United States District Court,
D. Colorado.

SHIRE LLC,
Plaintiff.
v.
SANDOZ, INC,
Defendant.

Civil Action No. 07-cv-00197-EWN-CBS

Sept. 24, 2008.

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ORDER AND MEMORANDUM OF DECISION

EDWARD W. NOTTINGHAM**, Chief Judge.**

This is a patent infringement case. Plaintiff, Shire LLC, asserts that Defendant Sandoz, Inc., infringed upon its patents. This matter comes before the court on (1) "Plaintiff Shire LLC's Motion for Summary Judgment and Memorandum of Law in Support," filed December 26, 2007, and (2) "Amended Version of Defendant Sandoz, Inc.'s Motion for Summary Judgment of Noninfringement," filed January 2, 2008. Jurisdiction is premised upon 28 U.S.C. s.s. 1331 and 1338 (2008).

BACKGROUND

1. The Hatch-Waxman Act

Companies marketing drug products in the United States under a New Drug Application ("NDA") must list the patents that "claim[ ] the drug or a method of using the drug that is the subject of the new drug application ... and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug product" in the Food and Drug Administration's ("FDA") Approved Drug Products with Therapeutic Equivalents Evaluations, commonly known as the "Orange Book." *See* 21 C.F.R. s. 314.53(b).

The Drug Price Competition and Patent Term Restoration Act of 1984, known as the "Hatch-Waxman Act," 21 U.S.C. s. 355 (2000), authorizes Abbreviated New Drug Applications ("ANDA") which substantially

"shorten the time and effort needed to obtain marketing approval," ... "as an additional means of eliminating the *de facto* extension at the end of the patent term in the case of drugs, and to enable new drugs to be marketed more cheaply and quickly [.]" Eli Lilly and Co. v. Medtronic, Inc., 496 U.S. 661, 676, 110 S.Ct. 2683, 2691, 110 L.Ed.2d 605 (1990); *see also* Merck KGAA v. Integra Lifesciences, Ltd., 545 U.S. 193, 196, 125 S.Ct. 2372, 2377, 162 L.Ed.2d 160 (2005) ("Drugmakers that desire to market a generic drug [a drug containing the same active ingredients as a drug already approved for the market] may file an abbreviated new drug application [ANDA] with the FDA.").

Pursuant to 21 U.S.C. s. 355(j)(2)(A)(vii), an application to market a generic version of an NDA drug product must contain one of four certifications concerning all patents listed in the Orange Book for the referenced NDA drug. A "paragraph IV certification" certifies the patent listed in the Orange Book for the referenced NDA drug will not be infringed by the manufacture, use, or sale of the generic applicant's drug product. 21 U.S.C. s. 355(j)(2)(A)(vii). If an ANDA applicant makes this "paragraph IV certification," it must send a notice letter to the NDA holder and the patentee of its certification and provide a detailed statement of the basis for its certification of noninfringement and/or invalidity. 21 U.S.C. s. 355(j)(2)(B)(ii).

According to 35 U.S.C. s. 271(e)(2), the filing of an ANDA with a "paragraph IV certification" provides a federal court with subject matter jurisdiction to adjudicate infringement on a prospective basis, before the ANDA applicant has made, used, sold, or offered to sell its generic product in the United States. 35 U.S.C. s. 271(e)(2); Eli Lilly, 496 U.S. at 676, 110 S.Ct. 2683 at 2691, 110 L.Ed.2d 605 (section 271(e)(2) defines "a new [and somewhat artificial] act of infringement for a very limited and technical purpose that relates only to certain drug applications.") If the NDA holder and/or patentee files an infringement suit within 45 days after receiving the notice letter, FDA approval of the ANDA is automatically stayed for 30 months. *See* 21 U.S.C. s. 355(j)(5)(B)(iii).

2. Factual Background

Plaintiff is a Kentucky corporation with its principal place of business in Kentucky. (Compl. para. 1 [filed Jan. 26, 2007] [hereinafter "Compl."].) Defendant is a Colorado corporation with its principal place of business in Colorado. (*Id*. para. 2.)

Shire is the holder of NDA No. 21-303, approved by the FDA for the manufacture and sale of pharmaceutical compositions containing mixed amphetamine salts for the treatment of Attention Deficit Hyperactivity Disorder ("ADHD"). (Pl. Shire LLC's Mot. for Summ. J. and Mem. of Law in Supp. [filed Dec. 26, 2007] [hereinafter "Pl.'s Br."], Statement of Undisputed Material Facts [hereinafter "SOF"] para. 1; *admitted at* Def. Sandoz, Inc.'s Resp. to Shire LLC's Mot. for Summ. J. [filed Feb. 8, 2008] [hereinafter "Def.'s Resp."], Resp. to Statement of Undisputed Material Facts [hereinafter "RSOF"] para. 1.) Adderall XR(R) is marketed and sold in the United States under NDA No. 21-303. (*Id.,* SOF para. 2; *admitted at* Def.'s Resp., RSOF para. 2.)

Shire is also the assignee of the U.S. Patent No. 6,322,819 ("the '819 patent") and U.S. Patent No. 6,605,300 ("the '300 patent"), both entitled "Oral Pulsed Dose Drug Delivery System." (Id., SOF para. 3; *admitted at* Def.'s Resp., RSOF para. 3; Preliminary Pretrial Order [filed Nov. 1, 2007] [hereinafter "PPO"] at 1.) Shire listed the '819 and '300 patents with the FDA Orange Book, in connection with NDA No. 21-303, as covering Adderall XR(R). (Id., SOF para. 4; *admitted at* Def.'s Resp., RSOF para. 4.) Shire has Pediatric Exclusivity on these patents through April 21, 2019. (PPO at 1.)

