UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY,	)	
	)	
Plaintiff/Counterclaim Defendant,	)	
	)	
vs.	)	**No. 1:16-cv-0308-TWP-DKL**
	)	
DR. REDDY'S LABORATORIES, LTD., *et al.*,	)	
	)	
	)	
Defendants/Counterclaimants.	)	

Entry and Order on Motion to Strike Portions of Plaintiff's Expert Reports [doc. 74]

Defendants have moved for an order striking portions of two of Plaintiff's expert reports—the Expert Report of Bruce A. Chabner, M.D., and the Expert Report of Rodolfo Pinal, Ph.D.—and prohibiting Plaintiff from introducing evidence regarding the stricken portions of the reports. Defendants contend that certain infringement theories were first disclosed in the expert reports in violation of the Patent Case Management Plan ("PCMP") as well as the Federal Rules of Civil Procedure and Local Rules. The portions of the reports at issue concern all opinions and bases therefor directed to literal infringement, all opinions and bases therefor concerning infringement under the doctrine of equivalents that are beyond the scope of those set forth in *Plaintiff's Preliminary Infringement Contentions* ("*Infringement Contentions*"), and all opinions and bases therefor concerning inducement of infringement and contributory infringement that are beyond the scope of those set forth in the *Infringement Contentions*.

Plaintiff opposes the motion, arguing that it did not violate the PCMP or any rule. Plaintiff asserts that its *Infringement Contentions* gave notice that it was asserting all of the theories of infringement identified in the expert reports. Plaintiff argues that the contentions served on September 6, 2016 were preliminary, that it was entitled to develop its infringement case through discovery, and that it properly did so. Plaintiff also argues that there is no basis to strike any portion of its expert reports; that Defendants have not been prejudiced; and even if Defendants were prejudiced, the prejudice can easily be cured. For the reasons that follow, the undersigned finds that the motion to strike should be granted.

Background

Eli Lilly and Company ("Lilly") commenced this patent-infringement action on February 5, 2016, against Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively "DRL"). DRL had filed a New Drug Application (NDA) with the U.S. Food and Drug Administration, seeking approval to manufacture and sell its Pemetrexed for Injection 100 mg/vial and 500 mg/vial products prior to the expiration of U.S. Patent No. 7,772,209 ("the '209 patent"). Lilly believes that DRL's NDA Products will be marketed as competing products to ALIMTA®, a chemotherapy agent developed and distributed by Lilly and used for treatment of cancer. Lilly alleges that DRL's filing of NDA No. 208297 and the use of the product described therein infringe its '209 patent". DRL alleges that the patent is invalid. Lilly received DRL's Notice Letter relating to NDA No. 208297 on December 29, 2015. A thirty-month stay of approval of NDA No. 208297 is in effect until June 29, 2018.

On June 20, 2016, the undersigned held the Initial Pretrial Conference in the case, discussing discovery, case management, and other matters. The parties expressed a desire to have this matter resolved before the approval of DRL's NDA 208297 and the parties' proposed case management deadlines were designed with the thirty-month stay of approval in mind. Yet, the parties disputed the appropriate deadline for infringement contentions. Lilly proposed an October 5, 2016 deadline, whereas DRL proposed a July 15, 2016 deadline. Lilly acknowledged the parties' interests in early disclosure of contentions; DRL asserted it was important to discover Lilly's infringement theories as early as practicable. DRL argued for resolution of this case before the expiration of the stay in order to avoid a potential "launch at risk" scenario. They also argued that the specific nature of Lilly's infringement theories (which were unknown at that time), including whether Lilly was alleging literal infringement or infringement under the doctrine of equivalents, would impact discovery. More specifically, DRL asserted that the infringement theories would affect the categories of documents requested and the number and type of experts they would need to obtain. After much discussion, the undersigned proposed a September 6, 2016 infringement-contentions deadline.

