

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

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UCB, INC. and	:	
UCB MANUFACTURING, INC.,	:	
	:	
Plaintiffs,	:	
	:	
v.	:	C.A. No. 12-463-LPS
	:	
MALLINCKRODT INC.,	:	
	:	
Defendant.	:	

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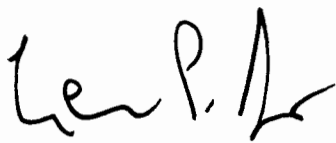
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**MEMORANDUM OPINION**

July 25, 2013  
Wilmington, Delaware.



STARK, U.S. District Judge:

## **I. INTRODUCTION**

Plaintiffs UCB, Inc. and UCB Manufacturing, Inc. (“UCB” or “Plaintiffs”) filed suit against Defendant Mallinckrodt Inc. (“Mallinckrodt” or “Defendant”) alleging infringement of U.S. Patent No. 6,344,215 (“the ’215 Patent”), which is entitled “Methylphenidate Modified Release Formulations.” The Court held a *Markman* hearing on April 5, 2013. (See *Markman* Hr’g Tr., April 5, 2013 (D.I. 56) (hereinafter “Tr.”)) The Court now construes the disputed claims in the ’215 Patent.

## **II. BACKGROUND**

The ’215 Patent has been litigated previously in this Court. See *UCB, Inc. v. KV Pharm. Co.*, Civ. No. 08-223-JJF. In an earlier claim construction opinion, the Honorable Joseph J. Farnan, Jr. provided the following background:

The ’215 patent pertains to multiparticulate pharmaceutical dosage forms that include both immediate release (“IR”) beads and extended release (“ER”) beads. ’215 patent at 1:60–65. The former type of beads are designed to release all of their active ingredient rapidly and thus provide a “bolus dose for rapid onset of action.” *Id.* at 1:65–67. The latter beads, by contrast, are designed to release their active ingredient over an extended period. *Id.* at 1:67–2:3. According to the patent, one can combine the IR and ER beads in different combinations and then conduct “[t]esting to determine in vitro/in vivo correlations . . . to predict desirable profiles which can be expected to maintain blood levels of the active agent within a desired therapeutic range over an extended period of time.” *Id.* at 2:4–7. The patent emphasizes the use of the dosage form with the active ingredient methylphenidate hydrochloride, which the specification explains is the “drug of choice for treatment of ADD and ADHA in children.” *Id.* at 1:5–8. Indeed, the patent is entitled “Methylphenidate Modified Release Formulations.” Furthermore, all of the claims are limited to a “modified release methylphenidate hydrochloride capsule ....” *Id.*

at 7:33–35.

*UCB, Inc. v. KV Pharm Co.*, 2009 WL 2524519, at \*2 (D. Del. 2009). Of the six claim terms Judge Farnan construed, two are again disputed in the instant case. The parties are in agreement that Judge Farnan’s constructions in the prior case are not dispositive. (Tr. at 8)

### III. LEGAL STANDARDS

“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) (internal quotation marks omitted). Construing the claims of a patent presents a question of law. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977-78 (Fed. Cir. 1995), *aff’d*, 517 U.S. 370, 388-90 (1996). “[T]here is no magic formula or catechism for conducting claim construction.” *Phillips*, 415 F.3d at 1324. Instead, the Court is free to attach the appropriate weight to appropriate sources “in light of the statutes and policies that inform patent law.” *Id.*

“[T]he words of a claim are generally given their ordinary and customary meaning . . . [which 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 (internal citations and quotation marks omitted). “[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent.” *Id.* at 1321 (internal quotation marks omitted). The patent 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.” *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

While “the claims themselves provide substantial guidance as to the meaning of particular

claim terms,” the context of the surrounding words of the claim also must be considered.

*Phillips*, 415 F.3d at 1314. Furthermore, “[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment . . . [b]ecause claim terms are normally used consistently throughout the patent . . . .” *Id.* (internal citation omitted).

“Differences among claims can also be a useful guide. . . . For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim.” *Id.* at 1314-15 (internal citation omitted). This “presumption is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim.” *SunRace Roots Enter. Co., Ltd. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003).

