# UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE PATENT TRIAL AND APPEAL BOARD SANDOZ INC.,

v.

**Petitioners** 

### PHARMACYCLICS LLC, Patent Owner.

U.S. Patent No. 9,795,604 to Byrd *et al*.

Issue Date: October 24, 2017

Title: Methods of Treating and Preventing Graft Versus Host Disease *Inter Partes* Review No.: IPR2019–00865

DECLARATION OF JAMES L. FERRARA, M.D.



#### **TABLE OF CONTENTS**

I.	Introduction			
II.	My Background and Qualifications			
III.	List	of Documents Considered	4	
IV.	Background of the Technology			
	A.	Ibrutinib	4	
	B.	Graft Versus Host Disease	8	
		1. Two Types of GVHD: Acute and Chronic	10	
		2. Chronic GVHD	13	
V.	Claim Construction			
	A.	"Therapeutically Effective Amount"	16	
	B.	"Thereby Treating the Chronic GVHD in the Patient"	17	
	C.	Ibrutinib's Chemical Structure	18	
VI.	Perso	on of Ordinary Skill in the Art	20	
VII.	The Prior Art Pertinent to the Petition			
	A.	The '085 Publication	21	
	B.	Shimabukuro-Vornhagen	23	
	C.	Herman	26	
	D.	Uckun	28	
VIII.		nd 1: The Challenged Claims Are Anticipated by the '085 cation	30	
	A.	Legal Standard for Anticipation	30	
	В.	The '085 Publication Anticipates Independent Claim 1 of the '604 Patent	30	



		1. "A method of treating chronic graft versus host disease (GVHD)"	31
		2. "Administering to a patient having chronic GVHD a therapeutically effective amount of" ibrutinib	32
		3. "thereby treating the chronic GVHD in the patient"	34
	C.	The '085 Publication Anticipates Dependent Claims 4, 13, and 15	35
	D.	The '085 Publication Anticipates Dependent Claims 6, 7, 8, 29, 30, 31, 44, 45, 46, 51, 52, 53	36
	E.	The '085 Publication Anticipates Dependent Claim 9	37
	F.	The '085 Publication Anticipates Dependent Claim 10	39
	G.	The '085 Publication Anticipates Dependent Claims 24, 28, 35, 39, 43, 50 and Independent Claim 55	40
IX.		nd 2: The Challenged Claims Would Have Been Obvious in of the '085 Publication	42
	A.	Legal Standard for Obviousness	42
	B.	Claim 1 Would Have Been Obvious in View of the '085 Publication	43
	C.	Dependent Claims 4, 13, and 15 Would Have Been Obvious in View of the '085 Publication	44
	D.	Dependent Claims 6, 7, 8, 29, 30, 31, 44, 45, 46, 51, 52, and 53 Would Have Been Obvious in View of the '085 Publication	45
	E.	Dependent Claim 9 Would Have Been Obvious in View of the '085 Publication	45
	F.	Dependent Claim 10 Would Have Been Obvious in View of the '085 Publication	46
	G.	Dependent Claims 24, 28, 35, 39, 43, 50 and Independent Claim 55 Would Have Been Obvious in View of the '085 Publication	47



	H.	Secondary Considerations of Nonobviousness	47
X.	Ground 3: The Challenged Claims Would Have Been Obvious in View of the '085 Publication Combined with Shimabukuro-Vornhagen and Herman		
	A.	Motivation to Combine the '085 Publication, Shimabukuro- Vornhagen, and Herman	48
	B.	The Combination of References Render Claim 1 Obvious to a POSA with a Reasonable Expectation of Success	51
	C.	Dependent Claims 4, 13, and 15 Would Have Been Obvious in View of the '085 Publication	52
	D.	Dependent Claims 6, 7, 8, 29, 30, 31, 44, 45, 46, 51, 52, 53 Would Have Been Obvious in View of the '085 Publication	53
	E.	Dependent Claim 9 Would Have Been Obvious in View of the '085 Publication	53
	F.	Dependent Claim 10 Would Have Been Obvious in View of the '085 Publication	54
	G.	Dependent Claims 24, 28, 35, 39, 43, 50 and Independent Claim 55 Would Have Been Obvious in View of the '085 Publication	54
XI.	Ground 4: The Challenged Claims Would Have Been Obvious Over the '085 Publication in view of Shimabukuro-Vornhagen and Uckun		
	A.	Motivation to Combine the '085 Publication, Shimabukuro- Vornhagen, and Uckun	55
	В.	The Combination of References Rendered the Challenged Claims Obvious to a POSA, with a Reasonable Expectation of Success	57
XII.	Conc	lusion	59



#### I. Introduction

- 1. I have been retained as an expert witness on behalf of Sandoz Inc. ("Sandoz") for the above-captioned *inter partes* review ("IPR") proceeding. I am over the age of eighteen (18) and otherwise competent to make the statements contained in this Declaration, which I understand will be submitted in support of Sandoz's IPR petition. I am being compensated for my time in connection with this IPR proceeding at my standard consulting rate, which is \$500 per hour. My compensation does not depend in any way on the outcome of this proceeding. I hold no interest in Sandoz Inc. or Lek Pharmaceuticals D.D.
- 2. I have been informed that the IPR proceeding involves the validity of U.S. Patent No. 9,795,604 (the "'604 Patent"), EX1001. In analyzing the validity of the '604 Patent, I have been instructed to consider references published prior to October 25, 2013. I have been informed that such references are referred to as "prior art." Thus, I will refer to these references as prior art in this Declaration. I confirm



<sup>&</sup>lt;sup>1</sup> While I am not an attorney, Sandoz's counsel has explained certain aspects of patent law to me that are relevant to the discussion in this Declaration. I state throughout this Declaration where my understanding of an aspect of patent law has been informed by counsel.

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