IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ETHYPHARM S.A. FRANCE,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civ. No. 08-126-SLR
	)	
ABBOTT LABORATORIES,	)	
	)	
Defendant.	)	

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MEMORANDUM OPINION

Dated: February 20, 2009
Wilmington, Delaware

ROBINSON, District Judge

I. INTRODUCTION

Plaintiff Ethypharm S.A. France ("Ethypharm") brought this action against defendant Abbott Laboratories ("Abbott") on March 3, 2008. (D.I. 1) Both parties are manufacturers of pharmaceutical drugs, more specifically, fenofibrate. Ethypharm alleges that Abbott has interfered with Ethypharm's licensee from marketing and selling Ethypharm's fenofibrate product under an exclusive licensing agreement with a United States distributor. Ethypharm brings antitrust claims under sections 1 and 2 of the Sherman Act, as well as several common law claims and a claim for sham litigation. Presently before the court is Abbott's motion to dismiss all claims of the amended complaint (D.I. 30).[1] For the reasons that follow, the court grants in part and denies in part the motion.

II. BACKGROUND

Ethypharm is a privately-held French pharmaceutical company that develops, formulates and manufactures numerous drug products, including a fenofibrate product called Antara®. (D.I. 26 at ¶¶ 4, 6, 37) Antara® is not a generic product; it is a branded drug marketed directly to physicians. (*Id.* at ¶ 53) Ethypharm does not directly sell or distribute Antara® in the United States; it contracted with an American company, Reliant Pharmaceuticals, Inc. ("Reliant"), to market and distribute the drug. (*Id.* at ¶¶ 5, 6)

Abbott is a pharmaceutical company that manufactures, markets and sells a brand name fenofibrate drug product called TriCor® in the United States. (*Id.* at ¶ 2)

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[1]Abbott previously filed a motion to dismiss the original complaint. (D.I. 12) This motion is denied as moot.

Abbott licenses the exclusive rights to manufacture and sell TriCor® in the United States from a French company called Laboratoires Fournier ("Fournier"). (*Id.*) Abbott and Fournier have been involved in extensive antitrust litigation in this district regarding TriCor®. Civ. No. 02-1512 (lead case).

Ethypharm gave Reliant an exclusive license in 2001, termed the "Development, License, and Supply Agreement" ("the DLS Agreement"), in which Reliant licensed Ethypharm's intellectual property rights and agreed to seek FDA approval for Antara® and market Antara® in the United States. (D.I. 26 at ¶ 5)

Reliant did not file a Paragraph IV certification[2] for the patents that Abbott had identified in the Orange Book for TriCor®. (*Id.* at ¶¶ 103, 104) Reliant elected to market Antara® immediately upon FDA approval, taking the risk of exposure to large infringement damages in the future. (*Id.* at ¶¶ 105,106) Reliant filed suit in this court on June 1, 2004 seeking a declaration of non-infringement and that the Fournier patents under which Abbott was manufacturing TriCor® are unenforceable due to inequitable conduct.[3] (*Id.* at ¶ 99, Civ. No. 04-350 ("the Abbott/Reliant action")) Abbott filed an infringement counterclaim. (*Id.* at ¶ 115) According to Ethypharm, this counterclaim was a sham and further restrained Antara®'s sales prospects in the United States. (*Id.* at ¶ 119) The Abbott/Reliant action was dismissed by stipulation of

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[2]*See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The filing of a Paragraph IV certification under the Hatch-Waxman Act is itself an act of patent infringement. *See* 35 U.S.C. § 271(e)(2)(A).

