IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, LLC, FOREST LABORATORIES HOLDINGS, LTD., and ALLERGAN PHARMACEUTICALS INTERNATIONAL LTD., Plaintiffs, v. SIGMAPHARM LABORATORIES, LLC, et al., Defendants.	)	Civ. No. 14-1119- MSG CONSOLIDATED

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OPINION

Dated: November 15, 2018
Wilmington, Delaware

GOLDBERG, MITCHELL S., District Judge

I. INTRODUCTION

This Hatch-Waxman patent infringement action revolves around an Abbreviated New Drug Application ("ANDA") filed by Sigmapharm Laboratories, LLC ("Sigmapharm") seeking approval to market a generic version of Saphris®, a sublingual asenapine maleate tablet commonly used to treat schizophrenia and bipolar related disorders. Plaintiffs Forest Laboratories LLC, Forest Laboratories Holdings, Ltd., and Allergan Pharmaceuticals International Ltd. (collectively, "Forest") are the assignee of U.S. Patent Nos. 5,763,476 ("the '476 patent"), 7,741,358 ("the '358 patent"), and 8,022,228 ("the '228 patent"), which are listed in the Food and Drug Administration's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") as covering Saphris®. (PTX 563).

From June 18-20, 2018, I held a three-day bench trial on the only remaining issue in this matter: Sigmapharm's alleged infringement of claim 1 of the '476 patent.[1] After review of the evidence and briefing submitted by the parties, I find that Forest has proven by a preponderance of the evidence that Sigmapharm's ANDA infringes claim 1 of the '476 patent. Pursuant to Fed. R. Civ. P. 52(a)(1), the facts and conclusions supporting this decision are set forth below.

II. PROCEDURAL HISTORY

A. Consolidation and Stay

On August 7, 2014, Sigmapharm notified Forest that it had submitted an ANDA to the FDA seeking approval of a generic version of sublingual asenapine maleate tablets with a

[1] On May 18, 2017, Chief Judge D. Brooks Smith of the United States Court of Appeals for the Third Circuit designated me as a visiting judge for the District of Delaware, pursuant to 28 U.S.C. § 292(b), to handle this and other Delaware cases.

Paragraph IV certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), stating that the patents-in-suit are invalid and/or will not be infringed. (PTX 118). On September 3, 2014, Forest sued Sigmapharm for infringement of two of the three patents covering Saphris®—the '476 patent and '358 patent. (D.I. 1, C.A. No. 14-1119). Forest brought similar suits against Hikma Pharmaceuticals, LLC, Hikma Pharmaceuticals, PLC, and West-Ward Pharmaceutical Corp. (collectively, "Hikma") (see D.I. 1, C.A. No. 14-1266); Breckenridge Pharmaceutical, Inc. ("Breckenridge") (see D.I. 1, C.A. No. 14-1504); Alembic Pharmaceuticals Ltd., Alembic Global Holding S.A., and Alembic Pharmaceuticals, Inc. (collectively, "Alembic") (see D.I. 1, C.A. No. 15-0158); and Amneal Pharmaceuticals, LLC, Amneal Pharmaceuticals of New York, LLC, and Amneal Pharmaceuticals Co. India PVT., Ltd. (collectively, "Amneal") (see D.I. 1, C.A. No. 15-0430). These cases were initially overseen by the Honorable Sue L. Robinson, now retired, and consolidated under Civil Action No. 14-1119. (D.I. 21; D.I. 35; D.I. 70).

On June 10, 2015, Sigmapharm filed counterclaims seeking a declaratory judgment of invalidity and non-infringement for all three patents covering Saphris®—i.e., the '476 patent, the '358 patent, and the '228 patent. (D.I. 43). On April 15, 2016, Judge Robinson entered the following judgments pursuant to a stipulation by the parties: (i) in favor of Sigmapharm for Forest's claim of infringement of the '358 patent; (ii) in favor of Sigmapharm for Sigmapharm's counterclaim of non-infringement of the '358 patent; and (iii) in favor of Sigmapharm for Sigmapharm's counterclaim of non-infringement of the '228 patent. (D.I. 181 at ¶ 1(a-c)). Also by stipulation of the parties, Judge Robinson dismissed without prejudice, Sigmapharm's counterclaims seeking a declaration that the '358 patent and '228 patent were invalid. (Id.). As a result, the only remaining claim and counterclaim between Forest and Sigmapharm related to the infringement and validity of the '476 patent.

On October 13, 2016, Judge Robinson ordered that all issues relating to Sigmapharm's infringement of the '476 patent be stayed and that the 30-month stay of FDA approval of Sigmapharm's ANDA be tolled until the stay was lifted. (D.I. 278). Judge Robinson further ordered that she would proceed to trial with the remaining four defendants (Hikma, Breckenridge, Alembic, and Amneal) to determine, among other things, the validity of the '476 patent. (Id.). Pursuant to that order, Sigmapharm would be bound by any final judgment concerning the validity of the '476 patent. (Id.).

Judge Robinson held a bench trial with the remaining four defendants between October 24, 2016 and November 3, 2016 and issued an opinion and order on June 30, 2017. (D.I. 322; D.I. 323). A final judgment was entered on July 11, 2017. (D.I. 325). All four trial defendants stipulated to infringement of claims 1, 2, 5, and 6 of the '476 patent. (D.I. 323). Two of the four defendants (Hikma and Amneal) also stipulated to infringement of claims 4, 9, and 10 of the '476 patent. (Id.). The other two defendants (Alembic and Breckenridge) were found not to infringe claims 4, 9, and 10 of the '476 patent. (Id.). Finally, Judge Robinson held that the '476 patent was valid and entered judgment on that issue in favor of Forest and against all defendants, including Sigmapharm. (D.I. 325).

The four trial defendants have appealed Judge Robinson's decision finding the asserted claims of the '476 patent valid, and Forest has cross-appealed Judge Robinson's decision that Alembic and Breckenridge did not infringe claims 4, 9, and 10 of the '476 patent. (D.I. 326; D.I. 327; D.I. 328; D.I. 329; D.I. 334). That appeal is pending before the Court of Appeals for the Federal Circuit. (See Lead Case No. 17-2369; Cross Appeal Nos. 17-2436, 17-2441).

On July 25, 2017, the case was reassigned to my docket. On February 9, 2018, I lifted Judge Robinson's stay on Sigmapharm. (D.I. 358). On June 21, 2018, the 30-month stay of FDA

approval of Sigmapharm's ANDA expired. (D.I. 362 at 2). Effective July 17, 2018, the FDA approved Sigmapharm's ANDA No. 206107, for Asenapine Sublingual Tablets, 5 mg and 10 mg. (D.I. 398 at 1 n. 1).

