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.	)	

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)).

"The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Phillips*, 415 F.3d at 1316. Courts may also consider extrinsic evidence, such as expert testimony or dictionaries, but such evidence is "less significant" than the patent specification and prosecution history (*i.e.*, the written history of patentee's prior dealings with the patent office). *Id.* at 1317. "Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Id.* "[I]t is necessary to consider the specification as a whole, and to read all portions of the written description, if possible, in a manner that renders the patent internally consistent." *Budde v. Harley-Davidson, Inc.*, 250 F.3d 1369, 1379-80 (Fed. Cir. 2001). "A claim construction that excludes a preferred embodiment. . .is rarely, if ever correct." *SanDisk Corp. v. Memorex Products, Inc.*, 415 F. 3d 1278, 1285 (Fed. Cir. 2005) (citation and internal quotation omitted).

At the hearing, the parties set forth different constructions of claim 12's meaning. (*See* Filing No. 182 at 23, 30.) It is undisputed that claim 12 is a method claim, but the parties essentially dispute the meaning of "administration of pemetrexed disodium." Lilly argues that "administration of pemetrexed disodium" refers to the act of giving the patient the liquid solution of pemetrexed disodium after it has been diluted and reconstituted because no salt form is given to patients. (Filing No. 182 at 30.) Lilly explains that its experts have opined that a POSA would understand claim 12 to embrace the meaning of a solution with pemetrexed ions and two sodium ions that is given to patients intravenously. *Id.* Dr. Reddy's argues that this construction would

improperly require "changing each instance of 'pemetrexed disodium' in the claims to a 'solution comprising pemetrexed ions and sodium ions.'" (Filing No. 167 at 3.)

"Claim construction begins with the language of the asserted claims." *SanDisk*, 415 F.3d at 1284 (citation omitted). As stated previously the relevant asserted claim at issue is "administration of pemetrexed disodium". The dispute between the parties' different claim construction arguments turns on the word "administration". This is primarily due to the fact that the patient receives the product through a liquid solution, but ALIMTA® is sold in solid or salt form.[3]

The Federal Circuit prefers intrinsic evidence over extrinsic evidence in construing claims. *See Phillips*, 415 F.3d at 1317 ("However, while extrinsic evidence 'can shed useful light on the relevant art,' we have explained that it is 'less significant than the intrinsic record in determining 'the legally operative meaning of claim language.''") (citations omitted). Turning to the intrinsic evidence first, the Court begins with the specification. The specification must conclude with the claims "particularly pointing out and distinctly claiming the subject matter" which the applicant regards as his invention. *See* 35 U.S.C. §112. This apprises the public of the metes and bounds of the subject matter for which the inventor seeks patent protection.

The '209 Patent's specification distinctly claims pemetrexed disodium. The prosecution history is consistent with this result. "The court must always consult the prosecution history, when offered in evidence, to determine if the inventor surrendered disputed claim coverage." *SanDisk*, 415 F.3d at 1286. Here, the prosecution history reveals that the amendments to the detailed

[3] Although Dr. Reddy's product is not on the market yet, it is also being proposed to sell in a solid form.

description section of the specification as well as the claims were made in response to the U.S. Patent and Trademark Office's ("Patent Office") rejections. (Filing No. 133-1 at 147-48.) Lilly limited the chemical compound used in claim 12 to pemetrexed disodium. "As a basic principle of claim interpretation, prosecution disclaimer promotes the public notice function of the intrinsic evidence and protects the public's reliance on definitive statements made during prosecution. *SanDisk,* 415 F.3d at 1287 (citation omitted).

Unlike pemetrexed disodium, the parties' dispute over the word "administration" is not completely resolved by resorting to intrinsic evidence alone. The specification, claims, nor prosecution history do not resolve this dispute. "There is no 'clear and unmistakable' disclaimer if a prosecution argument is subject to more than one reasonable interpretation, one of which is consistent with a proffered meaning of the disputed term." *Id.* (citation omitted). The '209 Patent does reveal that it is a method invention, but the claims do not address how ALIMTA® *i.e.*, pemetrexed disodium, is actually given to the patient. That requires reading the label's detailed directions. Both products' labels require the powdered form of the drugs to be diluted and reconstituted, using different liquid solvents.[4] The expert reports shed light on what a POSA would understand "administration" to mean. The Court finds it very persuasive that both products are administered in liquid form to be indicative that a POSA would understand the '209 Patent to refer to a method of liquid administration of pemetrexed disodium.

