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Paper 76
Entered: December 3, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

WOCKHARDT BIO AG,
Petitioner,

v.

JANSSEN ONCOLOGY, INC.,
Patent Owner.

Case IPR2016-01582
Patent 8,822,438 B2

Before JEFFREY N. FREDMAN, KRISTINA M. KALAN and JACQUELINE T. HARLOW, *Administrative Patent Judges*.[1]

KALAN, *Administrative Patent Judge*.

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

[1] A Panel Change Order issued on September 28, 2018, indicating that the judges named herein now constitute the panel. Paper 75.

I. INTRODUCTION

Janssen Oncology, Inc. ("Patent Owner") filed a Request for Rehearing (Paper 73, "Request" or "Req.") of our Final Written Decision (Paper 72, "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 issues with our Final Written Decision, which Patent Owner groups into two arguments: first, whether the Board misapprehended evidence regarding Petitioner's reasoning for administration of prednisone with abiraterone acetate and whether the Board overlooked or misapprehended the evidence regarding motivation to combine abiraterone acetate with prednisone based on the teachings of Sartor; and second, whether the Board misapprehended Petitioner's arguments as to the 1000 mg dose of abiraterone acetate in claims 4, 11, 19, and 20. Req. 1–4.

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 Arguments

Patent Owner argues that the Board "misapprehended or overlooked that Petitioner's admissions negated the motivation to combine in the Petition." Req. 4. Patent Owner argues that the Board overlooked Dr. Godley's testimony that "no treating physician would prescribe prednisone alone as an anti-cancer agent to a patient with prostate cancer" (Ex. 1002 ¶ 116), which Patent Owner argues is an admission "at odds with the Board's findings." *Id.* at 6. Patent Owner further argues that we overlooked that Dr. Godley testified that Sartor is just a chart review that a skilled researcher would not rely on. *Id.* at 7. Patent Owner also argues that the Board advanced a new "palliation"-based motivation theory. *Id.* at 7–8. In sum, Patent Owner argues that the Board overlooked or misapprehended the evidence demonstrating there was no motivation to combine abiraterone acetate with prednisone based on the teachings of Sartor. Req. 11–12.

In our Final Written Decision, in connection with our assessment of motivation to combine Sartor with Gerber and O'Donnell, we addressed the disputed portion of Dr. Godley's testimony directly. Dec. 26 ("Fourth, Patent Owner argues that Petitioner's expert agrees that prednisone was not known to have anti-cancer treatment effects in prostate cancer patients.") There, we agreed with Petitioner that Dr. Godley's interpretation of Sartor was "consistent with Petitioner's position regarding Sartor, i.e., that

prednisone has its own anti-cancer effect." *Id.* (citing Ex. 1002 ¶ 116; Ex. 2162, 61:15–62:17). Patent Owner's disagreement with our analysis is not a proper basis for a rehearing request. Regarding the Board's consideration of Sartor's credibility, we evaluated the evidence and testimony before us to conclude that, despite the fact that Sartor was a chart review, it is a "peer-reviewed article published in a reputable journal" and its format did not undercut its teachings. Dec. 24. Regarding the Board's use of the word "palliative," we disagree that such use constitutes a new theory advanced by the Board. Req. 7–8. Rather, we used the term "palliative" three times in the Final Written Decision—once to accurately quote the language used by Dr. Godley in his Declaration (Dec. 26 (citing Ex. 1002 ¶ 116)), once to accurately quote Dr. Godley's testimony (Dec. 26–27 (citing Ex. 2162, 66:1–10, 66:17–67:1), and once in our discussion of claim construction (Dec. 33). None of these instances advances a new theory. Although we noted that Dr. Godley stated that prednisone could be prescribed for palliative treatment in reconciling that statement with our claim construction (*id.* at 26–27), we relied on Petitioner's arguments in chief regarding reasons to combine Gerber, O'Donnell, and Sartor in reaching our ultimate determination of unpatentability. *Id.* at 11–13.

Patent Owner also argues 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. Req. 3–4, 10–11. Patent Owner, however, does not point us to where this argument was raised previously. 37 C.F.R. § 42.71(d). Therefore, Petitioners did not have an opportunity to respond to this issue, 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 this argument was raised previously and because we cannot be assured that Petitioner has had any opportunity to respond, we do not consider this argument in our present order.

We considered the disputed evidence and argument in our Final Written Decision, and thus, we are not persuaded that we overlooked it. Dec. 26. We also are not persuaded by Patent Owner's arguments that we misapprehended the evidence and arguments, or that we improperly created a new theory. In sum, we are not persuaded by Patent Owner's arguments that we should grant a request for rehearing based on this group of arguments.

(B) Patent Owner's Second Argument

Patent Owner argues that the Board misapprehended that the prior art did not teach or suggest a 1000 mg abiraterone acetate dose as required by claims 4, 11, 19, and 20. Req. 12. 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 13; *see also* Dec. 45 ("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.

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