

U.S. Patent No.: 8,859,623  
Paper No. \_\_\_\_  
Petition for Post-Grant Review

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

*Altaire Pharmaceuticals, Inc.*

Petitioner

v.

*Paragon Biotech, Inc.*

Patent Owner

U.S. Patent No. 8,859,623  
Issue Date: October 14, 2014  
Entitled: METHODS AND COMPOSITIONS OF STABLE PHENYLEPHRINE  
FORMULATIONS

---

Post-Grant Review No.: Unassigned

---

**PETITION FOR POST-GRANT REVIEW**

**TABLE OF CONTENTS**

**Page No.**

I.	MANDATORY NOTICES.....	III
A.	<b>Real Party-In-Interest Pursuant to 37 C.F.R. § 42.8(b)(1).....</b>	<b>1</b>
B.	<b>Related Matters Pursuant to 37 C.F.R. § 42.8(b)(2).....</b>	<b>1</b>
C.	<b>Lead and Back-Up Counsel Pursuant to 37 C.F.R. § 42.8(b)(3).....</b>	<b>1</b>
D.	<b>Service Information Pursuant to 37 C.F.R. § 42.8(b)(4) .....</b>	<b>2</b>
E.	<b>Payment of Fees Under 37 C.F.R. §§ 42.15(b) and 42.203 .....</b>	<b>2</b>
II.	GROUNDS FOR STANDING .....	2
III.	TIMING .....	3
IV.	STATEMENT OF PRECISE RELIEF REQUESTED.....	3
A.	<b>Identification of Claims Challenged and Relief Sought .....</b>	<b>3</b>
B.	<b>Statutory Grounds and Prior Art Relied Upon for Each Ground .....</b>	<b>3</b>
V.	SPECIFIC CLAIMS AND GROUNDS FOR RELIEF .....	3
VI.	STATEMENT OF REASONS FOR THE RELIEF REQUESTED.....	4
A.	<b>Brief Summary of Reasons for Relief Requested.....</b>	<b>4</b>
B.	<b>The '623 Patent .....</b>	<b>13</b>
1.	Prosecution History of the '623 Patent .....	15
C.	<b>One of Ordinal Skill in the Art at the Time of the Alleged Invention.....</b>	<b>30</b>
D.	<b>Claim Interpretation of the '623 Patent.....</b>	<b>31</b>
1.	“chiral purity” and “initial chiral purity” .....	31
2.	“wherein the chiral purity of R-phenylephrine hydrochloride is at least 95% of the initial chiral purity after 6 months” .....	32
3.	“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” .....	32
4.	“allowed to be” .....	33

**E. Specific Identification of Where Each Element of the Claims is Disclosed in Prior Art Patents and Printed Publications .....33**

1. Claims 1-13 of the '623 patent are invalid under 35 U.S.C. § 102 as lacking novelty over Altaire's Product, or, in the alternative, invalid under 35 U.S.C. § 103 as obvious in view of Altaire's Product and the knowledge of one of ordinary skill in the art.....33
2. Claims 1-13 of the '623 patent are invalid under 35 U.S.C. § 102, or in the alternative, 35 U.S.C. § 103 as anticipated or rendered obvious in view of Altaire's Package Insert, or alternatively, in view of common knowledge in the art or, alternatively or in addition, in view of U.S. Patent No. 3,966,749 and in further view of Syn-Tech's Commercially Available product. ....45
3. Claims 1-13 of the '623 patent are invalid under 35 U.S.C. § 103 as being obvious in view of Applicants' Admitted Prior Art ("AAPA"), Altaire's Package Insert, and/or the common knowledge in the art or, alternatively or in addition, in view of U.S. Patent No. 3,966,749.....57
4. Claims 1-13 of the '623 patent are invalid 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 .....66

**VII. CONCLUSION .....68**

**TABLE OF AUTHORITIES**

	<b>Page(s)</b>
<b>CASES</b>	
<i>In re Cuozzo Speed Techs., LLC</i> , 2014-130, 778 F.3d 1271 (Fed. Cir. Feb. 4, 2015).....	31
<i>Markman v. Westview Instruments</i> , 517 U.S. 370 (U.S. 1996) .....	69
<i>Nautilus, Inc. v Biosig Instruments, Inc.</i> , 134 S. Ct. 2120 (U.S. 2014) .....	69
<b>STATUTES</b>	
35 U.S.C. § 102.....	3, 4, 34, 46
35 U.S.C. § 102(a)(1).....	3, 37, 46
35 U.S.C. § 103.....	passim
35 U.S.C. § 112.....	41, 42, 52
35 U.S.C. § 112(b) .....	4, 67, 69
35 U.S.C. §§ 321-328 .....	3
35 U.S.C. § 322(a)(3).....	3
35 USC §§ 102 and 103 .....	3
<b>REGULATIONS</b>	
37 C.F.R. § 42.8(b)(1).....	1
37 C.F.R. § 42.8(b)(2).....	1
37 C.F.R. § 42.8(b)(3).....	1
37 C.F.R. § 42.8(b)(4).....	2
37 C.F.R. § 42.10(b) .....	1
37 C.F.R. §§ 42.15(b) and 42.203.....	2
37 C.F.R. §§ 42.200-42.224.....	3
37 C.F.R. § 42.200(b) .....	31, 32

U.S. Patent No. 8,859,623  
Petition for Post Grant Review

37 C.F.R. § 42.202(a).....3  
37 C.F.R. § 42.204(a).....2  
37 C.F.R. § 42.204(b) .....3  
37 CFR 1.75(e).....58

# 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.