#### UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FRONTIER THERAPEUTICS, LLC

### Petitioner

v.

# MEDAC GESELLSCHAFT FÜR KLINISCHE SPEZIALPRÄPARATE MBH

Patent Owner
Inter Partes Review Case No. IPR2016-00649
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

Medac Exhibit 2058



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 a January 8, 2016 letter from Frontier Therapeutics to Medac Pharma, Inc., which I understand was received by Ms. Terri Shoemaker, President and CEO of Medac Pharma, Inc. on January 8, 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 the State of Washington's Secretary of State's Corporations Division Registration Data Search entry for Frontier Therapeutics LLC, which I accessed and printed from http://www.sos.wa.gov/corps/search\_detail.aspx?ubi=603566537 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.
- 5. Exhibit 2003 hereto is a true and correct copy of the State of Washington's Secretary of State's Corporations Division Registration Data Search entry for Jason Paul Greer Enterprises Limited Liability Company, which I accessed and printed from http://www.sos.wa.gov/corps/search\_detail.aspx?ubi=603185788 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.

- 6. Exhibit 2004 hereto is a true and correct copy of the State of Washington Business Licensing Service entry for Jason Paul Greer Enterprises Limited Liability Company, which was accessed and printed by Ropes & Gray librarian David Kolpin at my request from http://washington.intercreditreport.com/company/jason-paul-greer-enterprises-limited-liability-company-603185788 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.
- 7. Exhibit 2005 hereto is a true and correct copy of the Whois Data entry for frontiertherapeuticsnw.com, which I accessed and printed from http://www.whoismind.com/whois/frontiertherapeuticsnw.com.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.
- 8. Exhibit 2006 hereto is a true and correct copy of Dr. Weinblatt's Declaration from IPR2014-01091, which I downloaded from the Patent Trial and Appeal Board's Patent Review Processing System



(https://ptabtrials.uspto.gov/prweb/PRServlet/HcI5xOSeX\_yQRYZAnTXXCg%5 B%5B\*/!STANDARD?) on May 17, 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 2007 hereto is a true and correct copy of a redline comparison of Dr. Gershwin's Declaration (Ex. 1012) and Dr. Weinblatt's Declaration from IPR2014-01091, which I generated on May 17, 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 2008 hereto is a true and correct copy of a search of the National Center for Biotechnology Information's PubMed database for "Gershwin" and "methotrexate," which I accessed and printed from https://www.ncbi.nlm.nih.gov/pubmed on May 22, 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.
- 11. Exhibit 2009 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.

- 12. Exhibit 2010 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.
- 13. Exhibit 2011 hereto is a true and correct copy of Drugs@FDA database for which I accessed printed entry Mexate. and from http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Searc h.DrugDetails on May 22, 2016, and which his 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.
- 14. Exhibit 2012 hereto is a true and correct copy of an article entitled "Parenteral methotrexate should be given before biological therapy," published by



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