[3]At this time, Abbott was simultaneously defending another charge of inequitable conduct in the context of litigation in this court with Impax Laboratories, Inc. (Civ. No. 03-120)

the parties on April 19, 2006. (Civ. No. 04-350, D.I. 110)

Antara® received FDA approval in November of 2004, and was launched in February 2005. (D.I. 26 at ¶¶ 52, 55) In its eighteen months on the market, Antara® had sales over $40 million and "was poised to take an increasing percentage of TriCor®'s market." (*Id.* at ¶¶ 7, 59) Reliant incurred a total of $17.3 million in sales and marketing expenses for Antara® during the first quarter of 2005 alone. (*Id.* at ¶ 60) Reliant had about 700 representatives selling Antara®. (*Id.* at ¶61) The DLS Agreement did not restrict or limit the pool of pharmaceutical companies to whom Reliant could sell or sublicense Antara® rights. (*Id.* at ¶ 49)

On or about April 3, 2006, Abbott and Reliant entered into a series of agreements, including a "Settlement Term Sheet" (the "STS"). The STS permits Reliant to sell Antara® without the risk of infringement. In exchange, Reliant is barred from selling the rights to Antara® to a select list of competitors capable of more efficiently expanding Antara® sales, imposed a 7% royalty on Antara® sales, restrained Reliant from making any new formulations or combination products containing fenofibrate formulations, and restricted Reliant from co-promoting Antara® with specific companies.[4] (*Id.* at ¶¶ 9, 10, 71) At the time, Antara® had a proven sales record, making rights to the product attractive. (*Id.* at ¶ 87)

In mid 2006, Reliant sold the exclusive rights to market and sell Antara® to Oscient Pharmaceutical Company ("Oscient"), a smaller company not listed in the STS.

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[4]The DLS agreement provided that a sublicense or transfer of rights to any "restricted entity" "shall require the prior written consent of Abbott"; such relationships are not completely foreclosed. (D.I. 19 at 16)

(*Id.* at ¶¶ 11, 12) Oscient has "limited resources and [a] relatively small sales force" and, therefore, "does not have the capacity to promote Antara® and finance extensions of Antara® in the marketplace so as to allow Ethypharm to compete effectively with Abbott and Abbott's TriCor® product." (*Id.* at ¶ 12) Abbott continues to enforce the STS against Oscient, requiring a 7% royalty to be paid to Abbott on Antara® sales, and restricting Oscient from co-promoting or contracting out the promotion and sale of Antara to those companies.

In this suit, Ethypharm asserts that Abbott has wrongfully interfered with its agreement with Reliant in a manner equivalent to an "output restraining agreement." (*Id.* at ¶ 78) Ethypharm asserts that Abbott's conduct in contractively restricting the promotion and sale of Antara® via Ethypharm's distributor is anticompetitive conduct prohibited by Sherman Act §§ 1 and 2. Ethypharm also alleges violations of the common laws of unfair competition; tortious interference with contract; tortious interference with prospective economic advantage; that Abbott committed a common law restraint of trade; and that Abbott's infringement counterclaim in the Abbott/Reliant action constituted sham litigation in violation of 15 U.S.C. § 1.

III. STANDARD

In reviewing a motion filed under Federal Rule of Civil Procedure 12(b)(6), the court must accept all factual allegations in a complaint as true and take them in the light most favorable to plaintiff. *See Erickson v. Pardus*, 551 U.S. 89, 127 S.Ct. 2197, 2200 (2007); *Christopher v. Harbury*, 536 U.S. 403, 406 (2002). A complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief, in

order to give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 127 S.Ct. 1955, 1964 (2007) (interpreting Fed. R. Civ. P. 8(a)) (internal quotations omitted). A complaint does not need detailed factual allegations; however, "a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Id.* at 1964-65 (alteration in original) (citation omitted). The "[f]actual allegations must be enough to raise a right to relief above the speculative level on the assumption that all of the complaint's allegations are true." *Id.* at 1959.

IV. DISCUSSION

A. Sherman Act Claims

Abbott asserts that Ethypharm does not have the requisite "antitrust injury" to have standing. More specifically, Abbott argues that Ethypharm is neither a competitor nor consumer in the relevant (fenofibrate) market. Ethypharm does not compete directly with Abbott; rather, it is a supplier lacking antitrust standing. (D.I. 31 at 18-19)

In *Associated General Contractors of California, Inc. v. California State Council of Carpenters*, the Supreme Court articulated five factors that courts should consider in analyzing the existence of antitrust standing (hereinafter, the "AGC factors"). 459 U.S. 519, 545 (1983). The Third Circuit has summarized them as follows:

> (1) the causal connection between the antitrust violation and the harm to the plaintiff and the intent by the defendant to cause harm, with neither factor alone conferring standing; (2) whether the plaintiff's alleged injury is of the type for which the antitrust laws were intended to provide redress; (3) the directness of the injury, which addresses the concerns that liberal application of standing principles might produce speculative claims; (4) the existence of more direct

victims of the alleged antitrust violations; and (5) the potential for duplicative recovery or complex apportionment of damages.

