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

Meets the Pemetrexed Disodium Limitation in the Claims of the '209 Patent," comprised of paragraphs 72 and 73 at page 30 of the report; and (2) a partial doctrine of equivalents analysis under the function-way-result test in paragraphs 15 and 16 at pages 4-5.

DRL's counsel contacted Lilly's counsel and asserted that Lilly's expert reports violated the PCMP by raising new infringement contentions not disclosed in the *Infringement Contentions*. The parties attempted to resolve their dispute in a telephone conference, but were unable to do so.

On January 9, 2017, the parties filed a joint motion for extension of time for discovery and related deadlines, including the deadline for expert reports. The motion was granted, and the deadline for opening expert reports was extended to March 7, 2017. The parties moved for another extension of the discovery and related deadlines, and their motion was granted, extending the deadline for opening expert reports to March 21, 2017.

Lilly never sought a modification of the infringement contentions deadline. Nor has it sought leave to amend its *Infringement Contentions*.

On March 31, 2017, DRL filed its *Motion to Strike*. The undersigned attempted to resolve the parties' dispute informally during a telephonic conference but was unable to do so. Lilly has filed a response to the motion, and DRL has filed its reply. The motion has been referred to the undersigned for ruling.

Discussion

A court scheduling order "controls the course of the action unless the court modifies it." Fed. R. Civ. P. 16(d). Federal Rules of Civil Procedure 16(b) and 6(b) govern motions to modify scheduling orders filed after the deadline sought to be modified has

expired. "A schedule may be modified only for good cause and with the judge's consent." Fed. R. Civ. P. 16(b)(4); *see Trustmark Ins. Co. v. Gen. & Cologne Life Re of Am.*, 424 F.3d 542, 553 (7th Cir. 2005) ("To amend a pleading after the expiration of the trial court's Scheduling Order deadline …, the moving party must show 'good cause.'"). The "good cause" standard focuses on the party's diligence. *Trustmark Ins. Co.*, 424 F.3d at 553. Further, "[w]hen an act may or must be done within a specified time, the court may, for good cause, extend the time … on motion made after the time has expired if the party failed to act because of excusable neglect." Fed. R. Civ. P. 6(b)(1)(B). Under Rule 16 "the court may issue any just orders, including those authorized by Rule 37(b)(2)(A)(ii)-(vii)" for the failure "to obey a scheduling or other pretrial order." Fed. R. Civ. P. 16(f)(1)(C). Such orders include striking expert witness testimony and portions of an expert report that violate the court's scheduling order. Fed. R. Civ. P. 37(b)(2)(A)(ii).

"[I]nfringement contentions are intended to frame the scope of the case so that the parties can conduct appropriate discovery." *Robert Bosch LLC v. Snap-On Inc.*, No. 12-11503, 2013 WL 673718, at *3 (E.D. Mich. Feb. 25, 2013) (quoting *Realtime Data, LLC v. Packeteer, Inc.*, No. 6:08cv144, 2009 WL 2590101, at *5 (E.D. Tex. Aug. 18, 2009)). Infringement contentions should "'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) (quoting *Fujitsu Ltd. v. Tellabs Operations, Inc.*, No. 08 C 3379 & 09 C 4530, 2012 U.S. Dist. LEXIS 101766, *25 (N.D. Ill. July 23, 2012)). Thus, "'infringement contentions must set forth particular theories of infringement with sufficient specificity to provide defendants with notice of infringement'" and expert

"'reports may not introduce theories not previously set forth in infringement contentions.'" *Id.* Mere reference to a theory in infringement contentions may not act as a placeholder for later clarification of the theory. *Trading Techs. Int'l*, 2014 WL 4477932, at *3-4; *ASUS Computer Int'l v. Round Rock Research, LLC*, Case No. 12-cv-02099 JST (NC), 2014 WL 1463609, at *3 (N.D. Cal. Apr. 11, 2014) (placeholder language stating that "to the extent that any claim element is found not to be literally embodied in the Accused Instrumentalities, [defendant] contends that the Accused Instrumentalities embody such claim elements under the doctrine of equivalents" was insufficient to assert infringement under the doctrine of equivalents and defendant's experts could not assert that theory).

