UCB Inc. et al v. KV Pharmaceutical Company Doc. 93

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UCB, INC. and CELLTECH MANUFACTURING CA, INC.,	:	
Plaintiff,	:	
v.	:	Civil Action No. 08-223-JJF
KV PHARMACEUTICAL COMPANY,	:	
Defendant.	:	

Robert L. Baechtold, Esquire; Scott K. Reed, Esquire; Steven C. Kline, Esquire and Ha Kung Wong, Esquire of FITZPATRICK, CELLA, HARPER & SCINTO, New York, New York.
Jack B. Blumenfeld, Esquire and Karen Jacobs Louden, Esquire of MORRIS, NICHOLS, ARSHT & TUNNELL LLP, Wilmington, Delaware.
Attorneys for Plaintiffs.

Richard L. DeLucia, Esquire; Charles A. Weiss, Esquire and Robert F. Broom, Esquire of KEYNYON & KENYON LLP, New York, New York.
Frederick L. Cottrell, III, Esquire; Chad M. Shandler, Esquire and Laura D. Hatcher, Esquire of RICHARDS, LAYTON & FINGER, P.A., Wilmington, Delaware.
Attorneys for Defendant.

MEMORANDUM OPINION

August 18, 2009
Wilmington, Delaware

Dockets.Justia.com

Joseph J. Farnan Jr.
Farnan, District Judge.

This is a patent infringement case brought by UCB, Inc. and Celltech Manufacturing CA, Inc. against KV Pharmaceutical Company alleging infringement of U.S. Patent No. 6,344,215 ("the '215 patent"), which pertains to pharmaceutical dosage forms that provide a modified release of methlyphenidate for the treatment of attention deficit hyperactivity disorder ("ADHD"). The parties briefed their respective positions on claim construction, and the Court conducted a Markman hearing on the disputed terms. This Memorandum Opinion provides constructions for the disputed terms.

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.

DISCUSSION

I. The Legal Principles Of Claim Construction

Claim construction is a question of law. Markman v. Westview Instruments, Inc., 52 F.3d 967, 977-78 (Fed. Cir. 1995), aff'd, 517 U.S. 370, 388-90 (1996). When construing the claims of a patent, a court considers the literal language of the claim, the patent specification and the prosecution history. Markman, 52 F.3d at 979. Of these sources, the specification is "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 v. AWH Corporation, 415 F.3d 1303, 1312-17 (Fed. Cir. 2005) (citing Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)). However, "[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) (quoting Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1327 (Fed. Cir. 2002)).

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

In addition to these fundamental claim construction principles, a court should also interpret the language in a claim by applying the ordinary and accustomed meaning of the words in the claim. Envirotech Corp. v. Al George, Inc., 730 F.2d 753, 759 (Fed. Cir. 1984). If the patent inventor clearly supplies a different meaning, however, then the claim should be interpreted according to the meaning supplied by the inventor. Markman, 52 F.3d at 980 (noting that patentee is free to be his own lexicographer, but emphasizing that any special definitions given

to words must be clearly set forth in patent). If possible, claims should be construed to uphold validity. In re Yamamoto, 740 F.2d 1569, 1571 (Fed. Cir. 1984).

II. The Meaning of the Disputed Terms

Below is the sole independent claim from the '215 patent, with the disputed terms emphasized:

> 1. 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:

Time, hours	(20 IR/80 ER Beads)	(30 IR/70 ER Beads)	(40 IR/60 ER Beads)	(30 IR/70 ER Beads)	(30 IR/70 ER Beads)
0.0	0.0	0.0	0.0	0.0	0.0
1.0	24.5%	31.6%	42.1%	33.4%	41.3%
2.0	29.8%	37.4%	48.3%	44.9%	50.9%
4.0	57.8%	59.0%	66.3%	66.2%	69.6%
8.0	79.2%	76.3%	83.5%	87.1%	89.2%
12.0	89.1%	84.6%	88.2%	97.1%	98.0%

An exemplary dependent claim from the '215 patent is below, again with the disputed term emphasized:

> 6. The capsule of claim 5 wherein the immediate release and extended release beads are further coated with a seal coat in **an amount up to about 4%**.

