UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY, Plaintiff, v. TEVA PARENTERAL MEDICINES, INC., APP PHARMACEUTICALS, LLC, PLIVA HRVATSKA D.O.O., TEVA PHARMACEUTICALS USA INC., BARR LABORATORIES, INC., Defendants.	)	Case No. 1:10-cv-01376-TWP-DKL
ELI LILLY AND COMPANY 1:11-cv-00942-TWP-TAB, Consol Plaintiff, v. APP PHARMACEUTICALS, LLC 1:11-cv-00942-TWP-TAB, Consol Defendants.	)	

ENTRY ON MOTION *IN LIMINE*

This matter is before the Court on a Motion *in Limine* filed by Defendants Teva Parenternal Medicines, Inc., Teva Pharmaceuticals USA, Inc. (collectively, "Teva"), APP Pharmaceuticals, LLC ("APP"), Pliva Hrvastka D.O.O. ("Pliva"), and Barr Laboratories, Inc. ("Barr") (collectively, "Defendants") (Filing No. 370). Defendants seek to prevent Plaintiff Eli Lilly and Company ("Lilly") from offering any testimony or evidence relating to the claim of infringement under the doctrine of equivalents. For the reasons set forth below, Defendants' Motion is **DENIED**.

I. BACKGROUND

This is a patent infringement case involving the administration of pemetrexed disodium ("pemetrexed"), which Lilly markets as the drug ALIMTA® for the treatment of malignant pleural mesothelioma. U.S. Patent No. 7,772,209 (the "'209 patent" or "patent-in-suit") covers the administration of folic acid and vitamin B_{12} followed by the administration of pemetrexed, which reduces the toxicity of pemetrexed. Lilly obtained the patent-in-suit in August 2010. Lilly sued Defendants for infringement of the '209 patent based on Defendants' filing of Abbreviated New Drug Applications ("ANDAs") seeking United States Food & Drug Administration ("FDA") approval to sell generic versions of Lilly's ALIMTA® treatment before the expiration of the '209 patent.

Following a bench trial on the issue of the validity of the '209 patent in August 2013, this Court upheld the validity of every asserted claim of the '209 patent. (Filing No. 336). Prior to the bench trial, Defendants conditionally stipulated that under the law of infringement at that time, the sale of its ANDA products would induce the infringement of the asserted claims, and thus would have been liable for infringement. (Filing No. 233 at ECF p. 2). This stipulation was contingent upon the U.S. Supreme Court's decision in *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S.Ct. 2111, 2117 (2014), in which the court was to determine the legal standard for inducement of infringement. Because the Supreme Court ruled that for there to be inducement of infringement there must be an underlying direct infringer, this case was remanded for a bench trial on the issue of infringement. The parties agreed that no additional fact or expert discovery was required, and that a trial would proceed on the basis of the prior disclosures and record.

II. LEGAL STANDARD

The Court excludes evidence on a motion *in limine* only if the evidence clearly is not admissible for any purpose. *See Hawthorne Partners v. AT&T Techs., Inc.*, 831 F. Supp. 1398, 1400 (N.D. Ill. 1993). Unless evidence meets this exacting standard, evidentiary rulings must be deferred until trial so questions of foundation, relevancy, and prejudice may be resolved in context. *Id*. at 1400–01. Moreover, denial of a motion *in limine* does not necessarily mean that all evidence contemplated by the motion is admissible; rather, it only means that, at the pretrial stage, the court is unable to determine whether the evidence should be excluded. *Id*. at 1401.

III. DISCUSSION

Defendants ask the Court to exclude any testimony or evidence by Lilly regarding the doctrine of equivalents as a theory of infringement. "[A] patentee may invoke this doctrine to proceed against the producer of a device if it performs substantially the same function in substantially the same way to obtain the same result." *Graver Tank & Mfg. Co. v. Linde Air Products Co.*, 339 U.S. 605, 608 (1950) (internal quotations omitted). Defendants assert that this is a "new" theory that was not previously disclosed by Lilly as a basis for its infringement allegations, and that it was only disclosed for the first time in Lilly's Pre-Trial Brief regarding infringement. (Filing No. 369). More specifically, Defendants argue that Lilly's expert, Dr. Bruce Chabner ("Dr. Chabner"), did not provide a substantive analysis of infringement under the doctrine of equivalents in his expert report served on January 8, 2013, therefore, his testimony should be excluded under Federal Rule of Civil Procedure 37(c)(1) for failure to disclose under Rule 26(a)(2(B).

Defendants have not provided any basis for excluding all evidence and testimony on the doctrine of equivalents. The cases cited by Defendants do not support their position that all such evidence should be excluded under these circumstances, or even that the testimony of Dr. Chabner should be excluded. Defendants argue that *AquaTex Indus., Inc. v. Techniche Solutions*, 479 F.3d 1320 (Fed. Cir. 2007), stands for the proposition that the expert report must include "particularized testimony and linking argument as to the 'insubstantiality of the differences' between the claimed invention and the accused . . . process," and because Dr. Chabner's expert report failed to do so, it must be excluded. 479 F.3d at 1328; *see also Hewlett-Packard Co. v. Mustek Sys., Inc.*, 340 F.3d 1314, 1323 (Fed. Cir. 2003). However, in the cases cited by Defendants, the issue was whether sufficient evidence was presented at summary judgment or trial, not whether the Rule 26 expert disclosure was adequate. *See AquaTex*, 479 F.3d at 1323 ("[W]e affirm the grant of summary judgment because AquaTex did not satisfy its burden to present particularized evidence of equivalents *in opposition to the motion for summary judgment*.") (emphasis added); *Hewlett-Packard*, 340 F.3d at 1322-23 (denying motion for new trial because testimony at trial fell short of the evidentiary requirements for proof of infringement under the doctrine of equivalents).