The '819 patent teaches a "multiple pulsed dose delivery system for amphetamine salts and mixtures thereof." (Def.'s Br., Ex. 1 [the '819 Patent] at col.3.) The '819 patent contains:

A multiple pulsed dose drug delivery system for pharmaceutically active amphetamine salts, comprising an immediate-release component and an enteric delayed-release component wherein (1) the enteric release coating has a defined minimum thickness and/or (2) there is a protective layer between the pharmaceutically active amphetamine salt and the enteric release coating and/or (3) there is a protective layer over the enteric release coating.

(Id. at 1.) The enteric release coating layer delays the release of the drug for a specific period of time and then releases the drug rapidly and completely within about 30-60 minutes. (Id. at col. 3.)

The '300 patent states: "This application is a 371 of PCT/US99/24554 filed Oct. 20, 1999, which is continuation-in-part of application Ser. No. 09/176,542, filed Oct. 21, 1998, now U.S. Pat. No. 6,322,819...." (Def.'s Br., SOF para. 7; *admitted in relevant part at* Pl.'s Resp., RSOF para. 7.) "A continuation-in-part is an application filed during the lifetime of an earlier nonprovisional application, repeating some substantial portion or all of the earlier nonprovisional application and *adding matter not disclosed* in the said earlier nonprovisional application." *U.S. Patent & Trademark Ofc., Manual of Patent Examining Procedure* s. 201.08 (emphasis in original). Comparing the '819 and '300 patents, the '300 patent (1) refers to an "enteric release dosage form" instead of an "enteric release coating" and (2) states that the formulation will be "sufficient to maintain an effective level of amphetamine base salts in the patient over the course of at least 8 hours without further administration of amphetamine base salt." (Id., Ex. 2 [the ' 300 patent] at col. 13.)

Sandoz filed ANDA No. 78-497 with the FDA, including paragraph IV certifications to both the '819 and '300 patents. (Id., SOF para. 5; *admitted at* Def.'s Resp., RSOF para. 5.) On November 29, 2006, Sandoz notified Shire of its paragraph IV certifications to both the '819 and '300 patents. (Id., SOF para. 6; *admitted at* Def.'s Resp., RSOF para. 6.) This notice letter specified that the FDA has received an ANDA for Adderall XR(R) brand amphetamine aspartate, amphetamine sulfate, dextroamphetamine saccharate, dextroamphetamine sulfate extended release capsules, 5 mg, 10 mg, 15 mg, 20 mg, 25 mg and 30 mg, which contains data from bioequivalence and/or bioavailability studies. (Id., SOF para. 7; *admitted at* Def.'s Resp., RSOF para. 7.) Sandoz's ANDA, assigned No. 78-497, seeks approval to engage in the commercial manufacture, use, and sale of generic versions of Adderall XR(R) ("Defendant's proposed products") before expiration of Shire's '819 and '300 patents. (PPO, at 2.)

"On January 31, 2008, the Patent and Trademark Office ("the PTO") mailed a Notice of Allowance on the '300 reissued patent application[,]" (Pl.'s Reply at 23), and the '819 is currently in the reissuing process. (*See* Pl.'s Resp. at 119-20.)

3. Procedural Background

On January 26, 2007, Shire filed a complaint against Sandoz for infringement of the '819 and '300 patents, claiming that (1) Sandoz's submissions to FDA of paragraph IV certifications for the '819 and '300 patents to obtain approval to engage in the commercial manufacture, use, or sale of its ANDA products before expiry of the '819 and '300 patents constitute infringement of the '819 and '300 patents; (2) the commercial manufacture, use, sale, offer for sale, or importation into the United States of Sandoz's ANDA products will infringe the '819 and '300 patents; and (3) these acts of infringement are willful, rendering this case

"exceptional" under 35 U.S.C. s. 285. (*See* Compl.) Shire claims that it will prove by a preponderance of the evidence that Sandoz's ANDA products: (1) literally meet each and every claim limitation of the '300 patent, and therefore literally infringe this patent; and (2) infringe the '819 patent under the doctrine of equivalents. (PPO at 3.)

On March 26, 2007, Defendant filed its answer, asserting affirmative defenses for noninfringement, invalidity of the patents under 35 U.S.C. s.s. 101, 102, 103 and/or 112, sham litigation, and patent misuse, and counterclaims for invalidity of the patents and declaratory judgment of noninfringement. (*See* Answer, Affirmative Def [sic] and Counterclaims of Sandoz, Inc. [filed Mar. 26, 2007].)

On December 21, 2007, Defendant filed a brief in support of a motion for summary judgment, FN1 arguing that the intrinsic evidence demonstrates that Sandoz's "product is outside the literal scope of the asserted claims," and also precludes "Shire from arguing infringement under the doctrine of equivalents." (Mem. in Supp. of Def. Sandoz, Inc.'s Mot. for Summ. J. of Noninfringement [filed Dec. 21, 2007] [hereinafter "Def.'s Br."] at 8.) The core of Defendant's argument appears to be the allegations that (1) Sandoz's products contain a pH-independent coating that Shire had disclaimed from the scope of the '819 and ' 300 patents and (2) Sandoz's ANDA products provide for continuous, sustained release while both the '819 and ' 300 patents require a period of no drug release. (*See* id.)