The parties have two core disputes. First, the parties dispute the meaning of the claim terms "approximately" and "about." Briefly, Defendant wishes to construe these terms in a narrow fashion such that the scope of whatever quantity they modify is limited. However, Defendant does not go so far as to associate these terms with precise numerical boundaries. Rather, it proposes that "about" be understood to refer to "rounding" or "measurement error," and that "approximately" be construed as "almost exactly." Plaintiffs, on the other hand, contend the term "about" should be understood more broadly to simply mean "approximately" and, similarly, that the claim term "approximately" requires no construction.

Second, Defendant contends that certain claim terms are indefinite. Specifically, Defendant maintains (1) that claim terms referring to the percentages of certain components in the beads are indefinite for failing to specify the basis of the percentage, and (2) that the final clause of Claim 1 is indefinite because it calls for a single ratio of IR and ER beads to yield two different dissolution profiles, which is allegedly impossible.

For the reasons that follow, the Court construes the disputed terms as follows:

A. "The Total Amount of Methylphenidate Hydrochloride Present Is About 10 To 40 mg"

Plaintiffs' Construction	Defendant's Construction
The term "about" should be given its ordinary and customary meaning of "approximately."	The total amount of methylphenidate hydrochloride present is very close to 10 to 40 mg (due to rounding or within measurement error).

The parties dispute the level of precision that the Court should impute to the word "about." Plaintiffs contends that the term "about" should be defined simply as "approximately," while Defendant contends that it should be understood more stringently as requiring precision within "rounding" or "measurement error."

Although the specification explains that "[a] typical dose is expected to be from about 10 to 40 mg of active drug," ('215 patent at 2:60-61), Defendant acknowledges that "nowhere else in the specification is the term 'about' used in conjunction with the amount of drug." (D.I. 40 at 13.) Thus, in support of their proposed construction, Defendant contends that "every description of the total dose of methylphenidate hydrochloride is from 10 mg to 40 mg and stated in 5 mg or 10 mg increments," which, according to Defendant, "shows that the variance permitted by the word 'about' must be less than the 5 mg increments in dosages shown in the specification." This, Defendant contends, further confirms that "the total amount of methylphenidate hydrochloride in the claimed capsule is limited to being very close to 10 to 40

mg with the variations outside that range due to rounding or within measurement error." (D.I. 40 at 13-14.) In addition, Defendant notes that although Plaintiff UCB listed the '215 patent in the Orange Book for 10, 20, 30, and 40 mg dosage forms,[1] it did not do so for the 50 and 60 mg dosage forms. This, Defendant contends, demonstrates that "a claim of patent infringement cannot reasonably be asserted against the 50 and 60 mg dosage strengths" and, as such, that the Court should adopt Defendant's proposed construction to preclude Plaintiffs from making such an infringement allegation. Defendant further notes that the "about 10 to 40 mg" limitation was added during prosecution in response to an examiner rejection, and that this also confirms that the claims cannot be understood to reach a 50 mg dosage form.

Plaintiff responds that the plain and ordinary meaning of the word "about" is "approximately" and that there is nothing in the specification that would alter this understanding. With regard to Defendant's position that the specification, by providing examples of dosage strengths separated by only 5 mg,

---

[1] Under the Hatch-Waxman statutory scheme for the approval of new and generic drugs, a pioneer drug manufacturer that has had its drug approved by the FDA must notify the FDA of all patents it owns "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). These patents are listed in an FDA publication commonly referred to as the "Orange Book."

distinguishes dosage forms that differ in strengths by 5 mg, Plaintiffs contend that the exemplary dosage strengths in the patent "provide no support for [Defendant's] position that "about 10 to 40 mg" must be defined to mean "very close to 10 to 40 mg with variations outside that range due to rounding or within measurement error." (D.I. 50 at 6.) As to Defendant's reliance on the prosecution history, Plaintiff contends that during prosecution there was no discussion of the word "about" and that, in these circumstances, there was no "clear and unmistakable" disavowal of claim scope or intention to otherwise limit the meaning of the word "about." (Id. at 4-5.) Finally, with regard to the fact that Plaintiff UCB declined to list the '215 patent in the Orange Book for the 50 and 60 mg dosage forms, Plaintiffs note that the failure to list a patent in the Orange Book does not foreclose its assertion against a generic and that, in any event, this is extrinsic evidence that has little bearing on how the term "about" should be construed.