In re Lower Lake Erie Iron Ore Antitrust Litig., 998 F.2d 1144, 1163 n. 9 (3d Cir. 1993).

The question posed by the motion at bar is whether a foreign name-brand drug manufacturer, which does not itself market and distribute its product in the United States but does so through an exclusive United States distributor, is entitled to avail itself of the protection of the antitrust laws for the purpose of challenging the conduct of a manufacturer of a competing brand name drug.

The court begins by addressing Abbott's cited caselaw. In *Barton & Pittinos v. Smithkline Beecham Corporation*, 118 F.3d 178 (3d Cir. 1997), the Third Circuit held that plaintiff ("B&P"), a telemarketing company hired to "drum up demand for [defendant's] vaccine, solicit orders [from nursing homes], and pass the orders along to . . . a licensed medical supply house," did not have standing to sue defendant drug manufacturer upon its termination from this role. *Id.* at 180. B&P was not a drug manufacturer and, in fact, was "legally barred from buying, possessing, or selling the vaccine because it lacked the required prescription-drug license." *Id.* at 183. B&P fell into the category of "advertisers and brokers of a good or service [which] are not competitors of companies that actually supply the good or service." *Id.* at 184.[5] Similarly, suppliers of active pharmaceutical ingredients lack standing to bring antitrust claims against a drug manufacturer, as they neither manufacture the product at issue nor compete in the drug market itself. *Asahi Glass Co., Ltd. v. Pentech*

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[5]Abbott asserts that Ethypharm falls within the class of "licensors, franchisors or landlords [that] are not the concern of the antitrust laws[.]" (D.I. 31 at 18, citing *R.C. Dick Geothermal Corp. v. Thermogenics, Inc.*, 890 F.2d 139, 148 (9th Cir. 1989))

Pharmaceuticals, Inc., 289 F. Supp. 2d 986, 990 (N.D. Ill. 2003). The case at bar is distinguishable from the foregoing because Ethypharm is a manufacturer of a cholesterol lowering drug (Antara®) that competes directly with Abbott's TriCor®.

In *Carpet Group International v. Oriental Rug Importers Association, Inc.*, 227 F.3d 62 (3d Cir. 2000), also cited by Abbott, plaintiffs sponsored trade shows in the United States in which foreign rug manufacturers were invited to display rugs and sell directly to American retailers. *Id.* at 64. Typically, American wholesalers purchase and import oriental rugs for sale to U.S. retailers. *Id.* Over defendants' standing challenge, the Third Circuit held that plaintiffs, despite being brokers and not rug manufacturers, had antitrust standing to challenge defendants' boycott of manufacturers who attended plaintiffs' shows because plaintiffs "offered an alternative avenue of distribution to that offered by rug importer/wholesalers." *Id.* at 77. Put another way, there was a "cross-elasticity of demand between the plaintiffs' offering and the defendants' offering," rendering plaintiffs' injury "inextricably intertwined" with defendants' wrongdoing. *Id.* at 77-78 (citation omitted). In this case, Ethypharm alleges that Abbott caused it injury by restricting the ability of its exclusive United States distributor to sell its drug. The allegations, if true, establish that Abbott restricted the availability of a competing name-brand drug. Discovery will reveal the precise nature of the market relationship between Antara® and TriCor®.

