

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

WATSON LABORATORIES, INC.

Petitioner

v.

UNITED THERAPEUTICS, INC.

Patent Owner

Patent No. 9,358,240

Issue Date: June 7, 2016

Patent No. 9,339,507

Issue Date: May 17, 2016

Title: TREPROSTINIL ADMINISTRATION BY INHALATION

Inter Partes Review No. 2017-01621

Inter Partes Review No. 2017-01622

**PATENT OWNER UPDATED EXHIBIT LIST¹
AS OF AUGUST 21, 2018**

¹ A word-for-word identical document is being filed in IPR2017-01621 and IPR2017-1622.

| Exhibit No. | Description |
|-------------|---|
| 2001 | Declaration of Dr. Richard Dalby |
| 2002 | <i>Oxford Dictionary of English</i> , 2 nd ed. Revised. Oxford University Press, 2005 (excerpt). |
| 2003 | Newman, Stephen P., <i>Respiratory drug delivery: essential theory and practice</i> . Respiratory Drug Delivery Online, 2009 (excerpt). |
| 2004 | Hill, N., <i>Therapeutic Options for the Treatment of Pulmonary Hypertension</i> , Medscape Pulmonary Medicine 9(2) (2005). |
| 2005 | Exhibits Accompanying First Declaration of Dr. Roham Zamanian and Amendment and Reply filed in 12/591,200 (Nov. 9, 2015) (Ex. 1162) |
| 2006 | Declaration of Dr. Edmund Elder and Exhibits Accompanying Second Declaration of Dr. Roham Zamanian, Amendment and Reply filed in 12/591,200 (Feb. 2, 2016) (Ex. 1163) |
| 2007 | Finlay, Warren H., <i>The Mechanics of Inhaled Pharmaceutical Aerosols: an Introduction</i> . Academic Press, 2002 (excerpt). |
| 2008 | “Mechanical Ventilation,” <i>American Journal of Respiratory and Critical Care Medicine</i> 196(2):P3-4 (2017). |
| 2009 | Motion for Leave to File An Amended Complaint and Exhibits Filed in Civil Action No: 3:15-cv-05723 PGS-LHG |
| 2010 | Email Correspondence to Watson’s Counsel Serving Motion for Leave to File An Amended Complaint and attached Exhibits (Ex. 2009). |
| 2011 | Consent Order Entering Motion for Leave to File An Amended Complaint in Civil Action No: 3:15-cv-05723 PGS-LHG |
| 2012 | Orange Book Listing for Tyvaso® (Accessed October 3, 2017) |
| 2013 | First Notice Letter Sent June 12, 2015 by Watson Regarding Orange Book Listed Tyvaso® Patents |
| 2014 | Issue Notifications for US Patent No. 9,399,507 and US Patent No. 9,358,240 |
| 2015 | FDA Form 3542, Listing US Patent No. 9,399,507 in Orange Book |
| 2016 | FDA Form 3542, Listing US Patent No. 9,358,240 in Orange Book |
| 2017 | Email Correspondence between United Therapeutics and Watson Regarding Proposed Schedule for Civil Action No: 3:15-cv-05723 PGS-LHG in view of US Patent No. 9,399,507 and US Patent No. 9,358,240 |
| 2018 | Second Notice Letter Sent June 29, 2016 by Watson Regarding Orange Book Listed Tyvaso® Patents |

| Exhibit No. | Description |
|-------------|---|
| 2019 | Docket Navigator Summary Statistics on Unopposed Motions for Magistrate Judge Lois H. Goodman |
| 2020 | Declaration of Dr. Werner Seeger |
| 2021 | Bourge <i>et al.</i> , <i>Cardiovascular Therapeutics</i> 31:38-44 (2013) |
| 2022 | <i>Curriculum vitae</i> of Dr. Richard Dalby |
| 2023 | <i>Curriculum vitae</i> of Dr. Lewis Rubin |
| 2024 | 2002 Press Release Regarding Promotion of Robert Roscingo (accessed October 10, 2017) |
| 2025 | Shield Therapeutics Biography for Carl Sterritt (accessed October 10, 2017) |
| 2026 | Declaration of Dr. Hossein A. Ghofrani |
| 2027 | Declaration of Dr. Frank Reichenberger |
| 2028 | Declaration of Dr. Freidrich Grimminger |
| 2029 | Excerpts from Deposition of Dr. Maureen Donovan in Civil Action No: 3:15-cv-05723 PGS-LHG |
| 2030 | Email Correspondence with Orange Book Staff Confirming Date of Listing for US Patent No. 9,399,507 and US Patent No. 9,358,240 |
| 2031 | Email Correspondence with USTPO regarding Petitioner's Request to File a Reply |
| 2032 | Feb. 23, 2018 Conference Call Transcript |
| 2033 | Transcript from March 28, 2018 Deposition of Dr. Scott Bennett |
| 2034 | Transcript from April 4, 2018 Deposition of Dr. Maureen Donovan |
| 2035 | Transcript from April 6, 2018 Deposition of Dr. DeForest McDuff |
| 2036 | Email Correspondence with Petitioner regarding Deposition of Christopher Butler |
| 2037 | Listing of Issues and Supplements of <i>Circulation</i> Accessible on <i>Circulation</i> Website (accessed April 17, 2018) |
| 2038 | Second Declaration of Dr. Richard Dalby |
| 2039 | US 4,319,155 ("Nakai") |
| 2040 | Declaration of Dr. Aaron Waxman |
| 2041 | <i>Curriculum vitae</i> of Dr. Aaron Waxman |
| 2042 | <i>Mosby's Medical Dictionary</i> , 7 th ed. Mosby Elsevier, 2006 (excerpt). |
| 2043 | Leung, K, Louca E., & Coates, A., "Comparison of Breath-Enhanced to Breath-Actuated Nebulizers for Rate, Consistency, and Efficiency," <i>Chest</i> , 126(5):1619-1627 (2004) |
| 2044 | Rau, J.L., "Design Principles of Liquid Nebulization Devices Currently in Use," <i>Respir. Care</i> , 47(11):1257-1275 (2002) |