It is also possible 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. It bears emphasis that “[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction.” *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (internal quotation marks omitted), *aff’d*, 481 F.3d 1371 (Fed. Cir. 2007).

In addition to the specification, a court “should also consider the patent’s prosecution history, if it is in evidence.” *Markman*, 52 F.3d at 980. The prosecution history, which is “intrinsic evidence,” “consists of the complete record of the proceedings before the PTO [Patent

and Trademark Office] and includes the prior art cited during the examination of the patent.”

*Phillips*, 415 F.3d at 1317. “[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.” *Id.*

A court may also rely on “extrinsic evidence,” which “consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” *Markman*, 52 F.3d at 980. For instance, technical dictionaries can assist the Court in determining the meaning of a term to those of skill in the relevant art because such dictionaries “endeavor to collect the accepted meanings of terms used in various fields of science and technology.” *Phillips*, 415 F.3d at 1318. Overall, while extrinsic evidence “may be useful” to the Court, it is “less reliable” than intrinsic evidence, and its consideration “is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence.” *Id.* at 1318-19.

Finally, “[t]he construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be, in the end, the correct construction.”

*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).

#### **IV. CONSTRUCTION OF DISPUTED TERMS**

Claim 1 of the ’215 Patent, the patent’s sole independent claim, is reproduced below, with emphasis added to show the disputed terms:

*A modified release methylphenidate hydrochloride capsule comprising immediate release (IR) and extended release (ER) methylphenidate-containing beads wherein the immediate release beads are present in an amount of about 20 to 40 percent and the extended release beads are present in an amount of about 60 to 80 percent and the total amount of methylphenidate hydrochloride present is about 10 to 40 mg; further wherein the immediate release beads are made up of a core particle coated with a layer of a methylphenidate-containing water soluble film-forming composition and the extended release beads are made up of a core particle layered with a methylphenidate-containing water soluble film-forming composition which is further coated with a dissolution rate controlling polymer in an amount up to 20 percent, and when the immediate release and the extended release beads are mixed in the amounts shown in the following table and tested using USP apparatus 2 at 50 rpm in 500 ml water, the mixed beads release methylphenidate approximately in the percentages shown in the following table based on the total methylphenidate: [table omitted]*

**A. “a modified release methylphenidate hydrochloride capsule comprising immediate release (IR) and extended release (ER) methylphenidate containing beads”**

1. Plaintiffs’ Proposed Construction: Plain and ordinary meaning; no construction necessary, or, in the alternative, “a modified release methylphenidate hydrochloride capsule comprising both immediate release (IR) and extended release (ER) methylphenidate-containing beads”
2. Defendant’s Proposed Construction: “a modified release methylphenidate hydrochloride capsule comprising two types of bead populations – one an immediate release (IR) methylphenidate-containing bead and the other an extended release (ER) methylphenidate-containing bead”
3. Court’s Construction: “a modified release methylphenidate hydrochloride capsule comprising both immediate release (IR) and extended release (ER) methylphenidate-containing beads”

The parties agree that the '215 patent claims a formulation containing two kinds of beads: immediate release and extended release. (*See* D.I. 44 at 1, 15; D.I. 38 at 5; D.I. 45 at 1) The apparent dispute is whether the claim may be practiced in a formulation consisting of beads that themselves contain both IR and ER components, as one might think if the Court merely states “plain and ordinary meaning,” or whether instead the claim requires formulations that contain at least some IR beads and separately contain at least some ER beads, as Defendants argue.

The Court concludes that this apparent dispute is appropriately resolved by adopting Plaintiffs’ alternative proposed construction. This construction will adequately convey to the factfinder that the formulations of the claims must contain both IR and ER beads.<sup>1</sup> Reading in the concept of “populations,” as Defendant requests, risks confusing the factfinder. While Defendant points out that the Examiner made reference to “two different bead populations that are mixed in specific amounts” (Tr. at 53) in its Reason for Allowance, this is not a persuasive basis to add “population” to the claim.

