

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS LLC and AMNEAL
PHARMACEUTICALS OF NEW YORK, LLC,
Petitioners,

v.

ALMIRALL, LLC.
Patent Owner

Case IPR2019-00207

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

Declaration of Elaine S. Gilmore, M.D., Ph.D.

Inter Partes Review of U.S. Patent No. 9,517,219
Declaration of Elaine S. Gilmore, M.D., Ph.D.
(Exhibit 1018)

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***Inter Partes Review of U.S. Patent No. 9,517,219
Declaration of Elaine S. Gilmore, M.D., Ph.D.
(Exhibit 1018)***

I, Elaine S. Gilmore, 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 Petitioners Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York, LLC 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 \$500/hr. I understand that the petition for IPR involves U.S. Patent No. 9,517,219 (“the ’219 patent”), AMN1001, 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

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

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

7. I am the medical director of Universal Dermatology, PLLC in Fairport, NY, a former Assistant Professor of Dermatology and Medical Director of University Dermatology Associates (Henrietta, NY), and former Director of the Medical Student Dermatology Course and Clerkship at the University of Rochester School of Medicine and Dentistry, Department of Dermatology. I am Board Certified in Dermatology by the American Board of Dermatology. I have worked and taught extensively in the fields of cell and molecular physiology and dermatology. I have a full-time private practice in which I treat patients with general dermatological disorders, including numerous patients suffering from acne vulgaris and rosacea. My *curriculum vitae* is provided as AMN1019.

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.

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