IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

COSMO TECHNOLOGIES LIMITED, VALEANT PHARMACEUTICALS INTERNATIONAL, and VALEANT PHARMACEUTICALS LUXEMBOURG S.À R.L.,	:	REDACTED PUBLIC VERSION
Plaintiffs,	:	C.A. No. 15-164-LPS
v.	:	
ACTAVIS LABORATORIES FL, INC.,	:	
Defendant.	:	
COSMO TECHNOLOGIES LIMITED, VALEANT PHARMACEUTICALS INTERNATIONAL, and VALEANT PHARMACEUTICALS LUXEMBOURG S.À R.L.,	:	
Plaintiffs,	:	C.A. No. 15-193-LPS
v.	:	
ALVOGEN PINE BROOK, LLC,	:	
Defendant.	:	

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MEMORANDUM OPINION

October 27, 2017
Wilmington, Delaware

STARK, U.S. District Judge:

Cosmo Technologies Limited, Valeant Pharmaceuticals International, and Valeant Pharmaceuticals Luxembourg S.à r.l. (collectively, "Plaintiffs") brought this patent infringement action under the Hatch-Waxman Act, 21 U.S.C. § 355(j), against Defendants Actavis Laboratories FL, Inc. ("Actavis") and Alvogen Pine Brook, LLC ("Alvogen"), which each submitted an Abbreviated New Drug Application ("ANDA") to market a generic version of Uceris®, which are oral tablets containing 9 mg of budesonide for treatment of mild to moderate ulcerative colitis. (C.A. No. 15-164-LPS D.I. 118 at ¶ 23; C.A. No. 15-193-LPS D.I. 116 at ¶ 20)[1] Plaintiffs assert Orange Book-listed U.S. Patent No. 8,784,888.[2] Specifically, Plaintiffs assert claim 9 against Actavis and claim 6 against Alvogen. (D.I. 221, 223) As relevant here, the '888 patent generally claims budesonide tablets having a macroscopically homogenous composition.

The Court held a claim construction hearing on July 11, 2016 to construe disputed claim terms and issued a claim construction opinion and order on September 7, 2016. (D.I. 183, 184)

In May 2017, the Court held a bench trial. (*See* D.I. 241, 243 ("Tr.")) At the close of Plaintiffs' case-in-chief, both Defendants moved for partial judgment of non-infringement under Federal Rule of Civil Procedure 52(c). The Court granted Defendants' motions from the bench.

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[1]All references to the Docket Index are to C.A. No. 15-164, unless otherwise noted.

[2]In their second amended complaint, Plaintiffs also asserted U.S. Patent Nos. 7,410,651; 8,293,273; RE 43,799; and 9,320,716 against Actavis (D.I. 118 at ¶ 5) and U.S. Patent Nos. 7,410,651; RE 43,799; and 9,320,716 against Alvogen (C.A. No. 15-193 D.I. 118 at ¶ 5), but they narrowed the asserted patents and claims before trial. (*See* D.I. 221) At trial, Plaintiffs also asserted claim 3 of the '273 patent against Actavis. After trial, Plaintiffs dropped their allegations of infringement of the '273 patent. (*See* D.I. 230 Ex. 1)

(*See* Tr. at 332) The Court subsequently allowed the parties to submit briefs to assist the Court in issuing written findings of fact and conclusions of law (D.I. 232, 234), and the parties also submitted a joint Statement of Uncontested Facts ("SUF") (D.I. 233).

Pursuant to Rule 52(c), after having considered the entire record in this case and the applicable law, and consistent with the Court's ruling after the close of Plaintiffs' case, the Court concludes that Plaintiffs have failed to prove by a preponderance of the evidence that (1) Actavis infringes claim 9 of the '888 patent and (2) Alvogen infringes claim 6 of the '888 patent.

FINDINGS OF FACT

This section contains the Court's findings of fact ("FF") on disputes raised by the parties during trial, as well as facts to which the parties have stipulated. Certain findings of fact are also provided in connection with the Court's conclusions of law.

