

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: IPR2018-00608

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

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

AMN1050

Amneal v. Almirall LLC

Inter Partes Review of U.S. Patent No. 9,161,926
Second Declaration of Bozena B. Michniak-Kohn, Ph.D., FAAPS,
M.R.Pharm.S. (Exhibit 1050)

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 1-6 of U.S. Patent No. 9,161,926 (“the ’926 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. Klibanov’s Declaration (Ex. 2003) as well as certain documents cited in Dr. Klibanov’s declaration, and the documents cited herein.

III. A construction of “dapsonе” is not necessary as Garrett discloses the claimed “dapsonе” and a POSA would understand the amounts of dapsonе shown in Garrett would apply to 4-4’diaminodiphenyl sulfone.

4. Dr. Klibanov argues that the challenged claims are limited to a specific “dapsonе” chemical name: 4,4’-diaminodiphenyl sulfone. Ex. 2003, ¶¶142-43.

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5. A POSA would have understood from the prior art that dapsons has the chemical formula $C_{12}H_{12}N_2O_2$ and can be referred to as 4,4'-diaminodiphenyl sulfone or 4,4'-sulfonyldianiline or bis (4-aminophenyl)sulfone. AMN1007, [0022]; AMN1004, 8:17-22; AMN1010, 1. The fact that the '926 patent says "[d]apsone (4,4'-diaminophenyl sulfone)" (AMN1001, 2:6) would simply be understood by a POSA to refer to dapsons generally, and would not have been understood to exclude synonymous chemical names for dapsons.

6. Next, Dr. Klibanov argues that (1) Garrett does not disclose the claimed "dapsons" structure and (2) a POSA would not understand Garrett's teaching of using about 5% to 10% w/w dapsons in a topical composition would apply to the claimed "dapsons." Ex. 2003, ¶¶79, 82-85, 142, 148. I disagree. Regardless of whether the claimed "dapsons" was limited to the compound 4-4'-diaminodiphenyl sulfone, Garrett discloses this compound and teaches that the amount taught in Garrett would apply to this compound.

7. First, Garrett says that "'dapsons' refers to the chemical compound dapsons having the chemical formula $C_{12}H_{12}N_2O_2S$ as well as bis(4-aminophenyl)sulfone, 4'4'-diaminodiphenyl sulfone, and its hydrates ... dapsons analogs, and dapsons related compounds." AMN1004, 8:18-22 (emphasis added). From this disclosure a POSA would understand that 4'4'-diaminodiphenyl sulfone is the claimed compound that Dr. Klibanov seeks to limit the claimed "dapsons"

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to.¹ Moreover, Garrett discloses the chemical structure of dapsone “C₁₂H₁₂N₂O₂S” and then identifies several different ways of identifying that structure using different naming conventions (“bis(4-aminophenyl)sulfone” versus “4’4’-diaminodiphenyl sulfone”) but a POSA would understand these chemical names to be synonyms because they are referring to the same chemical structure. It appears that Dr. Klibanov agrees. AMN1004, 8:18-27, 10:28-31; Ex. 2003, ¶47. And the “dapsone analogs” and “dapsone related compounds” in Garrett are derived from that same basic chemical structure, so if a POSA were considering “dapsone analogs” or “dapsone related compounds” she would additionally envisage the 4,4-diaminodiphenyl sulfone structure. AMN1004, 8:22-27.

¹ The only difference between the “4’4’-diaminodiphenyl sulfone” structure in Garrett and Almirall’s proposed construction is the first apostrophe which is bolded for emphasis: **4’4’**-diaminodiphenyl sulfone. Dr. Klibanov does not appear to argue that this difference is meaningful, and a POSA would not consider it so, because the apostrophe in the chemical name merely conveys that each phenyl ring contains an amino group at the 4-position. Because both amino groups in the structure could not be located at the same 4-position, a POSA would be able to understand the chemical structure regardless of the added apostrophe.

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8. Second, a POSA would understand that the amount of dapsone disclosed by Garrett would apply to the 4,4'-diaminodiphenyl sulfone compound. Throughout Garrett, it distinguishes between “dapsone” and “dapsone analogs and related compounds.” Garrett says that ACZONE Gel, 5% is “a topical formulation of *dapsone*” and that it is approved by Food and Drug Administration (“FDA”) to treat acne vulgaris. AMN1004, 10:6-9 (emphasis added). Garrett also says that “dapsone” was first synthesized in 1908. AMN1004, 10:27-28. Conversely, Garrett later describes “dapsone analogs and related compounds” and discusses activity and toxicity comparison testing *against dapsone*. AMN1004, 11:1-12. From these disclosures, and notwithstanding Garrett’s definition of “dapsone,” a POSA would have understood that when Garrett simply refers to “dapsone,” it means the 4,4'-diaminodiphenyl sulfone compound. Accordingly, a POSA would consider Garrett’s disclosure of compositions containing about 5% to 10% w/w dapsone to apply to the 4,4'-diaminodiphenyl sulfone structure.

9. Third, of the compounds encompassed by Garrett’s definition of “dapsone,” the 4,4'-diaminodiphenyl sulfone compound was the only one approved by FDA for the treatment of acne, thus Garrett’s disclosure of using topical compositions containing “about 5% to 10% dapsone,” which encompasses the FDA-approved amount of 4,4'-diaminodiphenyl sulfone, would have been understood by a POSA to apply to the 4,4'-diaminodiphenyl sulfone compound.

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