

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 DEFENDANTS' MOTION FOR LEAVE TO AMEND  
AND MOTIONS TO COMPEL**

**I. Introduction**

Defendants Wockhardt Limited and Wockhardt USA, Inc. (“Wockhardt”) have moved for leave to amend their first amended answer and counterclaims [Docket No. 208] and to compel discovery from Plaintiff Eli Lilly and Company. [Docket Nos. 210, 222.] For the reasons explained below, the Court grants Wockhardt’s motion for leave to amend and grants in part its motions to compel.

**II. Background**

Lilly sued Wockhardt for patent infringement in November 2008 and began collecting potentially relevant documents in July 2009. In August 2009, Wockhardt served Lilly with 127 requests for production. Wockhardt’s requests instructed Lilly to use production numbers and either make documents available as kept by Lilly in the usual course of business or organized and labeled to correspond with Wockhardt’s requests. [Docket No. 212, Ex. 12 at 8.] Wockhardt did not ask that Lilly identify by Bates number the documents responsive to particular requests.

In September and October 2009, Lilly produced 625,000 documents. [Docket No. 233,

Ex. 3 at 3–4.] On October 19, Wockhardt expressed dissatisfaction with Lilly’s production because the documents were not electronically searchable and lacked creation date and custodian information. [Docket No. 233, Ex. 5.] By December, Lilly and Wockhardt had agreed to provide each other with electronically searchable documents, creation date information, and custodian information “to the extent and in the form” that it existed. [Docket No. 233, Exs. 6–7.] The parties made no agreement about providing Bates numbers responsive to particular requests for production. By the end of 2009, Lilly had produced over 1.6 million pages to Wockhardt. [Docket No. 233, Ex. 3 at ¶¶ 10–14.]

Lilly produced a substantial number of documents to Wockhardt in January 2010 to comply with the Court’s January 31 “substantially complete” deadline. By January 31, Lilly had produced a total of approximately 3.5 million pages. [*Id.* at ¶ 20.] This production required 67 attorneys working 15,000 hours at great cost. [*Id.* at ¶¶ 8–9.]

On March 19, 2010, Wockhardt informed Lilly that its production was inadequate and asked Lilly, by letter and interrogatory, to “[s]eparately for each Wockhardt Request for Production of Documents, identify the Documents produced by Lilly that are responsive to the Request.” [Docket No. 233, Ex. 8; Docket No. 233, Ex. 12 at 7.] Lilly balked at Wockhardt’s request, claiming that its documents were produced as kept in the usual course of business, and that Wockhardt had not previously requested Bates number identification. Lilly wrote that “it is completely unreasonable for Wockhardt to belatedly demand that Lilly engage in such an unnecessary and burdensome exercise, months after Lilly has substantially completed its document review and production.” [Docket No. 233, Ex. 9.] Although Wockhardt had apparently not yet begun its review of Lilly’s production, it further complained that 60,000 of

Lilly's documents were undated, 3,000 lacked date information, and 50,000 lacked custodian information. [Docket No. 211 at 4, 13.]

Wockhardt also served its first requests for admission on March 19. [Docket No. 223, Ex. 4.] These requests sought information about Lilly's European Patent Application No. 87311181.9. Lilly objected to these requests because they were related to the issue of inequitable conduct, which Wockhardt had not yet pleaded. [Docket No. 223, Ex. 5 at 5.]

On April 30, 2010—the deadline for seeking leave to amend the pleadings—Wockhardt moved for leave to amend its first amended answer and counterclaims to add affirmative defenses and counterclaims of patent misuse, inequitable conduct, and expiration. [Docket No. 208.] Lilly objected to Wockhardt's proposed amendments. [Docket No. 216.]

The parties unsuccessfully met and conferred throughout April and May. On May 7, Wockhardt moved to compel discovery from Lilly and for a four-month extension of time to complete fact discovery, and on May 17, Wockhardt filed a supplemental motion to compel responses to its requests for admission.

