

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

GILEAD SCIENCES, INC.,
Petitioner,

v.

REGENTS OF THE UNIVERSITY OF MINNESOTA,
Patent Owner.

IPR2017-01753
Patent 8,815,830 B2

Before ERICA A. FRANKLIN, ZHENYU YANG, and
CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

Opinion for the Board filed by *Administrative Patent Judge* YANG.

Opinion Dissenting filed by *Administrative Patent Judge* PAULRAJ.

YANG, *Administrative Patent Judge*.

DECISION

Denying Petitioner's Request for Rehearing of Decision Denying Institution
37 C.F.R. § 42.71(d)

INTRODUCTION

Gilead Sciences, Inc. (“Petitioner”) filed a Petition (Paper 1 (“Pet.”)), seeking an *inter partes* review of claims 1–9, 11–21, 23, 24, and 26–28 of U.S. Patent No. 8,815,830 B2 (Ex. 1101, “the ’830 patent”). We denied the Petition. Paper 42 (“Dec.”). Petitioner filed a request for rehearing of the Decision, along with Exhibits 1135–1137. Paper 43 (“Req. Reh’g”). For the reasons discussed below, we deny Petitioner’s request for rehearing.¹

STANDARD OF REVIEW

The party challenging a decision in a request for rehearing bears the burden of showing the decision should be modified. 37 C.F.R. § 42.71(d). A request for rehearing “must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed.” *Id.* When rehearing a decision on institution, the Board reviews the decision for an abuse of discretion. 37 C.F.R. § 42.71(c). It is not an abuse of discretion to have made an analysis or conclusion with which a party disagrees. Instead, an abuse of discretion occurs if a decision is based on an erroneous interpretation of law, if a factual finding is not supported by substantial evidence, or if the decision represents an unreasonable judgment in weighing relevant factors. *Arnold P’ship v. Dudas*, 362 F.3d 1338, 1340 (Fed. Cir. 2004).

ANALYSIS

In the Decision Denying Institution, we determined that Petitioner did not demonstrate a reasonable likelihood of success in showing that the challenged claims would have been obvious over the asserted combination

¹ Petitioner also filed a request for Precedential Opinion Panel Review. *See* Paper 44. That request was denied. Paper 45.

of the '985 patent, Maruyama, and Sato. *See* Dec. 14–23. In its Request for Rehearing, Petitioner contends that our determination not to institute an *inter partes* review is improper for two reasons. First, Petitioner argues that we misapprehended the weight afforded to the evidence submitted by Petitioner and Patent Owner. Reh'g Req. 2–6. Second, Petitioner argues that we misapprehended the scope and content of the prior art as viewed by a person of ordinary skill in the art. *Id.* at 6–15. We address each of these arguments in turn.

Weight Afforded to the Evidence Submitted by the Parties

Petitioner argues that Rule 42.108(c) applies broadly and is not limited to testimonial evidence. Reh'g Req. 2–3. According to Petitioner, the Majority “perceived that a dispute of material fact existed regarding what a POSA would understand the prior art’s teachings to be.” *Id.* at 2 (citing Dec. 21, 23). “But rather than resolve this genuine dispute in the light most favorable to the Petitioner,” Petitioner continues, “the Majority deferred to Patent Owner’s attorney argument and denied institution.” *Id.* We are not persuaded.

Under Rule 42.108(c),

The Board’s decision will take into account a patent owner preliminary response where such a response is filed, including any testimonial evidence, but a genuine issue of material fact created by such testimonial evidence will be viewed in the light most favorable to the petitioner solely for purposes of deciding whether to institute an *inter partes* review.

Thus, under the Rule, it is only genuine issues of material fact created by testimonial evidence provided by a patent owner with its preliminary response that we view “in the light most favorable to the petitioner.”

37 C.F.R. § 42.108(c) (2017).² Because Patent Owner did not provide testimonial evidence in this proceeding, there is no “genuine issue of material fact created by such testimonial evidence.”

