United States District Court,
N.D. West Virginia.

WYETH,
Plaintiff.
v.
MYLAN PHARMACEUTICALS, INC,
Defendant.

Civil Action No. 1:07CV91

May 22, 2009.

Alan A. Wright, Finnegan Henderson Farabow Garrett & Dunner LLP, Reston, VA, Allen M. Sokal, Antigone G. Kriss, Barbara R. Rudolph, Basil J. Lewris, Linda A. Wadler, Robert D. Litowitz, Robert A. Pollock, Finnegan Henderson Farabow Garrett & Dunner LLP, Washington, DC, Denise W. Defranco, Finnegan Henderson Farabow Garrett & Dunner LLP, Cambridge, MA, James F. Companion, John Porco, Schrader, Byrd & Companion, PLLC, Wheeling, WV, Mary R. Henninger, Robert C. Stanley, Finnegan Henderson Farabow Garrett & Dunner LLP, Atlanta, GA, for Plaintiff.

George J. Barry, III, McGuire Woods LLP, Atlanta, GA, Gordon H. Copland, Michael B. Pallay, Robert L. Florence, Robert J. Waddell, Timothy H. Kratz, Steptoe & Johnson, PLLC, Clarksburg, WV, Lynn E. Eccleston, McGuire Woods LLP, McLean, VA, for Defendant.

MEMORANDUM OPINION AND ORDER

IRENE M. KEELEY**, District Judge.**

This case involves three patents issued to the plaintiff, Wyeth, for an extended release formulation of the antidepressant known as "Effexor(R)." Pending before the Court is the construction of six disputed terms or phrases found in the asserted claims of the patents-in-suit. Having considered the parties' submissions and their arguments made at the *Markman* hearing, the Court construes the disputed terms as follows.

I. BACKGROUND

Wyeth initiated this patent infringement suit under the Hatch-Waxman Act against Mylan Pharmaceuticals, Inc. ("Mylan") in response to Mylan's development of a generic version of Wyeth's successful antidepressant drug, Effexor(R) XR. Effexor(R) XR is an extended-release version of Wyeth's immediate-release drug, Effexor(R). Both use venlafaxine as the active ingredient. The immediate-release version requires that a patient consume several doses a day and is notorious for causing undesirable side-effects. Effexor(R) XR reduces the frequency of dosing to once-a-day, and thereby reduces several of the side-effects that had been associated with Effexor(R), including nausea and emesis, or vomiting.

On May 22, 2007, Mylan notified Wyeth that it had filed an Abbreviated New Drug Application ("ANDA"), seeking United States Food and Drug Administration ("FDA") approval to market Venlafaxine HC1 Extended-Release Capsules, a generic form of Effexor(R) XR, in three dosage strengths (37.5 mg, 75 mg, and 150 mg). In addition, Mylan filed a certificate with the FDA alleging that certain claims of the three patents issued to Wyeth for Effexor(R) XR are invalid and not infringed by Mylan's ANDA. These three patents are United States Patent Numbers 6,274,171 B1 ("the '171 patent"), 6,403,120 B1 ("the '120 patent"), and 6,419,958 B2 ("the '958 patent") (collectively, the "patents-in-suit"). Each patent is titled "Extended Release Formulation of Venlafaxine Hydrochloride," and Wyeth is the owner of each by assignment. These three patents are related and share essentially identical specifications. FN1

FN1. For convenience, all citations to the specifications will be to the '171 patent unless otherwise noted.

In its current suit, Wyeth alleges that Mylan's ANDA infringes specific claims in the three patents-in-suit: claims 20-25 of the '171 patent, claims 1, 2, 13 and 14 of the '120 patent, and claims 1-6 of the '958 patent (collectively, the "asserted claims"). All of the asserted claims are "method claims," which set forth methods for using the extended release formulation of venlafaxine hydrochloride. Specifically, each claim is directed to one of two methods: (1) "a method for providing a therapeutic drug plasma concentration over a twenty four hour period with diminished incidences of nausea and emesis," *see, e.g.,* Claim 20 of the '171 patent; or (2) "a method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride," *see, e.g.,* Claim 24 of the '171 patent.

In accordance with the Scheduling Order in this case, the parties identified six terms and phrases from the asserted claims that they contend the Court must construe and submitted their proposed constructions. Following briefing, the Court conducted a *Markman* hearing on March 2, 2009.

In addition to considering the parties' briefings and oral arguments, the Court has also had the benefit of reviewing several decisions by other district courts that have already construed many of the same terms and phrases at issue in this case. Specifically, the District of Delaware issued a construction opinion in Wyeth v. Impax Laboratories, Inc., 526 F.Supp.2d 474 (D.Del.2007), on December 13, 2007. Shortly thereafter, on December 20, 2007, the Central District of California issued an unpublished construction decision in *Wyeth v. Anchen Pharmaceuticals,* Case No. SACV 06-386-JVS (C.D.Cal. Dec. 20, 2007). Later, in July 2008, the Eastern District of North Carolina issued an opinion in Wyeth v. Sandoz, Inc., 570 F.Supp.2d 815 (E.D.N.C.2008). In addition, two courts issued construction opinions in cases that were subsequently settled where, pursuant to the terms of the settlement, those opinions were vacated: *Wyeth v. Teva Pharmaceuticals USA, Inc.,* WL 2175440 (D.N.J. Sept. 6, 2005); and Wyeth v. Lupin Ltd., 579 F.Supp.2d 711 (D.Md.2008).

II. LEGAL STANDARDS

Claim construction is a matter of law, Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed.Cir.1995), for which this Court looks to the Federal Circuit Court of Appeals for guidance. "To ascertain the meaning of claims, we consider three sources: The claims, the specification, and the prosecution history." *Id. (quoting* Unique Concepts, Inc. v. Brown, 939 F.2d 1558, 1561 (Fed.Cir.1991)). In Phillips v. AWH Corporation, 415 F.3d 1303 (Fed.Cir.2005)(en banc), the Federal Circuit reaffirmed its longstanding principles of claim construction, beginning with the "bedrock principle" that "the claims of a patent define the invention to which the patentee is entitled the right to exclude." Id. at 1312 *(quoting*

Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1115 (Fed.Cir.2004)); *see also* Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996) ("[W]e look to the words of the claims themselves ... to define the scope of the patented invention."). Thus, an invention must be limited to what is described in the claims. *Id*.

Generally, claim terms should be 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." *Id*. at 1313. The question for claim construction, therefore, is how a person of ordinary skill in the art would have understood the term or phrase in question. "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*.

To evaluate a term in the context of the entire patent, a court must consider both asserted and unasserted claims. *Id*. at 1314. Importantly, claim terms are normally used consistently throughout a patent, and thus "the usage of a term in one claim can often illuminate the meaning of the same term in other claims." *Id*. at 1314. Differences among claims may be equally revealing. For example, "the presence of a dependant claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Id*. at 1315.

Beyond the language of the claims themselves, the specification is considered the "best source for understanding a technical term." *Id*. at 1315 *(quoting* Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1478 (Fed.Cir.1998)). By statute, inventors are required to describe their claimed invention in "full, clear, concise, and exact terms" in the specification. 35 U.S.C. s. 112, para. 1. Accordingly, "[t]he claims of a patent are always to be read or interpreted in the light of its specifications." Schriber-Schroth Co. v. Cleveland Trust Co., 311 U.S. 211, 217 (1940).

