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Paper 87
Entered: December 3, 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,
Petitioner,

v.

JANSSEN ONCOLOGY, INC.,
Patent Owner.

Case IPR2016-01332[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)

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[1] Case IPR2017-00853 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 86.

I. INTRODUCTION

Janssen Oncology, Inc. ("Patent Owner") filed a Request for Rehearing (Paper 85, "Request" or "Req.") of our Final Written Decision (Paper 84, "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 three 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 improperly relied on new theories that Petitioners raised for the first time in the Reply to find a different motivation to combine prednisone with abiraterone acetate; and third, whether the Board misapprehended the 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 "misapprehended the significance of Petitioner's admission that ketoconazole does not cause mineralocorticoid excess." Req. 3. Patent Owner indicates that, in its Response, it argued ketoconazole did not cause mineralocorticoid excess, and pointed to prior art that showed ketoconazole suppressed production of mineralocorticoids. *Id.* at 5 (citing PO Resp. 18–19). Patent Owner argues that the Board's focus on the fact that ketoconazole would inhibit production of cortisol misapprehended that the Petition "did not portray the supposed inhibition of the production of cortisol as an 'independent' reason" to administer prednisone with abiraterone acetate. *Id.* at 6–7.

We considered this evidence and argument in our Final Written Decision, particularly noting Patent Owner's argument that "there is no prior art evidence that ketoconazole causes mineralocorticoid excess." Dec. 17 (citing PO Resp. 18). We also considered Petitioner's countervailing evidence (*id.* at 17–18), Patent Owner's Identification of New Arguments and Evidence in Petitioner's Reply (Paper 65), and Petitioner's reply to the same (Paper 74). We also noted in our Final Written Decision that Petitioner's motivation to combine appeared to be premised on the adverse effects caused by reduced production of cortisol. Dec. 13. We also relied, in the Final Written Decision, on Dr. Garnick's testimony that CYP17 inhibitors undesirably suppressed the production of cortisol, which is necessary for other biochemical cycles in the body, and which led to adverse

side effects. *Id.* at 12–13 (citing Ex. 1002 ¶¶ 42, 44, 58). We also relied on Dr. Garnick's testimony that "in light of steroid synthesis inhibitors' known effects on the adrenal pathways," one of ordinary skill in the art "would have been motivated to administer a glucocorticoid with administered abiraterone acetate to counteract expected endocrine disruptions." Dec. 17 (citing Ex. 1097 ¶¶ 21–66). We expressly addressed Petitioner's arguments and evidence, Patent Owner's arguments and evidence, and the respective testimony on this issue, and did not overlook Patent Owner's testimony or other testimony regarding the relationship between ketoconazole and mineralocorticoid excess. Nor are we persuaded, given our consideration and analysis of the testimony and other evidence, that we misapprehended the import of this testimony and evidence, or Petitioner's reliance on the same for Petitioner's arguments to support motivation to combine the relied-upon references.

(B) Patent Owner's Second Argument

Patent Owner argues that the Board overlooked or misapprehended evidence that abiraterone acetate does not cause adrenal insufficiency. Req. 11. Patent Owner argues that the Board relied on Petitioner's new theory, presented for the first time in the Reply, that skilled person would have been motivated to combine abiraterone acetate with prednisone because abiraterone acetate might cause "adrenal insufficiency" and/or a "low adrenal reserve." *Id.* Patent Owner also faults the Board for overlooking or misapprehending the Synacthen test results and the follow-on abiraterone acetate monotherapy study. *Id.* at 13.

