NOT FOR PUBLICATION

UNITED	STATES	DISTF	RICT	COURT
DIST	RICT O	F NEW	JER	SEY

: NOVEN PHARMACEUTICALS, INC.,	
Plaintiff,	
V	
WATSON LABORATORIES, INC., and WATSON PHARMACEUTICALS, INC., :	
Defendants.	

Hon. Dennis M. Cavanaugh

OPINION

Civil Action No. 11-cv-5997 (DMC)(JBC)

DENNIS M. CAVANAUGH, U.S.D.J.:

This matter comes before the Court upon the following Motions: i) the Motion of Defendants Watson Laboratories, Inc. and Actavis, Inc.¹ (collectively "Defendants") for Summary Judgment of Invalidity of Asserted Claims of US Patent No 6,210,705; ii) Defendants' Motion for Partial Summary Judgment of Non-Infringement of US Patent No 6,348,211; iii) the Cross-Motion of Plaintiff Noven Pharmaceuticals, Inc. ("Plaintiff") for Leave to File Amended Infringement Contentions and For Additional Claim Construction; and iv) Plaintiff's Cross-Motion for Summary Judgment of No Invalidity of the Asserted Claims of U.S. Patent No. 6,210,705. Pursuant to FED. R. CIV. P 78, no oral argument was heard. Based on the following and for the reasons expressed herein, Defendants' Motion for Summary Judgment of Invalidity of Asserted Claims of US Patent No 6,210,705 is **granted**, Defendants' Motion for Partial Summary Judgment of Non-Infringement of US Patent No 6,348,211 is **granted**, Plaintiff's

¹ Effective January 24, 2013, the entity name of Watson Pharmaceuticals, Inc. was changed to Actavis, Inc.

Cross-Motion for Leave to File Amended Infringement Contentions and For Additional Claim Construction is **denied**, and Plaintiff's Cross-Motion for Summary Judgment of No Invalidity of the Asserted Claims of U.S. Patent No. 6,210,705 is **denied**.

<u>I.</u> <u>BACKGROUND²</u>

A. The Patents-in-Suit

The instant Motions stem from the following two patents that are lawfully owned by Plaintiff: i) United States Patent No. 6,210,705, entitled "Compositions and Methods For Treatment of Attention Deficit Disorder and Attention Deficit/Hyperactivity Disorder With Methylphenidate" (the "'705 Patent"), and ii) United States Patent No. 6,348,211, also entitled "Compositions and Methods For Treatment of Attention Deficit Disorder and Attention Deficit/Hyperactivity Disorder With Methylphenidate" (the "'211 Patent"). Both patents claim, *inter alia*, compositions and methods for treatment of attention deficit disorder and attention deficit/hyperactivity disorder (collectively "ADHD") with transdermal methylphenidate delivery systems.

1) The '705 Patent

The '705 Patent was duly issued by the United States Patent and Trademark Office ("USPTO") on April 3, 2001. Claims 1, 16, 18, and 25 of the '705 Patent include a limitation that requires that the composition compromise of no more than about 5 wt % of acid functional monomers. The claims are as follows:

1. A composition for topical application of methylphenidate comprising methylphenidate in a flexible, finite system, wherein the methylphenidate is present in a therapeutically effective amount sufficient to achieve substantially zero order kinetics for delivery to the skin or mucosa of a patient in need thereof over a period of [time] at least 10 hours, and *wherein the composition comprises no more than about 5 wt % of acid functional monomers*.

² The facts from this section are taken from the parties' pleadings.

16. A method of treating attention deficit disorder and attention deficit/hyperactivity disorder comprising topically administering methylphenidate in a flexible, finite system, wherein the methylphenidate is present in a therapeutically effective amount sufficient to achieve substantially zero order kinetics for delivery to the skin or mucosa of a patient in need thereof over a period of time at least 10 hours, and *wherein acid functional monomers are present in an amount of no more than about* 5 wt %.

