IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

RECKITT BENCKISER PHARMACEUTICALS INC., RB PHARMACEUTICALS LIMITED, and MONOSOL RX, LLC, Plaintiffs, v. DR. REDDY'S LABORATORIES S.A., and DR. REDDY'S LABORATORIES, INC., Defendants.	Civil Action No. 14-1451-RGA
RECKITT BENCKISER PHARMACEUTICALS INC., RB PHARMACEUTICALS LIMITED, and MONOSOL RX, LLC, Plaintiffs, v. PAR PHARMACEUTICAL, INC. and INTELGENX TECHNOLOGIES CORP., Defendants.	Civil Action No. 14-1573-RGA
RECKITT BENCKISER PHARMACEUTICALS INC., RB PHARMACEUTICALS LIMITED, and MONOSOL RX, LLC, Plaintiffs, v. WATSON LABORATORIES, INC. and ACTAVIS LABORATORIES UT, INC., Defendants.	Civil Action No. 14-1574-RGA

TRIAL OPINION

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ANDREWS, U.S. DISTRICT JUDGE:

Plaintiffs Reckitt Benckiser Pharmaceuticals, Inc.,[1] RB Pharmaceuticals Limited,[2] and MonoSol Rx, LLC (collectively, "Plaintiffs") bring this suit against Defendants Dr. Reddy's Laboratories S.A. and Dr. Reddy's Laboratories, Inc. (collectively, "DRL"),[3] Defendant Watson Laboratories, Inc.[4] ("Watson"), and Defendants Par Pharmaceutical, Inc. and IntelGenx Technologies Corporation (collectively, "Par"). This opinion addresses allegations of infringement and invalidity with respect to U.S. Patent Nos. 8,603,514 ("the '514 patent") and 8,900,497 ("the '497 patent").

The Court held a four-day bench trial relating to these patents. (D.I. 299; D.I. 300; D.I. 301; D.I. 302).[5] The parties filed proposed findings of fact (D.I. 275), post-trial briefing with respect to infringement (D.I. 279; D.I. 285; C.A. No. 14-1574, D.I. 184; C.A. No. 14-1573, D.I. 203; D.I. 295), and post-trial briefing with respect to invalidity (D.I. 278; D.I. 288; D.I. 293). I have also considered letters submitted regarding *Medicines Co. v. Mylan, Inc.*, 853 F.3d 1296 (Fed. Cir. 2017). (D.I. 309; D.I. 310). Having considered the documentary evidence and testimony, I make the following findings of fact and conclusions of law pursuant to Federal Rule of Civil Procedure 52(a).

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[1] Citations to "D.I.___" are to the docket in C.A. No. 14-1451 unless otherwise noted. Plaintiff Reckitt Benckiser Pharmaceuticals, Inc. is now known as Indivior Inc. (D.I. 228-2, Admitted Fact No. 2).

[2] Plaintiff Reckitt Benckiser Pharmaceuticals Limited is now known as Indivior UK Limited. (D.I. 228-2, Admitted Fact No. 4).

[3] DRL was substituted as a party in place of Teva Pharmaceuticals USA, Inc. following Teva's transfer of ownership of ANDA Nos. 205299 and 205806 to DRL. (D.I. 228-2, Admitted Fact No. 12 at n.2).

[4] Defendant Watson Laboratories, Inc. is now known as Actavis Laboratories UT, Inc. (D.I. 228-2, Admitted Fact No. 6).

[5] Although the official transcript is filed in four parts (D.I. 299; D.I. 300; D.I. 301; D.I. 302), citations to the transcript herein are generally cited as "Tr."

I. BACKGROUND

Plaintiff Reckitt Benckiser Pharmaceuticals, Inc. is the holder of approved New Drug Application No. 22-410 for Suboxone® sublingual film, which is indicated for maintenance treatment of opioid dependence. (D.I. 228-2, Admitted Fact Nos. 13–14, 20). The active ingredients of Suboxone® sublingual film are buprenorphine hydrochloride and naloxone hydrochloride. (D.I. 228-2, Admitted Fact No. 15). Suboxone® sublingual film is available in four dosage strengths (buprenorphine hydrochloride/naloxone hydrochloride): 2 mg/0.5 mg, 4 mg/1 mg, 8 mg/2 mg, and 12 mg/3 mg. (D.I. 228-2, Admitted Fact Nos. 16–18). Since the approval of NDA No. 22-410, Suboxone® sublingual film has been exclusively manufactured in the United States by Plaintiff MonoSol and exclusively sold in the United States by Plaintiff Reckitt Benckiser Pharmaceuticals, Inc. (D.I. 228-2, Admitted Fact No. 19).

The '514 patent, entitled "Uniform Films for Rapid Dissolve Dosage Form Incorporating Taste-Masking Compositions," issued on December 10, 2013. (D.I. 228-2, Admitted Fact No. 21). The '514 patent is listed in the FDA's Approved Drug Products with Therapeutic Equivalences Evaluations (the "Orange Book") as covering Suboxone® sublingual film. (D.I. 228-2, Admitted Fact No. 23).

The '497 patent, entitled "Process for Making a Film Having a Substantially Uniform Distribution of Components," issued on December 2, 2014. (D.I. 228-2, Admitted Fact No. 27). Plaintiff MonoSol owns the '514 and '497 patents and Plaintiff Reckitt Benckiser Pharmaceuticals, Inc. is an exclusive licensee of the '514 and '497 patents. (D.I. 228-2, Admitted Fact Nos. 22, 28).

Plaintiffs are asserting claims 62–65, 69, 71, and 73 of the '514 patent against DRL. (D.I. 228-2, Admitted Fact No. 91; D.I. 279 at 1 n.1). Claim 62 of the '514 patent is an

independent claim. Claims 63, 64, 65, 69, 71, and 73 all depend from claim 62. (D.I. 228-2, Admitted Fact No. 92). The '514 patent was separately tried against Watson and Par. (C.A. No. 13-1674, D.I. 446).

The asserted independent claim of the '514 patent reads as follows.

> 62. 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 selected from the group consisting of flavors, sweeteners, flavor enhancers, and combinations thereof to provide taste-masking of the active;
>
> wherein the particulate active has 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.

(JTX-2, claim 62) (emphases added).

Plaintiffs are asserting claim 24 of the '497 patent against all Defendants. (D.I. 228-2, Admitted Fact Nos. 30, 64, 95). Claim 24 of the '497 patent depends from claim 1. (D.I. 228-2, Admitted Fact No. 96). Claims 1 and 24 of the '497 patent reads as follows.

> 1. A process for making a film having a substantially uniform distribution of components, comprising the steps of:
>
> (a) forming a flowable polymer matrix comprising an edible polymer, a solvent and a desired amount of at least one active, said matrix having a substantially uniform distribution of said at least one active;

(b) casting said flowable polymer matrix;

(c) rapidly evaporating at least a portion of said solvent upon initiation of *drying* to form a visco-elastic film within about the first 4.0 minutes to maintain said substantially uniform distribution of said at least one active by locking-in or substantially preventing migration of said at least one active within said visco-elastic film;

(d) further *drying* said visco-elastic film to form a self-supporting edible film having a substantially uniform distribution of said at least one active component; and wherein said substantially uniform distribution of said at least one active component 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.

(JTX-3, claim 1) (emphases added).

24. The process of claim 1, wherein said active is in the form of a particle.

(JTX-3, claim 24).

II. LEGAL STANDARDS

A. Infringement

A patent is infringed when a person "without authority makes, uses, offers to sell, or sells any patented invention, within the United States . . . during the term of the patent . . . ." 35 U.S.C. § 271(a). A two-step analysis is employed in making an infringement determination. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). First, the court must construe the asserted claims to ascertain their meaning and scope. *See id.* The trier of fact must then compare the properly construed claims with the accused infringing product. *See id.* This second step is a question of fact. *Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1353 (Fed. Cir. 1998).

"Literal infringement of a claim exists when every limitation recited in the claim is found in the accused device." *Kahn v. Gen. Motors Corp.*, 135 F.3d 1472, 1477 (Fed. Cir. 1998). "If any claim limitation is absent from the accused device, there is no literal infringement as a matter

of law." *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1247 (Fed. Cir. 2000). If an accused product does not infringe an independent claim, it also does not infringe any claim depending thereon. *See Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1553 (Fed. Cir. 1989). However, "[o]ne may infringe an independent claim and not infringe a claim dependent on that claim." *Monsanto Co. v. Syngenta Seeds, Inc.*, 503 F.3d 1352, 1359 (Fed. Cir. 2007). The patent owner has the burden of proving infringement by a preponderance of the evidence. *See SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, 859 F.2d 878, 889 (Fed. Cir. 1988).

