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. and BARR LABORATORIES, INC., Defendants.	)	Case No. 1:10-cv-1376-TWP-DKL

ENTRY ON CLAIM CONSTRUCTION

This patent infringement case is before the Court for construction of patent terms relevant to methods of administering the compound pemetrexed disodium ("pemetrexed"), the active pharmaceutical ingredient in the drug ALIMTA®. The Plaintiff in this matter is Eli Lilly and Company ("Lilly") and the Defendants are Teva Parenteral Medicines, Inc., App Pharmaceuticals, LLC, Pliva Hrvatska, D.O.O., Teva Pharmaceuticals USA, Inc., and Barr Laboratories, Inc. (collectively, "Defendants"). On April 24, 2012, the Court conducted a *Markman* hearing at which time the parties presented oral arguments as to the proper construction of two disputed terms of the patent at issue, U.S. Patent No. 7,772,209 (the "'209 patent"). The parties submitted thorough and well-crafted briefs and helpful presentations at the *Markman* hearing. Jurisdiction is proper under 28 U.S.C. §§ 1331, 1338, 2201 and 2202.

I. FACTUAL BACKGROUND

Lilly and Defendants are companies involved in the formulation and manufacture of pharmaceuticals. The patent at issue in this infringement suit, the '209 patent, relates to Lilly's

anti-cancer agent ALIMTA®, which is used to treat mesothelioma – the cancer caused by asbestos exposure – and other forms of lung cancer. Lilly contends that the Abbreviated New Drug Applications ("ANDAs") filed by the Defendants with the Food and Drug Administration ("FDA") for the manufacture and sale of generic versions of ALIMTA® before the '209 patent expires, infringes upon the '209 patent. As a result, Lilly filed this action against Defendants on October 29, 2010.

ALIMTA's® active ingredient, pemetrexed, is an antifolate that is known to disrupt the folic acid pathway which can contribute to the reduction of cancer cells. The '209 patent relates to a method of administering pemetrexed, along with folic acid and vitamin B12, a methylmalonic acid lowering agent, in order to reduce the toxicities associated with the administration of pemetrexed. This discovery made by Lilly results in a significant reduction of certain toxic effects caused by the administration of antifolates, such as pemetrexed, through the presence of a methylmalonic acid lowering agent without adversely affecting therapeutic efficacy. Dkt. 1-1, col. 2, ll. 32-37. As a result of ALIMTA® therapy, mesothelioma patients often live longer and the severity of the disease has been lessened so that patients are able to have a more normal life.

Originally, Defendants had five claims that they proposed were in dispute, however, the parties now agree upon the construction of three of those terms. Only two terms remain in dispute as they relate to the '209 patent: 1) the first concerns the proper construction of the term "patient" and 2) the second concerns the proper construction of the term "vitamin B12." Additional facts are added below as needed.

II. LEGAL STANDARD

Prevailing in a patent infringement suit requires "a finding that the patent claim 'covers the alleged infringer's product or process,' which in turn necessitates a determination of 'what the words in the claim mean.'" *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 374 (1996) (citation omitted); *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1581-82 (Fed. Cir. 1996) ("A literal patent infringement analysis involves two steps: the proper construction of the asserted claim, and a determination as to whether the accused method or product infringes the asserted claim as properly construed."). The construction of patent claims, which requires determining the meaning and scope of the claims, is a matter of law for the court. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 970-71 (Fed. Cir. 1995), *aff'd* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed. 2d 577 (1996). The Federal Circuit has emphasized that "[i]t is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (citations and quotations omitted); *see also Vitronics*, 90 F.3d at 1582 ("we look to the words of the claims themselves…to define the scope of the patented invention").

The words in patent claims are "given their ordinary and customary meaning", which is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips*, 415 F.3d at 1313; *see Home Diagnostics, Inc. v. LifeScan, Inc.*, 381 F.3d 1352, 1358 (Fed. Cir. 2004) ("customary meaning" refers to the "customary meaning in [the] art field"). "In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges," in which case claim construction "involves little more than the application of the widely accepted meaning of the commonly understood words." *Phillips*, 415 F.3d at 1314; *see also Renishaw PLC v. Marposs*

Societa' per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998) (articulating that when there are several common meanings for a certain term, "the patent disclosure serves to point away from the improper meanings and toward the proper meaning"). However, there are two exceptions to the general rule of applying the ordinary meaning to claim terms: 1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution. *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012).