18. A composition for topical application of methylphenidate comprising methylphenidate in a flexible, finite system, wherein the methylphenidate is present in an amount sufficient to permit a therapeutically effective dose in a patient over a total duration of 24 hours, wherein the total delivered amount of methylphenidate is from about 0.5 mg to about 100 mg, and *wherein acid functional monomers are present in an amount of no more than about 5 wt %*.

25. A method of treating attention deficit disorder and attention deficit/hyperactivity disorder comprising topically administering methylphenidate in a flexible, finite system, wherein the methylphenidate is present in an amount sufficient to permit a therapeutically effective dose in a patient over a total duration of 24 hours, wherein the total delivered amount of methylphenidate is from about 0.5 mg to about 100 mg, and *wherein acid functional monomers are present in an amount of no more than about 5 wt %*.

Additionally, claims 15, 17, 24, and 26 include limitations of 1 wt % of acid functional

monomers. The claims containing the 5 wt % limitations and the claims containing the 1 wt %

limitations will be referred to collectively as the "'705 Claims."

During claim construction proceedings, Plaintiff argued that the wt % limitations

compare the weight of acid functional monomers to the total monomer content. After a Markman

hearing held on December 6, 2012, this Court adopted Plaintiff's construction for the wt %

limitations as follows:

Wherein, for the monomers in the flexible, finite system, no more than about 5 wt % are acid functional.

Wherein, for the monomers in the flexible, finite system, no more than about 1 wt % are acid functional.

(ECF No. 91, Jan. 4, 2013).

2) The '211 Patent

The '211 Patent was duly issued by the USPTO on February 19, 2002. Claims 1-2, 6-7, 11-14, 16-21, and 28 of the '211 Patent (the "'211 Claims") recite or incorporate the following limitation: "wherein the proportion of methylphenidate:silicone adhesive:acrylic adhesive (wt % dry) is about 5-30:0-70:0-70, respectively" (hereinafter "the proportion limitation"). During claim construction proceedings, Plaintiff argued that the term "about" allows for ranges of 0-80% or 0-90% acrylic adhesive. However, this Court agreed with Defendants' construction and held that the term "about" only allows for the additional margin appropriate for rounding decimals to whole numbers.

B. The Watson ANDA Product

The accused product is Abbreviated New Drug Application No. 200147 (the "Watson ANDA Product"), submitted by Defendants on August 31, 2009. The Watson ANDA Product is a methylphenidate transdermal system that is indicated for the treatment of ADHD. Plaintiff believes that the Watson ANDA Product infringes various claims of the '705 and '211 Patents.

C. The Motions

On July 8, 2013, Defendants filed a Motion for Summary Judgment of Invalidity of Asserted Claims of US Patent No 6,210,705 ("Def.'s '705 Mot.," ECF No. 120) and a Motion for Partial Summary Judgment of Non-Infringement of US Patent No 6,348,211 (ECF No. 121). On August 9, 2013, Plaintiff filed an Opposition to Defendants' Motion for Partial Summary Judgment of Non-Infringement of US Patent No 6,348,211 and a Cross-Motion for Leave to File Amended Infringement Contentions and For Additional Claim Construction (ECF No. 128). On August 10, 2013, Plaintiff filed a Cross-Motion for Summary Judgment of No Invalidity of the Asserted Claims of U.S. Patent No. 6,210,705 ("Pl.'s '705 Mot.," ECF No. 134). On August 30, 2013, Defendants filed a Combined Reply Brief in Support of their Motion for Partial Summary Judgment of Non-Infringement of US Patent No 6,348,211 and Opposition to Plaintiff's Cross-Motion for Leave to File Amended Infringement Contentions and for Additional Claim Construction (ECF No. 139) and a Combined Reply in Support of their Motion for Summary Judgment of Invalidity of Asserted Claims of US Patent No 6,210,705 and Opposition to Defendants' Cross-Motion for Summary Judgment of No Invalidity ("Def.'s '705 Reply." ECF No. 140).

