

Filed: August 8, 2018

Filed on behalf of: Eli Lilly and Company

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ELI LILLY AND COMPANY
Petitioner

v.

TEVA PHARMACEUTICALS INTERNATIONAL GMBH
Patent Owner

Case No. IPR2018-01425
Patent No. 9,890,210

PETITION FOR *INTER PARTES* REVIEW

TABLE OF CONTENTS

I.	Introduction.....	1
II.	Requirements for <i>Inter Partes</i> Review Under 37 C.F.R. § 42.104	2
	A. Grounds for Standing	2
	B. Identification of Challenge.....	3
III.	The '210 Patent and Its Provisional Application.....	4
	A. The Challenged Claims	5
	B. Patent Owner Admissions in the Specification.....	6
	1. Anti-CGRP Antagonist Antibodies and Methods of Making Them, Including Humanization Techniques, Were Known	7
	2. Limitations of Dependent Claims Were Also Known	8
	a) Anti-CGRP Antagonist Antibodies That Bound to the C-Terminus of CGRP Were Known.....	8
	b) IgG Sub-Types and Constant Regions Were Known.....	9
	C. Prosecution of the '210 Patent	9
IV.	Background and the Asserted Prior Art.....	10
	A. CGRP Structure, Isoforms, and Function	10
	B. Anti-CGRP Antagonist Antibodies Were Well Known in the Art and Had Been Disclosed for Therapeutic Use in Humans	11
	C. IgG Antibodies	12
	D. Humanization of Antibodies	15
	E. The Asserted Prior Art	16
	1. Tan 1995	16

2.	Wimalawansa	18
3.	Queen	18
V.	Person of Ordinary Skill in the Art.....	20
VI.	Claim Construction.....	20
VII.	Claim 1 Is Obvious over Tan 1995, Wimalawansa, and Queen	22
A.	A POSA Would Have Been Motivated to Generate a Humanized Anti-CGRP Antagonist Antibody of Claim 1	23
1.	The Prior Art Recommended the Use of Anti-CGRP Antagonist Antibodies, Including Humanized Antibodies, for Therapeutic Use in Humans	23
2.	The Confirmed <i>In Vivo</i> Effectiveness of Prior Art Anti- CGRP Antagonist Antibodies Provided Additional Motivation to Prepare a Humanized Antibody	26
3.	The Prior Art Provided Additional Motivation to Prepare a Humanized Antibody	28
B.	A POSA Would Have Had a Reasonable Expectation of Successfully Making a Humanized Anti-CGRP Antagonist Antibody of Claim 1	30
1.	A POSA Would Have Had a Reasonable Expectation of Successfully Producing an Antibody Against Human CGRP	30
2.	A POSA Would Have Had a Reasonable Expectation of Successfully Producing a Humanized Anti-CGRP Antagonist Antibody of Claim 1	33
C.	The Prior Art Did Not Teach Away from Humanizing Anti- CGRP Antagonist Antibodies, as Teva Incorrectly Argued During Prosecution.....	37
D.	The Claimed Antibodies Would Have Been Obvious	42
VIII.	The Challenged Dependent Claims Would Have Been Obvious.....	44

A.	Claims 2, 6, and 11	44
B.	Claims 3, 7, 8, and 12.....	47
C.	Claims 4, 9, and 13	49
D.	Claims 5, 10, 14, and 15.....	49
IX.	Secondary Considerations Do Not Support Nonobviousness	52
A.	Teva Cannot Establish Nexus to the Full Scope of the Challenged Claims	52
B.	Lilly’s and Other’s Own Near-Simultaneous Development Precludes a Holding of Nonobviousness.....	53
X.	The Evidence Submitted in this Petition Was Not Previously Considered by the Office	55
XI.	Mandatory Notices Under 37 C.F.R. § 42.8.....	55
A.	Real Parties-in-Interest	55
B.	Related Matters.....	56
C.	Lead and Backup Counsel.....	56
D.	Service Information	58
XII.	Payment of Fees.....	58
XIII.	Conclusion	58
	CERTIFICATION OF COMPLIANCE	1
	CERTIFICATE OF SERVICE	2

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Abbott GmbH & Co., KG v. Centocor Ortho Biotech, Inc.</i> , 971 F. Supp. 2d 171 (D. Mass. 2013).....	30, 36
<i>AbbVie Deutschland GmbH v. Janssen Biotech, Inc.</i> , 759 F.3d 1285 (Fed. Cir. 2014)	52
<i>Akorn, Inc. v. Senju Pharm. Co.</i> , IPR2015-01205, Paper 39 (PTAB Nov. 22, 2016).....	37
<i>Allergan, Inc. v. Apotex Inc.</i> , 754 F.3d 952 (Fed. Cir. 2014)	53
<i>Ecolochem, Inc. v. S. Cal. Edison Co.</i> , 227 F.3d 1361 (Fed. Cir. 2000)	53
<i>Geo. M. Martin Co. v. Alliance Mach. Sys. Int’l LLC</i> , 618 F.3d 1294 (Fed. Cir. 2010)	53, 54
<i>In re Am. Acad. of Sci. Tech Ctr.</i> , 367 F.3d 1359 (Fed. Cir. 2004)	21
<i>In re Mouttet</i> , 686 F.3d 1322 (Fed. Cir. 2012)	38, 42
<i>KSR Int’l Co. v. Teleflex Inc.</i> , 550 U.S. 398 (2007).....	30, 41
<i>Paice LLC v. Ford Motor Co.</i> , 881 F.3d 894 (Fed. Cir. 2018)	36
<i>PharmaStem Therapeutics, Inc. v. ViaCell, Inc.</i> , 491 F.3d 1342 (Fed. Cir. 2007)	6, 32
<i>Phillips v. AWH Corp.</i> , 415 F.3d 1303 (Fed. Cir. 2005) (en banc)	21
<i>Senju Pharm. Co. v. Lupin Ltd.</i> , 780 F.3d 1337 (Fed. Cir. 2015)	37

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.