FN1. Defendant incorporated this brief by reference in its amended version of the motion for summary judgment, filed January 2, 2008, even though the original motion for summary judgment, filed December 21, 2007, was rendered moot upon Defendant's filing of the amended version of the motion. (*See* 09/16/08 Courtroom Minutes.)

On February 8, 2008, Plaintiff responded, arguing, *inter alia,* that contrary to Defendant's assertions of continuous, sustained release, Shire has shown through independent testing and expert opinion that Sandoz's ANDA products demonstrate a period of no drug release; and "[a]s to each and every claim limitation introduced by Sandoz in its opening brief, Shire presents-through its experts-compelling arguments to the contrary[,]" and that "questions of material fact exist as to the foreseeability of the use of coatings, such as those used in Sandoz's ANDA products, for a once-daily formulation of amphetamine for the treatment of Attention-Deficit Hyperactivity Disorder ('ADHD')." (*See* Pl. Shire LLC's Mem. in Opp'n to Def. Sandoz, Inc.'s Mot. for Summ. J. of Noninfringement [filed Feb. 8, 2008] [hereinafter "Pl.'s Resp."] at 13-14.) Defendant replied on February 28, 2008. (Reply in Supp. of Sandoz, Inc.'s Mot. for Summ. J. of Noninfringement [filed Feb. 28, 2008] [hereinafter "Def.'s Reply"].)

On December 26, 2007, Plaintiff filed a motion for summary judgment, arguing that the '819 and '300 patents are not invalid under 35 U.S.C. s.s. 101 and 102, and requesting that the court strike and/or dismiss Defendant's affirmative defenses of sham litigation and patent misuse. (*See* Pl. Shire LLC's Mot. for Summ. J. and Mem. of Law in Supp. [filed Dec. 26, 2007] [hereinafter "Pl.'s Br."].) On February 8, 2008, Defendant responded, stating that (1) it stipulates "to dismissal of its defenses under 35 U.S.C. s.s. 101 and 102 and does not object to the Court entering summary judgment on those defenses" but arguing that (2) Plaintiff's request for summary judgment on Defendant's "affirmative defenses of patent misuse and sham litigation should be denied because there is at least a question of fact as to whether Shire brought this lawsuit without basis and merely to delay approval of Sandoz's ANDA for as long as possible." (Def. Sandoz, Inc.'s Resp. to Shire LLC's Mot. for Summ. J. [filed Feb. 8, 2008] [hereinafter "Def.'s Resp."].) Plaintiff replied on February 28, 2008. (Pl. Shire LLC's Reply to Sandoz, Inc.'s Resp. to Shire LLC's Mot. for Summ. J. [filed

Feb. 28, 2008] [hereinafter "Pl.'s Reply"].)

ANALYSIS

1. Legal Standard for Summary Judgment

Pursuant to Rule 56(c) of the Federal Rules of Civil Procedure, the court may grant summary judgment where "the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." FED.R.CIV.P. 56(c); *see* Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248-50, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986); Concrete Works, Inc. v. City & County of Denver, 36 F.3d 1513, 1517 (10th Cir.1994). The moving party bears the initial burden of showing an absence of evidence to support the nonmoving party's case. Celotex Corp. v. Catrett, 477 U.S. 317, 325, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). "Once the moving party meets this burden, the burden shifts to the nonmoving party to demonstrate a genuine issue for trial on a material matter." Concrete Works, 36 F.3d at 1518 (citing Celotex, 477 U.S. at 325). The nonmoving party may not rest solely on the allegations in the pleadings, but must instead designate "specific facts showing that there is a genuine issue for trial." Celotex, 477 U.S. at 324; *see* FED.R.CIV.P. 56(e). A fact in dispute is "material" if it might affect the outcome of the suit under the governing law; the dispute is "genuine" if the evidence is such that it might lead a reasonable jury to return a verdict for the nonmoving party. Allen v. Muskogee, 119 F.3d 837, 839 (10th Cir.1997) (citing Anderson, 477 U.S. at 248). The court may consider only admissible evidence when ruling on a summary judgment motion. *See* World of Sleep, Inc. v. La-Z-Boy Chair Co., 756 F.2d 1467, 1474 (10th Cir.1985). The factual record and reasonable inferences therefrom are viewed in the light most favorable to the party opposing summary judgment. Byers v. City of Albuquerque, 150 F.3d 1271, 1274 (10th Cir.1998) (citing Concrete Works, 36 F.3d at 1517).

2. Patent Infringement

A patent infringement analysis involves a two-step process. "First, the court determines the scope and meaning of the patent claims asserted," Cybor Corp. v. FAS Technologies, Inc., 138 F.3d 1448, 1454 (Fed.Cir.1998) (en banc) (citing Markman v. Westview Instruments, Inc., 517 U.S. 370, 371-73, 116 S.Ct. 1384, 1387-88 [1996]), "and then the properly construed claims are compared to the allegedly infringing device." *Id*. (citation omitted). "The first step is a question of law; the second step is a question of fact." Freedman Seating Co. v. Am. Seating Co., 420 F.3d 1350, 1357 (Fed.Cir.2005) (citation omitted).

"[A]n invention is construed not only in the light of the claims, but also with reference to the file wrapper or prosecution history in the Patent Office." Graham v. John Deere Co., 383 U.S. 1, 33, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966).

