

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

KOIOS PHAMRACEUTICALS LLC

Petitioner

v.

MEDAC GESELLSCHAFT FÜR KLINISCHE
SPEZIALPRÄPARATE MBH

Patent Owner

Inter Partes Review Case No. IPR2016-01370
Patent Number 8,664,231

**DECLARATION OF BRIAN GUMMOW IN SUPPORT OF PATENT
OWNER'S PRELIMINARY RESPONSE**

I, Brian Gummow, make the following Declaration pursuant to
28 U.S.C. § 1746:

1. I am an Associate at Ropes & Gray LLP.
2. I provide this Declaration in connection with the above-identified

Inter Partes Review proceeding that is being requested at the United States Patent

and Trademark Office. Unless otherwise stated, the facts stated in this Declaration are based on my personal knowledge.

3. Exhibit 2001 hereto is a true and correct copy of an article entitled “Bioavailability of oral vs. subcutaneous low-dose methotrexate in patients with Crohn’s disease,” published by *Alimentary Pharmacology & Therapeutics*, which I downloaded from <http://onlinelibrary.wiley.com/doi/10.1046/j.1365-2036.2003.01614.x/pdf> on May 22, 2016. Page numbers and an exhibit label have been added to the bottom of this document but no other alterations have been made.

4. Exhibit 2002 hereto is a true and correct copy of an article entitled “Improving Tolerance and Bioavailability of Methotrexate by Switching from Oral to Subcutaneous Route of Administration,” published by *Rheumatology*, which was downloaded by Ropes & Gray Librarian Derrik Albertelli, at my request from http://rheumatology.oxfordjournals.org/content/44/suppl_1/i145.full.pdf+html on May 31, 2016. Page numbers and an exhibit label have been added to the bottom of this document but no other alterations have been made.

5. Exhibit 2003 hereto is a true and correct copy of an article entitled “Pharmacokinetics of Subcutaneous Methotrexate,” published by the *Journal of Clinical Oncology*, which was downloaded by Ropes & Gray Librarian Derrik

Albertelli, at my request from
<http://jco.ascopubs.org/content/6/12/1882.full.pdf+html> on June 1, 2016. Page numbers and an exhibit label have been added to the bottom of this document but no other alterations have been made.

6. Exhibit 2004 hereto is a true and correct copy of a book chapter entitled “Human: Veterinary Technology Cross Over,” published by Springer, in the book *Long Acting Animal Health Drug Products: Fundamentals and Applications*, which was downloaded from http://link.springer.com/chapter/10.1007/978-1-4614-4439-8_16 at my request by Ropes & Gray librarian Michele Prevost on May 23, 2016. Page numbers and an exhibit label have been added to the bottom of this document but no other alterations have been made.

7. Exhibit 2005 hereto is a true and correct copy of book chapters entitled “Drug Administration” and “Life Span: Children,” published by Wolters Kluwer Health | Lippincott Williams & Wilkinson, in the book *Drug Therapy in Nursing*, which was photocopied from the University of Wisconsin Library by WTS Article Delivery at my request on May 31, 2016. Page numbers and an exhibit label have been added to the bottom of this document but no other alterations have been made.

8. Exhibit 2006 hereto is a true and correct copy of a press release by Antares Pharma entitled, “Antares Pharma Announces the Publication of a Head-to-Head, Randomized, Crossover Study of Oral Versus Subcutaneous Methotrexate in Patients with Rheumatoid Arthritis,” published and released by Business Wire on April 17, 2014, which I downloaded from <http://www.businesswire.com/news/home/20140417005273/en/Drug-Exposure-Limitations-Oral-Methotrexate-Doses-Greater-Equal> on November 8, 2016. An exhibit label on the first page and page numbers on all pages have been added to the bottom of this document but no other alterations have been made.

9. Exhibit 2009 hereto is a press release by Koios Pharmaceuticals LLC entitled, “Koios Pharmaceuticals Files Challenge to High-Cost Drug’s Patent” published and released by Business Wire on July 20, 2016, which I downloaded from <http://www.businesswire.com/news/home/20160720006500/en/Koios-Pharmaceuticals-Files-Challenge-High-Cost-Drug’s-Patent> on October 29, 2016. An exhibit label on the first page and page numbers on all pages have been added to the bottom of this document but no other alterations have been made.

10. I have been informed that willfully false statements are punishable by fine or imprisonment, or both. I make this declaration of my own personal knowledge, and all statements are true. If called to testify as to the truth of the matters stated herein, I could and would testify competently.

IPR2016-01370
U.S. Patent No. 8,664,231

Attorney Docket No.
110670-0009-651

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 10 day of November, 2016, at New York, NY.



Brian Gummow