The parties appeared by counsel for a pretrial conference on May 20, 2010, and discussed the pending motions, which were not yet fully briefed. The Court extended the liability discovery deadline by one month to June 30, 2010. [Docket No. 227.]

### **III. Discussion**

#### *A. Wockhardt's motion for leave to amend*

Federal Rule of Civil Procedure 15(a) governs amendment of pleadings before trial. Rule 15(a)(2) provides that when a party can no longer amend as a matter of course, it may amend its pleading "only with the opposing party's written consent or the court's leave. The court should

freely give leave when justice so requires.” The rule reflects a liberal attitude toward amendments, but “courts in their sound discretion may deny a proposed amendment if the moving party has unduly delayed in filing the motion, if the opposing party would suffer undue prejudice, or if the pleading is futile.” *Soltys v. Costello*, 520 F.3d 737, 743 (7th Cir. 2008).

Wockhardt seeks leave to include defenses and counterclaims of patent expiration, patent misuse, and inequitable conduct. [Docket No. 208, Ex. A.] Because Lilly does not oppose Wockhardt’s proposed defense and counterclaim of patent expiration, the Court grants Wockhardt’s motion as to those amendments. Lilly, however, opposes Wockhardt’s proposed defenses and counterclaims of patent misuse and inequitable conduct.

1. Patent misuse

Lilly first argues that Wockhardt’s proposed defense and counterclaim of patent misuse should not be permitted because they are futile. [Docket No. 216 at 12–20.] Amendment is futile if “the complaint, as amended, would fail to state a claim upon which relief could be granted.” *Wallace v. Free Software Found., Inc.*, No. 1:05-cv-0618-JDT-TAB, 2006 WL 2038644, at \*4 (S.D. Ind. Mar. 20, 2006).

Wockhardt’s proposed patent misuse defense and counterclaim are not futile. As Lilly candidly notes, its argument that patent misuse cannot be based on an improper listing with the FDA has not been uniformly adopted by courts. [Docket No. 216 at 15–18.] And, despite Lilly’s argument to the contrary, Wockhardt’s proposed amended answer and counterclaims allege anticompetitive effect. [Docket No. 208, Ex. A at ¶ 43 (“Lilly has improperly and illegally expanded the legitimate scope of the ’269 patent to delay or prevent FDA approval of Wockhardt’s ANDA.”), ¶ 137 (realleging all preceding paragraphs).] Because Wockhardt’s

proposed patent misuse defense and counterclaim are not futile, the Court grants leave for Wockhardt to include them by amendment.

## 2. Inequitable conduct

Next, Lilly argues that Wockhardt’s proposed defense and counterclaim of inequitable conduct should not be permitted because of Wockhardt’s undue delay and the prejudice that would result to Lilly. Lilly stresses that Wockhardt waited until the last possible day to file its motion for leave to amend, and Wockhardt’s proposed defense and counterclaim relies on items that were available in the public record—and relied on by Defendant Sun Pharma Global, Inc. in its nearly identical defense and counterclaim fifteen months earlier. *Eli Lilly and Co. v. Sun Pharms. Indus. Ltd.*, No. 1:08-cv-1629-LJM-DML (S.D. Ind. Feb. 9, 2009) (answer to complaint). Most “distressing” to Lilly is its view that “Wockhardt specifically informed Lilly on *three* separate occasions that it was not asserting this defense.”<sup>1</sup> [Docket No. 216 at 1.]