Accepting Petitioner’s argument that we must always resolve any genuine dispute of material fact in the light most favorable to the petitioner would compel institution in every case where a petitioner presents un rebutted expert testimony. But a patent owner has no obligation to rebut the petitioner’s contentions or to submit an expert declaration rebutting the petitioner’s expert testimony. *See* 37 C.F.R. §§ 42.107(a) (“The patent owner *may* file a preliminary response to the petition.” (emphasis added)); 42.108(c) (“The Board’s decision will take into account a patent owner preliminary response *where such a response is filed, including any testimonial evidence.*” (emphasis added)). And the Board is not required to accept every statement made by a petitioner’s expert as established fact simply because the patent owner does not submit contradictory expert testimony. *Fanduel, Inc. v. Interactive Games LLC*, 966 F.3d 1334, 1344 (Fed. Cir. 2020). Instead, “it is the Board’s duty to independently assess the strength of a petitioner’s argument and evidence.” *Id.*, *see also id.* (“[I]n every case, it remains the Board’s essential function to make factual findings based on its view of the record.”).

² This Rule has recently been amended. The new Rule no longer provides for a presumption in favor of a petitioner for a genuine issue of material fact created by testimonial evidence submitted with a patent owner’s preliminary response. *See* 85 Fed. Reg. 79120, 79129 (December 9, 2020). The new Rule, however, does not apply here as it will not become effective until January 8, 2021. *Id.* at 79120. In any event, the outcome of this case remains the same under either Rule.

Petitioner argues that the Majority erred by relying on “attorney arguments alone about how a person of skill would have viewed” the art. Reh’g Req. 5. According to Petitioner, the Majority relied “on Patent Owner’s attorney arguments characterizing two references presented for the first time in Patent Owner’s preliminary response.” *Id.* at 5–6. We are not persuaded.

In the Decision denying institution, we concluded that the evidence before us did not support Petitioner’s alleged reasons to modify the references (Dec. 16–22), nor establish a reasonable expectation of success of doing so (*id.* at 22–23). In reaching this conclusion, we did not rely solely on references presented by Patent Owner. Instead, we mainly relied on the express teachings of the art cited by Petitioner, including Marquez I and Marquez II. *Id.* at 17–20. Our plain reading of the prior art persuades us that Petitioner has not demonstrated a reasonable likelihood of prevailing in its patentability challenge. *See Rovalma, S.A. v. Bohler-Edelstahl GmbH & Co. KG*, 856 F.3d 1019, 1027 (Fed. Cir. 2017) (noting that the Board is not precluded “from relying on arguments made by a party and doing its job, as adjudicator, of drawing its own inferences and conclusions from those arguments, even when the result is use of the party’s submissions against it”).

In sum, we are not persuaded that we misapprehended the weight afforded to the evidence submitted by Petitioner and Patent Owner.

Scope and Content of the Prior Art

Petitioner contends the Board “misapprehended how a POSA would have understood Meier and Marquez III in 2004, including overlooking critical statements and data that contradict its own conclusion that a 2’ fluoro

down ‘destroys the activity and increases the toxicity.’” Reh’g Req. 6 (citing Dec. 21). Petitioner contends that its expert’s testimony “addressed a POSA’s understanding of the prior art as a whole in 2004” in contrast to Patent Owner’s preliminary response which “presented **no** evidence supporting a POSA’s perspective as of 2004.” *Id.* at 6–7. We are not persuaded by this argument either.

As in initial matter, as explained above, when denying institution, we relied mainly on the express teachings of Marquez I and Marquez II, both of which were cited by Petitioner, not Patent Owner. *See* Dec. 17–20.

Moreover, while the Board may appreciate receiving expert opinion from both sides to help it decide a case, no expert submissions are required. *See Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1079 (Fed. Cir. 2015) (“No rule requires . . . an expert guiding the Board as to how it should read prior art.”). Indeed, although expert testimony may be presented to help establish the scope and content of the prior art, expert testimony “cannot take the place of a disclosure in a prior art reference.” Patent Trial and Appeal Board Consolidated Trial Practice Guide (Nov. 21, 2019) (“Consolidated TPG”) 36.³ In the Decision, we considered the testimony of Petitioner’s expert in light of the other evidence of the record, including prior art cited by Petitioner. As discussed in the Decision, Petitioner’s argument, including the expert’s testimony, “fails to consider that the prior art as a whole, including references Petitioner relies on, teaches that substituting fluorine at the 2’ down position renders numerous anti-HIV compounds inactive, and increases their toxicity.” Dec. 23.