I. The Parties

1. Plaintiff Cosmo Technologies Limited ("Cosmo") is an Irish corporation, having its principal place of business at Riverside II, Sir John Rogerson's Quay, Dublin 2, Ireland. (SUF ¶ 1)

2. Plaintiff Valeant Pharmaceuticals International ("VPI") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807. (SUF ¶ 2)

3. Plaintiff Valeant Pharmaceuticals Luxembourg S.à r.l. ("Valeant S.à r.l.") is a Luxembourg corporation, having a principal place of business at 13-15 Avenue de la Liberté, L-1931 Luxembourg, Grand Duchy of Luxembourg. Valeant S.à r.l. is a wholly-owned subsidiary of VPI. (SUF ¶ 3)

4. Defendant Actavis Laboratories FL, Inc. ("Actavis") is a corporation organized and existing under the laws of the State of Florida, having a place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054. (SUF ¶ 4)

5. Defendant Alvogen Pine Brook, LLC ("Alvogen") is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 10 Bloomfield Avenue, Pine Brook, New Jersey 07058. (SUF ¶ 5)

II. Uceris®

6. VPI holds New Drug Application ("NDA") No. 203634 for oral tablets containing 9 mg of the active ingredient budesonide, which are sold in the United States under the brand name Uceris®. (SUF ¶ 6)

7. Uceris® is indicated for the induction of remission in patients with active, mild to moderate ulcerative colitis. (SUF ¶ 7)

8. Uceris® was launched on February 14, 2013 by Santarus, Inc. (SUF ¶ 8)

III. Defendants' ANDAs

9. Actavis submitted ANDA No. 205457 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) seeking FDA approval to engage in the commercial manufacture, use, sale, or offer for sale of extended release tablets containing 9 mg of budesonide ("Actavis ANDA product") prior to the expiration of the patents-in-suit. The Actavis ANDA product is a pharmaceutical composition for oral administration. Actavis' ANDA describes a manufacturing process for the production of the Actavis ANDA product. (SUF ¶¶ 21-23)

10. Alvogen submitted ANDA No. 205556 to the FDA under 21 U.S.C. § 355(j)

seeking FDA approval to engage in the commercial manufacture, use, sale, or offer for sale of extended-release tablets containing 9 mg of budesonide ("Alvogen ANDA product") prior to the expiration of the patents-in-suit. The Alvogen ANDA product is a pharmaceutical composition for oral administration. Alvogen's ANDA describes a manufacturing process for the production of the Alvogen ANDA product. (SUF ¶¶ 24-26)

IV. The '888 Patent

11. U.S. Patent No. 8,784,888 was issued by the USPTO on July 22, 2014. The '888 patent will expire on June 20, 2020. The patent names Roberto Villa, Massimo Pedrani, Mauro Ajani, and Lorenzo Fossati as inventors, and lists Cosmo as assignee. (SUF ¶¶ 11, 14-15)

12. Cosmo owns the '888 patent, and Valeant S.à r.l. holds an exclusive license to the patent in the United States. (SUF ¶¶ 16-17)

13. Plaintiffs assert claim 9 against Actavis and claim 6 against Alvogen. (*See* D.I. 221, 223; Tr. at 101, 78-79)

14. Claims 6 and 9 both depend indirectly from claim 1. Claim 1 recites:

> A controlled release oral pharmaceutical composition consisting essentially of:
>
> (1) a tablet core consisting essentially of:
>
> a) budesonide in an amount effective to treat intestinal inflammatory disease; and
>
> b) a ***macroscopically homogeneous composition*** comprising at least one lipophilic excipient, at least one amphiphilic excipient, and at least one hydrogel-forming hydrophilic excipient other than a gum, wherein said budesonide is dispersed in said macroscopically homogeneous composition; and

(2) a coating on said tablet core, said coating consisting essentially of a gastro-resistant film.

