

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.
Petitioners,

v.

ALMIRALL, LLC.
Patent Owner

Case IPR2019-01095

U.S. Patent No. 9,517,219

Declaration of Marc Serota, M.D.

TABLE OF CONTENTS

I. Overview	1
II. Summary of Opinions	2
III. My Background and Qualifications	3
IV. List of documents I considered in formulating my opinions	5
V. Basis of my analysis with respect to obviousness.....	6
VI. The Person of Ordinary Skill in the Art	7
VII. Claim Construction.....	9
VIII. Background: Dapsone was a well-known topical treatment for skin conditions, including acne vulgaris and rosacea, and methods of using topical dapsone to treat these conditions were well-known in the art.....	12
IX. Garrett teaches methods for treatment of acne vulgaris and rosacea by administering to a patient having such a condition topical compositions containing 7.5% w/w dapsone.	15
X. Topical dapsone compositions that did not include adapalene would have been obvious.....	18
XI. No clinical objective indicia of non-obviousness exist.....	18
XII. Conclusion.....	21

I, Marc Serota, hereby declare as follows.

I. Overview

1. I am over the age of eighteen (18) and otherwise competent to make this declaration.

2. I have been retained as an expert witness on behalf of Petitioner Mylan Pharmaceuticals Inc. for the above-captioned *inter partes* review (“IPR”). I am being compensated for my time in connection with this IPR at my standard consulting rate, which is \$700/hr. I understand that the petition for IPR involves U.S. Patent No. 9,517,219 (“the ’219 patent”), MYLAN1001, which resulted from U.S. Application No. 14/885,805 (“the ’805 application”), filed on October 16, 2015, and is a divisional application derived from the application that issued as U.S. Patent No. 9,161,926. The ’219 patent names Kevin S. Warner, Ajay P. Parashar, Vijaya Swaminathan, and Varsha Bhatt as inventors. The ’219 patent issued on December 13, 2016, from the ’805 application. The face of the ’219 patent states that it is assigned to Allergan, Inc., but I understand that, according to USPTO records, the ’219 patent is assigned to Almirall, LLC (“Almirall”).¹

3. The ’219 patent is generally directed to methods of treating acne vulgaris or rosacea, in patients with those conditions, by administering a topical

¹ Throughout this declaration, I will refer to both Allergan and Almirall as “Almirall.”

pharmaceutical composition comprising 7.5% w/w dapsone and various excipients, including: diethylene glycol monoethyl ether; a polymeric viscosity builder comprising acrylamide/sodium acryloyldimethyl taurate copolymer; water; and wherein the composition does not include adapalene. Some of the claims of the '219 patent are directed to this method of treatment, but also include methyl paraben as a preservative.

II. Summary of Opinions

4. I have been asked by Counsel for Mylan to assess the obviousness of the '219 patent from a clinical perspective. Claim 1 is exemplary of the clinical issues I address in my declaration. Claim 1 reads:

1. A method for treating a dermatological condition selected from the group consisting of acne vulgaris and rosacea comprising administering to a subject having the dermatological condition selected from the group consisting of acne vulgaris and rosacea a topical pharmaceutical composition comprising:
about 7.5% w/w dapsone;
about 30% w/w to about 40% w/w diethylene glycol monoethyl ether;
about 2% w/w to about 6% w/w of a polymeric viscosity builder consistent of acrylamide/sodium acryloyldimethyl taurate copolymer;
and water; wherein the composition does not comprise adapalene.

5. In my opinion, the treatment of acne vulgaris or rosacea by administering a pharmaceutical composition comprising 7.5% w/w dapsone in a topical composition would have been obvious in view of Garrett and the general

knowledge in the prior art.² In addition, in view of Garrett and the general knowledge in the art, topical dapson e compositions that did not contain adapalene would have been obvious. Finally, in my opinion, there are no clinical objective indicia of nonobviousness.

III. My Background and Qualifications

6. I am an expert in the field of dermatology and in the treatment of patients suffering from dermatological disorders, including acne, atopic dermatitis, chronic urticaria, psoriasis, allergic contact dermatitis and many other skin conditions treated by a dermatologist.

7. I am a supervising physician in Dermatology at the University of Colorado and a Physician and Attending/Supervising physician at the Veteran's Affairs Hospital in Denver and am in private practice at Peak Dermatology in Littleton, CO. Prior to holding these positions I was a physician with the Colorado Dermatology Specialists from 2015-2017. I have been practicing general medical dermatology for nearly 10 years and am triple Board Certified in Dermatology, Pediatrics, and Allergy/Immunology and am licensed to practice Dermatology and

² I understand from Counsel that "prior art" means the store of knowledge, including scientific, clinical, and patent literature, and other publically available information and disclosures that are relevant to the subject matter claimed in the '219 patent.

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.