Wockhardt responds that its proposed amendments met the CMP deadline, and it disputes Lilly’s view that it waived the inequitable conduct defense, pointing to its interrogatory

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<sup>1</sup> Lilly relies on the following statements by Wockhardt:

- “Wockhardt’s defense is not based on inequitable conduct, and thus, a detailed pleading set forth with particularity is not required.” [Docket No. 216, Ex. 6.]
- “To be clear, Wockhardt’s Third Defense does not encompass unenforceability on the grounds of inequitable conduct, as that will be separately pleaded in accordance with Rule 9 should sufficient grounds be determined as discovery progresses.” [Docket No. 217, Ex. 8 at 3.]
- “Moreover, if you will recall your phone call to us prior to service of these interrogatories, reference to notice pleading was offered to reassure Lilly that the defense in question did not encompass any allegations of inequitable conduct over which you had expressed great concern.” [Docket No. 216, Ex. 9 at 3–4.]

responses in which it advised Lilly that “Wockhardt’s Third Defense does not encompass unenforceability on the grounds of inequitable conduct, as that will be pleaded in accordance with Rule 9 should sufficient grounds be determined as discovery progresses.” [Docket No. 217, Ex. 8 at 3.]

Despite any inconsistency in Wockhardt’s statements regarding inequitable conduct, the Court grants Wockhardt leave to amend its inequitable conduct defense and counterclaim. Wockhardt’s behavior is distinguishable from the behavior of the plaintiff in *Serio v. Jojo’s Bakery Restaurant*, 102 F. Supp. 2d 1044 (S.D. Ind. 2000), a case relied on by Lilly in which leave to amend was denied. Unlike the plaintiff in *Serio*, who “expressly disavowed a retaliation theory through the course of its summary judgment submissions,” *id.* at 1054, Wockhardt—though not always sending clear signals—never expressly disavowed its inequitable conduct defense and counterclaim. Moreover, the plaintiff in *Serio* sought to amend his complaint six months after the close of discovery and four months after the parties filed their fully briefed summary judgment motions. *Id.* at 1053–54. Wockhardt moved for leave to amend within the CMP deadline, if only barely. Finally, Rule 15 favors liberal amendment. Under these circumstances, the Court grants leave for Wockhardt to include its inequitable conduct defense and counterclaim.

*B. Wockhardt’s motion to compel*

Wockhardt’s motion to compel [Docket No. 210] seeks an order compelling Lilly to provide the following within twenty days:

- (1) Identify by Bates number each of Lilly’s documents that are responsive to each of Defendants’ First Request for the Production of Documents and Things (Nos. 1–127);
- (2) Answer each of Wockhardt’s Third Set of Interrogatories (Nos. 20–29);
- (3) Provide date information, custodian information and OCR

information for each of Lilly's documents without such metadata; and (4) Complete Lilly's document production, including all documents responsive to Wockhardt's Requests, as well as Bates numbers relating them to Wockhardt's Requests.

[*Id.*] Wockhardt also seeks a four-month extension of fact discovery.

1. Identification of Bates numbers/  
Wockhardt's third set of interrogatories

First, Wockhardt argues that Lilly's production "is not usable and fails to comply with the requirements of Rule 34(b)(2)." [Docket No. 211 at 14.] Wockhardt seeks responsive Bates numbers and answers to its third set of interrogatories to make Lilly's production usable. Lilly responds that it complied with Rule 34 by producing its documents as kept in the ordinary course of business, and that its production complied with the agreement of the parties. [Docket No. 232 at 13.] Wockhardt questions Lilly's response, noting that a key 1972 memorandum was "sandwiched between files which evidently relate to June 2000 laboratory tests of duloxetine . . . and 2004 abstracts of publications relating generally to antidepressants," and duloxetine laboratory data was mixed with promotional files relating to urinary incontinence. [Docket No. 242 at 11–12.]

Rule 34(b)(2)(E)(i) provides that a party "must produce documents as they are kept in the usual course of business or must organize and label them to correspond to the categories in the request." In this case, Wockhardt wants Lilly to do both. Wright & Miller's *Federal Practice & Procedure* speaks directly to Wockhardt's request:

Requiring further that these requested materials be segregated according to the requests would impose a difficult and usually unnecessary additional burden on the producing party. The categories are devised by the propounding party and often overlap or are elastic, so that the producing party might be compelled to decide which best suits each item in order to consign it to the proper batch. Such

an undertaking would usually not serve any substantial purpose, and it could become quite burdensome if considerable numbers of documents were involved.

