

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. REDDY'S LABORATORIES, LTD. AND DR. REDDY'S
LABORATORIES, INC.,

Petitioner,

v.

MONOSOL RX, LLC,

Patent Owner.

Case IPR2016-01111

Patent 8,603,514 B2

Before ERICA A. FRANKLIN, TINA E. HULSE, and
CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

FRANKLIN, *Administrative Patent Judge*.

DECISION

Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I. INTRODUCTION

Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "Petitioner") filed a Petition to institute an *inter partes* review of claims 1–3, 9, 15, 62–65, 69–73, and 75 of U.S. Patent No. 8,603,514 B2¹ (Ex. 1001, "the '514 patent"). Paper 1 ("Pet."). MonoSol RX, LLC ("Patent Owner") filed a Preliminary Response to the Petition. Paper 10 ("Prelim. Resp.").

We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a).

Upon considering the Petition and Preliminary Response, we determine that the Petitioner has not demonstrated a reasonable likelihood that it would prevail in showing the unpatentability of at least one of the challenged claims. Accordingly, we decline to institute an *inter partes* review of any challenged claim.

A. Related Proceedings

Petitioner and Patent Owner identify a number of district court proceedings that "may affect or be affected by a decision in the proceeding." Pet. 8–9; Paper 4, 2–3. In particular, both parties identify *Reckitt Benckiser Pharmaceuticals Inc. v. Watson Laboratories, Inc. et al.*, C.A. No.1:13-CV-01674-RGA (D. Del.) and *Reckitt Benckiser Pharmaceuticals Inc. v. Par Pharmaceutical, Inc. et al.*, C.A. No.1:14-CV-00422-RGA (D. Del.),

¹ Issued to Robert K. Yang et al., Dec. 10, 2013.

wherein each case included MonoSol Rx among the plaintiffs and for which a consolidated trial opinion addressing the '514 patent was issued on June 3, 2016. Ex. 2009.

B. The '514 Patent (Ex. 1001)

The '514 patent relates to rapidly dissolving films for delivering orally administered active ingredients. Ex. 1001, 1:43–44. The films comprise a polymer component and active ingredients as taste-masked coated particles uniformly distributed throughout the film. *Id.* at 1:44–47. The Specification explains that some film forming techniques suffer from aggregation or conglomeration of particles, resulting in a random distribution of film components and any actives present in a non-uniform manner. *Id.* at 2:7–28, 60–62. Non-uniform film “necessarily prevents accurate dosing.” *Id.* at 2:51–52. The Specification explains also that such films would not likely meet standards set by the U.S. Federal Drug Administration (“FDA”) for an acceptable amount of variation in dosage forms. *Id.* at 2:38–42. According to the Specification, “as required by various world regulatory authorities, dosage forms may not vary more than 10% in the amount of active present.” *Id.* at 2:42–45.

The Specification describes the instant invention as providing “rapid-dissolve film products for drug delivery whereby the active agents are taste-masked or controlled-release coated particles uniformly distributed throughout the film,” wherein the film may be “divided into equally sized dosage units having substantially equal amounts of each compositional component present.” *Id.* at 4:27–33. The invention is described as particularly advantageous for the pharmaceutical industry because it permits “large area films to be initially formed, and subsequently cut into individual

dosage units without concern for whether each unit is compositionally equal” and “contain the proper predetermined amount of drug.” *Id.* at 4:33–42.

C. Illustrative Claim

Independent claim 1 of the ’514 patent is illustrative and reproduced below:

1. A drug delivery composition comprising:
 - (i) a cast film comprising a flowable water-soluble or water swellable film-forming matrix comprising one or more substantially water soluble or water swellable polymers; and a desired amount of at least one active; wherein said matrix has a viscosity sufficient to aid in substantially maintaining non-self-aggregating uniformity of the active in the matrix;
 - (ii) a particulate active substantially uniformly stationed in the matrix; and
 - (iii) a taste-masking agent coated or intimately associated with said particulate to provide taste-masking of the active;wherein the combined particulate and taste-masking agent have a particle size of 200 microns or less and said flowable water-soluble or water swellable film-forming matrix is capable of being dried without loss of substantial uniformity in the stationing of said particulate active therein; and
wherein the uniformity subsequent to casting and drying of the matrix is measured by substantially equally sized individual unit doses which *do not vary by more than 10% of said desired amount of said at least one active.*

Ex. 1001, 67:34–56; (emphasis added to identify dispositive limitation).