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| 2045 | Atkins, P.J. & T.M. Crowder, "The Design and Development of Inhalation Drug Delivery Systems," <i>Pharmaceutical Inhalation Aerosol Technology</i> , 2nd Ed. (A.J. Hickey ed., CRC Press), Ch. 9 (2003) |
| 2046 | Ventavis® Patient Brochure |
| 2047 | Rau, J.L., <i>Respiratory Care Pharmacology</i> . 6 th Ed. Mosby, 2002 (excerpt) |
| 2048 | Declaration of Dr. Robert Roscigno |
| 2049 | Excerpts from Tyvaso® NDA Integrated Summary of Efficacy (ISE) |
| 2050 | Clinical Investigation Report Synopsis for LungRx Study No: LRX-TRE-INH-0004 |
| 2051 | Clinical Investigation Report Synopsis for LungRx Study No: LRX-TRE-INH-0007 |
| 2052 | Letter from FDA confirming IND filing |
| 2053 | Declaration of Dr. Jeffrey Stec |
| 2054 | <i>Curriculum vitae</i> and Record of Prior Testimony of Dr. Jeffrey Stec |
| 2055 | Tyvaso® (treprostinil) An Inhaled Prostacyclin Analogue, Internal Presentation |
| 2056 | Classes of Heart Failure, American Heart Association (accessed April 19, 2017) |
| 2057 | FDA Approves TYVASO (Treprostinil) Inhalation Solution for the Treatment of Pulmonary Arterial Hypertension, July 30, 2009 |
| 2058 | 2014 Fourth-Quarter and Annual Financial Results, Investor Conference Call Q&A |
| 2059 | Voswinckel, R., <i>et al.</i> , "Favorable Effects of Inhaled Treprostinil in Severe Pulmonary Hypertension: Results from Randomized Controlled Pilot Studies," <i>JACC</i> , 48(6): 1672-1681(2006) |
| 2060 | Tyvaso®: Just Prescribed (accessed April 5, 2018) |
| 2061 | The World's Biggest Public Companies – United Therapeutics, Forbes (accessed April 26, 2018) |
| 2062 | America's Best Small Public Companies, Forbes (accessed April 26, 2018) |
| 2063 | Fastest-Growing Companies, Fortune (accessed April 26, 2018) |
| 2064 | United Therapeutics Corp., Morningstar (accessed March 29, 2017) |
| 2065 | Tyvaso 2014 Brand Plan, Internal |
| 2066 | 2013 Marketing Plan, Internal |
| 2067 | Tyvaso Marketing Overview, August 19, 2015, Internal |

| Exhibit No. | Description |
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| 2068 | Pulmonary Arterial Hypertension (PAH) Therapeutics – Global Drug Forecasts and Treatment Analysis to 2020, Internal |
| 2069 | Frumkin L.R., “The Pharmacological Treatment of Pulmonary Arterial Hypertension” <i>Pharmacol. Rev.</i> 64:583-620 (2012) |
| 2070 | Khaybullina D., <i>et al.</i> , “Riociguat (Adempas): a Novel Agent For the Treatment of Pulmonary Arterial Hypertension and Chronic Thromboembolic Pulmonary Hypertension,” <i>Pharmacy and Therapeutics.</i> 39(11):749-758. |
| 2071 | Project Clock Discussion Materials, February 3, 2016, Internal |
| 2072 | Actelion Delivers Outstanding 2014 Results, Actelion website (accessed April 26, 2018) |
| 2073 | Bloomberg L.P. WACC Report for UTHR (accessed March 14, 2017) |
| 2074 | Pulmonary Arterial Hypertension Market Surveillance ATU: Wave 5 (Q2 '15) – Final Report, Fielded July 2015, Internal |
| 2075 | 2014 Fourth-Quarter and Annual Financial Results, Investor Conference Call Q&A, Internal |
| 2076 | RESERVED |
| 2077 | Gagnon, M-A & Lexchin, J., “The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States,” <i>PLoS Medicine.</i> 5(1):epub (2008). |
| 2078 | McDuff, R.D., <i>et al.</i> , “Thinking Economically about Commercial Success,” <i>Landslide Magazine</i> 9(4) (2017) |
| 2079 | David, J. & Stewart M.B., “Commercial Success: Economic Principles Applied to Patent Litigation.” Leonard G.K. & Stiroh L.J.(Ed.), <i>Economic Approaches to Intellectual Property: Policy, Litigation, and Management</i> , New York: National Economic Research Associates Inc. 196-207 (2005) |
| 2080 | Grabowski, H. & Vernon, J., “The Distribution of Sales Revenue from Pharmaceutical Innovation,” <i>Pharmacoeconomics</i> , 18 Suppl.1 (2000) |
| 2081 | US 8,410,121 (“the ’121 patent”) |
| 2082 | US 9,550, 716 (“the ’716 patent”) |
| 2083 | TRIUMPH I Phase II Clinical Trial Protocol, created by January 11, 2005 |
| 2084 | ClinicalTrials.gov entry for TRIUMPH trial, NCT00147199 (accessed April 20, 2018) |

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