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Paper 8
Entered: July 18, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARGENTUM PHARMACEUTICALS LLC,
Petitioner,

v.

ALCON RESEARCH, LTD.,
Patent Owner.

Case IPR2016-00544
Patent 8,791,154 B2

Before JENNIFER MEYER CHAGNON, CHRISTOPHER M. KAISER, and CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges.*

KAISER, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

INTRODUCTION

A. Background

Argentum Pharmaceuticals LLC ("Petitioner") filed a Petition (Paper 1, "Pet.") requesting *inter partes* review of claims 1–4, 8, 12, 13, 21, and 22 of U.S. Patent No. 8,791,154 B2 (Ex. 1001, "the '154 patent"). Alcon Research, Ltd. ("Patent Owner") did not file a Preliminary Response.

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314(b); 37 C.F.R. § 42.4(a). The standard for instituting an *inter partes* review is set forth in 35 U.S.C. § 314(a), which provides that an *inter partes* review may not be instituted unless "there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition."

After considering the Petition and the evidence currently of record, we determine that Petitioner has demonstrated that there is a reasonable likelihood that it would prevail with respect to at least one of the claims challenged in the Petition. Accordingly, we institute *inter partes* review.

B. Related Matters

The parties note that the '154 patent is the subject of *Alcon Research, Ltd. v. Watson Laboratories, Inc.*, Case No. 1-15-cv-01159-SLR (D. Del.). Pet. 1; Paper 6, 2.

C. The Asserted Grounds of Unpatentability

Petitioner contends that claims 1–4, 8, 12, 13, 21, and 22 of the '154 patent are unpatentable based on the following grounds (Pet. 17–60):[1]

[1] Petitioner also relies on declarations from Erning Xia, Ph.D., and Leonard Bielory, M.D. Ex. 1002 ("the Xia Declaration" or "Xia Decl."); Ex. 1003 ("the Bielory Declaration" or "Bielory Decl.").

Statutory Ground	Basis	Challenged Claims
§ 103	Bhowmick,[2] Yanni,[3] and Castillo[4]	1–4, 8, 12, 13, 21, and 22
§ 103	Schneider,[5] Hayakawa,[6] Bhowmick, and Castillo	1–4, 8, 12, 13, 21, and 22

D. The '154 Patent

The '154 patent relates to "an ophthalmic composition containing a relatively high concentration of olopatadine." Ex. 1001, at [57]. This "invention is directed to an ophthalmic composition for treatment of allergic conjunctivitis." *Id.* at 2:41–42. The '154 patent describes the claimed compositions as including "at least 0.67 w/v % olopatadine, preferably dissolved in solution." *Id.* at 2:42–45. The claimed compositions also are described as "typically includ[ing] a cyclodextrin, and more particularly, a γ-cyclodextrin derivative and/or a β-cyclodextrin derivative to aid in solubilizing the olopatadine." *Id.* at 2:45–48. In addition, the '154 patent describes other ingredients to assist in solubilization of the olopatadine, including "a lactam polymer (e.g., polyvinylpyrrolidone (PVP))" and "a

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[2] Bhowmick et al., WO 2008/015695 A2, published Feb. 7, 2008 (Ex. 1004, "Bhowmick").

[3] J.M. Yanni et al., *The* In Vitro *and* In Vivo *Ocular Pharmacology of Olopatadine (AL-4943A), an Effective Anti-Allergic/Antihistaminic Agent*, 12 J. OCULAR PHARMACOLOGY & THERAPEUTICS 389, 389–400 (1996) (Ex. 1005, "Yanni").

[4] Castillo et al., U.S. Patent No. 6,995,186 B2, issued Feb. 7, 2006 (Ex. 1006, "Castillo").

[5] Schneider et al., US 2011/0082145 A1, published Apr. 7, 2011 (Ex. 1007, "Schneider").

[6] Hayakawa et al., U.S. Patent No. 5,641,805, issued June 24, 1997 (Ex. 1008, "Hayakawa").

polyether (e.g., polyethylene glycol (PEG)).” *Id.* at 2:52–57. The claimed compositions also are described as including “a preservative” such as “benzalkonium chloride,” as well as “borate and/or polyol to aid in achieving desired preservation.” *Id.* at 2:60–67. In addition to the claimed compositions, the ’154 patent also describes “a method of treating ocular allergy symptoms” by “topically applying [the claimed compositions] to an eye of a human,” preferably by “dispensing an eyedrop from an eyedropper.” *Id.* at 3:1–6.

E. Illustrative Claims

Of the challenged claims in the ’154 patent, claims 1, 4, 8, and 21 are independent. Ex. 1001, 26:28–28:13. Independent claims 1 and 4 and dependent claim 12 are illustrative. They recite:

> 1. An aqueous ophthalmic solution for treatment of ocular allergic conjunctivitis, the solution comprising:
>
> at least 0.67 w/v % olopatadine dissolved in the solution;
>
> PEG having a molecular weight of 300 to 500;
>
> polyvinylpyrrolidone;
>
> hydroxypropyl-γ-cyclodextrin;
>
> benzalkonium chloride; and
>
> water.

Ex. 1001, 26:28–35.

4. An aqueous ophthalmic solution for treatment of ocular allergic conjunctivitis, the solution comprising:

at least 0.67 w/v % but no greater than 1.0 w/v % olopatadine dissolved in the solution;

2.0 w/v % to 6.0 w/v % PEG having a molecular weight of 300 to 500;

2.0 w/v % to 6.0 w/v % polyvinylpyrrolidone;

at least 0.5 w/v % but no greater than 2.0 w/v % cyclodextrin derivative selected from the group consisting of SAE-β-cyclodextrin, HP-γ-cyclodextrin, HP-β-cyclodextrin and combinations thereof; and

water.

Ex. 1001, 26:39–50.

12. A method of treating at least one ocular allergy symptom in humans, the method comprising:

topically applying to an eye of a human an amount of the solution of claim 4 sufficient to treat the at least one ocular allergy symptom.

Ex. 1001, 27:7–11.

ANALYSIS

A. Claim Construction

In an *inter partes* review, we construe claim terms in an unexpired patent according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *see Cuozzo Speed Techs. LLC v. Lee*, No. 15–446, 2016 WL 3369425, at *12 (U.S. June 20, 2016) (upholding the use of the broadest reasonable interpretation standard). Claim terms also are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the

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