NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

VIVUS, INC., Plaintiff, v. ACTAVIS LABORATORIES FL, INC., Defendant.	:	Civil Action No. 14-3786 (SRC)(CLW) Civil Action No. 15-2693 (SRC)(CLW) **OPINION**
VIVUS, INC., Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	:	

CHESLER, District Judge

This matter comes before the Court on the application for claim construction by Plaintiff Vivus, Inc. ("Vivus") and Defendant Actavis Laboratories FL, Inc. ("Actavis") in Civil Action No. 14-3786, and the application for claim construction by Vivus and Defendant Teva Pharmaceuticals USA, Inc. ("Teva") in Civil Action No. 15-2693. In the pharmaceutical patent infringement suit between Vivus and Actavis, the parties seek construction of claims in U.S Patent Nos. 7,056,890 ("the '890 patent"), 7,553,818 ("the '818 patent"), 7,659,256 ("the '256 patent"), 7,674,776 ("the '776 patent"), 8,580,298 ("the '298 patent"), 8,580,299 ("the '299

patent"), 8,895,057 ("the '057 patent"), 8,895,058 ("the '058 patent"), 9,011,905 ("the '905 patent"), and 9,011,906 ("the '096 patent"). Vivus and Teva are currently litigating a parallel action asserting infringement of the same patents-in-suit. Vivus and Teva have limited their claim construction dispute to the term "delayed release" [Docket Entry 55], which is also in dispute between Vivus and Actavis, and thus the Court will construe all terms related to the patents-in-suit in both actions in this Opinion. Teva filed a claim construction brief responding to Vivus's and Actavis's proposed constructions of the disputed claim term "delayed release" [Civ. Action No. 15-2693, Docket Entry 48].

Vivus owns the patents-in-suit, which are directed to the treatment of weight loss and obesity through the use of phentermine and topiramate extended-release capsules sold under the trade name QSYMIA®. The patents-in-suit cover pharmaceutical compositions containing combinations of phentermine and topiramate, as well as methods of use and administration of phentermine-topiramate combination drugs. The patents-in-suit belong to two families: the '890 family, including the '890 patent, the '818 patent, the '256 patent, and the '776 patent; and the '298 family, including the '298 patent, the '299 patent, the '057 patent, the '058 patent, the '905 patent, and the '096 patent. Defendants Teva and Actavis have filed ANDAs seeking FDA approval to manufacture and sell generic versions of QSYMIA® prior to the expiration of the patents-in-suit.

ANALYSIS

I. THE LAW OF CLAIM CONSTRUCTION

A court's determination "of patent infringement requires a two-step process: first, the court determines the meaning of the disputed claim terms, then the accused device is compared to the claims as construed to determine infringement." *Acumed LLC v. Stryker Corp.*, 483 F.3d

800, 804 (Fed. Cir. 2007). "[W]hen the district court reviews only evidence intrinsic to the patent (the patent claims and specifications, along with the patent's prosecution history), the judge's determination will amount solely to a determination of law." *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015).

The focus of claim construction is the claim language itself:

> 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. Attending this principle, a claim construction analysis must begin and remain centered on the claim language itself, for that is the language the patentee has chosen to 'particularly point[ ] out and distinctly claim[ ] the subject matter which the patentee regards as his invention.'

Innova/Pure Water, Inc. v. Safari Water Filtration Sys., 381 F.3d 1111, 1115-16 (Fed. Cir. 2004) (citations omitted). The Federal Circuit has established the following framework for the construction of claim language:

> We have frequently stated that the words of a claim 'are generally given their ordinary and customary meaning.' We have made clear, moreover, that the ordinary and customary meaning of a claim term 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, i.e., as of the effective filing date of the patent application. The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation . . .
>
> 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. In many cases that give rise to litigation, however, determining the ordinary and customary meaning of the claim requires examination of terms that have a particular meaning in a field of art. Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks to those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean. Those 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.

Phillips v. AWH Corp., 415 F.3d 1303, 1312-14 (Fed. Cir. 2005) (citations omitted).

II. CLAIM CONSTRUCTION OF THE DISPUTED TERMS

a. "ABOUT"

The term "about" appears in various claims in both families of patents.[1] In asserted claim 1 of the '890 patent, the term "about" refers to dosage amounts:

> 1. A pharmaceutical composition comprising about 50 mg to 250 mg topiramate and about 5 mg to about 15 mg phentermine.

'890 patent at 21:12-14. In asserted claim 1 of the '298 patent, as well as other claims in the '298 family, "about" refers to periods of time, percentages, and dosages:

> 1. A unit dosage form for weight loss for oral administration to a patient having a body mass index of at least 30 kg/mg^2 and a condition associated with obesity, comprising a combination of:
> an immediate release phentermine formulation containing a unit dosage of phentermine in the range of 2 mg to 8 mg; and
> a controlled release topiramate formulation containing a unit dosage of topiramate in the range of 15 mg to 50 mg,
> wherein the dosage of phentermine in mg/day is about 16% of the dosage of topiramate in mg/day, and
> wherein the controlled release topiramate formulation reaches a maximum plasma concentration (Cmax) at exhibits a lower Cmax, than non-controlled release topiramate, without decreasing total drug exposure defined by the area under concentration-time curve (AUC), thereby enabling reduction of concentration-dependent side effects without a decrease in efficacy.

'298 patent at 21:2-21. Vivus asserts that no construction is necessary for the term "about," while Actavis proposes the construction "allowing for minor variations." Teva has not requested claim construction on this term.

