United States District Court,
C.D. California.

WYETH,
v.
ANCHEN PHARMECEUTICALS.

No. SACV 06-386 JVS (MLGx)

Dec. 20, 2007.

Attorneys Present for Plaintiffs, Not Present.

Attorneys Present for Defendants, Not Present.

Proceedings: ***(IN CHAMBERS) Order re Claim Construction***

Present: The Honorable JAMES V. SELNA**, J.**

Karla J. Tunis, Deputy Clerk

Not Present, Court Reporter.

I. *BACKGROUND*

In this patent infringement action, plaintiff Wyeth alleges that defendant Anchen Pharmaceuticals Inc.'s ("Anchen") generic extended-release venlafaxine infringes U.S. Patents Nos. 6,274,171 BI ("the '171 patent"), 6,403,120 B1 ("the '120 patent") and 6,419,958 B2 ("the '958 patent') (collectively "Wyeth patents"). The patents are related and share an essentially identical specification.

The instant claim construction hearing involves ten disputed terms, all of which appear in each of the Wyeth patents. The terms and this Court's constructions are discussed in Section III, below.

II. *LEGAL STANDARD*

It is well settled that claim construction is "exclusively within the province of the court." Markman v. Westview Instruments, Inc., 517 U.S. 370, 372 (1996). Such construction "begins and ends" with the claim language itself, Interactive Gift Express, Inc. v. Compuserve, Inc., 256 F.3d 1323, 1331 (Fed.Cir.2001), but extrinsic evidence may also be consulted "if needed to assist in determining the meaning or scope of technical terms in the claims." Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1216 (Fed.Cir.1995).

In construing the claim language, the Court begins with the principle that "the words of a claim are generally given their ordinary and customary meaning." Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed.Cir.2005) (internal quotation marks omitted). Further, this ordinary and customary meaning "is the

meaning that the [claim] term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." Id. at 1313. "[T]he 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*.

"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, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words. In such circumstances general purpose dictionaries may be helpful." *Id*. at 1314. In other cases, "determining the ordinary and customary meaning of the claim requires examination of terms that have a particular meaning in a field of art." *Id*. In those cases, "the court looks to 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." *Id*. These sources include "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Id*. (internal quotation marks omitted).

The claim terms are not presumed to have the meaning that a person of ordinary skill in the relevant art would ordinarily attribute to them if (1) the patentee acts as his own lexicographer, or (2) the claim term is too vague for an accurate meaning to be ascertained from the language used. Novartis Pharms. Corp. v. Abbott Labs., 375 F.3d 1328, 1334 (Fed.Cir.2004). All that is required for a patentee to act as his own lexicographer is that a different meaning is set out in the specification in a manner sufficient to provide notice of the meaning to a person of ordinary skill in the art. In re Paulsen, 30 F.3d 1475, 1480 (Fed.Cir.1994).

With these principles in mind, the Court now turns to the construction of the claim language at issue.

III. *DISCUSSION*

Each of the following subsections discusses one of the ten claim terms at issue. The disputed language is underlined and appears as the title to the subsection. The claim term is followed by the parties' proposed constructions and then the construction adopted by the Court.

A. *Extended Release Formulation*

Wyeth's Construction	Anchen's Construction
A formulation, other than a hydrogel tablet, which 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.	A modified-release formulation comprising venlafaxine hydrochloride, microcrystalline cellulose and, optionally, hydroxypropylmethylcellulose, coated with a mixture of ethyl cellulose and hydroxypropylmethylcellulose in an amount needed to provide a specific unit dosage administered once-a-day to provide a therapeutic blood plasma level of venlafaxine over a 24-hour period of administration.

As Wyeth concedes in its opening brief, the central issue in this case involves the claim term "extended release formulation." (Pl.'s Opening Br. at 1.) Wyeth argues that the phrase should be construed according to its "ordinary meaning" and not limited to any particular set of ingredients. (*Id*.) Anchen contends that

Wyeth acted as its own lexicographer and, therefore, construes the phrase as restricted to the particular formulation set forth in the patents. (Def.'s Opening Br. at 13-14.)

In a separate case involving the patents-in-suit, the District Court of New Jersey had the opportunity to construe the same term at issue here. Wyeth v. Teva Pharmaceuticals, 2005 WL 2175440 at (D.N.J.2005) (hereinafter " *Teva* "). The Court in *Teva* adopted the definition now proposed by Anchen, limiting the claim term to the narrow formula laid out in the specification. *Id*. at *5. Anchen argues that this construction should also control the outcome of this Court's order, because the ruling is "highly persuasive, if not preclusive, authority." (Def.'s Opening Br. at 19.)

While it is clear that this Court is not bound by a vacated decision issued in the District Court of New Jersey in an unrelated case, the Court does acknowledge the similarity of the issues at stake and the reasoning employed by the *Teva* court. For the reasons discussed below, the Court finds that the doctrine of claim differentiation and the patents' prosecution history both support Wyeth's broad construction for the term "extended release formulation." In contrast, the evidence of lexicography supporting a narrower construction is, at best, inconclusive. Accordingly, the Court finds that there is insufficient evidence to justify a departure from the ordinary meaning in this instance, and adopts Wyeth's construction for the term "extended release formulation." FN1

FN1. The Court has also had the benefit of a very recent decision from the District of Delaware, *Wyeth v. Impax Laboratories, Inc.,* Civil Action No. 06-222 JJF (December 13, 2007).

