

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 IPR2015-00169
Patent 8,765,167 B2

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

PRATS, *Administrative Patent Judge*.

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

I. INTRODUCTION

In the Final Written Decision in this proceeding (Paper 69; "Final Decision" or "Final Dec."), we held that BioDelivery Sciences International, Inc. ("Petitioner") had not shown by a preponderance of the evidence that claims 17, 18, 30, 31, 37, 49, 56, 63, 70, 77, 80, 81, 87, 93, 110–116, and

124 of U.S. Patent No. 8,765,167 B2 (Ex. 1001, “the ’167 patent”) are unpatentable under 35 U.S.C. § 103(a) for obviousness over Chen¹ and Tapolsky,² the only ground for which we instituted trial. Final Dec. 37.

Claims 17 and 110 are the sole independent claims among the claims for which we instituted trial. Central to our holding was our finding that Petitioner had not shown that Chen and Tapolsky described, or rendered obvious, compositions meeting the requirement in claims 17 and 110 that the active ingredient in the claimed films be distributed substantially uniformly, where that substantially uniform distribution is measured by substantially equally sized individual unit doses which do not vary by more than 10% of the desired amount of said active component. *Id.*

On rehearing, Petitioner contends that we erred in not giving preclusive effect to two Board decisions in appeals of *inter partes* reexaminations of two patents in the same family as the ’167 patent, involving the same parties as this proceeding. Req. Reh’g 1–2, 10–15 (Paper 71); *see also* Ex. 1027 (Decision on Appeal in Reexamination Control 95/001,753, U.S. Patent No. 7,824,588 B2) (“the ’588 decision”); Ex. 1057 (Decision on Appeal in Reexamination Control 95/002,171, U.S. Patent No. 7,666,337 B2) (“the ’337 decision”).³ Petitioner contends that

¹ WO 00/42992 A2 (published July 27, 2000) (Ex. 1002).

² WO 99/55312 A2 (published Nov. 4, 1999) (Ex. 1003).

³ Petitioner contends also that the Board’s holding in a non-final decision in a third appeal from an *inter partes* reexamination involving another related patent also should be given preclusive effect if that decision becomes final during this rehearing. Req. Reh’g 10, fn. 1 (citing Ex. 1056 (Decision on Appeal in Reexamination Control 95/002,170, U.S. Patent No. 7,897,080 B2) (“the ’080 decision”)). No final decision has issued in that proceeding, however. *See* Reexamination Control 95/002,170.

the '588 and '337 decisions hold that the same reference at issue in this proceeding, Chen, described compositions meeting the same substantial uniformity limitation as that recited in claims 17 and 110 of the '167 patent. Req. Reh'g 1–2, 10, 12–13.

We have reconsidered our Final Decision in light of Petitioner's points, but decline to modify that decision.

II. STANDARD OF REVIEW

The party requesting rehearing has the burden of showing that 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.” 37 C.F.R. § 42.71(d).

III. ANALYSIS

As we noted 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].” *In re Freeman*, 30 F.3d 1459, 1465 (Fed. Cir. 1994). In *Freeman*, the court explained that the rationale underlying issue preclusion is that “a party who has litigated an issue and lost should be bound by that decision and cannot demand that the issue be decided over again.” *Id.* The court set out the requirements of the doctrine as follows:

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. (citations omitted).

As to element (3), when determining whether the issue in question in the second action was essential to the final judgment in the first action, the court advised that “statements regarding the scope of patent claims made in a former adjudication should be narrowly construed.” *Id.* at 1466.

Petitioner’s rehearing arguments 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 presented during trial. To the contrary, rather than identifying points of argument, fact, or law that we misapprehended or overlooked, Petitioner’s rehearing arguments merely express disagreement with our finding that resolution of whether Chen’s compositions meet the distribution uniformity requirement of claims 17 and 110 of the ’167 patent was not essential to the judgment in the ’588 decision.

In its Petition, Petitioner contended that the Board found in the ’588 decision that Chen described film compositions having “‘a weight deviation of ± 0.001 [which] is well within the less than 10% variation of active content per film unit.’” Pet. 37 (quoting Ex. 1027, 19 (the ’588 decision)).⁴ Based on this language in the ’588 decision, Petitioner concluded that “resolution of the issue was essential to the Board’s decision in the ’588 patent reexamination, i.e., patentability depended on whether Chen

⁴ In citing to the ’588 decision we cite to the original page numbers of the decision, not the pages numbers entered by Petitioner as part of Exhibit 1027.

disclosed” that limitation, among others. Pet. 38.

As we explained in our Final Decision, however (Final Dec. 18), the language in the ’588 decision quoted by Petitioner regarding a less than 10% variation of active component appears in claim 3 of the ’588 patent. *See* Ex. 1027, 19 (“weight deviation” described in Example 1 of Chen described as being “well within the less than 10% variation of active content per film unit requirement of *claim 3*” of the ’588 patent) (emphasis added).