II. STANDARD OF REVIEW

Pursuant to Fed. R. Civ. P. 56(c), summary judgment must be granted "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." The moving party "bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of the [the record] which it believes demonstrate the absence of a genuine issue of material fact." Celotex Corp. v Catrett, 477 U.S. 317, 323 (1986). A genuine issue of material fact exists only if sufficient evidence is presented favoring the nonmoving party for a jury to return a verdict for that party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). "Thus, to withstand a properly supported motion for summary judgment, the nonmoving party must identify specific facts and affirmative evidence that contradict those offered by the moving party." Red Roof Franchising, LLC v. AA Hospitality Northshore, LLC, 877 F. Supp. 2d 140, 147 (D.N.J. 2012) (citing Anderson, 477 U.S. at 256-57). To do so, "[a] party opposing summary judgment must do more than just rest upon mere allegations, general denials, or vague statements." Id. (citing Saldana v. Kmart Corp., 260 F.3d 228, 232 (3d Cir. 2001)). Accordingly, "[w]here the record taken as a whole could not lead a

rational trier of fact to find for the non-moving party, there is no 'genuine issue for trial.'" <u>Matsushita Elec. Indus. Co. v. Zenith Radio Corp.</u>, 475 U.S. 574, 587 (1986).

III. DISCUSSION

A. The '705 Patent

Defendants move for Summary Judgment of invalidity of the '705 Claims, arguing that the claims are invalid for lack of adequate written description. Plaintiff opposes Defendants' Motion and simultaneously moves for Summary Judgment of no invalidity.

A claim is invalid if it lacks written description support in the specification as required by 35 U.S.C. § 112. To comply with this requirement, "the specification must describe an invention understandable to [the] skilled artisan and show that the inventor actually invented the invention claimed." <u>Ariad Pharm., Inc. v. Eli Lilly & Co.</u>, 598 F.3d 1336, 1351 (Fed. Cir. 2010); <u>see also Carnegie Mellon Univ. v. Hoffmann-La Roche Inc.</u>, 541 F.3d 1115, 1122 (Fed. Cir. 2008) ("To satisfy the written description requirement, the applicant does not have to utilize any particular form of disclosure to describe the subject matter claimed, but the description must clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." (internal quotations and citation omitted)). Although compliance with this requirement is a question of fact, it "is amenable to summary judgment in cases where no reasonable fact finder could return a verdict for the non-moving party." <u>Boston Scientific Corp. v. Johnson & Johnson</u>, 647 F.3d 1353, 1361 (Fed. Cir. 2011) (citation omitted).

1) The 5 wt % Limitations

Defendants assert that the '705 Claims containing the 5 wt % limitation are invalid, arguing that these claims lack written description support because this Court construed the 5 wt % limitations as referring to the amount of acid functional monomers *by the weight of the*

monomer content, but the '705 Patent specification refers to the amount of acid functional monomers *by weight of acrylic monomer* (Def.'s '705 Mot. at 1). Thus, Defendants claim that the specification does not convey to a person of ordinary skill in the art "that the acrylic adhesive may contain an excess of about 5 wt% acid functional monomers provided that the acid functional monomers [do] not exceed about 5 wt% of the total monomer content of the composition" (Id. at 8). Essentially, Defendants argue that the invention claimed is broader than the invention described in the specification.

