Trials@uspto.gov
Tel: 571-272-7822

Paper 6
May 20, 2015

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 IPR2015-00167
Patent 8,765,167 B2

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

BONILLA, *Administrative Patent Judge*.

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

I. INTRODUCTION

BioDelivery Sciences International, Inc. ("Petitioner") filed a Petition (Paper 2, "Pet.") requesting an *inter partes* review of claims 13, 33, 39, 45, 52, 59, 66, 73, 83, 89, 95–108, 117, and 118 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 have jurisdiction under 35 U.S.C. § 314.

An *inter partes* review may be instituted only if "the information presented in the [Petition and Preliminary Response] . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). Upon consideration of the Petition and evidence cited therein, we do not institute an *inter partes* review of the challenged claims.

A. 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, in a case captioned *Reckitt Benckiser Pharms. Inc. v. Biodelivery Sciences Int'l, Inc.*, 3:14-cv-5892 (D.N.J.). Paper 3, 2.

Concurrently with the instant Petition, Petitioner has filed three other Petitions for *inter partes* review, challenging different claims of the '167 patent. Those cases are numbered IPR2015-00165, IPR2015-00168, and IPR2015-00169.

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. 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 by the Examiner, and the Board affirmed the rejections. *Id.*; Ex. 1027. Patent Owner did not appeal the Board's decision. Pet. 2. As a result, the reexamination certificate for the '588 patent has been issued, cancelling all claims.

B. Proposed Grounds of Unpatentability

Petitioner advances the following grounds of unpatentability (Pet. 18–19):[1]

Reference[s]	Statutory Basis	Challenged Claims
Chen[2]	35 U.S.C. § 102(b)	13, 33, 39, 45, 52, 59, 66, 73, 83, 89, 95–108, 117, and 118
Chen	35 U.S.C. § 103(a)	13, 33, 39, 45, 52, 59, 66, 73, 83, 89, 95–108, 117, and 118
Chen in view of Leung[3]	35 U.S.C. § 103(a)	13, 33, 39, 45, 52, 59, 66, 73, 83, 89, 95–108, 117, and 118
Chen in view of Leung and Modern Coating[4]	35 U.S.C. § 103(a)	13, 33, 39, 45, 52, 59, 66, 73, 83, 89, 95–108, 117, and 118

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

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

[3] WO 00/18365 A2 (published Apr. 6, 2000) (Ex. 1005).

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

Reference[s]	Statutory Basis	Challenged Claims
Tapolsky[5]	35 U.S.C. § 102(b)	13, 33, 45, 52, 66, 73, 83, 89, 95, 96, 98, 101–103, 106, 108, 117, and 118
Tapolsky	35 U.S.C. § 103(a)	13, 33, 39, 45, 52, 59, 66, 73, 83, 89, 95–108, 117, and 118
Tapolsky in view of Modern Coating	35 U.S.C. § 103(a)	13, 33, 39, 45, 52, 59, 66, 73, 83, 89, 95–108, 117, and 118

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.

Some of those previously known films, however, suffered 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 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

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

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 13 and 95 of the '167 patent are the independent claims challenged in the Petition, and read as follows:

> 13. An oral film for delivery of a desired amount of an active component comprising:
>
> an ingestible, water-soluble polymer matrix comprising at least one polymer selected from the group consisting of hydroxypropyl cellulose, hydroxypropylmethyl cellulose, hydroxyethyl cellulose, carboxymethyl cellulose, polyethylene oxide and combinations thereof;
>
> 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
>
> an anti-tacking agent selected from the group consisting of Vitamin E, Vitamin E TPGS, and sodium benzoate, wherein said anti-tacking agent is present in amounts of about 0.01% to about 20% by weight of said film;
>
> 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*.
>
> 95. An oral film for delivery of a desired amount of an active component comprising:

> an ingestible, water-soluble polymer matrix comprising a polymer selected from the group consisting of hydroxyethylcellulose, hydroxypropylcellulose and carboxymethyl cellulose and combinations thereof;
>
> at least one anti-tacking agent comprising sodium benzoate;
>
> a substantially uniform distribution of said desired amount of said active component within said polymer matrix, wherein said active component is selected from the group consisting of cosmetic agents, pharmaceutical agents, vitamins, bioactive agents and combinations thereof, *said film being formed by a controlled drying process which rapidly forms a viscoelastic matrix to lock-in said active in place within said matrix and maintain said substantially uniform distribution*;
>
> wherein said film is self-supporting and the active component is substantially uniformly distributed, *whereby said substantially uniform distribution is measured by substantially equally sized individual unit doses which do not vary by more than 10% of said desired amount of said active component*.

Ex. 1001, 41:50–42:8, 46:58–47:12 (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 Techs., LLC*, 778 F.3d 1271, 1278–81 (Fed. Cir. 2015). Under that standard, claim terms are given 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. 10–18.

