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Paper 69
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIODELIVERY SCIENCES INTERNATIONAL, INC.,
Petitioner,

v.

MONOSOL RX, LLC,
Patent Owner.

Case IPR2015-00169
Patent 8,765,167 B2

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

PRATS, *Administrative Patent Judge.*

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

A. Statement of the Case

BioDelivery Sciences International, Inc. ("Petitioner") filed a Petition (Paper 2, "Pet.") requesting an *inter partes* review of claims 17, 18, 30, 31, 37, 49, 56, 63, 70, 77, 80, 81, 87, 93, 110–116, and 124 of U.S. Patent No.

8,765,167 B2 (Ex. 1001, "the '167 patent"). MonoSol Rx, LLC ("Patent Owner") did not file a Preliminary Response.

We instituted trial, as to all of those claims, only on the ground of obviousness under 35 U.S.C. § 103(a) over Chen[1] and Tapolsky.[2] Paper 6, 24 ("Decision to Institute," or "Dec."); Pet. 43–59 (setting forth instituted ground of unpatentability).[3]

After trial was instituted, Patent Owner filed a Response (Paper 15; "PO Resp."), and Petitioner filed a Reply (Paper 35, "Reply").

Both parties filed Motions to Exclude Evidence. Paper 50 ("Pet. Mot. to Exclude") and Paper 52 ("PO Mot. to Exclude").

Both parties filed Oppositions to the Motions to Exclude Evidence. Paper 60 ("Pet. Opp."); Paper 57 ("PO Opp."). Both parties filed Replies to the Oppositions to the Motions to Exclude Evidence. Paper 64 ("Pet. Reply Opp."); Paper 63 ("PO Reply Opp.").

Patent Owner filed a Motion for Observation Regarding Cross Examination of a Reply Witness (Paper 53; "PO Mot. Observ."), and Petitioner filed a Response to that motion (Paper 59; "Resp. Observ.").

An oral hearing was held on February 12, 2016, and the hearing transcript has been entered in the record. Paper 68 ("Tr.").

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

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

[3] The application which issued as the '167 patent was filed on September 8, 2006. Ex. 1001, cover page. Accordingly, the version of § 103 in effect before the Leahy-Smith America Invents Act ("AIA") applies to the claims of the '167 patent. *See* AIA, Public Law 112-29, § 3, 125 Stat. 288.

We have jurisdiction under 35 U.S.C. § 6(c). This Final Written Decision is entered pursuant to 35 U.S.C. § 318(a).

"In an inter partes review instituted under this chapter, the petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence." 35 U.S.C. § 316(e).

We conclude that Petitioner has not proved by a preponderance of the evidence that claims 17, 18, 30, 31, 37, 49, 56, 63, 70, 77, 80, 81, 87, 93, 110–116, and 124 of the '167 patent are unpatentable for obviousness under 35 U.S.C. § 103(a) over Chen and Tapolsky.

Petitioner's Motion to Exclude Evidence is dismissed as moot. Patent Owner's Motion to Exclude Evidence is denied-in-part and dismissed-in-part as moot.

B. Related Proceedings

Patent Owner states that on September 22, 2014, it filed, along with its licensee, a complaint against Petitioner for infringement of the '167 Patent, captioned *Reckitt Benckiser Pharmaceuticals Inc. v. Biodelivery Sciences International, Inc.*, 3:14-cv-5892 (D.N.J.). Paper 3, 2.

Concurrently with the instant Petition, 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.

Petitioner identifies a number of proceedings, within the U.S. Patent and Trademark Office, as well as in district court, which involve patents in the same family as the '167 patent. Pet. 1–4.

C. The ’167 Patent (Ex. 1001)

The ’167 patent discloses “edible water-soluble delivery systems in the form of a film composition including a water-soluble polymer, an active component selected from cosmetic agents, pharmaceutical agents, vitamins, bioactive agents and combinations thereof, and at least one anti-tacking agent.” Ex. 1001, Abstract.

