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Paper No. 89
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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 IPR2015-00169
Patent 8,765,167 B2

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

PRATS, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. Summary of Decision on Remand—Denying Institution

Our reviewing court, the United States Court of Appeals for the Federal Circuit, has remanded this proceeding to this 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, 1210 (Fed. Cir. 2018). For the reasons discussed below, pursuant to the *SAS* decision as well as the Board's authority in relation to instituting and terminating *inter partes* reviews, we reconsider our original decision to institute trial, and instead deny review of the challenges presented in the Petition, thereby terminating this proceeding.

B. Statement of the Case

BioDelivery Sciences International, Inc. ("Petitioner") filed a Petition (Paper 2, "Pet.") requesting an *inter partes* review of some, but not all, of the claims of U.S. Patent No. 8,765,167 B2 (Ex. 1001, "the '167 patent").[1] Aquestive Therapeutics, formerly known as MonoSol Rx, LLC ("Patent Owner"), did not file a Preliminary Response.

We instituted trial as to only one of the five grounds of unpatentability advanced by Petitioner. *See* Paper 6, 3 and 24 ("Decision to Institute" or "DI"). We issued a Final Decision holding that Petitioner had not shown

[1] With the Petition under consideration herein, Petitioner filed three other petitions for inter partes review, challenging different claims of the '167 patent. Those cases are numbered IPR2015-00165, IPR2015-00167, and IPR2015-00168. No trial was instituted in IPR2015-00167. Decisions in IPR2015-00165 and IPR2015-00168 are issued concurrently herewith.

that the claims for which trial was instituted were unpatentable. Paper 69, 37 ("Final Decision" or "Final Dec.").

While Petitioner's appeal of our Final Decision was pending before the Federal Circuit, the Supreme Court issued the *SAS* decision, holding that if an *inter partes* review is instituted, the Board must consider the patentability of all claims challenged in the petition. *See BioDelivery v. Aquestive*, 898 F.3d at 1207–08 (citing *SAS*, 138 S. Ct. at 1355–56). Petitioner subsequently requested the Federal Circuit to remand this proceeding to the Board to consider non-instituted claims and non-instituted grounds in accordance with *SAS*, and the court granted that request. *Id.* at 1207, 1210.

On remand, we directed the parties to provide input as to whether, at this time, an appropriate course of action going forward would be to vacate our prior Decision to Institute and deny the Petition in its entirety. Paper 77, 2. The parties have completed briefing. *See* Papers 80, 81, 86, 88. Petitioner contends the Board "cannot change its mind now and vacate its determination to institute the ''167 IPRs." Paper 80, 3. Patent Owner argues the opposite. Paper 81, 1.

Having considered the parties' arguments, and given the particular circumstances of this case, we modify our Decision to Institute and instead deny the Petition in its entirety, thereby terminating this proceeding.

C. Grounds of Unpatentability

Petitioner presents the following grounds of unpatentability (Pet. 18):

Ground	Reference[s]	Statutory Basis	Challenged Claims
1	Tapolsky[2]	35 U.S.C. § 102(b)	17, 18, 30, 31, 37, 49, 56, 70, 77, 80, 87, 93, 110, 112, 114–116, and 124
2	Tapolsky in view of Chen[3]	35 U.S.C. § 103(a)	17, 18, 30, 31, 37, 49, 56, 63, 70, 77, 80, 81, 87, 93, 110–116, and 124
3	Tapolsky in view of Chen and Modern Coating[4]	35 U.S.C. § 103(a)	17, 18, 30, 31, 37, 49, 56, 63, 70, 77, 80, 81, 87, 93, 110–116, and 124
4	Chen in view of Tapolsky	35 U.S.C. § 103(a)	17, 18, 30, 31, 37, 49, 56, 63, 70, 77, 80, 81, 87, 93, 110–116, and 124
5	Chen in view of Tapolsky and Modern Coating	35 U.S.C. § 103(a)	17, 18, 30, 31, 37, 49, 56, 63, 70, 77, 80, 81, 87, 93, 110–116, and 124

Petitioner supports its challenges with a Declaration by Edward D. Cohen, Ph.D. ("Cohen Decl.") (Ex. 1007).

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[2] WO 99/55312 A2 (published Nov. 4, 1999) (Ex. 1003).
[3] WO 00/42992 A2 (published Jul. 27, 2000) (Ex. 1002).
[4] MODERN COATING AND DRYING TECHNOLOGY (Edward D. Cohen & Edgar B Gutoff eds., 1992) (Ex. 1009).

D. Related Proceedings

In addition to IPR2015-00165, IPR2015-00167, and IPR2015-00168, noted above, the parties identify a number of proceedings, within the U.S. Patent and Trademark Office as well as in district court, which involve the '167 patent as well as patents in the same family as the '167 patent. *See* Pet. 1–4; Papers 79, 85.

E. Reconsideration of Decision to Institute

An *inter partes* review may be instituted only if "the information presented in the [Petition and Preliminary Response] . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a).

As the Supreme Court explained in *SAS*, the decision whether to institute an *inter partes* review is discretionary. *See SAS*, 128 S. Ct. at 1356 ("[Section] 314(a) invests the Director with discretion on the question *whether* to institute review . . . .").[5]

Section 316(b) requires that, when prescribing regulations for conducting *inter partes* reviews, "the Director shall consider the effect of any such regulation on . . . the efficient administration of the Office. . . ." 35 U.S.C. § 316(b); *see also* 37 C.F.R. § 42.1(b) (The rules promulgated by the Director "shall be construed to secure the just, speedy, ***and inexpensive*** resolution of every proceeding.") (Emphasis added).

