UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 1:16-cv-00308-TWP-MPB
	)	
DR. REDDY'S LABORATORIES, LTD., and DR. REDDY'S LABORATORIES, INC.,	)	
	)	
Defendants.	)	

ENTRY ON PLAINTIFF'S OBJECTION AND DEFENDANTS' MOTION TO STRIKE NEW ARGUMENTS IN PLAINTIFF'S REPLY

This matter is before the Court on Defendants Dr. Reddy's Laboratories, LTD's and Dr. Reddy's Laboratories, Inc.'s (collectively, "DRL") Motion to Strike Portions of Plaintiff's Expert Reports Served On Defendants On March 21, 2017 (Filing No. 74), and Plaintiff Eli Lilly and Company's ("Lilly") Objections to Order on Motion to Strike Portions of Plaintiff's Expert Reports ("the Order") (Filing No. 97). Also before the Court is a Motion to Strike New Arguments in Plaintiff's Reply That Were Neither Raised in its Objections nor Made to the Magistrate Judge (Filing No. 112). For the following reasons, the Court **sustains** Lilly's objections, **reverses** the Order, and **denies** DRL's motion to strike portions of Lilly's expert report. The Court also **denies** DRL's motion to strike alleged new arguments in Lilly's reply.

I. BACKGROUND

On August 10, 2010, U.S. Patent No. 7,772,209 ("the '209 patent") was issued to Lilly. The '209 patent covers the method of administering ALIMTA® (pemetrexed for injection)—an anti-cancer drug that requires physicians to co-administer the drug with folic acid and vitamin B_{12} to reduce the incidence of patient toxicity. This case surrounds a patent dispute. DRL filed a New

Drug Application (NDA) with the United States Food and Drug Administration seeking approval to manufacture and sell its pemetrexed products ("NDA Products")—a similar[1] anti-cancer injection that requires physicians to co-administer the drug with folic acid and vitamin B_{12}. On February 5, 2016, Lilly filed a Complaint against DRL, asserting DRL's NDA Products will be marketed as competing products to ALIMTA® and the use of the NDA Products infringe on the '209 patent. (Filing No. 1.)

Several months later, on June 20, 2016, the Magistrate Judge held an Initial Pretrial Conference, discussing discovery, case management, and other matters. The Magistrate Judge approved as amended the parties' Case Management Plan ("CMP"), setting September 6, 2016 as the deadline for Lilly's infringement contentions and DRL's invalidity contentions. (Filing No. 45 at 5.) On September 6, 2016, Lilly filed infringement contentions, asserting:

> The use of DRL's NDA Products meets all limitations of [claims 1-22 of the '209 patent], either literally or under the doctrine of equivalents. DRL is liable as a direct infringer based on the filing of its NDA, as well as for active inducement of infringement and/or for contributory infringement.

(Filing No. 48 at 1-2).

On March 21, 2017, Lilly provided DRL with the expert reports of Bruce A. Chabner, M.D. ("Dr. Chabner"), and Rodolfo Pinal, Ph.D. ("Dr. Pinal"). Ten days after receiving the expert reports, DRL filed a Motion to Strike large portions of the reports, asserting they violated the CMP by raising new theories of infringement not disclosed in Lilly's infringement contentions. (Filing No. 74.) The Court referred the Motion to Strike to the Magistrate Judge and, on April 28, 2017, the Magistrate Judge granted DRL's Motion to Strike. (Filing No. 96.) The Magistrate Judge specifically concluded that Lilly alleged only infringement under the doctrine of equivalents in its

[1] The only difference between the '209 patent and DRL's NDA Products is: the '209 patent requires administration of pemetrexed disodium and DRL's NDA Products require administration of pemetrexed ditromethamine.

infringement contentions; however, Lilly's expert reports address literal infringement, as well as inducement and contributory infringement. Accordingly, the Magistrate Judge excluded the following portions of Dr. Chabner's eight-six (86) paragraph report:

> (1) the literal infringement analysis in paragraphs 38-59, and literal infringement-related statements in the report in paragraphs 60, 63, and 80;
> (2) the "Inducement of and Contribution to Infringement" section at paragraphs 81 and 82, as well as a portion of paragraph 60;
> (3) portions of the Claims Chart attached as Exhibit C to the report; and
> (4) the theories under the doctrine of equivalents in paragraphs 60-61, 64-73, and 77-80.

Id. at 20; *see also* Filing No. 75 at 19-40; 42-44. The Magistrate Judge also excluded the following portions of Dr. Pinal's report:

> (1) the partial doctrine of equivalents analysis in paragraphs 15 and 16; and
> (2) the section entitled, "DRL's NDA Products Administered with Saline Literally Meets the Pemetrexed Disodium Limitation in the Claims of the '209 Patent," in paragraphs 72 and 73.

