United States District Court,
N.D. California.

**DEPOMED, INC,**
Plaintiff.
v.
**IVAX CORPORATION,**
Defendant.

No. C 06-00100 CRB

**Dec. 20, 2006.**

Christine Saunders Haskett, Michael K. Plimack, M. Patricia Thayer, Heller Ehrman LLP, San Francisco, CA, for Plaintiff.

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## ORDER

CHARLES R. BREYER**, United States District Judge.**

This suit involves the alleged infringement by Ivax Corp. ("Ivax") of two United States patents issued to DepoMed, Inc. ("DepoMed"). The patents teach compositions and methods for the delivery of highly soluble drugs over an extended period of time to the upper gastrointestinal ("GI") tract.

The parties submitted a Joint Claim Construction and Prehearing Statement ("Joint Statement") in which they report agreement as to the meaning of one term, and propose constructions of five disputed terms and phrases. (Docket No. 58, Aug. 28, 2006). Upon consideration of the briefing and the arguments made at the Markman hearing, the Court now sets forth constructions of the disputed terms.

## I. BACKGROUND

DepoMed is the assignee of U.S. Patent Nos. 6,340,475 and 6,635,280 (the "'475 patent" and the "'280 patent," respectively), both of which are entitled "Extending the duration of drug release within the stomach during the fed mode." The '280 patent is a continuation of the '475 patent, which itself is a continuation-in-part of an application now abandoned. See ' 280 patent at [63]. These two patents, therefore, provide substantively identical disclosures. FN1

FN1. The specifications of the two patents differ only by the cross-references made to related applications and spacing changes incident to publication. Unless a passage is unique to the '280 patent, such as the

claims, only the '475 patent will be cited.

The patents disclose oral drug dosage forms-that is, pills or tablets suitable for ingestion-that incorporate doses of a drug into a polymeric matrix. The polymeric matrix swells on contact with water that is present in the stomach as gastric fluid. Such swelling serves two purposes. First, it hinders passage of the dosage form out of the stomach, which allows the dosage form to remain in the stomach for a longer period of time. Second, the swelling retards the rate of diffusion of the incorporated drug out of the tablet and into the upper GI tract, thereby moderating the rate at which the drug is released. The invention thus promotes delivery of certain drugs to the upper GI tract, thereby enhance the efficacy of the drugs contained therein, or preventing the deleterious consequences of delivery to the lower GI tract. The invention also also helps avoid transient overdosing by extending delivery of the drug.

It is critical to the operation of the invention that the dosage form is administered following a meal, when the stomach is in the "fed mode," a term used to describe the state of the stomach lasting for roughly six hours after ingetion of food. In the fed mode, the pylorus-the passageway between the stomach and the large intestine-constricts and permits only liquids and small particles to pass. Larger objects are retropelled and remain in the stomach for further digestion. To perform as claimed, the dosage form must be large enough that it remains in the stomach and avoids passage through the constricted pylorus.

The '475 and '280 patents particularly teach that highly soluble drugs are capable of delivery by swellable polymers of high molecular weight that do not depend on erosion of the polymer. Unlike other controlled drug delivery systems known to the art that rely upon the dual mechanisms of swelling and erosion in order to deliver a drug, experiments disclosed in the DepoMed patents demonstrate that formulations of the invention gave a controlled release of the drug for 4 to 6 hours (or longer), and also that the polymers were retained in the stomach, when given during the fed mode, for a similar period of time. One of the claimed properties of the dosage form is that delivers substantially all of the incorporated drug over this timeframe, which corresponds to the typical duration of the fed mode.

## II. STANDARD OF REVIEW

Claim construction is a matter of law for the court to decide. *Markman v. Westview Instruments, Inc.,* 57 F.3d 967, 979 (Fed.Cir.1995), *aff'd,* 517 U.S. 370, 372, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). When construing claims, a court first looks to intrinsic evidence of record, and thereafter, if appropriate, to extrinsic evidence. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996). Intrinsic evidence comprises the patent claims, the specification, and, if entered into evidence, the prosecution history. *Id.* Intrinsic evidence also comprises the prior art cited in a patent or during the prosecution. Kumar v. Ovonic Battery Co., 351 F.3d 1364, 1368 (Fed.Cir.2003). In most cases, the intrinsic evidence alone will determine the proper meaning of the claim terms. Vitronics, 90 F.3d at 1583.

