

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMERIGEN PHARMACEUTICALS LIMITED

and

ARGENTUM PHARMACEUTICALS LLC

Petitioners

v.

JANSSEN ONCOLOGY, INC.,

Patent Owner

Case IPR2016-00286¹

Patent 8,822,438 B2

**PETITIONERS' RESPONSE TO PATENT OWNER'S
MOTION FOR OBSERVATIONS ON CROSS-EXAMINATION**

¹Case IPR2016-01317 has been joined with this proceeding.

1. Response to Observation No. 1

Petitioners respond that the cited testimony is not relevant to this proceeding. The cited testimony is not relevant because the testimony does not address the manner or extent in which the targets are in common and in which the targets are different. In particular, the answer also does not address the targets in common which inhibit the key components of the cortisol (glucocorticoid) synthesis pathway.

2. Response to Observation No. 2

Petitioners respond that the cited testimony is not relevant to this proceeding. The cited testimony is not relevant because the testimony does not conflict with any opinions in his declaration. Paragraphs 30, 37, 39 of Dr. Ratain's declaration address evidence of adrenal toxicity and O'Donnell's (Exh. 1003) disclosure of administration of glucocorticoids with ketoconazole to treat prostate cancer. Further, it is not relevant as to whether both ketoconazole and abiraterone acetate were known to reduce cortisol (a glucocorticoid) levels, thereby requiring administration of prednisone (replacement glucocorticoid).

3. Response to Observation No. 3

Petitioners respond that the cited testimony is not relevant to this proceeding. The cited testimony is not relevant because the testimony does not

contradict that ketoconazole was known to treat prostate cancer. For example, O'Donnell (Exh. 1003) states: "A direct antitumour effect of ketoconazole *in vitro* has also been demonstrated (Eichenberger and Trachtenberg, 1988). . . . In clinical trials, both agents [ketoconazole and aminoglutethimide] have shown some activity as second-line agents (measured by clinical benefit as well as reduction in PSA), . . ."

4. Response to Observation No. 4

Petitioners respond that the cited testimony is not relevant to this proceeding. The cited testimony is not relevant because the testimony does not contradict that prednisone was known to treat prostate cancer, which the answer does not address. In this regard, in Ex. 2124, at p. 65, l. 11-18, the witness testified:

Q. To a person of ordinary skill in the art, would they consider reduced PSA sufficient to reflect an anti-cancer effect or would the person of ordinary skill require evidence of enhanced life expectancy?

A. A person of ordinary skill would not require evidence of life expectancy nor would the FDA.

Further it does not contradict that prednisone was known to be used in combination with other drugs for the treatment of prostate cancer. See for example

AMG 1091, paragraph 36, and O'Donnell (Exh. 1003) states: "A direct antitumour effect of ketoconazole in vitro has also been demonstrated (Eichenberger and Trachtenberg, 1988). . . . In clinical trials, both agents [ketoconazole and aminoglutethimide] have shown some activity as second-line agents (measured by clinical benefit as well as reduction in PSA), . . ."

5. Response to Observation No. 5

Petitioners respond that the cited testimony is not relevant to this proceeding. The cited testimony is not relevant because the testimony does not conflict with any opinions in his declaration. The cited testimony is not relevant because the testimony does not contradict that dexamethasone was known to treat prostate cancer, which the answer does not address. In this regard, in Ex. 2124, at p. 65, l. 11-18, the witness testified:

Q. To a person of ordinary skill in the art, would they consider reduced PSA sufficient to reflect an anti-cancer effect or would the person of ordinary skill require evidence of enhanced life expectancy?

A. A person of ordinary skill would not require evidence of life expectancy nor would the FDA.

6. Response to Observation No. 6

Petitioners respond that the cited testimony is not relevant to this proceeding. The cited testimony is not relevant because the question is completely vague and ambiguous. It is unclear what "this sentence" is or what quote in the declaration is being referred to. Further, Patent Owner's explanation of relevance is attorney argument and speculation because the question is so incomprehensible.

7. Response to Observation No. 7

Petitioners respond that the cited testimony is not relevant to this proceeding. The cited testimony is not relevant because the question is vague as to whether Dr. Ratain regularly treats patients with prostate cancer now or has ever regularly treated patients with prostate cancer. In fact, in Ex. 2124, at p. 24, l. 23- p. 25, l. 4, the witness testified:

Q. Has there ever been a time in your professional career where you've regularly treated patients with prostate cancer?

MR. CASIERI: Object to form.

BY THE WITNESS:

A. Yes.

8. Response to Observation No. 8

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.