Trials@uspto.gov
571-272-7822

Paper No. 88
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIODELIVERY SCIENCES INTERNATIONAL, INC.,
Petitioner,

v.

AQUESTIVE THERAPEUTICS, INC. f/k/a MONOSOL RX, LLC,
Patent Owner.

Case IPR2015-00168
Patent 8,765,167 B2

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

YANG, *Administrative Patent Judge*.

DECISION ON REMAND
35 U.S.C. § 144; 37 C.F.R. § 42.5(a)

INTRODUCTION

BioDelivery Sciences International, Inc. ("Petitioner") filed a Petition (Paper 2 ("Pet.")), seeking 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"). Petitioner asserted five grounds of unpatentability. Pet. 18–19. Aquestive Therapeutics, Inc., formerly known as Monosol Rx, LLC ("Patent Owner"), did not file a Preliminary Response. We instituted review of all challenged claims based on one ground, but denied the other four grounds on the merits. Paper 6 ("DI"), 9–19. At the completion of the trial, we sustained the patentability of all challenged claims.[1] Paper 69 ("FD"), 29.

Petitioner appealed to the U.S. Court of Appeals for the Federal Circuit. Paper 75. After the oral argument, Petitioner requested a remand to the Board to implement the Supreme Court's decision in *SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348 (2018). *BioDelivery Sci. Int'l, Inc. v. Aquestive Therapeutics, Inc.*, 898 F.3d 1205, 1207 (Fed. Cir. 2018). The Federal Circuit granted that request, vacated our decision, and remanded. *Id.* at 1210.

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[1] Petitioner also sought *inter partes* reviews in IPR2015-00165 and IPR2015-00169, challenging certain other claims of the '167 patent. In each of those cases, we instituted review based on fewer than all the asserted grounds. *See* IPR2015-00165, Paper 6; IPR2015-00169, Paper 6. Further, in IPR2015-00165, we instituted review of some, but not all, challenged claims. *See* IPR2015-00165, Paper 6. In both cases, we sustained the patentability of all instituted claims on the instituted grounds. *See* IPR2015-00165, Paper 70; IPR2015-00169, Paper 69.

On remand, we sought the parties' input on whether, at this time, an appropriate course of action going forward would be to vacate our prior institution Decision and deny the Petition in its entirety. Paper 76, 2. The parties have completed briefing. *See* Papers 79, 80, 85, 87. Petitioner contends the Board "cannot change its mind now and vacate its determination to institute the '167 IPRs." Paper 79, 3. Patent Owner argues the opposite. Paper 80, 1.

After considering the parties' arguments, and under the circumstances of this case, we modify our institution Decision, deny the Petition in its entirety, and terminate this proceeding.

The '167 Patent

The '167 patent relates to rapidly dissolving films incorporating anti-tacking agents and an active ingredient that is evenly distributed throughout the film. Ex. 1001, 1:18–21.

According to the '167 patent, conventional film forming techniques inherently suffer from self-aggregation and non-uniformity of active ingredients. *Id.* at 1:59–2:33. Prior attempts to overcome this problem have other disadvantages, such as rendering the actives ineffective or even harmful. *Id.* at 2:34–53. In addition, adherence between films strips is a common problem. *Id.* at 4:1–2.

The invention of the '167 patent provides "a substantially reduced occurrence of, i.e. little or no, aggregation or conglomeration of components within the film as is normally experienced when films are formed by conventional drying methods." *Id.* at 5:63–67. It also includes anti-tacking

agents in the film compositions to reduce the adherence of the films to the roof of the mouth and to one another. *Id.* at 18:64–19:13.

Illustrative Claim

Claim 16 is the sole independent claim challenged in the Petition. It is reproduced below, with added emphasis:

> 16. An oral film for delivery of a desired amount of an active component comprising:
>
> (a) a self-supporting film having at least one surface, said film comprising:
>
> (i) an ingestible, water-soluble polymer matrix; and
>
> (ii) a substantially uniform distribution of said desired amount of said active component within said polymer matrix, wherein said active component is selected from the group consisting of cosmetic agents, pharmaceutical agents, vitamins, bioactive agents and combinations thereof; said film being formed by a controlled drying process which rapidly forms a viscoelastic matrix to lock-in said active in place within said matrix and maintain said substantially uniform distribution; and
>
> (b) a coating on said at least one surface of said self-supporting film, said coating comprising at least one anti-tacking agent selected from the group consisting of stearates; stearic acid; vegetable oil; waxes; a blend of magnesium stearate and sodium lauryl sulfate; boric acid; surfactants; sodium benzoate; sodium acetate; sodium chloride; DL-Leucine; polyethylene glycol; sodium oleate; sodium lauryl sulfate; magnesium lauryl sulfate; talc; cornstarch; amorphous silicon dioxide; syloid; metallic stearates, Vitamin E, Vitamin E TPGS, silica and combinations thereof; and
>
> wherein said film is self-supporting and *the active component is substantially uniformly distributed, whereby 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.

