UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY, Plaintiff,	)	
vs.	)	1:08-cv-1547-WTL-TAB
WOCKHARDT LIMITED, et al., Defendants.	)	

ORDER ON PLAINTIFF'S MOTION TO COMPEL

I. Introduction

What's a high-stakes patent case without a fierce discovery dispute and cries of an unfair "fishing expedition"? This case does not disappoint. Defendants Wockhardt Limited and Wockhardt USA, LLC (together, "Wockhardt") claim that Plaintiff Eli Lilly and Company has caught its fair share of discovery documents and needs to return to shore. Lilly wants to fish a little deeper. Fortunately, the parties have done a superior job briefing this discovery dispute. After considering these submissions, the Court decides that Lilly's discovery requests are largely permissible, and grants Lilly's motion to compel in part. [Docket No. 186.]

II. Background

Lilly holds a patent covering duloxetine—marketed as Cymbalta—and methods of using duloxetine to treat depression and anxiety. Wockhardt is in the process of seeking FDA approval to market generic versions of duloxetine by way of an Abbreviated New Drug Application ("ANDA"). Lilly brought this suit, alleging that Wockhardt's duloxetine ANDA infringes its patent.

The parties are currently in discovery, and Lilly has filed the first of several motions to

compel.[1] Lilly seeks complete noninfringement and invalidity contentions, responses to its requests for production, and responses to interrogatory nos. 7, 10, and 11.[2] [Docket No. 186.]

III. Discussion

A. Lilly's requests for production

The parties first dispute the scope of discovery. Federal Rule of Civil Procedure 26(b) provides for broad discovery: "[p]arties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense." Wockhardt takes a narrow view of what is relevant, accusing Lilly of undertaking a "fishing expedition" and arguing that "[t]he only information that is relevant to a determination of infringement . . . is the description in the ANDA of the characteristics of the generic drug which the applicant proposes to market in the future, because it is the only drug that can be legally marketed after FDA approval." [Docket No. 195 at 7–8.] Lilly's view of relevance is much broader. Lilly stresses that Wockhardt has produced only 17,000 pages of documents to Lilly's 3.5 million, and that Wockhardt's production is lacking in emails and PowerPoints and devoid of research reports and laboratory notebooks—documents that Lilly claims are relevant to the issues of infringement, induced infringement, and non-obviousness.

Given the broad scope of discovery permitted by the federal rules, the Court rejects

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[1]The parties appeared for a pretrial conference on May, 20, 2010, to address several discovery-related disputes, including this motion to compel. As the Court noted at the pretrial conference, the Court cannot decide all of the parties' motions at this time because they are not yet fully briefed.

[2]The Court will not discuss Lilly's interrogatory no. 11 or Wockhardt's noninfringement and invalidity contentions because Lilly indicated in its reply that Wockhardt has since responded to these items. [Docket No. 202 at 17.]

Wockhardt's view that Lilly's requests are "patently unjust" or "manifest[ly]" irrelevant. [Docket No. 195 at 4.] The Federal Circuit has held that whether infringement exists depends on "all the relevant evidence, including the ANDA." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997); *see also Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1248–49 (Fed. Cir. 2000). Moreover, Lilly has pointed to several cases in which documents such as those at issue have been produced. *E.g.*, *Eli Lilly and Co. v. Teva Pharms. USA, Inc.*, No. 1:06-cv-1017-SEB-JMS (S.D. Ind. July 29, 2008) (analyses, methods, bioequivalence studies, communications with FDA); *Eisai Co. v. Teva Pharms. USA, Inc.*, 247 F.R.D. 440, 443–45 (D.N.J. 2007) (marketing documents); *SmithKline Beecham Corp. v. Apotex Corp.*, No. 98 C 3952, 1999 WL 311697, at *8 (N.D. Ill. May 13, 1999) (laboratory notebooks). And even if non-ANDA materials are irrelevant to infringement, Lilly has made a strong case that they are relevant to other issues, such as induced infringement and non-obviousness. Therefore, Wockhardt shall produce to Lilly within 28 days of this order documents that are not privileged and that are relevant to Lilly's requests for production, including those concerning Wockhardt's decision-making, proposed marketing, proposed market share, correspondence with FDA concerning proposed labeling, meeting minutes, emails, spreadsheets, PowerPoint presentations, reports, memoranda, and laboratory notebooks.

