NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

DEPOMED, INC. and VALEANT INTERNATIONAL (BARBADOS) SRL, Plaintiffs, v. SUN PHARMA GLOBAL FZE, SUN PHARMACEUTICAL INDUSTRIES LTD., and SUN PHARMACEUTICAL INDUSTRIES INC., Defendants.	)	Civil Action No. 11-3553 (JAP) **MEMORANDUM OPINION**

PISANO, Judge

Plaintiffs Depomed, Inc. and Valeant International (Barbados) SLR (collectively "Plaintiffs" or "Depomed") bring this patent infringement action against defendants Sun Pharma Global FZE, Sun Pharmaceutical Industries Ltd., and Sun Pharmaceutical Industries Inc. (collectively "Defendants" or "Sun"). The five patents asserted in this case, assigned to Plaintiffs, are United States Patent No. 6,340,475 (the "'475 Patent"), United States Patent No. 6,635,280 (the "'280" Patent"), United States Patent No. 6,488,962 (the "'962 Patent"), United States Patent No. 7,736,667 (the "'667 Patent"), and United States Patent No. 7,780,987 (the "'987 Patent"). The patents relate to drug-delivery systems that provide controlled delivery of an incorporated drug in the upper gastrointestinal system. Presently before the Court is the parties' request for claim construction.

I. BACKGROUND

There are five patents-in-suit, all of which relate to a drug-delivery system that allows for extended, controlled release of an incorporated drug into the upper gastrointestinal system, which includes the stomach and upper small intestines. Plaintiffs design, develop, and market pharmaceutical products that use this technology, one of those products being the diabetes drug Glumetza (metformin hydrochloride). Defendants seek to market a generic version of Glumetza, and, to that end, they submitted an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") pursuant to 21 U.S.C. § 355(j). In their ANDA, Defendants certified pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '475 Patent, '280 Patent, '962 Patent, and '987 Patent are invalid or will not be infringed by Defendants' generic version of Glumetza. Plaintiffs filed this patent infringement lawsuit against Defendants, claiming that Defendants' generic Glumetza will infringe the '475 Patent, '280 Patent, '962 Patent, '987 Patent, as well as the '667 Patent.

The '475 Patent and '280 Patent, issued on January 22, 2002 and October 21, 2003 are directed towards "extending the duration of drug release within the stomach during the fed mode." (See generally, '475 Patent and '280 Patent.) Conventional tablets or capsules can release a drug too quickly when they come into contact with body fluids, which results in an unwanted transient overdose followed by a period of underdosing. (See '475 Patent, 1:30-25.)[1] In addition, some drugs, including metformin hydrochloride, must be absorbed high in the gastrointestinal tract in order to work properly. (Id. 2:21-33.) However, the drug may be forced

[1] Citations to the patents-in-suit will be in a column:line format. Further, because the '475 Patent and '280 Patent are based on the same patent application, Ser. No. 08/870,509, they share the same disclosure. Thus, throughout the remainder of this Memorandum Opinion, citations to these two patents will be only to the '475 Patent with the understanding that those cited portions of the '475 Patent also appear in the '280 Patent, unless otherwise noted.

out of the stomach and through the passage leading to the intestines (the "pylorus") before the drug has time to release completely and be absorbed. (See id.; see also 3:16-41.)

The '475 and '280 Patents address these and other related issues. The patents teach a dosage form[2] comprising a "drug dispersed in a polymeric matrix" that "swells upon ingestion." (Id. 5:57 – 6:3.) Particularly for highly soluble drugs like metformin hydrochloride, "the swelling of the polymeric matrix thus achieves two objectives—(i) the tablet swells to a size large enough to cause it to be retained in the stomach during the fed mode, and (ii) it retards the rate of diffusion of the highly soluble drug long enough to provide multi-hour, controlled delivery of the drug into the stomach." (Id. 6:18-24.)

The '962 Patent, issued on December 3, 2002, claims an improvement of the extended-release technology of the '475 and '280 Patents and covers "tablet shapes to enhance gastric retention of swellable controlled-release oral dosage forms." (See generally '962 Patent.) The '962 Patent teaches that dosage forms of particular shapes and sizes are both easy to swallow and resist escape through the pylorus into the intestines. (See id. 3:22-42.) "The shape that achieves this result is a non-circular, non-spherical shape which, when projected onto a planar surface, has two orthogonal axes of different lengths[.]" (Id. 3:27-30.) An example of a shape with these characteristics is an oval. (Id. 4:15-16.) In addition, the dosage form must be of a size such that when the dosage form swells, the shorter axis of the dosage form expands to a size large enough so that it resists passage through the pylorus. (Id. 4:22-31.)