As seen above, claims 13 and 95 both recite expressly that the substantially uniform distribution of the active component is measured by substantially equally sized individual unit doses that do not vary by more than 10% of the desired amount of the active component. Ex. 1001, 42:3–8 (claim 13); 47:8–12 (claim 95). Because Petitioner's proposed construction of "substantially uniform distribution" tracks that language (*see* Pet. 17–18), we are persuaded that Petitioner's proposed construction is consistent with the broadest reasonable construction of that term in light of the Specification of the '167 patent.

As to Petitioner's construction of the term "controlled drying process," however, claims 13 and 95 both recite expressly that the controlled drying process, which produces the film, rapidly forms a viscoelastic matrix to lock-in the active component in place within the matrix to maintain the above-discussed substantially uniform distribution. Ex. 1001, 41:62–65 (claim 13); 47:4–7 (claim 95). Accordingly, we are not persuaded that the claims do not recite any conditions on the "controlled drying process," as Petitioner contends. *See* Pet. 10–11.

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 (Pet. 12), the '167 patent does provide a standard for the term "rapidly" as recited in claims 13 and 95.

The '167 patent also discloses that "the faster drying time allows viscosity to quickly build within the film, further encouraging a uniform distribution of components." Ex. 1001, 6:64–67. It states that "the viscosity of the film or film-forming components or matrix" is a critical consideration for achieving film uniformity. *Id.* at 7:15–28. According to the Specification,

> [a] stable suspension is an important characteristic for the manufacture of a pre-mix composition which is to be fed into the film casting machinery film, as well as the maintenance of this stability in the wet film stage until sufficient drying has occurred to lock-in the particles and matrix into a sufficiently solid form such that uniformity is maintained.

Id. at 8:30–35. These disclosures inform us that, with the controlled drying process, the substantially uniform distribution of the active is maintained from when the film-forming components are cast into a wet film.

In sum, given the express language in the claims, we conclude that, under the broadest reasonable construction in light of the Specification, the phrase including the term "controlled drying process" refers to drying with at least one controlled drying parameter, which forms a viscoelastic matrix within a few minutes of the drying process to lock-in the active within the matrix, and maintains a "substantially uniform distribution" of the active

component so that substantially equally sized individual unit doses do not vary by more than 10% of the desired amount of the active component.

B. Anticipation—Chen

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, among other polymers, the hydrocolloid may be be selected from a group of "synthetic hydrocolloids exemplified by any of the following: . . . hydroxyethyl cellulose, sodium carboxymethyl cellulose, carboxymethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, methyl cellulose, ethyl cellulose, . . . polyethylene oxides . . . ." *Id.* at 14:24–29. Chen discloses that "[a]ctive agents (for human and veterinary applications) include therapeutic agents . . . . The therapeutic agents are exemplified by analgesics . . . ." *Id.* at 10:22–24.

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.

Chen discloses that "[t]aste modifying agents include flavoring agents, sweetening agents and taste masking agents and are exemplified by: the essential oils or water soluble extracts of . . . peppermint, . . . acesulfame

potassium, . . . saccharin, sodium saccharin . . . ." *Id.* at 10:7–14. Chen discloses that "[p]reservatives which here include anti-microbial agents and non-organic compounds are exemplified by sodium benzoate . . . ." *Id.* at 11:28–29.

Chen discloses that "[b]uffering agents include acidulants and alkalizing agents exemplified by citric acid . . . . " *Id.* at 11:17–19. Chen discloses that "[c]oloring agents may include . . . pigments such as titanium oxide, silicon dioxide and zinc oxide." *Id.* at 11:20–22. Chen discloses that "[s]tabilizers . . . include anti-oxidants, chelating agents, and enzyme inhibitors as exemplified by . . . vitamin E . . . ." *Id.* at 11:23–27.

Chen discloses that, in certain embodiments, its dosage unit is in the form of a "flexible, non-tacky, dry conveniently packaged film. Once removed from the package and placed on a mucosal surface, the mucosal surface-coat-forming film hydrates substantially immediately to form a coating on the moist surface of the mucous membrane and then disintegrates and dissolves to release the active agent from the film." *Id.* at 6:25–29.

Chen discloses that its films may be prepared by a "solvent casting method" shown in its Figure 2, the method using a hydrocolloid that is "completely dissolved or dispersed in water or in a water alcoholic solution under mixing to form a homogenous formulation. In addition to the active agent and the hydrocolloid, any of the ingredients listed above may be added and dispersed or dissolved uniformly in the hydrocolloid solution." *Id.* at 15:20–23; Fig. 2. This "homogeneous mixture" is then degassed, coated on a non-siliconized side of a polyester film, and "dried under aeration at a temperature between 40-100°C so as to avoid destabilizing the agents contained within the formulation . . . . The dry film formed by this process

is a glossy, stand alone, self supporting, non-tacky and flexible film." *Id.* at 15:25–31 (citations to Fig. 2 omitted). The film may then be cut, using a die, into shapes and sizes suitable for administration as a single dosage unit. *Id.* at 16:1–7.

