

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MONOSOL RX, LLC,
Petitioner,

v.

ARIUS TWO, INC.,
Patent Owner.

Case IPR2014-00376
Patent No. 7,579,019 B2

Before SHERIDAN K. SNEDDEN, CHRISTOPHER L. CRUMBLEY, and
ZHENYU YANG, *Administrative Patent Judges*.

CRUMBLEY, *Administrative Patent Judge*.

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

Petitioner, Monosol RX, LLC, requests rehearing of our Final Written Decision (Paper 45, “Final Dec.”), made at the conclusion of an *inter partes* review trial, finding that claims 1–7 of U.S. Patent No. 7,579,019 B2 (Ex. 1001, “the ’019 patent”) had not been proven unpatentable. Paper 46, “Req. Reh’g.”

For the reasons that follow, the request is *denied*.

I. STANDARD OF REVIEW

A party dissatisfied with a decision of the Board may file a request for rehearing. 37 C.F.R. § 42.71(d). The party requesting rehearing has the burden of showing the decision should be modified, and “[t]he 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.” *Id.*

II. PROCEDURAL HISTORY

We begin by summarizing the relevant history of this proceeding; further details may be found in the Final Written Decision and our Decision on Institution (Paper 11, “Dec. on Inst.”).

Monosol’s Petition presented five proposed grounds of unpatentability, based on various combinations of five prior art references. Paper 1 (“Pet.”), 4. We instituted trial on three of those grounds, involving

Flockhart,¹ Babaian,² and Keith.³ Our Decision did not rely on the remaining two references, Heiber⁴ and Schiraldi.⁵ In some instances, the Petition presented a ground based entirely on one of these references, such as anticipation by Heiber (*id.* at 29); in others, the Petition presented grounds in the alternative, such as Keith “in view of any one of” Babaian, Flockhart, or Heiber, or Schiraldi” (*id.* at 32). In the latter case, Petitioner did not provide any reason for selecting from among “any one of” the secondary references, or distinguish the references in any significant way. *Id.*

Our denial of institution on particular grounds was based on the fact that we had determined to institute trial on other grounds, and Monosol had not explained why the grounds (such as anticipation by Heiber, or obviousness over Keith combined with Heiber or Schiraldi) were sufficiently distinctive from the instituted grounds. Dec. on Inst. 16, 20 n.2. We, therefore, exercised our discretion to deny these grounds as redundant of the instituted grounds. *Id.*

Monosol did not seek reconsideration of our decision not to institute trial on grounds involving Heiber or Schiraldi.

In instituting trial, we construed various terms in the challenged claims, but determined that other terms, such as “bioerodable device,” did

¹ U.S. Patent No. 5,298,256 to Flockhart et al. (Mar. 29, 1994) (Ex. 1008).

² U.S. Patent No. 4,713,239 to Babaian et al. (Dec. 15, 1987) (Ex. 1007).

³ U.S. Patent No. 4,764,378 to Keith et al. (Aug. 16, 1988) (Ex. 1011).

⁴ U.S. Patent No. 5,346,701 to Heiber et al. (Sept. 13, 1994) (Ex. 1009).

⁵ U.S. Patent No. 4,713,243 to Schiraldi et al. (Dec. 15, 1987) (Ex. 1010).

not require construction as they appeared to be immaterial to determining whether Monosol had established a reasonable likelihood of prevailing. *Id.* at 10. Following trial, however, we determined on the full record that “bioerodable device” required construction, as it was determinative of the instituted grounds of unpatentability. Final Dec. 6. We recognized that both parties had proffered constructions of the term, but these constructions focused on the “bioerodable” aspect of it; neither party had addressed whether the “device” was required to have more than one layer. *Id.* Upon review of the specification of the ’019 patent and its prosecution history, we determined that the broadest reasonable interpretation of “bioerodable device” in light of the specification of the ’019 patent is “a multilayer bioerodable device.” *Id.* at 7–12. Because none of prior art that formed the basis of the instituted grounds of unpatentability disclosed a multilayer device, we determined that Monosol had not established by a preponderance of the evidence that claims 1–7 of the ’019 patent were unpatentable over that art. *Id.* at 12–15.