To become one's own lexicographer, a patentee must set forth a definition of the disputed claim term other than the term's ordinary and plain meaning. *Id.* Moreover, "it is not enough for a patentee to simply disclose a single embodiment or use a word in the same manner in all embodiments, the patentee must 'clearly express an intent' to redefine the term." *See id.*; *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004) ("[T]he inventor's written description of the invention, for example is relevant and controlling insofar as it provides *clear lexicography*...") (emphasis added). Additionally, "[t]he patentee may demonstrate an intent to deviate from the ordinary and accustomed meaning of a claim term by including in the specification expression of manifest exclusion or restriction, representing a clear disavowal of claim scope." *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002).

In the absence of an express intent to impart a new meaning to a claim term, the court, when interpreting claim terms, first reviews the intrinsic evidence, which includes the claims themselves, the specification, and the prosecution history. *See Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001) ("The words used in the claims are interpreted in light of the intrinsic evidence of record, including the written description, the drawings, and the prosecution history, if in evidence."). With respect to the specification, it

serves an important purpose by providing for a written description of the invention that would allow a person of ordinary skill in the art to make and use the patented invention.[1] *See Phillips*, 415 F.3d at 1317. Moreover, in reviewing the specification or prosecution history, if these intrinsic sources define a claim term, that definition shall apply even if it differs from the term's ordinary meaning. *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366-67 (Fed. Cir. 2002). However, although claims must be read in light of the specification, the court should not limit a claim by restricting its scope based on a preferred embodiment within the specification. *Phillips*, 415 F.3d at 1323.

Along with the specification, the Court may also review the prosecution history, as part of the intrinsic record, in determining whether a patentee intended to define a particular term differently from its ordinary and customary meaning. *Teleflex*, 299 F.3d at 1326. Further, the prosecution history can act to "limit[] the interpretation of claims so as to exclude any interpretation that may have been disclaimed or disavowed during prosecution in order to obtain claim allowance." *Id.* (citing *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 452 (Fed. Cir. 1985)).

In addition to relying on intrinsic evidence in ascertaining the scope of an invention's claim, the Court also can rely upon extrinsic evidence, which includes evidence outside of the patent and prosecution history, such as expert testimony, dictionaries, and learned treatises. *Phillips*, 415 F.3d at 1317. However, "[C]ourts may rely on dictionary definitions when construing claim terms, 'so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents." (internal citation omitted); *see also Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999).

[1] Pursuant to 35 U.S.C. § 112, "the specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains…to make and use the same…." 35 U.S.C. § 112 ¶ 1.

Lastly, indefiniteness, like claim construction, "is a legal question." *Young v. Lumenis, Inc.*, 492 F.3d 1336, 1344 (Fed. Cir. 2007). To satisfy the definiteness requirement of 35 U.S.C. § 112[2], "the boundaries of the claim, as construed by the court, must be discernible to a skilled artisan based on the language of the claim, the specification, and the prosecution history, as well as her knowledge of the relevant field of art." *Power-One, Inc. v. Artesyn Techs., Inc.*, 599 F.3d 1343, 1350 (Fed. Cir. 2010) (citation omitted). A claim is indefinite if it is "not amenable to construction or [is] insolubly ambiguous." *Datamize LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1347 (Fed. Cir. 2005).

III. DISCUSSION

For the purposes of this discussion, the Court will briefly trace the background of the '209 patent, resolve the disagreement regarding the person of ordinary skill in the art and then construe the disputed claim terms at issue.

A. The '209 Patent

The '209 patent is directed at administering pemetrexed in combination with folic acid and a methylmalonic acid lowering agent to reduce the toxicity levels associated with administration of pemetrexed. Specifically, the antifolate, pemetrexed, prevents other compounds, known as reduced folates, from binding to particular enzymes that are essential in the growth of potentially cancerous tumors. However, certain toxicities are associated with the administration of pemetrexed disodium. The '209 patent discloses a method of administering pemetrexed in conjunction with certain amounts of folic acid and a methylmalonic acid lowering agent, such as vitamin B12, to reduce the toxicity levels without affecting the efficacy of the antifolate.

[2] 35 U.S.C. § 112 ¶ 2 sets forth the definite requirement, which provides that specification of a patent must "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112 ¶ 2.

B. Person of Ordinary Skill in the Art

Claim terms are construed from the perspective of the person of ordinary skill in the art to whom the patent is addressed. *Phillips*, 415 F.3d at 1313 ("The descriptions in patents are not addressed to the public generally, to lawyers or to judges, but, as section 112 [of title 35] says, to those skilled in the art to which the invention pertains or with which it is most nearly connected."). Although the determination of whom the person in the ordinary skill in the art is not dispositive of the claims construction in this case, the resolution of this issue is helpful to the Court.