1. Claim Differentiation

Wyeth argues that the ordinary meaning of the term "extended release formulation" is, in essence, any formula that allows a reduction in dosing frequency as compared to the drug presented in a conventional form. (PL's Opening Br. at 9.) Such a definition does not require, and is not limited to, any particular set of ingredients or formula. (*Id*. at 9-10.) Anchen does not appear to disagree with this description of the ordinary meaning of the term "extended release." Anchen argues, however, that the world "formulation" implies only a "single composition made up of a precise ingredient list." (Def.'s Opening Br. at 13.)

"It 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, 415 F.3d at 1312. Under the doctrine of claim differentiation, when a patent contains dependent claims that add a particular limitation, the court must initially apply a presumption that the limitation in question is not present in the independent claim. Id. at 1314-15. The absence of a limitation in the dependent claims is "strong evidence" that the independent claims are not bound by the limitations listed in narrower, dependent claims. *See* Honeywell International v. Universal Avionics Systems Corp., 488 F.3d 982, 994 (Fed.Cir.2007.)

The '120 patent claims support Wyeth's argument that it intended the claim term, "extended release formulation," to be broader than the construction Anchen proposes. Independent claim 1 of the '120 patent discloses the following broad description of the invention:

A method for providing a therapeutic blood plasma concentration of venlafaxine over a twenty-four hour period with diminished incidence of nausea and emesis which comprises administering orally to a patient in need thereof, an extended release formulation that provides peak blood plasma levels of venlafaxine of no

more than about 150 ng/ml, said formulation containing venlafaxine hydrochloride as the active ingredient.

(10:35-42, '120 patent.) By way of comparison, dependent claim 2 discloses the "method of claim 2 wherein the extended release formulation is encapsulated," (10:43-44, '120 patent) and dependent claim 3 discloses, separate and distinct from the independent claims, a particular chemical make-up for that formula:

The method of claim 1 wherein the extended release formulation comprises venlafaxine hydrochloride in spheroids comprised of venlafaxine hydrochloride, microcrystalline cellulose and optionally, hydroxypropylmethylcellulose.

(10:45-49, '120 patent.) Further, dependent claim 13 discloses "[t]he method of claim 1 wherein the extended release formulation comprising venlafaxine hydrochloride in a spheroid," and dependent claim 14 discloses "[t]he method of claim 1 where in the extended release formulation comprises venlafaxine hydrochloride in an encapsulated spheroid." (12:33-38, '120 patent.)

The doctrine of claim differentiation clearly applies to the claims at issue here. Therefore, a presumption arises that the term "extended release formulation" does not contain the limitations specified in claim 3: namely, the specific ingredients listed in Anchen's construction. The fact that dependent claim 2 specifically discloses those particular ingredients is "the strongest indication" that the term "extended release formulation" was not meant to include those same ingredients as a matter of definition. *See* Saunders Group Inc. v. Comfortrac, Inc., 492 F.3d 1326, 1334 (Fed.Cir.2007) (noting that the "strongest indication" a claim term did not include unstated, additional limitations as a matter of definition was found by comparing the patents' dependent claims, which included those limitations, with the independent claims, which did not.)

Because the doctrine of claim differentiation applies here, the Court finds that there is strong evidence the term "extended release formulation" is not limited to any particular set of ingredients. The claims, however, "do not stand alone," but rather," must be read in view of the specification, of which they are a part." Phillips, 415 F.3d at 1315. Accordingly, the Court turns it analysis to construing the claim terms as they appear in the specification.

2. Whether Wyeth Acted as Its Own Lexicographer

As noted above, the parties do not dispute the ordinary meaning of "extended release formulation." The only question before this Court is whether the specification limited the ordinary meaning of that term, within the scope of the patents-in-suit, to include only a formulation comprised of venlafaxine hydrochloride in spheroids comprised of venlafaxine hydrochloride, microcrystalline cellulose and optionally, hydroxypropylmethylcellulose ("VHMC-HCH").

Narrowing the term "extended release formulation" requires a showing that the specification gives a special definition to the claim term that differs from the meaning it would otherwise possess. Phillips, 415 F.3d at 1316. The specification acts as a dictionary "when it expressly defines terms used in the claims or when it defines terms by implication." Bell Atlantic Network Services, Inc. v. Covad Commc'n Group., 262 F.3d 1258, 1268 (Fed.Cir.2001) (citations omitted). While the inventor is free to define terms used in the specification, "this must be done with reasonable clarity, deliberateness and precision" to overcome the presumption that the term holds its ordinary meaning. In re Paulsen, 30 F.3d at 1480.