On July 8, 2016, the undersigned approved as amended the parties PCMP, setting September 6, 2016 as the deadline for Lilly's infringement contentions and DRL's invalidity contentions. [*See Patent Case Management Plan*, Section IV.B, doc. 45 at 5.] The PCMP set May 15, 2017 as the deadline for all liability discovery and stated: "The parties should focus their early discovery in a manner that prepares them to respond timely to discovery requests concerning their *preliminary* infringement and invalidity contentions."

[*Id.* at 4-5 (emphasis added).] The PCMP set June 16, 2017 as the dispositive motion deadline and stated that "the party with the burden of proof must file a statement of the claims or defenses it intends to prove at trial" within 14 days after the liability discovery deadline. [*Id.* at 7, 8.] Further, the PCMP said that "[u]pon approval, this Plan constitutes an Order of the Court. Failure to comply with an Order of the Court may result in sanctions … as provided under Rule 16(f) …." [*Id.* at 13.] The parties having moved for and having been granted enlargements of time, the liability discovery deadline is now June 20, 2017, the dispositive motion deadline is July 14, 2017, and the case is set for trial on January 29, 2018.

On September 6, 2016, Lilly filed its *Infringement Contentions*. [Doc. 48.] Lilly contended that DRL infringes each of claims 1-22 of the '209 patent, asserting that "[t]he use of DRL's NDA Products meets all limitations of each of the asserted claims, either literally or under the doctrine of equivalents." [*Infringement Contentions*, doc. 48 at 1.] Lilly asserted that DRL is liable as a direct infringer as well as "for active inducement of infringement and/or for contributory infringement." [*Id.* at 1-2.] A few weeks later, on September 23, 2016, DRL advised Lilly that its contentions were deficient, focusing on the doctrine of equivalents. [*Mot. Strike Portions of Pl.'s Expert Reports, Ex. A*, doc. 74-1.] DRL did not mention any other theory of alleged infringement.

In a letter dated November 29, 2016, Lilly responded to DRL's claim that its infringement contentions were deficient. The response repeatedly referenced the doctrine of "equivalents" or "equivalence" and used terms such as "equivalent infringement" and "equivalency analysis." The letter stated:

> As the claim chart reflects, setting aside the question of the salt form of the pemetrexed, each step of the claimed methods is carried out literally; the only remaining question is whether the administration of DRL's NDA product is equivalent, in the context of the claimed methods, to administering pemetrexed disodium, which is what the claims recite.

[*Mot. Strike, Ex. B*, doc. 74-2 at 1.] The letter did not address infringement under any theory other than the doctrine of equivalents. Lilly wrote that there was no "need for Lilly to supplement its initial infringement contentions" but "it will disclose further evidence on which it intends to rely consistent with the Case Management Plan, including in conjunction with expert discovery." [*Id.* at 3.]

On March 21, 2017, Lilly provided DRL with the Expert Report of Bruce A. Chabner, M.D., and the Expert Report of Rodolfo Pinal, Ph.D. The reports go beyond the claims of infringement under the doctrine of equivalents, asserting literal infringement, inducement of infringement, and contributory infringement as well as new opinions of infringement under the doctrine of equivalents that were not disclosed in the *Infringement Contentions*. The Chabner Report contains: (1) a literal infringement analysis and opinion at Exhibit C (a Claim Chart) to the report and in paragraphs 38-59 of the report at pages 15-28 and literal infringement-related statements in the report (see, *e.g.*, paragraphs 60, 63, and 80); (2) an "Inducement of and Contribution to Infringement" section, comprised of paragraphs 81 and 82 at pages 39-40 of the report, as well as a portion of paragraph 60; (3) a different Claims Chart attached as Exhibit C to the report in support of Lilly's new theories; and (4) in paragraphs 60-61, 64-73, 77-80, new theories under the doctrine of equivalents that are outside the scope of Lilly's *Infringement Contentions*. The Pinal Report contains: (1) a section entitled, "DRL's NDA Products Administered with Saline Literally

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