NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

WARNER CHILCOTT LABORATORIES IRELAND LIMITED, et al.,	:	**Hon. William J. Martini**
Plaintiffs,	:	**Civil Action Nos. 08-6304 (WJM); 09-0228 (WJM); 09-0469 (WJM); 09-1233 (WJM); 09-2073 (WJM)**
- vs -	:	
IMPAX LABORATORIES, INC., et al.,	:	**OPINION**
Defendants.	:	

Falk, U.S.M.J.

Before the Court is a dispute over the scope of a discovery confidentiality order. The parties agree that there should be a confidentiality order in these complex patent cases but disagree on two issues. Plaintiffs request that the Court enter the discovery confidentiality order referenced in Local Patent Rule 2.2 and reprinted in Appendix "S" to the Court's Local Civil Rules. Defendants request that the order include two additional provisions: (1) a patent prosecution bar; and (2) an FDA bar. The Court decides this matter without oral argument. Fed. R. Civ. P. 78(b); L.Civ.R. 37.1(b)(4). For the reasons that follow, the Court will not include Defendants' proposed restrictions in the confidentiality order at the present time.

BACKGROUND

Plaintiffs Warner Chilcott Laboratories Ireland Limited, Warner Chilcott Company, Inc., Warner Chilcott (US), LLC, and Mayne Pharma International Pty, Ltd. (collectively, "Plaintiffs") have commenced five separate actions against an array of Defendants, including Impax Laboratories, Inc., Actavis Elizabeth, LLC, Sandoz Inc., Mutual Pharmaceutical Company, and Mylan Pharmaceuticals, Inc. (collectively, "Defendants"), alleging infringement of United States Patent No. 6,958,161 ("the '161 patent").[1] The '161 patent claims modified release preparations of doxycycline hyclate for treating various forms of bacterial infections, marketed under the brand name Doryx®.

The present dispute is focused on the parties' proposed discovery confidentiality order. Defendants seek to preclude any attorney who views or receives confidential information in this case from: (1) appearing in any FDA related proceeding on any doxycycline drug application, including the preparation of any pleadings or citizens' petitions; and (2) prosecuting any patents with respect to "the use of doxycycline" for the duration of this case, including any appeals, and one year thereafter.[2] Both the FDA and patent prosecution provisions are meant to restrict the

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[1] The actions have been consolidated for pretrial purposes.

[2] The material portions of the disputed provisions read:

> 12. a . . . [O]utside attorneys that receive Confidential information pursuant to this Order shall not engage, formally or informally, in patent prosecution for the use of doxycycline, for the duration of the Related Cases, including appeals and one year thereafter.
> . . .
> e. . . . [I]nside counsel that receives Confidential information pursuant to this Order shall not engage, formally or informally, in patent prosecution related to doxycycline, for the duration of the Related Cases, including appeals and one year thereafter.

future conduct of any lawyer who views confidential material in this case. Because the primary relief sought is the same under both provisions, the Court will address the propriety of the provisions together unless noted otherwise.

Defendants argue the confidentiality order must contain FDA and patent prosecution restrictions because Plaintiffs "might . . . unintentionally" use their confidential information in proceedings before the FDA or the United States Patent and Trademark Office. Defendants note that similar provisions are frequently adopted by courts in patent cases, and that Plaintiffs have not "proffered **any** explanation" why they oppose the provisions. (Defs.' Letter at 2.) Finally, Defendants argue that there is no prejudice to the Plaintiffs by virtue of the restrictions.

Plaintiffs counter that Defendants have not met the good cause standard needed to impose the prosecution bar or FDA restriction. They argue that Defendants base their desire for the disputed provisions solely on a vague assumption that inadvertent disclosure is likely and that confidential information could possibly be used to Plaintiffs' advantage in other

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> 13. a. . . . [O]utside attorneys that receive Confidential Attorneys' Eyes Only information pursuant to this Order shall not engage, formally or informally, in patent prosecution related to doxycycline, for the duration of the Related Cases, including appeals and one year thereafter.
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> . . .
>
> 16. No person who receives Confidential – FDA Information may, as to any Doxycycline Drug Application, appear before the FDA, prepare any pleadings in such matters, participate in the preparation of any citizens' petitions before the FDA, or appear in a federal district court action challenging FDA action under the APA, without prior approval to do so from this Court . .

(Proposed Discovery Confidentiality Order, attached to Defendants' Correspondence to the Court dated October 9, 2009, at Ex. 1.)

proceedings. Plaintiffs further argue that Defendants' restrictions are contrary to Federal and Third Circuit precedent.

