

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

<b>FARMACEUTISK LABORATORIUM</b>	:	<b>CIVIL ACTION</b>
<b>FERRING A/S T/A FERRING A/S,</b>	:	
<b>FERRING INTERNATIONAL CENTER</b>	:	
<b>S.A., and FERRING</b>	:	
<b>PHARMACEUTICALS A/S</b>	:	<b>NO. 08-941</b>
<b>Plaintiffs,</b>	:	
<b>v.</b>	:	
	:	
<b>SHIRE U.S., INC.</b>	:	
<b>Defendant.</b>	:	

**DuBOIS, J.**

**APRIL 7, 2009**

**MEMORANDUM**

**I. BACKGROUND**

For the purposes of this Memorandum, the factual and procedural history, as alleged in the Complaint, is as follows. Plaintiffs Farmaceutisk Laboratorium Ferring A/S t/a Ferring A/S, Ferring International Center S.A., and Ferring Pharmaceuticals A/S (collectively “plaintiffs” or “Ferring”) own the trademark PENTASA®. (Compl. ¶ 13.) PENTASA® is a pharmaceutical product approved by the United States Food and Drug Association (“FDA”) for the treatment of ulcerative colitis; the active ingredient is 5-aminosalicylic acid (“5-ASA”). (Compl. ¶¶ 13, 20.) For many years, plaintiffs also owned and licensed patents that covered certain oral formulations of 5-ASA, including the specific formulation of PENTASA® marketed by defendant; the last of these patents expired on October 2, 2007. (Compl. ¶¶ 15, 17.)

On April 25, 1983, plaintiffs entered into an exclusive license agreement with Marion Laboratories, Inc. (“Marion”), which allowed Marion to manufacture and sell certain 5-ASA formulations under the patents and the trademark PENTASA® in the United States and Canada (“1983 Agreement”). (Compl. ¶ 21; 1983 Agreement, Ex. A to Compl.) On April 1, 1998, Marion, “now known as” Hoechst Marion Roussel, Inc. (“HMRI”) granted to Roberts

Laboratories, Inc. (“Roberts”) an exclusive sublicense under the 1983 Agreement (“1998 Sublicense”). (Compl. ¶¶ 22, 23; 1998 Sublicense, Ex. B. to Compl.) Roberts thereafter merged with Shire Pharmaceuticals Group, PLC, the parent company of Shire U.S, Inc., defendant; defendant then possessed an exclusive sublicense to manufacture and sell the licensed formulations under the trademark PENTASA®. (Compl. ¶¶ 24–26.) To resolve a dispute over the definition of the term “Net Sales” in the 1983 Agreement and the 1998 Sublicense, plaintiffs and defendant entered into a settlement agreement dated February 18, 2005, which provided that the 1983 Agreement and the 1998 Sublicense would expire on October 2, 2007 (“2005 Settlement Agreement”). (Compl. ¶¶ 39–40; 2005 Settlement Agreement §§ 2.1.2, 2.1.3., Ex. F to Compl.) Plaintiffs also granted defendant an exclusive license for the use of the PENTASA® trademark “in connection with all oral products containing 5-ASA, for consideration of 2% of Net Sales . . . .” (2005 Settlement Agreement § 2.4.)<sup>1</sup>

On March 19, 2007, defendant began marketing and selling LIALDA®, a different formulation of 5-ASA also approved by the FDA to treat ulcerative colitis. (Compl. ¶¶ 47–55.)

On February 22, 2008, plaintiffs filed a Complaint naming as defendants Shire U.S., Inc. and Shire Pharmaceutical Development, Inc. The Complaint alleged the following causes of action:

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|-----------|---|
| Count I   | Shire U.S.’s Breach of the Implied Duty of Good Faith/Best Efforts/Due Diligence to Exploit the Exclusive License |
| Count II  | Shire U.S.’s Breach of the 1983 License Agreement   |
| Count III | Shire U.S.’s Breach of the 2005 Settlement Agreement  |

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<sup>1</sup> On August 29, 2005, plaintiffs entered into an agreement with Shire Pharmaceutical Development, Inc., requiring the parties to exchange reports of adverse effects from the use of PENTASA® (“2005 Safety Information Agreement”). (Compl. ¶¶ 45, 46.) All counts involving the 2005 Safety Information Agreement have been dismissed by stipulation of the parties.

- Count IV      Fraudulent Inducement of the 2005 Settlement Agreement  
Count V      Shire Pharmaceutical Development, Inc.’s Breaches of the 2005 Safety Information Agreement

Defendants answered the Complaint and asserted two counterclaims, as follows:

- Count I      Shire U.S. v. Farmaceutisk Laboratorim A/S t/a Ferring A/S—Declaratory Judgment  
Count II      Shire Pharmaceuticals v. Ferring Pharmaceuticals A/S—Declaratory Judgment and Breach of Safety Information Agreement

On November 25, 2008, the parties stipulated to the dismissal of Count II of defendants’ counterclaims, which the Court approved. On December 5, 2008, the Court approved the parties’ stipulation to the dismissal of Count V of plaintiffs’ Complaint and the dismissal of defendant Shire Pharmaceutical Development, Inc. On December 29, 2008, defendant filed the instant Motion for Judgment on the Pleadings, seeking dismissal of the remaining counts.

