Filed: August 8, 2018

Filed on behalf of: Eli Lilly and Company

UNITED STATI	ES PATENT ANI	D TRADEMARK	OFFICE
BEFORE THE	PATENT TRIAL	AND APPEAL B	OARD

# ELI LILLY AND COMPANY Petitioner

v.

# TEVA PHARMACEUTICALS INTERNATIONAL GMBH Patent Owner

.....

Case No. IPR2018-01423 Patent No. 9,266,951

PETITION FOR INTER PARTES REVIEW



### **TABLE OF CONTENTS**

I.	Intro	roduction			
II.	Requirements for <i>Inter Partes</i> Review Under 37 C.F.R. § 42.104				3
	A.	Grounds for Standing			3
	B.	Identification of Challenge			3
III.	The	The '951 Patent and Its Provisional Application			
	A.	The Challenged Claims			5
	B.	Patent Owner Admissions in the Specification			6
		1.	Mak	-CGRP Antagonist Antibodies and Methods of ting Them, Including Humanization Techniques, te Known	6
		2.		hods of Measuring Inhibition of CGRP-Induced  IP Activation Were Known	8
		3.	Lim	itations of Dependent Claims Were Also Known	8
			a)	Anti-CGRP Antagonist Antibodies That Bound to the C-Terminus of CGRP Were Known	9
			b)	IgG Sub-types, Constant Regions, and Fc Regions Were Known	9
			c)	Antibody Formulations and Methods of Administering Them Were Known	10
	C.	Prosecution of the '951 Patent			10
IV.	Background and the Asserted Prior Art			11	
	A.	CGRP Structure, Isoforms, and Function1			11
	B.	Anti-CGRP Antagonist Antibodies Were Well Known in the Art and Had Been Disclosed for Therapeutic Use in Humans13			13
	C.	IgG Antibodies14			



	D.	Huma	anization of Antibodies	17
	E.	The Asserted Prior Art		18
		1.	Tan 1995	18
		2.	Wimalawansa	20
		3.	Queen	20
		4.	Doods	22
V.	Perso	n of O	Ordinary Skill in the Art	24
VI.	Clain	n Cons	struction	24
VII.	Claim 1 Is Obvious over Tan 1995, Wimalawansa, Queen, and Doods2			26
			OSA Would Have Been Motivated to Generate the anized Anti-CGRP Antagonist Antibody of Claim 1	27
		1.	The Prior Art Recommended the Use of Anti-CGRP Antagonist Antibodies, Including Humanized Antibodies, for Therapeutic Use in Humans	27
		2.	The Confirmed <i>In Vivo</i> Effectiveness of Prior Art Anti-CGRP Antagonist Antibodies Provided Additional Motivation to Prepare a Humanized Antibody	30
		3.	The Prior Art Provided Additional Motivation to Prepare a Humanized Antibody	32
		4.	A POSA Would Have Been Motivated to Make an Antibody that Inhibits cAMP Activation in Cells	34
	В.	Succe	OSA Would Have Had a Reasonable Expectation of essfully Making a Humanized Anti-CGRP Antagonist body of Claim 1	36
		1.	A POSA Would Have Had a Reasonable Expectation of Successfully Producing an Antibody Against Human αCGRP	36



		2.	A POSA Would Have Had a Reasonable Expectation of Successfully Producing an Anti-CGRP Antagonist Antibody that Inhibits cAMP Activation	38		
		3.	A POSA Would Have Had a Reasonable Expectation of Successfully Producing a Humanized Anti-CGRP Antagonist Antibody of Claim 1	39		
	C.	The Prior Art Did Not Teach Away from Humanizing Anti-CGRP Antagonist Antibodies, as Teva Incorrectly Argued During Prosecution				
	D.	The C	Claimed Antibodies Would Have Been Obvious	47		
VIII.	The Challenged Dependent Claims Would Have Been Obvious					
	A.	Clain	ns 3 and 5	50		
	B.	Clain	ns 2, 4, and 6	52		
	C.	Clain	n 14	53		
	D.	Clain	n 15	55		
	E.	Clain	n 16	56		
	F.	Clain	n 17	58		
	G.	Clain	n 18	58		
	H.	Clain	ı 19	59		
IX.	Secondary Considerations Do Not Support Nonobviousness					
	A.		Cannot Establish Nexus to the Full Scope of the enged Claims	60		
	B.	-	s and Other's Own Near-Simultaneous Development udes a Holding of Nonobviousness	61		
X.		Evidence Submitted in this Petition Was Not Previously idered by the Office63				
XI.	Mand	Mandatory Notices Under 37 C.F.R. § 42.8				



	A.	Real Parties-in-Interest	.63		
	B.	Related Matters	.64		
	C.	Lead and Backup Counsel	.64		
	D.	Service Information	.66		
XII.	Paym	ment of Fees6			
XIII.	Conclusion60				
CERT	ΓIFICA	ATION OF COMPLIANCE	1		
CERT					



# 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.

