

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HOLOGIC, INC.,
Petitioner,

v.

BIOMÉRIEUX, INC.,
Patent Owner.

Case IPR2018-00568
Case IPR2018-00569
Patent 8,697,352 B2

Before JAMES T. MOORE, SUSAN L. C. MITCHELL, and
KRISTI L. R. SAWERT, *Administrative Patent Judges*.

SAWERT, *Administrative Patent Judge*.

DECISION

Denying Petitioner's Requests for Rehearing¹
37 C.F.R. § 42.71(d)

¹ Petitioner filed Requests for Rehearing in IPR2018-00568 and IPR2018-00569 that, other than for differences in paper citations, are identical. We exercise our discretion to issue a single Decision to be entered in each case using a joint caption. For efficiency, we refer only to the papers filed in IPR2018-00568. The parties are not permitted to use this caption.

I. INTRODUCTION

Petitioner filed a Petition for an *inter partes* review of claims 1–6 of U.S. Patent No. 8,697,352 B2 (“the ’352 patent,” Ex. 1002). Paper 1 (“Pet.”). The Board denied institution, deciding that it was proper to exercise its discretion under 35 U.S.C. § 325(d). Paper 9 (“Institution Decision” or “Instit. Dec.”), 2. Petitioner files a Request for Rehearing. Paper 10 (“Rehearing Request” or “Reh’g Req.”). For the following reasons, we deny Petitioner’s Rehearing Request.

II. STANDARD OF REVIEW

A party requesting rehearing bears the burden of showing that a decision should be modified. 37 C.F.R. § 42.71(d). The party must identify all matters it believes the Board misapprehended or overlooked, and the place where each matter was addressed previously in a motion, an opposition, or a reply. *Id.* When rehearing a decision on petition, we review the decision for an abuse of discretion. 37 C.F.R. § 42.71(c). An abuse of discretion occurs when a “decision was based on an erroneous conclusion of law or clearly erroneous factual findings, or . . . a clear error of judgment.” *PPG Indus. Inc. v. Celanese Polymer Specialties Co.*, 840 F.2d 1565, 1567 (Fed. Cir. 1988) (citations omitted).

III. DISCUSSION

Petitioner requests rehearing the decision declining to institute review. Petitioner argues that the Rehearing Request “focuses the 35 U.S.C. § 325(d) analysis on the Examiner’s legal error in finding unexpected results and the Board’s conclusion that there was no legal error by the Examiner.” Reh’g Req. 1. In particular, Petitioner argues:

This request focuses on the Board's erroneous analysis of the new arguments and evidence in the Petition showing that the Laayoun Declaration is not evidence of unexpected results because it lacks the required comparison of the claimed invention to the closest prior art. Because the Laayoun Declaration lacks a legal requirement for a showing of unexpected results, it cannot serve as a basis for establishing patentability over the prior art. Thus, the Petition established that the Examiner erred *as a matter of law* in allowing the claims based on his acceptance of the Laayoun Declaration as evidence of unexpected results. Petitioner requests reconsideration of the Decision because the Board repeated the Examiner's *legal error* and thus the Decision was based on an erroneous interpretation of law.

Id. at 2–3 (citing Pet. 52–54) (emphasis in original).

A. The Institution Decision

In declining institution of an *inter partes* review of claims 1–6 of the '352 patent, the Board determined that it should exercise discretion under 35 U.S.C. § 325(d). Instit. Dec. 2. The Board considered and weighed six non-exclusive factors relevant to § 325(d): (a) the similarities and material differences between the asserted art and the prior art involved during examination; (b) the cumulative nature of the asserted art and the prior art evaluated during examination; (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection; (d) the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art; (e) whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art; and (f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of prior art or arguments.

Id. at 11 (citing *Becton, Dickinson and Co. v. B. Braun Melsungen AG*, Case IPR2017-01586, Paper 8 at 17–18 (PTAB Dec. 15, 2017) (informative)).

The Board determined that these factors weighed in favor of denying institution because, *inter alia*: the Examiner considered the same prior art or prior art cumulative to Petitioner’s prior art during prosecution, *id.* at 12–13; the Examiner thoroughly considered the patentability of the ’352 patent’s claims over the lengthy period of prosecution, *id.* at 13–15; Petitioner’s arguments were substantially the same as the findings the Examiner made with respect to prior-art reference Montagnier, which is a strong (if not stronger) reference than the prior art Petitioner asserted in these Petitions for *inter partes* review, *id.* at 15–18; Petitioner failed to address §325(d) in the Petition, *id.* at 18; and Petitioner failed to persuade the Board that the Examiner erred in relying on the unexpected results shown in the Laayoun Declaration, *id.* at 18–21; *see also id.* at 21–22 (weighing the factors).