What happens to pemetrexed disodium or pemetrexed ditromethamine after the liquid solution is prepared and administered to the patient is not a question that needs to be resolved in

[4] Lilly's label requires saline, while Dr. Reddy's label requires dextrose.

construing claim 12. In any event, the parties agree on the science of what happens during the administration of the liquid solution the patient. "And Dr. Chabner is saying, well, I think people would understand the claim to mean this. And, basically, what he's saying is, because that makes sense, that's what Lilly should have done, *people know that it's the pemetrexed that matters*." (Filing No. 182 at 51) (emphasis added). The patient receives pemetrexed treatment. "Claim construction is a matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement. It is not an obligatory exercise in redundancy." *U.S. Surgical Corp., v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997). Having already determined based on the intrinsic evidence, Lilly claimed "pemetrexed disodium," the Court declines further claim construction based on Lilly's assertion that the term "embraces the administration in liquid form of pemetrexed ions in combination with two sodium ions. (Filing No. 182 at 30.) In sum, the Court construes claim 12's "administration of pemetrexed disodium" language to refer to a liquid administration of pemetrexed disodium. The liquid administration is accomplished by dissolving the solid compound pemetrexed disodium into solution as instructed by the ALIMTA® label. This construction is consistent with the '209 Patent's specification and the plain meaning of claim 12 as well as the prosecution history. It is undisputed that a POSA would understand that the '209 Patent refers to a method of liquid administration because pemetrexed is the active ingredient that treats the cancer and the patient receives the solution intravenously. Further, this construction adheres to the bedrock patent claim construction principle to not exclude a preferred embodiment *i.e.*, pemetrexed disodium, and renders the patent internally consistent.

B. Literal Infringement

"Literal infringement requires a patentee to prove by a preponderance of the evidence that every limitation of the asserted claim is literally met by the allegedly infringing device." *Biovail Corp. Intern. v. Andrx Pharmaceuticals, Inc.*, 239 F. 3d 1297, 1302 (Fed. Cir. 2001). Lilly's theory of literal infringement involves Dr. Reddy's product's use in combination with certain patients that require another chemotherapy drug called cisplatin. In these instances, Dr. Reddy's label instructs that the pemetrexed product is to be infused thirty minutes before cisplatin. Cisplatin requires prehydration with saline solution—sodium chloride. (Filing No. 146 at 2.) Lilly contends that the cisplatin use and pemetrexed infusion will overlap because they are administered thirty minutes apart and that when this happens Dr. Reddy's product will mix with the saline solution due to the prehydration requirement. The resulting solution will contain pemetrexed molecules and sodium and tromethamine ions that disassociate from each other. Lilly explains that Dr. Reddy's product will be mixed with saline solution as it is being infused into a patient through the same intravenous line as the saline prehydration. The resulting solution will contain pemetrexed and sodium ions—that is pemetrexed disodium.

Dr. Reddy's responds that Lilly's theory of literal infringement would require healthcare providers to completely disregard its label instructions to use the Dr. Reddy's product with dextrose solution only. Lilly relies on the fact that the label does not explicitly instruct not to use saline and that a POSA would know that saline is suitable for use with pemetrexed drugs as Lilly's product has been safely administered with saline for over a decade. (Filing No. 146 at 15.) Dr. Reddy's label states that co-administration of Dr. Reddy's products with other diluents has not been studied and is therefore not recommended. Dr. Reddy's argues that Lilly's literal

infringement claim must prove that the Dr. Reddy's label instructs users to mix the Dr. Reddy's product with saline. Dr. Reddy's label also states that its product should not mix with anything except dextrose before it is infused. Dr. Reddy's also explains that even if healthcare providers mixed Dr. Reddy's pemetrexed ditromethamine with saline this would not be "administration of pemetrexed disodium" as required by Lilly's patent claims.

The claim construction issue has been resolved as a liquid administration of pemetrexed disodium. For purposes of summary judgment, the Court must credit Lilly's literal infringement theory that cisplatin's requirement and established practice of saline prehydration would overlap with the pemetrexed infusion and the two would mix via healthcare providers administering both through the same intravenous line. Furthermore, because saline contains sodium ions that this would result in infringement when Dr. Reddy's pemetrexed ditromethamine product is mixed with the saline resulting in a liquid administration of the pemetrexed disodium solution. Based on the foregoing, viewing the facts in a light favorable to Lilly, there are disputed issues of material fact as to whether every limitation of the asserted claim is literally met by the allegedly infringing device. Thus, Dr. Reddy's Motion for Summary Judgment of Noninfringement (Filing No. 132) is **denied** as to literal infringement.

