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: IPR2015-01835
Patent No. 8,618,135

DECLARATION OF DR. S. DAVID KIMBALL, PH.D.

PENN EX. 2025
CEAD v. PENN

TABLE OF CONTENTS

1. I, S. David Kimball, 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.

I. SUMMARY OF OPINIONS

2. I am aware that Petitioner Coalition for Affordable Drugs VIII, LLC ("CFAD") has sought to challenge 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 each of the patents-at-issue.

3. I am aware that although Penn is the sole assignee and owner of the patents-at-issue, the patent is currently licensed to Aegerion Pharmaceuticals, Inc. ("Aegerion"). I am also aware that, according to the terms of this license, Aegerion currently markets the drug compound lomitapide in the United States under the trade name JUXTAPID®.

4. I have been retained to address the assertions in the Declaration of Michael Mayersohn, Ph.D. (CFAD Ex. 1003, "Mayersohn Dec.") and the Declaration of Randall J. Zusman, M.D. (CFAD Ex. 1002, "Zusman Dec.")

regarding the alleged invalidity of the patents-at-issue. In my Declaration, I will provide my opinion regarding how the chemical structure of a drug compound can impact its biological performance and clinical use. It is my opinion that the patents-at-issue are not invalid for obviousness because (1) there are significant chemical differences between lomitapide, implitapide, and other contemporary MTP inhibitors; (2) there is no motivation in the prior art for a person of ordinary skill in the art to specifically select lomitapide for development over other MTP inhibitors; and (3) a person of ordinary skill in the art would not have a reasonable expectation of success dosing lomitapide in the same manner as proposed for implitapide in "Bayer/PPD Implitapide Development Follows Zetia Model", The Pink Sheet, Vol. 66, No. 7, p. 17 (2004) (CFAD Ex. 1013, "Pink Sheet 2004") and/or Evan Stein, "Microsomal Triglyceride Transfer Protein (MTP) Inhibitor (implitapide) program", Presentation Given at PPD's Analyst Day (February 5, 2004) (CFAD Ex. 1014, "Stein").

5. Additionally, I have been asked to address the non-obviousness of certain proposed claims that I understand Penn has submitted with its Motion to Amend in this proceeding to claim priority to Provisional U.S. Patent Application No. 60/550,915 ("the '915 Provisional"). As explained in further detail below, and

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