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Paper No. 14
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ALTAIRE PHARMACEUTICALS, INC.,
Petitioner,

v.

PARAGON BIOTECK, INC.,
Patent Owner.

Case PGR2015-00011
Patent 8,859,623 B1

Before SHERIDAN K. SNEDDEN, ZHENYU YANG, and CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

YANG, *Administrative Patent Judge*.

DECISION
Institution of Post-Grant Review
37 C.F.R. § 42.208

INTRODUCTION

Altaire Pharmaceuticals, Inc. ("Petitioner") filed a Petition for a post-grant review of claims 1–13 of U.S. Patent No. 8,859,623 B1 ("the '623 patent," Ex. 1001). Paper 1 ("Pet."). Paragon Bioteck, Inc. ("Patent Owner") filed a Preliminary Response. Paper 7 ("Prelim. Resp."). Thereafter, at our request (Paper 8), Petitioner filed a Reply, addressing the issue of whether the Petition properly identifies all real parties in interest (Paper 11). We have jurisdiction under 35 U.S.C. § 324, which provides that post-grant review shall not be instituted unless it is determined that "the information presented in the petition filed under section 321, if such information is not rebutted, would demonstrate that it is more likely than not that at least 1 of the challenged claims in the petition is unpatentable." 35 U.S.C. § 324(a).

For the reasons provided below, we determine that Petitioner has demonstrated that it is more likely than not that at least one claim of the '623 patent is unpatentable. Because Petitioner has satisfied the threshold requirement set forth in 35 U.S.C. § 324(a), we institute a post-grant review of claims 1–13 of the '623 patent.

Related Proceedings

Patent Owner identifies two district-court cases involving the parties. Paper 5, 1. Those cases, however, appear to involve issues unrelated to the '623 patent. Prelim. Resp. 6 n.7.

The '623 Patent

The '623 patent "is directed to methods and compositions of stabilizing phenylephrine formations." Ex. 1001, Abstract. "Phenylephrine is a selective α1-adrenergic receptor agonist used primarily as a decongestant, as an agent to dilate the pupil, and to increase blood pressure." *Id.* at 1:6–8. Specifically, the '623 patent provides "a composition comprising at least 95% R-phenylephrine hydrochloride and an aqueous buffer, wherein the composition substantially maintains an initial chiral purity of R-phenylephrine hydrochloride for at least 6 months stored between –10 to 10 degree Celsius." *Id.* at 1:16–21. It also discloses "methods of dilating the pupil comprising administering a composition comprising R-phenylephrine hydrochloride topically to a mammal, wherein the composition substantially maintains the initial chiral purity of R-phenylephrine hydrochloride for at least 6 months." *Id.* at 1:38–42.

At the time of the '623 patent invention, it was known that R-phenylephrine, but not S-phenylephrine, was useful to dilate the pupil. *Id.* at 6:21–30. Thus, "it is important that an eye drop containing Phenylephrine Hydrochloride used for dilation of the pupil contains predominantly the R-isomer in order to maintain maximum efficacy of the ophthalmic solution." *Id.* at 6:30–33.

According to the '623 patent, generally, commercially available phenylephrine hydrochloride ophthalmic solutions were stored at 20 to 25 degree Celsius, with the container tightly closed. *Id.* at 2:60–65. A solution under such condition, however, often turns brown over time and cannot be

used. *Id.* at 2:66–3:3. The '623 patent states that it "provides the improvement to overcome such instability problem." *Id.* at 3:4–5.

Illustrative Claim

Claims 1 is the sole independent claim. It reads:

> 1. A method of using an ophthalmic composition for pupil dilation, the composition comprising R-phenylephrine hydrochloride having an initial chiral purity of at least 95% and an aqueous buffer, wherein the chiral purity of R-phenylephrine hydrochloride is at least 95% of the initial chiral purity after 6 months, the method comprising:
>
> administering the composition into an eye of an individual in need thereof, wherein the composition is stored between –10 to 10 degree Celsius prior to administration, and wherein the composition comprises R-phenylephrine hydrochloride having a chiral purity of at least 95% when administered after storage.

Asserted Ground of Unpatentability

Petitioner asserts the following grounds of unpatentability:

1. claims 1–13 as anticipated by, or in the alternative, rendered obvious over, Altaire's Product ("the Altaire's Product ground");

2. claims 1–13 as anticipated by, or in the alternative, rendered obvious over, Altaire's Package Insert,[1] "or alternatively, in view of common knowledge in the art or, alternatively or in addition, in view of U.S.

[1] Sterile Phenylephrine Hydrochloride Ophthalmic Solution, USP (Revised August 2010) (Ex. 1018).

Patent No. 3,966,749[2] and in further view of Syn-Tech's Commercially Available product ("the Altaire's Package Insert ground");

3. claims 1–13 as "obvious in view of Applicants' Admitted Prior Art ('AAPA'), Altaire's Commercial Product, and/or the common knowledge in the art or, alternatively or in addition, in view of U.S. Patent No. 3,966,749" ("the AAPA ground"); and

4. claims 1–13 as unpatentable "under 35 U.S.C. § 112(b) for failing to particularly point out and distinctly claim the subject matter which the joint inventors regard as the invention" ("the indefiniteness ground").

In support of its patentability challenge, Petitioner relies on the Declaration of Assad Sawaya. Ex. 1003.

ANALYSIS

Eligibility for Post-Grant Review

The '623 patent issued on October 14, 2014, from an application filed on November 14, 2013. Ex. 1001, (22). It does not claim the benefit of any earlier filing date. Because it issued from an application that contains a claim with an effective filing date after March 16, 2013, the '623 patent is available for post-grant review. *See* Leahy-Smith America Invents Act (Pub. L. No. 112-29, 125 Stat. 284 (2011), §§ 3(n)(1), 6(f)(2)(A).

The Petition was filed on May 11, 2015 (Pet. 69), within 9 months of the grant of the '623 patent. *See* 35 U.S.C. § 321(c). Petitioner further

[2] U.S. Patent No. 3,966,749, issued on June 29, 1976 (Ex. 1011).

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