(Filing No. 96 at 20; Filing No. 75 at 122-23; 148.)

II. LEGAL STANDARD

A district court may refer a non-dispositive pretrial motion to a magistrate judge under Federal Rule of Civil Procedure 72(a). Rule 72(a) provides:

> When a pretrial matter not dispositive of a party's claim or defense is referred to a magistrate judge to hear and decide, the magistrate judge must promptly conduct the required proceedings and, when appropriate, issue a written order stating the decision. A party may serve and file objections to the order within 14 days after being served with a copy. A party may not assign as error a defect in the order not timely objected to. The district judge in the case must consider timely objections and modify or set aside any part of the order that is clearly erroneous or is contrary to law.

Fed. R. Civ. P. 72(a). The clear error standard is highly deferential, permitting reversal only when the district court "is left with the definite and firm conviction that a mistake has been made." *Weeks v. Samsung Heavy Indus. Co., Ltd.*, 126 F.3d 926, 943 (7th Cir. 1997).

III. DISCUSSION

Lilly objects to the Order, contending the Magistrate Judge erred by: 1) excluding evidence disclosed in Lilly's infringement contentions; 2) sanctioning Lilly for violating the CMP; and 3) misapplying the four-factor test that determines when to exclude expert testimony.

A. Motion to Strike New Arguments in Reply (Filing No. 112).

As an initial matter, the Court addresses DRL's request to strike two arguments included in Lilly's Reply Brief, specifically that: 1) Lilly disclosed its "equivalence" contentions in a November 29, 2016 letter to DRL, and 2) subsequent events cured DRL of prejudice. DRL contends that these arguments are new and were not presented to the Magistrate Judge. *See Silver Streak Indus., LLC v. Squire Boone Caverns, Inc.*, No. 4:13-CV-00173-RLY, 2014 WL 220682, at *1 (S.D. Ind. Jan. 21, 2014) ("New arguments and evidence may not be raised for the first time in a reply brief. Reply briefs are for replying, not raising new arguments or arguments that could have been advanced in the opening brief"); *see also United States v. Melgar*, 227 F.3d 1038, 1040 (7th Cir. 2000) ("district courts should not consider arguments not raised initially before the magistrate judge").

Upon review of the parties' briefing, the Court determines that Lilly's Reply Brief did not inject new evidence, arguments, or issues. Instead, the Reply Brief provided Lilly's response to the arguments advanced by DRL in its Response Brief. Specifically, Lilly asserts that DRL maintained notice of Lilly's claims and DRL will not suffer prejudice by the inclusion of Lilly's expert reports. Accordingly, the Court **denies** DRL's Motion to Strike arguments in Lilly's reply brief. *See Lady Di's, Inc. v. Enhanced Servs. Billing, Inc.*, 2010 U.S. Dist. LEXIS 29463, at *4 (S.D. Ind. Mar. 25, 2010) (The "purpose for having a motion, response and reply is to give the movant the final opportunity to be heard and *to rebut the non-movant's response*, thereby

persuading the court that the movant is entitled to the relief requested by the motion") (emphasis added).

B. Lilly's Infringement Contentions.

Regarding the merits of the motion to strike portions of its expert report, Lilly argues that the Magistrate Judge erred in excluding paragraphs 38-47, 60-61, 63-73, and 77-82 of Dr. Chabner's report, as well as paragraphs 15 and 16 of Dr. Pinal's report because the issues addressed in those paragraphs were disclosed on September 6, 2016 in Lilly's infringement contentions.

The Court agrees. The Magistrate Judge erred in striking paragraphs 38 through 47, as well as certain sections in paragraph 63 of Dr. Chabner's report, which address DRL's infringement on the '209 patent with respect to the administration of folic acid and vitamin B_{12}. (*See* Filing No. 76 at 21-22.) The Magistrate Judge concluded that these paragraphs regard literal infringement and that Lilly did not disclose literal infringement in its infringement contentions. To the contrary, Lilly's infringement contentions make clear that, "the use of DRL's NDA Products meets all limitations of each of the asserted claims, either *literally* or under the doctrine of equivalents" because, among other things, "the labeling for DRL's NDA Products directs administration of…*folic acid"* and *"vitamin* B_{12}*."* (Filing No. 48 at 1; 5-10; 11-14) (emphasis added).