D. The Cited References and Declaration

Petitioner relies upon the following references:

Bess	US Patent No. 7,067,116, issued Jun. 27, 2006	Ex. 1004
Chen	Patent Application Publication No. WO 00/42992, published Jul. 27, 2000	Ex. 1005
Cremer	Patent Application Publication No. CA 2,274,910 A1, issued Jun 25, 1998	Ex. 1006

Petitioner relies also upon the Declaration of Metin Çelik, Ph.D. (Ex. 1003).

E. The Asserted Grounds of Unpatentability

Petitioner challenges the patentability of claims 1–3, 9, 15, 62–65, 69–73, and 75 of the '514 patent on the following grounds (Pet. 12):

Claims Challenged	Basis	References
1–3, 9, 15, 62–65, 69–73, and 75	§ 103	Bess and Chen
1–3, 9, 15, 62–65, 69–73, and 75	§ 103	Chen and Cremer

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, the Board interprets claim terms in an unexpired patent according to the broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142 (2016) (affirming applicability of broadest reasonable construction standard to *inter partes* review proceedings). Under that standard, and absent any special definitions, we give 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 re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definitions for claim terms must be set forth with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Only terms which are in controversy need to be construed, and only to the extent necessary to resolve the controversy. *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

Petitioner proposes a construction for one claim phrase: “dried without the loss of substantial uniformity,” appearing in independent claims 1 and 62. Pet. 15. According to Petitioner, that claim phrase should be construed broadly to mean “any method of drying.” *Id.* In support of that construction, Petitioner asserts only that Patent Owner’s expert witness in a co-pending litigation “testified that the claims were not limited to any particular form of drying, or any particular drying parameters.” *Id.*

Patent Owner correctly notes that Petitioner has not explained why it has failed to account for the phrase “without the loss of substantial uniformity” in its proposed construction. Prelim. Resp. 8. Further, Patent Owner proposes that, under the broadest reasonable construction standard, the claim phrase “dried without the loss of substantial uniformity” should be given its plain meaning. *Id.* Based on the record, we agree.

B. Obviousness over Bess and Chen

Petitioner contends that claims 1–3, 9, 15, 62–65, 69–73, and 75 would have been obvious over the combination of Bess and Chen. Pet. 27–50. Patent Owner disagrees. Prelim. Resp. 11–26.

1. *Bess*

Bess discloses “fast dissolving orally consumable films containing an ion exchange resin to mask the taste of a pharmaceutically active agent therein.” Ex. 1004, 1:67–2:3. The average particle size of the pharmaceutically active agent/resin complexes is about 60 to about 250 micrometers, and more preferably, between about 55 and about 160 micrometers, and most preferably between about 60 and 150 micrometers. *Id.* at 11:53–63. Bess teaches that the film may be prepared by combining all of the ingredients to form a uniform polymer gel, deaerating the film to remove air bubbles, casting the uniform mixture on a suitable substrate, and drying the cast mixture to form a film. *Id.* at 12:4–16.

2. *Chen*

Chen discloses a dosage unit comprising a water-soluble hydrocolloid and a mucosal surface-coat-forming film that includes an effective dose of an active agent. Ex. 1005, 3:30–32. Chen’s film may also include a taste modifying agent. *Id.* at 4:4–5. Chen describes a number of disadvantages provided by a variety of prior art dosage forms, including those having particle sizes greater than 25 microns. In particular, Chen states, “many quick dissolving tablets contain particulates (>25 microns) which leave a ‘gritty’ and unpleasant taste in the mouth.” *Id.* at 2:19–20.

