NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SUPERNUS PHARMACEUTICALS, INC., Plaintiff, v. ACTAVIS INC., et al., Defendants.	Civil Action No. 14-06102 (SDW) (LDW) (Consolidated with Civil Action No. 14-07272) **MARKMAN OPINION** March 9, 2016
SUPERNUS PHARMACEUTICALS, INC., Plaintiff, v. ZYDUS PHARMACEUTICALS (USA) INC., et al., Defendants.	

WIGENTON, District Judge.

Before the Court are the briefs and supporting materials of Plaintiff Supernus Pharmaceuticals, Inc. ("Plaintiff") and Defendants Actavis, Inc., Actavis Laboratories FL, Inc., Actavis Pharma, Inc., Watson Laboratories, Inc., ANDA, Inc., and Actavis plc k/n/a Allergan plc (collectively, "Actavis"), and Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Limited (collectively, "Zydus") (Actavis and Zydus hereafter collectively referred to as "Defendants") regarding the request for a patent claim construction pursuant to Local Patent Rule 4.5(a).

This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a). Venue is proper under 28 U.S.C. §§ 1391(b) and 1400(b). This Court held a Markman[1] hearing on February 3, 2016 regarding patent claims in Plaintiff's U.S. Patent Nos. 8,298,580 ("the '580 patent"), 8,663,683 ("the '683 patent"), 8,877,248 ("the '248 patent"), 8,889,191 ("the '191 patent"), and 8,992,989 ("the '989 patent") (collectively, "the patents in suit"). After carefully considering the parties' written and oral arguments regarding seven claim terms in the patents in suit, this Court has construed the disputed claim terms as discussed below.

I. PROCEDURAL AND FACTUAL HISTORY[2]

This matter relates to five of Plaintiff's patents relating to topiramate extended release capsules, a drug product indicated for initial monotherapy for patients with partial onset seizures and primary generalized tonic-clonic seizures, and as an adjunctive therapy for patients with partial onset seizures, primary generalized tonic-clonic seizures, and seizures associated with Lennox-Gastaut syndrome. Each of Plaintiff's five patents is titled "Sustained-release formulations of topiramate" and claims pharmaceutical compositions of topiramate for once-a-day oral administration, comprising a sustained release component and an optional immediate release component, the compositions of which can be selectively adjusted to release the active ingredient along a pre-determined release profile. Plaintiff's branded product—Trokendi XR®—is an extended release capsule with topiramate as its active ingredient.

Plaintiff asserts that Defendants have infringed or will infringe the patents in suit by filing abbreviated new drug applications ("ANDAs") with the United States Food and Drug Administration seeking approval to market generic versions of Trokendi XR®. Defendants

[1] *Markman v. Westview Instruments Inc.*, 52 F.3d 967 (Fed. Cir. 1995).
[2] Unless otherwise noted, the facts are taken from the parties' submissions.

contend that the products proposed in their ANDAs will not infringe asserted claims of the patents in suit and/or that the asserted claims are invalid.

Plaintiffs commenced this lawsuit on October 1, 2014, and filed an Amended Complaint on April 28, 2015. Plaintiff asserted the following six Counts in the Amended Complaint: (I) infringement of the '576 Patent (no longer asserted against any Defendant); (II) infringement of the '580 Patent; (III) infringement of the '683 Patent; (IV) infringement of the '248 Patent; (V) infringement of the '191 Patent; and (VI) infringement of the '989 Patent. (Am. Compl. ¶¶ 53-142.) On April 16, 2015, Magistrate Judge Mannion issued an Order consolidating the "topiramate extended release capsule" cases together.[3]

II. LEGAL STANDARD

Patent claim construction is a matter of law for the court. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995). During interpretation of a claim, courts should initially look to intrinsic evidence, namely "the patent claims, the specification and the prosecution history if in evidence." *Bristol-Myers Squibb Co. v. Immunex Corp.*, 86 F. Supp. 2d 447, 448 (D.N.J. 2000). "[I]ntrinsic evidence is the most significant source of the legally operative meaning of disputed claim language." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). "The court should presume that the terms in the claim mean what they say, and, unless otherwise compelled, give full effect to the ordinary and accustomed meaning of claim terms." *Bristol-Myers Squibb Co.*, 86 F. Supp. 2d at 448. A person of ordinary skill in the art "is deemed to read the claim term . . . in the context of the entire patent." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005); *see Medrad, Inc. v. MRI Devices Corp.*, 401 F.3d 1313, 1319 (Fed. Cir. 2005) ("We cannot look at the ordinary meaning of the term . . . in a vacuum. Rather,

[3] The lead case is 14-cv-06102 and the member case is 14-cv-07272. Another member case, 15-cv-00326, was settled on October 16, 2015.

we must look at the ordinary meaning in the context of the written description and the prosecution history." (citation omitted)); *see also Markman*, 52 F.3d at 979.