Lilly suggests that "the person of ordinary skill in the art for the'209 patent would have the skills of a medical oncologist, with the knowledge and experience regarding the use of antifolates in the treatment of cancer, as well as knowledge and experience regarding the use of antifolates in the treatment of cancer, as well as knowledge and experience regarding the management of toxicities…." Pl. Claim Const. Br., Dkt. 94 at 9. Defendants argue that a person of ordinary skill in the art "would have a medical degree and additional qualifications or experience in the field of nutritional sciences and/or oncology, as well as practical experience in a clinical setting and/or academia." Def. Resp. Br., Dkt. 97 at 6. In addition, Defendants contend that the person of ordinary skill in the art would collaborate with other medical professionals in certain fields, including oncology. *Id.* The parties agreed at the *Markman* hearing that the person of ordinary skill in the art would be a medical doctor, Dkt. 114, Tr. at p. 25, ll. 16-19, but disagreed on whether the person of ordinary skill in the art can be only a medical oncologist or whether he or she could be a medical doctor with expertise in nutritional sciences.[3]

[3] Both parties reiterated during oral arguments that the issue of determining who is the person of ordinary skill in the art as it applies to the '209 patent is not dispositive with respect to the Court's resolution of the parties' proposed

In the Court's view, neither party's proposal is incorrect. Based on the '209 patent and the representations of the parties and their experts, the Court finds that the person of ordinary skill in the art, for purposes of this claim construction order, can be a medical doctor who specializes in oncology *or* a medical doctor with extensive experience in the areas of nutritional sciences involving vitamin deficiencies. However, as to the latter person, this individual would need to have collaborated with medical oncologists who have knowledge and experience in the treatment of cancer through the use of antifolates.

C. The Disputed Terms

The parties dispute two terms in the '209 patent for the purposes of claim construction. Each disputed term is addressed in turn.

Claim 1:

> **A method of administering pemetrexed disodium to a patient in need thereof comprising administering an effective amount of folic acid and an effective amount of folic acid and an effective amount of a methylmalonic acid lowering agent followed by administering an effective amount of pemetrexed disodium, wherein**
>
> > **the methylmalonic acid lowering agent is selected from the group consisting of vitamin B12, hydroxocobalamin, cyano-10-chlorocobalamin, aquocobalamin perchlorate, aquo-10-chlorocobalamin perchlorate, azidocobalamin, cobalamin, cyanocobalamin, or chlorocobalamin.**[4]

---

constructions of the disputed claim terms. *See* Tr. at p.25, ll. 10-15. However, for purposes of this claim construction order the Court finds it necessary to resolve the dispute. *See Candela Corp. v. Palomar Medical Techs. Inc.*, 2008 WL 3285255, at *2-*3 (E.D. Tex. Aug. 6, 2008) (resolving the parties' dispute concerning who is the person of ordinary skill in the art before construing the disputed claim terms); *Black & Decker Inc. v. Robert Bosch Tool Corp.*, 389 F. Supp.2d 1010, 1017 (N.D. Ill.) *aff'd in part, vacated in part for other reasons*, 260 Fed. Appx. 284 (Fed. Cir. 2008) (citing *Phillips*, 415 F.3d at 1313) ("The Court must construe the claims from the vantage point of a person of ordinary skill in art…therefore, [the Court] must determine the level of ordinary skill in the art for purposes of this [claim construction] motion.").

[4] The term "hydroxycobalamin" in claim 1 has been corrected to read "hydroxocobalamin." Additionally, there is a typographical error in claim 1: "aquo-10-cobalamin perchlorate" should read "aquo-10-chlorocobalamin perchlorate." Dkt. 95-2 at 21, ¶7 n.4; Dkt. 99-1at 21, ¶54 n.6.

Claim 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 B12, prior to the first administration of pemetrexed disodium; and

c) administration of pemetrexed disodium.

1. Term 1: "patient"

Claim Term/Phrase	Plaintiff's Proposed Construction	Defendants' Proposed Construction
"patient"	"human undergoing medical treatment"	"mammal"

The parties dispute the meaning of the term "patient" as it is referred to in the claims of the '209 patent. Lilly argues that "patient" should have its ordinary and customary meaning, which is: a human undergoing medical treatment. Pl. Claim Const. Br., Dkt. 94 at 27. Defendants counter that the intrinsic record establishes that the term "patient" means mammal for two reasons: 1) Lilly implicitly redefined the term "patient" in the specification when it used it interchangeably with mammal, and 2) the proposed construction of "patient" is supported by the '209 patent's prosecution history. After reviewing the '209 patent, the Court agrees with Lilly's construction that the ordinary and customary meaning of "patient" should apply over the construction proposed by Defendants.

