

Filed on behalf of Phigenix, Inc.
By: Ping Wang, M.D., Esq.
Gregory Porter, Esq.
Michael Ye, Ph.D., Esq.
ANDREWS KURTH, LLP
1350 I Street, NW
Suite 1100
Washington, D.C. 20005
Tel.: (202) 662-2700
Fax: (202) 662-2739
Email: PingWang@AndrewsKurth.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PHIGENIX, INC.
Petitioner
v.
IMMUNOGEN, INC.
Patent Owner of
U.S. Patent No. 8,337,856 to Walter Blättler, *et al.*
Issued on December 25, 2012
Appl. No. 11/949,351 filed on December 3, 2007

IPR Trial No. 2014-TBD

**PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,337,856
PURSUANT TO 35 U.S.C. §312 AND 37 C.F.R. §42.108**

Mail Stop PATENT BOARD
Patent Trial and Appeal Board
U.S. Patent & Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

TABLE OF CONTENTS

PETITION FOR *INTER PARTES* REVIEW OF U.S. PAT. NO. 8,337,856..... 1

I. INTRODUCTION..... 1

II. GROUNDS FOR STANDING (37 C.F.R. § 42.104(a))..... 1

III. MANDATORY REQUIREMENTS, NOTICES AND FEES..... 1

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

 B. Related Matters (37 C.F.R. §42.8(b)(2))..... 1

 C. Lead and Back-Up Counsel (37 C.F.R. §42.8(b)(3)) and Service
 Information (37 C.F.R. §42.8(b)(4))..... 2

 D. Power of Attorney (37 C.F.R. §42.10(b))..... 2

 E. Petition Fees (35 U.S.C. § 312(1) and 37 C.F.R. § 42.15) 2

 F. Proof of Service (37 C.F.R. §§ 42.6(c) and 42.105(a))..... 2

IV. STATEMENT OF THE PRECISE RELIEF REQUESTED (37 C.F.R.
§42.22(a)(1))..... 3

V. RELEVANT INFORMATION CONCERNING THE CONTESTED
PATENT..... 3

 A. The ‘856 Patent..... 3

 B. Technical Background 4

 C. Ordinarily Skilled Artisan (Person of Ordinary Skill in the Art)..... 6

 D. Construction of Terms Used in the Claims..... 7

VI. IDENTIFICATION OF CHALLENGE (37 C.F.R. §42.104(b))..... 7

 A. Ground 1: Claims 1-8 Are Obvious Over Chari 1992 In View Of
 HERCEPTIN® Label..... 8

 B. Ground 2: Claims 1-8 Are Obvious Based on Chari 1992 In View Of
 HERCEPTIN® Label, Further In View Of Hudziak 1998 And/Or
 Rosenblum 1999 17

 C. Ground 3: Claims 1-8 Are Obvious Over Chari 1992 In View Of
 HERCEPTIN® Label, Further In View Of Hudziak 1998 And/Or
 Rosenblum 1999 And Further In View Of Baselga 1998 And/Or
 Pegram 1999..... 20

 D. Ground 4: Claims 4 and 6-8 Are Obvious Based On Chari 1992 In
 View Of HERCEPTIN® Label And Further In View Of Morgan... 23

 E. Ground 5: Claims 1-8 Are Obvious Based On Chari 1992 In View Of
 Carter 1992 And Common Knowledge In The Art..... 26

 F. Ground 6: Claims 1-5 and 7 Are Obvious Over Liu 1996 In View Of
 HERCEPTIN® Label..... 32

G.	Ground 7: Claims 6 and 8 Are Obvious Over Liu 1996 In View Of HERCEPTIN® Label And Further In View of Morgan 1990.....	39
H.	Ground 8: Claims 1-8 Are Obvious Over Cohen 1999 In View Of Chari 1992	41
VII.	ISSUES RAISED DURING PROSECUTION OF THE '856 PATENT...	48
A.	The “Incompatible Mechanism of Action”.....	48
B.	Reasonable Expectation of Success.....	53
C.	No Unexpected Results.....	57
VIII.	CONCLUSION.....	59

TABLE OF AUTHORITIES

Cases

<i>Asyst Techs., Inc. v. Emtrak, Inc.</i> , 544 F.3d 1310, 1316 (Fed. Cir. 2008)	58
<i>Ecolab, Inc. v. FMC Corp.</i> , 569 F.3d 1335, 1350 (Fed. Cir. 2009)	14, 37
<i>In re Debaun</i> , 687 F.2d 459 (CCPA 1982).....	47
<i>In re Huang</i> , 100 F.3d 135, 139 (Fed.Cir.1996).....	58
<i>In re Mathews</i> , 408 F.2d 1393 (CCPA 1969).....	46
<i>In re Spada</i> , 911 F.2d 705, 708 (Fed. Cir. 1990).....	12, 29, 36
<i>In re Zierden</i> , 411 F.2d 1325, 1328 (CCPA 1969).....	12, 29, 36
<i>Iron Grip Barbell Co. v. USA Sports, Inc.</i> , 392 F.3d 1317, 1322 (Fed. Cir. 2004)	58
<i>KSR Int'l Co. v. Teleflex Inc.</i> , 550 U.S. 398, 127 S.Ct. 1727, 1739, 1741 (2007).....	59

EXHIBIT LIST

Exhibit No.	Description	Issue or Publication Date
1001	U.S. Patent No. 8,337,856 (Blättler, <i>et al.</i>)	December 25, 2012
1002	Slamon, <i>et al.</i> , "Studies of the HER-2/ <i>neu</i> proto-oncogene in human breast and ovarian cancer." <i>Science</i> 244:707-712 (1989).	May, 1989
1003	Press, <i>et al.</i> , "HER-2/ <i>neu</i> gene amplification characterized by fluorescence in situ hybridization: poor prognosis in node-negative breast carcinomas." <i>J. Clin. Oncol.</i> 15:2894-2904 (1997).	August, 1997
1004	Phillips, <i>et al.</i> , "Targeting HER2-positive breast cancer with trastuzumab-DM1, an antibody-cytotoxic drug conjugate." <i>Cancer Res.</i> 68: 9280-9290 (2008).	November 15, 2008
1005	Hudziak, <i>et al.</i> , "p185 ^{HER2} monoclonal antibody has antiproliferative effects in vitro and sensitizes human breast tumor cells to tumor necrosis factor." <i>Mol. Cell. Biol.</i> , 9:1165-1172 (1989).	March, 1989
1006	McKenzie, <i>et al.</i> , "Generation and characterization of monoclonal antibodies specific for the human <i>neu</i> oncogene product, p185." <i>Oncogene</i> , 4:543-548 (1989).	May, 1989
1007	Ring, <i>et al.</i> , "Identity of BCA200 and c-erbB-2 indicated by reactivity of monoclonal antibodies with recombinant c-erbB-2." <i>Mol. Immunol.</i> , 28: 915-917 (1991).	August, 1991
1008	HERCEPTIN® Label	September, 1998
1009	Blythman, <i>et al.</i> "Immunotoxins: hybrid molecules of monoclonal antibodies and a toxin subunit specifically kill tumour cells." <i>Nature</i> , 290:145-146 (1981).	March 12, 1981

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.