IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ETHYPHARM S.A. France,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 08-126-SLR-MPT
	)	
ABBOTT LABORATORIES,	)	
	)	
Defendants.	)	
	)	

MEMORANDUM ORDER

I. INTRODUCTION

Plaintiff Ethypharm S.A. France ("Ethypharm") and defendant Abbott Laboratories ("Abbott") manufacture drugs containing fenofibrate. Fenofibrate is used to reduce cholesterol levels in patients at risk of cardiovascular disease. Ethypharm, a privately-held French company, manufactures a brand name fenofibrate called Antara. Ethypharm does not directly sell or distribute Antara in the United States; instead, Ethypharm contracted with Reliant Pharmaceuticals, Inc. ("Reliant") to market and distribute the drug in 2001. Abbott manufactures, markets, and sells another brand name fenofibrate called TriCor within the United States. Abbott licenses the exclusive rights to manufacture and sell TriCor in the United States from Laboratoires Fournier ("Fournier"), a French company credited with the drug's discovery. Abbott lists five TriCor-related patents in the Orange Book–Nos. '729, '670, '405, '552, and '881.

II. BACKGROUND

On June 1, 2004, Reliant filed a declaratory action in the United States District

Court for the District of Delaware seeking a declaration of non-infringement regarding Abbott's fenofibrate patents. Reliant claimed that Abbott's fenofibrate patents were unenforceable due to inequitable conduct during their prosecution before the United States Patent and Trademark Office ("USPTO"). Abbott filed a counterclaim alleging infringement of the '405 and '881 patents.

On or about April 3, 2006, Abbott and Reliant entered into a series of agreements, including a "Settlement Term Sheet" ("STS"). The STS allowed Reliant to sell and distribute Antara without the risk of infringement. In exchange, the STS barred Reliant from selling the rights to Antara to a select list of competitors capable of more efficiently expanding Antara sales. Additionally, the STS imposed a 7% royalty on Antara sales, restrained Reliant from making any new formulations or combination products containing fenofibrate formulations, and prevented Reliant from co-promoting Antara with specific companies without Abbott's written consent. The court dismissed the declaratory action by stipulation of the parties on April 19, 2006. Later that year, Reliant sold the exclusive rights to market and sell Antara to Oscient Pharmaceutical Company ("Oscient").

Ethypharm filed this suit against Abbott on March 3, 2008. In its amended complaint, Ethypharm alleges that Oscient has limited resources and a relatively small sales force, preventing the ability of Antara to compete with TriCor. Ethypharm claims that the STS, and therefore Abbott, wrongfully interfered with Ethypharm and Reliant's licensing agreement in a manner equivalent to an "output restraining agreement." Ethypharm asserts that Abbott's contractual restrictions rise to the level of

anticompetitive conduct prohibited by Sections 1 and 2 of the Sherman Act.[1] Ethypharm further claims that Abbott's infringement counterclaims during Reliant's declaratory action constituted sham litigation in violation of Section 1 of the Sherman Act. Ethypharm also alleges violations of the common laws of unfair competition, tortious interference with prospective economic advantage, and unlawful restraint of trade.

On February 15, 2010, Abbott acquired complete ownership of Fournier as part of Abbott's purchase of Solvay Pharmaceuticals. As a result of this ownership, Ethypharm argues that Abbott has also acquired Fournier's document production responsibilities as well as the responsibility to produce certain current and former Fournier employees living outside of the United States for deposition. The parties differ regarding the proper procedure by which Ethypharm must request the production of these foreign witnesses. Ethypharm argues that it may proceed under the Federal Rules of Civil Procedure ("Federal Rules"), while Abbott argues that Ethypharm's request must comport with the Convention on the Taking of Evidence Abroad in Civil or Commercial Matters ("Hague Convention"). Because the discovery deadline in this case is scheduled for December 17, 2010, the court instructed the parties, on September 9, 2010, to prepare letters of request pursuant to the requirements of the Hague Convention while the discovery jurisdictional issue is resolved.

On September 21, 2010, Ethypharm filed a motion to issue letters of request for international judicial assistance regarding production for deposition of at least six

[1] 15 U.S.C. § 1-7.

current or former Fournier employees. Ethypharm also submitted two draft letters of request written on behalf of the court and in accordance with the requirements expressed in Article 3 of the Hague Convention. The first, addressed to the French judicial authorities, requests judicial assistance to compel the appearance of five former or current Fournier employees for deposition. The second, addressed to judicial authorities in Switzerland, requests assistance in the production of a former Fournier CEO currently residing in Switzerland. Abbott filed a partial opposition on October 5, 2010 and Ethypharm submitted a reply brief in support of its original motion on October 18, 2010. In its partial opposition, Abbott contends that the topic of inequitable conduct during the prosecution of Abbott's '726 patent is an inappropriate subject matter for discovery in this action because Ethypharm's sham litigation claim is unrelated to the '726 patent.