B. Issues and Asserted Claims for Trial

Forest asserts that Sigmapharm infringes claims 1-2, 4-6, and 9-10 of the '476 patent. (D.I. 384-1, Ex. 4). The parties agree that Sigmapharm's infringement of claims 2, 5, and 6 rises and falls with infringement of claim 1. (D.I. 362 at ¶ 3). The parties further agree that Sigmapharm's infringement of claims 4, 9, and 10 will depend on the outcome of the appeal pending before the Federal Circuit, because any finding as to infringement of those claims by Alembic and Breckenridge will apply with equal force to Sigmapharm. (Id. at ¶ 4). Given these agreements, the sole issue before me is whether Sigmapharm infringes claim 1 of the '476 patent either literally or under the doctrine of equivalents. (Id. at ¶ 3).

III. FINDINGS OF FACT

A. The '476 Patent

The '476 patent, entitled "Sublingual or Buccal Pharmaceutical Composition," was issued from the United States Patent and Trademark Office on June 9, 1998. (D.I. 384, Ex. 1 at ¶ 5). Claim 1 of the '476 patent is a composition claim and recites:

> A pharmaceutical composition comprising as a medically active compound: trans-5-chloro-2-methyl-2,3,3a,12b-tetrahydro-1H-dibenz[2,3:6,7]oxepino-[4,5-c] pyrrole or a pharmaceutically acceptable salt thereof;[2] wherein the composition is a solid composition and disintegrates within 30 seconds in water at 37° C.

[2] "[T]rans-5-chloro-2-methyl-2,3,3a,12b-tetrahydro-1H-dibenz[2,3:6,7]oxepino-[4,5-c] pyrrole" is the chemical name for asenapine. (D.I. 384, Ex. 1 at ¶ 16).

(Id. at ¶ 15). No terms from claim 1 were construed in the only claim construction order issued in this case. (See D.I. 133). Judge Robinson did, however, construe claim 1 in her June 2017 trial opinion. She found claim 1 "limited to sublingual or buccal compositions." (D.I. 322 at 18). For sublingual tablets, the patient places the formulation under the tongue and waits for it to dissolve. (Id. at 2). For buccal tablets, the formulation is placed in the pouch of the cheek. (Id. at 12).

B. The Experts

Four experts testified at trial. Forest presented the expert testimony of Dr. Adam Myers ("Dr. Myers") and Dr. Lisbeth Illum ("Dr. Illum") and Sigmapharm stipulated to their qualification as experts. (D.I. 386 at 82:8-22; D.I. 388 at 29:10-21). Dr. Myers is a PhD organic chemist. (D.I. 386 at 36:4-7, 85:1-8). He performed testing on samples of Sigmapharm's product and was generally offered as an expert in disintegration testing, pharmaceutical analysis, and U.S. Pharmacopeia, Chapter <701> ("USP <701>"). (D.I. 386 at 89:23-90:2). Dr. Illum has a PhD and DSc in pharmacy. (D.I. 388 at 28:1-25). She was generally offered as an expert in drug delivery systems, transmucosal drug delivery, and disintegration testing. (D.I. 388 at 34:22-25). Sigmapharm presented the expert testimony of Dr. Thomas Kupiec ("Dr. Kupiec") and Dr. Harry Brittain ("Dr. Brittain"). Dr. Kupiec has a PhD in pharmaceutical sciences. He performed testing on samples of Sigmapharm's product and was generally offered as an expert on disintegration testing and USP <701>. (D.I. 390 at 4:25-5:3). Dr. Kupiec was found to be qualified as an expert. (Id. at 39:24-25). Dr. Brittain is a pharmaceutical scientist with a PhD in physical chemistry. (D.I. 391 at 4:22-25). He was generally offered as an expert on USP <701> and Forest stipulated to his qualification as an expert. (Id. at 4:22-5:22). Finally, Sigmapharm offered the testimony of Dr. Spiridon Spireas ("Dr. Spireas"), the CEO of Sigmapharm, but did not seek to have him qualified as an expert. (D.I. 386 at 9:18-14:1).

C. U.S. Pharmacopeia, Chapter <701>

A determination of whether Sigmapharm's accused product infringes claim 1 of the '476 patent depends on one issue: does the accused product "disintegrate[] within 30 seconds in water at 37° C." The parties agree that USP <701> is the proper method for measuring disintegration. (D.I. 386 at 33:16-22, 59:17-60:11; D.I. 388 at 46:15-47:16; D.I. 398 at 3; D.I. 400 at 3). Because Forest relies on USP <701> to prove infringement and the parties criticize how the opposing experts conducted their tests, it is useful to first understand the purpose of the test, the testing procedures prescribed by USP <701>, and the possible test outcomes.

1. The Purpose of the USP <701> Test

USP<701> is a standardized test used in the United States to determine whether tablets disintegrate within the time prescribed. (D.I. 384, Ex. 1 at ¶ 39). USP<701> is most commonly used by manufacturers to test whether a batch of tablets is in compliance with a disintegration specification before a product is released for use or sale. (D.I. 387 at 59:13-22; D.I. 390 at 13:24-14:3). For example, if a disintegration specification requires the tablets to disintegrate in 30 seconds in water at 37° C, then USP <701> is used to confirm that a batch of tablets will perform as required before being released. The test is conducted on a representative sample of tablets from a drug product batch. (D.I. 391 at 15:12-16). Then, the results of a single USP <701> disintegration test are imputed to the entire batch. (D.I. 387 at 73:10-19; D.I. 389 at 40:12-19). Thus, in the case of Sigmapharm, the characteristics of anywhere between 6 and 18 sample tablets are imputed onto a batch of 150,000 tablets. (PTX 679 at 1).

2. Test Procedures

USP <701> requires a basket-rack assembly with six open-ended transparent tubes held in a vertical position.[3] (PTX 631 at 3; PTX 592). The bottom of each tube is a stainless-steel wire screen. (PTX 631 at 3; DTX 29 at SIGMA111656, SIGMA112023-SIGMA112024). An apparatus is used to raise and lower the basket in an immersion fluid, such as water, at a constant frequency rate. (PTX 631 at 3; PTX 594; DTX 29 at SIGMA111806; D.I. 386 at 110:23-24). "Dips per minute" refers to the rate at which the apparatus moves the basket up and down in the water, which the experts here set at 30 per minute. (D.I. 386 at 109:6-7). To conduct the test, one tablet is placed in each of the six tubes and a plastic cylindrical disk is added above the tablet. (PTX 631 at 4). After loading the tablets into the tubes, the apparatus is operated for the time specified. (Id.). Here, the time specified by the '476 patent is 30 seconds. (PTX 1 at 6:2-3).