As we explained in our Final Decision (Final Dec. 15), in the ’588 decision the Board resolved the issue of whether Chen met the substantially uniformity requirement based on claim 1 of the ’588 patent, because Patent Owner had not argued the rejected claims separately. *See* Ex. 1027, 12 (“Patent Owner does not argue for the separate patentability of any dependent claims. Accordingly, the dependent claims stand or fall with claim 1.”); *see also id.* at 19, fn. 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.”) (Emphasis added.).

Thus, even if we were to agree (which we do not, as discussed *infra*), that claim 3 of the ’588 patent includes the same limitation regarding the uniformity of active agent distribution as claims 17 and 110 of the ’167 patent at issue here, resolution of the uniformity requirement of claim 3 of the ’588 patent was not essential to the judgment in the ’588 decision. Moreover, because the ’588 decision resolved unpatentability over Chen based on claim 1 of the ’588 patent, that the ’588 decision ultimately held claim 3 to be unpatentable over Chen (*see* Req. Reh’g 13 (citing Ex. 1027,

20)) does not persuade us that we should give preclusive effect to statements by the Board in the '588 decision regarding claim 3 of the '588 patent.

Petitioner argues that Patent Owner (Monosol Rx, LLC), at oral argument in the appeal in the '588 patent reexamination, contended that claim 1 of the '588 patent included the less than 10% variability requirement. Req. Reh'g 14 (citing Ex. 1040 (Record of Oral Hearing in '588 patent reexamination)). 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 In re Trans Texas Holdings Corp.*, 498 F.3d 1290, 1299 (Fed. Cir. 2007) (“[W]hile ‘the specification [should be used] to interpret the meaning of a claim,’ courts must not ‘import[] limitations from the specification into the claim.’ . . . [I]t is improper to ‘confine the claims to th[e] embodiments’ found in the specification”) (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed. Cir. 2005)) (citations omitted, bracketed text in internal quotes in original).

Petitioner also alleges error in our finding (Final Dec. 18–19) that claim 93 of the '588 patent, rather than claim 3 of the '588 patent, has the language closest to claims 17 and 110 of the '167 patent, and our resultant finding that the resolution of the substantial uniformity requirement at issue here was not essential to the Board's '588 decision. Req. Reh'g 14–15.

As we noted in our Final Decision (Final Dec. 19), however, like claims 17 and 110 of the '167 patent, claim 93 of the '588 patent requires

the substantial uniformity of active component distribution to be based on substantially same-sized film units. *See* Ex. 1026, 44:7–10 (the '588 patent, claim 93). In contrast, claim 3 of the '588 patent does not require uniformity to be based on same-sized film units. Ex. 1026, 40:7–9.

As explained in our Final Decision, claims 3 and 93 of the '588 patent presumptively have different scope. Final Dec. 19 (citing *Kraft Foods Inc. v. Int'l Trading Co.*, 203 F.3d 1362, 1366 (Fed. Cir. 2000)). Thus, even if we were to agree (which we do not) that the statement in the '588 decision as to claim 3 of the '588 patent might have a preclusive effect, Petitioner's arguments (Req. Reh'g 14–15) do not persuade us that the '588 decision has a preclusive effect as to claim 93 of the '588 patent, the claim having the limitation closest to that of claims 17 and 110 of the '167 patent at issue here.

We acknowledge, as Petitioner contends (Req. Reh'g 14–15 (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 the '588 decision resolved unpatentability over Chen based on claim 1 of the '588 patent, as discussed above, and given that the '588 decision did not otherwise mention claim 93.

In sum, for the reasons discussed, Petitioner's rehearing arguments 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, initially, the Petition noted that a final rejection had issued in the '337 reexamination proceeding. *See* Pet. 2, 9. We acknowledge, as we did in our Final Decision (Final Dec. 19), that Petitioner's Reply contended that the Board's '337 decision in the appeal from that rejection held that Chen met the same uniform active component distribution limitation as involved in this proceeding. Paper 35, 3 ("Reply").

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 Board's '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.

Accordingly, Petitioner does not persuade us that we misapprehended or overlooked any point of fact or law, or any arguments Petitioner presented during trial, on the issue of whether the '337 decision should be given preclusive effect. 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 explain with any particularity why the '337 decision meets the four elements of collateral estoppel. *See, e.g.*, Req. Reh'g 12–13.

Petitioner contends also that, in our 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. In any event, Petitioner contends, because the '337 decision is now final, the '337 decision must be given preclusive effect. *Id.* at 11–12. To that end, Petitioner contends that “the Federal Circuit, in *Fresenius USA, Inc. v. Baxter Intern., Inc.*, 721 F.3d 1330, 1347 (Fed. Cir. 2013), specifically found that the results of reexamination proceedings must be given preclusive effect on other concurrent proceedings whenever the reexamination becomes final.” Req. Reh'g 12.