Chen describes forming its film, in one respect, by mixing hydrocolloid, dissolved or dispersed in water, to form a homogenous formulation. *Id.* at 15:19–21. Chen explains, “[i]n addition to the active agent and the hydrocolloid, any of the ingredients listed above may be added and dispersed or dissolved uniformly in the hydrocolloid solution.” *Id.* at 15:21–23. Thereafter, the “homogeneous mixture (coating solution) . . . was

degassed (8) and coated on the non-siliconized side of a polyester film . . . and dried under aeration.” *Id.* at 15:24–28.

3. Analysis

A conclusion that the claimed subject matter is obvious must be supported by evidence, as shown by some objective teaching in the prior art or by knowledge generally available to one of ordinary skill in the art that would have led that individual to combine the relevant teachings of the references to arrive at the claimed invention. *See In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988). Obviousness grounds must be supported with “articulated reasoning with some underpinning” and not by “mere conclusory statements.” *See KSR Int’l Co. v. Teleflex Inc.*, 550 U.S 398, 418 (2007).

Petitioner asserts that Bess and Chen each disclose certain limitations shared by independent claims 1 and 62, i.e., a cast film comprising a flowable, water-soluble or water swellable film-forming matrix, one or more substantially water-soluble or water swellable polymers, at least one particulate active to be present in the claimed formulation, and a taste-masking agent that is coated or intimately associated with the particulate to provide taste-masking of the active. Pet. 28–30.

With regard to the requirement that “the combined particulate and taste-masking agent have a particle size of 200 microns or less,” Petitioner asserts that “Chen teaches that small particles are desirable to avoid gritty mouth feel” and that “Bess teaches particle sizes of less than 100 microns.” *Id.* at 30. Additionally, Petitioner and its declarant, Dr. Çelik, assert that a person of ordinary skill in the art would have been “motivated to decrease particle size to reduce settling rate of the suspension.” *Id.*; Ex. 1003 ¶ 140.

For the claim limitation reciting “the uniformity subsequent to casting and drying of the matrix is measured by substantially equally sized individual unit doses which do not vary by more than 10% of said desired amount of said at least one active,” Petitioner asserts that a person of ordinary skill in the art would have recognized that Chen discloses film formulations that satisfy the claimed 10% variability limitation. Pet. 30–31. According to Petitioner and Dr. Çelik, a person of ordinary skill would have understood that Chen’s process of forming its film composition would have provided a matrix sufficiently viscous to substantially prevent settling and self-aggregation of particulate active ingredients . . . during casting and drying.” *Id.* at 31.

Further, Petitioner asserts that a person of ordinary skill in the art would have recognized that Chen’s films meet the 10% variability limitation because Chen used a rotary die to cut the coated and dried sheet. *Id.* at 31–32. According to Petitioner, a person of ordinary skill in the art “would have understood that individual doses of pharmaceutical film can only be manufactured this way if the film is at least as uniform as the claimed 10% limit.” *Id.* at 32 (citing Ex. 1003 ¶ 101). In support of that assertion, Dr. Celik refers to a section of the challenged patent that states, “[c]urrently, as required by various world regulatory authorities, dosage forms may not vary more than 10% in the amount of active present.” Ex. 1003 ¶ 101; Ex. 1001, 2:42–45. According to Petitioner and Dr. Celik, “the entire purpose of Chen’s process was to make pharmaceutical film drug products that were at least as uniform as the 10% limit.” Pet. 32 (citing Ex. 1003 ¶ 101).

Additionally, Petitioner asserts that data disclosed by Chen would have confirmed for a person of ordinary skill in the art that Chen’s films

were at least as uniform as the claimed 10% variation limitation. Pet. 32. To support that assertion, Petitioner refers to Chen's disclosure of the weight and thickness of individual dosage units of film in Example 1, which did not contain an active ingredient. *Id.* According to Petitioner, that data indicating a low standard of deviation for those units demonstrates that the film was manufactured in a "very uniform manner." *Id.* Petitioner refers also to Chen's description of exemplary films containing either sildenafil or dextromethorphan as an active agent wherein the individual dosages had less than a 10% variance in either the thickness (sildenafil films) or weight (dextromethorphan films). *Id.* at 33–34.

