

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.

~~ALLERGAN, INC.~~ ALMIRALL, LLC.
Patent Owner

Case: IPR~~2018-00608~~ 2019-00207

U.S. Patent No. ~~9,161,926~~ 9,517,219

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

AMN1018

Inter Partes Review of U.S. Patent No. ~~9,161,926~~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. ~~9,161,926~~9,517,219 (“the ‘926219 patent”), AMN1001, which resulted from U.S. Application No. ~~14/082,955~~885,805 (“the ‘955805 application”), filed on ~~November 18, 2013,~~
~~naming~~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 ‘926219 patent issued on ~~October 20, 2015,~~December 13, 2016, from the ‘955805 application. The face of the ‘219 patent states that it is assigned to
Allergan, Inc., but I~~further~~ understand that, according to USPTO records, the ‘926219 patent is assigned to ~~Allergan, Inc. (“the Patent Owner~~Almirall, LLC

[\("Almirall"\)](#).¹

3. The '926219 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 '926219 patent are directed to this ~~topical dapsone composition~~[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 '926219 patent from a clinical perspective. Claim 1 is exemplary of the clinical issues I address in my declaration. [Claim 1](#) reads:

[A1. 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](#)

¹ [Throughout this declaration, I will refer to both Allergan and Almirall as "Almirall."](#)

adapalene.

5. In my opinion, the ~~use of~~ treatment of acne vulgaris or rosacea by administering a pharmaceutical composition comprising 7.5% w/w dapsones in a topical composition would have been obvious in view of Garrett and the general knowledge in the prior art.^{1 2} In addition, in view of Garrett and the general knowledge in the art, topical dapsones 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

~~¹ I understand “prior art” to mean 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 ’926 patent.~~

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.

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

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.

8. ~~7.~~ I earned a Bachelor of Science degree in Biology and a Bachelor of Arts degree in Chemistry from Providence College, *summa cum laude*, in 1996. I earned an M.D. and Ph.D. from the University of North Carolina at Chapel Hill in 2003 and 2001, respectively. My doctoral research focused on cell and molecular physiology, specifically on ion channel regulation in the lungs and kidneys. I completed a residency in dermatology at Yale-New Haven Hospital in 2006 and a research fellowship in dermatology at Yale in 2008.

9. ~~8.~~ I have received several honors in my career, including the Brian P. Flanagan Faculty Teaching Award at the University of Rochester (2013); Wilmot Cancer Research Fellowship Grant (2011); Wilmot Cancer Center Lymphoma SPORE Career Development Award (2011); Dermatology Foundation Fellowship Grant (2007); Medical Scientist Training Program (MSTP) Scholarship (1996-2003); University of North Carolina Travel Grant (2000); Renaissance Physiology Department Travel Award (2000); John B. Graham Research Society Travel Grant

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