Defendants also argue that Dr. Chabner failed to include in his report any analysis on a limitation-by-limitation basis concerning any element of the asserted claims under the doctrine of equivalents, and in particular the element concerning the administration of folic acid. Evidence and argument on the doctrine of equivalents cannot be subsumed in the plaintiff's case of literal infringement; however, the standard "does not require [the expert] to re-start his testimony at square one when transitioning to a doctrine of equivalents analysis." *Amgen Inc. v. F. Hoffman-La Roche Ltd.*, 580 F.3d 1340, 1382 (Fed. Cir. 2009); *Paice LLC v. Toyota Motor Corp.*, 504 F.3d 1293, 1305 (Fed. Cir. 2007). "These requirements 'ensure that a jury is provided with the proper

evidentiary foundation from which it may permissibly conclude that a claim limitation has been met by an equivalent.'" *Amgen*, 580 F.3d at 1382 (quoting *Comark Commc'ns, Inc. v. Harris Corp.*, 156 F.3d 1182, 1188 (Fed. Cir. 1998)). The relevant case law consistently states that the patentee—not the expert report—must provide this evidence to the finder of fact at trial. In addition, Dr. Chabner's report states "for each claim limitation there is a corresponding aspect of each of Teva's and APP's ANDA Products that performs substantially the same function, in substantially the same way, to achieve substantially the same result." (Filing No. 372-1, at ECF p 17). Further, Dr. Chabner references his comparison of the claims of the '209 patent and Teva's and APP's ANDA products. This is not, as Defendants argue, generalized testimony as to the overall similarity between the claims and Defendants' products or processes, rather, it provides sufficient notice that Dr. Chabner intends to testify as to the substantial similarity of each claim limitation. Defendants are asking the Court to exclude the very testimony and evidence that is required *at trial* in order to support a claim of infringement under the doctrine of equivalents. Such a blanket exclusion is not warranted under these circumstances.

Defendants have also failed to show that a Rule 37 sanction excluding all evidence related to the doctrine of equivalents is warranted. Even if this Court were to find that Dr. Chabner's report did not comply with Rule 26(a), "[t]he determination of whether a Rule 26(a) violation is justified or harmless is entrusted to the broad discretion of the district court." *David v. Caterpillar, Inc.*, 324 F.3d 851, 857 (7th Cir. 2003) (quoting *Mid–America Tablewares, Inc. v. Mogi Trading Co., Ltd.*, 100 F.3d 1353, 1363 (7th Cir. 1996)). In determining whether to apply an exclusion sanction under Rule 37, the Court must consider the following factors: "(1) the prejudice or surprise to the party against whom the evidence is 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." *Id*. First, contrary to Defendant's assertion that this theory is "new" and "surprising," Lilly explicitly referenced this theory in both their Preliminary Disclosure of Claims and Contentions and their Final Infringement Contentions. (Filing No. 377, at ECF p. 10; Filing No. 375-2, at ECF p. 12). Dr. Chabner's report also states "for each claim limitation there is a corresponding aspect of each of Teva's and APP's ANDA Products that performs substantially the same function, in substantially the same way, to achieve substantially the same result." (Filing No. 372-1, at ECF p 17.) These documents clearly give notice to Defendants of Lilly's intention to assert that the Defendants' products infringe the '209 patent under the doctrine of equivalents. Second, to the extent Defendants were prejudiced, they had ample opportunity to cure such prejudice during discovery. Defendants had notice of this theory as early as May 2011 in Lilly's Preliminary Disclosure of Claims and Contentions, and Dr. Chabner submitted his report in January 2013. Defendants had the opportunity to respond to Dr. Chabner's expert report and depose him on the theories of infringement contained in his report. Third, the Court sees no likelihood of disruption to the trial. As previously stated, Defendants had ample opportunity to respond to this legal theory, and any failure to prepare should not form the basis for finding that the trial would be disrupted. Finally, the Court finds no bad faith or willfulness on the part of Lilly in failing to disclose its intention to present evidence at trial on this theory. There is no basis for Defendants to claim that a theory of infringement under the doctrine of equivalents is new or surprising, nor that it was only first disclosed in Lilly's pre-trial brief. Therefore, the Court finds that exclusion of evidence relating to the doctrine of equivalents is not warranted under Rule 37.

IV. CONCLUSION

For the reasons set forth above, Defendants' Motion *in limine* (Filing No. 370) is **DENIED**.

SO ORDERED.

Date: 2/20/2015

Hon. Tanya Walton Pratt, Judge
United States District Court
Southern District of Indiana

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