

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CIPLA LTD.,
Petitioner

v.

ABRAXIS BIOSCIENCE, LLC,
Patent Owner

Case IPR2018-00164
Patent 8,138,229 B2
Issued: March 20, 2012

Title: COMPOSITIONS AND METHODS OF
DELIVERY OF PHARMACOLOGICAL AGENTS

**PETITIONER'S REPLY TO PATENT OWNER'S
OPPOSITION TO MOTION FOR JOINDER**
Pursuant to 35 U.S.C. § 315(c), 37 C.F.R. §§ 42.23 and 42.122(b)

TABLE OF CONTENTS

	Page
I. DISCOVERY FROM CIPLA HAS NOTHING TO DO WITH THE INVALIDITY OF ABRAXIS'S '229 PATENT	1
II. CONFIDENTIAL INFORMATION CREATES NO COMPLICATION TO JOINDER	3
III. ABRAXIS FAILS TO RAISE A CREDIBLE CHALLENGE TO CIPLA'S DESIGNATION OF THE NO REAL-PARTY-IN-INTEREST IN ITS PETITION	4
IV. ABRAXIS SUFFERS NO PREJUDICE FROM JOINDER AND NO EXTENSION IS REQUIRED	5
V. CONCLUSION.....	5

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Actavis LLC v. Abraxis Bioscience, LLC</i> , IPR2017-01104	1
<i>CaptionCall, LLC v. Ultratec, Inc.</i> , IPR2015-00636, Paper 42 (PTAB Feb. 23, 2016)	5
<i>Garmin Int'l, Inc. v. Cuozzo Speed Techs. LLC</i> , IPR2012-00001, Paper 26 (PTAB Mar. 5, 2013).....	3
<i>In re Keller</i> , 642 F.2d 413 (C.C.P.A. 1981)	2
<i>In re Yale</i> , 434 F.2d 666 (C.C.P.A. 1970)	2
Other Authorities	
37 C.F.R. § 42.1(b)	5
77 Fed. Reg. 48756, 48759–60 (Aug. 14, 2012)	5

As stated in Cipla's motion for joinder, Cipla's Petition is nearly identical to the Actavis Petition, including the same grounds for unpatentability and the same exhibits. Cipla's Petition relies upon the same expert declarant, and Cipla is not asking for additional briefing, hearing time, deposition time, or any change to the existing schedule in *Actavis LLC v. Abraxis Bioscience, LLC*, IPR2017-01104 ("Actavis IPR"). Cipla would take an understudy role in the joined proceeding, and Actavis does not oppose this motion for joinder.

Patent Owner Abraxis Bioscience, LLC's ("Abraxis"), nonetheless, opposes joinder. Contrary to Abraxis's assertions, there are no complications with the requested joinder, no genuine discovery issues with Cipla, no confidentiality concerns, and no actual issue about whether Cipla designated the real-party-in-interest. Abraxis's attempt to manufacture issues looks more like an excuse to request a six-month extension in the Actavis IPR proceeding—which itself is unjustified.

I. DISCOVERY FROM CIPLA HAS NOTHING TO DO WITH THE INVALIDITY OF ABRAXIS'S '229 PATENT

Abraxis states that it needs time to take meaningful discovery from Cipla. (Paper 6 at 6.) In particular, Abraxis suggests that it may seek to compel Cipla to produce "all documents and things relating to loss of paclitaxel during processing or development of any albumin-bound paclitaxel nanoparticle formulation." (Paper 6 at 7.) Any paclitaxel loss during the commercial-scale manufacture of

Cipla's product would be irrelevant to the invalidity of the '229 patent. The claims of the '229 patent are not limited to a particular manufacturing process, and a commercial-scale process has little in common with the prior art teaching of a 9:1 ratio of albumin to paclitaxel disclosed by Example 1 of Desai. (Exhibit 1006.)

When instituting the Actavis IPR, the Board found that "Desai teaches a cancer treatment using final pharmaceutical composition with a ratio of albumin to paclitaxel that is 'about 9:1' as required by claim 1 of the '229 patent." (IPR2017-01104, Paper 7 at 18.) Although Abraxis's expert speculated that the starting and final ratios could differ due to loss of paclitaxel during manufacturing, this is irrelevant: The inquiry for anticipation is whether Example 1 places the claimed 9:1 ratio of albumin and paclitaxel within the possession of the public. *See In re Yale*, 434 F.2d 666, 668 (C.C.P.A. 1970). The inquiry for obviousness is whether Example 1 suggests a 9:1 ratio to a person of ordinary skill in the art at the time of the invention. *See In re Keller*, 642 F.2d 413, 425 (C.C.P.A. 1981).

Although the Board invited Abraxis to provide evidence from actual Capxol™ or Abraxane® production that demonstrates significant loss of paclitaxel during commercial synthesis, Cipla respectfully disagrees that such evidence is relevant. Neither Abraxis's manufacturing process of Abraxane nor Cipla's manufacturing process of generic Abraxane can explain what a person of ordinary skill in the art would have gleaned from Example 1 of Desai at the time of the

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.