The ’167 patent explains that films incorporating a pharmaceutical agent were known to be suitably administered to mucosal membranes, such as the mouth and nose. *Id.* at 1:42–58. Such 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. The ’167 patent attributes this non-uniform distribution to the long drying times and excessive air flow used previously when drying the films. *Id.* at 1:62–67. Because sheets of such films are usually cut into individual doses, the 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 “a controlled drying process. Examples of controlled drying processes include, but are not limited to, the use of the apparatus disclosed in U.S. Pat. No. 4,631,837 to Magoon . . . , as well as hot air impingement across the bottom substrate and bottom heating plates.” *Id.* at 6:21–27. The ’167 patent discloses that “[a]nother drying technique for obtaining the films of the present invention

is controlled radiation drying, in the absence of uncontrolled air currents, such as infrared and radio frequency radiation (i.e. microwaves)." *Id.* at 6:27–30. "[A]lternatively, drying may be achieved by using balanced fluid flow, such as balanced air flow, where the bottom and top air flows are controlled to provide a uniform film." *Id.* at 6:47–50.

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. This can take place within the first few minutes, e.g. about the first 0.5 to about 4.0 minutes of the drying process." *Id.* at 24:52–56.

Claims 17 and 110 of the '167 patent, the independent claims for which trial was instituted, 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).

II. ANALYSIS

A. Claim Construction

The Board interprets claims in an unexpired patent using the "broadest reasonable construction in light of the specification of the patent in which [they] appear[]." 37 C.F.R. § 42.100(b); *In re Cuozzo Speed Tech., LLC,*

793 F. 3d 1268, 1275 (Fed. Cir. 2015), *cert. granted sub nom. Cuozzo Speed Techs. LLC v. Lee*, 136 S. Ct. 890 (2016). Under that standard, the Board gives claim terms their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

Petitioner advances constructions for the claim terms "controlled drying process" and "'substantially uniform'/'substantially uniformly distributed.'" Pet. 10–17.

As to Petitioner's proposed construction of the term "controlled drying process," claims 17 and 110 expressly recite that the controlled drying process, which produces the film, rapidly forms a viscoelastic matrix to lock the active component in place within the matrix to maintain the above-discussed substantially uniform distribution. Ex. 1001, 43:60–63 (claim 17), 48:21–24 (claim 110). Accordingly, contrary to Petitioner's contentions (*see* Pet. 10–11), we conclude that claims 17 and 110 do limit the conditions of the "controlled drying process."

As noted above, moreover, the '167 patent discusses the advantages of the controlled drying process, including the faster drying times. Ex. 1001, 6:61–7:1. According to the Specification, "[d]esirably, the drying of the film will occur within about ten minutes or fewer, or more desirably within about five minutes or fewer." *Id.* at 7:1–3. It further discloses that the initial film setting period, "during which a solid, visco-elastic structure is formed . . . can take place within the first few minutes, e.g. about the first 0.5 to about 4.0 minutes of the drying process." *Id*. at 24:52–56. Thus, contrary

to Petitioner's contention, the '167 patent does provide a standard for the term "rapidly" as recited in claims 17 and 110.

Especially given the express language in the claims, we conclude that the claims encompass a film having a structure which would result from a controlled drying process which forms a viscoelastic matrix within a few minutes of the drying process to lock-in the active component within the matrix, the film having a substantially uniform distribution of the active component, measured by substantially equally sized individual unit doses which do not vary by more than 10% of the desired amount of the active component.

Patent Owner does not allege specific error in the above claim construction. Patent Owner instead emphasizes that claims 17 and 110 recite the substantially uniform distribution of the active component as being based on the "desired amount" of the active component. PO Resp. 6. Therefore, Patent Owner contends, the determination of whether the amounts of active component in substantially equal-sized individual unit doses of a film vary by less than 10% from the desired amount of the active component "is not a measurement of the difference in the amount of active between individual unit doses." *Id.* Rather, Patent Owner contends:

> [T]he calculation required for determining what falls within the scope of the claim language is: the amount of active ingredient actually present in an individual unit dose minus the amount of active ingredient desired to be present in an individual unit dose divided by the amount of active desired to be present in an individual unit dose times 100%.

Id. at 6–7.

We conclude, based on the language of claims 17 and 110, that it is reasonable to determine the percent variation of the distribution of the active component of a particular film based on the desired amount of the active component, as Patent Owner contends. Patent Owner does not persuade us, however, that the "desired amount" of the active component is reasonably limited to a specific dosage amount, or labeled amount. *See* PO Resp. 6 (asserting that the desired amount of the active component may be a "predetermined, targeted, labeled amount of active."); *id.* at 20 ("'*desired amount'* means the dosage (label) amount").