³ Available at <https://www.uspto.gov/sites/default/files/documents/tpgnov.pdf?MURL=>

Petitioner argues that the Majority ignored “other relevant compounds in Meier that, like compounds 5 and 6 of the ’985 patent, include a pronucleotide moiety at the 5’-position.” Reh’g Req. 8. Petitioner contends the Majority disregarded Meier’s additional teachings that “when the pronucleotide [sic] moiety was present at the 5’ position, compounds with a fluorine at the 2’ down position were some of the most active against HIV that Meier studied.” *Id.* at 10. According to Petitioner, an ordinarily skilled artisan would not “disregard such compounds in favor of nucleoside analogues without prodrug moieties at the 5’ position, let alone do so to draw the conclusion that the Majority does that **ALL** compounds with a 2’-fluoro down are inactive.” *Id.* at 11. We are not persuaded by Petitioner’s argument.

First, the Decision did not conclude that the prior art teaches that *all* compounds with a 2’-fluoro down substitution are inactive. Rather, we determined that: (1) “substituting fluorine at the 2’ down position of *several* compounds with anti-HIV activity not only renders the compounds inactive, but also increases their toxicity;” (2) “fluorine atoms at the same positions, but with inverted stereochemistry, *consistently* produced inactive compounds;” and (3) “substituting fluorine at the 2’ down position renders *numerous* anti-HIV compounds inactive, and increases their toxicity.” Dec. 17, 21, 23 (emphases added). Simply put, the prior art as a whole teaches that substituting fluorine at the 2’ position in the down orientation yields unpredictable results.

Second, the Petition argues that it would have been obvious to modify the ’985 patent in view of Maruyama and Sato, not in view of Meier. Pet. 40. Neither Maruyama nor Sato teaches compounds with pronucleotide moieties

at the 5'-position. Accordingly, Petitioner has not shown that the Board overlooked Meier's teachings as applied to modifying the '985 patent with Maruyama and Sato. *See In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1381 (Fed. Cir. 2016) (stating that the Board is not "free to adopt arguments on behalf of petitioners that could have been, but were not, raised by the petitioner during an IPR. Instead, the Board must base its decision on arguments that were advanced by a party, and to which the opposing party was given a chance to respond").

Petitioner further argues that "Marquez's later work highlighted the importance of ring orientation on biological activity" and "includes nucleosides with hydroxy groups at the 3' down position—just like those that Maruyama and Sato reported." Reh'g Req. 12–14. As support, Petitioner submits Exhibits 1135–1137. *See id.* at 12–14.

Exhibits 1135–1137 were not of record when we issued the Decision denying institution. Petitioner argues that good cause exists for the Board to consider these new exhibits because the exhibits "support Petitioner's testimonial evidence already of record about the proper view of the art and contradict Patent Owner's attorney argument." *Id.* at 13 n. 2.

Absent a showing of "good cause" prior to filing the request for rehearing or in the request for rehearing itself, new evidence will not be admitted. Consolidated TPG 90 (citing *Huawei Device Co., Ltd. v. Optis Cellular Tech., LLC*, IPR2018-00816, Paper 19 at 4 (Jan. 8, 2019) (precedential)). Here, we are not persuaded that there is good cause to consider Petitioner's new exhibits because they support the new argument that Marquez's later work includes nucleosides with hydroxy groups at the 3' down position. *See* Reh'g Req. 14. Petitioner does not explain how the

Board misapprehended or overlooked this new argument, or why Petitioner could not have submitted the new evidence and argument with the Petition. Accordingly, these exhibits should not be admitted and are not entitled to consideration. Consequently, we exercise our authority under 37 C.F.R. § 42.7(a) to expunge Exhibits 1135–1137.

In sum, we are not persuaded that we misapprehended how an ordinarily skilled artisan would have understood the scope and content of prior art.

CONCLUSION

For the foregoing reasons, Petitioner has not demonstrated that we abused our discretion, or that we misapprehended or overlooked any issue in denying institution of an *inter partes* review in this case.

ORDER

Accordingly, it is
ORDERED that Petitioner’s Request for Rehearing is *denied*; and
FURTHER ORDERED that, pursuant to 37 C.F.R. § 42.7(a),
Exhibits 1135–1137 are expunged from the record of this proceeding.

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PAULRAJ, *Administrative Patent Judge*, dissenting.

I respectfully dissent for the reasons previously stated in my dissent from the original Decision Denying Institution. In this rehearing decision, the majority declines to consider the new evidence that Petitioner cites in its request for rehearing. While I agree that a rehearing request is typically not the appropriate stage to introduce new evidence, the presence of such exhibits does highlight the fact that the majority resolved critical factual issues at the institution stage based on an incomplete record.

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