[5] The Director has delegated the authority whether to institute to the Board. 37 C.F.R. § 42.4(a).

In the present case, as discussed below, of the five grounds of unpatentability presented in the Petition, we determined previously that Petitioner failed to establish, on the merits, a reasonable likelihood of prevailing as to four of those grounds entirely (Grounds 1–3 and 5), based on the analysis set out in the Decision to Institute. DI 10–21, 23–24. Because the overwhelming majority of unpatentability grounds presented by Petitioner fail to meet the standard for institution of *inter partes* review, we find that instituting trial as to those grounds at this time is neither in the interest of the efficient administration of the Office, nor in the interest of securing an inexpensive resolution of this proceeding. Accordingly, we reconsider our Decision to Institute and determine it is appropriate to exercise our discretion to deny review of all challenges presented in the Petition on this basis alone.

Nonetheless, as discussed in more detail below, we address the one previously instituted ground (Ground 4) again, and determine now that Petitioner does not establish a reasonable likelihood of prevailing in its challenges based on that ground. Thus, we determine that Petitioner fails to establish a reasonable likelihood that it would prevail in relation to any of the five grounds presented in the Petition, and deny review on remand on that basis also.

Petitioner does not persuade us (*see* Paper 80, 1–2 and 4–6) that our decision herein is contrary to the requirements of § 314(a). First, we base our reconsideration of the original Decision to Institute only on the information presented in the Petition. The fact that Petitioner did not ultimately prevail as to the only ground and claims for which trial was

actually instituted (Ground 4) simply underscores that instituting trial as to the remaining *insufficient* grounds (Grounds 1–3 and 5) at this time is neither in the interest of the efficient administration of the Office, nor in the interest of securing this proceeding's inexpensive resolution. In addition, as noted above, on remand, we reconsider the Petition and accompanying evidence, and for the reasons explained in Section II, C below, modify our decision and determine that Petitioner fails to establish a reasonable likelihood that it would prevail as to Ground 4, in addition to Grounds 1–3 and 5.

Petitioner also does not persuade us that § 314(d) prohibits us from reconsidering our Decision to Institute. *See* Paper 80, 3–4.

Rather than being directed to whether the Director, or the Board, may reconsider an institution decision, both the title and the text of § 314(d) refer to the finality of an institution decision in relation to the decision's appealability. *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 specific authority, or provide persuasive argument, supporting its position that the Board, having issued an institution decision, cannot reconsider that decision afterwards.

To the contrary, the statute requires the Director to "prescribe regulations . . . establishing and governing inter partes review," 35 U.S.C. § 316(a)(4), and under those regulations, a party dissatisfied with a decision may file a request for rehearing. 37 C.F.R. § 42.71(d). Section 42.71(d) expressly contemplates rehearing an institution decision. *See* 37 C.F.R.

§ 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 whether to institute a review outside the three-month period under 35 U.S.C. § 314(b).

The Board has in other instances changed its determination as to whether to institute a review outside the three-month period institution period set out under § 314(b). *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, Papers 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 § 314(b).

Moreover, the statute governing this proceeding expressly contemplates that a proceeding can be "dismissed" after institution. *See* 35 U.S.C. § 318(a) (requiring the Board to issue a final written decision "[i]f an inter partes review is instituted and not ***dismissed***") (emphasis added). Consistent with that provision, the Board has terminated *inter partes* reviews after institution without issuing final written decisions. *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).

Indeed, in relation to the decision by this Board in IPR2014-00488 to terminate an instituted *inter partes* review without issuing a final decision, the Federal Circuit explained that the 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.'" *Medtronic, Inc. v. Robert Bosch Healthcare Sys., Inc.*, 839 F.3d 1382, 1386 (Fed. Cir. 2016) (quoting *GTNX, Inc. v. INTTRA, Inc.*, 789 F.3d 1309, 1313); *see also id.* at 1385 ("[A]dministrative agencies possess inherent authority to reconsider their decisions, subject to certain limitations, regardless of whether they possess explicit statutory authority to do so.") (quoting *Tokyo Kikai Seisakusho, Ltd. v. United States*, 529 F.3d 1352, 1360 (Fed. Cir. 2008)). Thus, whether we label our decision herein as reconsidering the Petition, dismissing the Petition, or denying the Petition in its entirety, Petitioner does not persuade us that we lack the authority to reconsider our original Decision to Institute.

Petitioner also does not persuade us that the Federal Circuit's remand decision in this case does not authorize us to reconsider our original Decision to Institute. *See* Paper 80, 6–7.

The Federal Circuit remanded the case for us "to implement the Court's decision in *SAS*." *BioDelivery v. Aquestive*, 898 F.3d at 1210. The Federal Circuit 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)).

In implementing *SAS*, therefore, we evaluate the Petition to make "a binary choice—either institute review or don't." *SAS*, 138 S. Ct. at 1355. Having evaluated the Petition, we decide, for the reasons discussed herein, that we do not institute review.

Petitioner does not persuade us that reconsidering our original Decision to Institute, and thereby terminating this proceeding, is contrary to Office guidance, policy, and practice. *See* Paper 80, 7–9. We first note that the Office's *SAS* Guidance discusses only "pending trials" and does not address post-remand proceedings, like this one, in which a final decision has already been rendered. *See* https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial.

