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

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.'

> Additionally, in *Pfizer Inc. v. Teva Pharmaceuticals, USA, Inc.*, 429 F.3d 1364 (Fed. Cir. 2005), this court further clarified that 'before unclaimed subject matter is deemed to have been dedicated to the public, that unclaimed subject matter must have been identified by the patentee as an alternative to a claim limitation.'

Id. (citations omitted). Although the '209 Patent did not expressly incorporate Akimoto by reference, it cited that preferred examples of antifolates can be found in the derivatives described by Akimoto. (Filing No. 1-1 at 5.) Because this issue hinged on what a POSA would recognize as unclaimed subject matter disclosed in the '209 Patent specification and if Akimoto's disclosures in combination would disclose pemetrexed ditromethamine, it left a factual dispute for trial.

At trial, Dr. Pinal testified that Akimoto included pemetrexed and any "pharmaceutically acceptable salt thereof." (Filing No. 231 at 249.) From this concession, Dr. Reddy's argues that pharmaceutically accepted salts would include substituted ammonium salts of which tromethamine is one of a few FDA-approved substituted ammonium salts. (Filing No. 234 at 24.) Thus, Dr. Reddy's contends that a POSA would have recognized pemetrexed in combination with tromethamine as an alternative to pemetrexed disodium. (Filing No. 234 at 26-27.) Lilly responds that while Dr. Pinal testified that pemetrexed is within the genus covered by Akimoto, Dr. Pinal also testified that Akimoto disclosed a genus of thousands of antifolates. (Filing No. 231 at 227.) Further, tromethamine is not specifically disclosed in any referenced patent nor is the compound pemetrexed ditromethamine. (Filing No. 238 at 16-17.) Because Akimoto was not expressly incorporated, as required, in the '209 Patent, and in any event Akimoto does not specifically disclose pemetrexed ditromethamine as an alternative to pemetrexed disodium, the disclosure-dedication rule does not bar Lilly's doctrine of equivalents claim. At most, the reference to Akimoto and what was contained therein amounts to a generic reference which does not dedicate all members of a particular genus to the public.

C. Doctrine of Equivalents

Lilly asserts, and the Court agrees, that healthcare providers using the proposed Dr. Reddy's product will directly infringe under the doctrine of equivalents, and that Dr. Reddy's is liable as an indirect infringer under 35 U.S.C. §§ 271(b) and (c).

As an initial matter, the relevant POSA must be defined for a doctrine of equivalents analysis. "What constitutes equivalency must be determined against the context of the patent, the prior art, and the particular circumstances of the case." *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.,* 520 U.S. 17, 24 (1997) (citation omitted). Thus, a POSA becomes an important factor as to "whether persons reasonably skilled in the art would have known of the interchangeability of an ingredient not contained in the patent with one that was." *Id.* Dr. Reddy's contends that the POSA should be the type of person who solves the problems to which the claims are addressed such as Dr. Niyikiza, the inventor of the patent.[1] (Filing No. 234 at 28, 30.) ("The POSA could be trained as a chemist, biochemist, pharmaceutical scientist, physician, or molecular biologist. The POSA, even if he is a physician, should have a strong background in chemistry and biochemistry, understand the folate pathways and metabolism, and have a solid grasp of acid-base.") Dr. Reddy's proposed POSA would examine the doctrine of equivalents from the perspective of the chemical and biochemical properties between pemetrexed disodium and pemetrexed ditromethamine. (Filing No. 234 at 30.) Lilly responds that the '209 Patent makes clear, from the plain language of the claims and testimony from the inventor, Dr. Niyikiza, that the POSA is directed to a medical oncologist. (Filing No. 235 at 13.) Lilly's proposed POSA would perform a doctrine of equivalents analysis focusing on the medical treatment aspects of the claims. (Filing No. 238 at 19.) This Court has "previously defined the POSA as 'a medical doctor who specializes in