There is a presumption that the claim terms chosen by the patentee "mean what they say and have the ordinary meaning that would be attributed to those words by persons skilled in the relevant art." *ACTV, Inc. v. Walt Disney Co.*, 346 F.3d 1082, 1088 (Fed. Cir. 2003). However, determining the ordinary and customary meaning of a claim term, in certain fields of art, requires

a further examination of "those sources available to the public that show what a person of skill in the art would have understood the disputed claim language to mean." *Phillips*, 415 F.3d at 1314 (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004)). These sources include the claims themselves, the specification, the prosecution history and extrinsic evidence. *Id.*

a. The '209 Patent Claims

The Federal Circuit has articulated that the courts should also consider the context of the surrounding words of the claims in an effort to determine the ordinary and customary meaning of a disputed term. *ACTV*, 346 F.3d at 1088. In addition, claim terms are usually understood to carry their ordinary and customary meaning. *Phillips*, 415 F.3d at 1312 (citing *Vitronics*, 90 F.3d at 1582). In this case, the claims of the '209 patent describe that a "patient" is to be administered effective amounts of methylmalonic acid lowering agent, folic acid, and pemetrexed disodium. Lilly contends that "patient" should be construed to have its ordinary and customary meaning – a human being undergoing medical treatment – however, the Court must review the specification to determine if Lilly has used the term "patient" in a manner that is inconsistent with its ordinary meaning. *Vitronics*, 90 F.3d at 1582.

b. The '209 Patent Specification

In their briefing and oral argument, the parties agreed that the words "patient" and mammal are used in the specification. Defendants argue that the plain and ordinary meaning of the term "patient" cannot be adopted when it was implicitly redefined in the specification because the patentee used the word mammal and "patient" interchangeably in the '209 patents specification, therefore they must have the same meaning. And, Defendants argue that this interchange shows that "patient" was redefined to mean mammal. Pursuant to *Phillips*, the Court

will give "patient" it's ordinary and customary meaning unless Lilly has redefined the term by acting as its own lexicographer or disavowed the full scope of the claim term. *See Thorner*, 669 F.3d at 1365 (setting forth the exceptions to the general rule of applying the plain and ordinary meaning of a claim term). Defendants argue that Lilly redefined the term "patient" by using that term in conjunction with the word mammal in the following section of the specification:

> As used herein, the term "in combination with" refers to the administration of the methylmalonic acid lowering agent, the antifolate drug, and optionally the folic acid; in any order such that sufficient levels of methylmalonic acid lowering agent and optionally folic acid are present to reduce the toxicity of an antifolate in a mammal. The administration of the compounds maybe simultaneous as a single composition or as two separate compositions or can be administered sequentially as separate compositions such that an effective amount of the agent first administered is in the patient's body when the second and/or third agent is administered. The antifolate drug may be administered to the mammal first, followed by treatment with the methylmalonic acid lowering agent. Alternatively, the mammal may be administered the antifolate drug simultaneously with the methylmalonic acid lowering agent. Preferably, the mammal is pretreated with the methylmalonic acid lowering agent and then treated with the antifolate. If folic acid is to be administered in addition to the methylmalonic acid lowering agent, the folic acid may be administered at any time prior, post, or simultaneously to the administration of either the methylmalonic acid lowering agent or the antifolate. Preferably, the mammal is pretreated with the methylmalonic acid, and then treated with folic acid, followed by treatment with the antifolate compound.

Dkt. 1-1, col. 4, 11. 4-27. Defendants also emphasized the interchangeable use of the two terms in the following description of a preferred embodiment:

> In the especially preferred embodiment of this invention, about 0.1 mg to about 30 mg, most preferably about 0.3 mg to about 5 mg, of folic acid is administered orally to a mammal about 1 to 3 weeks post administration of the methylmalonic acid lowering agent and about 1 to 24 hours prior to the parenteral administration of the amount of an antifolate. However, it will be understood that the amount of the methylmalonic acid lowering agent actually administered will be determined by a physician, in light of the relevant circumstances, including the condition to be treated, the chosen route of administration, the actual agent administered, the age, weight, and response of the individual patient, and the severity of the patient's symptoms, and therefore the above dosage range are not intended to limit the scope of the invention in any way.

Id. at col. 6, ll. 35-54.

