

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ANTARES PHARMA, INC., LEO PHARMA A/S and LEO PHARMA INC.,

Petitioners

v.

MEDAC GESELLSCHAFT FUER KLINISCHE SPEZIALPRÄPARATE MBH

Patent Owner

Case No.: IPR2014-01091

Patent No. 8,664,231

Title: Concentrated Methotrexate Solutions

Before TONI R. SCHEINER, ERICA A. FRANKLIN, and
JACQUELINE WIRGHT BONILLA

**PETITIONERS ANTARES PHARMA, INC., LEO PHARMA A/S and LEO
PHARMA INC. LIST OF EXHIBITS**

Further to 37 C.F.R. § 42.63(e), Petitioners Antares Pharma, Inc., Leo Pharma A/S and Leo Pharma Inc. hereby submit a current listing of Antares Exhibits to the Board and counsel for Patent Owner medac Pharma, Inc. and medac Gesellschaft für klinische Spezialpräparate mbH.

FILED EXHIBITS	DESCRIPTION	PREVIOUSLY SUBMITTED
Exhibit 1001	U.S. 8,664,231 to Heiner WILL, titled, “Concentrated Methotrexate Solutions,” filed on March 4, 2009, and issued on March 4, 2014 (“the ’231 Patent”).	x
Exhibit 1002	Excerpts from File History for U.S. Patent No. 8,664,231.	x
Exhibit 1003	U.S. 6,544,504 to Paul GRINT et al., titled, “Combined Use of Interleukin 10 and Methotrexate for Immunomodulatory Therapy,” filed on Jun. 26, 2000, and issued on April 8, 2003 (“ <i>Grint</i> ”).	x
Exhibit 1004	Hoekstra <i>et al.</i> (2004) J. Rheumatol 31(4):645-648 (“ <i>Hoekstra</i> ”).	x
Exhibit 1005	Jørgensen <i>et al.</i> (1996) Ann Pharmacother 30:729-32 (“ <i>Jørgensen</i> ”).	x
Exhibit 1006	Alsufyani <i>et al.</i> (2003) J. Rheumatol 31:179-82 (“ <i>Alsufyani</i> ”).	x
Exhibit 1007	1985 Ed. Physician’s Desk Reference for Mexate [®] (“ <i>the PDR for Mexate</i> ®”).	x
Exhibit 1008	Brooks <i>et al.</i> (1990) Arthritis and Rheum. 33(1):91-94 (“ <i>Brooks</i> ”).	x
Exhibit 1009	Product Summary for the “Methotrexate 100 mg/ml Injection” product by Hospira UK Ltd., Date of First Authorization 13 March 1987, Date of Revision of the Text 22 November 2005 (“ <i>the Hospira reference</i> ”).	x
Exhibit 1010	Zackheim (1992) J. Am. Acad. of Derm. 23(6) p. 1008 (“ <i>Zackheim</i> ”).	x
Exhibit 1011	Müller-Ladner (2010) The Open Rheumatology Journal 4:15-22. (“ <i>Müller-Ladner</i> ”).	x

