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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 IPR2015-00168
Patent 8,765,167 B2

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

YANG, *Administrative Patent Judge*.

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

# I. INTRODUCTION

BioDelivery Sciences International, Inc. ("Petitioner") filed a Petition for an *inter partes* review of claims 16, 36, 42, 48, 55, 62, 69, 76, 86, 92, 122, and 123 of U.S. Patent No. 8,765,167 B2 (Ex. 1001, "the '167 patent"). Paper 1 ("Pet."). Monosol Rx, LLC ("Patent Owner") did not file a Preliminary Response. The Board instituted trial to review the patentability of all challenged claims. Paper 6 ("Dec."). Thereafter, Patent Owner filed a Response (Paper 15 ("PO Resp.")), and Petitioner filed a Reply (Paper 34 ("Reply")). The parties also briefed on whether certain exhibits should be excluded from the record. *See* Papers 50, 52, 57, 59, 63, 64. Oral hearing was held on February 12, 2016. *See* Paper 68 ("Tr.").

The Board has jurisdiction under 35 U.S.C. § 6(c) and issues this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

For the reasons provided below, we determine that Petitioner has not met its burden of proving the unpatentability of claims 16, 36, 42, 48, 55, 62, 69, 76, 86, 92, 122, and 123 of the '167 patent by a preponderance of the evidence. *See* 35 U.S.C. § 316(e). Petitioner's Motion to Exclude is dismissed as moot. Patent Owner's Motion to Exclude is denied-in-part and dismissed-in-part as moot.

## *A. Related Proceedings*

According to the parties, Patent Owner previously asserted the '167 patent against Petitioner in *Reckitt Benckiser Pharmaceuticals Inc. v. BioDelivery Sciences International, Inc.*, 3:14-cv-5892 (D.N.J.). Pet. 4; Paper 3, 2.

Concurrently with the instant Petition, Petitioner also filed petitions in IPR2015-00165, IPR2015-00167, and IPR2015-00169, challenging certain other claims of the ’167 patent. We denied the petition in one proceeding. *See BioDelivery Sciences Int’l, Inc. v. MonoSol Rx, LLC,* IPR2015-00167, Paper 6 (PTAB May 20, 2015); Paper 9 (PTAB Nov. 12, 2015). For the other two proceedings where we instituted trial, we issue decisions therein concurrently with this Final Written Decision. *See BioDelivery Sciences Int’l, Inc. v. MonoSol Rx, LLC,* IPR2015-00165, Paper 70 (PTAB Mar. 24, 2016); *BioDelivery Sciences International, Inc. v. MonoSol Rx, LLC,* IPR2015-00169, Paper 69 (PTAB Mar. 24, 2016).

Petitioner identifies a number of other proceedings, both at the U.S. Patent and Trademark Office and in district court, which involve patents in the same family as the ’167 patent. Pet. 1–4; Papers 5, 67.

*B. The ’167 Patent*

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

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

The invention of the ’167 patent provides “a substantially reduced occurrence of, i.e. little or no, aggregation or conglomeration of components

within the film as is normally experienced when films are formed by conventional drying methods." *Id.* at 5:63–67. It also includes anti-tacking agents in the film compositions to reduce the adherence of the films to the roof of the mouth and to one another. *Id.* at 18:64–19:13.

*C. Illustrative Claim*

Claim 16 is the sole independent claim challenged in the Petition. It reads:

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

> substantially uniform distribution is measured by substantially equal sized individual unit doses which do not vary by more than 10% of said desired amount of said active component.

*D. Reviewed Ground of Unpatentability*

The Board instituted trial to review whether the combination of Chen[1] and Tapolsky[2] renders claims 16, 36, 42, 48, 55, 62, 69, 76, 86, 92, 122, and 123 obvious. Dec. 19.