If the desired amount of the active component in the substantially equally sized portions of the film was based on a labeled dosage, then films with no labeled dosage could never be uniform, even if they had a perfectly homogeneous distribution of active component. Moreover, if uniformity was based solely on a desired dosage, a film with a perfectly homogeneous distribution of active component could be considered non-uniform under claims 17 and 110, simply by cutting from the film equal-sized portions that contain twice the desired dosage, or simply by deciding on a different dosage than that contained in the equally sized portions of the film. Accordingly, we conclude that it is not reasonable to limit the "desired amount" of active component in claims 17 and 110 to a labeled or dosage amount. This is consistent with Patent Owner's own contentions of how a desired amount of active may be determined in a film lacking a predetermined dosage or labeled dosage. *See* PO Resp. 40–42 (desired amount determined by weight percentage of active ingredient present in the film, rather than dosage or label).

In sum, we conclude that the claims encompass a film having a structure which would result from a controlled drying process which forms a viscoelastic matrix within a few minutes of the drying process to lock-in the active component within the matrix, the film having a substantially uniform distribution of the active component, as measured by substantially equally sized individual unit doses which do not vary by more than 10% of the desired amount of the active component.

B. Obviousness—Chen and Tapolsky

1. Chen (Ex. 1002)

Chen discloses a "dosage unit comprising a water-soluble hydrocolloid and a mucosal surface-coat-forming film, such film including an effective dose of active agent." Ex. 1002, Abstract. Chen explains that the hydrocolloid "includes a polymer selected from the group consisting of a natural, semi-natural and synthetic biopolymer being exemplified by a polysaccharide and a polypeptide." *Id.* at 4:1–3.

Chen discloses that, "[i]n addition to hydrocolloids and the active agents, the films may contain any or all of the following ingredients: emulsifying agents, solubilizing agents, wetting agents, taste modifying agents, plasticizers, active agents, water soluble inert fillers, preservatives, buffering agents, coloring agents, and stabilizers." *Id.* at 15:4–7.

Example 1 of Chen describes preparation of a film that contains, among other ingredients, peppermint, hydroxypropyl methylcellulose ("Methocel E5"), aspartame, citric acid, and "Cremphor EL40," a surfactant.[4] *Id.* at 18:1–17. Chen describes the process of making the film

[4] As Petitioner contends (Pet. 21), the '167 patent identifies "Cremophor® EL" as a surfactant that is "commercially available from BASF." Ex. 1001,

as follows:

> According to Examples 1-8, the hydrocolloid was dissolved in water under agitated mixing to form a uniform and viscous solution. Additional ingredients were then added sequentially to the viscous solution such as peppermint, aspartame, propyl glycol, benzoic acid and citric acid under agitated mixing until they were uniformly dispersed or dissolved in the hydrocolloid. The resultant mixture was degassed in a vacuum chamber until trapped air bubbles were removed. The viscosity, pH and specific gravity were measured. The formulation was then coated on the non-siliconized side of a polyester film at a wet thickness of 10 mil and dried in a hot air circulating oven at 50°C for 9 minutes. A glossy, substantially transparent, stand alone, self-supporting, non-tacky and flexible film was obtained after drying. The dry film was cut into different shapes for measurement of dry tack, wet tack, tensile strength modulus, elongation, tear resistance, residual water content, disintegration and dissolution. The dosage form was 25-250 mg in various shapes, sizes, and thickness.

Id. at 17. As to Example 1, Chen also discloses the following:

> The films were prepared as follows: a homogeneous mixture of ingredients was prepared in a coating solution in the amounts indicated in Table 1. The amounts are given as percentage weight of coating solution. The mixture was degassed in a vacuum chamber and coated on the non-siliconized side of a polyester film and dried in a hot air circulating oven to form a self supporting non-tacky and flexible film. The film was then cut into dosage units ready for packaging.

Id.

As to the weight of the films prepared in Example 1, Chen discloses a mean value of 0.028 "g/dosage film" with a "±SD (n)" of "0.001 (4)." *Id.* at 20 (Table 4).

22:60–61.

Example 7 of Chen describes preparation of a film that contains, among other ingredients, oxybutynin, peppermint, hydroxypropyl methylcellulose (HPMC), aspartame, citric acid, and Cremphor EL40. *Id.* at 20:17–21:17.

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 the adhesive layer may contain at least one "film-forming water-erodable polymer (the 'film-forming polymer') and at least one pharmacologically acceptable polymer known for its bioadhesive capabilities (the 'bioadhesive polymer')." *Id*. at 10:14–17. Tapolsky discloses that the non-adhesive backing layer "may comprise a water-erodable, film-forming pharmaceutically acceptable polymer such as hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, [and] hydroxyethylmethyl cellulose," among others. *Id.* at 12:5–8.