When construing claims, the analysis begins with, and must focus on, the language of the claims themselves. Interactive Gift Exp., Inc. v. Compuserve Inc., 256 F.3d 1323, 1331 (Fed.Cir.2001). If the claim language is clear on its face, then the rest of the intrinsic evidence is considered only to determine whether any deviation from the plain meaning is specified. *Id.* Deviation may be warranted if, for example, the patentee has "chosen to be his own lexicographer," or if the patentee has disclaimed a certain portion of the claim scope that would otherwise be afforded by the plain meaning. *Id.* (citations omitted). Where the claim language is not clear, other intrinsic evidence is used to resolve the lack of clarity. *Id.* Generally, a court

gives the words of a claim their ordinary and customary meaning. Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed.Cir.2005). The "ordinary and customary meaning of a claim term 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 1313. The context in which a word appears in a claim informs the construction of that word. Id. at 1314. Where there are several common meanings, the patent disclosure "serves to point away from the improper meanings and toward the proper meanings." Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc., 334 F.3d 1294, 1300 (Fed.Cir.2003) (citation omitted). If more than one definition is consistent with the usage of a term in the claims, the term may be construed to encompass all consistent meanings. Texas Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1203 (Fed.Cir.2002).

Claims must be read in light of the specification. *Markman,* 52 F.3d at 979. The specification "is the single best guide to the meaning of a disputed term." Vitronics, 90 F.3d at 1582. Where a claim term has multiple, yet potentially consistent, definitions, the rest of the intrinsic record, beginning with the specification, provides further guidance. *Brookhill-Wilk,* F.3d at 1300. If the patentee explicitly defined a claim in the specification, that definition trumps the ordinary meaning of the term. CCS Fitness v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed.Cir.2002). The specification also may define a term by implication, Phillips, 415 F.3d at 1321, or it may reveal a disclaimer of the claim scope by indicating that the invention and all of its embodiments only occupy part of the broad meaning of a claim term. SciMed Life Sys. v. Advanced Cardiovascular Sys., 242 F.3d 1337, 1343-44 (Fed.Cir.2001).

It is error, however, to import a limitation from the specification into the claim. Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 904 (Fed.Cir.2004). Standing alone, an embodiment disclosed in the specification does not limit the claims. Id. at 906. Even when the specification describes only a single embodiment, the claims of the patent are not to be construed as restricted to that embodiment unless the patentee demonstrates a clear intention to limit the claim scope using "words or expressions of manifest exclusion or restriction." Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1327 (Fed.Cir.2002). Absent clear statements of scope, courts must follow the language of the claims and not that of the written description provided by the specification. Id. at 1328; *see also* Specialty Composites v. Cabot Corp., 845 F.2d 981, 987 (Fed.Cir.1988) (stating that a limitation should not be read into the claims unless a specification so requires).

Conversely, a construction that excludes a preferred embodiment is "rarely, if ever, correct." Pfizer Inc. v. Teva Pharm., USA, Inc., 429 F.3d 1364, 1374 (Fed.Cir.2005) (quoting Sandisk Corp. v. Memorex Prods., Inc., 415 F.3d 1278, 1285 (Fed.Cir.2005)). Courts require highly persuasive evidence that the claims do not encompass a preferred embodiment. Vitronics, 90 F.3d at 1583.

## III. DISCUSSION

All the disputed terms are found in claim 1 of the '475 patent or claim 1 of the '280 patent. Those claims are reproduced here for reference:

Claim 1. A controlled-release oral drug dosage form for releasing a drug whose solubility in water is greater than one part by weight of said drug in ten parts by weight of water, said dosage form comprising a solid polymeric matrix with said drug dispersed therein at a weight ratio of drug to polymer of from about 15:85 to about 80:20, said polymeric matrix being one that swells upon imbibition of water thereby attaining a size large enough to promote retention in the stomach during said fed mode, that releases said drug into gastric fluid by the dissolution and diffusion of said drug out of said matrix by said gastric fluid, that upon

immersion in gastric fluid retains at least about 40% of said drug one hour after such immersion and releases substantially all of said drug within about eight hours after such immersion, and that remains substantially intact until all of said drug is released.

'475 patent.

Claim 1. A controlled-release oral drug dosage form for releasing a drug whose solubility in water is greater than one part by weight of said drug in ten parts by weight of water, said dosage form comprising *one or more polymers forming* a solid polymeric matrix with said drug incorporated therein at a weight ratio of drug to polymer of from [ ] 15:85 to [ ] 80:20, said *dosage form* being one that *when swollen in a dimensionally unrestricted manner as a result of* imbibition of water *is of* a size *exceeding the pyloric diameter in the fed mode* to promote retention in the stomach during said fed mode, that releases said drug into gastric fluid by the dissolution and diffusion of said drug out of said matrix by said gastric fluid, that upon immersion in gastric fluid retains at least about 40% of said drug one hour after such immersion and releases substantially all of said drug [ ] after such immersion, and that remains substantially intact until *substantially* all of said drug is released.

