IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SHIRE DEVELOPMENT LLC, SHIRE LLC, and SHIRE US INC., Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., et al., Defendants.	Civil Action No. 1:17-cv-01696-RGA

MEMORANDUM OPINION

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ANDREWS, U.S. DISTRICT JUDGE:

Presently before me is the issue of claim construction of multiple terms in U.S. Patent Nos. 6,913,768 ("'768 Patent"), 8,846,100 ("'100 Patent"), and 9,173,857 ("'857 Patent). (D.I. 89).

I have read and considered the Parties' Joint Claim Construction Brief and letters. (D.I. 89, 105, 106, 107, 108). I heard oral argument on January 23, 2019. (D.I. 104 ("Tr.")).

II. LEGAL STANDARD

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (citation omitted). "'[T]here is no magic formula or catechism for conducting claim construction.' Instead, the court is free to attach the appropriate weight to appropriate sources 'in light of the statutes and policies that inform patent law.'" *SoftView LLC v. Apple Inc.*, 2013 WL 4758195, at *1 (D. Del. Sept. 4, 2013) (quoting *Phillips*, 415 F.3d at 1324) (alteration in original). When construing patent claims, a court considers the literal language of the claim, the patent specification, and the prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979-80 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Of these sources, "the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315.

"[T]he words of a claim are generally given their ordinary and customary meaning. . . . [This 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." *Id.* at 1312-13. "[T]he ordinary meaning of a claim term is its meaning to [an] ordinary artisan after reading the entire patent." *Id.* at 1321. "In some cases, the ordinary meaning of claim language

as understood by a person of skill in the art ["POSA"] 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." *Id.* at 1314.

When a court relies solely on the intrinsic evidence—the patent claims, the specification, and the prosecution history—the court's construction is a determination of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015). The court may also make factual findings based on consideration of extrinsic evidence, which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Phillips*, 415 F.3d at 1317-19. Extrinsic evidence may assist the court in understanding the underlying technology, the meaning of terms to one skilled in the art, and how the invention works. *Id.* Extrinsic evidence, however, is less reliable and less useful in claim construction than the patent and its prosecution history. *Id.*

"A claim construction is persuasive, not because it follows a certain rule, but because it defines terms in the context of the whole patent." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that "a claim interpretation that would exclude the inventor's device is rarely the correct interpretation." *Osram GMBH v. Int'l Trade Comm'n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (citation omitted).

I. BACKGROUND

The patents-in-suit relate generally to pharmaceutical compositions capable of sustained release of amphetamines or amphetamine salts. (D.I. 89).

The Parties dispute a term in claims 1, 7, 9, 11, 12, 13, 14, 15, and 35 of the '768 Patent. This patent relates to "compositions for providing an orally administrable sustained release (SR)

form of one or more amphetamines and/or amphetamine salts." ('768 Patent at 1:6-8). The following claims of the '768 Patent are representative:

> 1. A pharmaceutical composition comprising a mixture of dextro- and levo-amphetamine and/or salt(s) thereof and a sustained release coating or matrix which comprises an amount of polyvinyl acetate, cellulose acetate, cellulose acetate butyrate, cellulose acetate propionate, ethyl cellulose, a fatty acid, a fatty acid ester, an alkyl alcohol, a wax, zein (prolamine from corn), a poly(meth)acrylate, microcrystalline cellulose or poly(ethylene oxide) effective to achieve continuous sustained release of said amphetamines and/or salt(s) to provide a mean plasma concentration profile in human ADHD patients which is substantially the same as the dextroamphetamine XR profile and/or the levoamphetamine XR profile of FIG. 1 over the course of the first twelve hours after administration, for a 20 mg total dose, or to provide a profile directly proportional to said XR profile(s) for a total dose other than 20 mg.
>
> 14. A pharmaceutical composition comprising a mixture of dextro- and levo-amphetamine and/or salt(s) thereof and a sustained release coating or matrix which comprises an amount of polyvinyl acetate, cellulose acetate, cellulose acetate butyrate, cellulose acetate propionate, ethyl cellulose, a fatty acid, a fatty acid ester, an alkyl alcohol, a wax, zein (prolamine from corn), a poly(meth)acrylate, microcrystalline cellulose or polyethylene oxide) [sic] effective to achieve about a first order sustained dissolution release of said amphetamines and/or salt(s), which has [a recited plasma concentration profile], for a 20 mg total dose, or respective AUC and C_{max} values directly proportional thereto for a total dose other than 20 mg.