(JTX-2004 at col. 10 ll. 19-31) (emphasis added)

15. Claim 6 depends from claim 5. Claim 5 recites: "A controlled release oral pharmaceutical composition according to claim 1, wherein said at least one lipophilic excipient comprises stearic acid or magnesium stearate." (JTX-2004 at col. 10 ll. 44-46) Claim 6 recites: "A controlled release oral pharmaceutical composition according to claim 5, wherein said at least one hydrogel-forming hydrophilic excipient comprises at least one hydroxyalkyl cellulose." (JTX-2004 at col. 10 ll. 47-50)

16. Claim 9 depends from claim 7. Claim 7 recites: "A controlled release oral pharmaceutical composition according to claim 1, wherein said at least one amphiphilic excipient comprises lecithin." (JTX-2004 at col. 10 ll. 51-53) Claim 9 recites: "A controlled release oral pharmaceutical composition according to claim 7, wherein said at least one lipophilic excipient comprises stearic acid or magnesium stearate." (JTX-2004 at col. 10 ll. 58-60)

17. Each of the asserted claims recites a limitation requiring a "macroscopically homogenous composition," which the Court construed, in accordance with Plaintiffs' proposed construction, to mean "a composition of uniform structure throughout, as observed by the naked eye." (D.I. 183 at 7-8)

V. Plaintiffs' Witnesses

18. Dr. Davis is an emeritus professor at the University of Nottingham, England, where he ran a research group studying drug delivery systems. (PTX-45 at 1) He has worked in

pharmaceutical sciences and formulation development for nearly 50 years. (Davis Tr. at 66)[3] Dr. Davis provided testimony regarding Defendants' alleged infringement of the '888 patent.

19. Dr. Shen Luk has a Ph.D. in chemistry and is currently the Chief Scientific Officer of Juniper Pharmaceuticals. (Luk Tr. at 202, 204) Dr. Luk testified that he bisected Defendants' sample tablets (PTX-24; PTX-25) but did not testify regarding the visual appearance of Actavis' or Alvogen's tablets (Luk Tr. at 205, 211).

20. Plaintiffs also presented the deposition testimony of Defendants' fact witnesses Dr. Arun Katragadda, Actavis' primary formulator for the accused product (Katragadda Tr. at 168-69, 182); Dr. Parag Shah, Actavis' Director of Formulation Development (Shah Tr. at 182); Dr. Kavitha Koushik Bandi, Alvogen's formulation manager (Bandi Tr. at 196-97; Joshi Tr. at 185); and Dr. Mayank Joshi, Alvogen's Vice President of Research and Development and corporate designee (Joshi Tr. at 183-85). Each of these fact witnesses possesses a Ph.D. in drug delivery, pharmaceutics, or pharmaceutical sciences.

VI. Actavis' ANDA Product

[redacted]

22. Plaintiffs presented no evidence of anyone examining Actavis' tablets with his or her naked eye to determine whether the tablets had a "uniform structure throughout." Dr. Davis admitted that observation with the naked eye is an available test to determine whether the macroscopically homogenous limitation is satisfied, but he never performed that observation.

[3]Citations to trial testimony are in the form: "([Witness last name] Tr. at [page])."

(Davis Tr. at 115, 141-43)

23. Plaintiffs had samples of Actavis' tablets. (PTX-24) Plaintiffs sent samples of Actavis' tablets to one of their experts, Dr. Luk, but asked him only to bisect them. (Luk Tr. at 205) He offered no opinion at trial about their structure. (Luk Tr. at 205, 209-10) Dr. Davis did not examine any tablets, either whole or bisected. (Davis Tr. at 141-42)

24. Dr. Davis reviewed the magnified photograph of a bisected Actavis tablet included in the report of Dr. Alexander Mullen, Actavis' formulation expert on non-infringement, and testified that the photograph "shows a homogenous structure throughout." (Davis Tr. at 115-16; PTX-641) Dr. Davis testified that even though Dr. Mullen's photograph was enlarged, he could not see a non-homogenous dispersion of excipients. (Davis Tr. at 115) Plaintiffs introduced no evidence that the photographs reflected the level of detail that can be observed with the naked eye, and Dr. Davis admitted that he had no way of knowing whether that was the case. (Davis Tr. at 155) Dr. Davis did not know the lighting in the room when the photographs were taken, the distance between the camera and the tablets, or whether the images Dr. Davis reviewed had been reduced from the full size of the original photographs. (Davis Tr. at 153-54)