If the intrinsic evidence alone will not resolve the ambiguity, the Court may rely on extrinsic evidence, which includes expert testimony, treatises, dictionaries and articles. *Bristol-Myers Squibb Co.*, 86 F. Supp. 2d at 448-49. Extrinsic evidence may not be used to vary or contradict the meaning established by the intrinsic evidence. *Phillips*, 415 F.3d at 1318-19, 1324. "The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be . . . the correct construction." *Id.* at 1316.

A key aspect of claim construction is to assist the jury in understanding complicated language and concepts. *See Encap LLC v. Oldcastle Retail, Inc.*, No. 11-cv-808, 2012 WL 2339095, at *9 (E.D. Wis. June 19, 2012) ("Claim construction is not intended to allow for needless substitution of more complicated language for terms easily understood by a lay jury."); *see also C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 863 (Fed. Cir. 2004) ("[M]erely rephrasing or paraphrasing the plain language of a claim by substituting synonyms does not represent genuine claim construction."); *AFG Indus., Inc. v. Cardinal IG Co., Inc.*, 239 F.3d 1239, 1247 (Fed. Cir. 2001) ("It is critical for trial courts to set forth an express construction of the material claim terms in dispute, in part because the claim construction becomes the basis of the jury instructions, should the case go to trial. It is also the necessary foundation of meaningful appellate review." (citation omitted)).

III. PERSON OF ORDINARY SKILL IN THE ART

Claims are construed from the vantage point of a person of ordinary skill in the art ("POSA") at the time of the invention. *Phillips*, 415 F.3d at 1313. Thus, before the Court reviews the bounds of the claims in light of the specification, it must establish the level of skill that a POSA

possessed at the time of the invention. *AllVoice Computing PLC v. Nuance Commc'ns, Inc.*, 504 F.3d 1236, 1240 (Fed. Cir. 2007).

A POSA, as a person of ordinary skill, is "also a person of ordinary creativity." *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 420 (2007). A POSA is "presumed to be one who thinks along the line of conventional wisdom in the art and is not one who undertakes to innovate." *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 1985). In contrast, a multidisciplinary "drug team[]," including scientists, medical doctors, economists, and marketing personnel, (Thakker Resp. Decl. Ex. 13 (Mayersohn Tr. 26:6-28:18)), would be innovative and more than ordinarily creative. This District has previously "reject[ed] the notion that the 'person' of ordinary skill must possess all of the attributes of a multi-member team." *Otsuka Pharm. Co. v. Sandoz, Inc., Otsuka Pharm. Co. v. Sandoz, Inc.*, No. 3:07-CV-01000, 2010 WL 4596324, at *9 (D.N.J. Nov. 15, 2010) (Cooper, J.), *aff'd*, 678 F.3d 1280 (Fed. Cir. 2012). Defendants' position that a POSA is "one or more of, or a team including, a Ph.D. or [] M.D., having three or more years of industrial experience (or a comparable level of additional research and/or laboratory experience in academia), or alternatively, a Bachelor's or Master's Degree and a commensurately greater number of years of experience in the appropriate field" at the time of the invention, (Defs.' Op. Br. 2-3),[4] however, runs counter to the generally accepted definition of a POSA. This Court will, for the purposes of this suit, define a POSA as someone who, at the time of the invention, had "at least a Bachelor of Science degree in Pharmaceutical Sciences or a related field, approximately 3-5 years of experience in drug delivery technology or a related field, and working knowledge regarding pharmacokinetics (or . . . commensurate education and experience)." (Pl.'s Op. Br. 5.)

