Trials@uspto.gov
571-272-7822

Paper 28
Entered: December 27, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DERMIRA, INC.,
Petitioner,

v.

PUREPHARM, INC.,
Patent Owner.

Case IPR2015-01594
Patent 8,252,316 B2

Before LORA M. GREEN, DEBORAH KATZ, and ZHENYU YANG, *Administrative Patent Judges*.

YANG, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

INTRODUCTION

Dermira, Inc. ("Petitioner") filed a Petition (Paper 1 ("Pet.")), seeking an *inter partes* review of claims 1–8 of U.S. Patent No. 8,252,316 B2 ("the '316 patent," Ex. 1004). On January 7, 2016, the Board instituted a review of the patentability of the challenged claims. Paper 6 ("Dec."). Thereafter, Purepharm, Inc. ("Patent Owner") filed a Response (Paper 15 ("PO Resp.")), and Petitioner filed a Reply (Paper 25).

The Board has jurisdiction under 35 U.S.C. § 6 and issues this final written decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons provided below, we conclude Petitioner has established by a preponderance of the evidence that claims 1–3 and 5–8 of the '316 patent are unpatentable. Petitioner, however, has failed to meet its burden of proof regarding the unpatentability of claim 4.

Related Proceedings

Petitioner also filed IPR2015-01593, seeking an *inter partes* review of U.S. Patent No. 8,679,524 B2, a patent in the same family as the '316 patent. Pet. 1. We instituted trial in that case, and issue a final decision therein concurrently with this Final Written Decision. *See Dermira, Inc. v. Purepharm, Inc.*, Case IPR2015-01593 (PTAB Dec. 27, 2016) (Paper 28).

The '316 Patent

The '316 patent relates to a method of topically applying glycopyrrolate to reduce excessive sweating in localized areas for those who suffer from the condition. Ex. 1004, 1:11–14.

Before the invention of the '316 patent, using topical glycopyrrolate to reduce excessive sweating had been known for two decades. *Id.* at 1:25–3:2. According to the '316 patent, however, "[u]sing the previously

available delivery methods, the topical application of glycopyrrolate can be messy and inconvenient." *Id.* at 3:60–62. The '316 patent discloses "a pad containing an amount of glycopyrrolate in solution, for topical application of a therapeutically effective amount of glycopyrrolate, which is useful in reducing sweating in humans." *Id.* at 3:6–9.

Illustrative Claim

Claim 1 is the only independent claim. It reads:

> 1. A method of reducing sweating by applying a dosed amount of glycopyrrolate solution to effect the topical application of a therapeutically effective amount of glycopyrrolate to a part of the human body, with the exception of mucous membranes, so as to reduce sweating on said part of the human body, the dosed amount of glycopyrrolate solution contained in an absorbent pad applied to said part of the human body and made of a material capable of containing the dosed amount for application, wherein said amount of glycopyrrolate in solution is an amount ranging from 3.0 wt. % to 4 wt. %.

Reviewed Grounds of Unpatentability

The Board instituted trial to review the following grounds of unpatentability:

Claims	Basis	Reference(s)
1 and 2	§ 102	Hays[1]
1, 2, 4, 5, and 8	§ 103	Bobrove[2] and Bodor[3]
3 and 6–8	§ 103	Bobrove and Thaman[4]

Patent Owner notes that we did not address claim 7 in the Decision to Institute and thus "it is presumed that this claim is deemed to be patentable over the prior art relied upon by the Petitioner." PO Resp. 1. This statement is incorrect. As Patent Owner acknowledges, we instituted to review, among other grounds, whether "claims 3 and 6–8" would have been obvious over asserted prior art. *Id.* Claim 7 is subsumed under "claims 6–8."

ANALYSIS

As an initial matter, we emphasize that in an *inter partes* review, the burden of persuasion is on the petitioner to prove unpatentability, and that burden never shifts to the patent owner. *See* 35 U.S.C. § 316(e); *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir.

---

[1] Leonard L. Hays, *The Frey Syndrome: A Review and Double Blind Evaluation of the Topical Use of a New Anticholinergic Agent*, 88 THE LARYNGOSCOPE 1796–1824 (1978) (Ex. 1009, "Hays").
[2] Bobrove et al., U.S. Patent No. 5,962,505, issued Oct. 5, 1999 (Ex. 1008, "Bobrove").
[3] Nicholas Bodor, U.S. Patent No. 4,824,676, issued Apr. 25, 1989 (Ex. 1030, "Bodor").
[4] Thaman et al., U.S. Patent No. 4,891,227, issued Jan. 2, 1990 (Ex. 1010, "Thaman").

2015). Thus, we do not hold the challenged claims unpatentable simply because, as Petitioner alleges, Patent Owner has not taken certain actions. *See* Reply 8–9 (stating, for example, that Patent Owner did not take the deposition of the witness for Petitioner, and did not offer any expert testimony in support of its own argument). Instead, we analyze the entire record developed during trial in analyzing the patentability of the challenged claims.

Claim Construction

In an *inter partes* review, the Board interprets 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. § 42.100(b); *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 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 the Decision to Institute, we determined that under the broadest reasonable interpretation, "dosed amount," as recited in claim 1, is not limited by the volume of the glycopyrrolate solution. Dec. 6. Similarly, we concluded that an "absorbent pad" is not limited by the volume of the glycopyrrolate solution it absorbs. *Id.* Patent Owner challenges our interpretations as rendering "the term[s] 'dose' and 'solution' [to] have absolutely no meaning in the claim whatsoever." PO Resp. 4. Patent Owner appears to refer to its arguments presented in the Preliminary Response

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.