IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INDIVIOR INC., INDIVIOR UK LIMITED, and MONOSOL RX, LLC Plaintiffs; v. MYLAN TECHNOLOGIES INC., MYLAN PHARMACEUTICALS INC. and MYLAN N.V., Defendants.	Civil Action No. 15-cv-1016-RGA
RECKITT BENCKISER PHARMACEUTICALS INC., RB PHARMACEUTICALS LIMITED, and MONOSOL RX, LLC Plaintiffs; v. ALVOGEN PINE BROOK INC. Defendant.	Civil Action No. 15-cv-0477-RGA

MEMORANDUM OPINION

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ANDREWS, U.S. DISTRICT JUDGE:

Plaintiffs brought separate patent infringement actions against Mylan Technologies Inc., Mylan Pharmaceuticals Inc., and Mylan N.V., and Alvogen Pine Brook Inc., in 2015. (No. 15-0477-RGA, D.I. 1, D.I. 48; No. 15-1016-RGA, D.I. 1, D.I. 66).[1] The two cases were consolidated. (D.I. 140). On September 26, 2017, Plaintiffs and the Mylan Defendants entered into a Settlement Agreement, leaving Alvogen as the sole remaining defendant. (D.I. 242).

Alvogen filed Abbreviated New Drug Application ("ANDA") No. 205954, seeking approval for a generic version of the 2 mg/0.5 mg, 4 mg/1 mg, 8 mg/2 mg, and 12 mg/3 mg dosage strengths of Plaintiffs' Suboxone® sublingual film. (D.I. 211-1 at 5-6). Suboxone® sublingual film is indicated for maintenance treatment of opioid dependence. (*Id.* at 2). Since its FDA approval for certain dosage strengths in 2010, Suboxone® sublingual film has been exclusively manufactured in the United States by Plaintiff MonoSol and exclusively sold in the United States by Plaintiff Indivior Inc.[2] (*Id.*). Approval of additional dosage strengths followed in 2012. (*Id.*).

At issue in this case is the process for drying the sublingual film.

The Court held a bench trial September 26-27, 2017. Plaintiffs assert that Alvogen's ANDA submission constitutes infringement of claim 24 of U.S. Patent No. 8,900,497 ("the '497 patent"), and claims 62, 63, 65, 69, 71, and 73 of U.S. Patent No. 8,603,514 ("the '514 patent).

[1] All citations to "D.I. __" are to the docket in Civil Action No. 15-1016-RGA.

[2] Indivior Inc. was formerly known as Reckitt Benckiser Pharmaceuticals, Inc.

(Trial Transcript ("Tr.") 9:24-10:4; D.I. 235 at 1-2).[3,4] Alvogen does not argue that the asserted claims are invalid. (Tr. 5:4-15).

Independent claim 1 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.

(emphasis added). Dependent claim 24 of the '497 patent covers, "The process of claim 1, wherein said active is in the form of a particle."

Independent claim 62 and dependent claims 63, 65, 69, 71, and 73 of the '514 patent read as follows:

> **62.** A drug delivery composition comprising:

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[3] Plaintiffs also allege infringement of U.S Patent No. 8,017,150 ("the '150 patent"). However, Plaintiffs did not present any evidence at trial with respect to the '150 patent, and agree that it is not infringed under the Court's claim construction. (Tr. 6:21-8:9).

[4] The trial transcript is available on the docket at D.I. 281 and D.I. 282. It is consecutively paginated.

(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.

63. The drug delivery composition of claim 62, wherein the particulate active has a particle size of 150 microns or less.

65. The drug delivery composition of claim 62, wherein said variation of drug content is less than 5% by weight per film dosage unit.

69. The drug delivery composition of claim 62, wherein said taste-masking agent is present in the amount of about 0.1-30% by weight of the drug delivery composition.

71. The drug delivery composition of claim 62, wherein said active is selected from the group consisting of antimicrobial agents, non-steroidal anti-inflammatory drugs, anti-tussives, decongestants, antihistamines, expectorants, anti-diarrheals, H_2 antagonists, proton pump inhibitors, general non-selective CNS depressants, general non-selective CNS stimulants, selective CNS functional modifiers, anti-parkinsonism drugs, narcotics, analgesics, erectile dysfunction therapies, anti-pyretics, psychopharmacological drugs and combinations thereof.

73. The drug delivery composition of claim 62, wherein said active is an opiate or opiate derivative.

(emphasis added).

I. LEGAL STANDARD

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). 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).

For jurisdictional purposes, 35 U.S.C. § 271(e)(2)(A) defines filing an ANDA application for a drug covered by a patent as an act of infringement. 35 U.S.C. § 271(e)(2)(A); *see also Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997) ("[Section] 271(e)(2) provided patentees with a defined act of infringement sufficient to create case or controversy jurisdiction to enable a court to promptly resolve any dispute concerning infringement and validity.").

II. INFRINGEMENT OF THE '514 AND '497 PATENTS

A. Findings of Fact

1. Alvogen's proposed commercial manufacturing process for its ANDA product (hereinafter, "ANDA process") is designed to avoid the "rippling effect."

2. There is insufficient evidence for me to conclude that Alvogen's ANDA process uses unconventional drying.

3. The extent of bottom drying employed by Alvogen is conventional.

4. Drag bars used in Alvogen's ANDA process do not substantially dry films from the bottom, alone or in conjunction with any other bottom heat sources.

5. Contact between the web and lower plenum of the oven in Alvogen's ANDA process does not substantially dry films from the bottom, alone or in conjunction with any other bottom heat sources.

6. Air flow underneath the web in Alvogen's ANDA process does not substantially dry films from the bottom, alone or in conjunction with any other bottom heat sources.

7. There exist two plausible explanations for films produced using Alvogen's exhibit batch process and commercial process having equal moisture contents.

8. Alvogen does not infringe the "drying" limitation of the '497 patent or the "dried" limitation of the '514 patent.

9. Dr. Prud'homme's testimony that a viscoelastic solid results after about four minutes of drying is given little weight.

10. Dr. Fassihi's visual evidence demonstrating that Alvogen's mix remains a liquid after four minutes of drying is given little weight.

