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Paper 8
Entered: October 5, 2016

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.

ANALYSIS

Because the asserted grounds of unpatentability, the arguments, and the supporting evidence here are identical to those in IPR2016-00544, we adopt the analysis explained in our Decision to Institute in that case. *See Argentum Pharm. LLC v. Alcon Research, Ltd.*, Case IPR2016-00544, slip op. at 5–27 (PTAB July 18, 2016) (Paper 8). Consistent with that analysis, we determine that Petitioner has shown a reasonable likelihood of prevailing in showing the obviousness of each of the challenged claims over the combinations of Bhowmick, Yanni, and Castillo and of Schneider, Hayakawa, Bhowmick, and Castillo. Accordingly, we institute *inter partes* review. *See* 35 U.S.C. § 314(a) (permitting institution of *inter partes* review if "there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition").

In addition, Petitioner moves for joinder as a party to IPR2016-00544. Paper 3. Because Petitioner has filed a Petition that we have "determine[d] warrants the institution of an inter partes review," the requirements of 35 U.S.C. § 315(c) are met. Therefore, we must consider whether to exercise our discretion to join Apotex Inc. and Apotex Corp. as Petitioners to IPR2016-00544.

Apotex Inc. and Apotex Corp., together with the parties to IPR2016-00544, filed a Joint Stipulation explaining the agreement between and among them regarding the prosecution of the consolidated proceedings should joinder be granted. Paper 7. Apotex Inc. and Apotex Corp. agree not to file any papers, objections, or discovery requests separately from those filed jointly with Argentum Pharmaceuticals, the current Petitioner in IPR2016-00544. *Id.* at 2. Apotex Inc., Apotex Corp., and Argentum

Pharmaceuticals agree to identify a single questioning or defending attorney for each deposition, and Apotex Inc. and Apotex Corp. agree not to participate in any oral hearing in the consolidated proceedings. *Id.* at 2–3. Moreover, Apotex Inc. and Apotex Corp. agree to proceed on the evidence and arguments advanced by Argentum Pharmaceuticals and that the presence of Apotex Inc. and Apotex Corp. shall not be the basis for alteration of the schedule or page limits currently in place in IPR2016-00544. *Id.* at 3–4.

Given these concessions by Apotex Inc. and Apotex Corp., we exercise our discretion and join Apotex Inc. and Apotex Corp. as Petitioners to IPR2016-00544. We also conclude that there is no need to maintain separate proceedings. Accordingly, we consolidate the present trial with IPR2016-00544, and we terminate the trial in the present case. *See* 37 C.F.R. § 42.72 (permitting termination of trial following consolidation of trial with another proceeding).

CONCLUSION

Upon consideration of the Petition and the evidence before us, we determine that Petitioner has demonstrated a reasonable likelihood that it would prevail in showing that the claims it challenges are unpatentable on the following grounds:

Claims 1–4, 8, 12, 13, 21, and 22 as obvious over the combination of Bhowmick, Yanni, and Castillo; and

Claims 1–4, 8, 12, 13, 21, and 22 as obvious over the combination of Schneider, Hayakawa, Bhowmick, and Castillo.

Accordingly, we institute *inter partes* review of these claims on these grounds. The Board has not made a final determination on the patentability of any challenged claim.

We also join Petitioner as a party to IPR2016-00544, consolidate the present trial with IPR2016-00544, and terminate the present trial. The caption for IPR2016-00544 is modified to reflect the joinder of Apotex Inc. and Apotex Corp. as Petitioners in accordance with the example attached as the last page of the present Decision.

ORDER

It is hereby

ORDERED that, pursuant to 35 U.S.C. § 314, an *inter partes* review is hereby instituted to determine:

whether claims 1–4, 8, 12, 13, 21, and 22 are obvious over the combination of Bhowmick, Yanni, and Castillo; and

whether claims 1–4, 8, 12, 13, 21, and 22 are obvious over the combination of Schneider, Hayakawa, Bhowmick, and Castillo;

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial commencing on the entry date of this decision;

FURTHER ORDERED that Petitioner is joined as a party to IPR2016-00544;

FURTHER ORDERED that the trial in this case is consolidated with IPR2016-00544;

FURTHER ORDERED that, pursuant to 37 C.F.R. § 42.72, the trial in this case is terminated;

FURTHER ORDERED that all further filings shall be made only in IPR2016-00544;

FURTHER ORDERED that the asserted grounds of unpatentability on which trial was instituted in IPR2016-00544 are unchanged;

FURTHER ORDERED that the current Scheduling Order for IPR2016-00544 shall continue to govern IPR2016-00544;

FURTHER ORDERED that Apotex Inc. and Apotex Corp. shall abide by the Joint Stipulation with respect to consolidated filings, discovery, and objections;

FURTHER ORDERED that all filings by Apotex Inc. and Apotex Corp. in IPR2016-00544 shall be consolidated with the filings of the other Petitioner, unless the filing involves an issue unique to Apotex Inc. and Apotex Corp. or states a point of disagreement related to the consolidated filing, and, in such circumstances, Apotex Inc. and Apotex Corp. shall seek authorization from the Board to file a separate paper;

FURTHER ORDERED that all page limits set forth in 37 C.F.R. § 42.24 will apply to all consolidated filings;

FURTHER ORDERED that Apotex Inc. and Apotex Corp. shall be bound by any discovery agreements, including deposition arrangements, between the existing parties to IPR2016-00544;

FURTHER ORDERED that Patent Owner shall not be required to provide any additional discovery or deposition time as a result of joinder;

FURTHER ORDERED that Petitioners shall resolve any disputes between them and shall contact the Board only if such matters cannot be resolved;

FURTHER ORDERED that the case caption in IPR2016-00544 shall be changed to reflect the joinder of Apotex Inc. and Apotex Corp. as Petitioners in accordance with the attached example; and

FURTHER ORDERED that a copy of this Decision shall be entered into the file of IPR2016-00544.

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARGENTUM PHARMACEUTICALS LLC,
APOTEX INC., and APOTEX CORP.,
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ALCON RESEARCH, LTD.,
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Case IPR2016-00544[1]
Patent 8,791,154 B2

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[1] Petitioner Apotex Inc. and Apotex Corp. from IPR2016-01640 has been joined as a Petitioner to this proceeding.