25. In the course of performing hardness tests on the ANDA products, Dr. Katragadda personally saw tablets that had been broken. (Katragadda Tr. at 177) Dr. Katragadda testified that he "didn't see any pockets of excipients" and that the tablet "appeared to be uniform in color." (Katragadda Tr. at 177) He also "didn't observe any, any non-uniform distribution in the broken part of the tablet or the – or the circumference of the tablet. . . . It all looked the same . . . ." (Katragadda Tr. at 178)

26. Plaintiffs entered bisected Actavis tablets into evidence. (PTX-24) The Court observed that the tablets had "yellow dots that are not uniformly distributed throughout." (Tr. at 335)

27. Actavis' ANDA describes the design of its ANDA product formulation and its manufacturing process, including testing for blend uniformity and content uniformity. (PTX-175; Davis Tr. at 106-108)

[redacted]

29. The blend of Actavis' ANDA product is prepared in several steps. (PTX-230 at 41, 96; PTX-234 at 2) This process is designed to ensure a uniform distribution of budesonide and the other tablet core components throughout the blend. (Katragadda Tr. at 174-75; Davis Tr. at 99, 106-08, 109; PTX-230 at 41, 96; PTX-234 at 2; PTX-125 at 5) Actavis' ANDA states that "[t]his process of blending in a series of steps ensured homogeneous mixing of 9 mg of active ingredient in 300 mg of blend as evidenced by blend uniformity data and [content uniformity] data from the core tablet." (PTX-230 at 41-42; *see also* Davis Tr. at 106-12; PTX-230 at 72, 77-78, 81-82; PTX-232 at 44)

30. Actavis' ANDA describes the final blend as "homogeneous." (PTX-230 at 4; Davis Tr. at 114) [redacted] There are no irregular pockets of excipients in the final blend. (Katragadda Tr. at 176-77 ("[Y]ou would not see pockets of white or yellow powder after the final blending has taken place.")) Actavis' formulator testified that "the expectation is to

have uniform distribution. . . . [o]f each of the excipients." (Katragadda Tr. at 176; Davis Tr. at 99, 106, 109)

31. Actavis performs blend uniformity testing at the end of processing of the final blend before it is compressed to form tablet cores. (*E.g.*, PTX-232 at 52; PTX-234 at 5; PTX-230 at 88; Davis Tr. at 112-13) Blend uniformity testing entails sampling the final blend from different locations within the blender to ensure that the proportionally correct amount of budesonide is present in the samples taken from each location. (Davis Tr. at 148; PTX- 125 at 6-7) The results of Actavis' blend uniformity testing show that each sample had the correct amount of budesonide with a very narrow standard deviation. (PTX-230 at 42, 88; Davis Tr. at 112-13) Because budesonide is mixed with each of the other tablet core components during the manufacturing process, the final blend uniformity tests are also expected to be indicative of the distribution of excipients in the final blend. (Davis Tr. at 114)

32. [redacted] compression process was designed to prevent segregation of the blend components during tableting, which means that the homogeneity reported throughout the manufacturing process would be conserved. (Katragadda Tr. at 177; Davis Tr. at 99, 108) The compressed tablet cores, thus, have approximately the same uniformity and homogeneity as the final blend. (Katragadda Tr. at 176; Davis Tr. at 99, 106, 108; PTX-230 at 41-42)

33. Following compression of the final blend, Actavis performs content uniformity testing on a number of the manufactured tablets. (PTX-234 at 5) Content uniformity testing involves determining the amount of budesonide present in each of those tablets. (Davis Tr. at

113-14; PTX-232 at 61) As with Actavis' blend uniformity testing, the results of its content uniformity testing are within its specifications and show that each tablet has the correct amount of budesonide. (PTX- 232 at 61; PTX-230 at 42, 88; Davis Tr. at 106, 113-14) Actavis' formulator testified that based on the active ingredient testing, the active ingredient and excipients are expected to be uniformly distributed. (Katragadda Tr. at 178)