Courts have stricken theories of infringement presented in expert reports that were not previously disclosed in infringement contentions. *See, e.g.*, *Howmedica Osteonics Corp. v. Zimmer*, 822 F.3d 1312, 1324-25 (Fed. Cir. 2016) (concluding district court did not abuse its discretion in applying local patent rules to preclude theory that was not disclosed in infringement contentions); *Baltimore Aircoil Co. v. SPX Cooling Techs. Inc.*, Civ. No. CCB-13-2053, 2016 WL 4426681, at *15 (D. Md. Aug. 22, 2016) (granting motion to strike portions of expert report regarding infringement under doctrine of equivalents that was not disclosed in infringement contentions); *Trading Techs. Int'l*, 2014 WL 4477932, at *3-4, *5 (striking doctrine of equivalents argument in expert report and precluding reliance on theories and evidence related to stricken portions where infringement contentions addressed only literal infringement). "The threshold question in deciding whether to strike an expert report is whether the expert has permissibly specified the application of

a disclosed theory or impermissibly substituted a new theory altogether." *Finjan, Inc. v. Proofpoint, Inc.*, No. 13-cv-05808-HSG, 2016 WL 612907, at *1 (N.D. Cal. Feb. 16, 2016).

Lilly contends that the authorities cited by DRL where courts struck portions of expert reports that relied on theories not disclosed in the infringement contentions are inapposite because the infringement contentions at issue were "final" or "supplemental" and were served after the close of discovery. While discovery was closed when the new theories were presented in the expert reports, which is an important consideration, it is not the only relevant consideration. The crux of the matter was the prejudice to the opposing party. Here, although discovery is not yet closed, as discussed later in this Entry, the prejudice to DRL in allowing Lilly to proceed on its new infringement theories is substantial.

Lilly also argues that DRL's authorities are inapplicable because those cases involved violations of local patent rules or court orders regarding the timing of infringement contentions and supplementation thereof. This distinction is of no practical or legal importance. Here, the Court entered an order approving the PCMP as amended, setting the deadline for disclosure of infringement contentions. As a court scheduling order, the order controls the course of this case. Lilly offers no persuasive reason why a violation of the Court's scheduling order should be treated less seriously than a violation of a local patent rule. *See* O2 *Micro Int'l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1363 (Fed. Cir. 2006) (stating that local patent rules "are essentially a series of case management orders"). Though the PCMP does not describe the infringement contentions due on September 6, 2016, as "final"; no language in the PCMP provides that the

contentions are "preliminary" either. The text of the PCMP is clear: Lilly's infringement contentions were due September 6, 2016. The PCMP did not contemplate separate "preliminary" and "final" contentions, but rather, "infringement contentions."

Review of the *Infringement Contentions* confirms DRL's assertion that the contentions address only the doctrine of equivalents. [*See, e.g.*, *Infringement Contentions*, doc. 48 at 2 ("There is an insubstantial difference between administering pemetrexed ditromethamine and administering pemetrexed disodium in accordance with claim 1.")] In addition, counsel's November 29, 2016 letter indicated that Lilly's contentions disclose infringement under the doctrine of equivalents; it does not even hint at any other theory of infringement. Thus, the letter reinforced the DRL's view that Lilly was asserting infringement under the doctrine of equivalents only, and not under any other theory.