Additionally, Petitioner relies upon Chen's data for dissolution tests conducted on exemplary films containing one of a variety of active agents. *Id.* According to Petitioner, Chen's Figure 5 shows the end state in which all of the drug has been released and that the final values are clustered within the claimed $\pm 10\%$ limit, causing a person of skill in the art to have reasonably expected that "Chen's methods could be used to make films that fall within the 10% limit." *Id.* (citing Ex. 1005, 23; Ex. 1003 ¶ 103).

Patent Owner asserts a number of reasons why Petitioner has not demonstrated a reasonable likelihood of establishing that a person of skill in the art would have found it obvious to combine the teachings of Bess and Chen in a manner that yields the claimed invention. Having considered the arguments and the evidence, we agree with Patent Owner. In particular, we agree with Patent Owner that Petitioner has not established that either Bess or Chen teaches or suggests a drug delivery composition wherein the uniformity of individual unit doses, subsequent to casting and drying, does not vary by more than 10% of the desired amount of at least one active in the

cast film. PO Resp. 11. For that limitation in its claim chart, Petitioner refers to Bess' description of providing a "uniform gel." See Pet. 42. Bess, however, describes casting that gel on a substrate and drying the cast to provide the film. Ex. 1004, 2:14–27. Petitioner has not identified, nor do we see, any disclosure in Bess that teaches or suggests any specific degree of uniformity regarding the film product at all, and notably not subsequent to casting and drying. Nor has Petitioner shown that Bess recognizes a potential loss of uniformity with respect to the amount of active ingredient in individual unit doses after casting and drying. To the extent that Petitioner refers to Bess' disclosure of the thickness and weight of the film after drying, Petitioner has not explained persuasively how those properties establish that the desired amount of the active ingredient in the individual unit doses does not vary by more than 10%.

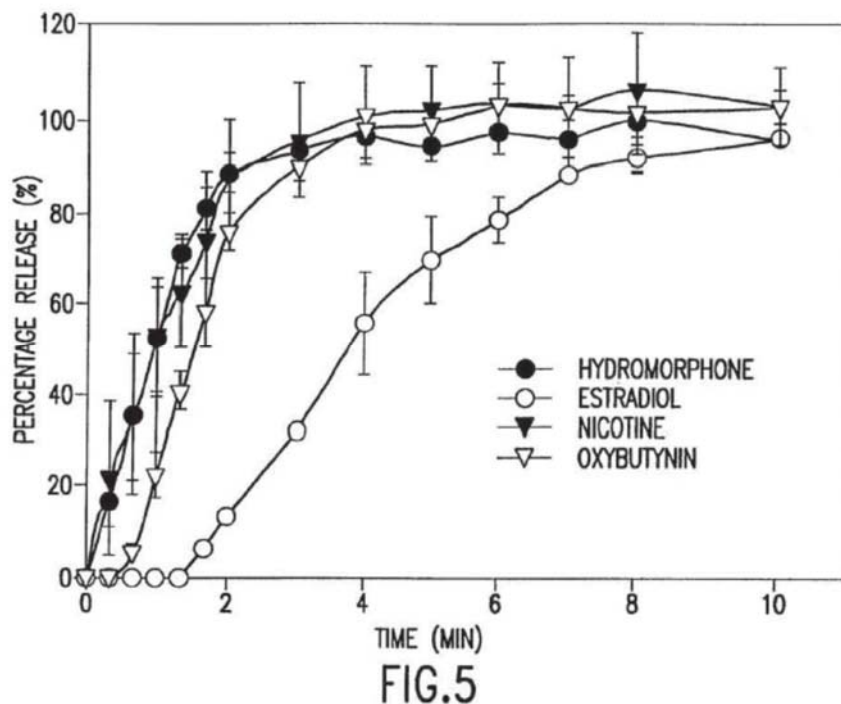
For that same limitation, Petitioner's claim chart refers to Chen's teaching that viscosity plays a significant role in determining the properties of the film. Pet. 42. Petitioner has not shown, however, that Chen teaches or suggests that viscosity plays a role in providing a uniform film product or that it may aid in achieving the variation limit recited in the challenged claims. Petitioner relies also on Dr. Çelik's testimony that because Chen's matrix has a viscosity range that falls within a range disclosed in the challenged patent, a person of skill in the art "would have understood Chen's matrix to be sufficiently viscous to substantially prevent settling and self-aggregation of particulate active ingredients . . . during casting and drying." Ex. 1003 ¶ 99. In addition to "generally" disclosing various ranges for the viscosity of its matrix, the '514 patent explains the importance of selecting a proper viscosity, and making adjustments to the viscosity "based on the