The '667 Patent, issued on June 15, 2010 teaches a "shell-and-core dosage form approaching zero-order drug release." (See generally '667 Patent.) The dosage forms contemplated by the '667 Patent contain a polymeric matrix, but in a "dual-matrix configuration"

[2] A "dosage form" contains an active ingredient (the drug) and excipients, which are inactive components that provide certain desirable characteristics to the dosage form.

with "one matrix forming a core of polymeric material in which drug is dispersed and the other matrix forming a casing that surrounds and fully encases the core, the casing being of polymeric material that swells upon imbibition of water." (Id. 7:9-13.) Such dosage forms allow the release rate of the drug to be substantially constant over several hours, with release being confined to the upper gastrointestinal tract. (Id. 7:5-8.)

The final patent-in-suit, the '987 Patent, was issued on August 24, 2010. The '987 Patent is directed towards a "monolithic film coating for obtaining controlled release of drugs from oral dosage forms." ('987 Patent, 1:10-11.) The coating comprises, among other things, a poly glycol. (Id. 4:28-32.) The poly glycol must have a melting point greater than 55° C, and the coating must be "cured at a temperature at least equal to or greater than the melting point of the poly glycol." (Id. 4:30-34.) The '987 Patent explains that this coating can be manipulated to obtain a desired drug release profile. (Id. 5:45-48.)

The parties requested claim construction to construe terms in each of the patents-in-suit. Actually, this is not the first time that a district court has construed terms in several of the patents-in-suit. In 2006 and 2007, Judge Charles R. Breyer of the Northern District of California construed six terms from the '475 Patent and '280 Patent. See Depomed, Inc. v. Ivax Corp., Case No. C 06-00100, 2006 U.S. Dist. LEXIS 100311 (N.D. Cal. December 20, 2006); Depomed, Inc. v. Ivax Corp., 532 F. Supp. 2d 1170 (N.D. Cal. 2007) (collectively "Ivax"). And in 2011, Judge Phyllis J. Hamilton construed nine terms from the '475 Patent, '280 Patent, and '962 Patent. See Depomed, Inc. v. Lupin Pharms., Inc., Case No. C 09-5587, 2011 U.S. Dist. LEXIS 52839 (N.D. Cal. May 17, 2011) ("Lupin"). Indeed, a few of the disputed terms in this case overlap with those already construed by Judge Hamilton and Judge Breyer, although the parties here have identified a number of additional disputed terms. The parties submitted

opening briefs on March 5, 2012, (DE 45, 47), and responsive briefs on May 4, 2012, (DE 51, 53). The Court held a Markman hearing on July 18, 2012. This Opinion addresses the proper construction of the twenty-five (25) disputed terms.

II. LEGAL STANDARD

In order to prevail in a patent infringement suit, a plaintiff must establish that the patent claim "covers the alleged infringer's product or process." Markman v. Westview Instruments, Inc., 517 U.S. 370, 374 (1996). "It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotations omitted) (citing Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). Consequently, the first step in an infringement analysis involves determining the meaning and the scope of the claims of the patent. Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 988 (Fed. Cir. 1995). Claim construction is a matter of law for the court. Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995), aff'd 517 U.S. 370. Therefore, it is "[t]he duty of the trial judge . . . to determine the meaning of the claims at issue." Exxon Chem. Patents, Inc. v. Lubrizol Corp., 64 F.3d 1553, 1555 (Fed. Cir. 1995).

Generally, the words of a claim are given their "ordinary and customary meaning," which is defined as "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." Phillips, 415 F.3d at 1312-13 (citations omitted). In this regard, the Federal Circuit has noted:

> It is the person of ordinary skill in the field of the invention through whose eyes the claims are construed. Such person is deemed to read the words used in the patent documents with an understanding of their meaning in the field, and to have knowledge

> of any special meaning and usage in the field. The inventor's words that are used to describe the invention—the inventor's lexicography—must be understood and interpreted by the court as they would be understood and interpreted by a person in that field of technology. Thus the court starts the decisionmaking process by reviewing the same resources as would that person, viz., the patent specification and the prosecution history.