## II. ANALYSIS

### *A. Claim Construction*

In an *inter partes* review, the Board interprets a claim term in an unexpired patent according to its broadest reasonable construction in light of the specification of the patent in which it appears. 37 C.F.R. § 42.100(b); *In re Cuozzo Speed Techs., LLC*, 778 F.3d 1271, 1278–81 (Fed. Cir. 2015), *cert. granted sub nom. Cuozzo Speed Techs. LLC v. Lee*, 136 S. Ct. 890 (2016). Under that standard, absent any special definitions, we assign claim terms their ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention, in the context of the entire patent disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

In the Decision to Institute, we determined that "substantially uniform distribution" is "measured by substantially equal sized individual unit doses

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[1] Chen et al., International Publication No. WO 00/42992, published July 27, 2000 (Ex. 1002, "Chen").
[2] Tapolsky et al., International Publication No. WO 99/55312, published November 4, 1999 (Ex. 1003, "Tapolsky").

which do not vary by more than 10% of said desired amount of said active component." Dec. 6. During trial, the parties did not dispute this conclusion. Having considered the complete record developed at trial, we see no reason to change our interpretation of this term.

In the Decision to Institute, we also stated

> the phrase including the term "controlled drying process" refers to drying with at least one controlled drying parameter, which forms a viscoelastic matrix within a few minutes of the drying process to lock-in the active within the matrix and to maintain the distribution of the active so that substantially equal sized individual unit doses do not vary by more than *10% of the amount* of the active.

Dec. 8–9 (emphasis added). As Patent Owner correctly points out, claim 16 recites "substantially equal sized individual unit doses which do not vary by more than *10% of said desired amount* of said active component." Ex. 1001, claim 16 (emphasis added); PO Resp. 5. We agree with Patent Owner that the omission of the word "desired" in our construction is inconsistent with the express language of claim 16. *See* PO Resp. 5. Thus, we modify our construction of the term "controlled drying process" and conclude that the phrase including the term "controlled drying process" refers to drying with at least one controlled drying parameter, which forms a viscoelastic matrix within a few minutes of the drying process to lock-in the active within the matrix and to maintain the distribution of the active so that the resulting film has a substantially uniform distribution of the active, as measured by substantially equal sized individual unit doses do not vary by more than 10% of the desired amount of the active.

We, however, disagree with Patent Owner on what the term "desired amount" means. Patent Owner asserts that the "desired amount" of active is the "labeled amount of active." *See* PO Resp. 16–17, *see also id.* at 20 ("[T]he term '*desired amount*' means the dosage (label) amount."). According to Patent Owner, "[t]his and only this interpretation is consistent with" the Specification of the '167 patent. *Id.* at 17. We are not persuaded.

Patent Owner relies on the Background section of the '167 patent where it discloses: "Currently, as required by various world regulatory authorities, dosage forms may not vary more than 10% in the amount of active present." *Id.* at 18 (quoting Ex. 1001, 2:1–20). According to Patent Owner, "[i]n order for individual unit doses containing drugs to be legally sold they must contain, according to the prescribed limits, the drug in the desired dosage amount, also commonly referred to as the labeled dosage amount." *Id.*

Patent Owner may well be correct in that statement. Yet, the argument does not impact our patentability analysis of claim 16 and its dependent claims, because the challenged claims are not limited to pharmaceutical films, much less such films that are regulated because they contain a "labeled" dosage amount. Indeed, claim 16 recites "said active component is selected from the group consisting of cosmetic agents, pharmaceutical agents, vitamins, bioactive agents and combinations thereof." Patent Owner does not explain, and we are not aware, what a labeled dosage is for a film with a cosmetic agent or a vitamin as the active component. Moreover, if we were to, as Patent Owner insists, limit the "desired amount" to the labeled dosage, then such a film, even with a

homogeneous distribution of the active component, would be considered non-uniform simply because it does not have a labeled dosage required by the regulatory authorities. Such a construction would not be reasonable.

In fact, Patent Owner itself recognizes so. In its Example 7, Chen does not provide a "labeled amount" for an individual unit dose. Patent Owner, however, argues that "Chen provides all the information necessary to calculate the desired dosage amount of drug active in Chen's individual unit doses for Chen's Example 7 film." PO Resp. 40. Patent Owner proposes such calculation based, not on the non-existing labeled amount, but rather, on the weight percentage of the active, the size of the individual dosage unit, and the density of the film. *See id.* at 40–42.