[1] The term "about" appears in various claims in both families of patents: the '890 patent in claims 1-3, 8-10, 22, 36, 38-43, and 52-54; the '818 patent in claims 15-17; the '298 patent in claims 1, 4-6, and 21; the '299 patent in claims 1-3, and 9; the '057 patent in claims 1, 12-14, 17, 18, 29, 30, and 33; the '058 patent in claims 1, 18, and 20-23; the '905 patent in claims 1, 10, 12-15, and 34; and the '906 patent in claims 1, 11-13, 16-17, 27-28, and 31.

Federal Circuit law states that claim terms having plain meanings "do not require additional construction." *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1326 (Fed. Cir. 2012). "[A] party wishing to alter the meaning of a clear claim term must overcome the presumption that the ordinary and accustomed meaning is the proper one, demonstrating why such an alteration is required." *K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356 (Fed. Cir. 1999).

Using these principles, the Court finds that there is no support in the intrinsic evidence for limiting the term "about" to Actavis's proposed definition, "allowing for minor variations," given that the meaning of "about" is clear in the patent claims. The specifications of the patents-in-suit do not provide or indicate any unique definitions of "about" that are inconsistent with its plain and ordinary meaning. Furthermore, the term "about" does not have a universal meaning in patents, "but is dependent on the factual situation presented," including what the effects may be of varying ranges or parameters of an invention. *See, e.g., W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 842 F.2d 1275, 1280 (Fed. Cir. 1988). Vivus notes correctly that the term "about" is indeed used in a context-specific manner in these patents.

The purpose of claim construction is to reduce ambiguity for the jury. *See, e.g., U.S. Surgical Corp. v. Ethicon*, 103 F.3d 1554, 1568 (Fed. Cir. 1997) (claim construction is appropriate when needed to "clarify and when necessary to explain what the patentee covered by the claims"). Actavis's proposed definition does not appear anywhere in the patents or in other intrinsic evidence before this Court. The phrase "allowing for minor variations" is at least as open to interpretation as the term "about." Actavis's proposed construction therefore fails to provide any clarification for a finder of fact. For these reasons, the Court will decline to construe

the term "about" to mean "allowing for minor variations." Instead, the Court finds that no construction is necessary for the term "about."

b. "PHENTERMINE" AND "TOPIRAMATE"

The terms "phentermine" and "topiramate" describe the active pharmaceutical ingredients in Vivus's QSYMIA® weight loss drug, as well as in the proposed generic products from Actavis and Teva. These terms appear frequently in the patents-in-suit,[2] including in asserted claim 1 of the '298 patent, and various other asserted claims from that family:

> 1. A unit dosage form for weight loss for oral administration to a patient having a body mass index of at least 30 kg/m^2 and a condition associated with obesity, comprising a combination of:
> an immediate release phentermine formulation containing a unit dosage of phentermine in the range of 2 mg to 8 mg; and
> a controlled release topiramate formulation containing a unit dosage of topiramate in the range of 15 mg to 50 mg,
> wherein the dosage of phentermine in mg/day is about 16% of the dosage of topiramate in mg/day, and
> wherein the controlled release topiramate formulation reaches a maximum plasma concentration (Cmax) at about 6 to about 10 hours (Tmax) after administration and exhibits a lower Cmax, than non-controlled release topiramate, without decreasing total drug exposure defined by the area under the concentration-time curve (AUC), thereby enabling reduction of concentration-dependent side effects without a decrease in efficacy.
>
> 15. The dosage form of claim 1, wherein the unit dosage of phentermine is 3.75 mg and the unit dosage of topiramate is 23 mg.
>
> 16. The dosage form of claim 15, wherein the 3.75 mg phentermine is in the form of 4.92 mg phentermine hydrochloride.

[2] The term "phentermine" also appears in asserted claims 4, 8, 17, 22, 23, 26-28, 30, 36, 38, 46, and 52 of the '890 patent; claims 13 and 15-17 of the '818 patent; claims 1, 3, 7, 15, 16, 20, 21, 26, 28, and 29 of the '256 patent; claims 1, 2, 10, 15, 17, 25, 27, 28, 42, 45, and 57-59 of the '776 patent; claims 1-3, 10, 15-18, and 21 of the '298 patent; claims 1-3 of the '299 patent; claims 1, 12, 13, 18, and 29 of the '057 patent; claims 1, 12, 17-20, 24, and 25 of the '058 patent; claims 1, 9-12, 16-17, and 32-33 of the '905 patent; and claims 1, 11-12, 17, and 27 of the '906 patent. The term "topiramate" also appears in asserted claims 2-4, 6-10, 18, 19, 23, 26-28, 30, 32-34, 36, 38, 46-48, and 52-54 of the '890 patent; claims 13 and 15-17 of the '818 patent; claims 2, 4-6, 8-10, 20, 21, 25, and 27-29 of the '256 patent; claims 10-17, 25, 26, and 42 of the '776 patent; claims 1, 3, 54, 6, 7, 11-15, 17, and 21 of the '298 patent; claims 1 and 7 of the '299 patent; claims 1, 14, 15, 18, 30, and 31 of the '057 patent; claims 1, 13-17, 19, 21, 23, 25, and 26 of the '058 patent; claims 1, 8-9, 11, 13, 15, 17-18, 29, and 32-35 of the '905 patent; and claims 1, 10, 13-14, 17, 26, and 28-29 of the '906 patent.

