

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.
IPR2016-00460

**PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,331,415
UNDER 35 U.S.C. § 311-319 AND 37 C.F.R. § 42.100 et seq.**

TABLE OF CONTENTS

	<u>Page</u>
I. INTRODUCTION	1
II. REQUIREMENTS FOR INTER PARTES REVIEW	2
A. Grounds for Standing (37 C.F.R. § 42.104(a))	2
B. Identification of Challenge (37 C.F.R. § 42.104(b)).....	2
III. RELEVANT INFORMATION REGARDING THE '415 PATENT	3
A. Brief Description of the Challenged Patent	3
B. Discussion of the File History and Related Proceedings in the PTO.....	7
1. Prosecution of the '419 application.....	8
2. Interference with the Boss Patent	8
3. Ex Parte Reexamination of the '415 Patent.....	9
a. Rejections Over the Axel Patent.....	9
b. Owners' Arguments in Response to the Rejections.....	12
i. Owners Contrive a So-Called "Prevailing Mindset" before April 1983 that Only One Eukaryotic Protein of Interest Should Be Produced in a Transformed Host Cell.....	12
ii. Owners Argue that the Axel Patent Does Not Disclose the Co-Expression of "One or More" Genes of Interest	14
C. Person of Ordinary Skill in the Art	15
D. Claim Construction	16
IV. RELEVANT PRIOR ART	16
A. Technology Background	16

TABLE OF CONTENTS

(continued)

	<u>Page</u>
1. The Sophistication of Recombinant DNA Technology Was Advanced by April 8, 1983, and Mammalian Proteins Were Being Made in Host Cells Transformed with Foreign Genes	16
2. The Prior Art Taught Expression of Single Immunoglobulin Chains.....	18
3. The Prevailing Mindset by April 1983 Was That One or More Proteins of Interest Could be Made in a Single Host Cell	21
B. References Underlying the Grounds for Rejection	25
1. Bujard Teaches Introducing and Expressing a "Plurality of Genes" in Bacterial or Mammalian Host Cells and Identifies "Immunoglobulins" as a Protein of Interest	25
2. Cohen & Boyer Teaches Introducing and Expressing "One or More Genes" in Bacteria and Identifies "Antibodies" as a Protein of Interest.....	28
3. Riggs & Itakura Teaches Hybridomas as a Source of Antibody Genes and the In Vitro Assembly of Heavy and Light Chains	32
4. Southern Teaches One Host Cell Transformed with Two Vectors	33
V. FULL STATEMENT OF PRECISE RELIEF REQUESTED AND THE REASONS THEREFORE (37 C.F.R. § 42.22(a))	34
A. Explanation of Ground 1 for Unpatentability: Bujard Anticipates Claims 1, 3, 4, 9, 11, 12, 15-17, 19 and 33	34
1. Bujard Anticipates Independent Claims 1, 15, 17 and 33	37
VI. Bujard Anticipates Dependent Claims 3, 4, 9, 11, 12, 16 and 19	42

TABLE OF CONTENTS
(continued)

	<u>Page</u>
A. Explanation of Ground 2 for Unpatentability: Claims 1, 3, 4, 11, 12, 14, 19 and 33 Are Obvious Over Bujard in View of Riggs & Itakura	44
B. Explanation of Ground 3 for Unpatentability: Claims 1, 2, 18, 20 and 33 Are Obvious Over Bujard in View of Southern.....	47
C. Explanation of Ground 4 for Unpatentability: Claims 1, 3, 4, 11, 12, 14 and 33 Are Obvious Over Cohen & Boyer in View of Riggs & Itakura	50
1. The Disclosures of Cohen & Boyer.....	50
2. Cohen & Boyer in Combination with Riggs & Itakura's Teachings of In Vitro Assembly of Heavy and Light Chains Renders Obvious Claims 1, 3, 4, 11, 12, 14 and 33.....	54
D. Secondary Indicia of Non-Obviousness in the Public Record Do Not Rebut Petitioner's Prima Facie Case of Obviousness	56
VII. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8(a)(1).....	58
A. Real Party-In-Interest Under 37 C.F.R. § 42.8(b)(1)	58
B. Related Matters Under 37 C.F.R. § 42.8(b)(2)	59
C. Lead and Back-up Counsel and Service Information Under 37 C.F.R. § 42.8(b)(3), (4)	59
VIII. CONCLUSION.....	60

TABLE OF AUTHORITIES

	<u>Page</u>
Cases	
<i>Allergan v. Apotex</i> , 754 F. 3d 952 (Fed. Cir. 2014)	34
<i>Amgen v. Hoechst Marion Roussel</i> , 314 F.3d 1313 (Fed. Cir. 2003)	36
<i>In re Antor Media Corp.</i> , 689 F. 3d 1282 (Fed. Cir. 2012)	36
<i>Bristol-Myers Squibb v. Ben Venue Labs.</i> , 246 F.3d 1368 (Fed. Cir. 2001)	36
<i>Cabilly v. Boss</i> , 55 U.S.P.Q.2d 1238 (Bd. Pat. App. & Int. 1998)	8
<i>Callaway Golf Co. v. Acushnet Co.</i> , 576 F. 3d 1331 (Fed. Cir. 2009)	49
<i>CBS Interactive Inc. v. Helferich Patent Licensing, LLC</i> , IPR2013-00033	57
<i>Continental Can Co. USA v. Monsanto</i> , 948 F. 2d 1264 (Fed. Cir. 1991)	35
<i>In re Cuozzo Speed Techs., LLC</i> , No. 2014-1301, 2015 WL 4097949 (Fed. Cir. Jul. 8, 2015)	16
<i>Dayco Prods. v. Total Containment</i> , 329 F.3d 1358 (Fed. Cir. 2003)	34
<i>In re Donohue</i> , 632 F.2d 123 (C.C.P.A. 1980)	35
<i>In re Gleave</i> , 560 F.3d 1331 (Fed. Cir. 2009)	35, 36
<i>In re Graves</i> , 69 F.3d 1147 (Fed. Cir. 1995)	35

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.