III. DISCUSSION

A. The Request for Rehearing

Monosol requests rehearing of our Final Written Decision, namely our post-trial construction of “bioerodable device,” and asks that we consider the entirety of the prior art presented in the Petition, including Heiber and Schraldi. Req. Reh’g. 15. Specifically, Monosol contends that our adoption of a claim construction in our Final Written Decision violated that Administrative Procedure Act (5 U.S.C. § 551 *et seq.*, “APA”), because it

was a “changed” or “new” theory of which Monosol had no notice. *Id.* at 4–8. Second, Monosol argues that it presented prior art (Heiber and Schiraldi) that disclose multilayer devices which meet the Board’s adopted construction, and we should have instituted trial on these references. *Id.* at 11–14.

Importantly, Monosol does not contend in its Request that the Board’s adopted construction of “bioerodable device” was incorrect. Nor does Monosol contest our finding that, given this construction, none of the instituted prior art references of Flockhart, Babaian, and Keith discloses a “bioerodable device.”

*B. The Claim Construction Did Not Violate The
Administrative Procedure Act*

Monosol correctly notes that the Office is an “agency” that is subject to the APA. Req. Reh’g. 3. For support, Monosol cites *Progressive Cas. Ins. Co. v. Liberty Mut. Ins. Co.*, 625 Fed. Appx. 552 (Fed. Cir. 2015) (nonprecedential), in which our reviewing court recognized that, in the context of post-grant trials before the Board, the APA restricts our ability to “change theories in midstream without giving respondents reasonable notice of the change” and “the opportunity to present argument under the new theory.” 625 Fed. Appx. at 556–57 (quoting *Rodale Press, Inc. v. Fed. Trade Comm’n*, 407 F.2d 1252, 1256 (D.C. Cir. 1968)). Monosol contends that our construction of “bioerodable device” in the Final Written Decision was such a change in theory. Req. Reh’g. 11.

Subsequent to Monosol filing its Rehearing Request,⁶ the Federal Circuit decided *SAS Inst., Inc. v. ComplementSoft, LLC*, 825 F.3d 1341, 1343 (Fed. Cir. 2016). In *SAS*, the court addressed a final written decision by the Board that altered a claim construction previously adopted in the decision to institute. 825 F.3d at 1350–51. Citing the APA, the court found that the altered claim construction was a midstream change of theory: “It is difficult to imagine either party anticipating that already-interpreted terms were actually moving targets, and it is thus unreasonable to expect that they would have briefed or argued, in the alternative, hypothetical constructions not asserted by their opponent.” *Id.* at 1351.

At the outset, we note that the premise of Monosol’s argument—that we changed theories in our Final Written Decision—is incorrect. Our Decision on Institution did not articulate a construction for “bioerodable device,” or even state that we were not providing an express construction because the plain and ordinary meaning of the term controlled. Rather, we noted that an explicit construction was not necessary at that stage of the proceeding, because it was not material to resolving the question before us at the time: whether Monosol had established the reasonable likelihood of success required by 35 U.S.C. § 314 to institute trial. Dec. on Inst. 10–11. In this sense, our determination in the Decision on Institution was similar to a trial court’s ruling on a motion for preliminary injunction, and the

⁶ After issuance of *SAS*, Monosol requested authorization to file supplemental briefing to bring the decision to the Board’s attention. We declined, as the panel was already sufficiently familiar with the Federal Circuit’s holding.

associated determination of likelihood of success on the merits. In such situations, the Federal Circuit has acknowledged that a complete claim construction may be premature. *Sofamor Danek Grp., Inc. v. DePuy-Motech, Inc.*, 74 F.3d 1216, 1221 (Fed. Cir. 1996) (“the trial court has no obligation to interpret [a claim] conclusively and finally during a preliminary injunction proceeding. . . . A trial court may exercise its discretion to interpret the claims at a time when the parties have presented a full picture of the claimed invention and prior art.”) (citing *Ill. Tool Works, Inc. v. Grip-Pak, Inc.*, 897 F.2d 1572, 1575 (Fed. Cir. 1990)).

