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

U.S. Patent No. 9,517,219

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

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TABLE OF CONTENTS

I. Overview 3
II. My background and qualifications 4
III. Basis for my opinion 7
IV. Person of ordinary skill in the art 9
V. State of the art before November 20, 2012 11
VI. The '219 patent and its claims 19
A. Independent claims 1 and 6 20
B. Dependent claims 2-8 21
VII. Claims 1-4 and 6-7 would have been obvious over Garrett in view of Nadau-Fourcade 22
A. Garrett (AMN1004) 23
B. Nadau-Fourcade (AMN1005) 25
C. Independent claims 1 and 6 25
1. A POSA would have had reason to prepare a topical composition comprising "about 7.5% w/w dapsone," "about 30% w/w to about 40% w/w diethylene glycol monoethyl ether," and "water," wherein "the composition does not comprise adapalene" 31
2. A POSA would have had a reason to prepare a topical composition comprising "about 2% w/w to about 6% w/w of a polymeric viscosity builder comprising acrylamide/sodium acryloyldimethyl taurate copolymer" 34
3. A POSA would have had reason to prepare a topical composition comprising "about 30% w/w diethylene glycol monoethyl ether" and "about 4% w/w of a polymeric viscosity builder comprising acrylamide/sodium acryloyldimethyl taurate copolymer" 37
4. The claimed compositional components are well-known for use in topical compositions and therefore a POSA would have had a reasonable expectation of successfully combining them 39
D. Dependent Claims 2-4 and 7 41

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1. Claim 2 41
2. Claim 3 42
3. Claims 4 and 7 42

VIII. Claims 1-4 and 6-7 would have been obvious over Garrett in view of Bonacucina 43

A. Bonacucina (AMN1015) 43
B. Independent claims 1 and 5 45
1. A POSA would have had reason to prepare a topical composition comprising "about 7.5% w/w dapsone," "about 30% w/w to about 40% w/w diethylene glycol monoethyl ether," and "water," wherein "the composition does not comprise adapalene" 49
2. A POSA would have had reason to prepare a topical composition comprising "about 2% w/w to about 6% w/w of a polymeric viscosity builder comprising acrylamide/sodium acryloyldimethyl taurate copolymer" 53
3. A POSA would have had reason to prepare a topical composition comprising "about 30% w/w diethylene glycol monoethyl ether" and "about 4% w/w of a polymeric viscosity builder comprising acrylamide/sodium acryloyldimethyl taurate copolymer" 60
4. The claimed compositional components are well-known for use in topical compositions and therefore a POSA would have had a reasonable expectation of successfully combining them 62
C. Dependent Claims 2-4 and 7 64
1. Claim 2 64
2. Claim 3 65
3. Claims 4 and 7 65

IX. No objective indicia of non-obviousness exist 66

A. Incompatibility and smaller particle size would not have been unexpected. 66
B. There was no "teaching away" from combining the claimed components in the prior art 72

X. Conclusion 72

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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 1-8 of U.S. Patent No. 9,517,219 ("the '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 '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. As set forth below, claims 1-4 and 6-7 of the '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 compositional components were known in the art for use in topical compositions. Specifically,

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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 '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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