[4] For the purposes of this Opinion, "Pl.'s Op. Br." refers to Plaintiff's Opening Claim Construction Brief (Dkt. No. 88), "Defs.' Op. Br." refers to Defendants' Opening Claim Construction Brief (Dkt. No. 91), "Pl.'s Resp. Br." refers to Plaintiff's Responding Claim Construction Brief (Dkt. No. 112), and "Defs.' Resp. Br." refers to Defendants' Responding Claim Construction Brief (Dkt. No. 113).

IV. CLAIM CONSTRUCTIONS

The parties dispute the meanings of seven claim terms or phrases with respect to the patents in suit.[5] The disputed terms are: (1) "at least two different extended release topiramate-containing components"; (2) "population[s] of beads"; (3) "coating material"; (4) "release controlling coating"; (5) "a maximum steady state plasma concentration (Cmax) of topiramate"; (6) "a relative steady state AUC"; and (7) "the same amount of topiramate administered as an immediate release formulation BID."

A. "at least two different extended release topiramate-containing components"

Plaintiff's Proposed Construction	Defendants' Proposed Construction	Court's Construction
at least two extended release topiramate-containing components, wherein each component has its own in vitro rate of drug release	at least two different extended release topiramate-containing components having different compositions and release rates for topiramate, within normal variation	at least two extended release topiramate-containing components having different in vitro release rates for topiramate

For the reasons discussed below, this Court defines "at least two different extended release topiramate-containing components" as used in claim 1 of the '580 patent to mean "at least two extended release topiramate-containing components having different in vitro release rates for topiramate."

The parties agree, and the intrinsic evidence supports, that the "at least two different extended release topiramate-containing components" are defined, at least in part, by having their own in vitro rate of drug release. (Pl.'s Op. Br. 6, Defs.' Op. Br. 5.) However, to the extent that the words "its own" in Plaintiff's construction could allow components to have the same properties, this Court adopts the "different" language of the original claim, ('580 patent, claim 1),

[5] Two other terms previously in dispute have been withdrawn. (Defs.' Op. Br. 1.)

with respect to the "in vitro release rates" so as to give effect to all terms in the claim and not read out the express requirement in the claim that the at least two extended release components be "different." *See Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006).

The parties also disagree as to (1) whether the two different extended release topiramate-containing components must also have different compositions, and (2) whether the claim construction should explicitly state that a single component may have a degree of "normal variation"[6] in its composition and release rate arising from the inherent variations that occur during normal manufacturing and testing.

On the first issue, Defendants characterize structural changes that occur due to changes in process parameters during manufacture as compositional changes, and this leads them to argue that the patent specification[7] teaches only one way to change the release rate of an extended release component as required by claim 1, which is changing the composition. In fact, the specification teaches multiple ways to change the release rate. This Court finds that a POSA would interpret composition as "the ingredients that go into the final product and must remain in the final product." (Byrn Reply Decl. ¶ 17 (citing FDA GUIDANCE FOR INDUSTRY: DRUG PRODUCT at 6, lines 238-39).) Thus, a POSA would understand the language of claim 1 to mean that changing any one of the listed variables ("the nature of the coating, coating level, type of concentration of a pore former, [and] process parameters" ('580 patent, 7:16-18)) could change the rate of release without changing the final composition of the component. For this reason, "different compositions" is a narrower requirement than that required by claim 1, which is different release rates.

[6] Defendants also seek to add the "within normal variation" limitation to another claim term, "population[s] of beads," *infra* Part IV.B.

[7] All references made to the specification of the patents in suit in this Opinion are made to that of the '580 patent. Because the patents in suit are continuations of the same patent application, each of their specifications contains identical language.

Moreover, Defendants' argument for the "different compositions" limitation rests entirely on the contention that different compositions are required to change release rates. Even assuming, *arguendo*, that this contention is correct, the "different compositions" requirement is unnecessary because both the original claim language and this Court's construction already require different release rates. This Court will not add a limitation to the claims that is not required by the specification. *See Renishaw PLC v. Marposs Societa' Per Azioni*, 158 F.3d 1243, 1249 (Fed. Cir. 1998).

