

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

**PETITIONER'S RESPONSE TO
PATENT OWNER'S OBSERVATIONS ON CROSS-EXAMINATION OF
PETITIONER'S REPLY WITNESS**

1. Response to Observation No. 1

Petitioners respond that the cited testimony is not relevant to this proceeding. In Ex. 2306, on pages 44, lines 9-15 (cited in the observation), Dr. Zusman testified, “That dose was one of the factors that was associated with side effects in the previously conducted trials.” The cited testimony is not relevant because the testimony does not address the manner or extent in which the dose was a factor with side effects in the previously conducted trials. The answer also does not address the other factors and if the extent those other factors increased the side effects of lomitapide.

2. Response to Observation No. 2

Petitioners respond that the cited testimony is not relevant to this proceeding. In Ex. 2306, on pages 50, line 22-page 51, line 14 (cited in the observation), Dr. Zusman testified that he saw that Chang (Ex. 1015) stated, “similar AST and ALT elevations of a magnitude sufficient to halt the development of BMS-20138 [lomitapide] were also reported.” The cited testimony is not relevant because the testimony is there is no dispute as to the specific wording of that one sentence in Chang. While Dr. Zusman answers the question that is asked, the answer does not address the basis for his opinion as why a POSA would have had motivation to restart development of lomitapide.

3. Response to Observation No. 3

Petitioners respond that the cited testimony is not relevant to this proceeding. Patent Owner cites to Ex. 2306, on pages 51, line 15-page 54, line 14 (cited in the observation). Patent Owner claims, Dr. Zusman testified that that Exhibit 2001, which includes the Technology Donation Agreement, is dated “May 19, 2006” and “is not prior art.” As an initial matter, Patent Owner inappropriately condenses three pages of testimony into one sentence. Regardless, the cited testimony is not relevant because Exhibit 2001 contains, as an Exhibit, a restated and amended version of the Original TDA from 2003.

Date: November 10, 2016

Respectfully Submitted,



Christopher Casieri

CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing PETITIONER’S RESPONSE TO PATENT OWNER’S OBSERVATIONS ON CROSS-EXAMINATION OF PETITIONER’S REPLY WITNESS list for this proceeding were served on November 10, 2016 by delivering copies via electronic mail on the following attorneys of record for the Patent Owner.

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Date: November 10, 2016

Respectfully Submitted,

/Gregory J. Gonsalves/

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