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.
Patent Owner

Case: IPR2018-00608

U.S. Patent No. 9,161,926

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

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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 ("the '926 patent"), AMN1001, which resulted from U.S. Application No. 14/082,955 ("the '955 application"), filed on November 18, 2013, naming Kevin S. Warner, Ajay P. Parashar, Vijaya Swaminathan, and Varsha Bhatt as inventors. The '926 patent issued on October 20, 2015, from the '955 application. I further understand that, according to USPTO records, the '926 patent is assigned to Allergan, Inc. ("the Patent Owner").

3. The '926 patent is generally directed to 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 '926 patent are

directed to this topical dapsone composition 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 '926 patent from a clinical perspective. Claim 1 is exemplary of the clinical issues I address in my declaration:

> 1. 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 use of 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.[1] 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.

[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.

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 and rosacea. My *curriculum vitae* is provided as AMN1019.

8. 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. 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

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