

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 TREPASTINIL, THE ACTIVE
INGREDIENT IN REMODULIN®

Case IPR2016-00006

Updated Patent Owner's Exhibit List

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U.S. Patent and Trademark Office
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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 |

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| 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. |

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| 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) |

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| 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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