Paper 9

Entered: July 15, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

OCULAR THERAPEUTIX, Petitioner,

v.

MATI THERAPEUTICS, INC., Patent Owner.

Case IPR2019-00442 Patent 9,463,114 B2

Before ERICA A. FRANKLIN, J. JOHN LEE, and RYAN H. FLAX, *Administrative Patent Judges*.

LEE, Administrative Patent Judge.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314(a)



INTRODUCTION

Ocular Therapeutix ("Petitioner") filed a Petition (Paper 8, "Pet.")¹ requesting an *inter partes* review of claims 1, 3, 5–8, 10, and 12–14 ("the challenged claims") of U.S. Patent No. 9,463,114 B2 (Ex. 1001, "the '114 Patent"). Mati Therapeutics, Inc. ("Patent Owner") timely filed a Preliminary Response (Paper 7, "Prelim. Resp.").

We have authority to institute an *inter partes* review only if the information presented in the Petition shows "there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). Upon consideration of the Petition and the Preliminary Response, we conclude the information presented fails to show a reasonable likelihood that Petitioner would prevail in establishing the unpatentability of the challenged claims. Accordingly, the Petition is denied.

A. Related Cases

The parties identify a petition requesting *inter partes* review of U.S. Patent 9,849,082 (IPR2019-00448), which relates to the technology of the '114 Patent, but is not in the same patent family. Pet. 3; Paper 5, 2.

B. The '114 Patent

The '114 Patent relates to punctal plugs that are removably inserted into the punctal apertures of the eye to block the openings and prevent

¹ Petitioner filed the original Petition on December 14, 2018 (Paper 1), and subsequently filed a Corrected Petition on May 13, 2019 (Paper 8), to address a typographical error in the original Petition. All references to "Petition" herein refer to the Corrected Petition (Paper 8).



drainage of lacrimal fluid (tears). Ex. 1001, 1:13–18. In particular, the '114 Patent is directed to a method for administering an active agent in the eye of a subject by implanting a punctal plug to which the active agent is applied. *Id.*, Abstract. Figure 1 of the '114 Patent is reproduced below:

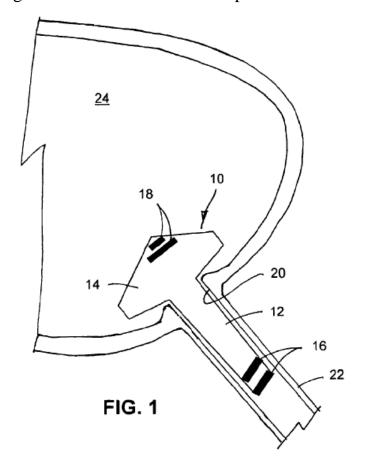


Figure 1 illustrates punctal plug 10 with stem 12, which has been inserted into punctal aperture 20 of eye 24 to seal canaliculus 22 against the flow of tears onto the surface of eye 24. *Id.* at 1:65–67, 2:7–14. Figure 2 of the '114 Patent is reproduced below:

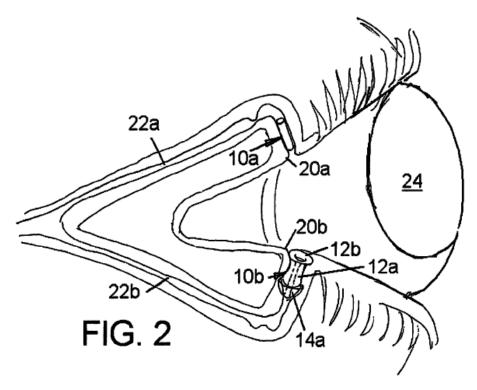


Figure 2 depicts two versions of plug 10 as implants 10*a* and 10*b*. *Id*. at 2:1–2, 15–18. Implant 10*a* is a substantially-cylindrical solid collagen plug inserted into the upper punctum or tear duct 20*a*. *Id*. at 2:18–20. Implant 10*b*, which is inserted in lower punctum 20*b*, is hollow and includes a tapered stem 12*a* having flared open end 12*b*. *Id*. at 2:22–24. Plug 10 may be made entirely of a porous or absorbent material that is saturated with an active agent. *Id*. at 2:38–40. A "[p]olymer that is absorbent to the agent is preferable so that sufficient [active] agent is present and available for discharge into the surrounding tissues." *Id*. at 2:35–38. Appropriate active agents include a variety of medications for treating conditions, such as glaucoma, corneal infections, chronic diseases, allergic conjunctivitis and rhinitis, and dry eye. *See id*. at 2:51–64, 3:3–8.



C. Challenged Claims

Petitioner challenges claims 1, 3, 5–8, 10, and 12–14 of the '114 Patent. Claims 1, 8, and 14 are the independent claims. Claim 1 is illustrative and is reproduced below:

1. A method for administering an active agent to a subject using a punctal plug, the method comprising:

inserting the punctal plug into a punctal aperture of the subject, wherein the composition of the punctal plug comprises:

- a) an active agent selected from the group consisting of topical prostaglandin; latanoprost; travoprost; bimatoprost; a medication for treatment of a corneal infection; ciprofloxacin; moxifloxacin; gatifloxacin; a systemic medication; a medication for treating hypertension; atenolol; nifedipine; hydrochlorothiazide; and a medication for treating allergic conjunctivitis, and
- b) a porous or absorbent material, and

wherein the shape of the punctal plug consists of a constant diameter cylinder configured to be inserted into a canalicular puncta of the subject.

Ex. 1001, 3:31–47.

D. Asserted Grounds of Unpatentability and Asserted Prior Art
Petitioner challenges the patentability of claims 1, 3, 5–8, 10, and 12–
14 of the '114 Patent on the following grounds (Pet. 27–28):



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