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: August 23, 2011
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 brought antitrust claims under Sections 1 and 2 of the Sherman Act, as well as several common law claims and a claim for sham litigation. On February 20, 2009, the court granted Abbott's motion to dismiss with respect to Ethypharm's common law restraint of trade claim (count six) and denied Abbott's motion to dismiss all other counts of the amended complaint. (D.I. 39) Discovery has been completed and trial is scheduled to commence on September 30, 2011. Currently before the court are Abbott's motions for summary judgment: (1) on counts one through five regarding its alleged "anticompetitive conduct" (D.I. 176); and (2) on count seven and Ethypharm's allegations of "sham litigation" (D.I. 180).

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,

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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) 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"), through 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. 179, pt.1 at ex. 2)

Reliant did not file a Paragraph IV certification[1] for the patents that Abbott had identified in the Orange Book for TriCor®. Rather, Reliant elected to market Antara® immediately upon FDA approval. In light of the risk of exposure to infringement claims by Abbott, Reliant filed suit in this court on June 1, 2004, seeking a declaration of non-infringement vis a vis four Fournier fenofibrate patents: U.S. Patent Nos. 6,074,670 ("the '670 patent"); 6,277,405 ("the '405 patent"); 6,589,552 ("the '552 patent"); and 6,652,881 ("the '881 patent"). Civ. No. 04-350 ("the Abbott/Reliant action") Reliant also sought a declaration that the foregoing TriCor® patents are unenforceable due to

[1]*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).

inequitable conduct.[2] Abbott filed a counterclaim for infringement of the '405 and '881 patents. According to Ethypharm, the counterclaims were a sham and further restrained Antara®'s sales prospects in the United States.

Reliant's NDA for Antara® was filed pursuant to Section 505(b)(2) of the Federal Food Drugs and Cosmetics Act. That is, Reliant did not present its own safety and efficacy studies for Antara®, but presented data showing that patients taking Antara® would attain similar blood concentrations of fenofibrate as would patients taking TriCor® 200, and relied on Abbott's studies showing the safety and efficacy of TriCor® 200. (D.I. 179, pt. 1 at ex. 3) Antara® received FDA approval in November of 2004, and Reliant began marketing Antara® in February 2005.

Ethypharm states that Antara®'s net sales totaled $23.5 million in 2005. (D.I. 1 at ¶ 55) According to Reliant documents, sales of Antara® exceeded expectation in April and May 2005, but came short of projection in June 2005. (D.I. 192, pt. 2 at ex. 9, RLNTE00062604) Notwithstanding, sales of Antara® increased during this period, while sales of TriCor® decreased.[3] (*Id.* at RLNTE00062604, RLNTE00062608) According to the complaint, Antara® earned $18.9 million in net sales in the first half of 2006. (D.I. 1 at ¶ 56)

On April 3, 2006, Abbott and Reliant settled the Abbott/Reliant action and executed a "Settlement Term Sheet" embodying the terms of their agreement (the

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[2]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)

[3]Other competitors in the market included Lofibra®, Triglide®, gemfibrozil, Lopid® and fenofibrate.

"STS").[4] The STS permits Reliant to sell Antara® without the risk of infringement. That is, the STS grants Reliant a nonexclusive license to the '670, '405, '552, and '881 patents (the "Stamm patents"), as well as U.S. Patent No. 4,895,726 ("the '726 patent"), another Fournier fenofibrate patent (collectively hereinafter, the "Fournier patents"). (STS §§ 1(q); 2) The Reliant products subject to the license were defined as

> the 43 mg, 87 mg and 130 mg fenofibrate capsule products that are the subject of Reliant's New Drug Application 21-695, as supplemented and/or amended from time to time. Reliant Products do not include (i) any pharmaceutical products where fenofibrate is not the sole active ingredient, (ii) any combination therapy products or (iii) any products in a form other than a 43 mg, 87 mg or 130 mg fenofibrate capsule.

(STS § 1(o)) The license also extended to "any continuations, continuations-in-part or divisional applications and patents thereof and any reissued or reexamined version(s)" of the Stamm patents. (STS § 1(q))

As consideration, Reliant agreed to a 7% royalty on net sales of the Reliant Products. (STS § 3(a)) The royalty would increase, however, to 10% of net sales under specified conditions relating to a change of control, e.g., acquisition of Reliant or any portion of its business relating to the Reliant Products. (STS §§ 3(a), (d), (e)) The parties dispute the proper interpretation of Section 8(ii) of the STS, providing as follows.