This is the court's decision on Ethypharm's September 21, 2010 motion. The court recognizes that this decision may be rendered moot by its decision regarding the application of the Federal Rules or the Hague Convention to the issues at hand. The court further recognizes that Ethypharm's efforts to begin the issuance of Hague Convention letters of request will not prejudice Ethypharm's concurrent claim that Abbott is obliged to produce the requested witnesses pursuant to the Federal Rules. Finally, the court acknowledges that Abbott does not challenge the relevance of any discovery regarding the '726 patent and its disclosure as prior art in the '670, '405, '552, and '881 patents.

III. DISCUSSION

Rule 28(b) of the Federal Rules provides that a deposition may be taken in a

foreign country: (1) under an applicable treaty or convention; (2) under a letter of request, whether or not captioned a "letter rogatory"; (3) on notice, before a person authorized to administer oaths either by federal law or by the law in the place of examination; or (4) before a person commissioned by the court to administer any necessary oath and take testimony.[2]

The United States, France, and 15 other nations entered into the Hague Convention on March 18, 1970.[3] The Convention "prescribes certain procedures by which a judicial authority in one contracting state may request evidence located in another contracting state."[4] Article 1 of the Convention provides that "[i]n civil or commercial matters a judicial authority of a Contracting State may . . . request the competent authority of another Contracting State, by means of a Letter of Request, to obtain evidence, or to perform some other judicial act."[5] 28 U.S.C. § 1781(b)(2) permits the court to transmit letters of request to a foreign or international tribunal, officer, or agency.[6] "[A] letter rogatory is the request by a domestic court to a foreign court to take evidence from a certain witness."[7] Courts have found "that some good reason must be shown by the opposing party for a court to deny an application for a letter rogatory."[8]

Through its proposed letters rogatory, Ethypharm seeks discovery on the

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[2] FED. R. CIV. P. 28(b).

[3] *See Societe Nationale Industrielle Aerospatiale v. U.S. Dist. Ct. for the S. Dist. of Iowa*, 482 U.S. 522, 524 (1987).

[4] *Id*.

[5] Convention on the Taking of Evidence Abroad in Civil or Commercial Matters, art. 1, Mar. 18, 1970, 23 U.S.T. 2555, T.I.A.S. No. 7444.

[6] 28 U.S.C. § 1781(b)(2) (permitting "the transmittal of a letter rogatory or request directly from a tribunal in the United States to [a] foreign or international tribunal, officer, or agency to whom it is addressed and its return in the same manner.").

[7] *Intel Corp. v. Advanced Micro Devices, Inc.*, 542 U.S. 241, 248 (2004).

[8] *DBMS Consultants Ltd. v. Computer Assocs. Int'l, Inc.*, 131 F.R.D. 367, 369 (D. Mass. 1990).

"prosecution of some or all of the TriCor patents before the USPTO," and "issues of inequitable conduct and sham litigation in connection with each of the TriCor Patents." In its partial opposition to Ethypharm's motion, Abbott requests the court insert a restriction stating: "This court has reviewed Ethypharm's requested topics for questioning and has determined that there should be no questioning regarding the procurement or prosecution of the '726 patent." According to Abbott, the enforceability of the '726 patent is not an issue in this litigation, and as a result, any questioning about the prosecution of the '726 patent is irrelevant and inappropriate under both the Hague Convention and the Federal Rules.

Article 1 of the Hague Convention provides that a letter of request "shall not be used to obtain evidence which is not intended for use in judicial proceedings, commenced or contemplated."[9] Under the liberal discovery provisions of the Federal Rules, parties may inquire through deposition as to a matter whose admissibility is not immediately apparent, provided the inquiry is reasonably calculated to lead to the discovery of admissible evidence.[10] That discovery, however, must nevertheless comport with Federal Rule 26, which requires that discoverable evidence be "relevant to [a] party's claim or defense."[11] Rule 28(b), authorizing foreign discovery, "must be read together with Rule 26(c), which permits a court to make any order 'which justice requires to protect a party or person from annoyance, embarrassment, oppression, or

[9] Convention on the Taking of Evidence Abroad in Civil or Commercial Matters, art. 1, Mar. 18, 1970, 23 U.S.T. 2555, T.I.A.S. No. 7444.

[10] *DBMS Consultants Ltd.*, 131 F.R.D. at 369.