Case History

Petitioner challenged the '167 patent based on the following grounds:

Ground	Claims	Basis	Reference(s)
1	16, 36, 48, 55, 69, 76, 86, 92, 122, 123	§ 102	Tapolsky[2]
2	16, 36, 42, 48, 55, 62, 69, 76, 86, 92, 122, 123	§ 103	Tapolsky in view of Chen[3]
3	16, 36, 42, 48, 55, 62, 69, 76, 86, 92, 122, 123	§ 103	Tapolsky in view of Chen and Modern Coating[4]
4	16, 36, 42, 48, 55, 62, 69, 76, 86, 92, 122, 123	§ 103	Chen in view of Tapolsky
5	16, 36, 42, 48, 55, 62, 69, 76, 86, 92, 122, 123	§ 103	Chen in view of Tapolsky and Modern Coating

In support of its patentability challenges, Petitioner relies on the Declaration of Dr. Edward D. Cohen (Ex. 1007).

In our institution Decision, we denied—based on substantive analyses—four out of the five asserted grounds. DI 9–15, 18. Specifically, we concluded that based on the Petition and accompanying evidence, Petitioner did not establish a reasonable likelihood it would prevail on the grounds of (1) anticipation by Tapolsky (*id.* at 9–11); (2) obviousness over Tapolsky in view of Chen (*id.* at 11–14); (3) obviousness over Tapolsky in

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[2] Tapolsky et al., International Publication No. WO 99/55312, published November 4, 1999 (Ex. 1003, "Tapolsky").
[3] Chen et al., International Publication No. WO 00/42992, published July 27, 2000 (Ex. 1002, "Chen").
[4] MODERN COATING AND DRYING TECHNOLOGY (Edward D. Cohen & Edgar B Gutoff eds., 1992) (Ex. 1009, "Modern Coating").

view of Chen, and further in view of Modern Coating (*id.* at 15); and (4) obviousness over Chen in view of Tapolsky, and further in view of Modern Coating (*id.* at 18). We, however, instituted trial to review whether the combination of Chen and Tapolsky renders all challenged claims obvious. *Id.* at 16–19.

Neither party sought reconsideration of our Decision to Institute. The case proceeded. Patent Owner filed a Response (Paper 15), and Petitioner filed a Reply (Paper 34). After hearing the oral argument (Paper 68), we issued a Final Written Decision, concluding that Petitioner did not meet its burden of proving the unpatentability of any challenged claim by a preponderance of the evidence. FD 29. Specifically, we found Petitioner failed to adequately account for the limitation of "substantially uniform distribution," as required in all challenged claims. *Id.* at 16–26. We also rejected Petitioner's contention that Patent Owner should be estopped from contesting the Board's findings as to Chen in *inter partes* reexamination of three patents related to the '167 patent. *Id.* at 11–15.

Petitioner filed a rehearing request, seeking redress of the collateral-estoppel issue only. Paper 70. We denied Petitioner's request. Paper 74. Petitioner appealed. Paper 75.

On February 9, 2018, the Federal Circuit heard oral argument in the appeal of this case. *BioDelivery Sci. Int'l*, 898 F.3d at 1207. Before the Federal Circuit issued an opinion on the merits, on April 24, 2018, the Supreme Court issued its decision in *SAS*, holding that a decision under 35 U.S.C. § 314 may not institute on fewer than all claims challenged in the petition. *SAS*, 138 S. Ct. at 1355. Thereafter, Petitioner requested that the

Federal Circuit remand the final decision for the Board to consider the non-instituted grounds. *BioDelivery Sci. Int'l*, 898 F.3d at 1209. The Federal Circuit granted that request, vacated our decision, and remanded the case for us "to implement the Court's decision in *SAS*." *Id.* at 1210.

ANALYSIS

Modification of Institution Decision

Overview

In our institution Decision, we denied four out of the five asserted grounds. DI 9–15, 18. Those denials were based on substantive analyses.

For Ground 1, we declined to review whether the challenged claims are anticipated by Tapolsky because Petitioner failed to show that "Tapolsky discloses, expressly or inherently, a film having a 'substantially uniform distribution' of the active." *Id.* at 10–11.

For Ground 2, we declined to review whether the challenged claims would have been obvious over Tapolsky in view of Chen because Petitioner failed to (1) properly identify the differences between the subject matter of the challenged claims and prior art; (2) sufficiently explain the reason to modify the teachings of Tapolsky with those of Chen; and (3) adequately explain how to modify Tapolsky's disclosures to arrive at the claimed subject matter with a reasonable expectation of success. *Id.* at 11–14.

For Ground 3, we declined to review whether the challenged claims would have been obvious over Tapolsky in view of Chen and Modern Coating because Petitioner failed to show the film produced according to the drying processes taught in Modern Coating did, or would necessarily, result in a film with "substantially uniform distribution" of the active. *Id.* at 15.

For Ground 5, we declined to review whether the challenged claims would have been obvious over Chen in view of Tapolsky and Modern Coating because Petitioner's entire argument is a single sentence, that is, Petitioner "incorporates by reference the discussion in Ground 3." *Id.* at 18.

On remand, after reconsideration of the Petition and accompanying evidence, we see no reason to change our analyses. Thus, we maintain our position that Petitioner has not established a reasonable likelihood of prevailing in showing the unpatentability of any of the claims challenged in Grounds 1–3 and 5.