While terms are usually given their "ordinary and customary" meaning, an inventor may act as his own lexicographer in defining a claim term. Where a specification reveals a special definition for a claim term, or limits the term in a way that differs from its otherwise commonly understood meaning, that definition or limitation governs interpretation of the term. Phillips, 415 F.3d at 1316. Thus, it is "entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims." Id. at 1317.

Courts must be careful, however, to avoid reading limitations from the specification into the claims. Id. at 1323. "[T]hough the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments." *Id*. Indeed, the Federal Circuit has "expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment." *Id*. *(citing* Gemstar-TV Guide Int'l Inc. v. Int'l Trade Comm' n, 383 F.3d 1352, 1366 (Fed.Cir.2004)).

Courts may additionally consider the prosecution history of the patent-in-suit. "Like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent." Id. at 1317. Thus, a prosecution history that reveals an inventor has limited an invention during the course of the prosecution can indicate that the scope of a claim is narrower than it would be otherwise. *Id*.

Finally, while a court may consider extrinsic evidence such as expert testimony, dictionaries, and learned treatises in defining the "ordinary and customary meaning" of a term, such evidence carries less legal

significance than the intrinsic record. *Id*. Reliable extrinsic evidence includes "those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean." *Id*. at 1314 *(quoting* Innova, 381 F.3d at 1116).

III. ANALYSIS

The parties have identified six terms and phrases found in the asserted claims of the patents-in-suit that they ask the Court to construe. Bearing in mind the principles recited above, the Court addresses each in turn.

A. "Extended release formulation"

Both parties focus primarily on the proper construction of the phrase "extended release formulation," as that term is used in asserted claims 20-25 of the '171 patent, claims 1, 2, 13, and 14 of the '120 patent, and claims 1-6 of the '958 patent.

Wyeth proposes the following construction:

A drug formulation (other than a hydrogel tablet) that releases the active ingredient at a slower rate than the immediate release formulation of the active ingredient such that the dosing frequency is once-a-day rather than the plural daily dosing for the immediate release formulation.

Mylan, on the other hand, argues that the Court should construe the term as:

An extended release formulation consisting of venlafaxine hydrochloride, microcrystalline cellulose and, optionally, hydroxypropyl methylcellulose coated with a mixture of ethyl cellulose and hydropropyl methylcellulose.

Both parties agree that Wyeth's construction is the "ordinary and customary" meaning in the art given to the term "extended release formulation." Moreover, both parties urge the Court to consider the patent in its entirety, including the claims, specification and prosecution history, in construing the term in accordance with "what the inventors actually invented and intended to envelop with the claim." Phillips, 415 F.3d at 1316 *(quoting* Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250 (Fed.Cir.1998)).

Mylan, however, contends that the specification reveals that Wyeth has acted as its own lexicographer in defining the term "extended release formulation," by limiting the term, as used in these patents, to include venlafaxine hydrochloride, microcrystalline cellulose and, optionally, hydroxypropyl methylcellulose coated with a mixture of ethyl cellulose and hydropropyl methylcellulose ("the specific ingredients"). It asserts that, by consistently limiting the formulation to the specific ingredients throughout the specification, the inventors *implicitly* redefined the term. *See* Bell Atlantic Network Serv ., Inc. v. Covad Comm. Group, 262 F.3d 1258, 1271 (Fed.Cir.2001) ("when a patentee uses a claim term throughout the entire patent specification, in a manner consistent with only a single meaning, he has defined that term 'by implication.' " *)(quoting* Vitronics, 90 F.3d at 1582).

Initially, the Court must apply a " 'heavy presumption' that a claim term carries its ordinary and customary meaning." CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed.Cir.2002). This presumption is overcome, however, where an inventor has chosen to be his own lexicographer, thereby defining a term differently from the meaning it would otherwise possess. Phillips, 415 F.3d at 1316. Such special meaning may be bestowed explicitly or implicitly, Bell Atlantic, 262 F.3d at 1268, but the new definition must be

reasonably clear and have been done deliberately. *In re Paulson,* 30 F.3d at 1480. Indeed, "the intrinsic evidence must 'clearly set forth' or 'clearly redefine' a claim term so as to put one reasonably skilled in the art on notice that the patentee intended to so redefine the claim term." Bell Atlantic, 262 F.3d at 1268.

In determining whether a new definition has been implicitly bestowed, courts consider how the term is used in the claims, the specification and, if provided, the prosecution history. *See id.*

1. The Claims

The term "extended release formulation" appears in each of the asserted claims in this case. A typical example of its use appears in Claim 1 of the '958 patent:

A method of providing a therapeutic blood plasma concentration of venlafaxine ... which comprises administering orally to a patient in need thereof, an *extended release formulation* ..., said formulation containing venlafaxine hydrochloride as the active ingredient.

(Emphasis added.)

To refute Mylan's assertion that the inventors acted as their own lexicographer with regard to the term "extended release formulation," Wyeth relies heavily on the ways in which the term is used in the claims. It contends that adopting Mylan's proposed construction for that term would render certain aspects of the claims redundant, and that such construction would violate the doctrine of claim differentiation.

a. Redundancy

Within the asserted claims, each use of the term "extended release formulation" is followed by the limitation "said formulation containing venlafaxine hydrochloride as the active ingredient." Wyeth argues that such limitation strongly implies that the term is not defined by its specific ingredients.

In *Phillips,* the Federal Circuit explained that the term "steel baffles" "strongly implies that the term 'baffles' does not inherently mean objects made of steel." 415 F.3d at 1314. The court then reiterated its longstanding principle that "the use of the term within a claim provides a firm basis for construing the term." *Id.* Thus, where, as here, a term used in a claim is followed by a limitation, a strong implication exists that the term does not already include that limitation. To find otherwise would render the limitation redundant or superfluous. *See* Oak Tech., Inc. v. Int'l Trade Com'n, 248 F.3d 1316, 1330 (Fed.Cir.2001) (finding that the language of a claim itself can impose significant restrictions on a term within the claim).

As used in the asserted claims, the term "extended release formulation" is consistently followed by the limitation "said formulation containing venlafaxine hydrochloride as the active ingredient;" a strong presumption thus exists against construing the term as suggested by Mylan, whose proposed construction begins "consisting of venlafaxine hydrochloride." Indeed, Mylan's construction of "extended release formulation" would render the limiting phrase found in the asserted claims redundant.

b. Claim Differentiation

Wyeth next argues that the doctrine of claim differentiation further indicates that the inventors did not act as their own lexicographer in narrowly defining the term "extended release formulation." Under the doctrine of claim differentiation, "dependent claims are presumed to be of narrower scope than the independent claims

from which they depend." Regents of Univ. of Cal. v. Dakocytomation Cal., Inc., 517 F.3d 1364, 1375 (Fed.Cir.2008), *(quoting* AK Steel Corp. v. Sollac and Ugine, 344 F.3d 1234, 1242 (Fed.Cir.2003)). Thus, "the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." Phillips, 415 F.3d at 1315. This doctrine originates with 35 U.S.C. s. 112, which states that "a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed."

The presumption created by this doctrine is rebuttable, however; thus, if a patent's specification clearly sets forth the scope of the claim language, claim differentiation cannot be used to broaden the claim's scope. Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1480 (Fed.Cir.1998). The presumption may therefore be overcome if, after looking to the specification, the court determines that the inventor bestowed a special definition on a claim term, even though such definition renders aspects of the dependent claim superfluous.

