United States District Court,
D. Delaware.

WYETH,
Plaintiff.
v.
IMPAX LABORATORIES, INC,
Defendant.

Civil Action No. 06-222-JJF

Dec. 13, 2007.

Background: Manufacturer of brand name drug brought action against manufacturer of generic version of that drug, alleging infringement of patents for methods of treating patients with depression or other disorders responsive to venlafaxine by administering an extended release formulation of venlafaxine hydrochloride that provided a therapeutic concentration of the drug over a 24-hour period and resulted in less nausea and vomiting than with an immediate release formulation of venlafaxine hydrochloride.

Holdings: The District Court, Joseph J. Farnan, J., held that:
(1) term "extended release formulation" was not limited to specific ingredients;
(2) term "incidences" as related to the phrase "diminished incidences of nausea and emesis" meant degree and/or frequency of nausea and emesis from extended release formulation administered once-a-day was less than what would be experienced by patients receiving same total daily dose of an immediate release formulation that was administered at least twice a day; and
(3) term "method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma" meant elimination of multiple sharp peaks and troughs resulting from multiple daily dosing.

Ordered accordingly.

6,274,171, 6,403,120, 6,419,958. Cited.

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MEMORANDUM OPINION

JOSEPH J. FARNAN**, District Judge.**

This action was brought by Plaintiff Wyeth against Defendant Impax Laboratories, Inc. ("Impax") alleging infringement of U.S. Patent Nos. 6,274,171 B1 ("the '171 patent"), 6,419,958 B2 ("the '958 patent") and 6,403,120 B2 ("the '120 patent") under the Hatch-Waxman Act in connection with Impax's Abbreviated New Drug Application ("ANDA") for a generic version of Wyeth's Effexor (R) XR. The issue currently before the Court is the claim construction of three terms and/or phrases from the patents-in-suit. The parties have briefed their respective positions on claim construction, and the Court has conducted a Markman hearing. This Memorandum Opinion represents the Court's construction of the disputed claim terms and/or phrases.

I. BACKGROUND

The three patents-in-suit share the same specification and relate to a product marketed by Wyeth under the registered name Effexor (R) XR. Generally, the asserted claims of the patents-in-suit pertain to methods for treating patients with depression or other disorders responsive to venlafaxine by administering an extended release formulation of venlafaxine hydrochloride that provides a therapeutic concentration of the drug over a 24 hour period and results in less nausea and vomiting than with an immediate release formulation of venlafaxine hydrochloride. The asserted claims are all method claims which require either peak blood plasma levels of venlafaxine within a specified time period or peak blood plasma levels of venlafaxine within specified concentrations. Some claims also provide that the claimed method result in "diminished incidences of nausea and emesis."

Wyeth has asserted against Impax the following claims from the patents-in-suit: claims 20-25 of the '171 patent, claims 1-6 of the '958 patent and claims 1, 2, 13 and 14 of the '120 patent. From these claims, the parties have identified three disputed claim terms and/or phrases: (1) "extended release formulation," (2) "diminished incidences of nausea and emesis," and (3) "a method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma." The following claims from the '171 patent are illustrative of how these terms and/or phrases are used in all of the asserted claims:

20. 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.

21. *A method for eliminating the troughs and peaks of drug concentration in a patients [sic] 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 formula* 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.

The patents-in-suit have also been the subject of litigation between Wyeth and Teva Pharmaceuticals in the United States District Court for the District of New Jersey (the "Teva Litigation"). A Markman ruling was issued in that case concerning, among other things, two of the same terms asserted by Wyeth here. The

parties settled the case before trial, and the New Jersey district court vacated its Markman ruling.

III. LEGAL STANDARD

[1] [2] Claim construction is a question of law. Markman v. Westview Instruments, Inc., 52 F.3d 967, 977-78 (Fed.Cir.1995), *aff'd,* 517 U.S. 370, 388-90, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). When construing the claims of a patent, a court considers the literal language of the claim, the patent specification and the prosecution history. Markman, 52 F.3d at 979. Of these sources, the specification is considered the single best guide for discerning the meaning of a claim. Phillips v. AWH Corporation, 415 F.3d 1303, 1312-1317 (Fed.Cir.2005).

