

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC,
Petitioners,

v.

ALMIRALL, LLC
Patent Owner

Case IPR2019-01095

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

DECLARATION OF AUDRA L. STINCHCOMB, Ph.D.

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I, Audra L. Stinchcomb, 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 Mylan Pharmaceuticals Inc. (“Mylan”). 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”) (MYLAN1001).

2. I am being compensated for my time in connection with this IPR at my standard legal consultant rate of \$500/hr. I have no personal or financial interest in Mylan or in the outcome of this proceeding.

3. In preparing this declaration, I have reviewed the ’219 patent (MYLAN1001) 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 Mylan will address claims 5 and 8. Each of the claimed compositional components 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 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 (MYLAN1004), Nadau-Fourcade (MYLAN 1005), and a POSA's knowledge of the prior state of the art, or

(2) the disclosures of Garrett (MYLAN1004), Bonacucina (MYLAN1015), 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 MYLAN1036. I am an expert in the field of topical pharmaceutical compositions and transdermal drug delivery systems. Over almost 30 years, I have accumulated significant experience designing and testing novel formulations for topical and transdermal drug delivery systems including creams, gels, ointments, and patches.

7. I received my Pre-Pharmacy Degree at the University of Southern Colorado, Pueblo, Colorado in 1986, and my B.S. in Pharmacy from the University

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