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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).

[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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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

[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.

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Paper No. 91
Entered: February 7, 2019

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 IPR2015-00165
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 seven grounds of unpatentability advanced by Petitioner, and only as to a subset of the claims challenged in that unpatentability ground. *See* Paper 6, 3–4 and 31

[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 IPR2015-00167, IPR2015-00168, and IPR2015-00169. No trial was instituted in IPR2015-00167. Decisions in IPR2015-00168 and IPR2015-00169 are issued concurrently herewith.

("Decision to Institute" or "DI"). We issued a Final Decision holding that Petitioner had not shown that the claims for which trial was instituted were unpatentable. Paper 70, 30 ("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 79, 2. The parties have completed briefing. *See* Papers 82, 83, 88, 90. Petitioner contends the Board "cannot change its mind now and vacate its determination to institute the '167 IPRs." Paper 82, 3. Patent Owner argues the opposite. Paper 83, 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. 19):

Ground	Reference[s]	Basis	Challenged Claims
1	Chen[2]	§ 102(b)	1, 4, 6–8, 11, 12, 26, 27, 32, 38, 44, 51, 58, 65, 72, 82, 109, and 125–127
2	Chen	§ 103(a)	1, 4, 6–8, 11, 12, 26, 27, 32, 38, 44, 51, 58, 65, 72, 82, 109, and 125–127
3	Chen in view of Leung[3]	§ 103(a)	1, 4, 6–8, 11, 12, 26, 27, 32, 38, 44, 51, 58, 65, 72, 82, 109, and 125–127
4	Chen in view of Leung and Modern Coating[4]	§ 103(a)	1, 4, 6–8, 11, 12, 26, 27, 32, 38, 44, 51, 58, 65, 72, 82, 109, and 125–127
5	Tapolsky[5]	§ 102(b)	1, 4, 6–9, 11, 12, 26, 27, 32, 44, 51, 65, 72, 82, and 125–127
6	Tapolsky	§ 103(a)	1, 4, 6–9, 11, 12, 26, 27, 32, 38, 44, 51, 58, 65, 72, 82, and 125–127
7	Tapolsky in view of Modern Coating	§ 103(a)	1, 4, 6–9, 11, 12, 26, 27, 32, 38, 44, 51, 58, 65, 72, 82, and 125–127

[2] WO 00/42992 A2 (published July 27, 2000) (Ex. 1002).
[3] WO 00/18365 A2 (published Apr. 6, 2000) (Ex. 1005).
[4] MODERN COATING AND DRYING TECHNOLOGY (Edward D. Cohen & Edgar B. Gutoff eds., 1992) (Ex. 1009).
[5] WO 99/55312 A2 (published Nov. 4, 1999) (Ex. 1003).

Petitioner supports its challenges with Declarations by Edward D. Cohen, Ph.D. ("Cohen Decl.") (Ex. 1007), and Maureen Reitman, Sc. D. ("Reitman Decl.") (Ex. 1047).

D. Related Proceedings

In addition to IPR2015-00167, IPR2015-00168, and IPR2015-00169, 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 81, 87.

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 . . . .").[6]

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

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

Director "shall be construed to secure the just, speedy, ***and inexpensive*** resolution of every proceeding.") (Emphasis added).

In the present case, as discussed below, of the seven grounds of unpatentability presented in the Petition, we determine that Petitioner failed to establish, on the merits, a reasonable likelihood of prevailing as to six of those grounds entirely (Grounds 2–7), based on either the analysis set out in the prior Decision to Institute (DI 19–31), or the analysis set forth below. And as to the seventh ground (Ground 1), we previously determined that Petitioner showed a reasonable likelihood of prevailing as to only some, but not all, of the claims challenged, for the reasons discussed in our prior Decision to Institute. DI 10–19.