## **II. STANDARD OF REVIEW**

A motion for judgment on the pleadings under Federal Rule of Civil Procedure 12(c) is analyzed under the same standard as a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6). See Shelly v. Johns-Manville Corp., 798 F.2d 93, 97 n.4 (3d Cir. 1986); Regalbuto v. City of Phila., 937 F. Supp. 374, 376 (E.D. Pa. 1995), aff’d 91 F.3d 125 (3d Cir. 1996). A motion for judgment on the pleadings will only be granted where “the plaintiffs would not be entitled to relief under any set of facts that could be proved.” Green v. Fund Asset Mgmt., L.P., 245 F.3d 214, 220 (3d Cir. 2001). In determining whether a plaintiff has stated a claim for relief, the court must view the facts and inferences to be drawn from the pleadings in the light most favorable to the non-moving party. Inst. for Scientific Info., Inc. v. Gordon & Breach, Sci. Publishers, Inc., 931 F.2d 1002, 1004 (3d Cir. 1991).

A motion for judgment on the pleadings, like a motion to dismiss, tests the legal

sufficiency of a claim in light of the facts pled in the complaint. To survive such a motion, “a civil plaintiff must allege facts that ‘raise a right to relief above the speculative level . . . .’” Victaulic Co. v. Tieman, 499 F.3d 227, 234 (3d Cir. 2007) (quoting Bell Atl. Corp. v. Twombly, 127 S. Ct. 1955, 1965 (2007)). In other words, a claim must contain “enough factual matter (taken as true) to suggest” the elements of the claims asserted. Phillips v. County of Allegheny, 515 F.3d 224, 234 (3d Cir. 2008) (quoting Twombly, 127 S. Ct. at 1965).

### **III. DISCUSSION**

#### **A. Choice of Law**

The 1983 Agreement and the 1998 Sublicense contain Missouri choice of law provisions. (1983 Agreement § 16.00, Ex. A to Compl.; 1998 Sublicense § 15.01, Ex. B. to Compl.) The 2005 Settlement Agreement, however, does not expressly designate what law will control, and the parties dispute whether the Court should apply Missouri or Pennsylvania law. (See Def.’s Mot. 10; Pls.’ Resp. 19–20 n.10.) For the purposes of this Memorandum, whether Missouri or Pennsylvania law governs the construction of the 2005 Settlement Agreement is irrelevant, as the Court would reach the same conclusions applying the law of either jurisdiction. Accordingly, the Court declines to rule at this time on the question of what law governs the 2005 Settlement Agreement.

#### **B. Count I: Shire U.S.’s Breach of the Implied Duty of Good Faith/Best Efforts/Due Diligence to Exploit the Exclusive License**

In Count I, plaintiffs allege that by marketing and selling LIALDA®, allegedly a PENTASA® competitor, defendant breached the duties of good faith and best efforts contained, by implication, in the 1983 Agreement, the 1998 Sublicense, and the 2005 Settlement Agreement.<sup>2</sup>

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<sup>2</sup> Defendant argues that it was not a party to the 1983 Agreement and that plaintiffs were not parties to the 1998 Sublicense. (Def.’s Mot. 14.) As plaintiffs and defendant are

(Compl. ¶¶ 120–127.) In its motion, defendant counters that the only express non-compete clause contained in the contracts expired eight years ago and that courts will not imply a non-compete obligation. (Def.’s Mot. 15.)

Both Missouri and Pennsylvania law imply a general obligation of good faith and fair dealing in every contract. Finova Capital Corp. v. Ream, 230 S.W.3d 35, 45 (Mo. Ct. App. 2007); Countrywide Servs. Corp. v. SIA Ins. Co., 235 F.3d 390, 393 (8th Cir. 2000) (applying Missouri law); Pierce v. QVC, Inc., 555 F. Supp. 2d 499, 502–03 (E.D. Pa. 2008) (applying Pennsylvania law); Kaplan v. Cablevision of PA, Inc., 671 A.2d 716, 721–22 (Pa. Super. Ct. 1996). “This implied covenant imposes upon each party the duty to do nothing destructive of the other party’s right to enjoy the fruits of the contract and to do everything that the contract presupposes they will do to accomplish its purpose.” Conoco, Inc. v. Inman Oil Co., 774 F.2d 895, 908 (8th Cir. 1985) (applying Missouri law) (citation omitted); accord John B. Conomos, Inc. v. Sun Co., 831 A.2d 696, 706 (Pa. Super. Ct. 2003). The implied covenant of good faith and fair dealing is not “an everflowing cornucopia of wished-for legal duties; indeed, the covenant cannot give rise to new obligations not otherwise contained in a contract’s express terms.” Comprehensive Care Corp. v. RehabCare, 98 F.3d 1063, 1066 (8th Cir. 1996) (applying Missouri law) (citation omitted); accord John B. Conomos, 831 A.2d at 706.

Courts have distinguished between the general duty of good faith and the more specific duty to use reasonable efforts,<sup>3</sup> which is implied in the context of an exclusive license. See, e.g.,

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indisputably parties to the 2005 Settlement Agreement, the Court defers ruling on defendant’s argument regarding the other two contracts.