After operating the apparatus for the time specified, one must determine if "complete disintegration" has occurred. Under USP <701>, complete disintegration "does not imply complete solution of the [tablet] or even of its active constituent." (PTX 631 at 3). Instead, "complete disintegration" is defined as "that state in which any residue of the [tablet], except fragments of insoluble coating or capsule shell, remaining on the screen of the [basket-rack assembly] or adhering to the lower surface of the disk is a soft mass having no palpably firm core." (Id.). Therefore, a tablet is considered to have completely disintegrated under USP <701> even if some part of the tablet remains at the end of the time specified, as long as the remaining pieces are "fragments of insoluble coating or capsule shell" or "a soft mass having no palpably firm core." (D.I. 386 at 102:8-24). The experts agree "palpably firm core" means that any remaining mass

[3] A photo of a disintegration apparatus with a basket-rack assembly attached can be found at Appendix A to this opinion.

should be probed or palpated, typically with a spatula, to determine if it is soft or hard. (Id.; D.I. 391 at 64:1-4).

3. Possible Test Outcomes

USP<701> has two stages of testing. In stage one, a run of 6 tablets is tested. (PTX 631 at 4). If all 6 tablets (written by the parties as 6/6) completely disintegrate within 30 seconds, testing stops because the results are conclusive: The batch from which the sample tablets were taken will disintegrate within 30 seconds. (Id.; D.I. 386 at 106:4-11). If 3 or fewer tablets (1/6, 2/6, or 3/6) completely disintegrate within 30 seconds, then testing stops and the product cannot be released because the batch is not "in control," meaning the tablets are not uniformly performing within the required specifications. (D.I. 386 at 105:18-106:3; D.I. 390 at 13:24-14:3; D.I. 391 at 33:23-34:18). If 4 or 5 tablets (4/6 or 5/6) completely disintegrate within 30 seconds, the results are inconclusive, requiring a second stage of testing. (D.I. 386 at 106:4-7).

In stage two, an additional 12 tablets are tested. (PTX 631 at 4). USP <701> then considers the results from testing all 18 tablets (the initial 6 plus the additional 12). (Id.). If 16 or 17 tablets (16/18 or 17/18) completely disintegrate within 30 seconds, then the batch from which the sample tablets were taken will disintegrate within 30 seconds, and the product can be released. (Id.; D.I. 386 at 107:2-4). If fewer than 16 tablets (4/18 – 15/18) completely disintegrate within 30 seconds, no further testing is done, and the product may not be released. (D.I. 386 at 106:21-107:1). Thus, test results of 6/6, 16/18, and 17/18 confirm that a batch from which the sample tablets were taken will disintegrate within 30 seconds. (D.I. 389 at 29:6-9). This means USP <701> requires between 89% (16/18) and 100% (6/6) of the sample tablets to perform a certain way in order to impute the characteristics of those sample tablets onto an entire batch. (Id.).

Sigmapharm has characterized USP <701> as a "pass/fail" test. I disagree with the characterization. USP <701> itself makes no reference to "pass/fail" with respect to possible test outcomes. (See PTX 631). The only time USP <701> refers to "fail" is for an individual tablet assessment. (D.I. 387 at 80:15-23). And, the parties did not consistently ascribe the same meaning to the terms "pass" and "fail." During trial, experts on both sides occasionally employed the term "pass" to mean a test result of 6/6, 16/18, and 17/18 and "fail" to mean any other test result. (See, e.g., id. at 80:6-14; D.I. 389 at 29:6-9). But Sigmapharm also used the term "pass" to mean infringement and "fail" to mean non-infringement. (D.I. 389 at 26:24-27:22; D.I. 391 at 12:18-21). As will be discussed further below, those meanings of "pass" and "fail" are not equivalent. "Pass" and "fail" were also used at trial to mean that the tablets were "compliant" and "not compliant," respectively, with the requirements of a disintegration specification. (D.I. 387 at 48:5-7, 79:23-25). But, Sigmapharm further complicates the meaning of "pass/fail," by urging that tablets are compliant with its disintegration specification (i.e. "pass") only if they "fail" USP <701> at 30 seconds in 37° C. As Forest's expert, Dr. Myers, noted, Sigmapharm's use of "fail" in this context to indicate compliance is "inverted." (D.I. 387 at 48:8-11).

D. Sigmapharm's Disintegration Specification

Sigmapharm's ANDA specifies the disintegration time for its generic drug product. (PTX 666 at 7). Sigmapharm's monograph is a document that establishes the testing procedures used to determine whether the drug product, as manufactured, is in compliance with that disintegration specification. PTX 635 at 16-18; D.I. 387 at 40:5-41:5). Sigmapharm amended its disintegration specification several times, but it never made changes to the formulation of its accused product. (PTX 414 at 13-15; PTX 525; PTX 416; PTX 632; PTX 630; D.I. 384-1, Ex. 1 at ¶ 33).

Under Sigmapharm's current specification, there are two disintegration tests with two different time limits: a "30-Seconds Test," in which the tablets must "fail" USP <701> at 30 seconds, and a "55-Seconds Test," in which the tablets must "pass" USP <701> at 55 seconds. (PTX 635 at 16). In other words, Sigmapharm asserts that it can release a batch of its drug product if: (1) the number of sample tablets that disintegrate within 30 seconds is between 0/6 – 3/6 or between 4/18 – 15/18; and (2) the number of sample tablets that disintegrate within 55 seconds is 6/6, 16/18, or 17/18. (PTX 631 at 4; D.I. 386 at 50:3-7, 51:10-21).

E. Forest Testing

To prove infringement, Dr. Myers performed USP <701> disintegration testing on Sigmapharm's batches of 5 mg and 10 mg strength tablets. (D.I. 386 at 107:17-21; PTX 158; PTX 159; PTX 588). The parties refer to one test of 6 tablets as "one run." Dr. Myers tested twenty-two runs of Sigmapharm's generic product: one run each from batches PD0054:33 and PD0054:34 and ten runs each from batches PD0054:43 and PD0054:44. (PTX 158, PTX 159, PTX 588). Forest asserts that, of the twenty-two runs, 6/6 tablets completely disintegrated within 30 seconds for seven runs.[4] (D.I. 396 at 9). Of the seven runs where Dr. Myers recorded a 6/6 result, three came from PD0054:43, three came from PD0054:44, and one came from the only test of PD0054:33. Sigmapharm has several criticisms regarding how Dr. Myers performed his testing, some specific to the seven runs of 6/6 and some not. (D.I. 398 at 8-14). For the reasons explained below, I find that Sigmapharm's criticisms either lack merit or do not reflect biased test results.