In its Petition, Petitioner advanced three obviousness grounds (Grounds 2–4) on a contingency basis, i.e., only if the Board found that reference(s) discussed in Ground 1 failed to disclose elements of the challenged claims. Pet 38 (Ground 2), 43-44 (Ground 3), 45 (Ground 4); DI 19–22. In our prior Decision to Institute, we determined that Petitioner established a reasonable likelihood of success in relation to some claims (claims 1, 4, 11, 12, 26, 27, 44, 51, 58, 65, 72, 82, and 125–127), but not others (claims 6–8, 32, 38, and 109), challenged in Ground 1. DI 19. Because we determined that Petitioner established a reasonable likelihood of success on a subset of claims in relation to Ground 1, and in view of Petitioner's asserted contingencies, we declined to institute in relation to that same subset of claims challenged in Grounds 2–4. DI 20–22. In this decision now, as discussed in more detail below in Section II, C–E, we address Grounds 2–4 on the merits in relation to those claims, and find that

Petitioner does not establish a reasonable likelihood of success in relation to those claims and grounds.

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. As noted above, moreover, as to the only ground and claims for which trial was actually instituted, Petitioner did not ultimately prevail in showing those claims to be unpatentable. *See* Final Dec. 30.

Accordingly, because the overwhelming majority of unpatentability grounds presented by Petitioner fail to meet the standard for institution of *inter partes* review, we reconsider our Decision to Institute, and instead exercise our discretion to deny review of the challenges presented in the Petition.

Petitioner does not persuade us (*see* Paper 82, 1–2 and 4–6) that our decision herein is contrary to the requirements of § 314(a). Here, 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 1) simply underscores that instituting trial as to the remaining *insufficient* grounds (Grounds 2–7) 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.

Petitioner also does not persuade us that § 314(d) prohibits us from reconsidering our Decision to Institute. *See* Paper 82, 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 circumstances 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 describe 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. Moreover, Petitioner already received the benefit of our Decision to Institute in that we conducted a trial and issued a Final Decision.

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 82, 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 82, 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 82, 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 82, 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 seven grounds Petitioner presented, no ground advanced in the Petition meets 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 but 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 and claims would

result in conducting a trial as to six grounds for which Petitioner has not met the standard for instituting trial.

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 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. We, therefore, reconsider our Decision to Institute, and instead exercise our discretion to deny review of the challenges presented in the Petition.

As noted above, moreover, as to the only ground and claims for which trial was actually instituted (Ground 1), Petitioner did not ultimately prevail in showing those claims to be unpatentable. *See* Final Dec. 30. That fact underscores that instituting trial as to the remaining insufficient grounds (Grounds 2–7) 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.

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.

Claim 1 of the ’167 patent is representative of the claims challenged in the Petition, and reads as follows:

> 1. An oral film for delivery of a desired amount of an active component comprising:
>
> an ingestible, water-soluble, polymer matrix;

> 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 sodium 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 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;
>
> wherein said film is self-supporting and the active component is substantially uniformly distributed, ***whereby said 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***.

Ex. 1001, 40:62–41:22 (emphasis added to show dispositive limitation).

B. Grounds 1 and 5–7

We have previously evaluated Grounds 1 and 5–7 on the merits, either in our Decision to Institute, in our Final Decision, or in both of those decisions.

As to Ground 1, we determined initially that Petitioner had shown a reasonable likelihood of prevailing in its challenge to claims 1, 4, 11, 12, 26,

27, 44, 51, 58, 65, 72, 82, and 125–127 as anticipated by Chen. DI 12–16, 31.

Ultimately, however, we found in our Final Written Decision that Petitioner had not shown by a preponderance of the evidence that Chen anticipates claims 1, 4, 11, 12, 26, 27, 44, 51, 58, 65, 72, 82, and 125–127. Final Dec. 30. In particular, we found that Petitioner had not shown that Chen describes a film meeting the requirement in claim 1 for an active component to be substantially uniformly distributed within the film, whereby 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 the active component. *See id.* at 11–28. On remand, because we instituted trial as to this ground and claims, we do not reevaluate either our initial findings, or our ultimate findings, as to claims 1, 4, 11, 12, 26, 27, 44, 51, 58, 65, 72, 82, and 125–127 in relation to Ground 1.