In response, Plaintiff first argues that this Court should rule against Defendants because it already rejected Defendants' written description arguments when it adopted Plaintiff's construction of the wt % limitations after the Markman hearing. However, Plaintiff is mistaken in believing that the '705 Claims are necessarily valid simply because this Court adopted Plaintiff's broad interpretation of the wt % limitations during claim construction proceedings. In Liebel-Flarsheim Co. v. Medrad, Inc., 481 F.3d 1371, 1383 (Fed. Cir. 2007), one of the terms at issue was "physical indicia." In claim construction proceedings, the district court agreed with the plaintiff's broad interpretation of the term. Id. at 1376. However, the district court subsequently found that the plaintiff's patent claims were invalid because the limited written description did not sufficiently convey the breadth of the patent. Id. The Federal Circuit affirmed and noted that the plaintiff "argued for a broad meaning, and succeeded, but suffers a Pyrrhic victory." Id. at 1383. Thus, this Court will not deny Defendants' Motion and grant Plaintiff's solely because it ruled for Plaintiff during claim construction proceedings.

Second, Plaintiff points to portions of the '705 Patent specification and argues that they show that the degradation of methylphenidate is reduced by minimizing acid functional groups, regardless of the source. For example, the specification states that "methylphenidate, in

particular the base form, can be unstable and undergoes degradation in the presence of acid functional groups which are contained in adhesives . . . and other components of the topical composition" and discloses that the degradation of methylphenidate increases with each 1% increase of acid functional component. However, Defendants persuasively argue that although this language describes the effect of reducing acid functional groups in general, it "provides no blaze marks that would lead a person of ordinary skill to compositions having no more than 5 wt % acid functional monomers by weight of the total monomer content" (Def.'s '705 Reply at 9).

Third, Plaintiff contends that the '705 Patent specification includes the original claims filed, and that a number of these claims "demonstrate ample written description beyond the specific preferred 5 wt % acrylic embodiment" (Pl.'s '705 Mot. at 9). However, during the prosecution of the '705 Patent, the Examiner rejected these claims as "not reasonably provid[ing] enablement for a composition wherein the amounts and proportions are not claimed," leaving a person of ordinary skill unable to obtain the "desired flux rate for the desired period of time" based on the patent's teachings. Plaintiff acquiesced in the rejection and amended the original claims to include the 5 wt % limitations. Thus, Plaintiff cannot argue that the original claims render the specification sufficient.

Fourth, Plaintiff points to the following language in the '705 Patent specification and argues that it shows that a 5 wt % functional acrylic polymer is only a *preferred* embodiment:

In view of the foregoing, *acrylic polymers* that are non-functional, hydroxyl functional, *or minimally acid functional are preferred*.

A *preferred embodiment* for attaining at least 10 hours of substantially zero-order delivery is *to include in the composition the polymers described above*, such as the *acrylics having no or minimal functional groups*.

Plaintiff contends that it is improper to consider only the preferred embodiments in assessing the scope of a patent's written description. This Court finds that nothing in the above quoted

language relates to a person of ordinary skill that Plaintiff possessed other embodiments having an acrylic adhesive with more than 5 wt % acid functional monomers. Thus, contrary to Plaintiff's assertion, the scope of the '705 Claims cannot be "'derived' from the teachings of the specification" (<u>Id.</u> at 13).

Fifth, Plaintiff claims that Defendants' overbreadth argument defies logic and common sense because nothing in the '705 Patent supports the contention that "the degradation of methylphenidate changes substantially if the same overall level of acid functional monomers came from just one acrylic, instead of coming from two different acrylics" (Id. at 14). Plaintiff argues that Defendants' expert, Dr. Walters, testified that he did not know if it would make a difference if the overall acid functional monomer level was the preferred 5 wt % or less, but one of more of the acrylic components was above the 5 wt % criterion. However, at issue is what Plaintiff's specification disclosed, and Dr. Walters concluded that a person of ordinary skill would not understand that the inventors possessed the full breadth of the invention covered by the 5 wt % limitation. See ICU Med., Inc. v. Alaris Med. Sys., Inc., 558 F.3d 1368, 1377-78 (Fed. Cir. 2009) (affirming a finding of invalidity when the patent specification only included valves with spikes but the claims covered valves both with and without spikes). This Court finds that this conclusion is sound for the reasons discussed above. Further, this Court agrees that the testimony of Dr. Enscore, Plaintiff's expert, is suspect, as Dr. Enscore admitted at his deposition that his opinions were based on inserting the word "acrylic" into the Court's claim construction a word that is completely absent from the construction that the court upheld after the Markman hearing.