<sup>3</sup> Plaintiffs use the term “best efforts” to describe this implied duty. “While the phrase ‘best efforts’ is often used to describe the extent of the implied undertaking, this has properly been termed an ‘extravagant’ phrase. A more accurate description of the obligation owed would be the exercise of ‘due diligence’ or ‘reasonable efforts.’” Permanence, 908 F.2d at 100 n.2

Permanence Corp. v. Kennametal, Inc., 908 F.2d 98, 100 n.2 (6th Cir. 1990) (applying Pennsylvania law); Emerson Radio Corp. v. Orion Sales, Inc., 253 F.3d 159, 169 (3d Cir. 2001); Flights Concepts Ltd. P'ship v. Boeing Co., 819 F. Supp. 1535, 1550 (D. Kan. 1993), aff'd 38 F.3d 1152 (10th Cir. 1994); Beraha v. Baxter Health Care Corp., 956 F.2d 1436, 1443 (7th Cir. 1992). The implied duty of an exclusive licensee to use reasonable efforts to raise revenue originated in the landmark case of Wood v. Lucy, Lady Duff-Gordon, 118 N.E. 214 (N.Y. 1917). In Wood, defendant, a fashion designer, granted plaintiff the exclusive right to place her indorsement on the designs of others and to market defendant's designs. Id. at 214. Although the contract contained no express promise, the court implied an obligation to use "reasonable efforts to bring profits and revenues into existence" because defendant's only recompense from the contract was royalties from plaintiff's sales of her indorsement and designs and defendant was thus at plaintiff's mercy. Id. at 214–15. "Unless [plaintiff] gave his efforts, [defendant] could never get anything." Id. at 214. Such implication is necessary "because otherwise the contract at issue would lack mutuality of obligation and be inequitable." Permanence, 908 F.2d at 100 (citations omitted); accord Nat'l Refining Co. v. Cox, 57 S.W.2d 778, 781 (Mo. Ct. App. 1933).

Both Missouri and Pennsylvania law have recognized that an obligation to use reasonable efforts "will be implied in a contract granting an exclusive agency if the plaintiff depends for its consideration solely upon sales of the licensed product." Permanence, 908 F.2d at 100; accord Nat'l Refining, 57 S.W.2d at 781; Maxwell v. Schaefer, 112 A.2d 69, 72 (Pa. 1955). The cases recognizing such an implied obligation in Missouri and Pennsylvania, as well as in other jurisdictions, do so when the licensor must rely entirely on the good faith of the licensee to receive

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(internal citations omitted). For the purposes of this Memorandum, in analyzing plaintiffs' argument that defendant owed an implied duty to exercise "best efforts," the Court will use the terms "reasonable efforts" and "due diligence."

any consideration because the licensor's sole compensation is royalties from sales of the licensed product. See, e.g., Permanence, 98 F.2d at 102; Post Mach. Co. v. Tanges, 705 F. Supp. 55, 58 (D.N.H. 1989); Vacuum Concrete Corp. v. Am. Mach. & Foundry Co., 321 F. Supp. 771, 773 (S.D.N.Y. 1971); Mech. Ice Tray Corp. v. Gen. Motors Corp., 144 F.2d 720, 725 (2d Cir. 1944). When the licensor receives other compensation for the exclusive license, such as an advance payment or a guaranteed minimum royalty payment, the licensor is no longer completely at the mercy of the licensee and the need for an implied obligation of reasonable efforts diminishes. See, e.g., Permanence, 98 F.2d at 102; Vacuum Concrete, 321 F. Supp. at 773. Even if the licensor's compensation is solely royalty-based, however, there is an exception to the duty to use reasonable efforts to exploit the licensed product "where there is outside competition which the exclusive licensee cannot meet with reasonable chance of success with the licensed article." Mech. Ice Tray, 144 F.2d at 725–26 (citations omitted); accord Post Mach., 705 F. Supp. at 58–59.

In the instant case, plaintiffs have alleged that they granted defendant an exclusive license for the use of the PENTASA® trademark "for consideration of 2% of Net Sales . . . ."; defendant concedes that it received such an exclusive license. (2005 Settlement Agreement § 2.4; Compl. ¶ 87; Def.'s Mot. 1, 6.) Plaintiffs also allege that defendant failed to use reasonable efforts to market and sell PENTASA® when it began selling LIALDA®, an alleged competitor. (Compl. ¶¶ 123, 124.) Pursuant to the aforementioned authority, these allegations are sufficient to state a claim for breach of the implied obligation to use reasonable efforts to exploit the PENTASA® trademark.<sup>4</sup> Whether plaintiffs' receipt of compensation is wholly within defendant's control is a

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<sup>4</sup> Because the parties have raised the issue, and notwithstanding the fact that it is not necessary to a decision on the pending motion, the Court is of the view that, assuming *arguendo* defendant was bound by such an implied obligation, it is premature to determine whether marketing LIALDA® was a violation of defendant's duty. See, e.g., Hayes Lemmerz Int'l, Inc. v. Epilogics Group, 531 F. Supp. 2d 789, 807–08 (E.D. Mich. 2007), aff'd Kuhl Wheels, LLC v.

question of fact not appropriate for resolution on a motion for judgment on the pleadings. So too is the question of whether there was outside competition such that defendant was released from its obligation to use reasonable efforts to market PENTASA®. Accordingly, the Court denies defendant's Motion for Judgment on the Pleadings with respect to Count I.

**C. Count II: Shire U.S.'s Breach of the 1983 License Agreement**

In Count II, plaintiffs allege that defendant breached its obligation under section 7.01 of the 1983 Agreement to actively promote the sale of PENTASA®. (Compl. ¶¶ 128–130; 1983 Agreement § 7.01.) Defendant was not a signatory to the 1983 Agreement, but, in 1998, defendant's predecessor was granted an exclusive sublicense under the 1983 Agreement. (Compl. ¶¶ 22–26.) Both the 1983 Agreement and the 1998 Sublicense state that they will be construed pursuant to Missouri law. (1983 Agreement § 16.00; 1998 Sublicense § 15.01.) The Court will thus apply Missouri law with respect to Count II.