> **Other Licensing Terms.** The license would contain additional customary terms and conditions including, without limitation, the following: (i) reports and audits and (ii) no assignment, sublicense or other transfer of any rights relating to the Reliant Products (including the right to market and promote the Reliant Products) except: . . . (e) to acquirers . . . of any portion of Reliant [or its business] relating to the Reliant Products other than pursuant to a Change of Control, provided that any assignment, sublicense or other transfer of rights granted pursuant to

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[4]The STS is docketed at D.I. 179 (pt. 1), ex. 1; hereinafter, the court will cite "STS §__" for ease of reference. The parties did not subsequently negotiate a definitive agreement.

> Section 8(ii)(e), (A) to a Restricted Entity or Affiliate thereof, shall require the prior written consent of Abbott and (B) to any entity other than a Restricted Entity or Affiliate thereof shall be limited to [the '726, '670, '405, '552 and '881 patents] unless Abbott consents to the assignment, sublicense or other transfer (in which case, Reliant's rights to all of the Stamm Patents may be included).

Schedules I and II to the STS identify the Restricted Entities under that agreement: about 20 large pharmaceutical companies, 10 generic companies and a few specialty pharmaceutical companies. Reliant was also permitted under the STS to "authorize Contract Sales Organizations[5] to market the Reliant products" on its behalf. (STS § 8(ii)(b))

On or about July 24, 2006, Reliant sold the exclusive rights to market and sell Antara® to Oscient Pharmaceutical Company ("Oscient"), a smaller, specialty pharmaceutical company not listed in schedules I or II of the STS. (D.I. 179, pt.1 at ex. 27; D.I. 192, pt. 5 at ex. 66) Oscient paid $78 million plus the cost of the existing Antara® inventory. (D.I. 179, pt.1 at ex. 6, § 3.1) The DLS provided Ethypharm a right of first offer with respect to the divestiture of Antara®. (*Id.*, ex. 2 at § 12.4) Ethypharm executed a document approving the sale. (*Id.*, ex. 4) Abbott did not consent to the transfer of Reliant's rights to any later-issued patents in the Stamm patent family, and Reliant and Oscient entered into a separate agreement addressing any risk that Abbott may sue Oscient in this regard. (*Id.*, ex. 40)

In the summer of 2009, Oscient discontinued its sales force promotion of

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[5]Defined as "a pharmaceutical sales and marketing organization that is not a Restricted Entity [listed on schedules I and II to the STS] and whose principal business is the marketing and sale of pharmaceutical products for third parties (for example, Innovex), engaged by a Reliant Licensed Entity to detail the Reliant Products on a fee-for-service basis." (STS § 1(f))

Antara® and filed for bankruptcy. (D.I. 192, pt. 5 at exs. 76, 77) This is, in Ethypharm's characterization, directly related to Reliant's sale of Antara® to Oscient, a company with "limited resources and a relatively small sales force" that "[did] not have the capacity to promote and develop Antara® in the marketplace to compete with TriCor® effectively." (D.I. 1 at ¶ 11) Ethypharm asserts that the 7% royalty to Abbott weakened the profitability of Antara® and raised the cost of its promotion, sales and distribution. (*Id.* at ¶ 74) Ethypharm argues that the STS restricts its abilities to develop new fenofibrate formulations or combination products, or by adding to the indications for which physicians can prescribe Antara®. (*Id.* at ¶ 75) Ethypharm characterizes the STS as equivalent to an "output restraining agreement" in these regards. (*Id.* at ¶ 78)

Ethypharm brings antitrust claims under Sections 1 and 2 of the Sherman Act, and 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. On Abbott's motion to dismiss, the court found that Ethypharm had standing vis a vis its Sherman Act claims.[6] *See Ethypharm S.A. France v. Abbott Labs.*, 598 F. Supp. 2d 611, 618 (D. Del. 2009). The court also held that Ethypharm articulated the essential elements of its unfair competition and tortious interference

[6]The court characterized the question posed by Abbott's motion as "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."

claims under Delaware law. *Id.* at 619-20. The court granted Abbott's motion with respect to Ethypharm's common law restraint of trade claim, however, insofar as such actions (pursuant to 6 Del. C. § 2103) may only be brought by Delaware's Attorney General. *Id.* at 620.