We are not persuaded that *Fresenius* mandates that we give preclusive effect to the '337 decision, in light of the fact that Petitioner did not, as

discussed above, present its collateral estoppel contentions regarding the '337 decision in a timely fashion or with adequate specificity. 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 any claims of the '167 patent. Accordingly, we are not persuaded that the holding in *Fresenius* mandates that we give preclusive effect to the '337 decision, particularly given that, as discussed above, Petitioner does not identify with particularity where it presented its collateral estoppel contentions regarding the '337 decision in a timely fashion or with adequate specificity, such that we may have misapprehended or overlooked those contentions.

In sum, for the reasons discussed, Petitioner's rehearing arguments 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 our Final Decision, as Petitioner discusses (Req. Reh'g 4–5), in addition to the reasons discussed above for not giving preclusive effect to the '588 decision, we also noted that *inter partes* reviews under the Leahy-Smith America Invents Act (Public Law 112–29, § 3, 125 Stat. 288, “AIA”)

afford the parties the opportunity to cross examine witnesses presenting affidavit testimony, a significant procedural advantage as compared to *inter partes* reexaminations. Final Dec. 16–17.

Petitioner contends that, based on the Supreme Court’s decision in *B & B Hardware, Inc. v. Hargis Industries, Inc.* 135 S. Ct. 1293, 1302 (2015), our Final Decision erred in finding that the procedural differences between the two types of proceedings are sufficient to prevent according the ’588 and ’337 decisions preclusive effect in this proceeding. Req. Reh’g 4–8. For the reasons discussed above, however, Petitioner’s rehearing arguments do not persuade us that we erred in not giving preclusive effect to the ’588 and ’337 decisions, even setting aside the question of whether the procedural differences between the two types of proceedings allow us the discretion not to apply the doctrine of collateral estoppel in this instance.

As to the differences between AIA *inter partes* reviews and *inter partes* reexaminations, Petitioner also does not persuade us that the decision in *B & B Hardware* demonstrates error in our Final Decision.

In *B & B Hardware*, the Supreme Court considered whether 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 Supreme Court held that the Eighth Circuit “erred in this case. On 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 between TTAB trademark registration procedures and trademark infringement litigation in district courts, the Supreme Court stated that “there is no categorical ‘reason to doubt the quality, extensiveness, or fairness,’ [Montana v. United States, 440 U.S. 147, 164, fn. 11 (1979)], 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. The Court noted, however, that in certain rare instances, for example where a party was unable to submit pertinent evidence, the doctrine of collateral estoppel might be inapplicable. *See id.* (“It 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.”).

Thus, in *B & B Hardware*, the Court implicitly endorsed the principle, noted in our Final Decision, 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). We conclude that, even under *B & B Hardware*, discretion may be exercised not to apply collateral estoppel when the “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.” *Id.* at 1468 (citing Restatement (Second) of Judgments § 29 (1980)).

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, allowed discovery of facts significant to our evaluation of the issue of anticipation, resulting in a determination on that issue different from that in the '588 decision. *See* Final Dec. 14–15. Thus, unlike the situation in *B & B Hardware*, where, procedurally, the proceedings at issue 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. We acknowledge, as Petitioner argues (*see* Req. Reh'g 6), that parties in *inter partes* reexaminations may challenge witness testimony by submitting responsive declarations. That fact does not persuade us, however, that, at least based on the facts before us in this case, we erred by not to giving preclusive effect to the '588 decision, given the procedural difference in the proceedings at issue.

Indeed, in *Abbott Labs. v. Cordis Corp.*, 710 F.3d 1318 (Fed. Cir. 2013) the Federal Circuit held that, unlike *inter partes* reviews under the AIA, *inter partes* reexaminations are not contested cases in which subpoenas can be obtained under 35 U.S.C. § 24. The court underscored as significant the same difference between the two types of proceedings we identified in our Final Decision, noting 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.” *Abbott*, 710 F.3d at 1326 (citing H.R. Rep. No. 112–98, pt. 1, at 46–47 (2011)) (brackets in internal quotations in original).

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 presents arguments explaining why the testimony of Drs. Reitman and Goldberg demonstrate that the ultimate conclusion in our Final Decision was erroneous. Req. Reh'g 8–10. 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. We, therefore, decline to consider these new arguments.

IV. CONCLUSION

Having considered the Request for Rehearing, Petitioner does not persuade us, for the reasons discussed, that it has shown that our Final Decision misapprehended or overlooked any point of law or fact, or any arguments Petitioner presented during trial, on the issues raised in the Request for Rehearing.

V. ORDER

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

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