[3] [4] A court may consider extrinsic evidence, including expert and inventor testimony, dictionaries, and learned treatises, in order to assist it in understanding the underlying technology, the meaning of terms to one skilled in the art and how the invention works. Phillips, 415 F.3d at 1318-19; Markman, 52 F.3d at 979-80 (citations omitted). However, extrinsic evidence is considered less reliable and less useful in claim construction than the patent and its prosecution history. Phillips, 415 F.3d at 1318-19 (discussing "flaws" inherent in extrinsic evidence and noting that extrinsic evidence "is unlikely to result in a reliable interpretation of a patent claim scope unless considered in the context of intrinsic evidence").

[5] [6] In addition to these fundamental claim construction principles, a court should also interpret the language in a claim by applying the ordinary and accustomed meaning of the words in the claim. Envirotech Corp. v. Al George, Inc., 730 F.2d 753, 759 (Fed.Cir.1984). If the patent inventor clearly supplies a different meaning, however, then the claim should be interpreted according to the meaning supplied by the inventor. Markman, 52 F.3d at 980 (noting that patentee is free to be his own lexicographer, but emphasizing that any special definitions given to words must be clearly set forth in patent). If possible, claims should be construed to uphold validity. In re Yamamoto, 740 F.2d 1569, 1571 (Fed.Cir.1984) (citations omitted).

IV. CONSTRUCTION OF THE DISPUTED TERMS AND/OR PHRASES

A. "*Extended Release Formulation*"

[7] With respect to the term "extended release formulation," Impax contends that the term requires specific ingredients referred to in the specification. Specifically, Impax contends that "extended release formulation" means "a formulation comprising venlafaxine, microcrystalline cellulose, and optionally, HPMC coated with a mixture of ethyl cellulose and HPMC in an amount needed to provide a specific unit dosage administered once-a-day to provide a therapeutic blood plasma level of venlafaxine over the entire 24 hour period of administration." Impax contends that other extended release technologies exist and were known to those skilled in the art, including such technologies as drug-coated sugar beads, diffusion systems, reservoir systems, enteric coatings and waxing coatings. However, Impax contends that these other technologies are not embraced by the specifications for the patents-in-suit, because the inventors specifically referenced certain ingredients necessary for the extended release formulation they claimed. Impax also directs the Court to the Markman ruling issued by the New Jersey district court in the Teva Litigation, which adopted this approach.

In response, Wyeth contends that the term "extended release formulation" should be construed consistent with its ordinary and customary meaning, and therefore, no specific ingredients are required to define the term. In support of its argument, Wyeth relies on the doctrine of claim differentiation, pointing out to the Court that the asserted method claims recite "extended release formulation" without specifying ingredients,

whereas other unasserted claims recite an "extended release formulation" with specific ingredients. Because the unasserted claims would become redundant if "extended release formulation" is construed to require specific ingredients, Wyeth contends that the term "extended release formulation" must be construed more generally to mean "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."

[8] Reviewing the plain language of the asserted claims in light of the patents' specifications and prosecution histories, the Court agrees with Wyeth's position that the term "extended release formulation" should not be limited to specific ingredients. As Wyeth points out, the asserted claims do not define the claimed "extended release formulation" by reference to any specific ingredients except for the active ingredient venlafaxine hydrochloride. Several unasserted claims, however, including certain claims dependent on those asserted here, recite specific inactive ingredients. As the Court of Appeals for the Federal Circuit recently reiterated in *Honeywell Int'l Inc. v. Universal Avionics Sys. Corp.*, " '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.' " *Id.* (quoting Phillips v. AWH Corp., 415 F.3d at 1315;) see also Saunders Group, Inc. v. Comfortrac, Inc., 492 F.3d 1326, 1333 (Fed.Cir.2007) (noting that some passages of patent specification described device as comprising at least one pressure activated seal, but noting that those passages do not expressly state that the pressure activated seal is an essential component of the invention and declining to limit the claims "where the language of the claims so clearly distinguishes between those claims that require the presence of a pressure activated seal and those that do not ...").

