In the U	nited State	es Patent a	nd Tradem	ark Office
				_

Before the Patent Trial and Appeal Board

AMERIGEN PHARMACEUTICALS LIMITED,

Petitioner

V.

JANSSEN ONCOLOGY, INC.,

Patent Owner

U.S. Patent No. 8,822,438 to Auerbach *et al.*Issue Date: September 2, 2014
Title: Methods and Compositions for Treating Cancer

Inter Partes Review No. Unassigned

Petition for *Inter Partes* Review of U.S. Patent No. 8,822,438 Under 35 U.S.C. §§ 311-319 and 37 C.F.R. §§ 42.1-42.80, 42.100-42.123

Mail Stop "PATENT BOARD"

Patent Trial and Appeal Board U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, Virginia 22313–1450

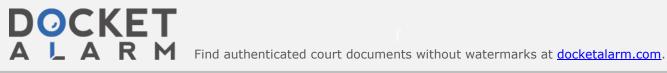
Submitted Electronically via the Patent Review Processing System



		TABLE OF CONTENTS	Page
TABI	LE OF C	TABLE OF CONTENTS CONTENTS	i
		EXHIBITS PURSUANT TO 37 C.F.R. § 42.63(e) AND TABLE OF	
	ABBE	REVIATIONS	iii
TABI	LE OF A	ABBREVIATIONS	X
CHA	LLENG	ED CLAIMS OF U.S. PATENT NO. 8,822,438	xi
I.	INTR	ODUCTION	1
II.	MAN	DATORY NOTICES (37 C.F.R. § 42.8(a)(1))	1
	A.	Real Party-In-Interest Under 37 C.F.R. § 42.8(b)(1)	1
	В.	Related Matters Under 37 C.F.R. § 42.8(b)(2)	1
	<i>C</i> .	Lead And Back-Up Counsel Under 37 C.F.R. § 42.8(b)(3)	2
	D.	Service Information Under 37 C.F.R. § 42.8(b)(4)	2
	E.	Service on Patent Owner Under 37 C.F.R. § 42.106(a) and 42.105(a)	2
III.	GROU	JNDS FOR STANDING (37 C.F.R. §§ 42.101 and 42.104)	3
IV.	PAYN	MENT OF FEES (37 C.F.R. § 42.103)	4
V.	STATEMENT OF THE PRECISE RELIEF REQUESTED AND THE REASONS THEREFOR (37 C.F.R. § 42.22(a))		
VI.	IDEN	TIFICATION OF CHALLENGE (37 C.F.R. § 42.104(b))	4
VII.		ODUCTION AND SUMMARY OF ARGUMENT	
VIII.	LEVE	L OF ORDINARY SKILL IN THE ART	7
IX.	U.S. F	PATENT NO. 8,822,438 AND ITS FILE HISTORY	8
	A.	Specification of the '438 Patent	8
	В.	File History of the '438 Patent	<i>1</i>
X.	CLAI	M CONSTRUCTION (37 C.F.R. §§ 42.100(b), 42.104(b)(3))	17
XI.	SCOP	E AND CONTENT OF THE PRIOR ART	19
	A.	Overview	<i>1</i>
	В.	Background of Prostate Cancer and Its Treatment	2
	<i>C</i> .	Prior Art References	
	1.	IN 2004, O'DONNELL DESCRIBED THE ADMINISTRATION OF ABIRATERONE ACETATE AS MORE EFFECTIVE FOR TREATING METASTATIC REFRACTORY PROSTATE CANCER THAN KETOCONAZOLE, AND POSSIBLY REQUIRING CONCOMITANT GLUCOCORTICOID REPLACEMENT THERAPY	28
	2.	IN 1990, GERBER DISCLOSED THE USE OF KETOCONAZOLE WITH PREDNISONE, A GLUCOCORTICOID, IN PATIENTS WITH HORMONE REFRACTORY METASTATIC	21