The Court is not persuaded by Defendants' argument. Here, Defendants conceded in their claim construction response brief that the term "patient" is not explicitly defined in the '209 patent specification. *See* Def. Resp. Br., Dkt. 97 at 26. Thus, their argument is narrowed to whether Lilly implicitly redefined the term "patient." In order for a term to be redefined implicitly, "the redefinition must be so clear that it equates to an explicit one." *Thorner*, 669 F.3d at 1368. *Thorner* further states that "a person of ordinary skill in the art would have to read the specification and conclude that the applicant has clearly disavowed claim scope or has acted as its own lexicographer." *Id.* The Court finds that Lilly has not acted as its own lexicographer or disavowed the full scope of the claim term "patient." Even though the two terms appeared in the specification, there is nothing problematic with Lilly's use of the term "patient" in describing that a human undergoing medical treatment will be administered the methylmalonic acid lowering agent, folic acid, and antifolate. *See id.* ("Simply referring to two terms as alternatives or disclosing embodiments that all use the term the same way is not sufficient to redefine a claim term.").

Moreover, Defendants proposed construction of the term "patient" is not consistent with how the term is interpreted in light of the specification. As the Defendants conceded, the specification did not explicitly define the term "patient." In addition, the Federal Circuit has emphasized that courts cannot rewrite claims, but instead should give effect to the claim terms chosen by the patentee. *K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1364 (Fed. Cir. 1999).

Additionally, the Court finds that the specification does not support the Defendants' proposed construction of the term "patient" to encompass mammals. Specifically, a person of ordinary skill in the art reading the specification would not associate the administration of

pemetrexed disodium and methylmalonic acid lowering agent to mammals. The fact that the specification sets forth the administration of methylmalonic acid lowering agents and folic acid to mammals in pre-clinical trials does not mean that the claim term "patient" must be construed to encompass all potential functions outlined in the specification. *See Phillips*, 415 F.3d at 1327 ("We have held that 'the fact that a patent asserts that an invention achieves several objectives does not require that each of the claims be construed as limited to structures that are capable of achieving all of the objectives.'") (internal citation omitted).

When the '209 patent specification discussed pre-clinical trials, it disclosed tests involving mice and referred to them as animals. *See* Dkt. 1-1, col. 6, l. 56 – col. 8, l. 38. When the specification discussed clinical trials, on the other hand, it used the term "patient" in association with the treatment of cancer through the administration of an antifolate. For example, following the discussion of mice involved in a pre-clinical study, the specification discussed the administration of an antifolate "[i]n a typical clinical evaluation involving cancer patients." Dkt. 1-1, col. 8, ll. 39-42. A person of ordinary skill in the art would understand the term patient when discussed in the context of a clinical trial to involve a human undergoing medical treatment and not a mammal. Accordingly, the Court finds that the specification of the '209 patent supports Lilly's proposed construction of the claim term "patient."

c. The Prosecution History of the '209 Patent

In addition to consulting the specification, courts should also consult the prosecution history, which consists of the complete record of the proceedings before the United States Patent and Trademark Office ("PTO"). *Phillips*, 415 F.3d at 1317 ("Like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent."). The '209 patent was issued from the U.S. Patent Application No. 11/776,329 ("the '329

application"), which was filed as a division of U.S. Patent Application No. 11/288,807 ("the '807 application). In addition, the '807 application was filed as a division of U.S. Patent Application No. 10/297,821 ("the '821 application"). In support of their position, Defendants cite to two draft claims originating from the '807 application and the '329 application, respectively. Amended claim 3 of the '807 application stated the following: "A method of inhibiting tumor growth in *humans* comprising…." Dkt. 98-10 at 3 (emphasis added). Amended claim 29 of the '329 application stated the following: "an improved method for administering pemetrexed disodium to a *patient* in need of chemotherapeutic treatment, wherein the improvement comprises…." Dkt. 98-14 at 3 (emphasis added). Based on these amendments, Defendants contend that the change from the word "human" to the word "patient" had a broadening effect so that the amended claim included non-humans. *See* Def. Resp. Br., Dkt. 97 at 29.

The Court disagrees. Defendants emphasis on the prosecution history related to the issuance of the '209 patent to show that the claim term "patient" was broadened is misplaced; the claim scope was actually narrowed – not broadened – by the use of the term "patient" instead of human. Unlike the word human, "patient" encompasses a human undergoing medical treatment, whereas the word human, by itself, does not refer to a human receiving any additional treatment. After all, some humans go decades without visiting the doctor. Accordingly, the prosecution history does not support the Defendants' proposed construction.

d. Extrinsic Evidence

Finally, in construing the meaning of claim terms a court can turn to the extrinsic evidence, such as dictionaries, treaties, and expert testimony in determining patent claim scope. *See Phillips*, 415 F.3d at 1317-18. On their own, the claims do not provide sufficient aid in defining the term "patient" because "patient" is not explicitly defined in the specification or in

the prosecution history. Thus, the Court looks to the extrinsic evidence to provide context in an effort to arrive at the ordinary and customary meaning of the term. *See Phillips*, 415 F.3d at 1317 (articulating that courts may refer to extrinsic evidence if they deem it useful in determining a claim term's true meaning).

