UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CIPLA LTD.,
Petitioner

v.

ABRAXIS BIOSCIENCE, LLC,
Patent Owner

Case IPR2018-00163
Patent 7,923,536 B2
Issued: April 12, 2011

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

TABLE OF AUTHORITIES

Page(s)

Cases

Other Authorities

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*, IPR2017-01103 ("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 '536 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 '536 patent. The claims of the '536 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 a final pharmaceutical composition with a ratio of albumin to paclitaxel that is 'about 9:1' as required by claim 1 of the '536 patent." (IPR2017-01103, Paper 7 at 17.) 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

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