**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In the *Inter Partes* Review of: Trial Number: To Be Assigned

U.S. Patent No. 9,187,405

Filed: April 21, 2014

Issued: November 17, 2015

Inventor(s): Peter C. Hiestand, Christian Schnell

Assignee: Novartis A.G.

Title: S1P receptor modulators for treating relapsing-remitting multiple sclerosis Panel: To Be Assigned

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Mail Stop *Inter Partes* Review
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

# PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,187,405 UNDER 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42.100

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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, Actavis Elizabeth LLC and Teva Pharmaceuticals USA, Inc., ("Petitioners") request review of U.S. Patent No. 9,187,405 to Peter C. Hiestand *et al.* ("the '405 patent," EX1001), issued on November 17, 2015, and assigned to Novartis A.G. ("Patent Owner"). Petitioners are filing, concurrently herewith, a Motion for Joinder under 35 U.S.C. § 315(c), 37 C.F.R. § 42.22 and § 42.122(b) to the *inter partes* review involving the same patent and the same grounds of invalidity in *Apotex, Inc. and Apotex Corp. v. Novartis AG*, IPR2017-00854 ("Apotex IPR"), which was filed on February 3, 2017. The instant Petition is substantially identical to the Petition filed in the Apotex IPR.

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.

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