B. Obviousness

The presumption that all patents are valid is the starting point for any obviousness determination. 35 U.S.C. § 282. A patent claim is invalid as obvious under 35 U.S.C. § 103 "if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains." *Id.* § 103(a); *see also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406–07 (2007). Obviousness is a question of law that depends on the following factual inquiries: (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the relevant art; and (4) any objective indicia of nonobviousness. *See KSR*, 550 U.S. at 406; *see also Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1347 (Fed. Cir. 2012). A court is required to consider secondary considerations, or objective indicia of nonobviousness, before reaching an obviousness determination, as a "check against hindsight bias." *See In re Cyclobenzaprine Hydrochloride Extended–Release Capsule Patent Litig.*, 676 F.3d 1063, 1078–79 (Fed. Cir. 2012). Relevant secondary considerations include commercial success, long felt but unsolved needs, failure of others, praise, unexpected

results, and copying, among others. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 (1966); *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 662–63 (Fed. Cir. 2000); *Tex. Instruments, Inc. v. U.S. Int'l Trade Comm'n*, 988 F.2d 1165, 1178 (Fed. Cir. 1993).

"Generally, a party seeking to invalidate a patent as obvious must demonstrate . . . that a skilled artisan would have had reason to combine the teaching of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success from doing so." *In re Cyclobenzaprine Hydrochloride*, 676 F.3d at 1068–69. "The Supreme Court has warned, however, that, while an analysis of any teaching, suggestion, or motivation to combine known elements is useful to an obviousness analysis, the overall obviousness inquiry must be expansive and flexible." *Id.* at 1069. The improvement over prior art must be "more than the predictable use of prior art elements according to their established functions." *KSR*, 550 U.S. at 417. Evidence of obviousness, however, especially when that evidence is proffered in support of an "obvious-to-try" theory, is insufficient unless it indicates that the possible options skilled artisans would have encountered were "finite," "small," or "easily traversed," and "that skilled artisans would have had a reason to select the route that produced the claimed invention." *In re Cyclobenzaprine Hydrochloride*, 676 F.3d at 1072. Obviousness must be proven by clear and convincing evidence. *Id.* at 1078.

III. DISCUSSION

A. Infringement

1. DRL

a) Findings of Fact

1. DRL uses the CL02 and CL03 dryers where the sole source of heat is hot air coming from air nozzles over the liner.

2. DRL's proposed ANDA manufacturing process (hereinafter, "ANDA process") is extensively controlled to achieve drug content uniformity.

3. DRL's ANDA process is designed to avoid the "rippling effect."

4. The extent of bottom drying employed by DRL is conventional.

5. General testimony that DRL's method is unconventional is conclusory and not credible.

6. There is insufficient evidence for me to conclude that DRL's ANDA process utilizes unconventional drying.

7. DRL does not infringe the "drying" limitation of the '497 patent or the "dried" limitation of the '514 patent.

8. About four minutes after "drying," the majority of the wet matrix is still water.

9. Dr. Prud'homme's testimony that a visco-elastic solid results after about four minutes of drying is given little to no weight.

10. DRL does not infringe the visco-elastic solid film limitation of the '497 patent.

11. DRL's ANDAs report drug content uniformity measurements across the 12 mg/3 mg, 8 mg/2 mg, 4 mg/1 mg, and 2 mg/0.5 mg dosage strengths.

12. The '514 and the '497 patents do not require that Plaintiffs use the "three sigma rule" standard to establish infringement.

13. Plaintiffs establish that DRL infringes the drug content uniformity limitation of the asserted claims of both patents.

14. DRL's polymer matrix is specified to range between 5,000 to 20,000 centipoise for the 12 mg/3 mg, 8 mg/2 mg, 4 mg/1 mg, and 2 mg/0.5 mg dosage strengths.

15. Dr. Davies offers credible testimony as to whether DRL's ANDA process is "sufficient to provide little to no aggregation of the active within the film."

16. Plaintiffs establish that DRL infringes the viscosity limitation of the asserted claims of the '514 patent

17. DRL does not infringe any asserted claim of the '497 and '514 patents.

b) Conclusions of Law

(1) Dried/Drying

DRL argues that it does not infringe the "dried" limitation of the asserted claims of the '514 patent or the "drying" limitation of the asserted claim of the '497 patent. I construed "dried" in the '514 patent to mean "dried without solely employing conventional convection air drying from the top." (C.A. No. 15-1016, D.I. 87 at 5). I further clarified this construction as follows:

> "[D]ried without solely employing conventional convection air drying from the top" is meant to exclude drying techniques that are associated with the problem of the "rippling effect." This problem takes place when the initial drying of the upper surface of the film leads to the trapping of moisture inside the film, causing the top surface to be ripped open and reformed when the moisture trapped inside later evaporates. This does not necessarily exclude techniques where the only direct sources of air are from the top. This also should not be understood to require techniques to use direct sources of air from the bottom.

(*Id.* at 5–6). "Drying" in the '497 patent is construed similarly. (*Id.* at 8–9). DRL argues that their ANDA process is "conventional" because (1) the drying method used by DRL was ordinary and commonplace in the web coating industry as of 2001, (2) DRL's ANDA products are dried solely using top air, and (3) no bottom air or heat is used during the drying of DRL's products.

In conventional coating and drying equipment, a POSA could control the temperature, line speed, air velocity, and the direction of air nozzles. (*See, e.g.*, Tr. 785:6–10, 784:17–24, 785:1–5, 799:18–21). It would be conventional to adjust these settings in order to produce a desired product. (Tr. 1066:19–22, 784:17–785:10). Dr. Gogolin opines that it was conventional for an operator in 2001 to control a top air impingement dryer to prevent defects like rippling. (Tr. 1344:1–14). I agree with Plaintiffs that merely employing a conventional oven does not necessarily mean that a drying technique is conventional.

DRL uses the CL02 and CL03 dryers where the sole source of heat is hot air coming from air nozzles over the liner. (Tr. 1353:20–1354:2, 1360:16–1361:4). In both the CL02 and CL03, there are no air nozzles below the liner. (D.I. 228-2, Admitted Fact No. 121). DRL's ANDA process is extensively controlled. (*See, e.g.*, Tr. 577:7–14). DRL's ANDAs state, "The most critical aspect during coating and drying for this product is to achieve content uniformity in the master roll." (JTX-59 at 32). To meet that objective, DRL's ANDA process regularly monitors the oven temperature, fan speeds, supply dampers, and exhaust dampers in each zone. (JTX-59 at 32).

Plaintiffs' evidence shows that DRL's ANDA process is designed to avoid the "rippling effect." To avoid rippling, DRL's drying parameters are such that lower temperatures and air velocities are employed at the beginning and higher temperatures and air velocities are used toward the end of the drying process. (Tr. 982:1–983:3). DRL's ANDAs suggest that their films did not have visual defects. (JTX-12 at 11). DRL's technique employs low airflow at the surface of the web during the initial drying phase, such that the amount of heat transfer from the bottom web approaches the amount of heat transfer from the top.[6] (Tr. 830:12–831:4). This is consistent with a technique that is associated with minimizing the rippling effect. This is not dispositive because my construction left open the possibility as to whether conventional convection air drying techniques could also avoid the "rippling effect." Whether a technique causes rippling is only a factor as to whether a technique constitutes conventional convection air drying.

Plaintiffs argue that DRL's ANDA process is unconventional because it employs bottom drying. I am not persuaded that the extent of DRL's bottom drying is unconventional. No

[6] In this opinion, "web" is synonymous with "liner."

measurements were taken of the temperature of the metal rollers. (Tr. 558:19–559:19). The CL02 and CL03 dryers use a conventional exhaust system, which suggests that any bottom drying is at most a conventional amount. (D.I. 228-2, Admitted Fact Nos. 122–124; Tr. 1410:18–1411:2, 1352:2–19, 1356:8–21, 1358:9–1359:12, 1353:3–1354:13, 1360:3–15). I think that DRL's use of "bottom drying" is essentially that the inside of the oven simply gets hot and as a result, the bottom of film is incidentally heated. This is a conventional bottom drying method. (*See, e.g.*, JTX-24 at 4:37–42, Fig. 2; Tr. 1367:19–1368:19).

Taken as a whole, this evidence is not enough to persuade me that DRL's process is unconventional. I am not persuaded that evidence of a controlled process that does not result in rippling and that achieves drug content uniformity automatically amounts to an unconventional process. Watson raises two good points that apply here. Watson argues that finding unconventionality based on this kind of evidence would be using a "results-determinative" approach. I agree. Finding infringement based on this evidence would put too much focus on whether drug content uniformity is achieved, and would gloss over whether the parameters employed are actually unconventional. This is similar to the "efficient mixing" issue that the Federal Circuit addressed in *Medicines Co. v. Mylan, Inc.*, 853 F.3d 1296 (Fed. Cir. 2017). There, the court resisted the patentee's construction of "efficient mixing" which sought "to claim all solutions to the identified 'impurities' problem, without describing the entire range of solutions to that problem.'" *Medicines Co.*, 853 F.3d at 1307 (citing *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1352–53 (Fed. Cir. 2010)). If I were to find infringement, I would effectively be construing the drying limitation to claim all drying techniques that solve the drug content uniformity problem. This is not what the patents claim, however.