As Wyeth suggested during oral argument, the Court cannot apply the lexicography exception here because

there is no clear expression of intent to provide any particular "special definition" for the term "extended release formulation" outside of the meaning it would otherwise possess.FN2

FN2. However, the patent does clearly disclaim hydrogel tablets and the Court accordingly excludes those from its construction. (4:60-65, ' 171 patent (noting that, "[n]umerous attempts to produce extended release tablets by hydrogel technology proved to be fruitless because the compressed tablets were either physically unstable ... or dissolved too rapidly in dissolution studies); 10:53-57, '171patent ("Thus the desired dissolution rates of sustained release dosage forms.. impossible to achieve with hydrogel technology, has been achieved with this ... invention.").

The first sentence in the abstracts describes the patented invention, without reference to any particular formulation or ingredients, as follows:

This invention relates to a 24 hour extended release dosage formulation and unit dosage form thereof of venlafaxine hydrochloride, an antidepressant, which provides better control of blood plasma levels than conventional tablet formulations which must be administered two or more times a day and further provides a lower incidence of nausea and vomiting than the conventional tablet.

(Abstract.) FN3 This description supports Wyeth's broad construction of the term because it emphasizes that the invention is "a dosage" that distributes venlafaxine hydrochloride with increased control of blood plasma levels and diminished incidence of nausea and vomiting. The first sentence in the Description is similar:

FN3. Both parties note that the three patents-in-suit have the same specification, with the exception of the lineage of parent patent applications, and therefore provide citations only to the '171 patent. The Court adopts the same convention.

In accordance with this invention, there is provided an extended release (ER), encapsulated formulation containing venlafaxine hydrochloride as the active drug component, which provides in a single dose, a therapeutic blood serum level over a twenty four hour period.
(2:15-20.) The description's analysis of the "use aspect" of the invention also supports Wyeth's claims that no limitations are included in the definition of "extended release formulation." It states that,
in accordance with this use aspect of the invention there is provided a method for reducing the level of nausea and incidence of emesis attending the administration of venlafaxine hydrochloride which compromises dosing a patient in need of treatment with venlafaxine hydrochloride with an extended release formulation of venlafaxine hydrochloride once a day in a therapeutically effective amount.

(2:55-62.)
From the above passages, it appears that the specific formulation of the dosage is secondary, if not irrelevant, to the benefits of a protracted distribution of the active ingredient, venlafaxine hydrochloride. As Anchen points out, however, the specification also uses the term in ways that would support a significantly narrower construction.

The second sentence in the abstract describes the invention as follows:

More particularly, the invention comprises an extended release formulations 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.

(Abstract.) The "more particularly" qualification is also repeated in the Brief Description, which states that the "extended release formulation of this invention are those ... wherein the spheroids are comprised of" stated percentages of VHMC-HCH. (3:6-8.)

Anchen argues that this description should govern because the inventor only developed and recommended the one formula listed in the patent, and the specification fails to state any other clinically viable extended release formulations. (Def.'s Opening Br. at 4, 7-8.) The Court agrees that it is possible to draw the conclusion that the VHMC-HCH formula is the only "extended release formulation" covered by the patent if these portions of the specification are read in isolation. Such a reading, however, is not the proper approach to claim construction.

Two additional reasons support this conclusion: the prosecution history and the inherent ambiguity in Anchen's proposed construction.

a. Impact of the Prosecution History on the Court's Lexicography Analysis

The importance of this the patent's limiting language is further diminished when the Court considers the prosecution history leading up to its addition. As described in more detail in the following section, Wyeth originally submitted two broad method claims to the Examiner that disclosed an extended release formulation without reference to the VHMC-HCH formula. (Wright Decl. Ex. 15 at p. 181-183.) The Examiner then amended those claims to specifically disclose the inactive ingredients. (Id., at 228, 240-42.)

What followed evidences Wyeth's intent not to limit the term "extended release formulation" as Anchen proposes: Wyeth abandoned the amended method claims and again filed the original un-amended method claims without the inactive ingredients. (Id. at 250, Ex. 17 at 276.) As Wyeth described during oral argument, the "more particularly" language in the Abstract and Brief Description was not added to the specification until after it had demonstrated a clear intent to disclaim any such limitations in the method claims.

If the Court adopted Anchen's proposed construction, it would have to effectively find that Wyeth went to great lengths to reject the Examiner's amendments only to then rewrite the specification in such a way as to reincorporate them by adding the "more particularly" language. Such a finding would be at odds with Wyeth's clear intent to disclaim the VHMC-HCH formulation and is contrary to the evidence that the inventors did not intend to engage in lexicography with respect to this term.

The Federal Circuit has advised that a patentee may act as its own lexicographer even without an explicit statement of redefinition. Bell Atlantic, 262 F.3d at 1268. "In other words, the specification may define claim terms by implication, such that the meaning may be found in or ascertained by a reading of the patent documents." *Id*. (internal quotations omitted). However, it has also warned that one wishing to act as his own lexicographer must do so "with reasonable clarity, deliberateness, and precision." In re Paulsen, 30 F.3d at 1480.

b. Impact of Ambiguity on the Court's Lexicography Analysis

As Wyeth demonstrated during oral argument, the specification does not support the inference that the patentee clearly redefined the term "extended release formulation" to one particular, narrower embodiment. Anchen is correct that the specification does often reference the term with the qualification that it "comprises" the VHMC-HCH specification. (*See, e.g.,* Abstract; 2:66-3:5; 4:9-12.) However, it is also inconsistent in specifying which limitations it attaches to the term, such that it is difficult to articulate a precise definition for the term "extended release formulation" provided by the specification.