selected active depending on the other components within the matrix.” Ex. 1001, 11:24–37. We note that Dr. Çelik does not discuss any such required adjustments in the cited portion of his declaration. Moreover, the ’514 patent explains that, for example, if one of the other components within the matrix is not soluble within the selected solvent, “a proper viscosity may be selected to prevent the component from settling which would adversely affect the uniformity of the resulting film.” *Id.* at 11:35–37. In other words, although the ’514 patent explains that selecting a proper viscosity is important to achieving uniformity in a resulting film, it does not suggest that simply providing a film having any viscosity falling within the disclosed range will ensure such uniformity.

Petitioner’s claim chart refers also to Chen’s teaching that ingredients may be dispersed uniformly within the gel for the 10% variation limitation. Pet. 42. However, Chen’s discussion of dispersing ingredients uniformly actually involves dispersing or dissolving ingredients “uniformly in the hydrocolloid solution” to provide a “homogenous mixture” that is *subsequently* degassed and coated on a film and dried. Ex. 1005, 15:19–29. In other words, Chen is addressing the uniformity and homogeneity of the mixture prior to casting and drying. In terms of the resulting dry film, Chen characterizes it only as “a glossy, stand alone, self supporting, non-tacky and flexible film” that may be die-cut into a single dosage unit. *Id.* at 15:30–16:4.

Petitioner relies also on Chen’s Figure 5 to establish the 10% variance limitation, asserting that Figure 5 “shows low variance in the desired amount of the active.” Pet. 42. Dr. Çelik explains that Figure 5 demonstrates the time when the amount of drug released from each tested film plateaued,

indicating near-maximal release, and that the final values for the drug release “are clustered within $\pm 10\%$ of 100.” Ex. 1003 ¶ 103. According to Dr. Çelik, “[f]rom these data, a person of ordinary skill would reasonably have concluded that the films were within the claimed 10% limit.” *Id.* We are unpersuaded. In particular, what is missing from Dr. Çelik’s testimony is an explanation of his data analysis. Chen’s Figure 5 is reproduced below: Ex. 1005, Fig. 5.



Chen’s Figure 5 shows the release profile of four active agents from films according to Chen’s Examples 5–8. Ex. 1005, 16:27–28. Chen does not discuss the data represented in Figure 5 or otherwise provide it.² Nor does

² Petitioner asserts that the Board “has found on appeal in three reexaminations directed to similar subject matter that Chen discloses substantial uniformity.” Pet. 35. As discussed, *infra*, those decisions did not

Dr. Çelik present his opinion regarding the relevant specific data points reflected in Figure 5. Rather, Dr. Çelik opines, in a conclusory fashion, that the data shows, despite the unexplained error bars in the figure and lack of specific data points provided, that “the final recorded values for the data collected . . . fall at or within $\pm$ 10% of 100% (i.e., 90% to 110%),” and that a person of skill in the art would, therefore, conclude that “Chen’s films had at least the claimed uniformity.” Ex. 1003, 38 n.7. Because Dr. Çelik has not provided a reliable factual basis for his opinion on this matter, those opinions are not entitled to persuasive weight. *See Office Patent Trial Practice Guide*, 77 Fed. Reg. 48,756, 48763 (Aug. 14, 2012) (a declaration expressing an opinion of an expert without disclosing underlying facts may be given no weight).