’298 patent at 21:2-21; 21:59-64. In addition, the terms appear in asserted claim 1 of the ’890 patent:

> 1. A pharmaceutical composition comprising about 50 mg to 250 mg topiramate and about 5 mg to about 15 mg phentermine.

’890 patent at 21:12-14.

Teva has not requested claim construction on these terms. For the patents in the ’298 family, Vivus and Actavis have stipulated that “phentermine” shall be construed as “phentermine, in the form of free base or its salts or derivatives,” and “topiramate” shall be construed as “topiramate, in the form of free base or its salts or derivatives.” Therefore, the parties only dispute the construction of “phentermine” and “topiramate” in the ’890 patent family, for the ’890, ’818, ’256, and ’776 patents. For these patents, Vivus asserts that “phentermine” should be construed as “phentermine, in the form of free base or its salts or derivatives,” and “topiramate” should be construed as “topiramate, in the form of free base or its salts or derivatives.” Actavis proposes the constructions of “phentermine free base” and “topiramate free base.”

The primary dispute between the parties on these terms is whether, in the ’890 family of patents, the patentee’s identification of the compounds phentermine and topiramate by name alone properly includes known forms of these compounds that deliver the specified amount of active pharmaceutical ingredient, or whether the patentee has limited its claims to just the free base forms of phentermine and topiramate. At the outset, the Court notes that the term “free base” does not appear in the specifications of these patents, and these patents also make no direct mention of substituting pharmaceutically acceptable salts for the free base form of the drug.[3]

[3] The parties largely treat the construction of these terms together, likely because there are fewer references to topiramate than phentermine in the intrinsic evidence of these patents.

First, the intrinsic evidence shows that references to "phentermine" include its salts and derivatives. The '890 specification refers to phentermine as "phentermine (Fastin®, Ionamin®)." '890 patent at 1:46. Fastin® is a trade name for phentermine hydrochloride, and Ionamin® refers to phentermine resin [Docket Entry 110, Exs. 12, 17]. Given that "[t]he specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication," the specification's definition of phentermine as including a phentermine salt and a phentermine derivative is compelling evidence in favor of Vivus's constructions. *Vitronics Corp. v. Conceptronics, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). Furthermore, the remainder of the specification does not show that the patentee intended to limit "phentermine" to the free base form. "Absent a clear disavowal or contrary definition in the specification or the prosecution history, the patentee is entitled to the full scope of its claim language." *Home Diagnostics, Inc. v. LifeScan, Inc.*, 381 F.3d 1352, 1358 (Fed. Cir. 2004). Vivus's construction is supported by Table 1 in the '890 patent, which lists the chemical structure of various sympathomimetic agents, including some "phentermine-like compounds." If the patentee had intended to expressly disavow salts and derivatives of phentermine as part of the claimed invention, then it could have listed these compounds in the table, along with "phentermine-like compounds," but it did not.

Actavis focuses on the definition of a "phentermine-like compound" in the '890 specification, in support of its argument that derivatives should not be included in this court's construction of the term "phentermine":

> As defined herein, a phentermine-like compound is a compound structurally related to phentermine (e.g. an analog or derivative) which maintains an anorectic activity similar to that of phentermine.

’890 patent at 7:50-53. The ’890 specification makes clear that “phentermine-like compounds” are structurally related to phentermine, with similar anoretic activity. But these compounds are not phentermine, and Vivus does not claim that the term “phentermine” should include these “phentermine-like compounds.” ’890 patent at 7:48-55. With this definition, the patentee made a distinction between phentermine, and compounds that are “structurally related” to phentermine, but do not have the exact same pharmacologic activity. This definition does not exclude derivatives *per se* from inclusion in the term “phentermine”; it excludes compounds that I wrote sodo not have the same pharmacologic activity as phentermine. In the end, the Court has not been asked to construe the term “phentermine-like compounds,” and finds the specification’s explicit inclusion of phentermine salts and phentermine resin as part of a definition of the term “phentermine” indicative of the patentee’s intention to include salts and derivatives in the scope of the term “phentermine.”

Second, the Federal Circuit has explained that a court should consider the patent’s file history in claim construction, because the file history “provides evidence of how the PTO and the inventor understood the patent.” *Phillips*, 415 F.3d at 1317. The prosecution history of the ’890 patent shows that the term “phentermine,” as used in the claims of this patent, includes corresponding amounts of phentermine salts. In a non-final rejection dated November 18, 2004, the patent examiner stated that the “[Physician’s Desk Reference] teaches the use of phentermine HCl to induce weight loss. The recommended dosages are 37.5 mg/day or 18.75 mg/day. These dosages of the HCl salt correspond to 30 mg and 15 mg, respectively, of phentermine base, as recited in the claims” [Docket Entry 110, Ex. 13 at 5]. Throughout this rejection, the examiner made no distinction between phentermine base and the phentermine salt, in discussion of the active pharmaceutical ingredient claimed in the patent application. (Ex. 13.) The prosecution

history makes other references to "phentermine" where it has been used interchangeably with, or to refer to, "phentermine hydrochloride." *See, e.g.,* December 5, 2005 Amendment, Submission of Decl., and Request for Interview at 20 [Docket Entry 110, Ex. 14]; November 28, 2005, Decl. of Dr. Donald M. Schumacher, M.D. submitted pursuant to 37 C.F.R. § 1.132 [Docket Entry 110, Ex. 15, at ¶¶ 1(a)-1(b)]; February 8, 2006 Notice of Allowance [Docket Entry 110, Ex. 16, at 2].