11. Alvogen does not infringe the "visco-elastic film" limitation of the '497 patent.

12. Alvogen conceded that its ANDA process meets the "rapidly evaporating" limitation of the '497 patent.

13. Alvogen does not infringe any asserted claim of the '497 and '514 patents.

B. Conclusions of Law

At trial, the parties stipulated that Alvogen infringes all limitations of the asserted claims except (1) the "dried" limitation of the '514 patent and "drying" limitation of the '497 patent, and (2) the "visco-elastic film" limitation of the '497 patent. (D.I. 235 at 2).

1. "Dried" and "Drying"

The Court construed the "dried" limitation of the '514 patent and "drying" limitation of the '497 patent to mean "dried without solely employing conventional convection air drying from the top." (D.I. 87 at 5, 8). The Court further clarified that this construction

> exclude[s] 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.

(D.I. 87 at 5-6, 8).

Plaintiffs make two separate arguments to show that Alvogen's ANDA process does not "solely employ[] conventional convection air drying from the top," and that therefore, Alvogen's ANDA products and process meet the "dried"/"drying" limitation. First, Plaintiffs argue that Alvogen's ANDA process does not employ "conventional convection air drying." (D.I. 262 at 4-10). Second, Plaintiffs argue that Alvogen's films are "substantially dried from the bottom," and therefore are not dried "solely . . . from the top." (*Id.* at 1, 10-12).

a. *"Conventional Convection Air Drying" Argument*

Plaintiffs argue that Alvogen's drying process is "extremely unusual," and thus does not employ "conventional convection air drying." (D.I. 262 at 1).

Alvogen's drying process is carried out using a flotation oven called the "S-Coater." (Tr. 24:1-2). Alvogen's film is coated onto a "web," which enters the right end of the oven.[5] (Tr. 36:12-19, 37:9-15). The film moves on the coated web from right to left, resulting in a dried product exiting at the left end of the oven. (Tr. 41:5-13, 41:18-42:2). Evaporated components are removed from the oven using exhaust ducts. (Tr. 42:17-21). By default, the film is suspended with bottom-sourced air. (Tr. 37:16-24). The oven also supplies hot air from nozzles above the web. (Tr. 355:7-9, 77:2-5). The oven is divided into four ten-foot zones, called zones 1, 2, 3, and 4. (Tr. 342:14-17). Three metal drag bars support the web between these zones. (Tr. 57:2-14, 58:3-6, 88:15-89:2). Each drag bar is located approximately 1.5 inches above the lower plenum, and is approximately 0.5 inches in diameter. (Tr. 57:18-22, 73:20-23, 90:1-3). The lower plenum of the oven is a conduit that brings air into the oven. (Tr. 43:10-16). Air travels from the lower plenum into the interior of each zone of the oven through a perforated surface. (Tr. 43:24-44:7). The lower plenum is located above the bottom of the oven. (Tr. 409:3-5). The S-Coater's temperature, air velocity, and web speed are controlled. (Tr. 423:4-424:10).

[5] The parties also refer to the "web" as the "web liner" or "liner."

The following figure depicts the drying process:

FIGURE 3B FROM PLAINTIFFS' OPENING EXPERT REPORT OF DR. JAMES F. GILCHRIST CONCERNING THE INSPECTION OF ALVOGEN'S MANUFACTURING PROCESS (May 17, 2017)

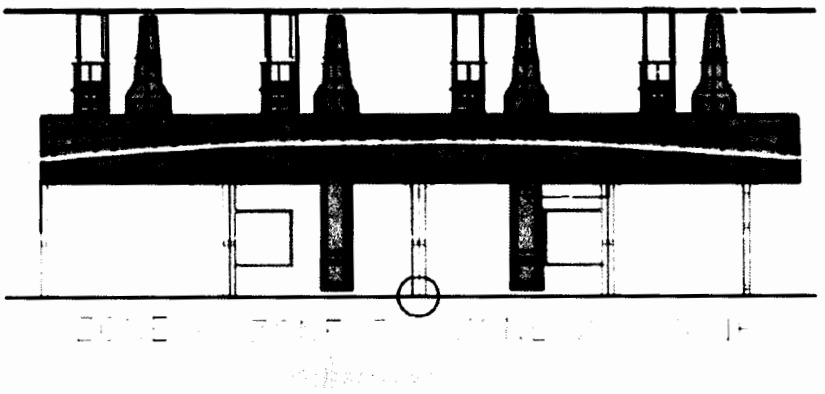

Figure 3B: Schematic of S-Coater oven showing each oven zone and intake duct in red, and exhaust ducts in blue (Ex. C, at ALV0001719) (excerpted and annotated).

(PTX-1398).

Alvogen argues that it has converted the S-Coater into a conventional top-down impingement dryer by disabling the bottom-sourced air and removing the fuses. (D.I. 267 at 3; Tr. 54:4-9, 347:13-20, 335:19-21, 335:2-5, 360:9-17, 437:5-17). With the bottom-sourced air having been disabled, Alvogen's dryer supplies hot air solely from nozzles above the web. (Tr. 355:7-9, 77:2-5).

Plaintiffs do not dispute that Alvogen made these modifications, but disagree that the modified oven is in fact a conventional top-down impingement dryer. (D.I. 262 at 5-6). Plaintiffs' expert Dr. Prud'homme testified that this modified flotation oven would have been "highly unconventional" in 2001, and that he has never seen another flotation oven so modified. (D.I. 262 at 6; Tr. 150:7-15, 161:13-19, 218:22-219:16, 238:20-240:5). Plaintiffs note, "Alvogen's own expert admitted he has never seen or heard of" disabling the bottom-sourced air. (D.I. 269 at 2). Plaintiffs argue that the converted dryer is "very different from a conventional

top-air-only impingement dryer" because the "web drags along the floor of the dryer in at least a portion of zones 1 and 4 because the bottom-sourced air has been disabled."[6] (D.I. 262 at 6; Tr. 57:18-58:2, 58:22-60:16; Tr. 409:10-22). Therefore, Plaintiffs say, Alvogen cannot contend that its dryer is "indistinguishable" from conventional top-down impingement dryers. (D.I. 269 at 2).