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 37:3–25. The first bioadhesive 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.

3. Analysis

a. Introduction

Petitioner contends that Chen describes multi-layer active component-containing films that have all of the ingredients and functional properties required by the challenged claims. Pet. 43–59. Petitioner concedes, however, that "Chen's disclosure of the application of a controlled drying process to a multi-layer film is limited." *Id.* at 44.

Petitioner contends, nonetheless, that because multi-layer films had been successfully made in the prior art, an ordinary artisan "would have been motivated to combine existing knowledge of polymer-based, multi-layer film, such as disclosed in Tapolsky, with Chen's teaching of polymer-based film to create multi-layer, polymer-based film for oral delivery of a desired amount of active." *Id.* In particular, Petitioner contends that an ordinary artisan "would have been motivated to combine the second film layer of Chen with the backing film of Tapolsky's Example 37, for example, to adjust or reduce adhesion on one surface of Chen's oral film." *Id.* at 58.

Petitioner advances several rationales to explain why the active component in Chen's film compositions is distributed in accordance with the substantial uniformity requirement of claims 17 and 110. Initially, Petitioner contends that we should adopt the Board's previous finding, in a decision on appeal in an *inter partes* reexamination of a different patent in the same family as the '167 patent, involving the same parties as here (Ex. 1027 ("the '588 decision")), that Chen meets the uniformity requirement. Pet. 56 (incorporating by reference "[s]ubsection 3 of Ground 2"). In particular, Petitioner contends that Patent Owner is collaterally estopped from

contesting the Board's prior finding that Chen inherently meets the claimed uniformity requirement. Pet. 36–39 (subsections 3 and 4 of Ground 2).

Petitioner contends also that the visual inspection and consistent dosage unit 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. Pet. 56–57.

Patent Owner does not allege specific error in Petitioner's contention that an ordinary artisan would have considered it obvious to combine the second layer of Chen's film with the backing film of Tapolsky's Example 37, so as to adjust or reduce adhesion on one surface of Chen's film. *See* PO Resp. 21–54. Rather, Patent Owner contends that Petitioner, for a number of reasons, has not shown that Chen's film compositions include an active component distributed substantially uniformly throughout the film in the manner required by claim 17 and 110. *See id.*

Having considered the parties' arguments and supporting evidence, we find, for the reasons that follow, that Petitioner has not shown by a preponderance of the evidence that the film compositions described in Chen meet the requirement in claims 17 and 110 of a substantially uniform distribution of the active component, measured by substantially equally sized individual unit doses which do not vary by more than 10% of the desired amount of the active component.

a. Collateral Estoppel

As an initial matter, Petitioner does not persuade us that collateral estoppel applies in this instance. 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.

The court noted however, 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." *Id.* at 1467 (citations omitted). Thus, "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." *Id.* In that vein, the court noted that 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. Indeed, as seen herein, the testimony on cross-examination of one of Petitioner’s witnesses uncovered facts significant to our evaluation of the disclosure of the Chen reference, resulting in a determination on that issue different from the prior ’588 reexamination appeal decision cited by Petitioner. 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 likely yield a result different from that in the prior *inter partes* reexamination.

We also 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. As to that requirement, in *Freeman* the court noted that “statements regarding the scope of patent claims made in a former adjudication should be narrowly construed.” *In re Freeman*, 30 F.3d at 1466.

With that in mind, we note again that 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, because Patent Owner had not argued any claims separately, 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).[5] In contrast to the language at issue here, claim 1 of the ’588 patent, as amended, required 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 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,

[5] 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.

claim 3 of the ’588 patent recites only a “self-supporting therapeutic active-containing film [which] 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 contends that two additional Board decisions on appeals in *inter partes* reexaminations, involving the same parties as here, also found that Chen’s films meet the same substantial uniformity requirement as that recited in claim 1 of the ’167 patent. Pet. Reply 3 (citing Ex. 1056 (“the ’080 decision”) and Ex. 1057 (“the ’337 decision”)). As noted above, however, because of the procedural differences between *inter partes* reexaminations and *inter partes* review under the AIA, we are not persuaded that the Board’s decision in the cited *inter partes* reexamination appeals, on the issue of whether Chen meets the substantial uniformity requirement,

precludes consideration of that issue in the instant *inter partes* review under the AIA.