34. However, blend uniformity and content uniformity testing do not answer the question of whether Actavis' tablets have uniform structure throughout. These tests evaluate only the amount of active ingredient – not the arrangement of the active ingredient or the excipients. (Davis Tr. at 145, 148-50) Having active ingredient "uniformly distributed" in this context refers to each sample of blend, or each tablet, having approximately the same quantity of active ingredient. It says nothing about how the particles of active ingredient (or any excipient) are arranged in the sample. (*See, e.g.*, Davis Tr. at 148 ("Q. So actually there would be no way to determine from this test how the API looks in the sample because when you find it, it is in solution; right? A. You have dissolved it. That's correct."), 149 ("Q. Okay. And when you do that test on the tablet to get the uniformity of contents, you crush the tablet; correct? A. That would be a normal process, I would imagine. . . . Crush each one and extract them, yes."))

35. Plaintiffs identified only a single document from Actavis that used the word "homogeneous," and the statements in that document refer to uniformity studies on the pre-tableted blend, not on the tablets as a whole. (PTX-0230 at 4; Tr. at 317)

VII. Alvogen's ANDA Product

36. With respect to Alvogen, Plaintiffs present similar evidence. Alvogen's ANDA product is a tablet that contains a delayed-release or enteric coating and a tablet core that

provides controlled release of the active ingredient in a time-dependent manner in the large intestinal sectors. (PTX-176 at 2; PTX-416 at 7; PTX-228 at 11) In its ANDA product, Alvogen uses [redacted] Thus, Alvogen designed its product to have [redacted] interspersed in the separate excipient structure.

37. Plaintiffs presented no evidence of Dr. Davis examining Alvogen's tablets with his naked eye to determine whether they had a "uniform structure throughout." (Davis Tr. at 95, 150-51) Dr. Davis reviewed pictures of bisected Alvogen tablets included in the report of Dr. Reza Fassihi, Alvogen's formulation expert on non-infringement, and testified that they showed a uniform distribution of materials; he further testified that he did "not see a non-homogeneous distribution" even though the photographs were enlarged. (Davis Tr. at 95-96; PTX-640) Dr. Davis opined that with correctly-sized depictions of Alvogen's tablets, "one would also see something [that] has homogeneous and uniform [structure]." (Davis Tr. at 96)

38. Plaintiffs entered bisected Alvogen tablets into evidence (PTX-25), which the Court inspected. The Court observed "holes or bumps" or "striations" that are not evenly distributed throughout the tablets. (Tr. at 337, 311-12)

39. Alvogen's ANDA describes the design of its ANDA product formulation and its manufacturing processes, including testing for blend uniformity and content uniformity. (PTX-176 at 29; Davis Tr. at 88-89; Joshi Tr. at 190-91, 199-200)

40. [redacted]

[redacted]

43. Alvogen performs blend uniformity testing on the final blend before it is compressed to form tablet cores. (*E.g.*, PTX-237 at 21; PTX-176 at 31; Davis Tr. at 92-93) The results of Alvogen's blend uniformity testing show that each sampled location had the correct amount of budesonide with a narrow standard deviation within the required limits. (PTX-237 at 21) Because budesonide is mixed with each of the other tablet core components during the manufacturing process, the final blend uniformity testing suggests that each of the excipients is also uniformly distributed throughout the final blend. (Bandi Tr. at 199-200; Davis Tr. at 93-95; PTX-176 at 43; PTX-228 at 193)

[redacted]

[redacted]

45. Following compression of the final blend, Alvogen performs content uniformity testing on a number of the manufactured tablets. (PTX-237 at 23-24, 29) The results of its content uniformity testing are within its specifications and show that each tablet has the correct amount of budesonide. (Davis Tr. at 93)

46. Plaintiffs identified only one document from Alvogen that refers to homogeneity, and those statements refer to uniformity studies on the pre-tableted blend, rather than the tablets as a whole. (PTX-228 at 193; Tr. at 317)