III. STANDARD

A court shall grant summary judgment only if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). The moving party bears the burden of proving that no genuine issue of material fact exists. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 n.10 (1986). "Facts that could alter the outcome are 'material,' and disputes are 'genuine' if evidence exists from which a rational person could conclude that the position of the person with the burden of proof on the disputed issue is correct." *Horowitz v. Fed. Kemper Life Assurance Co.*, 57 F.3d 300, 302 n.1 (3d Cir. 1995) (internal citations omitted). If the moving party has demonstrated an absence of material fact, the nonmoving party then "must come forward with 'specific facts showing that there is a genuine issue for trial.'" *Matsushita*, 475 U.S. at 587 (quoting Fed. R. Civ. P. 56(e)). The court will "view the underlying facts and all reasonable inferences therefrom in the light most favorable to the party opposing the motion." *Pa. Coal Ass'n v. Babbitt*, 63 F.3d 231, 236 (3d Cir. 1995). The mere existence of some evidence in support of the nonmoving party, however, will not be sufficient for denial of a motion for summary judgment; there must be enough

evidence to enable a jury reasonably to find for the nonmoving party on that issue. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). If the nonmoving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof, the moving party is entitled to judgment as a matter of law. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

IV. DISCUSSION

A. Counts Relating to Reliant's Alleged "Anticompetitive Agreement"[7]

Abbott moves to dismiss Ethypharm's claims on several bases. First, Abbott argues that it has the right to refuse to license a patent. (D.I. 177 at 11-13) Secondly, Abbott argues that the STS did not prohibit Reliant's divestiture of Antara® to anyone it saw fit; only the Stamm patent rights were subject to a condition precedent (Abbott's consent). (D.I. 177 at 13, 15) Finally, Abbott argues that Ethypharm has no direct evidence of antitrust injury, insofar as it cannot demonstrate (with any reasonable certainty) that another company (other than Oscient) would have bought Antara® and made that product a commercial success. (*Id.* at 17-20)

1. Scope of the patent test

The first inquiry at bar is the legality of the STS. The Federal Circuit has stated that a district court analyzing the anticompetitive effects of a settlement agreement may begin its analysis under either antitrust law (by applying a rule of reason approach to evaluate the agreement's anticompetitive effects) or patent law (by analyzing the right to exclude afforded by the patent); the essence of either inquiry is "whether the [STS]

[7]All asserted claims but for Ethypharm's allegations that Abbott engaged in sham litigation.

restrict[s] competition beyond the exclusionary zone of the [Stamm patents]."[8] *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336 (Fed. Cir. 2008). The parties at bar present their arguments under the "scope of the patent" framework (D.I. 141 at 11; D.I. 177 at 11), and the court agrees that it must discern whether the STS grants greater rights than those conferred under the Stamm patents. *Cf. King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 702 F. Supp. 2d 514 (E.D. Pa. 2010).

2. Contract interpretation

The parties dispute the interpretation of the STS. Ethypharm argues that Section 8(ii) of the STS is a general prohibition on Reliant's divestiture of **Antara®**. (D.I. 191 at 1) Abbott, on the other hand, reads the STS as prohibiting the future transfer of the **intellectual property** rights licensed under the STS absent Abbott's consent. (D.I. 177 at 13)

The threshold inquiry is whether the contract is ambiguous. *See, e.g., GB Biosciences Corp. v. Ishihara Sangyo Kaisha, Ltd.*, 270 F. Supp. 2d 476, 481 (D. Del. 2003) ("[D]isputes involving the interpretation of unambiguous contracts are resolvable as a matter of law"); *Johnston v. Tally Ho, Inc.*, 303 A.2d 677, 679 (Del. Super. 1973) (clear and unambiguous language in a contract should be given its ordinary and usual meaning). The court answers this question in the affirmative.

Section 2 of the STS provides that "Abbott and Fournier would grant Reliant a non-exclusive license (subject to the provisions of Section 8) under the Stamm Patents (the "License") to exploit the Reliant Products in the United States and its territories and

[8]A patent is, of course, a carefully-crafted exception to the general rule against monopolies.

possessions[.]" (STS § 2) While the STS also contemplates that the future License would contain "additional customary terms and conditions," these specifically include "**no** assignment, sublicense or other transfer of **any rights** relating to the **Reliant Products** (including the right to market and promote the Reliant Products)." (STS § 8)(emphasis added) As noted above, Reliant Products are narrowly defined as the 43 mg, 87 mg and 130 mg fenofibrate capsule products that are the subject of Reliant's NDA, and exclude all other product forms, including "any combination therapy products" or other products having fenofibrate as their sole active ingredient. (STS § 1(o)) The restriction on permissible activities is broad, however, encompassing "any rights" relating to these named products. (STS § 8)

The inquiry does not end here, however. In its subsections, STS § 8 subsequently flip-flops in focus from the Reliant Products to intellectual property rights. STS § 8(ii)(e), containing exceptions to the "no transfer" clause, provides that an exception is made if a "transfer of rights" "relating to the Reliant Products" is made to a Restricted Entity with Abbott's consent. Alternatively, this section provides that transfer of rights under the '726, '670, '405, '552 and '881 patents may be made without Abbott's consent, while transfer to "all of the Stamm patents" may only occur with Abbott's consent. (STS § 8(ii)(e)(B)) In sum, the STS is ambiguous insofar as it inconsistently restricts the right to sell Reliant Products with the right to sublicense rights under Abbott's patents.