'280 patent. The differences between the two claims are highlighted by formatting changes in the block quotes above. Text omitted from claim 1 of the '475 patent is indicated by brackets, while text added or substituted into claim 1 of the '475 patent is indicated by underlining. The parties have asked the Court to construe five terms and phrases; the construction of these disputed terms is set forth below.

**A. "substantially all of said drug"**

Claim 1 of the '475 patent teaches that the dosage form "releases substantially all of said drug within about eight hours after such immersion," referring to the period over which the drug is released from the polymeric matrix into the gastric fluid. The parties dispute the meaning of the term "substantially all." While this term is common to claim 1 of both patents, the Court notes that claim 1 of the '280 patent omits reference to an eight-hour time period. The time period over which "substantially all" of the drug is released is not an issue disputed by the parties.

Common sense indicates that "substantially all" of a substance refers to some percentage approaching 100% of the relevant material-in other words, some measure just short of all of it. Many physical processes and phenomena, however, defy and may even be incapable of attaining completeness, or may reach completeness at varying rates and with varying expected degrees of succes. Therefore, each case must be resolved with attention to its specific facts. The plain meaning of such a term of approximation is rarely apparent from the claim language alone, and this instance is no different.

Here, Ivax contends that the amount released within eight hours must be at least 90% of the total. In particular, Ivax relies on a passage in the '475 patent indicating that a "substantial" period of time amounts to at least 90% of the dosing period, and contends that the term "substantial" therefore generally should mean a level of 90% whenever it is used in connection with the patent. *See* '475 patent at 9:13-16. The cited passage, however, actually points away from Ivax's position. First, the passage implies that a substantial period of time includes periods of time shorter than 90% of the dosing period. Second, despite the fact that drug release levels are a function of time, what is substantial with respect to one variable (time) is not necessarily pertinent to another variable (released amount of drug).

By contrast, DepoMed contends that release of "substantially all of said drug" indicates the release of about 80% of the drug incorporated into the polymeric matrix. DepoMed finds support for this position in the examples that demonstrate that roughly two-thirds (21 out of 31) of the formulations reported in the patent released at least 80% of the drug after eight hours. Ivax counters that only three of the samples actually demonstrated a release between 80% and 90%, and argues the samples therefore provide just as much support for its preferred interpretation of 90%. These competing contentions, both of which are reasonable, demonstrate why the proffered compilation provides an inadequate basis for a definitive construction of the disputed term. Moreover, as a policy matter, an outcome based solely on the type of testing examples disclosed in the patent would make the construction of a term turn entirely on the degree of testing that the patentee chose to perform-or to report. A firmer foundation, preferably rooted in the science, is necessary.

It is apparent that the release of drug from within a polymeric matrix is dependent on many factors. Moreover, the rate at which release occurs is subject to the control and manipulation of a host of variables. *See, e.g.,* ' 475 patent at 12:10-17:37. For guidance as to what one of skill in the art would consider to be the release of "substantially all" of a drug from a delivery vehicle, the Court finds it appropriate to consider, as extrinsic evidence, the testing guidelines provided by the Food and Drug Administration (FDA) for pharmaceutical companies engaged the development of controlled release drug dosage forms. The FDA is the regulatory agency charged with regulating the entry of drugs into the marketplace, and marketing the drug dosage forms claimed by the patents would require FDA approval. Although extrinsic evidence is viewed as "less significant than the intrinsic record," reliance on extrinsic sources is valid where it may help understand how one of skill in the art might use the claim terms. *See* Phillips, 415 F.3d at 1317-18 (citations omitted). Here, extrinsic evidence in the form of guidance documents issued by the FDA, the regulatory gatekeeper to the commercial field, is particularly reliable because it is devoid of defects often associated with extrinsic works. *See* id. at 1318. FDA documents are written for those skilled in the art, and are issued by the single relevant regulatory agency, which thereby avoids the danger inherent in choosing from an "unbounded universe" of potential extrinsic sources. *See id*. In the absence of any strong indication in the intrinsic record as to the boundary of the vague and approximate term "substantially all," the extrinsic FDA source offers the clearest insight into the understanding that one of skill in the art would have of the term.

DepoMed notes that the FDA advises companies that perform dissolution tests on extended-release dosage forms that such testing may be stopped when 80% of the drug is released. Hopfenberg Reply Decl. para. 20. The most relevant point is the FDA guidance on using an in vitro/in vivo correlation ("IVIVC") to set dissolution specifications-guidance that was issued by the FDA only eighteen months prior to the filing date of the '475 patent. *See* Hopfenberg Opening Decl., Exh. M (Guidance for Industry: Extended Release Oral Dosage Forms: Development, Evaluation, and Application of In Vitro/In Vivo Correlations) at 1, 16-19. Under all circumstances delineated in this FDA document, the last time point "should be the time point where at least 80% of the drug has dissolved." Id. at 17, 18. For the purpose of assessing product performance and setting specifications of pharmaceutical products, the FDA considers the release of 80% of the drug to be the relevant endpoint for release of the drug. In accord with the FDA's guidance, this Court construes the phrase "releases substantially all of said drug within about eight hours after such immersion" of claim 1 of the '475 patent to mean that at least 80% of the drug has been released after eight hours.