Claim One of the '120 patent, an independent method claim asserted in this case, includes the term "extended release formulation" but does not recite the specific ingredients. Dependant Claim Three, however, states "[t]he method of claim 1 wherein the extended release formulation comprises venlafaxine hydrochloride in a spheroid comprised of [the specific ingredients]." Under the doctrine of claim differentiation, the Court must presume that the specific ingredients listed in Claim Three narrows the scope of Claim One. Thus, the Court further presumes that those ingredients are not included in the definition of "extended release formulation." Because claim terms are generally used consistently throughout a patent, the differentiation established in this example is applicable throughout. *See* Phillips, 415 F.3d at 1314.

2. The Specification

In this case, Mylan contends that the presumption of differentiation is overcome by looking at the specification. It argues that the inventors bestowed a special meaning on the term "extended release formulation" by limiting the term to a formulation containing the specific ingredients.

Specifically, Mylan asserts that the inventors repeatedly apply a narrow definition, including the specific ingredients to the term in the specification. As examples, it points to the Abstract, which, after indicating that the invention relates to "a 24 hour extended release dosage formulation," states:

More particularly, the invention comprises an extended release formulation of venlafaxine hydrochloride comprising a therapeutically effective amount of venlafaxine hydrochloride, microcrystalline cellulose and, optionally, hydroxypropylmethylcellulose coated with a mixture of ethyl cellulose and hydroxypropylmethlycellulose.

'171, Abstract. Similarly, the "Brief Description of the Invention" describes the invention as

an extended release formulation of venlafaxine hydrochloride comprising a therapeutically effective amount of venlafaxine hydrochloride in spheroids comprised of venlafaxine hydrochloride, microcrystalline cellulose and, optionally, hydroxypropylmethylcellulose coated with a mixture of ethyl cellulose and hydroxypropylmethylcellulose.

'171, Col. 2:63-67, 3:1-2. Finally, the "Detailed Description of the Invention" states:

The extended release formulations of this invention are comprised of 1-[2-(dimethyla mino)-1-(4-methoxyphenyl)ethyl]cyclohexano hydrochloride in admixture with micro-crystalline cellulose and hydroxypropylmethylcellulose. Formed as beads or spheroids, the drug containing formulation is coated with a mixture of ethyl cellulose and hydroxypropylmethyl cellulose to provide the desired level of coating....

Id. at Col. 4:9-16. Mylan contends that these passages, as well as others not cited here, indicate that the term is limited to the specific ingredients.

Although acknowledging that the specification repeatedly references the specific ingredients, Wyeth argues that nothing in the specification reveals that the inventors clearly intended to apply a special meaning to the term "extended release formulation." Instead, it contends that the specification describes the invention broadly and the specific ingredients are merely included as a preferred embodiment of the invention, not the sole embodiment. Wyeth further points out that the "Brief Description of the Invention" describes a broad "use aspect" of the invention, which describes an extended release formulation of venlafaxine hydrochloride, but does not suggest that any specific inactive ingredients are required. *See* '171, Col. 2:55-62. It contends that the specification reveals that term is limited by its pharmacologic properties rather than any specific set of ingredients.

Wyeth further points out that the inventors understood how to limit a claim by its specific ingredients, and did so in the product claims. Thus, the fact that the inventors did not include the specific ingredients in any of the method claims would appear to be intentional. As the court in *Impax* concluded:

That [a] list of ingredients was not provided with respect to the method claims and the portions of the specification corresponding to the method claims leads the Court to believe that the inventors knew how to limit the term when they so desired, and chose not to do so with respect to the method claims.

526 F.Supp.2d at 480.

After closely considering the specification, the Court concludes that the inventors did not set forth a new definition for "extended release formulation" with the reasonable clarity, deliberateness and precision required when an inventor applies his own lexicography to a claim term. *See In re Paulson,* 30 F.3d at 1480. Rather, it agrees with Wyeth that the term, as used in the specification, is defined by its pharmacologic properties, such as creating "twenty-four hour therapeutic blood levels," rather then the specific ingredients.

Moreover, because the Federal Circuit has "expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment," Phillips, 415 F.3d at 1323, the Court declines to limit the meaning of "extended release formulation" merely because Wyeth has disclosed only one set of specific ingredients.

3. The Prosecution History

The prosecution history further supports a conclusion that "extended release formulation" is not limited to the specific ingredients. During the prosecution of a related patent application, an examiner with the Patent and Trademark Office ("PTO") apparently understood that the term "extended release formulation" was being used in the patents according to its ordinary meaning. That application, like the subsequent applications that became the patents-in-suit, included product claims that recited the specific ingredients, as

well as method claims that recited the term "extended release formulation" but did not recite any of the specific ingredients. Wyeth Ex. 23. During a telephone conference, the examiner informed the inventors that they had to amend the method claims to make them dependent on a product claim that recited the specific ingredients, because the method claims would otherwise be too broad. Wyeth Ex. 24, 002-000850 to 582.

After considering this recommendation, Wyeth abandoned that application rather than make the method claims dependant on the product claims, which recited the specific ingredients. Wyeth Ex. 25. Shortly thereafter, it filed a continuation-in-part application that included the same independent method claims, set forth in the same manner. Wyeth Ex. 26. In other words, the inventors specifically chose not to limit the method claims by including the specific ingredients or by making them dependant on a product claim that included those ingredients. During the prosecution of this second application, a new examiner allowed the patents to issue without requiring that the method claims include the limitation. Wyeth Ex. 27, 002-000719. Moreover, the second examiner explicitly noted that the method claims "[do] not recite any limitations describing the formulation." *Id*. at 002-000718.

This history clearly indicates that the inventors as well as both PTO examiners understood the term "extended release formulation" to hold its common and ordinary meaning. Moreover, Wyeth explicitly declined to limit its method claims by including the specific ingredients or making the claims dependant on a product claim that recited those ingredients. Thus, the prosecution history clearly supports Wyeth's proposed construction of this term.

Although Mylan argues that "a rejection by a first examiner followed by the allowance of the same claims in a continuation application by a new examiner raises serious questions about the reliability of the new examiner's conclusion," Mylan Opening Brief, p. 17 *(citing* Syntex (USA) LLC v. Apotex, Inc., 407 F.3d 1371, 1382-83 (Fed.Cir.2005)), this argument challenges the validity of the patent, and thus is not appropriate at this time.

In conclusion, the Court finds that the inventors did not clearly and deliberately set forth a new definition for "extended release formulation" in the specification. Mylan therefore has failed to overcome the strong presumption against its proposed construction because, among other things, adopting that construction would render certain dependent claims in the patents redundant, thus violating the doctrine of claim differentiation. Finally, the prosecution history further supports the conclusion that the inventors intended the common and ordinary meaning of the term to apply. For these reasons, the Court adopts Wyeth's proposed construction of this term.

B. "A method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine **hydrochloride**"

The parties next seek construction of the term "a method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride" as used in claims 21, 24, and 25 of the '171 patent and in claims 2, 5, and 6 of the '958 patent.

Wyeth proposes that the term be construed to mean

A method in which the extended release formulation is administered once in a 24-hour period, resulting in a venlafaxine blood plasma concentration that rises to a maximum value, followed by a generally protracted

decrease over the remaining period while maintaining during that 24-hour period levels of venlafaxine in blood plasma that are sufficient to provide relief from the condition being treated, thereby eliminating the multiple sharp peaks and troughs resulting from multiple daily dosing of the same total daily dose of the immediate release formulation as reflected in a graph of venlafaxine blood plasma concentration versus time.

Mylan, on the other hand, argues that (1) the Court need not construe the term because it is merely an unnecessary "preamble" to the claims, and (2) if the Court does construe the term, it simply means "lowering the occurrence of peaks and troughs associated with multiple daily dosing of venlafaxine hydrochloride."