Alvogen's expert Dr. Carvalho, on the other hand, testified that "[b]asically the only source of heated air is the air coming out from the nozzles . . . . So I think the process is completely conventional." (Tr. 437:9-17). Dr. Carvalho agreed with Plaintiffs that there is contact between the web and the lower plenum, which occurs for approximately two feet of the 40-foot long dryer. (D.I. 267 at 9; Tr. 83:15-23). He further agreed that contact between the web and the bottom of the oven is "not conventional," and admitted that he had never seen contact between the web and either the bottom of the oven or the lower plenum.[7] (Tr. 408:18-22, 409:10-22). Nonetheless, Dr. Carvalho testified that any contact is "negligible," and is similar to contact made with metal rollers in other conventional impingement dryers. (Tr. 373:15-22; Tr. 419:20-420:19). Alvogen urges that Plaintiffs' argument improperly focuses on the conventionality of the *equipment* at the expense of focus on the conventionality of the *technique*. (D.I. 267 at 8-10).

My construction for the "dried"/"drying" limitation makes clear that it refers to drying technique, as opposed to drying equipment. (D.I. 87 at 5). It is therefore of no significance that Alvogen uses a piece of equipment that was manufactured to be something other than an actual top-down impingement dryer. For that reason, I find Dr. Prud'homme's testimony about the

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[6] Alvogen notes that Dr. Prud'homme observed that there was contact between the lower plenum only when the S-Coater door was open, but not when it was closed, as it is during the S-Coater's operation. (Tr. 84:4-10).

[7] However, he did not agree that contact between the web and the lower plenum is "not conventional." (Tr. 409:10-22).

conventionality of the equipment unpersuasive. Rather, I find Dr. Carvalho's testimony that Alvogen uses a modified flotation dryer to carry out a "conventional" technique more convincing. I also agree with Dr. Carvalho that any contact between the web and the lower plenum of the oven is negligible, and does not render Alvogen's drying process unconventional.

Plaintiffs' additional attempts to characterize Alvogen's drying process as unconventional are unavailing.

Plaintiffs argue that Alvogen's air drying process is not associated with the rippling effect, and therefore, is not "conventional." (D.I. 262 at 1, 6-7). The problem of the "rippling effect" "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." (D.I. 87 at 5-6). My construction of the "dried"/"drying" limitation indicates that "conventional convection air drying from the top" is often associated with the "rippling effect." (D.I. 87 at 5-6).

Plaintiffs note that Alvogen controls parameters to avoid the rippling effect, and argue that Alvogen has in fact succeeded in avoiding the rippling effect. (D.I. 262 at 8-9; Tr. 159:15-160:5, 161:5-12, 420:20-421:14, 423:4-424:2, 299:5-10, 300:4-10).

Alvogen agrees that it controls drying parameters to avoid the rippling effect, including air velocity, oven temperature, and web speed. (D.I. 267 at 12; Tr. 366:24-367:17, 214:19-215:7). However, it argues that these controls are "conventional." (*Id.*). Alvogen also contests that its process inherently prevents all rippling. Alvogen notes that the manufacturer of its ANDA product inspects for rippling defects, and points to testimony from the manufacturer's Rule 30(b)(6) designee that he had "no idea" if rippling occurred in the ANDA product. (D.I. 267 at 11-12; Tr. 297:22-298:14, 299:18-300:3). The designee testified that "there is evidence

that rippling may have occurred simply due to the air bubbles that express themselves on the surface of the film that [the manufacturer] produced." (*Id.*).

My construction left open the possibility that conventional convection air drying techniques could avoid the rippling effect. Plaintiffs' argument is results-oriented insofar as it puts the focus on whether the rippling effect is actually avoided, as opposed to whether conventional parameters are used to obtain that result. *See Medicines Co. v. Mylan, Inc.*, 853 F.3d 1296, 1306 (Fed. Cir. 2017) (rejecting a proposed construction of "efficient mixing" as "problematic because it amounts to a mere recitation of the results obtained from 'efficient mixing' rather than a definition of what the efficient mixing process is."). Accordingly, even if Alvogen's technique actually does avoid the rippling effect, which the parties dispute, that alone cannot render the technique unconventional.

Plaintiffs contest Alvogen's assertion that its controls to avoid the rippling effect, such as drying slowly and at low temperatures, are "conventional." (D.I. 269 at 4-5). Dr. Prud'homme testified that "it may have been known to control certain parameters to avoid rippling" in certain types of films, but not in the "pharmaceutical films, which [are] the basis or orientation of this patent . . . ." (D.I. 269 at 5; Tr. 214:12-215:7). Dr. Carvalho does not argue otherwise, but does emphasize that the "rippling" effect was known prior to 2001, and that controlling parameters to avoid drying too fast and at too high a temperature was "very well-known in the industry" to prevent defects. (D.I. 267 at 12; Tr. 366:24-367:15, 370:14-18; DTX-1316).

Dr. Prud'homme's testimony does not establish that Alvogen's process is unconventional. I construed the "dried"/"drying" limitation to mean "dried without solely employing conventional convection air drying from the top." (D.I. 87 at 5, 8). My construction does not limit "conventional convection air drying" to conventional convection air drying of

"pharmaceutical films." Dr. Carvalho's testimony establishes that Alvogen's parameter control techniques were conventional for drying films generally. Thus, under my construction, Alvogen's techniques are not unconventional. However, even if my construction did limit "conventional convection air drying" to conventional convection air drying of "pharmaceutical films," that would not render Alvogen's process unconventional. Lowering oven temperature and slowing drying speed were conventional controls for preventing the rippling effect and other defects in at least some films. Alvogen's parameter control techniques were sensible and well-known for use in films generally. As a result, the techniques were conventional for use in "pharmaceutical films." Thus, Dr. Prud'homme's testimony is not enough to persuade me that Alvogen's controls render the drying process as a whole, which is otherwise conventional, unconventional.