Under Missouri law, whether a contract is ambiguous is a question of law for the court. Finova Capital Corp. v. Ream, 230 S.W.3d 35, 49 (Mo. Ct. App. 2007); Press Mach. Corp. v. Smith R.P.M. Corp., 727 F.2d 781, 784 (8th Cir. 1984) (construing Missouri law). “Ambiguities in written instruments are of two kinds: (1) patent, arising on the face of the document, and (2) latent.” Finova, 230 S.W.3d at 48–49 (citation omitted); accord Busch & Latta Painting Corp. v. State Highway Comm'n, 597 S.W.2d 189, 197 (Mo. Ct. App. 1980). “An ambiguity is . . . latent if language, which is plain on its face, becomes uncertain upon application. A latent ambiguity, not being apparent on the face of the writing, must be developed by extrinsic evidence to show the real

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Gen. Motors Corp., Nos. 2008-1158, 2008-1179, 2009 WL 306732 (Fed. Cir. Feb. 10, 2009) (holding that selling a competing product was not a breach of the licensee's implied duties as it was standard procedure for the licensee to offer six or seven competing products simultaneously, a factual determination).

intent of the parties.” Finova, 230 S.W.3d at 49 (internal citations omitted). “Where a contract is ambiguous, use of extrinsic evidence for interpretation is proper; the resolution of the ambiguity is a question of fact to be determined by the jury.” Press Mach., 727 F.2d at 784 (citation omitted); accord Monsanto Co. v. Syngenta Seeds, Inc., 226 S.W.3d 227, 231 (Mo. Ct. App. 2007) (“If an ambiguity exists, the trier of fact, using extrinsic evidence, resolves the ambiguity.”) (citation omitted). In examining extrinsic evidence, the goal is to determine the original intent of the parties. Press Mach., 727 F.2d at 784–85; Finova, 230 S.W.3d at 49. “[A] court will consider the entire contract, subsidiary agreements, the relationship of the parties, the subject matter of the contract, the facts and circumstances surrounding the execution of the cont[r]act, the practical construction the parties themselves have placed on the contract by their acts and deeds, and other external circumstances . . . .” Finova, 230 S.W.3d at 49 (citing Royal Banks of Mo. v. Fridkin, 819 S.W.2d 359, 362 (Mo. 1991) (*en banc*)); accord Press Mach., 727 F.2d at 785; Busch & Latta, 597 S.W.2d at 197–98.

Defendant argues that it was not a party to the 1983 Agreement and that the 1998 Sublicense did not delegate any of HMRI’s duties under the 1983 Agreement to defendant. (Def.’s Mot. 12–13.) Thus, according to defendant, it was not bound by section 7.01 of the 1983 Agreement and cannot be held liable for a failure to actively promote the sale of PENTASA®. (Id.)

Defendant is correct in its assertion that the 1998 Sublicense did not expressly delegate the duty of active promotion. Yet, as plaintiffs argue, the 1998 Sublicense also did not expressly delegate the duty to pay royalties to plaintiffs; defendant, however, has paid millions of dollars in royalties to plaintiffs since 1998. (Pls.’ Resp. 22–23.) While the words of the 1998 Sublicense themselves are clear, reading the 1983 Agreement and the 1998 Sublicense in tandem and

considering extrinsic evidence, there is a latent ambiguity as to whether defendant or HMRI or both owe duties to plaintiffs with respect to the marketing and sale of PENTASA®.

As the aforementioned authority makes clear, determining the intent of the parties in the face of a latent ambiguity is an extremely fact-bound inquiry that cannot be undertaken on a motion for judgment on the pleadings. The 1998 Sublicense contains a latent ambiguity with regard to whether defendant was delegated the duty of active promotion of PENTASA® found in section 7.01 of the 1983 Agreement. To resolve this ambiguity, the fact finder will have to consider extrinsic evidence. Plaintiffs have thus stated a claim for breach of the 1983 Agreement.

Defendant also argues that Counts I and II of the Complaint are inconsistent as Count I alleges that defendant breached an *implied* duty while Count II alleges that defendant breached an *express* duty. (Def.'s Mot. 14.) This argument is a non-starter. Federal Rule of Civil Procedure 8(d), which governs pleadings, states as follows:

(2) ***Alternative Statements of a Claim or Defense.*** A party may set out 2 or more statements of a claim or defense alternatively or hypothetically, either in a single count or defense or in separate ones. If a party makes alternative statements, the pleading is sufficient if any one of them is sufficient.

(3) ***Inconsistent Claims or Defenses.*** A party may state as many separate claims or defenses as it has, regardless of consistency.

Assuming *arguendo* that Counts I and II of the Complaint are inconsistent, under the Federal Rules of Civil Procedure, this presents no reason to dismiss either count on a motion for judgment on the pleadings. Accordingly, the Court denies defendant's Motion for Judgment on the Pleadings with respect to Count II.

**D. Count III: Shire U.S.'s Breach of the 2005 Settlement Agreement**

In Count III, plaintiffs allege that defendant breached section 2.4 of the 2005 Settlement Agreement by failing to pay plaintiffs a two percent royalty on sales of LIALDA®. (Compl.

¶¶ 131–134.) Defendant argues that the express language of the 2005 Settlement Agreement, when read in reference to the 1983 Agreement and the 1998 Sublicense, does not require defendant to make such payments. (Def.’s Mot. 18–22.) As discussed *supra*, the parties dispute whether the Court should apply Missouri or Pennsylvania law in interpreting the 2005 Settlement Agreement. The Court declines to resolve this dispute at this time as its analysis with respect to Count III is the same under both Missouri and Pennsylvania law.