Id. (quoting Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1477 (Fed. Cir. 1998)).

In order to determine the meaning of a claim as understood by a person skilled in the art, a court may look to various sources from which the proper meaning may be discerned. These sources include intrinsic evidence, which consists of "the words of the claims themselves, the remainder of the specification, [and] the prosecution history," id. at 1314, and extrinsic evidence "concerning relevant scientific principles, the meaning of technical terms, and the state of the art," id.

When considering the intrinsic evidence, the court's focus must begin and remain on the language of the claims, "for it is that language that the patentee chose to 'particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.'" Interactive Gift Express, Inc. v. Compuserve, Inc., 256 F.3d 1323, 1331 (Fed. Cir. 2001)(quoting 35 U.S.C. § 112, ¶2). The specification is often the best guide to the meaning of a disputed term. Honeywell Int'l v. ITT Indus., 452 F.3d 1312, 1318 (Fed. Cir. 2006). It is improper, however, to import limitations from the specification into the claims. Seachange Int'l v. C-COR Inc., 413 F.3d 1361, 1377 (Fed. Cir. 2005). The court may also consider as intrinsic evidence a patent's prosecution history, which is evidence of "how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." Phillips, 415 F.3d at 1317.

While a court is permitted to turn to extrinsic evidence, such evidence is generally of less significance and less value in the claim construction process. Id. at 1317. Extrinsic evidence is evidence that is outside the patent and prosecution history, and may include expert testimony, dictionaries, and treatises. Id. The Federal Circuit has noted that caution must be exercised in the use of extrinsic evidence, as this type of evidence may suffer from inherent flaws affecting its reliability in the claim construction analysis. Id. at 1319 ("We have viewed extrinsic evidence in general as less reliable than the patent and its prosecution history in determining how to read claim terms."). While "extrinsic evidence may be useful to the court, . . . it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." Extrinsic evidence may never be used to contradict intrinsic evidence. Id. at 1322-23.

Finally, the Court will give deference to the prior claim constructions announced in Lupin and Ivax. Although issue preclusion is inapplicable, the Supreme Court in Markman noted that treating claim construction as a purely legal issue will allow "intrajurisdictional certainty through the application of stare decisis." Markman, 517 U.S. at 391. Therefore, "[w]hile a court's previous opinions [do] not have issue preclusive effect against [Defendants] in this case, to the extent the parties do not raise new arguments, the court will defer" to previous constructions of the same patent claims. Kx Indus., L.P. v. Pur Water Purification Prods., 108 F. Supp. 2d 380, 387 (D. Del. 2000).

III. CONSTRUCTION OF THE CLAIM TERMS

A. "Polymeric Matrix"

The term "polymeric matrix" appears in the '475 Patent and '280 Patent. Plaintiffs define the term to mean "a surrounding medium comprising polymer." Defendants construe the term as "a polymeric formulation containing a sufficient amount of suitable polymer or polymer mix to provide extended, controlled release of a drug dispersed throughout the formulation." Plaintiffs assert that Defendants' construction reads limitations into the term. But Defendants counter that the "limitations" in their construction are not limitations at all because the claims themselves so limit the term.

Claim 1 of the '475 Patent reads as follows:

> A controlled-release oral drug dosage form for releasing a drug . . . , 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 that remains substantially intact until all of said drug is released.

('475 Patent, Claim 1.) The claim is clear as to the characteristics of the polymeric matrix. It must swell upon imbibition of water, it must have a weight ratio of drug to polymer of from about 15:85 to about 80:20, and it must attain a size large enough to promote retention in the stomach during the fed mode. (Id.) Defendants argue that the construction of the term must reflect these required characteristics. However, although the claims require an oral drug dosage form to have these characteristics in order to fall within the scope of the invention, the Court finds it improper to define this simple, straightforward term in such a drawn-out manner.

