

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

U.S. Patent No. 8,822,438 to Auerbach et al.
Issue Date: September 2, 2014
Title: Methods and Compositions for Treating Cancer

Inter Partes Review No. 2016-00286¹

**PETITIONERS' REPLY TO PATENT OWNER'S
RESPONSE TO PETITION**

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

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I. Introduction

The claims of the '438 patent are directed to treating prostate cancer by administering therapeutically effective amounts of abiraterone acetate ("AA"), a 17 α -hydroxylase/C17,20-lyase inhibitor ("CYP17 inhibitor"), in combination with prednisone, a glucocorticoid. The prior art taught use of AA as an effective anti-cancer agent which suppresses testosterone synthesis in prostate cancer patients. AMG Ex. 1002, ¶¶ 26, 45, 56, 58. The prior art also taught that the combination of ketoconazole and prednisone is safe and effective in treating human patients with hormone-refractory advanced prostate cancer. AMG Ex. 1004, *Abstract*, pp. 1177-1178, 1179. A POSA would have been motivated to combine AA and a glucocorticoid, like prednisone, in view of the express teachings of the prior art. And the POSA would have expected that such a combination would result in a safe and effective treatment of prostate cancer. None of the arguments presented by the Patent Owner changes this conclusion.

II. Claim Construction

In the Institution Decision ("ID"), the Board construed a number of terms from the claims of the '438 patent. Of those construed terms "treat," "treating," and "treatment" were construed to mean "include the eradication, removal, modification, management or control of a tumor or primary, regional, or metastatic cancer cells or tissue and the minimization or delay of the spread of cancer." ID,

Paper 14 at 5. The Patent Owner agrees with this construction. PO Response at 8. Subsequent to filing their Response, the Patent Owner sought and received permission to file the Markman Order from the co-pending District Court litigation. Because the District Court construction of these terms is narrower than the construction in the ID, the District Court construction is not the “broadest reasonable construction in light of the specification,” and is thus irrelevant to the current proceeding. 37 C.F.R. § 42.100(b); see *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1275–79 (Fed. Cir. 2015), cert. granted sub nom. *Cuozzo Speed Techs. LLC v. Lee*, 136 S. Ct. 890 (mem.) (2016). Petitioners therefore believe no change in the claim construction from the ID is warranted, especially in view of the agreement of the Patent Owner to the construction in the Institution Decision. *SAS Institute, Inc. v. ComplementSoft, LLC*, 825 F.3d 1341, 1351 (Fed. Cir. 2016).

III. The Claims are a Combination of Two Known Elements for a Predictable Result

A. A POSA would have expected that AA to treat prostate cancer might require co-administration of a GC based on the disclosures in the prior art regarding the predicted impact of AA on the adrenal steroid synthesis pathway

As Patent Owner admits, AA and ketoconazole are both CYP 17 inhibitors. (See Preliminary Response at Figures 1, 2). The prior art, including Barrie and O’Donnell, disclose that (1) the CYP 17 enzyme has two separate activities in the adrenal androgen synthesis pathway, a 17 α -hydroxylase and a C 17,20 lyase

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