As under Missouri law, discussed in Part III.C, *supra*, under Pennsylvania law, whether a contract is ambiguous is a question of law for the court. St. Paul Fire & Marine Ins. Co. v. Lewis, 935 F.2d 1428, 1431 (3d Cir. 1991) (applying Pennsylvania law). Once a contract is determined to be ambiguous, its interpretation is a question for the jury. Allegheny Int’l, Inc. v. Allegheny Ludlum Steel Corp., 40 F.3d 1416, 1424 (3d Cir. 1994) (applying Pennsylvania law). “A contract is ambiguous if it is reasonably susceptible of different constructions and capable of being understood in more than one sense.” Hutchison v. Sunbeam Coal Corp., 519 A.2d 385, 390 (Pa. 1986) (citations omitted); accord Monsanto Co. v. Syngenta Seeds, Inc., 226 S.W.3d 227, 231 (Mo. Ct. App. 2007) (“Where two reasonable constructions of a contract exist, it is ambiguous.”) (citation omitted).

Under Pennsylvania law, in determining whether a contract is ambiguous, the Court looks to the actual words of the agreement, the alternative meanings offered by counsel, and extrinsic evidence offered in support of those alternative meanings. St. Paul Fire, 935 F.2d at 1431. Under Missouri law, however, “[a] trial court must consider the whole instrument and the natural and ordinary meaning of the language when determining whether a contract is ambiguous.” Teets v. Am. Family Mut. Ins. Co., 272 S.W.3d 455, 462 (Mo. Ct. App. 2008) (internal quotation marks and citation omitted). “An ambiguity must appear from the four corners of the contract and

extrinsic evidence cannot be used to create an ambiguity.” Id. (internal quotation marks and citation omitted).

Section 2.4 of the 2005 Settlement Agreement reads, in relevant part, that “the parties shall enter into an exclusive license for the use of the Trademarks in the Territory in connection with all oral products containing 5-ASA, for consideration of 2% of Net Sales . . . .” The term “Net Sales” is capitalized, signaling that it is defined elsewhere in the 2005 Settlement Agreement as “gross sales of Products containing Licensed Compound, less [certain expenses].” (2005 Settlement Agreement § 2.1.2.).<sup>5</sup> The phrase “all oral products” is not capitalized and is not defined in the 2005 Settlement Agreement. The combination of the defined term “Net Sales” and the undefined term “all oral products” makes the scope of section 2.4 unclear.

Staying within the four corners of the 2005 Settlement Agreement, the Court concludes that the meaning of section 2.4 is ambiguous. In context of the definition of “Net Sales,” it is unclear whether the use of the phrase “all oral products containing 5-ASA” requires defendant to pay royalties to plaintiffs on sales of LIALDA® in addition to paying royalties on sales of PENTASA®. Resolving this ambiguity is a question for the fact finder and may require the examination of extrinsic evidence. As such, it is not properly considered on a motion for judgment on the pleadings. Accordingly, the Court denies defendant’s motion “gross sales of Products containing Licensed Compound, less [certain expenses].” (2005 Settlement Agreement § 2.1.2.)

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<sup>5</sup> “Product”—“Pentasa® for oral administration containing, in controlled release form, 5-aminosalicylic acid (5-ASA) useful and for use in the treatment of ulcerative colitis and Crohn’s disease in humans as more fully described in the Patents.” (2005 Settlement Agreement Preamble.)

“Licensed Compound”—“a controlled release form, and method of use, of 5-aminosalicylic acid (“5-ASA”), useful for and for use in the treatment of ulcerative colitis and Crohn’s disease in humans, all as more fully described in the Patents.” (1983 Agreement § 1.02; incorporated by 2005 Settlement Agreement Preamble.)

with respect to Count III.

### **E. Fraudulent Inducement of the 2005 Settlement Agreement**

In Count IV, plaintiffs allege that defendant made a fraudulent representation that induced plaintiffs to enter into the 2005 Settlement Agreement. (Compl. ¶¶ 135–141.) In particular, plaintiffs allege that defendant affirmatively stated that the new 1200-mg 5-ASA drug, currently marketed as LIALDA®, would be branded under the PENTASA® trademark. (*Id.* ¶¶ 91–94, 137). Plaintiffs also contend that defendant intentionally concealed its position that LIALDA® would not be covered by the 1983 Agreement or by section 2.4 of the 2005 Settlement Agreement. (*Id.* ¶¶ 90–92, 138.) Plaintiffs aver that absent these material misrepresentations and omissions by defendant, plaintiffs would not have entered into the 2005 Settlement Agreement. (*Id.* ¶¶ 95, 140.)

Defendant argues that Count IV should be dismissed on three grounds: (1) the gist of the action doctrine bars the fraudulent inducement claim; (2) the parol evidence rule bars consideration of the prior representations; and (3) the requirements of Federal Rule of Civil Procedure 9(b) are not satisfied as plaintiffs did not plead the claim with particularity. (Def.’s Mot. 23.) The Court will address each of these arguments in turn.<sup>6</sup>

#### **1. Gist of the Action Doctrine**

Pennsylvania’s gist of the action doctrine “bars claims for allegedly tortious conduct where the gist of the alleged conduct sounds in contract rather than tort.” Hospicomm, Inc. v. Fleet Bank, N.A., 338 F. Supp. 2d 578, 582 (E.D. Pa. 2004) (internal quotation marks & citations omitted). The purpose of the doctrine is to “preclude[] plaintiffs from re-casting ordinary breach of contract claims into tort claims.” eToll v. Elias/Savion Adver., Inc., 811 A.2d 10, 14 (Pa.

