UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Apotex Inc. and Apotex Corp., Petitioners

v.

ABRAXIS BIOSCIENCE, LLC, Patent Owner

> Case IPR2018-00152 Patent 7,820,788 B2 Issued: October 26, 2010

Title: COMPOSITIONS AND METHODS OF DELIVERY OF PHARMACOLOGICAL AGENTS

PETITION FOR INTER PARTES REVIEW

DOCKET A L A R M Find authenticated court documents without watermarks at <u>docketalarm.com</u>.

TABLE OF CONTENTS

I.	INTRODUCTION1					
II.	MANDATORY NOTICES					
III.	REQUIREMENTS FOR REVIEW					
IV.	LEVEL OF ORDINARY SKILL IN THE ART7					
V.	THE PRIOR ART AND THE '788 PATENT					
	A.	Taxol [®] (paclitaxel) was an FDA-approved "wonder drug," but initially could only be administered with a toxic solvent7				
	В.	The inventors repeatedly patented albumin-paclitaxel nanoparticles as a solution to the known problems of Taxol [®] 9				
	C.	Desai (EX1006) specifically discloses a nanoparticle formulation with an albumin-paclitaxel ratio of 9:110				
	D.	Desai, Kadima (EX1004), and Liversidge (EX1005) taught varying ranges of albumin-paclitaxel ratios, and taught lowering the ratio to increase drug concentration and reduce cost				
	E.	The inventors obtained their <i>third</i> round of patents on albuminpaclitaxel by arguing that a 9:1 ratio has "unexpected" benefits.				
VI.	PLA	IN AND ORDINARY MEANINGS17				
	A.	"the weight ratio of albumin to paclitaxel in the composition" and "the ratio (w/w) of albumin to the paclitaxel in the pharmaceutical composition"				
	B.	"a particle size of less than about 200 nm"				
VII.	ANA	LYSIS OF GROUNDS FOR TRIAL				
	A.	GROUND I: ANTICIPATION UNDER 35 U.S.C. §102(b)21				
		1. Claim 1 is anticipated21				
		a. Albumin-paclitaxel combination22 i				

		b.	Partic	cle size of less than about 200 nm23
		c.	Albu	min-paclitaxel ratio of about 1:1 to 9:124
	2.	Clain	ns 2–9	and 11–12 are anticipated25
	3.	The "	startin	g" albumin-paclitaxel ratio does not change28
B.	GRO	UND I	I: OB	VIOUSNESS UNDER 35 U.S.C. §103(a)32
	1.	Clain	n 1 wo	uld have been obvious32
		a.	GRO	UND II.A: Desai alone32
			i.	The albumin-paclitaxel ratio of about 9:1 falls within a range disclosed by Desai
			ii.	Desai would have motivated a skilled artisan to lower Capxol [™] 's albumin-paclitaxel ratio37
			iii.	A skilled artisan would have reasonably expected the claimed albumin-paclitaxel ratio of 9:1 to retain stability
		b.	GRO	UND II.B: Desai, Kadima, and Liversidge42
			i.	Kadima and Liversidge also disclose ranges of albumin-paclitaxel ratios including 9:142
			ii.	Kadima teaches additional reasons to lower Capxol ^{TM} 's 13.3:1 ratio to about 9:145
	2.	Clain	ns 2–12	2 would have been obvious
	3.	There	e is no	probative evidence of secondary considerations51
		a.		llegedly "unexpected" cell-binding results lack a s to the '788 patent and were expected
		b.		llegedly "unexpected" clinical data did not compare osest prior art and were expected
		c.		king patents prevented others from developing the ed invention

VIII.	CONCLUSION	.5	9
-------	------------	----	---

DOCKET A L A R M Find authenticated court documents without watermarks at <u>docketalarm.com</u>.

TABLE OF AUTHORITIES

Page(s)

Cases

Abraxis BioScience, LLC v. Actavis LLC, C.A. No. 16-1925-JMV-MF5
Abraxis BioScience, LLC v. Cipla Ltd., C.A. No. 16-9074-JMV-MF5
<i>Agrizap, Inc. v. Woodstream Corp.</i> , 520 F.3d 1337 (Fed. Cir. 2008)
Amneal Pharms, LLC v. Supernus Pharms., Inc., IPR2013-00368, Paper 8 (PTAB Dec. 17, 2013)51
Apotex, Inc. v. Cephalon, Inc., 2012 WL 1080148 (E.D. Pa. Mar. 28, 2012)20
<i>Arthrocare Care Corp. v. Smith & Nephew, Inc.,</i> 406 F.3d 1365 (Fed. Cir. 2005)24
Brown & Williamson Tobacco Corp. v. Philip Morris Inc., 229 F.3d 1120 (Fed. Cir. 2000)46
Exxon Chem. Patents, Inc. v. Lubrizol Corp., 64 F.3d 1553 (Fed. Cir. 1995)19, 20
<i>Galderma Labs., L.P. v. Tolmar, Inc.,</i> 737 F.3d 731 (Fed. Cir. 2013)4, 35, 58
<i>In re Ethicon, Inc.</i> , 844 F.3d 1344 (Fed. Cir. 2017)
In re Geisler, 116 F.3d 1465 (Fed. Cir. 1997)
<i>In re GPAC Inc.</i> , 57 F.3d 1573 (Fed. Cir. 1995)
<i>In re Harris</i> , 409 F.3d 1339 (Fed. Cir. 2005)

iv

DOCKET A L A R M



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.