The Court's construction is supported by other sections of the specification as well. The titles of Tables 2 and 3 refer to "Topiramate Bead Compositions" and do not list process parameters, such as the curing temperature or method, whereas the title of Table 1 refers to "Compositions and process Parameters" and includes process parameters in the body of the table. Adopting Defendants' "composition" language would render the "process [p]arameters" language of the title of Table 1 redundant. Even if, for the sake of argument, the POSA would understand "composition" to include process parameters, the Federal Circuit held in *Phillips* that "the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316. The *Phillips* court further stated that the specification is "the single best guide to the meaning of a disputed term and . . . acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." *Id.* at 1321 (citing *Vitronics*, 90 F.3d at 1582; *Irdeto Access, Inc. v. Echostar Satellite Corp.*, 383 F.3d 1295, 1300 (Fed. Cir. 2004)) (internal quotation marks omitted). Here, a comparison of the table titles in the specification makes it clear that the inventors did not intend "composition" to include process parameters. Therefore, this lexicography will govern.

On the second issue, both sides agree that a POSA would not describe something as being different if it was "within normal variation." (Byrn Reply Decl. ¶ 31, Park Decl. ¶ 35.) Thus, the limitation is unnecessary and adding it would create a source of ambiguity. For these reasons, and because the specification does not mention "within normal variation," this Court declines to adopt the "within normal variation" language for any of the claim terms in dispute.

B. "population[s] of beads"

Plaintiff's Proposed Construction	**Defendants' Proposed Construction**	**Court's Construction**
population[s] of particles, spheres, beads, granules, pellets, particulates or any structural units that may be incorporated into an oral dosage form *Construction of "population" is not necessary. The term has its plain and ordinary meaning, e.g., group, collection, or class.*	multiple structural units with the same composition and rate of release, within normal variation	population[s] of particles, spheres, beads, granules, pellets, particulates or any structural units that may be incorporated into an oral dosage form *Construction of "population" is not necessary. The term has its plain and ordinary meaning, e.g., group, collection, or class.*

Plaintiff and Defendants disagree on the meaning of "population[s] of beads" as used in claims 1 and 15 of the '683 patent, claim 2 of the '248 patent, claim 1 of the '191 patent, and claim 2 of the '989 patent. As this Court has already declined to adopt the "within normal variation" language, the remaining two points of disagreement are the constructions of "population[s]" and "beads." For the reasons discussed below, this Court declines to construe "populations[s]," and adopts the definition of "beads" contained in the specification.

The specification does not assign a special meaning to the word "population." "In the absence of an express intent to impart a novel meaning to claim terms, an inventor's claim terms take on their ordinary meaning." *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed.

Cir. 2002). Defendants argue that the plain and ordinary meaning fails to provide any guidance about what constitutes a "population" of beads, and theoretically permits all beads in a capsule—even if there are both immediate release and extended release beads—to constitute a single bead population. (Defs.' Op. Br. 12.) However, when beads in a population have particular characteristics, the claims identify those characteristics. For example, claim 1 of the '683 patent and claim 1 of the '191 patent characterize each bead population "[comprising] an extended release (XR) component" as having "its own release controlling coating" and "its own rate of release." Thus, while Defendants' "multiple structural units" language has no basis in the intrinsic evidence, the plain language meaning of "population[s]" is supported by the specification in conjunction with the guidance of *Teleflex*, 299 F.3d at 1325. Therefore, this Court declines to construe "populations[s]" and gives the term its plain and ordinary meaning.

For the term "beads," the specification provides an explicit definition: "The term 'beads,' as used herein, includes, without any limitations on the nature and size thereof, any particles, spheres, beads, granules, pellets, particulates or any structural units that may be incorporated into an oral dosage form." ('580 patent, 4:40-43.) As discussed above, when the specification reveals a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess, the inventor's lexicography will govern. *Phillips*, 415 F.3d at 1316. Moreover, Defendants in their own brief do not contest that their "proposed construction incorporates the phrase 'structural units' to be inclusive of 'particles, spheres, beads, granules, pellets, particulates or any structural units,'" and that "there does not appear to be a dispute between the parties with respect to that aspect of the construction." (Defs.' Op. Br. 10.) For these reasons, this Court gives "beads" its definition from the specification.