The remaining question is whether, in view of the parole evidence of record, a genuine issue of material fact exists as to the parties' interpretation of the STS. *See,*

gen., Nova Chemicals, Inc. v. Sekisui Plastics Co., Ltd., 579 F.3d 319, 323 (3d Cir. 2009) (where contract language is ambiguous, parol evidence is properly considered to determine the intent of the parties) (citation omitted); *Eagle Industries, Inc. v. DeVilbiss Health Care, Inc.*, 702 A.2d 1228, 1233 (Del. Supr. 1997) ("In construing an ambiguous contractual provision, a court may consider evidence of prior agreements and communications of the parties as well as trade usage or course of dealing."). In this regard, Abbott argues that all of Reliant's witnesses have testified that they neither understood nor intended STS § 8 to have the meaning Ethypharm now ascribes to it. For example, Reliant's "architect" of the STS, Joe Zakrzewski ("Zakrzewski"), testified that he read the STS to mean that Reliant "had the ability to deal with anybody on [the Restricted Entity] list [ ] with or without Abbott's consent." (D.I. 179, pt. 2, ex. K at 167:9-168:5, 341:20-343:14) John Poulos ("Poulos"), Abbott's counterpart "architect" of the STS (D.I. 191 at 7), testified that Abbott did not want sublicensing, while Reliant did, and STS § 8(ii)(e) was the resulting compromise. (D.I. 179, pt. 2, ex. E at 181:3-182:16) Poulos stated that the deal "had nothing to do with restricting [the right to sell] Antara® or the sale of the company[; t]his was only . . . on a sublicense right of the Stamm patents. We weren't restricting [the right to sell] Antara® or the sale of the company at all." (*Id.*) Fournier's 30(b)(6) witness testified that his personal understanding of the purpose of including Restricted Entities was that, "in the event Reliant decide[d] to sublicense its rights to one of these compan[ies] and if one of these compan[ies] want[ed] to have our license on our Stamm patents or on the patents covered by this agreement, they would have to ask us for consent." (*Id.*, ex. L at 69:7-16)

In response, Ethypharm points to a presentation from a June 2006 Reliant Board of Directors Meeting contrasting Reliant's divestiture of a drug called InnoPran EL, for which Reliant stated it was "contacting more than 100 pharma/biotech companies," with Antara®, for which Reliant was "surgically approaching select companies." (D.I. 192, pt. 4, ex. 60) Ethypharm argues that Reliant's approach of contacting "a small handful of companies on a discrete basis" evidences Reliant's view that it was severely restricted by the STS. (*Id.*) Ethypharm also points to a July 10, 2006 email from Poulos to Mary Szela of Abbott indicating that Abbott was concerned with "Oscient's financial status." (*Id.*, ex. 81) Poulos stated that, if Abbott consents, it "should strengthen the change of control provision that Oscient will assume." (*Id.*) In July 2006, Zakrzewski expressed concern about Abbott's response to the potential divestiture of Antara® as follows:

> I think the verbatim goes that Poulos gave us his word Abbott would not stand in [the] way of [a] small company when we did [the] deal in April.
>
> Now [a] small company is a problem and it really doesn't feel right. They state concerns about what [a] small company would do to [the] market. I think we hit them frontal with the antitrust implications.

(*Id.*, ex. 65)[9]

The foregoing parol evidence does not resolve the "product" versus "patent" differentiation at the core of the contract dispute. While Poulos testified that he did not believe the STS restricted Reliant's right to divest Antara®, this interpretation is directly contrary to certain language used in the STS itself. Issues of intent and contract interpretation, when arising out of the ambiguous use of language, are rarely amenable

[9]This is an email from Zakrzewski to an Ernest Mario dated July 25, 2006.

to summary judgment. *See Peck v. Donovan*, Civ. No. 07-5500, 2010 WL 4628198, *2 (D.N.J. Nov. 4, 2010). The court would not take the decision of whether the STS exceeds the scope of the patents away from the jury on this record.