Example 1 of Chen describes the preparation of a film that contains Methocel E5 (i.e., hydroxypropyl methylcellulose, HPMC),[6] propylene glycol, aspartame, peppermint, citric acid, Cremphor EL40 (a surfactant),[7] and benzoic acid. *Id*. at 17-18. Table 4 in Chen indicates that the weight of the film of Example 1 (g/dosage film) was 0.028, with a standard deviation ("±SD (n)") of "0.001 (4)." *Id*. at 20. Example 7 of Chen describes preparation of a film that contains, among other ingredients, oxybutynin, peppermint, HPMC, aspartame, citric acid, and Cremphor EL40. *Id.* at 20-21.

2. Analysis

On the current record, Petitioner does not persuade us that Chen expressly or inherently describes a film comprising the specific polymers and anti-tacking agents recited in independent claim 13 or 95, where an active component in the film is "substantially uniformly distributed," as also required in those claims.

Independent claim 13 recites an oral film for delivery of a desired amount of an active component. Ex. 1001, 41:50–42:8. The film must contain three ingredients: (1) an ingestible, water-soluble polymer matrix comprising a polymer selected from hydroxypropyl cellulose,

[6] *See* Ex. 1002, 21:9, Table 5 (identifying "Methocel E5" as "(HPMC)").

[7] The '167 patent identifies "Cremophor® EL" as a surfactant that is "commercially available from BASF." Ex. 1001, 22:60–61.

hydroxypropylmethyl cellulose (HPMC), hydroxyethyl cellulose, carboxymethyl cellulose, and polyethylene oxide, (2) an anti-tacking agent selected from the group consisting of Vitamin E, Vitamin E TPGS, and sodium benzoate, and (3) the active component, which may be a pharmaceutical agent. *See id.* at 41:52–62, 41:66–42:2. Claim 95 requires similar ingredients, but requires "a polymer selected from the group consisting of hydroxyethylcellulose, hydroxypropylcellulose and carboxymethyl cellulose and combinations thereof," i.e., does not recite HPMC or polyethylene oxide, and requires "at least one anti-tacking agent comprising sodium benzoate." *Id*. at 46:58–47:12.

As required by claims 13 and 95, and as Petitioner discusses (Pet. 20, 24), Chen describes films, useful for oral administration, which contain therapeutic agents. Ex. 1002, Abstract; *see also id.* at 5:28–29 ("Figure 1 shows possible application sites in the oral cavity for the inventive dosage unit."). Petitioner also points us to where Chen discloses that its active component may be a pharmaceutical agent, as required by claims 13 and 95. *Id*. at Abstract, 10:22–24 (disclosing a pharmaceutical agent, such as an analgesic); Pet. 20–21, 24–25.

In relation to the specific polymers recited in claims 13 and 95, Petitioner points us to where Chen discloses that its films include an ingestible water soluble polymer matrix, described as a "water-soluble hydrocolloid." Pet. 20–21, 24; Ex. 1002, Abstract. Petitioner points to where Chen describes suitable hydrocolloids, such as hydroxyethylcellulose, hydroxypropylcellulose, carboxymethyl cellulose, and hydroxypropyl methyl cellulose (HPMC), among a number of other options, and a

"preferred embodiment" and Examples in Chen that include HPMC in particular. Pet. 20–21; Ex. 1002, 14:22–15:1, 20:17–20.

In relation to the specific anti-tacking agent(s) recited in claims 13 and 95, Petitioner points to where Chen discloses that its films may include sodium benzoate, among other options, as a preservative, and vitamin E, among other options, as a stabilizer. Pet. 22, 24; Ex. 1002, 11:23–31. Petitioner also points to where Chen further discloses that, in a preferred embodiment, ingredients in Chen's films include "preservatives (0.01-10%) . . . and stabilizers (0.01-5%)." Pet. 22; Ex. 1002, 15:7–12.

As discussed above, the films of claims 13 and 95 require a structure resulting from a controlled drying process that forms a viscoelastic matrix within a few minutes of the drying process to lock-in the active within the matrix, so that the active component is substantially uniformly distributed, as measured by substantially equal sized individual unit doses that do not vary by more than 10% of the desired amount of the active component. Petitioner relies on the Cohen Declaration (Ex. 1007), the Reitman Declaration (Ex. 1047), as well as statements during the '588 patent reexamination proceeding, to show that Chen's film compositions inherently meet those limitations. Pet. 31–36, 9–10.

Specifically, in relation to the "substantial uniform distribution" element of the challenged claims, Petitioner points to Example 1 in Chen as providing this feature when "employing the same tests and to same degree as required by the '167 patent." Pet. 32. Petitioner contends that "Chen reports the weights of Example 1 film dosages as 0.028 ±0.001g," and contends that "[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*. at 33 (citing

Ex. 1002, 20:3 (Table 4)). Thus, according to Petitioner, the active component (peppermint) in Chen's film of Example 1 meets the "substantial uniform distribution" element of claims 13 and 95. Pet. 33 (citing Ex. 1007 ¶¶ 52, 54).

