

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

APOTEX INC. AND  
APOTEX CORP.,  
Petitioners,

v.

NOVARTIS A.G.,  
Patent Owner.

---

Patent No. 9,187,405

---

**DECLARATION OF BARBARA S. GIESSER**

**TABLE OF CONTENTS**

I. QUALIFICATIONS ..... 1

II. SCOPE OF WORK.....2

III. OVERVIEW OF THE 9,187,405 PATENT .....3

IV. RELATED PROSECUTION.....6

V. LEGAL STANDARDS .....13

VI. LEVEL OF ORDINARY SKILL AND RELEVANT TIME.....16

VII. CLAIM CONSTRUCTION .....17

VIII. STATE OF THE ART.....20

IX. PRIOR ART REFERENCES DISCLOSE THE CLAIMED FEATURES OF THE  
'405 PATENT .....33

X. THE PRIOR ART TEACHES EVERY ELEMENT OF CLAIMS 1-6 OF THE '405  
PATENT .....45

XI. NO EVIDENCE OF UNEXPECTED RESULTS OR SECONDARY  
CONSIDERATIONS ARE ATTRIBUTABLE TO NOVEL ASPECTS OF THE  
CLAIMS .....70

XII. CONCLUDING STATEMENTS.....72

XIII. APPENDIX – LIST OF EXHIBITS .....73

I, Barbara S. Giesser, declare as follows:

**I. QUALIFICATIONS**

1. I am currently a Professor of Clinical Neurology at the David Geffen School of Medicine at UCLA and have held faculty appointments there since 2002. Prior to my appointments at UCLA, I was an Associate Professor of Clinical Neurology at the Arizona Health Sciences Center at the University of Arizona, from 1992-2002. Prior to joining the University of Arizona, I was an Assistant Professor of Neurology at Albert Einstein College of Medicine in Bronx, New York from 1983-1991.

2. I received a Master's Degree in Virology from the University of Texas Graduate School of Biomedical Sciences in 1974 and an M.D. from the University of Texas Medical School at San Antonio in 1978. I completed a medical fellowship in Neurology at the Albert Einstein College of Medicine in 1983 after first completing my medical residency in Neurology at the Bronx Municipal Hospital Center.

3. I became board certified by the American Board of Psychiatry and Neurology in 1985 and by the American Society of Neurorehabilitation in 1992. I became a Fellow of the American Academy of Neurology in 1993 and of the American Neurological Association in 2012. I continue to hold active medical licenses in New York and in California.

4. I have more than thirty years of experience in the treatment of patients with, and research regarding, multiple sclerosis (“MS”), including relapsing-remitting MS. I have received numerous research grants, including several research grants from the National Multiple Sclerosis Society. I have also participated in numerous clinical trials for MS, including trials involving patients with relapsing-remitting MS. I have given dozens of invited lectures and presentations and have been an author or co-author of dozens of books, book chapters, reviews, or peer-reviewed research papers. I have served on numerous professional committees, received many awards, and provided editorial services for multiple journals. For a more detailed listing of my credentials and publications, please see my curriculum vitae, attached as EX1003.

## II. SCOPE OF WORK

5. I understand that a petition is being filed with the United States Patent and Trademark Office for *Inter Partes* Review of U.S. Patent No. 9,187,405 (“the ’405 patent,” EX1001). I have been retained by the Petitioner to provide analysis and opinions regarding the ’405 patent. I have reviewed the ’405 patent (EX1001) and relevant sections of its prosecution history in the United States Patent and Trademark Office. EX1011. I have also reviewed certain publications in arriving at my opinions, and cite them in this declaration. For convenience, documents cited in this declaration are listed in the Appendix in Section XIII.

6. I am compensated at the rate of \$350/hour for my work except that I will be paid \$500 per hour for time spent testifying in deposition or at trial. My compensation does not depend on the outcome of this matter.

### III. OVERVIEW OF THE 9,187,405 PATENT

7. The '405 patent is entitled "S1P Receptor Modulators For Treating Relapsing-Remitting Multiple Sclerosis." The first page of the patent claims priority to a foreign application, 0612721.1 (GB), filed on June 27, 2006 via U.S. Patent Application No. 13/149,468 filed on May 31, 2011, now Patent No. 8,741,963, and via U.S. Patent Application No. 12/303,765 filed as application number PCT/EP2007/005597 on June 25, 2007. EX1001. For the purposes of my analysis, I have assumed that the applicable invention date of the '405 patent is June 27, 2006. However, the results of my analysis would not change if the applicable invention date were June 25, 2007, May 31, 2011, or April 21, 2014.

8. The '405 patent is generally directed to a dosing regimen for the prior art MS drug identified as 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol. For convenience, I will refer to this compound as fingolimod.

9. Claim 1 of the '405 patent is an independent claim and recites the following:

A method for reducing or preventing or alleviating relapses in Relapsing-Remitting multiple sclerosis in a subject in need thereof, comprising orally administering to said subject 2-amino-2-[2-(4-

# 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.