Finally, this Court finds that it is telling that not a single one of the twenty-nine examples

in the '705 Patent specification include an acrylic adhesive having more than 5 wt % acid functional monomers by weight of the acrylic polymer. Although Plaintiff correctly asserts that it is not required that the patent specification disclose every example that falls within the claims, the lack of any example including an acrylic adhesive having more than 5 wt % acid functional monomers by weight of the acrylic polymer weighs against Plaintiff's constant argument that '705 Patents' "general teachings" show that such a composition is included. Thus, this Court finds that Defendants have adequately shown that the '705 Claims are broader than the disclosure in the specification

Accordingly, Defendants' Motion for Summary Judgment is granted and Plaintiff's Cross-Motion for Summary Judgment is denied.

2) The 1 wt % Limitations

In its Motion for Summary Judgment, Defendants assert that "[c]laims 15, 17, 24 and 26 of the '705 patent, which contain the 1 wt % limitations, fail to satisfy the written description requirement for the same reasons as the claims containing the 5 wt % limitations" (Def.'s '705 Mot. at 19). Defendants do not elaborate on this argument because "Drs. Walters and Enscore are in agreement that the analysis for the 5 wt % limitations applies equally to the 1 wt % limitations" (Id.). In its Cross-Motion and Opposition, Plaintiff claims that Defendants' Motion should be denied because it did not address the 1 wt % limitations and states that "[Defendants'] overbreadth concerns do not apply to the 1 wt % limitations" (Pl.'s '705 Mot. at 22-23).

Plaintiff cannot argue that a different analysis applies to the 1 wt % limitations after consistently agreeing that the analysis for the 1 wt % limitations is the same as the analysis for the 5 wt % limitations. (See Lydisgen Dec., Ex. 7 ¶ 135 ("The same analysis applies to Dr. Walters' assertions concerning the 1 wt % limitation."); 2nd Lydisgen Dec., Ex 18 at 153 ("The claims containing the 1 wt % acid functional monomer limitations have adequate support for the same reasons as discussed, supra, for the 5 wt % acid functional monomer limitations.")). Accordingly, this Court rules in favor of Defendants with respect to the claims containing the 1 wt % limitations for the same reasons as discussed for the claims containing the 5 wt % limitations.

B. The '211 Patent

Defendants seek partial Summary Judgment of non-infringement of the '211 Claims, arguing that the Watson ANDA Product does not literally infringe these claims. Plaintiff Cross-Moves for leave to file amended infringement contentions and for additional claim construction.

1) Non-Infringement

A determination of patent infringement involves two steps. "The first step is determining the meaning and scope of the patent claims asserted to be infringed. The second step is comparing the properly construed claims to the device accused of infringing." <u>Markman v.</u> <u>Westview Instruments, Inc.</u>, 52 F.3d 967, 976 (Fed. Cir. 1995). A patentee must present proof that "the accused product meets each and every claim limitation." <u>Forest Labs., Inc. v. Abbott</u> <u>Labs.</u>, 239 F.3d 1305, 1310 (Fed Cir. 2001). If even one limitation is missing in the accused product, there is no literal infringement. <u>See Dolly, Inc. v. Spaulding & Evenflo Cos.</u>, 16 F.3d 394, 397 (Fed. Cir. 1994); <u>Kraft Foods, Inc. v. Int'l Trading Co.</u>, 203 F.3d 1362, 1370 (Fed. Cir. 2000). Therefore, the second step may be decided on summary judgment "when no reasonable jury could find that every limitation recited in the properly construed claim either is or is not found in the accused device." <u>Bai v. L & L Wings, Inc.</u>, 160 F.3d 1350, 1353 (Fed. Cir. 1998).