Because the majority of unpatentability grounds presented in the Petition fail to meet the institution standard, instituting trial at this time is not in the interest of either the efficient administration of the Office, or the inexpensive resolution of this proceeding.[5] Under the circumstances, it is appropriate that we exercise our discretion to deny the Petition in its entirety on this basis alone. *See SAS*, 128 S. Ct. at 1356 (explaining that the decision whether to institute an *inter partes* review is discretionary); *see also* 35 U.S.C. § 316(b) (mandating that, when prescribing regulations to conduct *inter partes* reviews, "the Director shall consider the effect of any such

[5] This is especially so because, at the completion of trial on Ground 4, we concluded that Petitioner did not meet its burden to show the unpatentability of the challenged claims. FD 29. Although we do not rely on information developed during trial in this Decision, the fact that Petitioner ultimately did not prevail as to the only ground for which trial was actually instituted underscores that instituting trial to include the remaining insufficient grounds (Grounds 1–3 and 5) would not be the best use of the Board's and the parties' limited resources.

regulation on . . . the efficient administration of the Office"); 37 C.F.R. § 42.1(b) (requiring *inter partes* reviews be conducted "to secure the just, speedy, and inexpensive resolution of every proceeding").

Nonetheless, as discussed in more detail below, we address the single ground previously instituted (Ground 4) again. For Ground 4, in the institution Decision, we stated we were persuaded that Petitioner had established a reasonable likelihood it would prevail on showing that claims 16, 36, 42, 48, 55, 62, 69, 76, 86, 92, 122, and 123 would have been obvious over Chen in view of Tapolsky.[6] *Id.* at 16–18. Specifically, we stated that "we agree with the Board's previous finding" in the reexamination of U.S. Patent No. 7,824,588 ("the '588 patent"), where "the Board found Chen teaching both a 'substantially uniform distribution' of the active and a 'controlled drying process.'" *Id.* at 17.

After reconsideration of the Petition and accompanying evidence, and for the reasons explained below, we determine that the Board's prior '588 decision is insufficient to establish that Chen teaches or suggests the "substantially uniform distribution" requirement. We also find unpersuasive Petitioner's other arguments addressing this limitation. As a result, we conclude that Petitioner has not established a reasonable likelihood of prevailing in showing the unpatentability of any of the claims challenged in

[6] We explained that we analyzed the ground based on Tapolsky in view of Chen separately from the ground based on Chen in view of Tapolsky because Petitioner relied on different disclosures and advanced different arguments. DI 16 n.5.

Ground 4 either. Thus, we modify our institution Decision and deny the Petition in its entirety on this basis also.

Claim Construction

In the institution Decision, we construed the term "substantially uniform distribution" and its variant "substantially uniformly distributed" based on the express language in claim 16 that "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." DI 6.

Similarly, we stated that "given the express language in claim 16, we conclude that, under the broadest reasonable construction in light of the Specification, the phrase including the term 'controlled drying process' refers to drying with at least one controlled drying parameter, which forms a viscoelastic matrix within a few minutes of the drying process to lock-in the active within the matrix and to maintain the distribution of the active so that substantially equal sized individual unit doses do not vary by more than 10% of the amount of the active." *Id.* at 8–9.

On remand, after reconsideration of the Petition and accompanying evidence, we see no reason to change our determination as to claim construction.

Prior Art Disclosures

Tapolsky relates to a water-erodible pharmaceutical carrier device suitable for delivery of pharmaceutical components to mucosal surfaces. Ex. 1003, 5:5–9. In one embodiment, the device comprises "a layered film

disk having an adhesive layer and a backing layer, both water-erodable, having the pharmaceutical in one or more of the layers." *Id.* at 5:9–13.

Chen teaches a novel dosage unit that "includes a water-soluble hydrocolloid, mucosal surface-coat-forming film, such film including an effective dose of an active agent." Ex. 1002, 3:30–32. In one embodiment, the dosage unit "is in the form of a flexible, non-tacky, dry[,] conveniently packaged film." *Id.* at 6:24–26. Once placed on a mucosal surface, the film forms a coating on the membrane and "disintegrates and dissolves to release the active agent from the film." *Id.* at 6:26–29.

Obviousness over Chen in view of Tapolsky

We focus our analysis on claim 16, the only independent claim challenged.

Chen teaches a film for mucosal delivery, which includes "an effective dose of active agent," such as a therapeutic agent or a nutritional supplement. Ex. 1002, Abstract, 10:22–23. Petitioner contends that Chen teaches a "controlled drying process" that results in a film with "substantially uniform distribution" of the active, as required in limitation (ii) and the final wherein clause of claim 16. Pet. 35–36, 38–40, 48–49, 52–56. First, Petitioner asserts the Board previously found, in a decision on appeal in an *inter partes* reexamination of a different patent in the same family as the '167 patent, that Chen meets the uniformity requirement. *Id.* at 54 (incorporating by reference "[s]ubsection . . . 5 of Ground 2"), 9 (citing Ex. 1027, 15–17, 19), 38 (citing Ex. 1027, 17, 19). According to Petitioner, Patent Owner is estopped from contesting that finding. *Id.* at 38–40. In addition, Petitioner contends that Chen's films

meet the substantially-uniform-distribution requirement as demonstrated by visual inspection, the consistent dosage unit weight, and the homogeneity of the starting solution. *Id.* at 48–49, 54–56. We address Petitioner's arguments in turn.