The prosecution history, which we have designated as part of the "intrinsic evidence," consists of the complete record of the proceedings before the PTO and includes the prior art cited during the examination of the patent. Like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent. Furthermore, like the specification, the prosecution history was created by the patentee in attempting to explain and obtain the patent. Yet because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes. Nonetheless, the prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.

Phillips v. AWH Corp., 415 F.3d 1303, 1317 (Fed.Cir.2005) (internal citations and quotation marks omitted). The court will address each step in turn, but first discusses two issues affecting the claim construction in this case.

a. Preliminary Matters

i. Collateral Estoppel

The parties have brought to the court's attention that the '819 and '300 patents have been subject matter of three other cases: *Shire Labs. Inc. v. Impax Labs., Inc.,* 03-CV-01164 (GMS) and 05-CV-00020 (GMS), and *Shire LLC v. Colony Pharmaceuticals, Inc., Actavis, Inc., and Actavis Group hf,* CV07-718 CCB. (Def.'s Br., SOF para. 47; *admitted at* Pl.'s Resp., RSOF para. 47.) On February 9, 2005, the *Impax* court issued an order construing certain terms in the '819 and '300 patents. (Id., SOF para. 48; *admitted at* Pl.'s Resp., RSOF para. 48.) On January 19, 2006, Plaintiff announced the settlement of its suit against Impax Laboratories, Inc. in a press release. (Id., SOF para. 48; *admitted at* Pl.'s Resp., RSOF para. 48.) The *Colony* court, on the other hand, determined that "Shire retracted its alleged disclaimers by accepting the Patent Office position and finding another way to distinguish the prior art." (Pl.'s Resp., Ex. 51 [the *Colony* court's decision] at 11.)

Plaintiff asserts that the analysis and holding in *Colony* are "consistent with Shire's position of no disclaimer of claim scope with respect to "enteric release coating" during prosecution of the '819 patent application[,]" and its "experts' analysis of the '819 patent file history." (Pl.'s Resp. at 100 [citations omitted].) Defendant, however, claims that the court should give preclusive or *stare decisis* effect to the *Impax* court's claim construction. (Def.'s Reply at 12.) Accordingly, the court will first address the issue of whether a *Markman* ruling FN2 is a judgment on the merits for purposes of collateral estoppel.

FN2. The Supreme Court, in Markman v. Westview Instruments, Inc., 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996), determined that claim construction is an issue of law for the court to resolve after considering evidence and argument regarding the proper interpretation of the patent claims and their terms.

Neither *Markman* nor the Federal or the Tenth Circuits has directly addressed the issue whether a *Markman* ruling is a final judgment for purposes of collateral estoppel, particularly where the parties have settled the case before the court entered a final judgment. Several district courts, however, have discussed and taken opposite positions regarding the application of collateral estoppel when dealing with other courts' claim construction. *Compare, e.g.,* TM Patents, L.P. v. Int'l Bus. Mach., Corp., 72 F.Supp.2d 370 (S.D.N.Y.1999) (holding that claim construction is a final judgment for the purpose of collateral estoppel), *with* Kollmorgen Corp. v. Yaskawa Elec. Corp., 147 F.Supp.2d 464, 468-69 (W.D.Va.2001) (collateral estoppel applies only when the previous court's *Markman* ruling "was essential to a final judgment on the question of the patents' infringement"); Graco Children's Prods., Inc. v. Regalo Int'l, 77 F.Supp.2d 660, 663 (E.D.Pa.1999) (" *Markman* did not guarantee that collateral estoppel would apply in every case, and this Court will not extend the Supreme Court ruling to mean as much.").

Moreover, the Federal Circuit's holding that "District courts may engage in a rolling claim construction, in which the court revisits and alters its interpretation of the claim terms as its understanding of the technology evolves" suggests that not every claim construction is a final judgment for the purpose of application of collateral estoppel. Jack Guttman, Inc. v. KopyKake Enters., Inc., 302 F.3d 1352, 1361 (Fed.Cir.2002). Also,

a District of Colorado court, in a general discussion of applicability of collateral estoppel, has taken a similar position:

The Restatement suggests that unless a judgment is avowedly tentative, the preclusive effect of the judgment should be determined by weighing a number of factors, including: (1) whether the parties were fully heard, (2) whether the court supported its decision with a "reasoned opinion," and (3) whether the decision was subject to appeal. Restatement of Judgments (Second) s. 13 cmt. g (1982). Most courts agree that a jury verdict on liability constitutes a final judgment even if damages have not yet been determined. *Morrell,* 913 F.2d at 563. However, the finality of an interlocutory order, such as a partial summary judgment, presents more difficult questions. In particular, Fed.R.Civ.P. 54(b) states that any order that is not made final and does not adjudicate all of the claims "is subject to revision at any time before the entry of judgment." Therefore, arguably all orders of partial summary judgment are tentative and should not be given preclusive effect.