('768 Patent, claims 1, 14).

The Parties dispute two terms which appear in claim 1 of the '100 Patent and claim 1 of the '857 Patent. The Patents relate to "a long-acting amphetamine pharmaceutical composition, which includes an immediate release component, a delayed pulsed release component and a sustained release component, to meet the therapeutic needs for ADHD patients with longer-day demands." ('100 Patent at 3:53-57). Claim 1 of the '100 Patent is representative:

> 1. A pharmaceutical composition comprising: (a) an *immediate release bead* comprising at least one amphetamine salt; (b) a *first delayed release bead* comprising at least one amphetamine salt; and (c) a *second delayed release bead* comprising at least one amphetamine salt; wherein the first delayed release bead

provides *pulsed release* of the at least one amphetamine salt and the second delayed release bead provides sustained release of the at least one amphetamine salt;

wherein the second delayed release bead comprises at least one amphetamine salt layered onto or incorporated into a core; a delayed release coating layered onto the amphetamine core; and a sustained release coating layered onto the delayed release coating, wherein the sustained release coating is pH-independent; and

wherein the first delayed release bead and the second delayed release bead comprise an enteric coating.

('100 Patent, claim 1 (emphasis added). The parties agree on constructions for ten additional terms. (D.I. 89 at 1).

III. CONSTRUCTION OF DISPUTED TERMS

1. '768 Patent Antecedent Basis Issue

a. *Plaintiffs' position*:

The pharmaceutical composition as a whole must provide the claimed plasma profile.

b. *Defendants' position*:

A sustained-release coating or matrix must provide [control][1] the claimed plasma profile.

Alternatively, indefinite.

c. *Court's construction*:

The pharmaceutical composition as a whole must provide the claimed plasma profile.

Although the Parties agree on the meanings of the individual words in the '768 Patent's claims, they disagree on the proper way to read those words in context.

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[1] D.I. 89 at 41-42.

Defendants' argue that the grammatical structure of the claims requires that the sustained-release coating or matrix provide the claimed plasma profile. Their argument stems from an application of the "last antecedent" doctrine. (D.I. 89 at 14-17). The last antecedent doctrine is a doctrine of statutory construction which advises that, absent clear contextual clues, "qualifying words, phrases and clauses must be applied to the words or phrases immediately preceding them and are not to be construed as extending to and including others more remote." *Wilshire Westwood Assocs. v. Atl. Richfield Corp.*, 881 F.2d 801, 804 (9th Cir. 1989). The doctrine is inapplicable, however, if it creates an absurd result. *See Demko v. United States*, 216 F.3d 1049, 1053 (Fed. Cir. 2000).

The Federal Circuit has not directly addressed the last antecedent doctrine's application to the claim construction analysis. It has, however, discussed the doctrine in the patent law context on a few occasions. *See, e.g.*, *Finisar Corp. v. DirecTV Grp., Inc.*, 523 F.3d 1323, 1335-36 (Fed. Cir. 2008) (applying doctrine to a prior art reference and noting that English grammar and statutory construction "are not entirely coterminous because the meaning of a prior art reference requires analysis of the understanding of an artisan of ordinary skill"); *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 2018 WL 1583031, at *3 (Fed. Cir. Jan. 16, 2018) (discussing the doctrine's application to the statutory interpretation of post-AIA Section 101). District courts have only rarely invoked the last antecedent doctrine during claim construction. Defendant points to just one district court case where the court applied the doctrine to resolve a claim construction dispute: *Iridescent Networks, Inc. v. AT&T Mobility, LLC*, 2017 WL 3033400 at *8 (E.D. Tex. July 18, 2017) (describing the last-antecedent doctrine as "dictating" an understanding of the claim). Other courts, however, have taken a more tentative approach to applying the doctrine to claim construction. *See CA, Inc. v. Simple.com, Inc.*, 780 F. Supp. 2d