The court finds this case most analogous to *Chemi SpA v. Glaxosmithkline*, 356 F. Supp. 2d 495 (E.D. Pa. 2005), cited by Ethypharm. Chemi SpA ("Chemi") asserted that Glaxosmithkline ("GSK") violated the antitrust laws by unlawfully procuring a patent

and subsequently filing a baseless patent infringement suit in order to delay the FDA's approval for ANDAs filed by Teva Pharmaceuticals USA ("Teva") and Eon Labs Manufacturing, Inc. ("Eon"). Chemi is a manufacturer of nabumetone[6]; Teva and Eon were listed on Cherni's Drug Master File as "companies authorized to reference its application in any subsequent filings those companies might make with the FDA" in bringing nabumetone drugs to market. 356 F. Supp. 2d at 497. GSK challenged Chemi's standing to bring its antitrust claims on the basis that Chemi, a supplier of nabumetone to GSK's competitors, Teva and Eon, "is not a direct market participant" and, therefore, unable to seek recovery under the antitrust laws. *Id.* at 501. The court stated the following:

> Even though Chemi was not a direct competitor of GSK, its alleged injury was inextricably intertwined with the injury GSK sought to inflict on the nabumetone market. After Chemi determined that it could manufacture nabumetone commercially, Chemi was prevented from selling nabumetone to these vendors when GSK brought a bogus patent infringement suit against them with the very purpose of perpetuating its monopoly with respect to nabumetone. Chemi's injury is direct, and its claim is not speculative.

Id. at 502. The court "[could] not say at this stage that there is likely to be duplicative recovery or complex apportionment of damages," and denied GSK's motion for judgment on the pleadings. *Id.* at 503.

Like Chemi, Ethypharm participates in the relevant market through a third party, and should be permitted to challenge Abbott's restrictive dealings with respect to that party. The crux of Ethypharm's claims is that Abbott asserted infringement counterclaims in the Abbott/Reliant action for the purpose of securing the STS; absent

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[6]A non-steroidal anti-inflammatory drug (or NSAID).

the STS (and any related agreement(s)), Reliant would have been able to sell to a company larger than Oscient and develop combination fenofibrate products. (D.I. 26 at ¶ 90) In the court's opinion, the absence of specific supporting facts regarding Reliant's "missed opportunities" at the pleading stage does not render Ethypharm's proffer on causation inadequate (as Abbott suggests). Moreover, Ethypharm specifically states that it was not informed of Reliant's entry into the STS prior to its execution. (D.I. 26 at ¶ 85) The fact that Ethypharm may have later acquiesced (or failed to object) to Reliant's later sale to Oscient of the exclusive rights to market or sell Antara® does not render Abbott's conduct immune from scrutiny under the circumstances at bar.[7]

With respect to the remaining AGC factors, the court, as in *Chemi SpA*, finds Ethypharm's injury sufficiently direct. As Ethypharm puts it, absent persuasive authority to the contrary, "Ethypharm does not forfeit the protection of the antitrust laws merely because it sought to enter the U.S. fenofibrate market by utilizing the route of an exclusive distributor rather than, for example, by purchasing a U.S. company or organizing its own U.S. marketing force." (D.I. 34 at 27) Reliant may be tasked by the DLS agreement with all of the responsibilities for Antara®, but it does not manufacture Antara® itself.[8] Therefore, Abbott's actions vis-a-vis Reliant indicate an intent to harm

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[7]With respect to the remainder of the first AGC factor, the harm to the plaintiff and the intent by the defendant to cause harm, Ethypharm sufficiently alleged that Abbott had the specific intent to foreclose Ethypharm's competition in the relevant market and unlawfully raise prices on TriCor®. (D.I. 26 at ¶¶ 125, 138)

[8]*Cf. Productive Inventions, Inc. v. Trico Products Corp.*, 224 F.2d 678, 679 (2d Cir. 1955) (holding that non-manufacturer licensee whose "sole interest in the patents is limited to its right to receive royalties" did not have antitrust standing) (cited by Abbott).

Ethypharm, if anyone.[9] Since Ethypharm has no other United States licensees, there appears at this juncture to be no risk of duplicative recovery.