**B. “bead”**

1. Plaintiffs’ Proposed Construction: plain and ordinary meaning; no construction necessary, or, in the alternative, “a core particle coated with one or more layers”
2. Defendant’s Proposed Construction: “a separate and distinct structure containing a core particle coated with one or more layers”
3. Court’s Construction: “a separate and distinct structure containing a core particle coated with one or more layers”

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<sup>1</sup>At the hearing, it appeared that Defendant agreed with Plaintiffs’ alternative proposed construction, “so long as we are talking about beads as not being the same thing but being different structures.” (Tr. at 55)

The parties agree that “bead” refers to “a core particle coated with one or more layers.” Defendant would add the limitation that a bead must be “a separate and distinct structure.” Plaintiffs counter that this additional language is “unnecessary and does nothing to clarify the scope of claim 1.” (D.I. 36 at 8) The Court disagrees. Without the “separate and distinct” limitation, there is ambiguity as to whether “IR and ER beads” refers to one or two populations of beads or both. Given particularly that Plaintiffs do not dispute that IR and ER beads must be separate and distinct (Tr. at 23), the Court concludes that construction will reduce confusion.

Plaintiffs cite *Shire Dev. LLC v. Watson Pharms., Inc.*, 2013 WL 174843 (S.D. Fla. 2013), as support for the proposition that the “separate and distinct” limitation should not be included because the term does not appear elsewhere in the patent or prosecution history. However, *Shire* construed a different claim of a different patent in a different context based on a different intrinsic record. In *Shire*, the intrinsic record – including the claims – presented no significant risk of confusion that the “inner lipophilic matrix” and “outer lipophilic matrix” were separate and distinct, making it unnecessary to add a “separate and distinct” limitation through claim construction. *See id.* at 8-9.

**C. “immediate release bead”**

1. Plaintiffs’ Proposed Construction: “a bead that delivers a portion of the total amount of methylphenidate for rapid onset of action”
2. Defendant’s Proposed Construction: “a bead formed by coating a core particle with a layer of methylphenidate-containing water soluble film forming composition, that releases the methylphenidate rapidly, preferably within 30 minutes”
3. Court’s Construction: “a bead that delivers a portion of the total amount of methylphenidate for rapid onset of action”



Defendant's proposed construction contains both a structural limitation and a temporal limitation. The structural limitation is unnecessary because the structure of the IR bead is disclosed elsewhere in claim 1. Nor is the proposed temporal limitation justified. Defendant's construction may instead confuse the factfinder, as a "preferred" time frame is not necessarily a restriction of any sort. (*See generally* Tr. at 59) (defense counsel stating defendant is "not standing on 'it has to be 30 minutes' as an important limitation in the claim")

**D. "extended release bead"**

1. Plaintiffs' Proposed Construction: "a bead that delivers a portion of the total amount of methylphenidate in a controlled manner over an extended period of time"
2. Defendant's Proposed Construction: "a bead formed by coating immediate release beads with a dissolution rate controlling polymer, that releases methylphenidate over at least a 12-hour period"
3. Court's Construction: "a bead that delivers a portion of the total amount of methylphenidate in a controlled manner over an extended period of time"

As with the parties' dispute over "immediate release bead," the Court is not persuaded to add Defendant's proposed structural limitation to "extended release bead," as it is unnecessary given the remainder of claim 1. Defendant again proposes the addition of a temporal limitation: "at least a 12-hour period." But the specification describes ER beads as "designed to release methylphenidate slowly over a period of 10-12 hours." ('215 patent, col. 4 lines 30-32) Hence, as Defendant concedes (*see* Tr. at 60), Defendant's proposed construction of "at least a 12-hour period" would read the specification's example of as little as 10 hours out of the claim. Construing a claim to exclude a preferred embodiment "is rarely, if ever, correct and would

require highly persuasive evidentiary support.” *Vitronics Corp. v. Conceptiontronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996). Defendant’s reliance on claim 1’s table showing approximate dissolution rates (none of which show 100% dissolution in 12 hours) and expert opinion provided in the earlier *KV* litigation are not so “highly persuasive” as to cause the Court to adopt Defendant’s construction.