The portion of the Abstract which uses the term with reference to the VHMC-HCH limitation specifically notes that the hydroxypropylmethylcellulose addition is optional:

More particularly, the invention comprises 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.

(Abstract, emphasis added.) In contrast, the description in the Detailed Description Of the Invention does not describe this additional ingredient as optional:

The extended release formulations of this invention are comprised of 1-[2-9dimethyla mino)-l-(4-methoxyphenyl)ethyl]cyclohexanol hydrochloride in a mixture with microcrystalline cellulose and hydroxypropylmethylcellulose. Formed as beads or spheroids, the drug containing formulation *is coated* with a mixture of ethyl cellulose and hydroxypropylmethylcellulose ...

(4:9-15, emphasis added.)

As noted above, where the specification describes a term with clarity, deliberateness and precision, a court may find that it provides a definition outside of the term's ordinary meaning. In re Paulsen., 30 F.3d at 1480. However, if no exact definition emerges from the specification, the court is not free to select arbitrarily between differing descriptions in deciding which one the patentee really "intended" to define his or her invention. As the Federal Circuit noted in *Phillips,* if the Court should "once begin to include elements not mentioned in the claim, in order to limit such claim ... [it] should never know where to stop." 415 F.3d at 1312 (citations omitted).

Anchen did not propose a solution to this problem at oral argument, and the Court does not believe that this is a case where the specification has so clearly redefined the term "extended release formulation" that the Court is justified in limiting it to the VHMC-HCH formulation. Further, the Court also notes that Anchen's proposed definition suffers from the same infirmity. The construction it proposes does not require spheroids, despite the fact that all descriptions of the VHMC-HCH formulation in the specification, which Anchen relies on to support its construction, specifically note that the formulation should be contained in spheroids. Again, at oral argument, Anchen was unable to provide sufficient explanation as to why the VHMC-HCH ingredients are required by the specification while, according to its construction, the spheroids are merely optional.

As the Court acknowledged in its tentative opinion and at oral argument, construction in this case, where the breadth of the claims seem to weigh against the narrowness of the specification, is not a clear cut issue. Because the specification does not clearly and precisely define the term as something other than its ordinary definition, however, the Court hesitates to find that Wyeth definitively acted as its own lexicographer in

these patents. As discussed below, the prosecution history further supports Wyeth's argument that "extended release formulation" should not be limited to the VHMC-HCH formulation, reinforcing the finding that Wyeth construction is the correct one in this instance.

3. The Prosecution History

At oral argument, Wyeth persuasively argued that this Court did not give proper deference to the prosecution history in its tentative opinion. While the Court does not believe that the history alone would mandate the result it reaches here today, given the above analysis regarding the claim differentiation presumption and the uncertainly over the patentees' intent to act as a lexicographer in the specifications, the Court finds that the prosecution history supports a finding that "extended release formulation" cannot be properly limited to the VHMC-HCH formulation.

In March of 1997, the patentees submitted an application containing the following method claims, labeled as claims 9 and 10 in the application. Claim 9 reads:

A method of 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.

(Wright Decl. Ex 16 at p. 228.) Claim 10 similarly discloses a "method for eliminating the troughs and peaks of drug concentration in a patients blood plasma," in "an encapsulated, extended release formulation ... said formulation containing venlafaxine hydrochloride as the active ingredient." (*Id*.)

Neither claim disclosed a limitation comprising the VHMC-HCH formulation. (Id) In the "Notice of Allowability," issued in August of that year, the Examiner specifically amended claims 9 and 10 to require those inactive ingredients. (*Id*. at 228, 240, 242 .) What followed is significant to Wyeth's argument that the term "extended release formulation" was not intended to require, by definition, VHMC-HCH.

The patentee then abandoned the method claims, as amended by the Examiner, and again filed the original un-amended method claims without the inactive ingredients as claims 13 and 14 in its CIP application. (*Id*. at 250, Ex. 17 at 276, 294.) In October of 1998, those un-amended method claims were allowed, without any listing of the VHMC-HCH formulation. (*Id*. at 716.) The patentee's rejection of the Examiner's reworking of claims 9 and 10 indicates a clear intent not to limit itself to a specific formulation.

In deciphering the ordinary meaning of a term as one skilled in the art would understand it, the Federal Circuit has instructed that courts may properly look to the prosecution history to construing the meaning of the term. Phillips, 415 F.3d at 1314. Here, the prosecution history clearly supports a broad construction, unlimited by any particular set of ingredients and the VHMC-HCH formulation in particular.

Because the Court finds that the claims and the prosecution history both support Wyeth's construction of the term, and the specification does not clearly demonstrate the patentee's intent to act as its own lexicographer in limiting the ordinary meaning of the term, the Court finds that defining the term "extended release formulation" as limited to the VHMC-HCH formulation would be improper. Accordingly, the Court adopts the following construction for "extended release formulation": "A formulation, other than a hydrogel tablet,

which 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."