Lilly offers that its letter was responding to DRL's own letter that only raised the deficiency of Lilly's infringement contentions under the doctrine of equivalents. But contrary to Lilly's suggestion, its *Infringement Contentions* did not plainly and sufficiently present the theories of literal infringement, inducement or contribution. While the *Infringement Contentions* state that "[t]he use of DRL's NDA Products meet all limitations of each of the asserted claims, either literally or under the doctrine of equivalents" [doc. 48 at 1], this conclusory assertion in an introductory paragraph of the contentions is insufficient to assert a theory of literal infringement, particularly where the accompanying claim chart fails to raise literal infringement. *See, e.g.*, *Baltimore Aircoil Co.*, 2016 WL 4426681, at *15 ("Allowing [plaintiff] to offer specific opinions under the doctrine of equivalents theory after it disclosed only its general belief that all claims were

infringed under the doctrine … would unfairly disadvantage [defendant] by subjecting it to a 'shifting sands approach' to litigation."). The same is true with regard to mere references in the introductory paragraph to theories of literal infringement, active inducement of infringement, and contributory infringement; these theories are asserted with insufficient particularity to give DRL fair notice of the scope of Lilly's infringement theory.

Lilly's *Infringement Contentions* purport to "reserve[] the right to modify, amend, or otherwise supplement these contentions as additional information becomes available during the court of fact and expert discovery." [Doc. 48 at 1.] But Lilly has no right to modify or amend its contentions after the deadline for filing infringement-contentions has expired. *See, e.g.*, *Baltimore Aircoil Co.*, 2016 WL 4426681, at *16 (rejecting the argument that plaintiff reserved the right to amend its infringement contentions where local rules required consent or good cause and leave of court for amendments); *Howmedica Osteonics Corp. v. Depuy Orthopaedics, Inc.*, Civil Action No. 11-6498 (SDW), 2014 WL 6675923, at *2, *4-5 (D.N.J. Nov. 24, 2014) (concluding that general reservation in infringement contentions of right to pursue theory under doctrine of equivalents was insufficient under local rules), *aff'd sub nom.*, *Howmedica Osteonics Corp. v. Zimmer*, 822 F.3d 1312 (Fed. Cir. 2016). Because the infringement-contentions deadline was entered as part of the Court's Rule 16(b) scheduling order, Lilly could modify or amend its contentions only upon first showing "good cause" and with the Court's consent. *See* Fed. R. Civ. P. 16(b)(4); S.D. Ind. L.R. 16–1(e). And since Lilly's expert reports effectively amend its infringement contentions after the time for filing contentions has expired, Federal Rule of Civil

Procedure 6(b) further requires a motion and "excusable neglect." Lilly has not shown good cause or excusable neglect. And Lilly has never requested the Court's permission to amend or modify its infringement contentions.

As for Lilly's right to supplement its contentions, Federal Rule of Civil Procedure 26(e) imposes a duty to supplement Rule 16 disclosures in a timely manner. Fed. R. Civ. P. 26(e)(1); *see Teashot LLC v. Green Mountain Coffee Roasters, Inc.*, Civil Action No. 12-cv-0198-WJM-KMT, 2014 WL 485876, at *6-7 (D. Colo. Feb. 6, 2014) (explaining that a party's infringement contentions subject to the scheduling order "operated as the legal and functional equivalent of responses to interrogatories, and were therefore subject to Rule 26(e)'s requirements"). Yet, Lilly's expert reports go way beyond supplementation of the *Infringement Contentions*; they seek to assert entirely *new* theories of infringement. And to the extent the expert reports supplement the contentions as to the doctrine of equivalents, Lilly has not properly supplemented its *Infringement Contentions*. Instead, it attempts to do so through a side door, which is improper.