[11] FED. R. CIV. P. 26(b)(1).

undue burden or expense.'"[12]

A. Ethypharm's Claims Regarding the STS and Related Agreements

In its amended complaint, Ethypharm alleges that, via the STS and other allegedly unlawful agreements, Abbott "planned and executed a sustained strategy to monopolize and attempt to monopolize the [fenofibrate] market . . . by entering [into] illegal and anticompetitive agreements with Ethypharm's exclusive licensee and distributor in the United States."[13] Under the STS, Abbott and Fournier agreed to "grant Reliant a non-exclusive license . . . under the Stamm Patents . . . to exploit the Reliant Products in the United States and its territories and possessions."[14] In exchange for this right to exploit products that may infringe upon the Stamm Patents, Reliant agreed to certain restrictions regarding the distribution and sale of those products.[15] The "Stamm Patents" as defined within the STS consist of '726, '670, '405, '552, and '881patents.[16] Ethypharm claims that the restrictions imposed by the STS and other related agreements were unlawful under antitrust law because the scope of the restrictions exceeded Abbott and Fournier's patent rights. Ethypharm argues that Abbott exceeded the scope of its legitimate patent rights because each of these patents, including the '726 patent, were unenforceable due to Abbott and Fournier's inequitable conduct.

Federal Rule 9(b) requires that a party alleging fraud or mistake "must state with particularity the circumstances constituting fraud or mistake."[17] "[T]o plead the

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[12] *Evanston Ins. Co. v. OEA, Inc.*, No. CIV S-02-1505, 2006 WL 1652315, at *2 (E.D. Cal. June 13, 2006) (quoting FED. R. CIV. P. 26(c)(1)).

[13] D.I. 28 at ¶ 122.

[14] D.I. 132, Exhibit C at 8.

[15] *Id*.

[16] *Id.* at 7.

[17] FED. R. CIV. P. 9(b).

'circumstances' of inequitable conduct with the requisite 'particularity' under Rule 9(b), the pleading must identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO."[18] Further, a pleading of inequitable conduct "must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO."[19] Regarding the '729 patent, Ethypharm's amended complaint does not specify any inequitable conduct related to its prosecution.

Among the purposes behind the particularity requirement of Rule 9(b) is "to deter the filing of charges of fraud as a pretext for discovery of unknown wrongs."[20] Although this and other courts have held that, under the Rule 16(b) requirements for good cause to amend an answer, a party may conduct discovery before making any allegations of inequitable conduct,[21] where a party requests discovery to determine whether it has any basis for inequitable conduct, it is improper to use discovery in search of a factual predicate required to be pled in the first instance.[22] The court therefore finds that any inequitable conduct during the '729 patent prosecution is not relevant to Ethypharm's

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[18] *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328 (Fed. Cir. 2009).

[19] *Id*. at 1328-29.

[20] *G&H Tech., Inc. v. U.S.*, 8 Cl. Ct. 572, 574 (Cl. Ct. 1985).

[21] *See Enzo Life Sciences, Inc. v. Digene Corp.*, 270 F. Supp. 2d 484, 487-90 (D. Del. 2003); *Ormco Corp. v. Align Tech., Inc.*, No. SACV 03-16, 2008 WL 4501805, at *10 (C.D. Cal. Oct. 3, 2008).

[22] *See e.g. Segan v. Dreyfus Corp.*, 513 F.2d 695, 696 (2d Cir. 1975); *Leonard v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 64 F.R.D. 432, 435 (S.D.N.Y. 1974); *see also* FED. R. CIV. P. 26(b)(1) advisory committee's note ("The rule change signals to the court that it has the authority to confine discovery to the claims and defenses asserted in the *pleadings*, and signals to the parties that they have *no entitlement* to discovery to develop new claims or defenses that are not already identified in the pleadings.") (emphasis added).

claims related to the STS and related agreements.

B. The '726 Patent and Ethypharm's Sham Litigation Claims

Abbott notes that, with regard to Ethypharm's sham litigation claims, the only patents at issue are those asserted against Reliant in response to Reliant's declaratory action–the '405 and '881 patents. Abbott reasons that because the '726 patent is in a different family than any of the other Stamm Patents ("PharmaPass patents"), and has different inventors and no priority relationship with the PharmaPass patents, any alleged inequitable conduct in connection with the prosecution of the '726 patent has no relevance to Ethypharm's sham litigation claims.