Collateral Estoppel

Petitioner points out that the '167 patent "is part of a large family of patents." Pet. 1–2. One of the patents in this family, U.S. Patent No. 7,824,588 ("the '588 patent"), was reexamined (control number 95/001,753). *Id.* at 2. In the reexamination, all claims of the '588 patent were rejected and the Board affirmed the rejections. *Id.*; Ex. 1027 ("the '588 decision"). In the '588 decision, the Board found that (1) "Chen teaches controlled drying" (Ex. 1027, 17); (2) "Chen inherently discloses a film with a substantially uniform content of therapeutic active composition per unit of film" (*id.* at 15); and (3) the "weight deviation of ±0.001 [shown in Table 4 of Chen] satisfies the limitation of 'substantially uniform' active content" (*id.* at 19). Petitioner argues that because Patent Owner did not appeal the '588 decision, the Board's decision is final. Pet. 39–40. As a result, Patent Owner should be estopped "from contesting the Board's findings as to Chen." *Id.*

As an initial matter, it is unclear whether, under our current rules, *inter partes* reexamination could give rise to collateral estoppel in *inter partes* review. Even assuming the doctrine could be applied generally, we determine that it does not apply in this case because the resolution of the issue here was not essential to the final judgment in the '588 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). 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.* When applying issue preclusion, "statements regarding the scope of patent claims made in a former adjudication should be narrowly construed." *Id.* at 1466.

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. 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."). Claim 1 of the '588 patent, as amended during the reexamination, requires "substantially uniform content of therapeutic active composition per unit of film." *Id.* at 4. Thus, the '588 decision did not resolve the issue of whether Chen met the substantially-uniform-distribution limitation, "measured by substantially equal sized individual unit doses which do not vary by more than 10% of said desired amount of said active component," as required by claim 16 of the '167 patent.

In the ’588 decision, the Board stated that the weight deviation of ±0.001 shown in Table 4 of Chen “is well within the less than 10% variation of active content per film unit requirement of claim 3” of the ’588 patent. *Id.* at 19. Claim 3 of the ’588 patent depends from claim 1 and further recites “wherein the self-supporting therapeutic active-containing film has a variation of active content of less than 10% per film unit.” Ex. 1026, 40:7–9. Still, it does not require “substantially equally sized individual unit doses,” as required in claim 16 of the ’167 patent. In other words, like claim 1 of the ’588 patent, claim 3 of the same patent does not require the substantially uniform distribution of the active content, as defined in claim 16 of the ’167 patent.

Indeed, the claim language closest to claim 16 of the ’167 patent appears in claim 93 of the ’588 patent, which recites “[t]he method of claim 1, further comprising forming a plurality of individual dosage units of substantially the same size, wherein the active content of individual dosage units has a variance of no more than 10%.” Ex. 1026, 44:7–10. In the ’588 decision, however, the Board did not separately address whether Chen taught the added limitation in claim 93. In fact, the Board did not even mention claim 93. As such, the issue of whether Chen met the substantially-uniform-distribution requirement at issue in this case was not essential to the ’588 decision. Because the requirements of issue preclusion have not been met, the doctrine is inapplicable in this case.

Petitioner also brings to our attention *inter partes* reexaminations of two other patents in the same family as the ’167 patent. Pet. 2 (“Similarly, the CRU finally rejected all reexamination claims of US Patent Nos.

7,897,080 (the '080 patent, Ex. 1030) and 7,666,337 (the '337 patent, Ex. 1033). *See* Ex. 1032, Control No. 90/002,170, RAN; and Ex. 1034, Control No. 90/002,171, RAN.").

As Petitioner correctly points out, we decided whether to institute an *inter partes* review based on the information presented in the Petition. Paper 79, 1 (citing 35 U.S.C. § 314(a)). At the time of the Petition, the appeals of the '080 patent and the '337 patent reexaminations were pending before the Board. Pet. 2. Thus, even if *inter partes* reexamination could give rise to collateral estoppel in *inter partes* review, the Petition does not refer to any final Board decision related to these two reexaminations for us to apply the doctrine.

We recognize that at the time of this Decision, the Board has issued final decisions in the appeals of the '080 patent and the '337 patent reexaminations. Paper 79, 6. Thus, for the sake of completeness, we address whether those decisions possibly could have preclusive effect in this case. And we conclude they could not.

"[U]nder certain circumstances, [even] where all of the requirements of issue preclusion have been met, the doctrine will not be applied." *Freeman*, 30 F.3d at 1467. Specifically, "[p]reclusion will not be effected when the quality or effectiveness of the procedures followed in the two suits differ." *Id.* For example, issue preclusion may be inappropriate 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." *Id.* at 1468. Such is the case here.

In this *inter partes* review, the availability of cross-examination of witnesses is a procedural opportunity for the parties that was not available in the prior *inter partes* reexamination proceedings. Specifically, *inter partes* reexamination proceedings are conducted essentially by the same procedure as routine examination of patent applications. 37 C.F.R. § 1.937(b). There, although submission of evidence in affidavit form is allowed (37 C.F.R. §§ 1.131, 1.132), the rules for *inter partes* reexaminations do not provide for cross-examination of those affiants. *See* 37 C.F.R. §§ 1.902–1.997. In contrast, in an *inter partes* review, witnesses presenting direct testimony by affidavit are subject to cross-examination via deposition.[7] 37 C.F.R. § 42.53. Additionally, in *inter partes* reviews, unlike in reexaminations, parties may request discovery, albeit in a more limited fashion as compared to that available in district court litigation. *See Garmin Int'l, Inc. v. Cuozzo Speed Techs. LLC*, Case IPR2012-00001, Paper 26 (PTAB Mar. 5, 2013) (precedential) (outlining factors the Board considers when determining whether to authorize additional discovery in an *inter partes* review). These types of procedural distinctions weigh against applying issue preclusion here based on the '588, '080, and '337 decisions in the prior *inter partes* reexaminations. Thus, we do not apply issue preclusion here.

