Filed on behalf of: Abraxis Bioscience, LLC

Filed: February 20, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CIPLA LTD.,
Petitioner

v.

ABRAXIS BIOSCIENCE, LLC
Patent Owner

Case IPR2018-00162
U.S. Patent 7,820,788

PATENT OWNER PRELIMINARY RESPONSE

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

TABLE OF CONTENTS

TABLE OF CONTENTS i
TABLE OF AUTHORITIES iv
TABLE OF ABBREVIATIONS vii
LIST OF EXHIBITS viii
I. INTRODUCTION 1
II. BACKGROUND 4
A. The Development of Abraxane® 4
B. The '788 Patent 8
C. Procedural History 9
III. LEVEL OF ORDINARY SKILL IN THE ART AND CLAIM CONSTRUCTION 10
A. The POSA 10
B. Claim Construction 10
1. The plain language of the claim is directed to the finished pharmaceutical product 11
2. The specification and prosecution history support this construction 12
3. Petitioner's proposed construction is flawed 14
IV. THE PETITION FAILS TO DEMONSTRATE A REASONABLE LIKELIHOOD THAT ANY CHALLENGED CLAIM IS ANTICIPATED (GROUND I) 14
A. Desai Does Not Expressly Disclose The Weight Ratio 15
1. Example 1 does not teach a final albumin-paclitaxel weight ratio of 9:1 15
2. The remainder of Desai is silent about the weight ratio in the final composition 16
B. Desai Does Not Inherently Disclose The Weight Ratio 16
1. Petitioner ignores that Example 1 produces Capxol, which has a final albumin-to-paclitaxel ratio of 13.3:1, not 9:1 18

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

2. Petitioner's argument that Example 16, rather than Example 1, produces Capxol is incorrect 19

3. Because of paclitaxel loss during processing, a 9:1 starting ratio will not necessarily remain in the finished product.....25

C. Dependent Claim 11 Requires Exactly "1:1 To 9:1" And Is Not Anticipated Either Expressly Or Inherently 29

V. THE PETITION FAILS TO DEMONSTRATE A REASONABLE LIKELIHOOD THAT DESAI ALONE RENDERS OBVIOUS ANY OF THE CHALLENGED CLAIMS (GROUND II.A) 30

A. Desai Does Not Teach All Of The Claimed Elements.....30

B. Desai Does Not Disclose A Range Of Final Albumin-To-Paclitaxel Weight Ratios That Includes 9:1 31

1. A POSA would not modify Example 1 32

2. A POSA would have no motivation to modify the 1% albumin concentration and not other parameters.....33

C. A POSA Would Have Sought To Maximize The Benefits Conferred By Albumin.....35

1. Albumin increases efficacy.....35

2. Albumin plays a critical stabilization role 36

3. Albumin inhibits crystallization.....37

D. There Was No Motivation To Reduce Capxol's Albumin-To-Paclitaxel Ratio.....37

1. Petitioner has not identified a motivating problem to be solved 37

2. A POSA would not have had a reasonable expectation that the claimed ratio of 9:1 would be stable 43

VI. THE PETITION FAILS TO DEMONSTRATE A REASONABLE LIKELIHOOD THAT ANY CHALLENGED CLAIM WOULD HAVE BEEN OBVIOUS OVER THE COMBINATION OF DESAI, KADIMA, AND LIVERSIDGE (GROUND II.B) 46

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

A. Desai In Combination With Kadima Does Not Render The Claims Obvious 46
1. Kadima does not teach the claimed weight ratio 46
2. A POSA would not have been motivated to reduce the ratio based on cost....50
3. Kadima teaches away from reducing the ratio from 13.3:1 to 9:1 52
4. A POSA would have had no reason to combine Desai and Kadima with a reasonable expectation of success 55
B. Desai In Further View Of Liversidge Does Not Render The Claims Obvious 56
1. An albumin-paclitaxel weight ratio of "about 1:1 to about 9:1" is not *prima facie* obvious....56
2. A POSA would have no reason to combine Desai and Liversidge with a reasonable expectation of success 58
VII. DEPENDENT CLAIM 12 IS NONOBVIOUS 59
VIII. SECONDARY CONSIDERATIONS SUPPORT NONOBVIOUSNESS....59
A. The Cell-Binding Results Were Unexpected And Have A Nexus To The Claims....60
B. The Results Of Clinical Studies Were Unexpected 62
IX. CONCLUSION 65

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

TABLE OF AUTHORITIES

Page

CASES

ACTV, Inc. v. Walt Disney Co.,
346 F.3d 1082 (Fed. Cir. 2003) 11

Allergan, Inc. v. Sandoz Inc.,
796 F.3d 1293 (Fed. Cir. 2015) 65

AstraZeneca Pharm. LP v. Anchen Pharm., Inc.,
No. 10-cv-1835 JAP TJB, 2012 WL 1065458 (D.N.J. Mar. 29, 2012) 45

Atofina v. Great Lakes Chem. Corp.,
441 F.3d 991 (Fed. Cir. 2006) 15

Avaya Inc. v. Network-1 Security Solutions, Inc.,
IPR2013-00071, Paper 103 (P.T.A.B. May 22, 2014) 25

Continental Can Co. U.S.A. v. Monsanto Co.,
948 F.2d 1264 (Fed. Cir. 1991) 17, 20, 25

Cumberland Pharm. Inc. v. Mylan Institutional LLC,
846 F.3d 1213 (Fed. Cir. 2017) 46

DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.,
567 F.3d 1314 (Fed. Cir. 2009) 53, 54, 55

Electro Med. Sys., S.A. v. Cooper Life Scis., Inc.,
34 F.3d 1048 (Fed. Cir. 1994) 17

Eli Lilly & Co. v. Actavis Elizabeth LLC,
435 F. App'x 917 (Fed. Cir. 2011) 18

Exxon Chem. Patents, Inc. v. Lubrizol Corp.,
64 F.3d 1553 (Fed. Cir. 1995) 14

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

DOCKET ALARM

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.