**B. "gastric fluid"**

The term "gastric fluid" appears in claim 1 of both the '475 patent and the '280 patent. DepoMed contends that the term should encompass the fluid of the human stomach, as well as simulated or artificial formulations of gastric fluid. This latter category encompasses, in particular, formulations used in laboratory

experiments that model the conditions of a human stomach. Ivax responds that the claim language and written description indicate instead that the term "gastric fluid" is limited to mean only "fluid in the human stomach," and that this interpretation is consistent with the overall purpose of the claimed invention, which is a controlled release drug delivery vehicle that promotes retention in the stomach.

The claim language does not expressly define "gastric fluid," and the context does not restrict the scope of its meaning. On a casual read of the claim, the phrases "promote retention in the stomach during said fed mode," and the repeated use of the term "gastric fluid" lead one to understand that the claimed drug dosage form targets the stomach. A closer read, however, leads to the understanding that the claim limitations do not include locations where certain events must occur, such as in a human stomach. First, the claim is to a composition, and the limitations simply relay the properties that the dosage form composition must possess. Second, the phrase "promote retention in the stomach during said fed mode" relates back to the size that the drug dosage form must achieve by swelling; it does not require that the drug dosage form actually be in a stomach. The claimed dosage form is further defined according to its behavior when immersed in "gastric fluid." When the dosage form is immersed, the polymeric matrix responds by swelling, and the embedded drug dissolves and diffuses out of the polymeric matrix to be released into the gastric fluid. This limitation does not require that the fluid actually be in a stomach, but merely that it be gastric fluid. The plain meaning gleaned from the claim language is that the drug dosage form is defined with reference to the stomach and to what happens in gastric fluid, but it does not require that the claim's scope be limited to fluid whose properties are manifest only in the stomach. In other words, the text does not require that gastric fluid be fluid that is actually within a stomach.

Moreover, although the term "gastric fluid" is not explicitly defined in the written description, as many other terms are, it is nonetheless defined by implication. *See* Phillips, 415 F.3d at 1321. Indeed, certain passages in the specification suggest the use of "gastric fluid" outside the confines of a stomach. In particular, the specification states: "The amount polymer will be sufficient however to retain at least about 40% of the drug within the matrix one hour after ingestion (or immersion in the gastric fluid)." '475 patent at 9:25-28. This passage is subject to two interpretations. First, the applicant may have used the parenthetical for greater precision; that is, although the overt act of taking the pill would be "ingestion," but the mode of action is triggered by the subsequent entry into the stomach and "immersion in gastric fluid." Under this interpretation, "gastric fluid" would indicate fluid in the stomach. Under a second reading, however, this parenthetical sets off and distinguishes the usual route of administration to a patient-that is, "ingestion," which inevitably leads to immersion in the gastric juice of the stomach-from an alternative, "immersion," as something that occurs directly and without ingestion. Under the latter construction, the conclusion is that the patentee contemplated usage of the composition ex vivo. This alternative reading is supported by the numerous examples describing test results from in vitro experiments using "modified simulated gastric fluid." Id. at 12:60, Examples 1-8, 10. Passages in a related patent, also issued to DepoMed, similarly uses the term "gastric fluid" to refer to artificial compositions used in ex vivo testing. *See* U.S. Patent No. 5,972,389 at 11:1-3 (describing, in Example 1, how pellets are placed into "stirred gastric fluid," which fluid is clearly a simulated formulation of gastric juice).

The Court concludes that, although the patent is directed toward a drug dosage form that is ultimately for use in a patient, and therefore in the human stomach, the claims to the composition are not necessarily limited to that milieu, as Ivax contends they should be. Ivax points to the abstract of the patents, highlighting the language stating that "the oral formulation is designed for gastric retention and controlled delivery of an incorporated drug into the gastric cavity, and thus administered, the drug is released form the matrix into the gastric fluid." Responsive Br. at 9:17-19 (emphasis in original). Yet the abstract, no more

than the rest of the written description, cannot be read into the claims as a limitation. Liebel-Flarsheim, 358 F.3d at 904. Second, the cited passage would only implicate the method claims. *See, e.g.,* '475 patent at claim 19 (setting forth "a method of administering to a subject a drug"). The passage does not necessarily imply any such limit on the scope of a composition claim. Despite the fact that the ultimate goal of the disclosed compositions and methods is to provide a drug dosage form for treatment of humans, claims to a composition are broad, and other intermediate uses fall within their scope.

