

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIODELIVERY SCIENCES INTERNATIONAL, INC.,
Petitioner,

v.

MONOSOL RX, LLC,
Patent Owner.

Case IPR2015-00168
Patent 8,765,167 B2

Before FRANCISCO C. PRATS, JACQUELINE WRIGHT BONILLA, and
ZHENYU YANG, *Administrative Patent Judges*.

YANG, *Administrative Patent Judge*.

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

I. INTRODUCTION

BioDelivery Sciences International, Inc. (“Petitioner”) filed a Petition for an *inter partes* review of claims 16, 36, 42, 48, 55, 62, 69, 76, 86, 92, 122, and 123 of U.S. Patent No. 8,765,167 B2 (Ex. 1001, “the ’167 patent”). Paper 1 (“Pet.”). The Board instituted trial to review whether the combination of Chen¹ and Tapolsky² renders the challenged claims obvious. Paper 6, 19. In the Final Written Decision, we held that Petitioner had not shown by a preponderance of the evidence that the challenged claims are unpatentable. Paper 69 (“Final Dec.”). Petitioner requests that we reconsider the Final Decision. Paper 70 (“Reh’g Req.”).

For the following reasons, we deny Petitioner’s request.

II. STANDARD OF REVIEW

A rehearing request for a final decision is governed by 37 C.F.R. § 42.71 (d), which requires the party requesting rehearing to “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.”

III. DISCUSSION

Claim 16 is the sole independent claim challenged in the Petition. It is directed to an oral film for delivery of a desired amount of an active component. It recites, among other limitations, that “the active component is substantially uniformly distributed, whereby said substantially uniform

¹ Chen et al., International Publication No. WO 00/42992, published July 27, 2000 (Ex. 1002, “Chen”).

² Tapolsky et al., International Publication No. WO 99/55312, published November 4, 1999 (Ex. 1003, “Tapolsky”).

distribution is measured by substantially equal sized individual unit doses which do not vary by more than 10% of said desired amount of said active component.” Petitioner contends that Chen teaches this limitation. Pet. 52–56.

First, Petitioner asserts the Board previously found, in a decision on appeal of an *inter partes* reexamination of a patent in the same family as the ’167 patent, that Chen meets the substantial uniformity requirement. *Id.* at 54 (incorporating by reference “[s]ubsection . . . 5 of Ground 2”), 9 (citing Ex. 1027,³ 15–17, 19), 38 (citing Ex. 1027, 17, 19). According to Petitioner, Patent Owner is estopped from contesting that finding. *Id.* at 38–40.

Second, Petitioner contends that Chen’s films meet the substantially-uniform-distribution requirement as demonstrated by three different tests. *Id.* at 54–56. We decided against Petitioner on both issues. Final Dec. 11–26. In its Request for Rehearing, Petitioner only seeks redress on the collateral-estoppel issue. Reh’g Req. 1–2.

On rehearing, Petitioner contends that the Board previously found, in both the ’588 decision and another decision on appeal of an *inter partes* reexamination of a second patent in the same family as the ’167 patent (the ’337 decision),⁴ that Chen meets the same substantial uniformity limitation as that recited in claim 16 of the ’167 patent. Req. Reh’g 1–2, 10, 12–13. According to Petitioner, because we misapprehended the law of collateral estoppel, we erred in not giving preclusive effect to the ’588 and ’337

³ Decision on Appeal in Reexamination Control 95/001,753, U.S. Patent No. 7,824,588 B2 (Ex. 1027, “the ’588 decision”).

⁴ Decision on Appeal in Reexamination Control 95/002,171, U.S. Patent No. 7,666,337 B2 (Ex. 1057, “the ’337 decision”).

decisions.⁵ Req. Reh’g 1–2, 10–15.

As we explained in our Final Decision, under the doctrine of collateral estoppel, also known as issue preclusion, a judgment on the merits in a first proceeding precludes relitigation in a second proceeding “of issues actually litigated and determined in the first [proceeding].” Final Dec. 12 (quoting *In re Freeman*, 30 F.3d 1459, 1465 (Fed. Cir. 1994)). Issue preclusion is appropriate only if: (1) the issue is identical to one decided in the first action; (2) the issue was actually litigated in the first action; (3) resolution of the issue was essential to a final judgment in the first action; and (4) the party against whom issue preclusion is asserted had a full and fair opportunity to litigate the issue in the first action. *Id.* (citing *Freeman*, 30 F.3d at 1465). When applying issue preclusion, “statements regarding the scope of patent claims made in a former adjudication should be narrowly construed.” *Id.* (citing *Freeman*, 30 F.3d at 1466).