Impax directs the Court to portions of the specification which it contends override this presumption and demonstrate that the inventors intended to limit the term "extended release formulation" to specific active ingredients. Reading the specification as a whole and in context, the Court is not persuaded that it supports the claim limitations sought by Impax. Throughout the specification, the claimed invention is described first in broad terms and later in more narrow terms. These broad terms describe a "use aspect" of the invention which correspond to the method claims Wyeth asserts here. The portions of the specification relating to this "use aspect" do not limit the "extended release formulation" to a specific list of inactive ingredients, and instead, describe the methods of achieving certain results that represent the claimed invention in terms of an "extended release formulation of venlafaxine hydrochloride." For example, the specification provides:

[I]n accordance with the *use aspect of this invention,* there is provided a method for moderating the plural blood plasma peaks and valleys attending the pharmocokinetic utilization of multiple daily tablet dosing with venlafaxine hydrochloride which comprises administering to a patient in need of treatment with venlafaxine hydrochloride, a one-a-day, extended release formulation of venlafaxine hydrochloride.

Ex. 1, col. 2:38-45 (emphasis added).

Similarly, the specification goes on to describe another "use aspect" of the invention in similar terms:

Thus, 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 comprises dosing a patient in needs of treatment with venlafaxine hydrochloride with an extended release formulation of venlafaxine hydrochloride once a day in a therapeutically effective amount.

Ex. 1, col. 2:55-62 (emphasis added). With respect to the more narrow descriptions provided for in the

specification, the Court concludes that those descriptions either relate to the "formulation aspect" of the invention contained in the unasserted claims and/or suggest preferred embodiments for practicing the invention. The Federal Circuit has cautioned against importing limitations from the specification into the claim language FN1, and the Court declines to do so, particularly, where as here, it is not clear to the Court from the portions of the specification cited by Impax that the inventors intended to depart from the ordinary and customary meaning of the term "extended release formulation." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996) (recognizing that a patentee may choose to be his own lexicographer and depart from the ordinary and plain meaning words, "as long as the special definition of the term is clearly stated in the patent specification or file history".) Indeed, when a departure from the ordinary meaning o the term "extended release formulation" was required, as in the unasserted formulation claims, the claim language and the corresponding portions of the specification specifically go on to list the ingredients required for the "extended release formulation." That this 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.

FN1. *See e.g.,* Pfizer Inc. v. Ranbaxy Labs., Ltd., 457 F.3d 1284, 1290 (Fed.Cir.2006) ("while the examples do describe reaction sequences that produce racemates, restricting claim 1 on this basis would improperly import limitations from the specification into the claims ..."); Phillips, 415 F.3d at 1323.

The Court's conclusion in this regard is also consistent with the prosecution histories of the patents. Initially, the patent examiner concluded that the method claims would only be patentable if Wyeth agreed to make those claims dependent upon the product claims recited in the patent. The first examiner's approach to the patents reflected his view that "extended release formulation" was broadly interpreted and not limited to specific ingredients. Although Wyeth initially agreed to this amendment and the examiner issued a Notice of Allowance, Wyeth later abandoned the application and refiled a continuation-in-part application which left the method claims in the broader form, without making them dependent on the narrower product claims. The second examiner allowed the refiled method claims to issue without rejection or amendment.

Impax also contends that the Court should not adopt Wyeth's proposed construction of the term "extended release formulation," because it excludes hydrogel tablets, and therefore, it is not consistent with the ordinary and plain meaning of the term "extended release formulation" as that term is used by one skilled in the art. As Wyeth points out, however, hydrogel tablets do not produce the desired dissolution rates called for in the patents. In this regard, the specification explains:

Numerous attempts to produce extended release tablets by hydrogel technology proved to be fruitless because the compressed tablets were either physically unstable (poor compressibility or capping problems) or dissolved too rapidly in dissolution studies.