FILED EXHIBITS	DESCRIPTION	PREVIOUSLY SUBMITTED
Exhibit 1012	Weinblatt Declaration; Dated June 17, 2014 (“Weinblatt Decl.”).	x
Exhibit 1013	Gammon Declaration; Dated June 27, 2014 (“Gammon Decl.”).	x
Exhibit 1014	Pincus <i>et al.</i> (2003) Clin Exp Rheumatol (Suppl. 31):S179-S185 (“Pincus”).	x
Exhibit 1015	Insulin Administration, <i>Diabetes Care</i> , 26:1 S121-124 (2003) (“ <i>Insulin Admin</i> ”)	x
Exhibit 1016	Complaint in Medac Pharma, Inc. v. Antares Pharma, Inc., Nos. 1:14-cv-01498-JBS-KMW	x
Exhibit 1017	Portion of EPO prosecution for EP Application No. 07 786 239.9 and Certified English Translation of the same.	x
Exhibit 1018	Weinblatt (1993) “Methotrexate,” in Textbook of Rheumatology, 4th Edition, Chapter 47, (Kelley et al., eds. 1993) (“ <i>Weinblatt 1993</i> ”)	x
Exhibit 1019	Hoffmeister (1983) “Methotrexate therapy in rheumatoid arthritis: 15 years experience,” <i>Am J Med</i> 75:69-73 (1993)	x
Exhibit 1020	Weinblatt (1995) Efficacy of Methotrexate in Rheumatoid Arthritis, Br. J. Rheum. 34(suppl. 2):43-48 (“ <i>Weinblatt 1995</i> ”)	x
Exhibit 1021	Weinblatt <i>et al.</i> (1985) “Efficacy of Low-Dose Methotrexate in Rheumatoid Arthritis,” New England J. Med. 312:818-822 (“ <i>Weinblatt 1985</i> ”)	x
Exhibit 1022	Hoffmeister (1972) Methotrexate in rheumatoid arthritis. <i>Arthritis rheum.</i> 15 (Suppl.): S114 (abstract) (“ <i>Hoffmeister 1972</i> ”)	x
Exhibit 1023	Weinblatt <i>et al.</i> (1994) Methotrexate in Rheumatoid Arthritis: a 5 Year Prospective Multicenter Study, <i>Arth. Rheum.</i> 37(10):1492-1498 (“ <i>Weinblatt 1994</i> ”)	x
Exhibit 1024	Weinblatt <i>et al.</i> (1992) Long-Term Prospective Study of Methotrexate the Treatment of Rheumatoid Arthritis: 84-Month Update, <i>Arth. Rheum.</i> 35(2):129-137 (“ <i>Weinblatt 1992</i> ”)	x

FILED EXHIBITS	DESCRIPTION	PREVIOUSLY SUBMITTED
Exhibit 1025	Gubner <i>et al.</i> (1951) Therapeutic suppression of tissue reactivity. II. Effect of aminopterin in rheumatoid arthritis and psoriasis. <i>Am J Med Sci.</i> , 22:176-82 (“ <i>Gubner</i> ”)	x
Exhibit 1026	Black <i>et al.</i> (1964) Methotrexate therapy in psoriatic arthritis. Double-blind study on 21 patients. <i>J Am Med Assoc</i> 189:743-7 (“ <i>Black</i> ”)	x
Exhibit 1027	Feagan <i>et al.</i> (1995) Methotrexate for the Treatment of Crohn’s Disease, <i>New England J. Med.</i> 332(5):292-297 (“ <i>Feagan</i> ”)	x
Exhibit 1028	Furst <i>et al.</i> (1989) Increasing Methotrexate Effect with Increasing Dose in the Treatment of Resistant Rheumatoid Arthritis, <i>J. Rheum</i> 16(3):313-20 (“ <i>Furst</i> ”)	x
Exhibit 1029	Giannini, <i>et al.</i> (1992) Methotrexate in resistant juvenile rheumatoid arthritis—results of the U.S.A.-U.S.S.R. double-blind, placebo-controlled trial. <i>N. Engl. Med.</i> 326:1043 (“ <i>Giannini</i> ”)	x
Exhibit 1030	Michaels, <i>et al.</i> (1992) Weekly Intravenous Methotrexate in the Treatment of Rheumatoid Arthritis, <i>Arthritis and Rheumatism</i> 25(3):339-341 (“ <i>Michaels</i> ”)	x
Exhibit 1031	Weinblatt Curriculum Vitae	x
Exhibit 1032	Gammon Curriculum Vitae	x
Exhibit 1033	Transcript of January 21, 2015, Conference Call	

Respectfully submitted,

March 16, 2015

/s/ Sanya SukduangBy: Sanya Sukduang (Lead Counsel)

Reg. No. 46,390

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(a), I, John W. Kozikowski, certify that on this 16th day of March, 2015, a copy of **PETITIONERS ANTARES PHARMA, INC., LEO PHARMA A/S and LEO PHARMA INC. LIST OF EXHIBITS** was served by electronic mail upon the following:

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Date: March 16, 2015



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