Watson also argues that finding unconventionality based on this kind of evidence would read out the uniformity limitation. I agree. If showing drug content uniformity was effectively all that was required to meet the drying limitation, there would be no need for a separate uniformity limitation. *See Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006) ("[C]laims are interpreted with an eye toward giving effect to all terms in the claim."). Thus, on these facts, Plaintiffs have not met their burden of showing that the "dried"/"drying" limitations of the '497 and '514 patents are met.[7]

(2) Visco-Elastic

DRL argues that its drying process does not meet the visco-elastic solid film limitation of the '497 patent. Claim 1 of the '497 patent requires "rapidly evaporating at least a portion of said solvent upon initiation of drying to form a visco-elastic film within about the first 4.0 minutes to maintain said substantially uniform distribution of said at least one active by locking-in or substantially preventing migration of said at least one active within said visco-elastic film . . . ." (JTX-3, claim 1). I construed the phrase "to maintain said substantially uniform distribution of said [pharmaceutical/at least one active] by locking-in or substantially preventing migration of said [pharmaceutical/at least one active]" to mean "to maintain a distribution of [an active/a pharmaceutical active] by drying to form a viscoelastic solid film, thereby limiting its migration such that the individual dosage units do not vary by more than 10% from the intended amount of the active for that dosage unit." (D.I. 175 at 8–9).

DRL's proposed product would lose about 20% of volatile solvent (water and alcohol) in about four minutes. (Tr. 693:4–11). As a result, the majority of the wet matrix is still water.

[7] DRL further argues that Dr. Davies is not qualified to offer an opinion concerning the phrase "conventional convection air drying from the top" in the context of the '514 patent. Having already found in DRL's favor, I do not reach this issue.

(Tr. 1218:2–16). Rheological testing shows that the DRL's formulation is at best a visco-elastic liquid after four minutes of drying. (Tr. 1224:3–22, 1227:17–1235:23, 773:14–774:1; JTX-488).

Plaintiffs' criticisms of this rheological testing make some points but are not persuasive. Plaintiffs complain that the tested sample did not include buprenorphine, but it is unclear that the inclusion of buprenorphine would be enough to change the results, that is, to render the sample a visco-elastic solid. (Tr. 1232:18–1233:3). Plaintiffs complain that the wet mixture of material was left out in open air to allow evaporation of solvent. This complaint neglects that after the dehydrated sample was placed in a petri dish on a balance to monitor weight loss until it reached the target 16% volatile weight loss, the sample was then transferred to a new vial, capped, and sealed to prevent further loss. (Tr. 1199:4–21). Dr. Prud'homme concedes that the measurements were well done on the solutions DRL used. (Tr. 772:17–773:7). Dr. Prud'homme concedes that he had no criticisms of the methodology of the experiment for the ends that were measured. (Tr. 773:3–7). I think the test was somewhat representative. Testing can be probative without exactly duplicating the process being examined. Thus, I attribute some weight to the rheological tests.

Plaintiffs argue that Dr. Prud'homme's testimony demonstrates that a visco-elastic solid results because the solvent loss leads to a resulting increase in buprenorphine particle concentration, which causes a particle network to form. Specifically, Plaintiffs argue that the citric acid in DRL's casting dispersion interacts with PEO, causing the buprenorphine particles to stick to each other to form large open aggregates of particles through micro-scale chaining and aggregation. They argue that this finds support from Dr. Prud'homme's research conducted in 2010 regarding citric acid-PEO facilitated network formulation and literature showing micro-scale aggregation when particles are flowed in a visco-elastic fluid.

I do not find this persuasive. First, Dr. Prud'homme did not perform any actual testing to see if DRL's proposed ANDA products exhibited a yield stress before or after four minutes of drying. (Tr. 781:19–782:7). Second, Dr. Prud'homme's work on the case had some sloppiness. His original opinion relied on calculations performed of both "viscosity" and "yield stress." (Tr. 774:24–775:20). Those calculations were overstated due to mathematical errors.[8] (Tr. 776:20–780:19). Third, Dr. Prud'homme fails to adequately explain when during the first four minutes of drying and at what concentration of buprenorphine a visco-elastic solid forms. At the beginning of the four minutes, the concentration of buprenorphine is 4.18%, and it is a visco-elastic liquid. At the end, the concentration of buprenorphine is 4.87%, when he argues it is a visco-elastic solid. (Tr. 762:14–22, 763.18–22, 764:14–19). His theoretical explanation does not provide useful insight about when the change occurs and how one would recognize that the change has occurred. In the end, what Dr. Prud'homme shows is that the concentration of buprenorphine has increased, but it is not helpful in determining whether the film is then a visco-elastic solid. Thus, Plaintiffs have failed to show that DRL infringes the visco-elastic solid film limitation of the '497 patent.

(3) Drug Content Uniformity

DRL argues that its ANDA products do not meet the drug content uniformity limitation of the '514 or the '497 patent. I construed "without loss of substantial uniformity" to mean "such that individual dosage units do not vary by more than 10% from the intended amount of active for that dosage unit." (D.I. 175 at 23). I also construed "substantially uniformly

[8] Dr. Prud'homme is a distinguished expert in his field. But when I have to choose which expert's testimony to accept, I am going to hesitate to rely on the expert whose report contained mistakes.

stationed" to mean "[s]tationed in the matrix such that individual dosage units do not vary by more than 10% from the intended amount of active for that dosage unit." (D.I. 156 at 15–16).

Plaintiffs successfully establish infringement of this limitation. DRL's ANDAs report drug content uniformity measurements for individual dosage units. (JTX-57 at 18; JTX-274 at 36; Tr. 926:16–20). The 8 mg/2 mg dose ranges from 96.9 percent to 102.2 percent buprenorphine content uniformity. (Tr. 927:2–16; JTX-57 at 18). For the 12 mg/3 mg dose, it ranges from 93.4 percent to 95.2 percent. (Tr. 927:24–928:11). For the 4 mg/1 mg dose, it ranges from 94.8 percent to 106.2 percent. (Tr. 928:19–929:12). For naloxone, the 8 mg/2 mg ranges from 97.2 percent to 101.8 percent. (Tr. 927:2–16). For the 12 mg/3 mg, it ranges from 95.3 percent to 96.1 percent. (Tr. 927:24–928:13). For the 4 mg/1mg dose, it ranges from 97.9 percent to 101.5 percent. (Tr. 928:19–929:12). As to the 2 mg/0.5 mg dose, information about "acceptance values" and "assay requirements" indicate adequate content uniformity. (Tr. 932:7–933:2). DRL does not substantively contest any of this.

DRL's only argument is that Plaintiffs should be held to "three sigma rule" in their infringement analysis and under such an approach, Plaintiffs have failed to adequate show infringement. (D.I. 285 at pp. 19–20). The three sigma rule requires a showing that approximately 99.8% of all samples fall within the claimed numeric ranges. (Tr. 1644:1–1645:1; PTX-82 at 145). I disagree that Plaintiffs must be held to the three sigma rule in order to establish infringement. There is no requirement in the claims for this to be necessary. The evidence presented is sufficient to establish a case of infringement of this limitation.

(4) Viscosity

DRL argues that its ANDA products do not meet the "viscosity" limitation of the '514 patent. I construed the phrase, "said matrix has a viscosity sufficient to aid in substantially

maintaining non-self-aggregating uniformity of the active in the matrix" to mean "viscosity sufficient to provide little to no aggregation of the active within the film." (D.I. 175 at 21–22). Viscosity plays a role to ensure that buprenorphine particles do not settle or aggregate. (Tr. 914:20–23). For context, the specification provides that the "most preferred" viscosity range is 1,000 to 40,000 centipoise. (JTX-2 at 11:28–29).

DRL's polymer matrix is specified to range between 5,000 centipoise to 20,000 centipoise for the 12 mg/3 mg, 8 mg/2 mg, 4 mg/1 mg, and 2 mg/0.5 mg dosage casting dispersions. (PTX-80 at 1; Tr. 917:4–918:3). Further, the viscosity of all the tested lots fell within the "most preferred" range. (Tr. 918:4–919:12). If uniformity of the active ingredient during casting and drying is lost, then it is unlikely to be regained at a subsequent point during casting and drying. (Tr. 574:6–14).

DRL took measurements that showed the buprenorphine content measurements of a casting dispersion batch for 8 mg/2 mg. (Tr. 921:9–11). The measurements ranged from 96.3% to 102.4% of the label claim, with a mean of 99.4%. (JTX-273 at 44; Tr. 922:9–20). I have no reason to believe that the compounding process used for the other dosage strengths is materially different. (*See* Tr. 923:20–24; JTX-11 at 53, 54). The ANDAs state that: "the selected compounding process . . . results in acceptable drug uniformity in the final blend." (JTX-11 at 54). Additionally, as discussed above, Plaintiffs establish infringement as to the drug content uniformity limitation.

DRL argues that Dr. Davies's opinion that DRL's ANDA process is "sufficient to provide little to no aggregation of the active within the film" is contradicted by Dr. Prud'homme's opinions regarding substantial aggregation prior to drying. Dr. Davies's opinions as to the viscosity limitation may be in tension with Dr. Prud'homme's opinion, but, as discussed

above, Dr. Prud'homme's substantial aggregation opinions were not persuasive to me and I find Dr. Davies's testimony credible and admissible at least with respect to the viscosity limitation. (*See* Tr. 943:19–944:16). Thus, I accept Dr. Davies' opinion over that of Dr. Prud'homme.