We acknowledge Petitioner's citation to a Board decision stating that the Office's *SAS* Guidance is to be interpreted "as *precluding termination* of a partially instituted proceeding in response to *SAS Institute*." Paper 80, 8 (quoting *ESET, LLC v. Finjan, Inc.*, IPR2017-01738, Paper 28, 10 (PTAB Aug. 10, 2018)) (emphasis added by Petitioner). *ESET* is a non-precedential panel decision, however. Moreover, that case is procedurally distinguishable from this proceeding in that the decision in *ESET* cited by Petitioner issued before a final decision was rendered, in contrast to the present situation in which a final decision has not only issued, but that decision has been appealed, and the proceeding remanded to the Board.

As to cases having post-remand procedural postures similar to this proceeding, we acknowledge Petitioner's contention that "since *SAS*, the

Board has consistently ordered the expansion of the scope of reviews on remand to include non-instituted claims and grounds." Paper 80, 8. All the decisions Petitioner cites, however, are non-precedential panel decisions and, moreover, are factually distinguishable from the present situation.

In *Nestle Purina PetCare Co. v. Oil-Dri Corp.*, the 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), 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. Unlike the present situation, moreover, the patent owner did not oppose the *SAS* remand in *Nestle*. *Id.* at 3.

More importantly, as discussed herein, of the five grounds Petitioner presented, no ground advanced in the Petition was held by the Decision to Institute to meet the standard for institution of an *inter partes* review, except for the single ground for which trial was actually instituted, and that ground ultimately failed as to the merits. This contrasts with the situation in nearly all of the cases cited by Petitioner, in which a majority, or at least a significant portion of the originally presented grounds, was found to meet the institution standard. *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); *Adidas AG v. Nike, Inc.*, IPR2016-00921, Paper 6 (PTAB Oct. 21, 2016) (originally instituted as to one of two asserted grounds).

Thus, in the cases cited by Petitioner, expansion of the scope of review required evaluation of only a few additional claims, or one or two additional unpatentability grounds. In contrast, expanding the scope of this proceeding to include originally non-instituted grounds, without reconsidering our original Decision to Institute, would result in conducting a trial as to four grounds for which Petitioner did not meet the standard for instituting trial. We find that undertaking review as to four grounds for which the standard for institution of *inter partes* review has not been met is neither in the interest of the efficient administration of the Office, nor in the interest of securing an inexpensive resolution of this proceeding, particularly when the only ground for which trial was actually instituted ultimately failed. *See* Final Dec. 37.

In sum, for the reasons discussed, Petitioner does not persuade us that the Board lacks the authority in this instance to reconsider its original Decision to Institute. Because four of the five unpatentability grounds (Grounds 1 and 3–5) presented by Petitioner fail to meet the standard for institution of *inter partes* review, we find that instituting trial as to those insufficient grounds at this time is neither in the interest of the efficient administration of the Office, nor in the interest of securing an inexpensive resolution of this proceeding.

Accordingly, we reconsider our Decision to Institute and determine it is appropriate to exercise our discretion to deny review of all challenges presented in the Petition on this basis alone. Nonetheless, we address the one previously instituted ground (Ground 4) below, and determine now that Petitioner does not establish a reasonable likelihood of prevailing in any of its challenges presented in the Petition, i.e., in relation to any claims challenged in any of Grounds 1–5.

II. ANALYSIS

A. The '167 Patent (Ex. 1001)

The '167 patent discloses that films incorporating a pharmaceutical agent were known to be suitably administered to mucosal membranes, such as the mouth and nose. Ex. 1001, 1:42–58. Some of those films were known, however, to suffer from particle agglomeration issues, resulting in non-uniform distribution of the active ingredient within the film. *Id.* at 1:59–62; 2:21–53. The '167 patent attributes this non-uniform distribution to the long drying times and excessive air flow conventionally used when drying the films. *Id.* at 1:62–67. Because sheets of such films usually are cut into individual doses, a non-uniform distribution of the active ingredient could result in a final individual dosage form containing insufficient active ingredient for the recommended treatment, as well as a failure to meet regulatory standards for dosage form accuracy. *Id.* at 2:1–20.

The '167 patent addresses the issue of particle agglomeration and its associated non-uniform distribution of therapeutic agent within film dosage forms by using a "selected casting or deposition method" or "controlled drying processes" known in the prior art. *Id.* at 6:21–27.

The ’167 patent describes a preferred embodiment in which “the film is dried from the bottom of the film to the top of the film.” *Id.* at 24:51–52. “This is accomplished by forming the film and placing it on the top side of a surface having top and bottom sides. Then, heat is initially applied to the bottom side of the film to provide the necessary energy to evaporate or otherwise remove the liquid carrier.” *Id.* at 24:59–64. “Desirably, substantially no air flow is present across the top of the film during its initial setting period, during which a solid, visco-elastic structure is formed.” *Id.* at 24:52–56.

Claims 17 and 110 of the ’167 patent are the independent claims challenged in the Petition, and read as follows:

> 17. A multi-layer film for delivery of a desired amount of an active component comprising:
>
> (a) at least one first film layer comprising:
>
> (i) an ingestible, water-soluble polymer matrix; and
>
> (ii) 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; corn starch; amorphous silicon dioxide; syloid; metallic stearates, Vitamin E, Vitamin E TPGS, silica and combinations thereof; and
>
> (b) a second film layer 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, wherein said first film layer is substantially in contact with said second film layer;

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

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***.

