

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

COALITION FOR AFFORDABLE DRUGS VIII, LLC

Petitioner,

v.

THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA

Patent Owner

Case: IPR2015-01836

Patent No. 7,932,268

**SUPPLEMENTAL DECLARATION OF
THOMAS A. BAILLIE, PH.D., D.SC.**

EXHIBIT 2305

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1. I, Thomas A. Baillie, have been retained to testify on behalf of Patent Owner the Trustees of the University of Pennsylvania (“Penn”) in this proceeding as an expert in medicinal chemistry and pharmacology.

I. SUMMARY OF OPINIONS

2. I am aware that Petitioner Coalition for Affordable Drugs VIII, LLC (“CFAD”) is challenging the validity of U.S. Patents Nos. 7,932,268 (“the ’268 patent”) and 8,618,135 (“the ’135 patent”) (collectively, the “patents-at-issue”) in separate *Inter Partes* Review (“IPR”) proceedings before the Patent Trial and Appeal Board (“PTAB”) of the United States Patent and Trademark Office. I am also aware that PTAB has instituted IPR proceedings with respect to both of the patents-at-issue.

3. I am aware that Penn has proposed a contingent amendment to the claims of the ’268 patent, in the event the PTAB finds the original claims unpatentable. Specifically, I understand that Penn has contingently proposed the addition of five substitute claims, numbered 9-14. I will henceforth refer to these proposed new claims of the patents-at-issue as the “substitute claims.”

4. I am aware that Penn is the sole assignee and owner of the patents-at-issue, and that rights to the patent have been licensed to Aegerion Pharmaceuticals, Inc. (“Aegerion”). I am also aware that Aegerion currently markets the drug

compound lomitapide in the United States for the treatment of homozygous familial hypercholesterolemia (“HoFH”) under the trade name JUXTAPID®.

5. I previously offered written testimony in this proceeding in my Declaration of Thomas A. Baillie, Ph.D., D.Sc. (Penn Ex. 2024, “Baillie Dec.”). In that Declaration, I opined that the both the original and substitute claims of the patents-at-issue were not unpatentable as obvious.

6. I am aware that both CFAD and its expert, Dr. Randall J. Zusman, M.D., have recently asserted that the substitute claims of the patents-at-issue are invalid as obvious. Petitioner’s Opposition To Patent Owner’s Contingent Motion To Amend (Paper No. 30, “CFAD Opposition”); Supplemental Declaration of Randall J. Zusman, M.D. (CFAD Ex. 1045, “Zusman Suppl. Dec.”). I have reviewed both the CFAD Opposition and Dr. Zusman’s Supplemental Declaration, and my opinions regarding the non-obviousness of the substitute claims have not changed. Accordingly, I submit this declaration to respond to CFAD’s and Dr. Zusman’s assertions regarding the alleged invalidity of the substitute claims.

7. I hereby incorporate by reference the entirety of my prior Declaration in this proceeding. While I will periodically refer to my non-obviousness opinions expressed therein, I will not, for the sake of brevity, repeat the sections of that Declaration regarding my qualifications, the claims of the patents-at-issue, legal

concepts relevant to my opinions, my tutorial on the background scientific issues relevant to my testimony, my prior testimony in other proceedings, and my compensation. Penn Ex. 2024 (Baillie Dec.) at ¶¶ 7-95, 147-48.

II. MATERIALS CONSIDERED

8. In forming my opinions and views expressed in this Declaration, I have relied upon my knowledge, education and training, as well as my many years of experience in the field of medicinal chemistry and pharmacology, as reflected in my qualifications and credentials set forth in the my previous Declaration, Penn Ex. 2024 (Baillie Dec.) at ¶¶ 7-13, and in my *curriculum vitae*, Penn Ex. 2028. I have also considered the documents cited herein and the documents listed in both Penn Ex. 2032 and Penn Ex. 2307.

III. OPINIONS

9. Dr. Zusman¹ has asserted that the subject matter of substitute claims of the '268 patent would have been obvious to a person of ordinary skill in the art.

¹ I will focus my opinions on responding to the invalidity arguments made by CFAD's expert Dr. Zusman in his Supplemental Declaration. However, because the invalidity arguments made by Dr. Zusman in his Supplemental Declaration are substantively the same as those made by CFAD in its Opposition, my opinions apply equally well in response to CFAD's Opposition.

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