* * * * * *

Thus, the desired dissolution rates of sustained release dosage forms of venlafaxine hydrochloride, *impossible to achieve with hydrogel tablet technology,* has been achieved with the film-coated spheroid compositions of this invention.

Ex. 1, col. 4, ll. 60-64, col. 10, ll. 53-57 (emphasis added). In the Court's view, the emphasized language

makes it clear that hydrogel tablets are not within the scope of the invention, and therefore, the Court concludes that hydrogel tablets are properly excluded from the construction of the term "extended release formulation." Accordingly, the Court construes the term "extended release formulation" to mean "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. "*Diminished Incidences of Nausea and Emesis*"

[9] Wyeth contends that the term "incidences" as related to the phrase "diminished incidences of nausea and emesis" should be construed to mean a reduced degree and/or frequency of nausea and emesis. Specifically, Wyeth contends that "diminished incidences of nausea and emesis" means "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."

In contrast, Impax contends that the term "incidences" refers to the number of patients with nausea and emesis. Thus, Impax contends that the "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."

The parties agree that the prosecution history is not instructive regarding the meaning of this phrase. Accordingly, the Court must turn to the claim language and the specification for instruction regarding the meaning of the phrase "diminished incidences of nausea and emesis." The term "diminished" is used only in the claim language and not elsewhere in the specification. However, the specification discusses the effect of the invention on nausea and emesis in three specific areas. First, the Abstract of the invention discloses that the invention "provides *a lower incidence* of nausea and vomiting than conventional tablets." (emphasis added). The Background of the Invention discusses nausea and emesis in the context of the immediate release tablets using a numerical focus. Specifically, the Background of the Invention explains that "[w]ith the plural daily dosing regimen, the most common side effect is nausea, experienced by about *forty five percent of patients* under treatment with venlafaxine hydrochloride. Vomiting also occurs in about *seventeen percent of the patients*." Ex. 1, col. 1, l. 63-col. 2, l. 11 (emphasis added). The Brief Description of the Invention contrasts the clinical advantages of the invention with the disadvantages of multiple daily dosing and discusses nausea and emesis in more general terms, as follows:

The use of the one-a-day venlafaxine hydrochloride formulations of this invention *reduces by adaptation, the level of nausea and incidence of emesis* that attend the administration of multiple daily dosing. In clinical trials of venlafaxine hydrochloride ER, the probability of developing nausea in the course of the trials was greatly reduced after the first week. Venlafaxine ER showed a statistically significant improvement over conventional venlafaxine hydrochloride tablets in two eight-week and one 12 week clinical studies. Thus, 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 comprises 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.

Ex. 1, col. 2, ll. 45-62 (emphasis added).

Reviewing the specification as a whole and in context, the Court concludes that the inventors did not intend to limit the term "diminished incidences of nausea and vomiting" to a numerical or percentage based definition. Interestingly, that portion of the specification that refers to specific percentages does not even use the term "incidences," which suggests to the Court that the inventors did not necessarily intend to equate the term "incidences" with percentages or numbers. Further, instructive to the Court is the specification's reference to nausea, which embraces terminology pertaining to both degree and/or frequency. For example, the Abstract discusses the "lower incidence of nausea and vomiting" while the Brief Description of the Invention refers to "reducing the level of nausea and incidence of emesis." The interchangeable use of the terms "level" and "incidence" in the specification with respect to nausea, along with the inventors' failure to specifically equate the term "incidences" with either percentages or numbers in the specification, leads the Court to believe that Wyeth's broader definition of the term "diminished incidences of nausea and emesis" is correct. Indeed, the Court agrees with Wyeth that if the inventors intended to maintain a strictly numerical focus with respect to the "diminished incidences of nausea and emesis" the claim language would have used a term more commonly connected to numerical values such as "fewer incidences of nausea and emesis" or would have alternatively linked the claim language more specifically to a decreased percentage or number of patients suffering from nausea and emesis. Instead, the inventors used the term "diminished incidences." Unlike the term "fewer," the term "diminished" is not limited to a numerical focus. Instead, the term "diminished" suggests the broader concept of a reduction in size, number and degree. Accordingly, the Court concludes that Wyeth's proposed construction of the term diminished is consistent with the choice of wording in the claim, as well as with the descriptions provided for in the specification, and therefore, the Court construes the phrase "diminished incidences of nausea and emesis" to mean "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."