[4] For the remaining fifteen runs, Dr. Myers obtained the following results: ten runs of 5/6, three runs of 4/6, one run of 3/6, and one run where the last tablet disintegrated at 51.4 seconds. (PTX 158; PTX 159; PTX 588).

1. Not Testing to a Specified Endpoint

Sigmapharm first argues that, for three of the seven runs where Dr. Myers obtained a 6/6 result, he did not test to the specified endpoint of 30 seconds. (D.I. 398 at 13-14). Instead, Dr. Myers noted the time at which the last tablet disintegrated. (D.I. 386 at 110:4-10). According to Dr. Myers, the last tablet disintegrated for PD0054:34 at 21.6 seconds, for PD0054:43 at 24.8 seconds, and for PD0054:44 at 27.9 seconds. (PTX 588 at 4; PTX 158).

Dr. Myers persuasively testified that although he did not test to a specified endpoint for these runs, the testing is nonetheless compliant with USP <701>, because complete disintegration at 30 seconds was still assessed. (D.I. 386 at 111:6-20). As he explained, "The fact that there's nothing left at the end, there's clearly no core left [before 30 seconds] indicates that there was complete disintegration [at 30 seconds] as defined by the USP." (Id.). USP <701> allows a tester to "make additional observations." (Id.). Dr. Myers' explanation comports with common sense—if a tablet has completely disintegrated before 30 seconds, then the tester already knows what the condition of the tablet will be a few seconds later at the actual 30-second mark.

2. Failure to Lift the Basket

For the same runs where Dr. Myers did not test to a specified endpoint, Sigmapharm argues that the results are invalid, because "Dr. Myers failed to 'lift the basket from the fluid, and observe the tablets,' as required by the USP <701> testing procedure." (D.I. 398 at 9-10). Sigmapharm points to USP <701> which states, "At the end of the time limit specified in the monograph, lift the basket from the fluid, and observe the tablets." (PTX 631 at 4). Sigmapharm assumes that, on these runs, Dr. Myers did not lift the basket to observe the tablets, because he was not testing to the specified endpoint of 30 seconds.

Sigmapharm's criticism is unfounded, because the evidence establishes that Dr. Myers did lift the basket to observe the tablets. Dr. Myers recognized that it was proper protocol under USP <701> to lift the basket out of the fluid at the end of the test and make observations. (D.I. 387 at 79:6-14). He credibly testified that he always lifts the basket out of the fluid at the end of a disintegration test to observe the tablets, whether testing to a specified endpoint or not. (D.I. 386 at 102:12-19). Indeed, Dr. Myers explained that he lifted the basket for these specific runs where he did not test to a 30-second endpoint. (D.I. 387 at 101:19-102:1, 111:10-14). Sigmapharm suggests that Dr. Myers did not lift the basket to observe the tablets, because his lab notebook does not reflect observations made at the end of the testing time. (Id. at 102:4-8). Dr. Myers explained that he recorded no additional observations after the basket was lifted, because there would be no reason to record additional observations unless there was an unusual or aberrant observation, which he did not observe. (Id. at 102:24-103:11). Because Sigmapharm has not shown that Dr. Myers failed to lift the basket from the fluid to make observations, I do not need to determine whether that failure would lead to invalid or biased test results.

3. "Reinterpreting" the Data

For eighteen runs, Dr. Myers tested to the specified end-point of 30 seconds, meaning at the end of 30 seconds, he stopped the apparatus, raised the basket-rack assembly, and inspected the tablets for complete disintegration. (D.I. 386 at 113:21-114:24). Sigmapharm claims that Forest improperly reinterpreted the data in Dr. Myers' lab notebook to claim that Dr. Myers obtained a 6/6 result for four of these eighteen runs. (D.I. 398 at 13-14). I disagree.

After each run, Dr. Myers recorded his observations regarding disintegration time in a lab notebook under a column titled "n=6 disintegration time." (See PTX 159 at 5). Usually, he would record "not complete @ 30 seconds," then add a footnote with how many of the 6 tablets had a

core remaining as probed by a spatula. (Id.). Four runs were different: at the moment Dr. Myers stopped the apparatus, 1 tablet in each run had not disintegrated by visual observation. (D.I. 387 at 11:19-12:13, 18:21-19:24; 20:20-21:11, 24:13-18, 139:13-140:7). But, in the short time it took to raise the basket-rack assembly out of the water and observe the tablets, Dr. Myers saw that each remaining tablet in all four runs had completely disintegrated, leaving no core left to probe. (Id.).

To note these four incidents in his lab notebook, Dr. Myers wrote the time at which he visually observed complete disintegration of the last tablet. Specifically, under the column "n=6 disintegration time," Dr. Myers recorded 31.4 seconds, 30.9 seconds, 31.4 seconds, and 31.1 seconds, respectively. (PTX 159 at 17-19). Under USP<701>, tablets are assessed for disintegration after the basket is removed from the water and any remaining core is probed. (PTX 631 at 4; D.I. 386 at 102:12-19). Because there was no core left to probe after Dr. Myers removed the basket, I find that, under USP <701>, all four runs questioned by Sigmapharm had 6/6 tablets completely disintegrate within 30 seconds. The fact that Dr. Myers was meticulous in trying to capture his additional observations does not change the results as determined by USP <701>.

4. Failure to Properly Orient the Disks

Sigmapharm further complains that Dr. Myers' testing did not comply with USP <701>, because the disks in tubes of the basket-rack assembly were not properly oriented and, therefore, his test results are unreliable. (D.I. 398 at 10). Dr. Myers did not dispute that some of the disks were oriented top down, but that is not the end of the issue.[5] (D.I. 387 at 110:1-3). Sigmapharm

[5] It is difficult to be certain which disks in particular were oriented top down as it depends on reading photographs not taken for that purpose. (See D.I. 387 at 99:5-7; DTX 252).

must show that: (1) USP <701> requires a certain disk orientation, and (2) disks not orientated in that direction effected the disintegration times of the tablets.

USP <701> itself sets forth specific dimensions for every aspect of the disk. (PTX 631 at 4). Per USP <701>, the disks are made of a smooth transparent plastic, have five holes cut through the ends of the cylinder, and have four identical trapezoidal shapes cut into the side. (Id.). In explaining the placement of the asymmetrical trapezoid, USP <701> refers to the "bottom of the cylinder" and the "top of the cylinder." (Id.). Finally, as shown in the image below, USP <701> includes a diagram of the various views of the disk with relevant dimensions, and labels two of the views "Top view" and "Bottom view." (Id.). After carefully reviewing the text of USP <701>, I agree with the view of Dr. Illum that, although it would be natural to put disks in the top up position, USP <701> itself does not mandate a specific orientation. (D.I. 389 at 35:18-24). The only references in USP <701> to "top" and "bottom" are to facilitate an explanation of the placement and dimensions of the trapezoid. (PTX 631 at 4).

