

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

MYLAN PHARMACEUTICALS, INC., <i>et al.</i> ,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. 02-1628-GMS
)	
KREMERS URBAN DEVELOPMENT CO., <i>et al.</i> ,)	
)	
Defendants.)	
)	

MEMORANDUM

I. INTRODUCTION

On November 2, 2002, plaintiff, Mylan Pharmaceuticals Inc. (“Mylan”), filed the above-captioned action alleging infringement of U.S. Patent No. 5,626,875 (“the ‘875 patent”) and tortious interference by the defendants, Kremers Urban Development Company, Schwartz Pharma, Inc., Schwartz Pharma Manufacturing, Inc., Schwartz Pharma USA Holdings, Inc. and Kremers Urban, Inc. (collectively “Kremers”).

On October 14, 2003, after considering the parties’ submissions and conducting a *Markman* hearing, the court issued an Order construing the disputed claims of the ‘875 patent. (D.I. 101). Presently before the court is Kremers’ Motion to Alter or Amend and for Re-argument Regarding Claim Construction of the Phrase “An Inert Core.” For the following reasons, the court will deny this motion.

II. BACKGROUND

The ‘875 patent is entitled, “Stabilized Galenic Formulations Comprising an Acid Labile Benzimidazole Compound and its Preparation.” In general, the claims of the ‘875 patent are related to a stable oral pharmaceutical formulation which does not include the alkaline compounds included

in the prior art. Initially, the parties disputed the construction of three claim limitations. Now, Kremers has moved for reconsideration of the court's construction of one of those limitations. The relevant claim language reads in columns 5 and 6:

A stable oral pharmaceutical preparation . . . , which consists essentially of :
(a) a nucleus formed by an inert core,

In its October 14, 2003 Order, the court construed “an inert core” to mean “one or more pharmaceutically inert seeds used to provide a starting material for the preparation of a pharmaceutical.” The court based this construction on intrinsic evidence, in particular, the claims themselves and the specification. The ‘875 specification gives a cursory description of the “inert core” limitation in both the “Outline of the Invention” and “Detailed Description of the Invention” sections. Nothing in the prosecution history is directly relevant to the construction of the “inert core” claim term.

The term “core” is recited in the specification three times, twice in its singular form and once in its plural form. The “Outline of the Invention” section first mentions a singular “inert sugar/starch spherical core” while characterizing the invention and its active and isolation layers. (‘875 patent, col. 2, l. 13). The second reference to “core” states that “[t]he core, the process conditions and the excipients have been selected in order to obtain the required coating efficiency for each layer.” *Id.* at ll. 20-22. Finally, the “Detailed Description of the Invention” recites the plural, “In a fluidized bed apparatus, uniform spherical inert cores (composition as per US Pharmacopoeia) are coated” *Id.* at l. 35. Subsequently, the remainder of the ‘875 specification, with the two exemplary embodiments provided, recite the word “spheres” instead of “cores.” *Id.* at cols. 2-4. Ostensibly, but not definitively, the plural recitations of “cores,” “spheres” or “pellets” refer to a batch of the formulation; thus, the specification is ambiguous with regard to a plural

construction of “an inert core.” The specification of the ‘875 patent focuses instead on the non-alkaline layers surrounding the inert core which differentiate it from the prior art.

Kremers moves for Reconsideration and/or Re-argument of the court’s construction of the term, “an inert core.” For two reasons, Kremers argues that “an inert core” should be construed as “a single pharmaceutically inert seed used to provide a starting material for the preparation of a pharmaceutical.” First, Kremers asserts the Mylan misled the court during the *Markman* oral argument by suggesting that the ‘875 patent specification discloses multiple cores. Emphatically arguing that “absolutely nowhere in the intrinsic evidence is [there] a disclosure of a pharmaceutical preparation having more than one core,” (D.I. 110 at 3), Kremers bemoans the fact that the court did not allow it a final sur-rebuttal to clarify the alleged misrepresentation made during the final sur-reply by Mylan.

Secondly, Kremers asserts that claims 12 and 13 do not allow for “one or more” inert cores and that the court has therefore made an error of law by construing the limitation as “one or more pharmaceutically inert seeds” Kremers attempts to support this argument with the recent Federal Circuit decision, *Abbott Laboratories v. Baxter Pharma Products Inc.*, 334 F.3d 1274 (Fed. Cir. 2003), which held that a closed transition phrase, e.g. “consisting of,” restricts the construction of a modified article to a singular form. *Id.* at 1281. However, the claims presently at issue do not use the phrase “consisting of,” or any other closed transition phrase. Instead, claim 3 uses the open transition phrase “comprising” and claims 12 and 13 use the partially-open transition phrase “consisting essentially of.” Kremers omits a discussion of this critical difference.