Neither, though, is the fluid of claim 1 limited only to simulated environments. DepoMed points to the term "immersion" as distinguishing between in vivo and ex vivo environments. The context of the claims and the specification does not support this position. Method claims, which clearly refer to steps occurring in the stomach, also use the term "immersion." *See, e.g.,* '475 patent at claim 19. Just as the term "gastric fluid" itself adopts differing meanings depending on the context of the claim, so too does "immersion." As noted above, the passage in the specification "ingestion (or immersion in the gastric fluid)" is susceptible to two readings, which supports a scope of the term covering both environments. *See* Texas Digital Systems, 308 F.3d at 1203 (noting that a term may be construed to encompass all consistent meanings if more than one definition is consistent with the usage of the term in the claims).

Given that two different words are used in the specification and in plaintiff's proposed construction to describe non-natural gastric fluid, "simulated" or "artificial" gastric fluid, the meaning of these terms must be clarified. First, the Court agrees with DepoMed's assertion that the two terms are interchangeable. Nothing about the use of the terms in the specifications indicate they carry any difference in meaning. This is particularly apparent from the fact that the two terms appear within a single example and refer to the same solution. '475 patent at 12:49-67. For simplicity, and following the usage established by United States Pharmacopeia-the official standards-setting authority for all prescription and over-the-counter medicines, dietary supplements, and other healthcare products manufactured and sold in the United States-such non-natural fluids will be referred to as "simulated gastric fluid." This term is also construed to include modified formulations of simulated gastric fluid. As long as the essential characteristics of gastric fluid are embodied by the fluid, that is, the salinity and pH levels are within the range of what a person of ordinary skill in the art would expect, then the fluid is within the scope of the claim language.

The Court concludes that the term "gastric fluid" is entitled to a broad construction that encompasses both the fluid in the human stomach, and any simulated or artificial fluids recognized by those skilled in the art as a suitable model for the fluid of the human stomach. Whether one form of the fluid or the other, or both, applies is to be determined by the context of the claim. The language of claim 1 of both patents supports a construction of "gastric fluid" that includes both the fluid of the stomach and simulated gastric fluid.

**C. "about 15:85 to about 80:20"**

The disputed phrase "about 15:85 to about 80:20," which refers to the drug-weight-topolymer-weight ratio of the claimed oral drug dosage form, is found in claim 1 of the '475 patent. The Court notes that claim 1 of the '280 patent recites the same range of ratios but omits the qualifying word "about" in both instances and therefore is limited to the stated numerical range. DepoMed asserts that "about" only operates to vary the amount of polymer in the drug-to-polymer ratio, and calculates a renormalized range of 14.4:85.6 to 80.8:19.2 for this claim limitation. Ivax would construe "about 15:85 to about 80:20" to indicate a range of 10:90 to 85:15.

There is no mention of the meaning of, or the scope of variation indicated by "about" in the patent claims,

the specification, or any other intrinsic evidence. Although it is rarely possible to attach a precise limit to "about," its meaning can usually be understood in light of the technology embodied in the invention. See Modine Mfg. Co. v. U.S. Int'l Trade Comm'n, 75 F.3d 1545, 1554 (Fed.Cir.1996). Thus, the best approach is to determine the technology-specific facts, and what one of skill in the art would understand a reasonable range to be. *Id.; see also* Eiselstein v. Frank, 52 F.3d 1035, 1040 (Fed.Cir.1995). DepoMed's approach relies on adjusting only the polymer content by 5%, while keeping "the amount" of the drug the same, and then recalculating the new ratio. For support of such a narrow construction, DepoMed cites the district court cases of Ranbaxy Laboratories Ltd. v. Abbott Laboratories, 2005 WL 3050608 (N.D.Ill. Nov.10, 2005), and Chiron Corp. v. SourceCF Inc., 431 F.Supp.2d 1019 (N.D.Cal.2006). *Chiron,* however, is readily distinguished from the present case. In *Chiron,* the amounts below the lower number of the range were disclaimed by the patentee, and therefore the lower number was construed to change only slightly due to the term "about." *See* 431 F.Supp.2d at 1029 (noting the patentee's remark that "concentrations below 60 mg/mL were normally ineffective"). The court held, in the context of the medical method claim at issue, that the term "about" connoted a variation no larger than the margin of error in a pharmacy professional's measuring capabilities. Id. at 1030. Unlike *Chiron,* the range under consideration here is not subject to any disclaimer of scope outside the recited range, nor is the margin-of-error rationale pertinent.