We do not understand SAS to hold to the contrary. Indeed, the Federal Circuit explicitly recognized that the Board is free to adopt new claim constructions in its final written decisions. See SAS, 825 F.3d at 1351. This is consistent with longstanding precedent that tribunals “may engage in a rolling claim construction, in which the court revisits and alters its interpretation of the claim terms as its understanding of the technology evolves.” *Jack Guttman, Inc. v. Kopykake Enters., Inc.*, 302 F.3d 1352, 1361 (Fed. Cir. 2002) (citing *Sofamore Danek Grp.*, 74 F.3d at 1221). The problem with the final written decision in SAS was that it *altered* a previously-adopted claim construction, in which the parties had a settled expectation. See SAS, 825 F.3d at 1351 (“What concerns us is *not* that the Board adopted a construction in its final written decision . . . but that the Board ‘change[d] theories in midstream.’ . . . It is difficult to imagine either party anticipating that *already-interpreted terms* were actually moving targets” (emphasis added) (citation omitted)).

The case at hand is thus distinguishable from *SAS* on several points. First, as noted above, we did not adopt a claim construction in the Decision on Institution that we later altered. Second, *SAS* makes clear that what led to a violation of the APA in that case is the unreasonableness of expecting a party to anticipate a claim construction not argued by the opposing party. See *SAS*, 825 F.3d at 1351. But Monosol admits that it anticipated that multilayer devices might have been relevant to this *inter partes* review trial—it states in the Rehearing Request that the Petition “specifically included [the Heiber and Schiraldi] references for their multilayer disclosure.” Req. Reh’g. 2. The problem is, Monosol never communicated the significance of this disclosure to the Board in its Petition.

In reviewing the record of the trial as a whole, and evaluating the parties’ arguments as to patentability, we determined that a construction of “bioerodable device” was necessary in order to evaluate whether Monosol had met its burden of proof. Our Final Written Decision, therefore, construed the claim term for the first time, but only after raising the issue with the parties during oral argument. We are not persuaded that this construction amounted to a “changed theory” violation of the APA, as Monosol contends.

C. Monosol Was Not Prejudiced By The Claim Construction

Even if our adoption of a claim construction in the Final Written Decision were a changed theory, there is no evidence that the timing of the construction harmed Monosol. The statute requires that, in reviewing agency action under the APA, “due account shall be taken of the rule of

prejudicial error.” 5 U.S.C. § 706. While courts have articulated this rule in various ways, in a case involving notice to a party, the Supreme Court has held that the party must explain “how the notice error to which [it] points could have made any difference” in the outcome of the proceeding. See *Shinseki v. Sanders*, 556 U.S. 396, 413 (2009).

As noted above, Monosol does not argue that the Board’s claim construction was incorrect; it merely asks for the opportunity to “present its argument and evidence” regarding the construction, presumably to show that the prior art discloses a multilayer device. Req. Reh’g. 15. Furthermore, as Monosol acknowledges, the Board engaged counsel for both parties in questioning at oral argument regarding the layered structure of the bioerodable device. Paper 44 (transcript of oral argument), 12–14, 28–30. From this, the parties were on notice that the Board was considering a construction of “bioerodable device” that required multiple layers, and the parties had the opportunity⁷ to present argument on that construction. In addition, the Board was on notice that both parties disagreed with this proposed construction; the Board, however, is not required to accept the claim construction positions proffered by the parties. See *Exxon Chem. Patents, Inc. v. Lubrizol Corp.*, 64 F.3d 1553, 1555 (Fed. Cir. 1995) (“the trial judge has an independent obligation to determine the meaning of the claims, notwithstanding the views asserted by the adversary parties”).

