

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ACTAVIS LLC,
Petitioner

v.

ABRAXIS BIOSCIENCE, LLC,
Patent Owner

Case IPR2017-01103
Patent 7,923,536 B2

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

Exhibit 1201
Prolenium v. Allergan
IPR2019-01505 et al.

TABLE OF CONTENTS

	Page
I. INTRODUCTION	1
II. BACKGROUND AND QUALIFICATIONS	2
III. LEGAL STANDARDS USED IN MY ANALYSIS	5
A. Prior art	5
B. Person of ordinary skill in the art	6
C. Anticipation	7
D. Obviousness	8
IV. THE '536 PATENT	11
A. The alleged invention	11
B. Challenged claims	16
C. Claim construction	17
V. THE PRIOR ART	18
A. Desai (EX1006)	18
B. Kadima (EX1004)	27
C. Liversidge (EX1005)	28
VI. ANTICIPATION	30
A. Claims 1–16 of the '536 patent are anticipated	30
1. Claim 1 is anticipated by Desai	30
a. Treatment of cancer in humans	31
b. Albumin-paclitaxel combination	33
c. Particle size of less than about 200 nm	33

d.	Albumin-paclitaxel ratio of about 1:1 to 9:1	34
B.	Claims 2–16 are anticipated by Desai.....	35
C.	The “starting” ratio of albumin to paclitaxel does not change.....	37
VII.	OBVIOUSNESS.....	40
A.	Claim 1 of the ’536 patent would have been obvious.....	41
1.	Obviousness over Desai alone	41
a.	The albumin-paclitaxel ratio of about 9:1 falls within a range disclosed by Desai.	44
b.	A skilled artisan would have been motivated to lower Capxol’s 13.3:1 albumin-paclitaxel ratio.	47
c.	A skilled artisan would have reasonably expected an albumin-paclitaxel ratio of 9:1 to retain stability.	49
2.	Obviousness over Desai, Kadima, and Liversidge	52
a.	Kadima and Liversidge also disclose ranges of albumin-paclitaxel ratios, including about 9:1.	52
b.	Kadima teaches additional reasons to lower a 13.3:1 ratio of albumin to paclitaxel to about 9:1.....	54
B.	The other challenged claims would have been obvious.....	57
C.	There are no relevant secondary considerations indicating that the challenged claims would not have been obvious.	59
1.	The allegedly “unexpected” cell-binding results lack a nexus to the ’536 patent and would have been expected.....	61
2.	The allegedly “unexpected” clinical data did not compare the closest prior art and would have been expected.	64
VIII.	CONCLUSION.....	68

EXHIBITS CITED

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

I, Cory J. Berkland, Ph.D., hereby declare as follows:

I. INTRODUCTION

1. I am currently appointed as the Solon E. Summerfield Distinguished Professor in the Department of Pharmaceutical Chemistry and the Department of Chemical and Petroleum Engineering at the University of Kansas. I have been retained by Petitioner Actavis LLC in connection with its request for *inter partes* review of U.S. Patent No. 7,923,536 (“the ’536 patent”). A copy of the ’536 patent has been marked EX1001. I have reviewed and am familiar with the ’536 patent. Generally, it describes and claims methods of treating cancer by administering pharmaceutical compositions comprising the anticancer drug paclitaxel bound to the protein albumin and formulated as nanoparticles.

2. I have been asked to provide my opinions regarding the patentability of claims 1–16 of the ’536 patent (the “challenged claims”). This declaration includes a discussion of my background and qualifications, the legal standards used in my analysis, an overview of the ’536 patent from the perspective of a person of ordinary skill in the art at the time that the patent was filed (a “skilled artisan”), and my opinions regarding the patentability of the challenged claims.

3. I am being compensated for my work in this proceeding at my standard hourly consulting rate of \$500.00 per hour. My compensation is in no way contingent on the substance of my opinions or the outcome of this proceeding.

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