Paper No. ___
Date Filed: May 5, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

WOCKHARDT BIO AG,
Petitioner,

v.

JANSSEN ONCOLOGY, INC.
Patent Owner.

Case IPR2016-01582
Patent 8,822,438 B2

PATENT OWNER'S MOTION FOR OBSERVATION ON CROSS-EXAMINATION

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Deposition of Dr. Godley

I. Approval of Docetaxel

1 (a). In Exhibit 2185, p. 68, l. 1 through p. 69, l. 5 the witness testified:

Q. When did you stop using ketoconazole? . . .

Mr. Powers: Objection, relevance.

A. I -- ketoconazole was effectively replaced as a therapy in my practice when Taxotere became available.

Q. Why was that?

Mr. Powers: Objection to form.

A. That was because Taxotere was well-tolerated, had more palliative benefit to patient and had a survival benefit. So when patients failed hormonal therapy, it was a clear choice, clearer choice, to use Taxotere rather than ketoconazole.

Q. . . . After the approval of Taxotere, were your fellow oncologists also showing a preference to use Taxotere over ketoconazole?

Mr. Powers: Objection, foundation, relevance, scope.

A. That is my -- that is my impression, is that Taxotere quickly became part of the standard of care and ketoconazole became much less used.

1 (b). In Exhibit 2185, page 71, ll. 6-10 the witness testified:

Q. After the approval of Taxotere, were researchers in the field of prostate cancer pursuing further research to build on the survival benefit observed with

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chemotherapy such as Taxotere?

A. I think they were.

This testimony is relevant to the state of the art at the time of the invention, Ex. 1104 at ¶ 21, Ex. 2161 at 78:14-24, ¶¶ 61 and 221-231 of Dr. Rettig's declaration (Ex. 2038), and Paper No. 43 ("PO Response") at § IV.A.1.

II. Claim Construction Applied in Analysis

2 (a). In Exhibit 2185, page 35, ll. 4-11 the witness testified:

Q. So what is your understanding, sir, of the meaning of the phrase, Minimization or spread of cancer, in the context of the claims of the '438 patent?

A. My understanding is that it means that the cancer, in this case prostate cancer, is either not growing or growing more slowly as a consequence or as part of treatment.

2 (b). In Exhibit 2185, page 36, l. 17 through page 37, l. 1 the witness testified:

Q. [D]oes the board's construction of treatment require a showing of minimization or delay of the spread of cancer?

A. The board's construction of treatment does not require the minimization or delay of the spread of cancer.

This testimony is relevant to ¶¶ 3-4 of Dr. Godley's reply declaration and impacts Dr. Godley's analysis of the prior art at ¶¶ 25 and 27 (Ex. 1104). It is

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further relevant to §§ II, III, and IV.B. of the PO Response, and Dr. Rettig's opinions at ¶¶ 77, 69-76, 196, and 225 of his declaration (Ex. 2038).

III. Attard (2009)

3. In Exhibit 2185, p. 88, l. 17 through p. 89, l. 5 the witness testified:

Q. [D]o you agree that prior ketoconazole therapy would not have had an impact on the time to PSA progression for 95 percent of patients enrolled in the Attard 2009 study?

Mr. Powers: Objection, form.

A. Since the authors document that greater than 95 percent of patients did not receive ketoconazole, it would be unlikely that ketoconazole would have affected the results of the abiraterone acetate therapy intervention in this study.

This testimony is relevant to ¶¶ 41 and 43 of Dr. Godley's reply declaration (discussing comparison of results from COU-AA-001 and COU-AA-002 studies) (Ex. 1104), and Dr. McKeague's declaration at ¶¶ 44-47 (opining the same) (Ex. 1106). This testimony is also relevant to Ex. 1022 (Attard 2009) at 3744.

4. In Exhibit 2185, p. 55, l. 15 through p. 57, l. 12 the witness testified:

Q. . . . (Reading) We have not previously observed, and to our knowledge there are no published reports of secondary responses to reinstitution of single-agent dexamethasone in patients who had previously experienced progression on this therapy. Correct?

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A. Correct. . . .

Q. And then it says: (Reading) These data suggest that AR may be activated by elevated hormone levels upstream of CYP17 and supports the future evaluation of a combination of abiraterone acetate with low-dose corticosteroids to maximize efficacy and minimize toxicity. Correct?

A. That is what they say, yes.

Q. And then it continues: (Reading) Abiraterone acetate is now being evaluated in combination with corticosteroids in a 1,180-patient, multicenter, double-blind randomized Phase III study comparing abiraterone acetate plus prednisone which is prednisone plus placebo in CRCP patients who have previously received docetaxel. Correct?

A. That is correct.

This testimony is relevant to Dr. Godley's reply declaration at ¶¶ 37-38, 40, and 42 (Ex. 1104), Dr. Rettig's declaration at ¶¶ 196-202 (discussing incorporation of dexamethasone extension study results into Phase III abiraterone acetate/prednisone trials) (Ex. 2038), and Ex. 1022 (Attard 2009) at 3747.

IV. Skepticism

5. In Exhibit 2185, p. 145, ll. 13- 20 the witness testified:

Q. Do you agree that as of August 2006 the role of the endocrine environment and mCRPC was not widely understood, and there was skepticism that further

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