IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the *Inter Partes* Review of: Trial Number: To Be Assigned

U.S. Patent No. 6,407,213

Filed: November 17, 1993

Issued: June 18, 2002

Inventor(s): Paul J. Carter, Leonard G. Presta

Assignee: Genentech, Inc.

Title: Method for making humanized antibodies Panel: To Be Assigned

---

Mail Stop *Inter Partes* Review
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION FOR *INTER PARTES* REVIEW OF
U.S. PATENT NO. 6,407,213
UNDER 35 U.S.C. §311 AND 37 C.F.R. §42.100

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

TABLE OF CONTENTS

I. INTRODUCTION 1

II. MANDATORY NOTICES – 37 C.F.R. §42.8(A)(1) AND (B) 2

A. 37 C.F.R. §42.8(b)(1): Real Party-In-Interest 2

B. 37 C.F.R. §42.8(b)(2): Related Matters 2

C. 37 C.F.R. §42.8(b)(3): Lead and Back-Up Counsel 3

D. 37 C.F.R. §42.8(b)(4): Service Information 3

III. PAYMENT OF FEES – 37 C.F.R. §42.103 3

IV. GROUNDS FOR STANDING – 37 C.F.R. §42.104(A) 4

V. IDENTIFICATION OF CHALLENGE – 37 C.F.R. §42.104(B) 4

VI. THRESHOLD REQUIREMENT FOR *INTER PARTES* REVIEW 6

VII. STATEMENT OF REASONS FOR THE RELIEF REQUESTED 7

A. Summary of the Argument 7

B. '213 Patent Background 11

1. The '213 Patent 11

2. Prosecution History and Related Proceedings 14

C. Level of Ordinary Skill in the Art 16

D. Claim Construction 17

1. "a humanized antibody variable domain" (claims 1, 62 and 80), "an antibody" (claim 30) or "a humanized antibody" (claim 63), "a humanized variant of a non-human parent antibody" (claims 64 and 79) or "a humanized antibody heavy chain variable domain" (claim 66). 17

DOCKET ALARM

Find authenticated court documents without watermarks at docketalarm.com.

2. "and further comprising a Framework Region (FR) amino acid substitution at a site selected from the group consisting of…" 17

3. "numbering system set forth in Kabat"....18

4. "up to 3-fold more" 19

E. Prior Art....19

1. Queen 1989 (Ex. 1534) 19

2. Queen 1990 (Ex. 1550) 21

3. PBD Database 23

4. Tramontano (Ex. 1551) 26

5. Kabat 1987 (Ex. 1552) 27

6. Hudziak (Ex. 1521) 27

VIII. THE PRIOR ART RENDERS THE CHALLENGED CLAIMS OBVIOUS 29

B. Grounds 1 and 2: Claims 1, 2, 4, 12, 25, 29, 62–67, 69 and 71–81 Are Unpatentable As Obvious over Queen 1989 or Queen 1990, In View of the PDB Database 31

1. Ground 1: Claim 1 is Obvious over Queen 1989 in view of the PDB Database 31

2. Ground 2: Claim 1 is Obvious over Queen 1990 in view of the PDB Database 36

3. Grounds 1 and 2: Claims 2, 12, 25 and 29 Are Obvious Over Queen 1989 and the PDB Database or Queen 1990 and the PDB Database 38

4. Ground 2: Claim 4 Is Obvious in View of Queen 1990 and PDB Database 40

5. Ground 2: Claim 62 Is Obvious in View of Queen 1990 and PDB Database 40

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

6. Grounds 1, 2: Claims 63–64 and 66 Are Obvious Over Queen 1989 or Queen 1990 and PDB Database 41

7. Ground 2: Claim 69 Is Obvious in View of Queen 1990 and PDB Database 45

8. Grounds 1, 2: Claims 67, 71–74 and 78 Are Obvious in View of Queen 1989 or Queen 1990 and PDB Database 45

9. Grounds 1, 2: Claims 75–77 and 79 Are Obvious in View of Queen 1989 or Queen 1990 and PDB Database.....47

10. Grounds 1 and 2: Claim 65 Is Obvious in View of Queen 1989 or Queen 1990 and the PDB Database.....51

11. Grounds 1, 2: Claims 80 and 81 Are Obvious in View of Queen 1989 or Queen 1990 and PDB Database 52

C. Grounds 3 and 4: Claims 75–77, 79, and 65 Are Obvious over Queen 1989 or Queen 1990 and PDB Database and Further in View of Tramontano. 53

D. Ground 5: Claims 4, 62, 64 and 69 are Obvious in View of Queen 1989 and the PDB Database, and Further in View of Kabat 1987 55

E. Grounds 6 and 7: Claims 30, 31, 33, 42 and 60 Are Obvious in View of Queen 1989 or Queen 1990; PDB Database; and Hudziak.....56

F. Secondary Considerations Cannot Overcome Obviousness. 60

1. The Challenged Claims Produced No Relevant Unexpected Results.....61

2. The ’213 Patent Satisfied No Long-Felt but Unmet Need 63

3. No Nexus Between Commercial Success of Genentech Drugs and the Challenged Claims 64

IX. CONCLUSION 65

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

TABLE OF AUTHORITIES

Page(s)

Cases

Atlas Powder Co. v. *Ireco Inc.*,
190 F.3d 1342 (Fed. Cir. 1999) 42, 52

In re Cuozzo Speed Techs., LLC,
793 F.3d 1268 (Fed. Cir. 2015) 16

Ecolochem, Inc. v. *Southern California Edison Co.*,
91 F.3d 169 (Fed. Cir. 1996) 17

In re Hall,
781 F.2d 897 (Fed. Cir. 1986) 24

In re Kubin,
561 F.3d 1351 (Fed. Cir. 2009) 62

Merck & Co. v. Teva Pharms. USA,
395 F.3d 1364 (Fed. Cir. 2005) 60

Norgren Inc. v. ITC,
699 F.3d 1317 (Fed. Cir. 2012) 64

Ormco Corp. v. Align Tech., Inc.,
463 F.3d 1299 (Fed. Cir. 2006) 64

In re Peterson,
315 F.3d 1325 (Fed. Cir. 2003) 51

Pfizer, Inc. v. Apotex, Inc.,
480 F.3d 1348 (Fed. Cir. 2007) 60

Ex Parte Takeshi Shimono,
2015 WL 1952506, Appeal 2013–003410 (PTAB Apr. 29, 2015) 61

In re Wyer,
655 F.2d 221 (C.C.P.A. 1981) 24

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

DOCKET ALARM

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.