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Paper 77
Date: May 15, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SLAYBACK PHARMA LLC,
Petitioner,

v.

EYE THERAPIES, LLC,
Patent Owner.

IPR2022-00142
Patent 8,293,742 B2

Before TINA E. HULSE, ROBERT A. POLLOCK, and RYAN H. FLAX, *Administrative Patent Judges.*

HULSE, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

Slayback Pharma, LLC ("Petitioner") filed a Petition requesting *inter partes* review of claims 1–6 of U.S. Patent No. 8,293,742 B2 (Ex. 1001, "the '742 patent"), owned by Eye Therapies, LLC ("Patent Owner"). Paper 2 ("Pet."). Upon considering the Petition, Preliminary Response (Paper 7), Petitioner's Reply to Patent Owner's Preliminary Response (Paper 10), and Patent Owner's Sur-Reply (Paper 12), on May 18, 2022, we instituted an *inter partes* review of the challenged claims of the '742 patent. Paper 13 ("Dec. Inst." or "Institution Decision").

Patent Owner then filed a Response to the Petition (Paper 30, "PO Resp."), Petitioner filed a Reply (Paper 43, "Pet. Reply"), and Patent Owner filed a Sur-reply (Paper 59, "PO Sur-reply").

Petitioner also filed a Motion to Exclude Evidence (Paper 57), to which Patent Owner filed an Opposition (Paper 62), and Petitioner filed a Reply (Paper 64).

An oral hearing was held on February 27, 2023. A portion of the hearing was closed so the parties could discuss confidential information filed under seal. A transcript of the public portion of the hearing has been entered in the record. Paper 75. A transcript of the closed portion of the hearing has been entered separately. Paper 74.

After the hearing, the Board requested supplemental briefing on two issues: (1) whether the preamble of the claims should be construed as limited to a statement of the intentional purpose for which the method must be performed and, if so, what impact that construction has on inherent anticipation; and (2) what impact the transitional phrase "consisting essentially of" has on the claims and whether there is a temporal and intent aspect to the term. *See* Paper 69. Both parties submitted opening briefs

(Paper 70, "PO Supp. Br."; Paper 71, "Pet. Supp. Br.") and both parties submitted simultaneous responses to those briefs (Paper 73, "Pet. Reply Supp. Br."; Paper 72, "PO Reply Supp. Br.").

We have authority under 35 U.S.C. § 6. We issue this Final Written Decision under 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons that follow, we determine Petitioner has shown by a preponderance of the evidence that claims 1–6 of the '742 patent are unpatentable.

A. Real Parties-in-Interest

Petitioner identifies itself, Slayback Pharma India LLP, Dr. Reddy's Laboratories S.A., and Dr. Reddy's Laboratories, Inc. as the real parties-in-interest. Paper 24, 1. Patent Owner identifies itself, Bausch & Lomb, Inc., and Bausch & Lomb Ireland Limited as the real parties-in-interest. Paper 4, 2.

B. Related Proceedings

Petitioner states that the '742 patent has been asserted in the following cases: *Bausch & Lomb, Inc. v. Slayback Pharma LLC*, 3:21-cv-16766 (D.N.J.); *Bausch & Lomb, Inc. v. Lupin Ltd.*, 3:22-cv-00534 (D.N.J.). Paper 24, 1. Patent Owner states that the '742 patent has also been asserted in *Bausch & Lomb, Inc. v. Harrow Health, Inc.*, 3:21-cv-19252 (D.N.J.). Paper 4, 2.

C. The '742 Patent

The '742 patent is entitled "Preferential Vasoconstriction Compositions and Methods of Use." Ex. 1001, code (54). The '742 patent application was filed on July 27, 2009, and claims priority to a series of provisional applications, the earliest of which was filed on August 1, 2008. *Id.*, codes (22), 60). Thus, the earliest possible effective filing date of the '742 patent claims is August 1, 2008. Pet. 14.

The '742 patent relates to compositions and methods for preferential vasoconstriction of smaller blood vessels relative to larger blood vessels. Ex. 1001, Abstract. According to the Specification, dilation of small blood vessels causes undesirable events, including surface hemorrhage and hyperemia (i.e., eye redness) following Lasik surgery, eye redness, and nasal congestion. *Id.* at 1:6–11.

Adrenergic receptors, which are divided into a-1 (or α-1 or alpha-1), a-2, and β-adrenergic receptor types, are involved in a variety of physiological functions, including functions of the cardiovascular and central nervous systems. *Id.* at 1:12–19. Agonists of a-2 adrenergic receptors are used in the treatment of hypertension, glaucoma, spasticity, and cancer pain. *Id.* at 1:25–29. Brimonidine is an example of a known compound having selective a-2 agonist activity. *Id.* at 1:48–49. According to the Specification, "[i]t is a known property of all a[lpha] adrenergic receptor agonists, including brimonidine, to cause vasoconstriction." *Id.* at 1:61–63. The Specification notes, however, that "known formulations of brimonidine and other known a-2 adrenergic receptor agonists are associated with a high incidence of rebound hyperemia,[1] or other side effects, in clinical use." *Id.* at 1:63–66.

Moreover, the Specification states that commercially available general alpha agonists for topical ophthalmic use have high alpha-1 receptor agonist activity and are known to cause rebound hyperemia and medicamentosa (i.e., a potentially prolonged inflammatory state that can last for several weeks or

[1] The '742 patent states that "[r]ebound hyperemia refers to induced vasodilation (instead of intended vasoconstriction) occurring, often with a lag time, after an application or, more typically, repeated applications of vasoconstrictors." Ex. 1001, 4:30–34.

months even after stopping the medication). *Id.* at 2:8–13, 26–28. Thus, clinical use of such a-1 receptor agonists are typically limited to several hours or days, even though users with more chronic conditions, like dry eye and allergic conjunctivitis, may require longer-term use. *Id.* at 2:14–21. The Specification explains that "there is a need for new methods and formulations that would provide safe and long term vasoconstriction with reduced or minimized side effects, such as rebound hyperemia." *Id.* at 2:30–33.

Accordingly, the Specification states that "[o]ne of the key discoveries of the present invention lies in using low doses of highly selective a-2 adrenergic receptor agonists to achieve vasoconstriction with significantly reduced hyperemia." *Id.* at 2:38–41.

D. Illustrative Claim

Petitioner challenges claims 1–6 of the '742 patent. Claims 1 and 3 are the only independent claims and are reproduced below.

> 1. A method for reducing eye redness consisting essentially of administering brimonidine to a patient having an ocular condition, wherein brimonidine is present at a concentration between about 0.001% weight by volume and about 0.05% weight by volume.
>
> 3. A method for reducing eye redness consisting essentially of topically administering to a patient having an ocular condition a composition consisting essentially of brimonidine into ocular tissue, wherein pH of said composition is between about 5.5 and about 6.5, wherein said brimonidine concentration is between about 0.001% and about 0.025% weight by volume and wherein said composition is formulated as an ocular drop.

Ex. 1001, 22:17–22, 26–32.

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