IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX, INC. Petitioner,

v.

UCB BIOPHARMA SPRL Patent Owner.

U.S. Patent No. 8,633,194 to Fanara *et al*.
Issue Date: January 21, 2014
Title: Pharmaceutical composition of piperazine derivatives

Inter Partes Review No.: <u>IPR2019-00400</u>

Petition for *Inter Partes* Review of U.S. Patent No. 8,633,194 Under 35 U.S.C. §§ 311-319 and 37 C.F.R. §§ 42.1-.80, 42.100-.123

Mail Stop "PATENT BOARD"

Patent Trial and Appeal Board U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450



TABLE OF CONTENTS

I.	INTRODUCTION1							
II.	OVERVIEW							1
III.	STANDING (37 C.F.R. § 42.104(A)); PROCEDURAL STATEMENTS						2	
IV.	MANDATORY NOTICES (37 C.F.R. § 42.8(A)(1))							
	A.	Each	Real Party	in Intere	st (37	7 C.F.R. § 42.8(b)(1))	3
	B. Notice of Related Matters (37 C.F.R. § 42.8(b)(2))							3
	1. Judicial Matters Involving the '194 Patent							3
		2.	Administ	rative Ma	tters			3
	C.	C. Designation of Lead and Back-Up Counsel and Service (37 C.F.R. §§ 42.8(b)(3), 42.8(b)(4))						
V.	STATEMENT OF THE PRECISE RELIEF REQUESTED AND THE REASONS THEREFOR (37 C.F.R. § 42.22(A))						4	
VI.	THE '194 PATENT							4
VII.	CLAIM CONSTRUCTION						5	
VIII.	I. PERSON OF ORDINARY SKILL IN THE ART ("POSA")							6
IX.	IDENTIFICATION OF CHALLENGE (37 C.F.R. § 42.104(B))						7	
X.	INVALIDITY ANALYSIS						8	
	A. The Level of Ordinary Skill in the Pertinent Art						8	
	B. The Scope and Content of the Prior Art						8	
		1.					rt Compound and	8
		2.	Methylpa Preservat		d Pro	opylparaben Aı	re "Widely Used"	12



	3.	WO	2004/050094 ("WO '094") (EX1007)1	3		
	4.	European Patent Application No. 0605203 A2 ("EP '203") (EX1004)				
	5.	The Handbook (EX1006)1				
	6.	U.S.	Patent No. 5,698,558 (EX1015)1	8		
C.			Claims 1-11 Would Have Been Obvious over WO w of the Handbook1	9		
	1.	Indep	pendent Claim 11	9		
		a)	"A liquid pharmaceutical composition comprising (i) levocetirizine or a pharmaceutically acceptable salt of levocetirizine"	1		
		b)	"a preservative mixture consisting essentially of a mixture of methyl parahydroxybenzoate and propyl parahydroxybenzoate in a ratio of 9/1 expressed in weight"	22		
			(1) There Is No Teaching Away in the Handbook2	4		
		c)	"said [paraben] mixture being present in an amount of more than 0 and up to 0.75 mg/ml of the composition".2	6		
		d)	"wherein said composition is substantially free of bacteria"	0		
	2.	Dependent Claim 2				
	3.	Dependent Claim 3				
	4.	Dependent Claim 4				
	5.	Dependent Claims 5 and 10				
	6.	Dependent Claim 6				
		a)	"wherein the hydrochloride salt of levocetirizine is present in amount of 0.5 mg/ml"3	4		
		b)	"the mixture of methyl p-hydroxybenzoate and propyl p-hydroxybenzoate is present in amount of 0.75 mg/ml."	7		



	7.	Dependent Claim 7					
	8.	Dependent Claim 8					
	9.	Dependent Claim 9					
	10.	Dependent Claim 11					
		a) "the composition is in the form of an oral solution comprising 0.50 mg/ml levocetirizine dihydrochloride"41					
		b) "0.675 mg/ml methyl p-hydroxybenzoate, and 0.075 mg/ml propyl p-hydroxybenzoate"41					
D.	Ground 2: Claims 1-11 Are Obvious over EP '203 in View of US '558 and the Handbook						
	1.	Independent Claim 143					
		a) "A liquid pharmaceutical composition comprising (i) levocetirizine or a pharmaceutically acceptable salt of levocetirizine"					
		b) "a preservative mixture consisting essentially of a mixture of methyl parahydroxybenzoate and propyl parahydroxybenzoate in a ratio of 9/1 expressed in weight"					
		c) "said [paraben] mixture being present in an amount of more than 0 and up to 0.75 mg/ml of the composition".50					
		d) "wherein said composition is substantially free of bacteria"52					
	2.	Dependent Claim 253					
	3.	Dependent Claim 3					
	4.	Dependent Claim 4					
	5.	Dependent Claims 5 and 1054					
	6.	Dependent Claim 654					
		a) "wherein the hydrochloride salt of levocetirizine is present in amount of 0.5 mg/ml"55					



			b)	"the mixture of methyl p-hydroxybenzoate and propyl p-hydroxybenzoate is present in amount of 0.75 mg/ml"	•
		7.	Depe	endent Claim 7	.57
		8.	Depe	endent Claim 8	.57
		9.	Depe	endent Claim 9	.58
		10.	Depe	endent Claim 11	.59
			a)	"the composition is in the form of an oral solution comprising 0.50 mg/ml levocetirizine dihydrochloride"	
			b)	"0.675 mg/ml methyl p-hydroxybenzoate, and 0.075 mg/ml propyl p-hydroxybenzoate"	
	E.	Obje	ctive I	ndicia of Nonobviousness	.63
XI.	THE APO			SHOULD INSTITUTE TRIAL BASED ON TION (35 U.S.C. § 325(D))	.64
5 /11	CON		IONI		



DOCKET

Explore Litigation Insights



Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time** alerts and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.

