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

PETITION FOR *INTER PARTES* REVIEW

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VI. THE PRIOR ART AND THE '229 PATENT 8

A. Taxol® (paclitaxel) was an FDA-approved "wonder drug," but initially could only be administered with a toxic solvent. 8

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

C. "about 0.5% to about 5% by weight of albumin" and "about 5% by weight of albumin" 22

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a. Albumin-paclitaxel combination 24

b. Particle size of less than about 200 nm 25

c. Albumin-paclitaxel ratio of about 1:1 to 9:1 26

d. Weight concentration of albumin 26

2. Claims 3 and 6 are anticipated. 28

3. Claims 15, 19, and 21–23 are anticipated. 29

4. Claims 29, 34, and 38 are anticipated. 31

5. Claims 7 and 33 are anticipated. 32

6. Claims 2, 8, 11–14, 16, 24, 27–28, 30, 35, and 39 are anticipated. 32

7. Claims 4–5, 9–10, 17–18, 25–26, 31–32, 36–37, and 40–41 are anticipated. 33

8. Claims 42–48 are anticipated. 33

9. The "starting" albumin-paclitaxel ratio does not change. 33

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1. Claim 1 would have been obvious. 37

a. GROUND II.A: Desai alone.....37

i. The albumin-paclitaxel ratio of about 9:1 falls within a range disclosed by Desai. 40

ii. Desai would have motivated a skilled artisan to lower Capxol™'s albumin-paclitaxel ratio. 41

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iii. A skilled artisan would have reasonably expected the claimed albumin-paclitaxel ratio of 9:1 to retain stability. 43

iv. The claimed albumin weight percentage when the formulation is reconstituted in saline falls within a range disclosed by Desai. 46

b. GROUND II.B: Desai, Kadima, and Liversidge 47

i. Kadima and Liversidge also disclose ranges of albumin-paclitaxel ratios including 9:1. 47

ii. Kadima teaches additional reasons to lower Capxol™'s 13.3:1 ratio to about 9:1. 49

2. Claims 3 and 6 would have been obvious. 52

3. Claims 15, 19, and 21–23 would have been obvious. 53

4. Claim 20 would have been obvious. 54

5. Claims 29, 34, and 38 would have been obvious. 55

6. Claims 7 and 33 would have been obvious. 56

7. Claims 2, 8, 11–14, 16, 24, 27–28, 30, 35, and 39 would have been obvious. 57

8. Claims 4, 5, 9, 10, 17–18, 25–26, 31–32, 36–37, and 40–41 would have been obvious. 57

9. Claims 42–48 would have been obvious. 57

10. There is no probative evidence of secondary considerations. 58

a. The allegedly "unexpected" cell-binding results lack a nexus to the '229 patent and were expected. 59

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b. The allegedly "unexpected" clinical data did not compare the closest prior art and were expected.....62

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