As to the final finding, the Board considered Petitioner’s argument that the Laayoun Declaration is not persuasive evidence of non-obviousness because the Declaration compares the claimed invention to Bell’s prior-art primers, rather than Backus’s “closest prior art” primers. *Id.* at 20–21. The Board explained that Petitioner bears the burden to prove unpatentability in an *inter partes* review, and had failed, in this case, to provide “some persuasive evidence that the claimed primers would not have been unexpectedly better than Backus’s primers.” *Id.* at 21. The Board noted that the Examiner was aware of Backus, but nevertheless “accepted Bell as the closest prior art.” *Id.* The Board “decline[d] to revisit that decision,”

because “Petitioner d[id] not persuade us that the Examiner erred in accepting that evidence as showing unexpected results.” *Id.* at 21–22.

B. Whether the Board Made an Error of Fact

Petitioner argues that the Board misapprehended the prosecution history because that prosecution history “provides no evidence that the Examiner decided Bell was closer prior art than Backus.” Reh’g Req. 3. For example, Petitioner argues that “the fact that the Examiner was aware of Backus’s primer sequences is not evidence that the Examiner . . . decided that Bell was closer prior art than Backus.” *Id.* at 4. Petitioner argues that the Examiner considered Bell’s primers merely “prior art” and “closely-related,” but not necessarily the “closest prior art.” *Id.* at 4–5 (citing Ex. 2001, 1868 ¶ 57, 1877). Petitioner also argues that Patent Owner could not have considered Bell the closest prior art because the Laayoun Declaration does not explicitly use the words “closest prior art.” *Id.* at 5 (citing Ex. 2001). We do not agree.

In the Institution Decision, the Board wrote that “the Examiner accepted Bell as the closest prior art, even though the Examiner had rejected the claims over Backus for disclosing a 30-mer oligonucleotide primer that encompasses the ’352 patent’s SEQ ID NO:5.” Instit. Dec. 21 (citing Ex. 2001, 1863–64 ¶ 45). In so doing, the Board made two findings: that the Examiner was aware of Backus’s primers, and that the Examiner was aware that, to be persuasive, unexpected results must be compared to the closest prior art. Petitioner fails to persuade us that either finding lacks substantial evidence in the record.

First, the record clearly shows that the Examiner used Backus as a prior-art reference during prosecution of the '352 patent, and thus had knowledge of the primers disclosed in that reference. *See, e.g.*, Ex. 2001, 1863–64 ¶ 45. Second, Petitioner presents no persuasive evidence that the Examiner was unaware of the requirement to compare the claimed invention to the closest prior art. *See PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1304 (Fed. Cir. 2008) (absent evidence to the contrary, “a qualified government agency [is] presumed to have properly done its job.” (quotation omitted)). From those factual findings, the Board reasonably inferred that the Examiner accepted Bell as the closest prior art. Instit. Dec. 21. Petitioner fails to persuade us that the Board’s findings lack evidentiary support, or that the inference therefrom was unreasonable.

C. Whether the Board Committed Legal Error

Petitioner argues that the Board “erred in declining to revisit the Examiner’s alleged decision that Bell’s primer pair was closer to the claimed invention than Backus’s primer pair absent evidence that the claimed primers would not have been unexpectedly better than Backus’s primers.” Reh’g Req. 10. Petitioner argues that Backus is, in fact, the closest prior art and that no evidence supports a conclusion that Bell is the closest prior art. *Id.* at 7–9. Petitioner argues that the Examiner erred by allowing the claimed subject matter in response to the Laayoun Declaration, and the Board compounded that error by placing the burden on Petitioner to prove the absence of unexpected results over the closest prior art. *Id.* at 11–12. “Where there is clear error by the Examiner,” Petitioner argues, “it is not proper for the Board to deny a petition under § 325(d).” *Id.* at 12 (citing

Neil Ziegmann, N.P.Z., Inc. v. Carlis G. Stephens, Case IPR2015-01860, Paper 13 at 9–10 (PTAB Sept. 6, 2017)); *see also id.* at 9 (citing *Ziegmann*). We do not agree.

