

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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FRONTIER THERAPEUTICS, LLC

Petitioner

v.

MEDAC GESELLSCHAFT FÜR KLINISCHE  
SPEZIALPRÄPARATE MBH

Patent Owner

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*Inter Partes* Review Case No. IPR2016-00649

Patent No. 8,664,231

Title: Concentrated Methotrexate Solutions

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**TABLE OF EXHIBITS**

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Exhibit No.	Description
<b>Exhibit 1001</b>	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”).
<b>Exhibit 1002</b>	Excerpts from File History for U.S. Patent No. 8,664,231.
<b>Exhibit 1003</b>	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 (“Grint”).
<b>Exhibit 1004</b>	Hoekstra et al. (2004) <i>J. Rheumatol.</i> 31(4):645-648 (“Hoekstra”).
<b>Exhibit 1005</b>	Jørgensen et al. (1996) <i>Ann. Pharmacother.</i> 30:729-32 (“Jørgensen”).
<b>Exhibit 1006</b>	Alsufyani et al. (2003) <i>J. Rheumatol.</i> 31:179-82 (“Alsufyani”).
<b>Exhibit 1007</b>	1985 Ed. Physician’s Desk Reference for Mexate® (“PDR”).
<b>Exhibit 1008</b>	Brooks et al. (1990) <i>Arthritis and Rheum.</i> 33(1): 91-94 (“Brooks”).
<b>Exhibit 1009</b>	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 (“Hospira”).
<b>Exhibit 1010</b>	Zackheim (1992) <i>J. Am. Acad. of Derm.</i> 23(6) p. 1008 (“Zackheim”).
<b>Exhibit 1011</b>	Müller-Ladner (2010) <i>The Open Rheumatology Journal</i> 4:15-22. (“Müller-Ladner”).
<b>Exhibit 1012</b>	Dr. Gershwin Declaration (“Gershwin Decl.”).
<b>Exhibit 1013</b>	Mr. Gammon Declaration (“Gammon Decl.”).
<b>Exhibit 1014</b>	Pincus et al. (2003) <i>Clin Exp Rheumatol</i> (Suppl. 31):S179-S185 (“Pincus”).
<b>Exhibit 1015</b>	Insulin Administration, <i>Diabetes Care</i> , 26:1 S121-124 (2003) (“Insulin Admin”)
<b>Exhibit 1016</b>	Complaint in <i>Medac Pharma, Inc. v. Antares Pharma, Inc.</i> , Nos. 1:14-cv-01498-JBS-KMW
<b>Exhibit 1017</b>	Portion of EPO prosecution for EP Application No. 07 786 239.9 and Certified English Translation of the same.
<b>Exhibit 1018</b>	Weinblatt (1993) “Methotrexate,” in Textbook of

	Rheumatology, 4 <sup>th</sup> Edition, Chapter 47, (Kelley et al., eds. 1993) (“Weinblatt 1993”)
<b>Exhibit 1019</b>	Hoffmeister (1983) “Methotrexate therapy in rheumatoid arthritis: 15 years experience,” <i>Am J Med</i> 75:69-73 (“Hoffmeister 1983”)
<b>Exhibit 1020</b>	Weinblatt (1995) Efficacy of Methotrexate in Rheumatoid Arthritis, <i>Br. J. Rheum.</i> 34(suppl. 2):43-48 (“Weinblatt 1995”)
<b>Exhibit 1021</b>	Weinblatt et al. (1985) “Efficacy of Low-Dose Methotrexate in Rheumatoid Arthritis,” <i>N. Engl. J. Med.</i> 312:818-822 (“Weinblatt 1985”)
<b>Exhibit 1022</b>	Hoffmeister (1972) Methotrexate in rheumatoid arthritis. <i>Arthritis Rheum.</i> 15 (Suppl.): S114 (abstract) (“Hoffmeister 1972”)
<b>Exhibit 1023</b>	Weinblatt et al. (1994) Methotrexate in Rheumatoid Arthritis: a 5 Year Prospective Multicenter Study, <i>Arth. Rheum.</i> 37(10):1492-1498 (“Weinblatt 1994”)
<b>Exhibit 1024</b>	Weinblatt et al. (1992) Long-Term Prospective Study of Methotrexate the Treatment of Rheumatoid Arthritis: 84-Month Update, <i>Arth. Rheum.</i> 35(2): 129-137 (“Weinblatt 1992”)
<b>Exhibit 1025</b>	Gubner et al. (1951) Therapeutic suppression of tissue reactivity. I. Comparison of the Effects of Cortisone and Aminopetrin, <i>Am. J. Med. Sci.</i> , 22:176-82 (“Gubner”)
<b>Exhibit 1026</b>	Black et al. (1964) Methotrexate therapy in psoriatic arthritis. Doubleblind study on 21 patients. <i>J. Am. Med. Assoc.</i> 189:743-7 (“Black”)
<b>Exhibit 1027</b>	Feagan et al. (1995) Methotrexate for the Treatment of Crohn’s Disease, <i>N. Engl. J. Med.</i> 332(5): 292-297 (“Feagan”)
<b>Exhibit 1028</b>	Furst et al. (1989) Increasing Methotrexate Effect with Increasing Dose in the Treatment of Resistant Rheumatoid Arthritis, <i>J. Rheum.</i> 16(3): 313-20 (“Furst”)
<b>Exhibit 1029</b>	Giannini, et al. (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. J. Med.</i> 326:1043 (“Giannini”)
<b>Exhibit 1030</b>	Michaels, et al. (1992) Weekly Intravenous Methotrexate in the Treatment of Rheumatoid Arthritis, Arthritis and Rheumatism 25(3): 339-341 (“Michaels”)
<b>Exhibit 1031</b>	Dr. Gershwin’s Curriculum Vitae

<b>Exhibit 1032</b>	Mr. Gammon's Curriculum Vitae
<b>Exhibit 1033</b>	<i>Petition for Inter Partes Review by Antares Pharma Inc. et al.</i> , PTAB-IPR2014-01091, Paper No. 7, January 6, 2015 ('091 IPR Institution).

Respectfully submitted,

/s/ Dr. Gregory J. Gonsalves

Dr. Gregory J. Gonsalves

Reg. No. 43,639

2216 Beacon Lane

Falls Church, Virginia 22043

(571) 419-7252

[gonsalves@gonsalveslawfirm.com](mailto:gonsalves@gonsalveslawfirm.com)

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