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WATSON LABORATORIES, INC., Petitioner,

v.

UNITED THERAPEUTICS CORP.

Patent Owner.
Case No. IPR2017-01622 Patent No. 9,339,507
Fatent 100. 9,339,307

PETITIONER'S UPDATED EXHIBIT LIST (AS OF JANUARY 25, 2018)

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PETITIONER'S EXHIBIT LIST

(as of January 25, 2018)

Exhibit	Description
1001	U.S. Patent No. 9,339,507
1002	Declaration of Maureen D. Donovan in Support of the Petition for
	Inter Partes Review of U.S. Patent No. 9,339,507
1003	Robert Voswinckel, et al. "Inhaled treprostinil sodium for the
	treatment of pulmonary hypertension" Abstract #1414, Circulation,
	110, 17, Supplement (Oct. 2004): III-295 ("Voswinckel")
1004	U.S. Patent Application Publication No. 2004/0265238 A1 to Chaudry
	("Chaudry")
1005	Hossein Ardeschi Ghofrani, Robert Voswinckel, et al., "Neue
	Therapieoptionen in der Behandlung der pulmonalarteriellen
	Hypertonie," Hertz, 30,4 (June 2005): 296-302 ("Ghofrani")
1006	Opti-Neb-ir® Operating Instructions, Model ON-100/2 (2005)
1007	RESERVED
1008	Venta-Neb-ir® A-I-C-I Operating Instructions, Model VN-100/4
1009	Annexes to Commission Decision C(2005)3436 of 05 September
	2005, http://ec.europa.eu/health/documents/community-
	register/2005/2005090510259/anx_10259_en.pdf (Annex III –
	Ventavis® Labelling and Package Leaflet)
1010	U.S. Patent No. 6,606,989 ("Brand '989")
1011	Amendment and Reply Accompanying RCE filed in 12/591,200 (Jul.
1010	2, 2013) (with accompanying Declaration of Lewis Rubin, M.D.)
1012	WO 93/00951 to Patton
1013	Declaration of Scott Bennett, Ph.D.
1014	Affidavit of Christopher Butler, June 15, 2017
1015	Affidavit of Christopher Butler, June 16, 2017
1016	RESERVED
1017	RESERVED
1018	U.S. Patent No. 6,521,212 ("Cloutier '212")
1019	U.S. Patent No. 4,306,075 ("Aristoff '075")
1020	U.S. Patent No. 5,190,972 ("Dumble '972")
1021	European Patent Specification 0347243 B1, published January 13,
1000	1993
1022	U.S. Patent No. 6,261,539 ("Adjei '539")
1023	European Patent Application Publication No. EP 0372777 A2
	("Purewal EP '777")



Exhibit	Description
1024	U.S. Patent No. 4,895,719 ("Radhakrishnan '719")
1025	U.S. Patent No. 5,153,222 ("Tadepalli '222")
1026	U.S. Patent No. 6,357,671 ("Cewers '671")
1027	Gessler, et al., Ultrasonic versus Jet Nebulization of Iloprost in Severe
	Pulmonary Hypertension, Eur. Respiratory J., 17:14-19 (2001)
1028	Olschewski H., et al., Aerosolized Prostacyclin and Iloprost in Severe
	Pulmonary Hypertension, 1996 Ann. Intern. Med. 124(9), 820-824
	(1996) ("Olschewski 199")
1029	Olschewski, et al., Pharmacodynamics and Pharmacokinetics of
	Inhaled Iloprost, Aerosolized by Three Different Devices, in Severe
	Pulmonary Hypertension, Chest J., 124(4), 1294-1304 (Oct. 2003)
1030	Byron, Drug Delivery Devices: Issues in Drug Development, Proc.
	Am. Thorac. Soc., 1:321-328 (2004)
1031	U.S. Patent No. 5,544,646 ("Lloyd")
1032	Edwards D.A. et al., Recent Advances in Pulmonary Drug Delivery
	Using Large Porous Inhaled Particles, Journal of Applied Physiology,
	85(2): 379-385 (1998) ("Edwards 1998")
1033	Badesch, et al., Prostanoid Therapy for Pulmonary Arterial
	Hypertension, J. of the Am. C. of Cardiology, 43(12):Suppl. S (2004)
1034	U.S. Patent No. 6,054,486 ("Crow '486")
1035	U.S. Food and Drug Administration, Drug Approval Package:
	Remodulin® (approved on May 21, 2002),
	http://www.accessdata.fda.gov/drugsatfda_docs/nda/2002/21-
	272_Remodulin.cfm ("Remodulin® Approval Package")
1036	Electronic Medicines Compendium, Ventavis®,
	http://www.medicines.org.uk/emc/medicine/13743
1037	European Agency Approves Ventavis for Primary Pulmonary
	Hypertension, P&T Community (Sep. 22, 2003),
	https://www.ptcommunity.com/news/2003-09-22-000000/european-
	agency-approves-ventavis-primary-pulmonary-hypertension
1038	EU Community Register of Medicinal Products, Homepage,
	http://ec.europa.eu/health/documents/community-
	register/html/index_en.htm
1039	EMEA Scientific Discussion, Ventavis® (2004),
	http://www.ema.europa.edu/docs/en_GB/document_library/
	EPAR_Scientific_Discussion/human/000474/WC500048688.pdf