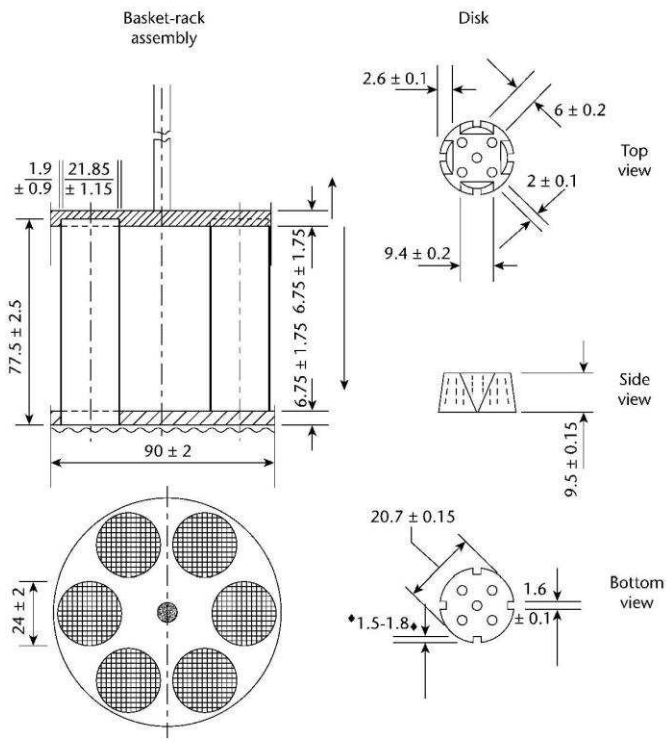

Figure 1. Disintegration apparatus. (All dimensions are expressed in mm.)

More importantly, Sigmapharm did not establish that a top-down orientation of the disks would impact the disintegration times of the tablets. Sigmapharm's evidence regarding the impact of disk orientation on disintegration times was either inadmissible or not credible. The opinion of Sigmapharm's expert, Dr. Brittain, was deemed inadmissible, because it was not disclosed in his expert reports. (D.I. 391 at 21:6-26:3). And Sigmapharm's other expert, Dr. Kupiec, testified in his deposition that he did not know what impact disk orientation would have on disintegration times until he ran the experiment. (See D.I. 390 at 87:12 – 88:24). At the same time, Dr. Kupiec acknowledged that he has never run this experiment. (Id.).

Finally, experts from both sides agree that the purpose of the disk is to prevent the tablets from floating to the top of the tube—like marshmallows on the top of hot chocolate. (D.I. 386 at 99:4-8; D.I. 387 at 37:7-11; D.I. 390 at 63:12-18, 106:2-3). I observed from video demonstrations that the disks performed that function no matter what their orientation. (See, e.g., DTX 30). In

addition, it appears that inadvertently orienting the disks top down is not uncommon. Indeed, Forest pointed to several photographs where the disks from the disintegration tests of Dr. Kupiec appeared to be in the top-down position. (D.I. 390 at 97:7-99:5). Given all of the foregoing, I do not find that orientation of the disks in Dr. Myers' tests either failed to comply with USP <701> or undermined his test results.

5. Pre-Wetted Tablets

Sigmapharm next argues that Dr. Myers practice of "equilibrating" the basket-rack assembly was improper, because it is not required by USP <701> and also leads to biased test results. (D.I. 398 at 11-12). "Equilibrating" means the basket-rack assembly is used to mix the immersion fluid before testing, which brings both the basket-rack assembly and the fluid to the same uniform temperature. (D.I. 387 at 57:9-14, 87:3-24). To mimic the temperature of the body, USP <701> requires that the immersion fluid be maintained at 37 ± 2° C. (PTX 631 at 4; D.I. 386 at 118:13-16). A basket-rack assembly in ambient room temperature will typically be around 23° C, which is 12° below the minimum temperature required for disintegration testing. (D.I. 387 at 56:1-6; D.I. 390 at 115:13-20). Adding a basket-rack assembly at 23° C to an immersion fluid at 37° C can cool down the water by more than 2° C, which can lead to longer disintegration times. (D.I. 387 at 56:5-6, 89:10-13; D.I. 386 at 118:10-21).

Sigmapharm is correct that USP <701> does not explicitly require equilibration of the basket-rack assembly. (D.I. 398 at 11; PTX 631). But USP <701> also does not prohibit the practice. (D.I. 390 at 112:7-16). It simply requires that the immersion fluid be "maintained" at 37 ± 2° C. (Id.; PTX 631 at 4). Dr. Myers persuasively testified that "the only real way to be sure" that the basket-rack assembly will not cool the water by more than 2° C during testing "is by equilibrating the system." (D.I. 387 at 88:23-89:3). Thus, equilibrating is done as a "good

practice." (Id. at 89:14-21). Given the foregoing, I find that it was not improper under USP <701> for Dr. Myers' to equilibrate the basket-rack assembly.

Sigmapharm presses that equilibration produces unreliable test results, because the tablets are loaded onto wet screens, and wet screens trigger the start of the disintegration process before the test has formally commenced. (D.I. 398 at 11-12). Sigmapharm, however, has provided no evidence that wet screens make a measurable impact on disintegration times. Sigmapharm's expert, Dr. Kupiec, testified: "I don't know the exact results, but one would expect the exposure of a tablet sublingual to moisture or water to initiate the disintegration process." (D.I. 390 at 74:5-16). Forest's experts, Dr. Myers and Dr. Illum, acknowledged the possibility that the screens could be wet before testing, but both persuasively testified that the amount of any water would be negligible. (D.I. 387 at 88:15-19; D.I. 389 at 36:14-16). Both of Forest's experts also acknowledged that "[i]f you do have water on the mesh [screens], there will be some water intake," but this is a "micro event" at the start of the disintegration process for which USP <701> takes account. (D.I. 389 at 36:14-23; D.I. 387 at 96:5-11). These experts explained that disintegration itself occurs when you are "actually breaking the tablet apart." (D.I. 387 at 96:5-11). Given the lack of evidence that a wet screen has a measurable impact on disintegration times, I do not find that Dr. Myers' practice of equilibrating the basket-rack assembly led to biased test results.

