

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
Patent 9,517,219

**DECLARATION OF LEON H. KIRCIK, M.D. IN SUPPORT OF PATENT
OWNER'S RESPONSE TO PETITION FOR *INTER PARTES* REVIEW**

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I, Dr. Leon H. Kircik, declare as follows:

I. INTRODUCTION

1. I am Leon H. Kircik, M.D., and I submit this declaration on behalf of Almirall, LLC (“Almirall”), the patent owner of United States Patent No. 9,517,219 (the “219 patent”), the subject matter of the above-referenced petition for *inter partes* review by Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York, LLC (“Amneal” or “Petitioner”). Specifically, I submit this declaration in response to the declaration of Dr. Elaine S. Gilmore proffered by Petitioner, and in support of Almirall’s Patent Owner Response.

A. Background and Qualifications

2. I am an expert in the field of dermatology and in the treatment of patients suffering from dermatological disorders, including acne and rosacea.

3. I earned a Bachelor of Arts in chemistry from New York University, *magna cum laude*, in 1985, where I was a member of the Phi Beta Kappa honor society. I subsequently earned my M.D. *cum laude* in 1989 from the State University of New York Health Sciences Center at Brooklyn, and was a member of the Alpha Omega Alpha Honor Medical Society. I completed an internship in internal medicine from 1989 to 1990 at New York Medical College, and completed a residency in dermatology from 1990 to 1993 at the State University of New York Health Sciences Center at Buffalo, and was chief resident during the last year. I

have been certified by the American Board of Dermatology since December 1993.

I also completed a Mohs micrographic surgery and cutaneous oncology fellowship at the University of Wisconsin in 1994. I am currently licensed to practice in New York, Wisconsin, Kentucky, Indiana, and Virginia.

4. I have served on faculties at State University of New York Health Sciences Center at Buffalo, State University of New York Health Sciences Center at Brooklyn, and currently hold appointments as Associate Clinical Professor of Dermatology at Indiana University Medical Center and at Mount Sinai Medical Center in New York, where I have been faculty since 2005 and 2008, respectively.

5. Throughout my career, I have published widely in peer-reviewed journals, with over 200 publications to my name. I have also presented hundreds of posters at industry meetings, and am frequently invited to give talks on new and emerging treatments in dermatology, including acne and rosacea treatments. In my career, I have given hundreds of talks at industry meetings and symposia as well as local seminars.

6. I was named one of the Stars of the Academy by the American Academy of Dermatology in 2016 and 2017. I serve on the editorial board of several key journals in the field, including the Journal of Drugs in Dermatology, the Journal of Clinical & Aesthetic Dermatology, Skin & Ageing, and Practical Dermatology. I have served as Medical Monitor for Kamedis Pharmaceuticals and

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