LEGAL STANDARDS

I. Rule 52(c) Motion

Under Federal Rule of Civil Procedure 52(c), the Court has discretion to enter judgment on any issue after hearing the evidence. *See In re Brimonidine Patent Litig.*, 666 F. Supp. 2d 429, 453 (D. Del. 2009). Rule 52(c) provides that "[i]f a party has been fully heard on an issue during a nonjury trial and the court finds against the party on that issue, the court may enter judgment against the party on a claim or defense that, under the controlling law, can be maintained or defeated only with a favorable finding on that issue."

In considering a motion for judgment under Rule 52(c), the Court "applies the same standard of proof and weighs the evidence as it would at the conclusion of the trial." *EBC, Inc. v. Clark Bldg. Sys., Inc.*, 618 F.3d 253, 272 (3d Cir. 2010). In doing so, the Court "does not view the evidence through a particular lens or draw inferences favorable to either party." *Id.* Further,

the Court will "make determinations of witness credibility where appropriate." *Id.* at 273.

II. Infringement

A patent is infringed when a person "without authority makes, uses, offers to sell, or sells any patented invention, within the United States . . . during the term of the patent." 35 U.S.C. § 271(a). In a Hatch-Waxman case, the ANDA itself informs the infringement inquiry. Under 35 U.S.C. § 271(e)(2)(A), the Court must determine whether, if the drug were approved based on the ANDA, the manufacture, use, or sale of that drug would infringe the patent in the conventional sense. *See Sunovion Pharm., Inc. v. Teva Pharm. USA, Inc.*, 731 F.3d 1271, 1278 (Fed. Cir. 2013). Courts employ a two-step analysis in making an infringement determination. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995). First, the Court must construe the asserted claims. *See id.* Next, the trier of fact must compare the properly construed claims with the accused infringing product. *See id.*

Infringement is a question of fact. *See Hilgraeve Corp. v. Symantec Corp.*, 265 F.3d 1336, 1341 (Fed. Cir. 2001). In order to establish literal infringement, "every limitation set forth in a claim must be found in an accused product, exactly." *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed. Cir. 1995). The plaintiff has the burden of proving infringement by a preponderance of the evidence. *See Siemens Med. Sols. USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc.*, 637 F.3d 1269, 1279-80 (Fed. Cir. 2011). "A patentee may prove infringement by any method of analysis that is probative of the fact of infringement, and circumstantial evidence may be sufficient." *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1372 (Fed. Cir. 2009).

DISCUSSION

Having considered Plaintiffs' testimonial, documentary, and other evidence, as well as the parties' arguments, the Court finds that Plaintiffs have failed to meet their burden of proving infringement of the asserted claims of the '888 patent by a preponderance of the evidence.

The only claim limitation at issue is whether Defendants' ANDA products have a "macroscopically homogeneous composition." During claim construction, the Court adopted Plaintiffs' proposed construction of this term, construing it to mean "a composition of uniform structure throughout, as observed by the naked eye." (D.I. 183 at 7-8) While this construction does not impose any particular requirement for how to determine whether a composition is macroscopically homogeneous, it does at least imply an appropriate starting point for the infringement inquiry: what the tablet's composition looks like when observed by the naked eye.[4]

Nevertheless, for reasons that are entirely unexplained on the record,[5] Plaintiffs did not provide samples of the accused products to their infringement expert, Dr. Davis, so Dr. Davis did not observe them with his naked eye. (*See* Davis Tr. at 141-42, 150-51) Instead, Dr. Davis only reviewed photographs of the tablets taken by Defendants' non-infringement experts. (Davis Tr.

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[4]Defendants contend that the claim construction ***requires*** an expert to observe the accused products by the naked eye and makes all other testing irrelevant. (*See* D.I. 234 at ¶ 23) (citing *Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1380-82 (Fed. Cir. 2005); *Genentech, Inc. v. Wellcome Found. Ltd.*, 29 F.3d 1555, 1563, 1566 (Fed. Cir. 1994)) The Court disagrees. Unlike the claims in *Chimie* and *Genentech*, the construction here does not demand a particular type of quantitative testing. Instead "macroscopically homogeneous composition" is, by its construction, qualitative and may be amenable to various observation techniques. Accordingly, the Court has considered all the evidence presented by Plaintiffs in determining that they have not carried their burden to prove infringement.

