

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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KOIOS PHARMACEUTICALS LLC

Petitioner

v.

MEDAC GESELLSCHAFT FÜR KLINISCHE  
SPEZIALPRÄPARATE MBH

Patent Owner

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

**DECLARATION OF BRIAN GUMMOW IN SUPPORT OF  
PATENT OWNER'S 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.

1. Exhibit 2013 hereto is a true and correct copy of an article entitled “The Use of Methotrexate in Rheumatoid Arthritis,” published by Seminars in Arthritis and Rheumatism, which was downloaded by Ropes & Gray Librarian Dan Braun, at my request from <http://www.sciencedirect.com/science/article/pii/S0049017204001556> 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.

2. Exhibit 2014 hereto is a true and correct copy of an article entitled “Pharmacokinetics and pharmacodynamics of methotrexate in non-neoplastic diseases,” published by Clinical Pharmacokinetics, which was downloaded by Ropes & Gray Librarian Ying Zhang, at my request from <http://link.springer.com/article/10.2165/00003088-200342020-00003> on May 24, 2016. Page numbers and an exhibit label have been added to the bottom of this document but no other alterations have been made.

3. Exhibit 2015 hereto is a true and correct copy of Drugs@FDA database entry for Mexate, which I accessed and printed from <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.DrugDetails> on May 22, 2016, and which is a record of the FDA to which all

parties have access. Page numbers and an exhibit label have been added to the bottom of this document but no other alterations have been made.

4. Exhibit 2016 hereto is a true and correct copy of an article entitled “Head-to-head, randomised, crossover study of oral versus subcutaneous methotrexate in patients with rheumatoid arthritis,” published by *Annals of the Rheumatic Diseases*, which I downloaded from <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4112421/pdf/annrheumdis-2014-205228.pdf> on June 1, 2016, and which is a record of the NIH to which all parties have access. Page numbers and an exhibit label have been added to the bottom of this document but no other alterations have been made.

5. Exhibit 2017 hereto is a true and correct copy of an article entitled “Parenteral methotrexate should be given before biological therapy,” published by *Rheumatology*, which I downloaded from <http://rheumatology.oxfordjournals.org/content/42/8/1009.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.

6. Exhibit 2019 hereto is a true and correct copy of a book chapter entitled “Antiproliferative Agents and Drugs Used for Immunosuppression,” published by Macmillan Publishing Company, in the book *Goodman and Gilman’s The Pharmacological Basis of Therapeutics, Seventh Edition*, which was

photocopied from the University of Minnesota Library at my request on June 2, 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 2020 hereto is a true and correct copy of an article entitled “2007 Guidelines for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings,” published by Centers for Disease Control and Prevention, which I downloaded from <http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf> on May 24, 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 2021 hereto is a true and correct copy of a letter from SICOR Pharmaceuticals, Inc. entitled “ANDA Suitability Petition Methotrxate Injections, USP (100 mg/mL),” published by the Food and Drug Administration, which I downloaded from <http://www.fda.gov/ohrms/dockets/dockets/06p0177/06p-0177-cp00001-01-vol1.pdf> on May 24, 2016, and which is a record to which all parties have access. Page numbers and an exhibit label have been added to the bottom of this document but no other alterations have been made.

9. Exhibit 2022 hereto is a true and correct copy of an article entitled “Current Perspectives on Pain Upon Injection of Drugs,” published by the

Journal of Pharmaceutical Sciences, which was downloaded by Ropes & Gray Librarian Dan Braun, at my request from <http://www.sciencedirect.com/science/article/pii/S0022354915505923> on May 26, 2016. Page numbers and an exhibit label have been added to the bottom of this document but no other alterations have been made.

10. Exhibit 2024 hereto is a true and correct copy of “Clinical Guidelines, Extravasation,” *West Suffolk Hospitals*, [http://www.wsh.nhs.uk/AboutUs/FOI/FOIRequestsAndResponses/Attachments/1033\(i\).pdf](http://www.wsh.nhs.uk/AboutUs/FOI/FOIRequestsAndResponses/Attachments/1033(i).pdf) (July 2011), which was downloaded at my request on June 7, 2017. 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.

11. Exhibit 2025 hereto is a true and correct copy of “Vesicant Extravasation: Myths and Realities” *Oncology Nursing Forum*, Vol. 22, No 1 [https://www.researchgate.net/publication/15489710\\_Vesicant\\_extravasation\\_myths\\_and\\_realities](https://www.researchgate.net/publication/15489710_Vesicant_extravasation_myths_and_realities) (January 1995), which I downloaded on June 8, 2017. 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.

12. Exhibit 2028 hereto is a true and correct copy of “Extravasation guidelines 2007, Guidelines Implementation Toolkit,” which I downloaded from

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