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Paper 25
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC. and APOTEX CORP.,
Petitioner,

v.

ALCON RESEARCH, LTD.,
Patent Owner.

Case IPR2016-01640
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

Apotex Inc. and Apotex Corp. ("Petitioner") filed a Petition (Paper 2, "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") waived its opportunity to file a Preliminary Response. Paper 7, 2. Petitioner also moved for joinder with IPR2016-00544, an ongoing *inter partes* review that we instituted on July 18, 2016. Paper 3. Patent Owner does not oppose the motion for joinder. Paper 7, 2.

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." Petitioner may be joined as a party to a previously instituted *inter partes* review if Petitioner "properly files a petition . . . that [we] . . . determine[] warrants the institution of an inter partes review." 35 U.S.C. § 315(c); 37 C.F.R. § 42.4(a).

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. Because Petitioner has filed a Petition that warrants institution, we join Petitioner as a party to IPR2016-00544, and we terminate the present proceeding.

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.), as well as *Alcon Research, Ltd. v. Lupin Ltd.*, Case No. 1-16-cv-00195 (D. Del.). Pet. 1–2; 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. 18–59):[1]

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

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

[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").

These are identical to the grounds of unpatentability asserted in IPR2016-00544.

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 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.

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