

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

STEADYMED LTD.  
Petitioner

v.

UNITED THERAPEUTICS CORPORATION  
Patent Owner

U.S. Patent No. 8,497,393

Issue Date: Jul. 30, 2013

Title: PROCESS TO PREPARE TREPROSTINIL, THE ACTIVE  
INGREDIENT IN REMODULIN®

---

Case IPR2016-00006

---

**Updated Patent Owner's Exhibit List**

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

<b>Ex #</b>	<b>Exhibit Description</b>
2001	November 19, 2015 Conference Call Before the Panel
2002	Remodulin® Label
2003	FDA Approval Letter
2004	Process Validation Report: (Protocol No.: “VAL 00131”)
2005	Process Optimization Report
2006	UTC Letter of January 2009 to FDA
2007	U.S. Patent No. 8,242,305; the '305 patent;
2008	U.S. Provisional Patent Application No. 61/014,232
2009	U.S. Patent No. 8,748,657; the '657 patent
2010	The '657 patent prosecution history
2011	Zumdahl, Chemistry, pp. A25, A36 (1986)
2012	Brown, et al., Chemistry: The Central Science, pp. G-2, G-10 (9th ed. 2003)
2013	Trial testimony of Dr. Williams and Dr. Aristoff
2014	Suchocki, et al., Conceptual Chemistry, p. G-6 (2001)
2015	U.S. Patent No. 4,668,814; the '814 patent

2016	UTC Form 10K 2014 Annual Report
2017	Declaration of Liang Gou, Ph.D., dated May 9, 2016 (not filed)
2018	Declaration of Rex Mauthe, dated May 10, 2016 (not filed)
2019	May 10, 2016 Conference Call Before the Panel
2020	Declaration of Robert M. Williams, Ph.D
2021	<i>Curriculum Vitae</i> of Robert M. Williams, Ph.D
2022	Declaration of Robert R. Ruffolo, Jr., Ph.D
2023	<i>Curriculum Vitae</i> of Robert R. Ruffolo, Jr., Ph.D
2024	<i>The Scotts Co., LLC v. Encap, LLC</i> , IPR2013-00110, Paper 79 (PTAB June 24, 2014)
2025	Prosecution History of U.S. Patent No. 6,209,259
2026	Williams, et.al., <i>Asymmetric, Stereocontrolled Total Synthesis of Paraherquamide A</i> , J. Am. Chem. Soc. 2003, 125, 12172-12178.
2027	Williams, et.al., <i>Stereocontrolled Total Synthesis of (+)- Paraherquamide B</i> , J. Am. Chem. Soc. 1996, 118, 557-579.
2028	Williams, et.al., <i>Synthetic Studies on Et-743. Assembly of the Pentacyclic Core and a Formal Total Synthesis</i> , J. Org. Chem. 2008, 73, 9594-9600.

2029	Winkler, J., et.al., <i>A Pauson-Khand Approach to the Synthesis of Ingenol</i> , Org. Lett., 2005, 8, 1489-1491.
2030	R. Adhiyaman, et.al., <i>Crystal modification of dipyridamole using different solvents and crystallization conditions</i> , Int'l J. Pharm. 2006, 321, 27-34.
2031	Marti, E., <i>Purity determination by differential scanning calorimetry</i> , Thermochemica Acta, 1972, 5, 173-220.
2032	U.S. Patent No. 4,306,075
2033	U.S. Patent Nos. 5,153,222
2034	ICH Guidance For Industry: Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients (2001).
2035	Reviewer Guidance: Validation of Chromatographic Methods (1994).
2036	Certificate of Analysis data for 56 samples of treprostinil product as produced by the prior art process according to Moriarty through 2004
2037	Certificate of Analysis data for 157 samples of treprostinil product as produced by the '393 patent processes
2038	ICH Harmonised Tripartite Guideline: Impurities in New Drug Substances Q3A(R2) (2006)

2039	ICH Guidance for Industry: M7 Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk (2015)
2040	Olsen, Bernard A., <i>What's New with Impurities in Pharmaceuticals?</i> , Southern California Pharmaceutical Discussion Group, January 15, 2015
2041	"Janet Woodcock," available at <a href="http://www.fiercebiotech.com/special-report/janet-woodcock-fda">http://www.fiercebiotech.com/special-report/janet-woodcock-fda</a> (accessed July 6, 2016)
2042	Carpenter, <i>The Political Economy of FDA Drug Review: Processing, Politics and Lessons for Policy</i> (2004)
2043	ICH Draft Consensus Guideline: Guideline for Elemental Impurities Q3D (2013)
2044	ICH Guidance For Industry: Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients (2001)
2045	Schrager et al., <i>Diethylstilbestrol Exposure, American Family Physician</i> , 2004, 10, 2395-2400.
2046	NTP Report on Carcinogens Background Document for Saccharin

# 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.