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.	)	

FINDINGS OF FACT AND CONCLUSIONS OF LAW FOLLOWING FEBRUARY 1, 2018 BENCH TRIAL

This matter was before the Court for a bench trial beginning on February 1, 2018 and concluding on February 2, 2018, on the issue of infringement of U.S. Patent No. 7,772,209 (the "'209 Patent"). This is a Hatch-Waxman patent infringement action brought by Eli Lilly and Company ("Lilly"), the owner of the '209 Patent, against Defendants Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively, "Dr. Reddy's") arising out of Dr. Reddy's filing of New Drug Application No. 208297 (the "NDA") with the Food and Drug Administration ("FDA") seeking approval to market the product described therein. The '209 Patent describes a method of administering a chemotherapy drug, pemetrexed disodium ("pemetrexed"), with vitamins, which is marketed by Lilly under the trade name ALITMA®. Lilly is asserting that Dr. Reddy's drug product, which uses pemetrexed ditromethamine, infringes the '209 Patent. Dr. Reddy's contends that its product is not a generic drug, rather, its product uses a different chemical. Particularly at issue is claim 12. The Court previously constructed claim 12 to refer to a liquid administration of pemetrexed disodium. (Filing No. 199 at 9.) Having heard testimony and

considered the exhibits and arguments of the parties, the Court makes the following findings of fact and conclusions of law pursuant to Federal Rule of Civil Procedure 52.

I. FINDINGS OF FACT

Lilly is a corporation organized and existing under the laws of the State of Indiana, having its corporate offices and principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285. Lilly sells pemetrexed in the United States under the trademark ALIMTA® for treatment of patients with malignant pleural mesothelioma, or for the initial treatment of locally advanced or metastatic nonsquamous non-small cell lung cancer, and other forms of lung cancer. ALIMTA® is covered under U.S. Patent No. 5,344,932, which is owned by The Trustees of Princeton University and licensed exclusively to Lilly.

Dr. Reddy's Ltd. is a drug manufacturer with a principal executive office at Hyderabad, Telangana 500 034, India, and Dr. Reddy's Inc. is a corporation organized and existing under the laws of the State of New Jersey. Dr. Reddy's is in the business of manufacturing, marketing, and selling both generic and non-generic drug products. In December 2015, Dr. Reddy's notified Lilly that it had submitted to the FDA New Drug Application No. 208297, a product that will be marketed as competing products to ALIMTA®

Dr. Clet Niyikiza ("Dr. Niyikiza"), the inventor of the '209 Patent, is a mathematician that was employed by Lilly in the 1990s to help with the clinical development of cancer compounds. In early 1997, Dr. Niyikiza performed a series of statistical analyses, known as multivariate analyses, on more than 60 variables in patients participating in pemetrexed clinical trials in efforts to better understand which patients were likely to develop the sporadic toxicities observed with pemetrexed. The problem the invention solves is toxicity in patients receiving chemotherapeutic treatment with pemetrexed. In particular, the '209 Patent provides for a method that mitigates the

toxicity associated with pemetrexed treatment, using the vitamin pretreatment regimen of vitamin B_{12} and folic acid. (Filing No. 231 at 35.)

The primary focus of this infringement trial is on whether Dr. Reddy's label, specifically the use of pemetrexed ditromethamine product described therein, infringes the '209 Patent, which uses pemetrexed disodium, under the doctrine of equivalents. The '209 Patent covers the method of administration of ALIMTA®, requiring that physicians co-administer the drug with folic acid and vitamin B_{12} to reduce the incidence of patient toxicity caused by ALIMTA®. Claim 12 of the '209 Patent describes an improved method for administering pemetrexed disodium, comprising "a) administration of between 3500 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).