[7] At the completion of trial on Ground 4, we concluded that Petitioner did not meet its burden to show the unpatentability of the challenged claims, in part because cross-examination of one of Petitioner's witnesses uncovered facts that cast doubts on her direct testimony. FD 24–25. We reiterate that we do not rely on information developed during trial in this Decision. Nevertheless, that example highlights the importance of the procedural distinctions between *inter partes* reviews and reexaminations.

Our conclusion is supported by the Supreme Court's decision in *B & B Hardware, Inc. v. Hargis Industries, Inc.* 135 S. Ct. 1293, 1302 (2015). There, 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 this *inter partes* review affords Patent Owner procedural opportunities in the presentation and determination of the issues, such as the opportunity for cross-examination and discovery, that were not available in the previous *inter partes* reexaminations.[8] *See Freeman*, 30 F.3d at 1468.

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. 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 above, we decline to apply the doctrine of issue preclusion in this proceeding.

"Substantially Uniform Distribution"

Petitioner argues that the '167 patent sets forth tests, including visual inspection and consistent dosage weight, for determining whether a film has

[8] We acknowledge 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 must give preclusive effect to those previous *inter partes* reexamination decisions.

a uniform distribution of active component. Pet. 54–56. According to Petitioner, in Chen, the uniform distribution of active component is demonstrated in Example 1 by the consistent dosage weight, and in Examples 1–8 by visual inspection. *Id.* Because Chen shows "uniform distribution of active in the film," Petitioner concludes, it "must satisfy the substantially uniform distribution required by the challenged claims." *Id.* at 55.

Specifically, Petitioner asserts that the '167 patent incorporates by reference its parent, U.S. Patent No. 7,425,292 (Ex. 1035, "the '292 patent"). *Id.* at 54 (citing Ex. 1001, 1:11–14). The '292 patent discloses:

> The uniform distribution of the components within the film was apparent by examination by either the naked eye or under slight magnification. By viewing the films it was apparent that they were substantially free of aggregation, i.e., the carrier and the actives remained substantially in place and did not move substantially from one portion of the film to another. Therefore, there was substantially no disparity among the amount of active found in any portion of the film.

Ex. 1035, 19:56–63.

Petitioner argues that the '167 patent, via the incorporated '292 patent, teaches that "uniform distribution of components, including active, can be demonstrated by visual inspection." Pet. 55–56. Petitioner refers to Chen for teaching "[a] glossy, substantially transparent, stand alone, self-supporting, non-tacky and flexible film was obtained after drying." *Id.* at 49 (citing Ex. 1002, 17:15–16), 56. According to Dr. Cohen, "[a] film that is 'substantially transparent' is one that is substantially free of aggregation when viewed by the unassisted (i.e., naked) eye or under slight

magnification." Ex. 1007 ¶ 110. Thus, Petitioner asserts, the films in Examples 1–8 of Chen have uniformly distributed active component, as confirmed by visual inspection disclosed in the '292 patent. Pet. 56. They, therefore, satisfy the substantially-uniform-distribution limitation in the challenged claims. *Id.*

In addition, according to the '292 patent, because each component has a unique density, "when the components of different densities are combined in a uniform manner in a film . . . individual dosages forms from the same film of substantially equal dimensions, will contain the same mass." Ex. 1035, 20:55–60. Based on this principle, the '292 patent concludes, consistent individual dosage weight shows that the distribution of the components within the film is uniform. *Id.* at 20:53–55.

Petitioner points out that "Chen reports the weights of Example 1 film dosages as 0.028±0.001g." Pet. 55 (citing Ex. 1002, Table 4). According to Petitioner, "[r]ounding Chen's reported weights to two significant digits results in a consistent 0.03 g per film dosage with a variation of 0%." *Id.* This, Petitioner contends, demonstrates that the film according to Example 1 in Chen meets the consistent-dosage-weight test disclosed in the '292 patent, and thus, satisfies the substantially-uniform-distribution limitation in the challenged claims. Pet. 55.

We are not persuaded by either argument. Claim 16 recites that the "substantially uniform distribution is measured by substantially equally sized individual unit doses which do not vary by more than 10% of said desired amount of said active component." Based on the express language of the claim, we conclude that the actual amount of the active component in

substantially equal sized individual unit doses of the film must be determined in order to evaluate whether the distribution of the active is substantially uniform. Petitioner does not explain how the amount of the active component in each individual unit dose can be ascertained by either visual inspection of a film or weighing the dosage units.

To be sure, the specification of the '292 patent does describe the visual inspection and the consistent-dosage-weight test as methods for determining the uniform distribution of components within the film. Ex. 1035, 19:56–63, 20:53–60. With a healthy dose of common sense, however, we question the reasonableness of Petitioner's contention that both tests are able to show the *absolute* uniform distribution of the active in a film. *See* Pet. 55 (arguing that because Chen meets the "higher bar of uniform distribution," it must satisfy the lower standard, i.e., substantially uniform distribution).