C. Doctrine of Equivalents

"The doctrine of equivalents extends the right to exclude beyond the literal scope of the claims." *Johnson*, 285 F.3d at 1053. "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). The doctrine of equivalents is restricted by the "all limitations" rule

and the prosecution history estoppel rule by limiting the range of equivalents when claims have been narrowed. *See Pozen Inc. v. Par Pharmaceutical, Inc.*, 696 F.3d 1151, 1167. Dr. Reddy's argues that Lilly's doctrine of equivalents infringement claim is foreclosed by prosecution history estoppel, the disclosure dedication rule, and doctrine of vitiation. The Court will address each of these threshold arguments in turn.

1. Prosecution History Estoppel

Dr. Reddy's argues that prosecution history estoppel bars Lilly's doctrine of equivalents claim at the threshold as a matter of law. (Filing No. 182 at 12.) It is undisputed that Lilly narrowed its broader antifolates claim to pemetrexed disodium during prosecution to avoid Arsenyan prior art. It is also undisputed that Dr. Reddy's product would fall within the scope of the original antifolates claim. Under *Festo*, Lilly's narrowing amendment triggers a presumption of surrender that Lilly must rebut to sustain its doctrine of equivalents claim. *Festo*, 535 U.S. at 725. *Festo* held three exceptions to defeat prosecution history estoppel:

> The equivalent may have been unforeseeable at the time of the application; the rationale underlying the amendment may bear no more than a tangential relation to the equivalent in question; or there may be some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question. In those cases the patentee can overcome the presumption that prosecution history estoppel bars finding an equivalence.

Id. at 740-41. Lilly argues that the tangential exception applies here, in that the different salt forms of pemetrexed used bear no more than a tangential relationship to the rationale for the underlying amendment. (Filing No. 146 at 23.) Lilly concedes that the amendment was to overcome a rejection in view of Arsenyan, however it explains that Arsenyan is a prior art article about the

administration of a compound called methotrexate, also an antifolate but distinguishable from pemetrexed.

Dr. Reddy's incorrectly reads *Festo* to hold that the rationale for the amendment must be both unforeseeable and tangential, but explains that even if tangential is an independent basis, Lilly is nevertheless precluded from asserting doctrine of equivalents because Lilly's narrowing amendment went to the identity of a particular type of antifolate—pemetrexed disodium. (Filing No. 167 at 6.) Dr. Reddy's goes on to cite Lilly's prosecution of the European equivalent of the '209 Patent where Lilly claimed pemetrexed broadly and used a dependent claim to claim the salt form: pemetrexed disodium. (Filing No. 182 at 16U.) This argument goes to foreseeability that Lilly allegedly knew how to draft a broad pemetrexed claim that was not narrowly limited to disodium salt.

Lilly argues that for the tangential exception "it makes no difference whether Lilly 'limited the scope of drugs in the claimed method' in a way that turned out to exclude the accused pemetrexed ditromethamine." Because pemetrexed, the active drug substance, actually treats the cancer patient, and pemetrexed disodium and pemetrexed ditromethamine are very similar, this exception necessarily presents a battle of the experts issue. In fact, it is undisputed that a POSA would understand that pemetrexed is the active antifolate (or drug) in both products.

In *Regents of University of Cal. v. Dakocytomation Cal. Inc.*, the Federal Circuit held that a patentee's narrowing amendment that centered on a method of blocking to avoid prior art that did *not* involve blocking was tangential to the particular nucleic acid used to accomplish the blocking. 517 F. 3d 1364, 1378 (Fed. Cir. 2008). The patent at issue in that case claimed "blocking nucleic acid" which was construed by the district court to involve human DNA, whereas the

accused product used synthetic (not human) nucleic acids referred to as peptide nucleic acids. *Id.* The district court granted summary judgment of noninfringement to the maker of the accused products because it held that the patentees had narrowed the scope of "blocking nucleic acid" during prosecution which barred the patentees from asserting the peptide nucleic acid equivalent. *Id.* The Federal Circuit reversed holding "[t]he prosecution history therefore reveals that in narrowing the claim to overcome the prior art rejections, the focus of the patentees' arguments centered on the method of blocking—not on the particular type of nucleic acid that could be used for blocking." *Id.* Thus, the Federal Circuit found the narrowing amendment was tangential.

The present case is similar to the distinction presented in *Regents*. The '209 Patent's specification describes a method for pemetrexed disodium treatment. Lilly's expert opined that a POSA would understand pemetrexed is the active antifolate that inhibits the enzymes at issue and treats the cancer. Dr. Reddy's argues that the salt form used in the patent goes to the identity of the antifolate that Lilly sought to claim and is thus barred from claiming pemetrexed as a class under prosecution history estoppel.