Moreover, the passage in the '167 patent that Petitioner relies on contradicts Patent Owner's assertion that the "desired amount" is the "labeled amount." *See* PO Resp. 17–18. Indeed, the '167 patent explains that a "dosage amount" is "determined by the size of the film and concentration of the active in the original polymer/water combination." Ex. 1001, 18:49–53. In other words, a film may be cut into a size to obtain the amount to active desired. Were it otherwise, that is, if the uniformity were determined based solely on a labeled dosage, a film with a homogeneous distribution of the active component would be considered non-uniform simply because each substantially equal sized individual unit dose contains twice, or half, the labeled dosage. Such a construction would not be reasonable.

In sum, we conclude that a "desired amount" of active component includes, but is not limited to, a labeled dosage amount. This determination

as to the scope of a "desired amount" is sufficient for purposes of this Decision, and we need not further address the term.

*B. Patentability Analysis*

Petitioner contends that claims 16, 36, 42, 48, 55, 62, 69, 76, 86, 92, 122, and 123 would have been obvious over Chen in view of Tapolsky. Pet. 44–58. In support of its patentability challenges, Petitioner relies on the Declaration of Dr. Edward D. Cohen (Ex. 1007). After reviewing the entire record, we conclude Petitioner has not shown by a preponderance of the evidence that the asserted prior art teaches a film with 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.

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

Tapolsky relates to a water-erodable pharmaceutical carrier device suitable for delivery of pharmaceutical components to mucosal surfaces. Ex. 1003, 5:5–9. In one embodiment, the device comprises "a layered film disk having an adhesive layer and a backing layer, both water-erodable, having the pharmaceutical in one or more of the layers." *Id.* at 5:9–13.

Petitioner points to Chen for teaching a film for mucosal delivery, which includes "an effective dose of active agent," as recited in the preamble of claim 16. Pet. 45 (citing Ex. 1002, Title, Abstract). According to Petitioner, the film formed according to Chen is self-supporting (*id.* at 46 (citing Ex. 1002, 15:30–31, 17:15–16)), and "necessarily has at least one surface" (*id.* at 52 (citing Ex. 1007, 50)), as required in limitation (a) and the wherein clause of claim 16. Petitioner also refers to Chen for teaching films made from water-soluble hydrocolloid polymers and administered through the oral cavity, thus satisfying limitation (i). *Id.* at 46 (citing Ex. 1002, 14:22–15:3, 16:22–25). Petitioner further argues that Chen teaches therapeutic agents and nutritional supplements as active agents, and thus, satisfies that aspect of limitation (ii). Pet. 46 (citing Ex. 1002, 10:22–23).

Limitation (b) of claim 16 recites a coating on at least one surface of the film, "said coating comprising at least one anti-tacking agent selected from" a group of compounds. Petitioner points out that the film of Chen is non-tacky. Pet. 48 (citing Ex. 1002, 15:30–31). Chen describes the ranges of "dry tack" and "wet tack" as related to the adhesion of the film to a mucosal surface. *Id.* at 51 (citing Ex. 1002, 12:13–19). Chen also teaches placing the film-forming mixture onto a backing layer. *Id.* at 57 (citing Ex. 1002, 4:31–32). Petitioner refers to Tapolsky for disclosing a multi-layer film. *Id.* at 58 (citing Ex. 1003, 5:9–13). Specifically, Petitioner points to Example 37 where Tapolsky teaches making a film with "backing layers" containing sodium benzoate, a compound recited as a possible "anti-tacking agent" in claim 16. *Id.* (citing Ex. 1003, 37:4–9). Therefore, Petitioner contends, one of ordinary skill in the art would have been

motivated to combine the active-containing film of Chen with the anti-tacking-agent-containing backing layer of Tapolsky, "to adjust or reduce adhesion" of Chen's film. *Id.* Patent Owner does not dispute that the prior art teaches these limitations.

