

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

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

PENN EX. 2024
CEAD v. PENN

TABLE OF CONTENTS

I. Summary of Opinions.....1

II. Materials Considered.....3

III. Qualifications.....3

IV. The Patents-At-Issue6

 A. The '268 Patent6

 1. Overview6

 2. Existing Claims7

 3. Proposed Claim Amendment8

 B. The '135 Patent10

 1. Overview10

 2. Existing Claims11

 3. Proposed Claim Amendment15

V. Legal Principles18

 A. Patent Validity19

 B. The Person of Ordinary Skill in the Art19

 C. Obviousness.....21

VI. Opinions.....22

 A. Tutorial22

 1. Understanding the relationship between a drug’s PK and PD properties is required to design an optimal dosing regimen.23

 2. The chemical structure of a drug determines its PK and PD properties.28

 3. MTP inhibitors have a distinct mechanism of action and toxicity profile. .36

 B. Obviousness.....39

 1. Dr. Mayersohn does not address the differences between lomitapide and implitapide.40

 2. Dr. Mayersohn overstates the teachings of Stein and Pink Sheet 2004.....51

 3. Dr. Mayersohn’s obviousness combinations fail to establish either a motivation to combine or a reasonable expectation of success.....54

4. Secondary considerations favor non-obviousness.64
5. Conclusion.....70
6. Proposed Claim Amendment71
VII. Conclusion.....72
VIII. Prior Expert Testimony72
IX. Compensation73

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”) 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 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 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

provide my opinions regarding the relationship between a drug compound's chemical structure and its pharmacological effects, and how that relationship has an impact on the dosing of the drug to patients. It is my opinion that the claims of the patents-at-issue are not invalid for obviousness for at least the following principal reasons: (1) implitapide and lomitapide have important differences in chemical structure that would preclude an expectation that they could be dosed in the same manner; (2) a person of ordinary skill in the art would not have had a reasonable expectation of success in applying the implitapide protocol mentioned in either "Bayer/PPD Implitapide Development Follows Zetia Model", THE PINK SHEET, Vol. 66, No. 7, p. 17 (2004) (CFAD Ex. 1013, "Pink Sheet 2004") 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") to lomitapide; (3) the obviousness combinations offered by CFAD, Dr. Zusman and Dr. Mayersohn establish neither a motivation to combine nor a reasonable expectation of success; and (4) secondary considerations, namely failure of others and unexpected results, further demonstrate non-obviousness.

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 these proceedings. As explained in further detail below, and for reasons

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.