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 MOTION FOR SUMMARY JUDGMENT OF NONINFRINGEMENT

This matter is before the Court on Defendants Dr. Reddy's Laboratories, LTD.'s and Dr. Reddy's Laboratories, Inc.'s (collectively, "Dr. Reddy's") Motion for Summary Judgment of Noninfringement of the U.S. Patent 7,772,209 (the "'209 Patent") (Filing No. 132). Plaintiff Eli Lilly and Company ("Lilly") initiated this Hatch-Waxman litigation alleging that Dr. Reddy's New Drug Application No. 208297 and the use of the product described therein, infringe Lilly's '209 Patent. On November 9, 2017, oral argument was held on the Motion at which the parties made helpful presentations. For the reasons stated below, the Court determines that summary judgment is not appropriate and Dr. Reddy's Motion is **denied**.

I. BACKGROUND

The '209 Patent describes a method of administering a chemotherapy drug, pemetrexed disodium, with a pretreatment regimen of vitamin B_{12} and folic acid ("pretreatment regimen"), which is marketed by Lilly under the trade name ALIMTA®. The '209 Patent has been the subject of two previous trials before this Court. *See Eli Lilly and Co. v. Teva Parenteral Medicines, Inc.*, 126 F. Supp.3d 1037, 1038 (S.D. Ind. 2015)[1]. Those cases specifically concerned generic drug

[1] The '209 Patent is also the subject of other pending infringement suits pending before this Court.

manufacturers that sought to market a generic version of ALIMTA® including labeling that induced physicians to direct patients to take folic acid and vitamin B_{12} in accordance with the pretreatment claims in the '209 Patent. Specifically, in the *Teva* case, the pretreatment regimen and whether the steps of the claimed method could be attributed to a single actor was at issue. *Id.*

During prosecution of its patent application for ALIMTA®, the U.S. Patent and Trademark Office originally rejected claim 2 of the '209 Patent as being anticipated by a prior art article, Arsenyan et.al. ("Arsenyan"). Arsenyan concerned the administration of the compound methotrexate.[2] To avoid rejection of its patent in view of Arsenyan, Lilly narrowed the scope of its claims from a broad category of antifolates to specifically pemetrexed disodium. (Filing No. 133-1 at 124; Filing No. 146 at 30.)

Dr. Reddy's is a drug manufacturer and does not treat patients, therefore any infringement would be based on indirect infringement. Dr. Reddy's set out to avoid infringing the '209 Patent by designing a different product. It ran experiments to investigate different salts, and chose tromethamine. Unlike the generic drug manufacturers that used pemetrexed disodium in the proposed generic drugs in previous trials, Dr. Reddy's seeks to market a new product that uses pemetrexed ditromethamine, rather than pemetrexed disodium.

A point of contention between the parties is whether pemetrexed ditromethamine was excluded (thus designated public use) from the claims during patent prosecution by Lilly's specification and narrowing amendment from the term "antifolates" to "pemetrexed disodium." Tromethamine is an inorganic, metallic salt, whereas sodium is an organic, nonmetallic salt.

[2] Both methotrexate and pemetrexed fall within the broader antifolate group, but they target different enzymes. (Filing No. 146 at 44.)

(Filing No. 135 at 8.) The liquid solution of both chemical compounds results in pemetrexed treatment, but the powdered solid form of the two products differ as a result of the different salt compounds used. The patient receives the liquid solution intravenously. The products are sold in solid form. At issue is claim 12 of the '209 Patent. Claim 12 reads as follows:

> 12. An improved method for administering pemetrexed disodium to a patient in need of chemotherapeutic treatment, wherein the improvement comprises:
>
> a) administration of between about 350 µg and about 1000 µg of folic acid prior to the first administration of pemetrexed disodium
>
> b) administration of about 500 µg to about 1500 µg of vitamin B_{12}, prior to the first administration of pemetrexed disodium; and
>
> c) administration of pemetrexed disodium.

(Filing No. 1-1 at 9).

