

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

Declaration of Scott E. Kamholz

Koios Exhibit 1036

I, Scott E. Kamholz, declare:

1. I am an attorney at Foley Hoag LLP, and counsel of record for Koios Pharmaceuticals LLC in the above-captioned matter. I am registered to practice before the United States Patent and Trademark Office.

2. Attached as Ex. 1004 is a true and correct copy of Hoekstra et al. (2004) J. Rheumatol. 31(4):645-47 (“*Hoekstra*”). *Hoekstra* was published in a periodical that is published in regular intervals.

3. Attached as Ex. 1005 is a true and correct copy of Jørgensen et al. (1996) Ann. Pharmacother. 30:729-32 (“*Jørgensen*”). *Jørgensen* was published in a periodical that is published in regular intervals.

4. Attached as Ex. 1006 is a true and correct copy of Alsufyani et al. (2003) J. Rheumatol. 31:179-82 (“*Alsufyani*”). *Alsufyani* was published in a periodical that is published in regular intervals.

5. Attached as Ex. 1007 is a true and correct copy of the Declaration of Dr. Elena Massarotti, dated June 2, 2016, in support of Medac’s Preliminary Response in IPR2016-00649, obtained from the docket in that proceeding.

6. Attached as Ex. 1008 is a true and correct copy of Brooks et al. (1990) Arthritis and Rheum. 33(1):91-94 (“*Brooks*”). *Brooks* was published in a periodical that is published in regular intervals.

7. Attached as Ex. 1009 is a true and correct copy of Medac's Preliminary Response in IPR2016-00649, dated June 2, 2016, obtained from the docket in that proceeding.

8. Attached as Ex. 1010 is a true and correct copy of Zackheim (1992) J. Am. Acad. of Derm. 23(6) p. 1008 ("*Zackheim*"). *Zackheim* was published in a periodical that is published in regular intervals.

9. Attached as Ex. 1011 is a true and correct copy of Müller-Ladner (2010) The Open Rheumatology Journal 4:15-22 ("*Müller-Ladner*"). *Müller-Ladner* was published in a periodical that is published in regular intervals.

10. Attached as Ex. 1012 is a true and correct copy of the Declaration of Dr. Michael E. Weinblatt, dated June 17, 2014, in support of Antares Pharma's Petition in IPR2014-01091, obtained from the docket in that proceeding.

11. Attached as Ex. 1013 is a true and correct copy of the Declaration of David C. Gammon, dated June 27, 2014, in support of Antares Pharma's Petition in IPR2014-01091, obtained from the docket in that proceeding.

12. Attached as Ex. 1014 is a true and correct copy of Pincus et al. (2003) Clin. Exp. Rheumatol. (Suppl. 31):S179-S185 ("*Pincus*"). *Pincus* was published in a periodical that is published in regular intervals.

13. Attached as Ex. 1015 is a true and correct copy of Insulin Administration, *Diabetes Care*, 26:1 S121-S124 (2003) (“*Insulin Admin*”). *Insulin Admin* was published in a periodical that is published in regular intervals.

14. Attached as Ex. 1016 is a true and correct copy of the Complaint in *Medac Pharma, Inc. v. Antares Pharma, Inc.*, Nos. 1:14-cv-01498-JBS-KMW, obtained from the docket in that proceeding.

15. Attached as Ex. 1018 is a true and correct copy of the provided pages from Weinblatt (1993) “Methotrexate,” in *Textbook of Rheumatology*, 4th Edition, Chapter 47, (Kelley et al., eds. 1993) (“*Weinblatt 1993*”).

16. Attached as Ex. 1019 is a true and correct copy of 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) (“*Schiff*”). *Schiff* was published in a periodical that is published in regular intervals.

17. Attached as Ex. 1020 is a true and correct copy of Weinblatt (1995) Efficacy of Methotrexate in Rheumatoid Arthritis, *Br. J. Rheum.* 34(suppl. 2):43-48 (“*Weinblatt 1995*”). *Weinblatt 1995* was published in a periodical that is published in regular intervals.

18. Attached as Ex. 1021 are two true and correct copies of the Product Label for the “Methotrexate Sodium for Injection” product by Wyeth (“*Wyeth*”),

date of first authorization August 10, 1959, date of supplement approval January 27, 2004, archived by Archive.org as of April 29, 2005.

19. The first page of Ex. 1021 is a true and correct excerpt of the FDA's CDER New and Generic Drug Approvals webpage as of April 29, 2005, as saved by the Internet Archive, with the entry corresponding to *Wyeth* identified in the red bracket, and the link to the *Wyeth* reference shown in the far right in purple. The first page of Ex. 1021 is available at the URL shown in the browser bar, *i.e.*, <https://web.archive.org/web/20050405214343/http://www.fda.gov/cder/approval/index.htm>, under the letter M. Pages 2 through 28 of Ex. 1021 contain a copy of the *Wyeth* reference accessed by clicking on the purple link at the far right of page 1. The URL for pages 2 through 28 is shown in the header of those pages, *i.e.*, https://web.archive.org/web/20041210024809/http://www.fda.gov/CDER/foi/label/2004/11719slr106_methotrexate_lbl.pdf.

20. Also attached as Ex. 1021, at Page 29 of 82 of the exhibit, is a true and correct copy of the Affidavit of Christopher Butler on behalf of the Internet Archive, authenticating a second copy of the *Wyeth* reference attached as Exhibit A to the Butler Declaration. The two copies of the *Wyeth* reference contained in Ex. 1021 are substantively identical except that the version provided by Mr. Butler omits bolding contained in the original copy of *Wyeth*.

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