Lilly argues its *Infringement Contentions* were only "preliminary." After all, it says, the PCMP identified its contentions as "preliminary" and the contentions themselves are titled, "*Preliminary Infringement Contentions*." While the PCMP mentioned "preliminary infringement and invalidity contentions" in the first section concerning discovery and related deadlines, the use of the word "preliminary" appears to be a carryover from another, possibly earlier, version of the Court's standard PCMP. The use of the term "preliminary" in the section preceding the section addressing the dispute over the deadline for infringement contentions does not convey the intent that the contentions be

only preliminary. Furthermore, the Court inserted language regarding the deadline for infringement contentions that does not refer to the contentions as "preliminary." This language provides even greater clarity. Moreover, DRL has pointed to other patent case management plans that did set deadlines for both preliminary contentions and final contentions. [*See, e.g.*, *Reply Brief, Ex. H* at 4-5, 9, doc. 92-4 at 4-5, 9.] Some of these patent case management plans were entered in cases in which Lilly is a party. The other case management plans show that the parties and the Court allow for preliminary contentions when they intend for the contentions to be preliminary. But the PCMP in this case does not make a distinction between preliminary and final contentions. The September 6, 2016 deadline for infringement contentions was the only infringement-contentions deadline contemplated by the Court's order.

That Lilly chose to identify its infringement contentions as "Preliminary" is not controlling where the order does not identify the contentions as "preliminary." The fact that DRL referred to the contentions as "Preliminary Infringement Contentions" is not controlling: DRL was simply using Lilly's own terminology. Lilly argues that DRL took a position in its March 10 letter to counsel that is inconsistent with its position here: DRL thought Lilly should supplement its contentions. Yet, an earlier request for supplementation does not preclude DRL from arguing that the expert reports improperly and belatedly introduce new infringement theories. And the fact that DRL could have filed a motion seeking to compel Lilly to supplement its contentions, but did not do so, does not relieve Lilly of any consequences coming from its late disclosures after the deadline for infringement contentions has passed. *See Teashot LLC*, 2014 WL 485876, at *7

(noting that defendants were not required to complain about Plaintiff's contentions or serve discovery related to plaintiff's infringement theories).

Lilly attempts to fault DRL for not surmising that Lilly would assert theories of infringement other than that specifically raised in its *Infringement Contentions*. DRL had a right to believe that the *Infringement Contentions* asserted all of Lilly's theories it was pursuing in this case. *See Teashot LLC*, 2014 WL 485876, at *7 ("A party has the right to assume that opposing counsel is acting with diligence, and in compliance with the Federal Rules of Civil Procedure, during discovery. Because Plaintiff was already ordered … to provide its infringement contentions, and required by Rule 26€ to timely supplement the same, Defendants were justified in believing that Plaintiff's disclosures contained all of the infringement theories it was pursuing in the case."). Besides, if DRL who was not a party to *Teva Parenteral Medicines* litigation should have divined that Lilly would assert the same theories it raised in that litigation, then Lilly who was *the plaintiff* in that litigation should have known it would raise all those same theories in this case. Also, DRL's awareness of that prior litigation may explain why DRL could have thought (as Lilly argues) that DRL would receive "final" contentions early in the discovery phase. Further, *Teva Parenteral Medicines* involved the defendants' generic version of Lilly's ALIMTA®, whereas this case does not involve a generic—DRL's product is pemetrexed ditromethamine, not pemetrexed disodium. Thus, in contrast with the *Teva Parenteral Medicines*, this case has been about infringement under the doctrine of equivalents.

Lilly asserts that it served its *Infringement Contentions* near the beginning of discovery and long before it had received the information necessary to develop that

information with its experts and build its infringement case. (More on that later.) Yet Lilly still has not sought leave to amend its *Infringement Contentions* at any time. Its failure to have done so by even this late point in time suggests a lack of diligence on Lilly's part.

As for Lilly's argument that it has not sought to alter a scheduling order and it has complied with the scheduling order, this argument elevates form over substance. With its expert reports, Lilly attempts to introduce new theories of infringement into the case, and does so without seeking leave to amend its infringement contentions. Because the deadline for infringement contentions has long passed, good cause and excusable neglect, in addition to the court's consent, are required for Lilly to assert new theories that go beyond those timely identified in the *Infringement Contentions*.