1. Unnecessary Preambles

Initially, Mylan contends that the phrase "a method for eliminating troughs and peaks ... attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride," is merely an unnecessary preamble to the claims in which it is found, and thus the Court need not construe it. "If the body of the claim sets out the complete invention, and the preamble is not necessary to give life, meaning and vitality to the claim, then the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation." Bristol-Myers Squibb Co. v. Ben Venue Lab., Inc., 246 F.3d 1368, 1373 (Fed.Cir.2001) (internal quotations omitted). Thus, as Mylan contends, there are occasions when preambles are insignificant to the claims, rendering construction inappropriate.

"In considering whether a preamble limits a claim, the preamble is analyzed to ascertain whether it states a necessary and defining aspect of the invention, or is simply an introduction to the general field of the claim." *On* Demand Mach. Corp. v. Ingram Indus., 442 F.3d 1331, 1343 (Fed.Cir.2006). To this end, a court should consider whether the written description and applicants' statements during prosecution emphasize this feature of the invention. *Id*. If such feature is emphasized, but the limitation does not appear in the body of the claims, then it is a "necessary and defining aspect of the invention." *Id*. Stated another way, if "the preamble is essential to understand the limitations or terms in the claim body, the preamble limits claim scope." Catalina Mktg. Int'l v. Coolsaving.com, Inc., 289 F.3d 801, 808 (Fed.Cir.2002).

Importantly, however, "[n]o litmus test defines when a preamble limits claim scope." In re Cruciferous Sprout Litig., 301 F.3d 1343, 1347 (Fed.Cir.2002). Thus, the determination of whether to treat a preamble as a limitation is " 'resolved only on review of the entirety of the patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim.' " *Id*. *(quoting* Corning Glass Works v. Sumitomo Elec. U.S.A., Inc ., 868 F.2d 1251, 1257 (Fed.Cir.1989)).

As used in the patents-in-suit, the Court cannot conclude that the phrase "a method for eliminating troughs and peaks. attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride" is an unnecessary preamble. As an example of the use of the preamble, asserted Claim 21 of the '171 patent states:

A method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine *hydrochloride* which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride as the active ingredient.

(Emphasis added.)

In considering the written description, it is clear that eliminating the troughs and peaks of the drug concentration in a patient's blood plasma is an important aspect of the invention. For example, the Abstract states that the invention is for a 24-hour extended release formulation that "provides better control of blood plasma levels than conventional tablet formulations...." The "Brief Description of the Invention" explains that "this invention provides a method for eliminating the sharp peaks and troughs (hills and valleys) in blood plasma drug levels...." '171, Col. 2:25-30. After further explaining the reduction in peaks and troughs, the inventors state: "Hence, in accordance with the use aspect of this invention, there is provided a method for moderating the plural blood plasma peaks and valleys attending the pharmacokinetic utilization of multiple daily tablet dosing...." *Id*. at Col. 2:38-43.

Accordingly, because the written description clearly emphasizes that eliminating the peaks and troughs associated with plural daily doses of venlafaxine hydrochloride is an important use aspect of the invention, and because this use aspect does not appear in the body of the claim, the Court concludes that this preamble is a "necessary and defining aspect of the invention." On Demand Mach. Corp., 442 F.3d at 1343.

Furthermore, in Jansen v. Rexall Sundown, Inc., 342 F.3d 1329, 1333 (Fed.Cir.2003), the Federal Circuit noted that when a claim's preamble sets forth the objective of the method, and the body of the claim directs that the method be performed on someone "in need," then "the claims' recitation of a patient or a human 'in need' gives life and meaning to the preambles' statement of purpose." FN2 Thus, a preamble is "not merely a statement of effect that may or may not be desired or appreciated. Rather, it is a statement of the intentional purpose for which the method must be performed." *Id*.

FN2. The independent method claims construed in *Jansen* are similar in structure to those at issue in this case. For example:
A method of treating or preventing macrocyticmegaloblastic anemia in humans which anemia is caused by either folic acid deficiency or by vitamin B_{12} deficiency which comprises administering a daily oral dosage of a vitamin preparation *to a human in need thereof* comprising at least about 0.5 mg. of vitamin B_{12} and at least about 0.5 mg. of folic acid.

(Emphasis added.)
As in *Jansen,* the preamble here sets forth the objective of the method, eliminating the troughs and peaks, and the body of the claim directs that the method be performed on "a patient in need thereof." Accordingly, following the Federal Circuit's lead in Jansen, this Court concludes that the preamble at issue "gives life" to the claim and is appropriate for construction.

2. Ordinary Meaning Versus Inventor's Lexicography

Mylan argues that, because the term "a method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride" does not include any calculations showing the maximums and minimums of the blood/drug concentration, or any description of the rate within which the concentration rises and falls, the term should not be construed to describe the shape of the resulting concentration/time curve or the magnitude of that curve, as provided by Wyeth's construction.

Mylan further contends that, at the time of the invention, it was well known by persons of ordinary skill in the art that extended release drug formulations reduce multiple peaks and troughs of a drug concentration in a patient's blood plasma. It therefore argues that those familiar with the art would understand the ordinary meaning of the term simply to be "lowering the occurrence of peaks and troughs associated with multiple daily dosing of venlafaxine hydrochloride."

Wyeth, on the other hand, asserts that, because this is not a term of art with a customary meaning, the inventors necessarily acted as their own lexicographers in defining the term in the specification. Wyeth's expert in the field of pharmacokinetics, Dr. Ronald J. Sawchuk, Ph.D. ("Sawchuk"), a Professor of Pharmaceutics at the University of Minnesota, states that a person of ordinary skill in the art who had reviewed the written description would have understood the term as Wyeth proposes. Wyeth Ex. 32, p. 19.

In reaching that conclusion, Sawchuk points to the "Brief Description of the Invention," which states:

In essence, the plasma levels of venlafaxine [ ] hydrochloride rise, after administration of the extended release formulations of this invention, for between five to about eight hours (optimally about six hours) and then begin to fall through a protracted, substantially linear decrease from the peak plasma level for the remainder of the twenty four hour period, maintaining at least a threshold therapeutic level of the drug during the entire twenty-four hour period.

Wyeth contends that this passage, as well as others throughout the specification, indicate that because the extended release formulation of venlafaxine hydrochloride is administered only once a day, it necessarily results in only one peak and one trough over the twenty-four hour period, and, thus, eliminates the sharp peaks and troughs associated with multiple dosings.

Although the inventors did not explicitly set forth a definition for the phrase "a method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride," the specification establishes that the phrase is implicitly defined as Wyeth suggests. Contrary to Mylan's assertion, the fact that the terms "peak" and "trough" do not, by themselves, provide a description regarding the rate at which blood concentrations of drug rise and fall after once-a-day administration does not undermine Wyeth's definition. Rather, the specification reveals that the inventors understood that the oncea-day administration of the extended release formulation would result in a venlafaxine hydrochloride blood plasma concentration that would rise to a maximum value and then slowly decline over the remaining time period, thereby creating a "flattened drug plasma concentration to time profile." '171, Col. 2:22. Accordingly, the Court construes the phrase as requested by Wyeth.

C. "Diminished incidences of nausea and emesis"

The phrase "diminished incidences of nausea and emesis" is found in asserted claims 20, 22, and 23 of the '171 patent, 1 of the '120 patent, and 1, 3, and 4 of the '958 patent. For example, claim 20 of the '171 patent states:

A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty four hour period with diminished incidences of nausea and emesis which comprises administering orally to a patient in need thereof, an encapsulated, extended release formulation that provides a peak blood plasma level of venlafaxine in from about four to about eight hours, said formulation containing venlafaxine hydrochloride

as the active ingredient.