As noted above, we considered Patent Owner's Identification of New Arguments (Paper 74) in rendering our Final Written Decision, as well

Petitioner's Reply (Paper 78) and the arguments presented by both parties on this issue. Dec. 2, 16–19; *see also Ericsson Inc. v. Intellectual Ventures I LLC*, 901 F.3d 1374, 1380 (Fed. Cir. 2018) (stating that reply arguments should not be parsed "with too fine a filter"). The arguments and evidence identified in Patent Owner's second argument here are part of a broader argument concerning cortisol deficiency as a result of abiraterone acetate and/or ketoconazole activity. We stated in the Final Written Decision that "we understand that ketoconazole and abiraterone acetate do not have identical mechanisms," but noted that the parties "appear to agree that, based on their respective mechanisms of action, administration of ketoconazole would inhibit production of cortisol, and administration of abiraterone acetate inhibits one of the pathways of cortisol production." Dec. 18 (citing Pet. 26; Tr. 12:18–19; Ex. 1003, 2318). We also considered and discussed the results of the Synacthen test. Dec. 20–22. Patent Owner's disagreement with our conclusions is not a proper basis for a rehearing request. Thus, our Final Written Decision, as part of a broader inquiry, looked not only at the differences, but also at the similarities, of the mechanisms of ketoconazole and abiraterone, and to the comparative discussions of both in the prior art, to determine that one of ordinary skill would have been aware of the differences and the similarities in the mechanisms. Dec. 18 (citing Ex. 1003, 2318, Figure 1). We are not persuaded that this constitutes overlooking or misapprehending aspects of Patent Owner's argument concerning cortisol deficiency.

Patent Owner also argues in the introduction of its second argument (Req. 2) that the Board disregarded the presumption of validity that patents—including those undergoing inter partes review—are entitled to

under 35 U.S.C. § 282. Patent Owner further argues that the Board overlooked or misapprehended that evidence that skilled artisans evaluated O'Donnell and nevertheless proceeded to undertake studies based on abiraterone acetate monotherapy. Req. 13. Patent Owner, however, does not point us to where these argument were raised previously. 37 C.F.R. § 42.71(d). Therefore, Petitioners did not have an opportunity to respond to these issues. Nor did Patent Owner previously address the question of why the presumption of validity in 35 U.S.C. § 282 controls inter partes review proceedings in light of the statement in 35 U.S.C. § 316(e) that "In an inter partes review instituted under this chapter, the petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence." Accordingly, because Patent Owner does not demonstrate that these arguments were raised previously, and because we cannot be assured that Petitioner has had any opportunity to respond, we do not consider these arguments in our present order.

(C) Patent Owner's Third Argument

Patent Owner argues that the Board misapprehended that the prior art does not teach or suggest a 1000 mg abiraterone acetate dose. Req. 14. More particularly, Patent Owner faults the Board for adopting Petitioners' assertions made in support of its arguments that a skilled person would have been motivated to increase the dose of abiraterone acetate disclosed in the prior art references. *Id.* at 15*; see also* Dec. 43 ("We also have considered Petitioner's arguments and evidence as to dependent claims 2–20, which reasoning we adopt as our own.").

Patent Owner now presents a new argument that we misapprehended the teachings of the prior art with respect to claims 4, 11, 19, and 20.

Req. 14–15. Patent Owner, however, does not point out where this matter was previously raised. Because Patent Owner has not previously raised any of its arguments presented in the Request, we are not permitted to consider its arguments now. 37 C.F.R. § 42.71(d). Moreover, we did not overlook Patent Owner's arguments regarding these claims; rather, we considered and adopted Petitioner's arguments regarding these claims. Dec. 43; *cf. Cutsforth, Inc. v. Motive Power, Inc.*, 636 F. App'x 575 (Fed. Cir. 2016) (nonprecedential). Patent Owner's failure to argue specifically against these claims during trial does not permit Patent Owner to now present arguments in this regard.

IV. CONCLUSION

We have reviewed and considered the arguments in Patent Owner's Request and conclude that Patent Owner has not carried its burden of demonstrating that the Board misapprehended or overlooked any matters in rendering the Final Written Decision. 37 C.F.R. § 42.71(d). Rather, Patent Owner uses its Request as an opportunity to argue positions with which we disagreed in our Final Written Decision. Merely disagreeing with our analysis or conclusions does not serve as a proper basis for a request for rehearing. Patent Owner also uses its Request to raise matters without adequately demonstrating where those matters previously were raised. Thus, Patent Owner's challenge does not meet the standard set forth for a request for rehearing.

The Request for Rehearing is *denied*.

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