6. "Over-Immersed" Tablets

Sigmapharm next contends that Dr. Myers' process for starting and stopping the disintegration apparatus biased the test results, because the tablets were "over-immersed" in water. (D.I. 398 at 12-13). It was Dr. Myers' practice to start the apparatus, let the basket fully descend, start the stopwatch at the bottom of the downstroke, stop the apparatus at 30 seconds, and let the basket rise out of the water. (D.I. 387 at 91:18-21, 92:22-93:1, 93:13-16). According to

Sigmapharm, the downstroke of the basket at the start of the test and the upstroke of the basket at the end of the test added 2 seconds to the required 30 seconds. (D.I. 398 at 12-13).

USP <701> itself does not explicitly address the appropriate time to start and stop the timer. It simply requires operation of the apparatus "for the set duration of time." (PTX 631 at 4-5). Dr. Myers reasonably explained that the apparatus is not operating for the set duration of time when, for some of that time, "everything is out of the water." (D.I. 387 at 91:24-92:7). And, Sigmapharm's current monograph, which sets forth its disintegration testing protocol, also instructs the tester to "[t]urn on the timer when the basket-rack assembly is in its lowest position." (PTX 630 at 15; PTX 635 at 16). Because USP <701> does not mandate a particular procedure for ensuring that the apparatus is operated for the required amount of time, and Sigmapharm itself adopts the very process Dr. Myers employed, I am not convinced that Dr. Myers' method of starting and stopping the apparatus failed to comply with USP <701>.

In summary, I do not find that any of the alleged deficiencies raised by Sigmapharm undermine the testing and opinions offered by Dr. Myers.

F. Sigmapharm's Testing

To refute Forest's testing evidence, Sigmapharm presented evidence of testing by its own expert Dr. Kupiec. Sigmapharm also introduced evidence regarding the disintegration testing performed by its own internal scientists during the FDA approval process. For the reasons stated below, I do not give significant weight to either set of test results.

1. Dr. Kupiec

Dr. Kupiec tested a total of 24 runs—12 runs each from Sigmapharm's batches PD0054:43 and PD0054:44—and concluded that none of the 24 runs "passed" USP <701> at 30 seconds. (DTX 262; DTX 270; D.I. 390 at 75:21-24). Dr. Kupiec did not perform stage two testing, and as

such, in this context, "pass" means a test result of 6/6. Thus, Dr. Kupiec concluded that there were no 6/6 test results from two of Sigmapharm's batches. However, several aspects of Dr. Kupiec's testing methods call into question the reliability of his test results.

First, Dr. Kupiec did not equilibrate the basket-rack assembly with the water. (D.I. 390 at 53:19-54:2, 112:17-113:13). Instead, he used an oven to dry the basket and then a refrigerator to cool the basket. (Id.). In that scenario, one would expect, based on the testimony of Dr. Myers, that the basket-rack assembly would have changed the temperature of the water from the 37 ± 2° C required by USP <701>. There is no way to know whether this happened, because Dr. Kupiec only measured the temperature of the water once, before putting the basket in the water, and he did not check the temperature during or after his experimentation. (D.I. 390 at 113:19-21, 116:9-25).

Second, Dr. Kupiec testified that he did not probe all of the remaining cores, only a "majority" or a "fair amount." (Id. at 81:1-82:7, 131:3). But complete disintegration under USP <701> requires a determination of whether or not any remaining mass has a "palpably firm core." (PTX 631 at 3; D.I. 386 at 101:21-103:21).

Third, Dr. Kupiec's lab notebook provides little detail, especially compared to Dr. Myers' lab notebook. For example, Dr. Myers added a footnote to each test result stating how many tablets completely disintegrated within 30 seconds, whereas Dr. Kupiec simply states "no" under a column titled "disintegration within 35 seconds."[6] (DTX 262; PTX 159 at 4). Thus, it is unknown whether zero tablets disintegrated or three, both of which would have resulted in a "no" in Dr. Kupiec's lab notebook. Those details would have been persuasive, because the experts agree that

[6] Dr. Kupiec tested to 35 seconds instead of 30 seconds. (D.I. 390 at 50:22-51:2).

zero sample tablets (0/6) disintegrating within 30 seconds is conclusive proof that a batch will not disintegrate within 30 seconds. (D.I. 387 at 53:9-16; D.I. 388 at 63:8-14; D.I. 391 at 40:12-18).

Finally, after careful examination of each expert's background and experience, I conclude that Dr. Kupiec did not have the same level of expertise with USP <701> as Dr. Myers. (D.I. 386 at 89:7-15; D.I. 390 at 18:10-12, 32:10-13). For example, Dr. Kupiec had not personally performed disintegration testing before this case and did not believe that he was an expert in disintegration testing. (D.I. 390 at 18:10-12, 32 at 11-13). By comparison, Dr. Myers has performed disintegration testing under USP <701> outside the context of this litigation. (D.I. 386 at 88:18-25). His job responsibilities for the past eleven years involve performing and overseeing disintegration testing. (Id. at 85:17-88:17). He has personally performed or overseen "hundreds" of tests and received specialized training in disintegration testing. (Id.). For these reasons, I will afford Dr. Kupiec's test results less weight than Dr. Myers' test results.

2. Sigmapharm's Internal Testing

For purposes of FDA submission, Sigmapharm's internal scientists tested 94 runs from batches PD0054:43 and PD0054:44 using Sigmapharm's 30-Second Test. (DTX 89; DTX 90; DTX 91; DTX 182; DTX 183). At trial, the results of these tests were presented by Sigmapharm's CEO, Dr. Spiridon Spireas, who testified that only 2 tablets out of the 564 total tablets tested across the 94 runs disintegrated within 30 seconds. (D.I. 391 at 87:2-7). In other words, Dr. Spireas contends that for all but a couple of runs, zero tablets (0/6) disintegrated within 30 seconds.

I do not find this testimony entirely credible. To start, Dr. Spireas was not the person who performed the tests, nor was he the supervisor to whom the test results were "disclosed to and understood by." (See DTX 89; DTX 90; DTX 91; DTX 182; DTX 183). Instead, Dr. Spireas was simply providing his interpretation of his scientists' lab notebooks. And these notebooks lack any

detail that would allow Dr. Spireas to credibly conclude how many tablets out of six disintegrated within thirty seconds. Specifically, the lab notebooks do not state how many tablets out of 6 remained after 30 seconds. Instead, the lab notebooks simply report, with few exceptions, "At 30 Seconds: Fails."[7] (See, e.g., DTX 89 at 80). Under the Sigmapharm monograph governing these testing procedures, "fails" means a test result of 0/6, 1/6, 2/6, or 3/6. (PTX 635 at 16-18). In other words, many more than zero tablets could have disintegrated within 30 seconds, and the internal scientist would have been in compliance with the Sigmapharm monograph by recording "At 30 Seconds: Fails." Thus, how many tablets actually disintegrated within 30 seconds is simply unknown.