Siemens Med. Sys., Inc. v. Nuclear Cardiology Sys., Inc., 945 F.Supp. 1421, 1434 (D.Colo.1996). However, considering that two previous holdings from different district courts address the patents in question in this case, taking opposite positions regarding issues affecting the claim construction in this case, and considering the fact that the *Impax* court's claim construction does not provide any reasoning for its findings, it is impossible for this court to apply collateral estoppel, even if it found it to be appropriate. Therefore, the court will conduct an independent claim construction.

ii. Disclaimer and Retraction of Claims

Another issue central to the infringement is Defendant's argument that there was a disavowal of claim scope during prosecution of the '819 patent that carries over to the '300 patent, namely, that Shire disclaimed the coating used on Sandoz's ANDA products. (*See* Def.'s Br. at 43-49.) Defendant contends that statements during the prosecution of the earlier '819 patent for one claim term-"enteric release coating"-must be determined to be a clear disavowal of claim scope and concludes that such limitations must then be applied to a different term-the "delayed enteric release dosage form"-of the descendant '300 patent.

Under the doctrine of prosecution disclaimer, "[t]he inventor ... disavow[s] or disclaim[s] scope of coverage, by using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." Tex. Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1204 (Fed.Cir.2002). However, this doctrine does not apply "where the alleged disavowal of claim scope is ambiguous," Omega Eng., Inc, v. Raytek Corp., 334 F.3d 1314, 1324 (Fed.Cir.2003), or where the alleged disclaimer is retracted by amendments or other means. *Cf.* Springs Window Fashions LP v. Novo Indus., L.P., 323 F.3d 989, 995 (Fed.Cir.2003) (stating that the applicant should retract a claim by amending it in order to straighten the public record of the patentee's claim, on which the public rely.)

(1) Relevant Prosecution History

A. Ph-Independent Enteric Release Coating

On October 21, 1998, Plaintiff filed its '819 Patent application with the PTO, with 13 claims. (*See* id., Ex. 7 [the '819 Patent File] at SLS 000036-39.) On March 19, 1999, the Examiner rejected all 13 claims as anticipated and obvious. (Id. at SLS 000220-226.) On September 7, 1999 Plaintiff amended claims 1, 6, and 10; canceled claim13; and added claims 14-19. (Id. at SLS 000256-263.) On November 8, 1999, the Examiner rejected all of the claims as obvious over the prior art. (Id. at SLS 000267-270.) In rejecting all

claims, the Examiner explained that "enteric release coating" means a coating that releases in the intestines:

Mehta discloses a pulsatile dosage form comprising a methylphenidate salt (claim 2). The dosage form comprises immediate release particles and delayed release particles (claim 1). The delayed release particles are not released until 2 to 7 hours after ingestion. By this time the medication would be in the intestines instead of the stomach and, therefore, is considered to contain an enteric release coating.

(Id. at SLS 000268.)

On March 2, 2000, Plaintiff responded, trying "to distinguish their invention over the prior art, stating, *inter alia,* '[t]he enteric release coatings of Applicants' claimed compositions, in contrast to those disclosed in [prior art], are enteric coatings that are pH dependent.' " (Id. at SLS 000500-502.) On May 18, 2000, the Examiner indicated that Plaintiff's arguments had been fully considered but were not persuasive and rejected applicants' distinction between pH-dependent and independent coatings. (Id. at SLS 000505.) The Examiner explained that she did not consider

"enteric polymers" to be characterized by pH-dependency: Applicant argues the [prior art] does not disclose enteric release coatings. However, it discloses Eudragit(R) polymers as the coatings for the delayed release particles. The reference ... encompasses enteric polymers by teaching Eudragit(R) polymers. *It would be obvious to modify the pH dependency of the coating to adjust the rate of release*.

(Id. [emphasis added].)

On November 21, 2000, in an attempt to distinguish their invention over the ' 284 patent Plaintiff submitted the below arguments:

Mehta discloses dosage forms for oral administration of a methylphenidate drug. The drug, as shown in the examples, is coated with Eudragit RS30D, and Eudragit NE30D. As shown in the accompanying copy of *Pharmaceutical Excipients,* Third Edition, Pages 401-402, such Eudragit polymers are sustained release coatings, not enteric release coatings.

(Id. at SLS 000510 [emphasis in original].) On December 6, 2000, once more, the PTO rejected Plaintiff's position, stating:

The request for reconsideration has been considered but does NOT place the application in condition for allowance because: US 5,837,284 teaches the use of ammonio methacrylate polymers in general and lists Eudragit polymers as examples. The entire disclosure of a reference is prior art and a reference is not bound by working examples. Therefore, U.S. '284 encompasses all ammonio methacrylate polymers. It is within the skill in the art to select an optimal species within a disclosed genus in order to achieve desired results. *The reference teaches that the composition contains coated particles that do not release the drug until about 2 to 7 hours after the time of ingestion. This is adequate time for the composition to leave the stomach and enter the intestines, thereby constituting enteric release*.

(Id. at SLS 000517 [emphasis added].) In the Examiner interview, on May 11, 2001, "the Examiner suggested that amendment of the independent claims to recite that, following a specified time of no drug release, 100% of the second, delayed dose of the drug is released within 1 hour would advance the prosecution." (Id. at SLS 000518.)

On June 25, 2001, Plaintiff submitted an amended claim which canceled all previous claims and added claims 20 through 46.FN3 (Id. at SLS 000533.) Plaintiff, in the section titled "Remarks," stated that "[t]he fact that [its] claims have been cancelled without prejudice is not to be construed as an admission by [Shire or Shire's attorneys] that such claims are not patentable." (Id. at SLS 000539.) The new claim 27, which ultimately issued as claim 7 in the ' 819 patent, also referred to "an enteric release coating that provides for delayed pulsed enteric release," but noted that "said enteric release coating is a non pH-dependent enteric release coating." (Id. at SLS 000541-542.)