Ethypharm avers that at the time of the Reliant litigation, Abbott was aware that Abbott and/or Fournier had misrepresented the dissolution profile of a new version of TriCor, for which the PharmaPass patents were sought. Ethypharm suggests that Abbott aggressively, and improperly, pursued the PharmaPass patents because it was aware of the vulnerability of the unenforceable '726 patent.[23] In April 2000, as part of a reexamination of the '726 patent, Fournier submitted a forged affidavit to the USPTO, purportedly signed by Bernard Curtet, one of the inventors listed on the '726 patent, that had not been prepared or reviewed by Curtet. Fournier withdrew that forged declaration in December of that year.

Ethypharm argues that these events coincided with the prosecution of the PharmaPass patents and that the timing is important to the relevance inquiry of the

[23] The European equivalent of the '726 patent, the '532 patent, was revoked on prior art grounds by the European Patent Organisation on August 5, 1999. Fournier sought reexamination of the '726 patent before the USPTO shortly thereafter.

instant motion.[24] Ethypharm contends that inequitable conduct relating to one patent is relevant to the questions of (1) whether the patent applicant was simultaneously engaging in inequitable conduct in connection with other patents for a different version of the same product, for which the first patent was prior art; (2) whether the same Abbott or Fournier personnel that may have committed inequitable conduct during the prosecution of the'726 patent may have done the same in the prosecution of the PharmaPass patents; and, (3) whether the history of the '726 patent may have motivated Abbott or Fournier to engage in inequitable conduct in the prosecution of the PharmaPass patents.

Ethypharm's argument amounts to an accusation of unclean hands surrounding the prosecution of the entirety of the Stamm Patents. The Supreme Court, however, has found that misconduct unrelated to the matter at litigation is not relevant to the demonstration of inequitable conduct during the prosecution of the patent at issue.[25] Ethypharm argues that the relationship between the '726 patent and the PharmaPass patents distinguish this case from previous holdings.[26] This argument finds credence in the Federal Circuit's findings, in dicta, that inequitable conduct "early in the prosecution may render unenforceable all claims which eventually issue from the same or related application,"[27] where the inequitable conduct has an "immediate and necessary relation"

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[24] Abbott filed an application that would become the '405 patent in May 2000, and an application that would become the '881 patent in November 2002.

[25] *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240, 245 (1933) ("[Courts] do not close their doors because of plaintiff's misconduct . . . that has no relation to anything involved in the suit, but only for such violations of conscience as in some measure affect the equitable relations between the parties in respect of something brought before the court for adjudication."); *see also FMC Corp. v. Hennessy Indus., Inc.*, 836 F.2d 521, 524 (Fed. Cir. 1987) (finding alleged inequitable conduct associated with unasserted patent irrelevant in infringement action).

[26] The '726 patent is cited as prior art for the PharmaPass patents.

[27] *Fox Indus., Inc. v. Structural Preservation Sys.,* 922 F.2d 801, 804 (Fed. Cir. 1990).

to the enforcement of the related patents.[28]

In the case *sub judice*, Ethypharm has not claimed in its amended complaint, nor argued in either of its briefs in support of this motion, that the '726 patent, or any inequitable conduct during its prosecution, bears such an "immediate and necessary relation" to the enforcement of the PharmaPass patents that a demonstration of inequitable conduct in the prosecution of the '726 patent will render the '405 and '881 patents unenforceable. Ethypharm only alleges that because Abbott and/or Fournier may have acted improperly during the prosecution of one patent, because of the temporal relationship between the '726 reexamination and the '405 and '881 prosecutions, and because of the personnel involved, Abbott and/or Fournier may have also acted improperly during the prosecution of '405 and '881 patents. To allow discovery regarding any inequitable conduct during the prosecution of the '726 patent in the absence of a claim concerning the enforceability of that patent or an allegation regarding the relationship between the enforceability of the '726 patent and the enforceability of the PharmaPass patents would authorize a fishing expedition beyond that which is nominally permitted by the Federal Rules.[29]

IV. CONCLUSION

For the foregoing reasons, Ethypharm's motion to issue letters of request for international judicial assistance (France and Switzerland) (D.I. 114) is hereby

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[28] *Consol. Aluminum Corp. v. Foseco Intern. Ltd.*, 910 F.2d 804, 810-11 (Fed. Cir. 1990) (noting in dicta that inequitable conduct in the prosecution of a patent with an immediate and necessary relation to a patent at issue may demonstrate the unenforceability of the latter patent).

[29] *See Bastin v. Fed. Nat'l Mortgate Ass'n*, 104 F.3d 1392, 1396 (D.C. Cir. 1997) (denial of discovery is not abuse of discretion where a plaintiff is "unable to offer anything but rank speculation to support" a claim and if discovery "would amount to nothing more than a fishing expedition.").

GRANTED in-part and DENIED in-part.

Date: November 2, 2010

/s/ Mary Pat Thynge
UNITED STATES MAGISTRATE JUDGE