In sum, the court finds that Ethypharm's alleged injury is inextricably intertwined with the injury Abbott allegedly sought to inflict on the fenofibrate market. The AGC factors favor standing. Thus, Abbott's motion is denied with respect to Ethypharm's Sherman Act claims.[10]

B. Common Law Claims

1. Unfair competition and tortious interference with business relations

a. Standards

At common law, the spectrum of conduct actionable under the umbrella of unfair competition has been characterized as "notoriously undefined." *State of Delaware ex rel. Brady v. Wellington Homes, Inc.*, No. Civ. A. 99C-09-168, 2003 WL 22048231, *1 (Del. Super. Aug. 20, 2003) (citing the prefatory note to the 1964 Uniform Deceptive Trade Practices Act). The claim has been characterized as "unfair competition between businesses or trades," consistent with the historical application of the action "whenever one trader diverted patronage from a rival." *Id.* The Delaware Superior Court has

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[9]In exchange for limiting its abilities to sell Antara® domestically, Reliant received assurance from Abbott that it would not be sued for patent infringement. Reliant, therefore, obtained a benefit from its bargain – it does not have to bear the financial burden of litigation. If Abbott intended to hurt anyone by entering into this contract, it was Ethypharm, not the party with which it exchanged benefits.

[10]Ethypharm may pursue injunctive relief under section 16 of the Clayton Act, which is "not as demanding" as section 4, and which requires a demonstration of antitrust injury and a "significant threat of injury" from a violation of the antitrust laws. *See In re Warfarin Sodium Antitrust Litigation*, 214 F.3d 395, 399 (3d Cir. 2000).

stated that the "elements of the tort of unfair competition are that the plaintiff has a reasonable expectancy of entering a valid business relationship, with which the defendant wrongfully interferes, and thereby defeats the plaintiff's legitimate expectancy and causes him harm." *Total Care Physicians, P.A. v. O'Hara*, 798 A.2d 1043, 1057 (Del. Super. 2001). In a recent decision, Delaware's Court of Chancery has stated that "[t]he essential element separating unfair competition from legitimate market participation . . . is an unfair action on the part of defendant by which he prevents plaintiff from legitimately earning revenue." *Edix Media Group, Inc. v. Mahani*, No. Civ. A. 2186-N, 2006 WL 3742595, *11 (Del. Ch. Dec. 12, 2006).

Similarly, "[t]he basic elements which establish a prima facie tortious interference with a business relationship in Delaware are the existence of a valid business relation . . . or expectancy; knowledge of the relationship or expectancy on the part of the interferer; an intentional interference inducing or causing a breach or termination of the relationship or expectancy; and resultant damage to the party whose relationship or expectancy has been disrupted." *Bove v. Goldenberg*, Civ. No. 05-134, 2007 WL 446014, *4 (Del. Super. Feb. 7, 2007) (citing *Bowl-Mor Co. v. Brunswick* Corp., 297 A.2d 61, 65 (Del. Ch. 1972)). Put another way, a plaintiff must establish: (1) the reasonable probability of a business opportunity; (2) intentional interference; (3) proximate causation; and (4) damages, "all of which must be considered in light of defendant's privilege to compete or protect his business interests in a fair and lawful manner." *Lipson v. Anesthesia Services, P.A.*, 790 A.2d 1261, 1285 (Del. Super. 2001) (citations omitted).

b. Discussion

In its counts 3 and 4, Ethypharm asserts that Abbott's contract with Reliant interfered with Ethypharm's reasonable expectation that Reliant would increase Antara®'s market share and extend the Antara® product line, and assign its rights to, if anyone, a company with the ability to do the same. (D.I. 26 at ¶¶ 147-148) Abbott contests the claims on several bases: (1) Reliant did not breach the DLS agreement, which did not state a duty to extend the Antara® line; (2) "[t]here is no allegation of contract discussions between Reliant and any of the companies that Ethypharm prefers over Oscient"; (3) Reliant, not Abbott, caused Ethypharm's business expectations to be defeated when it sold the Antara® rights; and (4) "Ethypharm apparently consented to the sale by Reliant to Oscient." (D.I. 31 at 31-35)

Abbott's arguments fall short. Ethypharm's claims do not require a breach of the DLS agreement. Under the facts as alleged, there would be no reason for Reliant to discuss contracts with any companies foreclosed by the STS. It is Ethypharm's prerogative not to contest Reliant's sale to Oscient in favor of challenging the potential anticompetitive effects of the STS itself.