**E. “are made up of”**

1. Plaintiffs’ Proposed Construction: “comprise”
2. Defendant’s Proposed Construction: “consisting of”
3. Court’s Construction: “comprise”

The term “are made up of” is not a commonly used transitional phrase in patent claims. (See D.I. 36 at 13; D.I. 38 at 13; D.I. 45 at 11) In the context of the patent-in-suit, Plaintiffs contend the term is open (“comprising”) while Defendant counters that it is closed (“consisting of”). As Plaintiffs point out, the patentee used the terms “made up of” and “comprising” interchangeably, as is evident from the fact that in places in which the original claims use the term “comprising” the amended claims use the term “are made up of.” (See D.I. 36 at 14) Plaintiffs also cite various cases supporting their construction. See *Nat’l Prods., Inc. v. Palmetto W. Trading Co.*, 2006 WL 1207895, at \*5 (W.D. Wash. 2006) (“‘Comprising’ is an open-ended term which creates a presumption that the invention is made up of at least as many elements as described.”); *Nikon Corp. v. ASM Lithography B.V.*, 308 F. Supp. 2d 1039, 1103 (N.D. Cal. 2004) (“‘[C]omprise’ denotes something akin to ‘included in,’ ‘made up of,’ or ‘constituting.’”). Defendant neither distinguishes these cases nor provides persuasive contrary authority. (See D.I.

36 at 15; Tr. at 28)

Defendant cites the fact that claim 1 already uses the word “comprising,” so the patentee’s use of “made up of” must be intended to mean something different than “comprising.” (See D.I. 45 at 13) There are, however, exceptions to this general norm, and the Court finds such an exception here. See generally *BigBand Networks, Inc. v. Imagine Commc’n, Inc.*, 2010 WL 2898288 (D. Del. 2011); Tr. at 30-31. Likewise, Defendant’s prosecution history arguments are unavailing, particularly as Defendant does not contend that changing the transitional phrase was necessary for allowance of claim 1 (see Tr. at 65) and adopting Plaintiffs’ construction will not run afoul of the Examiner’s reasons for allowance (given the Court’s agreement to adopt Defendant’s “separate and distinct” limitation). (Tr. at 65-66)

**F. “the total amount of methylphenidate hydrochloride present is about 10 to 40 mg”**

1. Plaintiffs’ Proposed Construction: The term “about” should be given its ordinary and customary meaning of “approximately.” Accordingly, the phrase should be construed to mean “the total amount of methylphenidate hydrochloride present is approximately 10 to 40 mg”
2. Defendant’s Proposed Construction: “the total amount of methylphenidate hydrochloride present is between the specific amounts of 10 to 40 mg”
3. Court’s Construction: “the total amount of methylphenidate hydrochloride present is approximately 10 to 40 mg”

Defendant agreed at the hearing that “‘about’ and ‘approximately’ do mean about the same thing.” (Tr. at 35) Defendant further conceded that adopting this construction does not raise a concern Defendant might otherwise have that the Examiner’s reasons for allowance are being contradicted. (Tr. at 38) In the earlier litigation, Judge Farnan construed “approximately”

to be “about.” *See KV Pharm.*, 2009 WL 2524519, at \*6. The Court reaches the same conclusion on this occasion.

**G. “the immediate release beads are present in an amount of about 20 to 40 percent and the extended release beads are present in an amount of about 60 to 80 percent”**

1. Plaintiffs’ Proposed Construction: the term “about” should be given its ordinary and customary meaning of “approximately.” Accordingly, the phrase should be construed to mean: “the immediate release beads are present in an amount of approximately 20 to 40 percent and the extended release beads are present in an amount of approximately 60 to 80 percent.”
2. Defendant’s Proposed Construction: “the immediate release beads are present between the specific amounts of 20 to 40 percent and the extended release beads are present between the specific amounts of 60 to 80 percent”
3. Court’s Construction: “the immediate release beads are present in an amount of approximately 20 to 40 percent and the extended release beads are present in an amount of approximately 60 to 80 percent”

The issue is the same as with the previous term and the Court’s resolution is the same as well. (*See Tr.* at 35, 38)