110. A multi-layer film for delivery of a desired amount of an active component comprising:

(a) a first film layer comprising:

(i) an ingestible, water-soluble or water-swellable polymer matrix; and

(b) at least a second film layer comprising:

(i) an ingestible, water-soluble or water-swellable polymer matrix comprising a water-soluble or swellable polymer;

wherein the first and/or second layers further comprise:

a desired amount of a substantially uniformly

> distributed active component, said active component being selected from the group consisting of cosmetic agents, pharmaceutical agents, vitamins, bioactive agents and combinations thereof; a component selected from the group consisting of an anti-tacking agent, a sweetener, a flavor, an acidulent, an oxide filler, propylene glycol, vitamin E acetate, polyacrylic acid, a preservative, a buffer, a coloring agent and combinations thereof; and
>
> wherein said first film layer is substantially in contact with said second film layer;
>
> said film being formed by a controlled drying process which rapidly forms a viscoelastic matrix to lock-in said active component in place and maintain said substantially uniform distribution; and
>
> wherein said film is self-supporting, ***whereby said substantially uniform distribution of said active component 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.***

Ex. 1001, 43:37–44:2, 47:66–48:29 (emphases added).

B. Grounds 1–3 and 5

We previously evaluated grounds 1–3 and 5 on the merits in our Decision to Institute, and determined that Petitioner had not shown a reasonable likelihood of prevailing in establishing the unpatentability of any of the claims challenged in those grounds. DI 10–21, 23. On remand, having reconsidered the Petition and accompanying evidence, we see no

reason to change our analysis. We, therefore, maintain our position and, again, determine that Grounds 1–3 and 5 do not meet the standard for instituting *inter partes* review.

C. Ground 4—Obviousness in view of Chen and Tapolsky

1. Chen (Ex. 1002)

Chen discloses a dosage unit in the form of a "flexible, non-tacky, dry conveniently packaged film. Once removed from the package and placed on a mucosal surface, the mucosal surface-coat-forming film hydrates substantially immediately to form a coating on the moist surface of the mucous membrane and then disintegrates and dissolves to release the active agent from the film." Ex. 1002, 6:25–29.

Chen discloses that its films may be prepared by a "solvent casting method" shown in its Figure 2, the method using a hydrocolloid that is "completely dissolved or dispersed in water or in a water alcoholic solution under mixing to form a homogenous formulation. In addition to the active agent and the hydrocolloid, any of the ingredients listed above may be added and dispersed or dissolved uniformly in the hydrocolloid solution." *Id.* at 15:20–23, Fig. 2.

This "homogeneous mixture" is then degassed, coated on a non-siliconized side of a polyester film, and "dried under aeration at a temperature between 40–100°C so as to avoid destabilizing the agents contained within the formulation . . . . The dry film formed by this process is a glossy, stand alone, self supporting, non-tacky and flexible film." *Id.* at 15:25–31 (citations to Fig. 2 omitted). The film may then be cut, using a

die, into shapes and sizes suitable for administration as a single dosage unit. *Id.* at 16:1–7.

2. Tapolsky (Ex. 1003)

Tapolsky discloses a device "for application of a pharmaceutical to mucosal surfaces. The device comprises an adhesive layer and a nonadhesive backing layer, and the pharmaceutical may be provided in either or both layers. Upon application, the device adheres to the mucosal surface, providing localized drug delivery and protection to the treatment site." Ex. 1003, Abstract. Tapolsky discloses that its device "comprises a layered film disk having an adhesive layer and a backing layer, both water-erodable, having the pharmaceutical in either or both of the layers." *Id.* at 7:25–27.

In Example 37, Tapolsky describes the preparation of a four-layered film composed of two non-adhesive backing layers, onto which were coated two bioadhesive layers that contained albuterol sulfate as the active agent. *Id.* at 37:5–25. The two backing layers were obtained by preparing a gel containing 79.74% water, 0.01% FD&C red dye 40, 0.05% sodium benzoate, 2.5% peppermint flavor, 13.5% hydroxyethyl cellulose, and 4.5% hydroxypropyl cellulose by weight. *Id.* at 37:4–6. The first backing film was coated onto a substrate and then dried at 80° C for 8 minutes. *Id.* at 37:6–9. The second backing film was then coated directly onto the first backing film and dried at 80° C for 8 minutes. *Id.* at 37:9–10.

The two bioadhesive layers of the film described in Example 37 of Tapolsky were obtained by preparing a gel containing 45.2% water USP, 45.3% ethyl alcohol, 1.6% hydroxyethyl cellulose, 0.6% hydroxypropyl

cellulose, 2.8% polyacrylic acid Noveon® AA1 USP, 2.5% sodium carboxymethyl cellulose, 0.1 % titanium dioxide, and 1.9% albuterol sulfate by weight. *Id.* at 37:15–19. The first bioadesive layer was coated directly on top of the two-layered backing film and dried at 60° C for 8 minutes. *Id.* at 37:19–21. The second bioadhesive layer was coated directly onto the first bioadhesive layer and dried at 60° C for 20 minutes. *Id.* at 37:21–22. Tapolsky states that the final film "contained 1.46mg/cm^2 albuterol sulfate . . . [and] also exhibited excellent tensile strength." *Id.* at 37:24–25.

3. Analysis

a. Introduction

We previously evaluated ground 4 on the merits in our Decision to Institute, and determined that Petitioner had shown a reasonable likelihood of prevailing in establishing the unpatentability of the claims challenged in that ground. DI 21–23. On remand, having reconsidered the Petition and accompanying evidence, we modify our original Decision to Institute and instead determine that Ground 4 does not meet the standard for instituting *inter partes* review, for the reasons discussed below.