The parties disagree on the relevance of any chemical differences between pemetrexed disodium and pemetrexed ditromethamine, nevertheless both Lilly's and Dr. Reddy's experts, Dr. Bruce A. Chabner, M.D., ("Dr. Chabner"), Rodolfo Pinal ("Dr. Pinal"), and George Gokel ("Dr. Gokel"), agreed on what the differences were between the two chemical compounds. Sodium is an inorganic metallic salt, and tromethamine is an organic, nonmetallic salt. (Filing No. 231 at 181.) Tromethamine weighs more than sodium. *Id.* Because tromethamine can raise pH, it can be used as buffer; however, sodium may not be used as a buffer because it cannot be used as a pH adjuster. *Id.* at 158. Additionally, it is undisputed that pemetrexed disodium is more hygroscopic and absorbs more than twice the amount of water than pemetrexed ditromethamine. *Id.* at 173. As noted in the Court's claim construction finding, regardless if pemetrexed disodium or pemetrexed ditromethamine is administered to the patient, the patient receives an intravenous

solution of pemetrexed in treating the patient's cancer. The evidence presented at trial demonstrates that the person who solves the problems to which the claims are addressed requires a medical oncologist.

II. CONCLUSIONS OF LAW

A. Prosecution History Estoppel

In the Court's amended Final Pretrial Entry, the Court permitted the parties, at trial, to supplement the summary judgment record on the issue of prosecution history estoppel. (Filing No. 216 at 4.) In its Entry on Motion for Summary Judgment of Noninfringement, the Court found Lilly was not barred, as a matter of law under prosecution history estoppel, from asserting the doctrine of equivalents. (Filing No. 199 at 15.) ("Lilly has met its burden of showing that it did not surrender the equivalent in question because the choice of pemetrexed salt is tangential to the reasons for the amendment and summary judgment is precluded on this issue.")

As in the summary judgment briefing, Dr. Reddy's continues to collapse the foreseeability exception with the tangential exception, on which the Court relied in holding in Lilly's favor. *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.,* 535 U.S. 722, 733 (2002). Dr. Reddy's focuses on the unexplained reason that Lilly limited the '209 Patent to pemetrexed disodium, in essentially arguing that Lilly could have drafted a better claim. ("[A]" patentee cannot argue in litigation that a narrowing amendment in prosecution was excessive, and that the patentee could have avoided the prior art (and gained allowance) with a less severe amendment that would have literally embraced the accused equivalent." (Filing No. 234 at 6).) In any event, Lilly has explained the reason for the narrowing amendment: it was narrowed to overcome a rejection in view of Arsenyan, a prior art article about a different antifolate, methotrexate. (Filing No. 235 at 35.) The Court agrees with Lilly that at trial Dr. Reddy's expert, Dr. Gokel, did nothing to dispute or add to

the summary judgment record as to the prosecution history evidence from which tangentiality is analyzed. (Filing No. 232 at 42.) Accordingly, the Court again concludes that Lilly's rationale for limiting its claim to pemetrexed disodium (to avoid a rejection based on the prior art Arsenyan) is tangential to the accused equivalent—pemetrexed ditromethamine. The Court directs the parties to Filing No. 199 for a more detailed analysis regarding the Court's holding that Lilly has rebutted the presumption that prosecution history estoppel applies.

B. Disclosure-Dedication Rule

Another issue, extensively briefed by the parties on summary judgment, was the disclosure-dedication doctrine. Again, the trial record and the summary judgment record contain significant overlap as to this issue. Because Lilly did not move for summary judgment on this issue, it was not decided on summary judgment, rather it was fleshed out by expert testimony at the trial. The disclosure-dedication rule bars a doctrine of equivalents claim when a patentee discloses but does not claim subject matter. *Johnson & Johnston Associates, Inc. v. R.E. Service Co., Inc.,* 285 F.3d 1046, 1054 (Fed. Cir. 2002).

As noted in the Court's Entry on Motion for Summary Judgment of Noninfringement, it is undisputed that the '209 Patent's specification did not expressly disclose pemetrexed ditromethamine. Rather, Dr. Reddy's bases its disclosure-dedication argument on the fact that the '209 Patent referenced U.S. Patent No. 4,997,838 to Akimoto and that from Akimoto the hypothetical person of skill in the art ("POSA") could find pemetrexed ditromethamine disclosed among the alternatives disclosed in Akimoto. (Filing No. 234 at 25-26.) Generic references in a written specification do not necessarily dedicate all members of a particular genus to the public. *SanDisk Corp. v. Kingston Technology Co., Inc.,* 695 F.3d 1348, 1363 (Fed. Cir. 2012).

> Rather, the 'disclosure must be of such specificity that one of ordinary skill in the art could identify the subject matter that had been disclosed and not claimed.'

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