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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**

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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.

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