In the Final Decision, we found that in the ’588 decision, “because Patent Owner did not argue for the patentability of any dependent claims separately, the Board resolved the issue of whether Chen met the uniformity requirement solely based on the language of claim 1.” Final Dec. 12–13 (citing Ex. 1027, 12). Claim 1 of the ’588 patent, however, does not include the substantially-uniform-distribution limitation disputed in the instant

⁵ Petitioner notes that the Board reached the same conclusion in a non-final decision in a third appeal from an *inter partes* reexamination involving another related patent. *See* Decision on Appeal in Reexamination Control 95/002,170, U.S. Patent No. 7,897,080 B2) (Ex. 1056, “the ’080 decision”). Petitioner argues that the ’080 decision also should be given preclusive effect if it becomes final during this rehearing. Req. Reh’g 10 n. 1. No final decision has issued in that proceeding.

proceeding. *Id.* at 13. Thus, we determined that issue preclusion does not apply because the resolution of the issue in this case was not essential to the final judgment in the '588 decision. *Id.* at 12–14.

In its Request for Rehearing, Petitioner merely express disagreement with our conclusion in this regard. Petitioner argues that Patent Owner, at oral argument in the appeal in the '588 patent reexamination, agreed that the substantially uniform requirement of claim 1 of the '588 patent is the same as that of the challenged claim 16 in this proceeding. Req. Reh'g 14 (citing Ex. 1040). Petitioner, however, directs us to no specific controlling law suggesting that we must construe the scope of claim 1 of the '588 patent based solely on argument during an oral hearing. To the contrary, to the extent Patent Owner might have sought to import limitations from the specification into claim 1 of the '588 patent, claim construction on that basis would be erroneous. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed. Cir. 2005) (explaining that in claim construction, it is improper to import limitations from the specification into the claim).

Petitioner contends that in the '588 decision, the Board specifically found Chen “disclosed a film that ‘is well within the less than 10% variation of active content per film unit requirement of claim 3,’” and held claim 3 unpatentable. Req. Reh'g 13 (citing Ex 1027, 19, 20). Petitioner argues that “if Chen disclosed a film that is within less than 10% variation, an arguably more stringent limitation, then it certainly also disclosed a film that satisfied the ‘substantially uniform content’ limitation.” *Id.* Thus, according to Petitioner, the decision “as to the scope of the disclosure of the Chen reference was essential to the final determination of patentability of claim 1 and thus meets this requirement for the doctrine of collateral estoppel.” *Id.*

at 14. We are not persuaded.

In the '588 decision, the Board stated “Patent Owner does not argue for the separate patentability of any dependent claims. Accordingly, the dependent claims stand or fall with claim 1.” Ex. 1027, 12; *see also id.* at 19 n. 7 (“While Patent Owner does not clearly argue the limitation of claim 3 separately from independent claims 1, 192[,] and 193, we note that Patent Owner refers to claim 3 in distinguishing the scope over that of claim 1.”). Thus, resolution of the scope of claim 3 of the '588 patent was not essential to the judgment in the '588 decision.

Moreover, claim 3 of the '588 patent does not require “substantially equally sized individual unit doses,” as recited in the challenged claim 16 in this proceeding. *See* Final Dec. 13 (citing Ex. 1026, 40:7–9 (claim 3 requiring the film “has a variation of active content of less than 10% per film unit”)). According to Petitioner, in the '588 reexamination, Patent Owner agreed that the phrase “unit of film” could be a dosage unit. Req. Reh’g 14–15 (citing Ex. 1027, 9). Thus, Petitioner argues that “[i]f Chen satisfies the no more than 10% variation limitation for the dosage units,” as required in claim 3, “then it also meet[s] the ‘substantially equally sized’ dosage units recited in claim 16 of the '167 patent.” *Id.* at 15. We disagree.

First, the logic in Petitioner’s argument that “a no more than 10% variation is more stringent than ‘substantially equally sized’” (Req. Reh’g 15) is not apparent to us. The challenged claim 16 recites “said substantially uniform distribution is measured by substantially equal sized individual unit doses which do not vary by more than 10% of said desired amount of said active component.” In other words, it requires both “a no more than 10% variation” and “substantially equally sized.”

Second, as we pointed out in the Final Decision, claim 93, and not claim 3, of the '588 patent has the language closest to the challenged claim 16. Final Dec. 13; *see also* Ex. 1026, 44:7–10 (claim 93 reciting “dosage units of substantially the same size, wherein the active content of individual dosage units has a variance of no more than 10%”). Claims 3 and 93 of the '588 patent are presumed to have different scope. Final Dec. 13 (citing *Kraft Foods Inc. v. Int’l Trading Co.*, 203 F.3d 1362, 1366 (Fed. Cir. 2000)).