We remain unpersuaded by Petitioner’s assertion that Chen’s disclosure of the thickness and/or weight of films not containing active ingredient or of exemplary films comprising an active ingredient suggest that Chen’s films satisfy the claimed 10% variation. Pet. 32. Petitioner has not explained the relevance of discussing a property of a film that does not contain an active ingredient when addressing a claim limitation that relates to achieving a uniform amount of an active ingredient in the film. Moreover, as discussed regarding Bess, *supra*, Petitioner has not explained how the thickness or weight of a film containing an active ingredient provides a person of skill in the art insight into whether individual unit doses vary by more than 10% of the desired amount of the active agent.

squarely address the 10% variation limitation presented in the challenged claims.

Nor has Petitioner explained persuasively that a skilled artisan would have understood that individual doses of a pharmaceutical film cut by a rotary die can only be manufactured this way if the film does not vary more than 10%. Pet. 31–32. Petitioner’s argument and Dr. Celik’s testimony in that regard rely upon a statement in the challenged patent that “[c]urrently, as required by various world regulatory authorities, dosage forms may not vary more than 10% in the amount of active present.” Pet. 32; Ex. 1003 ¶ 101; Ex. 1001, 2:42–45. Petitioner and Dr. Celik acknowledge, however, that not all regulatory authorities require that limit. Specifically, Petitioner and Dr. Celik recognize that in the United States, “any given dose of the drug must have the same amount of active as any other dose, within a variance of 15%,” referring to the standard set by the United States Food and Drug Administration. Pet. 22; Ex. 1003 ¶ 81. Thus, at best, Petitioner’s reliance on the disclosure of the challenged patent regarding the standards set by the FDA or “various world regulatory authorities” provides a motivation for a person of skill in the art to modify the cited prior art to achieve a product film wherein the individual unit doses do not vary by more than 15%, or perhaps not more than 10%. However, even if such motivation exists, Petitioner has not shown how that the cited prior art or other knowledge in the art at the time of the invention would have informed an artisan how to reach that goal. As Patent Owner correctly asserts, “[r]ecognition of a need does not render obvious the achievement that meets that need.” Prelim. Resp. 17 (quoting *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 381 F.3d 1371, 1377 (Fed. Cir. 2004) and *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1352 (Fed. Cir. 2008)).

Insofar as Petitioner asserts that a person of ordinary skill in the art would have needed only routine experimentation to make films within the claimed variance limitation, we are unpersuaded. Pet. 27, 34. In a somewhat cursory manner, Petitioner supports that contention by asserting that a person of skill in the art “would have understood that mixing, degassing, viscosity and drying are all important variables to control in order to ensure uniformity, and would have been able to make routine adjustments of these variables in Chen’s process to meet the 10% limit.” Pet. 34. Dr. Celik makes a similar statement in his declaration. Ex. 1003 ¶ 104. However, neither statement by Petitioner or Dr. Celik includes a discussion of facts allegedly supporting those assertions.

To the extent Petitioner asserts that “collateral estoppel will preclude re-argument” regarding the issue of whether Chen discloses films wherein “the uniformity subsequent to casting and drying of the matrix is measured by substantially equally sized individual unit doses which do not vary by more than 10% of said desired amount of at least one active,” as recited by independent claims 1 and 62, that argument is misplaced. Pet. 35–38. According to Petitioner, the Board already found that Chen discloses that limitation in Appeal 2014-000547, an *inter partes* reexamination of U.S. Patent 7,824,588 B2 (“the ’588 patent”) (Ex. 1038). Pet. 35, 37. We disagree. In the ’588 patent decision, because Patent Owner did not argue any claims separately, the Board resolved the issue of whether Chen met the uniformity requirement based on independent claim 1 of the ’588 patent. Ex. 1038, 12. Unlike independent claims 1 and 62 of the challenged patent, claim 1 of the ’588 patent, as amended, required only “substantially uniform content of therapeutic active composition per

unit of film.” Ex. 1038, 4. Thus, the ’588 patent decision did not resolve the issue of whether Chen met the 10% variation limit required by the challenged patents. Consequently, Petitioner has not shown that the instant situation meets the requirements for applying collateral estoppel, i.e., issue preclusion, because the issue presented in the ’588 patent decision is not identical to the issue presented here, and resolution of the issue presented in this case was not essential to the final judgment in the ’588 patent decision. *See In re Freeman*, 30 F.3d 1459, 1465 (Fed. Cir. 1994) (setting forth the four requirements for issue preclusion).³

For all of the foregoing reasons, we determine that Petitioner has not established persuasively that a person of ordinary skill in the art would have found it obvious to combine the teachings of Bess and Chen in a manner that resulted in a cast film drug delivery system wherein the uniformity subsequent to casting and drying the matrix is measured by substantially equally sized individual unit doses which do not vary by more than 10% of the active agent, as required by independent claims 1 and 62.

