

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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CIPLA LTD.,  
Petitioner

v.

ABRAXIS BIOSCIENCE, LLC,  
Patent Owner

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Case IPR2018-00163  
Patent 7,923,536 B2

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**DECLARATION OF CORY J. BERKLAND, Ph.D.  
IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW**

## TABLE OF CONTENTS

	<b>Page</b>
I. INTRODUCTION .....	7
II. BACKGROUND AND QUALIFICATIONS .....	8
III. LEGAL STANDARDS USED IN MY ANALYSIS .....	11
A. Prior art.....	11
B. Person of ordinary skill in the art .....	12
C. Anticipation .....	14
D. Obviousness.....	14
IV. THE '536 PATENT .....	17
A. The alleged invention.....	17
B. Challenged claims.....	22
C. Claim construction.....	23
V. THE PRIOR ART.....	24
A. Desai (EX1006) .....	24
B. Kadima (EX1004).....	33
C. Liversidge (EX1005) .....	34
VI. ANTICIPATION .....	36
A. Claims 1–16 of the '536 patent are anticipated.....	36
1. Claim 1 is anticipated by Desai.....	36
a. Treatment of cancer in humans .....	37
b. Albumin-paclitaxel combination .....	38
c. Particle size of less than about 200 nm.....	39

d.	Albumin-paclitaxel ratio of about 1:1 to 9:1.....	40
B.	Claims 2–16 are anticipated by Desai. ....	41
C.	The “starting” ratio of albumin to paclitaxel does not change. ....	43
VII.	OBVIOUSNESS.....	46
A.	Claim 1 of the ’536 patent would have been obvious. ....	46
1.	Obviousness over Desai alone.....	46
a.	The albumin-paclitaxel ratio of about 9:1 falls within a range disclosed by Desai. ....	50
b.	A skilled artisan would have been motivated to lower Capxol’s 13.3:1 albumin-paclitaxel ratio.....	52
c.	A skilled artisan would have reasonably expected an albumin-paclitaxel ratio of 9:1 to retain stability. ....	55
2.	Obviousness over Desai, Kadima, and Liversidge.....	58
a.	Kadima and Liversidge also disclose ranges of albumin-paclitaxel ratios, including about 9:1.....	58
b.	Kadima teaches additional reasons to lower a 13.3:1 ratio of albumin to paclitaxel to about 9:1. ....	60
B.	The other challenged claims would have been obvious. ....	63
C.	There are no relevant secondary considerations indicating that the challenged claims would not have been obvious. ....	65
1.	The allegedly “unexpected” cell-binding results lack a nexus to the ’536 patent and would have been expected.....	67
2.	The allegedly “unexpected” clinical data did not compare the closest prior art and would have been expected.....	70
VIII.	CONCLUSION .....	74

## EXHIBITS CITED

EX	Description
<b>1001</b>	Desai et al., U.S. Patent No. 7,923,536 B2, “Compositions and Methods of Delivery of Pharmacological Agents” (issued Apr. 12, 2011) (the “536 patent”)
<b>1004</b>	Kadima et al., WO 00/06152, “Pharmaceutically Acceptable Composition Comprising an Aqueous Solution of Paclitaxel and Albumin” (published Feb. 10, 2000) (“Kadima”)
<b>1005</b>	Liversidge et al., U.S. Patent No. 5,399,363, “Surface Modified Anticancer Nanoparticles” (issued Mar. 21, 1995) (“Liversidge”)
<b>1006</b>	Desai et al., WO 1999/000113, “Novel Formulations of Pharmacological Agents, Methods for the Preparation thereof and Methods for the Use thereof” (published Jan. 7, 1999) (“Desai”)
<b>1007</b>	Li et al., “Fluorescein Binding to Normal Human Serum Proteins Demonstrated by Equilibrium Dialysis,” Arch Ophthalmol. vol. 100, 484–87 (March 1982)
<b>1009</b>	FDA Guideline on Sterile Drug Products Produced by Aseptic Processing (June 1987, reprinted June 1991 and Feb. 1997)
<b>1010</b>	EMA Guidance on Manufacture of the Finished Dosage Form (April 1996)
<b>1011</b>	Elan Pharma Int’l Ltd. v. Abraxis BioScience, Inc., Judgment and Verdict Form, No. 06-438-GMS, Dkt. 614 (D. Del. June 16, 2008)
<b>1017</b>	Damascelli, B et al. “Intraarterial chemotherapy with polyoxyethyl-ated castor oil free paclitaxel, incorporated in albumin nanoparticles (ABI-007),” Cancer 2001 Nov; 92(10):2592–2602 (“Damascelli”)
<b>1018</b>	Ibrahim et al., “Phase I and pharmacokinetic study of ABI-007, a Cremophor-free, protein-stabilized, nanoparticle formulation of paclitaxel,” Clin Cancer Res. 2002 May; 8:1038–44 (“Ibrahim”)

**1023**

U.S. Application No. 11/553,339, Declaration of Neil P. Desai  
Pursuant to 37 C.F.R. § 1.132 (dated Apr. 14, 2010)

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