UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SLAYBACK PHARMA, LLC
Petitioner,

v.

EYE THERAPIES, LLC
Patent Owner

Case No. IPR2022-00142
U.S. Patent No. 8,293,742

DECLARATION OF PAUL LASKAR, PH.D IN SUPPORT OF PETITIONER'S REPLY

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I, Paul Laskar Ph.D., declare as follows:

I. INTRODUCTION

1. I am the same Paul Laskar, Ph.D., who submitted a declaration dated November 4, 2021, in support of Petitioner's *inter partes* review of U.S. Patent 8,293,742 (EX-1001, "the '742 patent"). I understand that the Board has instituted *inter partes* review of claims 1–6 of the '742 patent, and that the Patent Owner has filed a Patent Owner's Response ("POR"), together with Dr. Noecker's Declaration (EX-2020, "the Noecker Declaration"), Dr. Williams' Declaration (EX-2021, "the Williams Declaration"), and Dr. Davies' Declaration in support of the POR (EX-2022, "the Davies Declaration"). I submit this reply Declaration in support of Petitioner's reply to the POR and to respond to the arguments made by Dr. Noecker, Dr. Williams, and Dr. Davies.

2. I am being compensated at my standard rate for my time spent preparing this declaration, and my compensation is not contingent on the outcome of any matter or on any of the opinions provided below. I have no financial interest in the outcome of this proceeding.

3. In my Opening Declaration, I provided a summary of my background, qualifications and expertise, together with a copy of my *curriculum vitae*. I also provided my understanding of the relevant legal principles. My understanding of these principles has not changed since I wrote my Opening Declaration.

II. MATERIALS CONSIDERED

4. In preparing this Reply Declaration, I considered the Board's Institution Decision, the POR, the Williams Declaration (Ex. 2021), the Noecker Declaration (Ex. 2020), the Davies Declaration (Ex. 2022), the materials cited in those declarations that are relevant to my opinions, and materials identified in Exhibit D to this declaration. I also considered my first declaration and the materials listed in Exhibit C that I considered in preparing my first declaration.

III. ABOUT 0.025% INCLUDES 0.03%

5. I have reviewed and considered Dr. Williams's and Dr. Noecker's opinions that "about 0.025%" does not include 0.03%. For the reasons I explain in more detail below, the opinions by Dr. Williams and Dr. Noecker do not change my opinion that a POSA would understand "about 0.025%" to include a brimonidine concentration of 0.03%.

6. Dr. Williams opines that 0.025% does not include 0.03% because, according to Dr. Williams, a POSA would have understood "about" to mean ± 10% due to "typical" FDA acceptance criteria and statements in the U.S. Pharmacopoeia ("USP"). EX-2021 (Williams Decl.), ¶¶ 39, 44–50. Dr. Williams also disagrees that typical rounding principles should apply to "about 0.025%." *Id.*, ¶¶ 39, 46. Dr. Noecker states that a POSA would have understood that 0.025% and 0.03% do not overlap because they are listed separately in the '742 patent.

EX-2020 (Noecker Decl.),¶ 109. I disagree with the conclusions that Dr. Williams and Dr. Noecker draw, and I address each of these in turn below.

A. FDA Acceptance Criteria and the U.S. Pharmacopoeia Are Not the Proper References for Interpreting the '742 Patent

7. I disagree with Dr. Williams that a POSA would turn to "typical" FDA acceptance criteria and a definition in the USP to determine the meaning of "about" in the context of the '742 patent. EX-2021 (Williams Decl.), ¶ 43. At the outset, there is no indication in the '742 patent that the inventors intended to define the "about" using manufacturing tolerance levels set by United States "regulatory authorities" such as FDA and USP. The '742 patent does not direct a POSA to FDA acceptance criteria or limitations imposed by the USP. Neither document is cited or otherwise referred to in the specification.

8. I also disagree with Dr. Williams' reliance on the manufacturing tolerances set by U.S. regulatory authorities for the separate reason that the tolerances set by USP and FDA serve different purposes than the use of "about 0.025%" in the claims of the '742 patent. *Id*., ¶¶ 44-45. The claims of the '742 patent are directed toward "method[s] for reducing eye redness," without regard to the many additional factors used by FDA and USP when setting manufacturing tolerances. EX-1001 ('742 patent), claims 1, 3. For example, FDA does not limit itself to the efficacy of products when setting acceptance criteria. Rather,

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