§ 2213 (2010). Because of the considerable number of documents involved, the Court will not require Lilly to precisely match its documents with Wockhardt's requests. Further, because Wockhardt did not object to Lilly's manner of production until months after it was substantially completed, it would be unfair to require Lilly to go back and correlate its voluminous production with Wockhardt's requests.

Nevertheless, some additional guidance from Lilly is necessary. As Wright & Miller observe, "the court should have the authority where necessary to direct some disclosure of the manner of organization of the producing party's files." *Id.* Within fourteen days, Lilly must in good faith generally match up its documents with Wockhardt's requests by letter, chart, or some form of index. Given Lilly's demonstrated ample resources, some additional guidance is not too much to ask.

## 2. Metadata

Wockhardt argues that Lilly's production is "not usable" because it lacks date, OCR, and custodian information. [Docket No. 211 at 14.] Wockhardt believes that of the 257,408 documents produced by Lilly, 60,000 (23%) lack date information, 50,000 (19%) lack custodian information, and 3,000 (1%) lack OCR. [Docket No. 211 at 4, 13.] Lilly disagrees with Wockhardt's numbers and believes that about 30,000 lack date information, 200 lack custodian information, and 3,000 lack OCR. [Docket No. 232 at 12–13.] Wockhardt suggests that the discrepancy in dated documents may be because Lilly did not add date metadata where the date was stated on the face of the documents. [Docket No. 242 at 14.] Wockhardt requests that Lilly revise its production to add date metadata where the date is stated on the face of documents, and



Wockhardt wants Lilly to provide it with disks containing the missing custodian information.

[*Id.*]

The parties agreed to produce date, custodian, and OCR metadata “to the extent and in the form such information exists.” [Docket No. 233, Exs. 6–7.] Lilly has produced date information to the extent and in the form that it currently exists. The Court will not require Lilly to revise its production to add metadata that does not already exist. However, Lilly shall provide custodian information to Wockhardt for the approximately 49,800 documents that Wockhardt believes lack custodian information. As far as OCR information, Lilly asserts that it has produced everything available [Docket No. 232 at 13], and it is not unreasonable that 1% of Lilly’s production—presumably handwritten documents—would lack OCR information. The Court therefore denies Wockhardt’s motion to compel additional OCR information. Lilly must supplement its metadata production within fourteen days of this order.

### 3. Missing categories

Next, the Court considers the categories of documents that Wockhardt claims are missing from Lilly’s production. Some of these items are now moot: Lilly produced documents relating to the prosecution of the ‘269 patent on June 4, 2010 [Docket No. 242 at 1]; Lilly agreed to provide the foreign patent application files if the Court granted Wockhardt’s motion to amend [Docket No. 232 at 23–24]; and Lilly has provided some responsive Bates ranges and will be providing an index to its production. Other categories remain in dispute.

- **Documents relating to the closest prior art.** Wockhardt believes that information related to prior art compounds disclosed by Molloy, et al. is relevant to Wockhardt’s obviousness defense. [Docket No. 211 at 6–7.] Lilly responds that its private information is irrelevant because prior art includes only public information. Wockhardt does not counter Lilly’s argument and explain why information related to

prior art compounds is relevant. [Docket No. 242 at 6–7.] Therefore, the Court denies Wockhardt’s motion to compel on this point.

