# UNITED STATES PATENT AND TRADEMARK OFFICE ————— BEFORE THE PATENT TRIAL AND APPEAL BOARD ——————

HOPEWELL PHARMA VENTURES, INC., Petitioner,

v.

MERCK SERONO S.A., Patent Owner.

Case IPR2023-00480 U.S. Patent No. 7,713,947

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DECLARATION OF AARON E. MILLER, M.D.

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## TABLE OF CONTENTS

I.	Introduction1				
II.	My Background and Qualifications				
III.	Summary of Opinions5				
IV.	List of documents I considered in formulating my opinions				
V.	The Person of Ordinary Skill in the Art ("POSA")13				
VI.	State of the Art Prior to December 22, 200414				
	A.	Multiple sclerosis is a chronic disease with no known cure14			
	B.	Immunosuppression was a common therapeutic strategy to treat multiple sclerosis before December 2004			
	C.	Cladribine, a known immunosuppressant, was used to treat multiple sclerosis before December 2004			
	D.	MS often requires cyclical drug therapy to prevent relapses and limit progression of the disease			
	E.	Oral cladribine compositions for treating MS were known in the art before December 2004			
VII.	The '947 Patent Specification and Claims				
VIII.	Claim Construction				
	A.	"Total Dose of Cladribine"45			
	B.	"Induction Period"			
	C.	"Maintenance Period"			
IX.	Basis	of my analysis with respect to obviousness			
X.	My analysis with respect to claim 3650				
	A.	Bodor and Stelmasiak teach orally administering cladribine to treat multiple sclerosis			



# Inter Partes Review of U.S. Patent No. 7,713,947 Declaration of Aaron E. Miller, M.D. (EX1002)

В.	an "i	Bodor's and Stelmasiak's cladribine dosing regimens include an "induction period;" Bodor's induction period is 2 months long				
C.		Bodor teaches the claimed total dose of cladribine administered in an induction period				
D.		Bodor and Stelmasiak teach retreating with cladribine after a cladribine-free period				
E.	the r POS	Stelmasiak teaches administering a lower dose of cladribine in the retreatment period compared to the induction period; a POSA would have known how to optimize the maintenance period dose and length.				
F.	mair	Stelmasiak teaches a cladribine-free period after the maintenance period; a POSA would have known how to optimize the length of the second cladribine-free period				
G.	A POSA would have had a reason to combine Bodor and Stelmasiak to arrive at the claimed method					
	1.	A POSA would have been motivated to formulate an oral cladribine composition per Bodor, with a reasonable expectation of success	66			
	2.	A POSA would have been motivated to treat MS by administering Bodor's oral cladribine composition according to Stelmasiak's induction period/cladribine-free period/maintenance period/cladribine-free period framework	67			
	3.	A POSA would have been motivated to administer "about 1.7 mg/kg to about 3.5 mg/kg" in an induction period	74			
	4.	A POSA would have been motivated to administer a lower total dose of cladribine in the maintenance period compared to the total dose in the induction period	74			



# Inter Partes Review of U.S. Patent No. 7,713,947 Declaration of Aaron E. Miller, M.D. (EX1002)

	5.	A POSA would have been motivated to optimize the prior art to arrive at the claimed total cladribine dose and length of the maintenance period	76
	H. AF	POSA would have had a reasonable expectation of success	77
XI.	My analys	sis with respect to claim 38	83
XII.	My analys	sis with respect to claim 39	84
XIII.	My analys	sis with respect to claims 41 and 42	84
XIV.	My analys	sis with respect to claim 43	86
XV.	My analys	sis with respect to claim 44 and 45	87
XVI.	My analys	sis with respect to claim 46	88
XVII.	. No object	ive indicia of non-obviousness exist	89
XVIII	I Coi	nclusion	90



I, Aaron E. Miller, M.D., hereby declare as follows.

#### I. Introduction

- 1. I am over the age of eighteen (18) and otherwise competent to make this declaration.
- 2. I have been retained as an expert witness on behalf of Petitioner Hopewell Pharma Ventures, Inc. ("Hopewell") for the above-captioned *inter partes* review ("IPR"). I am being compensated for my time in connection with this IPR at my standard consulting rate, which is \$790/hr.
- 3. I understand that the petition for IPR involves U.S. Patent No. 7,713,947 ("the '947 patent"), EX1001, which resulted from U.S. Application No. 11/722,018 ("the '018 application"), which is the National Phase Entry of International Patent Application No. PCT/EP2005/056954, filed on December 20, 2005, which claims the benefit of the U.S. Provisional Application No. 60/638,669, filed on December 22, 2004, and the Foreign Patent Application No. EP04106909, filed on December 22, 2004. The '947 patent issued on May 11, 2010, from the '018 application. The '947 patent names Giampiero De Luca, Arnaud Ythier, Alain Munafo, and Maria Lopez-Bresnahan as inventors. The face of the '947 patent states that it is assigned to Merck Serono S.A. ("Merck").



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