C. "*A Method For Eliminating The Troughs And Peaks Of Drug Concentration In A Patient's Blood Plasma*"

[10] The phrase "[a] method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma" appears as the preamble to claims 21, 24, and 25 of the '171 patent and claims 2, 5, and 6 of the '958 patent. Each of these asserted claims recite a method of orally administering an encapsulated extended release formulation that provides a single peak blood plasma level in about four to about eight hours after administration, thereby eliminating the troughs and peaks of drug concentration in a patient's blood plasma.

Impax contends that the disputed phrase means that "the peak(s) and trough(s) due to the 'therapeutic metabolism' of any second or third dose given in a single day is eliminated by dosing only once in 24 hours." Wyeth contends that Impax's definition does not correctly grasp the claims, because eliminating the peaks and troughs of a second or third dose of venlafaxine hydrochloride, but not the sharp peak and trough of the first dose, is not the same as having a profile of one peak and one trough extended over a twenty-four hour period. Thus, Wyeth proposes a more detailed construction that explains how the troughs and peaks are eliminated:

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.

Reviewing the claim language in light of the specification FN2, the Court concludes that Wyeth's proposed construction is correct. The specification explains that this invention provides a method for obtaining a "flatted drug plasma concentration to time profile" compared to what could be achieved with multiple daily dosing. Ex. 1, col. 2, ll. 22-24. According to the Brief Description, this effect is possible because immediate release tablets give peak blood plasma levels in two to four hours followed by a gradual decline, while extended release formulations allow the blood plasma levels to rise for "between about five to about eight hours (optimally about six hours) and then begin to fall through a protected, 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." *Id*. at col. 2, ll. 29-38. Stated another way, the claimed extended release formulations provide a method of eliminating the sharp, multiple peaks and troughs associated with multiple daily dosing of the immediate release formulation and replacing those sharp, multiple peaks and troughs with a more controlled flattened blood plasma drug concentration to time profile which includes a peak followed by a gradual and protracted decline.

FN2. The prosecution histories of the patents do not illuminate the meaning of this term, and therefore, the Court limits its discussion to the specification and claim language.

Impax's proposed construction requires the peaks and troughs of the second and third doses to be eliminated, but maintains the plasma concentration to time profile of immediate release formulations, which is at odds with the specification. Thus, the Court adopts Wyeth's position that the claimed method is a way to flatten the plasma concentration to time profile into a single peak and trough, and not merely to eliminate multiple peaks and troughs. Accordingly, the Court adopts Wyeth's construction, and construes "a method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma" 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, 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.

V. CONCLUSION

For the reasons discussed, the Court has construed the disputed terms and/or phrases of the '171 patent, the '958 patent and the '120 patent as provided herein. An Order consistent with this Memorandum Opinion will be entered setting forth the meaning of the disputed terms and/or phrases in the ' 171 patent, the '958 patent and the '120 patent.

ORDER

At Wilmington, this 13th day of December 2007, for the reasons discussed in the Memorandum Opinion issued this date;

IT IS HEREBY ORDERED that the following terms and/or phrases in U.S. Patent Nos. 6,274,171 B1, 6,419,958 B2 and 6,403,120 B2 are assigned the following meanings:

1. The meaning of the phrase **"extended release formulation"** is "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."

2. The meaning of the phrase **"diminished incidences of nausea and emesis"** is "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"

3. The meaning of the phrase **"a method for eliminating the troughs and peaks of drug concentration in a patient's blood plasma"** is:

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.

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