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<sup>6</sup> The parties both argue that the Court’s analysis with respect to Count IV—a tort claim—should be governed by Pennsylvania law. (Def.’s Mot. 10; Pl.’s Resp. 19–20 n.10.) The Court agrees and applies Pennsylvania law.

Super. Ct. 2002) (citation omitted). Although a breach of contract can give rise to an actionable tort, “to be construed as in tort, . . . the wrong ascribed to defendant must be the gist of the action, the contract being collateral.” Bash v. Bell Tel. Co., 601 A.2d 825, 829 (Pa. Super. 1992) (internal quotation marks & citation omitted). “In other words, a claim should be limited to a contract claim when ‘the parties’ obligations are defined by the terms of the contracts, and not by the larger social policies embodied by the law of torts.” Bohler-Uddeholm Am., Inc. v. Ellwood Group, Inc., 247 F.3d 79, 104 (3d Cir. Pa. 2001) (citing Bash, 601 A.2d at 830).

Fraud in the inducement claims are not barred by the gist of the action doctrine where the fraud involves representations of fact independent of promises of performance made in the contract. See eToll, 811 A.2d at 17; TruePosition, Inc. v. Sunon, Inc., No. 05-CV-3023, 2006 WL 1451496, at \*3 (E.D. Pa. May 25, 2006) (DuBois, J.); Air Prods. & Chems., Inc. v. Eaton Metal Prods. Co., 256 F. Supp. 2d 329, 341 (E.D. Pa. 2003). “[F]raud to induce a person to enter into a contract is generally collateral to (i.e., not interwoven with) the terms of the contract itself.” Air Prods., 256 F. Supp. 2d at 341 (citing eToll, 811 A.2d at 17) (internal quotation marks omitted). On the other hand, when fraud in the inducement is based on statements made with regard to performance of the contract, such claims are barred under that doctrine. In such circumstances a plaintiff’s remedy lies in contract. See Williams v. Hilton Group PLC, 93 F. App’x 384, 386–87 (3d Cir. 2004) (finding that fraud in the inducement claim that defendant had no intention of honoring the contract was barred by gist of the action doctrine). “Moreover, promises made to induce a party to enter into a contract that eventually become part of the contract itself cannot be the basis for a fraud-in-the-inducement claim under the gist of the action doctrine.” Freedom Props., L.P. v. Landsdale Warehouse Co., No. 06-CV-5469, 2007 WL 2254422, at \*6 (E.D. Pa. Aug. 2, 2007) (citations omitted).

The Court notes that “caution should be exercised in determining the gist of an action at the motion to dismiss stage. Judicial caution is appropriate because often times, without further evidence presented during discovery, the court cannot determine whether the gist of the claim is in contract or tort.” Interwave Tech., Inc. v. Rockwell Automation, Inc., No. 05-CV-398, 2005 WL 3605272, at \*13 (E.D. Pa. Dec. 30, 2005) (internal quotation marks & citations omitted).

Plaintiffs allege that during the negotiations of the 2005 Settlement Agreement, defendant represented that the new 1200-mg 5-ASA drug in development would be branded under the PENTASA® trademark. (Compl. ¶ 92.) No provision in the 2005 Settlement Agreement expressly mentions a new 5-ASA drug or the trademark under which new 5-ASA drugs would be sold. In other words, the 2005 Settlement Agreement does not clearly impose upon defendant a duty to market any new 5-ASA drug under the PENTASA® trademark. As such, defendant’s failure to do so would not be actionable as a breach of contract, and defendant’s representation during precontractual negotiations would instead sound in tort.

Section 2.4 of the 2005 Settlement Agreement, while not directly addressing the naming of the new 1200-mg 5-ASA drug, could be interpreted to touch on this question. It states, in relevant part, that “the parties shall enter into an exclusive license for the use of the Trademarks in the Territory in connection with all oral products containing 5-ASA . . . .” One possible meaning of this language is that defendant must use the PENTASA® trademark for *all* oral products containing 5-ASA, including the new 1200-mg drug; this is the meaning that plaintiffs advance with respect to Count III.<sup>7</sup> Under such an interpretation, defendant’s precontractual statement regarding the naming of the new drug would be part of the contract itself, barring plaintiffs’

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<sup>7</sup> As discussed in Part III.C., *supra*, at this stage, it is of no moment that the arguments that plaintiffs present in Counts III and IV may be contradictory. Federal Rule of Civil Procedure 8(d) allows such inconsistent pleading.

fraudulent inducement claim under the gist of the action doctrine. See Freedom Props, 2007 WL 2254422, at \*6. Yet, as discussed in Part III.D, *supra*, the language of section 2.4 is ambiguous. Under another possible interpretation, section 2.4 would not require defendant to market all new 5-ASA drugs as PENTASA®; utilizing that interpretation, defendant’s statements would be “collateral to (i.e., not interwoven with) the terms of the contract itself,” and the gist of the action doctrine would not apply. Air Prods., 256 F. Supp. 2d at 341.

As the language of the 2005 Settlement Agreement is capable of either meaning, and given the permissiveness of federal pleading rules, the Court concludes that both the contract claim (Count III) and the fraud claim (Count IV) survive the gist of the action doctrine challenge at this stage of the proceedings. See Interwave Tech., 2005 WL 3605272, at \*13. For purposes of the motion for judgment on the pleadings, plaintiffs “must allege facts in the complaint that if proven, would amount to fraud in the inducement to enter into the contract, with such facts being analytically separable from allegations of breaches in the performance of the contract.” Id. at \*14. The Court concludes that plaintiffs have done so; accordingly, Count IV is not barred by the gist of the action doctrine.

