Trials@uspto.gov
571-272-7822

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.

---

[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.

PETITIONER:

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

PATENT OWNER:

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

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