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Filed on behalf of: Sun Pharmaceutical Industries, Ltd., Sun Pharmaceutical Industries, Inc. & Sun Pharma Global FZE
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SUN PHARMACEUTICAL INDUSTRIES, LTD., SUN PHARMACEUTICAL INDUSTRIES, INC. and SUN PHARMA GLOBAL FZE
Petitioners,

v.

NOVARTIS A.G.,
Patent Owner.

IPR2017-01929
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, Sun Pharmaceutical Industries, Ltd., Sun Pharmaceutical Industries, Inc., and Sun Pharma Global FZE, ("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"). Petitioner is filing, concurrently herewith, a Motion to Join pursuant to 35 U.S.C. § 315(c) and 37 C.F.R. § 42.122(b) the pending *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, and trial instituted on July 18, 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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