Petitioner also contends that Chen teaches a "controlled drying process" that results in a film with "substantially uniform distribution" of the active, as required in limitation (ii) and the wherein clause of claim 16. *Id.* at 52–56. First, Petitioner asserts the Board previously found, in a decision on appeal in an *inter partes* reexamination of a different patent in the same family as the '167 patent, that Chen meets the uniformity requirement. *Id.* at 54 (incorporating by reference "[s]ubsection . . . 5 of Ground 2"), 9 (citing Ex. 1027, 15–17, 19), 38 (citing Ex. 1027, 17, 19). According to Petitioner, Patent Owner is estopped from contesting that finding. *Id.* at 38–40. In addition, Petitioner contends that Chen's films meet the substantially-uniform-distribution requirement as demonstrated by visual inspection, the consistent dosage unit weight, and the homogeneity of the starting solution. *Id.* at 54–56. Petitioner challenges Petitioner's position regarding this limitation. We address each of Petitioner's arguments in turn.

1. Collateral Estoppel

Petitioner points out that the '167 patent "is part of a large family of patents." Pet. 1–2. One of the patents in this family, U.S. Patent No. 7,824,588 ("the '588 patent"), was reexamined (control number 95/001,753). *Id.* at 2. In the reexamination, all claims of the '588 patent were rejected and the Board affirmed the rejections. *Id.*; Ex. 1027 ("the '588 decision"). In the '588 decision, the Board found that (1) "Chen teaches controlled drying"

(Ex. 1027, 17); (2) "Chen inherently discloses a film with a substantially uniform content of therapeutic active composition per unit of film" (*id.* at 15); and (3) the "weight deviation of ±0.001 [shown in Table 4 of Chen] satisfies the limitation of 'substantially uniform' active content" (*id.* at 19). Petitioner argues that because Patent Owner did not appeal the '588 decision, the Board's decision is final. Pet. 39–40. As a result, Patent Owner should be estopped "from contesting the Board's findings as to Chen." *Id.* We disagree.

Under the doctrine of collateral estoppel, also known as issue preclusion, a judgment on the merits in a first proceeding precludes relitigation in a second proceeding "of issues actually litigated and determined in the first [proceeding]." *In re Freeman*, 30 F.3d 1459, 1465 (Fed. Cir. 1994). Issue preclusion is appropriate only if: (1) the issue is identical to one decided in the first action; (2) the issue was actually litigated in the first action; (3) resolution of the issue was essential to a final judgment in the first action; and (4) the party against whom issue preclusion is asserted had a full and fair opportunity to litigate the issue in the first action. *Id.* When applying issue preclusion, "statements regarding the scope of patent claims made in a former adjudication should be narrowly construed." *Id.* at 1466.

We determine that issue preclusion does not apply here because the resolution of the issue in this case was not essential to the final judgment in the '588 decision. In the '588 decision, because Patent Owner did not argue for the patentability of any dependent claims separately, the Board resolved the issue of whether Chen met the uniformity requirement solely based on

the language of claim 1. Ex. 1027, 12. Claim 1 of the '588 patent, as amended during the reexamination, requires "substantially uniform content of therapeutic active composition per unit of film." *Id.* at 4. Thus, the '588 decision did not resolve the issue of whether Chen met the substantially-uniform-distribution limitation, "measured by substantially equal sized individual unit doses which do not vary by more than 10% of said desired amount of said active component," as required by claim 16 of the '167 patent.

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

Indeed, the claim language closest to claim 16 of the '167 patent appears in claim 93 of the '588 patent, which recites "[t]he method of claim 1, further comprising forming a plurality of individual dosage units of substantially the same size, wherein the active content of individual dosage units has a variance of no more than 10%." *Id.* at 44:7–10. Under the doctrine of claim differentiation, claims 3 and 93 of the '588 patent are presumed to have different scope. *See Kraft Foods Inc. v. Int'l Trading Co.*,

203 F.3d 1362, 1366 (Fed. Cir. 2000). The Board, in the '588 decision, did not separately address whether Chen taught the added limitation in claim 93. As such, the issue of whether Chen met the substantially-uniform-distribution requirement at issue in this case was not essential to the '588 decision. Because the requirements of issue preclusion have not been met, the doctrine is inapplicable.