C. "release controlling coating"

Plaintiff's Proposed Construction	Defendants' Proposed Construction	Court's Construction
a coating that modifies and controls the release of the active ingredient *Construction of "coating" is not necessary. The term has its plain and ordinary meaning, e.g., a covering.*	a layer of material coated onto a core or other layer that modifies and controls the extended release of the active ingredient	a coating that modifies and controls the release of the active ingredient *Construction of "coating" is not necessary. The term has its plain and ordinary meaning, e.g., a covering.*

Plaintiff and Defendants disagree on the meaning of "release controlling coating" as used in claim 1 of the '580 patent, claims 9 and 12 of the '683 patent, claims 1 and 14 of the '248 patent, claims 7 and 21 of the '191 patent, and claims 1, 14, 15, and 18 of the '989 patent. Defendants admit that the term means that the coating "modifies and controls the release of the active ingredient," and this corresponds to the definition of the term found in the specification. (Defs.' Op. Br. 18.) Therefore, the only point of disagreement is whether "coating" requires construction, and, if so, how it should be construed. Defendants argue that "coating" requires "a layer of material coated onto a core or other layer." However, both "coated onto" and "core or other layer" are limitations unsupported by the intrinsic evidence, and, for the reasons discussed below, this Court rejects both limitations.

The phrase "coated onto" appears to require the active application of a coating, whereas a POSA at the time of the invention would have understood that a coating can be created by other means, such as microencapsulation.[8] Indeed, two texts that Defendants rely on to support their proposed construction, (Joint Claim Construction at C7), both describe and discuss microencapsulation as an established method of coating. (Byrn Decl. ¶ 54, citing HOWARD C.

[8] Microencapsulation involves mixing the material to be encapsulated into a solution containing the encapsulating material and then adding a polymer concentrating agent, which forms a film or coat around the particles, resulting in coated microcapsules. (Byrn Decl. ¶ 54.)

ANSEL ET AL., PHARMACEUTICAL DOSAGE FORMS & DRUG DELIVERY SYSTEMS 232-33 (7th ed. 1999) and 3 HERBERT A. LIEBERMAN ET AL., PHARMACEUTICAL DOSAGE FORMS, TABLETS 77, 161 (2d ed. 1990).) Because "coated onto" requires a limitation not required by the specification, this Court declines to adopt it. *See Renishaw*, 158 F.3d at 1249.

The specification's explicit definition of "release controlling coating" reads: ". . . at least one population of beads coated with a coating that modifies and controls the release of topiramate from the beads (release controlling coating)." ('580 patent, 6:39-42.) As this definition requires the *beads* to be coated, "core or other layer" unnecessarily narrows the scope of that definition. *See Phillips*, 415 F.3d at 1321 (teaching that "the specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication"). In addition, although the specification only discloses embodiments in which the release controlling coating is coated onto a core or other layer, "it is improper to read limitations from a preferred embodiment described in the specification—even if it is the only embodiment—into the claims absent a clear indication in the intrinsic record that the patentee intended the claims to be so limited." *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 913 (Fed. Cir. 2004). Such a "clear indication" does not exist here. Therefore, this Court declines to adopt the "core or other layer" language.

D. "coating material"

Plaintiff's Proposed Construction	Defendants' Proposed Construction	Court's Construction
a material that modifies and controls the release of the active ingredient and is capable of forming a coating *Construction of "coating" is not necessary. The term has its plain and ordinary meaning, e.g., a covering.*	a material coated onto a core or other layer	*Construction of "coating material" is not necessary. The term has its plain and ordinary meaning, e.g., a material used as a covering.*

Plaintiff and Defendants disagree on the meaning of "coating material" as used in claim 1 of the '580 patent, claims 9 and 12 of the '683 patent, claims 1 and 14 of the '248 patent, claims 7 and 21 of the '191 patent, and claims 1, 14, 15, and 18 of the '989 patent. The dispute between the parties regarding the construction of "coating material" centers on the following three issues: (1) whether the "coating material" must be a coating or just capable of forming a coating, (2) whether the range of potential substrates is limited to "a core or other layer," and (3) whether the coating material must be "coated onto" the substrate, thus permitting only active application as a method of applying the coating material. This Court declines to adopt the "core or other layer" and "coated onto" language for the reasons stated in Part IV.C. Thus, the only remaining point of disagreement is whether the "coating material" must be a coating or just capable of forming a coating. For the reasons discussed below, this Court finds that a "coating material" must be a coating, and gives the term its plain and ordinary meaning, e.g., a material used as a covering.

