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

PETITION FOR *INTER PARTES* REVIEW

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A. Taxol® (paclitaxel) was an FDA-approved "wonder drug," but initially could only be administered with a toxic solvent. 9

B. The inventors repeatedly patented albumin-paclitaxel nanoparticles as a solution to the known problems of Taxol®. 10

C. Desai (EX1006) specifically discloses a nanoparticle formulation with an albumin-paclitaxel ratio of 9:1. 12

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. 12

E. The inventors obtained their *third* round of patents on albumin-paclitaxel by arguing that a 9:1 ratio has "unexpected" benefits. 15

VII. PLAIN AND ORDINARY MEANINGS 19

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" 19

B. "a particle size of less than about 200 nm" 22

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As shown below, claims 1–16 are anticipated by Desai (EX1006). 23

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a. Treatment of cancer in humans 24

b. Albumin-paclitaxel combination 25

c. Particle size of less than about 200 nm 26

d. Albumin-paclitaxel ratio of about 1:1 to 9:1 27

2. Claims 2–16 are anticipated.....28

3. The "starting" albumin-paclitaxel ratio does not change. 30

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1. Claim 1 would have been obvious.....35

a. GROUND II.A: Desai alone.....35

i. The albumin-paclitaxel ratio of about 9:1 falls within a range disclosed by Desai. 38

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

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.....49

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2. Claims 2–16 would have been obvious. 52

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TABLE OF AUTHORITIES

Page(s)

Cases

Abraxis BioScience, LLC v. Actavis LLC,
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Abraxis BioScience, LLC v. Cipla Ltd.,
C.A. No. 16-9074-JMV-MF 5

Agrizap, Inc. v. Woodstream Corp.,
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Amneal Pharms,, LLC v. Supernus Pharms., Inc.,
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Apotex, Inc. v. Cephalon, Inc.,
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Exxon Chem. Patents, Inc. v. Lubrizol Corp.,
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Galderma Labs., L.P. v. Tolmar, Inc.,
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In re Ethicon, Inc.,
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In re Geisler,
116 F.3d 1465 (Fed. Cir. 1997) 40

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