B. ***That Provides Peak Blood Plasma Levels of*** Venlafaxine ***of No More Than About 150 ng/ml***

Wyeth's Construction	Anchen's Construction
The maximum concentration of venlafaxine in blood plasma after administration of the formulation does not exceed about 150 ng/ml. The term "about" in this claim phrase indicates a possible variation of up to 20% so that the concentration of venlafaxine in blood plasma should not exceed a maximum limit of 180 ng/ml.	An extended release venlafaxine hydrochloride formulation that provides a maximum blood plasma level (C_{max}) of 150 ng/ml or less.

The Federal Circuit has specifically held that use of the word "about" avoids strict numerical boundaries to specified parameters. Ortho-McNeil Pharm. v. Caraco Pharm Labs., 476 F.3d 1321, 1326 (Fed.Cir.2007). It has also noted that the word "does not have a universal meaning in patent claims" because "the meaning depends upon the technological facts of the particular case."

As intrinsic evidence in support of its interpretation, Wyeth points to the specification's Table 2, which gives the results of administering two 75 mg extended release capsules once a day. The maximum mean concentration identified there is 149 ng/ml at 6 hours after administration. (7:39-8:11.) Because this is the mean value for the entire group of subjects, Wyeth asserts that one skilled in the art would understand that individual plasma concentrations would fall above or below this value. (Pl.'s Opening Brief at 31.)

Wyeth's expert, Dr. Sawchuk, also reported that one of ordinary skill would view the term as "permitting a window of 20% around the value of 150 ng/ml ... based upon the variability one of skill in the art would expect to find in this parameter." (Joint Statement Tab 22 at 10.) Thus, he posits that "no more than about 150 ng/ml," means a concentration of venlafaxine that does not exceed 180 ng/ml. (*Id*.)

Anchen argues that use of the phrase "no more than" conclusively affirms that the concentration level cannot exceed 150 ng/ml. (Def.'s Opening Brief at 22.) While the Court agrees that this modifier certainly implies a restriction on the outer bounds of the value, Anchen's argument would also render the term "about" surplusage. The Court does not believe that result is justified by the language of the patent.

Accordingly, the Court concludes that Wyeth's construction is appropriate. The following construction for "that provides peak blood plasma levels of venlafaxine of no more than about 150 ng/ml" is therefore adopted: "The maximum concentration of venlafaxine in blood plasma after administration of the formulation does not exceed about 150 ng/ml. The term 'about' in this claim phrase indicates a possible variation of up to 20% so that the concentration of venlafaxine in blood plasma should not exceed a maximum limit of 180 ng/ml."

C. ***A Peak Blood Plasma Level of*** Venlafaxine ***in About 6 Hours***

Wyeth's Construction	Anchen's Construction
The maximum concentration of venlafaxine in blood plasma after administration of the formulation occurs at about 6 hours. The term "about" in this claim phrase indicates a range,	The time in which an extended release formulation teaches its maximum concentration (T_{max}) in a patient's blood

based upon rounding, of 5.5 hours up to, but not including, 6.5 hours.	plasma is 6 hours within the range of statistical error.

The dispute here is similar to the one discussed in Section B, above. While both parties agree that the word "about" in the claim phrase "a peak blood plasma level of venlafaxine in about 6 hours," indicates an approximate range of valuation, they differ in how they define the scope of that range.

Wyeth proposes that "about" means a range, based on rounding, to the nearest half-hour interval. The specification describes, at Table 2, data observed during administration of both regular and extended release venlafaxine hydrochloride. (7:50-8:11.) The Table provides mean values for plasma concentration, measured at both hourly and half-hour intervals. (*Id*.) Dr. Sawchuk argues that the rounding approach is appropriate for this parameter because the plasma concentrations were measured at discrete time points, the shortest of which is half hour intervals. (Joint, Tab 22 at 12-13). Because the blood plasma concentrations indicated may actually be reached before or after those points in time, Wyeth argues that the proper interpretation of "about" should embrace the same period of variation. (Pl.'s Opening Br. at 33.)

Anchen also relies on Table 2 in arguing that because blood plasma levels can change dramatically within even half hour increments, a more precise range for "about" is required. (Def.'s Opening Br. at 23.) Accordingly, Anchen proposes that the term must be construed as "within the range of statistical error" because "those performing these types of tests understand that obtaining data at the precise hour marks is essential to having valid data to analyze in the first place." (*Id*.)

The Court finds Anchen's argument unpersuasive. While it may be true that accurate data requires measurement at precise intervals, the phrase currently before this Court for construction involves the time at which the maximum concentration of blood plasma occurs. The exact time when researchers are required to gather the data regarding those plasma levels is irrelevant to this inquiry. Because, as Anchen itself suggests, the plasma levels may change dramatically within a short time period, there is no assurance that the range of statistical error would capture actual variances. According, the Court finds that Wyeth's "rounding" construction is appropriate for expressing when the maximum concentration should occur.