Lilly contends that absent prior notice to a party that infringement contentions cannot be amended, a court errs in precluding a party from amending its contentions. But *MIT v. Abacus Software*, 462 F.3d 1344 (Fed. Cir. 2006), cited as support, is inapposite. This case is unlike *MIT* where, after the plaintiff had filed its preliminary infringement contentions, the court ordered that the preliminary contentions were deemed final. *Id.* at 1358. The court concluded that the plaintiff was not given sufficient notice that its preliminary contentions would be deemed final or that it could only update them for good cause. *Id.* at 1359. Unlike *MIT*, Lilly's contentions were not "preliminary" and preliminary contentions were not deemed "final" after the fact. The PCMP and Federal and Local rules provided Lilly with sufficient notice that modifying or amending their infringement contentions would require a showing of "good cause."

The Chabner and Pinal reports seek to introduce new theories of infringement not properly disclosed in the *Infringement Contentions*. Lilly's belated disclosure of these new theories violated the PCMP. Thus, the Court must decide the appropriate sanction for the failure to disclose these new theories of infringement.

In deciding whether to impose sanctions for a discovery violation, a district court should consider: "(1) the prejudice or surprise to the party against whom the evidence is being offered; (2) the ability of the party 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)). Although *Judson Atkinson Candies* addressed the imposition of sanctions for a Rule 45 violation, the factors identified apply equally to the consideration of whether sanctions are appropriate for other discovery rule violations. *See Eli Lilly and Co. v. Teva Parenteral Medicines, Inc.*, No. 1:10-cv-01376-TWP-DKL, 2015 WL 735724, at *3 (S.D. Ind. Feb. 20, 2015) (applying factors to exclude expert testimony and evidence relating to the infringement under the doctrine of equivalents on the ground that report failed to comply with Rule 26(a)).

DRL contends that they are prejudiced by Lilly's belated infringement contentions in several ways. First, they argue that they formulated their defense strategy, discovery plan, expert work, and case preparation based on the *Infringement Contentions* and counsel's representations that the contentions were sufficient under the doctrine of equivalents. DRL asserts that allowing Lilly to augment its infringement theories at this

stage in the proceedings would require DRL to undertake additional discovery, including finding new experts, with an enlarged deadline for discovery, and DRL would incur substantial additional expenses. An enlargement of the discovery deadline, DRL argues, would require extension of other case management deadlines, including the deadline for expert disclosures and reports. DRL submits that even without additional time for discovery, because of the new theories advanced in the expert reports, the expert discovery deadlines need to be enlarged by at least sixty days. Most importantly, DRL asserts that they have a great interest in resolving this action within the thirty-month Hatch-Waxman Act stay. DRL maintains that Lilly's late disclosure of its new contentions jeopardizes the ability to resolve this action within the stay, thus exposing DRL to substantial harm including a "launch at risk" scenario, and a modification of the case management deadlines cannot avoid this risk of harm. The deadlines for expert reports has already been extended—twice—at Lilly's request but with DRL's consent. [*See* docs. 60 & 67.]

Lilly argues that it served its expert reports months before the close of fact and expert discovery and that under the PCMP, a party need not provide a statement of its claims and defenses it intends to prove at trial until after the close of discovery. The statement of claims and defenses to be proven at trial may contemplate refinement of the theories of infringement. But greater clarity is required to transform this deadline into a deadline for infringement contentions. Furthermore, "infringement contentions are intended to frame the scope of the case so that the parties can conduct appropriate discovery." *Robert Bosch*, 2013 WL 673718, at *3. Springing the new infringement theories

on DRL so close to the discovery deadline may deprive DRL of the full opportunity to conduct appropriate discovery before the deadline. According to Lilly, nothing prevents DRL from taking more discovery and serving additional expert reports; the fact and expert discovery deadline is not until June 20, 2017. Lilly asserts that DRL had not taken a single deposition or filed a single expert report when they filed their motion to strike. Lilly also maintains that there is sufficient time to extend the discovery deadline and that the trial date and timeline for resolving this case would not be jeopardized.