We note, moreover, that the ’080 decision states expressly that “no portion of the decision is final for purposes of judicial review.” Ex. 1056, 44. We note also that a decision on rehearing in the ’337 reexamination issued on January 27, 2016. *See* Reexamination Control 95/002,171. Accordingly, because the time for appeal has not expired, the Board’s ’337 decision, like the Board’s ’080 decision, is not final, and collateral estoppel is not applicable. *See Vardon Golf Co., Inc. v. Karsten Mfg. Corp.*, 294 F.3d 1330, 1333–35 (Fed. Cir. 2002).

In sum, for the reasons discussed, Petitioner does not persuade us that the doctrine of collateral estoppel is applicable in this proceeding.

b. Substantially Uniform Distribution—Visual Inspection

Petitioner does not persuade us that a preponderance of the evidence supports its contention 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)[6] by reference.

[6] Robert K. Yang et al., U.S. Patent No. 7,425,292 B2 (issued Sept. 16, 2008).

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).

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).

Thus, although we do not agree with Patent Owner's construction of the term "desired amount," we agree, nonetheless, with Patent Owner's argument to the extent that the language at issue in claims 17 and 110 expressly requires a determination of the actual amount of active component in the substantially equal sized individual unit doses of the film. 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. Petitioner does not persuade us, however, 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.

c. 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. Pet. 56 (citing Ex. 1035, 20:53–62); Reply 11. 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. Pet. 56; Reply 11. Accordingly, 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. Pet. 56; *see also* Reply 11–12 (noting the Board’s previous findings as to the allegedly consistent weight of the films of Chen’s Example 1 in the ’588, ’080, and ’337 reexam appeal decisions discussed above).

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).

In addition, 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.

Patent Owner advances evidence, in the form of the Goldberg Declaration,[7] undermining Petitioner’s contentions in relation to Example 1

[7] Declaration of Judith D. Goldberg, Sc.D. (Ex. 2006; “Goldberg Declaration” or “Goldberg Decl.”).

of Chen. As Patent Owner contends, Dr. Goldberg testifies that the disclosure in Chen's Example 1 of a mean film weight of 0.028 "g/dosage film," with a "±SD (n)" of "0.001 (4)" (Ex. 1002, 20), does not signify a weight deviation. Ex. 2006 ¶ 17. Rather, Dr. Goldberg explains, Chen's disclosure signifies a *standard deviation* of ± 0.001 from the mean weight of 0.028 grams, based on a sample size of four film units. *Id.* Dr. Goldberg explains further:

> [A] standard deviation of +/- 0.001 is only a way of indicating that there is an approximately 2/3 chance that the sample weights will fall within the 0.028 +/- 0.001 g/dosage range and an approximately 1/3 chance that the sample weights will fall outside the 0.028 +/- 0.001 g/dosage range, and that assumption is based on only 4 samples, a very small sample.

Id. Petitioner does not dispute Dr. Goldberg's characterization of this aspect of Chen's disclosure, nor Dr. Goldberg's explanation of the meaning of standard deviation. Given her education and experience in biostatistics (*see* Ex. 2006 ¶¶ 1–9), we credit her testimony on this issue. Thus, as Dr. Goldberg explains, the standard deviation disclosed in Example 1 of Chen represents only a degree of probability that the weights of the four tested dosage units of film were within a certain range of the mean dosage unit weight. Ex. 2006 ¶ 17.

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).

Dr. Goldberg testifies, moreover, that the ± 0.001 standard deviation disclosed in Chen's Example 1 encompasses a set of four hypothetical dosage unit weight values that differ by more than 10% from the mean weight of the dosage units, and thus lie outside the variance allowed by claims 17 and 110 of the '167 patent. Ex. 2006 ¶¶ 18–20. Petitioner replies that Dr. Goldberg's calculations regarding the hypothetical weights are erroneous. Reply 10–11 (citing Ex. 1060 ¶ 12 (Lavin Decl.)).[8]

We acknowledge the education and experience in biostatistics of Dr. Lavin, Petitioner's witness, as well as his testimony regarding Dr. Goldberg's calculations. Ex. 1060 ¶¶ 1–5, 10–17. Significantly, however, despite the errors he alleges in Dr. Goldberg's calculations, Dr. Lavin does not assert error in Dr. Goldberg's ultimate conclusion that the ± 0.001 standard deviation disclosed in Chen's Example 1 encompasses a set of four hypothetical dosage unit weight values that differ by more than 10% from the mean weight of the dosage units. Rather, Dr. Lavin bases his assertion of error in Dr. Goldberg's declaration on the assumption that the weights of the individual dosage units should be rounded to whole centigrams. *See id.* at ¶ 17 ("If each of the hypothetical weights in Dr. Goldberg's Table A is simply rounded to whole centigrams (one significant digit or the second decimal place) in accordance with the standard for determining uniformity used in the '292 patent, her data would then show 0% variation . . . .").