Separately, Plaintiffs argue that Alvogen's process is unconventional because it follows the patents' teaching that "multi-zone" drying can be used to avoid the rippling effect. (D.I. 262 at 8-9; '514 patent at 32:49-50; '497 patent at 28:29-31). However, the patent's mention of multi-zone drying does not alone render a process that employs multi-zone drying unconventional. Alvogen presented evidence that multi-zone dryers were conventional in 2001, and Dr. Prud'homme acknowledged that evidence. (D.I. 267 at 13; Tr. 339:21-340:5, Tr. 218:4-21; DTX-1350). Thus, Plaintiffs' multi-zone drying argument is unavailing.

b. *"Substantially Dried From the Bottom" Argument*

As to Plaintiffs' argument that Alvogen's films are "substantially dried from the bottom" and therefore do not "solely employ[] conventional convection air drying from the top," Plaintiffs point to three sources of bottom heat: (1) drag bars, (2) contact between the web and lower plenum of the dryer, and (3) air flow underneath the web. (D.I. 262 at 10-12).

The drag bars contact the web for less than 1.5 inches of the 40-foot length of the S-Coater. (D.I. 267 at 15; Tr. 90:4-13, 377:6-12). The drag bars do not provide independent heat, and are at ambient oven temperature. (Tr. 377:24-378:2). Accordingly, I find that the drag bars do not "substantially dry" Alvogen's films from the bottom.

Contact between the web and the oven's lower plenum occurs for about one foot in zone 1 and about one foot in zone 4. (D.I. 267 at 15; Tr. 371:17-20, 373:16-18, 83:15-23, 65:17-66:3). Heat transfer between two solid surfaces is a function of the contact pressure between the surfaces. (D.I. 267 at 15; Tr. 371:20-23). Dr. Carvalho calculated the contact force between the web and the lower plenum to be on the order of 10^{-4} megapascals, which causes heat transfer that Dr. Carvalho characterizes as "limited" and "completely negligible." (D.I. 267 at 15-16; Tr. 373:10-22). Plaintiffs criticize Dr. Carvalho for measuring this contact force when no film was on the web. (D.I. 269 at 7; Tr. 84:18-21). However, Plaintiffs' expert Dr. Gilchrist offered no competing calculation. To the contrary, Dr. Prud'homme testified that heat transfer is "making an incremental difference but . . . I don't believe that that contact is driving drying . . . in this Alvogen case." (Tr. 237:14-238:9). Accordingly, I am unconvinced that Plaintiffs have shown that these two feet of contact (out of the 40-foot length of the S-Coater) "substantially dry" Alvogen's films, alone or in conjunction with any other bottom heat sources.

Heat transfer to the film will cause drying. The amount of drying is proportional to the velocity of air in the oven. (D.I. 262 at 12; Tr. 355:24-356:2, 378:19-379:8). At trial, Dr. Gilchrist testified to a 3:1 ratio between the top air velocity and the bottom air velocity. (D.I. 269 at 7-8; Tr. 69:13-16, 66:4-69:20). This ratio comes from a measurement at one location in zone 1. (D.I. 269 at 8 n. 1; Tr. 69:13-16, 66:4-69:20). Plaintiffs argue the 3:1 ratio demonstrates "substantial" bottom drying. (D.I. 269 at 7).

Alvogen's expert Dr. Carvalho agreed that "there is heat transfer from underneath the web to the web [because] the air underneath the web is hotter than the web." (D.I. 262 at 11; Tr. 378:8-18). However, Alvogen disputes that this heat transfer results in "substantial" bottom drying. Alvogen argues that even with conventional top air impingement drying, "there is some incidental air flow that occurs underneath the web." (D.I. 267 at 14; Tr. 358:24-359:14). Alvogen notes that within zone 2, measurements indicate an air velocity as high as 814 feet per minute above the web, and as low as 21 feet per minute below the web—a 39:1 ratio. (D.I. 267 at 16; Tr. 114:19-115:3, 115:11-16).

Both parties argue that the other party cherry-picks numbers to obtain its ratio. (D.I. 267 at 16; D.I. 269 at 7). Plaintiffs also make two specific arguments that Alvogen's 39:1 ratio is wrong. First, they note that Alvogen's measurements come from two different locations within zone 2, whereas their own measurements come from a single location. (D.I. 269 at 8; Tr. 117:6-20). Second, they argue that Dr. Gilchrist selected his 3:1 ratio using maximum velocities measured above and below the web because they were "indicative of the magnitude of airflow with the way the probe is oriented," whereas Alvogen's selected ratios are unsupported. (D.I. 269 at 7-8; Tr. 69:21-24).

Even accepting Dr. Gilchrist's maximum velocity principle and Plaintiffs' critique of Alvogen's 39:1 ratio, Plaintiffs' 3:1 ratio is still cherry-picked to best demonstrate "substantial" bottom drying. For example, at the end of zone 2, the maximum velocity measured under the web is 66 feet per minute. (PTX-1414). At the same location above the web, the maximum velocity is 761 feet per minute. (PTX-1413). This is a ratio of over 11:1. This ratio, contrasted to the 3:1 ratio at the end of zone 1, indicates considerable variability in the bottom air drying. Thus, any drying from the bottom has not been shown to be controlled or substantial.

Alvogen further notes that Dr. Gilchrist was unable to use his anemometer[8] to measure velocity underneath the web in many parts of the dryer. Thus, argues Alvogen, Dr. Gilchrist's air velocity data does not cover the entirety of the oven. (D.I. 267 at 16; Tr. 82:15-84:22). This casts further doubt on Plaintiffs' argument that it has shown that Alvogen's process employs "substantial" bottom drying.

Given the variation in, uncertainty surrounding, and insubstantiality of Dr. Gilchrist's air velocity measurements underneath the web, as well as the insubstantiality of drying done by the drag bars and contact between the web and the lower plenum of the oven, I agree with Alvogen that any bottom drying during its ANDA process is at most an insubstantial amount. Any dryer that "solely" employs "conventional convection air drying from the top" will result in *some* drying from the bottom. Accordingly, Plaintiffs have not demonstrated "substantial" bottom drying such that Alvogen's dryer can be said to employ anything but "conventional convection air drying from the top."