196, 233 (E.D.N.Y. 2009) (applying the last antecedent doctrine, but noting the lack of contrary intent in the intrinsic record); *Gamesa Eolica, S.A. v. Gen. Elec. Co.*, 359 F. Supp. 2d 790, 801 (W.D. Wis. 2005) (finding that the claim language and the specification negated a strict application of the last antecedent rule). I have similarly found the last antecedent doctrine unpersuasive when faced with intrinsic evidence that a POSA would not understand the claim to have the meaning which grammar might normally command. *St. Jude Med. v. Volcano Corp.*, 2013 WL 2372190, at *1 (D. Del. May 30, 2013).

This is all to say, the claim construction inquiry, as described in *Markman* and *Philips*, is not hamstrung by the rigidities of English grammar. A court is to consider the claims, the specification, and the prosecution history to give the claims meaning. Thus, although the last antecedent doctrine may be a factor in deciding a claim construction, it is far from dispositive.[2]

Plaintiffs argue that Defendants' proposed construction reads an unwritten limitation into the claims. (D.I. 89 at 6). Specifically, Plaintiffs argue that Defendants' construction requires that "the claimed drug release and pharmacokinetic characteristics are provided *solely* by the amount of sustained release material." (*Id.* (emphasis added)).

Plaintiffs also argue, essentially, that Defendants' reading of the claims is inconsistent with a POSA's understanding of pharmaceutical compositions. (*Id.* at 7). They argue that a POSA knows that a pharmaceutical composition's plasma profile is necessarily dependent on the components. (*Id.* at 7-8). Moreover, as to independent claims 14 and 15 of the '768 Patent, they

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[2] We read claims in light of the understanding of a POSA. In more than fifty patent trials, I have never heard that a POSA had any particular ability in English grammar. I expect that, on average, POSAs are less likely than lawyers and judges to concern themselves with the technicalities of grammar.

note that a POSA knows that a sustained release coating does not "have" a plasma concentration profile. (*Id.* at 9). Defendants respond that the claim language controls over extrinsic evidence, such as the evidence presented by Plaintiffs' expert regarding a POSA's understanding of the technology. (*Id.* at 38-39).

I agree with Defendants' position that relying on extrinsic evidence to determine a claim's meaning is not an appropriate starting point for construing a claim. I also agree with Defendants that a reading of the claims, in a vacuum, supports Defendants' position that the plain language of the claims requires that the sustained-release coating or matrix must provide the claimed plasma profile. The claims, however, are not the end of the inquiry.

Plaintiffs argue that the specification associates the plasma profiles with the overall formulation. (*Id.* at 9-11). They note that the '768 Patent's specification repeatedly refers to the overall formulation as providing the plasma profile, rather than a specific component, such as:

> Other than beads in a capsule shell, tablets in a capsule shell (e.g., *one immediate-release tablet* and one delayed, sustained release tablet in a capsule shell, to provide an *overall sustained release*) also can be used to *attain the desired plasma profile*.

('768 Patent, 3:11-15 (emphasis added)).

> A pharmaceutical *composition* comprises a once-a-day sustained release formulation of at least one amphetamine salt *which provides mean plasma concentration* profile aspects in human ADHD patients which are substantially the same as that provided by ADDERALL XR® type pulsatile formulations.

('768 Patent, abstract (emphasis added)).