8 Declaration of Philip T. Lavin, Ph.D. (Ex. 1060; "Lavin Declaration" or "Lavin Decl.").

We are not persuaded, however, that it is reasonable to evaluate the uniformity requirement of claims 17 and 110 of the '167 patent based on dosage unit weights rounded to whole centigrams, merely because one example in the '292 patent specification reported consistent dosage weights only to the centigram level. As noted above, it is improper to limit language in claims based on specific embodiments in the specification. *In re Trans Texas Holdings Corp.*, 498 F.3d at 1299.

Accordingly, Petitioner does not persuade us that it has shown error in Dr. Goldberg's conclusion that the ± 0.001 standard deviation disclosed in Chen's Example 1 encompasses a set of four dosage unit weight values that differ by more than 10% from the mean weight of the dosage units. Petitioner also does not persuade us, therefore, that Chen's disclosure of four dosage units with a mean weight of 0.028 grams and a standard deviation of ± 0.001 equates to an inherent disclosure of dosage units with weights that vary by less than 10%.

In sum, as discussed above, 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. In addition, given the Goldberg Declaration, Petitioner does not persuade us that the consistent dosage unit weight standard inherently meets the uniformity requirement recited in claims 17 and 110 of the '167 patent. Accordingly, for the reasons discussed, 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.

d. 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

[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).

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).

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.

e. Petitioner's Additional Arguments

Petitioner contends that obviousness must be evaluated from the viewpoint of an ordinarily skilled artisan. Reply 21. To that end, Petitioner contends that, in addition to Chen and Tapolsky, a number of references of record, including several patents cited as background art in the '167 patent

(*see* Ex. 1001, 1:48–2:54), establish that uniform films were well known in the prior art. Reply 22–24 (citing Ex. 1052 ("Fuchs"), Ex. 1065 ("Schmidt"), Ex. 1063 ("Horstman"), Ex. 1064 ("Zerbe"), Ex. 1009 (Modern Coating)).

We note that none of Exhibits 1052, 1063, 1064, or 1065 was cited in the Petition, but instead were first cited in Petitioner's Reply. Thus, other than Chen, Tapolsky, and Modern Coating, discussed above, the ground of unpatentability for which we instituted trial was not based on the disclosures of any of these newly cited references. *See* Pet. 43–59 (setting forth instituted ground of unpatentability).

We acknowledge that, in an appeal of an *inter partes* review decision under the AIA by this Board, the Federal Circuit remanded the case because the Board panel had not sufficiently addressed background art fairly raised in the initial petition in that proceeding. *Ariosa Diagnostics v. Verinata Health, Inc.*, 805 F.3d 1359, 1365–67 (Fed. Cir. 2015). The situation here is distinguishable from that in *Ariosa*, however, because none of Exhibits 1052, 1063, 1064, or 1065 were cited in the Petition in this proceeding. *See Ariosa*, 805 F.3d at 1365 ("Ariosa's Petitions and opening declarations invoked Exhibit 1010 . . . .").

In any event, even considering the newly cited references, Petitioner fails to explain specifically how the asserted background knowledge in the prior art, gleaned from the quoted portions of the newly cited references (*see* Reply 22–23), remedies the inadequacies, discussed above, in Petitioner's explanation of why Chen inherently describes, or renders obvious, films meeting the substantial uniformity requirement of claims 17 and 110, even when viewed alongside Tapolsky and Modern Coating.

Lastly, we note that Petitioner did not advance the Reitman Declaration (Ex. 1047) in support of the ground of unpatentability for which trial was instituted in this proceeding. Pet. 43–59 (setting forth instituted ground of unpatentability). Petitioner did, however, advance the Reitman Declaration in support of the Petition in IPR2015-00165, filed concurrently with the Petition in this proceeding. *See* IPR2015-00165, Paper 2. Patent Owner, in turn, cited the Reitman Declaration in this proceeding to question the reproducibility of Chen's disclosure. PO Resp. 38–42.