Separately, Plaintiffs argue that Alvogen's exhibit batch process and its proposed commercial process "produce substantially identical films with substantially the same moisture content," and therefore, "the two processes deliver the same total amount of drying." (D.I. 262 at 11). In the exhibit batch process, the S-Coater's bottom air nozzles produced hot air. (Tr. 50:24-53:10). In the commercial process, on the other hand, the bottom air nozzles are disabled. (Tr. 54:4-9). All other drying parameters, including web speed and nozzle temperature, are the same. (Tr. 56:13-18, 140:21-142:2). Thus, disabling the dryer's bottom air nozzles does not result in a different product. Plaintiffs argue that the exhibit batch process substantially dries

[8] An anemometer is a tool used to measure air velocity. (Tr. 93:11-14).

films from the bottom.[9] Plaintiffs argue that it follows that, "the air flow below the web [also] provides significant convective bottom drying in Alvogen's commercial process." (D.I. 262 at 12).

Alvogen responds that Plaintiffs' argument is based on unfounded assumptions, including the assumption that "the films produced using the exhibit batch process complete drying at the same rate as those produced using the commercial drying process." (D.I. 267 at 17). Alvogen's expert Dr. Carvalho testified that the equivalent moisture contents of the exhibit and commercial films might be due to the films being substantially dried at some point before reaching the end of the oven, meaning the exhibit and commercial processes are not necessarily comparable. (D.I. 267 at 17; Tr. 432:8-433:1).

The exhibit batch and commercial processes produce a like product. It does not necessarily follow, however, that the drying processes are alike. *Medicines Co.*, 853 F.3d at 1306. I agree with Alvogen that Plaintiffs' argument is based on an unfounded assumption. There exist two plausible explanations for the equal moisture contents of films produced using the exhibit batch and commercial processes. Thus, Plaintiffs' comparison between Alvogen's exhibit batch and commercial processes fails to demonstrate that Alvogen's commercial process does not "solely" employ drying from the top. It does not change my conclusion that Plaintiffs have not demonstrated "substantial" bottom drying.

For these reasons, I find that Plaintiffs have not met their burden of proving by a preponderance of the evidence that Alvogen's ANDA products and process meet the "dried"/"drying" limitation, and therefore have not proven that Alvogen infringes any of the

[9] Alvogen does not agree that the exhibit batch process substantially dries films from the bottom, arguing that there is no evidence to support a 50% bottom drying contribution. (D.I. 267 at 17). This dispute is not dispositive. Accordingly, I need not resolve it.

asserted claims.

2. "Visco-Elastic Film"

The "visco-elastic film" limitation appears in claim 1 of the '497 patent, from which asserted claim 24 depends. Claim 1 requires as the third step of the process:

> (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*;

(emphasis added). The Court construed the phrase "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" 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 individual dosage units do not vary by more than 10% from the intended amount of the active for that dosage unit." (D.I. 82 at 3). Thus, the "visco-elastic film" limitation requires "form[ing] a viscoelastic solid film."

Alvogen's expert Dr. Fassihi conducted rheological experiments on batches of Alvogen's product for the purpose of responding to Plaintiffs' now-abandoned thermogravimetric analysis (TGA) experiments. (D.I. 267 at 22; Tr. 190:22-191:2, 459:19-460:15). The parties agree that prior to entering the S-Coater, Alvogen's mix is a liquid. (D.I. 267 at 19; Tr. 292:18-24). The liquid mix in Dr. Fassihi's experiments started with an actual water content of 75.6%. (D.I. 267 at 19; Tr. 457:8-10). Using zones 1 and 2 of the S-Coater, Dr. Fassihi dried one sample of the liquid mix for four minutes at 80 °C and another sample for four minutes at 90 °C. (D.I. 267 at 19; Tr. 457:4-13, 458:1-17; DTX-1536). The temperature of the top air in zones 1 and 2 of