> Particularly preferably, the SR *formulations* according to the invention *exhibit a single dose in vivo plasma concentration profile* substantially the same as that shown in FIG. 1.

('768 Patent at 1:29-32 (emphasis added)).

> Other amphetamines and amphetamine salts and mixtures thereof can be used in a sustained-release delivery *system to achieve the plasma concentration profiles* of the invention.

('768 Patent at 2:41-44 (emphasis added)). Plaintiffs also note that the specification contemplates the use of disintegrants which "disperse the beads once the tablet is ingested" and, thus, affect the composition's plasma profile. (D.I. 89 at 11; '768 Patent at 5:5-6).

Defendants respond that these references refer to unclaimed embodiments which are present in the specification due to a restriction requirement. (D.I. 89 at 21-23). The restriction requirement required the Applicant to pursue claims on one of two inventions:

> I. Claims 1-5, 11, 13 and 14, drawn to a pharmaceutical composition comprising a once-a-day sustained release formulation comprising an immediate release dose and delayed release dose (no coating required), classified in class 424, subclasses 489, 484.
>
> II. Claims 6-10, 12 and 15-22, drawn to a pharmaceutical composition comprising a once-a-day sustained release formulation (coating required), classified in class 424, subclass 490.

('768 Patent File History: Office Action (Oct. 6, 2004) at 2 (D.I. 73-1 at 252)). The Applicant elected to pursue the Group II claims which were directed at formulations requiring a coating. (*Id.* at 3 (D.I. 73-1 at 253). Defendants argue that the restriction required the Applicant to eliminate claims to composition which contained immediate release components. (D.I. 89 at 22-23).

Plaintiffs respond by arguing, "Defendants' interpretation of the restriction requirement is factually and legally incorrect." (*Id.* at 30). They note that it is legally wrong because a restriction requirement is a non-substantive administrative procedure. (*Id.*). They also point out that Defendants' interpretation is inconsistent with the

language of the restriction requirement. (*Id.*). Moreover, the Group II claims are "comprising" claims which allow the composition to contain other, unclaimed components. (*Id.* at 31).

I agree with Plaintiffs. The restriction requirement, by its plain language, related to the presence or absence of a coating. The Applicants' election of Group II does not shed any light on whether the immediate release related formulations are unclaimed embodiments. I also agree with Plaintiffs that the specification indicates that the Applicant understood the entire composition, not a single component, to provide a certain plasma profile. On balance, the '768 Patent's specification provides strong support for Plaintiffs' position that the entire composition provides the claimed plasma profile.

Defendants argue that the prosecution history supports their reading of the claims. (D.I. 89 at 17-21). Defendants identify four occasions in the prosecution history where the Applicant and the Examiner refer to formulations with "sustained release components" which are effective to achieve, can be used to achieve, or result in the claimed plasma profile. (*Id.*). Defendants particularly highlight the Examiner's reason for allowance:

> The primary reason for allowance is that the prior art does not disclose nor fairly suggest a pharmaceutical composition comprising the instantly claimed sustained release components in an amount effective to achieve continuous sustained release of said amphetamines and/or salt(s) to provide a mean plasma concentration profile as that of Fig. 1. The prior art offers no teaching or suggestion of the specific sustained release formulation components for achieving plasma profile features of Fig. 1, as claimed by Applicant.

('768 Patent File History: Notice of Allowability (Dec. 17, 2004) at 2 (D.I. 73-1 at 290)).

Plaintiffs respond, essentially, that none of these exchanges link the claimed plasma profile only, or solely, to the claimed sustained-release component. (D.I. 89 at 33-36). I agree with Plaintiffs' understanding of the prosecution history. The Applicant

and the Examiner understood that the specific sustained release components would contribute to the claimed plasma profile. However, the prosecution history does not reasonably support a conclusion that the Examiner or the Applicant understood the sustained release components as the sole source of the plasma profile. Thus, I find that the prosecution history does not clearly support Defendants' position.