The prosecution history reveals that the Patent Office rejected various Lilly claims due to the prior art Arsenyan.

> Claims 2, 7, 10, 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Arsenyan et al. (Abstract; *Onkol., Nauchn.*, (1978) 12(10); 49-54. Arsenyan et al. teaches a method of pretreating mammals (mice) with various types of cancer with methylcobalamin (a vitamin B12 derivative which reduces methylmalonic acid) then administering methotrexate (an antifolate), and reports increased tumor inhibition and survival with methylcobalamin treatment.

(Filing No. 133-1 at 115.) The Arsenyan prior art rejection also served as the basis for an obviousness rejection. (Filing No. 133-1 at 117.) The prior art rejections thus went to

patentability. The Patent Office's communications do not refer to pemetrexed broadly, but also refer to pemetrexed disodium in combination with the pretreatment regimen as not being anticipated by the prior art. This is probably because ALIMTA® is sometimes used interchangeably with pemetrexed disodium during Lilly's patent prosecution. (*See* Filing No. 133-1 at 136.) At one point the Patent Office rejected Lilly's use of the trade name ALIMTA® in its claims as being vague and indefinite language, and Lilly responded with substituting pemetrexed disodium for ALIMTA®. (Filing No. 133-1 at 115.)

To overcome the prior art rejection, Lilly argued that the invention was new and nonobvious because it used the pretreatment regimen in combination with administration of pemetrexed disodium to treat the cancer and reduce the toxicities associated with pemetrexed disodium administration. (Filing No. 133-1 at 127.) The narrowing amendment (from antifolates as a class to pemetrexed disodium) was only tangential to the accused pemetrexed equivalent—pemetrexed ditromethamine. Thus, 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.

2. Disclosure Dedication Doctrine

Dr. Reddy's argues that Lilly's equivalents claim is also barred by the disclosure dedication rule. "[W]hen a patent drafter discloses but declines to claim subject matter. . .this action dedicates that unclaimed subject matter to the public." *Johnson,* 285 F. 3d at 1054. "[T]he public notice function of patents suggests 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." *Pfizer,* 429 F. 3d 1379.

It is undisputed that the '209 Patent's specifications do not expressly disclose pemetrexed ditromethamine. Dr. Reddy's bases its disclosure dedication argument on the fact that the '209 Patent referenced another patent, Akimoto, and the pemetrexed salt derivatives described by Akimoto would include pemetrexed ditromethamine. (Filing No. 167 at 13.) Lilly responds that "[t]he Federal Circuit has recognized the possibility of using the specification of a different patent only where it was expressly incorporated by reference." (Filing No. 146 at 28.)

The disclosure dedication rule has limitations. 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). There are two issues with Dr. Reddy's disclosure dedication argument. First, the '209 Patent did not expressly incorporate Akimoto by reference. Rather, the '209 Patent cites that preferred examples of antifolates can be found in the derivatives described by Akimoto. (Filing No. 1-1 at 5.) Dr. Reddy's argues that if a POSA went looking in Akimoto that the POSA would find pemetrexed and other substituted ammonium salts. To this second issue, Lilly responds that its experts will testify that Akimoto discloses a broader genus which would balloon out to over 200,000 compounds. The Court agrees that because of this large generic genus, no POSA would understand Akimoto to specifically disclose pemetrexed, tromethamine, or pemetrexed ditromethamine from the broader genus of compounds that Akimoto discloses unless they knew

to go looking for it. The disclosure dedication issue presented in this case hinges 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. The Akimoto reference does not satisfy the disclosure dedication rule's requirements of a specific identification that amounted to a disclosure of an alternative to a claim limitation. Because pemetrexed ditromethamine was not disclosed and identified with specificity, the disclosure dedication rule does not prevent Lilly from pursuing a doctrine of equivalents infringement theory nor dedicated it to the public.

3. Doctrine of Vitiation

"[I]n cases where the patentee's theory of equivalents would 'entirely vitiate a particular claim element, partial or complete summary judgment should be rendered by the court.'" *Sage Products, Inc., v. Devon Industries, Inc.*, 126 F.3d 1420, 1429 (Fed. Cir. 1997) (citation omitted). The doctrine of vitiation or the "all elements" rule forecloses a patentee's resort to the doctrine of equivalents when the facts or theories presented in a case would completely read a limitation out of a claim because "all elements" of a claim must be present in an accused product for there to be infringement. *See Depuy Spine,* 469 F.3d at 1017.