In *Ranbaxy,* the court looked to guidance from the FDA as to what range to ascribe to the term "about" in the phrase "about 5 to about 50% by weight" of the formulation, which was also for an extended release drug dosage form. Ranbaxy, 2005 WL 3050608, at * 12. The *Ranbaxy* court was persuaded that extrinsic guidance, which stated that varying the amount of polymer more than 5% could have a significant impact on quality and performance, should control the construction. *Id.* at * 12-13. The *Ranbaxy* court noted that even though the regulations address post-approval products, FDA materials were a relevant source of guidance for those skilled in the art. *Id.* at * 13.

Here, although the term "about" applies to the drug-to-polymer ratio, the Court agrees that the term "about" ascribes variance only as to the amount of non-active polymer component, and not the drug component. First, the patent focuses on the drug delivery vehicle, and not the amount of drug; therefore, it is reasonable to assume the therapeutic amount of drug is set according to other considerations, such as the medical needs of a patient, which are independent of the '475 patent's disclosures, and that the patent instead concentrates on the formulation of "release controlling excipients" of the drug delivery dosage form. The percentage by weight of drug varies, but only insofar as the amounts of other components vary. The Court concludes that the variation suggested by the term "about," which modifies the drug-to-polymer ratio, only creates variation in the amounts of those other non-drug components.

The Court also notes that the FDA guidance cited in *Ranbaxy* is directed specifically at the subject matter covered in this case, and thus is relevant extrinsic evidence. The FDA guidance directs that if the additive effect from changes to all release-controlling excipients is no more than 5% by weight of the total release controlling excipients in the approved formulation, there is unlikely to be a detectable impact on quality and performance. *See* Hopfenberg Opening Decl., Exh. D (Guidance for Industry: SUPAC-MR: Modified Release Solid Oral Dosage Forms), at 8-10. The FDA further instructs that changes between 5-10% by weight of total release controlling excipients may have a significant impact on formulation. *Id.* at 10-13. For changes in this range, more testing and documentation of the modified dosage form is required to maintain compliance. *Id.* On the basis of such guidance, compliance with which is mandatory for commercial activity, the Court finds that one of skill in art would recognize that 5% represents a modest change in the non-drug components of a drug release dosage form. Such a modest change constitutes a fair reading of the range understood by the term "about" as it modifies the amount of polymer within a dosage form. "About" itself

implies the amount would be similar to, or not substantially different from, the amount recited. Here, a reading that the polymer may vary by 5% is consistent with this definition of "about," because such a change would not trigger notification or regulatory compliance activities.

The Court notes that it is normally improper to rely on industry standards where the patent specification makes no suggestion that those standards should apply. E-Pass Techs. v. 3COM Corp., 343 F.3d 1364, 1368 (Fed.Cir.2003). For example, the question considered in *E-Pass* was whether a technology standard suggested in the patent itself should be construed as a limitation on a claim element. *Id*. at 1367 (noting that the sole question was whether the term "electronic multi-function card" requires the card to have industry-standard dimensions). Numerous passages in the written description demonstrated that the standard-sized card was merely an embodiment and not a definition of the claim scope. *Id*. at 1369. Unlike *E-Pass,* which presented the question of whether an industry-standard embodiment is limiting, this case requires the Court to find a technological basis for construing the term "about" as someone of ordinary skill in the art would reasonably understand it. Under these circumstances, it is appropriate to consider extrinsic evidence in the form of guidance from the FDA, when those practicing in field are compelled to follow it. *See* Modine Mfg., 75 F.3d at 1554.

The Court finds Ivax's proffered approach unpersuasive. Ivax contends that the ratios should be simply adjusted by 5% in either direction-that is, in contends that the term "about" should expand the ratio by a 5% decrease in the drug and a 5% increase in the polymer, and vice versa. Ivax supplies no reasoning to support its proffered construction, other than its observation that as adjusted the ratios would still describe formulations that fulfill the purpose of the invention. By simultaneously adjusting both components, however, this construction gives rise to significant changes between the relative amounts of drug and polymer. Such variation is not consistent with the narrow construction that is appropriate to the circumstances. Most significantly, there is no authority suggesting that one of skill in the art would adopt such an approach.

The Court concludes that the term "about 15:85 to about 80:20" requires a narrow construction that permits variation of the non-active component polymer matrix by up to 5%. Therefore, consistent with DepoMed's proposed construction, the range as modified by the term "about" is construed to be 14.4:85.6 to 80.8:19.2.

**D. "said polymeric matrix being one that swells upon imbibition of water thereby attaining a size large enough to promote retention in the stomach during said fed mode"** '475 patent

**"said *dosage form* being one that *when swollen in a dimensionally unrestricted manner as a result of* imbibition of water is of a size *exceeding the pyloric diameter in the fed mode* to promote retention in the stomach during the fed mode"** '280 patent

These disputed limitations appear in claim 1 of the '475 patent and claim 1 of the '280 patent, respectively. Both limitations teach that the dosage form must expand and that, upon expansion, they attain a size sufficient to prevent or inhibit their own passage into the lower GI tract. The second passage differs from the first due to several amendments made to the claim language (underlined above), one of which teaches that the dosage form must swell to "a size exceeding the pyloric diameter." The Court therefore initially addresses the question of whether these terms require different constructions.