[1] Dr. Niyikiza is a statistician, with a Ph.D. in mathematics and statistics, not a chemist, biochemist, pharmaceutical scientist, physician, or molecular biologist. (Filing No. 238 at 21.)

oncology or a medical doctor with extensive experience in the areas of nutritional sciences involving vitamin deficiencies [,who] collaborated with medical oncologists who have knowledge and experience in the treatment of cancer through the use of antifolates.'" *Eli Lilly and Company v. Teva Parenteral Meds., Inc.,* 1:10-cv-1376-TWP-MPB, 2012 WL 2358102, at *4 (S.D. Ind. June 20, 2012), ECF 115 at 8. Essentially, the point of contention between the proposed POSAs advanced by the parties is whether the POSA is a chemist or an oncologist.

Dr. Reddy's POSA definition is defeated by the plain language of the '209 Patent as the invention explicitly identifies it as "a method of reducing the toxicity associated with the administration of an antifolate to a mammal. . ." (Filing No. 1-1 at 5). Lilly is correct that the relevant POSA who works to mitigate the toxicities of chemotherapy would be an oncologist, particularly an oncologist with extensive experience in the areas of nutritional sciences involving vitamin deficiencies as confirmed by Dr. Chabner. Thus, equivalency is examined from an oncologist POSA. The relevant POSA is critical (and dispositive) to resolving the doctrine of equivalents analysis in the context of the claims as to whether the POSA would focus on the different salt forms of pemetrexed disodium and pemetrexed ditromethamine as being substantial differences, or instead would focus on the pemetrexed treatment that the patient receives.

The United States Supreme Court has set out two frameworks for evaluating equivalence—the function, way, result test (whether the accused product performs 'substantially the same function in substantially the same way to obtain the same result'), and the insubstantial differences test (whether the accused product or process is substantially different from what is patented). *Mylan Institutional LLC v. Aurobindo Pharma Ltd.,* 857 F.3d 858, 866–67 (Fed. Cir. 2017) ("Thus, the Court seemingly blessed two equivalents tests, leaving to the lower courts in future cases the choice of which to apply.") (quoting *Graver Tank & Mfg. Co. v. Linde Air Prod. Co.,* 339 U.S.

605, 608 (1950). Additionally, the Federal Circuit, relying on *Graver*, noted that the insubstantial differences test may be more appropriate in chemical arts cases. *Id.* ("The Supreme Court was surely correct in stating that non-mechanical cases may not be well-suited to consideration under the FWR test.") Because equivalence in this case is based on chemical properties, the Court determines that the insubstantial differences test is the more appropriate framework for evaluating equivalence.

"Under the doctrine of equivalents, a claim limitation not literally met may be satisfied by an element of the accused product if the differences between the two are 'insubstantial' to one of ordinary skill in the art." *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.,* 320 F.3d 1339, 1351 (Fed. Cir. 2003). "The doctrine of equivalents allows the patentee to claim those insubstantial alterations that were not captured in drafting the original patent claim but which could be created through trivial changes." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.,* 535 U.S. 722, 733 (2002). As noted previously, the relevant POSA, in this case, is a medical oncologist. Dr. Chabner testified that the invention claimed in the '209 Patent relates to "using pretreatment B_{12} and folic acid to mitigate the toxicity of pemetrexed when it's given to a patient with cancer." (Filing No. 231 at 70.) Additionally, Dr. Chabner testified that the pemetrexed disodium could not exert an anti-cancer effect in solid form, thus the POSA would understand that pemetrexed disodium is administered by first putting it into solution and then intravenously administering the solution to the patient for an anti-cancer effect. *Id.* at 72.