The specification demonstrates that the patentees did not intend to define a "coating material" solely by the chemical identity of the excipient in question (regardless of its function in the formulation), but instead intended for that term to include only those materials that are actually used in coatings. (Park Decl. ¶ 55.) For example, the common specification describes

hydroxypropylmethylcellulose (HPMC) as a release controlling coating material, a pore former, a material in an overcoat, an enhancing agent, and a binder. ('580 patent, 7:9, 7:57, 8:10, 9:34, 10:22.) These descriptions in the specification show that the patentees recognized that excipients can have different functions depending on where and how they are incorporated into the formulation, and that an excipient is only a "coating material" when it is in a coating. Moreover, Plaintiff's proposed construction broadens the scope of the claims to the point of reading out the word "coating" from the claim term, and this runs counter to Federal Circuit precedent which requires courts to give full "effect" and "respect" to every word in a claim term. *Pause Tech LLC v. Tivo Inc.*, 419 F.3d 1326, 1334 (Fed. Cir. 2005); *Bicon*, 441 F.3d at 950. For these reasons, this Court declines to adopt the "and is capable of forming a coating" language.

Neither construction proposed by the parties defines the word "material." Instead, the proposed constructions use the word "material" as the part of the proposed definition of "coating material." For this reason, and because this Court declines to construe "coating" for the reasons discussed above, this Court declines to construe "coating material" and gives it its plain and ordinary meaning, e.g., a material used as a covering.

E. "a maximum steady state plasma concentration (Cmax) of topiramate"

Plaintiff's Proposed Construction	**Defendants' Proposed Construction**	**Court's Construction**
a maximum plasma concentration (Cmax) of topiramate reached during a dosing interval while at steady state	a maximum plasma drug concentration (Cmax) of topiramate that is the calculated mean value based on values obtained from a group of subjects tested during a dosing interval while at steady state	a maximum plasma concentration (Cmax) of topiramate reached during a dosing interval while at steady state that is the calculated mean value based on values obtained from a group of subjects tested

Plaintiff and Defendants disagree on the meaning of "a maximum steady state plasma concentration (Cmax) of topiramate" as used in claim 10 of the '580 patent, claim 11 of the '248 patent, claim 2 of the '191 patent, and claim 11 of the '989 patent.

The parties agree that pharmacokinetic results from clinical studies involve a mean value that is calculated "based on values obtained from a group of subjects" that are tested. (Defs.' Op. Br. 20, Pl.'s Resp. Br. 23.) In other words, to determine pharmacokinetic parameters, it is understood that at some point subjects must be tested to determine concentrations of drug in the blood. This is supported by the specification: "unless otherwise indicated, when a drug plasma concentration is listed, the value listed is the calculated mean value based on values obtained from a group[] of subjects tested." ('580 patent, 4:22-29.) Because both sides agree that the language is factually correct, and because the language is included expressly in the patent specification, this Court includes "calculated mean value based on values obtained from a group of subjects tested" as part of the construction of "a maximum steady state plasma concentration (Cmax) of topiramate."

The parties also agree that the "maximum plasma concentration (Cmax) of topiramate" should be based on "a dosing interval while at steady state," a construction that is consistent with the intrinsic evidence. However, the parties dispute whether the Cmax must be determined by testing subjects *during* the dosing interval at steady state. This limitation would require the administration of repeated doses to subjects (until steady state is reached) before measuring plasma concentrations. This limitation would exclude steady state Cmax values that are calculated by applying the superposition principle to data obtained from a single-dose study, a method that is disclosed in Example 6 of the specification. ('580 patent, 18:55-19:50; *see* Thakker Decl. ¶¶ 37, 42, 54.) Extrinsic evidence shows that a POSA would have known that the superposition principle

was commonly used to obtain steady state pharmacokinetic results based on single-dose study data. (Thakker Decl. ¶¶ 37, 58.)

This Court will not construe the claims to exclude an alternative means of accomplishing the claimed result when the alternative means is disclosed in the specification. *See 3M Innovative Props. Co. v. Tredegar Corp.*, 725 F.3d 1315, 1331 (Fed. Cir. 2013). Such a construction would require a limitation that the specification does not require. *See Renishaw*, 158 F.3d at 1249. For these reasons, this Court construes "a maximum steady state plasma concentration (Cmax) of topiramate" to mean "a maximum plasma concentration (Cmax) of topiramate reached during a dosing interval while at steady state that is the calculated mean value based on values obtained from a group of subjects tested."