3. Injury

The court next addresses Abbott's argument that judgment should be entered in its favor because Ethypharm has not sufficiently alleged antitrust injury.

a. Standards

Antitrust injury is "an injury of the type the antitrust laws were intended to prevent and that flows from that which makes the defendants' acts unlawful." *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977). "The injury should reflect the anticompetitive effect either of the violation or of anticompetitive acts made possible by the violation." *Id.* "The antitrust-injury requirement helps ensure 'that the harm claimed by the plaintiff corresponds to the rationale for finding a violation of the antitrust laws in the first place, and it prevents losses that stem from competition from supporting suits by private plaintiffs for . . . damages.'" *West Penn Allegheny Heath Sys. Inc. v. UPMC*, 627 F.3d 85, 101 (3d Cir. 2010) (citing *Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 342 (1990)).

b. Discussion

The court agrees with Abbott that Ethypharm has not proffered evidence of a "causal connection between the [alleged] antitrust violation and actual damage suffered." *See Callahan v. A.E.V., Inc.*, 182 F.3d 237, 250 (3d Cir. 1999) (citations and internal brackets omitted). In its opposition papers to Abbott's motion, Ethypharm

describes its injury (without citation to record evidence) as follows:

> First, Abbott itself licensed Ethypharm's technology for just this purpose [of competing against TriCor®] in Latin America. Second, Ethypharm initially approached certain Restricted Entities who expressed interest in purchasing Antara®. Third, AstraZeneca, one of the Restricted Entities, partnered with Abbott in an effort to develop a fenofibrate/statin combination just after the STS. Ethypharm's product was equally, if not better, positioned with a lower dose of fenofibrate to do so. Finally, a jury is entitled to exercise its common sense and ask: if Abbott did not believe these 36 companies would be interested in purchasing the Antara® Rights, what possible reason did Abbott have to include them on a Restricted Entities list?

(D.I. 191 at 20) At oral argument, Ethypharm directed the court to a 2009 Abbott Latin America "Executive Summary" on fenofibrate licensing, describing the competitive landscape for ControLip®, the Latin American version of Antara®. (D.I. 192, pt. 3, ex. 36) That document states that "[Ethypharm's] ControLip® 130mg would provide Abbott with a new and innovative next generation fenofibrate product[,] thus staying one step ahead of the generic competition and protecting its fenofibrate market from possible new competitors." (*Id.*) Ethypharm also pointed to a 2006 Abbott presentation regarding TriCor® competition; in the context of Reliant's sale to Oscient, Abbott stated that "[t]he sale of Antara® was not a surprise, however Oscient is[.]" (*Id.*, ex. 26 at 17) Abbott believed at that time that "Oscient's lack of resources, coupled with a small, non-specialty sales force, are unlikely to pose significant competition to TriCor®." (*Id.*)

Ultimately, it is Ethypharm's position that "Abbott can't restrict 36 companies from bidding on the Antara® Rights and then argue that Ethypharm has no specific proof that any of these 36 companies was interested." (D.I. 191 at 19) It is true that "[i]t is not necessary to show with total certainty the amount of damages sustained, just that the antitrust violation caused the antitrust injury suffered by the plaintiff." *Rossi v.*

Standard Roofing, Inc., 156 F.3d 452, 483 (3d Cir. 1998). As the Supreme Court has held,

> damage issues in [antitrust] cases are rarely susceptible of the kind of concrete, detailed proof of injury which is available in other contexts. . . [T]he factfinder may conclude as a matter of just and reasonable interference from the proof of defendants' wrongful acts and their tendency to injure plaintiffs' business, and from the evidence of the decline in prices, profits and values, not shown to be attributable to other causes, that defendants' wrongful acts had caused damage to the plaintiffs.

J. Truett Payne Co., Inc. v. Chrysler Motors Corp., 451 U.S. 557, 565 (1981) (quoting *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 123-24 (1969) (internal quotations omitted)). Ethypharm, however, does not cite evidence from which a jury could infer a "decline in [ ] profits and values, not shown to be attributable to other causes." *Id.*

The crux of Ethypharm's argument is that Oscient did not have the ability to effectively compete from the outset. (D.I. 191 at 19-20) Even if the court were to assume that the Restricted Entities were better equipped to market Antara® (due to, for example, having larger sales forces and more expendable resources), there is no factual basis from which the court (or a jury) could infer that such a company would have had success with Antara® where Oscient failed. Put simply, there are many market influences that may have contributed to Oscient's failure with Antara®. Ethypharm's arguments are speculative and, absent more, Ethypharm has not evidenced any causal connection to an antitrust injury. Abbott's motion for summary judgment is granted on this ground.