In Ground 1, Petitioner also challenged claims 6–8, 32, 38, and 109. *See* Pet. 19, 23–25, 27–29. In our original Decision to Institute, we determined that Petitioner had not established a reasonable likelihood of prevailing in showing that Chen anticipated the subject matter recited in those claims, and therefore declined to institute review of those claims. *See* DI 16–19. 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 Ground 1 does not meet the standard for instituting *inter partes* review as to claims 6–8, 32, 38, and 109.

As to Ground 5, in our original Decision to Institute, we found that Petitioner had not established a reasonable likelihood of prevailing in

showing that Tapolsky anticipated the subject matter recited in the challenged claims, and therefore declined to institute review based on Ground 5. *See* DI 22–25.

Similarly, as to Grounds 6 and 7, in our original Decision to Institute, we found that Petitioner had not established a reasonable likelihood of prevailing in showing that Tapolsky rendered obvious the subject matter recited in the challenged claims, even when combined with Modern Coating. *See id.* at 26–31. Accordingly, we declined to institute review based on Grounds 6 and 7. *See id.*

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 5–7 do not meet the standard for instituting *inter partes* review.

C. Ground 2—Obviousness in view of Chen

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. Analysis

Petitioner does not persuade us that it has established a reasonable likelihood of prevailing in showing that the claimed subject matter challenged in Ground 2 would have been obvious in view of Chen.

As an initial matter, we note that, in our Decision to Institute, we found that Petitioner had failed to explain with adequate specificity why an ordinary artisan would have been prompted to combine the specific ingredients required by claims 6–8, 32, 38, and 109, and therefore declined to institute review of those claims for obviousness in view of Chen as presented in Ground 2. DI 20. 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 Ground 2 does not meet the standard for instituting *inter partes* review as to claims 6–8, 32, 38, and 109.

As to the remaining claims challenged in Ground 2, for the reasons that follow, Petitioner does not persuade us that it has established a reasonable likelihood of prevailing in showing that the subject matter recited in claims 1, 4, 11, 12, 26, 27, 44, 51, 58, 65, 72, 82, and 125–127 would have been obvious in view of Chen, based on the contentions and evidence properly advanced in Ground 2.

The two independent claims challenged in Ground 2 are claims 1 and 109. *See* Pet. 38. As discussed above, we decline to institute review of claim 109, based on the original analysis in our Decision to Institute.

Claim 1, the remaining independent claim, recites oral films for delivering a desired amount of an active component, "wherein . . . the active component is substantially uniformly distributed, whereby said 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." Ex. 1001, 41:17–22.

Petitioner contends that a film having the substantially uniform active component distribution required by claim 1 would have been obvious in view of Chen. Pet. 41–42.

Specifically, Petitioner contends that an ordinary artisan "would have been motivated to adjust the film manufacturing process to produce film featuring a distribution of active that does not vary by more than 10% of the desired amount" because, "[a]s admitted in the '167 patent, the recited uniformity was a known [regulatory] requirement." *Id.* at 41 (citing Ex. 1001, 2:16–19).

Petitioner contends that, because "Chen's process begins by forming a homogenous mixture . . . [, m]aintaining uniformity in the intermediate steps and in the final product would have been obvious." *Id.* (citing Ex. 1002, 15:19–25, 17:6–12 (Chen); also citing Ex. 1007 ¶¶ 49, 50, 68–73 (Cohen Decl.)). Petitioner contends that, "[i]ndeed, as stated by Dr. Cohen, '[w]hen working with a homogenous or completely dissolved coating solution, like the one disclosed 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 [component]." *Id.* at 41–42 (citing Ex. 1007 ¶ 72).