As to the substantially uniform distribution of active component recited in claims 17 and 110 (*see* Ex. 1001, 43:64–44:2 (claim 1); *id.* at 48:25–29 (claim 110)), Petitioner advances several rationales why the combination of Chen and Tapolsky teaches or suggests a film having that feature. Pet. 47, 52, 56–57.

In particular, Petitioner contends that under the doctrine of collateral estoppel, we must adopt the Board's finding in a prior decision in a related patent ("the '588 reexamination appeal decision"), that Chen's disclosure of

a weight deviation of ±0.001 between film doses (Ex. 1002, 20:3 (Table 4)) met the requirement of no more than 10% variation of active content per film dosage unit. *See id*. at 56 (incorporating by reference "[s]ubsection 3 of Ground 2"). Petitioner also incorporates by reference subsection 3 of Ground 1. *Id.* Petitioner contends also that the visual inspection and consistent dosage weight described in Chen (Ex. 1002, 17:15–16, 20:3), as well as the homogeneity of the starting solution (*id.* at 15:19–25, 17:6–12), establish that Chen's films meet the substantially uniform active agent distribution requirement of claims 17 and 110. *Id.* at 56–57.

In our original Decision to Institute, we stated that, "[a]s to the substantially uniform active agent distribution required by claims 17 and 110, on the current record, in the absence of evidence to the contrary, we agree with the Board's previous finding [in the '588 reexamination appeal decision] that Chen's active agent-containing film layer possesses that feature." DI 22.

Having reconsidered the Petition and its accompanying evidence, we modify our original Decision to Institute and instead determine, for the reasons below, that the Board's prior decision in the '588 reexamination appeal decision is insufficient to establish that Chen teaches or suggests a film that meets the uniform distribution requirement of claims 17 and 110. For the reasons discussed below, we also determine that the teachings in Tapolsky and Chen cited in Ground 4 are insufficient to establish that the combination of Chen and Tapolsky teaches or suggests a film having the uniform distribution of active component required by claims 17 and 110.

b. Substantially Uniform Distribution--Collateral Estoppel

Petitioner does not persuade us that collateral estoppel applies in this instance. 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, for the reasons discussed below, we determine that it does not apply in this case.

As Petitioner contends (Pet. 37–39), 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. In *Freeman*, the court noted in particular that "statements regarding the scope of patent claims made in a former adjudication should be narrowly construed." *Id.* at 1466.

We find that the instant situation does not meet the requirements for applying issue preclusion because resolution of the issue in this case was not essential to the final judgment in the ’588 decision, and because the issues are not identical. In particular, the limitation at issue in this proceeding is not identical to the limitation at issue in the ’588 decision, and therefore was not essential to the final judgment in the ’588 decision.

The limitation at issue in claims 17 and 110 of the ’167 patent states that the 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.” Ex. 1001, 43:66–44:2 (claim 17), 48:27–29 (claim 110).

In the prior ’588 decision, the Board resolved the issue of whether Chen met the uniformity requirement based on claim 1 of the ’588 patent. Ex. 1027, 12 (the ’588 decision).[6] In contrast to the language in claims 17 and 110 of the ’167 patent, claim 1 of the ’588 patent, as amended, requires only “substantially uniform content of therapeutic active composition per unit of film.” Ex. 1027, 4. Thus, the ’588 decision did not resolve the issue of whether Chen met the substantial uniformity requirement based on the claim language at issue in this proceeding.

We acknowledge the statement in the ’588 decision that, as to claim 3 of the ’588 patent, the “weight deviation” described in Example 1 of Chen “is well within the less than 10% variation of active content per film unit

[6] 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 Exhibit 1027.

requirement of claim 3" of the '588 patent. Ex. 1027, 19. As noted immediately above, however, the '588 decision resolved the uniformity issue based on claim 1 of the '588 patent, not on claim 3, which depends from claim 1.

Moreover, unlike claims 17 and 110 of the '167 patent, claim 3 of the '588 patent does not require the substantial uniformity to be based on substantially equal sized unit doses derived from a single film. Instead, claim 3 of the '588 patent recites only a "self-supporting therapeutic active-containing film [that] has a variation of active content of less than 10% per film unit." Ex. 1026, 40:7–9. Rather than claim 3 of the '588 patent, the claim language closest to claims 17 and 110 of the '167 patent appears in claim 93 of the '588 patent. Ex 1026, 44:7–10. Specifically, claim 93 of the '588 patent 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%." *Id.*

Claims 3 and 93 of the '588 patent are presumed to not have the same scope. *See Kraft Foods Inc. v. Int'l Trading Co.*, 203 F.3d 1362, 1366 (Fed. Cir. 2000) ("Under the doctrine of claim differentiation, two claims of a patent are presumptively of different scope."). Thus, even assuming that the '588 decision made findings as to claim 3 of the '588 patent, because claims 3 and 93 of the '588 patent do not have the same scope, it is apparent that the '588 decision did not resolve the issue of whether Chen met the substantial uniformity requirement at issue in this proceeding.

Petitioner also identifies *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."); *see also* Paper 80, 6 (noting the finality of the '080 and '337 patent reexamination decisions).[7]

As Petitioner points out, in the present case, our decision whether to institute an *inter partes* review is based only on the information presented in the Petition. Paper 80, 1 (citing 35 U.S.C. § 314(a)). At the time of the Petition, the appeals of the '080 and '337 patent reexaminations were pending before the Board. Pet. 2. Thus, even if *inter partes* reexamination could give rise to collateral estoppel in an *inter partes* review, the Petition does not identify a final Board decision in these two reexaminations that provides a basis for us to apply the doctrine.