F. "a relative steady state AUC"

Plaintiff's Proposed Construction	**Defendants' Proposed Construction**	**Court's Construction**
an area under the plasma concentration-time curve (AUC) of topiramate from the formulation administered once-daily while at steady state in relation to the AUC of topiramate from an immediate release formulation administered daily in two divided doses while at steady state	an area under the plasma concentration-time curve (AUC) of topiramate from the formulation administered once-daily while at steady state in relation to the AUC of topiramate from an immediate release formulation administered twice a day in two equal doses while at steady state based on values obtained from a group of subjects tested by a crossover study	an area under the plasma concentration-time curve (AUC) of topiramate from the formulation administered once-daily while at steady state in relation to the AUC of topiramate from an immediate release formulation administered daily in two divided doses while at steady state

Plaintiff and Defendants disagree on the meaning of "a relative steady state AUC" as used in claim 11 of the '580 patent, claim 12 of the '248 patent, claim 5 of the '191 patent, and claim 12 of the '989 patent. Both sides' proposed constructions recite "an area under the plasma

concentration-time curve (AUC) of topiramate from the formulation administered once-daily while at steady state in relation to the AUC of topiramate from an immediate release formulation." Such language is consistent with the intrinsic evidence, ('580 patent, 4:34-36), and this Court adopts it.

Although the parties' competing constructions both provide for two doses a day, the parties disagree whether the doses should be "equal" or "divided." The intrinsic evidence uses "divided doses" to describe the relative steady state AUC. Moreover, Plaintiff's expert explains that "if only 50 mg tablets of an immediate release product are available and 25 mg of the immediate release product is to be administered twice a day ("BID"), a POSA would know to physically divide the 50 mg tablet into two halves. In such circumstances, the two divided doses (i.e. each half of the tablet) would have a similar dosage amount, but they likely would not be exactly equal." (Thakker Resp. Decl. ¶ 44.) This Court adopts Plaintiff's "daily in two divided doses" language.

The parties also dispute whether the specification requires the use of a crossover study to calculate the relative steady state AUC. This limitation is not required by the claim language or specification, and would exclude other methods for comparing formulations, such as parallel study designs, in which the formulations are administered to different subjects. A POSA would know that other study designs, such as parallel studies, can be used and that such studies may even be preferable for drugs such as topiramate with relatively long half-lives. (Thakker Resp. Decl. ¶¶ 35-36.) And although the specification recognizes that there is interpatient variability in blood plasma concentrations, the specification expressly teaches that mean values, not crossover studies, are to be used to account for the problem. ('580 patent 4:22-29.)

Moreover, the use of a crossover study in Example 6 of the specification is not sufficient to read the limitation into the claims. "[I]t is improper to read limitations from a preferred

embodiment described in the specification—even if it is the only embodiment—into the claims absent a clear indication in the intrinsic record that the patentee intended the claims to be so limited. *Liebel-Flarsheim Co.*, 358 F.3d at 913. The specification here does not indicate that the claim language should be so limited; nor does it require—or even state a preference for—a crossover study over any other kind of clinical study that could be used. (Thakker Resp. Decl. ¶¶ 33-34.) This Court will not construe the claims to require a limitation that the specification does not require. *See Renishaw*, 158 F.3d at 1249. For these reasons, this Court adopts Plaintiff's proposed construction.

G. "the same amount of topiramate administered as an immediate release formulation BID"

Plaintiff's Proposed Construction	**Defendants' Proposed Construction**	**Court's Construction**
the equivalent amount of topiramate administered daily as an immediate release formulation given twice a day	the equivalent amount of topiramate administered daily as an immediate release formulation given twice a day in the same subjects	the equivalent amount of topiramate administered daily as an immediate release formulation given twice a day

Plaintiff and Defendants disagree on the meaning of "the same amount of topiramate administered as an immediate release formulation BID" as used in claims 10 and 11 of the '580 patent, claims 11 and 12 of the '248 patent, claims 2-6 and 14 of the '191 patent, and claims 11 and 12 of the '989 patent. The parties agree on the language "the equivalent amount of topiramate administered daily as an immediate release formulation given twice a day," and this portion of the proposed constructions is supported by the intrinsic evidence.