Plaintiffs further argue that the prosecution history explains the origin of the antecedent basis issue. (D.I. 89 at 34). I agree. Original claim 6 claimed:

> A pharmaceutical composition comprising a *once-a-day sustained release formulation* of at least one amphetamine salt which provides a mean plasma concentration profile in human ADHD patients which is substantially the same as that of Fig. 1, for a 20 mg total dose, or a profile directly proportional thereto for a total dose other than 20 mg.

('768 Patent File History: Preliminary Amendment (March 5, 2003) at 1 (D.I. 73-1 at 142) (emphasis added)). During prosecution, the Examiner suggested that the Applicant "recite specific formulations that result in the plasma profiles in Fig. 1." ('768 Patent File History: Interview Summary (Nov. 4, 2004) (D.I. 73-1 at 266)). In response, the Applicant added specific details in place of the originally claimed "sustained release formulations. This change is reflected in claim 1, which was original claim 6:

> 1. A pharmaceutical composition comprising *a mixture of dextro- and levo-amphetamine and/or salt(s) thereof and a sustained release coating or matrix which comprises an amount of polyvinyl acetate, cellulose acetate, cellulose acetate butyrate, cellulose acetate propionate, ethyl cellulose, a fatty acid, a fatty acid ester, an alkyl alcohol, a wax, zein (prolamine from corn), a poly(meth)acrylate, microcrystalline cellulose or poly(ethylene oxide) effective to achieve continuous sustained release* of said amphetamines and/or salt(s) to provide a mean plasma concentration profile in human ADHD patients which is substantially the same as the dextroamphetamine XR profile and/or the levoamphetamine XR profile of FIG. 1 over the course of the first twelve hours after administration, for a 20 mg total dose, or to provide a profile directly proportional to said XR profile(s) for a total dose other than 20 mg.

('768 Patent, claim 1 (emphasis added)). The Applicant's mid-prosecution insertion of the much longer and much more complex clause describing the formulation of the sustained release component explains, in part, the existence of a technically grammatically incorrect antecedent basis. This reasonable explanation weighs against a strict application of the "last antecedent" doctrine.

In addition to support in the intrinsic record, Plaintiffs argue that a POSA would understand that the claimed plasma profile results from the composition as a whole. (D.I. 89 at 6, 8-9, 27-28). I find, however, that the intrinsic evidence clearly gives meaning to the claims. Thus, I need not consider extrinsic evidence of a POSA's understanding.

Defendant is correct, as a technical matter, that the last antecedent doctrine would result in a construction requiring that the sustained release component provides the claimed plasma profile. However, the specification and the prosecution history strongly support Plaintiffs' proposed construction. Thus, I will construe the claim as requiring that the pharmaceutical composition as a whole must provide the claimed plasma profile.

2. "pharmaceutical composition comprising: (a) an immediate release bead ...; (b) a first delayed release bead ...; and (c) a second delayed release bead ..."

a. *Plaintiffs' proposed construction*:

"pharmaceutical composition comprising: (a) a discrete immediate release component . . .; (b) a discrete first delayed release component . . .; and (c) a discrete second delayed release component . . ."

b. *Defendants' proposed construction*:

The claimed "pharmaceutical composition" requires three distinct beads: an immediate release bead, a first delayed release bead, and a second delayed release bead.

c. *Court's construction*:

> "pharmaceutical composition comprising: (a) a discrete immediate release component . . .; (b) a discrete first delayed release component . . .; and (c) a discrete second delayed release component . . . "

The Parties agree that the '100 and '857 Patents' specifications define "bead" as "discrete component of a dosage form." (D.I. 89 at 44, 48). They disagree, however, on how to reconcile that definition with the rest of the claim language.

Plaintiffs argue that the stipulated definition controls the construction of the disputed claim term. Specifically, Plaintiffs propose that the words "discrete" and "component" should be substituted for the claim term "bead." (*Id.* at 44-45).