As explained in the institution Decision, "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." DI 6. Indeed, Petitioner proposes the same construction. Pet. 18. Yet, here, Petitioner asks us to import the visual inspection and the consistent-dosage-weight test from the specification into the challenged claims. This, we cannot do. *See In re Trans Texas Holdings Corp.*, 498 F.3d 1290, 1299 (Fed. Cir. 2007) (explaining that "while the specification should be used to interpret the meaning of a claim, courts must not import limitations from the specification into the claim") (citing *Phillips*

v. AWH Corp., 415 F.3d 1303, 1323 (Fed. Cir. 2005) (en banc) (quotation marks and alterations omitted)).

We, again, emphasize that the express language in claim 16 requires measurement of the amount of active component in substantially equal sized individual unit doses. Thus, we are not persuaded that Chen teaches the substantially-uniform-distribution limitation merely because the films thereof are substantially transparent as shown by visual inspection, or because the weights of the dosage units are consistent.

Citing the Declaration of Dr. Cohen, Petitioner further contends that Chen teaches the substantially-uniform-distribution limitation because "Chen's process begins by forming a homogeneous mixture," and because "[m]aintaining uniformity in the intermediate steps and in the final product would have been obvious." Pet. 56 (citing Ex. 1007 ¶¶ 106–107, 112–115). We are not persuaded.

In making his Declaration, Dr. Cohen relies on Modern Coating, which teaches drying of thin films, including the basic principles, methods, and apparatus used. *See* Ex. 1009, 267–95. Dr. Cohen testifies that "[w]hen working with a homogenous or completely dissolved coating solution, like the one described in Chen, it would be difficult for a person of ordinary skill in the art not to obtain a film that has uniform content of active." Ex. 1007 ¶ 107 (citing Ex. 1009, 268). Dr. Cohen also states that "the role of drying in maintaining uniformity of distribution was known in the art well prior to" the earliest possible priority date of the '167 patent, and that an ordinary artisan would have been aware of the variables in the drying process, and would have been able to optimize these variables to maintain uniformity of

the coating solution during drying. *Id.* ¶ 113 (citing Ex. 1009, 286), ¶ 114 (citing Ex. 1009, 268). According to Dr. Cohen, "beginning in the 1960s, my colleagues and I were able to produce film with *high degree of uniformity* of distribution of components." *Id.* ¶ 112 (emphasis added).

Dr. Cohen, however, does not assert that a skilled artisan would have been able to produce film with any particular desired degree of (or absolute) uniformity. And he does not explain what the "high degree of uniformity" he and his colleagues were able to achieve, and whether it satisfies the substantially-uniform-distribution requirement recited in claim 16 of the '167 patent, that is, as measured by substantially equally sized individual unit doses having the active component that do not vary by more than 10% of the desired amount.

Similarly, Petitioner does not argue that the "uniform film" produced according to the drying processes taught in Modern Coating meets this limitation.[9] In addition, Dr. Cohen does not opine, Petitioner does not assert, and we do not find, that an ordinary artisan would have understood an unspecified degree of uniformity as satisfying the "substantially uniform" required in the challenged claims.

[9] Petitioner does not present any other persuasive evidence, such as its own testing data, to demonstrate that the drying processes described in Modern Coating would necessarily result in a film with "substantially uniform distribution" of the active, as required in the challenged claims. *See*, *e.g.*, Ex. 1009, 268 ("Modern precise coating applicators can [maintain uniformity] for *most coatings*.") (emphasis added).

Furthermore, as Dr. Cohen points out, the variables of the drying process that are amenable to optimization are numerous. Ex. 1007 ¶ 27 (citing Ex. 1009, 286, 271). For example, Modern Coating lists key drying variables as including dry bulb temperatures (i.e., temperature of the air), the solvent content of the air, air velocities, film temperature, nozzle design and spacing, air flow return path, uniformity of velocity across the nozzle width and from nozzle to nozzle and the transverse direction, dryer insulation, humidity of the incoming air, and surface temperature of the coating. Ex. 1009, 286, 271.

Yet, neither Petitioner nor Dr. Cohen explains sufficiently which particular variables of the many would have been optimized, or would have been critical to substantially uniform distribution of an active component. As such, Petitioner merely suggests that one of ordinary skill in the art would have known to "vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful." *See In re Kubin*, 561 F.3d 1351, 1359 (Fed. Cir. 2009). As instructed by our reviewing court, we cannot analyze obviousness with this hindsight. *See id.* Thus, we are not persuaded that Chen teaches the substantially-uniform-distribution limitation merely because it starts with a homogeneous mixture.

Because the Petition does not adequately account for the substantially-uniform-distribution limitation, Petitioner has not established a reasonable likelihood it would prevail on its assertion that claim 16, as well as claims

36, 42, 48, 55, 62, 69, 76, 86, 92, 122, and 123, which depend from claim 16, would have been obvious over Chen in view of Tapolsky.

The Board's Authority to Deny Petition on Remand

Citing 35 U.S.C. § 314(b), Petitioner argues that "[a] determination *whether* to institute an inter partes review must be made within three months after a preliminary response or the deadline for a preliminary response."[10] Paper 79, 3. Because the deadline for Patent Owner to file a preliminary response was years ago, Petitioner contends that "[t]he Board cannot change its mind on 'whether to institute' now." *Id.* Petitioner also asserts that "the law does not authorize a 'do over' on determinations to institute" because the determination on whether to institute an *inter partes* review is final. *Id.* at 4 (citing 35 U.S.C. § 314(d)). We are not persuaded.