Under the relevant context that the claim relates to medical treatment, pemetrexed ditromethamine treats the patient's cancer in exactly the same way as pemetrexed disodium. It is undisputed that when both pemetrexed disodium and pemetrexed ditromethamine are placed in solution, that both compounds dissociate completely in solution resulting in free pemetrexed and

therapeutically irrelevant counterions. *Id.* at 208-09. In fact, in aqueous solution, the two products will be identical. (Filing No. 231 at 212.) Recognizing these similarities, Dr. Reddy's relied on Lilly's clinical trials of pemetrexed disodium, in demonstrating the safety and efficacy of its product, when it told the FDA that the salt form does not matter when it comes to treating the patient to support approval of its NDA product. (Filing No. 231 at 80-81.) It is undisputed that the products are bioequivalent; however, the parties disagree on whether there is patent equivalence in the context of the claimed method. (Filing No. 234 at 42-43; Filing No. 238 at 24.) "[W]hen a commercial product meets all of the claim limitations, then a comparison to that product may support a finding of infringement." *Adams Respiratory Therapeutics, Inc. v. Perrigo Co.,* 616 F.3d 1283, 1289 (Fed. Cir. 2010).

The differences in the chemical properties between pemetrexed disodium and pemetrexed ditromethamine with regards to solubility, stability, pH, and buffering capacity are irrelevant in the context of the claimed method including this Court's claim construction. (Filing No. 234 at 42.) Additionally, the theoretical phenomenon of the difference of salting out between the two products is irrelevant, as ALIMTA®'s label "requires the solution to be clear prior to administration and specifically instructs physicians not to administer it if any particulate matter is observed." (Filing No. 235 at 22-23.) To be sure, the evidence shows that tromethamine differs from sodium with regards to the chemical properties as alleged by Dr. Reddy's. Lilly does not dispute that there are differences when the products are in solid form, instead Lilly argues that the differences are insubstantial. (Filing No. 231 at 80.) The Court agrees. The differences are irrelevant in the context of the claimed method which is a liquid administration of pemetrexed sodium. What is in fact ultimately administered to the patient is injectable pemetrexed ions that enter the patient's cells. (Filing No. 231 at 79-80.) The products are identical in liquid form as

pemetrexed is the active moiety in both Dr. Reddy's and Lilly's products dissolved in solution. (*See* Filing No. 232 at 124-25; Filing No. 235 at 18.) Furthermore, Dr. Reddy's incorrectly relies on a chemist POSA in posing nonequivalence, who would not administer the drugs to a patient as the '209 Patent is a claimed method of treatment. Accordingly, Lilly has shown by a preponderance of the evidence that Dr. Reddy's product is equivalent to Lilly's product.

D. Inducement and Contribution to Infringement of '209 Patent

A party can be held liable for indirect infringement by actively inducing or contributing to direct infringement by others. 35 U.S.C. § 271(b), (c). Direct infringement occurs when one party makes, uses, offers to sell, sells, or imports each element of a patented invention. 35 U.S.C. § 271(a). Because Dr. Reddy's does not provide care to patients, the direct infringement is attributed to the healthcare providers.

"Inducement requires that the alleged infringer knowingly induced infringement and possessed a specific intent to encourage another's infringement." *AstraZeneca LP v. Apotex, Inc.,* 633 F.3d 1042, 1056 (Fed. Cir. 2010). Courts have inferred intent to induce infringement based on the contents of labels. *Id.* (holding circumstantial evidence may suffice to prove specific intent to induce infringement). Similarly, labels may also form the basis to infer intent under contributory infringement when they instruct users to perform a patented method. *See Eli Lilly & Co. v. Actavis Elizabeth LLC,* 435 F. App'x 917, 926 (Fed. Cir. 2011).