Defendants assert that the Watson ANDA Product does not infringe the '211 Claims because all dosage strengths of the Watson ANDA Product include methylphenidate:silicone adhesive:acrylic adhesive (wt % dry) in the following proportion: 21:0:79. Thus, Defendants argue that because this Court found that the term "about" in the proportion limitation only allows for the rounding of decimals to whole numbers, the 79% acrylic adhesive present in the Watson ANDA product does not literally fall within the "0-70" claimed range for the acrylic adhesive required by the proportion limitation. Plaintiff, however, contends that the terms "proportion" and "ratio" refer to the *total weight* of the composition (which includes components other than methylphenidate, silicone adhesive, and acrylic adhesive). Therefore, according to Plaintiff, because the Watson ANDA Product contains 18.3 % methylphenidate and 68.7 % acrylic adhesive, it literally infringes the '211 Claims.

This Court finds no support for the proposition that the terms "proportion" and "ratio" refer to the entire composition rather than to the dry weight of the three components. Plaintiff's expert even admitted that "Watson's ANDA Products contain a slightly different ratio of methylphenidate:silicone adhesive:acrylic adhesive (wt % dry) [than the proportion limitation], namely the ratio of 21%:0%:79%," and went on to assert that the use of 79% acrylic adhesive in the Watson ANDA Product is nonetheless equivalent to the proportion limitation under the doctrine of equivalents (Pe Decl., Ex. 10 ¶ 115-117). As discussed below, the doctrine of equivalents arises when a claim element is not literally present in the accused product. Further, the language used by Plaintiff throughout this action shows that Plaintiff understood that "proportion" refers to the ratio of the three components based on their combined dry weight, not the weight of the entire composition. For example, in its Amended Infringement Contentions, Plaintiff asserts that "Watson's ANDA Products contain methylphenidate:silicone adhesive:acrylic adhesive (wt % dry) *in the ratio of*: 21%:0%:79%" (Lydisgen Dec., Ex. 5) (emphasis added).

This Court finds no need to conduct additional claim construction regarding the word "proportion." Plaintiff was free to raise this issue during claim construction proceedings. It seems that Plaintiff is attempting to find an alternative way to show literal infringement after its interpretation of the word "about" was denied. Additionally, this Court finds that Plaintiff has not been diligent in seeking to amend its infringement contentions, as it has known of the composition of the Watson ANDA Product since November 4, 2011, the date that Defendant produced its ANDA to Plaintiff. Further, allowing Plaintiff to amend its infringement contentions would prejudice Defendants, as Defendants have already gone through the claim construction process, engaged in expert discovery, and filed a motion for summary judgment in reliance upon the interpretation of the word "proportion" that has been used by both parties. Accordingly, Plaintiff's Cross-Motion for Leave to File Amended Infringement Contentions and for Additional Claim Construction is denied.

2) The Doctrine of Equivalents

The doctrine of equivalents allows a plaintiff to establish, in certain instances, that a claim element, though not literally present, is nevertheless met by demonstrating that the missing element has been replaced by a structure that performs the same function in the same way to achieve the same result as the claim element in the patented device. <u>See Warner–Jenkinson Co.</u> <u>v. Hilton Davis Chem. Co.</u>, 520 U.S. 17, 35 (1997). The doctrine of equivalents, however, is an "equitable" tool that is applicable "only when the changes [in the accused product] are so insubstantial as to result in a fraud on the patent." <u>Slimfold Mfg. Co. v. Kinkead Indus., Inc.</u>, 932 F.2d 1453, 1457 (Fed. Cir. 1991).

