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Paper 12
Date: August 6, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AYLA PHARMA LLC,
Petitioner,

v.

NOVARTIS AG,
Patent Owner.

IPR2020-00295
Patent 9,533,053 B2

Before GRACE KARAFFA OBERMANN, CHRISTOPHER M. KAISER, and JAMIE T. WISZ, *Administrative Patent Judges.*

KAISER, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314

INTRODUCTION

A. Background

Ayla Pharma LLC ("Petitioner") filed a Petition (Paper 1, "Pet.") requesting an *inter partes* review of claims 1–13 of U.S. Patent No. 9,533,053 B2 (Ex. 1002, "the '053 patent"). Novartis AG ("Patent Owner") filed a Preliminary Response.[1] Paper 7 ("Prelim. Resp."). With our authorization, Petitioner filed a Reply (Paper 10), and Patent Owner filed a Sur-Reply (Paper 11).

We have authority to determine whether to institute an *inter partes* review. 35 U.S.C. § 314(b) (2018); 37 C.F.R. § 42.4(a) (2019). 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, the Preliminary Response, the Reply, the Sur-Reply, and the evidence currently of record, we conclude that Petitioner has not shown a reasonable likelihood that it would prevail with respect to at least one challenged claim. Accordingly, we do not institute an *inter partes* review of the challenged claims on the grounds asserted in the Petition.

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[1] Pursuant to the Notice of Waiver of Patent-Related Timing Deadlines under the Coronavirus Aid, Relief, and Economic Security Act issued March 31, 2020, Patent Owner requested, and we granted, a 30-day extension of the deadline for Patent Owner to file its Preliminary Response. Ex. 3001.

B. Related Matters

The parties identify five lawsuits as related to this proceeding: *Alcon Research, Ltd. v. Cipla Ltd.*, No. 1-17-cv-01244 (D. Del.); *Alcon Research, Ltd. v. Lupin Ltd.*, No. 1-17-cv-00321 (D. Del.); *Alcon Research, Ltd. v. Watson Labs. Inc.*, No. 1-17-cv-00252 (D. Del.); *Alcon Research, Ltd. v. Watson Labs., Inc.*, No. 1:15-cv-1159 (D. Del.); and *Alcon Research, Ltd. v. Lupin Ltd.*, No. 1:16-cv-00195 (D. Del.). Pet. 4; Paper 5, 2–3. In addition, the '053 patent previously was challenged in IPR2018-01021, and a related patent, U.S. Patent No. 8,791,154 B2 (Ex. 1001, "the '154 patent"), previously was challenged in IPR2016-00544, IPR2016-01640, and IPR2018-01020. *Id.*

C. The Asserted Grounds of Unpatentability

Petitioner contends that claims 1–13 of the '053 patent are unpatentable based on the following grounds (Pet. 13–66):[2]

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–13	103(a)	Bhowmick,[3] Yanni,[4] and Castillo[5]

[2] Petitioner also relies on a Declaration from S. Craig Dyar, Ph.D., adopting the earlier testimony of Paul A. Laskar, Ph.D. Ex. 1042 (adopting Ex. 1014).

[3] WO 2008/015695 A2, published Feb. 7, 2008 (Ex. 1003).

[4] 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. 1004).

[5] US 6,995,186 B2, issued Feb. 7, 2006 (Ex. 1005).

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–13	103(a)	Schneider,[6] Hayakawa,[7] Bhowmick, and Castillo
1–13	103(a)	Bhowmick, Schneider, and Castillo

D. The '053 Patent

The '053 patent, titled "High Concentration Olopatadine Ophthalmic Composition," issued on January 3, 2017. Ex. 1002, codes (45), (54). The '053 patent "relates to an ophthalmic composition containing a relatively high concentration of olopatadine." *Id.* at 1:17–19.

According to the '053 patent, symptoms of "allergic conjunctivitis," including "ocular irritation [and] redness" are known to be "significantly reduced using topical ophthalmic solutions containing olopatadine." *Id.* at 1:28–35. Using higher concentrations of olopatadine in these topical ophthalmic solutions leads to "significantly improved reduction of late phase ocular allergic conjunctivitis symptoms" and "significantly improved reduction of redness in the early phase." *Id.* at 1:36–46. Additionally, with these higher concentrations, symptom relief "can be achieved through once a day dosing" rather than only with "greater dosing frequencies." *Id.* at 1:46–50. These benefits come at a cost, though: "[s]olubilizing high concentrations of olopatadine in a stable manner has proven difficult." *Id.* at 2:3–4. The '053 patent describes polyethylene glycol and polyvinylpyrrolidone as "hav[ing] proven incapable, alone or in combination, of solubilizing sufficient concentrations of olopatadine in

[6] US 2011/0082145 A1, published Apr. 7, 2011 (Ex. 1006).

[7] US 5,641,805, issued June 24, 1997 (Ex. 1007).

compositions having approximately neutral pH." *Id.* at 2:10–18. In addition, although cyclodextrins "have the ability to solubilize significantly higher concentrations of olopatadine," the "use of undesirably high concentrations of cyclodextrins has been found to reduce olopatadine efficacy and/or preservation efficacy of solutions." *Id.* at 2:19–29. Accordingly, the invention of the '053 patent "is directed at an ophthalmic composition that can provide high concentrations of olopatadine topically to the eye," particularly "such a composition wherein the olopatadine is solubilized in solution in a stable manner, the composition exhibits consistent efficacy against late phase symptoms of allergic conjunctivitis, the composition exhibits sufficient antimicrobial activity to provide desired levels of preservation efficacy or any combination thereof." *Id.* at 2:34–42.

E. Illustrative Claims

Claims 1–13 of the '514 patent are challenged. Claims 1 and 8 are independent, and claim 1 is illustrative; it recites:

> 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 200 to 800;
>
> polyvinylpyrrolidone;
>
> a cyclodextrin selected from the group consisting of SAE-β-cyclodextrin, hydroxypropyl-β-cyclodextrin and hydroxypropyl-γ-cyclodextrin; and
>
> water.

Ex. 1002, 27:46–55.

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