- **Documents relating to IND 37,071 and the non-enteric formulation of duloxetine.** Wockhardt believes that information about Lilly’s non-enteric formulation is relevant to Wockhardt’s obviousness defense because it shows that Cymbalta’s success is due to the enteric coating rather the invention claimed in the ’269 patent. [Docket No. 211 at 9.] Lilly responds that Wockhardt’s theory “has no merit as demonstrated by Wockhardt’s own decision to sell its generic duloxetine product using a formulation *different* from that used by Lilly.” [Docket No. 232 at 29.] But Wockhardt’s decision to use a different formulation does not rule out the possibility that Lilly’s enteric coating allowed for Cymbalta’s success. The Court therefore grants Wockhardt’s motion to compel on this point.
- **Documents relating to Lilly’s FDA submissions.** In its reply, Wockhardt argues that Lilly should be required to produce information relating to its FDA submissions because the Court’s May 27, 2010, order required Wockhardt to produce these documents to Lilly. Wockhardt, however, does not explain why this information is relevant. The Court therefore denies Wockhardt’s motion to compel on this point.
- **Documents concerning Lilly’s projected marketing and projected market share.** As with the documents relating to Lilly’s FDA submissions, the Court denies Wockhardt’s motion to compel on this point because Wockhardt does not explain why this information is relevant.
- **Documents concerning Lilly’s current market share.** Lilly produced “representative samples” of marketing documents, to which Wockhardt did not object. Now—after omitting the issue from its motion to compel and supplemental motion to compel, and nine months after Lilly advised Wockhardt that it was producing only representative samples—Wockhardt seeks all marketing documents. As Lilly notes, representative samples are sometimes used where production of all materials would be voluminous. [Docket No. 247, Ex. 1 at 8 (citing cases).] Under these circumstances, the Court denies Wockhardt’s motion to compel on this point.
- **Improper redactions.** Finally, Wockhardt argues that Lilly improperly redacted many documents. [Docket No. 242 at 15.] Lilly must provide Wockhardt unredacted versions consistent with the Court’s above orders. Moreover, as the Court previously stated in its May 27, 2010, order, “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.” [Docket No. 230 at 4.] Therefore—just as the Court ordered Wockhardt on May 27—Lilly must provide a privilege log covering any remaining redactions.

4. Extension of time

Finally, the Court grants in part Wockhardt's request for extension of the liability discovery deadline. The Court previously extended the deadline from May 31, 2010, to June 30, 2010, and noted that it would revisit this deadline after ruling on the pending motions. Given the time taken to brief and resolve the pending motions, further extension of the fact discovery deadline is reasonable. The Court therefore extends the liability discovery deadline to August 31, 2010.

*C. Wockhardt's supplemental motion to compel*

Wockhardt's supplemental motion to compel [Docket No. 222] seeks an order compelling Lilly to substantively respond to Wockhardt's first requests for admission within three days. Lilly responded that Wockhardt's requests were irrelevant, but that "[i]f . . . the Court grants Wockhardt's motion to amend its pleadings to include an inequitable conduct defense, Lilly will respond to Wockhardt's requests for admission nos. 1–8 and provide other discovery." [Docket No. 232 at 23–24.] Because the Court grants Wockhardt's motion for leave to amend, the Court also grants Wockhardt's supplemental motion to compel in part and orders Lilly to respond to Wockhardt's requests for admission nos. 1–8 within seven days of this order.

**IV. Conclusion**

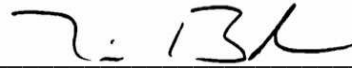
For these reasons, the Court grants Wockhardt's motion for leave to file an amended answer and counterclaims. [Docket No. 208.] Wockhardt's Second Amended Answer and Counterclaims [Docket No. 208, Ex. A] shall be deemed filed as of the date of this order.

The Court grants in part Wockhardt's motion to compel. [Docket No. 210.] Within fourteen days, Lilly shall provide Wockhardt with an index to its production, supplement its date

and custodian metadata, and provide Wockhardt with the specific categories of documents set out above. Additionally, the Court extends the liability discovery deadline until August 31, 2010.

Finally, the Court grants in part Wockhardt's supplemental motion to compel. [Docket No. 222.] Lilly shall respond to Wockhardt's requests for admission nos. 1-8 within seven days of this order.

Date: 06/22/2010

A handwritten signature in black ink, appearing to read 'T. Baker', is written above a horizontal line.

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

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