	3.	IN 1997, THE '213 PATENT DISCLOSED ABIRATERONE ACETATE, AND ITS SUPERIORITY OVER KETOCONAZOLE IN THE TREATMENT OF PROSTATE CANCER	33
XII.	EXPL	ANATION OF GROUNDS FOR UNPATENTABILITY	36
	A.	Claim 1	36
	В.	Claims 2 and 3	40
	C.	Claim 4	41
	D.	Claim 5	42
	<i>E</i> .	Claims 6-9	43
	F.	Claim 10	44
	G.	Claim 11	44
	Н.	Claims 12-16	45
	I.	Claim 17	46
	J.	Claim 18	47
	<i>K</i> .	Claim 19	47
	L.	Claim 20	48
XIII.		ONDARY CONSIDERATIONS DO NOT INDICATE THAT THE CLAIMS HE '438 PATENT ARE NON-OBVIOUS	48
	<i>A</i> .	Applicants Did Not Offer Relevant Evidence of Commercial Success and the Examiner Issued the '438 Patent Based on the Erroneous Conclusion that the Asserted Commercial Success of Zytiga® Overcame the Obviousness of the Claimed Invention	48
	В.	One of Skill Would Not Anticipate Unexpected Benefits from the Claimed Invention and Applicants Did Not Offer Any Evidence of Relevant Unexpected Results	52
	<i>C</i> .	The '438 Patent Satisfied No Long-Felt But Unmet Need	56
	D.	The '213 is a Blocking Patent that Limits the Applicability of Commercial Success	57
	E.	Copying By Generic Drug Makers Is Irrelevant	59
XIV.	CON	CLUSION	59
CERT	TIFICA	ΓE OF SERVICE	60



LISTING OF EXHIBITS PURSUANT TO 37 C.F.R. § 42.63(e) AND TABLE OF ABBREVIATIONS

Exhibit	Description		
AMG 1001	U.S. Patent No. 8,822,438, Auerbach and Belldegrum, "Methods		
AMG 1001	and Compositions for Treating Cancer" ("the '438 patent")		
AMG 1002	Declaration of Dr. Scott Serels, MD ("Serels Decl.")		
	O'Donnell, A. <i>et al.</i> , "Hormonal impact of the 17α -hydroxylase/ C_{17} -		
AMC 1002	₂₀ -lyase inhibitor abiraterone acetate (CB7630) in patients with		
AMG 1003	prostate cancer," British Journal of Cancer, (90):2317-2325 (2004)		
	("O'Donnell")		
	Gerber, G.S. et al., "Prostate specific antigen for assessing response		
A 3 4 C 100 4	to ketoconazole and prednisone in patients with hormone refractory		
AMG 1004	metastatic cancer," The Journal of Urology, 144(5):1177-9 (1990)		
	("Gerber")		
AMC 1005	U.S. Patent No. 5,604,213, Barrie S.E. et al., "17-Substituted		
AMG 1005	Steroids Useful In Cancer Treatment" ("the '213 patent")		
	Tannock et al., "Chemotherapy with mitoxantrone plus prednisone		
AMC 1006	or prednisone alone for symptomatic hormone-resistant prostate		
AMG 1006	cancer: a Canadian randomized trial with palliative end points," The		
	Journal of Clinical Oncology, 14:1756-1764 (1996) ("Tannock")		
AMC 1007	February 3, 2012 Office Action (excerpt from prosecution history of		
AMG 1007	'438 patent)		
AMG 1008	July 3, 2012 Response (excerpt from prosecution history of '438		
A TIVIO TOUG	patent)		



	Ryan et al., "Abiraterone in metastatic prostate cancer without
AMG 1009	previous chemotherapy," The New England Journal of Medicine,
	368:138-148 (2012).
AMG 1010	January 11, 2013 Response (excerpt from prosecution history of
	'438 patent)
AMG 1011	March 4, 2013 Office Action (excerpt from prosecution history of
AWIO 1011	'438 patent)
AMC 1012	June 4, 2013 Response (excerpt from prosecution history of '438
AMG 1012	patent)
AMG 1013	July 3, 2013 Notice of Allowance (excerpt from prosecution history
AMG 1013	of '438 patent)
AMG 1014	October 25, 2013 Notice of Allowance (excerpt from prosecution
AMO 1014	history of '438 patent)
AMG 1015	February 11, 2014 Notice of Allowance (excerpt from prosecution
Tivid 1013	history of '438 patent)
AMG 1016	June 2, 2014 Notice of Allowance (excerpt from prosecution history
AMO 1010	of '438 patent)
AMG 1017	Declaration of Dr. DeForest McDuff, PhD ("McDuff Declaration")
AMG 1018	2011 Zytiga® Approval Prescribing Information
AMG 1019	2015 Zytiga® Prescribing Information, Co-administration Brochure
	Harris et al., "Low dose Ketoconazole with replacement doses of
AMG 1020	hydrocortisone in patients with progressive androgen independent
11110 1020	prostate cancer," The Journal of Urology, volume 168:542-545
	(August 2002)
	William Oh, "Secondary hormonal therapies in the treatment of
AMG 1021	prostate cancer," <i>Urology</i> , volume 60:87-93 (Supplement 3A)
	(September 2002)
L	



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.