Exhibit	Description
1040	Muller et al., "Use of Inhaled Iloprost in a Case of Pulmonary
	Hypertension during Pediatric Congenital Heart Surgery," 99
	Anesthesiology 743-747 (2003)
1041	Mueller et al., "Inhaled Iloprost in the Management of Pulmonary
	Hypertension in Infants Undergoing Congenital Heart Surgery,"
	21 Eur. J. Anaesthesiology (suppl. 33) 2-36 (2004)
1042	Commission Decision C(2005)3436 of 05 September 2005,
	http://ec.europa.eu/health/documents/community-
	<u>register/2005/2005090510259/dec_10259_en.pdf</u>
1043	EU Community Register of Medicinal Products for Human Use,
	Ventavis, http://ec.europa.eu/health/documents/community-
	register/html/h255.htm#
1044	Summary of Community Decisions, Official Journal of the European
	Union (Oct. 28, 2005) http://eur-lex.europa.eu/legal-
	content/EN/TXT/?uri=uriserv:OJ.C2005.268.01.0002.01.ENG&toc=
	OJ:C:2005:268:TOC (noting a modification of marketing approval for
	Ventavis®)
1045	Electronic Medicines Compendium, Ventavis®,
	http://www.medicines.org.uk/emc/history/13743#version1 (noting a
	change to section 4.2 – Posology and Method of Administration on
1015	September 22, 2005)
1046	Voswinckel, R., et al., "Inhaled treprostinil is a potent pulmonary
	vasodilator in severe pulmonary hypertension," 25 European Heart
1015	Journal 22, at 218 (2004) ("Voswinckel II")
1047	Sulica, R and Poon, M. "Medical Therapeutics for Pulmonary Arterial
	Hypertension From Basic Science and Clinical Trial Design to
	Evidence-Based Medicine." 3(2) Expert Rev. Cardiovas. Ther. 347-
1040	360 (2005)
1048	American Heart Association's Scientific Sessions 2004 – Largest
	Cardiovascular Meeting Plans to 'Jazz It Up' in New Orleans, PR
	Newswire (Oct. 13 2004), http://www.prnewswire.com/news-releases/american heart associations acientific associations 2004
	releases/american-heart-associations-scientific-sessions-2004
	largest-cardiovascular-meeting-plans-to-jazz-it-up-in-new-orleans-74293197.html#
1040	
1049	EU Community Register of Medicinal Products, Frequently Asked
	Questions, http://ec.europa.eu/health/documents/community-register/register-fag-2015.pdf
	register/register_faq_2015.pdf



Exhibit	Description
1050	Regulation (EC) No 726/2004 of the European Parliament and of the
	Council of 31 March 2004, http://eur-lex.europa.eu/LexUriServ/
	LexUriServ.do?uri=OJ:L:2004:136:0001:0033:en:PDF
1051	Register of Commission Documents, European Union,
	https://ec.europa.eu/transparency/regdoc/index.cfm?fuseaction=home
1052	Regulation (EC) No. 1049/2001 of the European Parliament and of the
	Council of 30 May 2001,
	http://www.europarl.europa.eu/RegData/PDF/r1049_en.pdf
1053	Register of the Commission Documents, European Commission,
	https://ec.europa.eu/transparency/regdoc/index.cfm?fuseaction=
	list&n=10&adv=0&coteId=&year=2005&number=
	3436&version=ALL&dateFrom=&dateTo=
	&serviceId=&documentType=&title=&titleLanguage=&titleSearch=
	EXACT&sortBy=NUMBER&sortOrder=DESC (search result for
	document search of Commission reference number '3436' for year
1071	(2005')
1054	U.S. Patent No. 5,234,953 ("Crow '953")
1055	Declaration of DeForest McDuff, Ph.D.
1056	U.S. Patent No. 9,358,240
1057	U.S. Patent No. 6,756,033
1058	Amendment and Reply filed in 13/469,854 (Jan. 4, 2013) (with
1070	accompanying Declaration of Lewis Rubin, M.D.)
1059	Reply in 13/469,854 (June 13, 2014)
1060	William F. Ganong, Review of Medical Physiology 591-92 (17th ed. 1995)
1061	Actelion Pharmaceuticals, "Actelion Announces Full Year 2003
	Financial Results" (March 2, 2004)
1062	Actelion Pharmaceuticals, "Actelion Announces Full Year 2005
	Financial Results" (Feb. 23, 2006)
1063	Actelion Pharmaceuticals, Annual Report, 2002
1064	Actelion Pharmaceuticals, Annual Report, 2006
1065	Actelion Pharmaceuticals, Annual Report, 2007
1066	Actelion Pharmaceuticals, Annual Report, 2008
1067	Actelion Pharmaceuticals, Annual Report, 2010
1068	Actelion Pharmaceuticals, Annual Report, 2011
1069	Actelion Pharmaceuticals, Annual Report, 2012
1070	Actelion Pharmaceuticals, Annual Report, 2013
1071	Actelion Pharmaceuticals, Annual Report, 2014



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