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

U.S. Patent 7,932,268 to Rader

Inter Partes Review No.: IPR2015-01836

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. 7,932,268 and Opposition To Motion To Amend

Exhibit 1045

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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," 9

(c) "wherein a first and a second dose level is 50% of the immediately following dose level, and" 12

(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 4 weeks. 16

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CONCLUSION.....**Error! Bookmark not defined.**

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TABLE OF EXHIBITS

Ex. No.	Description
1001	Certified U.S. Patent No. 7,932,268 to Rader.
1002	Declaration of Randall M. Zusman, M.D.
1003	Declaration of Michael Mayersohn, Ph.D.
1004	Affidavit of Christopher Butler, Office Manager, Internet Archive, authenticating Internet Archive URLs (June 16, 2015) (attaching as Ex. A: *PPD News & IR Presentations (2004/04/15)* (available at https://web.archive.org/web/20040415065142/http://ppdi.com/PPD_6_12.htm)).
1005	Affidavit of Christopher Butler, Office Manager, Internet Archive, authenticating Internet Archive URLs (June 12, 2015) (attaching as Ex. A: *PPD News Releases(2004/02/13)* (available at https://web.archive.org/web/20040213233245/http://www.ppdi.com/PPD_U6.htm?ID=126662); *PPD News & IR Presentations(2003/12/12)* (available at https://web.archive.org/web/20031212193444/http://ppdi.com/PPD_6_12.htm); *PPD News & IR Presentations (2004/06/04)* (available at https://web.archive.org/web/20040604203252/http://www.ppdi.com/PPD_6_12.htm)).
1006	Certified U.S. Provisional Patent Application No. 60/550,915.
1007	U.S. Patent No. 7,932,268 (highlighting dosing information not present in U.S. Provisional Patent Application No. 60/550,915).
1008	U.S. Patent Application No. 10/591,923.
1009	In re Application of: Rader, U.S. Patent Application No. 10/591,923, Response to Oct. 21, 2009 Office Action (Apr. 14, 2010).

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