Contrary to this evidence, Actavis argues that the prosecution history indicates that the patentee intended to narrow the scope of its invention with respect to phentermine and topiramate. Actavis asserts that the common ancestor of the '890 patent family included claims that cover other sympathomimetic agents besides phentermine, but the patentee narrowed its focus to phentermine in its claims for the '890 patent [Docket Entry 112-4, Ex. 12]. Second, Actavis alleges that the information submitted by the applicant to overcome the initial non-final rejection did not discuss phentermine-like compounds [Docket Entry 112-4, Ex. 27, at 3]. It is well-established that statements made in prosecution only limit the scope of the claims when disavowal is "both clear and unmistakable." *See, e.g., Elbex Video, Ltd. v. Sensormatic Elecs. Corp.*, 508 F.3d 1366, 1371 (Fed. Cir. 2007). The statements Actavis highlights do not come close to meeting the standard for disavowal explained by the Federal Circuit. The absence of a mention of a phentermine derivative in information submitted by the applicant cannot be a clear and unmistakable disavowal of a broader claim scope, and furthermore the evidence cited by Actavis does not address phentermine salts at all.

In support of its constructions, Vivus also offers extrinsic evidence to show that a person of ordinary skill in the art in 1999 would have understood a reference to phentermine or topiramate to include other forms of the active pharmaceutical ingredient that does not change

the pharmacologic activity of the compound. (Sinko Decl. ¶ 15.5.) Vivus's expert Patrick J. Sinko states that "[i]n general use, if a person of ordinary skill in the art refers to an active pharmaceutical ingredient by name alone, without specifying a particular form of the API, then the reference would be understood to include any known forms of the API. This has been the common usage in the art since before 1999 and remains the common usage in the art today." (Sinko Decl. ¶ 14.) Sinko further opines that "a person of ordinary skill in the art in 1999 would have understood a reference to 'phentermine' that did not specify 'phentermine **base**,' to include salts and derivatives of phentermine. Likewise, a person of ordinary skill in the art in 1999 would have understood a reference to 'topiramate' that did not specify 'topiramate **base**' to include salts and derivatives of topiramate." (Sinko Decl. ¶ 21 (emphasis in original)). In *Phillips*, the Federal Circuit discussed the role of extrinsic evidence in claim construction and stated this conclusion:

> In sum, extrinsic evidence may be useful to the court, but it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence. Nonetheless, because extrinsic evidence can help educate the court regarding the field of the invention and can help the court determine what a person of ordinary skill in the art would understand claim terms to mean, it is permissible for the district court in its sound discretion to admit and use such evidence.

Phillips, 415 F.3d at 1319. Given that the Sinko Declaration's opinions fit with the Court's conclusions based on the intrinsic evidence as to the scope of the patentee's claims, the Court will consider this extrinsic evidence as part of its analysis of these terms.

Vivus's construction includes various forms of active pharmaceutical ingredients commonly found in FDA-approved drugs: free bases, salts, resins, and other derivatives. Actavis's arguments do not convince the Court that the scope of these terms should be limited to only the free base forms of the compounds, because the patentee did not make a clear disavowal

of a broader scope for the claims. "It is well-settled that, in interpreting an asserted claim, the court should look first to the intrinsic evidence of record, *i.e.*, the patent itself, including the claims, the specification and, if in evidence, the prosecution history." *Vitronics Corp.*, 90 F.3d at 1582. There is no indication in the intrinsic record that the patentee sought to limit the invention to just the free base forms of phentermine and topiramate. In addition, the Court finds that the extrinsic evidence that a person of ordinary skill in the art in 1999 would have known that "phentermine" and "topiramate" were shorthand for all pharmaceutically acceptable forms supports its conclusions based on the intrinsic evidence from this family of patents. For these reasons, "phentermine" shall be construed as "phentermine, in the form of free base or its salts or derivatives" and "topiramate" shall be construed as "topiramate, in the form of free base or its salts or derivatives."

c. "DELAYED RELEASE"

The term "delayed release" appears in numerous places in the patents-in-suit,[4] including dependent claim 6 of the '890 patent. Claim 6 depends from claim 4, which depends from claim 1 of the '890 patent:

> 1. A pharmaceutical composition comprising about 50 mg to 250 mg topiramate and about 5 mg to about 15 mg phentermine.
>
> 4. The composition of claim 1, comprising a dosage form that provides immediate release of the phentermine and controlled release of the topiramate.
>
> 6. The composition of claim 4, wherein the dosage form provides for delayed release of the topiramate.

[4] The term "delayed release" also appears in asserted claims 20, 32 and 52 of the '890 patent; claims 3, 10, 25, 26 and 42 of the '776 patent; claims 7, 19 and 21 of the '298 patent; claim 7 of the '299 patent; claims 15 and 31 of the '057 patent; claims 26 and 29 of the '058 patent; claims 18-20, 24 and 35 of the '905 patent; and claims 14 and 29 of the '906 patent.