For the foregoing reasons, the Court construes the disputed term, "about," to mean "a range, based upon rounding, of 5.5 hours up to, but not including, 6.5 hours.

D. ***A Peak Blood Plasma Level of*** Venlafaxine ***in From About 4 to About 8 Hours***

Wyeth's Construction	Anchen's Construction
The maximum concentration of venlafaxine in blood plasma after administration of the formulation occurs at between about 4 to about 8 hours. The term "about" in this claim phrase indicates a range based upon rounding of 3.5 hours up to, but not including, 8.5 hours .	The time in which an extended release formulation reaches its maximum concentration (T_{max}) in a patient's blood plasma is 4 to 8 hours within the range of statistical error.

The analysis from Section C applies equally to the disputed phrase here. Accordingly, the Court finds the term "about" in this claim phrase to mean "a range based upon rounding of 3.5 hours up to, but not including, 8.5 hours."

E. ***A Peak Blood Plasma Level of*** Venlafaxine ***in From About 5 to About 8 Hours***

Wyeth's Construction	Anchen's Construction
The maximum concentration of venlafaxine in blood plasma after administration of the formulation occurs at between about 5 to about 8 hours. The term "about" in this claim phrase indicates a range, based upon rounding of 4.5 hours up to but not including 8.5 hours.	The time in which an extended release formulation reaches its maximum concentration (T_{max}) *in a patient's blood plasma is 5-8 hours within the range of statistical error.*

The analysis from Section C applies equally to the disputed phrase here. Accordingly, the Court finds the term "about" in this claim phrase to mean "a range based upon rounding of 4.5 hours up to, but not including, 8.5 hours."

F. ***Diminished Incidence(s) of Nausea and Emesis***

Wyeth's Construction	Anchen's Construction
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 dose of an immediate release formulation that is administered at least twice a day.	A decrease in the number of patients suffering from nausea and vomiting (and/or a decrease in the number of incidences of a patient suffering from nausea and emesis), who are actually administered the accused product, compared to patients receiving the same total daily dose of an immediate release venlafaxine hydrochloride formulation that is administered at least twice a day.

Wyeth argues that its construction for the phrase "diminished incidence(s)," which encompasses severity as well as frequency, is supported by the patents' specifications. For reasons similar to those stated in the *Teva* opinion, this Court disagrees.

Looking first to the claim language, the Court notes that the patents refer only to "diminished incidence(s) of nausea and emesis" throughout their respective claims' sections. (12:65, '171 patent; 10:37, '120 patent; 10:59, 11:7, 11:15, '958 patent.) Wyeth argues that the plain meaning of "incidence" is "extent, frequency, rate, range or amount of occurrence of influence." This argument, however, does not account for the usage of the term "incidence" in the specification, which is twice listed separately from the word "level," implying that the two words have different meanings.

The Abstract claims only that the extended release dosage "provides a lower incidence of nausea and vomiting than the conventional tablets." (Abstract.) However, the Brief Description of the Invention states that it "reduces by adaptation, the level of nausea and incidences of emesis that attend the administration of multiple daily dosing." (2:47-49.) Further, it states that the invention provides "a method for reducing the level of nausea and incidence of emesis attending the administration of venlafaxine hydrochloride ..." (2:56-58.)

As the *Teva* Court also found in construing this term, the specification draws a distinction between the terms "level" and "incidence." *Teva* at *11. If "incidence" in fact encompassed the meaning of "level," there would be no reason to use both terms. The only explanation for the specification's phrasing is "that the patentees meant to differentiate between the two terms." *Id*. Accordingly, the term "incidence" must to limited to the meaning afforded by the specification: a word connoting frequency, rather than severity or degree.

Anchen also argues that the term "diminished" is too vague for construction, because the specification does not set forth an objective standard against which the frequency or severity of emesis can be measured. (Def.'s Opening Br. at 26.) Wyeth's construction proposes that the appropriate comparison is the incidence of nausea and emesis that would be experienced by patients receiving the same total dose of an immediate release formulation that is administered twice a day. (Joint Statement Tab 11 at 1.)

The Court agrees with Wyeth that a person skilled in the art would understand that "diminished incidence" implies a comparison to the immediate release formulation of the drug. The patent clearly discloses that the purpose of the invention is to provide better results than the "conventional table formulations which must be administered two or more times a day." (Abstract.)

Accordingly, the Court finds that the term "diminished incidence(s) of nausea and emesis" means "the 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 dose of an immediate release formulation that is administered at least twice a day."

G. *Spheroid*

Wyeth's Construction	Anchen's Construction
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.	One or more particles that are generally shaped like a sphere and result from an extrusion and spheronization process

The parties agree that the term "spheroid" describes particles that are "generally shaped like a sphere." Anchen argues, however, that the term does not encompass granules, beads or pellets, because one skilled in the art would understand that each of those particles result from a unique manufacturing method. (Def.'s Opening Br. at 30.) In particular, it argues that spheroids refer only to particles resulting from an extrusion and spheronization process. (*Id*. at 29.)