First, Defendants' construction would render the claim language redundant several times over. For example, Defendants argue that it is necessary to include the limitation that the polymeric matrix contain a "sufficient amount of polymer." But the claims already specify what amounts are required to practice the invention. (See '475 Patent, 17:48-50 ("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"); see also '280 Patent, 23:4-6 ("solid polymeric matrix with said drug incorporated therein at a weight ratio of drug to polymer of from about 0.01:99.9 to about 80:20").) Defendants admit that their construction includes limitations that are expressly required by the claims. Yet it is exactly for this reason that those limitations do not need to be repeated in the construction of "polymeric matrix." See e.g., Intervet Inc. v. Merial Ltd., 617 F.3d 1282, 1290 (Fed. Cir. 2010) (criticizing a construction that included a limitation that was already included in the same claim). In addition, a person of ordinary skill in the art would understand that the polymeric matrix is the first of two components that make up the dosage form; the second component, the "drug dispersed therein," is separate and should be defined independently. (See Hopfenberg Decl. ¶ 66, DE 45-42.) Therefore, the Court also rejects the aspect of Defendants' construction that includes a construction of "drug dispersed therein" in the construction of "polymeric matrix."

Second, Defendants' construction is vague and would not achieve the purpose of claim construction. "The construction of claims is simply a way of elaborating the normally terse claim language in order to understand and explain, but not to change, the scope of the claims." Terlep v. Brinkmann Corp., 418 F.3d 1379, 1382 (Fed. Cir. 2005) (citing Embrex, Inc., v. Serv. Eng'g Corp., 216 F.3d 1343, 1347 (Fed. Cir. 2000)). Here, defining "polymeric matrix" using the words "suitable" and "sufficient amount" only serves to add vagueness to the term, such that

Defendants' proposed construction would itself require additional defining. See E-Pass Techs., Inc. v. 3Com Corp., 473 F.3d 1213, 1220 (Fed. Cir. 2007) (explaining that the words the court uses in construing a claim should not be limitations that require additional interpretation). "Claim interpretation is the process of giving proper meaning to the claim language," AbTox, Inc. v. Exitron Corp., 122 F.3d 1019, 1023 (Fed. Cir. 1997), not assigning a construction to a term that is more unhelpful than the term by itself. No person of ordinary skill in the art, for instance, would believe the "polymeric matrix" to be made of "unsuitable" polymer, and it is therefore of no benefit to construe the "polymeric matrix" to be made of only "suitable" polymer. Defendants' construction, in sum, does not help the Court in its role as claim construer.

The Court will instead adopt Plaintiffs' construction with one alteration. The specifications of the '475 and '280 Patents explain that a drug is dispersed in the polymeric matrix. "[T]he beneficial effects" are "achieved by using a formulation in which the drug is dispersed in a polymeric matrix." ('475 Patent, 5:57-59.) The drug also can be mixed with or impregnated in the polymeric matrix. (See '475 Patent, 10:40-41.) Therefore, the polymeric matrix is properly understood by a person of ordinary skill in the art as a "medium." (See Hopfenberg Decl. ¶ 65.) Defendants take issue with the use of the modifier "surrounding," arguing that the word is not in the patents. Plaintiffs, however, agreed to drop "surrounding" from the construction. (Markman Hearing Tr. 33:4-7.) Finally, the '475 Patent and '280 Patent also make clear that the polymeric matrix is composed of "polymer," and the patents list a number of polymer and polymer derivatives that may make up the polymeric matrix. (See '475 Patent 7:56-8:67.) The Court will therefore construe "polymeric matrix" to mean "a medium comprising polymer."

B. "Solid polymeric matrix with drug dispersed therein" and "one or more polymers forming a solid polymeric matrix with said drug incorporated therein"

The first term, "solid polymeric matrix with drug dispersed therein," is found in both the '475 Patent and '280 Patent. Plaintiffs' construction of this first term is "a medium comprising polymer that surrounds drug particles." Defendants define the first term to mean "a solid polymeric matrix with the drug dispersed throughout the matrix." The second term, "one or more polymers forming a solid polymeric matrix with said drug incorporated therein" is in the '280 Patent. Plaintiffs define the second term as "one or more polymeric materials forming a medium that surrounds drug particles." Defendants contend that the second term means "the drug is dispersed throughout a solid polymeric matrix formed by one or more polymers."