Notably, Petitioner does not explain sufficiently how Chen's Example 1 meets all of the limitations recited in independent claim 13 or 95. Our own analysis of Chen indicates that the film in Example 1 includes Methocel E5, i.e., a HPMC polymer, as recited in claim 13, but not claim 95. Petitioner does not explain, however, where Example 1 (or any of Examples 1–8 in Chen) includes vitamin E, vitamin E PTGS, or sodium benzoate, as also required in claim 13, or includes the specific polymers (other than HPMC) and sodium benzoate, as required in claim 95. Ex. 1002, 17–18 (Table 1), 21 (Table 5).

Thus, even if we assume, as Petitioner contends, that the film of Example 1 in Chen meets the "substantial uniform distribution" element of claim 13 or 95, Petitioner does not explain sufficiently how Chen discloses, expressly or inherently, a film having components exactly as recited in claim 13 or 95 that presents the recited "substantial uniform distribution" of an active component. This lack of sufficient explanation is even more prominent in relation to claim 95, which recites three specific polymers other than HPMC (i.e., polymers not included in Chen's Examples), and further requires sodium benzoate in particular (also not included in Chen's Examples).

Petitioner's arguments in relation to previous findings by the Board during the '588 patent reexamination do not persuade us otherwise. Petitioner relies on what the Board "already found" in relation to Chen films

"having 'a weight deviation of ±0.001 [which] is well within the less than 10% variation of active content per film unit.'" Pet. 34 (quoting Ex. 1027, 17, 19). In the previous Decision on Appeal cited by Petitioner (Pet. 34), the Board discussed Table 4, i.e., Example 1, in Chen and referred to the "weight deviation of ±0.001" disclosed therein, when addressing claims that differed from those at issue in this case. Ex. 1027, 17–19. In that capacity, the Board upheld the Examiner's finding of inherency in relation to a "substantially uniform content" claim limitation at issue in the reexamined claims. *Id*. at 19, 3–5.

Again, even if we assume that the film of Example 1 (or any of Examples 1–8 in Chen) inherently meets the "substantial uniform distribution" limitation recited in claims 13 and 95, for example, based on statements by the Board during the '588 patent reexamination, Petitioner does not establish sufficiently that Chen discloses a film having all ingredients as recited in claim 13 or 95, where that film inherently meets the "substantial uniform distribution" limitation.

Thus, Petitioner does not persuade us that Chen describes, expressly or inherently, a film as recited in claim 13 or 95. Consequently, Petitioner does not persuade us that it has shown a reasonable likelihood of prevailing in its anticipation challenge, based on Chen, of claim 13 or 95, or their dependent claims 33, 39, 45, 52, 59, 66, 73, 83, 89, 96–108, 117, and 118.

C. Obviousness—Chen

Petitioner incorporates by reference the facts and arguments made in the anticipation ground based on Chen, discussed above, and states further that, "[t]o the extent the Board may believe that any element of any claim is not expressly or inherently disclosed in Chen, the same claims are obvious

over Chen." Pet. 36–37. Petitioner advances further argument and evidence in an effort to show that the controlled drying process and uniformity of less than 10% variation between identically-sized dosage units would have been obvious from Chen's teachings. *Id.* at 37–40.

In relation to the "substantial uniform distribution" limitation of claims 13 and 95, Petitioner contends that "achieving uniformity and maintaining it by controlling the drying process was known long before the priority date of the '167 patent." Pet. 37–38 (citing Ex. 1008 ("a patent issued in 1887"), Ex. 1009 ("Modern Coating")). Petitioner also contends, citing the Cohen Declaration, that an ordinary artisan "would have been able to optimize drying variables in . . . known drying processes in order to avoid film defects and produce film with a high degree of uniformity." Pet. 38 (citing Ex. 1007 ¶ 28). In addition, Petitioner contends that an ordinary artisan "would have been motivated to adjust the film manufacturing process to produce film featuring a distribution of active that does not vary by more than 10% of the desired amount." Pet. 40 (citing Ex. 1001, 2:16–19). Petitioner also relies on the Cohen Declaration (Ex. 1007 ¶¶ 49–50, 68–74) to establish that "'[w]hen working with a homogenous or completely dissolved coating solution, like the one disclosed in Chen, it would be difficult for a person of ordinary skill in the art not to obtain a film that has uniform content of active." Pet. 40 (quoting Ex. 1007 ¶ 72).

Notably, however, Petitioner does not explain adequately why an ordinary artisan reading Chen would have been motivate to prepare a film having the specific polymers *and* specific anti-tacking agents recited in claim 13 or 95, as discussed above. As the Supreme Court has noted, a conclusion of obviousness "cannot be sustained by mere conclusory

statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l Co. v. Teleflex Inc.,* 550 U.S. 398, 418 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)).