Wyeth asks the Court to construe the phrase as:

The degree and/or frequency of nausea and emesis from the extended release formulation administered once-a-day is less than what would be experienced by patients receiving the same total daily doses of an immediate release formulation that is administered at least twice a day.

Mylan again argues that the phrase is an unnecessary preamble to the claim; to the extent that the Court determines otherwise, however, it provides the following alternate construction:

A decrease in the number of patients suffering from nausea and vomiting compared to patients receiving the same total daily dose of an immediate release formulation that is administered at least twice a day.

Thus, the parties' dispute centers on the meaning of the term "incidence," and whether it refers solely to the number of occurrences of the side effects, or also encompasses the severity of those occurrences.

1. Unnecessary Preamble

Despite Mylan's contention that the term "diminished incidence of nausea and emesis" is merely an unnecessary preamble to the claims in which it is found, the Court concludes that this phrase is necessary to give "life, meaning and vitality" to those claims. The specification reveals that reducing the negative side effects associated with the immediate release version of the drug is an important use aspect of the invention. The "Background of the Invention" explains that the most common side effect associated with the plural daily dosing regime is nausea, and that many patients also experienced vomiting, or emesis. '171, Col. 2:7-11. The "Brief Description of the Invention" then states "in accordance with this use aspect of the invention, there is a method for reducing the level of nausea and incidence of emesis attending the administration of venlafaxine hydrochloride...." *Id*. at Col. 2:55-58.

Consequently, because the specification reveals that "reducing the incidence of nausea and emesis" is a stated and intended objective of the invention, *see* Cruciferous Sprout, 301 F.3d at 1347, the phrase is not an unnecessary preamble but instead constitutes a claim limitation that must be construed.

2. Meaning of "Incidence"

Both parties agree that "incidence" refers to the frequency, or number of occurrences, of the nausea and emesis. Wyeth, however, contends that the term also encompasses the severity or degree of those side-effects, arguing that, because the specification uses the terms "incidence" and "level" interchangeably, the inventors intended the term "incidence" to encompass both meanings. Wyeth additionally contends that the use of "diminished" to modify "incidences" further indicates that the reduction refers not only to the number of patients experiencing side effects, but also the severity or degree of those effects.

The claims themselves refer only to "diminished incidences" of nausea and emesis. Wyeth relies on *Webster's Third New International Dictionary* (1993) for the proposition that "diminish" means "to make less or cause to appear less: reduce in size, number or degree." Wyeth Ex. 33. Thus, as Wyeth contends, the term is not necessarily limited to a numerical focus. Nevertheless, just because the term may be used to reference degree, as well as number, does not mean it is used in that capacity in every case. Unfortunately, taken alone, the claim language does not indicate the intended meaning of the term, and thus the Court must

turn to the specification for guidance.

The "Abstract" states that the invention provides a "lower incidence of nausea and vomiting than conventional tablets." In the "Background of the Invention," the inventors describe the side effects commonly associated with immediate release Effexor(R), stating that the most common side effect is nausea, "experienced by about forty five percent of patients under treatment with venlafaxine hydrochloride." '171, Col. 2:7-10. They then state that vomiting occurs in approximately seventeen percent of patients using the immediate release version. *Id*. at Col. 2:10-11. Thus, the inventors describe the problem in terms of the number of patients experiencing the side effects, rather then in the context of the severity of those side effects.

The inventors then describe the positive effect of the extended release version of the drug in the "Brief Description of the Invention," explaining that, during clinical trials of extended release venlafaxine hydrochloride, "the probability of developing nausea" greatly reduced after the first week. *Id*. at Col. 2:49:52. Again, the inventor's description of the benefit achieved by the extended release formulation is given in the context of the number of people affected, rather than the severity of the nausea.

Beginning in the "Brief Description of the Invention," the inventors use an additional term that is not used anywhere else in the patent. Specifically, they twice refer to "the *level* of nausea and *incidence* of emesis." *See* '171, Col. 2:47-48 and 56-57. Wyeth asserts, and the Court agrees, that the term "level" implies "degree" or "severity" rather then "number." Thus, in the "Brief Description," the inventors appear to describe a reduction in both the degree of nausea experienced and the number of patients experiencing vomiting, or emesis. Wyeth therefore argues that the inventors intended to associate both types of reductions with the new invention. It further asserts that, because the terms "level" and "incidence" are both used to modify "nausea," the inventors clearly intended the words to be used interchangeably.

To the Court, however, the inventors' use of the term "level" indicates that they understood a difference between "level" and "incidence." Specifically, they use "level" in reference to "degree" or "severity," and "incidence" in reference to the number of occurrences. This interpretation is supported by the fact that the inventors never refer to the "level of emesis," but instead only discuss the "incidence of emesis." Thus, they appear to have understood a difference between level and incidence, and used the terms accordingly. Consequently, the Court must find meaning in their decision to use only the term "incidence" in the body of the claims.

Moreover, because claim terms are presumed to be used consistently throughout a patent, *see* Phillips, 415 F.3d at 1314, the Court is unpersuaded that the inventors would have distinguished between "level" and "incidence" in the "Brief Description of the Invention," but then intended to incorporate both meanings into the term "incidence" within the body of the patent claims.

Finally, as Mylan points out, the fact that the specification indicates the "level" of nausea may be reduced by the extended release formulation does not require the Court to read that limitation into the claims. In *Phillips,* the Federal Circuit noted that " '[t]he 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.' " *Id*. at 1327 *(quoting* Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 908 (Fed.Cir.2004)).

For these reasons, the Court construes the term "diminished incidences of nausea and emesis" to mean "a

decrease in the number of patients suffering from nausea and vomiting compared to patients receiving the same total daily dose of an immediate release formulation that is administered at least twice a day."

D. "Spheroid"

The term "spheroid" is found in asserted claims 13 and 14 of the '120 patent. Wyeth proposes that the term be construed to mean

one or more particles that are generally shaped like a sphere, although they do not have to be perfectly round. The term spheroid may include granules, beads, and pellets.

Mylan, on the other hand, proposes the following alternative:

One or more particles that are generally shaped like a sphere resulting from an extrusion and spheronization process.

Thus, Mylan argues that, as used in these patents, the term "spheroid" is limited to spheroids created by a certain method of manufacture, specifically an extrusion and spheronization process.

Mylan argues that a person of ordinary skill in the art would understand that the specification limits the term to spheroids created through an extrusion and spheronization process. It points out that the specification repeatedly refers to this method of manufacture, and, indeed, mentions no other potential methods. While it admits that "spherical particles" can be manufactured through other methods, such as drug layering on a sugar crystal or seed, Mylan contends that a person of ordinary skill in the art would expect that, had the inventors intended to include spheroids made by other methods, they would have explained those methods. According to Mylan's pharmaceuticals expert, Glenn A. Van Buskirk, Ph.D. ("Van Buskirk"), other methods of manufacture could affect the sphere density and size of the spheroids, which, in turn, could affect the release of the drug in a patient's system. Mylan, Barry Dec., Ex. C, para. 30. FN3 Thus, Mylan contends, the methods are not easily interchangeable and a person of ordinary skill in the art seeking to duplicate the dissolution rates using spheriods that have been manufactured using a technique other than the extrusion and spheronization process would be required to do significant experimentation to achieve the same results. *Id*.

