

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GENOME & COMPANY
Petitioner,

v.

THE UNIVERSITY OF CHICAGO
Patent Owner.

PGR2019-00002
Patent 9,855,302 B2

Before SHERIDAN K. SNEDDEN, SUSAN L.C. MITCHELL, and
JOHN E. SCHNEIDER, *Administrative Patent Judges*.

SCHNEIDER, *Administrative Patent Judge*.

DECISION

Denying Patent Owner's Request on Rehearing of Decision Granting
Institution
37 C.F.R. § 42.71(d)

I. INTRODUCTION

The University of Chicago (“Patent Owner”) filed a Request for Rehearing (Paper 11, “Reh’g Req.”) of our Decision on Institution of Post-Grant Review (“Decision”), holding that Petitioner has established a reasonable likelihood that it would prevail in showing that claims 1–29 of U.S. Patent No. 9,855,302 B2 (Ex. 1001, “the ’302 patent”) are unpatentable.

Patent Owner requests rehearing arguing that we (1) improperly excused Petitioner from its burden of presenting evidence that the asserted experimentation was undue and not routine; (2) improperly shifted the burden to Patent Owner; (3) misapprehended Patent Owner’s argument that Petitioner had failed to show that Kohwi’s bacteria are immunostimulatory; (4) misapprehended Patent Owner’s argument that the record as a whole does not support Petitioner’s assertion that Kowhi’s bacteria are immunostimulatory; (5) misapprehended Patent Owner’s argument regarding Mohania. Reh’g Req. 1–14.

For the reasons stated below, Patent Owner’s request is *denied*.

II. STANDARD OF REVIEW

The party requesting rehearing has the burden to show that the decision should be modified. Under 37 C.F.R. § 42.71(d), the request for rehearing must identify, specifically, 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. When rehearing a decision on a petition, we review the decision for an abuse of discretion. 37 C.F.R. § 42.71(c). An abuse of discretion may arise if a decision is based on an erroneous interpretation of law, if a factual finding is not supported by

substantial evidence, or if an unreasonable judgment is made in weighing relevant factors. *In re Gartside*, 203 F.3d 1305, 1315-16 (Fed. Cir. 2000).

III. ANALYSIS

A. Enablement

Patent Owner contends that we erred in finding that Petitioner had demonstrated that it was more likely than not that the challenged claims were not enabled. Reh'g. Req. 3. Patent Owner contends that we ignored Patent Owner's argument that Petitioner had failed to present any evidence that the experimentation needed to practice the claimed invention would not involve repetition of known or commonly used techniques. *Id.* at 4–5. Patent Owner contends that the statements by Petitioner's expert alone are insufficient to establish that the experimentation required was undue. *Id.*

Patent Owner also contends that we improperly shifted the burden of proof to Patent Owner on the issue of enablement. *Id.* at 4–6. Patent Owner argues that by permitting Petitioner to show non-enablement without proof of undue experimentation, we have improperly forced Patent Owner to present evidence showing enablement. *Id.*

We are not persuaded that we misapprehended or overlooked Patent Owner's argument. As we noted in our Decision, the issue of whether undue experimentation is required to practice the claimed invention is evaluated using the factors outlined in *In re Wands*, a fact based inquiry. Dec. 8. Our conclusion for purposes of institution that undue experimentation would be required to practice the claimed invention was based, not only on Dr. Braun's statement to that effect, but on the detailed analysis presented by Petitioner and Dr. Braun of all of the *Wands* factors as supported by the evidence of record. Dec. 14–15.

We considered Patent Owner’s argument that Petitioner had failed to show that the experimentation required was other than routine and found it unpersuasive at the institution stage of the proceeding. *Id.* Patent Owner’s argument was based on the premise that Dr. Braun’s opinion regarding non-enablement was based on the number of experiments and not whether the experiments were routine. Prelim. Resp. 2–4. This argument ignores the fact that our consideration of Dr. Braun’s opinion was based on an analysis of all of the *Wands* factors, a fact based inquiry that includes analyzing the minimal guidance presented in the Specification and the unpredictability of cancer treatments and unpredictable nature of CPIS, and not merely the number of experiments required. *Id.* at 15; Ex. 1002 ¶ 166; *In re Morsa*, 713 F.3d 104, 109 (Fed. Cir. 2013) (“Enablement is a question of law based on underlying factual findings.”). Although we acknowledge Patent Owner’s argument in support of its position that the claimed subject matter is enabled, we remind Patent Owner that, for purposes of deciding whether to institute a post-grant review, we view a genuine issue of material fact in the light most favorable to the petitioner. 37 C.F.R. § 42.208(c). As Patent Owner offered attorney argument concerning enablement based on the current record, we resolved the parties’ dispute regarding enablement for which Petitioner offered Dr. Braun’s opinion as supported by evidence of record in favor of Petitioner.

With respect to the issue of burden of proof, we begin by noting that the burden of establishing unpatentability remains with Petitioner and our decision to institute does not shift that burden. The standard we apply in deciding whether to institute post-grant review is whether “the information presented in the petition filed under section 321, if such information is not rebutted, would demonstrate that it is more likely than not that at least 1 of

the claims challenged in the petition is unpatentable.” 35 U.S.C. § 324(a). As discussed in our Decision, Petitioner has presented a detailed analysis of the *Wands* factors showing that the challenged claims are not enabled based on the evidence of record. Dec. 9–13. Patent Owner did not present additional evidence to rebut the information presented in the Petition, but chose to respond with an argument that Petitioner had not presented sufficient evidence to support a conclusion of non-enablement. Pet. 3–6. In our decision we addressed Patent Owner’s argument and found it to be unpersuasive in light of the information presented in the Petition. Dec. 14–15. Our Decision is consistent with the standard for instituting post-grant review set forth in the statute.

Patent Owner contends that we should reconsider our decision to institute to avoid having Patent Owner address Petitioner’s legally insufficient enablement challenge. Reh’g. Req. 6–9. Patent Owner further contends that we should exercise our discretion and deny the Petition to help maintain the integrity of the patent system and promote fairness. *Id.* We have considered Patent Owner’s new arguments and are not persuaded. Those arguments were not previously raised in the Preliminary Response, and a request for rehearing is not the proper vehicle to set forth new argument.

B. Obviousness based on Kohwi

Patent Owner contends that we misapprehended its arguments with regards to the teachings of Kohwi. Reh’g. Req. 9–13. Patent Owner contends that we misapprehended Patent Owner’s argument that Petitioner failed to show that the bacteria used by Kohwi were immunostimulatory. *Id.* at 9. Patent Owner contends that we overlooked Patent Owner’s argument

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