Paper No. ____
Filed: February 3, 2017

Filed on behalf of: Apotex Inc. & Apotex Corp.
By: Steven W. Parmelee (sparmelee@wsgr.com)
Michael T. Rosato (mrosato@wsgr.com)
Jad A. Mills (jmills@wsgr.com)
WILSON SONSINI GOODRICH & ROSATI

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.

IPR2017-00854
Patent No. 9,187,405

PETITION FOR INTER PARTES REVIEW OF U.S. PATENT NO. 9,187,405

TABLE OF CONTENTS

Page

I. INTRODUCTION

Pursuant to 35 U.S.C. § 311 and § 6 of the America Invents Act ("AIA"), and 37 C.F.R. Part 42, Apotex, Inc. and Apotex Corp., ("Petitioners") request review of U.S. Patent No. 9,187,405 to Peter C. Hiestand *et al.* ("the '405 patent," EX1001) that issued on November 17, 2015, and is assigned to Novartis A.G. ("Patent Owner").

The '405 patent claims a method of administering fingolimod hydrochloride ("FTY720"), a previously known immunosuppressant, for the treatment of a subject with Relapsing-Remitting Multiple Sclerosis ("RR-MS"). The claimed method recites "a daily dosage of 0.5 mg" that was known and reported to be safe and pharmacologically effective in humans more than one year before the earliest effective filing date of the '405 patent. For example, International Publication No. WO 2006/058316 ("Kovarik," EX1004), teaches treating multiple sclerosis by administering a 0.5 mg oral daily dose of fingolimod hydrochloride.

The '405 patent claims also employ a negative limitation regarding the absence of a loading dose regimen. Yet, Kovarik teaches that a maintenance dose is a therapeutically effective dose and teaches 0.5 mg fingolimod hydrochloride as a standard daily (maintenance) dose for treating MS. Indeed, the evidence shows that of the six FDA-approved treatments for RR-MS, none described the use of loading doses as part of an approved regimen.

DOCKET ALARM

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.