

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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FRONTIER THERAPEUTICS, LLC

Petitioner

v.

MEDAC GESELLSCHAFT FÜR KLINISCHE  
SPEZIALPRÄPARATE MBH

Patent Owner

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*Inter Partes* Review Case No. IPR2016-00649  
Patent Number 8,664,231

**DECLARATION OF MARIA SALGADO IN SUPPORT OF PATENT  
OWNER'S PRELIMINARY RESPONSE**

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

1. I am a Principal at Cornerstone Research.
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 2030

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

3. Exhibit 2026 hereto is a document compiled from the Drugs@FDA Data Files, available on <http://www.fda.gov/Drugs/InformationOnDrugs/ucm079750.htm>. Page numbers and an exhibit label have been added to the bottom of this document but no other alterations have been made.

4. Exhibit 2027 hereto is a true and correct copy of the November 20, 2014 results of searching “methotrexate” on <https://www.accessdata.fda.gov/scripts/cder/drugsatfda/>, which was a record of the FDA. Page numbers and an exhibit label have been added to the bottom of this document but no other alterations have been made.

5. Exhibit 2056 hereto is a true and correct PDF of the excel file “October 2006 ASP Pricing File - Updated 12/19/07,” which I downloaded from <http://www.cms.gov/apps/ama/license.asp?file=/McrPartBDrugAvgSalesPrice/downloads/oct06asphepcs.zip>, which was data provided by *Centers for Medicare and Medicaid Services*, and which I downloaded on November 19, 2014. Page

numbers and an exhibit label have been added to the bottom of this document, and the excel file was converted to PDF, but no other alterations have been made.

6. Exhibit 2057 hereto is a true and correct PDF of the excel file “October 2014 ASP Pricing File 09/12/14,” which I downloaded from <http://www.cms.gov/apps/ama/license.asp?file=/McrPartBDrugAvgSalesPrice/downloads/2014-October-ASP-Pricing-File.zip>, and which was data provided by *Centers for Medicare and Medicaid Services*. Page numbers and an exhibit label have been added to the bottom of this document, and the excel file was converted to PDF, but no other alterations have been made.

7. Exhibit 2065 hereto is a true and correct copy of an article entitled “Arthritis Today Drug Guide”, published by the Arthritis Foundation, which I downloaded from <http://www.arthritistoday.org/arthritistreatment/medications/drug-guide/search-by-class.php?drugclass=DMARDs> on November 18, 2014. Page numbers and an exhibit label have been added to the bottom of this document but no other alterations have been made.

8. Exhibit 2067 hereto is a true and correct copy of an article entitled “Drug Guide: DMARDs”, published by the Arthritis Foundation, which I downloaded from <http://www.arthritistoday.org/arthritistreatment/medications/types-of-drugs/disease-modifying-drugs/drug-guide->

[dmards.php](#) on November 18, 2014. Page numbers and an exhibit label have been added to the bottom of this document but no other alterations have been made.

9. Exhibit 2078 hereto is a true and correct copy of an article entitled “Juvenile Idiopathic Arthritis (JIA),” published by the Department of Pediatrics Division of Pediatric Rheumatology, which I downloaded from <http://pediatrics.med.nyu.edu/rheumatology/patient-care/juvenile-idiopathic-arthritis-jia> on November 18, 2014. Page numbers and an exhibit label have been added to the bottom of this document but no other alterations have been made.

10. Exhibit 2080 hereto is a true and correct copy of a Methotrexate Fact Sheet, published by the American College of Rheumatology in May 2012, and which I downloaded from <https://www.rheumatology.org/practice/clinical/patients/medications/methotrexate.pdf>, on November 18, 2014. Page numbers and an exhibit label have been added to the bottom of this document but no other alterations have been made.

11. Ex. 2083 hereto is a true and correct copy of an article entitled “Questions and Answers about Juvenile Arthritis,” *National Institute of Arthritis and Musculoskeletal and Skin Diseases*, 8/13, which I downloaded on November 18, 2014 from [http://www.niams.nih.gov/Health\\_Info/Juv\\_Arthritis/#1](http://www.niams.nih.gov/Health_Info/Juv_Arthritis/#1) and which was a record of the National Institute of Arthritis and Musculoskeletal and Skin

Diseases (NIH). Page numbers and an exhibit label have been added to the bottom of this document but no other alterations have been made.

12. Ex. 2085 hereto is a true and correct copy of an article entitled “State and County QuickFacts,” which I downloaded on November 18, 2014 from <http://quickfacts.census.gov/qfd/states/00000.html>, and which was a record of *United States Census Bureau*. Page numbers and an exhibit label have been added to the bottom of this document but no other alterations have been made.

13. Exhibit 2086 hereto is a true and correct PDF of a .txt file entitled “patent.txt,” which I downloaded from the FDA’s Orange Book Data Files website, <http://www.fda.gov/Drugs/InformationOnDrugs/ucm129689.htm>, on October 17, 2014, which was a record of the FDA. Page numbers and an exhibit label have been added to the bottom of this document, and the text file was converted to PDF, but no other alterations have been made.

14. Exhibit 2087 hereto is a true and correct PDF of a .txt file entitled “products.txt,” which I downloaded from the FDA’s Orange Book Data Files website, <http://www.fda.gov/Drugs/InformationOnDrugs/ucm129689.htm>, on October 17, 2014. Page numbers and an exhibit label have been added to the bottom of this document, and the text file was converted to PDF, but no other alterations have been made.

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