The first source describes "patient" as "[a] person receiving or registered to receive medical treatment; a sick person, esp. one staying in a hospital." *New Shorter Oxford English Dictionary* 2123 (1993). The second source describes "patient" as "a person who is under medical care or treatment." *Random House Unabridged Dictionary* (2d revised ed. 1993). The third source describes "patient" as "an individual awaiting or under medical care and treatment…" *Merriam-Webster's Collegiate Dictionary* (10th ed. 1993). In addition to these dictionary definitions, Lilly provided an expert report from Dr. Peter O' Dwyer, a medical oncologist who has treated numerous patients with ALIMTA®. In Dr. O'Dwyer's expert report, he opined that a person of ordinary skill in the art would understand the term "patient" to mean a human undergoing medical treatment. Dkt. 95-1 at 9-10.

In short, the Court finds that the extrinsic evidence reinforces the Court's view that Lilly's proposed construction is correct from the extrinsic evidence. It is clear that the word "patient" involves a human's receipt of medical treatment or care. Moreover, Lilly's expert's opinion on the understanding of the term "patient" by a person of ordinary skill in the art does not contradict the meaning supported by the intrinsic evidence. Importantly, Defendants have not presented any other extrinsic evidence, in the form of expert reports, to support their proposed construction.

Because neither the intrinsic record nor extrinsic record supports the Defendants' proposed construction, the Court rejects it. For these reasons, the Court adopts Lilly's proposed construction, as it aligns with the ordinary and customary meaning of the claim term.

2. Term 2: "vitamin B12"

Claim Term/Phrase	Plaintiff's Proposed Construction	Defendants' Proposed Construction
"vitamin B12"	"cyanocobalamin"	"indefinite"

The parties disagree on the construction of the term vitamin B12 as it is used in the claim language of the '209 patent. Specifically, Lilly contends that there are two ordinary and customary meanings of the claim term "vitamin B12" – one narrow and one broad depending on the context in which it is used. Lilly argues that the Court should adopt the narrower ordinary meaning of "vitamin B12," which is "cyanocobalamin," over its broader plain meaning, "vitamin B12 and its pharmaceutical derivatives." Defendants counter by arguing that Lilly explicitly defined the term "vitamin B12" in the '209 patent's specification. In addition, Defendants argue that both the '209 patent's explicit definition and Lilly's proposed construction of the term "vitamin B12" are unreasonable and unworkable; therefore, the term is indefinite. Finally, Defendants ask the Court to rule that, because the term "vitamin B12" is indefinite, it necessarily follows that the claims containing this term are invalid. *See* Def. Resp. Br., Dkt. 97 at 25. The Court will address the parties' claim construction arguments in turn.

A. Construing the meaning of "vitamin B12"

Claim construction starts with the language of the claim itself. *See Vitronics*, 90 F.3d at 1582. In the '209 patent, claim 1 provides for a method of administering pemetrexed disodium along with folic acid and a methylmalonic acid lowering agent, wherein "the methylmalonic acid lowering agent is selected from the group consisting of vitamin B12, hydroxocobalamin, cyano-

10-chlorocobalamin, aquocobalamin perchlorate, aquo-10-chlorocobalamin perchlorate, azidocobalamin, cobalamin, cyanocobalamin, or chlorocobalamin." Dkt. 1-1, col. 10, ll. 60-65. In addition, claim 2 provides for "[t]he method of claim 1, wherein the methylmalonic acid lowering agent is vitamin B12." *Id.* at col. 10, ll. 66-67. When analyzing claim 1, the terms "vitamin B12" and "cyanocobalamin" are both used in the claim language.

Lilly contends that a person of ordinary skill in the art would understand "vitamin B12" to have two plain and ordinary meanings in the context of the patent: 1) cyanocobalamin and 2) vitamin B12 and its pharmaceutical derivatives. In support of its contention, Lilly presents testimony from its expert, Dr. O'Dwyer, stating that when vitamin B12 is prescribed in the medical field, the particular vitamin supplement is referred to as cyanocobalamin, whereas vitamin B12 deficiency would commonly refer to vitamin B12 and its pharmaceutical derivatives. *See* Dkt. 95-2 at 2, ¶5; Dkt. 96-5 at 81: 6-9; *see also Phillips*, 415 F.3d at 1318. Lilly proposes that the Court adopt the narrower construction of the term and construe "vitamin B12" to mean cyanocobalamin.