The doctrine of equivalents has limitations. When a patentee "originally claimed the subject matter alleged to infringe but then narrowed the claim in response to a rejection, he may

not argue that the surrendered territory comprised unforeseen subject matter that should be deemed equivalent to the literal claims of the issued patent." <u>Festo Corp. v. Shoketsu Kinzoku</u> <u>Kogyo Kabushiki Co., Ltd.</u>, 535 U.S. 722, 733-34 (2002). A narrowing amendment that is made to comply with any requirement of the Patent Act can evoke estoppel. <u>Id.</u> at 736. For example, if a § 112 amendment is necessary and narrows the patent's scope - even if only for the purpose of better description - estoppel may apply. <u>Id.</u> at 737. However, the Supreme Court also held that there are three exceptions to this rule:

[1] The equivalent [was] unforeseeable at the time of the application; [2] the rationale underlying the amendment . . . bear[s] no more than a tangential relation to the equivalent in question; or [3] there [is] some other reason . . . that the patentee could not reasonably be expected to have described the insubstantial substitute in question.

<u>Id.</u> at 740-41.

Defendants assert that Plaintiff is barred from relying on the doctrine of equivalents because during the prosecution of the '211 Patent, Plaintiff added the proportion limitation by amendment in order to overcome enablement rejection.³ Plaintiff, however, contends that the second <u>Festo</u> exception applies because the Examiner's rejection related to the methylphenidate range, not the acrylic range, and thus the 79 wt % acrylic in the Watson ANDA Product is only "tangential" to the narrowing amendment. To support this argument, Plaintiff points to the fact that it argued only as to the proportion of methylphenidate in response to the Examiner's rejection. However, the Examiner's rejection stated that the claims of the '211 Patent were insufficient because, among other things, "the claims are silent with regard to the composition of the flexible finite system" and "[t]he amounts and/or proportions and the carrier/system⁴ are both

³ Defendants also claim that Plaintiff is barred from relying on the doctrine of equivalents based on the disclosure dedication doctrine. Because this court finds that Plaintiff is barred from relying on the doctrine of equivalents due to prosecution history estoppel, it need not address the disclosure dedication doctrine.

⁴ It is clear from the language of the '211 Patent that an adhesive is a preferred type of carrier (See Lydisgen Dec.,

critical to the invention" (Lydisgen Dec., Ex. 7). Further, Defendants correctly argue that the fact that the Examiner's rejection called for the recitation of "proportions" shows that the rejection pertained not only to methylphenidate but to other components as well. Finally, Plaintiff's amendment defined not only the amount of methylphenidate, but the relative quantity of silicone and acrylic adhesive. This weighs against Plaintiff's argument that the 79 wt % acrylic in the Watson ANDA Product is only "tangential" to the narrowing amendment. See Felix v. Am. Honda Motor Co., Inc., 562 F.3d 1167, 1184 (Fed. Cir. 2009) ("[T]he inquiry into whether a patentee can rebut the Festo presumption under the 'tangential' criterion focuses on the patentee's objectively apparent reason for the narrowing amendment[, which must be] discernible from the prosecution history record" (citation omitted)). Therefore, this Court finds that Plaintiff' is barred from relying on the doctrine of equivalents. Accordingly, Defendants' Motion for Summary Judgment of non-infringement of the '211 Patent is granted.

IV. CONCLUSION

For the foregoing reasons Defendants' Motion for Summary Judgment of Invalidity of Asserted Claims of US Patent No 6,210,705 is **granted**, Defendants' Motion for Partial Summary Judgment of Non-Infringement of US Patent No 6,348,211 is **granted**, Plaintiff's Cross-Motion for Leave to File Amended Infringement Contentions and For Additional Claim Construction is **denied**, and Plaintiff's Cross-Motion for Summary Judgment of No Invalidity of the Claims of U.S. Patent No. 6,210,705 is **denied**. An appropriate order follows this Opinion.

Dennis M. Cavanaugh, U.S.D.J.

Date: Original: cc: November **26**, 2013 Clerk's Office Hon. James B. Clark U.S.M.J. All Counsel of Record File

Ex. 6) ("In a preferred embodiment, the carrier comprises an adhesive.").