However, the undersigned agrees that DRL will suffer substantial prejudice from Lilly's belated disclosure of new infringement contentions. Because of the late disclosure, DRL will be forced to choose between rushed discovery related to the new contentions, in the event the June 20, 2017 fact and expert discovery deadline is held firm, or an enlargement of the discovery deadline and other case management deadlines, including the dispositive motion deadline of July 14, 2017. The new contentions will require DRL to find and retain additional experts and conduct other appropriate discovery. It seems 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. Enlargements of the discovery and other deadlines would, undoubtedly, jeopardize the January 2018 trial setting. And it follows from any continuance of the trial setting—a setting picked to allow for resolution of this case before the expiration of the thirty-month stay—that resolution before the expiration of the stay is put in peril. Of course, it is reasonable to expect post-trial briefs and filings that will all have to be addressed by the Court in order to resolve the case. That all takes time. Lilly underestimates how much time is needed

to allow for a thoughtful, informed, and correct decision in the case. And there simply is no way to cure the prejudice—enlarging the remaining deadlines could alleviate the prejudice caused by hasty discovery, but only with the trade-off of jeopardizing the hopes of resolving this case before the end of the stay. Either way, DRL suffers substantial prejudice.

Lilly claims there was no bad faith on its part—that it developed the "new" theories during fact discovery, working with its experts and disclosed them promptly. It maintains that the analysis in its expert reports is based on confidential and other information provided by DRL through discovery as well as testimony from a witness deposed in March 2017. The undersigned's review of the cited portions of the expert reports [*see Chabner Report*, doc. 75, at 10-12, 17-22, 30-31, 39-40; *Pinal Report*, doc. 75 at 47-62], however, reveals that Lilly's new theories are based on DRL's labeling. The labeling was disclosed to Lilly on May 26, 2016, as part of DRL's NDA. Although the labeling has been updated and Dr. Chabner cites the updated labeling produced September 5, 2016, there has been no showing that the two labels are different in any relevant respect. And Dr. Pinal's references to documents produced after the September 6, 2016 deadline and testimony from the Veerender deposition do not appear to have been critical to Dr. Pinal's conclusions regarding whether pemetrexed disodium and pemetrexed ditromethamine are equivalent in the context of the method of administration claimed in the '209 patent and whether both substances are ionic salts that dissociate in solution. [*See* Pinal Report, doc. 75 at pages 17-23. Thus, Lilly should have disclosed its new theories at an earlier time and had no justification for waiting until filing its expert reports.

Therefore, the undersigned finds that the *Motion to Strike* should be granted.

Conclusion

DRL's *Motion to Strike Portions of Plaintiff's Expert Reports* [doc. 74] is **granted**. The following portions of the Chabner Report, dated March 21, 2017, attached as Appendix 1 to the sealed proposed order found at ECF No. 76, are **stricken**:

(1) The literal infringement analysis and opinion at Exhibit C (a Claim Chart) to the report and in paragraphs 38-59 at pages 15-28 and literal infringement-related statements in the report (see, *e.g.*, ¶¶ 60, 63, and 80);

(2) The "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) Portions of the 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 following portions of the Pinal Report, dated March 21, 2017, attached as Appendix II to the sealed proposed order found at ECF No. 76 are **stricken**:

(1) The partial doctrine of equivalents analysis under the function-way-result test in paragraphs 15 and 16 at pages 4-5; 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," comprised of paragraphs 72 and 73 at page 30.

These portions of the expert reports are highlighted in green in Appendices I and II found at ECF No. 76.

It is **ordered** that Lilly not argue or introduce evidence regarding the stricken infringement contentions, opinions, and underlying bases therefor.

DATED: 4/28/2017

Denise K. LaRue
United States Magistrate Judge
Southern District of Indiana

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