#### UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ACTAVIS, INC., ACTAVIS LABORATORIES FL, INC.,
ACTAVIS PHARMA, INC., AMNEAL PHARMACEUTICALS, LLC,
AMNEAL PHARMACEUTICALS OF NEW YORK, LLC,
AUROBINDO PHARMA LTD., AUROBINDO PHARMA USA, INC.,
BRECKENRIDGE PHARMACEUTICAL, INC., VENNOOT
PHARMACEUTICALS, LLC, SANDOZ INC., SUN PHARMA GLOBAL FZE,
and SUN PHARMACEUTICAL INDUSTRIES, LTD.,
Petitioners

v.

RESEARCH CORPORATION TECHNOLOGIES, INC., Patent Owner

Case: IPR2014-01126

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. RE 38,551

Mail Stop PATENT BOARD
Patent Trial and Appeal Board
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, Virginia 22313–1450
Submitted Electronically via the Patent Review Processing System



### TABLE OF CONTENTS

		Pa	ige		
I.	INT	ΓRODUCTION	1		
II.	MANDATORY NOTICES UNDER 37 C.F.R. § 42.8				
	A.	Real Parties-In-Interest	4		
	B.	Related Matters Under 37 C.F.R. § 42.8(b)(2)	5		
	C.	Lead And Back-Up Counsel Under 37 C.F.R. § 42.8(b)(3)	5		
	D.	Service Information	6		
III.	PA	YMENT OF FEES – 37 C.F.R. § 42.103	6		
IV.	RE	QUIREMENTS FOR IPR UNDER 37 C.F.R. § 42.104	6		
	A.	Grounds For Standing Under 37 C.F.R. § 42.104(a)	6		
	B.	Identification Of Challenge Under 37 C.F.R. § 42.104(b) And Relief Requested	7		
	C.	Claim Construction Under 37 C.F.R. §§ 42.100(b), 42.104(b)(3)	7		
V.	SU	MMARY OF THE '551 PATENT	8		
VI.	LE	VEL OF ORDINARY SKILL IN THE ART	.12		
VII.	BACKGROUND13				
	A.	In 1985, Dr. Kohn Co-Authors Prior Art That Discloses The Precursor To Lacosamide.	.13		
	B.	In 1987, Dr. Kohn's Student (LeGall) Modifies The Preferred Compound Of Cortes And Discloses The Chemical Structure Of Lacosamide.	.14		
	C.	In 1991, Dr. Kohn And A Colleague Disclose Compounds That Include Lacosamide.	.16		
	D.	In 1993, Drs. Kohn And Watson Apply For What Became The '301 Patent, Which Expressly Discloses Lacosamide As A Preferred Antiepileptic Compound	.18		



	E.	Mis	taken	The Examiner Issues The '551 Patent Based On A Belief That The '301 Patent <i>Does Not Disclose</i> ide	21
	F.			ntee Concedes That The '301 Patent <i>Does Disclose</i> ide.	24
VIII.	AN	ALY	SIS C	OF GROUNDS FOR TRIAL	26
	A.			: The '301 Patent Anticipates All Claims Of The '551	26
		1.	The	'301 Patent Is § 102(e) Prior Art.	27
		2.		And Every Limitation Of The '551 Patent Is Found In Prior Art '301 Patent	27
		3.		OSA Would Have At Once Envisaged Lacosamide From m 44 Of The '301 Patent.	29
		4.		'301 Patent Would Have Enabled A POSA To Practice Claims Of The '551 Patent	30
			a)	The '301 Patent Enabled A POSA To Obtain "Substantially" And "90%" Pure Lacosamide	30
			b)	The '301 Patent Enabled A POSA To Prepare A Therapeutic Composition For Lacosamide	32
			c)	The '301 Patent Enabled A POSA To Use Lacosamide To Treat CNS Disorders	33
	B.			2: The LeGall Thesis Anticipates All Claims Of The ent.	33
		1.	The	LeGall Thesis Is Prior Art Under § 102(b)	34
		2.		LeGall Thesis Discloses Lacosamide And Thus cipates Claims 1 And 3-8.	36
		3.		LeGall Thesis Directs A POSA To The Pure R eoisomer And Thus Anticipates Claims 2 And 9	37
		4.	Anti	LeGall Thesis Discloses Lacosamide's "Good convulsant Activity" And Thus Anticipates Claim 10 Of '551 Patent.	39
		5.	App	LeGall Thesis Discloses Lacosamide's "Clinical lications" And Thus Anticipates Claims 11-13 Of The	40



	C.	Ground 3: Claims 1-13 Are Obvious Over The LeGall Thesis In View Of The '729 Patent And Other Prior Art41				
		1.	Claims 1 And 3-8, Which Claim The Racemate Including Lacosamide, Are Obvious Over The LeGall Thesis, The '729 Patent, And Other Prior Art	42		
		2.	Claims 2 And 9, Which Claim "Substantially" Or "90%" Pure Lacosamide, Are Obvious Over The LeGall Thesis, The '729 Patent And Other Prior Art	44		
		3.	Claim 10, Which Covers A Therapeutic Composition Comprising Lacosamide, Is Obvious Over The LeGall Thesis, The '729 Patent And Other Prior Art	47		
		4.	Method Claims 11-13 Are Obvious Over The LeGall Thesis, The '729 Patent And Other Prior Art	48		
IX.			ECONDARY CONSIDERATIONS FAIL TO OVERCOME TH NG OF OBVIOUSNESS			
	A.	Lac	cosamide Produced No Relevant Unexpected Results	50		
	B.	The	e '551 Patent Satisfied No Long-Felt But Unmet Need	51		
	C.	Cop	pying By Generic Drug Makers Is Irrelevant	52		
X	CO	NCI	USION	53		



### **EXHIBITS**

Exhibit	Description
1001	U.S. Patent No. RE 38,551 to Kohn ("'551 patent") (reissue of U.S. Patent No. 5,773,475 ("'475 patent"))
1002	Declaration of Clayton H. Heathcock, Ph.D.
1003	U.S. Patent No. 5,654,301 to Kohn and Watson ("'301 patent")
1004	Jan. 28, 1998 Notice of Allowability (excerpt from prosecution history of '475 patent)
1005	Philippe LeGall, 2-Substituted-2-acetamido-N-benzylacetamides. Synthesis, Spectroscopic and Anticonvulsant Properties (Dec. 1987) ("LeGall thesis")
1006	Apr. 10, 1998 Amendment Under 37 C.F.R. § 1.312 (excerpt from prosecution history of '475 patent)
1007	Dec. 23, 2008 Application for Extension of Patent Term Under 35 U.S.C. § 156 (excerpt from prosecution history of '301 patent)
1008	U.S. Patent No. 5,378,729 to Kohn and Watson ("'729 patent")
1009	Sergio Cortes et al., Effect of Structural Modification of the Hydantoin Ring on Anticonvulsant Activity, 28 J. Med. Chem. 601 (1985) ("Cortes")
1010	Harold Kohn et al., <i>Preparation and Anticonvulsant Activity of a Series of Functionalized α-Heteroatom-Substituted Amino Acids</i> , 34 J. Med. Chem. 2444 (1991) ("Kohn 1991")
1011	U.S. Food and Drug Administration, Approved Drug Products With Therapeutic Equivalence Evaluations 3-202, ADA 101 (34th ed. 2014) ("Orange Book")



# 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.