ANALYSIS

A. Legal Standard

Routine discovery disputes in patent cases are controlled by the law of the regional circuit. See Computers Docketing Station Corp. v. Dell, Inc., 519 F.3d 1366, 1373 (Fed. Cir. 2008). Federal Circuit law controls resolution of discovery issues unique to patent law. See In re Spalding Sports Worldwide, Inc., 203 F.3d 800, 803 (Fed. Cir. 2000). The proper scope of a discovery confidentiality order in a patent case, while informed by Federal Circuit law, is controlled by Third Circuit law. See, e.g., Eli Lilly & Co. v. Actavis Elizabeth, LLC, No. 07-3770, 2008 WL 2783345, at *1 (D.N.J. July 15, 2008); AFP Advanced Food Prods., LLC v. Synder's of Hanover Mfg., No. 05-3006, 2006 WL 47374, at *2 (E.D. Pa. Jan. 6, 2006).

Federal Rule of Civil Procedure 26 states: "The court may, for good cause, issue an order to protect a party." Id. The Third Circuit has held that "good cause" is demonstrated, and a protective order is warranted, "when a party shows that disclosure will result in a clearly defined, specific and serious injury but that broad allegations of harm are not sufficient." Shingara v. Skiles, 420 F.3d 301, 306 (3d Cir. 2005) (citing Pansy v. Boro. of Stroudsburg, 23 F.3d 772, 786-87 (3d Cir. 1994)). The burden of showing good cause rests with the party seeking protection. See Cipollone v. Ligget Group, 785 F.2d 1108, 1114 (3d Cir. 1986); In re Gabapentin Patent Litig., 312 F. Supp. 2d 653, 659 (D.N.J. 2004) (stating "a party seeking a protective order must establish good cause to justify such an order").

B. Discussion

The focus of this motion is Defendants' request that any attorney who views or receives confidential information be precluded from engaging in future FDA and patent prosecution activities with respect to doxycycline.[3] This Court has previously addressed the propriety of a broad patent prosecution restriction in a Hatch-Waxman patent case. See Eli Lilly & Co. v. Actavis Elizabeth, LLC, No. 07-3770, 2008 WL 2783345 (D.N.J. July 15, 2008). As described herein, the Court concludes, for essentially the same reasons in Eli Lilly, that the disputed provisions are overbroad and not supported by sufficient good cause.

In U.S. Steel Corp. v. United States, 730 F.2d 1465 (Fed. Cir. 1984), the Federal Circuit discussed the proper parameters of a protective order relating to confidential information. There, the Federal Circuit rejected a protective order that barred U.S. Steel's in-house counsel access to confidential communications based solely on their status as in-house attorneys and the perceived likelihood of inadvertent disclosure. See id. at 1468. In rejecting the broad prohibition, the court endorsed a case and attorney specific approach to concerns of inadvertent disclosure, focusing on "the factual circumstances surrounding each individual counsel's activities, association, and relationship with a party, whether counsel be in-house or retained . . . ." Id. The court acknowledged that in certain circumstances there may be a legitimate basis to deny counsel access to confidential information, e.g., when counsel is involved in competitive

[3] The parties also appear to dispute some minor language in paragraph 15 of Defendants' proposed order, which states that information produced in this litigation is not to be used in the prosecution of any patents or in communications to the FDA or other agencies. The parties have already agreed to a provision that limits the use of discovery materials to the present action. This eliminates the need for additional language prohibiting the disclosure of materials to the FDA and others. Therefore, the proposed language should not be included in the parties' confidentiality order. See, e.g., Eli Lilly, 2008 WL 2783345, at *2 (rejecting similar FDA provision as excessive and duplicative).

decisionmaking; however, "[w]hether an unacceptable opportunity for inadvertent disclosure exists . . . must be determined, as above indicated, by the facts on a counsel-by-counsel basis." Id.[4]

In AFP Advanced Food Prods. v. Snyder's of Hanover Mfg., No. 05-3006, 2006 WL 47374 (E.D. Pa. Jan. 6, 2006), the court, relying on U.S. Steel and Third Circuit precedent, rejected a prosecution restriction substantially similar to the one sought by Defendants in this case. In AFP, the defendant sought to prevent the plaintiff's counsel from engaging in patent prosecution relating to "low protein containing products…including . . . cheese dips" for two years following suit. Id. at *2. Defendant's sole basis for the proposed restriction was the fear of inadvertent misuse of confidential information. See id. The court rejected the restriction as follows:

> . **. . [the] threat [of inadvertent disclosure], standing alone, under Shingara and U.S. Steel, is not enough to justify a protective order barring AFP's attorney's from prosecuting similar patents for two years. As further explained in U.S. Steel, the decision to deny access to discovered materials should be done on a case-by-case, and lawyer-by-lawyer basis.** In this case, there is no reason to believe that AFP's attorneys will not strictly follow the adopted order and refrain from using, either inadvertently or intentionally, Confidential Attorney's Eye's Only information for the sole purpose of this litigation. Barring AFP's attorneys from prosecuting similar patents for two years following this suit, without some tangible reason or good cause other than the general threat of inadvertent misuse of discovered materials, is the

[4] In an unpublished opinion, In re Sibia Neurosciences, Inc., 132 F.3d 50, 1997 WL 688174 (Fed. Cir. Oct. 22, 1997) (table), the Federal Circuit expanded U.S. Steel's reasoning to counsel actively involved in patent prosecutions. There, the Court held that simply because counsel may be involved in patent prosecutions, and thus present a real risk of inadvertent disclosure, the issue of access to confidential documents must be decided on a case-by-case, individual attorney basis. See id. at *3.

> exact type of overly broad and generalized fear rejected in Shingara, U.S. Steel, and In re Sibia Neurosciences, Inc.

Id. at *2 (emphasis added).

Relying on the authority cited above, this Court previously rejected an expansive patent prosecution restriction in Eli Lilly. There, the defendants sought to impose a two-year bar on any attorney involved in patent prosecutions with respect to compositions of the drug in suit. See id. at *1. The only justification for the proposed restriction was the possibility of inadvertent disclosure of allegedly confidential information. See id. at *2. This Court rejected that argument, standing alone, as sufficient to establish good cause under the Third Circuit's well-known standard governing protective orders. See id. at *3.

Here, Defendants similarly base their argument on the possibility that Plaintiffs "might" unintentionally use their confidential information in subsequent FDA or patent related proceedings.[5] This general possibility fails to establish good cause.

The Court has not been provided with any specifics showing that anyone serving as Plaintiffs' counsel will intentionally or unintentionally disclose or utilize confidential information in their future activities. The restrictions Defendants ask the Court to endorse are broad, blanket prohibitions applying to any lawyer that views confidential information, regardless of individual circumstances. The teaching of U.S. Steel and its progeny is that

[5] Defendants also allege that the non-binding Federal Judicial Center, Patent Case Management Judicial Guide recommends that patent prosecution restrictions be employed in nearly every case. (See Defs.' Letter at 1 (citing Federal Judicial Center, Patent Case Management Guide at § 4.2.5.3 (2009) ("The Judicial Guide"))). However, that is not accurate. Rather, The Judicial Guide ultimately concludes that "the decision on whether to impose a prosecution bar, and its conditions, should be informed by" multiple factors, including those referenced in U.S. Steel. Judicial Guide at §4.6.9.

restrictions on access to confidential documents or the activities of counsel will not be imposed absent some specific, identifiable showing and not on the basis of broad generalizations of potential harm. The notion that good cause can be shown simply by invoking the possibility of inadvertent disclosure has been rejected by the authorities cited herein. See, e.g., U.S. Steel, 730 F.2d at 1468; In re Sibia, 1997 WL 688174, at *3; Eli Lilly, 2008 WL 2783345, at *3; AFP, 2006 WL 47374, at *2. As a result, Defendants have failed to meet their burden of showing good cause, and their restrictions are unwarranted and shall not be included in the parties' discovery confidentiality order.

Nothing in this opinion should be read to imply that the Court is irrevocably opposed to the concept of a patent prosecution restriction or FDA bar in this case. The denial of Defendants' application is based on the breadth of the provisions and because the request is supported by mere general allegations of harm. Defendants are free to raise access to confidential communications and/or patent and FDA based bars on an individual attorney basis. On an individual basis, the Court will be in a better position to evaluate the propriety of prosecution bars, FDA bars, or access to confidential documents. If any party wishes to raise concerns about a prosecution bar with respect to an individual lawyer, the parties should meet and confer and then raise any dispute in accordance with the Court's Local Civil Rules. See, e.g., Eli Lilly, 2008 WL 2783345, at *2 n.3.

CONCLUSION

Defendants' request to include broad patent prosecution and FDA bars in the discovery confidentiality order is **DENIED**. The parties are directed to confer and submit a proposed discovery confidentiality order, consistent with this Opinion, within **ten (10) days**. An appropriate Order accompanies this Opinion.

s/Mark Falk
MARK FALK
United States Magistrate Judge

Dated: October 29, 2009