We acknowledge, as Petitioner contends, and as noted above, that Chen uses a homogeneous mixture as a starting material to produce its films. *See* Ex. 1002, 4:25–31. Nonetheless, Petitioner does not explain or identify *in its Petition* the particular steps or measures disclosed or suggested in the prior art that would have led an ordinary artisan to conclude that it would have been obvious to obtain, from that starting material, a film having the uniform distribution of active component required by claim 1 of the '167 patent.

Rather than providing, *in its Petition*, the substantive rationale as to why Chen's disclosure of a homogeneous starting material, by itself, would have rendered obvious a film having the uniform active component distribution recited in claim 1 of the '167 patent, Petitioner cites to ¶¶ 49, 50, and 68–73 of the Cohen Declaration, without specific discussion of the nature of the testimony and evidence presented therein. *See* Pet. 41–42.

The cited paragraphs of the Cohen Declaration, in turn, cite to a number of additional allegedly prior art teachings, none of which is cited in

the Petition in relation to Ground 2. *See* Ex. 1007 ¶¶ 50, 72 (Cohen Declaration citing Ex. 1009, 268 (Modern Coating)); Ex. 1007 ¶ 68 (citing Ex. 1009, 25 and Ex. 1010, 609 (Encyclopedia of Chemical Technology));[7] Ex. 1007 ¶ 69 (citing Ex. 1009, 271 and 276).

We decline to import the discussion regarding the obviousness alleged in Ground 2 from the Cohen Declaration into the Petition, based solely on the Petition's citation of certain paragraphs within that Declaration. As stated in 37 C.F.R. § 42.6(a)(3), "[a]rguments must not be incorporated by reference from one document into another document." In this instance, we find the attempt to incorporate substantive argument into the Petition particularly inappropriate, because the incorporated argument itself cites to additional evidence not discussed in the Petition in relation to Ground 2.

Moreover, we agree with our colleagues' reasoning in *Conopco, Inc. v. The Procter & Gamble Co.*, in that "[w]e decline to consider information presented in a supporting declaration, but not discussed in a petition, because, among other reasons, doing so would encourage the use of declarations to circumvent the page limits that apply to petitions." Case IPR2013-00510, slip op. at 8 (PTAB Feb. 12, 2014) (Paper 9). In that regard we note that, in the present case, the Petition is 59 pages in length, and paragraphs 49, 50, and 68–73 of the Cohen Declaration provide at least four additional pages of discussion.

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[7] Cohen, E. & Gutoff, E., "Coating Processes, Survey," ENCYCLOPEDIA OF CHEMICAL TECHNOLOGY, Vol. 6, pp. 606–635, Wiley (1993).

In addition, even considering the cited portions of the Cohen Declaration, we are not persuaded they establish a reasonable likelihood of prevailing in showing the obviousness of a film having the uniform active component distribution required by claim 1 of the '167 patent. As evidence that it would be difficult for Chen's homogeneous mixture *not* to result in a film with the uniform distribution required by claim 1 of the '167 patent, the Cohen Declaration cites Modern Coating as disclosing that "'[i]f the coating is applied uniformly, then the dryer must immobilize it and maintain its uniformity throughout the drying process. Modern precise coating applicators can do this for most coatings.'" Cohen Decl. ¶ 50 (quoting Ex. 1009, 268 (Modern Coating) (brackets added)); *see also id.* ¶ 72 (also citing Ex. 1009, 268).

We acknowledge this general disclosure in Modern Coating (not cited in Ground 2) regarding the capacity of modern applicators to achieve uniformity with respect to "most coatings." Ex. 1009, 268. We acknowledge also the Cohen Declaration's assertion that highly uniform coatings were achievable in the 1960s. Cohen Decl. ¶ 68; *see also id.* ¶ 24 ("For example, back in the 1960s, I was part of a team that produced x-ray silver halide film, which required extremely uniform distribution of active components in the film for the film to serve its intended purpose.").