Because the claim language, standing alone, does not fully alleviate the ambiguity surrounding the meaning of "vitamin B12," the Court turns to the specification because "it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315 (quoting *Vitronics*, 90 F.3d at 1582). The '209 patent specification provides in relevant part:

> The term "vitamin B12" refers to vitamin B12 and its pharmaceutical derivatives, such as hydroxocobalamin, cyano-10-chlorocobalamin, aquocobalamin perchlorate, aquo-10-chlorocobalamin perchlorate, azidocobalamin, chlorocobalamin, and cobalamin. Preferably the term refers to vitamin B12, cobalamin, and chlorocobalamin.

Dkt. 1-1, col. 5., ll. 5-10. From this language, Defendants assert that "vitamin B12" was explicitly defined by Lilly, and because that definition cannot be applied to the claim term

consistently throughout the patent, "vitamin B12" is indefinite. *See generally*, *Digital Biometrics v. Identix, Inc.*, 149 F.3d 1335, 1345 (Fed. Cir. 1998) ("[T]he same word appearing in the same claim should be interpreted consistently."). The Court disagrees.

First, the Court finds that the relevant language quoted above referring to "vitamin B12" is not an explicit definition of the claim term in the written description. Significantly, there is evidence to establish that Lilly does not provide an explicit definition for "vitamin B12." *See Abbott Labs. v. Andrx Pharm., Inc.*, 473 F.3d 1196, 1210-11 (Fed. Cir. 2007) (holding that the district court erred in determining a claim term was explicitly defined when there was evidence that the patentee did not provide a definition for the disputed term in the written description). In *Abbott*, the Federal Circuit concluded that a term definition within a patent's specification that contained words such as "means" or "as used herein" could be interpreted as redefinitions of those terms from their ordinary and customary meanings. *Id.* at 1210. Like the patent at issue in *Abbott*, the '209 patent provides for definitions of certain terms by using particular words, such as "means" or "as used herein," in the process of defining the term. *See, e.g.*, Dkt. 1-1, col. 3, ll. 53-55 ("As used herein, the term 'effective amount' refers to…"), Dkt. 1-1, col. 3, ll. 59-60 ("As used herein the term 'toxicity' refers to…"), Dkt. 1-1, col. 4, ll. 1-3 ("As used herein, the term 'nonhematolgic event' refers to…"), Dkt. 1-1, col. 4, ll. 4-9 ("As used herein, the term 'in combination with' refers to…"), Dkt. 1-1, col. 5, ll. 51-55 ("The term 'FBP binding agent' as used herein refers to…"), Dkt. 1-1, col. 6, ll. 53-54 ("The term 'pharmaceutical' when used as an adjective means…").

Notably, the '209 patent does not use those types of words and phrases with respect to the term "vitamin B12": "'vitamin B12' refers to…." Dkt. 1-1, col. 5., l. 5. This particular phrasing, when viewed in the context with the other additional terms located in the '209 patent, does not

signify an intent by Lilly to redefine the term "vitamin B12" under the rationale of *Abbott*. *See Abbott*, 473 F.3d at 1210 (concluding the phrase "'pharmaceutically acceptable polymer *is*…' [did] not…unambiguously signify that the description provided [was] definitional"). Moreover, neither Lilly nor Defendants have proposed that the Court adopt the so-called explicit definition of "vitamin B12" as the proper construction of the term. Therefore, the Court concludes that the term "vitamin B12" is not explicitly defined in the '209 patent.

Second, Defendants reliance on the principle that a single term should be construed consistently throughout a patent is misplaced in this case when the specification "puts the reader on notice of the different uses of a term." *Pitney Bowes*, 182 F.3d at 1311. "[W]here the language of the written description is sufficient to put a reader on notice of the different uses of a term, and where those uses are further apparent from publicly-available documents referenced in the patent file, *it is appropriate to depart from the normal rule of construing seemingly identical terms in the same manner*." *Id.* (emphasis added). Moreover, as discussed in more detail below, the prosecution history is consistent with the conclusion that the term "vitamin B12" can mean cyanocobalamin in the context of the '209 patent. Thus by analyzing the written description, in the context of the prosecution history, it is apparent that a person of ordinary skill in the art would understand "vitamin B12" to mean "cyanocobalamin" when it is used.

