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Paper 13
Date: May 18, 2022

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 JOHN G. NEW, TINA E. HULSE, and
ROBERT A. POLLOCK, *Administrative Patent Judges.*

NEW, *Administrative Patent Judge.*

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314, 37 C.F.R. § 42.4

I. INTRODUCTION

Slayback Pharma, LLC ("Petitioner") has 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"). Paper 2 ("Pet."). Eye Therapies, LLC. ("Patent Owner") filed a Preliminary Response to the Petition. Paper 7 ("Prelim. Resp."). With our authorization filed a Reply to Patent Owner's Preliminary Response and Patent Owner filed a Sur-Reply. Papers 10, 12.

Under 35 U.S.C. § 314, the Board "may not authorize an *inter partes* review to be instituted unless … the information presented in the petition … and any response … shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." Upon consideration of the Petition and Preliminary Response, and the evidence of record, we determine that the evidence presented demonstrates a reasonable likelihood that Petitioner would prevail in establishing the unpatentability of at least one of the challenged claims of the '742 patent. Accordingly, we institute *inter partes* review of claims 1–6 of the '742 patent.

II. BACKGROUND

A. Real Parties in Interest

Petitioner identifies itself and Slayback Pharma India LLP as the real parties-in-interest. Pet. 65. Patent Owner identifies itself and Bausch & Lomb, Inc. and Bausch & Lomb Ireland Limited as the real parties-in-interest. Paper 4, 2.

B. Related Matters

Petitioner states that the '742 patent has been asserted in pending civil action *Bausch & Lomb Inc. et al. v. Slayback Pharma LLC et al.*, 3:21-cv-16766 (D.N.J.). Ex. 2006. Pet. 65. Patent Owner adds that the '742 patent has also been asserted in *Bausch & Lomb, Inc, et al. v. Harrow Health, Inc. et al.*, 3:21-cv-19252 (D.N.J.). Paper 4, 2.

Petitioner also filed a petition for *inter partes* review of U.S. Patent No. 9,259,425 in IPR2022-00146.

C. The Asserted Grounds of Unpatentability

Petitioner contends that claims 1–6 of the '742 patent are unpatentable, based upon the following grounds:

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–2	102	Gil[1]
1–2	102	Walters[2]

[1] Gil et al. (US 6,294,553 B1, September 25, 2001) ("Gil"). Ex. 1004.

[2] T.R. Walters et al., *A Pilot Study of the Efficacy and Safety of AGN 190342-LF 0,02% and 0.08% in Patients with Elevated Intraocular Pressure*, 32(4) ASSOC. RES. VISION AND OPHTHALMOL. 988 (1991) ("Walters"). Ex. 1005.

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–6	103	Gil, Norden[3], Dean[4], Alphagan[5], and Federal Register[6]

Petitioner also relies upon the Declarations of Dr. Neal A. Sher (the "Sher Declaration," Ex. 1002) and Dr. Paul A. Laskar (the "Laskar Declaration," Ex. 1003).

D. The '742 Patent

The '742 patent is directed to compositions and methods for preferential vasoconstriction of smaller blood vessels relative to larger blood vessels. Ex. 1001 Abstr., col. 2, ll. 47–48. The compositions are administered to patients with ocular conditions, resulting in the reduction eye redness. *Id.* at col. 12, ll. 14–59.

In one embodiment, a selective α-2 adrenergic receptor agonist is administered to reduce vasoconstriction at a concentration below about 0.05% weight by volume. Ex. 1001, col. 5, ll. 19–26. The α-2adrenergic receptor agonist preferably has a binding affinity 100-fold to 500-fold or greater for α-2adrenergic receptors than a-1 adrenergic receptors. *Id.* at col.

[3] R.A. Norden, *Effect of Prophylactic Brimonidine or Bleeding Complications and Flap Adherence after Laser in Situ Keratomileusis*. 18(4) J. Refractive Surg. 468–471 (2002) ("Norden"). Ex. 1006.

[4] Dean et al. (US 6,242,442 B1, June 5, 2001) ("Dean"). Ex. 1007.

[5] *ALPHAGAN® (brimonidine tartrate ophthalmic solution) 0.2%.* Physicians' Desk Reference, 52th ed., Medical Economics Company, Inc., 487 (1998) ("Alphagan"). Ex. 1008.

[6] 53 Fed. Reg. 7076–7093 (Mar. 4, 1988) ("Federal Register"). Ex. 1009.

5, ll. 20–25, 46–48. The preferred α-2adrenergic receptor agonist is brimonidine. *Id.* at col. 5, ll. 52–55; cols. 5–6, ll. 65–4.

E. Illustrative Claim

Independent claim 1 of the '742 patent is representative of the challenged claims and recites:

> 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.

Ex. 1001, col. 22, ll. 17–22.

E. Prosecution History of the '742 Patent

The '742 patent issued from U.S. Application 12/460,941 (the "'941 Application") filed on July 27, 2009 and claims the priority benefit of provisional Application Ser. No. 61/207,481, which was filed on February 12, 2009; provisional Application Ser. No. 61/203,120, filed on December 18, 2008; provisional Application Ser. No. 61/192,777, filed on September 22, 2008; and provisional Application Ser. No. 61/137,714 filed on August 1, 2008. Ex. 1001, code (60).

The claims of the '742 patent, including claims 1–6, were allowed on October 23, 2012. *Id.*, code (45).

III. Analysis

A. Claim Construction

The Board applies the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b). *See* 37

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