Paper No. ___

Date Filed: February 16, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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,
Petitioners,

v.

JANSSEN ONCOLOGY, INC.
Patent Owner.

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

PATENT OWNER'S REQUEST FOR REHEARING

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

I. INTRODUCTION

Janssen Oncology, Inc. ("Patent Owner") respectfully requests rehearing of the Board's Final Written Decision (Paper 84) ("Final Decision") regarding U.S. Patent 8,822,438 (the "'438 patent") 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 hold claims 1-20 obvious.

First, the Board misapprehended the evidence contradicting the sole reason advanced in the Petition (which it 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." But ketoconazole – which the Board inaccurately portrayed as being equivalent to AA because both were "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 and AA to treat symptoms of (non-existent) mineralocorticoid excess.

The Board compounded its errors by relying on new theories that Petitioners raised for the first time in Reply to find a different motivation to combine prednisone with AA, particularly because other evidence in the record contradicted those new theories. More than a preponderance of the evidence in this record thus refutes the obviousness grounds as they were set forth in the Institution Decision.

The Board's decision also improperly disregards the presumption of validity that 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 not have increased the dose of AA from 500 mg to 1000 mg/day, as dependent claims 4, 11, 19, and 20 require,

because doing so was unnecessary and would cause more severe side 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 dependent 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

Mylan'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 57-58, *citing* Ex. 1002 at ¶¶ 44, 78-80.

To support this assertion, Petitioners relied on their expert, Dr. Garnick who

testified:

> [T]he 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 administration of ketoconazole to treat prostate cancer."
>
> Ex.1002 at ¶ 44 (emphasis added).

In its decision to institute trial, the Board relied on the same reasons given in its Institution Decision in the Amerigen IPR (IPR2016-00286), stating:

> Having reviewed the [Mylan] Petition and Janssen's Preliminary Response, we incorporate our analysis from our Institution Decision in the Amerigen IPR. IPR2016-00286, Paper 14, 4-15. For the same reasons given in the Institution Decision in the Amerigen IPR, we determine that Mylan has demonstrated a reasonable likelihood that it would prevail with respect to its challenge to claims 1-20 of the '438 patent on the asserted grounds.
>
> Paper 21 (ID) at 5.

In turn, the Amerigen Institution Decision found a reasonable likelihood that Petitioners would prevail in challenging the claims as obvious because:

DOCKET ALARM

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.