Dr. Reddy's argues that the amended (and limiting) term pemetrexed disodium would be read out of the claim and restored with the rejected term "antifolates" under Lilly's theory of equivalents as articulated in its expert reports. Lilly responds that its theory on the scope of equivalents does not encompass all antifolates; rather, Lilly poses the function-way-result test to prove that the two products are equivalent in the context of the claimed treatment claims because they both involve pemetrexed treatment that results in a chemotherapy effect. The dispute between

the parties on this issue includes a discussion of Lilly's expert, Dr. Bruce A. Chabner's ("Dr. Chabner"), report and deposition. Dr. Reddy's contends that Dr. Chabner raises new theories on defining the function-way-result test in his deposition which were not raised in his expert report that are inadmissible at trial and at the summary judgment stage. (Filing No. 167 at 16). Specifically, Dr. Reddy's argues that Dr. Chabner changed his "way" analysis from "inhibition of [] folate-dependent enzymes" to "inhibition of *particular* folate-dependent enzymes." *Id*. at 16. (emphasis added). Previously, the Court ruled that Dr. Chabner's report and deposition were admissible when the Court sustained Lilly's objection to the Magistrate Judge's striking portions of this evidence as well as Lilly's literal infringement theory. (Filing No. 154.) Additionally, the factual record on the distinction between pemetrexed disodium and pemetrexed ditromethamine precludes summary judgment as it presents a clear battle of the experts issue. The different salt form that is used between the two products goes directly to the heart of Lilly's doctrine of equivalents claim and the limitation is thus not entirely vitiated by the substitution. Because there are factual issues precluding summary judgment on the doctrine of equivalents and Lilly has met its burden in clearing the threshold issues raised by Dr. Reddy's, summary judgment is not warranted.

D. Indirect Infringement

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. 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).

The Court will address liability for inducement of infringement first. "Liability for inducement of infringement is predicated on a finding of direct infringement by a third party." *Eli Lilly and Co. v. Teva Parenteral Medicines, Inc.*, 126 F. Supp. 3d 1037, 1041 (S.D. Ind. 2015) (citing *Limelight Networks v. Akamai Technologies Inc.*, 134 S.Ct. 2111, 2117 (2014)). "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). "The pertinent question is whether the proposed label instructs users to perform the patented method. If so, the proposed label may provide evidence of [] affirmative intent to induce infringement." *AstraZeneca*, 633 F.3d at 1060. 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).

Liability for contributory infringement under 35 U.S.C. § 271(c) can be avoided if the product is a "staple article or commodity of commerce suitable for substantial noninfringing use." "One who makes and sells articles which are only adapted to be used in a patented combination will be presumed to intend the natural consequences of his acts; he will be presumed to intend that they shall be used in the combination of the patent." *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.* 545 U.S. 913, 932 (2005).

Reviewing the record in a light most favorable to Lilly, Lilly has shown that Dr. Reddy's product will result in induced or contributory infringement. With regards to the literal

infringement theory and cisplatin use, Lilly argues that standard practice would require healthcare providers to use saline solution with cisplatin which would then result in a solution containing pemetrexed and disodium ions—*i.e.* pemetrexed disodium. Specific, knowing intent is required for inducement and contributory infringement. Nevertheless, Lilly has shown there are disputed issues of material fact on whether Dr. Reddy's label instructs an infringing use under either literal infringement or the doctrine of equivalents to infer intent and knowledge necessary for either form of indirect infringement. "Even where a proposed label does not explicitly track the language of a claimed method, a package insert containing directives that will 'inevitably lead some consumers to practice the claimed method' provides sufficient evidence for a finding of specific intent." *Sanofi v. Glenmark Pharmaceuticals Inc., USA,* 204 F. Supp. 3d 665, 673-74 (D. Ct. Del.) (quoting *AstraZeneca,* 633 F. 3d at 1060). 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."). Viewing the facts in the light most favorable to Lilly, it has shown that Dr. Reddy's label will instruct users to perform the patented method by inducing or contributing to infringement and that Dr. Reddy's had the requisite intent and knowledge that its label would cause such infringement. Thus, summary judgment is precluded.

IV. CONCLUSION

There are genuine disputes of material fact with respect to the claims before the Court. For the reasons stated above, Dr. Reddy's Motion for Summary Judgment (Filing No. 132) is **DENIED**. Lilly's literal infringement and doctrine of equivalents claims remain pending for trial.

SO ORDERED.

Date: 12/14/2017

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

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