FN3. The new claim 20 was ultimately issued as claim 1 in the '819 patent.

Claim 7 reads: "The composition of claim 1 wherein said enteric release coating is a non-pH dependent enteric release coating." (Id., Ex. A-1 [the ' 819 patent].) Also, all claims now contain the language "wherein said enteric release coating releases essentially all of said one or more pharmaceutically active amphetamine salts within about 60 minutes." (Id., Ex. 7 [the '819 Patent File History] at SLS 000534.)

On August 13, 2001, the Examiner issued a Notice of Allowability, stating that the reason for allowance is that "the prior art does not teach or fairly suggest that essentially all of the enteric coated drug is release within 60 minutes from the initiation of the delayed pulsed enteric release[.]" (Id. at 000564-566.)

As discussed above, in the view of the PTO, the reason the subject of the ' 819 patent is distinguishable from the prior art, and therefore patentable, is that Plaintiff's composition, after a period of no release (the lag time), releases the second dose within about one hour. In 2000, the PTO made it clear that the term "enteric release" could not be limited to pH-dependent coatings. The record demonstrates that in response, Plaintiff canceled all claims without prejudice and added new claims in conformity with the PTO's clear position.

Accordingly, the court finds that the written document of the '819 patent (claim 7) specifically, and the prosecution history show that Plaintiff retracted its alleged disclaimer when it conformed with the PTO's position by amending the claims and finding another way to distinguish the prior art. Moreover, because the '300 patent is continuation-in-part of the '819 patent, and the '819 patent is incorporated by reference, this finding also applies to the '300 patent and the court does not need to address the issue whether such alleged disclaimer, if to be found, would apply to a descendant patent when, as here, the claim terms appear different.

b. Claim Construction

" *Markman* does not require a district court to follow any particular procedure in conducting claim construction." Ballard Med. Prod. v. Allegiance Healthcare Corp., 268 F.3d 1352, 1358 (Fed.Cir.2001).

It merely holds that claim construction is the province of the court, not a jury. To perform that task, some courts have found it useful to hold hearings and issue orders comprehensively construing the claims in issue. Such a procedure is not always necessary, however. If the district court considers one issue to be dispositive, the court may cut to the heart of the matter and need not exhaustively discuss all the other issues presented by the parties. District courts have wide latitude in how they conduct the proceedings before them, and there is nothing unique about claim construction that requires the court to proceed according to any

particular protocol. As long as the trial court construes the claims to the extent necessary to determine whether the accused device infringes, the court may approach the task in any way that it deems best.

Id.

In this case, the parties agreed that the intrinsic and submitted extrinsic evidence, *i.e*., the patents' written documents, prosecution history and the parties' briefings, together with the parties' expert reports, provide sufficient guidance for the court's claim construction. Therefore, the parties did not request a full *Markman* hearing. (The 09/16/08 Hearing.)

The parties dispute the literal meaning of the terms in claims 1 and 7 of the '819 patent and claim 1 of the '300 patent. Claim 1 of the '819 patent states:

1. A pharmaceutical composition for delivery of one or more pharmaceutically active amphetamine salts, comprising:

(a) one or more pharmaceutically active amphetamine salts covered with an *immediate release coating;* and

(b) one or more pharmaceutically active amphetamine salts that are covered with an *enteric release coating* that provides for *delayed pulsed enteric release,* wherein said enteric release coating releases essentially all of said one or more pharmaceutically active amphetamine salts coated with said enteric coating within about 60 minutes after initiation of said delayed pulsed enteric release.

(Pl.'s Resp., Ex. A-1 [the '819 patent] [emphasis added to disputed claim terms].). Claim 7 states:

7. The composition of claim 1 wherein said enteric release coating is a *non-pH dependent enteric release coating*.

(Id. [emphasis added to disputed claim term].).

Claim 1 of the '300 patent states:

1. A pharmaceutical formulation for delivery of a mixture of amphetamine base salts effective to treat ADHD in a human patient comprising:

an immediate release dosage form that provides immediate release upon oral administration to said patient;

a *delayed enteric release dosage form that provides delayed release upon oral administration* to said patient; and a pharmaceutically acceptable carrier; wherein said amphetamine base salts comprise dextroamphetamine sulfate, dextroamphetamine saccharate, amphetamine aspartate monohydrate and amphetamine sulfate;

wherein said pharmaceutical formulation is sufficient to maintain an effective level of amphetamine base salts in the patient over the course of at least 8 hours without further administration of amphetamine base salt, and the peak plasma concentration of amphetamine base salts reached after release of said delayed enteric release dosage form exceeds the peak plasma concentration previously reached after release of said immediate release dosage form; and

wherein said pharmaceutical formulation, when containing about a total dose of 20 mg, will produce in a human individual a plasma concentration versus time curve (ng/ml versus hours) having an area under the curve (AUC) of about 467 to about 714 ng hr/ml.