DRL further argues that the fact that DRL's final films meet drug content uniformity requirements is insufficient on its own to establish infringement of this limitation. DRL also argues that the fact that the viscosity of DRL's matrix falls within the preferred range described in the '514 patent alone is not enough. I am not relying on either of these alone, however. DRL's arguments are not persuasive because there is evidence that DRL's final films meet drug content uniformity requirements *and* fall within the preferred range, such that there is sufficient evidence of infringement of this limitation. Thus, Plaintiffs have demonstrated that DRL infringes the viscosity limitation.

2. Watson

a) Findings of Fact

1. Watson uses a Kraemer Koating dryer tunnel where the sole source of heat is hot air from nozzles above the web.
2. Watson's ANDA process is extensively controlled to achieve content uniformity.
3. It is unclear from the cited record whether Watson's films actually exhibit rippling.
4. The extent of bottom drying employed by Watson is conventional.
5. General testimony that Watson's method is unconventional is conclusory and not credible.
6. There is insufficient evidence for me to conclude that Watson's ANDA process utilizes unconventional drying. Watson does not infringe the "drying" limitation.
7. Watson's films were a visco-elastic solid prior to drying.
8. Watson does not infringe the visco-elastic solid limitation.
9. Watson does not infringe claim 24 of the '497 patent.

b) Conclusions of Law

(1) Drying

Watson argues that it does not infringe the "drying" limitation of the '497 patent because Watson's ANDA process uses solely conventional convection air drying from the top. Watson employs a Kraemer Koating drying tunnel, which is a three-zone impingement dryer, to make Watson's ANDA products. (Tr. 796:8–11, 798:11–15; JTX-262 at 7). Each of the three zones is independently controlled. (JTX-262 at 7).

Plaintiffs' evidence shows that Watson's ANDA process is extensively controlled. (*See, e.g.*, Tr. 593:1–605:13). The control parameters in this case were used to dry these films to get the appropriate uniformity. (Tr. 604:7–19). These parameters include controlling temperature, line speed, air speed, angle of air impingement, and nozzle distance relative to the web. (Tr. 594:16–598:8, 599:19–601:19, 836:3–13, 838:2–20; JTX–89 at 12; JTX-260 at 4). Watson's ANDA identifies the step of "coating/drying/laminating" as a "critical process step." (JTX-89 at 12). Parameters such as temperature and line speed are identified as impacting content uniformity and, as such, are parameters to be monitored. (JTX-89 at 12).

Plaintiffs argue that Watson employs bottom drying. The sole source of heat is hot air from nozzles above the web. (Tr. 796:12–16). The heat in a conventional top air dryer warms the air and rollers beneath the web. (Tr. 1364:7–22). No analysis of heat transfer from the rollers onto the film was conducted. (Tr. 886:24–887:4, 804:15–19). No temperature measurements were taken inside Watson's drying tunnel. (Tr. 837:3–7). As with DRL, I am not persuaded that the extent of Watson's bottom-drying is anything but conventional. (Tr. 1378:3–8).

Without more evidence, Plaintiffs have failed to show that Watson's ANDA process infringes the "drying" limitation for similar reasons discussed with respect to Dr. Reddy's. Again, I am not persuaded that evidence of a controlled process that does not result in rippling, which I am assuming is the case for Watson, and that achieves drug content uniformity, automatically amounts to an unconventional process. This would be using a results-determinative approach. I would effectively be construing the drying limitation to claim all drying techniques that solve the drug content uniformity problem. If showing drug content uniformity was effectively all that was required to meet the drying limitation, the uniformity limitation would be superfluous.

(2) Visco-Elastic

Watson argues that its drying process does not infringe the visco-elastic solid film limitation of the '497 patent because the active is already "locked in" before the casting dispersion enters the drying oven.

There is strong evidence that the film, prior to entering the dryer, had more solid properties than liquid properties. (*See, e.g.*, Tr. 1257:18–1258:2, 1260:15–20). When Watson's material was placed on the release liner, the forces from pumping and mixing did not exist, and the material gelled as a result. (Tr. 1263:6–19). The casting dispersion is on the incline for about thirty seconds prior to entering the oven. (Tr. 810:15–19). The casting dispersion, as it travels on a slope upward into the oven, does not flow down the liner. (Tr. 806:11–20, 810:20–811:1). This is confirmed by video evidence that also demonstrates that the film maintains its shape. (JTX-656 at 10:53:26–10:54:00). The widths of the films when cast are the same widths as the final product. (Tr. 1264:1–8). Melt fracture also takes place. (Tr. 1266:21–1267:8; JTX-

656 at 10:53:31, 11:04:45–11:04:51, 11:06:31). Melt fracture is evidence of a material behaving like a visco-elastic solid. (Tr. 1267:11–14).

Plaintiffs argue that Watson's casting dispersion has too much water, but the persuasiveness of this argument is undercut by the fact that Watson's casting dispersion has additional additives which cause greater gelation. (Tr. 1257:2–7, 1451:24–1455:1; JTX-658 at 26–27). Watson uses the E4M grade of HPMC, one of the highest molecular weight E grades of HPMC, with long chain length polymers. (Tr. 1442:18–1443:13, 1452:24–1453:2). The E4M grade is used in controlled release oral tablets where, when dissolved, they form a gel layer and the drug has to diffuse out of them. (Tr. 1444:3–9). High temperatures are not necessary for gelation to occur. (JTX-658 at 25–26; JTX-89 at 5).

Plaintiffs argue that Par's ANDA is a liquid during coating, which suggests that Watson's is too. (D.I. 279 at pp. 29–30). This is not particularly persuasive because the two generics have different processes. Additionally, although Par's casting dispersion uses roughly three times as much HPMC as Watson's casting dispersion, Par and Watson use different grades of HPMC. (Tr. 1442:18–1443:13; PTX-927 at 1).

Plaintiffs' arguments as to whether it would be a "chemical impossibility" for Watson's casting dispersion to form a visco-elastic solid prior to drying are not persuasive in light of the physical evidence discussed above and the published literature. (*See, e.g.*, Tr. 1255:8–18, 1285:20–1286:7, 1251:17–1252:3; JTX-89 at 5; JTX-658 at 25; JTX-43 at 17; JTX-696 at 123–124). It would have been helpful to Plaintiffs' case if Dr. Prud'homme had testified that he performed calculations or conducted rheological testing to determine that there was flow as Watson's films travelled up the ramp. He did not provide such analysis. (Tr. 812:5–10). The

absence of such testimony suggests that Plaintiffs did not expect such work would help their case. There is thus no persuasive evidence of flow after casting, but before drying.

Plaintiffs argue that Watson's current position contradicts the position it took in the 2015 Orange Book trial, when the '514 patent was asserted against Watson. They argue that Dr. McConville previously testified that the casting dispersion was a liquid after it is deposited on the liner and before it goes into the dryer, and starts solidifying as it begins to dry. (D.I. 279 at p. 28). They argue that, based in part on this testimony, I found that "[d]uring the casting process and prior to drying, the matrix that is used to form the cast films of Watson's and Par's ANDA Products is a flowable liquid." (C.A. 13-1674, D.I. 446 at 42). Plaintiffs cite to the following exchanges with Dr. McConville in the present trial record.

> Q. Can you generally summarize why you believe Watson does not meet this first drying step?
>
> A. Yes, I can. Basically, it's my understanding from my observation that the product was in the solid state before it entered the oven, so it was a visco-elastic solid.

(Tr. 1436:7–13).

> Q. And in the trial last year, you testified that the Watson film starts solidifying as it begins to dry; is that correct?
>
> A. My understanding now is that we don't need that heated roller, of course, to start solidifying. I've seen it work without the heated roller.
>
> Q. That was your testimony last year?
>
> A. It was my testimony.
>
> Q. And, in fact, in last year's trial, you specifically testified that the casting dispersion after it's deposited on the wire [rack] and before it enters the oven was a liquid; isn't that correct?
>
> A. Exactly. As it's being sheared, it's still a liquid. That's exactly right.
>
> . . . .

Q. If we can go to the trial transcript at 1169. And there was a question: And when it comes out of the dispersing header to the, to be dried and going into the dryers, it's at a fluid state at that point; is that correct? And you said, it's not static. It's in a liquid, and I think, and you went on, a continuous process.

A. It's being continuously sheared, now we know.

Q. It's not being continuously sheared after it comes out of the die; right?

A. As it's being forced out, it is sheared, and then as soon as that –

Q. You didn't say that last year?

. . . .

[A.] So the mixer is mixing, the recirculating pump which I was talking about today, which takes back any excess stuff back to the mixer, and it's forced out of this die under pressure, because of the recirculating pump. And because it's forced out under pressure, it's forced out as a liquid, and sometimes between where it hits that web and the 30 second foot-and-a-half before it gets into the oven, it's a visco-elastic solid. I believe it's very -- as soon as it comes out, you could consider that. It doesn't deform anymore. That's my testimony.

. . . .

Q. And it's your opinion that that testimony that you just gave is consistent with your trial testimony last year that it was a liquid when it came out of the coating die?