Accordingly, we determine that Petitioner has not demonstrated a reasonable likelihood of establishing that it would prevail in showing the unpatentability of independent claims 1 and 62, or their respective dependent claims, 2–3, 9, 15, 63–65, 69–73, and 75, over Bess and Chen.

³ We note that the district court has issued a decision addressing the disclosures of Chen and Bess with respect to the ’514 patent. *See* Ex. 2009. We note further that our findings are consistent with those set forth in that decision.

C. Obviousness over Chen and Cremer

Petitioner contends that claims 1–3, 9, 15, 62–65, 69–73, and 75 would have been obvious over the combination of Chen and Cremer. Pet. 50–62. Patent Owner disagrees. Prelim. Resp. 26–28.

1. Cremer

Cremer is directed to a medicament preparation for delivering a drug in the buccal cavity. Ex. 1006, Abstract. Cremer describes its preparation as a “foil-type” tape comprising an active substance and a binder. *Id.* at 4. According to Cremer, there is “a direct relation existing, by reason of the homogeneous thickness, density and width, between a unit of length of the tape and the dose of active substance contained therein.” *Id.*

2. Analysis

Petitioner again relies on Chen for the teachings asserted for the challenge over Bess and Chen. Pet. 50. Petitioner asserts that, like Chen, Cremer teaches a drug delivery composition that comprises a flat, water-soluble drug delivery preparation for pharmaceutical actives. *Id.* Petitioner asserts that Cremer teaches that “homogeneous thickness, density and width” of a gel will lead to a “direct relation . . . between a unit of length of the [film] and the dose of active substance contained therein.” *Id.* (quoting Ex. 1006, 1). Petitioner includes a claim chart referring to the teachings of Chen and the above-mentioned teaching of Cremer. Pet. 52–61. According to Petitioner, a person of skill in the art would have been motivated to achieve a film wherein the uniformity subsequent to casting and drying of the matrix, “as measured by substantially-equally sized individual unit doses, does not vary by more than 10% of the desired amount of active—to satisfy regulatory and manufacturing requirements of low variation in dose—

–and would have reasonably expected to succeed in doing so.” *Id.* at 51 (citing Ex. 1006, 1; Ex. 1003 ¶ 131). Petitioner does not provide any further explanation for those assertions or in support of its challenge of claims 1–3, 9, 15, 62–65, 69–73, and 75 over the combination of Chen and Cremer.

To the extent that Petitioner relies on Chen and Dr. Celik’s declaration in the same manner discussed, *supra*, regarding Petitioner’s ground challenging the claims over Bess and Chen, we are unpersuaded for the same reasons discussed regarding that ground. Insofar as Petitioner relies on Cremer in combination with Chen to yield the drug delivery compositions of the challenged claims, we remain unpersuaded as Petitioner has not explained sufficiently what that combination would involve or how the combined teachings and/or skill in the art are alleged to support it.

Accordingly, we determine that Petitioner has not demonstrated a reasonable likelihood of establishing that it would prevail in showing the unpatentability of claims 1–3, 9, 15, 62–65, 69–73, and 75 over the combination of Chen and Cremer.

III. CONCLUSION

For the foregoing reasons, we determine that the information presented in the Petition does not establish that there is a reasonable likelihood that Petitioner would prevail in showing that any of the challenged claims are unpatentable.

IV. ORDER

In consideration of the foregoing, it is hereby ordered that the Petition is *denied*.

IPR2016-01111
Patent 8,603,514 B2

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