In the '588 decision, the Board did not separately address whether Chen taught the added limitation in claim 93. Final Dec. 14. We acknowledge, as Petitioner contends (Req. Reh’g 14 (citing Ex. 1027, 20)), that the '588 decision ultimately held claim 93 to be unpatentable over Chen. Petitioner does not persuade us that we should give preclusive effect to the '588 decision, however, given that it resolved unpatentability of all dependent claims based on claim 1, and given that it did not even mention claim 93.

In sum, the arguments in Petitioner’s Request for Rehearing do not persuade us that, in finding that resolution of the issue central to this case was not essential to the final judgment in the '588 decision, we misapprehended or overlooked any point of fact or law, or any arguments Petitioner presented during trial, on that issue.

Petitioner’s rehearing arguments also do not persuade us that, in not giving preclusive effect to the '337 decision, we misapprehended or overlooked any point of fact or law, or any arguments Petitioner presented during trial, on that issue. We acknowledge that the Petition noted that a final rejection had issued in the '337 reexamination proceeding. *See* Pet. 2, 9. We also acknowledge, as we did in the Final Decision, that in the Reply

(Paper 34), Petitioner brought to our attention the '337 decision in the appeal from that rejection. Final Dec. 14 (citing Reply 3).

Petitioner does not, however, direct us to any specific contentions, in either the Petition or the Reply, asserting that the '337 reexamination proceeding, or the Board's '337 decision resulting therefrom, should be given preclusive effect as to this proceeding. Nor does Petitioner, on rehearing, direct us to any instance where it discussed, with any particularity, the factual circumstances of '337 decision, and explained specifically *why* those circumstances show that the '337 decision should be given preclusive effect. Rather, the sole specific contentions and explanation Petitioner advanced as to the issue of collateral estoppel involved the '588 decision, discussed above. *See* Pet. 38–39 (explaining why the '588 decision allegedly meets the four elements of collateral estoppel). That Petitioner merely asserted that the '337 decision held that same reference, Chen, allegedly met the same limitation at issue in this proceeding (*see, e.g.*, Reply 3), does not persuade us that we misapprehended or overlooked any specific contentions or analysis Petitioner presented on the issue of the collateral estoppel effect of the '337 decision.

To the extent that Petitioner attempts, in its Request for Rehearing, to present for the first time a specific explanation as to why the '337 decision meets the requirements of collateral estoppel, Petitioner does not explain why that discussion could not have been presented earlier in the proceeding, at the very least in its Reply. We, therefore, decline to consider those new contentions. In any event, Petitioner does not sufficiently explain why the '337 decision meets the four elements of collateral estoppel. *See, e.g.*, Req.

Reh'g 12–13.

In addition, Petitioner asserts that, in the Final Decision, we erred in concluding that the '337 decision was not final for appeal purposes, and therefore, for additional reasons, erred in not giving preclusive effect to the '337 decision. Req. Reh'g 10–11 (citing Final Dec. 14). In any event, Petitioner argues, because the '337 decision is now final, the '337 decision must be given preclusive effect. *Id.* at 11–12. According to Petitioner, “the results of reexamination proceedings must be given preclusive effect on other concurrent proceedings whenever the reexamination becomes final.” Req. Reh'g 11 (citing *Fresenius USA, Inc. v. Baxter Intern., Inc.*, 721 F.3d 1330, 1347 (Fed. Cir. 2013)).

In *Fresenius*, because a reexamination proceeding resulted in the PTO cancelling all claims that were at issue in a copending infringement action, the court instructed the district court to dismiss the infringement action. *See Fresenius*, 721 F.3d at 1347. The court explained that “the language and legislative history of the reexamination statute show that Congress expected reexamination to take place concurrent with litigation, and that cancellation of claims during reexamination would be binding in concurrent infringement litigation.” *Id.* at 1339. Here, in contrast, the '337 decision did not result in cancellation of any claims of the '167 patent. Accordingly, we are not persuaded that *Fresenius* mandates that we give preclusive effect to the '337 decision.

In sum, the arguments in Petitioner's Request for Rehearing do not persuade us that, in not giving preclusive effect to the '337 decision, we misapprehended or overlooked any point of fact or law, or any arguments Petitioner presented during trial, on that issue.

In the Final Decision, we declined to apply collateral estoppel for the additional reason that *inter partes* reviews afford the parties the opportunity to cross-examine witnesses presenting affidavit testimony, a significant procedural advantage as compared to *inter partes* reexaminations. Final Dec. 15. Citing the Supreme Court’s decision in *B & B Hardware, Inc. v. Hargis Industries, Inc.* 135 S. Ct. 1293, 1302 (2015), Petitioner contends that we erred in doing so. Req. Reh’g 5–9.