Moreover, even assuming an ordinary artisan would have had a reason, upon reading to Chen, to produce films having the recited components in particular, neither Petitioner, nor its cited expert testimony, provide sufficient evidence nor explanation to show that such films, in particular, would have exhibited necessarily the "substantial uniform distribution" feature of claims 13 and 95.

Rather, Petitioner appears to suggest that any film, containing any or all of the many components described in Chen, would have necessarily presented "substantial uniform distribution" of an active component, regardless of which components were picked or combined, or how much of any particular component was used, as long as one used the controlled drying process disclosed in Chen and/or was motivated to prepare a film having a uniform content of an active. Pet. 37–40. The evidence of record before us does not establish sufficiently this factual premise.

As discussed above, even assuming Petitioner has established sufficiently that certain films prepared and described in Examples in Chen provided "substantial uniform distribution" of an active component (such as peppermint, as Petitioner contends), that would not establish that all films comprising any or all components as disclosed in Chen, even if prepared using the drying process disclosed in Chen, also would have met this requirement. We are unpersuaded that Petitioner has made an adequate showing in this regard, even assuming an ordinary artisan had a reason to try

to "adjust the film manufacturing process to produce film featuring a distribution of active that does not vary by more than 10% of the desired amount," as Petitioner contends. Pet. 40.

In this regard, it is insufficient that Petitioner points to where Chen describes the use of HMPC, among over 60 suitable polymers described in Chen, along with Chen's list of about ten preservatives to show the description of sodium benzoate, Chen's list of about ten stabilizers to show description of vitamin E, especially in view of Chen's disclosure of many other possible components as well. *See* Pet 20–22, 24–25; *see also* Ex. 1002, 14:12–15:3 (Chen describing suitable polymers), 11:28–32 (suitable preservatives), and 11: 23–27 (stabilizers); 10:7–11:31 (describing many other possible components). Petitioner does not explain sufficiently why one would have picked the recited components in combination in particular, if one wanted to try to generate a film that presented a "substantial uniform distribution" in relation to an active ingredient. *Bayer Schering Pharma AG v. Barr Labs.* 575 F.3d 1341, 1347 (Fed. Cir. 2009) ("When 'what would have been "obvious to try" would have been 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' an invention would not have been obvious." (citing *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988)).

Thus, Petitioner does not persuade us that Chen renders obvious a film containing the specific combination of polymers and anti-tacking agents, as required by claim 13 or 95, that meets the "substantial uniform distribution" limitation also required in those claims. Consequently, Petitioner also does

not persuade us that it has shown a reasonable likelihood of prevailing in its obviousness challenge, based on Chen, of claim 13 or 95, or their dependent claims 33, 39, 45, 52, 59, 66, 73, 83, 89, 96–108, 117, and 118.

D. Obviousness—Chen and Leung

Petitioner incorporates by reference the facts and arguments made in the anticipation and obviousness grounds based on Chen, discussed above, and states further that, "to the extent the Board may believe that any element of claims 117 and/or 118 is not expressly or inherently disclosed in Chen, these claims are obvious over Chen in view of Leung." Pet. 43–44.

Petitioner contends that Leung discloses a "dissolvable oral film comprising a water soluble polymer matrix and an active . . . , in which the oil content is optimized to form a 'non-self-adhering film according to the invention [that] can be stored in contact with another such film (e.g., in a stack).'" Pet. 43 (citing Ex. 1005, Title, Abstract, 9:5–14).

As discussed above, Petitioner does not persuade us that it has shown a reasonable likelihood of prevailing in its challenge of claim 13 of the '167 patent as anticipated or rendered obvious by Chen. In relation to claims 117 and 118, which each depend on claim 13, Petitioner does not explain adequately how Leung overcomes the deficiencies discussed above in relation to claim 13 and Chen. Pet. 43 (citing Ex. 1005, Title, Abstract, 9:5–14). Rather, Petitioner contends that it would have been obvious to an ordinary artisan to "combine the teachings of Leung to optimize the formulation of film made according to Chen" to achieve the coefficient of friction limitations recited in claim 117 and 118. *Id*. at 43–44.

Consequently, Petitioner does not persuade us that it has shown a reasonable likelihood of prevailing in its obviousness challenge of claim 13,

or its dependent claims 117 and 118, or any of the other challenged claims, based on Chen in view of Leung.