I also give little weight to Sigmapharm's internal test results for several other reasons. The scientists who conducted the tests had little to no experience with USP <701> procedures before receiving training sometime during the period they were testing the tablets. (D.I. 391 at 100:16-101:8). These scientists followed Dr. Spireas' instructions on how to conduct the tests, but he did not consider himself an expert in USP <701>, and he had no experience with USP <701> before developing the accused product. (D.I. 388 at 88:1-4, 118:6-10, 120:11-25, 127:20-128:3; D.I. 391 at 92:21–93:10, 95:6–15). Moreover, both Dr. Spireas and the internal scientists (whose testimony was heard via video deposition) admitted that they were at times not conducting disintegration tests in accordance with USP <701>. (D.I. 388 at 128:4-18, 130:8-18; D.I. 391 at 65:10-15). Even if some errors, such as the lack of disks, were corrected by the time these 94 runs were performed, other questionable practices remained. (See, e.g., D.I.391 at 60:15-23). For example, the

[7] There were 9 runs where the same scientist who tested the vast majority of the 94 runs wrote "At 30 seconds all tablets failed to disintegrate." (PTX 182 at 15-57 (emphasis added)). But this phrase is equally ambiguous as it could fairly apply to any situation where 1 or more hard cores remained at the end of testing.

temperature of the water was measured only once—before a room temperature basket was added to the water. (D.I. 388 at 105:9-106:7). The temperature was not monitored during the test to ensure that it remained at 37 ± 2° C throughout the experiment. (Id.). In addition, one scientist indicated that she was not palpating any remaining cores to determine if it was hard or soft. (See, e.g., D.I. 388 at 133:9-13). As noted above, a hard core means there was no "complete disintegration" under USP <701> whereas a soft core means there was, and the difference between hard and soft can only be determined if any remaining mass is probed or palpated. (D.I. 386 at 102:8-24; D.I. 391 at 64:1-4). These practices all undermine the reliability of the internal test results.

IV. STANDARD OF REVIEW

It is an act of infringement to submit an ANDA "if the purpose of such submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent . . . before the expiration of such patent." 35 U.S.C. § 271(e)(2). The filing of an ANDA alone does not prove infringement. Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1570 (Fed. Cir. 1997). Rather, the patentee must show, using "traditional patent infringement analysis," that "the alleged infringer will likely market an infringing product." Id. at 1569-70; see also Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1365–66 (Fed. Cir. 2003).

Traditional infringement analysis employs a two-step inquiry. First, the court must construe the asserted claims to ascertain their meaning and scope. Markman v. Westview Instruments, Inc., 52 F.3d 967, 979–81 (Fed. Cir. 1995), aff'd, 517 U.S. 370 (1996). Second, the trier-of-fact must compare the properly construed claims with the accused infringing product. Id. Step one is a question of law, and step two is a question of fact. Id.

Infringement may be proven under one of two theories: literal infringement or the doctrine of equivalents. Id.; Baxter Healthcare Corp. v. Spectramed, Inc., 49 F.3d 1575, 1582 (Fed. Cir. 1995). Literal infringement occurs when each element of at least one claim of the patent is found in the alleged infringer's product. Panduit Corp. v. Dennison Mfg. Co., 836 F.2d 1329, 1330 n. 1 (Fed. Cir. 1987). A finding of infringement under the doctrine of equivalents requires a showing that: (1) "the difference between the claimed invention and the accused product or method was insubstantial," or (2) "the accused product or method performs the substantially same function in substantially the same way with substantially the same result as each claim limitation of the patented product or method." AquaTex Indus., Inc. v. Techniche Solutions, 479 F.3d 1320, 1326 (Fed. Cir. 2007). The party asserting infringement has the burden of proof and must meet its burden by a preponderance of the evidence. SmithKline Diagnostics, Inc. v. Helena Lab. Corp., 859 F.2d 878, 889 (Fed. Cir. 1988).

V. CONCLUSIONS OF LAW

A finding of literal infringement in this case depends on one issue: does Sigmapharm's generic sublingual asenapine tablets disintegrate "within 30 seconds in water at 37° C." Based upon the findings of fact set forth above, and for the following reasons, I find that Forest has proven, by a preponderance of the evidence, that Sigmapharm's tablets will literally infringe claim 1 of the '476 patent. I also find that, contrary to Sigmapharm's contentions, its disintegration specification does not preclude literal infringement.

A. Testing

Forest has proven by a preponderance of the evidence that Sigmapharm's accused product literally infringes claim 1 of the '476 patent, because Sigmapharm's accused product disintegrates within 30 seconds in water at 37° C. First, Forest presented credible proof that batches PD0054:33,

PD0054:34, PD0054:43, and PD0054:44 are representative of the product Sigmapharm intends to sell. (D.I. 388 at 53:8-54:15; PTX629 at 16 of 94). Indeed, Sigmapharm has made no assertion that these batches are not representative of the products it intends to sell. Second, there is no dispute that if 6/6 sample tablets disintegrate within 30 seconds, then under USP <701>, the entire batch is said to disintegrate within 30 seconds. (PTX 631 at 4; D.I. 386 at 106:4-11). Sigmapharm acknowledges that the results of a "single USP <701> disintegration test" are used to determine the characteristics of an entire batch. (D.I. 398 at 5). Third, Forest has proven that 6/6 tablets disintegrated within 30 seconds for at least one run each from batches PD0054:43, PD0054:44, and PD0054:33. (PTX 158 at 12; PTX 159 at 17-18; PTX 588 at 9). Thus, Forest has established that, under USP <701>, batches of Sigmapharm's product manufactured in compliance with its specification will disintegrate within 30 seconds in water at 37° C. Because these batches are representative of the product that Sigmapharm intends to market, I find that Forest has proven by a preponderance of the evidence that Sigmapharm's accused product will literally infringe claim 1 of the '476 patent.

In reaching this conclusion, I note that experts from both sides agree that if 0/6 sample tablets disintegrate within 30 seconds, then the entire batch will not disintegrate within 30 seconds. (D.I. 387 at 53:9-16; D.I. 388 at 63:8-14; D.I. 391 at 40:12-18). But out of the 140 test runs presented in this case—the 22 runs tested by Dr. Myers, the 24 runs tested by Dr. Kupiec, and the 94 runs tested by Sigmapharm—there was no credible evidence of a 0/6 test result.

B. Sigmapharm's Disintegration Specification

As previously stated, Sigmapharm's current specification has two disintegration tests: a "30-Seconds Test," in which the tablets must "fail" USP <701> at 30 seconds, and a "55-Seconds Test," in which the tablets must "pass" USP <701> at 55 seconds. Sigmapharm contends that its

disintegration specification precludes literal infringement. For the reasons explained below, I disagree.