We recognize that, at the time of the decision herein, the Board has issued final decisions in the appeals of the '080 patent and the '337 patent reexaminations. Paper 80, 6. For the reasons discussed below, however, we are not persuaded that the final decisions in the appeals of the '080 patent and the '337 patent reexaminations, or in the '588 patent reexamination, have preclusive effect.

[7] The correct control numbers for the '080 and '337 reexaminations are 95/002,170 and 95/002,171, respectively.

As explained in *In re Freeman*, "under certain circumstances, where all of the requirements of issue preclusion have been met, the doctrine will not be applied. Preclusion will not be effected when the quality or effectiveness of the procedures followed in the two suits differ." 30 F.3d at 1467. In particular, issue preclusion may be inappropriate 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)).

We find that the instant *inter partes* review under the AIA offers a significant procedural opportunity to the parties that was not available in the prior *inter partes* reexamination proceeding of the '588 patent cited by Petitioner. 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). Although normal examination procedure allows for submission of evidence in affidavit form (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 the instant proceeding, witnesses presenting direct testimony by affidavit are subject to cross-examination via deposition. 37 C.F.R. § 42.53. Thus, the availability of cross-examination of witnesses in this *inter partes* review under the AIA is a significant procedural opportunity for Patent Owner which is not present in the prior *inter partes* reexamination

proceeding, and that procedural distinction indeed could yield a result different from that in the prior *inter partes* reexamination.

In addition, unlike in reexaminations, parties in *inter partes* reviews may request discovery, although to a more limited extent than 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). This procedural distinction also weighs against applying issue preclusion in this proceeding, based on the '588, '080, and '337 decisions in the prior *inter partes* reexaminations. Accordingly, for the reasons discussed, Petitioner does not persuade us that the doctrine of collateral estoppel is applicable in this proceeding.

c. Substantially Uniform Distribution—Tapolsky

In Ground 4, Petitioner incorporates by reference subsection 3 of Ground 1 in asserting that the combination of Chen and Tapolsky teaches or suggests a film having the substantially uniform active component distribution required by claims 17 and 110. Pet. 56.

In subsection 3 of Ground 1, Petitioner asserts that Tapolsky describes a film having the uniform distribution of active component required by claims 17 and 110 of the '167 patent. Pet. 30–31. Petitioner notes that Tapolsky reports the amount of albuterol sulfate in Example 37 to be 1.46 mg/cm^2. *Id.* at 30. Petitioner contends that, "[g]iven the reported degree of certainty (i.e., out to the second decimal place), the greatest difference in the amount of active per centimeter squared would be, at most, 0.009 mg (i.e., the difference between 1.464 mg/cm^2 and 1.455 mg/cm^2)." *Id.*

Thus, Petitioner contends, "the greatest variation in active between equally sized individual unit doses of Tapolsky's film that could exist given the reported value, is 0.61% (0.009 mg/cm2 divided by 1.46 mg/cm2), a value well within" the variation limitation of claims 17 and 110. *Id.* at 30–31 (citing Ex. 1007 ¶ 103 (Cohen Decl.)). Petitioner contends that "[t]his percentage does not change with unit size." *Id.* at 31.

Petitioner does not persuade us that Tapolsky expressly or inherently describes a film having the uniform distribution of active agent required by claims 17 and 110 of the '167 patent. Petitioner does not direct us to disclosures in Tapolsky that describe anything specific about whether the albuterol sulfate was uniformly distributed within the film prepared in Example 37.

We note that Tapolsky describes the concentration of albuterol sulfate per cm^2 in Example 37's film to two decimal places. That concentration can be determined, however, by simply dividing the mass of the albuterol sulfate in the film by the total area of the final film. Although that calculation describes the final concentration of albuterol within the film of Example 37, Petitioner does not persuade us that it demonstrates an inherent uniform distribution of albuterol sulfate within that film. Petitioner does not direct us to any disclosure in Tapolsky explaining how the amount of albuterol sulfate per cm^2 was determined, in a way that would demonstrate inherently the uniform distribution required by claims 17 and 110 of the '167 patent. Nor does Petitioner direct us to any disclosure in which Tapolsky divides its film into substantially equal sized dosage units and determines the amount of active agent within those units. Accordingly, having considered the

contentions in subsection 3 of Ground 1, Petitioner does not persuade us that Tapolsky describes, teaches, or suggests, a film having the uniform distribution of active component required by claims 17 and 110 of the '167 patent.

d. Substantially Uniform Distribution—Visual Inspection

Petitioner does not persuade us that Chen inherently describes films meeting the substantial uniformity of active component distribution required by claims 17 and 110 of the '167 patent, based only on the visual appearance of the films.

Petitioner contends initially that, because Chen describes its dried composition as a "glossy, substantially transparent, stand alone, self-supporting, non-tacky and flexible film," Chen necessarily meets the substantially uniform distribution of active component required by claims 17 and 110. Pet. 56 (citing Ex. 1002, 17:15–16 (Chen)). Petitioner explains that the '167 patent incorporates the '292 patent (Ex. 1035)[8] by reference. Pet. 56 (citing Ex. 1001, 1:11–14). Accordingly, Petitioner reasons, because the wholly incorporated '292 patent states that uniformity of distribution of active component can be determined by visual inspection, Chen's description of the visual appearance of a uniform film lacking apparent aggregations demonstrates that Chen's film meets the uniform active component distribution required by claims 17 and 110 of the '167 patent. Pet. 56 (citing Ex. 1035, 19:56–63).