B. Sham Litigation

Ethypharm asserts two sham litigation theories, focusing on: (1) Abbott's counterclaims of infringement (as to the '405 and '881 patents in the Reliant action); and (2) Abbott's supposed knowledge of inequitable conduct by a Fournier employee (Reginault). Abbott moves for summary judgment on each claim.[10]

1. Standard for Noerr-Pennington immunity

A patent owner asserting its rights through patent infringement litigation is generally immune from antitrust liability. *Eastern R.R. Presidents Conference v. Noerr Motor Freight,* 365 U.S. 127 (1961); *United Mine Workers of Am. v. Pennington*, 381 U.S. 657 (1965). Commonly referred to as the *Noerr-Pennington* doctrine, this immunity extends to persons who petition all types of government entities, including legislatures, administrative agencies, and courts. *California Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510 (1972). *Noerr-Pennington* immunity, however, is subject to an exception for "sham" litigation. In this regard, the Supreme Court has outlined a two-part test to determine whether the "sham litigation" exception applies. *See Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Ind.*, 508 U.S. 49 (1993). As an objective first part, "the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits." *Id.* at 60. If an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, then the suit does not qualify as sham litigation and is immunized under the *Noerr-Pennington* doctrine. *Id.* The subjective second part of the definition

[10]Abbott also moved for judgment on Ethypharm's former allegation that Abbott lacked a reasonable basis to believe that any Stamm patent was valid; Ethypharm expressly abandons this theory in their answering brief. (D.I. 189 at 1, n.2) Judgment, therefore, should be entered for Abbott on this particular claim.

arises only if the challenged litigation is objectively meritless. In such a case, the court must decide whether the "baseless lawsuit conceals 'an attempt to interfere directly with the business relationships of a competitor.'" *Id.* at 60-61. To invoke the "sham" exception, plaintiffs must prove, by clear and convincing evidence, that defendant's activities were not really efforts to vindicate its rights in court. *See C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1368-69 (Fed. Cir. 1998) ("sham litigation requires more than a failed legal theory") (quoting *Handgards, Inc. v. Ethicon, Inc.*, 743 F.2d 1282, 1288 (9th Cir. 1984)); *MCI Communications v. Am. Telephone and Telegraph Co.*, 708 F.2d 1081, 1155 (7th Cir. 1983).

2. Sham litigation based on infringement

Claim 1 of the '405 patent and claim 37 of the '881 patent are representative of the asserted claims in the Abbott/Reliant action:

> 1. A composition comprising a hydrosoluble carrier and micronized fenofibrate having a dissolution of **at least 10% in 5 minutes, 20% in 10 minutes, 50% in 20 minutes and 75% in 30 minutes**, as measured using the rotating blade method at 75 rpm according to the European Pharmacopoeia, in a dissolution medium constituted by water with 2% by weight polysorbate 80 or with 0.025M sodium lauryl sulfate.
>
> 37. A granulate comprising micronized fenofibrate, wherein the granulate has a dissolution **of at least 10% in 5 minutes, 20% in 10 minutes, 50% in 20 minutes and 75% in 30 minutes**, as measured using the rotating blade method at 75 rpm according to the European Pharmacopoeia, in a dissolution medium constituted by water with 2% by weight polysorbate 80 or a dissolution medium constituted by water with 0.025 M sodium lauryl sulfate.

(emphasis added) It is not disputed that, before filing its counterclaims, Abbott received from Reliant the full Antara® NDA, which included testing data showing that Antara® does not dissolve close to the "at least 10% in 5 minutes" level required by the patents.

(D.I. 189 at 3; D.I. 181 at 8; D.I. 190 at ex. 7, p.3) Specifically, the Antara® NDA shows that Antara®'s dissolution at 5 minutes is 1.2-2.5%.

a. Abbott's infringement theories

Abbott argues that its counterclaims were premised upon two theories of infringement with respect to Antara®: the "Granulate Theory;" and the "10% in 6 minutes" DOE theory. As noted above, claim 37 of the '881 patent claims "[a] granulate comprising micronized fenofibrate, wherein the granulate has a dissolution of at least 10% in 5 minutes, 20% in 10 minutes, [etc.]" The Granulate Theory is that the granulates within Antara® literally meet the "at least 10% in 5 minutes" limitation. The Granulate Theory is based on the belief of Abbott's expert, Dr. Robert O. Williams III ("Williams"), that, because granulates dissolve more quickly than the capsule product, one can "reasonably expect" that the granulates achieve 10% dissolution at or near five minutes.[11] (D.I. 181 at 11-12; D.I. 190, ex. 10 at ¶ 39) Abbott argues that, because Reliant's NDA does not disclose the dissolution rate for the granulates within capsules of Antara®, there is no data contradicting its theory.