The dispute between the parties with respect to these related terms focuses on whether "dispersed therein" means "dispersed throughout" the polymeric matrix. Plaintiffs assert that Defendants' definition, which requires the drug be "dispersed throughout" the polymeric matrix, is too narrow. In support of their argument, Plaintiffs point to an embodiment that calls for a "drug-impregnated polymer matrix," and Plaintiffs explain that this means that the drug is dispersed in the polymeric matrix like the yolk of an egg is dispersed in egg white (i.e., the egg yolk is centered, like a core, within the surrounding egg white). ('475 Patent, 10:40-41.) Plaintiffs illustrate this embodiment in Figure 1 of their opening brief, reproduced below. [3]

[3] Figure 1 from Plaintiffs' opening brief is not a drawing found in either the '475 or '280 Patents, but instead was generated by Plaintiffs for purposes of illustrating their egg yolk analogy. The Court must look upon this extrinsic evidence with caution as it "is not part of the patent and does not have the specification's virtue of being created at the time of patent prosecution for the purpose of explaining the patent's scope and meaning." Phillips, 415 F.3d at 1318.

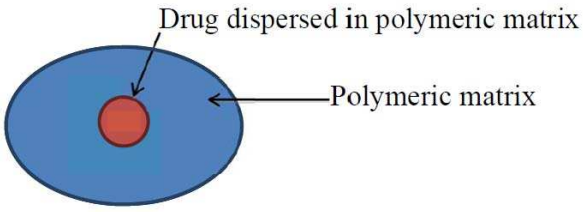


Figure 1. Embodiment of drug "dispersed" in the polymeric matrix

(Pls.' Opening Br. at 14; DE 45.) Thus, Plaintiffs argue that, to the extent that Defendants' construction requires that the drug be evenly distributed throughout the polymeric matrix, it is wrong because it reads out the "drug-impregnated" embodiment.

Neither patent elaborates on what it means to disperse a drug by impregnating it into the matrix, nor do any of the examples appear to use this method. However, a drug-impregnated polymeric matrix, as Plaintiffs understand it, would not accord with the "slow, continuous" delivery of the drug to the upper gastrointestinal system. ('475 Patent, 2:59-65.) If there was a drug core within the polymeric matrix, drug release into the stomach would not necessarily be continuous since the core's dissolution and diffusion would be delayed.

Besides the inference the Court takes from the phrase "slow, continuous" delivery, there is no additional intrinsic evidence to shed light on what a "drug-impregnated" polymeric matrix entails. Thus, the Court will turn to expert testimony for help in defining this term. See Callaway Golf Co. v. Acushnet Co., 576 F.3d 1331, 1338 (finding that "evidence of accepted practice within the art, when not at variance with the intrinsic evidence, is relevant to the question of how a person of skill in the pertinent field would understand the term."). Plaintiffs' expert, Dr. Harold B. Hopfenberg, has over forty years of experience in polymer science, and he specifically studies polymers used in controlled-release drug delivery systems, (see Hopfenberg Decl. ¶¶ 2-8), thus making his expert opinion particularly helpful in understanding the person of ordinary skill in the art of the patents-in-suit.

Dr. Hopfenberg takes issue with Plaintiffs' understanding of a drug-impregnated polymeric matrix. Upon considering Figure 1 from Plaintiffs' opening brief, Dr. Hopfenberg expressed concern that the illustration is "ambiguous" and does not "[have] anything to do with what the patent is about. If you take it literally, it's just a –- a small element of that matrix." (Hopfenberg Dep. 140:8-21; Defs.' Ex. 17 to Bogad Decl.; DE 53-3.) Instead, Dr. Hopfenberg offered his own illustration of what the patent describes, depicted below in Figure 2 and Figure 4:

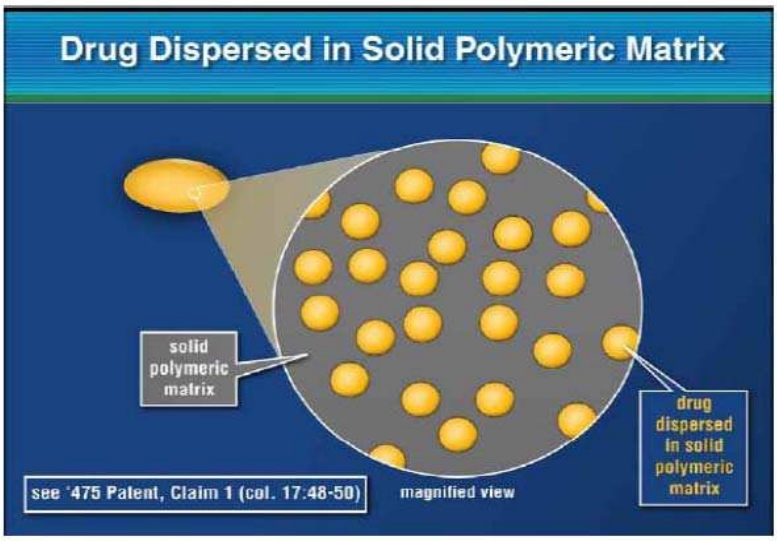


Figure 2

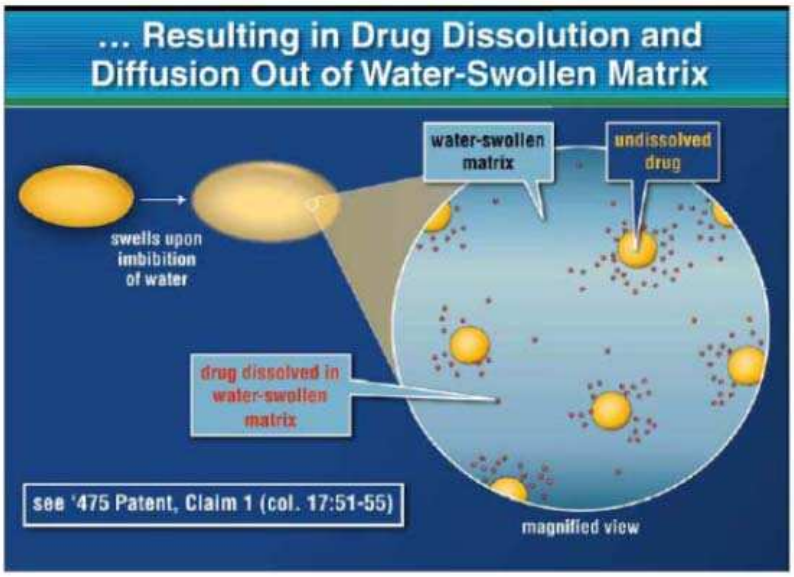


Figure 4

(Hopfenberg Decl. ¶ 55.) Dr. Hopfenberg explained that "[w]hen I say 'drug dispersed in a polymeric matrix," . . . I'm directed to Figure 2," which depicts drug particles separated in space by solid polymeric matrix. Moreover, he stated that Figure 4, a magnified shot of Figure 2, "is really the ultimate picture of what this invention is about." (Hopfenberg Dep. 139:19-21.) Dr. Hopfenberg apparently envisions a "drug-impregnated" matrix to be something different than Plaintiffs' egg yolk analogy, and he finds no support for such an analogy in the patent. (See id. at 108:13-15.) Accordingly, Dr. Hopfenberg's opinion is that a drug-impregnated matrix, as it is understood by a person of ordinary skill in the art, does not mean a drug core within a polymeric matrix shell. And Dr. Hopfenberg's illustrations of the dispersed drug in Figure 2 and Figure 4 show the drug being located "throughout" the polymeric matrix.

Further, it is not necessary that the drug be dispersed evenly in the polymeric matrix. (Id. at 139:8-17.) Indeed, Defendants stated during the Markman hearing that their definition does not require the drug to be distributed "homogenously" (i.e., evenly) in the polymeric matrix. (Markman Hearing Tr. 60:22-61:4.) Finally, Defendants' definition is consistent with the other ways in which a drug is dispersed in the polymeric matrix such as incorporated and mixed. (See '280 Patent, 7:58; '475 Patent 10:40-41.)

Therefore, "solid polymeric matrix with drug dispersed therein" means "a solid polymeric matrix with the drug dispersed throughout the matrix"; and "one or more polymers forming a solid polymeric matrix with said drug incorporated therein" means "the drug is dispersed throughout a solid polymeric matrix formed by one or more polymers."

C. "Said polymeric matrix being one that swells upon imbibition of water thereby attaining a size large enough to promote retention in the stomach during the fed mode" and "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"

The first term, "said polymeric matrix being one that swells upon imbibition of water thereby attaining a size large enough to promote retention in the stomach during the fed mode" is in the '475 Patent. The second term, "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," is found in the '280 Patent.

