

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ACTAVIS LLC,
Petitioner

v.

ABRAXIS BIOSCIENCE, LLC,
Patent Owner

Case IPR2017-01104
Patent 8,138,229 B2
Issued: March 20, 2012

Title: COMPOSITIONS AND METHODS OF
DELIVERY OF PHARMACOLOGICAL AGENTS

PETITION FOR *INTER PARTES* REVIEW

TABLE OF CONTENTS

	Page
I. INTRODUCTION	1
II. MANDATORY NOTICES	4
III. REQUIREMENTS FOR REVIEW	6
IV. LEVEL OF ORDINARY SKILL IN THE ART	7
V. THE PRIOR ART AND THE '229 PATENT	7
A. Taxol [®] (paclitaxel) was an FDA-approved “wonder drug,” but initially could only be administered with a toxic solvent.	7
B. 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 9:1.	11
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.	11
E. The inventors obtained their <i>third</i> round of patents on albumin-paclitaxel by arguing that a 9:1 ratio has “unexpected” benefits.	14
VI. PLAIN AND ORDINARY MEANINGS	18
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”	18
B. “a particle size of less than about 200 nm”	21
C. “about 0.5% to about 5% by weight of albumin” and “about 5% by weight of albumin”	21
VII. ANALYSIS OF GROUNDS FOR TRIAL	22
A. GROUND I: ANTICIPATION UNDER 35 U.S.C. §102(b).....	22
1. Claim 1 is anticipated.....	22

a.	Albumin-paclitaxel combination	23
b.	Particle size of less than about 200 nm	24
c.	Albumin-paclitaxel ratio of about 1:1 to 9:1	25
d.	Weight concentration of albumin	25
2.	Claims 3 and 6 are anticipated.	27
3.	Claims 15, 19, and 21–23 are anticipated.	28
4.	Claims 29, 34, and 38 are anticipated.	30
5.	Claims 7 and 33 are anticipated.	31
6.	Claims 2, 8, 11–14, 16, 24, 27–28, 30, 35, and 39 are anticipated.	31
7.	Claims 4–5, 9–10, 17–18, 25–26, 31–32, 36–37, and 40– 41 are anticipated.	32
8.	Claims 42–48 are anticipated.	32
9.	The “starting” albumin-paclitaxel ratio does not change.	32
B.	FOUNDATIONS II–III: OBVIOUSNESS UNDER 35 U.S.C. §103(a)	36
1.	Claim 1 would have been obvious.	36
a.	GROUND II.A: Desai alone	36
i.	The albumin-paclitaxel ratio of about 9:1 falls within a range disclosed by Desai.	39
ii.	Desai would have motivated a skilled artisan to lower Capxol™’s albumin-paclitaxel ratio.	40
iii.	A skilled artisan would have reasonably expected the claimed albumin-paclitaxel ratio of 9:1 to retain stability.	42
iv.	The claimed albumin weight percentage when the formulation is reconstituted in saline falls within a range disclosed by Desai.	45

- b. GROUND II.B: Desai, Kadima, and Liversidge.....46
 - i. Kadima and Liversidge also disclose ranges of albumin-paclitaxel ratios including 9:1.46
 - ii. Kadima teaches additional reasons to lower Capxol™’s 13.3:1 ratio to about 9:1.....48
- 2. Claims 3 and 6 would have been obvious.....51
- 3. Claims 15, 19, and 21–23 would have been obvious.52
- 4. Claim 20 would have been obvious.53
- 5. Claims 29, 34, and 38 would have been obvious.54
- 6. Claims 7 and 33 would have been obvious.....55
- 7. Claims 2, 8, 11–14, 16, 24, 27–28, 30, 35, and 39 would have been obvious.....56
- 8. Claims 4, 5, 9, 10, 17–18, 25–26, 31–32, 36–37, and 40–41 would have been obvious.....56
- 9. Claims 42–48 would have been obvious.56
- 10. There is no probative evidence of secondary considerations.....57
 - a. The allegedly “unexpected” cell-binding results lack a nexus to the ’229 patent and were expected.58
 - b. The allegedly “unexpected” clinical data did not compare the closest prior art and were expected.....61
 - c. Blocking patents prevented others from developing the claimed invention.....64
- VIII. CONCLUSION.....65

TABLE OF AUTHORITIES

	Page(s)
CASES	
<i>Abraxis BioScience, LLC v. Actavis LLC</i> , C.A. No. 16-1925-JMV-MF	4
<i>Abraxis BioScience, LLC v. Cipla Ltd.</i> , C.A. No. 16-9074-JMV-MF	4
<i>Apotex, Inc. v. Cephalon, Inc.</i> , 2012 WL 1080148 (E.D. Pa. Mar. 28, 2012)	21
<i>Brown & Williamson Tobacco Corp. v. Philip Morris Inc.</i> , 229 F.3d 1120 (Fed. Cir. 2000)	49
<i>Cent. Admixture Pharmacy Servs., Inc. v. Advanced Cardiac Sols.</i> , <i>P.C.</i> , 482 F.3d 1347 (Fed. Cir. 2007)	22
<i>Cohesive Techs., Inc. v. Waters Corp.</i> , 543 F.3d 1351 (Fed. Cir. 2008)	22
<i>Exxon Chem. Patents, Inc. v. Lubrizol Corp.</i> , 64 F.3d 1553 (Fed. Cir. 1995)	20
<i>Galderma Labs., L.P. v. Tolmar, Inc.</i> , 737 F.3d 731 (Fed. Cir. 2013)	40, 45, 51, 63
<i>In re Geisler</i> , 116 F.3d 1465 (Fed. Cir. 1997)	40
<i>In re GPAC Inc.</i> , 57 F.3d 1573 (Fed. Cir. 1995)	58
<i>In re Harris</i> , 409 F.3d 1339 (Fed. Cir. 2005)	48
<i>In re Merck & Co.</i> , 800 F.2d 1091 (Fed. Cir. 1986)	43, 50, 63

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.