

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

David L. Cavanaugh (Reg. No. 36,476)
Robert J. Gunther, Jr. (*Pro Hac Vice*)
Lisa J. Pirozzolo (*Pro Hac Vice*)
Kevin S. Prussia (*Pro Hac Vice*)
Andrew J. Danford (*Pro Hac Vice*)
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*)
DURIE TANGRI LLP
217 Leidesdorff Street
San Francisco, CA 94111

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PFIZER, INC. AND SAMSUNG BIOEPIS CO., LTD.,
Petitioners,

v.

GENENTECH, INC.,
Patent Owner.

Case IPR2017-01488
Patent No. 6,407,213

EXPERT DECLARATION OF DR. IAN A. WILSON

TABLE OF CONTENTS

	Page
I. INTRODUCTION AND BACKGROUND	1
A. Qualifications and Experience	3
B. Compensation	5
C. Prior Expert Testimony	5
II. LEGAL PRINCIPLES ON ANTICIPATION AND OBVIOUSNESS	6
III. BACKGROUND OF THE TECHNOLOGY	9
A. Proteins, Amino Acids, and Antibodies	10
1. Proteins are Made of Amino Acids	10
2. Antibodies are a Type of Protein	13
B. Research on Making Antibodies	20
1. Early Efforts to Produce Antibodies	20
2. Chimeric Antibodies	22
3. Humanized Antibodies	23
IV. The '213 Patent	32
A. The Invention	32
B. Claims 4, 12, 30, 31, 33, 42, 60, 62-67, 69, and 71-79	36
C. Advantages of the '213 Invention	37
D. Priority Application Support	40
V. PERSON OF ORDINARY SKILL IN THE ART	51
VI. CLAIM CONSTRUCTION	54
A. "Consensus Human Variable Domain"	54

B.	“Lacks Immunogenicity Compared To A Non-Human Parent Antibody”	54
C.	Other Claim Terms	54
VII.	SUMMARY OF THE ASSERTED PRIOR ART	55
A.	Queen 1989.....	55
B.	Queen 1990.....	59
C.	Kurrle.....	65
D.	Chothia & Lesk	69
E.	Chothia 1985	71
F.	Furey.....	71
G.	Hudziak.....	72
H.	Tramontano	73
I.	Protein Data Bank	75
J.	Kabat 1987	75
VIII.	OPINIONS REGARDING THE ASSERTED PRIOR ART	76
A.	IPR2017-01488 Grounds 1 and 3: Claims 66-67, 71-72, 75-76, and 78 are not Anticipated or Obvious Because the Asserted References Fail to Teach Non-Human CDRs “Which Bind Antigen Incorporated into a Human Antibody Variable Domain.”	78
B.	IPR2017-01488 Grounds 2 and 3: Claims 4 and 62, 64, and 69 are not Anticipated or Obvious Because Queen 1990 Fails to Teach Non-Human CDRs “Which Bind Antigen Incorporated into a Human Antibody Variable Domain.”	81
C.	IPR2017-01489 Grounds 1-7: Claims 4, 12, 33, 42, 60, 62, 64-67, 69, and 71-79 Would not have Been Obvious Based on the	

PDB Database Combined with Either Queen 1989 or Queen 1990	86
1. A Person of Ordinary Skill in the Art Would Not Combine the PDB Database with Queen 1990 or Queen 1989 as Proposed by Dr. Foote	87
2. The PDB Database, Combined with Either Queen 1990 or Queen 1989, Fails to Teach a Humanized Antibody that Incorporates Non-Human CDRs that Bind Antigen.....	91
D. IPR2017-01489 Grounds 1-4: None of the Asserted References Disclose or Suggest the Substitutions Recited in Claims 75-77, 79, and 65.	94
E. IPR2017-01488 Grounds 1-3 and IPR2017-01489 Grounds 1-2: None of the Asserted References Disclose or Suggest the “Lacks Immunogenicity” Limitations of Claim 63.....	96
F. IPR2017-01488 Grounds 2-3 and 8, and IPR2017-01489 Grounds 2, 5 and 7: None of the Asserted References Discloses or Suggests the “Consensus” Limitations of Claims 4, 33, 62, 64, and 69.	101
1. Queen 1990	102
2. Queen 1989 in View of Kabat 1987	106
3. Lack of Predictability of the Art Prevented Any Reasonable Expectation of Success in Creating a Consensus Variable Domain Based on Queen 1990 or Queen 1989 in View of Kabat 1987.....	109
G. IPR2017-01488 Grounds 3-10: Petitioners have not Shown that a Person of Ordinary Skill Would have Selected the Specific Framework Substitutions Recited in Claims 12, 42, 60, 65-67, and 71-79 from the Broad Genus of Potential Substitutions Allegedly Disclosed in the Asserted References.	113
1. The Asserted References Disclose a Vast Number of Potential Substitutions Without any Real Guidance that Would Lead a Skilled Artisan to the Specific Substitutions in the ’213 Patent Claims.	113

H.	IPR2017-01488 Grounds 4-7: A Person of Ordinary Skill in the Art Would Not Rely on the References that Petitioners Combine with Kurrle and Queen to Arrive at the Limitations Recited in Claims 12, 73, 74, 77, 79, and 65.	118
1.	Ground 4: Furey	118
2.	Ground 5: Chothia & Lesk.....	120
3.	Ground 6: Chothia 1985.....	122
4.	Ground 7: Chothia & Lesk and Chothia 1985	124
I.	IPR2017-01488 Ground 7 and IPR2017-01489 Grounds 1-4: The Asserted References do not Render Obvious the “Up to 3-Fold More” Binding Affinity Limitation of Claim 65.	125
J.	IPR2017-01488 Grounds 8-10 and IPR2017-01489 Grounds 6-7: the Asserted References do not Disclose or Suggest a Humanized Antibody with the Framework Substitutions Recited in Claims 30-31, 33, 42, and 60 that Binds p185 ^{HER2}	127
IX.	Secondary Considerations	129

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.