A. Yes.

(Tr. 1486:15–1490:5). For context, the manufacturing process at the time of the previous trial included a heated roller carrying Watson's release liner, which "immediately began heating that casting dispersion" as it was cast. (C.A. No. 13-1674, D.I. 417, Tr. 1161:11–15, 1163:9–18). Watson has since amended its ANDA to include a new manufacturing process, which does not include a heated roller. (Tr. 1486:15–22). The amended ANDA's formulation remained the same. (Tr. 1484:20–23).

Plaintiffs fail to convince me that there is a contradiction. Dr. McConville testified that the present ANDA process results in a visco-elastic solid after casting and prior to entering the

oven. Dr. McConville testified that the previous ANDA process resulted in a visco-elastic liquid up to the point of casting where the formulation was sheared. He did not testify that in the previous ANDA process the formulation remained a liquid up to the point where it entered the oven. Based on this evidence, I am not persuaded that there is a contradiction in Watson's litigation position.

Plaintiffs' evidence fails to show that Watson's films were a visco-elastic solid prior to drying. I find the visco-elastic solid limitation is not infringed.

(3) Further Drying

Watson argues that it does not meet the further drying limitation of the '497 patent. I do not need to reach this issue in light of my separate findings that Watson's product does not infringe the drying or visco-elastic limitations of the '497 patent, and I choose not to address this factual issue.

3. Par

a) Findings of Fact

1. Par uses a Kraemer Koating dryer tunnel where the sole source of heat is hot air from nozzles above the web.
2. Par's ANDA process is extensively controlled to achieve content uniformity.
3. Par's ANDA process was in part designed to avoid rippling.
4. The extent of bottom drying employed by Par is conventional.
5. General testimony that Par's method is unconventional is conclusory and not credible.
6. There is insufficient evidence for me to conclude that Par's ANDA process utilizes unconventional drying. Par does not infringe the "drying" limitation.
7. Touch tests of the film suggest that the film is not a visco-elastic solid after about the first 4.0 minutes of drying.
8. Low weight is attributed to Plaintiffs' TGA experiments.

9. Little to no weight is attributed to Plaintiffs' theoretical evidence.

10. Par does not infringe the visco-elastic solid limitation.

11. Par does not infringe claim 24 of the '497 patent.

b) Conclusions of Law

(1) Drying

Par argues that it does not infringe the "drying" limitation of the '497 patent. Par also uses a Kraemer Koating drying tunnel, which was manufactured in 1991. (Tr. 1010:24–1011:10). Plaintiffs' evidence shows that Par's ANDA process employs an extensively controlled process to ensure uniformity is maintained. (*See, e.g.*, Tr. 604:7–19). Par's ANDA recognizes the need to achieve drug content uniformity during the coating and drying process. (JTX-69 at 25). Par controls the drying of its films with a two-zone dryer to ensure that throughout the drying process, drug content uniformity is achieved. (Tr. 648:20–655:15). Par's ANDA provides that the manufacturing process requires control of the drying temperature of each zone, the blower speeds, exhaust speeds, and line/roll speed. (PTX-63 at 5). Specific ranges are indicated for each of these parameters. (PTX-63 at 5). Par's ANDA provides, "The oven temperature and blower parameters are responsible for how the film is dried on the liner," and, "Different oven temperatures were investigated to evaluate the adhesion of the film to the liner, visual and physical characteristics of the resulting film, water content and content uniformity." (JTX-69 at 28).

Plaintiffs' evidence shows that Par's ANDA process was in part designed to avoid the "rippling effect." Mr. Sisbarro, Par's former employee, testified that Par, through a trial-and-error process, determined the drying parameters that would be used to prevent rippling from

occurring. (Tr. 1034:5–1036:16).[9] The key parameters were temperature, airflow, thickness, and line speed. (Tr. 1033:24–1034:4). These were selected by Mr. Sisbarro to avoid rippling. (Tr. 1034:18–1035:9). Par's ANDA suggests that its films did not have visual defects. (JTX-69 at 31, 35–36, 53).

Plaintiffs argue that Par employs bottom drying. Conventional top air drying equipment warms everything inside of the oven. (Tr. 1365:10–15). Air under the web naturally warms in conventional ovens. (Tr. 1068:24–1069:11). The rollers and other web supports would also warm. (Tr. 1377:9–1378:2, 1068:8–1069:11). The sole source of heat is hot air coming out of the nozzles over the liner. (D.I. 228-2, Admitted Fact No. 47; Tr. 1015:16–24, 1014:6–8, 1012:3–22). Par's nozzles were in the same position for making over a hundred products and did not change for the manufacture of Par's ANDA products. (Tr. 1011:11–22). Par's process utilizes a low temperature, slow speed drying process. (Tr. 1012:23–1013:10). Mr. Berry, Par's Vice President of Transdermal Operations, has always preferred this method. (Tr. 1013:3–10). He has been using this method since 1986. (Tr. 1013:16–21). I am not persuaded that the extent of Par's bottom-drying is unconventional.

Considering all the evidence, as with DRL and Watson, Plaintiffs fail to provide adequate evidence to suggest that Par employs an unconventional drying technique.

(2) Visco-Elastic

Par argues that its drying process does not infringe the visco-elastic solid film limitation of the '497 patent. Mr. Sisbarro touched the film at the end of zone one and reported that "it was wet." (Tr. 1042:18). He reported that it was like "putting your finger in a gallon or a quart of

[9] The parties dispute whether Mr. Sisbarro is Par's Rule 30(b)(6) witness. (D.I. 275 at pp. 248–49). For the purposes of this analysis, I assume, as Plaintiff would have it, that he is.

Latex paint and pulling it away and looking at it." (Tr. 1042:19–22). This was across all four strengths. (Tr. 1043:3–8). Even after six minutes of drying, the film is not a visco-elastic solid. (Tr. 1140:13–1143:1, 1144:14–1145:21, 1157:6–11, 1077:14–1078:1, 1079:17–1080:22; JTX-547; JTX-562; JTX-588; JTX-576). Plaintiffs do not persuasively dispute this. (*See, e.g.*, Tr. 666:1–6).

Plaintiffs argue that the mechanism of drying is primarily through heat transfer in the oven. They argue that Par's representative accused 8 mg/2 mg dose, when first cast, would have an original water content of 28.5 mg/cm^2, and the entire 28.5 mg/cm^2 of water would evaporate from Par's film in just under four minutes at a temperature of 73 degrees Celsius. (D.I. 279 at p. 25). They argue that the water loss causes a visco-elastic solid film to form due to crystallization of PEO and the restriction of the motion of the PEO and HPMC polymer chains.

I attribute low weight to Plaintiffs' thermogravimetric analysis ("TGA") experiments. The TGA experiments use an instrument that is set at a desired temperature and measures the evaporation and loss of weight. (Tr. 626:7–17). I am not persuaded that the three TGA experiments on which Dr. Prud'homme relies were conducted under accurate temperature settings. Dr. Gilchrist rapidly heated the sample in a way that is different from what actually happens in Par's ANDA process. Par's ANDA process takes a film at room temperature and exposes it to an oven set at 73 degrees Celsius. (Tr. 1022:24–1023:18, 1024:24–1027:3). Dr. Gilchrist instead used a temperature ramp rate of 200 degrees Celsius per minute to heat the sample up to 73 degrees Celsius. (Tr. 894:21–895:3). This means that he tried to heat the sample up very quickly. (Tr. 894:21–895:3). This heating bears little relationship to what happens in Par's ANDA process. (Tr. 1130:24–1132:16, 895:5–9). As Dr. McKinley puts it, Par's process is like putting a turkey in an oven, whereas, Dr. Gilchrist's method is like putting a

turkey into a deep fat fryer. (Tr. 1132:5–9). The fact that the temperature settings that Dr. Gilchrist used were inappropriate is further supported by Dr. Fuller's temperature measurements of an uncoated liner as it traveled through Par's coater. Dr. Fuller determined that, after approximately four minutes of heating, the temperature of the liner only reached 46 degrees Celsius. (PTX-937 at ¶ 211 and Table 2; Tr. 740:21–741:5, 1133:1–8; JTX-653). Had the liner been coated, the liner would have been even cooler. (Tr. 1128:12–1129:2). Plaintiffs argue that Dr. Fuller's measurements were done with the oven door open and with no casting dispersion and that Dr. Fuller did not believe a steady state was reached when he took the measurements. Even assuming the criticisms are accurate, Dr. Fuller's measurements still cast substantial doubt on whether Dr. Gilchrist used appropriate temperature settings.

I further attribute low weight to Plaintiffs' evidence because of another experiment. There was a fourth TGA experiment, referred to as the "P4" experiment. This experiment had the instrument set at 40 degrees Celsius. (Tr. 1132:19–24). The drying in this experiment resulted in only about 14% water loss after four minutes. (Tr. 1134:24–1135:12). This is consistent with Dr. McKinley's calculated 12% water loss in the first four minutes of drying. (Tr. 1133:23–1134:23).