The "10% in 6 minutes DOE Theory" is also supported by Williams, who opines that reaching 10% in 6 minutes is equivalent under the DOE to 10% in 5 minutes. Abbott argues that Antara® reaches a dissolution rate of at least 10% in 6 minutes and, therefore, infringes under the doctrine of equivalents. The parties do not dispute that the NDA shows a rapid rise in dissolution for Antara® between 5 and 10 minutes. For

[11]Ethypharm's 30(b)(6) witness admitted that, if the granulates were tested without the capsule, the dissolution results "could be slightly superior probably" over testing the intact capsule. (D.I. 182, ex. 19 at 117:7-23)

example, one batch went from 3% at 5 minutes to 64.5% in 10 minutes. Thus, Abbott argues, Antara® must "pass through" the 10% point sometime between 5 and 10 minutes.[12] (D.I. 197 at 3; D.I. 190, ex. 10 at ¶ 43)

b. Discussion

Neither party to the Reliant action did scientific testing to either verify or discredit the Granulate Theory or 10% in 6 minutes DOE Theory. After Abbott proffered its counterclaims on the '405 and '881 patents on January 7, 2005, the parties entered into settlement discussions which culminated in a settlement agreement in April 2006. The Reliant action was dismissed on April 19, 2006 prior to the close of discovery.

Ethypharm argues that Abbott's DOE theories were shams in two regards. First, Ethypharm asserts that, because Williams did not rely on actual testing, his opinion cannot be reasonable.[13] However, Ethypharm does not cite, and the court is not aware of, caselaw suggesting that Williams was required to do actual testing (as compared to mathematical estimation) in support of his DOE theory before Abbott filed its compulsory counterclaims.

Ethypharm also argues that Abbott's theory is invalid as a matter of law, insofar as it vitiates the "at least 10% in 5 minutes" limitation. It is certainly true that the doctrine of equivalents is not unlimited, and it cannot be "used to ignore the actual

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[12]Ethypharm's expert stated it is not "impossible" that Antara® dissolves at 10% in 6 minutes. (D.I. 181 at 10) (further citation omitted)

[13]Williams estimated the dissolution at 6 minutes by "approximat[ing] by interpolation" the 5- and 10-minute data in the Antara® NDA, and relied on his beliefs that granulates dissolve more quickly than do capsules. (D.I. 189 at 12; D.I. 190, ex. 9 at 104:5-9; 96:14-97:14)

language of the patent." *See K-2 Corp. v. Salomon S.A.,* 191 F.3d 1356, 1366-67 (Fed. Cir. 1999) (cited by Ethypharm at D.I. 189 at 15). However, the Federal Circuit has specifically determined that the doctrine of equivalents may apply to claims containing specific numeric ranges, regardless of whether the claim also contains words of approximation. *See Adams Respiratory Therapeutics, Inc. v. Perrigo Co.*, 616 F.3d 1283, 1291, 1293 (Fed. Cir. 2010) (vacating district court's grant of summary judgment of noninfringement on the doctrine of equivalents, as plaintiff introduced sufficient evidence from which the jury could conclude that a mean response (AUC) value of 3493.38 hr*ng/mL is insubstantially different from the claimed value of "at least 3500 hr*ng/mL"). "The proper inquiry is whether the accused value is insubstantially different from the claimed value." *Id.*

Because the Reliant action settled expeditiously, neither the court nor the jury is in the position to judge the veracity of Abbott's position in this regard. Ethypharm does not point to anything in the prosecution history of the '405 and '881 patents that would preclude Abbott's arguments, which are not demonstrably invalid as a matter of law. For these reasons, there is insufficient evidence of record from which a reasonable jury could conclude that Abbott's DOE theories were a sham, and the court grants Abbott's motion for summary judgment of no sham litigation on its infringement counterclaims.

3. Sham litigation based on inequitable conduct

Ethypharm also argues that Abbott lacked a reasonable basis to believe that the Stamm patents were enforceable because Abbott was aware that Fournier committed inequitable conduct before the PTO. Ethypharm's theory of inequitable conduct in this

regard is that Fournier's chief scientist, Philippe Reginault ("Reginault"), violated his duty of candor by not informing the PTO in 2003 that a curve corresponding to "Lot 2177" of Fournier's Lipanthyl 200 fenofibrate product, which Fournier relied on to show the improved dissolution of its new fenofibrate formulation, was "inherently unreliable." (D.I. 189 at 17) The Lot 2177 data set was incorporated into the '405 and '881 patents as figure 1 of those patents, wherein it provided a contrast to the dissolution percentage of the tablet of the "invention."

