

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

**Declaration of Christopher Casieri 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 1060

Petitioner's Responses To Patent Owner's Objections Dated September 14, 2016
Petition for *Inter Partes* Review 2015-01835

I, Christopher Casieri, declare as follows:

1. I am a partner with the law firm of McNeely Hare & War LLP, counsel for Petitioner Coalition for Affordable Drugs VIII ("Coalition") in this matter.
2. I am a practicing attorney and am a member in good standing of the Bars of the State of New Jersey (2000) and the District of Columbia (2000), as well as the United States District Court for the District of New Jersey (2000). I am also admitted to practice before USPTO (Registration No. 50,919).
3. I submit this Declaration 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 Petition for *Inter Partes Review* of U.S. Patent No. 8,618,135 B2, and, in particular, to authenticate certain exhibits cited and referenced in Coalition's Petition. I understand that my declaration will be included in Petitioner's Exhibit List as CFAD Ex. 1060.
4. I have personal knowledge of the facts stated in this Declaration. All of the exhibits cited herein are publically available.
5. Exhibit 1061 is a true and correct copy of a document entitled "Guidance for Industry 2002, Estimating the Safe Starting Dose in Clinical Trials for Therapeutics in Adult Healthy Volunteers" (2002). It is publically available from the Food and Drug Administration's (FDA) website at

<http://www.fda.gov/OHRMS/DOCKETS/98fr/02d-0492-gdl0001-vol1.pdf>. This exhibit is included in Petitioner's Exhibit List as CFAD Ex. 1045. The yellow highlighting in Ex. 1045 does not appear in the original and is removed from Exhibit 1061.

6. Exhibit 1062 is a true and correct copy of ICH-E4, Dose-Response Information to Support Drug Registration (1994). It is publically available from the FDA's website at

<http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073115.pdf>. This exhibit is included in Petitioner's Exhibit List as CFAD Ex. 1046. The yellow highlighting in Ex. 1046 does not appear in the original and is removed from Exhibit 1062.

7. Exhibit 1063 is a true and correct copy of the FDA Label for Crestor®. It is publically available from the FDA's website at

http://www.accessdata.fda.gov/drugsatfda_docs/label/2003/21366_crestor_lbl.pdf.

This exhibit is included in Petitioner's Exhibit List as CFAD Ex. 1050. The yellow highlighting in Ex. 1050 does not appear in the original and is removed from Exhibit 1063.

8. Exhibit 1064 is a true and correct copy of the FDA Label for Vytorin™. It is publically available from the FDA's website at

http://www.accessdata.fda.gov/drugsatfda_docs/label/2004/21687lbl.pdf. This

exhibit is included in Petitioner's Exhibit List as CFAD Ex. 1051. The yellow highlighting in Ex. 1051 does not appear in the original and is removed from Exhibit 1064.

9. Exhibit 1065 is a true and correct copy of the FDA Label for Zocor®. It is publically available from FDA's website at http://www.accessdata.fda.gov/drugsatfda_docs/label/2001/19766s45s53lbl.pdf.

This exhibit is included in Petitioner's Exhibit List as CFAD Ex. 1052. The yellow highlighting in Ex. 1052 does not appear in the original and is removed from Exhibit 1065.

10. Exhibit 1066 is a true and correct copy of the FDA Label for Caduet®. It is publically available from the FDA's website at http://www.accessdata.fda.gov/drugsatfda_docs/label/2004/21540_caduet_lbl.pdf.

This exhibit is included in Petitioner's Exhibit List as CFAD Ex. 1053. The yellow highlighting in Ex. 1053 does not appear in the original and is removed from Exhibit 1066.

11. Exhibit 1067 is a true and correct copy of the FDA Label for Lipitor®. It is publically available from the FDA's website at http://www.accessdata.fda.gov/drugsatfda_docs/label/2001/20702s25lbl.pdf. This exhibit is included in Petitioner's Exhibit List as CFAD Ex. 1054. The yellow

Petitioner's Responses To Patent Owner's Objections Dated September 14, 2016
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highlighting in Ex. 1054 does not appear in the original and is removed from Exhibit 1067.

12. Exhibit 1068 is a true and correct copy of the FDA Label for ZetiaTM. It is publically available from the FDA's website at http://www.accessdata.fda.gov/drugsatfda_docs/label/2002/214451bl.pdf. This exhibit is included in Petitioner's Exhibit List as CFAD Ex. 1055. The yellow highlighting in Ex. 1055 does not appear in the original and is removed from Exhibit 1068.

13. I hereby declare that all statements made herein are true and correct; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Date: September 28, 2016

Respectfully Submitted,



Christopher Casieri