(Id., Ex. A-2 [the '300 patent] [emphasis added to disputed claim terms].). Upon careful review of the written document and considering the parties' submissions on the disputed terms, **IT IS ORDERED** that:

i. The term "immediate release coating" in claim 1 of the '819 patent is construed as "a coating that allows for the immediate release of the drug without intention of delaying its dissolution or absorption;"

ii. The term "enteric release coating" in claim 1 of the '819 patent is construed as "a coating that is at least 25 microns thick and delays release of the drug until it reaches the intestines;"

iii. The term "delayed pulsed enteric release" in claim 1 of the '819 patent is construed as "the dose of the drug is released in the intestines after a first dose by immediate release and a period of no release;"

iv. The term "non-pH dependent enteric release coating" in claim 7 of the ' 819 patent is construed as "a coating that does not depend on the acidity or alkalinity and is intended to delay the release of drug until the dosage form reaches the intestines;"

v. The term "delayed enteric release dosage form" in claim 1 of the '300 patent is construed as "a dosage form that delays release of the drug until it reaches the intestines;"

vi. The term "delayed release upon oral administration" in claim 1 of the ' 300 patent is construed as "the dose of the drug is released in the intestines after a first dose by immediate release and a period of no release."

d. Comparing the Construed Claims and the Allegedly Infringing Drug

In the second step of the patent infringement analysis, which is a question of fact, "the court must determine whether the accused product or process contains each limitation of the properly construed claims, either literally or by a substantial equivalent." Freedman, 420 F.3d 1350 at 1357. "Literal infringement requires that each and every claim limitation be present in the accused product." Abraxis Bioscience, Inc. v. Mayne Pharma (USA) Inc., 467 F.3d 1370, 1378 (Fed.Cir.2006). But "a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention." *Id*. (citation and quotation mark omitted). The doctrine of equivalents is a result of the courts' recognition that:

to permit imitation of a patented invention which does not copy every literal detail would be to convert the protection of the patent grant into a hollow and useless thing. Such a limitation would leave room for-indeed encourage-the unscrupulous copyist to make unimportant and insubstantial changes and substitutions in the patent which, though adding nothing, would be enough to take the copied matter outside the claim, and hence outside the reach of law.

Graver Tank & Mfg. Co. v. Linde Air Products Co., 339 U.S. 605, 607, 70 S.Ct. 854, 856, 94 L.Ed. 1097

(U.S.1950).

In this case, Defendant argues that its proposed products do not infringe the '819 or '300 patents because: (1) Defendant's proposed products do not have two separate coatings; (2) Defendant's proposed products do not use an "immediate release coating;" (3) Defendant's proposed products do not use a pH-dependent "enteric release coating;" (4) Defendant's proposed products do not exhibit a "delayed pulsed enteric release;" (5) the extended-release pellets in Defendant's proposed products do not release "within about 60 minutes after initiation of said delayed pulsed enteric release;" (6) claim 7 of the '819 patent is not infringed by Defendant's proposed products; (7) Defendant's proposed products do not use a "delayed enteric release dosage form;" (8) Defendant's proposed products do not exhibit a period of no release, and they do not provide "delayed release upon oral administration." (*See* Def.'s Br.)

Plaintiff responds arguing that Defendant's proposed products infringe the '819 and '300 patents literally and under the doctrine of equivalents because: (1) the '819 patent does not require two separate coating materials for the "immediate release coating" and "enteric release coating;" (2) Defendant's proposed products meet the "immediate release coating" limitation; (3) Defendant's proposed products meet the "enteric release coating" limitation; (4) even if the prosecution history estoppel prevents Plaintiff from arguing that Defendant's proposed products meet the "enteric release coating," Plaintiff's argument remains valid under the doctrine of equivalents; (5) Defendant's proposed products meet the "delayed pulsed enteric release" limitation; (6) Defendant's proposed products meet the "non-pH dependant enteric release coating" limitation; (7) Defendant's proposed products meet the "delayed enteric release dosage form which provides delayed release upon oral administration" limitation. (*See* Pl.'s Resp.)

"Summary judgment on the issue of infringement is proper when no reasonable jury could find that every limitation recited in a properly construed claim either is or is not found in the accused device either literally or under the doctrine of equivalents." U .S. Philips Corp. v. Iwasaki Elec. Co. Ltd., 505 F.3d 1371, 1374-75 (Fed.Cir.2007) (citation and quotation mark omitted). "Although infringement under the doctrine of equivalents is a question of fact, where the evidence is such that no reasonable jury could determine two elements to be equivalent, district courts are obliged to grant partial or complete summary judgment." *Id.* (citations and internal quotation mark and alteration omitted).

"[W]hen the patent holder relies on the doctrine of equivalents, as opposed to literal infringement, the difficulties and complexities of the doctrine require that evidence be presented to the jury or other fact-finder through the particularized testimony of a person of ordinary skill in the art, typically a qualified expert, who (on a limitation-by-limitation basis) describes the claim limitations and establishes that those skilled in the art would recognize the equivalents." AquaTex Indus., Inc. v. Techniche Solutions, 479 F.3d 1320, 1329 (Fed.Cir.2007). And "[e]ven where literal infringement is involved, expert infringement testimony is generally required in cases involving complex technology." *Id.* n. 7.

In this case, the parties have submitted extrinsic evidence, including expert witness reports in support of the above arguments. As demonstrated above, the parties have taken contrary positions on nearly every single issue regarding the infringement of the '819 and '300 patents, and not surprisingly, their expert reports strongly support each and every one of these contrary positions. (*See* Def.'s Br., Pl.'s Resp., Def.'s Reply, Pl.'s Br., Def.'s Resp., Pl.'s Reply.) Therefore, the court finds that with respect to most, if not all, "of these limitations there seems to be a classic 'battle of the experts' which renders summary judgment improper." *See* Edwards Systems Technology, Inc. v. Digital Control Systems, Inc., 99 Fed. Appx' 911, 921 (Fed.Cir.2004).

