

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

**PATENT OWNER'S PRELIMINARY RESPONSE
PURSUANT TO 37 C.F.R. § 42.207**

TABLE OF CONTENTS

	<u>Page</u>
I. INTRODUCTION	1
II. THE PETITION FAILS TO IDENTIFY SAWAYA AQUEBOGUE AS A REAL PARTY-IN-INTEREST	2
A. Sawaya Aquebogue is a Real Party-In-Interest.....	3
B. Correcting Real Party-in-Interest Would be Futile	6
III. BACKGROUND OF THE '623 PATENT AND PROSECUTION HISTORY	7
A. Paragon's Identification of Phenylephrine Temperature Instability.....	9
IV. THE PETITION RELIES UPON A FLAWED ANALYSIS	12
A. The USP Standard HPLC Protocol Used by Petitioner Does Not Reliably Detect Chiral Impurity.....	12
B. Petitioner's Reliance on an Optical Rotation Comparison is Misplaced	16
V. THE PETITION IS BASED ENTIRELY ON ATTORNEY ARGUMENT AND TESTIMONY FROM AN INTERESTED FACT WITNESS WHO LACKS EXPERTISE IN THE SUBJECT MATTER.....	18
VI. PETITIONER'S CLAIM CONSTRUCTION IGNORES KEY LIMITATIONS OF THE '623 PATENT CLAIMS.....	20
A. "... the composition comprising R-phenylephrine hydrochloride having an initial chiral purity of at least 95%"	21
B. "... wherein the chiral purity of R-phenylephrine hydrochloride is at least 95% of the initial chiral purity after 6 months"	22
VII. PROPOSED GROUNDS OF CHALLENGE	22
A. Ground 1 Fails.....	23
1. "Altaire's Product" Does Not Disclose "... the composition comprising R-phenylephrine hydrochloride having an initial chiral purity of at least 95%," as Recited in Claim 1	24
B. Ground 2 Fails.....	28
1. The Cited References Do Not Disclose "... the composition comprising R-phenylephrine hydrochloride	

having an initial chiral purity of at least 95%,” as Recited
in Claim 1 30

C. Ground 3 Fails 34

D. Ground 4 Fails 35

VIII. CONCLUSION..... 38

IX. APPENDIX..... 39

I. INTRODUCTION

The Board should not institute post grant review (PGR) of Claims 1-13 of U.S. Patent No. 8,859,623 (“the ’623 patent”) because Petitioner, Altaire Pharmaceuticals, Inc. (“Petitioner” or “Altaire”), has not met its burden of showing the challenged claims are more likely than not unpatentable.

First, the petition should be dismissed for failing to identify Sawaya Aquebogue as a real party-in-interest. Among other factors, Sawaya Aquebogue and Altaire are related entities under common control, including control by the same individual testifying as a fact witness in this PGR – Mr. Assad Sawaya.

Second, with regard to the asserted prior art, each of the stated grounds of challenge can be denied for failing to meet the chiral purity limitations of the claims, including at least the 95% initial chiral purity requirement of Claim 1. Phenylephrine comprises two enantiomers, an R-form and an S-form, but the petition relies entirely on methodologies incapable of reliably detecting S-form chiral impurity. Paragon demonstrated that its chiral column chromatography method uncovers degradation that was not detectible using methods pursuant to the United States Pharmacopeia (USP) published guidelines, and that improvement of testing methodology led to Paragon’s discovery regarding the unrecognized and unappreciated effect of temperature conditions on degradation of the chiral purity of phenylephrine. The petition relies on the faulty USP methodology, but omits any discussion of the deficiencies in that method as addressed by Paragon in *ex parte* prosecution. The petition instead attempts to remedy the defective nature of

its testing through faulty claim construction. In the end, Petitioner's case in chief collapses on itself once the claims are properly construed and petitioner's methodologies are scrutinized.

Finally, the challenge to the claims based on alleged indefiniteness is more appropriately interpreted as an advancement of Petitioner's preferred claim construction position, but fails to provide a bona fide basis for unpatentability.

Accordingly, institution of post grant review should be *denied*.

II. THE PETITION FAILS TO IDENTIFY SAWAYA AQUEBOGUE AS A REAL PARTY-IN-INTEREST

As a threshold matter, the petition should be dismissed for failing to identify Sawaya Aquebogue, LLC ("Sawaya Aquebogue") as a real party-in-interest as required by 35 U.S.C. § 322(a)(2) and 37 C.F.R. § 42.8(b)(1).

"A petition [for post grant review] may be considered only if . . . [it] identifies all real parties in interest." 35 U.S.C. § 322(a)(2); *see also* Trial Practice Guide, 77 Fed. Reg. 48,759, (Aug. 14, 2012). "A common consideration is whether the non-party exercised or could have exercised control over a party's participation in the proceeding." *Id.* The non-party's participation may be overt or covert, and the evidence may be direct or circumstantial, but the evidence as a whole must show that the non-party possessed control, or the ability to control, from a practical standpoint. *Gonzalez v. Banco Cent. Corp.*, 27 F.3d 751, 759 (1st Cir. 1994). Indeed, the Board has recognized that it is sufficient to establish an ability "to call the shots." *Galderma S.A. v. Allergan Indus., SAS*, IPR2014-01422, Paper 14 at 8, 12, (PTAB Mar. 5, 2015) (quoting *Gonzalez*, 27 F.3d at 758). As

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.