As previously noted, Dr. Reddy's product uses a different pemetrexed compound: pemetrexed ditromethamine. In addition, Dr. Reddy's label on the administration of the pemetrexed ditromethamine differs from Lilly's in that Dr. Reddy's label instructs that pemetrexed ditromethamine should be reconstituted and diluted with 5% dextrose in water ("dextrose"), whereas Lilly's label instructs that the pemetrexed disodium should be reconstituted and diluted in saline solution. (Filing No. 92-3; Filing No. 179-1.) Dr. Reddy's label states "[c]oadminstration of pemetrexed with other drugs and diluents has not been studied, and therefore is not recommended." (Filing No. 92-3 at 9.) Dr. Reddy's label also instructs that the pretreatment regimen be followed and mitigates the severe toxicities that pemetrexed can otherwise cause. *Id.* at 42.

Both Dr. Reddy's and Lilly's labels indicate that its products are to be administered along with cisplatin for some patients. *Id.* at 11. Before cisplatin can be administered to a patient it requires and is standard practice to prehydrate it with saline to prevent serious kidney toxicity. (Filing No. 146 at 13-14.) Dr. Reddy's label instructs that the cisplatin be administered intravenously approximately thirty minutes after the end of administration of pemetrexed treatment. (Filing No. 92-3 at 37.) Saline is commonly used in intravenous administration for many different drugs.

II. LEGAL STANDARD

The purpose of summary judgment is to "pierce the pleadings and to assess the proof in order to see whether there is a genuine need for trial." *Matsushita Electric Industrial Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). Federal Rule of Civil Procedure 56 provides that summary judgment is appropriate if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." *Hemsworth v. Quotesmith.Com, Inc.*, 476 F.3d 487, 489-90 (7th Cir. 2007). In ruling on a motion for summary judgment, the court reviews "the record in the light most favorable to the nonmoving party and draw[s] all reasonable inferences in that party's favor." *Zerante v. DeLuca*, 555 F.3d 582, 584 (7th Cir. 2009) (citation omitted). However, "[a] party who bears the burden of proof on a particular issue may not rest on its pleadings, but must affirmatively demonstrate, by specific factual allegations, that there is a genuine issue of material fact that requires trial." *Hemsworth*, 476 F.3d at 490 (citation omitted). "In much the same way that a court is not required to scour the record in search of evidence to defeat a motion for summary judgment, nor is it permitted to

conduct a paper trial on the merits of a claim." *Ritchie v. Glidden Co.*, 242 F.3d 713, 723 (7th Cir. 2001) (citation and internal quotations omitted). Finally, "neither the mere existence of some alleged factual dispute between the parties nor the existence of some metaphysical doubt as to the material facts is sufficient to defeat a motion for summary judgment." *Chiaramonte v. Fashion Bed Grp., Inc.*, 129 F.3d 391, 395 (7th Cir. 1997) (citations and internal quotations omitted).

III. DISCUSSION

As an initial matter, the Court notes that Lilly recently changed its ALIMTA® label in response to the Food and Drug Administration's ("FDA") instructions to change various aspects of the label. Nevertheless, both parties agree that the new label does not change the substance or legal theories of any of the briefings previously submitted to the Court and that the parties are prepared to go forward with the proceedings as they currently stand. (Filing No. 182 at 7-10.)

Lilly argues that Dr. Reddy's product infringes under two theories: literal infringement and the doctrine of equivalents. (Filing No. 146 at 19.) The Court will first address the embedded claim construction issue and then address each infringement theory.

A. Claim Construction

The claims define the scope of patent protection. *Johnson & Johnston Associates, Inc. v. R.E. Service Co., Inc.*, 285 F.3d 1046, 1052 (Fed. Cir. 2002). The words of a claim are generally given their ordinary and customary meaning, as understood by a person of skill in the art ("POSA") when the patent was filed. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (*en banc*). When the ordinary meaning of a claim is disputed, the Federal Circuit has directed courts to look to the patent specification, which is the single best guide to the meaning of a disputed term. *Id.* at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)).

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