UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

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

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

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