Considering all of the above, Plaintiffs have failed to show that Par infringes the visco-elastic limitation. The touch test evidence casts significant doubt on whether Par's films would be a visco-elastic solid within four minutes. The TGA experiments, with the exception of P4, are of very limited value.[10]

[10] Plaintiffs might wonder why the evidence of rheological testing done with respect to DRL was persuasive but not the TGA experiments done here. The accuracy concerns raised with respect to the TGA experiments are much more substantial.

(3) Further Drying

Par argues that it does not meet the further drying limitation of the '497 patent. I do not need to reach this issue in light of my separate findings that Par's product does not infringe the drying or visco-elastic limitations of the '497 patent, and I choose not to address this factual issue.

B. Validity

1. Findings of Fact

1. A person of ordinary skill in the art ("POSA") in the context of the '514 and '497 patents would possess a bachelor's degree in pharmaceutical science, chemistry, or a related field, plus two to five years of relevant experience in developing drug formulations. This person would also be a member of a team, which would include an engineer or scientist with one to three years of relevant experience manufacturing and optimizing various types of film products using coating and drying processes. Alternatively, a POSA could have a master's degree or Ph.D. and less practical experience.

2. Web coating has been used in the industry in the 1970s and decades prior for products such as thin polymer batteries, adhesives, fabrics, edible fruit pulp, and automobile converters.

3. Top air impingement convection dryers were commonly used in 2001.

4. These dryers have parameters for drying, such as air velocity and air temperature, which could be independently controlled.

5. The extent of which top air impingement convection dryers were used in the context of pharmaceutical products was very limited in 2001.

6. Schmidt (1989) is directed to a process for producing a dosage form that contains an active ingredient.

7. Chen (1999) is directed to a mucoadhesive film formulation that contains a water soluble hydrocolloid and an active agent.

8. Strobush (1999) is directed to "dry coated substrates used in the manufacture of photothermographic, thermographic, and photographic articles."

9. Sometime between 1971 to 1988, Dr. Gogolin made a film product where the back-coat film for a Polaroid film required the uniform dispersion of titanium dioxide particles.

10. At least in the context of traditional films, a person with substantial experience coating and drying would use visual observation to monitor whether rippling develops.

11. A POSA making a pharmaceutical formulation would understand that drug content uniformity is important.

12. A POSA would find that Schmidt did not disclose films meeting the 10% drug content uniformity limitation or teach how to make such films.

13. A POSA would find that Chen did not teach uniform films in the first step of the manufacturing process related to the mixing and removal of air bubbles.

14. Chen utilized a drying method that rapidly locked in active ingredients.

15. A POSA would find that Chen did not disclose films meeting the 10% drug content uniformity limitation or teach how to make such films.

16. A POSA would not be motivated to combine the prior art to achieve drug content uniformity primarily because such a person would have limited knowledge and access to knowledge of drying techniques.

17. A POSA would not have a reasonable expectation of success in achieving drug content uniformity. A POSA would not have a strong grasp of prior web coating techniques to apply to the context of pharmaceutical films.

18. MonoSol was the first to receive FDA approval for a pharmaceutical film product

19. Various articles have recognized "general challenges to achieving drug content uniformity in pharmaceutical films."

20. Various articles credit the inventors of the '514 and '497 patents for identifying issues related to achieving drug content uniformity.

21. The evidence of secondary considerations weighs in Plaintiffs' favor.

22. There is insufficient evidence that the asserted claims of the '514 and '497 patents are invalid as obvious.

2. Conclusions of Law

Defendants argue that the asserted claims of the '514 and '497 patents are invalid as obvious. The priority date of the '514 and '497 patents for the purposes of this discussion is October 2001. (*See* D.I. 278 at p. 1; Tr. 798:1–6, 999:6–21).

a) Person of Ordinary Skill in the Art

A POSA in the context of the '514 and '497 patents would possess a bachelor's degree in pharmaceutical science, chemistry, or a related field, plus two to five years of relevant experience in developing drug formulations. This person would also be a member of a team, which would include an engineer or scientist with one to three years of relevant experience manufacturing and optimizing various types of film products using coating and drying processes. Alternatively, a POSA could have a master's degree or Ph.D. and less practical experience. (Tr. 1666:8–24, 1317:2–15, 1547:20–24). While I think there is some merit to Plaintiffs' argument that the pharmaceutical film field as of 2002 was nascent, there is also merit to Defendants' argument that one of ordinary skill would have a degree of access to some of the body of prior-art knowledge relating to coating and drying.

This finding avoids entirely omitting relevant art. *See, e.g.*, *Mintz v. Dietz & Watson, Inc.*, 679 F.3d 1372, 1376 (Fed. Cir. 2012); *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1361–63 (Fed. Cir. 2006). This finding recognizes that a POSA would have some, albeit limited, knowledge of manufacturing solutions.

b) Scope and Content of the Prior Art

(1) Dried/Drying

Web coating has been used in the industry in the 1970s and decades prior for products such as thin polymer batteries, adhesives, fabrics, edible fruit pulp, and automobile converters. (Tr. 1304:18–1305:11). Top air impingement convection dryers were commonly used in 2001. (Tr. 1305:12–1307:10). Satas (1984) and Weiss (1977) depict a top air impingement dryer. (JTX-461 at 14–15; JTX-455 at 32). These dryers have parameters for drying, such as air velocity and air temperature, which could be independently controlled. (Tr. 1306:10–17).

The extent to which top air impingement convection dryers were used in the context of pharmaceutical products was very limited in 2001. Mr. Gogolin does not know whether pharmaceutical products were actually made with web coating prior to 2001. (Tr. 1384:6–1385:8). Mr. Gogolin does not know whether there was a product specification for any web-coated film product for dissolvable films prior to 2001. (Tr. 1386:16–20). There are differences between non-pharmaceutical and pharmaceutical cast films, one of which is that the FDA has stringent requirements for pharmaceuticals such as drug content uniformity requirements. (Tr. 1669:21–1670:10). Mr. Gogolin has worked on approximately one hundred film products out of which only one was a pharmaceutical film product. It was for a transdermal patch. (Tr. 1300:8–16).

Schmidt (1989) is directed to a process for producing a dosage form that contains an active ingredient. (Tr. 1554:16–18, 1556:16–20). The films in Schmidt are made using the roll coating process. (Tr. 1556:21–1557:6). Schmidt discloses a film dosage form made of edible cellulose-type polymers and other additives. (Tr. 1558:10–1559:6). Schmidt discloses that when applying coatings, one could do so through "a temperature-controlled pair of rollers and a drying tunnel which is controllable in sections." (JTX-448 at 6:46–49).

Chen (1999) is directed to a mucoadhesive film formulation that contains a water soluble hydrocolloid and an active agent. (Tr. 1571:19–22, 1572:4–8). Chen discloses a casting process to manufacture an oral thin film. (D.I. 228-2, Admitted Fact No. 183; JTX-24 at 10:58-59). Figure two of Chen discloses the following:

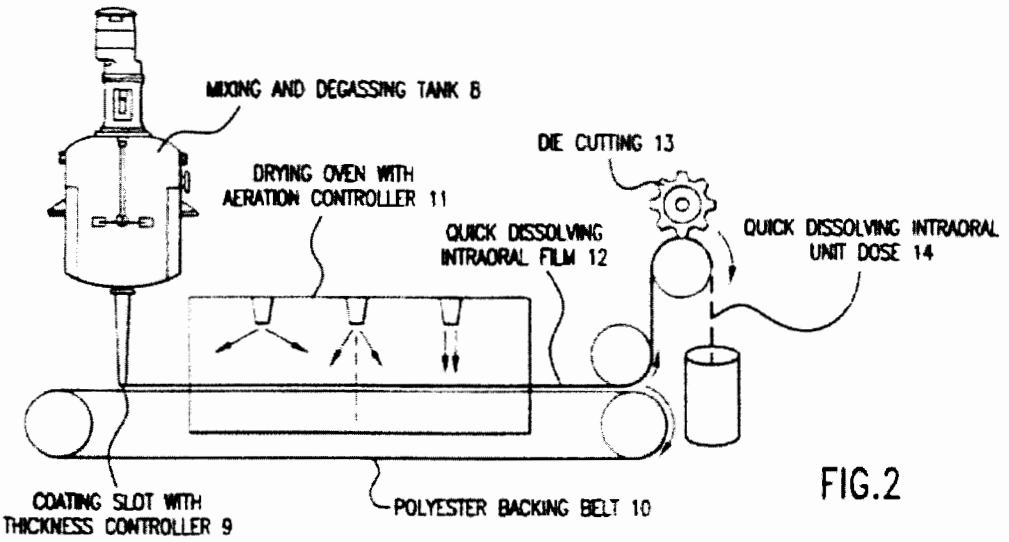

FIG.2

(JTX-24 at Fig. 2). Chen discloses an oven with air nozzles configured to different angles. (Tr. 1366:18–23). A POSA would understand that temperature and air speed could be controlled in this unit. (Tr. 1366:12–1367:18).

Strobush (1999) is directed to "dry coated substrates used in the manufacture of photothermographic, thermographic, and photographic articles." (JTX-450 at 6:21–24). It claims to do so "without introducing significant mottle and while running at higher web speeds than known drying methods." (JTX-450 at 6:24–27). Strobush is not directed to drug content uniformity. (Tr. 1727:7–21).