’890 patent at 21:12-14, 21:19-21, 21:25-26. In the ’298 family, the term “delayed release” first appears in claim 7 of the ’298 patent, which depends from claim 1:

> 1. A unit dosage form for weight loss for oral administration to a patient having a body mass index of at least 30 kg/m^2 and a condition associated with obesity, comprising a combination of: an immediate release phentermine formulation containing a unit dosage of phentermine in the range of 2 mg to 8 mg; and a controlled release topiramate formulation containing a unit dosage of topiramate in the range of 15 mg to 50 mg, wherein the dosage of phentermine in mg/day is about 16% of the dosage of topiramate in mg/day, and wherein the controlled release topiramate formulation reaches a maximum plasma concentration (Cmax) at about 6 to about 10 hours (Tmax) after administration and exhibits a lower Cmax, than non-controlled release topiramate, without decreasing total drug exposure defined by the area under the concentration-time curve (AUC), thereby enabling reduction of concentration-dependent side effects without a decrease in efficacy.
>
> 7. The dosage form of claim 1, wherein the controlled release topiramate formulation comprises controlled release beads of the topiramate, a binder, and a polymeric filler in a matrix core, wherein the matrix core is provided with a delayed release coating comprising ethyl cellulose and polyvinyl pyrrolidone.

’298 patent at 21:39-44.

In its opening brief, Vivus argued that the proper construction of this term is “formulated in such a way as to delay topiramate’s action for a period of time.” Actavis proposes the construction “measurable time delay before drug is released from the formulation into the patient’s body.” Teva proposes two alternate constructions, either of which it finds acceptable: “measurable time delay before drug is released from the formulation in to the patient’s body, wherein the release of the drug is delayed by an extended period of time,” or “formulated in such a way as to delay, for example, topiramate’s action for an extended period of time.” All parties seem to agree that one definition should be used for the term “delayed release” across the patents-in-suit.

Vivus pulls its suggested construction for the term "delayed release" from the express definition of the term in the specification of the '890 patent:

> As defined herein, a "delayed release form" is formulated in such a way as to delay, for example, topiramate's action for an extended period of time.

'890 patent at 14:30-32. Vivus removed two terms from the express definition of "delayed release" in its proposed construction: the phrase "for example," which the Court agrees does not provide any clarification as to the meaning of the term "delayed release"; and the word "extended," which provides meaningful clarification as to the scope of the timing in a delayed release form of drug delivery. Vivus recognizes the importance of including the word "extended" in its construction in its responsive briefing, where it states that "construing 'delayed release' as 'formulated in such a way as to delay topiramate's action for an extended period of time' is acceptable to Vivus" [Docket Entry 132, at 5].

Actavis, on the other hand, refers to the specification of the '298 patent for its construction:

> The term "delayed release" is also used in its conventional sense, to refer to a drug formulation which, following administration to a patient provides a measurable time delay before drug is released from the formulation into the patient's body.

'298 patent at 5:51-55.

Teva submits that the constructions proposed by either Vivus or Actavis would be acceptable, so long as the phrase "an extended period of time" is included in the construction. Teva objects to Vivus's removal of the word "extended" from the express definition in the '890 patent, and states that the construction proposed by Actavis requires further clarification because of the ambiguity as to the length of time of a "measurable time delay," given the context provided in the remainder of the specifications.

The patentee provides clarification as to why a delayed release form may be advantageous, explaining that when the combination drug is administered in the morning, delayed release of topiramate can minimize the sedative effects. '890 patent at 11:17-23, 13:38-42. The patentee gives an example of the appropriate time period for delayed release in the '890 specification:

> A delayed release form can be formulated in such a way as to delay the release of an effective dose of topiramate for 4, 8, 12, 16, or 24 hours following the release of phentermine.

'890 patent at 14:32-35. The '298 specification also provides an example to show the potential beneficial effects of a delayed release form:

> Release of the topiramate may also be delayed; that is, there is a time lag between administration and the start of topiramate release. In this way, for instance, an individual will not experience sleepiness or other side effects of topiramate during the school or work day.

'298 patent at 10:40-44. The term "extended" is critical to defining the patentee's intended scope of the claims. Without the term "extended," in fact, the term "period of time" would be ambiguous and could cover any period of time. The specification of the '890 patent makes clear that the patentee did not intend to claim all periods of time in its definition of "delayed release," just those that are "extended."

The Court will first examine the construction offered by Vivus. The Court agrees with Teva that it would be improper to delete the word "extended" from the express definition given in the '890 specification for "delayed release." Here, the patentee acted as its own lexicographer and specifically noted that topiramate's action in a delayed release formulation must be delayed "for an extended period of time." '890 patent at 14:32. Vivus presents no legal basis for omitting the word "extended" from its construction, and concedes this point in its reply briefing.

Where the patentee has acted as its own lexicographer, this definition should control. *See, e.g.*, *Phillips*, 415 F.3d at 1316.

Actavis argues that its construction is more faithful to the meaning of the claims, because the claim language of these patents refers to delayed release, not delayed action. Actavis selectively cites from the '298 specification to support this argument, however, given that this specification also discusses the delayed action of topiramate release in the context of "delayed release." *See* '298 patent at 10:40-44. The Court further agrees with Teva that the phrase "measurable time delay," as used in the '298 specification and in Actavis's construction, needs more clarification. Specifically, although Actavis's construction is faithful to the description of "delayed release" in the '298 specification, it leaves ambiguous how long the topiramate release must be delayed. Therefore, the intrinsic evidence indicates that construing the term "delayed release" to mean that release must be delayed for a "measureable time delay" is insufficiently specific.