I agree with Plaintiffs and see no basis to deviate from the lexicographic definition of "bead" when construing the larger phrase. Thus, I will adopt Plaintiffs' proposed construction: "pharmaceutical composition comprising: (a) a discrete immediate release component . . .; (b) a discrete first delayed release component . . .; and (c) a discrete second delayed release component . . . ."

I recognize, however, that this does not resolve the heart of the Parties' dispute. Defendants[3] do not agree with Plaintiffs' understanding of the meaning of the term "discrete" in the context of the claims. They contend that "discrete" means "distinct," "separate," or "noncontiguous" such that there can be only one bead per "core." (*Id.* at 48-49). They argue that various dictionary definitions of "discrete" support their position. (*Id.*). Plaintiffs respond that other dictionaries define "discrete" in a manner which would permit more than one bead per core. (*Id.* at 65). They also note that "noncontiguous" does not appear in the intrinsic record.

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[3] Defendant SpecGx took no position as to the proper construction of this term.

(*Id.*). I find that a review of standard dictionary definitions of "discrete" is not a useful exercise to determine the word's meaning in the context of the claims.

Plaintiffs argue that the claims clearly indicate that the Patentee contemplated the presence of more than one bead per core. In their view, dependent claims 13 and 14 of the '100 Patent prove as much:

> 13. The pharmaceutical composition of claim 1, wherein the immediate release bead and at least one delayed release bead are present on a single core.
>
> 14. The pharmaceutical composition of claim 1, wherein the immediate release bead and at least one delayed release bead are present on different cores.

('100 Patent, claims 13-14). Defendants' only response to Plaintiffs' argument is that claim 13 is invalid because it attempts to broaden independent claim 1. (D.I. 89 at 57-58). Defendants make no response to the impact of dependent claim 14.

Claim differentiation is a fundamental principle of claim construction. *Virnetx, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1317 (Fed. Cir. 2014). The doctrine creates a presumption that limitations added in dependent claims are not already present in the independent claim from which it depends. *InterDigital Commc'ns, LLC v. Int'l Trade Comm'n*, 690 F.3d 1318, 1324 (Fed. Cir. 2012). The presumption can be overcome by lexicography or disavowal of claim scope. Further, it is axiomatic that claims should be construed, if possible, to preserve their validity. *Rhine v. Casio, Inc.*, 183 F.3d 1342, 1345 (Fed. Cir. 1999).

Dependent claims 13 and 14 provide strong intrinsic support for Plaintiffs' position. Dependent claim 14 recites a limitation that beads be present on different cores. A straightforward application of the doctrine of claim differentiation leads to the conclusion that the independent claim is not limited to beads on separate cores. Otherwise, claim 14 would be redundant. As to dependent claim 13, it is true that it cannot be read to expand the scope of the

independent claim. But it can be considered in determining the scope of the independent claim. Principles of claim construction suggest that I construe the claims to preserve the validity of claim 13, which would require that the independent claim not require that the immediate release bead and the delayed release bead be on separate cores.

Plaintiffs next argue that the specification discloses embodiments where multiple beads are present on a single core. (D.I. 89 at 47). They argue the specification discloses such embodiments at two points:

> In one embodiment, the immediate release, delayed pulsed release and sustained release components of the composition are present on the same core.

('100 Patent at 5:53-55).

> It is contemplated that compositions of the present invention can include a combination of the hereinabove referred to cores (one or more cores that include three components on the same core, one or more cores that include two of the three components on the core, and one or more cores that include one of the three components on the core).

('100 Patent at 5:65-6:1). The specification further clarifies, "bead and pellet encompass any discrete component of a dosage form." ('100 Patent at 11:3-4).

Defendants respond by noting that the embodiments identified by Plaintiffs use the term "component" rather than bead. (D.I. 89 at 58-59). And, Defendants argue, even if the embodiments are relevant to the bead term, they are unclaimed. (*Id.* at 58-59).