"The word 'about' does not have a universal meaning in patent claims, and . . . the meaning depends on the technological facts of the particular case." Pall Corp. v. Micron Separations, 66 F.3d 1211, 1217 (Fed. Cir. 1995). "The use of the word 'about,' avoids a strict numerical boundary to the specified parameter. Its range must be interpreted in its technologic and stylistic context." Id. Courts should "thus consider how the

term . . . was used in the patent specification, the prosecution history, and other claims. It is appropriate to consider the effects of varying that parameter, for the inventor's intended meaning is relevant. Extrinsic evidence of meaning and usage in the art may be helpful in determining the criticality of the parameter, and may be received from the inventor and others skilled in the field of the invention." Id.

Instructive here is the recent Federal Circuit decision Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Labs., Ltd., 476 F.3d 1321, 1327-28 (Fed. Cir. 2007). In Ortho-McNeil, the Federal Circuit affirmed a district court's "narrow" construction of the term "about 1:5" as encompassing a range of ratios "no greater than 1:3.6 to 1:7.1." In so doing, the Federal Circuit noted a number of evidentiary hallmarks that supported the narrow construction, including (1) a "dichotomy" between the claimed ratio and broader ratios in other claims, (2) passages in the specification suggesting a narrow interpretation of "about" so as to avoid rendering similar ratios in other claims meaningless (3) language in the specification referring to ratios similar to the claimed ratio, and (4) expert witness testimony regarding statistical data in the patent that supported the narrow construction. Id.

The type of evidentiary hallmarks that supported a narrow construction of "about" in Ortho-Mcneil do not appear to be

prevalent here. For instance, only one claim in the '215 patent refers to the claimed dosage range of "about 10 to 40 mg" of methylphenidate. Thus, there are no differences among claims that suggest a narrow interpretation of the word "about," and, similarly, there is no danger of rendering claim limitations meaningless through a broad construction of "about."

With regard to the specification, as the parties note, the 10 to 40 mg methylphenidate dosage range is referred to only once, and there is no discussion of alternative dosage ranges to suggest that the 10 to 40 mg dosage range should be understood narrowly. Although, as Defendant notes, the specification describes various exemplary dosage strengths within the 10 to 40 mg dosage range (i.e., 10 mg, 20 mg, 25 mg, and 30 mg), the Court sees nothing about these particular examples suggesting that the endpoints of the 10 to 40 mg dosage range should be limited in terms of "measurement error" or "rounding error," as Defendant requests. To the extent this evidence suggests a distinction among dosage forms that differ in strength by 5 mg, Defendant has not proposed a construction that meaningfully incorporates this concept. Defendant has not, for instance, proposed that the end points of the claimed dosage range have error bars of ±2.5 mg. Likewise, with regard to extrinsic evidence, though Defendant notes that Plaintiff UCB declined to list the '215 patent in the Orange Book for the 50 and 60 mg dosage forms, Defendant fails to

specifically explain how this supports their proposal to define the term "about" as referring to "measurement error." At most, this evidence perhaps suggests that the term "about 10 to 40 mg" should not be understood to encompass 50 and 60 mg, which may, in turn, suggest an error bar of ±5 mg. But Defendant does not propose a construction along these lines either. Similarly, although the limitation "about 10 to 40 mg" was added to the claims during prosecution in response to a rejection, Defendant has not meaningfully explained how this calls for construing the term "about" in terms of "measurement error." In short, in the Court's view, there is a significant disconnect between the evidence relied upon by Defendant and its proposed construction.