DepoMed argues that they do. Based on test results disclosed in the ' 389 patent, and based on evidence about the size of the pyloric diameter, DepoMed proposes that the polymeric matrix must absorb water to

increase to a size exceeding 8 mm under the former term, and proposes that the polymer size after swelling must exceed 12 mm under the latter term. Ivax contends that these two limitations should receive the same construction, but proposes two different ways to construe them.

The Court agrees that the related limitations of the '475 and '280 patents require the same construction. The Court is unable to identify any aspect of the altered language in the '280 patent that demands a substantively different construction. The parties have not suggested that the reference to a "dosage form," as opposed to a "polymeric matrix," makes a substantial difference. Nor have the parties suggested that the additional language in the '280 about the swelling of the dosage form "in a dimensionally unrestricted manner" should lead to a substantively different construction of these two limitations; indeed, the parties have agreed upon a construction of this term.

Finally, the Court is unpersuaded that the specific language in the '280 patent regarding the expansion of the dosage form to "a size exceeding the pyloric diameter" should render the meaning of that term different in substance from the term in 475 patent, which refers only more generally to "a size large enough to promote retention in the stomach." Indeed, the equivalence of these two phrases is evident from the plain language of the '280 patent itself, which suggests that a swollen dosage form must achieve a size exceeding the pyloric diamete precisely in order to promote its retention in the stomach.

DepoMed has not offered any evidence about why a polymeric matrix smaller than the pyloric diameter would promote retention in the stomach. Thus, if the polymer at issue in claim 1 of the '475 patent, swollen to Depomed's preferred size of approximately 8 mm, would promote retention, it is reasonable to infer that such retention is due to the fact that it is larger than the pyloric opening. Indeed, the extrinsic evidence cited by DepoMed is inconsistent with its proposed construction of 12 mm under the '280 patent; for example, the study on which DepoMed chiefly relief concludes that the mean pyloric diameter in the fed mode is 7 mm. See Opening Br. at 13-14 (citing Munk et al.). It is certainly true that factors other than the size of the pyloric diameter may determine the rate of actual retention. For example, a pressure gradient within the stomach may actually require a larger sized object to resist being sent through the pylorus. See Opening Hopfenberg Decl., Exh. J (Gastrointestinal Transit of Non-Disintegrating Tablets in Fed Subjects) at 115. Yet the diameter itself would appears to be the minimum size necessary to promote retention.

Thus, despite the different language in the claims of the '475 and '280 patents, it is not clear that the phrase "large enough to promote retention" means anything different than does "exceeding the pyloric diameter." Indeed, the plain language of the '280 claim notes that the size of the swollen dosage form must "exceed" the pyloric diameter, and the claim thus recognizes that a dosage form larger than the pyloric opening is tantamount to keeping the dosage form within the stomach. In the Court's view, this is equivalent to a statement that a larger size than the opening is necessary to "promote retention." DepoMed asserts that the two phrases must have a different meaning because claim 1 of the '280 patent was only allowed over claim 1 of the '475 patent after it was amended to recite this limitation phrased in terms of the pyloric diameter. This change, however, was not the only one made to the claim. *See supra,* Section III (noting additions and deletions to claim 1 of the ' 280 patent). The Court concludes that the other amendments to the claim are sufficient to distinguish the one claim over the other, and the Court is therefore satisfied with a synonymous construction of these claims, notwithstanding the changes in the language of the two patents.

The next question is what these two claims mean (accepting, of course, that they mean the same thing). As to that question, the parties again have competing views. DepoMed primarily contends that the limitation means that the polymeric matrix absorbs water to increase to a size exceeding 8 mm. Ivax proposes

alternative constructions. First, it suggests that the claims require the polymer to be only of a size that promotes retention after imbibition of water-that is, after absorbing water and swelling-but not before. Second, Ivax suggests that, if a numeric boundary must be determined, then a dosage form will promote when it is within a range of 2 mm to 20 mm.