Dr. Gogolin testified that he made a film product where the back-coat film for a Polaroid film required uniform dispersion of titanium dioxide particles, where "[t]he typical specification at that time was plus or minus five percent of the grams per square meter in weight." (Tr. 1320:16–1322:9). Dr. Gogolin worked for Polaroid from 1971 to 1988. (Tr. 1295:18–21, 1297:24–1298:1).

At least in the context of traditional films, a person with substantial experience coating and drying would use visual observation to monitor whether rippling develops. (Tr. 1333:19–

1334:3). Such a person would know how to solve the problem of rippling by raising the humidity at the surface of the film and slowing the drying. (Tr. 1334:17–1335:6). Such a person would change air velocity. (Tr. 1338:9–1339:4; JTX-462 at 158, 177). Such a person would be hesitant to modify matrix viscosity. (*See* Tr. 1391:22–1393:1). Such a person might introduce the controlled application of bottom heat to the underside of the liner. (Tr. 1335:7–1336:7, 1336:19–1337:13; JTX-455 at 38; JTX-462 at 173).

(2) Drug Content Uniformity

Regulatory agencies require that "dosage forms may not vary more than 10% in the amount of active present." (JTX-3 at 2:48–52). A POSA making a pharmaceutical formulation would understand that drug content uniformity is important. (Tr. 783:14–784:3). With respect to web-coating generally, an objective of the process could be to produce films with a specified homogeneity and thickness. (JTX-462 at 46, 157).

(a) Schmidt

Plaintiffs argue that Schmidt did not disclose films meeting the 10% drug content uniformity limitation or teach how to make such films.

Schmidt discloses a regulatory requirement for 5–10% drug content uniformity. (JTX-448 at 1:63–68). Schmidt reports that a certain production method yields a "reproducible constant weight [that] is only ± 2.5% for 20 g/m^2 and approximately ±10% for 1 g/m^2 over entire surface." (JTX-448 at 6:1–3). Schmidt reports that using this method yields an accuracy of "±5% and is dependent on the coating thickness . . . . Within the individual product runs, it is possible to achieve a weight tolerance per surface unit down to ±1%." (JTX-448 at 6:37–42).

Claim 62 of the '514 patent requires that the "matrix has a viscosity sufficient to aid in substantially maintaining non-self-aggregating uniformity of the active in the matrix." (JTX-2 at

73:53–54). The '514 patent explains that weight measurements of individual dosages can show that the distribution of components within a film is consistent and uniform. (JTX-2 at 42:25–33). Dr. Amiji concedes that there is "no measure of actual drug content" in any Schmidt film. (Tr. 1612:1–6).

Schmidt describes a matrix viscosity between 30 and 10,000 centipoise to ensure uniformity at least as to the wet matrix. (Tr. 1563:13–1564:2; JTX-448 at 4:50–59). Yet, as Dr. Langer testified, that portion of Schmidt (JTX-448 at 4:50–59) does not talk about the drug content uniformity of the final dried film. (Tr. 1726:1–1727:1). Thus, while the '514 patent notes that Schmidt addressed the "problems of self-aggregation leading to non-uniformity of a film" (JTX-2 at 2:47–49), this is not the same as saying that Schmidt solved the issue of drug content uniformity.

Morales & McConville (2011) stated, "Yang et al. reported that using the protocol proposed by Schmidt did not render uniform films." (PTX-180 at 5). I agree. Morales, Su & McConville (2013) acknowledged that Yang was teaching drying times as one factor that will affect particle agglomeration. (PTX-184 at 8; Tr. 1691:18–1693:9).

In light of this contradictory evidence, a POSA would not understand Schmidt as disclosing how to achieve drug content uniformity.

(b) Chen

Plaintiffs argue that Chen (1999) does not teach how to achieve 10% drug content uniformity. It is doubtful drug content uniformity was even a goal of Chen. (Tr. 1701:17–1702:3). Further, a POSA would find that Chen did not adequately teach how to make uniform films in the first step in the manufacturing process of mixing and removal of air bubbles. Chen reports that a hydrocolloid was dissolved in water under agitated mixing to form a uniform and

viscous solution. Additional ingredients were added until they were uniformly dispersed or dissolved. (JTX-24 at 12:3–8). Example 1 is a film that was prepared through this method and Table 4 reports that the film had uniformity within plus or minus 5%. (Tr. 1585:14–1586:7; JTX-24 at 13:34–48).

Dr. Amiji testified that Example 1 did not have an active ingredient, but that inclusion of the active ingredient would still lead to a uniform film. (Tr. 1586:11–22). Dr. Langer testified that Table 4 relates to a placebo film, meaning there is no active drug in the film. That is the primary reason why Chen does not demonstrate drug content uniformity. (Tr. 1706:1–18). In light of Dr. Langer's testimony, I am not persuaded that the inclusion of the active would still lead to a uniform film.

I also note Defendants' expert Dr. Donovan tried to make the films of Example 1 in Chen as in the order laid out in Chen. She implemented a method where HPMC is added to the water first and all of the remaining components were to be added to the gel after that. She could not obtain a uniform gel dispersion and a homogeneous system under that approach. (Tr. 1500:7–18, 1617:15–1618:7, 1626:15–1628:1). Thus, I conclude that Example 1 and Table 4 do not teach drug content uniformity.

Dr. Amiji testified that the release profiles in Figure 5 of Chen support uniformity because the error bars at the ten-minute time points are within ten percent variance. (Tr. 1589:14–16). Figure 5 is as follows.

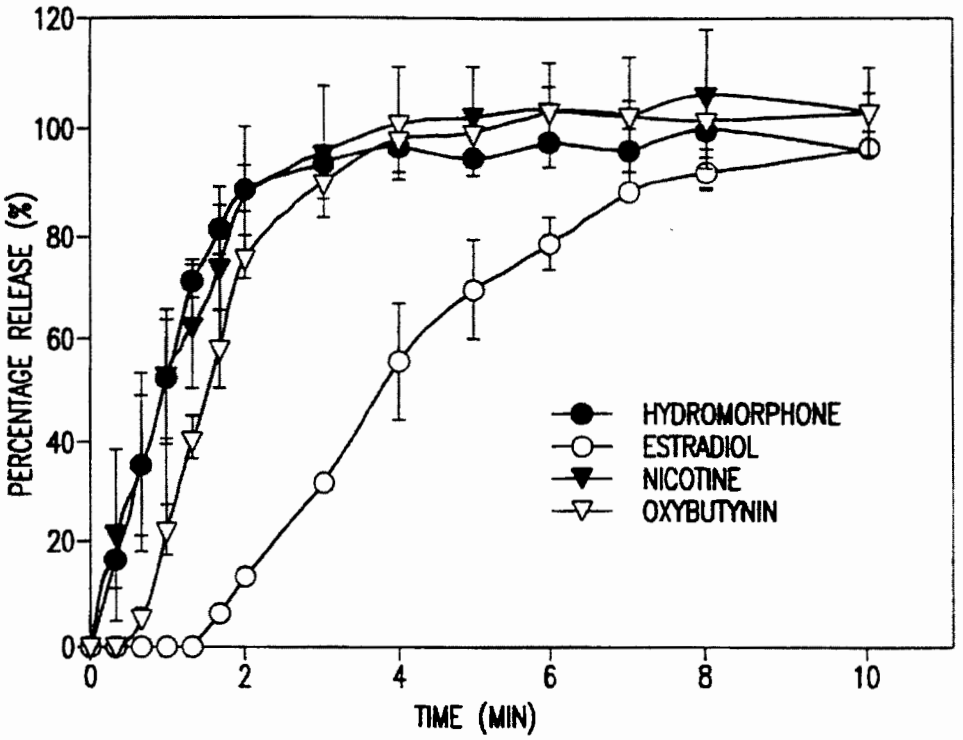

FIG.5

(JTX-24 at 7, Fig. 5). It is not clear what the error bars in Figure 5 in Chen represent. (*See* Tr. 1619:6–21 (Dr. Amiji), 1703:18–22 (Dr. Langer), 1648:4–23 (Dr. Levin)). In my prior decision, I did not say that Defendants necessarily needed to show the films of Chen meet the three sigma rule. (C.A. No. 13-1674, D.I. 446 at 39–40). And I do not require that now. Nonetheless, given Figure 5's vague presentation of data, a POSA would not read Figure 5 as disclosing drug content uniformity.

Example 13 of Chen is a human pharmacokinetic study that was done with sildenafil. (Tr. 1590:1–4). Dr. Amiji testified that one would not carry out a human pharmacokinetic study unless there were regularly uniform films and that it would be meaningless to compare the data because the dosages of the product would be different. (Tr. 1590:16–1591:3). Plaintiffs criticize Example 13 for failing to explicitly disclose 10% drug content uniformity. They also argue that there is no evidence Example 13 actually met any particular regulatory requirement or whether

the study was FDA-approved. On the whole, however, I am persuaded that Example 13 supports Defendants' argument.

