

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

STEADYMED LTD.,

Petitioner,

v.

UNITED THERAPEUTICS CORPORATION

Patent Owner.

Case IPR Unassigned

Patent No. 8,497,393

---

**PETITION FOR *INTER PARTES* REVIEW OF  
U.S. PATENT NO. 8,497,393 UNDER 37 C.F.R. § 42.100**

Mail Stop "Patent Board"  
Patent Trial and Appeal Board  
U.S. Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450

## TABLE OF CONTENTS

I.	COMPLIANCE WITH FORMAL REQUIREMENTS .....	1
A.	Mandatory Notices Under 37 C.F.R. § § 42.8(b)(1)-(4) .....	1
1.	Real Party-in-Interest .....	1
2.	Related Matters .....	1
3.	Lead And Back-Up Counsel .....	1
4.	Powers of Attorney and Service Information .....	2
B.	Proof of Service on the Patent Owner .....	2
C.	Fees .....	2
II.	GROUND FOR STANDING .....	2
III.	STATEMENT OF PRECISE RELIEF REQUESTED .....	3
IV.	IDENTIFICATION OF CHALLENGE .....	3
V.	LEVEL OF ORDINARY SKILL IN THE ART .....	4
VI.	SUMMARY OF THE '393 PATENT .....	5
A.	Brief Description of the '393 Patent .....	5
B.	Summary of the Prosecution History of the '393 Patent .....	7
VII.	CLAIM CONSTRUCTION .....	10
VIII.	THERE IS A REASONABLE LIKELIHOOD THAT AT LEAST ONE CLAIM OF THE '393 PATENT IS UNPATENTABLE .....	12
A.	Identification of the References As Prior Art .....	12
B.	State of the Prior Art & Summary of Invalidity Arguments .....	13
1.	Steps (a) – (b): The Synthesis of Treprostinil Was Well- Known .....	14
2.	Steps (c) & (d): Formation of a Carboxylate Salt and the Addition of an Acid to a Carboxylate Salt is Standard Chemical Purification Known in the Art .....	16
IX.	CLAIM-BY-CLAIM EXPLANATION OF GROUNDS FOR UNPATENTABILITY .....	22
A.	Ground 1: Detailed Explanation Under 37 C.F.R. § 42.104(b) of How Phares (Ex. 1005) Anticipates Claims 1-5, 7-9, 11-14 and 16-20 Under 35 U.S.C. § 102(b) .....	22

B.	Ground 2: Detailed Explanation Under 37 C.F.R. § 42.104(b) of How Claims 1-5, 7-9, 11-14 and 16-20 are Obvious under 35 U.S.C. § 103(a) over Moriarty (Ex. 1004) with either Phares (Ex. 1005) or Kawakami (Exs. 1006 & 1007) .....	37
C.	Ground 3: Detailed Explanation Under 37 C.F.R. § 42.104(b) of How Claims 6, 10, 15, 21 and 22 are Obvious under 35 U.S.C. § 103(a) over Moriarty (Ex. 1004) with Phares (Ex. 1005) or Kawakami (Exs. 1006 & 1007) and in further combination with Ege (Ex. 1008).....	53
X.	CONCLUSION.....	57

## TABLE OF EXHIBITS

EXHIBIT	DESCRIPTION	ABBREVIATION
1001	U.S. Patent No. 8,497,393 to Batra, et al.	'393 Patent
1002 - 1	Prosecution History of U.S. Patent No. 8,242,305 (excerpts)	--
1002 - 2	Prosecution History of U.S. Patent No. 8,497,393	--
1003	U.S. Patent No. 6,765,117 to Moriarty, et al.	'117 Patent
1004	J. Org. Chem. 2004, 1890-1902 by Moriarty, et al.	Moriarty
1005	International Publication No. WO 2005/007081 to Phares, et al.	Phares
1006	Japanese Patent App. No. 56-122328A to Kawakami, et al. (Japanese)	Kawakami
1007	Certified English translation of Japanese Patent App. No. 56-122328A to Kawakami, et al.	Kawakami
1008	Ege, S. (1989). <i>Organic Chemistry Second Edition</i> (pp. 543-547)	Ege
1009	Declaration of Jeffrey D. Winkler, Ph.D.	Winkler Decl.
1010	<i>Curriculum Vitae</i> of Jeffrey D. Winkler, Ph.D.	--
1011	Affidavit of Boris Levine certifying Translation of Japanese Patent App. No. 56-122328A to Kawakami, et al.	--

EXHIBIT	DESCRIPTION	ABBREVIATION
1012	Wiberg, Kenneth (1960), Laboratory Technique in Organic Chemistry (p. 112)	Wiberg
1013	U.S. Patent No. 6,441,245 to Moriarty, et al.	'245 Patent
1014	Schoffstall, "Microscale and Miniscale Organic Chemistry Laboratory Experiments," 200-202 (2d ed.) (2004)	Schoffstall
1015	U.S. Patent No. 3,703,544 to Morozowich, et al.	'544 Patent
1016	U.S. Patent No. 3,888,916 to Sinkula, et al.	'916 Patent
1017	"Getting Started in HPLC," Section 4D: Precision and Accuracy, available at <a href="http://www.lcresources.com/resources/getstart/4d01.htm">http://www.lcresources.com/resources/getstart/4d01.htm</a> (accessed Sept. 29, 2015)	--
1018	Gilbert, "Experimental Organic Chemistry: A Miniscale and Microscale Approach," 113-117 (5th. ed.) (2011)	Gilbert <sup>1</sup>

---

<sup>1</sup> For ease of reference, all citations to the above references are to the bates-labeled page number. Petitioner utilizes the "column, line number" format, however, for any referenced U.S. Patents (*i.e.*, Exhibit Nos. 1001, 1003, 1013, 1015, and 1016).

# 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.