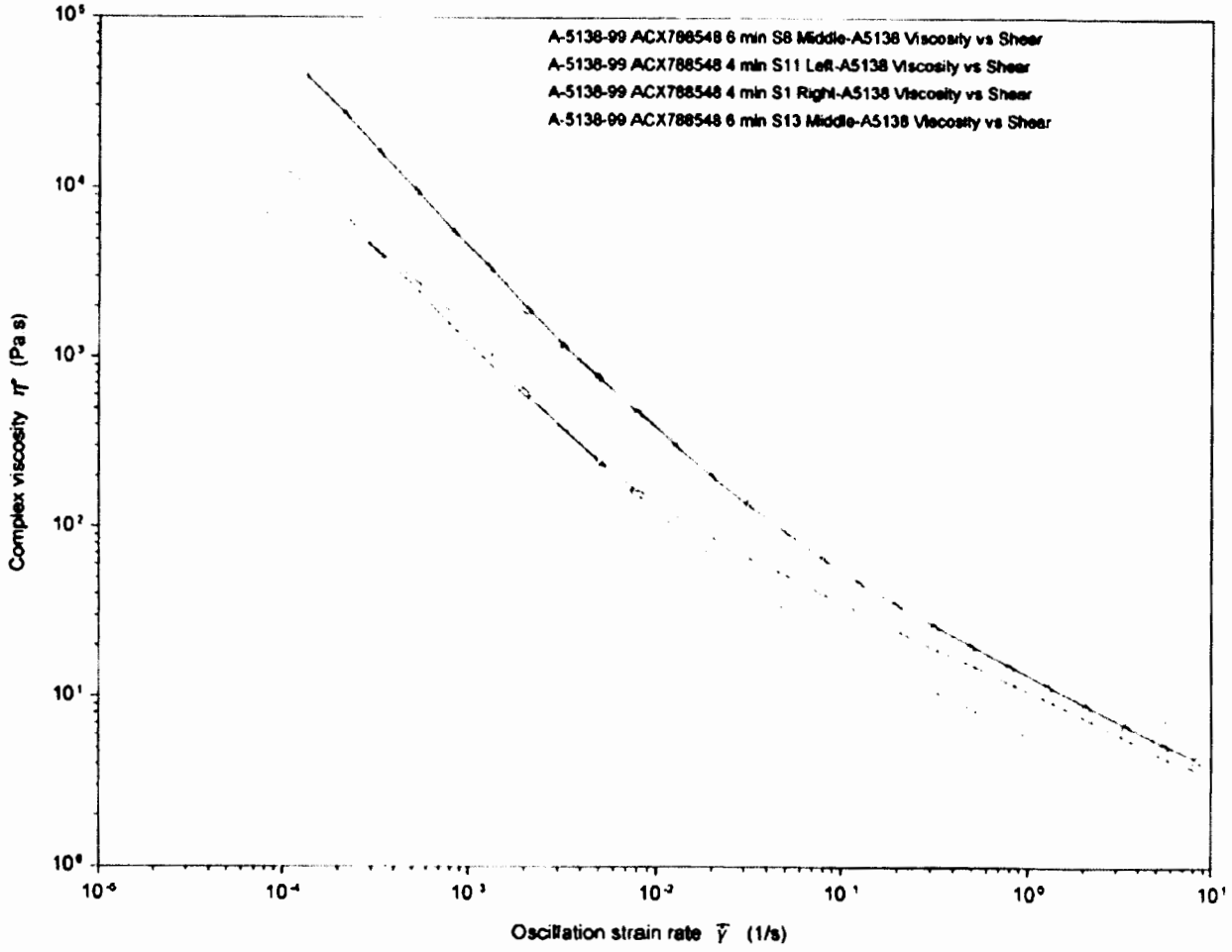
Alvogen's ANDA process is approximately 80 °C.[10] (Tr. 350:17-19, 121:4-19; D.I. 262 at 10). The drying reduced the water content to 72.0% and 71.0%, respectively. (D.I. 267 at 19; Tr. 457:4-13, 458:1-17; DTX-1536). Plaintiffs contend that at some point during this four minute window, and at some point between a moisture content of 75.6% and 72.0%/71.0%, the liquid mix became a viscoelastic solid. (Tr. 293:1-22). Dr. Fassihi also performed the same two experiments, but measuring the moisture content after six minutes of drying. (D.I. 262 at 15; Tr. 190:15-18, 448:12-18, 449:11-451:4, 498:24-499:5, 500:12-16, 501:21-502:2; DTX-1536).

From the data, Dr. Fassihi calculated the "complex viscosity"[11] of the four different Alvogen film samples, dried for four or six minutes at either 80 °C or 90 °C. Dr. Fassihi then plotted the "complex viscosity" of each sample against the oscillation strain rate, or shear rate. (D.I. 262 at 15; Tr. 194:2-20, 198:21-199:15; 465:10-20; PTX-1388).

[10] More specifically, the temperature is 80 ± 10 °C. (D.I. 262 at 9; PTX-1052-0010).

[11] "Viscosity" is defined as "stress" divided by "shear rate." (Tr. 174:5-8). "Stress" is force per area on a material. (Tr. 173:15-18). "Strain" is deformation of a material, or how far the material is moved. (Tr. 173:5-14). "Strain rate" is how fast that deformation or motion occurs. (*Id.*). Dr. Fassihi identified "strain rate" as "shear rate." (Tr. 173:10-14). Dr. Fassihi imposed a "shear rate," measured the "stress," and calculated a specific type of "viscosity" called "complex viscosity." (Tr. 174:9-12, 194:10-16). "Complex viscosity" is used interchangeably with "viscosity" in this opinion.

The plot is depicted below:



(PTX-1388).

Plaintiffs' expert Dr. Prud'homme testified that when "viscosity" is plotted against shear rate, a viscoelastic solid will always have a straight-line region in which the slope is -1 or less, while a viscoelastic liquid will always have a slope greater than -1.[12] (D.I. 262 at 15-16; D.I. 269

[12] Separately, Plaintiffs state, "The signature of a viscoelastic solid, what distinguishes it from a viscoelastic liquid, is a yield stress—a particular level of stress at and above which a viscoelastic material deforms or flows." (D.I. 262 at 13-14). However, as Alvogen notes, Plaintiffs do not identify a yield stress for the samples. (D.I. 267 at 27-28; D.I. 269 at 14). Rather, Plaintiffs argue that a viscoelastic solid, which has a yield stress, is signified by a slope of -1 or less. (D.I. 269 at 14). Thus, I do not separately consider Plaintiffs' yield stress argument.

at 12-14; Tr. 175:23-176:13). Alvogen challenges this assertion, arguing, "Plaintiffs provided no basis whatsoever, and cited no authority, for their argument about the meaning of a slope less than -1," besides the testimony of Dr. Prud'homme himself. (D.I. 267 at 24-25).

Plaintiffs note that Dr. Prud'homme used Dr. Fassihi's data and plot to calculate a slope of -1.09 in the low-stress region of the graph for both four-minute samples. (D.I. 262 at 16; Tr. 245:18-24, 246:5-12, 247:22-248:3, 253:11-13). Dr. Prud'homme's calculations, argue Plaintiffs, confirm that "Alvogen's material is a viscoelastic solid" after four minutes of drying. (D.I. 262 at 16).

Plaintiffs argue that Dr. Prud'homme's graphical analysis must be correct, because Dr. Prud'homme "used a standard and accepted way of measuring the slope of a plot." (D.I. 262 at 17). He "used a ruler to draw a line in [the low-stress] region" of the plot. (D.I. 262 at 16-17; Tr. 204:1-4, 205:2-4, 245:16-24, 246:5-12, 247:8-249:12, 250:23-251:24, 255:2-4). Plaintiffs further argue that the best-fit line for the data confirms Dr. Prud'homme's manual graphical analysis. (D.I. 262 at 17-18; 204:5-20, 206:17-207:4, 246:24-247:7, 249:13-19; PDX-337).

Alvogen attacks Dr. Prud'homme's conclusion on three grounds.

