

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

ALLERGAN, INC.  
Patent Owner

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Case: IPR2018-00608

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

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

*Inter Partes Review of U.S. Patent No. 9,161,926  
Declaration of Bozena B. Michniak-Kohn, Ph.D., FAAPS, M.R.Pharm.S.  
(Exhibit 1002)*

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(Exhibit 1002)*

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 this declaration is being submitted together with a petition for *Inter Partes* Review (“IPR”) of claims 1-6 of U.S. Patent No. 9,161,926 (“the ’926 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 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 1-6 of the ’926 patent would have been obvious over the prior art. Each of the claimed elements were known in the art for use in topical compositions. Specifically, each of the elements were known for use in dapsone compositions, many in the same amounts as claimed. Each element is performing

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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 1-6 of the '926 patent, with a reasonable expectation of success, by combining either:

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

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.

7. I received a B.S. in Pharmacy from DeMontfort University, Leicester, England, in 1977. I received my Ph.D. in Pharmacology from DeMontfort

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