The only evidence Anchen cites in support of the proposition that granules, beads, pellets and spheroids are all produced by distinct methods is the declaration of its own expert, Dr. Walter Chambliss ("Chambliss"). The cited passages do not even refer to pellets, beads or granules, let alone support Anchen's arguments that each particle is uniquely formulated. (Joint Statement Tab 24 at para.para. 36-39.) Chambliss does, however, report that "the most-widely used methods to make spheroids are extrusion/spheronization, solution/suspension layering and powder layering." (Joint Statement Tab 24 at para. 37.) Contrary to Anchen's assertions, the fact that there are several "most-widely used methods" for spheroid formulations demonstrates that the ordinary meaning of "spheroid" is not restricted to any particular manufacturing process.

The patent does not demonstrate an intent to narrow the ordinary meaning of the term. While the patents disclose only one process to create spheroids, the Federal Circuit has held that this alone is an insufficient basis to limit a term to a singular method of production. Vanguard Products Corp. v. Parker Hannifin Corp., 234 F.3d 1370, 1372 (Fed.Cir.2000). Moreover, the portions of the specifications referencing the extrusion and spheronization process identify it as a preferred manufacturing method, not an exclusive one. (*See* 1: 38-49, noting that the extended release formulations " *may be* formulated" according to this method, " *may be* " film-coated, and " *may then be* " placed in pharmaceutically acceptable capsules, (emphasis added).)

Neither Abbott Laboratories v. Novopharm Ltd., 323 F.3d 1324 (Fed.Cir.2003), nor Biovail Corp. Int'l v. Andrx Pharmaceuticals. Inc., 239 F.3d 1297 (Fed.Cir.2001), supports Anchen's contention that the term spheroids should be limited to a particular manufacturing process. In *Abbott Laboratories,* the relevant process-co-micronization-was specified in the claims. Abbott Laboratories, 323 F.3d at 1327, 1330. The dispute was over what ingredients went into the specified process. *Id*. Here, there is no parallel because the claims are silent with respect to process.

In *Biovail,* the process limitation could be traced to parent patents, and although the limitation-homogenization-was not in the language of the patent at issue, it would be read into the claims given the inclusion in the antecedent prosecution which defined the term "admixture" to be the result of homogenization. Biovail, 239 F.3d at 1301-02. There is no comparable prior prosecution history to read into the present patents.

Because the patents do not clearly disclaim the ordinary meaning of the term, nor define "spheroid" as limited to a product of the extrusion spheronization manufacturing method, the Court finds that Wyeth's construction is appropriate here. The term "spheroid" is construed as "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."

H. ***A Method for Providing a Therapeutic Blood [or Drug] Plasma Concentration of*** Venlafaxine ***Over a Twenty Four Hour Period***

Wyeth's Construction	Anchen's Construction
A method in which the formulation is administered once-a-day and maintains over the course of 24 hours levels of venlafaxine in blood plasma that provide, during the course of treatment, relief from the condition being treated.	A method for providing a level of extended release venlafaxine hydrochloride in a patient's blood plasma high enough to provide the desired pharmacologic response and low enough that it is not toxic for a period of twenty-four hours.

The primary disagreement here is over the meaning of "therapeutic." Wyeth argues that the word should be construed according to its "commonly understood meaning within the field of psychiatry," as "relief from the condition being treated." (Pl.'s Opening Br. at 28-29.) Anchen proposes that "therapeutic" means achieving a "desired pharmacologic response," which it equates to achieving a particular concentration of the drug in a patient's blood stream. (Def.'s Opening Br. at 32.)

The Court first looks to the specification to see where and how the phrase "therapeutic" is used throughout the patents. The Abstract discloses an "extended release formulation of venlafaxine hydrochloride comprising a therapeutically effective amount of venlafaxine hydrochloride." (Abstract.) The specification describes the benefits of the extended release formula as follows:

in therapeutic dosing (with the extended release formula) ... rapid dissolution results in a rapid increase in blood plasma levels of the active compound shortly after administration followed by a decrease in blood plasma levels over several hours as the active compound is eliminated or metabolized, until subtherapeutic plasma levels are approached after about twelve hours following administration, thus requiring additional dosing with the drug.

(1:66-2:7.)

If the Court assumes that the term is used similarly throughout the patent, and there is no indication to the contrary here, then Anchen's construction becomes unduly restrictive. Anchen proposes that "therapeutic" equates to achieving a particular concentration of the drug in a patient's blood stream. (Def.'s Opening Br. at 32.) If so, then the above description would require "therapeutic dosing" to maintain a consistent (if unnamed) drug concentration level. The description, however, plainly contemplates concentration levels will rise and fall, and yet describes the entire process as a "therapeutic dosing." (1:66.)

Accordingly, the Court finds that the most logical construction is the one Wyeth proposes. In the content of the specification, the term "therapeutic" plainly means "relief from the condition being treated." Wyeth does not object to Anchen's additional explanation that the dosage must be "low enough that is it not toxic for a period of twenty-four hours," if the court construes that to mean that the dosage does not "result in severe, poisonous, or otherwise life-threatening adverse events." (Wyeth's Opening Br. at 29-30.) Because the parties appear to agree to this interpretation, the Court adopts the language in its construction.