The parties dispute whether the formulation must be given twice a day "in the same subjects." This limitation is not required by the claim language or specification, and would require the use of crossover studies and exclude other methods for comparing formulations, such as parallel study designs, in which the formulations are administered to different subjects. Moreover,

the plain language of the claim term concerns the *amount* of topiramate to be administered, and Defendants provide no explanation as to why a POSA would assume that the *amount* of a drug to be administered would limit the *subjects* who should receive the drug. For these reasons, and for the reasons discussed above in Part IV.F, this Court finds that the formulation need not be given twice a day "in the same subjects."

CONCLUSION

For the reasons stated above, this Court orders that the disputed claims in the patents in suit be construed as set forth in this Opinion. A summary of this Court's construction of the disputed claims is provided in the corresponding Order.

s/ Susan D. Wigenton

Susan D. Wigenton, U.S.D.J.

Orig: Clerk
cc: Leda Dunn Wettre, U.S.M.J.
Parties

Claim Term	Plaintiff's Proposed Construction	Defendants' Proposed Construction	Court's Construction
at least two different extended release topiramate-containing components	at least two extended release topiramate-containing components, wherein each component has its own in vitro rate of drug release	at least two different extended release topiramate-containing components having different compositions and release rates for topiramate, within normal variation	at least two extended release topiramate-containing components having different in vitro release rates for topiramate
population[s] of beads	population[s] of particles, spheres, beads, granules, pellets, particulates or any structural units that may be incorporated into an oral dosage form *Construction of "population" is not necessary. The term has its plain and ordinary meaning, e.g., group, collection, or class.*	multiple structural units with the same composition and rate of release, within normal variation	population[s] of particles, spheres, beads, granules, pellets, particulates or any structural units that may be incorporated into an oral dosage form *Construction of "population" is not necessary. The term has its plain and ordinary meaning, e.g., group, collection, or class.*
release controlling coating	a coating that modifies and controls the release of the active ingredient *Construction of "coating" is not necessary. The term has its plain and ordinary meaning, e.g., a covering.*	a layer of material coated onto a core or other layer that modifies and controls the extended release of the active ingredient	a coating that modifies and controls the release of the active ingredient *Construction of "coating" is not necessary. The term has its plain and ordinary meaning, e.g., a covering.*
coating material	a material that modifies and controls the release of the active ingredient and is capable of forming a coating *Construction of "coating" is not necessary. The term has its plain and ordinary meaning, e.g., a covering.*	a material coated onto a core or other layer	*Construction of "coating material" is not necessary. The term has its plain and ordinary meaning, e.g., a material used as a covering.*

Claim Term	Plaintiff's Proposed Construction	Defendants' Proposed Construction	Court's Construction
a maximum steady state plasma concentration (Cmax) of topiramate	a maximum plasma concentration (Cmax) of topiramate reached during a dosing interval while at steady state	a maximum plasma drug concentration (Cmax) of topiramate that is the calculated mean value based on values obtained from a group of subjects tested during a dosing interval while at steady state	a maximum plasma concentration (Cmax) of topiramate reached during a dosing interval while at steady state that is the calculated mean value based on values obtained from a group of subjects tested
a relative steady state AUC	an area under the plasma concentration-time curve (AUC) of topiramate from the formulation administered once-daily while at steady state in relation to the AUC of topiramate from an immediate release formulation administered daily in two divided doses while at steady state	an area under the plasma concentration-time curve (AUC) of topiramate from the formulation administered once-daily while at steady state in relation to the AUC of topiramate from an immediate release formulation administered twice a day in two equal doses while at steady state based on values obtained from a group of subjects tested by a crossover study	an area under the plasma concentration-time curve (AUC) of topiramate from the formulation administered once-daily while at steady state in relation to the AUC of topiramate from an immediate release formulation administered daily in two divided doses while at steady state
the same amount of topiramate administered as an immediate release formulation BID	the equivalent amount of topiramate administered daily as an immediate release formulation given twice a day	the equivalent amount of topiramate administered daily as an immediate release formulation given twice a day in the same subjects	the equivalent amount of topiramate administered daily as an immediate release formulation given twice a day