Paper No. ___
Date Filed: May 3, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC., ACTAVIS LABORATORIES FL, INC., AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, DR. REDDY'S LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD., SUN PHARMACEUTICALS INDUSTRIES, LTD, SUN PHARMACEUTICALS INDUSTRIES, INC., TEVA PHARMACEUTICALS USA, INC., WEST-WARD PHARMACEUTICAL CORP., AND HIKMA PHARMACEUTICALS, LLC,
Petitioner,

v.

JANSSEN ONCOLOGY, INC.
Patent Owner.

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Case IPR2016-01332[1]
Patent 8,822,438 B2

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PATENT OWNER'S MOTION FOR OBSERVATIONS ON CROSS-EXAMINATION

[1] Case IPR2017-00853 has been joined with this proceeding.

Deposition of Dr. Garnick

I. Docetaxel

1. In Exhibit 2185, p. 54, l. 20, through p. 55, l. 4, the witness testified:

Q. Do you agree, upon the approval of docetaxel chemotherapy, the field became focused on finding additional chemotherapy treatments that would improve survival?

A. In general, we're constantly trying to improve therapies for our patients with prostate cancer.

Q. So my statement is correct.

A. Yes.

This testimony is relevant to Paper 35 ("PO Response") at p. 42 ("future clinical trials focused on building on the survival improvement seen with docetaxel-based therapy."). This testimony is relevant to Dr. Garnick's opinions at ¶¶ 39 and 113 of his reply declaration (Ex. 1104), and Dr. Rettig's opinions at ¶¶ 61, 188, and 220 of his declaration (Ex. 2038).

II. Abiraterone Acetate and Prednisone

2. In Exhibit 2185, p. 51, l. 21 through p. 52, l. 1, the witness testified:

Q. Do you agree that the approval of abiraterone acetate in combination with prednisone was also a significant milestone in the treatment of metastatic castration-resistant prostate cancer patients?

A. Yes.

This testimony is relevant to Dr. Garnick's opinions at ¶ 96 of his opening declaration (Ex. 1002), Dr. Rettig's declaration at ¶¶ 51, 220, and 210-213 (Ex. 2038), and the PO Response at p. 54. This testimony is further relevant to Dr. Garnick's deposition testimony at 139:13-140:16 (Ex. 2126).

III. Attard (2009)

3. In Exhibit 2185, p. 95, ll. 7-11, the witness testified:

Q. So over 95 percent of patients in the Attard 2009 study, who received a thousand milligrams of abiraterone acetate, did not receive prior treatment with ketoconazole, correct?

A. That's what it says.

This testimony is relevant to Dr. Garnick's opinions at fn. 4, ¶¶ 97-99, and ¶ 101 of his reply declaration (relying on the fact that "Attard 2009 enrolled patients who were previously on ketoconazole" as a basis for his opinion that it is improper to compare results from COU-AA-001 with COU-AA-002) (Ex. 1104). This testimony is further relevant to Dr. McKeague's opinions at ¶ 47 of his declaration (opining the same) (Ex. 1091). This testimony is relevant to Ex. 2015 (Attard 2009) at 3744.

4. In Exhibit 2185, p. 100, ll. 4-23, the witness testified:

Q. Okay. Just reading the sentence as it appears in Attard 2009, where the

researchers report that they have not previously observed, and to their knowledge, there are no published reports of secondary responses to reinstitution of single agent dexamethasone in patients who have previously experienced progression on this therapy, do you understand that to be an accurate statement concerning what is described in 2009?

Mr. Beel: Objection to form and foundation.

A. There's no reason for me to doubt what's stated there.

This testimony is relevant to Dr. Garnick's opinions at ¶¶ 104-106 of his reply declaration (Ex. 1104). This testimony is further relevant to Dr. Rettig's opinions at ¶¶ 196-202 of his declaration (opining that the dexamethasone extension study results were incorporated into design of Phase III trials of abiraterone acetate in combination with prednisone) (Ex. 2038), and Ex. 2015 (Attard 2009) at 3747.

IV. <u>Trump</u>

5. In Exhibit 2185, p. 104, ll. 13-19, the witness testified:

Q. So on page 1097, in the right-hand column, third full paragraph it states, "Overall, ketoconazole plus hydrocortisone would have to be judged ineffective as secondary hormone therapy for most patients with advanced prostatic cancer," correct?

A. Yes.

This testimony is relevant to Dr. Garnick's opinions at ¶¶ 17, 20, and 35 of his reply declaration (Ex. 1104). This testimony is also relevant to Ex. 1107 (Trump) at 1097, and Dr. Rettig's declaration at ¶¶ 186-188 and 225 (Ex. 2038).

V. Sonino

6. In Exhibit 2185, p. 108, l. 19 through p. 109, l. 5, the witness testified:

Q. Do you see where it says, "Since ketoconazole interferes with C17-20 lyase, and is a more potent inhibitor of cholesterol side-chain cleavage activity, it can be expected that patients treated with the agent will be free of side effects such as mineralocorticoid excess." Do you see that?

Mr. Beel: Objection to form and foundation. Outside the scope of the declaration.

A. Yes.

Q. This was part of what was known in the art as of August 2006, correct?

A. Yes.

This testimony is relevant to Dr. Garnick's opinions at ¶ 79 of his reply declaration (Ex. 1104), ¶¶ 33, 41, and 44 of his opening declaration (Ex. 1002), his testimony at p. 37 l. 17 - p. 38 l. 12 (Ex. 2126), and Ex. 2163 (Sonino) at 815. This testimony is further relevant to the PO Response at § IV.A.2.a.

VI. Gerber

7. In Exhibit 2185, p. 129, ll. 4-9, the witness testified:

Q. Is it correct that Gerber does not teach that the prednisone was administered

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