

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)

Exhibit No.	Description
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
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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