

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMERIGEN PHARMACEUTICALS LIMITED,
Petitioner,

v.

JANSSEN ONCOLOGY, INC.,
Patent Owner.

Case IPR2016-00286
Patent 8,822,438 B2

Before LORA M. GREEN, RAMA G. ELLURU, and
KRISTINA M. KALAN, *Administrative Patent Judges*.

KALAN, *Administrative Patent Judge*.

DECISION
Patent Owner's Request for Rehearing
37 C.F.R. § 42.71

I. INTRODUCTION

Patent Owner Janssen Oncology, Inc. (“Patent Owner”) filed a Request for Rehearing (Paper 16, “Req.”). In rendering the Decision to Institute (Paper 14, “Dec.”), we instituted an *inter partes* review as to claims 1–20 of U.S. Patent No. 8,822,438 B2 (Ex. 1001, “the ’438 patent”). In its Request for Rehearing, Patent Owner contends that the Board should grant rehearing and decline to institute *inter partes* review of claims 1–20 of the ’438 patent. Req. 1.

For the reasons set forth below, Patent Owner’s request for rehearing is *denied*.

II. ANALYSIS

A request for rehearing must identify specifically all matters the party believes the Board misapprehended or overlooked, and the place where each matter was addressed previously in a motion, an opposition, or a reply. 37 C.F.R. § 42.71(d). The Board applies an abuse of discretion standard in reviewing institution decisions. 37 C.F.R. § 42.71(c).

In its Request for Rehearing, Patent Owner contends that (1) the Decision to Institute ignores Petitioner’s admissions that the prior art does not teach or suggest the claim element “a therapeutically effective amount of prednisone” (Req. 5–10); and (2) the Board fails to credit the Patent Office’s prior determination of commercial success and Petitioner’s admission of unexpected results (*id.* at 10–13). We disagree.

We instituted *inter partes* review on two obviousness grounds asserted by Petitioner in the Petition. Dec. 19. In doing so, we determined that Petitioner had demonstrated a reasonable likelihood of prevailing with respect to its challenge of claims 1–20 of the ’438 patent. *Id.* In our

Decision to Institute, we construed the terms “treat,” “treating,” and “treatment” to “include the eradication, removal, modification, management or control of a tumor or primary, regional, or metastatic cancer cells or tissue and the minimization or delay of the spread of cancer.” *Id.* at 5. We construed the phrase “therapeutically effective amount of prednisone” to mean “an amount of prednisone effective for treating prostate cancer.” *Id.* at 7.

With respect to its first contention, Patent Owner argues that “every challenged claim requires administering “a therapeutically effective amount of prednisone.” Req. 5. Patent Owner argues, therefore, that

in keeping with its claim construction, in order to conclude that petitioner had demonstrated a reasonable likelihood of prevailing in its obviousness challenge under 35 U.S.C. § 314(a), the Board was required to determine if petitioner is likely to show at trial that the prior art patents and publications relied upon teach or suggest the claimed co-administration including a “therapeutically effective amount of abiraterone acetate,” and, separately, “an amount of prednisone effective for treating [*i.e.*, having an *anti-cancer effect on*] prostate cancer.

Id. at 6. Patent Owner’s related arguments expound on Petitioner’s failure to demonstrate that prednisone must have a “therapeutic anti-cancer effect.” *Id.* at 7–10.

Although Patent Owner does not advocate for a new claim construction in its Request for Rehearing, its arguments are based on a construction that we have not adopted, namely, that “treating” must mean “having an anti-cancer effect on.” *Id.* A Request for Rehearing is not an opportunity to present a new argument about claim construction, notwithstanding its framing as a matter that we addressed in our Decision to Institute. We are

not persuaded by Patent Owner's argument that we should revisit, on rehearing, our determination about the constructions of any terms in view of the arguments presented in the Request for Rehearing. In view of our claim constructions in the Decision to Institute, we considered both Petitioner's and Patent Owner's arguments and determined that Petitioner had demonstrated a reasonable likelihood of prevailing on its assertions. We are unpersuaded that this constitutes an abuse of discretion.

With respect to Patent Owner's second contention, we stated in our Decision to Institute:

The issue of secondary considerations is highly fact-specific. At this stage of the proceeding, the record regarding such secondary considerations is incomplete. Based on the record before us, we determine that Patent Owner's evidence of secondary considerations is insufficient to preclude trial. Such evidence of secondary considerations should be more fully evaluated in the context of a trial when the ultimate determination of obviousness is made.

Dec. 15.

Patent Owner argues that "the PTO previously determined that the invention of the '438 patent was commercially successful" and that "the preexisting record establishing commercial success is complete." Req. 10–11. We disagree. In an *inter partes* review proceeding, we are not bound by an Examiner's determinations in the prosecution of a patent. To the extent Patent Owner presented evidence that the Examiner had reasons for allowing the claims based on secondary considerations, we have considered that evidence in rendering our Decision to Institute.

In reaching our determination in the Decision to Institute, we acknowledged Patent Owner's arguments regarding secondary

considerations. Dec. 15. Accordingly, we did not overlook these arguments. Nor did we misapprehend Patent Owner's secondary considerations arguments. Our review of secondary considerations took into account pre-emptive arguments raised by the Petitioner as well as Patent Owner's arguments related to unexpected results, long-felt need, and commercial success. *Id.* We found, nevertheless, that Patent Owner's evidence was insufficient to preclude trial, and that Petitioner had established a reasonable likelihood of prevailing on its challenges. *Id.* at 15–16. It is a matter of discretion to proceed or not to proceed with any ground, and Patent Owner has not demonstrated that we abused that discretion.

For the forgoing reasons, Patent Owner has not shown that the Board misapprehended or overlooked any matter in instituting trial in this proceeding.

III. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Patent Owner's request for rehearing is *denied*.

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