

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

KOIOS PHARMACEUTICALS LLC

Petitioner

v.

MEDAC GESELLSCHAFT FUER KLINISCHE SPEZIALPRÄPARATE MBH

Patent Owner

IPR2016-01370

Patent No. 8,664,231

Title: Concentrated Methotrexate Solutions

PETITION FOR *INTER PARTES* REVIEW

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List of Exhibits

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").
Exhibit 1002	Excerpts from File History for U.S. Patent No. 8,664,231.
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 June 26, 2000, and issued on April 8, 2003 (" <i>Grint</i> ").
Exhibit 1004	Hoekstra et al. (2004) J. Rheumatol. 31(4):645-47 (" <i>Hoekstra</i> ").
Exhibit 1005	Jørgensen et al. (1996) Ann. Pharmacother. 30:729-32 (" <i>Jørgensen</i> ").
Exhibit 1006	Alsufyani et al. (2003) J. Rheumatol. 31:179-82 (" <i>Alsufyani</i> ").
Exhibit 1007	Declaration of Dr. Elena Massarotti, dated June 2, 2016, in support of Medac's Preliminary Response in IPR2016-00649.
Exhibit 1008	Brooks et al. (1990) Arthritis and Rheum. 33(1):91-94 (" <i>Brooks</i> ").
Exhibit 1009	Medac's Preliminary Response in IPR2016-00649, dated June 2, 2016.
Exhibit 1010	Zackheim (1992) J. Am. Acad. of Derm. 23(6) p. 1008 (" <i>Zackheim</i> ").
Exhibit 1011	Müller-Ladner (2010) The Open Rheumatology Journal 4:15-22. (" <i>Müller-Ladner</i> ").
Exhibit 1012	Weinblatt Declaration; Dated June 17, 2014 (" <i>Weinblatt Decl.</i> ").
Exhibit 1013	Gammon Declaration; Dated June 27, 2014 (" <i>Gammon Decl.</i> ").
Exhibit 1014	Pincus et al. (2003) Clin. Exp. Rheumatol. (Suppl. 31):S179-S185 (" <i>Pincus</i> ").
Exhibit 1015	Insulin Administration, Diabetes Care, 26:1 S121-S124 (2003) (" <i>Insulin Admin</i> ").
Exhibit 1016	Complaint in <i>Medac Pharma, Inc. v. Antares Pharma, Inc.</i> , Nos. 1:14-cv-01498-JBS-KMW.
Exhibit 1017	Portion of EPO prosecution for EP Application No. 07 786 239.9 and Certified English Translation of the same.
Exhibit 1018	Weinblatt (1993) "Methotrexate," in Textbook of Rheumatology, 4th Edition, Chapter 47, (Kelley et al., eds. 1993) (" <i>Weinblatt 1993</i> ").
Exhibit 1019	Schiff et al., "Head-to-head, randomized, crossover study of oral versus subcutaneous methotrexate in patients with rheumatoid arthritis," Ann. Rheum. Dis. 0:1-3 (2014) (" <i>Schiff</i> ").
Exhibit 1020	Weinblatt (1995) Efficacy of Methotrexate in Rheumatoid Arthritis, Br. J. Rheum. 34(suppl. 2):43-48 (" <i>Weinblatt 1995</i> ").
Exhibit 1021	Product Label for the "Methotrexate Sodium for Injection" product by Wyeth, Date of First Authorization August 10, 1959, Date of

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