First, Alvogen notes that Dr. Prud'homme did not maintain his work product for his slope calculations. (D.I. 267 at 25-26; Tr. 244:5-245:1, 254:3-255:4). Alvogen argues that it is therefore impossible to analyze or verify Dr. Prud'homme's slope calculations. (D.I. 267 at 25). Because Dr. Prud'homme's work product is missing, Plaintiffs rely on a trial demonstrative (PDX-337), which Plaintiffs say is an "enhanced" version of Dr. Fassihi's original plot.[13] (*Id.* at 26; Tr. 195:13-196:15). Alvogen notes that Dr. Prud'homme is unsure whether this "enhanced"

[13] PDX-337 is not in the record, and is not evidence. It is an "annotated" version of PTX-1388, which is in the record. (D.I. 262 at 17).

demonstrative may have been altered by photocopying or changed image resolution. (D.I. 267 at 26; Tr. 250:23-251:2).

In response, Plaintiffs note that Alvogen "cites no evidence that the graph was in fact altered," and that Dr. Prud'homme testified that the enhanced graph was the "graph that [he] used" to calculate slope. (D.I. 269 at 15; 197:11-198:6).

Second, Alvogen notes that the temperature of the film in the S-Coater—approximately 30 °C to 40 °C[14]— is higher than the 25 °C temperature at which Dr. Fassihi collected the viscosity data relied on by Dr. Prud'homme. (D.I. 267 at 23; Tr. 465:10-20, 470:23-471:19). Dr. Fassihi testified that even a small difference in temperature will have a "significant effect" on the viscoelastic properties of the samples. (Tr. 467:3-468:1). Thus, argues Alvogen, the data is reliable only as a response to Plaintiffs' TGA testing, and not for the purpose for which Dr. Prud'homme used it. (D.I. 267 at 23; Tr. 467:11-15).

Plaintiffs do not disagree that the temperature at which the rheological testing was conducted is lower than the temperature of the film in the S-Coater after four minutes of drying. Rather, Plaintiffs note that Dr. Prud'homme testified that temperature is not a critical variable, and that the "very small temperature difference" would not cause a "substantial difference in the rheology" of the samples. (D.I. 262 at 20-21; Tr. 282:8-19).

Third, Alvogen argues that Dr. Fassihi was "only able to measure a single sample at a particular time and temperature" due to time constraints. Therefore, according to Dr. Fassihi, Dr. Prud'homme's slope calculations that rely on that single sample are not "statistically

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[14] The parties disagree as to the approximate temperature of the film in the S-Coater after four minutes. Alvogen estimates it to be 40 °C, whereas Plaintiffs estimate it to be as low as 30 °C. (D.I. 267 at 23; D.I. 262 at 20). Neither Dr. Prud'homme nor Dr. Fassihi measured the temperature. (Tr. 512:1-3, 282:11-13). Thus, while I accept that it is in the 30 °C to 40 °C range, to be any more precise would be simply to speculate.

significant." (D.I. 267 at 23-24; Tr. 471:21-472:20). Dr. Fassihi testified that he always asks the "students in [his] lab . . . to [use] three samples to make it statistically significant and valid." (Tr. 472:3-8). Alvogen argues that the lack of data points is especially problematic given that "reasonable experts can and do disagree regarding the slope calculation and where to place to best fit line to measure the slope." (D.I. 267 at 26; Tr. 476:2-6). Alvogen notes that Dr. Fassihi in fact measured a slope between -1 and 0 using Dr. Prud'homme's ruler method of slope measurement. (D.I. 267 at 26-27; Tr. 476:17-20).

Plaintiffs respond with two arguments.

First, Plaintiffs argue that Dr. Fassihi "had no issue with relying on a single sample and did so himself in his expert report." (D.I. 262 at 21). However, Alvogen in turn notes that Dr. Fassihi used his measurements for a purpose different than determining the slope of the viscosity curve. He measured viscosity in response to the TGA experiments later abandoned by Plaintiffs. (D.I. 267 at 24; Tr. 459:23-460:15). A single sample was sufficient for Dr. Fassihi's original purpose, but is not sufficient for Dr. Prud'homme's purpose, argues Alvogen. (D.I. 267 at 24).

Second, Plaintiffs argue that Dr. Fassihi's data involves multiple samples. (D.I. 262 at 21-22). More specifically, Plaintiffs argue that Dr. Prud'homme found a slope of -1.09 for both of the two four-minute samples. (D.I. 262 at 21; Tr. 203:12-204:9, 245:5-12, 245:18-24, 246:5-12, 247:22-248:3, 253:13-14). However, this argument does not impact or respond to Alvogen's contention that Dr. Prud'homme's sensitive slope calculations are not statistically significant. Dr. Prud'homme performed one calculation for a sample dried for four minutes at 80 °C, and another calculation for a sample dried for four minutes at 90 °C. Claim 1 of the '497 patent specifies that the "visco-elastic film" limitation must be met after "the first 4.0 minutes" of drying. Thus, Dr. Prud'homme performed slope calculations for, at most, two relevant

samples.[15] This falls short of the three samples Dr. Fassihi testified are required for statistical significance. Plaintiffs do not argue that Dr. Prud'homme's slope calculations are statistically significant.

Plaintiffs' sole piece of evidence that purports to establish infringement of the "visco-elastic film" limitation is Dr. Prud'homme's slope calculation.

Even accepting Dr. Prud'homme's testimony that a slope of -1 or less signifies a viscoelastic solid as correct despite his lack of supporting citations, Dr. Fassihi testified that Dr. Prud'homme's slope calculations are not statistically significant. Plaintiffs do not dispute this piece of Dr. Fassihi's testimony. I agree with Alvogen that Dr. Prud'homme's manual slope calculations lack sufficient data points to be statistically significant. That Dr. Fassihi also relied on a single sample for each time and temperature for a related but ultimately different purpose does not affect my conclusion about the sufficiency of Dr. Prud'homme's own calculations.

