UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD
MYLAN PHARMACEUTICALS INC., 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, 1998 Issued: Dec. 18, 2001
Title: Methods of Producing Immunoglobulins, Vectors and Transformed Host Cells for Use Therein
Inter Partes Review No.: IPR2016-00710

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

I.	INT	RODU	CTIO	N		1		
II.	REQUIREMENTS FOR INTER PARTES REVIEW							
	A.	Grounds for Standing (37 C.F.R. § 42.104(a))						
	B.	Identification of Challenge (37 C.F.R. § 42.104(b))						
III.	RELEVANT INFORMATION REGARDING THE '415 PATENT							
	A.	Brief Description of the Challenged Patent						
	B.	Discussion of the File History and Related Proceedings in the PTO						
		1.	Pros	ecution	n of the '419 application	9		
		2.3.	Interference with the Boss Patent					
			Ex P	Ex Parte Reexamination of the '415 Patent				
			a.	Reje	ections Over the Axel Patent	10		
			b.	Owr	ners' Arguments in Response to the Rejections	14		
				i.	Owners Contrive a So-Called "Prevailing Mindset" before April 1983 that Only One Eukaryotic Protein of Interest Should be Produc in a Transformed Host Cell			
				ii.	Owners Argue that the Axel Patent Does Not Disclose the Co-Expression of "One or More" Genes of Interest	16		
	C.	Person of Ordinary Skill in the Art				17		
	D.	Claim Construction			18			
IV.	RELEVANT PRIOR ART				18			
	A.	Technology Background						



		1.	Was Advanced by April 8, 1983, and Mammalian Proteins Were Being Made in Host Cells Transformed with Foreign Genes	18			
		2.	The Prior Art Taught Expression of Single Immunoglobulin Chains	21			
		3.	The Prevailing Mindset by April 1983 Was That One or More Proteins of Interest Could be Made in a Single Host Cell	23			
	B.	Refe	rences Underlying the Grounds for Rejection	28			
		1.	Bujard Teaches Introducing and Expressing a "Plurality of Genes" in Bacterial or Mammalian Host Cells and Identifies "Immunoglobulins" as a Protein of Interest	28			
		2.	Riggs & Itakura Teaches Hybridomas as a Source of Antibody Genes and the <i>In Vitro</i> Assembly of Heavy and Light Chains	31			
		3.	Southern Teaches One Host Cell Transformed with Two Vectors	32			
V.			TEMENT OF PRECISE RELIEF REQUESTED AND SONS THEREFOR (37 C.F.R. § 42.22(a))	34			
	A.	3, 4,	anation of Ground 1 for Unpatentability: Claims 1, 11, 12, 14, 19, and 33 Are Obvious Over Bujard in of Riggs & Itakura	34			
	B.	2, 18	anation of Ground 2 for Unpatentability: Claims 1, , 20, and 33 Are Obvious Over Bujard in View of nern	39			
	C.	Reco	ndary Indicia of Non-Obviousness in the Public rd Do Not Rebut Petitioner's Prima Facie Case of ousness	42			
VI.	MANDATORY NOTICES UNDER 37 C.F.R. § 42.8(a)(1)						
	A.	Real	Party-In-Interest Under 37 C.F.R. § 42.8(b)(1)	44			



	В.	Related Matters Under 37 C.F.R. § 42.8(b)(2)	
	C.	Lead and Back-up Counsel and Service Information	
		Under 37 C.F.R. § 42.8(b)(3), (4)	45
VII.	CON	CLUSION	46



TABLE OF AUTHORITIES

Cases

Cabilly v. Boss, 55 U.S.P.Q.2d 1238 (Bd. Pat. App. & Int. 1998)	10
Callaway Golf Co. v. Acushnet Co., 576 F. 3d 1331 (Fed. Cir. 2009)	41
CBS Interactive Inc. v. Helferich Patent Licensing, LLC, IPR2013-00033	42
In re Cuozzo Speed Techs., LLC, 793 F.3d 1268 (Fed. Cir. 2015)	18
Iron Grip Barbell Co. v. USA Sports, Inc., 392 F.3d 1317 (Fed. Cir. 2004)	42
SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp., 225 F.3d 1349 (Fed. Cir. 2000)	42
Statutes	
35 U.S.C. § 120	4
35 U.S.C. § 146	10
35 U.S.C. § 314(a)	1
35 U.S.C. § 315(c)	2
35 U.S.C. §§ 311-319	1
Regulations	
37 C.F.R. § 42.204(b)	3
37 C.F.R. § 42.8(b)(2)	44



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.

