UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD
ARGENTUM PHARMACEUTICALS LLC
Petitioner,
v.
NOVARTIS A.G.,
Patent Owner.
<u> </u>
U.S. Patent No. 9,187,405
Issue Date: November 17, 2015
Title: S1P Receptor Modulators for Treating Relapsing-Remitting Multiple Sclerosis
Inter Partes Review No. <u>IPR2017-01550</u>

Petition For *Inter Partes* Review 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42.100 et seq.



Table of Contents

I.	INTRODUCTION					
	A.	Brief Overview of the '405 Patent				
	B.	Brief Overview of the Prosecution History5				
	C.	Brief Overview of the Grounds				
	D.	Brief Overview of the Scope and Content of the Prior Art				
		i.	International Publication No. WO 2006/058316 ("Kovarik," EX1004)	10		
		ii.	Thomson, FTY720 in multiple sclerosis: the emerging evidence of its therapeutic value, CORE EVIDENCE, 1(3): 157-167 (2006) ("Thomson," EX1005)			
		iii.	U.S. Patent No. 6,004,565 to Chiba ("Chiba," EX1006)	13		
		iv.	Kappos, et al., FTY720 in relapsing MS: results of a double-blind placebo-controlled trial with a novel oral immunomodulator, JOURNAL OF NEUROLOGY 252(Suppl 2): 11/41, Abstract O141(2005) ("Kappos 2005," EX1007)			
		v.	Budde, et al., First human trial of FTY720, a novel immunomodulator, in stable renal transplant patients, JOURNAL OF THE AMERICAN SOCIETY FOR NEPHROLOGY, 13:1073-1083 (2002) ("Budde," EX1008)	16		
		vi.	Kappos, et al., A Placebo-Controlled Trial of Oral Fingolimoa in Relapsing Multiple Sclerosis, NEW ENGLAND JOURNAL OF MEDICINE, 362(5):387-401 (2010) ("Kappos 2010," EX1038)			
	Ε.	Brief	Overview of the Level of Skill in the Art	19		
II.	GROUNDS FOR STANDING					
III.	MANDATORY NOTICES UNDER 37 C.F.R. §42.8					



Patent No. 9,187,405 Petition For *Inter Partes* Review

IV.	STATEMENT OF THE PRECISE RELIEF REQUESTED2				
V.	STATEMENT OF NON-REDUNDANCY				
VI.	CLAIM CONSTRUCTION				
	A. "a subject in need"				
	B.	"A method for"	25		
VII.	BACKGROUND KNOWLEDGE IN THE ART PRIOR TO JUNE 27, 2006				
	A.	Multiple Sclerosis	27		
	B.	Disease Modifying Therapies			
	C.	Fingolimod			
	D.	Loading Dose Regimens			
VIII.		TAILED EXPLANATION OF GROUNDS FOR UNPATENTABILIT			
	A.	[Ground 1] Claims 1-6 are Obvious under 35 U.S.C. § 103 over Kovarik and Thomson.	34		
		i. Claims 1, 3, and 5	34		
		ii. Claims 2, 4, and 6	49		
	B.	[Ground 2] Claims 1-6 are Obvious under 35 U.S.C. § 103 over Ch Kappos 2005, and Budde.			
		i. Claims 2, 4, and 6	59		
	C.	[Ground 3] Claims 1-6 are Anticipated under 35 U.S.C. § 102 by Kappos 2010 (EX1038)	60		
		i. Claims 2, 4, and 6	63		
IX.	CON	EVIDENCE OF UNEXPECTED RESULTS OR SECONDARY NSIDERATIONS ARE ATTRIBUTABLE TO NOVEL ASPECTS OF E CLAIMS			



Patent No. 9,187,405 Petition For *Inter Partes* Review

X.	PAYMENT OF FEES UNDER 37 C.F.R. §§ 42.15(A) AND 42.103	66
XI.	CONCLUSION	66
XII.	CERTIFICATE OF COMPLIANCE	67
УШ	APPENDIX _ I IST OF EXHIBITS	68



I. INTRODUCTION

Pursuant to 35 U.S.C. § 311 and § 6 of the America Invents Act ("AIA"), and 37 C.F.R. Part 42, Argentum Pharmaceuticals LLC, ("Petitioner") requests 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"). 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. 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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