The cited portions of the Cohen Declaration, however, do not identify any teaching in Modern Coating, or elsewhere in the record, regarding the specific polymeric materials used by Chen to make its edible films, or for that matter, the materials disclosed in the '167 patent for that purpose. Although we acknowledge the general teachings cited in the Cohen

Declaration regarding the alleged straightforwardness of achieving uniformity as to most coatings, those teachings contrast substantially with, and fail to recognize, the problem identified in the specification of the '167 patent and the patents cited therein, as to the issue of particle agglomeration when preparing the particular film-type of dosage forms recited in claim 1 of the '167 patent, and disclosed in Chen. *See* Ex. 1001, 1:59–2:53.

Thus, at best, the evidence advanced in the Cohen Declaration (but not discussed in the Petition in relation to Ground 2) shows that modern applicators could achieve some unspecified measure of uniformity as to "most coatings." Ex. 1009, 268. We are not persuaded that such evidence explains with sufficient detail how or why an ordinary artisan had a reasonable expectation of preparing a film having the particular degree of uniformity required by claim 1 of the '167 patent, using the specific materials disclosed in Chen.

We acknowledge the assertion in the Cohen Declaration that "numerous variables" that could be optimized in film-making and drying processes to produce uniform coatings were long known in the art. Ex. 1007 ¶ 69 (citing *id.* ¶¶ 27, 28); *see also id.* ¶¶ 70, 71, 73 (asserting that it would have been obvious to optimize Chen's process to achieve the uniform distribution of active component recited in claim 1 of the '167 patent).

Our reviewing court has explained, however, that non-specific general teachings like those advanced by the Petitioner are insufficient to support a conclusion of obviousness. In particular, similar to the situation presently before us, 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." *In re Kubin*, 561 F.3d 1351, 1359 (Fed. Cir. 2009) (quoting *In re O'Farrell*, 853 F.2d 894, 903–04 (Fed. Cir. 1988) (emphasis omitted).

Another circumstance in which the prior art fails to provide a reasonable expectation of success, also similar to the present fact situation, is where the art suggests exploring a "general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it." *Id.*

In the present case, the Cohen Declaration does not identify which of the concededly numerous parameters might be critical to achieving the uniform distribution of active component recited in claim 1 of the '167 patent, but instead provides only a general approach as to preparing a film having that property. Petitioner does not persuade us, therefore, that it has established a reasonable likelihood of prevailing in the challenge to claim 1 presented in Ground 2, even considering the evidence presented in the Cohen Declaration, which was improperly incorporated by reference into the Petition. Accordingly, for the reasons discussed, we determine that Petitioner's Ground 2 does not meet the standard for instituting *inter partes* review as to claim 1, or its dependent claims 4, 11, 12, 26, 27, 44, 51, 58, 65, 72, 82, and 125–127.

D. Ground 3—Obviousness in view of Chen and Leung

Petitioner does not persuade us that it has established a reasonable likelihood of prevailing in showing that the claimed subject matter challenged in Ground 3 would have been obvious in view of Chen and Leung.

Petitioner contends that the combination of Chen and Leung would have rendered obvious the subject matter recited in claims 1, 4, 6–8, 11, 12, 26, 27, 32, 38, 44, 51, 58, 65, 72, 82, 109, and 125–127. Pet. 43.

Petitioner, however, cites Leung only to show that an ordinary artisan would have considered the additional limitations recited in claims 26, 27, and 127 obvious features of the film suggested by Chen. *See id.* at 43–44 ("[T]o the extent the Board may believe that any element of claims 26, 27, or 127 are not expressly or inherently disclosed in Chen, these claims are obvious over Chen in view of Leung.").

Each of claims 26, 27, and 127 of the '167 patent depends from claim 1. *See* Ex. 1001, 44:38–44, 49:10–11. Each of claims 26, 27, and 127, therefore, recites a film having at least the substantially uniform distribution of active component, discussed above, required by claim 1.