I do not find Defendants' position persuasive. The specification discloses embodiments where more than one component is on a single core. The specification equates discrete components with beads. Thus, these embodiments indicate that the Patentee understood that more than one discrete component (or "bead"), could be present on a single core.

Defendants next argue that the prosecution history related to the Burnside reference and IPR proceedings are inconsistent with Plaintiffs' proposed construction. (D.I. 89 at 52-57). I

have reviewed their argument and find that the relevant statements made during prosecution and the IPR are unenlightening. The fact that the Patentee, the Examiner, and the PTAB, when considering prior art references, did not discuss the possibility of multiple beads on a single core does not, as Defendants would have it, amount to a disclaimer.

The claims and specification clearly establish that the "beads" of the '100 and '857 Patents may be on the same core. The specification defines "bead" to mean "discrete component of a dosage form." Inserting that language into the broader claim, there must be a discrete immediate release component, a discrete first delayed release component, and a discrete second delayed release component. Claim 13 and 14 of the '100 Patent confirm that independent claim 1 covers beads on the same and on different cores. Additionally, the specification confirms the meaning of the claims. And the prosecution history and IPR proceedings do not clearly disclaim multiple beads on a single core. Thus, I find that more than one discrete "bead" may be present on a single "core" within the meaning of the claim.

3. "pulsed release"

a. *Plaintiffs' proposed construction*:

> "a drug is delivered in one or more doses that fluctuate between a maximum and minimum dose over a period of time. This can be represented by a dose release profile having one or more distinct peaks or valleys. However, two or more pulsed releases may produce an overlapping, overall, or composite release profile that appears or effectively is constant. When two or more pulsed releases occur, there may or may not be a period of no release between pulses. Typically, pulsed release results in release of essentially all of a drug within about 60 minutes or less"[4]

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[4] Plaintiffs originally proposed: "release that fluctuates between a maximum and minimum dose over a period of time such that, typically, release of essentially all of a drug occurs within about 60 minutes or less after initial onset." (D.I. 89 at 71). They abandoned this position at the

b. *Defendants' proposed construction*:

Indefinite

or

"a drug is delivered in one or more doses that fluctuate between a maximum and minimum dose over a period of time"

c. *Court's construction*:

"a drug is delivered in one or more doses that fluctuate between a maximum and minimum dose over a period of time. This can be represented by a dose release profile having one or more distinct peaks or valleys. However, two or more pulsed releases may produce an overlapping, overall, or composite release profile that appears or effectively is constant. When two or more pulsed releases occur, there may or may not be a period of no release between pulses. Typically, pulsed release results in release of essentially all of a drug within about 60 minutes or less"

It is a basic tenet of claim construction that a court will not give a claim term its ordinary meaning "if the patentee acted as his own lexicographer and clearly set forth a definition of the disputed claim term in either the specification or prosecution history." *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002). Rather, the patentee's lexicography will govern the construction. *Phillips*, 415 F.3d at 1316. However, "[a]lthough an inventor is indeed free to define the specific terms used to describe his or her invention, this must be done with reasonable clarity, deliberateness, and precision." *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

The Parties agree that the lexicographic definition of "pulsed release" can be found in this paragraph of the specification:

Markman Hearing (Tr. at 76:17-20) and have provided argument for their current proposed construction in letters that they have since submitted. (D.I. 106, 108).

> "Pulsed" release means that a drug is delivered in one or more doses that fluctuate between a maximum and minimum dose over a period of time. This can be represented by a dose release profile having one or more distinct peaks or valleys. However, two or more pulsed releases may produce an overlapping, overall, or composite release profile that appears or effectively is constant. When two or more pulsed releases occur, there may or may not be a period of no release between pulses. Typically, pulsed release results in release of essentially all of a drug within about 60 minutes or less.