During the Markman hearing, the parties agreed to Judge Hamilton's construction. (Markman Hearing Tr. 40:6-15)); see also Lupin, 2011 U.S. Dist LEXIS 52839, at *23. Therefore, the terms "said polymeric matrix being one that swells upon imbibition of water thereby attaining a size large enough to promote retention in the stomach during the fed mode" and "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" mean "the dosage form, which comprises a polymeric matrix, increases in size due to the ingress of water, such that when the dosage form is introduced into the stomach in the fed mode, the dosage form remains in the stomach for several hours."

D. "Dissolution and Diffusion"

The term "dissolution and diffusion" is found in both the '475 Patent and '280 Patent. Plaintiffs' proposed construction is "rapid dissolution of the drug by the gastric fluid followed by slow diffusion of the drug out of the matrix, such that the drug is released at a rate primarily

controlled by the rate of diffusion." Defendants define the term to mean "rapid dissolution of the drug, followed by slow diffusion of the drug out of the water-swollen polymeric matrix, such that the drug is released at a rate controlled by the rate of diffusion from such matrix."

This term was construed in both Ivax and Lupin, and Plaintiffs simply adopt the construction announced by Judge Breyer in Ivax. See Ivax, 532 F. Supp. 2d at 1181. Neither party in this case has an issue with the word "primarily" being part of the construction, (see Markman Hearing Tr. 62:3-63:6), and the intrinsic evidence makes clear that the rate of release is controlled "primarily" by diffusion. (See '475 Patent, 5:57-61, 6:14-16.) Rather, the parties' dispute is whether the polymeric matrix must be "water-swollen" as Defendants' construction would require.[4]

Plaintiffs assert that there is no support for this precondition in the specification, but Plaintiffs are incorrect. The patents state that "[t]he release rate of a drug from the matrix is primarily dependent upon the rate of water imbibition and the rate at which the drug dissolves and diffuses from the swollen polymer." ('475 Patent, 9:7-10, 3:13-15.) As a matter of scientific principle, a drug will not dissolve without a solvent (a fluid), and if the drug is not dissolved in a fluid, it will not diffuse out of the matrix. (See Hopfenberg Decl. ¶ 59). The specification explains that swelling and dissolution/diffusion have a cause-effect relationship. (See '475 Patent, 6:22-24.) Moreover, Plaintiffs' own expert agrees that "water will enter the dosage form to cause matrix swelling and dissolution of the dispersed drug followed by diffusion of the drug out of the water-swollen matrix." (Hopfenberg Decl. ¶ 77.)

[4] This argument was not before either Judge Breyer or Judge Hamilton. However, Judge Hamilton recognized that the "release of water-soluble drugs can be achieved using a polymeric matrix that swells to create a diffusion barrier so that water-soluble drugs are released primarily by diffusion[.]" Lupin, 2011 U.S. Dist. LEXIS 52839, at *25.

Therefore, the Court will construe the term "dissolution and diffusion" to mean "rapid dissolution of the drug, followed by slow diffusion of the drug out of the water-swollen matrix, such that the drug is released at a rate primarily controlled by the rate of diffusion."

E. "Releases said drug into gastric fluid by the dissolution and diffusion of said drug out of said matrix" and "releases said drug into gastric fluid by the dissolution and diffusion of said drug out of said matrix by said gastric fluid"

These terms are found in the '475 and '280 Patents. Defendants offer one construction for both terms: "the water swollen polymeric matrix controls the dissolution and diffusion of the drug into the gastric fluid." Plaintiffs do not offer a specific construction because each of the words within this larger disputed phrase are being construed already. The Court agrees with Plaintiffs. The Court is construing the terms "dissolution and diffusion" and "polymeric matrix", and the parties have agreed on the construction of "gastric fluid." No further construction is necessary. (See also Pls.' Ex. 41 to Andre Decl.; DE 45-41.)