⁷ If Monosol was dissatisfied with its opportunity to present argument on the construction of “bioerodable device” at the hearing, it was free to contact the Board afterward to request supplemental briefing. But it did not do so.

Monosol has not demonstrated that any ability to further argue claim construction would have led the Board to adopt a different construction for “bioerodable device.”

Rather, Monosol’s argument appears to be that—had we adopted our construction of “bioerodable device” earlier—it would have presented evidence that the Heiber and Schiraldi references met that limitation. But Monosol could not have done so post-institution, because neither Heiber nor Schiraldi were part of any ground on which trial was instituted, and could not form any basis for our patentability determination. See Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,765 (Aug. 14, 2012) (“Any claim or issue not included in the authorization for review is not part of the trial.”). Relying on non-instituted prior art in the Final Written Decision—and thereby introducing factual assertions into the proceeding at the end of trial—would trade Monosol’s alleged APA violation for an actual one. See *Dell Inc. v. Accelaron, LLC*, 818 F.3d 1293, 1301 (Fed. Cir. 2016).

To the extent that Monosol is arguing that the Board’s error was in not *instituting* trial on grounds involving Heiber or Schiraldi, we first note that the Board is not required to institute trial on *any* ground of unpatentability. See *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, Case IPR2013-00324, 4 (PTAB Nov. 21, 2013) (Paper 19) (informative) (“Congress did not mandate that an *inter partes* review must be instituted under certain conditions. Rather, by stating that the Director—and by extension, the Board—*may not* institute review *unless* certain conditions are met, Congress made institution discretionary.”). Monosol’s argument also rests on the assumption that, had we had adopted our construction of “bioerodable

device” at institution, we would have instituted trial on either Heiber or Schiraldi. But this argument ignores that, even though Heiber or Schiraldi may disclose multilayer devices, they may suffer from other deficiencies that would result in non-institution on those grounds.

Furthermore, as we have held previously, a petitioner cannot complain of the non-institution of grounds of unpatentability for redundancy when it failed to distinguish the proposed grounds in its petition:

If Petitioner believed that any other grounds set forth in the Petition had certain weaknesses or strengths, as compared to grounds of unpatentability based on [the non-instituted art], for example based on alternative claim constructions that Patent Owner might have raised, it was incumbent upon Petitioner to identify those strengths or weaknesses in its Petition. Doing so would have allowed us to recognize and weigh such factors in rendering a decision as to whether to institute review based on the different asserted grounds. Simply proposing different grounds of unpatentability directed to the same subset of claims does not distinguish meaningfully the applied prior art references.

Aker Biomarine AS v. Neptune Techs. And Bioresources Inc., Case IPR2014-00003, 5–6 (PTAB July 8, 2015) (Paper 106). As noted above, Monosol claims it included grounds based on Heiber and Schiraldi in its Petition specifically because of their disclosure of multilayer devices. Req. Reh’g. 1–2. But Monosol never communicated this distinguishing feature to the Board; nor did it request rehearing of the Decision on Institution when the Board found those grounds redundant.

Finally, we note that any potential harm to Monosol caused by the non-institution of grounds on Heiber or Schiraldi is mitigated, if not eliminated, by the fact that the Federal Circuit has held that petitioners are

not estopped from later raising grounds on which trial was not instituted. *See Shaw Indus. Grp. Inc. v. Automated Creel Sys., Inc.*, 817 F.3d 1293, 1300 (Fed. Cir. 2016). Monosol is free to argue grounds based on Heiber or Schiraldi before a district court, or in a subsequent proceeding before the Board. To the panel's knowledge, Monosol has not filed a second petition requesting an *inter partes* review on these grounds.

IV. CONCLUSION

For the foregoing reasons, we are not persuaded that Monosol's Request for Rehearing has established any prejudicial error in the Final Written Decision in violation of the Administrative Procedure Act.

V. ORDER

Accordingly, it is

ORDERED that Petitioner's Request for Rehearing is *denied*.

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