Paper No. ___

Date Filed: February 16, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMERIGEN PHARMACEUTICALS LIMITED,
ARGENTUM PHARMACEUTICALS LLC,

Petitioners

v.

JANSSEN ONCOLOGY, INC.,
Patent Owner

Case IPR2016-00286[1]

Patent No. 8,822,438 B2

PATENT OWNER'S REQUEST FOR REHEARING

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

I. INTRODUCTION

Janssen Oncology, Inc. ("Patent Owner") respectfully requests rehearing of the Board's Final Written Decision (Paper 86) regarding U.S. Patent 8,822,438 pursuant to 37 C.F.R. §42.71(d). The Board misapprehended or overlooked evidence, and improperly relied on theories and evidence presented only in Petitioners' Reply, to find claims 1-20 unpatentable as obvious.

First, the Board misapprehended evidence contradicting the sole reason advanced in the Petition (which the Board adopted in its Institution Decision) as to why a skilled person would have found it obvious to administer prednisone with abiraterone acetate ("AA") – that there supposedly was a need to treat the side effects of mineralocorticoid excess caused by "CYP17 inhibitors." As Petitioners' expert admitted, ketoconazole – which the Board inaccurately portrayed as being equivalent to AA because both were alleged "CYP17 inhibitors"– does not cause mineralocorticoid excess. As he stated in his opening declaration, Petitioners' expert also confirmed that cortisol reductions alone are not enough to justify glucocorticoid replacement therapy and opined that such treatment is warranted only if cortisol reduction results in mineralocorticoid excess. Consequently, Petitioners failed to show by a preponderance of the evidence that a skilled person would have been motivated to co-administer prednisone with an alleged "CYP17 inhibitor" like ketoconazole or AA to treat (non-existent) symptoms of

mineralocorticoid excess.

The Board compounded its error by relying on a supposed new theory on motivation to combine prednisone with AA that Petitioners raised for the first time in Reply – that "CYP17 inhibitors" reduce cortisol production that results in adrenal insufficiency. But the rationale advanced in the Petition was not based on adrenal insufficiency. Further, other evidence in the record contradicted that new theory.

The Board also overlooked or misapprehended the evidence demonstrating that Petitioners' "congenital CYP17 deficiency" arguments were also new arguments and could not support the obviousness rationale set forth in the Petition.

The Board's decision cannot be sustained when Petitioners' admissions are accepted, and when the new theories advanced for the first time in Reply are properly excluded from the analysis. The decision improperly disregards the presumption of validity that all patents – including those undergoing *inter partes* review – are entitled to under 35 U.S.C. § 282. The statutory presumption of validity means that, in the absence of proof under the applicable evidentiary standard, the court must find the claims valid. In these proceedings, the Petitioners are required to establish the claims are unpatentable for the reasons set forth in their Petition by a preponderance of the evidence. Where the evidence before the Board on the Petitioners' theory of unpatentability falls short of that threshold –

such as when a key fact underpinning the Petitioners' theory has been disproven – the presumption of validity compels the Board to affirm the patentability of the claims.

Finally, the Board misapprehended the logical consequence of its dual findings that (i) O'Donnell taught that 500mg of AA effectively "treats" prostate cancer but (ii) results in "unquestionably abnormal" cortisol side effects. Under the Board's own reasoning, a skilled artisan would have had no reason to increase the dose of AA from 500mg to 1000mg/day, as dependent claims 4, 11, 19 and 20 require, because doing so was unnecessary and would cause more severe adverse effects. Patent Owner also could not have responded to the inconsistencies in the Board's reasoning with respect to these dependent claims because these two arguments were not articulated in any paper prior to the Final Decision. There is thus no rational basis for finding claims 4, 11, 19 and 20 obvious on this record.

Accordingly, the Board should vacate its Final Decision and confirm the patentability of claims 1-20 of the '438 patent.

II. STANDARD OF REVIEW

A request for rehearing may be filed that "specifically identif[ies] all matters the party believes the Board misapprehended or overlooked." 37 C.F.R. §42.71(d).

III. ARGUMENT

A. The Board Misapprehended the Significance of Petitioners' Admission that Ketoconazole Does Not Cause Mineralocorticoid

Excess.

Amerigen's Petition articulated a single rationale why the challenged claims were unpatentable:

> … it was known in the art that administering ketoconazole, also a CYP17 inhibitor like abiraterone acetate, to treat a prostate cancer may result in significant side effects, such as hypertension, hypokalemia and fluid retention as a result of a decrease in cortisol levels and consequent ACTH drive.
>
> Paper 1 (Petition) at 55-56, *citing* Ex. 1002 at ¶¶ 34, 68-70.

To support this assertion, Petitioners relied on their expert, Dr. Serels who testified:

> The administration of ketoconazole to treat prostate cancer was known to reduce cortisol levels and potentially result in mineralocorticoid excess, giving rise to side effects commonly associated with mineralocorticoid excess, including hypertension, hypokalemia, and fluid retention…These side effects reduced the safety and tolerability of administering ketoconazole…To address these side effects, it was standard practice in the art to co-administer a glucocorticoid such as…prednisone with ketoconazole to improve the safety and tolerability of ketoconazole to treat prostate cancer.
>
> Ex. 1002 at ¶34 (emphasis added).

The Board relied on these representations to find a reasonable likelihood that Petitioners would prevail in challenging the claims as obvious, stating:

> Our review of Dr. Serels's declaration and supporting evidence leads us to credit his testimony that "one of skill in the art would have expected

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