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

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

AMN1043
Amneal v. Almirall, LLC

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

I. Introduction

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 in an *Inter Partes* Review ("IPR") proceeding concerning claims 1-8 of U.S. Patent No. 9,517,219 ("the '219 patent") (AMN1001). 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.

2. I have previously submitted a declaration in this IPR.

II. Basis for my opinion

3. In arriving at my opinion below, I considered Dr. Osborne's Declaration (EX2057) as well as certain documents cited in Dr. Osborne's declaration, and the documents cited herein.

III. A POSA would have considered the referenced prior art

4. Dr. Osborne argues that a POSA would not have considered Garrett, Nadau-Fourcade, Bonacucina to arrive at the inventions claimed in the '219 patent. EX2057, ¶¶110-111. I disagree. A POSA would have understood that Garrett's dapsone formulations referenced the previously FDA-approved 5%

ACZONE formulation. I understand that Dr. Osborne has also admitted that John Steven Garrett, the inventor of the Garrett reference, was heavily involved in the development of the 5% ACZONE formulation. I also disagree that a POSA would have viewed the FDA Review Package to be the richest source of information about a drug after it is approved. I understand from counsel that a POSA would have been aware of all of the prior art and would not have given any particular reference "priority" as Dr. Osborne argues.

IV. Garrett does not teach away, or otherwise dissuade, a POSA from topical dapsone compositions.

A. A POSA would not have avoided topical compositions containing undissolved dapsone.

5. Dr. Osborne argues that a POSA had no reason to select Garrett as a prior art reference because of its formulation design where some dapsone was dissolved in the composition and some dapsone was undissolved. EX2057, ¶¶112-115. I disagree. Importantly, the challenged claims are not limited to any particular dissolution state and so the claimed dapsone can be in any form: dissolved, undissolved, a mixture of the two. Similarly, I disagree with Dr. Osborne's premise that a POSA would have avoided Garrett, especially since Garrett disclosed that "the dapsone may exist as a microparticulate form, a dissolved form, or both." AMN1004, 3:12-13, 4:29-31.

6. Dr. Osborne has also argued that "suspending a drug in undissolved solid particulate form for topical administration was loathed by artisans, and generally avoided as a formulation design choice." EX2057, ¶¶42, 115. This argument is contradicted by Dr. Osborne's own patented dapsone formulation, U.S. Patent No. 5,863,560, which describes its invention as "a pharmaceutical carrier system comprising…a semi-solid aqueous gel, wherein a pharmaceutical is dissolved…and wherein the composition also contains pharmaceutical in a microparticulate state…." AMN1016, 2:57-65. That is, Dr. Osborne's own patent disclosed the exact formulation design he argues is "loathed" by artisans. Furthermore, Dr. Osborne himself was also actively pursuing and patenting other suspension formulations prior to 2012. AMN1042.

7. In addition, a POSA would have known that the FDA-approved ACZONE 5% formulation already contained this dual-state formulation design. AMN1009, 4. Dr. Osborne's opinion is inconsistent with the fact that he asserts that ACZONE 5% Gel was "optimized" "[d]espite a relatively high amount of dispersed dapsone." EX2057, ¶¶44, 154, 186-187; AMN1009, 4. Indeed, Dr. Osborne agrees that Garrett discloses only one single topical dapsone embodiment, which is the commercially-available ACZONE 5%. EX2057, ¶53. And despite the dual-state design where some dapsone was dissolved and other dapsone was undissolved, FDA evaluated the ACZONE 5% Gel and assessed its

safety, efficacy, and stability and determined that it was safe and effective to treat acne. AMN1010, 1; AMN1004, 4; EX2042, 4. Therefore, a POSA would not have disregarded Garrett or otherwise been dissuaded from considering Garrett.

8. Dr. Osborne also argues that Ahluwahlia (EX2008) taught that the efficacy of ACZONE 5% was low because of poor absorption caused by the undissolved dapsone in the formulation. EX2057, ¶114. A POSA would not have avoided a suspended formulation with undissolved dapsone just from reading this reference. First, Garrett expressly taught that dapsone can be in dissolved form, undissolved form, or a mixture of both. AMN1004, 4:29-31. Therefore, a POSA would understand that poor absorption could be solved by adjusting the amount of undissolved dapsone in the formulation, which is expressly taught in Garrett and was within the skill of a POSA. Second, as stated above, a POSA would have been aware that the ACZONE 5% formulation contained undissolved dapsone and would not have avoided such a suspension formulation. Third, Ahluwalia doesn't mention undissolved dapsone so a POSA would not understand the reference to criticize or discredit the use of undissolved dapsone in a topical composition.

9. In sum, a POSA's consideration of topical dapsone compositions with undissolved dapsone would not have been the product of hindsight nor would a POSA have been dissuaded considering such compositions.

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