Although, in circumstances such as these, the Court may reject the parties' proposed constructions and formulate its own construction, the Court concludes that it would not be responsible to do so here. Because Defendant has not proposed constructions that genuinely reflect the evidence it relies upon, the parties have not, through their claim construction arguments, provided the Court with the necessary "technological facts" and "technologic and stylistic context" to confidently adopt any alternative construction of "about," including, for instance, constructions with specific numerical error bars. See Pall Corp., 66 F.3d at 1217. For instance, the factual record regarding Plaintiff's decision not to list the '215 patent in the

Orange Book for the 50 and 60 mg dosage remains almost entirely undeveloped. Likewise, unlike Ortho-McNeil, where expert interpretation of statistical data in the specification bolstered a narrow construction of "about," Defendant provides no such expert witness testimony explaining how one of skill in the art would understand the specification's description of 10 mg, 20 mg, 25 mg, and 30 mg dosage strengths may limit the claims, if at all.

In these circumstances, the Court concludes that, in the claim term "about 10 to 40 mg," the word "about" should simply be construed to mean "approximately." See Merck & Co. v. Teva Pharms. USA, Inc., 395 F.3d 1364, 1372 (Fed. Cir. 2005) (where, inter alia, "the patentee did not clearly redefine 'about' in the specification," holding "that the term 'about' should be given its ordinary and accepted meaning of 'approximately.'"); Unigene Labs., Inc. v. Apotex Inc., No. 06 CV. 5571 (RPP), 2008 U.S. Dist. LEXIS 66005, at *26-*27 (S.D.N.Y. Aug. 28, 2008) ("Without evidence, either intrinsic or extrinsic, that would provide a basis for construing the numerical limits of the term 'about 20 mM citric acid' in claim 19 of the '392 patent, the Court gives the word 'about' its ordinary meaning of 'approximately' and construes the claim term no further."). Accordingly, the Court will construe the claim term "the total amount of methylphenidate hydrochloride present is about 10 to 40 mg" to mean, as

Plaintiffs contend, "the total amount of methylphenidate hydrochloride present is approximately 10 to 40 mg."

Noting that the word "approximately" is a claim term, Defendant, citing Helmsderfer v. Bobrick Washroom Equipment, Inc., 527 F.3d 1379, 1382 (Fed. Cir. 2008), contends that this construction is inappropriate because it improperly gives two different claim terms (i.e., "about" and "approximately") the same meaning. See Helmsderfer, 527 F.3d at 1382 ("[P]recedent instructs that different claim terms are presumed to have different meanings . . . ."). However, notwithstanding this consideration, without a more concrete basis for either Defendant's construction or some alternative construction of "about," the most appropriate construction of "about" is simply "its ordinary and accepted meaning of 'approximately'." Merck, 395 F.3d at 1372.

B. "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"

Plaintiffs' Construction	Defendant's Construction
The term "about" should be given its ordinary and customary meaning of "approximately."	The immediate release beads are present in an amount very close to 20 to 40 percent (due to rounding or within measurement error) and the extended release beads are present in an amount very close to 60 to 80 percent (due to rounding or within measurement error).

The parties' dispute over this term parallels their dispute over the claim term discussed immediately above (i.e., "about 10 to 40 mg"). The legal principles governing the construction of that claim term apply to this claim term as well.

In support of their proposed construction, Defendant notes, first, that during prosecution the claims were amended to (1) narrow the allowed range of IR beads from 10 to 50% to only "about" 20 to 40% and (2) narrow the allowed range of ER beads from 50 to 90% to "about" 60 to 80%. (D.I. 40 at 17-18.) Defendant urges the Court to adopt a construction that precludes Plaintiffs from recapturing the specific territory surrendered during prosecution. Defendant further notes that, among other examples, the specification recites (1) an example where the dosage form comprises 30% IR beads and 70% ER beads and (2) an example where the dosage form comprises 40% IR beads and 60% ER

beads.[2] Based on this, Defendant argues that "if 'about' were to be construed to allow the ratio to vary by even five percentage points, then the patent's recitals of testing mixtures of 30 IR/70 ER and 40 IR/60 ER would be hopelessly conflicting . . . ." (Id. at 18.)