[8] Robert K. Yang et al., U.S. Patent No. 7,425,292 B2 (issued Sept. 16, 2008) ("the '292 patent").

We do not find this contention persuasive. Claims 17 and 110 of the '167 patent do not recite that the substantial uniformity requirement is measured by the absence of visible aggregations of substances in the claimed film. Rather, the limitation at issue in claims 17 and 110 states that the 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." Ex. 1001, 43:66–44:2 (claim 17), 48:27–29 (claim 110).

Indeed, the '292 patent explains that the substantial uniformity limitation recited in claim 1 of the '167 patent requires actual testing of the individual dosage units of the film to determine the amount of active component in the film units:

> An alternative method of determining the uniformity of the active is to cut the film into individual doses. The individual doses may then be dissolved and tested for the amount of active in films of particular size. This demonstrates that films of substantially similar size cut from different locations on the same film contain substantially the same amount of active.

Ex. 1035, 20:62–67.

In contrast, the passage in the '292 patent regarding visual inspection cited by the Petitioner mentions nothing about the amount of active component in equal sized portions of the film, and does not state that one can determine the amount of an active component in a particular unit of the film solely by visual inspection:

> 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.

Id. at 19:56–63.

Because visual inspection is not the measure of uniformity recited in claims 17 and 110 of the ’167 patent, Petitioner does not persuade us that it is reasonable to construe the uniformity limitation at issue in those claims as being met by a visual evaluation, based on the ’292 patent’s disclosure that substantial uniformity (as opposed to the claimed uniformity of distribution with a variation of no more than 10%) can be verified visually. We acknowledge that the passage cited above in column 20 of the ’292 patent describes actual testing of the amount of active component as an “alternative” method of verifying substantial uniformity. Ex. 1035, 20:62. The fact that the two methods of determining uniformity are described as alternatives, however, does not mean that the two methods are distinct.

In sum, Petitioner does not persuade us, for the reasons discussed, that it is reasonable to construe the measure of uniformity in claims 17 and 110 of the ’167 patent, which requires a determination of the amount of active component in equal size dosage units, as being met by a method (simple visual inspection) which no evidence has shown is capable of quantifying the active component amount.

e. Substantially Uniform Distribution—Consistent Dosage Unit Weight (Chen's Example 1)

Petitioner also does not persuade us that the disclosure in Example 1 of Chen of a film weight of 0.028 "g/dosage film" with a "±SD (n)" of "0.001 (4)," inherently meets the substantially uniform distribution of active component recited in claims 17 and 110 of the '167 patent. Pet. 56 (citing Ex. 1002, 20 (Table 4)).

Petitioner bases this contention on the first set of examples in the '292 patent (Examples A through I), in which the '292 patent weighed identically sized portions cut from the prepared films, and found the dosage weight of the portions consistently to be 0.04 grams. *Id.* (citing Ex. 1035, 20:53–62). Thus, Petitioner contends, the '292 patent, which is incorporated by reference into the '167 patent, determines substantial uniformity based on consistency in weight of same-sized portions cut from the film. *Id.* In turn, Petitioner contends, because Chen's Example 1 reports a consistent weight of "0.028 ±0.001 g/dosage film," the film of Chen's Example 1 meets the claimed substantial uniformity requirement to the extent required by the '167 patent. *Id.*

We do not find Petitioner's contentions persuasive. Consistent dosage unit weight is not the uniformity standard recited in claims 17 and 110 of the '167 patent. Rather, claims 17 and 110 expressly require a determination of the amount of active component. Ex. 1001, 43:66–44:2 (claim 17), 48:27–29 (claim 110) (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").

Moreover, by construing the uniformity requirement of claims 17 and 110 of the '167 patent as encompassing consistent dosage unit weights, based on the examples in the '292 patent, Petitioner improperly imports disclosure from embodiments of the incorporated '292 patent into the claims of the '167 patent. *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 'confin[e] the claims to th[e] embodiments' found in the specification . . . .") (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed. Cir. 2005) (en banc)) (citations omitted, bracketed text in internal quotes in original).

Further, although the ground of unpatentability under consideration herein is based on obviousness under § 103(a), Petitioner's contention, in this instance, is essentially that, because Chen describes a film that yields same-sized dosage units with consistent overall weights, Chen's film inherently meets the substantial uniformity requirement of claims 17 and 110 of the '167 patent. *See* Pet. 56.

It is well settled, however, that inherency "may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981); *see also Agilent Techs., Inc. v. Affymetrix, Inc.*, 567 F.3d 1366, 1383 (Fed. Cir. 2009) ("The very essence of inherency is that one of ordinary skill in the art would recognize that a reference *unavoidably* teaches the property in question.") (emphasis added). We are not persuaded that Petitioner has advanced evidence to show, or explained persuasively

how or why, the allegedly same-sized dosage forms in Example 1 of Chen, that weigh the roughly same *unavoidably* contain the same amount of active ingredient, to the specific extent required by claims 17 and 110 of the '167 patent.

In sum, Petitioner does not persuade us that the consistent dosage unit weight standard is the standard of uniformity required by claims 17 and 110 of the '167 patent. Nor are we persuaded that Petitioner has established that the consistent dosage unit weight standard inherently meets the uniformity requirement recited in claims 17 and 110 of the '167 patent. Accordingly, we find that Petitioner has not shown that Chen's disclosure in Example 1, of a film that yields four dosage units having a mean dosage unit weight of 0.028 grams and a standard deviation of ± 0.001, is an inherent disclosure of a film with a substantially uniform distribution of the active component, where the 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, as required by claims 17 and 110.

f. Substantially Uniform Distribution—Forming Film From Homogeneous Solution

Petitioner contends that, because Chen's process "begins by forming a homogen[e]ous mixture[,] . . . [m]aintaining uniformity in the intermediate steps and in the final product would have been obvious." Pet. 56–57 (citing

Ex. 1007 ¶¶ 108–109, 114–117) (Cohen Decl.)).[9] Petitioner contends that, "as Dr. Cohen stated, '[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.'" Pet. 57 (citing Ex. 1007 ¶ 109).