III. STANDARD OF REVIEW

Kremers moves for reconsideration and re-argument pursuant to Fed. R. Civ. P. 59(e) and

Delaware Local Rule 7.1.5. A party bringing a motion to alter or amend an order pursuant to Fed. R. Civ. P. 59(e), must establish one of three grounds in order to prevail: (1) there is an intervening change in controlling law; (2) new evidence has become available; or (3) there is a need to correct the court's clear error of law or fact or to prevent manifest injustice. *N. River Ins. Co. v. CIGNA Reinsurance Co.*, 52 F.3d 1194, 1218 (3d Cir. 1995). Similarly, re-argument is not appropriate under Delaware Local Rule 7.1.5, unless: (1) the court has patently misunderstood a party, (2) the court has made a decision outside the issues presented to the court by the parties, or (3) the court has made an error not of reasoning but of apprehension. *Schering Corp. v. Amgen, Inc.*, 25 F. Supp.2d 293, 295 (D. Del. 1998).

Motions for re-argument “should not re-hash arguments already briefed and decided.” *Id.* at 295. Similarly, motions for reconsideration should be granted sparingly and only in limited circumstances. *BP Amoco Chem. Co. v. Sun Oil Co.*, 200 F. Supp.2d 429, 432 (D. Del. 2002). Indeed, motions for reconsideration or re-argument are not a way for litigants to take a second bite at the apple.

IV. DISCUSSION

The core of an apple typically has one or more seeds. The core of an academic curriculum consists of one or more essential courses. The core of a politician's constituency consists of one or more particularly ardent supporters. Similarly, the core of a pharmaceutical preparation may consist of one or more seeds.

Although the context of a claim term may restrict it to a singular form, “[i]t is well settled that the term ‘a’ or ‘an’ ordinarily means ‘one or more.’” *Tate Access Floors, Inc. v. Interface Architectural Res., Inc.*, 279 F.3d 1357, 1370 (Fed. Cir. 2002). In addition, there is a “heavy

presumption” that the ordinary meaning applies. *Texas Digital Systems, Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1202 (Fed. Cir. 2002). The ordinary meaning of a term is the full range of interpretation reasonable to persons skilled in the art. *Id.* Since, neither the ‘875 specification nor the ‘875 prosecution history unambiguously depart from the ordinary meaning of the term “an inert core,” and since the plural form of “an inert core” does render the claim so ambiguous that there is “no means by which the scope of the claim may be ascertained from the language used,” the court construes the “an inert core” term according to its ordinary meaning. *Bell Atl. Network Servs., Inc. v. Covad Communications Group, Inc.*, 262 F.3d 1258, 1268 (Fed. Cir. 2001).

The court’s construction of the claim term “an inert core” is in accordance with the law. Kremers’ argument that a plural embodiment of “cores” is not disclosed in the specification is irrelevant because the specification does not consistently and unambiguously describe the invention with a single unitary core. Second, a plural construction of the term does not materially affect the basic and novel properties of the invention because the “required coating efficiency” does not specify the exemplary “sugar/starch spheres,” but a combination of cores, process conditions, and excipients that a person of ordinary skill in the art could devise in many different ways. Therefore, the court’s plural construction is reasonable in the context of the ambiguous usage of the plural form in the specification. Finally, contrary to Kremers’ implication, the preamble transition phrase of claims 12 and 13 does not necessarily restrict all subsequent limitations to a singular embodiment because “consisting essentially of” is a partially-open transition phrase, rather than a closed one.

- A. Kremers’ argument that a plural embodiment “cores” is not disclosed in the specification is irrelevant because the specification does not consistently and unambiguously describe the invention with a single unitary core.**

The intrinsic evidence supplies the context for determining whether a claim limitation is limited to a singular construction or is entitled to the full range of ordinary meaning. If the specification discloses a singular embodiment it “does not disclaim a plural embodiment.” *KJC Corp. v. Kinetic Concepts, Inc.* 223 F. 3d 1351, 1356 (Fed. Cir. 2000). Only when the intent of the written description is “clear” will the court accordingly restrict the limitation to a singular embodiment. *Id.* Since the intrinsic evidence is ambiguous regarding a single unitary embodiment of “an inert core,” this limitation should be construed according to the full range of ordinary meaning, which includes the plural embodiment.

B. The plural construction of “an inert core” does not materially affect the basic and novel properties of the invention.