## **2. Parol Evidence Rule**

Pennsylvania law concerning the application of the parol evidence rule to claims of fraudulent inducement is well established. The Pennsylvania Supreme Court has explained the law as follows:

Where the alleged prior or contemporaneous oral representations or agreements concern a subject which is specifically dealt with in the written contract, and the written contract covers or purports to cover the entire agreement of the parties, the law is now clearly and well settled that in the absence of fraud, accident or mistake the alleged oral representations or agreements are merged in or superseded by the subsequent written contract, and parol evidence to vary, modify or superseded the written contract is inadmissible in evidence.

HCB Contractors v. Liberty Place Hotel Assocs., 652 A.2d 1278, 1279 (Pa. 1995) (internal quotation marks and citations omitted). The exception to the parol evidence rule for fraud covers fraud in the

execution, i.e., the oral representations were fraudulently omitted from the contract, not fraud in the inducement. Dayhoff, Inc. v. H.J. Heinz Co., 86 F.3d 1287, 1300 (3d Cir. 1996); Freedom Props., L.P. v. Landsdale Warehouse Co., No. 06-CV-5469, 2007 WL 2254422, at \*3 (E.D. Pa. Aug. 2, 2007); Interwave Tech., Inc. v. Rockwell Automation, Inc., No. 05-CV-398, 2005 WL 3605272, at \*16 (E.D. Pa. Dec. 30, 2005). Applying the parol evidence rule to bar claims of fraudulent inducement, as in Pennsylvania, is the minority rule. Regent Nat'l Bank v. Dealers Choice Auto. Planning, Inc., No. 96-CV-7930, 1997 WL 786468, at \*6 (E.D. Pa. Nov. 26, 1997). Pennsylvania courts justify this position under the rationale that if the parties “relied on any understanding, promises, representations or agreements made prior to the execution of the written contract . . . , they should have protected themselves by incorporating into the written agreement the promises or representations upon which they now rely . . . .” 1726 Cherry St. P'ship v. Bell Atl. Props., Inc., 653 A.2d 663, 666 (Pa. Super. Ct. 1995) (internal quotation marks & citation omitted). Thus, where there is an integrated agreement and the asserted misrepresentations giving rise to fraud in the inducement are addressed by the agreement, the parol evidence rule bars extrinsic evidence of such a fraud claim.

To apply the HCB Contractors rule, courts must determine whether there is an integrated agreement and whether the asserted prior representations are specifically covered by the written agreement. Interwave Tech., 2005 WL 3605272, at \*17; Quorum Health Res. v. Carbon-Schuylkill Cmty. Hosp., Inc., 49 F. Supp. 2d 430, 433 (E.D. Pa. 1999). One key factor in concluding whether an agreement is integrated is the presence or absence of an integration or merger clause in the written agreement. See HCB Contractors, 652 A.2d at 1280; Interwave Tech., 2005 WL 3605272, at \*18; Quorum Health, 49 F. Supp. 2d at 433; G. Daniel Glass v. Singer Optical Group, Inc., No. 95-CV-308, 1995 WL 717411, at \*3–4 (E.D. Pa. Dec. 1, 1995). To determine whether the written contract specifically addresses the subject of the oral representations, courts ask whether “they relate to the

same subject matter and are so interrelated that both would be executed at the same time and in the same contract . . . .” Hershey Foods Corp. v. Ralph Chapek, Inc., 828 F.2d 989, 995 (3d Cir. 1987) (internal citation omitted).

In this case, the 2005 Settlement Agreement does not contain an integration or merger clause. Its preamble specifically refers to the 1983 Agreement and the 1998 Sublicense and incorporates definitions from the 1983 Agreement. Moreover, section 2.4 states that the parties will enter into an exclusive license once the 1983 Agreement and the 1998 Sublicense expire; the language of this section arguably anticipates that the parties will draft a future arrangement including consideration of 2% of Net Sales and “such other terms and conditions as are usual and customary in such agreements.” Viewing these facts in the light most favorable to plaintiffs, the Court concludes that the 2005 Settlement Agreement was not fully integrated.

Plaintiffs allege that defendant represented during the negotiations that the new 1200-mg 5-ASA drug would be marketed under the PENTASA® trademark. (Compl. ¶ 92.) The only section of the 2005 Settlement Agreement that possibly covers such a representation is section 2.4. As discussed in Part III.D, *supra*, the language of section 2.4 is ambiguous, particularly with respect to whether it requires defendant to market all new oral 5-ASA drugs as PENTASA®. In light of this ambiguity, the Court cannot determine at this stage whether the written agreement specifically addresses the content of the alleged oral representations such that they would be barred by the parol evidence rule. “For the Pennsylvania parol evidence rule to bar a claim for fraudulent inducement, the contract must be written, unambiguous, and fully integrated.” Coram Healthcare Corp. v. Aetna U.S. Healthcare, Inc., 94 F. Supp. 2d 589, 594–95 (E.D. Pa. 1999). As the Court concludes that the 2005 Settlement Agreement is ambiguous and not fully integrated, it will not dismiss plaintiffs’ fraudulent inducement claim as barred by the parol evidence rule.

### 3. Federal Rule of Civil Procedure 9(b)

Federal Rule of Civil Procedure 9(b) (“Rule 9(b)”) requires that “[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake.” The Third Circuit has cautioned, however, that “focusing exclusively on [the] particularity language is too narrow an approach and fails to take account of the general simplicity and flexibility contemplated by the rules.” Seville Indus. Mach. Corp. v. Southmost Mach. Corp., 742 F.2d 786, 791 (3d Cir. 1984) (internal quotation marks & citations omitted).

