transfer Protein (MTP) Inhibitor (implitapide) program</i> (Feb. 5, 2004).
CFAD 1015	George Chang et al., <i>Microsomal triglyceride transfer protein (MTP) inhibitors: Discovery of clinically active inhibitors using high-throughput screening and parallel synthesis paradigms</i> , 5 CURRENT OPINION IN DRUG DISCOVERY & DEV.

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	562 (2002).
CFAD 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).
CFAD 1018	John R. Wetterau et al., <i>An MTP Inhibitor That Normalizes Atherogenic Lipoprotein Levels in WHHL Rabbits</i> , 282 SCI. 751 (1998).
CFAD 1023	U.S. FOOD & DRUG ASS'N, ESTIMATING THE MAXIMUM SAFE STARTING DOSE IN INITIAL CLINICAL TRIALS FOR THERAPEUTICS IN ADULT HEALTHY VOLUNTEERS: GUIDANCE FOR INDUSTRY (2005).
CFAD 1026	Rowland & Tozer, <i>Clinical Pharmacokinetics: Concepts and Applications</i> , 58, 98 (1995)
CFAD 1029	Michael Mayersohn. Ph.D. Curriculum Vitae
CFAD 1032	M. Mayersohn, <i>Principles and Applications of Pharmacokinetics</i> , in MEDICAL TOXICOLOGY, 282 (2004)
CFAD 1033	Shiomi & Ito, "MTP inhibitor decreases plasma cholesterol levels in LDL receptor-deficient WHHL rabbits by lowering the VLDL secretion," <i>European Journal of Pharmacology</i> , 431:127-131 (2001)
CFAD 1038	Margaret A. McDowell et al., <i>Anthropometric Reference Data for Children and Adults: U.S. Population, 1999-2002</i> , CDC ADVANCE DATA FROM VITAL & HEALTH STATS. NO. 361 (2005)

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