Relying on *Commil USA, LLC v. Cisco Sys., Inc.,* 135 S. Ct. 1920, 1928 (2015), Dr. Reddy's contends that Lilly cannot prove Dr. Reddy's specifically intended to infringe because specific intent requires proof that Dr. Reddy's knew the acts were infringing. (Filing No. 234 at 44.) As evidence that Dr. Reddy's did not know its product would infringe the '209 Patent, Dr. Reddy's offers that it selected tromethamine, in good-faith belief, to avoid infringing the '209

Patent. *Id.* at 45. As Lilly correctly points out, Dr. Reddy's ignores how specific intent can be shown in the Hatch-Waxman context, particularly how specific intent can be inferred from an accused product's labeling. *AstraZeneca LP v. Apotex, Inc.* considered similar facts where Apotex's product development team testified that it "never intended to instruct or encourage either physicians or patients to use its generic drug once-daily." *Id*. However, AstraZeneca held "[t]he pertinent question is whether the proposed label instructs users to perform the patented method. If so, the proposed label may provide evidence of Apotex's affirmative intent to induce infringement." *Id.* at 1060. Specific intent and liability for inducement are established if "the product labeling that Defendants seek would inevitably lead some physicians to infringe." *Eli Lilly and Company v. Teva Parenteral Meds., Inc.,* 845 F.3d 1357, 1368-69 (Fed. Cir. 2017); *Takeda Pharms. USA, Inc. v. West-Ward Pharm. Corp., 758 F.3d 625, 631 (Fed. Cir. 2015)*. Dr. Reddy's has provided no defense to the infringing pretreatment regimen portion of its label that this Court has already found induced infringement in another case with label instructions substantively identical to those in Dr. Reddy's Label. *Eli Lilly and Company v. Teva Parenteral Meds., Inc.,* No.1:10-cv-1376-TWP-MPB, 126 F.Supp.3d 1037 (S.D. Ind. Aug. 25, 2015).

As noted previously, administration of pemetrexed ditromethamine according to Dr. Reddy's label infringes Lilly's product under the doctrine of equivalents. In a Hatch-Waxman case such as this, infringement "is focused on the product that is likely to be sold following FDA approval," including the relevant knowledge of the parties at the time the product is sold. *See Abbott Laboratories v. TorPharm, Inc.,* 300 F.3d 1367, 1373 (Fed. Cir. 2002) ("This determination is based on consideration of all the relevant evidence, including the ANDA filing, other materials submitted by the accused infringer to the FDA, and other evidence provided by the parties."). "We have long held that the sale of a product specifically labeled for use in a patented method

constitutes inducement to infringe that patent, and usually is also contributory infringement." *Eli Lilly & Co. v. Actavis Elizabeth LLC,* 435 F. App'x 917, 926 (Fed. Cir. 2011) (citing *AstraZeneca LP v. Apotex, Inc.,* 633 F.3d 1042, 1060 (Fed.Cir.2010)).

This Court has determined that Dr. Reddy's product infringes the '209 Patent under the doctrine of equivalents. Accordingly, it cannot avoid intent or infringement on the bases that it possessed a "good faith belief that its proposed product[s] would not infringe." Moreover, the Court finds, based on a preponderance of the evidence, Dr. Reddy's label instructs users to perform the patented method by both inducing and contributing to infringement and that Dr. Reddy's had the requisite specific intent and knowledge that its label would cause such infringement. Dr. Reddy's product does not have a substantial noninfringing use to avoid contributory infringement. A physician administering Dr. Reddy's product would constitute direct infringement under § 271(a); thus, the use the Dr. Reddy's NDA products would constitute inducement and contributory infringement of the '209 Patent by Dr. Reddy's under 35 U.S.C. § 271(b), (c).

III. CONCLUSION

Based upon the foregoing findings of fact and conclusions of law, the Court concludes that Lilly has shown by a preponderance of the evidence that the asserted claims of the '209 Patent would be infringed by Dr. Reddy's product under the doctrine of equivalents based upon inducement and contributory infringement. The Court finds that Dr. Reddy's product indirectly infringes the asserted claims of the '209 Patent, and finds in favor of Eli Lilly And Company and against Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd.. Final judgment shall issue separate from this Entry.

SO ORDERED.

Date: 6/22/2018

TANYA WALTON PRATT, JUDGE
United States District Court
Southern District of Indiana

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