

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

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Alexandria, VA 22313-1450

Ex #	Exhibit Description
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 http://www.fiercebiotech.com/special-report/janet-woodcock-fda (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

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