Petitioner also brings to our attention additional decisions on appeal in *inter partes* reexaminations of two other patents in the same family as the '167 patent. Reply 3 (citing Ex. 1056 ("the '080 decision"), Ex. 1057 ("the '337 decision")). According to Petitioner, in those decisions, the Board found "claims reciting 'active varies by no more than 10%' were unpatentable over Chen." *Id.* We conclude that doctrine of issue preclusion is not applicable because neither decision is final. *See Vardon Golf Co., Inc. v. Karsten Mfg. Corp.*, 294 F.3d 1330, 1333–35 (Fed. Cir. 2002). Indeed, the '080 decision states expressly that "no portion of the decision is final for the purposes of judicial review." Ex. 1056, 44. In the '337 patent reexamination, the Board denied Patent Owner's request for rehearing on January 27, 2016. *See* Paper 67. The time for appeal in that case, however, has not expired. *See* 35 U.S.C. § 142; 37 C.F.R. § 90.3(a). Thus, the '337 decision is not final either.

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

when "[t]he forum in the second action affords the party against whom preclusion is asserted procedural opportunities in the presentation and determination of the issues that were not available in the first action and could likely result in the issue being differently determined." *Id.* at 1468. We conclude such is the case here.

In this *inter partes* review, the availability of cross-examination of witnesses is a procedural opportunity for the parties that was not available in the prior *inter partes* reexamination proceedings. Specifically, *inter partes* reexamination proceedings are conducted essentially by the same procedure as routine examination of patent applications. 37 C.F.R. § 1.937(b). There, although submission of evidence in affidavit form is allowed (37 C.F.R. §§ 1.131, 1.132), the rules for *inter partes* reexaminations do not provide for cross-examination of those affiants. *See* 37 C.F.R. §§ 1.902–1.997. In contrast, in the instant *inter partes* review, witnesses presenting direct testimony by affidavit are subject to cross-examination via deposition. 37 C.F.R. § 42.53. As discussed below, the testimony during cross-examination of one of Petitioner's witnesses uncovered facts that cast doubts on her direct testimony. *See infra* at 24–25. As such, this procedural distinction weighs in favor of a determination on that issue different from the '588, '080, and '337 decisions in the prior *inter partes* reexaminations. Thus, issue preclusion is inappropriate here.

In sum, for the reasons discussed above, we conclude that the doctrine of issue preclusion is inapplicable in this proceeding.

2. Visual Inspection and Consistent Dosage Weight

Petitioner argues that the '167 patent sets forth tests, including visual inspection and consistent dosage weight, for determining whether a film has a uniform distribution of active component. Pet. 54–56. According to Petitioner, in Chen, the uniform distribution of active component is demonstrated in Example 1 by the consistent dosage weight, and in Examples 1–8 by visual inspection. *Id.* Because Chen shows "uniform distribution of active in the film," Petitioner concludes, it "must satisfy the substantially uniform distribution required by the challenged claims." *Id.* at 55. We disagree.

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

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

Ex. 1035, 19:56–63.

Petitioner argues that the '167 patent, via the incorporated '292 patent, teaches that "uniform distribution of components, including active, can be demonstrated by visual inspection." Pet. 55–56. In Chen, "[a] glossy, substantially transparent, stand alone, self-supporting, non-tacky and flexible film was obtained after drying." Ex. 1002, 17:15–16. According to

Dr. Cohen, "[a] film that is 'substantially transparent' is one that is substantially free of aggregation when viewed by the unassisted (i.e., naked) eye or under slight magnification." Ex. 1007 ¶ 110. Thus, Petitioner asserts, the films in Examples 1–8 of Chen have uniformly distributed active component, as confirmed by visual inspection disclosed in the '292 patent. Pet. 56. They, therefore, satisfy the substantially-uniform-distribution limitation in the challenged claims. *Id.*

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

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

We are not persuaded by either argument. Claim 16 recites that the "substantially uniform distribution is measured by substantially equally sized individual unit doses which do not vary by more than 10% of said

desired amount of said active component." Based on the express language of the claim, and despite that we disagree with Patent Owner that the "desired amount" should be limited to the labeled dosage amount, we conclude that the actual amount of the active component in substantially equal sized individual unit doses of the film must be determined in order to evaluate whether the distribution of the active is substantially uniform. Petitioner does not explain how the amount of the active component in each individual unit dose can be ascertained by either visual inspection of a film or weighing the dosage units.