**H. “when the immediate release and the extended release beads are mixed in the amounts shown in the following table”**

1. Plaintiffs’ Proposed Construction: No construction necessary; or, alternatively, “when the immediate release and the extended release beads are combined in the amounts shown in the following table”
2. Defendant’s Proposed Construction: “immediate release beads and extended release beads are mixed together in the amounts shown in the table”
3. Court’s Construction: No construction necessary

The parties' dispute is essentially whether to construe the claim term "mixed" as "combined," as Plaintiffs propose, or as "mixed together," as Defendant requests. At the hearing, Defendant stated that it does not oppose giving "mixed" its plain and ordinary meaning, so long as it is clear "whether we require two separate structures for the two IR and ER beads." (Tr. at 67) Because the Court has made this clear through its construction of bead (by including Defendant's proposed "separate and distinct" limitation), the parties' dispute regarding "mixed" has been resolved without the need to construe the term "mixed" itself.

**I. "the mixed beads"**

1. Plaintiffs' Proposed Construction: "the combined beads"
2. Defendant's Proposed Construction: "a mixture of immediate release methylphenidate-containing beads and extended release methylphenidate-containing beads"
3. Court's Construction: no construction necessary

Again, because the Court has construed "bead" to include Defendant's proposed "separate and distinct" limitation, there is no longer a dispute concerning "the mixed beads" that requires a construction.

**V. CONCLUSION**

The Court will enter an appropriate Order consistent with this Memorandum Opinion.

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

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UCB, INC. and	:	
UCB MANUFACTURING, INC.,	:	
	:	
Plaintiffs,	:	
	:	
v.	:	C.A. No. 12-463-LPS
	:	
MALLINCKRODT INC.,	:	
	:	
Defendant.	:	

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**ORDER**

At Wilmington this 25th day of July, 2013:

For the reasons set forth in the Memorandum Opinion issued this same date,

IT IS HEREBY ORDERED that

1. The Court adopts the following constructions of U.S. Patent No. 6,344,215 (“the ’215 patent”) as agreed upon by the parties:

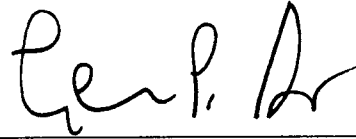
- a. The term “**water**,” as used in claim 1, means “purified water (per USP).”
- b. The term “**an amount up to 20 percent**,” as used in claim 1, means “an amount up to 20 percent by weight based on the total weight of the coated particle.”
- c. The term “**approximately**,” as used in claim 1, requires no construction.

2. The disputed terms of the ’215 patent are construed as follows:

- a. The term “**a modified release methylphenidate hydrochloride capsule comprising immediate release (IR) and extended release (ER) methylphenidate containing beads,**” as used in claim 1, means “a modified release methylphenidate hydrochloride capsule comprising both immediate release (IR) and extended release (ER) methylphenidate-containing beads.”
- b. The term “**bead,**” as used in claim 1, means “a separate and distinct structure containing a core particle coated with one or more layers.”
- c. The term “**immediate release bead,**” as used in claim 1, means “a bead that delivers a portion of the total amount of methylphenidate for rapid onset of action.”
- d. The term “**extended release bead,**” as used in claim 1, means “a bead that delivers a portion of the total amount of methylphenidate in a controlled manner over an extended period of time.”
- e. The term “**are made up of,**” as used in claim 1, means “comprise.”
- f. The term “**the total amount of methylphenidate hydrochloride present is about 10 to 40 mg,**” as used in claim 1, means “the total amount of methylphenidate hydrochloride present is approximately 10 to 40 mg.”
- g. The term “**the immediate release beads are present in an amount of about 20 to 40 percent and the extended release beads are present in an amount of about 60 to 80 percent,**” as used in claim 1, means “the immediate release beads are present in an amount of approximately 20 to 40 percent and the extended release beads are present in an amount of approximately 60 to 80 percent.”

h. The term “**when the immediate release and the extended release beads are mixed in the amounts shown in the following table,**” as used in claim 1, does not need to be construed.

i. The term “**the mixed beads,**” as used in claim 1, does not need to be construed.

A handwritten signature in black ink, appearing to read "L. P. Dr.", is written above a horizontal line.

UNITED STATES DISTRICT JUDGE