In response, Plaintiffs contend that there is nothing in the specification that defines the term "about," imposes a precise numerical limitation, or describes "the invention in terms of being 'very close to' a percentage of IR/ER Beads . . . 'due to rounding or within measurement error'." (D.I. 38 at 12.) As to the prosecution history, Plaintiffs contend that it contains nothing that would limit the scope of the term "about." At most, Plaintiffs contend, the prosecution history would prevent them from asserting the claims against a dosage form containing 10% IR/90% ER beads or 50% IR/50% ER beads (i.e., the limitation of the original, unamended claims), something that Plaintiff states they do not intend to do anyhow. (D.I. 50 at 5.)

As above, the Court concludes that there is a disconnect between Defendant's proposed construction and the evidence it cites in support of its construction. Put another way, the Court agrees with Defendant that there is nothing in the specification that describes "the invention in terms of being 'very close to' a

[2] In this regard, the Court further notes that the claims themselves refer to "20 IR/80 ER," "30 IR/70 ER," and "40 IR/60 ER" dosage forms.

percentage of IR/ER Beads . . . 'due to rounding or within measurement error'." (D.I. 38 at 12.) To the extent the claims and specification distinguish between dosage forms having, for instance, "20 IR/80 ER" and "30 IR/70 ER," this suggests that the word "about," when used in connection with the relative amounts of IR and ER beads, should offer enough precision to prevent such dosage forms from overlapping. Similarly, the narrowing during prosecution of the allowed range of IR beads from 10 to 50% to only 20 to 40% suggests, for instance, that the word "about" should offer enough precision to prevent "about" 20% from encompassing 10%. However, as above, Defendants do not appear to offer a construction that is genuinely focused on meeting these objectives. In these circumstances, the Court is again left without the proper "technological facts" and "technologic and stylistic context" to confidently adopt any alternative construction of its own. See Pall Corp., 66 F.3d at 1217. The Court will thus give the term "about" its ordinary and customary meaning of "approximately." Accordingly, the Court will construe the claim 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" to mean, as Plaintiffs contend, "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."

C. "Approximately"

Plaintiffs' Construction	**Defendant's Construction**
No construction necessary.	Almost exactly.

Pointing to a definition from the American Heritage College Dictionary 67 (3d ed. 2000), Defendant contends that the term "approximately" should be given its "plain and ordinary meaning" of "almost exactly." (D.I. 40 at 22.) Defendant further notes that in Claim 1 the dissolution results are reported to a tenth of a percentage point, a consideration that supposedly militates in favor of a narrow construction for "approximately." (Id. at 22-23.)

Again, there is a significant disconnect between the intrinsic evidence relied upon by Defendant and its proposed construction. Specifically, although Claim 1 reports dissolution results to the nearest tenth of a percentage, the Court fails to see how this compels a construction for "approximately" of "almost exactly." Though Defendant's extrinsic dictionary definition clearly supports such a construction, without some meaningful corresponding basis for it in the intrinsic record, the Court will not paraphrase the ordinary word "approximately" as "almost exactly." Indeed, the Court sees no reason to believe

that the American Heritage College Dictionary is particularly authoritative in the pharmaceutical sciences, or that the definition of "almost exactly" is particularly well accepted. In this regard, the Court notes that the Merriam-Webster's Online Dictionary – a resource that litigants in this Court are, unfortunately, all too familiar with – defines "approximate" to simply be "located close together," a much broader definition than "almost exactly." Accordingly, the Court agrees with Plaintiffs that the no further construction is warranted for the term "approximately."

D. "Water"

Plaintiffs' Construction	**Defendant's Construction**
No construction necessary.	Purified water (per the USP).

The dispute between the parties is whether the term "water" should be limited to "purified water" (Defendant's position) or not (Plaintiffs' position). In support of its proposed construction, Defendant notes that the Claim 1 explains that the dissolution results reported therein were obtained "using USP apparatus 2 at 50 rpm in 500 ml water," '215 patent at 7:50-51, and that the USP provides that "where 'water,' without qualification, is mentioned in the tests for reagents or in directions for preparing test solutions, etc. Purified Water (USP

monograph) is always to be used."[3] (D.I. 41, Exh. F at 2166 (emphasis in original.)) Plaintiffs respond that the meaning of "water" is readily apparent and that there is no basis to import limitations from the USP into the claims. (See D.I. 50 at 9.)