Defendants' argument that "vitamin B12" is indefinite because it violates the principles of claim construction is flawed because that is not the standard of indefiniteness. A claim is indefinite if it is "not amenable to construction or [is] insolubly ambiguous." *Datamize*, 417 F.3d 1347. The Court accepts Lilly's expert's (Dr. O'Dwyer) representation that a person of ordinary skill in the art would understand "vitamin B12" to mean cyanocobalamin. *See* Dkt. 95-2 at 4-5, ¶ 5; *see also Phillips*, 415 F.3d at 1318 (explaining that "extrinsic evidence in the form of

expert testimony can be useful to a court for a variety of purposes, such as…to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art") (citations omitted). Furthermore, both parties' experts agreed that if "vitamin B12" means cyanocobalamin it would comport with the doctrine of claim differentiation by making claim 2 narrower in scope than claim 1. *See* Dkt. 95-2 at 6, ¶ 8; *see also A.K. Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1242 (Fed. Cir. 2003). This lends further support to the notion that Lilly's proposed construction is "reasonable," and if a claim term "can be given any reasonable meaning," the claim cannot be indefinite. *Ultimax Cement Mfg. Corp. v. CTS Cement Mfg. Corp.*, 587 F.3d 1339, 1352 (Fed. Cir. 2009). The Court finds that "vitamin B12" is amenable to construction and the specification supports Lilly's proposed claim construction of "vitamin B12."

Lastly, the Court will consider the prosecution history in construing the term "vitamin B12." *See Phillips*, 415 F.3d at 1317. Lilly presented a draft claim (claim 3 of the '807 application) to the PTO referring to administering a "methylmalonic acid lowering agent selected from the group consisting of vitamin B12, hydroxocobalamin, cyano-10-chlorocobalamin, aquocobalamin perchlorate, aquo-10-chlorocobalamin perchlorate, azidocobalamin, chlorocobalamin, cobalamin, and cyanocobalamin…." Dkt. 96-17 at 10. During the prosecution of the '807 application, the examiner rejected claim 3 of the '807 application which listed "vitamin B12" and "cyanocobalamin" separately within the same claim because the examiner stated the two agents were the same. Dkt. 96-19 at 15.[5] Following the rejection, Lilly continued to file new draft claims as part of the '329 application (which issued as the '209 patent), that were based on the understanding that the definition of "vitamin B12" was "cyanocobalamin."

[5] The examiner after previously rejecting a claim containing both the terms vitamin B12 and cyanocobalamin, allowed such a claim to be issued. *See* Dkt. 1-1, col. 10, ll. 56-60.

See Dkt. 98-14 at 4. In light of the prosecution history between Lilly and the PTO, it demonstrates Lilly's understanding of the term "vitamin B12" to mean "cyanocobalamin." The Court finds that the prosecution history, along with the rest of the intrinsic record, supports Lilly's proposed construction of the term "vitamin B12."

IV. CONCLUSION

For these reasons set forth above, the disputed claim terms have the following meanings:

CLAIM TERM	MEANING
patient	human undergoing medical treatment
vitamin B12	cyanocobalamin

SO ORDERED.

Date: 06/20/2012

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

DISTRIBUTION:

Jan M. Carroll
BARNES & THORNBURG LLP
jan.carroll@btlaw.com

Michael B. Cottler
GOODWIN PROCTER, LLP
mcottler@goodwinprocter.com

Anne N. DePrez
BARNES & THORNBURG LLP
adeprez@btlaw.com

Bruce Roger Genderson
WILLIAMS & CONNOLLY LLP
bgenderson@wc.com

Dov P. Grossman
WILLIAMS & CONNOLLY, LLP
dgrossman@wc.com

Jonathan E. Grossman
GOODWIN PROCTER, LLP
jgrossman@goodwinprocter.com

Kandi Kilkelly Hidde
BINGHAM GREENEBAUM DOLL LLP
khidde@bgdlegal.com

Megan A. Hughes
WILLIAMS & CONNOLLY, LLP
mhughes@wc.com

David M. Krinsky
WILLIAMS & CONNOLLY, LLP
dkrinsky@wc.com

Ellen E. Oberwetter
WILLIAMS & CONNOLLY, LLP
eoberwetter@wc.com

Adam L. Perlman
WILLIAMS & CONNOLLY LLP
aperlman@wc.com

Emily L. Rapalino
GOODWIN PROCTER, LLP
erapalino@goodwinprocter.com

David O. Tittle
BINGHAM GREENEBAUM DOLL LLP
dtittle@bgdlegal.com

Daryl L. Wiesen
GOODWIN PROCTER, LLP
dwiesen@goodwinprocter.com

Eric H. Yecies
GOODWIN PROCTER, LLP
eyecies@goodwinprocter.com