Exempted from this order are Wockhardt's bioequivalence studies. Lilly does not dispute Wockhardt's contention that "[n]one of the asserted claims are directed to bioequivalence or bioequivalence testing, and none require Wockhardt's ANDA products to have any particular biological performance of any kind, let alone be bioequivalent to Cymbalta." [Docket No. 195 at 12.] Instead, Lilly cites *Eli Lilly and Company v. Teva Pharmaceuticals*, in which Magistrate

Judge Magnus-Stinson ordered Teva to produce bioequivalence studies. But before ordering the production of bioequivalence studies, Judge Magnus-Stinson noted that "Teva had no objection to the discovery requests with the exception of the deadlines contained therein." In this case, Wockhardt forcefully objects to the production of bioequivalence studies. Because Lilly has not explained why they are relevant, the Court will not require their production.

Additionally, Lilly takes issue with the heavy redaction of Wockhardt's production. [Docket No. 187 at 13.] Aside from privilege, Wockhardt claims that the redactions were made because "documents and materials reflecting Wockhardt's R&D and testing are not relevant to any of the asserted claims of the '269 patent." [Docket No. 195 at 17.] As discussed above, Wockhardt's research and testing materials—along with other internal documents—are relevant to the issues in this case, and a protective order is in place to protect Wockhardt's interests in confidentiality. Therefore, Wockhardt shall produce to Lilly within 28 days of this order documents redacted according to the Court's determination regarding relevance. And although the Court generally allows parties to independently work out privilege log issues to avoid burdens in cases such as this one, that approach appears unworkable here because the parties are already disputing redactions. Accordingly, Wockhardt must provide a privilege log if it continues to insist on redactions.

The foregoing rulings are made with due regard to Wockhardt's concern that additional production would be unduly burdensome. Discovery in a high-stakes patent infringement case is not without its burdens. Lilly indicated at the May 20, 2010, pretrial conference that it allocated significant resources—nearly 60 attorneys and millions of dollars—to responding to Wockhardt's discovery requests. Wockhardt, on the other hand, has produced only thirty emails and few of the

PowerPoints and other documents that are ubiquitous in this type of case. Of course, discovery—unlike some fishing—is not a contest, and Wockhardt need not engage 60 attorneys in a multimillion dollar document production. But Wockhardt will need to allocate more resources toward responding to Lilly's discovery requests. In this case, that is not an unreasonable burden.

B. Lilly's interrogatory nos. 7 and 10

Lilly's interrogatory nos. 7 and 10 seek Wockhardt's basis for its contention that each and every claim of its patent is invalid. [Docket No. 187 at 15.] Wockhardt responds that its defense was based on "notice pleading intended to encomplass non-statutory defenses now being investigated and/or which may be fleshed out through discovery which is ongoing." [Docket No. 190, Ex. 25 at 3–4.] Wockhardt further promises to supplement its responses as discovery progresses and after it has a fair opportunity to review the millions of documents produced by Lilly. [Docket No. 195 at 20.] Wockhardt requests that the Court not require answers to Lilly's contention interrogatories until completion of discovery or the final pretrial conference. [*Id.*] Lilly objects to Wockhardt's proposal, noting that "[a]t the very least, Wockhardt has an obligation to provide a response to these interrogatories based on the information it relied on to make its allegation in the first instance." [Docket No. 202 at 15.]

Lilly is correct. Wockhardt must answer Lilly's interrogatory nos. 7 and 10 in good faith and may supplement its responses as it is able to digest Lilly's large production. Within 28 days of this order, Wockhardt must provide Lilly with at least its basis for raising the defense identified in interrogatory no. 7 and the counterclaim identified in interrogatory no. 10, and Wockhardt must supplement its responses in good faith as discovery progresses.

IV. Conclusion

This case bring to mind *Eli Lilly and Company v. InvaGen Pharmaceuticals, Inc.*, 1:09-cv-87-WTL-TAB (S.D. Ind. Sept. 17, 2009), in which cries of a "fishing expedition" also were made. In addressing this concern, the Court observed that the Federal Rules of Civil Procedure allow courts to "determine the pond, the type of lure, and how long the parties can leave their lines in the water." The determination here is to grant in part Lilly's motion to compel. [Docket No. 186.] Wockhardt shall supplement its discovery responses within 28 days of this order as explained above.

Additionally, after a thorough review of the parties' submissions, the Court questions the necessity of sealing Wockhardt's response brief and exhibits. [Docket Nos. 195–97.] Wockhardt's response contains only legal argument, and only portions of the exhibits appear confidential under the protective order. Wockhardt shall show cause within 28 days why its response and exhibits should remain sealed.

Dated: 05/27/2010

Tim A. Baker
United States Magistrate Judge
Southern District of Indiana

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