E. Obviousness—Chen, Leung, and Modern Coating

1. Modern Coating (Ex. 1009)

Modern Coating discloses that, as to thin films, the "purpose of the drying process is to produce a uniform dry coating." Ex. 1009, 268. Modern Coating describes basic drying principles and related equations, different drying regimes and apparatuses, including air convection dryers, spiral dryers, single-side impingement dryers, two-sided floater dryers, as well as drying using infrared or radiant heat. *Id.* at 268–86. Modern Coating identifies key variables in the drying process, including dryer bulb temperatures, the solvent content of the air, the air velocities, film temperature, and line speed. *Id.* at 286-87. Modern Coating describes techniques for addressing a number of coating defects, including dryer bands, mottle, convection cells, fat edges (also known as picture framing), non-distribution of binder and solids, curling and cracking, holes, starry night, delamination, blisters, craters, crinkling, blushing, and reticulation. *Id.* at 287–95.

2. Analysis

Petitioner incorporates by reference the facts and arguments made in the anticipation and obviousness grounds discussed above, and states further that,

> [t]o the extent the Board finds that Chen, alone or in combination with Leung, somehow fails to disclose a "controlled drying process" under the broadest reasonable interpretation of that term, as Dr. Cohen explains, it would have been obvious to the POSITA [person of ordinary skill in the art]

> to use a "controlled drying process" disclosed in MODERN COATING to produce uniform film.

Pet. 45.

As discussed above, Petitioner does not persuade us that it has shown a reasonable likelihood of prevailing in its challenge of claim 13 or 95 of the '167 patent as anticipated or rendered obvious by Chen, or as obvious over Chen in view of Leung.

Petitioner does not explain adequately how Modern Coating overcomes the deficiencies discussed above in relation to the above-mentioned grounds and challenged claims. Pet. 44–45 (citing Ex. 1009, 267–295). Rather, Petitioner contends that it would have been obvious to an ordinary artisan to "use a 'controlled drying process' disclosed in MODERN COATING to produce uniform film." *Id*. at 45 (citing Ex. 1007 ¶ 92). This contention, and evidence cited by Petitioner, suffers the same deficiencies described above in relation to the anticipation and obviousness challenges based on Chen.

For the same reasons discussed above, we are unpersuaded that Petitioner has made an adequate showing in relation to the specific films, combination of components, and structural features recited in claims 13 and 95, even assuming an ordinary artisan had reason to try to "optimize the variables of the drying process and use known drying apparatus," as described in Modern Coating, "to produce uniform film," as Petitioner contends. *Id*. (quoting Ex. 1007 ¶ 92).

F. Anticipation—Tapolsky

1. Tapolsky (Ex. 1003)

Tapolsky discloses a device "for application of a pharmaceutical to mucosal surfaces. The device comprises an adhesive layer and a nonadhesive backing layer, and the pharmaceutical may be provided in either or both layers. Upon application, the device adheres to the mucosal surface, providing localized drug delivery and protection to the treatment site." Ex. 1003, Abstract. Tapolsky discloses that its device "comprises a layered film disk having an adhesive layer and a backing layer, both water-erodable, having the pharmaceutical in either or both of the layers." *Id.* at 7:25–27.

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'). The film forming polymer may comprise hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, [and] hydroxyethyl methyl cellulose," among others. *Id.* at 10:14–19. Tapolsky discloses that the bioadhesive polymer may be polyacrylic acid or sodium carboxymethyl cellulose. *Id.* at 10:30–11:1. 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 which contained albuterol sulfate as the active agent. *Id.* at 37:3–25. The two backing layers were obtained by preparing a gel containing 79.74% water, 0.01% FD&C red dye 40, 0.05% sodium benzoate, 2.5% peppermint flavor, 13.5% hydroxyethyl cellulose, and 4.5% hydroxypropyl cellulose by weight. *Id.* at 37:4–6. The first backing film was coated onto a substrate and then dried at 80° C for 8 minutes. *Id.* at 37:6–9. The second backing film was then coated directly onto the first backing film and dried at 80° C for 8 minutes. *Id.* at 37:9–10.

The two bioadhesive layers were obtained by preparing a gel containing 45.2% water USP, 45.3% ethyl alcohol, 1.6% hydroxyethyl cellulose, 0.6% hydroxypropyl cellulose, 2.8% polyacrylic acid Noveon® AA1 USP, 2.5% sodium carboxymethyl cellulose, 0.1 % titanium dioxide, and 1.9% albuterol sulfate by weight. *Id.* at 37:15-19. The first 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. Tapolsky states that the final film "contained 1.46mg/cm^2 albuterol sulfate . . . [and] also exhibited excellent tensile strength." *Id.* at 37:24–25.

2. Analysis

To show that Tapolsky describes a film having all of the features required by claim 13 or 95 of the '167 patent, the independent claims challenged in this ground, Petitioner presents a claim chart directing us to Example 37 of Tapolsky, as well as Tapolsky's general disclosure. Pet. 46–52.