FN3. Mylan attaches Van Buskirk's affidavit as Exhibit C to the "Declaration of George J. Barry III In Support of Defendant Mylan Pharmaceuticals Inc.'s Responsive Claim Construction Brief." Barry represents Mylan in this case.

Mylan further points out that the specification provides a table of dissolution rates, entitled "Acceptable Coated Spheroid Dissolution Rates," and limits the invention to the specific dissolution rates listed there. '171, Col. 6:55-65. Because the inventors only explain how to achieve those dissolution rates using a process of extrusion and spheronization, Mylan argues that they have implicitly limited the term "spheroid" to that method.

Wyeth, on the other hand, urges the Court to adopt the ordinary meaning of "spheroid," which it contends is "any particle generally shaped like a sphere, including granules, beads, and pellets." It cites expert testimony and extrinsic evidence, including dictionary definitions and scientific literature, to support this definition. Although only one method of manufacture for the spheroids is disclosed in the specification, Wyeth

contends this is merely a preferred method and there is no evidence that the inventors intended to narrow the scope of the term.

1.

The term "spheroid" appears in two of the asserted claims. Claim 13 of the ' 120 patent states "[t] he method of claim 1 wherein the extended release formulation comprising venlafaxine hydrochloride in a *spheroid*." (Emphasis added). Similarly, Claim 14 of the same patent states "[t]he method of claim 1 wherein the extended release formulation comprises venlafaxine hydrochloride in an encapsulated *spheroid*." (Emphasis added.) Thus, the plain meaning of the term, as used in the claims, does not imply a specific method of manufacture.

"Spheroid" also appears throughout the specification. Initially, in the "Background on the Invention," the inventors describe the convention in the drug industry for producing extended release capsules when the production of tablets is not feasible. '171, Col. 1:35-45. To that end, the inventors explain that

in this situation, extended release capsule dosage forms *may* be formulated by mixing the drug with one or more binding agents to form a uniform mixture which is then moistened with water ... to form an extrudable plastic mass from which small diameter ... cylinders of drug/matrix *are extruded,* broken into appropriate lengths and *transformed into spheroids using standard spheronization equipment*.

Id. (emphasis added). Although this section describes the extrusion and spheronization manufacturing process, the context makes clear that this is the convention of the drug industry for producing encapsulated extended release formulations, rather then a description of the claimed invention. In addition, despite Mylan's arguments to the contrary, the use of the term "may" in this context indicates that this is one possible method of formulating extended release dosage capsule forms.

Although the term appears several times throughout the "Brief Description of the Invention," no reference to a specific manufacturing process is made in this section. Rather, the term is used in the context of describing the percentages of specific ingredients found in the formulations, i.e. "spheroids comprised of [the specific ingredients]."

The "Detailed Description of the Invention" makes several references to "spheroids" and their manufacturing process. First, the inventors describe the drug formulation as being "formed as beads or spheroids." '171, Col. 4:13. The inventors then give a brief history of the invention, explaining that, after attempting, but failing, to create extended release tablets, *id*. at Col. 4:60-65, they then tried to create an encapsulated extended release formulation. Explaining that process, they state:

Numerous spheroid formulations were prepared using different grades of microcrystalline cellulose ... in order to find a formulation which would provide a suitable granulation mix which could be extruded properly. In the extrusion process, heat buildup occurred which dried out the extrudate so much that it was difficult to convert the extruded cylinders into spheroids. Addition of hydroxypropylmethylcellulose 2208 to the venlafaxine hydrochloride-microcrystalline cellulose mix made production of spheroids practical.

Id. at Col. 5:1-13. Thus, as asserted by Mylan, the inventors clearly focused their efforts on the extrusion and spheronization process to create an encapsulated extended release formulation of Effexor(R). This review of the steps the inventors took in reaching the invention does not, however, appear to be intended to

limit the invention itself.

Finally, the inventors provide several examples "to illustrate the applicant's solution to the problem of preparation of the extended release drug containing formulations of this invention." *Id*. at Col. 5:29-31. In Example No. 1, entitled "Venlafaxine Hydrochloride Extended Release Capsules," the inventors describe a mixture that is "extruded, spheronized and dried to provide uncoated drug containing spheroids." *Id*. at Col. 5:40-45. In Example No. 6, they state:

Spheroids comprising 16.5% venlafaxine Hcl and 83.5% microcrystalline cellulose were mixed with approximately 50% water to granulate in a Littleford Blender ... at a fixed speed through a 1.25 mm screen using a Nica extruder/spheronization machine ... for a 12/20 mesh cut after drying. Two portions of the resulting spheroids were coated with a 5% and 7% coating level

....

Id. at Col. 5:65-67, 6:1-8. The remaining examples do not reference any process for creating spheroids.

While these illustrations refer to only one method of manufacturing spheroids, the method appears to be a preferred embodiment, not an attempt to limit the scope of the invention. The Federal Circuit has repeatedly counseled against limiting a term on the basis of a preferred embodiment or other specific example from the specification. Phillips, 415 F.3d at 1323 ("[T]hough the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments."). The Court, therefore, cannot conclude that the inventors limited the term "spheroid" by referencing the extrusion and spheronization process in the Examples.

2.

Having carefully analyzed the language used in the claims and specification, the Court concludes that "spheroid" should be given its ordinary and customary meaning. *See* Phillips, 415 F.3d at 1313 (courts should look to the specification to understand the ordinary meaning of a claim term). As discussed earlier, a "heavy presumption" exists "that a claim term carries its ordinary and customary meaning." CCS Fitness, Inc., 288 F.3d at 1366. Although "[a]n accused infringer may overcome this 'heavy presumption' and narrow a claim term's ordinary meaning, ... he cannot do so simply by pointing to the preferred embodiment or other structures or steps disclosed in the specification or prosecution history." *Id*. *(citing* Johnson Worldwide Ass., Inc. v. Zebco Corp., 175 F.3d 985, 989-90, 992 (Fed.Cir.1999). Rather, the presumption may only be overcome in several specific instances, such as when a court concludes that the inventor acted as his own lexicographer and "clearly set forth a new definition of the disputed claim term," or that the intrinsic evidence establishes that the inventor distinguished the term from the prior art on the basis of a particular embodiment. *Id*. at 1366-67. Moreover, when a new definition is bestowed on a term, it must be done deliberately. *In re Paulson,* 30 F.3d at 1480.

Here, although the specification references only one manufacturing process for spheroids, it does not "clearly set forth a new definition" for the term. Because the Federal Circuit has cautioned against narrowing a term's ordinary meaning on the basis that the specification reveals only one preferred embodiment, the Court declines to limit the term "spheroid" in the manner requested by Mylan.

Moreover, Mylan's argument that, because the inventors set forth a table of dissolution rates and described

only one method of achieving those rates, they necessarily limited the invention to only that method is unpersuasive. While those specific dissolution rates must be met, nothing in the patents require that they be met only with spheroids made through a process of extrusion and spheronization. Indeed, Wyeth's expert, James McGinity, Ph.D. ("McGinity"), a Professor of Pharmaceutics in the College of Pharmacy at the University of Texas, Austin, states in his declaration that "[t]he method of manufacture of spheriods ... would be considered by one of ordinary skill in the art as totally irrelevant to how they work in delivering the drug to the body." Wyeth Ex. 19, para. 44. He explains that the coating that is applied after the spheriods have been manufactured actually controls the release of the drug in an extended release formulation; thus, the success of that formulation "is not dependant upon the process by which the spheroids are made." *Id*. Although Mylan's expert disagrees on this point, McGinity's explanation is compelling. Accordingly, the Court finds Mylan's argument without merit.