Chen discloses a homogeneous mixture with a viscosity of 500-15000 centipoise. (JTX-24 at 11:7–9). Dr. Donovan obtained, following the process of Example 4 of Chen, a visco-elastic solid film after four minutes of drying. (Tr. 1577:10–1581:2, 1505:2–11, 1509:6–12). At the minimum, Dr. Donovan's testing does show that Chen utilized a drying method that rapidly locked in active ingredients. (Tr. 1505:2–11). There is evidence, however, that Dr. Donovan's dried films exhibited significant variation in thickness, suggesting lack of uniformity. (Tr. 1519:21–1520:9, JTX-479 at 15). I am thus not persuaded that Dr. Donovan's findings are meaningful. (*See* Tr. 1500:7–18, 1617:15–1618:7, 1626:15–1628:1).

Considering everything, Defendants fail to demonstrate that Chen achieved or showed how to achieve drug content uniformity.

c) Motivation to Combine

Defendants argue that a POSA would have been motivated to combine known techniques to achieve drug content uniformity. A POSA would only have access to an engineer or scientist with one to three years of relevant experience manufacturing and optimizing various types of film products using coating and drying processes. A POSA would not be motivated to combine the prior art to achieve drug content uniformity primarily because the POSA would have limited knowledge, and access to knowledge, of drying techniques. Such a person would not have the significant skill of Dr. Gogolin. Furthermore, a POSA would not be motivated to combine Schmidt and Chen with the techniques in Strobush, especially given that Strobush is a step removed from the area of drug content uniformity. Strobush is not directed to drug content uniformity. (Tr. 1727:7–9). It is directed to surface defects called mottle. (Tr. 1727:11–16).

Having a lack of mottle does not necessarily mean that a film has the required drug content uniformity. (Tr. 1727:17–21).

d) Reasonable Expectation of Success

Defendants argue that a POSA would have had a reasonable expectation of success at achieving drug content uniformity. Based on the facts discussed above, a POSA would not have a reasonable expectation of success. Such a person would not have a strong grasp of prior web coating techniques to apply in the context of pharmaceutical films. A POSA would not have the experience of Dr. Gogolin with photographic film particulates, and bring it to bear into the context of pharmaceutical films. I am not persuaded that such a POSA would be able to successfully resolve the issues with air bubbles and rippling. A POSA would have to engage in substantial experimentation in adjusting the mixing parameters, drying profile, and viscosity of the matrix to achieve drug content uniformity. Adjusting some parameters would not be intuitive. (*See* Tr. 1391:22–1393:1). A POSA would not be able to successfully modify Chen and Schmidt to achieve drug content uniformity. A POSA would not have a reasonable expectation of success at achieving drug content uniformity.

e) Secondary Considerations of Nonobviousness

(1) Long-Felt Need and Failure of Others

Defendants acknowledge that various articles have recognized "general challenges to achieving drug content uniformity in pharmaceutical films." (D.I. 278 at p. 20). For example, Schmidt reported that drug content uniformity was a big issue. (Tr. 1672:3–11). Perumal (2008) discusses the difficulties for POSAs seeking to achieve uniform films. (PTX-182) Morales & McConville (2011) wrote, "Since the early development of medicated films, content uniformity has been a major challenge for the pharmaceutical scientist." (PTX-180 at 5). Kathpalia (2013)

noted that, "Dose uniformity is difficult to maintain." (PTX-179 at 2). Morales & McConville (2013) notes, "The main concern raised in the literature is the appearance of agglomerates upon drying of films." (PTX-184). Defendants' expert Dr. Rossman wrote in a 2009 book that "dosage per unit of use is critical and must be held to tolerances that are difficult to achieve with film manufacturing processes." (JTX-532 at 35).

In the previous trial, I stated the following:

> Reckitt argues that the asserted claims of the '514 patent are not obvious in light of objective considerations, including long-felt need, failure of others, and praise. (D.I. 406 at 18). Defendants effectively concede that there was a long-felt need for uniform pharmaceutical film formulations, but argue that Reckitt presented no evidence that the '514 patent met that need. (D.I. 396 at 30). Content uniformity, as Defendants note, continued to be a challenge in the context of cast films for years after the '514 patent's invention. (See Tr. 480:17–484:14; PTX215 at 1). Thus, long-felt need and failure of others do not support finding that the asserted claims are not obvious.

Reckitt Benckiser Pharm. Inc. v. Watson Labs., Inc., 2016 WL 3186659, at *17 (D. Del. June 3, 2016). Defendants argue that because Plaintiff relies on the same post-art publications and arguments, the same conclusion is warranted.

I take Defendants' argument to again concede that there was a long-felt need, and relatedly, a failure of others to achieve uniform pharmaceutical film formulations. In light of the citations recited above and Defendants' concession, I find that there is evidence of long-felt need and failure of others. Having thought about this issue some more and given that I am presented with a different case and record, I think that the '514 and '497 patents actually meet some of that need. Even if content uniformity remained a challenge in the context of cast films, I think the achievements of the '514 and '497 patents made it less of a challenge. This finding is corroborated by my discussion of praise below.

(2) Praise

Defendants acknowledge that MonoSol was the first to receive FDA approval for a pharmaceutical film product. (D.I. 278 at p. 3). Morales & McConville (2011) credits the inventors of the '514 and '497 patents for indicating that self-aggregation was the main reason for poor uniformity and showing how to solve that problem. (Tr. 1685:7–18). Perumal (2008) also credits the inventors for recognizing the same problem. (Tr. 1693:20–1694:3; PTX-182). Morales, Su & McConville (2013) credits the inventors for recognizing the extent of drying times as one factor that affects particle aggregation. (Tr. 1691:24–1693:9; PTX-184). Borges (2015) provides, "MonoSol, one of the pioneer companies in the oral film industry owns a protected drug delivery technology, PharmFilm®." (PTX-177 at 2). It states, "The success of the Reckitt Benckiser's prescription thin film proved the viability and value of this pharmaceutical form in the Rx market." (PTX-177 at 9). DRL prepared an internal memorandum stating, "Recently MonoSol has filed [a] patent application relating [to] rapidly dissolving films and methods of their preparation." (PTX-1012 at 16). It further provides, "The application covers various process[es] of preparing the film that yields uniform distribution of active (the advantageous factor which was not appreciated by the prior arts)." (PTX-1012 at 16).

Defendants argue that Plaintiffs fail to show nexus because the praise is for MonoSol generally or its patent portfolio, and not for these patents. Defendants argue that none of these examples even mention the asserted patents, let alone any claimed features. Defendants argue the internal memorandum refers to an unspecified MonoSol patent application, Borges (2015) does not mention drug content uniformity, and Morales, Su & McConville (2013) cites to various references, including Schmidt, for recognizing the extent of drying times as one factor that affects particle aggregation.

"A nexus between the merits of the claimed invention and evidence of secondary considerations is required in order for the evidence to be given substantial weight in an obviousness decision." *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 1327 (Fed. Cir. 2008). "[S]econdary considerations may presumptively be attributed to the patented invention only where the marketed product embodies the claimed features, and is coextensive with them." *Id.* at 1328.

Because Morales & McConville (2011), Perumal (2008), and Morales, Su & McConville (2013) give credit to the inventors for recognizing issues related to drug content uniformity, some weight is given to these articles. The fact that Morales, Su & McConville (2013) splits the praise with other references, such as Schmidt, detracts from its weight. Although the internal memorandum does not directly refer to a specific MonoSol patent application, the '497 patent is entitled, "Process for Making a Film Having a Substantially Uniform Distribution of Components," and the '514 patent is entitled "Uniform Films for Rapid Dissolve Dosage Form Incorporating Taste-Masking Compositions." These patents are sufficiently linked to the internal memorandum. Thus, the internal memorandum is given some weight. Borges (2015), although it does not mention drug content uniformity, praises PharmFilm®, which appears to be the marketed product of the patented invention. Thus, this article is given some weight as well.

f) Summary

Taking all of this evidence as a whole, Defendants have failed to demonstrate by clear and convincing evidence that the asserted claims of the '514 and '497 patents are invalid as obvious. A POSA would not find that Schmidt or Chen discloses how to achieve drug content uniformity. A POSA would not be motivated to combine known techniques to arrive at the claimed inventions. A POSA would not have a reasonable expectation of success in modifying

Schmidt or Chen to obtain the claimed inventions. The evidence of long-felt need, failure of others, and praise further supports the nonobviousness of the asserted claims of the '514 and '497 patents.

IV. CONCLUSION

For the foregoing reasons, Plaintiffs failed to meet their burden of showing that DRL infringes claims 62–65, 69, 71, and 73 of the '514 patent.[11] Plaintiffs failed to meet their burden of showing that DRL infringes claim 24 of the '497 patent. Plaintiffs failed to meet their burden of showing that Watson infringes claim 24 of the '497 patent. Plaintiffs failed to meet their burden of showing that Par infringes claim 24 of the '497 patent. Defendants failed to meet their burden of showing that the asserted claims of the '514 or '497 patents are invalid as obvious.

Plaintiffs are directed to submit three agreed-upon forms of final judgment within two weeks.

[11] I have not separately discussed the asserted dependent claims of the '514 patent, as the infringement and non-obviousness findings in regard to claim 62 require the same determination for the asserted dependent claims.