Kremers correctly notes in its Answering Memorandum to Plaintiff’s Claim Construction that it was not possible to overcome the Examiner’s §103 rejection by distinguishing the claimed “inert core” from the prior art. “Accordingly, neither the applicants nor the Examiner addressed the claim limitation “inert core” in the ‘875 patent application.” (D.I. 90 at 6). At the *Markman* hearing the parties argued the “inert core” term through sur-reply and sur-rebuttal. The court finally stopped the parley when it was clear that “an inert core” was not a specially defined term, per the HANDBOOK OF PHARMACEUTICAL EXCIPIENTS, but a concept susceptible to a broad, plain and ordinary, interpretation. *See* Arthur H. Kibbe, Ph. D., HANDBOOK OF PHARMACEUTICAL EXCIPIENTS 548 (3d ed. 2000).

The term “inert core” is a limitation to the claims. In particular, this limitation tells the public that the core must be inert and not contain alkaline reacting compounds. Furthermore, the core must be selected to match the process conditions and the excipients in order to obtain the “required coating efficiency for each layer.” (‘875 patent, col. 2, l. 22). The “required coating

efficiency” is not detailed in the specification or mentioned in the claims. Nevertheless, the court finds that a person of ordinary skill in the art could obtain the required coating efficiency for each layer with a wide variety of “inert core” embodiments by adapting the process conditions and the excipients. Consequently, a plural embodiment of “an inert core” does not materially affect the basic and novel properties of the invention. Instead, it is the absence of alkaline reacting compounds and the stability of the acid labile compound that are the basic and novel properties of the invention. Thus, a plain and ordinary interpretation of the limitation is proper. Such construction of “an inert core” does not unduly restrict the scope of the entire set of claims.

C. The partially-open transition phrase “consisting essentially of” does not restrict all subsequent modified articles to a singular form.

Kremers correctly argues in its *Markman* brief that the word “comprises” in the preamble of claim 3, modifies the claim limitations (a), (b), and (c). Then, Kremers argues that the transition phrase “consisting essentially of” in the preamble of claims 12 and 13 must apply to “an inert core.” (D.I. 110 at 6). Next, in what might be charitably characterized as a bit of sleight of hand, Kremers implicitly characterizes the transition phrase “consisting essentially of” as a closed transition phrase. *Id.* Finally, Kremers cites *Abbott Laboratories* for the proposition that “consisting essentially of” authoritatively restricts “an inert core” to singularity. *Id.* (citing *Abbott Labs. v. Baxter Pharm. Prods. Inc.*, 334 F.3d 1274, 1281 (Fed. Cir. 2003)). *Abbott Laboratories* is quite clearly inapposite on the point at issue.

The transition phrases “comprising” and “consisting essentially of” are words of art. For a patent practitioner these phrases may have a distinct meaning. In fact, they are specifically defined when they are used to connect the preamble to the body of a claim. *See Schering Corp. v. Amgen Inc.*, 18 F. Supp. 2d 372, 382 (D. Del. 1998); *Cal. Med. Prods., Inc. v. Technol Med. Prods., Inc.*,

921 F. Supp. 1219, 1227 (D. Del. 1995). The transition phrase “comprising” is an open transition phrase and does not preclude the presence of other elements. *AFG Indus., Inc. v. Cardinal IG Co., Inc.*, 239 F.3d 1239, 1245 (Fed. Cir. 2001). The transition phrase “consisting essentially of” is a partially-open transition phrase. *PGS Indus. v. Guardian Ind. Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998). A partially-open transition phrase, as applied to the limitations in the subclause of the (a) limitations of the ‘875 claims, signals the public that “the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention.” *Id.* The court is therefore not required to construe the transition phrase “consisting essentially of” as necessarily restricting the modified articles to a singular form.

V. CONCLUSION

The plural construction of the limiting term “an inert core” does not materially affect the basic and novel properties of the invention. Therefore, the open and partially-open terms “comprises” and “consisting essentially of” both allow a plural construction of “an inert core.” Since the word “seed” is well known to those skilled in the art and has a common meaning pertinent to a pharmaceutical preparation, the word “seed” is a starting term for the construction of the “inert core” limitation. Consequently, the limitation “an inert core” is construed as “one or more pharmaceutically inert seeds used to provide a starting material for the preparation of a pharmaceutical.”

Since Kremers has not enlightened the court to a clear error of law nor shown the court that it has made an error of apprehension, the court will deny this motion pursuant to Fed. R. Civ. P. 59(e) and Delaware Local Rule 7.1.5.

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ORDER

For the reasons set forth in the court’s Memorandum of this date, IT IS HEREBY ORDERED that:

The Motion to Alter or Amend and for Re-argument Regarding Claim Construction of the Phrase “An Inert Core” (D.I. 110) is DENIED.

Dated: January 13, 2004

Gregory M. Sleet
UNITED STATES DISTRICT JUDGE