Even considering the Reitman Declaration, Petitioner does not persuade us that Chen inherently discloses a film meeting the uniformity requirement of claims 17 and 110 of the '167 patent. The Reitman Declaration describes the preparation of a film having the ingredients of Example 7 of Chen,[11] using the drying techniques described in Chen, including in Figure 2. Ex. 1047 ¶ 5. Specifically, the Reitman Declaration states that, consistent with the '167 patent's disclosure, although the film was dried for 9 minutes, "[w]ithin about 4 minutes after initiation of drying, the film was self-supporting, non-tacky, flexible and viscoelastic, as verified by my team." *Id.* ¶ 9.

The Reitman Declaration asserts that active content uniformity was verified by visual inspection, and by the consistent dosage unit weight standard. *Id.* ¶¶ 6 and 7. As discussed above, however, we conclude that neither of those standards is the standard of uniformity required by claims 17 and 110 of the '167 patent. Accordingly, the fact that the asserted

[11] The Reitman Declaration notes that, because the manufacturer renamed Cremophor® EL product, the equivalent product from the same manufacturer was employed. Ex. 1047 ¶ 5 n.2.

reproduction of the film of Chen's Example 7 meets those standards does not demonstrate that the film of Chen's Example 7 meets the uniformity requirement of claims 17 and 110.

The Reitman Declaration asserts also that the film made according to Chen's Example 7 shows a substantially uniform distribution of an active component, i.e., a variation of the active component of less than 10% in substantially identical size dosage units, as confirmed by dissolution of individual dosage units of substantially identical size, and subsequent analysis by High Performance Liquid Chromatography (HPLC). *Id.* ¶ 8. Table 3 of the Reitman Declaration, reproduced below, shows the results of that analysis:

Table 3	
Sample	Oxybutynin weight (mg)
A	4.4
B	4.4
C	4.3
D	4.4
E	4.1

Id. The Reitman Declaration advances Table 3 to show the weight in milligrams of the active ingredient, oxybutynin, in each of five substantially identically sized dosage unit samples, A through E, cut from the film prepared according to Chen's Example 7. *Id.*

In response, Patent Owner contends that, despite the Reitman Declaration's assertion that substantially identical size dosage units were assayed for oxybutynin content, the Reitman Declaration "completely failed to account for the thickness of the samples." PO Resp. 43.

Dr. Reitman's testimony is, at best, equivocal on this point. She initially acknowledges that thickness contributes to the volume (and therefore the size) of the dosage units, and asserts that she considered thickness when assaying the film dosage units, but then admits that she does not believe, or at least does not recall, that she measured the thickness of the assayed dosage units:

> Q. Okay. What about the thickness of the film, does that come into play in substantially equal size?
>
> A. The film thickness would contribute to the overall volume, and the assessment I did included the thickness component of volume in that I was performing bulk measurements for the dosage units.
>
> Q. Did you measure the thickness then of the samples?
>
> A. No, I don't believe that we measured the thickness. Using the fixed area and the fixed manufactured film, we used that dosage unit for the assessment.
>
> Q. So to -- did you measure then the thickness of the film?
>
> A. I don't recall specifically measuring the thickness of the film.

Ex. 2012, 56:24–57:16.

We find that Petitioner has not shown sufficiently that the Reitman Declaration establishes that the amount of oxybutynin shown in Table 3, reproduced above, was determined using substantially equal sized individual dosage units, as required by claims 17 and 110 of the '167 patent. Petitioner does not identify any specific disclosure in the Reitman Declaration of a determination of the thicknesses of the dosage units, which is necessary to know the size of a three-dimensional film, i.e., whether the sizes of different films are the substantially the same. Dr. Reitman's deposition testimony similarly fails to establish that the thicknesses were actually determined. Accordingly, we find that Petitioner has not shown that Chen inherently

discloses a film meeting the uniformity requirement of claims 17 and 110 of the '167 patent, based on the Reitman Declaration's asserted reproduction of Example 7 of Chen.

C. Petitioner's Motion to Exclude Evidence

Petitioner moves to exclude the Peppas Declaration (Ex. 2002), the Wyse Declaration (Ex. 2003), the Myers Declaration (Ex. 2004), and the Lin Declaration (Ex. 2005). *See generally* Pet. Mot. to Exclude. Our decision does not rely on those declarations. Accordingly, we dismiss Petitioner's Motion to Exclude as moot.