We acknowledge Chen's disclosure that its films were formed from "uniform" solutions in which the ingredients "were uniformly dispersed or dissolved." Ex. 1002, 17:6–11; *see also id.* at 17:27–28 ("a homogeneous mixture of ingredients was prepared in a coating solution"). We acknowledge Dr. Cohen's testimony regarding an ordinary artisan's difficulty in not obtaining, from the homogeneous solutions described in Chen, a film with a uniform content of active component. Ex. 1007 ¶ 109 (citing Ex. 1009, 268 ("Modern Coating")).[10] We acknowledge also Dr. Cohen's testimony that uniform distribution of ingredients in film compositions had long been an achieved objective of ordinary artisans (Ex. 1007 ¶ 114), that an ordinary artisan seeking to achieve the degree of uniformity recited in claims 17 and 110 would have been aware of "numerous variables in the drying process" (*id.* ¶ 115 (citing Ex. 1009, 286 (Modern Coating)), and, accordingly, would have been able to optimize those parameters to achieve a film meeting the uniformity requirement of claims 17 and 110 of the '167 patent (*id.* ¶¶ 116–117).

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[9] Declaration of Edward D. Cohen, Ph.D. (Ex. 1007; "Cohen Declaration" or "Cohen Decl.").

[10] MODERN COATING AND DRYING TECHNOLOGY (Edward D. Cohen & Edgar B. Gutoff eds., 1992) (Ex. 1009).

Neither Petitioner nor Dr. Cohen, however, directs us to a clear or specific teaching in Modern Coating that the measure of "uniformity" described therein (Ex. 1009, 268) is the same measure as that required by claims 17 and 110 of the '167 patent, that is, a distribution of active component that varies by less than 10% between substantially equal size dosage units, as opposed to merely a uniform thickness. Moreover, neither Petitioner nor Dr. Cohen directs us to any clear or specific teaching in Modern Coating demonstrating that the films discussed therein actually satisfy the uniformity requirement of claims 17 and 110. Nor does Petitioner direct us to specific evidence, such as experimental test results, showing that any of the drying processes described in Modern Coating necessarily produce a film meeting the uniformity requirement of claims 17 and 110. That "[m]odern precise coating applicators can [maintain uniformity] for *most coatings*" (Ex. 1009, 268 (emphasis added)) at best demonstrates a degree of likelihood that Chen's films would meet the standard of uniformity of Modern Coatings. As noted above, however, one may not rely on probabilities or possibilities to show that a reference inherently meets a limitation. *In re Oelrich*, 666 F.2d at 581.

In addition, Petitioner does not explain specifically, in either the Petition or in the Cohen Declaration, which particular variables, of the many Dr. Cohen admits would have been recognized as amenable to optimization, would have been optimized, or would have been critical to producing the substantially uniform active component distribution required by claims 17 and 110. We find, therefore, that Petitioner has not explained with adequate specificity how or why an ordinary artisan would have reasonably expected

to be able to obtain a film having the required uniform active agent distribution. *See In re Kubin*, 561 F.3d 1351, 1359 (Fed. Cir. 2009) (discussing that one circumstance in which the prior art fails to provide a reasonable expectation of success is where the art suggests "vary[ing] all parameters or try[ing] 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") (quoting *In re O'Farrell*, 853 F.2d 894, 903–04 (Fed. Cir. 1988) (emphasis omitted)).

In sum, for the reasons discussed, we find that Petitioner has not shown that, based on the homogeneity of Chen's coating solutions, Chen inherently describes films that meet the uniformity requirement of claims 17 and 110, nor are we persuaded that Petitioner has shown that an ordinary artisan had a reasonable expectation of success in producing such films.

4. Conclusion—Ground 4

For the reasons discussed, Petitioner does not persuade us that the combination of Chen and Tapolsky teaches or suggests a film having the substantially uniform distribution of active component required by claims 17 and 110 of the '167 patent, which are the independent claims challenged in Ground 4. Petitioner, therefore, has not established a reasonable likelihood of prevailing in showing the unpatentability of any of the claims challenged in Ground 4.

III. CONCLUSION

For the reasons given, we determine that Petitioner has not established, based on the information presented in the Petition, a reasonable

likelihood of prevailing in showing the unpatentability of any claim challenged in Grounds 1–3 and 5. Because the overwhelming majority of unpatentability grounds presented by Petitioner fail to meet the standard for institution of *inter partes* review, we find that instituting trial as to those grounds at this time is neither in the interest of the efficient administration of the Office, nor in the interest of securing an inexpensive resolution of this proceeding.

In addition, having reevaluated the information presented in the Petition, we determine that Petitioner has not established a reasonable likelihood of prevailing in showing the unpatentability of any claim challenged in Ground 4. For all of the reasons discussed above, we reconsider our Decision to Institute, and deny review of all challenges presented in the Petition.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Decision to Institute 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 17, 18, 30, 31, 37, 49, 56, 63, 70, 77, 80, 81, 87, 93, 110–116, and 124 of the '167 patent is denied and no *inter partes* review is instituted.

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