The Court agrees with Defendant that because the claim specifically requires that testing be done in a USP apparatus, it is appropriate to construe the claim term "water" in terms of the definition set forth in the USP. As to Plaintiffs' objection that this is an improper importation of a limitation from the extrinsic record, the Court concludes that because the claim itself calls for the testing to be done in a USP apparatus, this construction does not reflect importation of limitations from the extrinsic record, but is a limitation compelled by the claim language. Accordingly, the Court will construe the term "water" to mean, as Defendant contends, "purified water (per the USP)."

[3] The U.S. Pharmacopoeia-National Formulary ("USP") is the official compendium of standards for drugs marketed in the United States and sets forth a set of approved dissolution apparatuses. See 21 U.S.C. § 321(j).

E. "An Amount Up To 20 Percent" And "An Amount Up TO About 4%"

Plaintiffs' Construction	Defendant's Construction
The claim terms refer to weight percentages based on the total weight of the coated particle.	These terms are indefinite.

Independent Claim 1 of the '215 patent calls for the ER beads to be "coated with a dissolution rate controlling polymer in an amount up to 20 percent . . . ." '215 patent at 7:43-47. Dependent Claim 6 of the '215 patent recites that both the IR and ER beads are "coated with a seal coat in an amount up to about 4%." The dispute between the parties is whether these claim terms are indefinite. Defendant contends that they are because the claims fail to specify (1) the basis of the percentages, and (2) whether the percentages are based on volume, weight, etc. (See D.I. 40 at 26-27.) Plaintiffs respond that the specification confirms that the percentages are weight

percentages based on the total weight of the coated particle.[4] (See D.I. 50 at 16.)

"If the meaning of the claim is discernible, even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree, [the Federal Circuit has] held the claim sufficiently clear to avoid invalidity on indefiniteness grounds." Exxon Res. & Eng'g Co. v. United States, 265 F.3d 1371, 1375 (Fed. Cir. 2001). "A claim will be found indefinite only if it 'is insolubly ambiguous, and no narrowing construction can properly be adopted . . . .'" Praxair, Inc. v. ATMI, Inc., 543 F.3d 1306, 1319 (Fed. Cir. 2008) (quoting Exxon, 265 F.3d at 1375). Thus, Defendant faces a difficult task in establishing by clear and convincing evidence that these claim terms are indefinite.

With regard to the "dissolution rate controlling polymer" limitation of Claim 1, the specification explains that "[g]enerally, the dissolution rate controlling polymeric coatings

---

[4] Plaintiffs further argue that it is inappropriate for the Court to consider whether the claims are invalid due to indefiniteness during the claim construction phrase. However, the Court may indeed consider indefiniteness during claim construction. See Praxair, Inc. v. ATMI, Inc., 543 F.3d 1306, 1319 (Fed. Cir. 2008) ("Indefiniteness is a matter of claim construction, and the same principles that generally govern claim construction are applicable to determining whether allegedly indefinite claim language is subject to construction."); Datamize, LLC v. Plumtree Software, Inc., 417 F.3d 1342, 1348 (Fed. Cir. 2005) ("In the face of an allegation of indefiniteness, general principles of claim construction apply.").

on the active core particle vary from 5 to 25%, preferably from 5 to 20% and more preferably from 5 to 10% by weight based on the total weight of the coated particle, depending on the coating materials and solvents selected. '215 patent at 3:1-6 (emphasis added). Thus, the specification explains clearly that the percentage is a weight percent based on the total weight of the coated particle. Nevertheless, Defendant contends that it is unclear whether the language "depending on the coating materials and solvents selected" modifies the basis of the percentage or the percentage ranges, and that this uncertainty leaves the claim indefinite. (See D.I. 40 at 28-29.) In the Court's view, Defendant is grasping at straws. Defendant does not offer any explanation as to why the basis of the percentage should change depending on the coating materials and solvents that are used. Nor can the Court see any such reason. The only reasonable interpretation of this clause is that it modifies the percentage ranges. Accordingly, the Court will construe the claim term "an amount up to 20 percent" to mean, as Plaintiffs contend, "an amount up to 20 percent by weight based on the total weight of the coated particle."