1. Sigmapharm's 30-Seconds Test

According to Sigmapharm, the '476 patent "claim[s] a pharmaceutical composition that passes USP <701> at 30 seconds" and, therefore, its 30-Seconds Test, which requires the batch to "fail" USP <701> at 30 seconds, precludes literal infringement of claim 1. (D.I. 401 at 2; D.I. 391 at 72:25-73:6). But claim 1 does not literally claim a pharmaceutical composition that "passes" USP <701> at 30 seconds. Rather, it claims a pharmaceutical composition that "disintegrates within 30 seconds in water at 37° C." (D.I. 384, Ex. 1 at ¶ 5; D.I. 389 at 26:2-9). This language must be the focus of any infringement analysis, because "[t]he words of the claims themselves define the scope of the invention." Allen Engineering Corp. v. Bartell Indus., Inc., 299 F.3d 1336, 1344 (Fed. Cir. 2002). At no time has the court construed "disintegrates within 30 seconds in water at 37° C" to mean that tablets must "pass" USP <701>. Thus, the words of claim 1 must be given their plain and ordinary meaning. Id. This means that, in order to prove infringement, Forest must prove that Sigmapharm's generic sublingual asenapine tablets will "disintegrate[] within 30 seconds in water at 37° C." Sigmapharm can attempt to undermine this proof by showing that the tablets will not "disintegrate[] within 30 seconds in water at 37° C." But Sigmapharm cannot short-cut the infringement analysis by focusing only on whether its tablets "pass" or "fail" USP <701>.

Admittedly, Sigmapharm sometimes uses the phrase "pass" to refer to a 6/6 test result under USP <701>. (See, e.g., D.I. 389 at 29:6-9). And, the parties do not dispute that a 6/6 test result is proof that a batch of tablets will disintegrate within 30 seconds in water at 37° C. (D.I. 389 at 27:16-22). Consequently, "pass" in this context is proof of literal infringement of claim 1.

(Id.). The problem is that "failing" USP <701> is not sufficient proof that a batch of tablets will not disintegrate within 30 seconds in water at 37° C, meaning "failing" is not proof of non-infringement. (D.I. 387 at 49:13-21). In short, "pass" equals infringement, but "fail" does not equal non-infringement.

There are several reasons why. To start, USP <701> is not designed to show that a batch of tablets will not disintegrate within a specified time. (D.I. 388 at 61:5-10, 62:11-15). Experts from both sides agreed that a test designed to show that a batch of tablets will not disintegrate within 30 seconds—and therefore not infringe claim 1—requires a higher standard of proof than just "failing" USP <701>. Specifically, to establish non-infringement, experts from both sides required 0/6 tablets to completely disintegrate within 30 seconds, meaning there is some hard core remaining for all 6 tablets. (D.I. 387 at 53:9-16; D.I. 388 at 63:8-14; D.I. 391 at 40:12-18). If a hard core remains for only 4 or 5 tablets, then the experts would proceed to stage-two testing on an additional 12 tablets. (D.I. 387 at 53:16-17). After stage-two testing, and again to establish non-infringement, a hard core must remain for 16 or 17 out of the 18 total tablets tested. (D.I. 387 at 53:16-23; D.I. 388 at 63:14-17; D.I. 391 at 40:19-22). Thus, consistent with the procedure established by USP <701>, the experts would require anywhere between 89% and 100% of the sample tablets to not disintegrate within 30 seconds in order to impute the characteristics of those samples onto an entire batch.

Failure under USP <701> is a much lower standard. (D.I. 387 at 45:17-46:3). Tablets fail after stage one if a hard core remains for at least 3 of the 6 tablets. (PTX 630 at 15; PTX 635 at 16). Tablets fail after stage two if a hard core remains for at least 3 of 18 tablets. Thus, failure under USP <701> requires between 17% and 50% of the sample tablets to not disintegrate within 30 seconds. In other words, under Sigmapharm's 30-Second Test, if only 17% of the sample

tablets demonstrate a particular characteristic, Sigmapharm proposes imputing that characteristic to an entire batch, even though USP <701> requires a minimum of 89% of the sample tablets to demonstrate a particular characteristic in order to make the same imputation. Sigmapharm's expert, Dr. Brittain, testified that if only 17% of the sample tablets did not disintegrate within 30 seconds, he "would not be comfortable" saying that the entire batch will not disintegrate within 30 seconds. (D.I. 391 at 34:19-35:11). I share that discomfort. Given the foregoing facts, I cannot conclude that Sigmapharm's 30-Seconds Test precludes literal infringement of claim 1 of the '476 patent.

2. The 55-Seconds Test

Sigmapharm's 55-Seconds Test also does not preclude literal infringement of claim 1 of the '476 patent. Experts from both sides agree that Sigmapharm's 55-Seconds Test is independent of the 30-Seconds Test. (D.I. 387 at 41:11-14; D.I. 390 at 123:12-14; D.I. 391 at 39:11-13). Because USP <701> is a destructive test, the same tablets from the 30-Seconds Test cannot be used in the 55-Second Test. (D.I. 387 at 134:12-17; D.I. 388 at 67:6-11). Instead, 6 new tablets are tested for the 55-Second Test. (D.I. 390 at 125:9-13). Therefore, the 30-Second Test does not operate as a gatekeeping mechanism for the 55-Second Test.

In addition, for the 55-Second Test, Sigmapharm only assesses whether complete disintegration has taken place at 55 seconds. (D.I. 387 at 47:1-2; D.I. 388 at 59:1-3, 108:5-24). It does not assess whether the tablets are still intact at 30 seconds. (Id.). As experts from both sides testified, there is no lower limit placed on the 55-Seconds Test. (D.I. 387 at 46:9-23; D.I. 390 at 125:2-5; D.I. 391 at 38:16-18). All of the tablets can completely disintegrate within 30 seconds and still comply with Sigmapharm's 55-Seconds Test. (D.I. 387 at 50:8-15; D.I. 388 at 67:11-15).

As Sigmapharm's expert acknowledges, nothing can be inferred from the 55-Seconds Test about what happens at 30 seconds. (D.I. 391 at 21:1-4, 39:7-10).

VI. CONCLUSION

For the reasons stated, I find that Forest has proven by a preponderance of the evidence, that Sigmapharm infringes claim 1 of the '476 patent. Accordingly, under the stipulation of the parties (D.I. 362 at ¶ 3), Forest has also proven that Sigmapharm infringes claims 2, 5, and 6 of the '476 patent. An appropriate order will be entered.

APPENDIX A

A disintegration apparatus with a basket-rack assembly. (DTX 29 at SIGMA111656).