To show that Tapolsky's film meets the requirement in claims 13 and

95 that the active agent be uniformly distributed with a variation of no more than 10%, Petitioner notes that the amount of albuterol sulfate in Example 37 in Tapolsky "is reported to be 1.46 mg/cm^2." *Id.* at 53. Petitioner contends that, "[g]iven the reported degree of certainty, i.e., out to the second decimal place, the greatest difference in the amount of active per centimeter squared would be, at most, 0.009 mg (i.e., the difference between 1.464 mg/cm^2 and 1.455 mg/cm^2)." *Id.* Thus, Petitioner contends, "the greatest variation in active between equally sized individual unit doses of Tapolsky's film that could exist given the reported value, is 0.61% (0.009 mg/cm2 divided by 1.46 mg/cm2), a value well within" the variation limitation of claim 13 or 95. *Id.* at 53–54 (citing Ex. 1007 ¶¶ 100–103 (Cohen Decl.)). Petitioner contends that "[t]his percentage does not change with unit size." *Id.* at 54.

Petitioner does not persuade us that Tapolsky expressly or inherently describes a film having the uniform distribution of active agent required by claims 13 and 95 of the '167 patent. Petitioner does not direct us to disclosures in Tapolsky that describe anything specific about whether the albuterol sulfate was uniformly distributed within the film prepared in Example 37. We note that Tapolsky describes the concentration of albuterol sulfate per cm^2 in Example 37's film to two decimal places. That concentration can be determined, however, by simply dividing the mass of the albuterol sulfate in the film by the total area of the final film. Although that calculation describes the final concentration of albuterol within the film of Example 37, Petitioner does not persuade us that it demonstrates an inherent substantially uniform distribution of albuterol sulfate within that film. Petitioner does not direct us to any disclosure in Tapolsky explaining

how the amount of albuterol sulfate per cm^2 was determined, in a way that would demonstrate inherently the substantial uniform distribution required by claims 13 and 95 of the '167 patent.

Accordingly, Petitioner does not persuade us that Tapolsky describes a film having all of the features of claim 13 or 95. Petitioner, therefore, does not persuade us that it has established a reasonable likelihood of prevailing in its challenge of claims 13 or 95, or their dependent claims 33, 39, 45, 52, 59, 66, 73, 83, 89, 96–108, 117, and 118, as anticipated by Tapolsky.

G. Obviousness—Tapolsky

Petitioner incorporates by reference contentions and cited evidence it raises in its anticipation ground based on Tapolsky, discussed above. Pet. 54–59. Petitioner further states that "[t]o the extent the Board may believe that any element of any claim challenged is not expressly or inherently disclosed in Tapolsky, the [challenged] claims are obvious over Tapolsky." *Id*. (citing Ex. 1007 ¶¶ 111–129 (Cohen Decl.)).

Petitioner also contends that "[t]o the extent that the Board determines that Tapolsky does not inherently or explicitly disclose a process for making films with active that varies by no more than 10% of the desired amount, such processes would have been obvious," and further argues that "[t]hose skilled in the art of making film would have been motivated to—and would have been able to—produce films with the claimed levels of uniformity." Pet. 55 (citing Ex. 1007 ¶¶ 114-117).

Beyond the arguments noted above, however, Petitioner does not explain with specificity how an ordinary artisan would have modified Tapolsky to produce a film having the "substantially uniform distribution" feature required by claim 13 or 95. As noted above, a conclusion of

obviousness "cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR*, 550 U.S. at 418 (quoting *Kahn*, 441 F.3d at 988).

Petitioner cites ¶¶ 114–117 of the Cohen Declaration to support its assertions regarding the "substantially uniform distribution" requirement in claims 13 and 95. Pet. 55. Nonetheless, essentially none of the discussion in the cited paragraphs of the Cohen Declaration, allegedly explaining why an ordinary artisan would have considered obvious a film having the "substantially uniform distribution" feature, appears in the Petition. We decline to import the discussion regarding obviousness from the declarations of Petitioner's expert into the Petition, based solely on the Petition's citation of certain paragraphs within the declarations.

As stated in 37 C.F.R. § 42.6(a)(3), "[a]rguments must not be incorporated by reference from one document into another document." Moreover, we agree with our colleagues' reasoning in *Conopco, Inc. v. Procter & Gamble Co.*, in that "[w]e decline to consider information presented in a supporting declaration, but not discussed in a petition, because, among other reasons, doing so would encourage the use of declarations to circumvent the page limits that apply to petitions." IPR2013-00510, slip op. at 8 (PTAB Feb. 12, 2014) (Paper 9).

Furthermore, as discussed above, one circumstance in which the prior art fails to provide a reasonable expectation of success is where the art suggests "vary[ing] all parameters or try[ing] each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as

to which of many possible choices is likely to be successful." *In re Kubin*, 561 F.3d 1351, 1359 (Fed. Cir. 2009) (quoting *O'Farrell*, 853 F.2d at 903).

Another circumstance in which the prior art fails to provide a reasonable expectation of success is where the art suggests exploring a "general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it." *Kubin*, 561 F.3d at 1359.