Teva attempts to modify Actavis's proposed construction to provide more clarity, by inserting the language "wherein the release of the drug is delayed by an extended period of time." This language is not found in the relevant part of the '298 specification, nor is it supported by the portions of the '298 specification cited above with respect to delayed release. Furthermore, Teva bases the addition of this term on examples from the '890 specification. It is improper to limit the construction of a term based solely on examples from the specification, especially from the specification from a different family of patents. *See, e.g.*, *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004).

Vivus asserts that, taking the entire '298 specification as a whole, that "there is no meaningful distinction between the clear lexicography in the '890 family and the use of the term

in the ’298 family” [Docket Entry 123, at 21]. Given that the ’298 specification does discuss “delayed release” both in terms of its action and its effects, the Court agrees. Since the patentee has acted as its own lexicographer and defined the term “delayed release” in the ’890 specification, and since the definition of “delayed release” in the ’890 specification is consistent with the intrinsic evidence from the ’298 patent as a whole, the Court shall construe the term “delayed release” as “formulated in such a way as to delay topiramate’s action for an extended period of time.”

d. “GRANULES”

The claims in the patents-in-suit that refer to granules discuss controlled release formulations with different components, including granules. The term “granules” appears in several claims in the patents-in-suit,[5] including claim 35 of the ’890 patent, which depends from claim 30. Claim 30 depends from claim 27, which depends from claim 26, which depends from claim 8 of the ’890 patent:

> 8. A method for effecting weight loss in a subject comprising administering to the subject a maintenance dose of topiramate in the range of about 50 mg to 250 mg daily and a daily dose of phentermine in the range of about 5 mg to 15 mg.
>
> 26. The method of claim 8, wherein the phentermine and the topiramate are administered simultaneously.
>
> 27. The method of claim 26, wherein the phentermine and the topiramate are contained in a single pharmaceutical formulation.
>
> 30. The method of claim 27, wherein the formulation provides for immediate release of the phentermine and controlled release of the topiramate.
>
> 35. The method of claim 30, wherein the controlled release formulation is composed of granules, hydrogels, matrix formulations, and combinations thereof.

[5] The term “granules” also appears in dependent claims 25, 26 and 42 of the ’776 patent.

’890 patent at 21:29-33; 22:3-7; 22:14-16; 22:34-36. Vivus asserts that no construction is necessary for this term, while Actavis proposes the construction “the product of granulation.” Teva has not requested claim construction on this term.

The specification of the ’890 patent refers to “granules” as one alternative type of component of a controlled release formulation:

> Preferred controlled release formulations include, but are not limited to, granules, delayed release granules, hydrogels (e.g., of synthetic or natural origin), other gelling agents (e.g., gel-forming dietary fibers), matrix-based formulations (e.g., formulations comprising a polymeric material having at least one active ingredient dispersed therethrough), granules within a matrix, polymeric mixtures, granular masses, and the like.

‘890 patent at 14:21-28. The term “granules” is not further defined or otherwise modified in the intrinsic record before the Court.

Actavis seeks to limit the scope of the claims including this term through its construction, by defining the term “granules” by a process by which they are made, granulation. Actavis findssupport for this construction in extrinsic evidence: dictionary definitions related to the process of granulation, and other patents [Docket Entry 112, Exs. 21-23]. Actavis supports its arguments with cites to sections of the ’298 specification, where Actavis claims that the patentee implicitly distinguished granules from other particles such as beads, powders, and pellets. ’298 patent at 9:54-56, 10:19-22, 11:5-6. As to the relevance of this reference, the Court notes that it has not been asked to construe the meaning of “granules” in the ’298 patent or indeed in the ’298 family at all, nor is the Court required to use implicit distinctions from other families of patents, if these distinctions even exist.

Actavis’s construction is improper for several reasons. The ’890 and ’776 patents set out no requirements as to how granules are formed, and nothing in the intrinsic evidence indicates that the patentee intended any sort of requirement as to how granules were made. In addition,

defining "granules" as "the product of granulation" fails to explain or clarify the scope of the claims.

In its briefing, Actavis acknowledges that "[a]t no time do the Patents-in-Suit expressly define "granules" to mean something different than its plain and ordinary meaning." (Actavis Opening Br. at 14.) The Court agrees. For these reasons, the Court sees no need to construe the term "granules."

e. "MATRIX/MATRIX FORMULATIONS"

The term "matrix" appears in asserted dependent claim 25 of the '776 patent:

> 25. A controlled release formulation comprising phentermine and topiramate, wherein oral administration of the formulation results in immediate release of the phentermine and controlled release of the topiramate, and further wherein the topiramate is present in the form of granules, delayed release granules, granules within a matrix, or a combination with a polymeric mixture.

'776 patent at 22:42-48. The term "matrix formulations" appears in asserted dependent claim 35 of the '890 patent:

> 35. The method of claim 30, wherein the controlled release formulation is composed of granules, hydrogels, matrix formulations, and combinations thereof.

'890 patent at 22:34-36.

Vivus assert that no construction is necessary for these terms. Actavis proposes the construction "formulations comprising a polymeric material having at least one active ingredient dispersed therethrough." Teva has not requested claim construction on these terms.

The specifications of these patents refer to "matrix-based formulations" and "granules within a matrix" as two of the preferred controlled release formulations for topiramate. *See, e.g.*, '890 patent at 14:21-28. Actavis's proposed construction reads in a limitation from an example

in the specification, as it imports an example of an embodiment into the definition of these terms. In both patents using this term, the key language in the specification is:

> Preferred controlled release formulations include, but are not limited to, granules, delayed release granules, hydrogels (e.g., of synthetic or natural origin), other gelling agents (e.g., gel-forming dietary fibers), matrix-based formulations **(e.g., formulations comprising a polymeric material having at least one active ingredient dispersed therethrough)**, granules within a matrix, polymeric mixtures, granular masses, polymeric mixtures, granular masses, and the like.

