

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 8,618,135 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 No.: IPR2015-01835

**Supplemental Declaration of Randall M. Zusman, M.D. in Support of
Coalition for Affordable Drugs' Petition
for *Inter Partes* Review of U.S. Patent No. 8,618,135 and Opposition To
Motion To Amend**

Exhibit 1049

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(a)	“A method of treating a subject suffering from hyperlipidemia or hypercholesterolemia, the method comprising administering to the subject an effective amount of an MTP inhibitor, wherein said administration comprises ...”	9
(b)	“administering to the subject an effective amount of an MTP inhibitor, wherein said administration comprises at least three step-wise, increasing dose levels of the MTP inhibitor,”	10
(c)	“wherein a first and a second dose level is 50% of the immediately following dose level, and”	13
(d)	“wherein a third dose level is from about 0.2 to about 0.59 mg/kg/day based on a weight between 62.5 and 74.9 kg, and.”	13
(e)	“wherein the MTP inhibitor is N-(2,2,2-trifluoroethyl)-9-[4-[4-[[[4’ (trifluoromethyl)[1,1’-biphenyl]-2-yl] carbonyl] amino]-1-piperidinyl]butyl]-9H-fluorene-9-carboxamide, methanesulfonate, and”	15
(f)	wherein each dose level is administered to the subject for about 1 to about 5 weeks.	16
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TABLE OF EXHIBITS

Exhibit	Title
1001	U.S. Patent No. 8,618,135
1003	Declaration of Michael Mayersohn, Ph.D.
1005	Declaration of Christopher Butler, dated June 12, 2015, authenticating Internet Archive URLs attached as Ex. A: <i>PPD News Releases(2/13/2004)</i> (available at https://web.archive.org/web/20040213233245/http://www.ppdi.com/PPD_U6.htm?ID=126662); <i>PPD News & IR Presentations(12/12/2003)</i> (available at https://web.archive.org/web/20031212193444/http://ppdi.com/PPD_6_12.htm); <i>PPD News & IR Presentations(6/4/2004)</i> (available at https://web.archive.org/web/20040604203252/http://www.ppdi.com/PPD_6_12.htm) (“PPD Screenshot”)
1006	U.S. Provisional Patent Application No. 60/550,915
1007	Highlighted 135 Patent identifying new dosing information not included in the 915 Provisional
1009	135 Patent File History, March 4, 2013 Amendment and Response
1010	135 Patent File History, Declaration of William Sasiela (“Sasiela Declaration”)
1013	<i>Bayer/PPD Implitapide Development Follows ZETIA Model As Statin Add-On</i> , 66 THE PINK SHEET 17 (Feb. 16, 2004) (“Pink Sheet”)
1014	Evan Stein, <i>Microsomal Triglyceride [sic] Transfer Protein (MTP) Inhibitor (implitapide) program</i> (Feb. 5, 2004) (“Stein 2004”)
1015	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 & DEVELOPMENT 562 (2002) (“Chang”)

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