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Paper 92
Entered: December 3, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMERIGEN PHARMACEUTICALS LIMITED and
ARGENTUM PHARMACEUTICALS LLC,
Petitioner,

v.

JANSSEN ONCOLOGY, INC.,
Patent Owner.

Case IPR2016-00286[1]
Patent 8,822,438 B2

Before JEFFREY N. FREDMAN, KRISTINA M. KALAN and JACQUELINE T. HARLOW, *Administrative Patent Judges*.[2]

KALAN, *Administrative Patent Judge*.

DECISION
Denying Patent Owner's Request for Rehearing
37 C.F.R. § 42.71(d)

[1] Case IPR2016-01317 has been joined with this proceeding.
[2] A Panel Change Order issued on September 28, 2018, indicating that the judges named herein now constitute the panel. Paper 91.

I. INTRODUCTION

Janssen Oncology, Inc. ("Patent Owner") filed a Request for Rehearing (Paper 90, "Request" or "Req.") of our Final Written Decision (Paper 86, "Final Written Decision" or "Dec.") in which claims 1–20 of U.S. Patent No. 8,822,438 B2 (Ex. 1001, "the '438 patent") are unpatentable. For the reasons that follow, Patent Owner's Request for Rehearing is denied.

II. THE REQUEST FOR REHEARING

In pertinent part, 37 C.F.R. § 42.71(d) states:

> The burden of showing a decision should be modified lies with the party challenging the decision. The request must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed in a motion, an opposition, or a reply.

Thus, a request for rehearing is not an opportunity merely to disagree with the Board's assessment of the arguments or weighing of the evidence, or to present new arguments or evidence.

Patent Owner requests rehearing to address four issues with our Final Written Decision: first, whether the Board misapprehended evidence regarding Petitioner's reasoning for administration of prednisone with abiraterone acetate; second, whether the Board overlooked or misapprehended Petitioner's evidence concerning patients with congenital CYP17 deficiency; third, whether the Board overlooked or misapprehended evidence regarding abiraterone acetate and adrenal insufficiency; and fourth, whether the Board misapprehended Petitioner's assertions as to the 1000 mg dose of abiraterone acetate in claims 4, 11, 19, and 20. Req. 1–3.

We have reviewed Patent Owner's Request and carefully considered all the arguments presented. For the following reasons, we are not persuaded that the Board misapprehended or overlooked arguments or evidence with respect to the contentions asserted by Patent Owner.

III. DISCUSSION

(A) Patent Owner's First Argument

Patent Owner argues that the Board "overlooked or misapprehended the consequences of the now undisputed fact that ketoconazole does not cause mineralocorticoid excess." Req. 7. Patent Owner argued, in its Response, that ketoconazole did not cause mineralocorticoid excess, and pointed to Dr. Serels's testimony that it asserts supported its argument. *Id.* at 5 (citing PO Resp. 23–26, Ex. 1095 ¶ 10).

We considered this evidence and argument in our Final Written Decision, and, as we stated, we did "not understand Petitioner's argument for motivation to combine to be premised on this assertion alone." Dec. 21–22 (citing Pet. 6, 26, 37–39). We noted that Dr. Serels appreciated that "mineralocorticoid excess does not occur with ketoconazole," yet this did not change his opinion that "cortisol deficiency would have been expected to have significant negative clinical impact in mCRPC patients treated with abiraterone" and that one of ordinary skill in the art "would have been motivated to co-administer a glucocorticoid, and in particular prednisone, as a first choice to suppress predicted ACTH drive in patients administered abiraterone acetate to treat CRPC." *Id.* at 22 (citing Ex. 1095 ¶ 10). Accordingly, we determined that Petitioner reasonably and with properly presented arguments established that one of ordinary skill in the art would have looked to the prior art's co-administration of ketoconazole and a

glucocorticoid to assess the possibility of administering a glucocorticoid with abiraterone acetate. We expressly addressed Dr. Serels's testimony on this issue, and did not overlook Dr. Serels's testimony or other testimony regarding the relationship between ketoconazole and mineralocorticoid excess. *Id.* Nor are we persuaded, given our consideration and analysis of Dr. Serels's testimony and the other evidence we considered, that we misapprehended the import of this testimony and evidence, or Petitioner's reliance on the same to support Petitioner's arguments for motivation to combine the relied-upon references. *Id.*

(B) Patent Owner's Second Argument

Patent Owner argues that the Board considered new arguments regarding congenital CYP17 deficiency that were allegedly improperly presented on Reply. Req. 9. Patent Owner argues that that the Board accepted and relied upon Petitioner's claims regarding congenital CYP17 deficiency despite Patent Owner's advising the Board that these were new arguments. *Id.* at 9–10.

We considered Patent Owner's Identification of New Arguments and Evidence in Petitioner's Reply (Paper 74) in rendering our Final Written Decision, as well Petitioner's reply to the same (Paper 78) and the arguments presented by both parties on this issue. Dec. 2, 21. We have been cautioned that reply arguments should not be parsed "with too fine a filter." *Ericsson Inc. v. Intellectual Ventures I LLC*, 901 F.3d 1374, 1380 (Fed. Cir. 2018). Accordingly, we evaluated the evidence and arguments in the Petition and those in the Reply we considered to be properly responsive, and stated that "Petitioner has reasonably established that one of ordinary skill in the art would have looked at mineralocorticoid production in the CYP17 inhibition

scheme to assess the possibility of mineralocorticoid imbalance in the administration of abiraterone acetate." Dec. 21 (citing Ex. 1002 ¶¶ 31–32 (Dr. Serels's Declaration, submitted with the Petition, discussing CYP17 inhibition); Ex. 1093 ¶¶ 25 (Dr. Serels's Declaration, submitted with the Reply, discussing CYP17 inhibition)). We also found that, on the record before us, Petitioner reasonably established that one of ordinary skill in the art "would have analogized to congenital CYP17 deficiency to assess the possibility of mineralocorticoid excess in patients administered abiraterone acetate." *Id.* (citing Ex. 1002 ¶¶ 31–32; Ex. 1085, 508; Reply 4). We acknowledged that "the analogy is not necessarily perfect or complete," but concluded that "an analogy to the problems arising from a congenital CYP17 deficiency likely would shed light on CYP17 inhibition in other, non-congenital situations." *Id.* Accordingly, we did not simply accept Petitioner's argument regarding congenital CYP17 deficiency on its face, but rather, we determined that Petitioner reasonably and with properly presented arguments established that one of ordinary skill in the art would have looked at the CYP17 inhibition scheme in general to assess the possibility of mineralocorticoid imbalance. Thus, we are not persuaded that we overlooked or misapprehended this argument.

(C) Patent Owner's Third Argument

Patent Owner argues that the Board overlooked evidence that abiraterone acetate does not cause adrenal insufficiency. Req. 12 (citing Dec. 16). Patent Owner argues that "adrenal insufficiency" and "diminished adrenal reserve" are both distinct from "mineralocorticoid excess," as demonstrated by opposite side effects—for example, hypertension for mineralocorticoid excess, and hypotension for adrenal insufficiency (i.e.,

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