Thus, even if we were to consider Dr. Cohen's assertions that optimizing different variables in film-making and drying processes to produce uniform coatings was known in the art (*see* Ex. 1007 ¶¶ 114–117), we are not persuaded that Dr. Cohen explains which specific variables of Tapolsky's processes would have been optimized, or would have been critical, to producing the "substantially uniform distribution" required in claims 13 and 95.

To show that substantially uniform distribution would have been obvious, Petitioner also "incorporates by reference subsection 2 of Ground 2," i.e., the ground asserting obviousness over Chen. Pet. 55. That subsection contends that the '167 patent admits that the recited uniformity of no more than 10% variation was a known regulatory requirement that would have motivated an ordinary artisan to prepare a film meeting that requirement. Pet. 40. As explained above, however, Petitioner does not explain convincingly, with adequate specificity, how one would have achieved that result upon reading the cited references. Subsection 2 of Ground 2 also contends that an ordinary artisan would have reasonably expected a uniform distribution of active agent meeting claims 13 and 95 of the '167 patent, based on Chen's disclosure that its film was prepared using

a homogeneous mixture. *Id*. Petitioner does not direct us, however, to an equivalent disclosure in Tapolsky.

In sum, for the reasons discussed, Petitioner does not persuade us that it has established a reasonable likelihood of prevailing in its obviousness challenge of claims 13, 33, 39, 45, 52, 59, 66, 73, 83, 89, 95–108, 117, and 118, based on Tapolsky.

H. Obviousness—Tapolsky and Modern Coating

In this ground, Petitioner incorporates by reference its contentions as to Ground 4 (obviousness over Cheng, Leung, and Modern Coating), Ground 5 (anticipation by Tapolsky), and Ground 6 (obviousness over Tapolsky alone). Pet. 59. Petitioner contends further that, "[t]o the extent the Board finds that Tapolsky somehow fails to disclose a 'controlled drying process' under the broadest reasonable interpretation of that term, it would have been obvious to the POSITA to use the controlled drying processes disclosed in MODERN COATING to produce uniform film." *Id.* (citing Ex. 1007 ¶¶ 130–134 (Cohen Decl.)).

Petitioner does not persuade us that it has established a reasonable likelihood of prevailing as to this ground. We acknowledge Petitioner's citation of ¶¶ 130–134 of the Cohen Declaration. We note that at least ¶ 133 further cross references a previous discussion regarding the teachings in Modern Coating. As discussed above, however, we decline to import the discussion regarding obviousness from the declaration of Petitioner's expert into the Petition, based solely on the Petition's citation of certain paragraphs within the declaration. *See* 37 C.F.R. § 42.6(a)(3); *see also Conopco, Inc. v. Procter & Gamble Co.*, Case IPR2013-00510, slip op. at 8 (PTAB Feb. 12, 2014) (Paper 9).

Moreover, as noted above, the controlled drying process recited in claim 13 or 95 of the '167 patent produces a film having a structure that would result from a controlled drying process that forms a viscoelastic matrix within a few minutes of the drying process to lock-in the active within the matrix, where the film has a substantially uniform distribution of the active component, measured by substantially equally sized individual unit doses that do not vary by more than 10% of the desired amount of the active component.

We acknowledge, as discussed above, that Modern Coating describes the general principles, procedures, and apparatuses useful for producing uniformly dried thin film coatings. Petitioner, nonetheless, does not explain with adequate specificity, in either the Petition or in the Cohen Declaration, which particular variables of Tapolsky's processes would have been optimized, or would have been critical, to producing a film having a "substantially uniform distribution" of an active agent, as required by claims 13 and 95.

Accordingly, for the same reasons discussed above in relation to other grounds, we are not persuaded that Petitioner has explained sufficiently why an ordinary artisan would have had a reasonable expectation in producing a film having the "substantially uniform distribution" feature required in claim 13 or 95 of the '167 patent. *Kubin*, 561 F.3d at 1359. Thus, Petitioner does not persuade us that it has established a reasonable likelihood of prevailing in its challenge to claims 13 or 95, or their dependent claims 33, 39, 45, 52, 59, 66, 73, 83, 89, 96–108, 117, and 118, as obvious over Tapolsky in view of Modern Coating.

III. CONCLUSION

For the reasons given, we determine that Petitioner has not established a reasonable likelihood that it would prevail as to its challenges of claims 13, 33, 39, 45, 52, 59, 66, 73, 83, 89, 95–108, 117, and 118 of the '167 patent on any of the grounds presented in the Petition.

IV. ORDER

In view of the foregoing, it is hereby ORDERED that the Petition is *denied*, and no trial is instituted.

PETITIONER:

Danielle Herritt
Kia Freeman
MCCARTER & ENGLISH, LLP
dherritt@mccarter.com
kfreeman@mccarter.com

PATENT OWNER:

Daniel Scola
Michael Chakansky
HOFFMANN & BARON, LLP
dscola@hbiplaw.com
mchakansky@hbiplaw.com