For the foregoing reasons, the Court construes "A Method for Providing a Therapeutic Blood [or Drug] Plasma Concentration of Venlafaxine Over a Twenty Four Hour Period" to mean "a method in which the formulation is administered once-a-day and maintains over the course of 24 hours levels of venlafaxine in blood plasma that provides, during the course of treatment, relief from the condition being treated, but does not result in severe, poisonous, or otherwise life-threatening adverse events."

I. ***Encapsulated***

Wyeth's Construction	Anchen's Construction
Filled into a pharmaceutically acceptable capsule.	A formulation of extended release venlafaxine that is filled into a hard gelatin capsule.

The parties agree that "encapsulated" means "filled into" some type of pharmaceutical capsule. Although Anchen appears to have initially accepted Wyeth's definition (Def. Opening Br. at 33), it now seeks to narrow the ordinary meaning of the term to "only include hard shelled capsules such as those made from hard gelatin and starch." (Def.'s Response Br. at 25.)

Anchen's argument for limiting the scope of the term does not reference the specification; indeed, it does not reference the claims or the patents to any degree. Rather, it asserts that "one of ordinary skill would recognize that spheroids could never be encapsulated using soft gelatin capsules," because "soft gelatin capsules are only used for liquids and semi-solids."

Anchen does not make any argument that Wyeth has acted as its own lexicographer in limiting the ordinary meaning of the term "encapsulated." Absent such a showing, the Court finds that it would be improper to limit the ordinary meaning of the term. Accordingly, the Court construes the term "encapsulated" to mean "filled into a pharmaceutically acceptable capsule."

J. ***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***

Wyeth's Construction	Anchen's Construction
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, during the course of treatment, 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.	The phrase "a method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma" means a method for eliminating the peaks and troughs (hills and valleys) in blood plasma drug levels induced by the by (sic) multiple daily dosing with conventional immediate release venlafaxine. The phrase "attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride" means associated with the process by which venlafaxine hydrochloride is chemically converted in the body to a metabolite in a patient that is administered more than one dose per day of venlafaxine hydrochloride.

The parties disagree as to whether the term "eliminating the troughs and peaks" is a term of art. Anchen argues that one skilled in the art would understand that this "means what it says, eliminating all drug concentration troughs and peaks in a patient's blood plasma." (Def.'s Opening Br. at 33.) For its part, Wyeth argues that there is no customary meaning for this term, but rather, than the term must be interpreted in accordance with the guidance found in the specification. (PL's Opening Br. at 27.) The Court agrees.

The patent clearly demonstrates an intent to mitigate the changes in blood plasma that occur with administration of the drug's immediate release formula. The Brief Description discloses "a method for obtaining a flattened drug plasma concentration to time profile, thereby affording a *tighter* plasma therapeutic range control than can be obtained with multiple daily dosing." (2:21-23, emphasis added.) The specification makes clear, however, than this "tighter" range is not, as Anchen suggests, an entirely constant blood plasma level. Rather, the Brief Description explains that,

[i]n essence, the plasma levels of venlafaxine ... hydrochloride rise, after administration of the extended release formulations of this invention, for between about 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.

(2:28-36.) As the patent specifically notes, this is a "method for *moderating* " the peaks and valleys in blood plasma levels, as opposed to obviating them altogether. (*See* 2:40, emphasis added.)

The Court agrees that one skilled in the art would understand the phrase as it is described in the specification itself. Accordingly, it adopts the following construction for the term "a method for eliminating the troughs

and peaks ... attending the therapeutic metabolism of plural daily doses of venlafaxine hydrochloride": "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, during the course of treatment, 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."

IV. *CONCLUSION*

The following summarizes the Court's constructions:

Disputed Term	Court's Construction
Extended release formulation	A formulation, other than a hydrogel tablet, which 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.
A peak blood plasma level of Venlafaxine in *about* 6 hours	About means: a range, based upon rounding, of 5.5 hours up to, but not including, 6.5 hours.
A peak blood plasma level of Venlafaxine in from about 4 to *about* 8 hours	About means: a range based upon rounding of 3.5 hours up to, but not including, 8.5 hours.
A peak blood plasma level of Venlafaxine in from about 5 to *about* 8 hours	About means: a range based upon rounding of 4.5 hours up to, but not including, 8.5 hours.
Diminished incidence(s) of nausea and emesis	The 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 dose of an immediate release formulation that is administered at least twice a day
Spheroid	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.
A method for providing a therapeutic blood [or Drug] plasma concentration of venlafaxine over a twenty four hour period	A method in which the formulation is administered once-a-day and maintains over the course of 24 hours levels of venlafaxine in blood plasma that provide, during the course of treatment, relief from the condition being treated, but does not result in severe, poisonous, or otherwise life-threatening adverse events.
Encapsulated	Filled into a pharmaceutically acceptable capsule.
A method for eliminating the troughs and peaks of drug concentration in	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

a patient's blood plasma attending the therapeutic metabolism of plural daily doses of Venlafaxine Hydrochloride	plasma that are sufficient to provide, during the course of treatment, 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

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