('100 Patent. 11:38-47). The Parties further agree that the construction should include "that a drug is delivered in one or more doses that fluctuate between a maximum and minimum dose over a period of time." (Tr. at 76:4-77:9). The Parties disagree, however, on the proper closing boundary of the lexicographic definition. (D.I. 105, 106, 107, 108).

Defendants argue that the lexicographic definition of "pulsed release" should be limited to the first sentence of the above quoted paragraph. They argue that in that sentence the "term is defined using . . . hallmarks of lexicography." (D.I. 105 at 3). From their letters, it appears their view is that the "hallmarks of lexicography" are definitive terms such as "is" or "means." (*Id.*; D.I. 107 at 1). On the other hand, non-limiting terms such as "can be," "may or may not," and "typically" fall outside the scope of lexicographical speech. (D.I. 105, 107). In support of their theory, Defendants cite several cases where the Federal Circuit found that the scope of a claim term should not be *limited* by exemplary language in the specification. *See, e.g.*, *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1380 (Fed. Cir. 2009) (explaining that particular preferred embodiments do not *limit* a claim term); *3form, Inc. v. Lumicor, Inc.*, 678 F. App'x 1002, 1006-07 (Fed. Cir. 2017) (reversing construction limiting a claim term to 75% compression where the specification stated that "compression" *may* mean that an object has compressed to 75% of its thickness). However, Defendants fail to identify a case where the Federal Circuit found the inclusion of non-limiting terms in a lexicographical construction was necessarily improper.

Plaintiffs argue that the entire paragraph informs a POSA's understanding of the claim term. (D.I. 106 at 3). Plaintiffs also identify district court cases where courts have emphasized the importance of including the entire lexicographical definition in the construction of a claim, have adopted multi-sentence lexicographic definitions for claim terms, and have included exemplary language in claim constructions. (*Id.* at 4-5; D.I. 108 at 2).

I am not persuaded by Defendants' "hallmarks of lexicography" argument. It seems to me that dictionaries regularly define terms by referencing key parameters. That is, a term may be defined by what it is, by what it may be, or by what it is typically.[5]

After considering Defendants' proposed definition, I am confident that it does not capture the Patentee's lexicographical definition of "pulsed release." Rather, the Patentee included important definitional information throughout the entire paragraph. Thus, I will construe "pulsed release" according to its lexicographical definition:

> "a drug is delivered in one or more doses that fluctuate between a maximum and minimum dose over a period of time. This can be represented by a dose release profile having one or more distinct peaks or valleys. However, two or more pulsed releases may produce an overlapping, overall, or composite release profile that appears or effectively is constant. When two or more pulsed releases occur, there may or may not be a period of no release between pulses. Typically, pulsed release results in release of essentially all of a drug within about 60 minutes or less"

Defendants further argue that the lexicographic definition renders the term indefinite. (D.I. 89 at 82). Defendants bear the burden of proving indefiniteness by clear and convincing

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[5] For example, the Oxford English Dictionary defines "Dog" as:

> A domesticated carnivorous mammal, *Canis familiaris* (or *C. lupus familiaris*), which typically has a long snout, an acute sense of smell, non-retractile claws, and a barking, howling, or whining voice, widely kept as a pet or for hunting, herding livestock, guarding, or other utilitarian purposes.

OED (3d ed. 2010).

evidence. *Biosig Instruments, Inc. v. Nautilus, Inc.*, 783 F.3d 1374 (Fed. Cir. 2015). Their indefiniteness argument, at the most basic level, is that the specification does not provide a POSA enough information to discern a difference between sustained release and pulsed release. (D.I. 89 at 77). This is not a typical claim construction position. I am not convinced, based on this record, that Defendants are correct. Thus, I decline Defendants' invitation to find the term indefinite at this juncture and invite them to brief the issue after trial when the factual record is complete.

IV. CONCLUSION

Within five days the parties shall submit a proposed order consistent with this Memorandum Opinion.