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

Moreover, in the Decision to Institute, we determined that "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." Dec. 6. In fact, Petitioner proposes the same construction. Pet. 18. Yet, here, Petitioner asks us to import the visual inspection and the consistent-dosage-weight test from the specification into the challenged claims. This, we cannot do. *See In re*

*Trans Texas Holdings Corp.*, 498 F.3d 1290, 1299 (Fed. Cir. 2007) (explaining that "while the specification should be used to interpret the meaning of a claim, courts must not import limitations from the specification into the claim") (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed. Cir. 2005) (en banc) (quotation marks and alterations omitted)).

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

3. Homogenous Starting Material

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

In making his Declaration, Dr. Cohen relies on Modern Coating,[3] which teaches drying of thin films, including the basic principles, methods, and apparatus used. *See* Ex. 1009, 267–95. Dr. Cohen testifies that "[w]hen working with a homogenous or completely dissolved coating solution, like

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

the one described in Chen, it would be difficult for a person of ordinary skill in the art not to obtain a film that has uniform content of active." Ex. 1007 ¶ 107 (citing Ex. 1009, 268). Dr. Cohen also states that "the role of drying in maintaining uniformity of distribution was known in the art well prior to" the earliest possible priority date of the '167 patent, and that an ordinary artisan would have been aware of the variables in the drying process, and would have been able to optimize these variables to maintain uniformity of the coating solution during drying. *Id.* ¶ 113 (citing Ex. 1009, 286), ¶ 114 (citing Ex. 1009, 268). According to Dr. Cohen, "beginning in the 1960s, my colleagues and I were able to produce film with *high degree of uniformity* of distribution of components." *Id.* ¶ 112 (emphasis added).

Dr. Cohen, however, does not assert that a skilled artisan would have been able to produce film with any particular desired degree of (or absolute) uniformity. And he does not explain what the "high degree of uniformity" he and his colleagues were able to achieve, and whether it satisfies the substantially-uniform-distribution requirement recited in claim 16 of the '167 patent, that is, as measured by substantially equally sized individual unit doses having the active component that do not vary by more than 10% of the desired amount. Similarly, Petitioner does not argue that the "uniform film" produced according to the drying processes taught in Modern Coating meets this limitation.[4] In addition, Dr. Cohen does not opine, Petitioner does

[4] Petitioner does not present any other persuasive evidence, such as its own testing data, to demonstrate that the drying processes described in Modern Coating would necessarily result in a film with "substantially uniform distribution" of the active, as required in the challenged claims. *See, e.g.*,

not assert, and we do not find, that an ordinary artisan would have understood an unspecified degree of uniformity as satisfying the "substantially uniform" required in the challenged claims.

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

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

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Ex. 1009, 268 ("Modern precise coating applicators can [maintain uniformity] for *most coatings*.") (emphasis added).

In sum, for the reasons above, we conclude that Petitioner has not shown by a preponderance of the evidence that Chen teaches the substantially-uniform-distribution limitation merely because it starts with a homogeneous mixture.

4. Reitman Declaration

Petitioner submits the Declaration of Dr. Maureen Reitman (Ex. 1047) with its Reply. The parties quarrel over whether we should consider the Reitman Declaration. *See* Papers 52, 59, 63. As explained below, we deny Patent Owner's Motion to Exclude in this aspect. *See infra* at 27–28. But, consideration of the Reitman Declaration[5] does not change our conclusion that Petitioner has not demonstrated the unpatentability of the challenged claims by a preponderance of the evidence.

According to Petitioner, Dr. Reitman reproduced Example 7 of Chen and demonstrated uniformity of the film "by visual inspection, by consistent unit dosage weights, and by HPLC [High Performance Liquid Chromatography]." Reply 21 (citing Ex. 1047 ¶¶ 6–8). As explained above, neither visual inspection nor consistent unit dosage weight is a proper standard to measure the substantially uniform distribution of active component, as required in the challenged claims. *See supra* at 16–19. Thus, even if the allegedly reproduced film according to Example 7 of Chen meets those standards (Ex. 1047 ¶¶ 6, 7), it does not demonstrate that the film

[5] We acknowledge that Petitioner does not rely on the Reitman Declaration in the Petition to support its *prima facie* case of unpatentability.

meets the substantially-uniform-distribution limitation of the challenged claims.

