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Paper No. 48
Entered: November 14, 2016

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*.

FINAL WRITTEN DECISION
35 U.S.C. § 328(a) and *37 C.F.R. § 42.73*

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."). On November 16, 2015, the Board instituted trial to review patentability of the challenged claims. Paper 14 ("Dec."). Thereafter, Paragon Bioteck, Inc. ("Patent Owner") filed a Response (Paper 20 ("PO Resp.")), and Petitioner filed a Reply (Paper 35). Oral hearing was held on July 12, 2016. *See* Paper 47 ("Tr.").

The Board has jurisdiction under 35 U.S.C. § 6 and issues this final written decision pursuant to 35 U.S.C. § 328(a) and 37 C.F.R. § 42.73.

For the reasons provided below, we determine that Petitioner has not met its burden of proving the unpatentability of claims 1–13 of the '623 patent by a preponderance of the evidence. *See* 35 U.S.C. § 326(e).

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. 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. According to the '623 patent, "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.

In addition, 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.

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.

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.

Reviewed Ground of Unpatentability

The Board instituted trial to review whether claims 1–13 of the '623 patent are unpatentable as obvious over Altaire's Product, i.e., the phenylephrine hydrochloride ophthalmic solution Lot # 11578 and Lot # 11581.[1]

ANALYSIS

Claim Construction

In a post-grant review, we interpret a claim term in an unexpired patent according to its broadest reasonable construction in light of the specification of the patent in which it appears. 37 C.F.R. § 42.200(b); *see also In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1281 (Fed. Cir. 2015) (concluding that "Congress implicitly adopted the broadest reasonable interpretation standard in enacting the AIA"), *aff'd sub nom. Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under that standard, and absent any special definitions, we assign claim terms their ordinary and customary meaning, as would be understood by one of ordinary skill in the

[1] Lot # 11578 is a 2.5% phenylephrine hydrochloride ophthalmic solution, manufactured in December 2011, and sold and distributed to an Altaire customer in October 2012. Ex. 1003 ¶¶ 4, 36; Ex. 1007. Lot # 11581 is a 10% phenylephrine hydrochloride ophthalmic solution, manufactured in January 2012, and sold and distributed to another Altaire customer in October 2012. Ex. 1003 ¶¶ 5, 6, 36; Ex. 1009.

art at the time of the invention, in the context of the entire patent disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

In its Response, Patent Owner states that it agrees with our determination in the Institution Decision that no terms require express construction. PO Resp. 14 (citing Dec. 9). Nonetheless, Patent Owner contends that "claim 1 requires storage after six months, between −10 to 10 degrees Celsius, such that the chiral purity after said storage is at least 95% of the initial chiral purity." *Id.* To the extent Patent Owner requests that we limit the method step by adding a six-months-cold-storage requirement, we reject this attempt.

We find no basis to interpret the claims as requiring a step of cold storage of the composition for six months before administering to a patient. The only step of claim 1 recites that the composition is "stored between –10 to 10 degree Celsius prior to administration." Ex. 1001, 12:45–48. It does not specify how long the storage must be at that cold temperature. Patent Owner, however, relies on the preamble, which explicitly recites the chiral purity "is at least 95% of the initial chiral purity *after 6 months*." Ex. 1001, 12:42–44 (emphasis added). This language of the preamble is consistent with the prosecution history, in which the applicants argued, and the examiner agreed, that claim 1 was patentable because the chiral purity remained at least 95% of the initial chiral purity after cold storage for six months. *See* Ex. 1002, 110, 113, 167.

Maintaining at least 95% of the initial chiral purity after six months, however, simply describes a property of the composition to be administered.

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