UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GENZYME CORPORATION,
Petitioner

v.

GENENTECH, INC. AND CITY OF HOPE,
Patent Owners

U.S. Patent No. 6,331,415 Appl. No. 07/205,419, filed June 10, 1988 Issued: Dec. 18, 2001

Title: Methods of Producing Immunoglobulins, Vectors and Transformed Host Cells for Use Therein

IPR Trial No. IPR2016-00383

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,331,415

719038588



TABLE OF CONTENTS

		<u>P</u>	age		
I.	INTE	INTRODUCTION			
II.	REQ	UIREMENTS FOR INTER PARTES REVIEW	3		
	A.	Grounds for Standing	3		
	B.	Identification of Challenge	3		
III.	OVE	RVIEW OF THE '415 PATENT	4		
	A.	Technology Background of the '415 Patent	5		
	B.	The Purported Invention of the '415 Patent and the Challenged Claims	9		
IV.	PERS	SON OF ORDINARY SKILL IN THE ART	15		
V.	CLA	IM CONSTRUCTION	16		
VI.		STATE OF PRIOR ART rDNA ANTIBODY EXPRESSION IN IL 1983 AND OWNERS' ARGUMENTS DURING REEXAM	16		
	A.	Prior Art Platform Technologies for Expressing Foreign Genes in Mammalian Cells	17		
		1. The Axel Patent	17		
		2. The Southern Reference	19		
	В.	The Prior Art Taught Expression of Single Immunoglobulin Chains in Transformed Mammalian Host Cells	21		
	C.	Owners' Arguments During Reexamination Regarding Axel	22		
VII.		TEMENT OF GROUNDS FOR THE UNPATENTABILITY OF CHALLENGED CLAIMS	26		
	A.	Ground 1: The Salser Patent Anticipates Claims 1-4, 9, 11, 12, 15-20 and 33 Under 35 U.S.C. § 102(e)	26		
		1 Overview of the Salser Patent Disclosures	26		



TABLE OF CONTENTS

(continued)

<u>Page</u>

2.	App	licable Law of Anticipation30
3.		Salser Patent Anticipates Independent ms 1, 15, 17, 18 and 33
	a.	Independent Process Claim 133
		 i. "A process for producing an immunoglobulin molecule or an immunologically functional immunoglobulin fragment comprising at least the variable domains of the immunoglobulin heavy and light chains, in a single host cell"
		ii. "comprising the steps of: (i) transforming said single host cell with a first DNA sequence encoding at least the variable domain of the immunoglobulin heavy chain and a second DNA sequence encoding at least the variable domain of the immunoglobulin light chain"
		iii. " and (ii) independently expressing said first DNA sequence and said second DNA sequence so that said immunoglobulin heavy and light chains are produced as separate molecules in said transformed single host cell."
	b.	Independent Process Claim 3344
	c.	Independent Composition Claims 15 and 1744
	d.	Independent Composition Claim 1845
4.		Salser Patent Anticipates Dependent Claims 2, 3, 4, 1, 12, 16, 19 and 2046



TABLE OF CONTENTS

(continued)

Page

	B.	Ground 2: All of the Challenged Claims Are Obvious Over Salser in View of Ochi (I)	47
		1. Claims 1-4, 9, 11, 12, 15-20 and 33	47
		2. Claim 14	50
	C.	Explanation of Ground 3 for Unpatentability: Claims 2, 18 and 20 Are Obvious Over Salser in View of Southern	51
	D.	The Immunoglobulin Co-Expression rDNA Work Reflected in the Boss Patent and Ochi (II) Supports a Finding of Obviousness	54
	Е.	The Publicly Available Licensing Record of the '415 Patent Does Not Rescue the Challenged Claims from Obviousness	56
VIII.	MAN	DATORY NOTICES	58
	A.	Real Party-In-Interest	58
	B.	Related Matters	58
	C.	Lead and Back-up Counsel and Service Information	59
137	CON	CLUCION	60



TABLE OF AUTHORITIES

	<u>Page</u>
Cases	
Amgen v. Hoechst Marion Roussel, 314 F.3d 1313 (Fed. Cir. 2003)	32
<i>In re Antor Media Corp.</i> , 689 F. 3d 1282 (Fed. Cir. 2012)	32
Arthrocare Corp. v. Smith & Nephew, Inc., 406 F. 3d 1365 (Fed. Cir. 2005)	30, 40
In re Baxter Travenol Labs., 952 F.2d 388 (Fed. Cir. 1991)	34
Bristol-Myers Squibb v. Ben Venue Labs., 246 F.3d 1368 (Fed. Cir. 2001)	32
Concrete Appliances Co. v. Gomery, 269 U.S. 177 (1925)	55
Continental Can Co. USA v. Monsanto, 948 F. 2d 1264 (Fed. Cir. 1991)	16, 31
In re Cuozzo Speed Techs., LLC, No. 2014-1301, 2015 WL 4097949 (Fed. Cir. Jul. 8, 2015)	16
Ecolochem v. S. Cal. Edison Co., 227 F.3d 1361 (Fed. Cir. 2000)	55, 56
Elan Pharm. v. Mayo Found., 304 F.3d 1221 (Fed. Cir.), vacated on other grounds, 314 F.3d 1299 (Fed. Cir. 2002)	31
Eli Lilly and Co. v. Zenith Goldline Pharms., Inc., 471 F. 3d 1369 (Fed. Cir. 2006)	, 34, 36
George M. Martin Co. v. Alliance Mach. Sys. Int'l LLC, 618 F.3d 1294 (Fed. Cir. 2010)	54, 56
<i>In re Gleave</i> , 560 F.3d 1331 (Fed. Cir. 2009)	31



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.