The Court holds that the first construction proposed by Ivax is not correct. Ivax asserts that the words "thereby attaining" requires the Court to read the claim as meaning that, absent swelling, the dosage form would not be of a size large enough to promote retention. Several factors counsel against this conclusion. First, accepting both this construction would place many of the examples of the patent, in which the smallest dimension of any dosage form is 6 mm, outside the claim scope. This would be an undesirable result under well-settled principles of patent law. *See* Pfizer, 429 F.3d at 1374 (noting that a claim construction excluding preferred embodiments is "rarely if ever, correct"). In the same vein, claims dependent on claim 1 recite dosage forms whose size prior to swelling exceed the size that "promotes retention," at least as proposed by Ivax. Moreover, as a matter of logic, Ivax's proposed construction is not coherent. The phrase "thereby attaining" merely implies that a dosage form, post-swelling, must promote retention within the stomach; in and of itself, this language says nothing of the pre-swelling dosage form. Both smaller and larger dosage forms may swell and "thereby attain" a size that promotes retention. Finally, Ivax's proposed construction also separates the claim language from the context of the claimed invention. The patents at issue stand in contrast to other drug dosage forms that release drugs by dissolving-that is, to other dosage forms that become smaller over time and thereby erode to a size that does not promote retention. The '475 patent directs that the dosage form will, over time, attain a size that promotes retention. The claim language relates to the pill's destination, not its starting point. It is silent about the starting size of the dosage form, but that silence does not preclude dosage forms that initially are of sufficient size to promote retention. The Court therefore concludes that Claim 1 also comprehends starting sizes larger than what would be necessary to promote retention within the stomach.

Regardless of the starting size of the unswollen dosage form, the crucial question is, as the plain language of the claim suggests, how large the swollen dosage form must be in order to "promote retention." In attempting to answer this question, the Court has examined both intrinsic and extrinsic evidence submitted by the parties.

For example, the strongest indication of what size is large enough to promote retention during the fed mode for the polymers of the invention is found in Example 9 of the '475 patent. Like the sizes used in the prior ' 389 patent, pills of either 4 mm or 6 mm were administered to humans and their retention in the stomach monitored. *See* '475 patent at 17:9-24. The results of the experiments demonstrated that pills of both sizes promoted retention in the stomach in the fed mode: in the fasting mode the tablets were cleared within 30-60 minutes, but in the fed mode 80% of all tablets were retained at 4 hours. Id. The specification teaches that the polymer matrix swells, preferably, to a size that is at least about twice its unswollen volume. Id. at 6:1-2. And although no data about swelling size is provided in the '475 patent, the polymers disclosed in the related '389 patent swelled to about twice their size in 2-4 hours. The teaching of the '389 patent thus stands as intrinsic evidence of what the same inventors recognized about the performance of these types of polymers and the requirements for gastric retention. Nonetheless, the polymers are not the same in the two patents, and the specific teaching about the rate of swelling '389 patent is only regarded as a preferred behavior in the '475 patent. *See* id. at 6:1-2.

DepoMed proposes that a swollen size of 8 mm is appropriate based on the teachings of the preferred range provided in the '389 patent, which notes that dosage forms that promote retention during the fed mode "will

normally be in the range of about 2 to about 22 mm, preferably about 8 to about 18 mm." ' 389 patent at 8:34-37. Yet the '475 patent itself teaches that "[p]articles exceeding about [10 mm] in size are thus retained in the stomach" during the fed mode. '475 patent at 11:67-12:1. DepoMed does not make clear why the full range taught in the earlier patent is not operative in the subsequent patent, nor does it explain why claim 1 should be construed to apply to an object that is smaller than the one and only size specifically noted in the patent's written description.

In the absence of compelling intrinsic or extrinsic evidence indicating that a specific size would be sufficient to promote retention, the Court concludes that imposing a minimum on the size of the swollen dosage form necessary to "promote retention" is unwarranted. A patentee has the right to claim the invention in terms that would be understood by persons of skill in the art, and "mathematical precision should not be imposed for its own sake." Modine Mfg., 75 F.3d at 1557. A person of skill in the art reading the patent as a whole would recognize that the claimed polymer matrices must swell upon adsorption of water, and must not significantly erode throughout the relevant period of immersion in gastric fluid. Moreover, a person of skill in the art would recognize that the patent discloses that a tablet of a given composition and of 4 mm in size would perform as claimed-that is, such a dosage form attained a size that is "large enough to promote retention" in the subjects that were studied. *See* '475 patent at 17:9-24. From this basic teaching, one of skill in art would understand both the requirements and the means for testing for compliance with the claim requirements. The Court declines to impose a more specific construction of the disputed claim terms, especially since tying the scope of the disputed claim to a minimum size that is supported primarily by the result from one example would impermissibly read a limitation into the claims.

In sum, the Court concludes that one of skill in the art would understand that the limitation "said polymeric matrix being one that swells upon imbibition of water thereby attaining a size large enough to promote retention in the stomach during said fed mode" means that the drug dosage form's polymeric matrix increases in size, and does not erode, such that when introduced to a stomach in the fed mode, the dosage form remains in the stomach for several hours.

**IT IS SO ORDERED.**

N.D.Cal.,2006.
DepoMed, Inc. v. Ivax Corp.