IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TEVA PHARMACEUTICALS USA, INC. AND WATSON LABORATORIES, INC.
Petitioners,

v.

MERCK SHARP & DOHME CORP.
Patent Owner.

U.S. Patent No. 7,326,708 to Cypes et al.
Issue Date: February 5, 2008
Title: Phosphoric acid salt of a dipeptidyl peptidase-IV inhibitor

Inter Partes Review No.: <u>IPR2020-01045</u>

Petition for Inter Partes Review of U.S. Patent No. 7,326,708 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

					<u>Page</u>	
I.	INTR	RODU	CTION	[1	
II.	OVERVIEW2					
III.	STANDING (37 C.F.R. § 42.104(A)); PROCEDURAL STATEMENTS6					
IV.	MANDATORY NOTICES (37 C.F.R. § 42.8(A)(1))6					
	A.	Each	Real P	earty in Interest (37 C.F.R. § 42.8(b)(1))	6	
	B.			elated Matters (37 C.F.R. § 42.8(b)(2))		
		1.	Judic	ial Matters Involving the '708 Patent	6	
		2.	Admi	nistrative Matters	8	
	C.	_	•	of Lead and Back-Up Counsel and Service (37 C.F. 42.8(b)(4))	0 0	
V.				THE PRECISE RELIEF REQUESTED AND THE EFOR (37 C.F.R. § 42.22(A))		
VI.	THE	'708 P	ATEN	Т	9	
VII.	CLA	IM CC	NSTR	UCTION	11	
VIII.	PERSON OF ORDINARY SKILL IN THE ART ("POSA")12					
IX.	IDEN	DENTIFICATION OF CHALLENGE (37 C.F.R. § 42.104(B))				
X.	INVALIDITY ANALYSIS14					
	A. Ground 1: Claims 1-3, 17, 19, and 21-23 Are Anticipated by WO					
		'498.				
		1.		osure of WO '498		
		2.		n 1		
		3.		n 2		
		4.	Claim	13	26	
		5.	Claim	ı 17		
			a)	A pharmaceutical composition comprising	27	
			b)	a therapeutically effective amount of the salt according 2	_	
			c)	in association with one or more pharmaceutically acceptable carriers.	28	



	6.	Clai	im 19	28
		a)	A method for the treatment of type 2 diabetes con	
		b)	administering to a patient in need of such treatment therapeutically effective amount of the salt according 2 or a hydrate thereof	ding to
	7.	Clai	ims 21-22	29
	8.	Clai	im 23	31
В.			Claims 1-3, 17, 19 and 21-23 Are Anticipated by t	
	1.	Disc	closure of the '871 Patent	32
	2.	Clai	ims 1 and 2	34
	3.	Clai	im 3	35
	4.	Clai	ims 17 and 19	36
	5.	Clai	ims 21-23	38
C.			Claims 3, 17, 19, and 21-23 Would Have Been Ob VO '498	
	1.	The	Level of Ordinary Skill in the Pertinent Art	40
	2.	The	Scope and Content of the Prior Art	40
		a)	WO '498 (EX1004)	40
		b)	Claim 3	41
		c)	Claim 17	43
			(1) A pharmaceutical composition comprising	43
			(2) a therapeutically effective amount of the salt according to claim 2	43
			(3) in association with one or more pharmaceutic acceptable carriers	•
		d)	Claim 19	44
			 (1) A method for the treatment of type 2 diabetes comprising. (2) administering to a patient in need of such treatherapeutically effective amount of the salt according 2 or a hydrate thereof. 	44 tment a ding to



		e) C	aims 21-23	45			
D.	Ground 4: Claims 1-3, 17, 19, and 21-23 Would Have Been Obvious in View of WO '498 and Bastin						
	1.						
	2.	The Scope and Content of the Prior Art					
			TO '498 (EX1004)				
		,	astin (EX1006)				
	3.	•	Gerences Between the Claims and Prior Art				
		a) C	aim 1	49			
		•) There Is No Requirement to Select a Lead Compalt Selection Cases	-			
		`) WO '498 and Bastin Would Have Rendered the nosphoric Acid Salt Obvious	52			
		b) C	aims 2 and 3	58			
		c) C	aims 17 and 19	58			
		d) C	aims 21-23	59			
Е.	Ground 5: Claim 4 Would Have Been Obvious in View of WO '498, Bastin and Brittain						
	1.	The Lev	el of Ordinary Skill in the Pertinent Art	61			
	2.	The Sco	pe and Content of the Prior Art	61			
		a) W	O '498 (EX1004) and Bastin (EX1006)	61			
		b) B	rittain (EX1005)	61			
	3.	The Diff	Perences Between the Claim and Prior Art	62			
F.	Ground 6: Claim 4 Would Have Been Obvious in View of WO '498 and Brittain						
	1.	The Lev	el of Ordinary Skill in the Pertinent Art	63			
	2.	The Sco	pe and Content of the Prior Art	64			
		a) W	O '498 (EX1004) and Brittain (EX1005)	64			
	3.	The Diff	Ferences Between the Claim and Prior Art	64			
G.	Seco	ndary Cor	siderations of Nonobviousness	65			
			LD INSTITUTE TRIAL BASED ON TEVA'S C. § 325(D) OR § 314(A))	68			



XI.

Dotition	for	Intor	Dartes	Pavious a	of USPN 7.	226	708
reillion	IOr	mier	Paries	neview o	OIUSPN/	JZ0.	7 UO

XII	CONCLUSION	7



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.

