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 IPR2018-00153 Patent 7,923,536 B2 Issued: April 12, 2011

Title: COMPOSITIONS AND METHODS OF DELIVERY OF PHARMACOLOGICAL AGENTS

PETITION FOR INTER PARTES REVIEW



TABLE OF CONTENTS

I.	INTRODUCTION1						
II.	MANDATORY NOTICES4						
III.	REQ	REQUIREMENTS FOR REVIEW6					
IV.	LEV	LEVEL OF ORDINARY SKILL IN THE ART6					
V.	THE PRIOR ART AND THE '536 PATENT						
	A.	Taxol® (paclitaxel) was an FDA-approved "wonder drug," but initially could only be administered with a toxic solvent					
	B.	The inventors repeatedly patented albumin-paclitaxel nanoparticles as a solution to the known problems of Taxol [®]					
	C.	Desai (EX1006) specifically discloses a nanoparticle formulation with an albumin-paclitaxel ratio of 9:1					
	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.	PLAIN AND ORDINARY MEANINGS						
	A.	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.	ANALYSIS OF GROUNDS FOR TRIAL						
	A.	GROUND I: ANTICIPATION UNDER 35 U.S.C. §102(b)20					
		1. Claim 1 is anticipated21					
		a. Treatment of cancer in humans21					
		b. Albumin-paclitaxel combination22					



		c.	Parti	cle size of less than about 200 nm	23		
		d. Albumin-paclitaxel ratio of about 1:1 to 9:1					
	2.	Claims 2–16 are anticipated2					
	3.	The "starting" albumin-paclitaxel ratio does not change2					
B.	GROUND II: OBVIOUSNESS UNDER 35 U.S.C. §103(a)						
	1.	Clair	ould have been obvious	31			
		a. GROUND II.A: Desai alone					
			i.	The albumin-paclitaxel ratio of about 9:1 falls within a range disclosed by Desai	35		
			ii.	Desai would have motivated a skilled artisan to lower Capxol [™] 's albumin-paclitaxel ratio			
			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 Liversidge	42		
			i.	Kadima and Liversidge also disclose ranges of albumin-paclitaxel ratios including 9:1	42		
			ii.	Kadima teaches additional reasons to lower Capxol [™] 's 13.3:1 ratio to about 9:1	44		
	2.	Claims 2–16 would have been obvious					
	3.	There is no probative evidence of secondary considerations					
		a.		allegedly "unexpected" cell-binding results lack as to the '536 patent and were expected			
		b.		allegedly "unexpected" clinical data did not complosest prior art and were expected			
		c.		king patents prevented others from developing the			
CON		ION			57		



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	Page(s)
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Abraxis BioScience, LLC v. Cipla Ltd., C.A. No. 16-9074-JMV-MF	4
Agrizap, Inc. v. Woodstream Corp., 520 F.3d 1337 (Fed. Cir. 2008)	49
Amneal Pharms, LLC v. Supernus Pharms., Inc., IPR2013-00368, Paper 8 (PTAB Dec. 17, 2013)	49
Apotex, Inc. v. Cephalon, Inc., 2012 WL 1080148 (E.D. Pa. Mar. 28, 2012)	20
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Exxon Chem. Patents, Inc. v. Lubrizol Corp., 64 F.3d 1553 (Fed. Cir. 1995)	19
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<i>In re Ethicon, Inc.</i> , 844 F.3d 1344 (Fed. Cir. 2017)	36
<i>In re Geisler</i> , 116 F.3d 1465 (Fed. Cir. 1997)	36
<i>In re GPAC Inc.</i> , 57 F.3d 1573 (Fed. Cir. 1995)	50
In re Harris, 409 F 3d 1339 (Fed. Cir. 2005)	43



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In re Omeprazole Patent Litig., 483 F.3d 1364 (Fed. Cir. 2007)	25
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PAR Pharm., Inc. v. TWI Pharm., Inc., 773 F.3d 1186 (Fed. Cir. 2014)34	4, 35, 44, 47
Petroleum Geo-Services Inc. v. WesternGeco LLC, IPR2014-01478, Paper 18 (PTAB Mar. 17, 2015)	49
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