The dissolution test, as analyzed by HPLC, however, is the same method of determining the amount of active in a film of a particular size as the one described in the '167 patent. *See* Ex. 1035, 20:62–67. Dr. Reitman testifies that "[b]y dissolution of individual dosage units of *substantially identical size* and analysis by High Performance Liquid Chromatography (HPLC) active content uniformity was verified by my team." Ex. 1047 ¶ 8 (emphasis added). 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.* Table 3 shows the weight of the active ingredient, oxybutynin, in each of five dosage units, Samples A–E, cut from the film prepared according to Chen's Example 7. *Id.* Dr. Reitman concludes that "[a]s can be seen in Table 3, the active varies by less than 10%." *Id.*

Patent Owner argues that "the '10%' value is +/–10% from the desired amount. It is not a measurement of the difference in the amount of active between individual unit doses." PO Resp. 6; *see also id.* at 43 (criticizing Dr. Reitman's analysis as "directed to a comparison of one sample to another, and not to a comparison of the sample to the desired

amount."). We do not need to resolve whether Dr. Reitman performed the correct comparison because Petitioner has not shown that the dosage units tested in Table 3 are of "substantially equal size," as the challenged claims require.

The Reitman Declaration does not reveal the size of Samples A–E in Table 3. To be sure, Table 2 of the Reitman Declaration, reproduced below, shows the area of each dosage unit is 5 $cm^2$:

| Table 2 | |
|---|---|
| Sample | Weight of 5 $cm^2$ dosage unit (grams) |
| 1 | 0.034 |
| 2 | 0.034 |
| 3 | 0.034 |
| 4 | 0.034 |
| 5 | 0.034 |
| 6 | 0.034 |
| 7 | 0.034 |

*Id.* ¶ 7. Table 2 shows the weight of seven 5 $cm^2$ dosage units, Samples 1–7. *Id.* Assuming each of Samples A–E in Table 3 is also of 5 $cm^2$, Patent Owner nevertheless argues that, despite Dr. Reitman's testimony 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. We agree.

Dr. Reitman's testimony on this point during the cross-examination is, at best, equivocal:

> 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.

During the hearing, counsel for Petitioner conceded that Dr. Reitman did not measure the thickness of the samples. Tr. 88:11–13. Nevertheless, Petitioner contends that we should "look at Table 2 first." *Id.* at 85:19–22. Because the samples in Table 2 are of the same area (5 $cm^2$), and have the same weight, Petitioner argues, "[h]ow could they have different thicknesses?" *Id.* at 83:13–15. Dr. Reitman, however, admits that Samples A–E in Table 3 are different from Samples 1–7 in Table 2. Ex. 2012, 155:4–6. Thus, even assuming that the samples in Table 2 are of the same thickness, we still cannot conclude the same is true for the samples in Table 3. Without sufficient information regarding the thickness of the samples at issue, we cannot ascertain whether those samples are substantially equal in size.

Because Petitioner does not point to any persuasive evidence to show that Samples A–E in Table 3 are of "substantially equal size," the fact that in each sample, "the active varies by less than 10%" does not support Petitioner's conclusion that a film prepared according to Chen's Example 7

meets the substantially-uniform-distribution limitation, as required by the challenged claims.

5. Petitioner's Additional Argument

Petitioner is correct that obviousness must be analyzed from the perspective of an ordinary artisan. Reply 21. To that end, Petitioner contends, "every reference cited in the background [of the '167 patent] reports the production of uniform pharmaceutical films." *Id.* at 22–23 (citing Exs. 1052, 1063, 1064, 1065).[6]

Petitioner, however, does not sufficiently explain how the alleged background knowledge, gleaned from the quoted portions of these references, remedies the inadequacies of Chen and Tapolsky. Indeed, Petitioner does not point to any of the references for teaching that uniformity of an active in a film 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," as required by the challenged claims. To the extent that Petitioner argues that these references teach *absolute* uniform distribution of the active in a film, and thus, necessarily teach "substantially uniform distribution" of the active, we reject the argument for the same reason as explained above. *See supra* at 16–19.