Under Rule 9(b), a plaintiff must plead “all of the essential factual background that would accompany the first paragraph of any newspaper story—that is, the who, what, when, where, and how of the events at issue.” In re Suprema Specialties, Inc. Sec. Litig., 438 F.3d 256, 276–77 (3d Cir. 2006) (internal quotation marks & citations omitted). Plaintiffs may satisfy Rule 9(b) “by pleading the ‘date, place or time’ of the fraud, or through ‘alternative means of injecting precision and some measure of substantiation into their allegations of fraud.’” Lum v. Bank of Am., 361 F.3d 217, 223–24 (3d Cir. 2004) (quoting Seville, 742 F.2d at 791). The requirements of Rule 9(b) ensure that plaintiff’s pleadings “place the defendants on notice of the precise misconduct with which they are charged, and . . . safeguard defendants against spurious charges of immoral and fraudulent behavior.” Seville, 742 F.2d at 791.

Under Pennsylvania law, fraudulent inducement requires: (1) a representation; (2) material to the transaction; (3) made falsely, with knowledge of its falsity or recklessness as to whether it is true or false; (4) with the intent of misleading another to relying on the misrepresentation; (5) justifiable reliance on the misrepresentation; and (6) injury proximately caused by the reliance on the misrepresentation. Shapiro v. UJB Fin. Corp., 964 F.2d 272, 284 (3d Cir. 1992); Gibbs v. Ernst, 647 A.2d 882, 889 (Pa. 1994).

The Court concludes that the Complaint states a claim of fraudulent inducement with the specificity required under Rule 9(b) based on the following allegations. Defendant affirmatively stated to plaintiffs during the 2005 Settlement Agreement negotiations that defendant would brand the new 1200-mg 5-ASA drug under the PENTASA® trademark. (Compl. ¶¶ 92, 137.) Defendant’s representatives repeatedly referred to the new drug as the “PENTASA® 1200-mg.” (Id. ¶ 93.) Defendant also intentionally concealed its position that LIALDA® would not be covered by the 2005 Settlement Agreement and the other licensing agreements. (Compl. ¶¶ 90, 138.) These statements and omissions were material to the negotiations. (Id. ¶¶ 95, 139.) Defendant, at the time of the negotiations, had no intention of marketing the 1200-mg drug as PENTASA®. (Id. ¶ 137.) Defendant made such statements to induce plaintiffs to enter into the 2005 Settlement Agreement, and plaintiff justifiably relied on them. (Id. ¶¶ 95, 139–140.) Plaintiffs have suffered injury as a result of defendant’s misrepresentations as they have not received royalty payments in connection with sales of LIALDA®. (Id. ¶¶ 102, 141.)

The allegations in the Complaint “place [defendant] on notice of the precise misconduct with which [it is] charged,” as required by Rule 9(b). Seville, 742 F.2d at 791. Plaintiffs need not identify the exact speaker or recipient of the alleged oral statements in the Complaint. See Charleswell v. Chase Manhattan Bank, N.A., 308 F. Supp. 2d 545, 570 (D. Virgin Islands 2004) (DuBois, J.). Accordingly, the Court declines to dismiss Count IV for failure to plead fraud with more specificity.

As plaintiffs’ claim of fraudulent inducement is not barred by the gist of the action doctrine, the parol evidence rule, or Rule 9(b), the Court denies defendant’s motion with respect to Count IV.

#### **IV. CONCLUSION**

For all of the aforementioned reasons, the Court denies the Motion of Defendant Shire U.S., Inc. for Judgment on the Pleadings.

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

<b>FARMACEUTISK LABORATORIUM</b>	:	<b>CIVIL ACTION</b>
<b>FERRING A/S T/A FERRING A/S,</b>	:	
<b>FERRING INTERNATIONAL CENTER</b>	:	
<b>S.A., and FERRING</b>	:	
<b>PHARMACEUTICALS A/S</b>	:	<b>NO. 08-941</b>
<b>Plaintiffs,</b>	:	
<b>v.</b>	:	
	:	
<b>SHIRE U.S., INC.</b>	:	
<b>Defendant.</b>	:	

**ORDER**

**AND NOW**, this 7th day of April, 2009, upon consideration of Motion of Defendant Shire U.S., Inc. for Judgment on the Pleadings (Document No. 23, filed December 29, 2008); Plaintiffs' Memorandum of Law in Opposition to Defendant's Motion for Judgment on the Pleadings (Document No. 28, filed January 29, 2009); Reply Brief in Support of the Motion of Defendant Shire U.S., Inc. for Judgment on the Pleadings (Document No. 30, filed February 19, 2009); Plaintiffs' Sur-Reply in Opposition to Defendant's Motion for Judgment on the Pleadings (Document No. 31, filed March 4, 2009); defendant's Request for Oral Argument (Document No. 32, filed March 6, 2009); and Plaintiffs' Opposition to Defendant's Request for Oral Argument (Document No. 33, filed March 9, 2009), for the reasons that follow in the attached Memorandum, **IT IS ORDERED** that the Motion of Defendant Shire U.S., Inc. for Judgment on the Pleadings is **DENIED**.

**IT IS FURTHER ORDERED** that defendant's Request for Oral Argument is **DENIED AS MOOT**.

**BY THE COURT:**

/s/ Honorable Jan E. DuBois  
**JAN E. DUBOIS, J.**