

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

U.S. Patent 7,923,536

PATENT OWNER'S PRELIMINARY RESPONSE

TABLE OF CONTENTS

I.	Introduction.....	1
II.	Background.....	4
	A. The need for and development of Abraxane®	4
	B. The '536 patent.....	9
III.	Level of Ordinary Skill in the Art and Claim Construction.....	9
	A. Level of ordinary skill in the art.....	9
	B. Claim construction	9
	1. The ratio term concerns the finished composition.....	10
	2. The other claim terms do not require construction.....	16
IV.	The Board Should Deny Institution Under 35 U.S.C. § 325(d).....	17
V.	The Petition Fails to Demonstrate a Reasonable Likelihood that Any Challenged Claim is Unpatentable	19
	A. Desai does not anticipate the challenged claims (Ground I).....	20
	1. Petitioner's anticipation argument relies on its erroneous construction of the ratio term.....	21
	2. Desai's starting albumin-to-paclitaxel ratio increases during manufacturing.....	22
	B. Desai alone does not render obvious any of the challenged claims (Ground II.A).....	30
	1. Desai does not disclose a range of albumin-to-paclitaxel ratios that includes 9:1	30
	2. A POSA would have not have been motivated to reduce Capxol™'s albumin-to-paclitaxel ratio	33
	3. A POSA would not have had a reasonable expectation that the claimed albumin-to-paclitaxel ratio of 9:1 would be stable.....	41
	C. Desai, Kadima, and Liversidge in combination do not render obvious any of the challenged claims (Ground II.B).....	45

1.	Kadima does not teach a ratio in the range of the claimed invention and teaches away from lowering Capxol TM 's 13:1 ratio to about 9:1	45
2.	A POSA would have no reason to combine, with a reasonable expectation of success, Desai, Kadima, and Liversidge.....	51
D.	Secondary considerations support nonobviousness	54
1.	The cell-binding results were unexpected and have a nexus to the '536 patent	56
2.	Clinical studies compared a claimed composition with the closest prior art and the results were unexpected	59
VI.	Conclusion	62

TABLE OF AUTHORITIES

	Page
CASES	
<i>ACTV, Inc. v. Walt Disney Co.</i> , 346 F.3d 1082 (Fed. Cir. 2003)	11
<i>Allergan, Inc. v. Sandoz Inc.</i> , 796 F.3d 1293 (Fed. Cir. 2015)	61
<i>AstraZeneca Pharm. LP v. Anchen Pharm., Inc.</i> , C.A. No. 10-1835, 2012 WL 1065458 (D.N.J. Mar. 29, 2012), aff'd, 498 F. App'x 999 (Fed. Cir. 2013)	44
<i>Atofina v. Great Lakes Chem. Corp.</i> , 441 F.3d 991 (Fed. Cir. 2006)	20
<i>Biotec Biologische Naturverpackungen GmbH & Co. KG v. Biocorp, Inc.</i> , 249 F.3d 1341 (Fed. Cir. 2001)	25
<i>C.R. Bard, Inc. v. Medtronic, Inc.</i> , 250 F.3d 760 (Fed. Cir. 2000)	53
<i>Cadence Pharm. Inc. v. Exela PharmSci Inc.</i> , 780 F.3d 1364 (Fed. Cir. 2015)	20
<i>Canon, Inc. v. Papst Licensing GMBH & Co. Kg</i> , No. IPR2016-01202	19
<i>Cont'l Can Co. USA, Inc. v. Monsanto Co.</i> , 948 F.2d 1264 (Fed. Cir. 1991)	20
<i>Creative Integrated Sys., Inc. v. Nintendo of Am., Inc.</i> , 526 F. App'x 927 (Fed. Cir. 2013)	15

<i>Cumberland Pharm. Inc. v. Mylan Institutional LLC</i> , 846 F.3d 1213 (Fed. Cir. 2017)	45
<i>Dell, Inc. v. Selene Comm. Tech., LLC</i> , No. IPR2014-01411	51
<i>Eli Lilly & Co. v. Actavis Elizabeth LLC</i> , 435 F. App'x 917 (Fed. Cir. 2011)	24
<i>Exxon Chem. Patents, Inc. v. Lubrizol Corp.</i> , 64 F.3d 1553 (Fed. Cir. 1995)	14
<i>Finnigan Corp. v. Int'l Trade Commission</i> , 180 F.3d 1354 (Fed. Cir. 1999)	30
<i>In re Applied Materials, Inc.</i> , 692 F.3d 1289 (Fed. Cir. 2012)	62
<i>In re Kahn</i> , 441 F.3d 977, 990 (Fed. Cir. 2006)	53
<i>In re O'Farrell</i> , 853 F.2d 894 (Fed. Cir. 1988)	44
<i>In re Oelrich</i> , 666 F.2d 578, 581 (C.C.P.A. 1981)	21
<i>KSR Int'l Co. v. Teleflex Inc.</i> , 550 U.S. 398 (2007)	34
<i>Leo Pharm. Prods., Ltd. v. Rea</i> , 726 F.3d 1346 (Fed. Cir. 2013)	34, 35
<i>Life Techs., Inc. v. Clontech Labs., Inc.</i> , 224 F.3d 1320, 1326 (Fed. Cir. 2000)	44
<i>Mars, Inc. v. H.J. Heinz Co.</i> , 377 F.3d 1369 (Fed. Cir. 2004)	14

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.