3.

Although the Court agrees with Wyeth that the inventors intended the term "spheroid" to be understood by its ordinary and customary meaning, it cannot adopt Wyeth's proposed construction in its entirety. McGinity states that his understanding of the term "spheroid" as used by those in the pharmaceutical industry is "one or more particles that are generally shaped like a sphere, although they do not have to be perfectly round." Wyeth, Ex. 19, para. 38. As support, he points to the definitions for "spheroid" that appear in the *American Heritage College Dictionary* (3rd ed.1993), and in Merriam-Webster's Collegiate Dictionary (10th ed.2001), both of which are consistent with Wyeth's proposed construction. *Id*. at para. 39.

Mylan does not dispute that definition. Indeed, its proposed construction similarly begins with "one or more particles that are generally shaped like a sphere." Thus, the Court finds that this constitutes the ordinary and customary meaning of this term to one of ordinary skill in the art.

Wyeth, however, seeks to add an additional sentence to this definition; specifically, that the term "spheroid" includes "granules, beads, and pellets." In McGinity's opinion, "the terms granules, beads and pellets can be used interchangeably with the term spheroid." Wyeth, Ex. 19, para. 38. He provides no basis for this opinion, however, and neither of the definitions that support the first part of Wyeth's proposed construction make reference to granules, beads or pellets.

Mylan argues that Wyeth is improperly attempting to broaden the definition of spheroid. Its expert, Van Buskirk, explains that a person of ordinary skill in the art would not consider a granule to be a spheroid because "granules would be the base units composed of the active ingredient and excipient(s) that make up the extrudate," which is then "broken into smaller lengths and then spheronized." Mylan, Barry Dec., Ex. C, para. 31. Thus, he contends that multiple granules may make up a spheroid, but one granule would not be considered a spheroid. *Id*.

Finally, the Detailed Description of the Invention refers to "beads or spheroids." If, as Wyeth contends, the term "spheroid" should be construed to include "granules, beads, and pellets," this language of the specification would be redundant. Thus, the Court rejects the assertion that the term "spheroid" includes "granules, beads, and pellets."

In sum, the Court finds that the inventors intended to apply the ordinary and customary meaning of the term "spheroid," which is "one or more particles that are generally shaped like a sphere, although they do not have to be perfectly round." Because Wyeth has failed to establish that the ordinary and customary meaning

of the term encompasses "granules, beads, and pellets," the Court rejects that portion of Wyeth's proposed construction.

E. "Encapsulated"

Wyeth asks the Court to construe the term "encapsulated," as found in asserted Claims 20 through 25 of the '171 patent and Claims 2 and 14 of the '120 patent, to mean "filled into a pharmaceutically acceptable capsule." Mylan asserts that the correct construction is "enclosed by a protective coating or membrane." Both parties contend that their definition constitutes the ordinary meaning of the term to someone skilled in the pharmaceutical arts.

In the opinion of Wyeth's expert, McGinity, Wyeth's construction comports with his understanding of the ordinary meaning of the term "encapsulated." Wyeth Ex. 19, para.para. 48-51. McGinity relies on a pharmaceutical textbook, *Remington: The Science and Practice of Pharmacy* 1642 (19th Ed.1995), for the proposition that "capsules" are "solid dosage forms in which the drug substance is enclosed in either a hard or soft, soluble container or shell of a suitable form of gelatin." *Id*. That definition is followed by a note that "encapsulation of medicinal agents remains a popular method for administering drugs." *Id*. From this, McGinity concludes that the definition found in *Remington* confirms that Wyeth's proposed construction is the ordinary meaning of the term. *Id*.

Mylan, on the other hand, relies on the opinion of its expert, Van Buskirk, that the *American Heritage Dictionary,* available at www.Dictionary.com, supports Mylan's contention that the ordinary meaning of the term "encapsulated," is "enclosed by a protective coating or membrane." Mylan, Barry Dec., Ex. C, para.para. 25-27. Van Buskirk acknowledges that a person of ordinary skill in the art would recognize that "materials that are 'encapsulated' can include drug product formulations that are placed into either hard or soft gelatin capsules." *Id*. at para. 26. He contends, however, that the term "encapsulated" is not limited to gelatin capsules and that the broader definition suggested by Mylan is more accurate. *Id*.

Claims 20-25 of the '171 patent use the term "encapsulated" identically: "A method ... which comprises administering orally to a patient in need thereof, an *encapsulated,* extended release formulation that provides...." (Emphasis added). Claim 2 of the '120 patent simply states: "A method of claim 1 wherein the extended release formulation is encapsulated." Similarly, Claim 14 of the ' 120 patent provides: "The method of claim 1 wherein the extended release formulation comprises venlafaxine hydrochloride in an encapsulated spheroid." Thus, the plain language of the claims provides no indication as to which construction is intended.

The specification, however, does provide guidance. In the "Background of the Invention," the inventors describe the conventional process in the pharmaceutical industry for preparing encapsulated drug formulations that provide extended or sustained release properties. '171, Col. 1:35-40. They explain that, after the spheroids are created, they are "film-coated to retard dissolution." *Id*. at Col. 1:45-47. "The film coated spheroids may then be placed into pharmaceutically acceptable capsules, such as starch or gelatin capsules, in the quantity needed to obtain the desired therapeutic effect." *Id*. at Col. 1:46-50.

While the information provided in the Background is a review of the conventions of the industry, rather than an explanation of the specific invention in this case, it clearly indicates that the inventors understood the process of filling spheroids into "pharmaceutically acceptable capsules" as a step separate from coating the spheroids with a film. This distinction is reenforced in the "Brief Description of the Invention," in which

the inventors describe various preferred formulations of the invention. Each formulation provides a specific formula for the "film coating" that is applied to the spheroids. Following a list of several "lower dose formulations," the Brief Description section concludes with the following sentence: "Each of these formulations is also preferably contained in a gelatin capsule, preferably a hard gelatin capsule." *Id*. at Col. 3:60-63. The term "encapsulated" does not appear anywhere in the "Brief Description."

Finally, Example No. 1, found in the "Detailed Description of the Invention," clearly distinguishes between coating the spheroids with a film and putting them into capsules. *Id*. at Col. 5:38-56. Specifically, the inventors state that, after separating out coated spheroids of a specific size, "[t]hese selected film coated spheroids are filled into pharmaceutically acceptable capsules conventionally, such as starch or gelatin capsules." *Id*. at Col. 5:53-56. Thus, they again distinguish between the process of coating the spheroids with a film and filling them into capsules, which they specify must be "pharmaceutically acceptable."

Because a patent's specification is considered the best source for understanding technical terms, Phillips, 415 F.3d at 1315, the Court has no trouble concluding that the ordinary meaning of "encapsulated" to one of ordinary skill in the art would be "filled into pharmaceutically acceptable capsules." Contrary to Mylan's assertions, Wyeth's construction does not limit the types of capsules that may be used, other then to require that they be "pharmaceutically acceptable." Rather, the inventors repeatedly describe the process of filling drug formulations into pharmaceutically acceptable capsules, which, as they indicate, *may* (not must) be starch or gelatin capsules.

Moreover, Mylan's definition, "enclosed by a protective *coating* or membrane," would create confusion, given that the inventors repeatedly refer to "coating" the spheroids with a film that aids in the extended-release process. Although Mylan insists that it is not trying to imply that the extended-release coating placed on the spheroids is the "encapsulation" of those spheroids, adopting Mylan's definition would certainly raise that inference.