First, Petitioner misinterprets § 314(d). Both the title and the text of the section refer to the finality of an institution decision in relation to the appealability of such a decision. *See* 35 U.S.C. § 314(d) ("No appeal.—The determination by the Director whether to institute an inter partes review under this section shall be final and nonappealable.") Petitioner does not cite to any authority or provide any persuasive argument to support its position that the Board, once issuing an institution decision, cannot reconsider that decision afterwards.

Second, Petitioner neglects that the statute requires the Director to "prescribe regulations . . . establishing and governing inter partes review."

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[10] As Petitioner acknowledges, we timely issued our institution Decision. Paper 79, 3.

35 U.S.C. § 316(a)(4). Under the Rules, a party dissatisfied with a decision may file a request for rehearing. 37 C.F.R. § 42.71(d). This Rule specifically contemplates rehearing an institution decision. *Id.* § 42.71(d)(1), (d)(2) (providing deadline for filing a request for rehearing a decision to institute a review or a decision not to institute a review). When granting such a request, the Board may change its determination on whether to institute a review outside the three-month period under 35 U.S.C. § 314(b).

The Board has indeed done so previously. *See, e.g.*, *Hospira, Inc. v. Genentech, Inc.*, IPR2017-00731, Paper 29 (PTAB Oct. 26, 2017) (granting Petitioner's request for rehearing the decision denying institution and instituting an *inter partes* review); *Incyte Corp. v. Concert Pharmaceuticals, Inc.*, IPR2017-01256, Paper 13, 14 (PTAB Apr. 9, 2018) (same); *AVX Corp. v. Greatbatch, Ltd.*, IPR2015-00710, Paper 13 (PTAB Jan. 13, 2016) (same). In all those decisions, an *inter partes* review was instituted after the three-month period required in 35 U.S.C. § 314(b).

Third, the statute contemplates that a proceeding can be "dismissed" after it is instituted. *See* 35 U.S.C. § 318(a) (requiring the Board to issue a final written decision if "an inter partes review is instituted and not *dismissed*") (emphasis added). As a result, the Board has, under certain circumstances, terminated a proceeding without a final written decision after instituting an *inter partes* review. *See, e.g.*, *Medtronic, Inc. v. Robert Bosch Healthcare Sys., Inc.*, IPR2014-00488, Paper 61 (PTAB May 22, 2015) (vacating the decision to institute and terminating the proceeding); *Corning Optical Commc'ns RF, LLC v. PPC Broadband, Inc.*, IPR2014-00440,

Paper 68 (PTAB Aug. 18, 2015) (same); *Blackberry Corp. v. MobileMedia Ideas, LLC*, IPR2013-00036, Paper 65 (PTAB Mar. 7, 2014) (*sua sponte* terminating the proceeding after institution).

As the Federal Circuit has explained, "administrative agencies possess inherent authority to reconsider their decisions, subject to certain limitations, regardless of whether they possess explicit statutory authority to do so." *Medtronic, Inc. v. Robert Bosch Healthcare Sys., Inc.*, 839 F.3d 1382, 1385 (Fed. Cir. 2016) (quoting *Tokyo Kikai Seisakusho, Ltd. v. United States*, 529 F.3d 1352, 1360 (Fed. Cir. 2008)). This principle applies to the Board, and does not, here, depend on whether we label this disposition as dismissing the Petition or denying the Petition in its entirety. *See id.* at 1386 ("[T]he Board has inherent authority to reconsider its decisions [and] 'nothing in the statute or regulations applicable here . . . clearly deprives the Board of that default authority.'") (quoting *GTNX, Inc. v. INTTRA, Inc.*, 789 F.3d 1309, 1313 (Fed. Cir. 2015)).

Nor does the fact that the case is on remand remove our ability to reconsider our decision to institute. The Federal Circuit remanded the case for us "to implement the Court's decision in *SAS*." *BioDelivery Sci. Int'l*, 898 F.3d at 1210. It explained that "*SAS* 'requires a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition.'" *Id.* at 1208 (quoting *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018)). Neither *SAS* nor the Federal Circuit's remand decision in this case requires that we must institute a review.

Indeed, under *SAS*, our previous Decision to institute runs afoul of the statute and cannot stand on its own. As a result, we must reevaluate the

Petition to make "a binary choice—either institute review or don't." *SAS*, 138 S. Ct. at 1355. And upon reconsideration, we decide no, we don't institute.

Petitioner argues that "[t]he Board cannot reverse its determination to institute reviews based on information presented after institution." Paper 79, 5. As detailed above, we deny institution of Ground 4 based on the Petition and accompanying evidence only. *See supra* 10–24. We acknowledge that we address in this Decision the preclusive effect of the Board's final decisions in the appeals of the '080 patent and the '337 patent reexaminations, which were not referenced in the Petition, or even available at the time the Petition was filed. *Supra* at 14. That consideration—which could only have benefitted Petitioner—is "for the sake of completeness" (*id.*), and does not affect our ultimate conclusion.

Finally, Petitioner argues that "Termination of an Instituted Review in Response to *SAS* is Contrary to Office Guidance, Policy, and Practice." Paper 79, 7. In support, Petitioner cites to the Office's Guidance on the Impact of *SAS* on AIA Trial Proceedings. *Id.* That Guidance, however, applies to "pending trials," and does not address a case, like this one, which is on remand from the Federal Circuit. *See* https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial.

