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

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

DECLARATION OF BOZENA B. MICHNIAK-KOHN, Ph.D., FAAPS, M.R.Pharm.S.

AMN1002

I, Bozena B. Michniak-Kohn, do hereby declare as follows:

I.   Overview

1.   I am over the age of 18 and otherwise competent to make this declaration. I have been retained as an expert on behalf of Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York, LLC ("Amneal"). I understand from counsel this declaration is being submitted together with a petition for *Inter Partes* Review ("IPR") of claims 1-~~6~~8 of U.S. Patent No. ~~9,161,926~~9,517,219 ("the '~~926~~219 patent") (AMN1001).

2.   I am being compensated for my time in connection with this IPR at my standard legal consultant rate of $650/hr. I have no personal or financial interest in Amneal or in the outcome of this proceeding.

3.   In preparing this declaration, I have reviewed the '~~926~~219 patent (AMN1001) and considered each of the documents cited therein, in light of the general knowledge in the art before November 20, 2012. I have also relied upon my experience in the relevant art and considered the viewpoint of a person of ordinary skill in the art ("POSA"; defined in § IV) before November 20, 2012.

4.   ~~Claims 1~~As set forth below, claims 1-4 and 6-7 of the '~~926~~219 patent would have been obvious over the prior art. I understand from counsel that another expert on behalf of Amneal will address claims 5 and 8. Each of the claimed ~~elements~~compositional components were known in the art for use in topical

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compositions. Specifically, each of the elements were known for use in dapsone compositions, many in the same amounts as claimed. Each element is performing the same function it is known for in the art, and the prior art teaches that modifications to these amounts were within the skill of the art and would result in predictable changes to the compositions.

5.   This declaration sets forth my opinion that a POSA would have had a reason to arrive at the subject matter recited in claims 1-4 and 6-7 of the '~~926~~219 patent, with a reasonable expectation of success, by combining either:

(1)   the disclosures of Garrett (AMN1004), Nadau-Fourcade (AMN1005), and a POSA's knowledge of the prior state of the art, or

(2)   the disclosures of Garrett (AMN1004), Bonacucina (AMN1015), and a POSA's knowledge of the prior state of the art, as discussed in this declaration below.

II.   My background and qualifications

6.   My qualifications and credentials are fully set forth in my *curriculum vitae*, attached as AMN1003. I am an expert in the field of topical pharmaceutical compositions and transdermal drug delivery systems. Over the past 37 years, I have accumulated significant experience designing and testing novel formulations for topical and transdermal drug delivery systems including creams, gels, emulsions, and micro- and nano-carrier systems.

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7.   I received a B.S. in Pharmacy from DeMontfort University, Leicester, England, in 1977. I received my Ph.D. in Pharmacology from DeMontfort University in 1980. I held Postdoctoral Fellowships at the University of Florida's College of Pharmacy from 1981-1983, and at the University of Bradford's Postgraduate School of Studies in Pharmacy from 1983-1986. I am a member of the Royal Pharmaceutical Society of Great Britain (license #73637.)

8.   I was an Assistant Professor in the Department of Basic Pharmaceutical Sciences-Pharmaceutics (tenure-track) at the University of South Carolina's College of Pharmacy from 1987-1993, an Associate Professor from 1993-1998, and Full Professor with tenure from 1998-2000. From 2000-2005, I was an Associate Professor in the Department of Physiology and Pharmacology at the University of Medicine and Dentistry of New Jersey- NJ Medical School. Since 2005, I have been a tenured Professor in Pharmaceutics at Rutgers- The State University of New Jersey.

9.   Since 2000, I have acted as the Director of the Laboratory for Drug Delivery at the New Jersey Center for Biomaterials at Rutgers. In 2011, I founded the Center for Dermal Research at Rutgers and continue to act as its Director. I am currently a member of the Editorial Boards of several peer-reviewed journals including the Clinical Dermatology Research Journal (SciTechnol), Research and Reports in Transdermal Drug Discovery (Dove Medical Press, Ltd.), Journal of Drug

Research and Development (Sciforshen), and the Journal of Drug Discovery (Hindawi Publishing Company).

10. Since 2007, I have been a member of the Steering Committee of the Dermatopharmaceutics Focus Group of the American Association of Pharmaceutical Scientists. I have been an invited member of the College of NIH CSR reviewers since 2010. I have been a member of the Faculty of the National Institute for Pharmaceutical Technology and Education since 2014. Since 2014, I have acted as the Academic Chair of the Transdermal section of the Non-Invasive Macromolecule Consortium Working Group of the Catalent Applied Drug Delivery Institute. I have also organized numerous industry events and conferences.

11. I have published hundreds of peer-reviewed articles, book chapters, and abstracts related to the field of topical drug delivery and pharmaceutical compositions. I have also been invited to speak about the field of topical drug delivery and formulations at numerous industry conferences.

12. In view of my experiences and expertise outlined above and provided in my CV, I am an expert in the field of topical pharmaceutical compositions and transdermal drug delivery. For this reason, I am qualified to provide an opinion as to what a person of ordinary skill in the art would have understood, known, or concluded as of November 20, 2012.

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