First, we disagree with Petitioner’s characterization of the Board’s decision in *Ziegmann*. In that case, the Board reviewed panel decisions focusing on the “previously . . . presented to the Office” language of § 325(d), and “the amount of weight to be accorded any identified errors made by the Examiner with respect to the consideration of those previously presented prior art or arguments.” Paper 13 at 12. The Board highlighted two decisions—one in which the panel invoked § 325(d) and one in which the panel did not invoke § 325(d). *Id.* at 12–13 (citing *Unified Patents Inc. v. Berman*, Case IPR2016-01571, Paper 10 at 11–12 (PTAB Dec. 14, 2016); *Black & Decker (U.S.) Inc. v. Christy, Inc.*, Case IPR2015-00468, Paper 13 at 13 (PTAB June 24, 2015)).

The Board stated that these cases, and others, “make clear that numerous Board decisions have weighed *all relevant factors* in determining whether to exercise our discretion under Section 325(d).” *Id.* at 13 (emphasis added). Thus, *Ziegmann* stands for the proposition that the Board consider all relevant factors in determining whether to invoke its discretion under § 325(d); it does not, however, require the Board to institute *in every case* containing an Examiner error, regardless of the weight of other relevant factors present in the case. Moreover, institution of *inter partes* review is discretionary. *Harmonic Inc. v. Avid Tech, Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) (“the PTO is permitted, but never compelled, to institute an IPR proceeding”).

Second, we disagree with Petitioner’s argument that the Board “erroneously shifted the burden to Petitioner to prove there would have been no unexpected results over the closest prior art.” Reh’g Req. 13. At the outset, we reiterate our statement in the Institution Decision that Petitioner bears the burden in an *inter partes* review to prove that the issued claims are unpatentable. Instit. Dec. 21 (citing *In re Magnum Oil Tools Int’l*, 829 F.3d 1364, 1380–81 (Fed. Cir. 2016)); *see also Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (“In an IPR, the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.”); *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (“In an *inter partes* review, the burden of persuasion is on the petitioner to prove ‘unpatentability by a preponderance of the evidence,’ and that burden never shifts to the patentee.” (quoting 35 U.S.C. § 316(e))).

Here, Petitioner attempted to show that Bell is not the closest prior art by presenting schematics comparing the nucleotide sequences of Backus’s primers to Bell’s primers and repeating Dr. Linnen’s statements that he considered the Backus primer set “closer” to the claimed primer set than the Bell primer set. Pet. 52–54 (citing Ex. 1020 ¶¶ 317–327). But neither Petitioner nor Dr. Linnen attempted to explain—or present any evidence—that Backus’s primers would have achieved the same results as the claimed primers. *See* Instit. Dec. 21. Put differently, Petitioner’s bare assertions failed to establish a reasonable likelihood that Patentee’s unexpected results would have been any different when compared to Backus. *See Kao Corp. v. Unilever U.S., Inc.*, 441 F.3d 963, 970 (Fed. Cir. 2006) (calling patent

challenger Unilever’s argument that patentee Kao’s unexpected results were not compared to the closest prior art “not sustainable”: “Even if we were to conclude that Gangadharan was clearly the closest prior art, Unilever has not demonstrated, or even alleged, that Gangadharan achieved [the unexpected results] reported by Kao. . . . In the absence of such an allegation, any error made by the trial court in using Gueret for its comparison would be harmless.”).

Third, we note that Petitioner’s case appears to rely on an overly mechanical application of the “closest prior art.” *See* Reh’g Req. 6–12. Although unexpected results must be shown to be unexpected compared to the closest prior art, the Federal Circuit has warned against applying that requirement “so rigidly as to require [patentee] to identify and focus on just one prior art product when multiple, similar” products “existed or were described in the prior art.” *Tris Pharma, Inc. v. Actavis Labs. FL, Inc.*, 2019 WL 254418, at *7 (Fed. Cir. Jan. 16, 2019). Thus, as we stated in the Institution Decision, we decline to revisit the Examiner’s decision to accept the Laayoun Declaration absent some persuasive evidence that the claimed primers would not have been unexpectedly better than Backus’s primers. Instit. Dec. 21.

D. Summary

In summary, none of the arguments Petitioner presents in the Rehearing Request persuade us that the Board abused its discretion in invoking § 325(d) to deny the Petition.

IPR2018-00568
IPR2018-00569
Patent 8,697,352 B2

IV. ORDER

Accordingly, it is:

ORDERED that Petitioner's Rehearing Request is denied.

IPR2018-00568
IPR2018-00569
Patent 8,697,352 B2

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