

Reply To Patent Owner's Response for *Inter Partes* Review of USPN 8,618,135

Filed on behalf of Coalition for Affordable Drugs VIII, LLC

By: Dr. Gregory Gonsalves

Reg. No. 43,639

2216 Beacon Lane

Falls Church, Virginia 22043

(571) 419-7252

gonsalves@gonsalveslawfirm.com

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

IPR Trial No. IPR2015-01835

Petitioner's Reply for *Inter Partes* Review of U.S. Patent No. 8,618,135

Mail Stop "PATENT BOARD"

Patent Trial and Appeal Board

U.S. Patent and Trademark Office

P.O. Box 1450

Alexandria, VA 22313-1450

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	THE LEVEL OF ORDINARY SKILL IN THE ART.	2
III.	CLAIM CONSTRUCTION STATEMENT (37 C.F.R. § 42.104(B)(3)).	3
IV.	GROUND 1: CLAIMS 1-10 ARE OBVIOUS IN VIEW OF THE <i>PINK SHEET 2004</i> AND <i>CHANG</i>	6
A.	The Protocol Proposed In The <i>Pink Sheet</i> Is Fundamentally The Same As The Claimed Invention.	6
B.	A POSA Would Have Been Motivated To Develop Lomitapide In March 2005.	8
C.	A POSA Would Have Had A Reasonable Expectation Of Success In Using the <i>Pink Sheet</i> Protocol With Lomitapide.	12
V.	GROUND 2: CLAIMS 1-10 ARE OBVIOUS IN VIEW OF <i>STEIN</i> AND <i>CHANG</i>	15
A.	<i>Stein</i> Is Prior Art.	15
B.	A POSA Would Have Been Motivated To Combine <i>Chang</i> and <i>Stein</i> And Would Have Had A Reasonable Expectation Of Success.	17
VI.	THERE IS NO NEXUS BETWEEN THE ALLEGED INDICIA OF NONOBVIOUSNESS AND THE CLAIMS.	18
A.	The Dosing Method That Was Alleged By Patent Owner To Have Unexpected Results Is Not Required By The Claims.	18
B.	The Long-Felt, But Unmet, Need Alleged By Patent Owner Has No Nexus To The Claimed Invention.	19
C.	The Failure Of Others Alleged By Patent Owner Has No Nexus To The Claimed Invention.	20

Reply To Patent Owner’s Response for *Inter Partes* Review of USPN 8,618,135

D.	The Praise Of Others Alleged By Patent Owner Has No Nexus To The Claimed Invention.	22
E.	The Alleged Commercial Success Of Juxtapid Has No Nexus To The Claimed Invention.	23
VII.	CONCLUSION.....	24

Reply To Patent Owner's Response for *Inter Partes* Review of USPN 8,618,135

EXHIBIT LIST PURSUANT TO 37 C.F.R. § 42.63(e) AND TABLE OF ABBREVIATIONS

Ex. No.	Description
1001	Certified U.S. Patent No. 8,618,135 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: <i>PPD News & IR Presentations (2004/04/15)</i> (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: <i>PPD News Releases(2004/02/13)</i> (available at https://web.archive.org/web/20040213233245/http://www.ppdi.com/PPD_U6.htm?ID=126662); <i>PPD News & IR Presentations(2003/12/12)</i> (available at https://web.archive.org/web/20031212193444/http://ppdi.com/PPD_6_12.htm); <i>PPD News & IR Presentations (2004/06/04)</i> (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. 8,618,135 (highlighting dosing information not present in U.S. Provisional Patent Application No. 60/550,915).
1008	U.S. Patent Application No. 13/046,118.

Reply To Patent Owner's Response for *Inter Partes* Review of USPN 8,618,135

1009	<i>In re Application of: Rader</i> , U.S. Patent Application No. 13/046,118, Amendment and Response to Oct. 2, 2012 Office Action (Mar. 4, 2013).
1010	<i>In re Application of: Rader</i> , U.S. Patent Application No. 13/046,118, Declaration of William Sasiela, Ph.D. (Apr. 8, 2010).
1011	<i>In re Application of: Rader</i> , U.S. Patent Application No. 13/046,118, Notice of Allowance (May 10, 2013).
1012	<i>In re Application of: Rader</i> , U.S. Patent Application No. 13/046,118, Notice of Allowance (Sept. 3, 2013).
1013	<i>Bayer/PPD Implitapide Development Follows Zetia Model As Statin Add-On</i> , 66 THE PINK SHEET 17 (Feb. 16, 2004).
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).
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. 562 (2002).
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).
1017	<i>FDA approves Zetia -- first new class to treat cholesterol since statins introduced</i> , DRUGS.COM (Oct. 28, 2002), http://www.drugs.com/news/fda-approves-zetia-first-new-class-cholesterol-since-statins-introduced-3164.html (last visited July 22, 2015).
1018	John R. Wetterau et al., <i>An MTP Inhibitor That Normalizes Atherogenic Lipoprotein Levels in WHHL Rabbits</i> , 282 SCI. 751 (1998).
1019	U.S. Patent No. 5,712,279 to Biller et al.

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.