The Court also finds error in striking paragraphs 60-61, 64-73, and 77-80 of Dr. Chabner's report, as well as paragraphs 15 and 16 of Dr. Pinal's report. These paragraphs explain that DRL's administration of pemetrexed ditromethamine amounts to infringement under the doctrine of equivalents because it performs in substantially the same way as Lilly's administration of pemetrexed disodium under the '209 patent. The Magistrate Judge concluded that the experts' analyses amount to new theories under the doctrine of equivalents and are outside the scope of

Lilly's infringement contentions. The Court disagrees and notes that, similar to the expert reports, Lilly's infringement contentions state verbatim that:

> DRL's NDA Products contain "pemetrexed ditromethamine." DRL0000171. There is an insubstantial difference between administering pemetrexed ditromethamine and administering pemetrexed disodium in accordance with claim 1; pemetrexed ditromethamine performs substantially the same function in substantially the same way to achieve substantially the same result as the pemetrexed disodium as claimed in claim 1.

(Filing No. 48 at 4) (emphasis added).

Lastly, the Magistrate Judge erred when concluding paragraphs 81 and 82 of Dr. Chabner's report assert new theories. In those paragraphs, Dr. Chabner explains that the NDA Products' label induces and contributes to infringement of the '209 patent. Lilly's infringement contentions state "DRL is liable as a direct infringer based on the filing of its NDA, as well as for a*ctive inducement of infringement and/or for contributory infringement*." (Filing No. 48 at 3-4.) The contentions go on to state that "the labeling for DRI's NDA Products *directs*" administration of certain drugs in a way that infringes on the '209 patent. *See id.* at 4-6 (emphasis added). The parties concede that DRL is a pharmaceutical company, rather than a physician. Therefore, the Court finds it reasonably clear from the infringement contentions that the term "directs" refer to Lilly's claim that DRL induces and contributes to physicians and others administering DRL's NDA Products in a way that infringes on the '209 patent. *See Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 188 (1980) (noting the purpose of the contributory infringement statute is "to protect patent rights from subversion by those who, without directly infringing the patent themselves, engage in acts designed to facilitate infringement by others"); *see also PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1357 (Fed. Cir. 2007) ("a person who provides a service that assists another in committing patent infringement may be subject to liability under section 271(b) for active inducement of infringement").

Although "[e]xpert infringement reports may not introduce theories not previously set forth in infringement contentions", "[i]nfringement contentions are generally considered adequate if they *provide fair notice* of the scope of the plaintiff's infringement theory." *Trading Techs. Int'l, Inc. v. CQG, Inc.*, No. 05-CV-4811, 2014 WL 4477932, at *2 (N.D. Ill. Sept. 10, 2014) (emphasis added). Accordingly, the Court **reverses** the Magistrate Judge's Order with respect to paragraphs 38-47, 60-61, 63-73, and 77-82 of Dr. Chabner's report, as well as paragraphs 15 and 16 of Dr. Pinal's report because Lilly's infringement contentions disclosed the information in those paragraphs. *See Weeks*, 126 F.3d at 943 (the clear error standard permits reversal when the district court "is left with the definite and firm conviction that a mistake has been made.").

The Court notes, and Lilly concedes, that its infringement contentions did not disclose its claim that the administration of DRL's pemetrexed ditromethamine in conjunction with cisplatin amounts to administration of Lilly's pemetrexed disodium. This information is included in paragraphs 48 through 59 of Dr. Chabner's report and paragraphs 72 and 73 of Dr. Pinal's report. For the reasons discussed below, however, the Court reverses the Order striking those paragraphs.

C. <u>The Case Management Plan</u>.

The Magistrate Judge granted DRL's Motion to Strike large portions of Lilly's expert reports after concluding Lilly violated the CMP's infringement contentions deadline. Lilly argues that the Court should reverse the sanction because Lilly did not have notice that "final", rather than "preliminary", infringement contentions were due September 6, 2016. Lilly points to the language directly preceding the CMP's deadline for infringement contentions, which states:

> Given that many of documents and witnesses concerning the DRL Defendants' proposed NDA product are in India, and given the degree of complexity of the scientific issues involved (and the concomitant need for expert testimony, including from clinicians), the parties anticipate that both fact and expert discovery concerning infringement will take longer than for most cases.

> Accordingly, all liability discovery—both fact and expert—must be completed by **May 15, 2017**…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*.

(Filing No. 45 at 4-5) (emphasis added). Lilly contends, based on the CMP's "*preliminary infringement and invalidity contentions*" language, it mistakenly thought that the infringement contentions due on September 6, 2016 were "preliminary", hence Lilly filing *Preliminary Infringement Contentions* on September 6, 2016. (*See* Filing No. 48.) Lilly also points to the following passage from the CMP when arguing that it reasonably believed "final" infringement contentions were due by May 30, 2017:

> *Within 14 days after the liability discovery deadline* (*i.e.*, by **May 30, 2017**), and consistent with the certification provisions of Fed. R. Civ. Proc. 11(b), *the party with the burden of proof must file a statement of the claims* or defenses it intends to prove at trial, *stating specifically the legal theories upon which the claims* or defenses *are based*.