In *B & B Hardware*, the Supreme Court held that the Eighth Circuit erred in concluding that a determination by the Trademark Trial and Appeal Board (TTAB) on the issue of likelihood of confusion should not have a preclusive effect on concurrent trademark infringement litigation. *B & B Hardware*, 135 S. Ct. at 1302–1303. The Court instructed that “[o]n remand, the court should apply the following rule: So long as the other ordinary elements of issue preclusion are met, when the [trademark] usages adjudicated by the TTAB are materially the same as those before the district court, issue preclusion should apply.” *Id.* at 1310.

Addressing arguments regarding the procedural differences at the TTAB and in district courts, the Court explained “there is no categorical reason to doubt the quality, extensiveness, or fairness, of the agency’s procedures. In large part they are exactly the same as in federal court.” *B & B v. Hargis*, 135 S. Ct. at 1309 (internal citation and quotation marks omitted). The Court noted, however, that “[i]t is conceivable, of course, that the TTAB’s procedures may prove ill-suited for a particular issue in a particular case, e.g., a party may have tried to introduce material evidence but was prevented by the TTAB from doing so, or the TTAB’s bar on live testimony may materially prejudice a party’s ability to present its case.” *Id.*

In other words, the Court implicitly endorsed the principle that because issue preclusion “is premised on principles of fairness . . . a court is not without some discretion to decide whether a particular case is appropriate for application of the doctrine.” *In re Freeman*, 30 F.3d at 1467 (citations omitted). As a result, even under *B & B Hardware*, we may exercise discretion not to apply collateral estoppel when “[t]he forum in the second action affords the party against whom preclusion is asserted procedural opportunities in the presentation and determination of the issues that were not available in the first action and could likely result in the issue being differently determined.” *See* Final Dec. 15 (quoting *In re Freeman*, 30 F.3d at 1468).

In the instant case, as discussed in our Final Decision, the opportunity for cross-examination, not present in the *inter partes* reexamination that culminated in the ’588 decision, uncovered significant facts, which led to a determination different from that in the ’588 decision. *See id.* Thus, unlike the situation in *B & B Hardware*, where, procedurally, the proceedings in “large part . . . [we]re exactly the same,” 135 S. Ct. at 1309, the two types of proceedings at issue here differ significantly as to the types of evidence the parties may introduce.⁶

Indeed, the Federal Circuit underscored as significant the same difference between an *inter partes* review under the AIA and *inter partes* reexaminations as we identified in our Final Decision. *Abbott Labs. v.*

⁶ We acknowledge, as Petitioner argues (*see* Req. Reh’g 6), that parties in *inter partes* reexaminations may challenge witness testimony by submitting responsive declarations. It, however, does not persuade us that, at least based on the facts before us in this case, we erred in not giving preclusive effect to the ’588 decision.

Cordis Corp., 710 F.3d 1318 (Fed. Cir. 2013). The court explained that “the purpose of this [AIA] reform was to ‘convert[] inter partes reexamination from an examinational to an adjudicative proceeding,’ and one of its touted ‘improvements’ over the former proceeding is to allow the limited use of depositions.” *Id.* at 1326 (citing H.R. Rep. No. 112–98, pt. 1, at 46–47 (2011)).

In sum, for the reasons discussed, Petitioner does not persuade us that we erred in our Final Decision by exercising discretion not to give preclusive effect to the ’588 and ’337 decisions, given the procedural differences between those proceedings and the instant *inter partes* review.

Lastly, Petitioner argues that “[m]easurement of film thickness . . . is not necessary to conclude that Dr. Reitman achieved substantially equally sized unit doses.” Req. Reh’g 8. According to Petitioner, “[s]ize may have many different meanings, and requiring a thickness dimension impermissibly narrows the claims beyond the broadest reasonable interpretation of the ’167 patent.” *Id.* at 9. Petitioner, however, does not identify specifically the place in the record where it presented these particular arguments, such that we may have misapprehended or overlooked them.⁷ We, therefore, decline to consider these new arguments.

IV. CONCLUSION

Having considered the Request for Rehearing, we conclude Petitioner has not shown that, in the Final Decision, we misapprehended or overlooked any point of law or fact, or any arguments Petitioner presented during trial.

⁷ In its Response, Patent Owner challenged that the Reitman Declaration “completely failed to account for the thickness of the samples.” PO Resp. 43. Petitioner could have, but chose not to address the issue in the Reply.

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V. ORDER

For the reasons given, it is hereby ORDERED that Petitioner's Request for Rehearing is *denied*.

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