In addition, to the extent that extrinsic evidence is helpful to determine what a person of ordinary skill in the art would have understood at the time of the invention, the Court concludes that Wyeth's source is more reliable. Wyeth's proposed construction comports with the definition of encapsulated provided by *Remington,* a pharmaceutical textbook, while Mylan's definition is drawn from the online *American Heritage Dictionary*. Because *Remington* is a guide used by those skilled in the pharmaceutical arts, while the *American Heritage Dictionary* is not specific to that field, the Remington definition is more persuasive.

Accordingly, the Court concludes that a person of ordinary skill in the pharmaceutical arts would have understood the term "encapsulated" to mean "filled into a pharmaceutically acceptable capsule," and therefore adopts Wyeth's construction of this term.

F. "Administering orally to a patient in need thereof"

Finally, the parties ask the Court to construe the phrase "administering orally to a patient in need thereof," which is found in asserted claims 20-25 of the '171 patent, 1 of the '120 patent, and 1-6 of the '958 patent. Wyeth's proposed construction is:

A patient in need of therapeutic blood plasma levels of venlafaxine, such as a patient suffering from one or more depressive or anxiety disorders, and the patient is being treated by a formulation that is swallowed.

Mylan's proposed construction is:

The claimed extended release formulations are administered to a patient by mouth.

Here, Wyeth and Mylan agree that the formulations are administered by mouth and swallowed by the patient. Mylan further concedes that the language "patient in need thereof" implies a patient "in need of treatment with venlafaxine hydrochloride." Mylan's Resp. Br. at 34. It contends, however, that the patents-at-issue only disclose the usefulness of venlafaxine hydrochloride as an anti-depressant "and nothing more." *Id*. Wyeth, on the other hand, asserts that a person of ordinary skill in the art at the time of the invention would have understood that a "patient in need thereof" includes patients being treated for any condition responsive to venlafaxine, not only those suffering from depression.

The specification makes several references to venlafaxine hydrochloride as being "an antidepressant" and as being "used in the treatment of depression." Specifically, in the "Abstract," the invention is introduced as being a formulation of "venlafaxine hydrochloride, an antidepressant," and in the "Background of the Invention" the inventors refer to venlafaxine as "an important drug in the neuropharmacological arsenal used for treatment of depression." '171, Col. 1:61. In the "Brief Description of the Invention," the inventors describe the use aspect of the invention as "a method for moderating the plural blood plasma peaks and valleys ... which comprises administering to a patient in need of treatment with venlafaxine hydrochloride...." '171, Col. 2:40-45. A similar statement is then repeated in reference to a method for reducing the level of nausea and incidence of emesis. '171, Col. 2:55-63.

Wyeth relies on the opinion of its expert in the fields of psychiatry and psychopharmacology, Eric Hollander, M.D. ("Hollander"), that patients with conditions other than depression, such as those with a variety of anxiety disorders, can be successfully treated with venlafaxine hydrochloride. Wyeth Ex. 31, p. 12. He states that, while he had treated individuals with both depression and anxiety disorders using immediate release Effexor(R), he has had much better results treating them with Effexor XR(R). *Id*. Thus, Hollander, a person of ordinary skill in the art, clearly understood at the time of the invention that venlafaxine hydrochloride was used to treat patients with anxiety disorders, in addition to those suffering from depression.

Mylan does not rely on expert testimony on this point, arguing instead that Wyeth's construction would leave the term open to the future addition of disorders not disclosed in the patents-in-suit, and thus would violate the notice function of the patents. It relies on *Phillips* for the proposition that the Court should not place undue reliance on extrinsic evidence, and asserts that no legal authority allows "additional disorders [other than depression] to be read into both the patent and the claims." Mylan Resp. Br. at 35.

Although *Phillips* counsels against undue reliance on extrinsic evidence, that case also states that

extrinsic evidence in the form of expert testimony can be useful to a court for a variety of purposes, such as to provide background on the technology at issue, ... 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, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field.

415 F.3d at 1318. Indeed, courts may rely on such evidence in construing terms so long as the testimony is not "clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent." *Id*. *(quoting* Key Pharms.

v. Hercon Labs. Corp., 161 F.3d 709, 716 (Fed.Cir.1998)).

Here, nothing in the written record associated with these patents explicitly limits the use of Effexor XR(R) to treating patients with depression. Accordingly, this Court must determine what "a person of ordinary skill in the art in question at the time of the invention" would have understood "a patient in need of treatment with venlafaxine hydrochloride" to mean. *See* Phillips, 415 F.3d at 1313. Because nothing in the intrinsic evidence reveals what a person of ordinary skill in the art at the time of the invention would have understood, this is an appropriate occasion for reliance on extrinsic evidence, such as an expert opinion.

Hollander's affidavit clearly indicates that a person of ordinary skill in the art at the time of the invention would have known that venlafaxine hydrochloride was commonly used to treat anxiety as well as depression. Indeed, the Court does not rely merely on his opinion on this matter, which, admittedly, was "generated at the time of and for the purpose of litigation and thus can suffer from bias." Phillips, 415 F.3d at 1318. Rather, Hollander states that, prior to the invention of the extended release formulation, he was, in fact, treating patients suffering from anxiety disorders with immediate release Effexor(R). Wyeth Ex. 31, p. 12. Thus, the Court concludes that a person of ordinary skill in the art at the time of the invention would have known that a "patient in need thereof" could include patients suffering from one or more depressive or anxiety disorders, as long as the disorder was *then known* to be treatable with venlafaxine hydrochloride.FN4

FN4. Limiting the term to disorders known to those of ordinary skill in the art at the time of the invention to be treatable with venlafaxine hydrochloride dispels Mylan's concern regarding the notice function of the patents.

Thus, because it finds that a person of ordinary skill in the art would have known, at the time of the invention, that venlafaxine hydrochloride could be used to treat patients with both depression and anxiety disorders, the Court adopts Wyeth's construction of this term.

IV. CONCLUSION

For the reasons set forth above, the Court ORDERS that the contested claim terms and phrases be construed as follows:

1. "Extended release formulation" means "a drug formulation (other than a hydrogel tablet) that releases the active ingredient at a slower rate than the immediate release formulation of the active ingredient such that the dosing frequency is once-a-day rather than the plural daily dosing for the immediate release formulation."

2. "A method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride" means "a method in which the extended release formulation is administered once in a 24-hour period, resulting in a venlafaxine blood plasma concentration that rises to a maximum value, followed by a generally protracted decrease over the remaining period while maintaining during that 24-hour period levels of venlafaxine in blood plasma that are sufficient to provide relief from the condition being treated, thereby eliminating the multiple sharp peaks and troughs resulting from multiple daily dosing of the same total daily dose of the immediate release formulation as reflected in a graph of venlafaxine blood plasma concentration versus

time.

3. "Diminished incidences of nausea and emesis" means "a decrease in the number of patients suffering from nausea and vomiting compared to patients receiving the same total daily dose of an immediate release formulation that is administered at least twice a day."

4. "Spheriod" means "one or more particles that are generally shaped like a sphere, although they do not have to be perfectly round."

5. "Encapsulated" means "filled into a pharmaceutically acceptable capsule."

6. "Administering orally to a patient in need thereof" means "a patient in need of therapeutic blood plasma levels of venlafaxine, such as a patient suffering from one or more depressive or anxiety disorders, and the patient is being treated by a formulation that is swallowed."

The Court directs the Clerk of the Court to transmit copies of this Order to counsel of record.

N.D.W.Va.,2009.
Wyeth v. Mylan Pharmaceuticals, Inc.

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