[5]*See* Tr. at 293 (Court: "[I]s there anything in the record as to why the plaintiffs didn't just simply have their own expert do his own naked eye test?" Counsel for Plaintiffs: "There is nothing in the record as to why the Plaintiffs did not do that.")

at 95-96, 115-16) Although the photographs may be representative of the tablets, reviewing a photograph is not a good substitute for examining the tablets themselves in the context of this case. Among other things, the photographs are magnified many times (although precisely how magnified is unknown), and the appearance of the photographed tablets may have been affected by factors like lighting and distance from the camera.[6]

Plaintiffs, however, did offer Defendants' tablets into evidence (PTX-24; PTX-25), and invited the Court to look at them itself. (*See* Tr. at 294; *see also id.* at 300, 304 (Defendants not objecting)) Although Defendants contend that issues of infringement must be evaluated from the perspective of a person of skill in the art, *see Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1361 & n.3 (Fed. Cir. 2008), it was appropriate for the Court to allow Plaintiffs to submit the tablets for lay observation by the naked eye, even unassisted by expert testimony as to how an ordinarily-skilled artisan would understand the structure of the bisected tablets. The Federal Circuit has "repeatedly approved the use of expert testimony to establish infringement" but has declined to "state a per se rule that expert testimony is ***required*** to prove infringement when the art is complex." *Centricut, LLC v. Esab Grp., Inc.*, 390 F.3d 1361, 1369-70 (Fed. Cir. 2004) (emphasis added). Thus, while it would have been preferable for Plaintiffs to have provided expert guidance on what an ordinarily-skilled artisan sees when looking at the accused tablets with the naked eye, the Court performed its own observations and used them as part of its

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[6]Plaintiffs presented evidence of observations by Dr. Katragadda regarding Actavis tablets broken during hardness testing. (*See* Katragadda Tr. at 177-78) Although Dr. Katragadda noted that the broken tablet cores looked the same to him, his observations arose in the context of testing for hardness. Thus, his observations were not focused on whether the tablets are macroscopically homogeneous, and there is no indication that he had in mind the claim language at issue here when he viewed the tablets. Dr. Katragadda's testimony, therefore, is not persuasive evidence of infringement.

calculus as to what a person of ordinary skill in the art would see had she looked at the product with her naked eye. *See generally Centricut*, 390 F.3d at 1370 (recognizing pitfalls of plaintiff's failure to supplement complex subject matter with expert opinion).

In viewing Actavis' tablets, the Court found that they do not, to a lay observer at least, appear to be a composition of uniform structure throughout. The Court observed yellow dots that were not uniformly distributed throughout the bisected tablets.[7] (*See* Tr. at 335) With respect to Alvogen's tablets, the Court similarly found that they did not, to a lay observer, appear to be a composition of uniform structure throughout. Instead, Alvogen's tablets appeared to have holes or bumps that were not evenly distributed throughout the bisected tablets. (*See* Tr. at 337)

Thus, the Court's observation of Defendants' tablets, in combination with the lack of observation of the tablets by Plaintiffs' expert, is evidence that Defendants' tablets are not macroscopically homogeneous. *See, e.g.*, *Gumbs v. Int'l Harvester, Inc.*, 718 F.2d 88, 96 (3d Cir. 1983); *Tzu Wei Chen Food Co. v. Chia-Chi Enters., Inc.*, 73 F.3d 379, 1995 WL 714589, at *6 (Fed. Cir. Dec. 5, 1995).

