

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

**EXPERT DECLARATION OF ELENA MASSAROTTI, M.D.**  
**June 2, 2016**

I, Dr. Elena Massarotti, have been retained as an expert by counsel for medac Gesellschaft Für Klinische Spezialpräparate Mbh, Inc. (“Medac”) in the above-captioned *Inter Partes* Review (“IPR”).

## I. QUALIFICATIONS

1. I am a medical doctor specializing in rheumatology, which encompasses inflammatory autoimmune diseases. I have a particular interest in inflammatory arthritis, lupus, and vasculitis. My professional time is divided between patient care, education, and clinical research. I routinely treat inflammatory autoimmune disease patients with methotrexate, including oral, intramuscular, and subcutaneous administration, and have done so throughout my more than twenty-five years of clinical experience.

2. I graduated from Tufts University School of Medicine in 1984. I completed my internship and residency in internal medicine at New England Medical Center (now known as Tufts Medical Center) between 1984 and 1987. I completed a fellowship in Rheumatology/Immunology at New England Medical Center from 1988 to 1990. I was then the Chief Medical Resident at the New England Medical Center from 1990 to 1991.

3. I am board certified in Internal Medicine and in Rheumatology. I am a member of the American College of Rheumatology.

4. Between 1990 and 2007, I had clinical academic positions at two different hospitals. From 1991 to 1993, I was the director of house staff training at the Mt. Auburn Hospital in Cambridge, Massachusetts (a Harvard Medical School affiliate). From 1993 to 2002, I was the director of clinical rheumatology training at Tufts Medical Center. From 2001 to 2002, I was the acting division chief of rheumatology at Tufts Medical Center. From 2002 to 2007, I was the clinical director of rheumatology at Tufts Medical Center.

5. Since 2007, I have been an Associate Professor at Harvard Medical School and an Associate Physician at the Brigham and Women's Hospital ("BWH") in Boston. I am Director of Clinical Trials at the Lupus Center at BWH and Co-Director of the Clinical Trials Center in the BWH Division of Rheumatology. Over the course of my career, I have held a number of major committee assignments and appointments at BWH and Tufts-New England Medical Center. I have also received a number of professional and teaching honors and awards, including recognition by *Boston Magazine* and *U.S. News and World Report*.

6. I have been or currently serve as an ad hoc reviewer for a number of medical journals including the *New England Journal of Medicine*, *Infectious Diseases in Clinical Practice*, *Lupus*, *Annals of the Rheumatic Diseases*, *Arthritis and Rheumatism*, and the *Journal of the American Medical Association*. I was a

member of the Editorial Board of *Arthritis Care and Research* from 2012-2015. I am on the Executive Committee of the Lupus Nephritis Trials Network. I am a member of the Harvard Medical School admissions committee and the Harvard Catalyst research committee. I have been an invited speaker at dozens of conferences and courses and have authored or co-authored over ninety peer-reviewed articles, review articles, book chapters, and abstracts. In addition, I have been or am currently an investigator on at least thirty-six clinical trials and studies. These publications include reports of clinical trials, epidemiologic studies and clinical observations in the areas of autoimmune disease.

7. My educational background, work experience and a list of my publications are set forth in my *curriculum vitae*, which is attached as Tab A to this report. A list of the cases in which I have testified as an expert at trial or by deposition over the previous 4 years is attached at Tab B.

## **II. SCOPE OF ASSIGNMENT AND SUMMARY OF MY OPINIONS**

8. I am informed and understand that Frontier Therapeutics, LLC (“Frontier”) has petitioned for an IPR of Medac’s U.S. Patent 8,664,231 (Ex. 1001, “the ‘231 Patent”) and has requested the cancellation of claims 1-22 of the ‘231 Patent. I am informed and understand that in the IPR, Frontier has relied upon, among other things, U.S. Patent 6,544,504 (Ex. 1003, “*Grint*”); the Mexate Product Information in the 1985 Physicians’ Desk Reference (Ex. 1007, “*Mexate*”)

and a Hospira Product Summary for Mexthotrexate 100 mg/ml Injection (“*Hospira*”) (Ex. 1009).

9. I am informed and understand that the claims of the ‘231 Patent have a date of July 21, 2006. I have been asked to assess the knowledge of the skilled artisan at that July 21, 2006 date and to consider what the skilled artisan at that date would have understood from *Grint*, *Mexate*, and *Hospira*.

10. In forming my opinions, I have relied upon my education, experience, and various written materials. A list of the written materials that I considered in rendering my opinions is attached to this declaration as Tab C. Each of these materials is a type of document that experts in my field would reasonably rely upon when forming their opinions.

11. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001. If called to testify as to the truth of the matters stated herein, I could and would testify competently.

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.