Based on the foregoing, the court finds that, in this case, because Plaintiff amended its claims and retracted the alleged disclaimer of pH-independent coatings in the term "enteric release coating," and because equivalence is a question of fact, a reasonable jury could find that the limitation recited in the claim construction is found in Defendant's proposed products, either literally or under the doctrine of equivalents. *See* Cybor Corp., 138 F.3d at 1470.

3. Patent Misuse and Sham Litigation

"Patent misuse occurs where the patent owner attempts to extend the impact of his patent beyond its proper scope." MACTEC, Inc. v. Gorelick, 427 F.3d 821, 831 (10th Cir.2005) (citation and internal quotation mark and alteration omitted). "The key inquiry is whether, by imposing conditions that derive their force from the patent, the patentee has impermissibly broadened the scope of the patent grant with anticompetitive effect." C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1372 (Fed.Cir.1998) (citations omitted).

The filing of an infringement claim does not constitute misuse "unless the claim is (1) objectively meritless and (2) brought in an attempt to interfere directly with the business of a competitor." In re Indep. Serv. Org. Antitrust Litig., 85 F.Supp.2d 1130, 1169-70 (D.Kan.2000) (citing *Prof'l* Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 60-61, 113 S.Ct. 1920, 1928 [1993].). "A claim is 'objectively meritless' if no reasonable litigant could realistically expect success on the merits." Id. at 1170 (citing Columbia Pictures, 508 U.S. at 60, 113 S.Ct. at 1928).

The Supreme Court has established a two-part test for determining if litigation is a "sham."

First, the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits. If an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, the suit is immunized ... and an antitrust claim premised on the sham exception must fail. Only if challenged litigation is objectively meritless may a court examine the litigant's subjective motivation. Under this second part of our definition of sham, the court should focus on whether the baseless lawsuit conceals "an attempt to interfere directly with the business relationships of a competitor," through the "use [of] the governmental process-as opposed to the outcome of that process-as an anticompetitive weapon[.]" This two-tiered process requires the plaintiff to disprove the challenged lawsuit's legal viability before the court will entertain evidence of the suit's economic viability.

Columbia Pictures Indus., Inc., 508 U.S. at 60 (internal citations omitted). Accordingly, as a result of the court's prior conclusion as to the existence of issues of material fact regarding the infringement, the court finds that summary judgment on Defendant's affirmative defenses of sham litigation and patent misuse is appropriate because a reasonable litigant "could realistically expect success on the merits" and, therefore, this lawsuit is not objectively baseless. *See id*.

4. Defendant's Affirmative Defense and Counterclaim Pursuant to 35 U.S.C. s. 112

Neither party has requested the court to enter summary judgment on Defendant's affirmative defense pursuant to 35 U.S.C. s.s. 103 or 112, but have addressed the issues of sufficiency of written description and enablement under section 112 in their briefs. (*See* Pl.'s Resp. at 103-04, 107, 109-10, 117, 118; Def.'s Reply at 49, 59-63, 73-74, 82-83.) However according to the Federal Circuit:

The general contours of our test for compliance with the best mode requirement are well known:

Compliance with best mode is a question of fact composed of two subsidiary factual inquiries. First, the factfinder must determine whether, at the time of filing the application, the inventor possessed a best mode for practicing the invention. The first prong, we have explained, is highly subjective and focuses on the inventor's state of mind as of the date of filing the application. Second, if the inventor subjectively considered one mode to be preferred over all others, then the second inquiry is whether the inventor's disclosure is adequate to enable one of ordinary skill in the art to practice the best mode of the invention. This inquiry is objective and depends upon the scope of the claimed invention and the level of skill in the relevant art.

Bayer AG v. Schein Pharm., Inc., 301 F.3d 1306, 1320 (Fed.Cir.2002) (internal citations alteration and quotation marks omitted). Accordingly, even if the issues of written description and enablement were properly before the court, adjudicating them in a motion for summary judgment, in this case, would not be proper because such determinations, *e.g.,* "whether, at the time of filing the application, the inventor possessed a best mode for practicing the invention" and "whether the inventor's disclosure is adequate to enable one of ordinary skill in the art to practice the best mode of the invention" entail unresolved and disputed or undiscussed issues of material facts.

5. Conclusion

Based on the foregoing, it is therefore ORDERED that:

1. DEFENDANT'S amended motion for summary judgment (# 88) is **DENIED.**

2. PLAINTIFF'S motion for summary judgment (# 86) is **GRANTED** as to Defendant's affirmative defenses of patent misuse and sham litigation; and Defendant's counterclaims and affirmative defenses of invalidity of the '819 and '300 patents pursuant to 35 U.S.C. s.s. 101 and 102, upon stipulation of the parties.

The court will hold a Final Pretrial Conference commencing at 3:45 o'clock p.m. on October 8, 2008 in Courtroom A201 of the Alfred A. Arraj United States Courthouse, 901 19th Street, Denver, Colorado. In preparing for and participating in the conference, the parties and counsel will (1) follow the Instructions for Preparation and Submission of Final Pretrial Order, a copy of which can be downloaded from the court's web site, specifically http:// www.cod.uscourts.gov/Documents/Judges/EWN/ewn_fin_pre_ord_ins .pdf and (2) utilize the specific template located at http:// www.cod.uscourts.gov/Documents/Judges/EWN/ewn_fin_pre_ord.wpd These specific web addresses should be used to insure that the proper format is observed.

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