On its face, the complaint identifies a contract (the DLS agreement), a reasonable expectation that Ethypharm would profit by Reliant's unbridled marketing of Antara®, intent by Abbott to interfere with Antara®'s growth in the U.S. fenofibrate market, a causal link between Abbott's assertion of infringement counterclaims, the STS, and the inability of Reliant to expand Antara® without restriction as Ethypharm had anticipated, and detriment to Ethypharm in terms of decreased profits and market share. The essential elements having been articulated, the court declines to require

more absent the benefit of discovery.

2. Tortious interference with contract

The elements of tortious interference with contract are as follows: "There must be (1) a contract, (2) about which defendant knew and (3) an intentional act that is a significant factor in causing the breach of such contract (4) without justification (5) which causes injury." *Irwin & Leighton, Inc. v. W.M. Anderson Co.*, 532 A.2d 983, 992 (Del. Ch. 1987).

Ethypharm asserts that, by its "inducement and interference," it was Abbott's intent to cause Reliant to breach the covenant of good faith and fair dealing that attaches to the DLS agreement. (D.I. 26 at ¶¶ 164, 168) Abbott points to no caselaw demonstrating that Ethypharm's claim is not viable. Abbott asserts, without support, that "[a]ny breach of the [DLS agreement] was caused by Reliant's decision to settle [suit with Abbott] – not by [Abbott's] assertions of the counterclaims." (D.I. 31 at 36) The court takes Ethypharm's assertions in its complaint – not Abbott's attorney argument – as true on the disposition of a motion to dismiss pursuant to 12(b)(6). On this record, and in view of the fact that Ethypharm has articulated facts corresponding to the essential elements of this claim, the court denies Abbott's motion.

3. Common law restraint of trade

Ethypharm alleges that the actions underlying its Sherman Act claims also constitute an unlawful restraint of trade under the common law. The Delaware legislature has codified an unlawful restraint of trade in the Delaware Antitrust Act. 6 Del. C. § 2103. The Court of Chancery has recognized that "the Delaware statute does not permit individuals to enforce their rights by bringing private actions." *Maddock v.*

Greenville Retirement Community, L.P., No. Civ. A. 12564, 1997 WL 89094, *6 (Del. Ch. Feb. 26, 1997) (citing 6 Del. C. § 2103).

Abbott asserts in its reply papers that 6 Del. C. § 2103 dissolved the private action at common law. No caselaw was cited in support. Neither party has thoroughly addressed this issue, and the court was unable to locate caselaw directly on point.

Most often, the Delaware legislature will specify when the codification of a common law action is not intended to affect the common law right. *See, e.g.*, 6 Del. C. § 2352(c) ("This section does not affect unfair trade practices otherwise actionable at common law or under other statutes of this state."). No comparable language is contained in 6 Del. C. § 2103. Moreover, the torts of unfair competition, interference with contract and interference with business relations were all derived from the common law rule against restraint of trade. *See J.E. Rhoads & Sons, Inc. v. Ammeraal, Inc.*, No. Civ. A. 83C-no-98, 1988 WL 32012, *7 (Del. Super. Mar. 30, 1988). It appears that this claim overlaps Ethypharm's counts 3-5, although the extent is unclear.

Despite the fact that Abbott's preemption argument appeared in its reply papers, it was Ethypharm's duty, in defending the motion at bar, to articulate in some manner how its pleading meets the legal requirements of its claim. This did not occur. (D.I. 34 at 37) Nor did Ethypharm request leave to file a surreply to address the issue. Ethypharm's count 6 is dismissed without prejudice.

V. CONCLUSION

For the aforementioned reasons, Abbott's motion is granted with respect to Ethypharm's common law restraint of trade claim (count 6) and denied in all other

respects.[11] An appropriate order shall issue.

[11]Abbott's motion (D.I. 30) is technically one to dismiss all counts of the amended complaint (D.I. 26). The parties did not address Ethypharm's sham litigation claim (count 7) and the motion is denied with respect to that claim.