[6] Patent Owner moves to exclude Exhibits 1052, 1063, 1064, and 1065 as "outside the scope of a permissible Reply." Paper 52, 14. As explained below, we deny Patent Owner's Motion to Exclude in this aspect. *See infra* at 28.

*C. Petitioner's Motion to Exclude*

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). Paper 50. In rendering this Decision, we do not rely on those declarations. Accordingly, we dismiss Petitioner's Motion to Exclude as moot.

*D. Patent Owner's Motion to Exclude*

Patent Owner moves to exclude the Reitman Declaration (Ex. 1047). Paper 52, 1–14. We deny Patent Owner's Motion to Exclude in this aspect.

Patent Owner challenges the Reitman Declaration as "outside the scope of a permissible Reply" and as "belatedly presented evidence for use in Petitioner's *prima facie* case." *Id.* at 14. Patent Owner is correct that the Reitman Declaration was not filed with the Petition in this case. Rather, Petitioner relied on the Reitman Declaration in its petition in IPR2015-00165, filed concurrently with the Petition in this proceeding. *See* IPR2015-00165, Paper 2, 32. Yet, Patent Owner filed a single Patent Owner Response in both IPR2015-00165 and this proceeding (*see* PO Resp., cover page, n.1), and discussed the Reitman Declaration in detail therein (*id.* at 38–47). We acknowledge Patent Owner's note that the Reitman Declaration was not provided with the Petition in this proceeding. *Id.* at 7 n.4. Patent Owner, however, does not distinguish between proceedings when asserting that the Reitman Declaration "demonstrates and confirms that Chen does not disclose or enable the production of individual unit doses having a substantially uniform distribution of components including active." *Id.* at

38–39. Thus, we are not persuaded that we should exclude the Reitman Declaration from the record.

Patent Owner also argues that Dr. Reitman made misleading statements, improperly excluded samples, and prepared and dried films "at a state-of-the-art drying facility by expert pilot line operators." Paper 52, 1–14. Patent Owner bases its assertions on information discovered from Dr. Reitman's depositions. *See id.* In addition, Patent Owner contends that we should exclude the Reitman Declaration under 37 C.F.R. § 42.65 for its failure to disclose every detail of the preparation and analysis of the films described therein. *Id.* at 15. We are not persuaded.

The alleged issues of the Reitman Declaration affect its probative value, and not its admissibility. That is, that Dr. Reitman's deposition testimony might undercut statements made in the Declaration does not demonstrate that the Declaration lacks relevance, is prejudicial, or is inadmissible as unreliable expert testimony.

Patent Owner further moves to exclude Exhibits 1052, 1062, 1063, 1064, and 1065, also as "outside the scope of a permissible Reply." *Id.* at 14. We acknowledge that Petitioner did not cite to any of Exhibit 1052, 1063, 1064, or 1065 in the Petition. Rather, these Exhibits were first submitted with the Reply. Nevertheless, because the '167 patent cites these references as background art (*see* Ex. 1001, 1:48–2:54), we exercise our discretion and deny Patent Owner's Motion to Exclude Exhibits 1052, 1063, 1064, and 1065.

Petitioner refers to Exhibit 1062 for the first time in the Reply to traverse Patent Owner's claim construction contentions. *See* Reply 4.

Because we do not rely on that Exhibit, we dismiss Patent Owner's Motion to Exclude Exhibit 1062 as moot.

## III. CONCLUSION

For the reasons discussed above, we determine that Petitioner has not shown, by a preponderance of the evidence, that claims 16, 36, 42, 48, 55, 62, 69, 76, 86, 92, 122, and 123 of the '167 patent would have been obvious over Chen in view of Tapolsky.

## IV. ORDER

Accordingly, it is

ORDERED that claims 16, 36, 42, 48, 55, 62, 69, 76, 86, 92, 122, and 123 of the '167 patent have not been shown 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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