Petitioner, in relying on Leung to show the obviousness of the features in dependent claims 26, 27, and 127, does not identify any specific teaching in Leung, or elsewhere in the record, that remedies the deficiency, discussed above, of Chen in relation to claim 1's uniform distribution of active component. Petitioner does not persuade us, therefore, that it has established a reasonable likelihood of prevailing in showing the obviousness of claim 1, or the other claims challenged in Ground 3, even considering the further

disclosures cited in Leung. Accordingly, we determine that Petitioner's Ground 3 does not meet the standard for instituting *inter partes* review as to claims 1, 4, 6–8, 11, 12, 26, 27, 32, 38, 44, 51, 58, 65, 72, 82, 109, and 125–127.

E. Ground 4—Obviousness in view of Chen, Leung, and Modern Coating

Petitioner does not persuade us that it has established a reasonable likelihood of prevailing in showing that the claimed subject matter challenged in Ground 4 would have been obvious in view of Chen, Leung, and Modern Coating.

Petitioner contends that the combination of Chen, Leung, and Modern Coating would have rendered obvious the subject matter recited in claims 1, 4, 6–8, 11, 12, 26, 27, 32, 38, 44, 51, 58, 65, 72, 82, 109, and 125–127. Pet. 45.

Petitioner, however, cites Modern Coating only to show that an ordinary artisan would have considered the controlled drying process, recited in claims 1 and 109 as producing the film recited in those claims, an obvious feature of the film suggested by Chen or the combination of Chen and Leung:

> To the extent the Board finds that Chen, alone or in combination with Leung, somehow fails to disclose a "controlled drying process" under the broadest reasonable interpretation of that term, as Dr. Cohen explains, it would have been obvious to the POSITA to use the "controlled drying process" disclosed in MODERN COATING to produce uniform film.

Id. at 45–46 (citing Ex. 1007 ¶ 92 (Cohen Decl.)).

Petitioner, in advancing Modern Coating in Ground 4 to show the obviousness of the controlled drying feature recited in claims 1 and 109, does not identify any specific teaching in Modern Coating, or elsewhere in the record, that remedies the deficiency, discussed above, of Chen in relation to the uniform distribution of active component recited in claim 1, as well as claim 109. Petitioner does not persuade us, therefore, that it has established a reasonable likelihood of prevailing in showing the obviousness of independent claims 1 and 109, or their dependent claims challenged in Ground 4, even considering the further disclosures cited in Modern Coating.

In addition, as to claims 6–8, 32, 38, and 109, as discussed above, Petitioner does not persuade us that it has explained with adequate specificity why an ordinary artisan would have been prompted to combine the specific ingredients required by those claims. That Modern Coating might render obvious a film produced by a controlled drying process does nothing to remedy the deficiency in Petitioner's challenge as to claims 6–8, 32, 38, and 109.

Accordingly, we determine that Petitioner's Ground 4 does not meet the standard for instituting *inter partes* review as to claims 1, 4, 6–8, 11, 12, 26, 27, 32, 38, 44, 51, 58, 65, 72, 82, 109, and 125–127.

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 2 through 7. For the reasons given, we also determine that Petitioner has not established, based on the information

presented in the Petition, a reasonable likelihood of prevailing in showing the unpatentability of claims 6–8, 32, 38, and 109, challenged in Ground 1.

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. We, therefore, reconsider our Decision to Institute, and instead exercise our discretion to deny review of the challenges presented in the Petition.

As noted above, as to the only ground and claims for which trial was actually instituted (Ground 1, claims 1, 4, 11, 12, 26, 27, 44, 51, 58, 65, 72, 82, and 125–127), Petitioner did not ultimately prevail in showing those claims to be unpatentable. *See* Final Dec. 30. That fact underscores that instituting trial as to the multiple remaining insufficient grounds (Grounds 2–7 in their entirety, and Ground 1 in relation to other claims) 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.

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 1, 4, 6–9, 11, 12, 26, 27, 32, 38, 44, 51, 58, 65, 72, 82, 125–127of the '167 patent is denied and no *inter partes* review is instituted.

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