'776 patent at 14:14:3-10; '890 patent at 14:21-28 (emphasis added). The term "matrix" also appears as part of an example embodiment in the specification of the '298 patent:

> [S]ustained release dosage forms can be formulated by dispersing the active agent within a **matrix** of a gradually hydrolysable material such as a hydrophilic polymer, or by coating a solid, drug-containing dosage form with such a material.

'298 patent at 10:49-53 (emphasis added). But "[t]he claims, not specification embodiments, define the scope of patent protection. The patentee is entitled to the full scope of his claims, and we will not limit him to his preferred embodiment or import a limitation from the specification into the claims." *Kara Tech. Inc. v. Stamps.com, Inc.*, 582 F.3d 1341, 1348 (Fed. Cir. 2009) (citing *Phillips,* 415 F.3d at 1323). Furthermore, to import a claim limitation from the specification, the Federal Circuit requires a "clear disavowal of claim scope":

> Mere criticism of a particular embodiment encompassed in the plain meaning of a claim term is not sufficient to rise to the level of clear disavowal. In *Spine Solutions, Inc. v. Medtronic Sofamor Danek USA, Inc.*, we explained that even where a particular structure makes it "particularly difficult" to obtain certain benefits of the claimed invention, this does not rise to the level of disavowal of the structure. It is likewise not enough that the only embodiments, or all of the embodiments, contain a particular limitation. We do not read limitations from the specification into claims; we do not redefine words. Only the patentee can do that. To constitute disclaimer, there must be a clear and unmistakable disclaimer.

Thorner v. Sony Computer Entm't Am. LLC, 669 F.3d 1362, 1366-67 (Fed. Cir. 2012) (internal citations omitted). Based on this clear Federal Circuit precedent, the Court will not limit the

scope of the terms "matrix" and "matrix formulations" to only the embodiments referenced in the sections of the specifications quoted above.

Actavis offers extrinsic evidence in the form of dictionary definitions to support its construction for these terms. Actavis's proffered dictionary definitions introduce an additional limitation, the requirement for "uniformity" in the distribution of the dissolved or dispersed drug. (Actavis Opening Br. at 10.) Nothing in the intrinsic evidence indicates that any requirement for uniformity exists for dispersal in a matrix or a matrix-based formulation.

The Court need not look beyond the intrinsic evidence to determine that these terms should be given their plain and ordinary meaning, and that a limitation from an embodiment in the specification of these patents should not be imported into the construction of these terms. For these reasons, the Court finds that no construction is necessary for these terms.

f. "MATRIX CORE"

The term "matrix core" appears in asserted dependent claim 7 and independent claim 21 of the '298 patent, as well as in dependent claim 26 of the '058 patent. The use of "matrix core" in claim 7 of the '298 patent is representative:

> 7. The dosage form of claim 1, wherein the controlled release topiramate formulation comprises controlled release beads of the topiramate, a binder, and a polymeric filler in a matrix core, wherein the matrix core is provided with a delayed release coating comprising ethyl cellulose and polyvinyl pyrrolidone.

'298 patent at 21:39-44. Vivus asserts that no construction is necessary for this term, while Actavis proposes the construction "topiramate, a binder and polymeric filler." Teva has not requested claim construction on this term.

Actavis's proposed construction seeks to eliminate the potential that the "matrix core" must only contain a polymeric filler, and not the active ingredient topiramate and a binder.

Actavis supports this construction with cites to examples from the specification of the '298 patent where the matrix core comprises topiramate, microcrystalline cellulose (a polymeric filler), and methylcellulose (a binder). '298 patent at 10:48-11:28, 11:45-52, 18:51-55. Actavis fails to point to any intrinsic evidence that the patentee intended to limit claim scope to the examples cited. *See Thorner*, 669 F.3d at 1366-67.

Vivus acknowledges that since the phrase "controlled release beads of the topiramate, a binder, and a polymeric filler in a matrix core" appears in the three claims that use the "matrix core" term, "[t]he elements of Actavis's proposed construction, 'topiramate, a binder, and a polymeric filler,' are therefore already limitations of any claim that includes the phrase 'matrix core.'" (Vivus Opening Br. at 27.) The Court agrees with Vivus's reading of the claim language, and therefore sees no need to construe this term, particularly given the illogical claim phrasing that would result if Actavis's construction were adopted: "controlled release beads of the topiramate, a binder, and a polymeric filler in a topiramate, a binder, and a polymeric filler." For these reasons, the Court finds that the term "matrix core" shall have its plain and ordinary meaning.

g. "A CORE COMPRISING TOPIRAMATE DISPERSED IN A GRADUALLY HYDROLYSABLE MATERIAL COMPRISING A BINDER, AND A POLYMERIC FILLER"

The phrase "a core comprising topiramate dispersed in a gradually hydrolysable material comprising a binder, and a polymeric filler" appears in asserted dependent claims 18 and 35 of the '905 patent. Claim 18's use of the phrase is representative, and claim 18 depends from claim 1 of the '905 patent:

> 1. A unit dosage form for weight loss for oral administration to a patient having a body mass index of at least 25 kg/m^2, comprising a combination of: an immediate release phentermine formulation containing a unit dosage of phentermine of 3.75 mg or 7.5 mg; and a controlled release topiramate formulation containing a unit dosage of

topiramate of 23 mg or 46 mg, wherein the controlled release topiramate formulation reaches a maximum plasma concentration (Cmax) at about 6 to about 10 hours (Tmax) after administration.