We acknowledge Patent Owner's submission of Exhibits 2023 and 2024, advanced to show the expertise of the team that worked with Dr. Wyse. PO Opp. 4–5. Because our decision does not rely on the Wyse Declaration, we did not consider those Exhibits.

D. Patent Owner's Motion to Exclude Evidence

Patent Owner moves to exclude the Reitman Declaration (Ex. 1047), based on alleged misleading statements, alleged deficiencies in the analytical techniques used, and the alleged fact that the films described in the Declaration were dried using state-of-the-art equipment. PO Mot. to Exclude 1–14. Patent Owner bases its assertions on information discovered from Dr. Reitman's depositions. *See id.* Patent Owner also asserts that the Reitman Declaration is outside the scope of a permissible Reply to Patent Owner's Response, and also is belatedly presented for use in Petitioner's *prima facie* case. *Id*. at 14–15.

Patent Owner's Motion to Exclude the Reitman Declaration is denied. Patent Owner correctly points out that Petitioner did not rely on the Reitman Declaration to support the ground of unpatentability for which trial was

instituted in this proceeding. *See* Pet. 43–59 (setting forth instituted ground of unpatentability). Rather, Petitioner relied on the Reitman Declaration in its Petition in IPR2015-00165, which, as noted above, was filed concurrently with the Petition in this proceeding. *See* IPR2015-00165, Paper 2, 32. That said, Patent Owner advanced the Reitman Declaration in its Patent Owner Response in this proceeding to show that Chen's process was not reproducible, and therefore not enabled. PO Resp. 38–42. Although we acknowledge that Patent Owner filed the same Patent Owner Response in both IPR2015-00165 and this proceeding (*see id.*, cover page, n.1), Patent Owner's use of the Reitman Declaration to show non-enablement of Chen does not distinguish between proceedings. Thus, Patent Owner itself put the Reitman Declaration before us in this proceeding.

In addition, that Patent Owner, from its cross-examination of Dr. Reitman, was able discover facts pertinent to our consideration of the Reitman Declaration, goes to the probative weight of the Declaration, rather than its admissibility. That is, that Dr. Reitman's deposition testimony might undercut statements made in her Declaration does not demonstrate that her Declaration lacks relevance, is prejudicial, or is inadmissible as unreliable expert testimony. For those reasons, moreover, Patent Owner does not persuade us that we should exercise our discretion to exclude the Reitman Declaration under 37 C.F.R. § 42.65, based on the alleged failure to disclose every detail of the preparation and analysis of the films described in the Declaration.

Patent Owner also moves to exclude Exhibits 1052, 1062, 1063, 1064, and 1065, as being outside the scope of a permissible Reply to Patent Owner's Response. PO Mot. to Exclude 14. As noted above, although

Exhibits 1052, 1063, 1064, and 1065 were first cited in Petitioner's Reply, the patents themselves were also cited as background art in the '167 patent. *See* Ex. 1001, 1:48–2:54. Accordingly, we exercise our discretion in this instance and deny Patent Owner's Motion to Exclude Exhibits 1052, 1063, 1064, and 1065.

As to Exhibit 1062, advanced by Petitioner to traverse Patent Owner's claim construction contentions (Reply 4), our decision does not rely on that Exhibit. Accordingly, we dismiss as moot Patent Owner's Motion to Exclude Exhibit 1062.

III. CONCLUSION

In sum, for the reasons discussed above, we find that Petitioner has not shown that Chen and Tapolsky describe, or render obvious, film compositions that have 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 of the '167 patent. Accordingly, we find also that Petitioner has not shown by a preponderance of the evidence that claims 17 and 110 of the '167 patent, or their dependent claims 18, 30, 31, 37, 49, 56, 63, 70, 77, 80, 81, 87, 93, 111–116, and 124, are unpatentable under 35 U.S.C. § 103(a) for obviousness over Chen and Tapolsky.

IV. ORDER

For the reasons given, it is

ORDERED that claims 17, 18, 30, 31, 37, 49, 56, 63, 70, 77, 80, 81, 87, 93, 110–116, and 124 of the '167 patent have not been shown by a preponderance of the evidence to be unpatentable;

FURTHER ORDERED that Petitioner's Motion to Exclude is dismissed as moot;

FURTHER ORDERED that Patent Owner's Motion to Exclude is denied-in-part and dismissed-in-part as moot; and

FURTHER ORDERED that, because this is a final written decision, parties to this proceeding seeking judicial review of our Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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