I also find Dr. Prud'homme's manual method for calculating slope to be imprecise. Dr. Prud'homme did not use a linear regression to calculate slope. Rather, he "used a ruler to draw a line" through points. (D.I. 262 at 16). Dr. Prud'homme measured a slope of -1.09 for both four-minute samples. (*Id.*). Dr. Fassihi, on the other hand, measured a slope between -1 and 0 using Dr. Prud'homme's manual ruler method. (D.I. 267 at 26-27; Tr. 476:17-20). That each expert employed this same method, yet achieved different outcomes, establishes imprecision. This imprecision diminishes the weight of Dr. Prud'homme's slope calculations.

Additionally, Dr. Fassihi took his rheological measurements at 25 °C. In Alvogen's ANDA process, the temperature of the film in the S-Coater after four minutes of drying is 30 °C

[15] Because the approximate temperature of the top air in zones 1 and 2 of Alvogen's ANDA process is 80 °C, I give lower weight to Dr. Prud'homme's slope calculation for the 90 °C sample.

to 40 °C. Thus, the temperature of the samples measured by Dr. Fassihi was lower than the actual temperature of the ANDA product after four minutes of drying in the oven. Dr. Fassihi testified that even this small difference in temperature will have a "significant effect" on the viscoelastic properties of the samples. (Tr. 467:3-468:1). Dr. Prud'homme, on the other hand, testified that the "very small temperature difference" will not cause a "substantial difference in the rheology" of the samples. (Tr. 282:8-19). I find that the temperature difference indicates that Dr. Fassihi's measured viscosities differ at least somewhat from the ANDA product's actual viscosity after four minutes of drying. This further diminishes the weight of Dr. Prud'homme's slope calculations, which rely on Dr. Fassihi's viscosity measurements.

I therefore cannot say it is more likely than not that Dr. Prud'homme's slope calculation of -1.09 represents a true value that demonstrates the presence of a viscoelastic solid.

However, I do not believe that Dr. Prud'homme's missing work product puts into question the reliability of his slope calculation. Dr. Prud'homme testified that the trial demonstrative (PDX-337) is the same as the plot he used to calculate slope. Alvogen does not provide any specific evidence that the plot was altered. I have no doubts that his testimony accurately recounted what he did.

Plaintiffs have therefore failed to meet their burden of proving infringement of this limitation by a preponderance of the evidence. *See SmithKline Diagnostics, Inc.*, 859 F.2d at 889.

To further disprove infringement. Alvogen affirmatively argues that "visual evidence confirms that Alvogen's mix remains a liquid after four minutes of drying." (D.I. 267 at 20-21). Dr. Fassihi sampled the Alvogen material from the S-Coater after four minutes of drying at 80 °C and 90 °C. Alvogen argues that these videos (DTX-1562-63; DTX-1565-68) show the

material flowing, pointing to discoloration at the edges of the slip sheet. (D.I. 267 at 20-21; Tr. 476:21-478:8, 483:1-8). Plaintiffs do not dispute this discoloration, or that the material flowed. Instead, Plaintiffs argue that the material is not a liquid, but rather a viscoelastic solid that has been fluidized. (D.I. 262 at 18). The videos do not show Alvogen's material flowing to fill the gaps of Dr. Fassihi's spatula, and the flow occurs only after "significant stress" has been applied. (D.I. 262 at 18-19; D.I. 269 at 10-11; Tr. 527:20-528:5 (showing that the spatula streaks have not been filled with flowing film material), Tr. 179:10-180:4, 207:16-21 (explaining that at high stress, a viscoelastic solid can become fluidized), Tr. 272:18-273:11 (explaining that gravity could cause said high stress)). Therefore, say Plaintiffs, the visual evidence is consistent with a viscoelastic solid material that has been fluidized due to high stress. (D.I. 269 at 10-11; D.I. 262 at 19; Tr. 186:10-13). Plaintiffs argue this means, "Dr. Fassihi's videos and related visual observations do not provide any information relevant to" the infringement inquiry. (*Id.*). Given that there exist two equally plausible explanations for the visualized flow—the mix remains a liquid, or the mix is a viscoelastic solid that has been fluidized—I do not find that the visual evidence tends to disprove infringement of this limitation. It therefore has no impact on my conclusion.

Separately, Alvogen makes an argument that its process does not meet a different part of the third claim limitation. Claim 1's third limitation in part requires "rapidly evaporating at least a portion of said solvent upon initiation of drying to form a viscoelastic film within about the first 4.0 minutes." Alvogen argues that its liquid mix loses between 4% and 6% of water during the first four minutes of drying, but loses approximately 67% of water during the next 14.8 minutes of drying. (Tr. 290:10-24). Thus, asserts Alvogen, "drying" during the first four minutes is not "rapid" "in the plain and ordinary sense of the word." (D.I. 267 at 29). The

parties' stipulation moots this argument. (D.I. 235). They agreed that based on the Court's claim construction, Alvogen's ANDA process "includes all limitations of the asserted claim of the '497 Patent except for the 'drying' and 'viscoelastic film' limitation`ns." (*Id.* at 2). In doing so, the parties treat "drying" and "visco-elastic film" as separate limitations. The claim recites "drying" in between "rapidly evaporating" and "visco-elastic film." Thus, by implication, the "rapidly evaporating" limitation is separate from the "visco-elastic film" limitation. Furthermore, the parties' stipulation provides a cross-reference to *Reckitt Benckiser Pharm. Inc. v. Dr. Reddy's Labs. S.A.*, No. 1:14-cv-01451-RGA, Trial Op. (D.I. 312) (D. Del. Aug. 31, 2017) and its treatment of the two disputed limitations. (D.I. 235 at 2). In that case, the "visco-elastic film" limitation was in no way about "rapid[ity]." Therefore, Alvogen has conceded that its ANDA process meets the "rapidly evaporating" limitation.

For these reasons, I find that Plaintiffs have not met their burden of proving by a preponderance of the evidence that Alvogen's ANDA process meets the "visco-elastic film" limitation, and therefore have not proven that Alvogen infringes claim 24 of the '497 patent.

III. CONCLUSION

Plaintiffs have not proven by a preponderance of the evidence that Alvogen infringes the asserted claims of the '497 and '514 patents.

Plaintiffs should submit an agreed upon form of final judgment within two weeks.