As to the "seal coat" limitation of Claim 6, the specification explains that "[t]he drug layered beads are provided with up to 4%, preferably up to 2% w/w seal coat . . . ." '215 patent at 2:39-42. Referring to the percentages as

"w/w," the specification again confirms that the percentages are weight percentages. However, Defendant contends that this portion of the specification may actually be referring to the concentration of the seal coating and that, accordingly, "perhaps the Claim Six is talking about the concentration of the coating being applied and not actually the amount being applied." (D.I. 73 at 69:4-7.) However, Claim 6 states in full: "The capsule of Claim 5 where in the immediate release and extended release beads are further coated with a seal coat in an amount up to about 4%." '215 patent at 8:39-41 (emphasis added). Thus, the claim does not refer to the concentration of the seal coat, but, contrary to Defendant's contention, explicitly requires that the beads have a seal coat in an "amount" up to about 4%. Accordingly, consistent with the Court's construction for "an amount up to 20 percent," the Court will construe the term "an amount up to about 4%" to mean, as Defendant contends, "an amount up to about 4% by weight based on the total weight of the coated particle."

F. Whether Claim 1 Is Invalid For Requiring Identical Combinations Of IR And ER Beads To Have Different Dissolution Profiles

Defendant notes that Claim 1 of the '215 patent contains two columns providing different dissolution profiles that are both for "30 IR/70 ER Beads" and two columns providing different dissolution profiles that are both for "40 IR/60 ER Beads." In these circumstances, Defendant contends that "Claim 1 requires

the impossible - that identical formulations release different amounts of methylphenidate." According to Defendant, this renders Claim 1 invalid as indefinite, not enabled, and lacking utility.

In support of this position, Defendant relies mainly on the Federal Circuit decision Process Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1357 (Fed. Cir. 1999). In Process Control, the claim at issue recited the term "discharge rate" twice. However, giving both instances of this term the same meaning would, the parties agreed, lead to a nonsensical conclusion. Process Control, 199 F.3d at 1359. Nevertheless, because the claim, as written by the patentee, was susceptible to only one meaning, the Federal Circuit construed both instances of the term "discharge rate" identically and held that the claim was invalid. In so holding, the Federal Circuit explained that "when an impossible limitation, such as a nonsensical method of operation, is clearly embodied within the claim, the claimed invention must be held invalid." Id. The Federal Circuit further explained that the claims were invalid as indefinite because the problem was not that the "clarity of the claim language prevent[ed] one skilled in the art from determining the scope of the claim." Id. at 1358 n.2. Rather, because the correctly construed claims were inoperative, the Federal Circuit invalidated the claims for lack of utility and enablement. Id. at 1359.

The Court agrees with Defendant that the instant case presents a situation similar to Process Control. As in Process Control, the issue here is not the clarity of the claim language. Although, for a particular ratio of IR to ER beads, Claim 1 of the '215 patent presents two infringing dissolution profiles, there is no indication that one of skill in the art would have trouble interpreting these dissolution profiles and thus determining the scope of the claims. Rather, the issue here is, as Defendant contends, whether Claim 1 of the '215 patent is inoperative as calling for the impossible. Accordingly, as in Process Control, if the claim is invalid, it will be so under the doctrines of either utility or enablement, not indefiniteness.

"Utility is a factual issue . . . ." Id. Similarly, "[w]hether a disclosure is enabling under 35 U.S.C. § 112, ¶ 1 is a legal conclusion, based upon underlying factual inquiries . . . ." Id. Given the factual underpinnings of both of these doctrines, the Court is unable to conclude at this early stage in the litigation - within the context of claim construction - that Claim 1 of the '215 patent is invalid as a matter of law due to either lack of utility or enablement. The Court thus reserves decision on both of these issues.

CONCLUSION

For the reasons discussed, the Court has construed the disputed terms and/or phrases of the '215 patent as provided

herein. An Order consistent with this Memorandum Opinion will be entered setting forth the meanings of the disputed terms and/or phrases in the patents-in-suit.