(Filing No. 45 at 7) (emphasis added).

After reviewing the CMP, the Court finds Lilly did not have actual notice that the September 6, 2016 deadline amounted to a "final" rather than "preliminary" deadline. Although September 6, 2016 is the only deadline that specifically states "infringement contentions," the CMP appears to anticipate both "preliminary" and "final" infringement contentions. (*See* Filing No. 45 at 4-5 "[t]he 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") (emphasis added). The Court also notes that the September 6, 2016 deadline was very early in the discovery process—nearly eight months prior to the liability discovery deadline. Accordingly, the Court finds it reasonable for Lilly to believe that only preliminary infringement contentions were due at such an early date in discovery. *See id.* Because the CMP did not give sufficient notice that final infringement contentions were due on September 6, 2016, the Court

sustains Lilly's objection as to each excluded paragraph of Lilly's expert reports. *See* Fed. R. Civ. P. 83 ("No sanction or other disadvantage may be imposed for noncompliance with any requirement not in federal law, federal rules, or the local rules unless the alleged violator has been furnished in the particular case with actual notice of the requirement"); *see also Massachusetts Inst. of Tech. & Elecs. For Imaging, Inc. v. Abacus Software*, 462 F.3d 1344, 1359 (Fed. Cir. 2006) (concluding the district court erred in barring plaintiff's claim against Windows as an infringing product because plaintiff was not given sufficient notice that its preliminary contentions would be deemed final or that plaintiff could update the contentions only after a showing of good cause).

D. Four-Factor Expert Exclusion test

The Court briefly discusses the four-factor expert exclusion test. In deciding whether to impose sanctions for a discovery violation, the Court considers: 1) the prejudice to DRL; 2) the ability of Lilly to cure the prejudice; 3) the likelihood of disruption to the trial; and 4) the bad faith or willfulness involved in not disclosing the evidence at an earlier date. *Judson Atkinson Candies, Inc. v. Latini-Hohberger Dhimantec*, 529 F.3d 371, 386 (7th Cir. 2008) (quoting *David v. Caterpillar, Inc.*, 324 F.3d 851, 857 (7th Cir. 2003)); *Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, No. 1:10-CV-01376-TWP, 2015 WL 735724, at *3 (S.D. Ind. Feb. 20, 2015).

The Magistrate Judge concluded that the inclusion of certain paragraphs in Lilly's expert reports will cause DRL to suffer substantial prejudice because: "DRL will be forced to choose between rushed discovery related to the new contentions… [and] will require DRL to find and retain additional experts and conduct other appropriate discovery." (Filing No. 96 at 18.) The Order goes on to state "that the only way for DRL to accomplish this within the current discovery deadline would be with undue haste, posing a risk of reduced quality of expert opinions." *Id.*

The Court previously found that Lilly did not violate any discovery deadlines with respect to paragraphs 38-47, 60-61, 63-73, and 77-82 of Dr. Chabner's report, as well as paragraphs 15 and 16 of Dr. Pinal's report. Accordingly, DRL is not prejudiced by the inclusion of those paragraphs. The Court also concludes, despite the Magistrate Judge's holding, the inclusion of Lilly's expert reports will not prejudice DRL because DRL recently conducted discovery and served responsive expert reports regarding each and every infringement theory discussed in Lilly's expert reports. Because any prejudice to DRL is cured and the trial remains scheduled for January 29, 2018, the Court **sustains** Lilly's objection.

IV. CONCLUSION

For the above-mentioned reasons, the Court **SUSTAINS** Lilly's Objection to Order to Strike Portions of Plaintiff's Expert Reports (Filing No. 97) in its entirety. In addition, the Court **DENIES** DRL's Motion to Strike New Arguments in Plaintiff's Reply Brief (Filing No. 112). The Court specifically concludes that Lilly disclosed in its infringement contention the information contained in paragraphs 38-47, 60-61, 63-73, and 77-82 of Dr. Chabner's report, as well as paragraphs 15 and 16 of Dr. Pinal's report. The Court also concludes that DRL is not prejudiced by the inclusion of Lilly's expert reports and that the CMP did not provide sufficient notice that September 6, 2016 amounted to the "final" contentions' deadline.

SO ORDERED.

Date: 9/6/2017

TANYA WALTON PRATT, JUDGE
United States District Court
Southern District of Indiana

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