IPR2016-01694 Patent Owner's Preliminary Response

Filed on behalf of Patent Owner Genentech, Inc. by:

David L. Cavanaugh
Reg. No. 36,476
Owen K. Allen
Reg. No. 71,118
Robert J. Gunther, Jr.

Pro Hac Vice to be filed
Wilmer Cutler Pickering
Hale and Dorr LLP
1875 Pennsylvania Ave., NW

Washington, DC 20006

Adam R. Brausa
Reg. No. 60,287
Daralyn J. Durie
Pro Hac Vice to be filed
Durie Tangri LLP
217 Leidesdorff Street
San Francisco, CA 94111

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS, INC., Petitioner,

V.

GENENTECH, INC., Patent Owner.

Case IPR2016-01694 Patent 6,407,213

PATENT OWNER'S PRELIMINARY RESPONSE



TABLE OF CONTENTS

		Page
I.	INTRODUCTION	1
II.	TECHNOLOGY BACKGROUND	4
A.	Antibody "Variable" And "Constant" Domains	4
B.	"Humanized" Antibodies	5
III.	THE '213 PATENT	8
A.	The Invention	8
B.	Advantages Of The '213 Invention	10
C.	Prosecution History	11
IV.	MYLAN'S ASSERTED REFERENCES	12
A.	Queen 1989	12
В.	Queen 1990	13
C.	PDB Database	15
D.	Tramontano	15
E.	Kabat 1987	16
F.	Hudziak	17
V.	PERSON OF ORDINARY SKILL	17
VI.	CLAIM CONSTRUCTION	18
VII.	ARGUMENT	19
A.	The Board Should Deny Grounds 2, 3, 4, And 7 Because Neither Queen 1990 Nor Tramontano Is Prior Art.	19



1.			nventors produced and tested humanized 4D5 antibodies their consensus sequence approach before July 26, 1990	20
	a)	Co	onsensus sequence	20
	b)	H	umanized 4D5 antibody sequences	22
	c)	Pr	oduction and testing of humanized 4D5 antibodies	25
		(i)	First humanized 4D5 variable domain fragment	26
		(ii)	First humanized 4D5 full length antibody	28
		(iii)	Other humanized 4D5 variants	30
2.			challenged claims were reduced to practice before July 26,	31
	a)		uMAb4D5-5 and HuMAb4D5-8 embody the challenged aims.	32
		(i)	Limitations common to all claims	32
		(ii)	Additional limitations for certain claims	37
	b)	H	ne inventors determined that HuMAb4D5-5 and uMAb4D5-8 would work for the intended purpose of the allenged claims before July 26, 1990.	39
	c)		ontemporaneous records from non-inventors corroborate e invention of the challenged claims.	39
3.		Quee	n 1990 and Tramontano are not prior art	40
	a)	Li	mitations common to all claims	41
	b)	A	dditional limitations for certain claims	41
	M	ulan'a	Proposed Grounds Fail On The Merits	13



B.

1.		Grounds 1, 3, 5, and 6: Queen 1989 in view of the PDB database does not render the challenged claims obvious.	44		
	a)	Queen 1989 contradicts Mylan's obviousness theory	44		
	b)	Queen 1989 does not disclose or suggest substituting residues within about 3 angstroms of a CDR	45		
	c)	Mylan's proposed combination of Queen 1989 with the PDB database results in a broad genus that would not have led to the claimed substitutions.	46		
2.		Grounds 2, 4, and 7: Queen 1990 in view of the PDB database does not render the challenged claims obvious			
	a)	Queen 1990 contradicts Mylan's obviousness theory	48		
	b)	Mylan's proposed combination of Queen 1990 with the PDB database results in a broad genus that would not have led to the claimed substitutions.	50		
3.		Grounds 1 and 2: Queen 1989 and Queen 1990 do not render obvious claims 63 and 65.			
	a)	Claim 63: "Lacks immunogenicity"	51		
	b)	Claim 65: "Up to 3-fold more" binding affinity	52		
		(i) Queen 1990	53		
		(ii) Queen 1989	53		
4.		Grounds 2, 5, and 7: Mylan's asserted references do not render obvious the "consensus" sequence limitations of claims 4, 33, 62, 64, and 69.	54		
	a)	Grounds 2 and 7: Queen 1990 does not render obvious the "consensus" sequence claimed in the '213 patent	55		



IPR2016-01694 Patent Owner's Preliminary Response

		b)	Ground 5: Queen 1989 in view of Kabat 1987 does not render obvious the "consensus" sequence claimed in the '213 patent.	57
	5.		Grounds 3 and 4: Claims 75-77 and 79 would not have been obvious in view of Mylan's proposed combinations.	59
		a)	Claim 75	59
		b)	Claims 76-77 and 79	61
	6.		Grounds 6 and 7: Claims 30, 31, 33, 42, and 60 would not have been obvious in view of Mylan's proposed combinations	62
C.			ojective Indicia Of Non-Obviousness Confirm The Patentability The Challenged Claims.	63
	1.		Unexpected results	63
	2.		Commercial success	65
VIII	C(NC	CLUSION	65



DOCKET

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.

