Filed: November 8, 2017

UNITED STA	ATES PATENT AND TRADEMARK (	OFFICE
BEFORE TH	HE PATENT TRIAL AND APPEAL B	OARD
	KVK-TECH, INC. and FLAT LINE CAPITAL, LLC, Petitioners,	
	v.	
SILVE	RGATE PHARMACEUTICALS, INC Patent Owner.	·-•
	Case PGR2017-00039 Patent 9,463,183	

PATENT OWNER'S PRELIMINARY RESPONSE



### **TABLE OF CONTENTS**

				rage
I.	PRE	CISE 1	RELIEF REQUESTED	1
II.	REA	REASONS FOR RELIEF.		
	A.	Intro	oduction	1
	B.	Back	kground	3
		1.	Qbrelis <sup>TM</sup> Is An Innovative Drug Formulation For Patients Suffering From Hypertension, Heart Failure, And Acute Myocardial Infarction	3
		2.	Prosecution History Of The '183 Patent	5
	C.	The	Petition Should Be Rejected For Rule Violations	5
		1.	Ground 3 Fails To Identify The Specific Evidence On Which It Relies	5
		2.	The Petition Fails To Provide A Detailed Explanation Of The Significance Of The References Upon Which It Relies	
	D.	Clair	m Construction.	9
		1.	"Stable"	9
	E.	KVK	K Has Not Shown A Lack Of Enablement	11
		1.	The Enablement Standard	11
		2.	KVK Failed To Articulate The Proper Standard For Enablement.	12
		3.	KVK Failed To Show Lack Of Enablement In View Of The Disclosed Formulations And Preparation Instruction	s 13
		4.	KVK Failed To Show That The Claimed Stability Profile Is Not Enabled	
		5.	Submitting Post-Filed Lisinopril Measurements Is Not A Showing Of Non-Enablement	
		6.	KVK Improperly Shifts The Enablement Burden Onto Silvergate	20



		7.	KVK Advances Contradictory Positions For Its Enablement and Obviousness Arguments	21
	F.		Has Failed To Show Lack Of Written Description and 2)	23
		1.	The Written Description Standard	23
		2.	KVK Fails To Show Lack Of Written Description When The Claimed Formulations Are Fully Described In The Specification.	24
	G.	Beide	Challenged Claims Would Not Have Been Obvious Over el, Nerurkar, Pharma Compounding Sept. 2006, and Beidel (Ground 3)	30
		1.	KVK Fails To Establish Any Motivation To Combine The References With A Reasonable Expectation Of Success	30
			a. KVK Fails To Show Motivation To Combine The References To Achieve The Claimed Formulation	31
			b. The References Do Not Teach Or Suggest The Claimed Sodium Benzoate Concentration	38
			c. KVK Presents Art that Teaches Away From The Selection Of Sodium Benzoate As A Preservative	39
			d. A Lisinopril Formulation That Is Stable At About 25°C For At Least 12 Months Would Not Be Predictable Based On The Cited References	41
		2.	KVK Fails To Identify A Lead Or Reference Composition To Be Modified In Beidel	46
		3.	Nerurkar Is Non-Analogous Art	47
		4.	The Dependent Claims Are Not Obvious Over The References	52
	H.		Relies On Impermissible Hindsight To Arrive At The ned Invention	53
III.	CON	CLUS	ION	55
CER	TIFIC	ATE C	F WORD COUNT	57
EVU	пріті	ICT		50



CERTIFICATE OF SERVICE
------------------------



## **TABLE OF AUTHORITIES**

	<b>Page</b>
CASES	
Alcon Research Ltd. V. Barr Labs, Inc., 745 F.3d 1180 (Fed. Cir. 2014)	24, 25
Allergan, Inc. v. Sandoz Inc., 796 F.3d 1293 (Fed. Cir. 2015)	25
Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336 (Fed. Cir. 2010) (en banc)	13, 23, 24
Bell & Howell Document Mgmt. Prods. Co. v. Altek Sys., 132 F.3d 701 (Fed. Cir. 1997)	11
Boehringer Ingelheim Int'l GmbH v. Biogen Inc., No. IPR2015-00418 (2015)	7
D'Agostino v. MasterCard Int'l Inc., 844 F.3d 945 (Fed. Cir. 2016)	9
Eli Lilly & Co. v. Actavis Elizabeth LLC, 435 Fed. Appx. 917 (Fed. Cir. 2011)	20
In re Baxter Travenol Labs., 952 F.2d 388 (Fed. Cir. 1991)	23
<i>In re Brana,</i> 51 F.3d 1560 (Fed. Cir. 1995)	20
In re Buchner, 929 F.2d 660 (Fed. Cir. 1991)	14
<i>In re Clay</i> , 966 F.2d 656 (Fed. Cir. 1992)	48
<i>In re Klein</i> , 647 F.3d 1343 (Fed. Cir. 2011)	48
<i>In re Robertson</i> , 169 F.3d 743 (Fed. Cir. 1999)	25
<i>In re Stepan Co.</i> , 868 F.3d 1342 (Fed. Cir. 2017)	38
<i>In re Wands</i> , 858 F.2d 731 (Fed. Cir. 1988)	
Janssen Pharmaceutica N.V. v. Teva Pharmaceuticals USA, Inc., 583 F.3d 1317 (Fed. Cir. 2009)	



# 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.

