UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC. AND APOTEX CORP., Petitioners

v.

AUSPEX PHARMACEUTICALS, INC., Patent Owner

Case IPR2021-01507 U.S. Patent No. 8,524,733 Issued: September 3, 2013

Title:

BENZOQUINOLINE INHIBITORS OF VESICULAR MONOAMINE TRANSPORTER 2

PETITION FOR INTER PARTES REVIEW



TABLE OF CONTENTS

		<u>Pag</u>	<u>e</u>		
I.	INT	RODUCTION	1		
II.	MANDATORY NOTICES				
	A.	Real Party-In-Interest			
	B.	Related Matters	6		
	C.	Designation of Lead and Back-Up Counsel	6		
	D.	Notice of Service Information	6		
III.	REQ	QUIREMENTS FOR INTER PARTES REVIEW	7		
	A.	Grounds for Standing	7		
	B.	Identification of Challenge	7		
IV.	BAC	CKGROUND	8		
	A.	Knowledge in the Prior Art Would Have Led a POSITA to the Claimed Invention	8		
		Tetrabenazine Was a Long-Known Therapeutic Compound with Drawbacks	9		
		2. Certain Positions of Tetrabenazine Were Known to Be Essential for Activity and Were Also Sites of Metabolism1	0		
		3. Strategic Deuteration Was Known to Slow Metabolism in Compounds Like Tetrabenazine	2		
		4. Deuteration Was Also Known to Impart Other Therapeutic Benefits	6		
	B. The '733 Patent		6		
		1. The Specification	6		
		2 The Claims 1	Q		



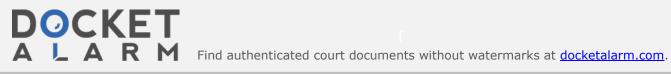
	C.	Disc	losures	ution History: The Examiner Was Missing Key s and Was Led to Error by Unsupported Arguments xpected Results	19
V.				PLANATION OF GROUNDS FOR ILITY	23
	A.	Lega	1 Stand	dards	23
	B.			Claims 1-3 Would Have Been Obvious Over Zheng Naicker '921 and Kohl	25
		1.	Prior	OSITA Would Have Been Motivated to Combine Art Teachings Regarding Tetrabenazine and teration to Arrive at the Claimed Invention	26
			a.	Zheng Would Have Motivated a POSITA to Select Tetrabenazine as a Lead Compound and Seek to Improve It	26
			b.	Naicker '921 Would Have Motivated a POSITA To Deuterate Tetrabenazine in Order to Improve Its Activity and Highlights Methoxy Groups Specifically as Promising Sites for Deuteration	28
			c.	Kohl Discloses Benefits from Deuterating Methoxy Groups and Also Teaches the Other Claim Limitations	32
		2.	of A	OSITA Would Have Had a Reasonable Expectation rriving at the Claimed Compounds and positions	35
		3.		Patentee Failed to Show Unexpected Results cient to Rebut Obviousness	36
			a.	The Results Were Not Unexpected	36
			b.	Patentee's Evidence of Reduced Side Effects Was Based on a Legally Irrelevant Comparison	39



	4.	Were Exam	nd 1 Presents New References and Disclosures That Not Before the Examiner and Highlights the niner's Error in Accepting Evidence of Unexpected lts	40	
C.	Ground 2: The '733 Patent Claims Would Have Been Obvious Over Zheng in View of Foster AB and Kohl				
	1.	A POSITA Would Have Been Motivated to Combine Prior Art Teachings Regarding Tetrabenazine and Deuteration to Arrive at the Claimed Invention			
		a.	Zheng Would Have Motivated a POSITA to Select Tetrabenazine as a Lead Compound and Seek to Improve It	43	
		b.	Foster AB Would Have Motivated a POSITA to Deuterate Tetrabenazine in Order to Improve Tetrabenazine's Activity and Highlights Methoxy Groups as Promising Sites for Deuteration	43	
		c.	Kohl Discloses Benefits from Deuterating Methoxy Groups and Also Teaches Other Dependent Claim Limitations	45	
	2.	A POSITA Would Have Had a Reasonable Expectation of Arriving at the Claimed Compounds and Compositions			
	3.		Patentee Has Not Shown Unexpected Results cient to Rebut Obviousness	47	
		a.	The Results Were Not Unexpected	47	
		b.	Patentee's Evidence of Reduced Side Effects Was Based on a Legally Irrelevant Comparison	49	
	4.	Were	nd 2 Presents New References and Disclosures That Not Before the Examiner and Highlights the niner's Error in Accepting Evidence of Unexpected	50	



	D.		iew of Schwartz and Gant '991	51
		1.	A POSITA Would Have Been Motivated to Combine Prior Art Teachings Regarding Tetrabenazine and Deuteration to Arrive at the Claimed Invention	52
			a. Gano Would Have Motivated a POSITA to Select Tetrabenazine as a Lead Compound and Seek to Improve It	52
			b. Schwartz Teaches that the Methoxy Groups of Deutetrabenazine Were Sites of Metabolism	53
			c. Gant '991 Would Have Motivated a POSITA to Deuterate the Methoxy Groups of Tetrabenazine and Discloses the Other Claim Limitations	54
		2.	A POSITA Would Have Had a Reasonable Expectation of Arriving at the Claimed Compounds and Compositions	58
		3.	The Patentee Has Not Shown Unexpected Results Sufficient to Rebut Obviousness	59
			a. The Results Were Not Unexpected	59
			b. Patentee's Evidence of Reduced Side Effects Was Based on a Legally Irrelevant Comparison	60
		4.	Ground 3 Presents New References and Disclosures That Were Not Before the Examiner and Highlights the Examiner's Error in Accepting Evidence of Unexpected	
			Results	61
VI.	CON	NCLUS	SION	62



DOCKET A L A R M

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.