Plaintiffs' other evidence does not persuade the Court to reach a different conclusion. Plaintiffs' infringement theory rests primarily on Defendants' "blend uniformity" and "content uniformity" testing. Although such tests could provide circumstantial evidence of infringement, the Court does not accord them great weight here. In particular, the Court is not persuaded that

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[7]Plaintiffs agreed that a non-uniform distribution of yellow dots (caused by an excipient, [redacted] would mean that the composition is not macroscopically homogeneous. (*See* Tr. at 314, 315 (Court: "If the yellow [redacted] is not distributed uniformly, then does Actavis infringe?" Plaintiffs counsel: "If the yellow [redacted] is, indeed, not distributed uniformly, which I don't think is the case here, then it would be an excipient that's not uniformly distributed and therefore we would have a non-macroscopically homogeneous composition."))

the testing provides strong evidence of how the composition looks in the ***tablet***, which is the inquiry required by the claims of the '888 patent.

Blend uniformity testing is performed on the pre-tableted blend before it is compressed into tablets, not on the final tablets themselves. (*See* Davis Tr. at 144, 155) Blend uniformity testing assesses the amount of an active ingredient in a sample, but does not indicate how the active ingredient is arranged within that sample. (*See* Davis Tr. at 145) In performing this type of test, samples are first taken from different parts of the blender. (*See* Davis Tr. at 155) Once a sample is taken from the blend, it is put in a volumetric flask, a solvent is added to dissolve the sample, and the active ingredient is extracted from the sample. (*See* Davis Tr. at 148) Because this testing method dissolves the sample, it does not help determine how the active ingredient looks or is distributed in the sample. (*See* Davis Tr. at 148)

Plaintiffs' evidence of content uniformity testing is likewise unavailing. Although content uniformity testing is performed on tablets, the testing does not reveal how an active ingredient appears within a tablet. Instead, content uniformity testing is a destructive test used to determine how much active ingredient is in a tablet. When a content uniformity test is performed, the tablet is crushed, dissolved in a solution, and then the active ingredient is extracted. (*See* Davis Tr. at 148-50) Thus, content uniformity testing is not strong evidence of how an active ingredient is distributed within a tablet or what the tablet looks like. (*See* Davis Tr. at 160)

Further, blend uniformity and content uniformity do not directly test any excipients. Although Defendants' corporate witnesses testified by deposition that the expectation is to have uniform distribution of each of the excipients, the testing relied on by Plaintiffs does not confirm

that expectation. (*See* Katragadda Tr. at 176; Joshi at 191) Again, blend uniformity and content uniformity testing do not measure the arrangement of the active ingredient within the tablet, or the amount or arrangement of excipients in a tablet.

With respect to Actavis' ANDA product, the materials and witnesses that describe the uniformity testing indicate that Actavis has a goal of creating a uniform, non-segregated distribution of all ingredients in the blend and the compressed tablets. (*See, e.g.*, Katragadda Tr. at 174-77; PTX-230 at 41-42) Having that goal, however, does not establish that the objective is achieved. Moreover, even if all ingredients are uniformly distributed in the tablet, it is not obvious (and the record does not establish) that such uniform distribution necessarily results in a tablet that appears to the naked eye to be macroscopically homogenous. Finally, Plaintiffs can identify only a single Actavis document that speaks of homogeneity and that document does so in the context of the final blend, not the tablets, reducing the weight the Court believes appropriate to give this document. (*See* PTX-230 at 4)

Plaintiffs' evidence is even less persuasive with respect to Alvogen's ANDA product. Alvogen's blend is composed of [redacted] of active ingredient distributed in a powder of excipients. (PTX-228 at 11) [redacted] As with respect to Actavis, Plaintiffs identify only a single reference to homogeneity, and it, too, is in the context of the pre-tableted blend. (*See* PTX-228 at 193) [redacted] Thus, Alvogen's testing to demonstrate that the amount of active ingredient is uniform

across samples, both in the blend and in the tableted form, is not persuasive evidence as to the appearance of the tablets.

CONCLUSION

For the above reasons, Plaintiffs have failed to prove by a preponderance of the evidence that (1) Actavis infringes claim 9 of the '888 patent and (2) Alvogen infringes claim 6 of the '888 patent. An appropriate Order follows.