18. The dosage form of claim 1, wherein the controlled release topiramate formulation comprises beads comprising a core comprising topiramate dispersed in a gradually hydrolysable material comprising a binder, and a polymeric filler, and wherein the core is provided with a delayed release coating.

'905 patent at 22:19-24. Vivus asserts that no construction is necessary for this term, while Actavis proposes the construction "a core comprising topiramate distributed uniformly within a matrix of gradually hydrolysable material, and in which the gradually hydrolysable material includes both a binder and a polymeric filler." Teva has not requested claim construction on this term.

To adopt the construction proposed by Actavis, the Court would first need to find that the term "core" in claims 18 and 35 of the '905 patent is synonymous with the term "matrix core" used elsewhere in the patents-in-suit, and therefore that the term "matrix" should be read into these claims. Actavis argues that these claims must refer to a matrix formulation, where topiramate is contained in a core and "dispersed in a gradually hydrolysable material," rather than a reservoir formulation, which the '298 patent describes as a drug contained in the dosage form, which is then coated with "a gradually hydrolysable material such as a hydrophilic polymer." '298 patent at 10:48-53. Actavis's argument is refuted by the plain language of these claims, however, which recite that "the core is provided with a delayed release coating." '905 patent at 22:19-24. The Court finds no intrinsic evidence to support a finding that the patentee intended to limit the claims such that the term matrix must be read into the construction.

Furthermore, Actavis's construction requires the Court to find that dispersal within a matrix must be uniform. The '298 patent specification describes dispersal within a matrix, but does not indicate any sort of limitation that the dispersal must be uniform:

> Generally, as will be appreciated by those of ordinary skill in the art, sustained release dosage forms active can be formulated by dispersing the agent within a matrix of a gradually hydrolyzable material such as a hydrophilic polymer, or by coating a solid, drug-containing dosage form with such a material. Hydrophilic polymers useful for providing a sustained release coating or matrix include, by way of example: cellulosic polymers such as hydroxypropyl cellulose . . .

'298 patent at 10:48 – 11:4 (emphasis added). Actavis has provided no intrinsic support, from the specification or elsewhere, for its contention that "dispersal" should be uniform. For the reasons stated in the previous section, the Court rejects the use of Actavis's extrinsic evidence to impart a limitation that dispersal must be uniform, and the Court will decline to read this limitation into a construction for this term, as it did for the term "matrix core." *See, e.g.*, *Honeywell Int'l, Inc. v. Int'l Trade Comm'n*, 341 F.3d 1332, 1341 (Fed. Cir. 2003) (rejecting a limitation "outside the bounds of the claims, the written description, and the prosecution history).

Finally, Actavis's construction requires the Court to construe this term to require that the "gradually hydrolysable material" contain both a binder and a polymeric filler. The language of the claim itself makes clear that this reading is improper. Given the standard meaning of "comprising" as "included but not limited to," a plain reading of the claim language makes clear that the core must include (i) "topiramate dispersed in a gradually hydrolysable material" that includes a binder, and (ii) a polymeric filler. *See, e.g., CIAS, Inc. v. Alliance Gaming Corp.*, 504 F.3d 1356, 1360 (Fed. Cir. 2007). Actavis's reading improperly modifies the punctuation and structure of the claim, and will be rejected.

As stated above, the purpose of claim construction is to provide clarity for the finder of fact. Actavis's construction reads in impermissible limitations and does not clarify the meaning of this term. For these reasons, the Court finds that no construction is necessary for this term.

CONCLUSION

The Court has examined the disputes over construction of eight claim terms raised by the parties, and for the reasons stated above, resolves these disputes as follows.

1. "phentermine": the term "phentermine" shall be construed as "phentermine, in the form of free base or its salts or derivatives," in the '890 patent, the '818 patent, the '256 patent, the '776 patent, the '298 patent, the '299 patent, the '057 patent, the '058 patent, the '905 patent, and the '906 patent.
2. "topiramate": the term "topiramate" shall be construed as "topiramate, in the form of free base or its salts or derivatives," in the '890 patent, the '818 patent, the '256 patent, the '776 patent, the '298 patent, the '299 patent, the '057 patent, the '058 patent, the '905 patent, and the '906 patent.
3. "delayed release": the term "delayed release" shall be construed as "formulated in such a way as to delay topiramate's action for an extended period of time," in the '890 patent, the '776 patent, the '298 patent, the '299 patent, the '057 patent, the '058 patent, the '905 patent, and the '906 patent.

The Court finds that no construction is necessary for the following terms:

1. "about," in the '890 patent, the '818 patent, the '298 patent, the '299 patent, the '057 patent, the '058 patent, the '905 patent, and the '906 patent.
2. "granules," in the '890 patent and the '776 patent.
3. "matrix" and "matrix formulations," in the '890 patent and the '776 patent.

4. “matrix core,” in the ’298 patent and the ’058 patent.
5. “a core comprising topiramate dispersed in a gradually hydrolysable material comprising a binder, and a polymeric filler,” in the ’905 patent.

An appropriate Order shall be filed herewith.

s/Stanley R. Chesler
STANLEY R. CHESLER, U.S.D.J.

Dated: July 20, 2016