Petitioner also relies on a Board decision stating that the Guidance is to be interpreted "as *precluding termination* of a partially instituted proceeding in response to *SAS Institute*." Paper 79, 8 (citing *ESET, LLC v. Finjan, Inc.*, IPR2017-01738, Paper 28 (PTAB Aug. 10, 2018), 10)

(emphasis added by Petitioner). Putting aside that *ESET* is a non-precedential panel decision, that case is procedurally distinguishable from this one. Indeed, the decision in *ESET* cited by Petitioner issued before a final decision was rendered. In contrast, in this case, a final decision not only has issued, but has been appealed and vacated, and the proceeding has been remanded to the Board. Thus, the interpretation of the Guidance in *ESET*—like the Guidance itself—does not instruct our analysis in this case.

Petitioner cites several other cases and argues "since *SAS*, the Board has consistently ordered the expansion of the scope of reviews on remand to include non-instituted claims and grounds." Paper 79, 8. As an initial matter, all the decisions Petitioner cites are panel decisions, and thus, not binding on this panel. More importantly, those cases are factually distinguishable.

For example, in some of those cases, the Board initially instituted review of the majority of the asserted grounds. *See, e.g.*, *Ulthera, Inc. v. DermaFocus LLC*, IPR2016-01459, Paper 11 (PTAB Jan. 23, 2017) (originally instituted all asserted grounds, for all except two claims); *Arctic Cat, Inc. v. Polaris Indus., Inc.*, IPR2015-01781, Paper 7 (PTAB Feb. 3, 2016) (originally instituted six out of eight asserted grounds, but not all claims); *Baker Hughes Oil Field Operations, Inc. v. Smith Int'l, Inc.*, IPR2016-01452, Paper 13 (PTAB Feb. 6, 2017) (originally instituted three out of five asserted grounds, but not all claims). In contrast, in our previous institution Decision, we instituted review of all challenged claims but only one out of five asserted grounds. As explained above, to institute on all

grounds now and start the trial again would not be the best use of the Board's and the parties' limited resources. *See supra* at 8–9.

In addition, in some of those prior cases, the initial denial of institution was not, as in our previous institution Decision, based on a substantive patentability analysis, but the Board's discretion. *See, e.g.*, IPR2016-01452, Paper 13, 19–22 (denying institution of one ground under 35 U.S.C. § 325(d)); *see also* IPR2017-01738, Paper 10, 25 (exercising discretion to deny institution of one ground because the prior art asserted "was considered extensively by the Office during prosecution").

In *Adidas AG v. Nike, Inc.*, the Board initially denied institution of one of two asserted grounds, again, not based on a substantive patentability analysis in light of prior art, but because "Petitioner's arguments, citations, and claim charts fail to provide appropriate guidance as to where limitations of the challenged claims are found with particularity." IPR2016-00921, Paper 6 (PTAB Oct. 21, 2016), 22; *see also id.* at 21 (stating "the claim chart offered to point out where the features of the claim are present in the prior art spans four pages and constitutes bulk citation to portions of" the prior art, and thus, "does not provide meaningful 'particularity'"). In contrast, we denied four out of five asserted grounds in our original institution Decision based on a substantive patentability analysis that considered cited prior art, pointing out where Petitioner failed to sufficiently address a claim limitation, the reason to combine prior art teachings, or a reasonable expectation of success. DI 9–15, 18.

Lastly, in *Nestle Purina PetCare Co. v. Oil-Dri Corp.*, Petitioner, after filing a notice of appeal with the Federal Circuit, sought remand, alleging

"Patent Owner committed fraud against the Board." IPR2015-00737, Paper 45 (PTAB July 31, 2018), 2–3. Although the Federal Circuit remanded that case pursuant to *SAS*, and did not "require the Board to address the issues of fraud or sanctions," the Board authorized briefing relating to that important issue. *Id.* at 3–4. That unique fact does not exist in this case.

In sum, the Board possesses inherent authority to, upon reconsideration of the Petition and accompanying evidence, deny the Petition in its entirety on remand.

CONCLUSION

We maintain that, as explained in the original institution Decision, the majority of unpatentability grounds (Grounds 1–3 and 5) presented in the Petition fail to meet the institution standard. Under the circumstances of this this case, we exercise our discretion to deny the Petition in its entirety.

Additionally, the information presented in the Petition does not establish a reasonable likelihood that Petitioner would prevail in showing the unpatentability of claims challenged in any grounds, including Ground 4. Thus, we deny review of the Petition in its entirety on this basis also.

ORDER

Accordingly, it is

ORDERED that the Decision on institution issued on May 20, 2015 (Paper 6) is modified according to this Decision;

FURTHER ORDERED that Petitioner's request for *inter partes* review of claims 16, 36, 42, 48, 55, 62, 69, 76, 86, 92, 122, and 123 of the '167 patent is denied and no *inter partes* review is instituted.

PETITIONER:

Kia L. Freeman
Wyley S. Proctor
Thomas F. Foley
McCarter & English, LLP
kfreeman@mccarter.com
wproctor@mccarter.com
tfoley@mccarter.com

PATENT OWNER:

John L. Abramic
Harold H. Fox
Steptoe & Johnson LLP
jabramic@steptoe.com
hfox@steptoe.com

Daniel A. Scola, Jr.
Michael I. Chakansky
Hoffmann & Baron LLP
dscola@hbiplaw.com
mchakansky@hbiplaw.com