It is Ethypharm's position that Abbott relied exclusively on the Lot 2177 data during prosecution of the Stamm patents without confirmation of the data from other sources, and despite 16 other Lipanthyl 200 dissolution data sets using either of the two dissolution media included in the patents (0.025M SLS or "Tween"). (*Id.* at 7-8) These 16 data sets were: (1) obtained in 1997; (2) "homogenous" (D.I. 190, ex. 16 at 88:11); (3) indicative of a faster dissolution of Lipanthyl 200 than that reported to the PTO by the Lot 2177 curve (*id.*, ex. 10, ¶ 61);[14] (4) incorporated into a 2005 declaration to the PTO; but (5) not disclosed to the PTO during prosecution of the Stamm patents.

The court need only address one aspect of Ethypharm's theory to resolve the motion at bar: specific intent. In this regard, Ethypharm stresses Reginault's testimony that the results of a single **lot** are not indicative of a sample's dissolution **range**, which

[14]In other words, the 16 other data sets provide a similar dissolution profile to the invention, rendering the contrast between the plot for the invention and for Lipanthyl 200 moot. Ethypharm provides a colored chart of these plots in its opposition papers. (D.I. 189 at 8)

can be comprised of variable results.[15] (D.I. 189 at 17 (citing D.I. 190, ex. 16 at 86:22-87:12, 93:3-94:16)) Ethypharm also argues that Abbott's characterization of the Lipanthyl 200 testing in prior litigation with Teva Pharmaceuticals USA, Inc. ("Teva") demonstrates Abbott's understanding that the Lot 2177 curve was inconsistent with other Lipanthyl 200 data. (D.I. 189 at 19) Specifically, Abbott previously dismissed Teva's argument that it committed inequitable conduct by failing to identify the 16 Lipanthyl 200 data sets to the PTO, by arguing that two inconsistent data sets were insufficient to demonstrate the falsity of the data supplied to the PTO against a backdrop of hundreds of tests overall. *See Teva Pharmaceuticals USA, Inc. v. Abbott Labs.*, 580 F. Supp. 2d 345, 366 (D. Del. 2008) (hereinafter, *"Teva*").[16] At oral argument, Ethypharm argued that the number of withheld results – 16, rather than "hundreds" – also demonstrates specific intent by Reginault. (D.I. 205 at 44-46)

On this record, Ethypharm cannot clear the high hurdle of proving that Abbott's counterclaims were objectively baseless based on inequitable conduct. To prove inequitable conduct, Ethypharm must ultimately show, by clear and convincing evidence, that Reginault[17] "knew of the [unreliability of the Lot 2177 curve], knew that it

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[15]Reginault stated that "the regularity standards for these tests are that the range is 20 percent minimum. So traditionally, it is known that results will vary, and this applies to any product." (D.I. 190, ex. 16 at 96:14-19)

[16]With respect to inequitable conduct, this court in *Teva* ultimately held that the record lacked evidence that Reginault recalled, and knowingly withheld, the two inconsistent data sets three years after receiving the data. 580 F. Supp. 2d at 369.

[17]Reginault is the only named person at Abbott specifically alleged to have committed inequitable conduct. Ethypharm couches many of its arguments in terms of what "Abbott" knew or intended; such allegations are too general to withstand scrutiny.

was material, and made a deliberate decision to withhold" this information from the PTO. *See Therasense, Inc. v. Becton, Dickinson & Co.*, --- F.3d ---, 2011 WL 2028255, *9 (Fed. Cir. May 25, 2011). Ethypharm has simply suggested that Reginault's omission was grossly negligent or negligent under a "should have known" standard, which is not sufficient.[18] *Id.* Reginault's testimony that several data sets make up a dissolution curve is too attenuated from the proposition that the Lot 2177 data was "unreliable." If it is true as a scientific principle, as Reginault testified, that one data set can never provide a complete portrait of the relevant information, the PTO would have taken this into account in its consideration of figure 1. Regardless, there is no evidence that Reginault deliberately set out to deceive the PTO in the manner suggested.[19] Abbott's motion for summary judgment of no sham litigation is granted.

V. CONCLUSION

For the foregoing reasons, Abbott's motions for summary judgment of no anticompetitive conduct and no sham litigation are granted. An appropriate order shall issue.

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[18]The *Therasense* decision issued two days prior to defendant's motion for summary judgment; Ethypharm does not address it in its answering papers.

[19]For example, as Abbott points out, there is no indication that Reginault was asked "**when** he came to this alleged understanding about inherent unreliability and [he] was never asked **whether** he had that understanding in mind when he submitted his 2003 declaration in connection with prosecution of the '881 patent." (D.I. 197 at 9, n.9) (emphasis in original)