F. "Releases substantially all of said drug within about eight hours after such immersion", "until substantially all of said drug is released", and "while releasing substantially all of said drug within said stomach where said drug is maintained in an acidic environment"

The first term, "releases substantially all of said drug within about eight hours after such immersion," is from the '475 Patent. The second term, "until substantially all of said drug is released," is from the '280 Patent. And the third term, "while releasing substantially all of said drug within said stomach where said drug is maintained in an acidic environment," is found in both the '475 and '280 Patents. Plaintiffs offer one construction for all three terms: "at least about 80% of the drug has been released after eight hours of immersion in gastric fluid." Defendants define the terms separately. Defendants' construction for the first term is "about 100% of the drug has been released into gastric fluid." Defendants define the second term to mean "until about 100% of the drug has been released into gastric fluid." And Defendants'

construe the third term to mean "releasing about 100% of the drug in the stomach having a pH value of less than 7."

The parties' dispute focuses on the meaning of "substantially all." Defendants argue that the term should be given its plain and ordinary meaning of "about 100%," but "substantially all" must be understood in the context of how the term is used in the claims and specification. See Phillips, 415 F.3d at 1313 (quoting Multiform Desiccants, Inc., 133 F.3d at 1477). The specification first describes drug release in terms of how much remains in the matrix, rather than how much is released:

> The amount of polymer will be sufficient . . . to retain at least about 40% of the drug within the matrix one hour after ingestion (or immersion in the gastric fluid). Preferably, the amount of polymer is such that at least 50% of the drug remains in the matrix one hour after ingestion. More preferably, at least 60%, and most preferably at least 80%, of the drug remains in the matrix one hour after ingestion. In all cases, however, the drug will be substantially all released from the matrix within about ten hours, and preferably within about eight hours, after injection[.]

('475 Patent, 9:25-35.) The patents also depict graphically the amount of drug released over time. The figures depicting the release of metformin hydrochloride are reproduced below from the '475 Patent and '280 Patent.

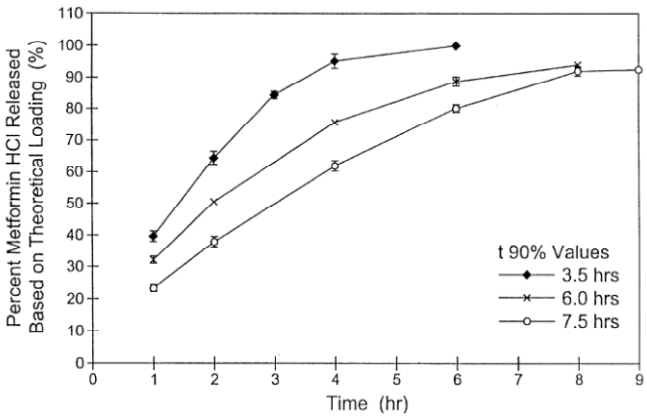


Fig. 1

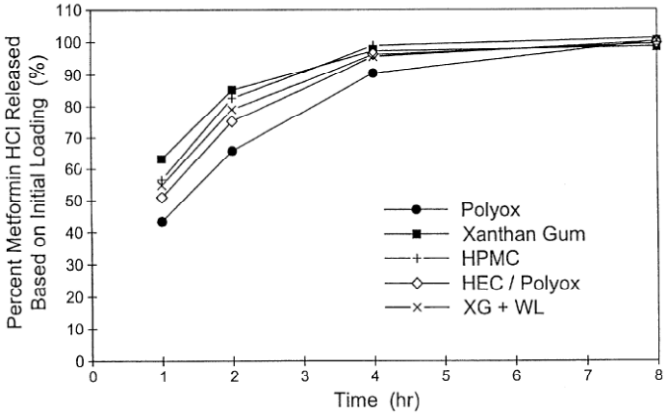


Fig. 4

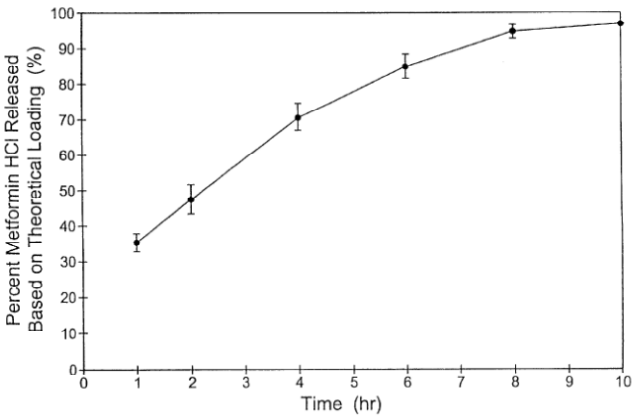


Fig. 5

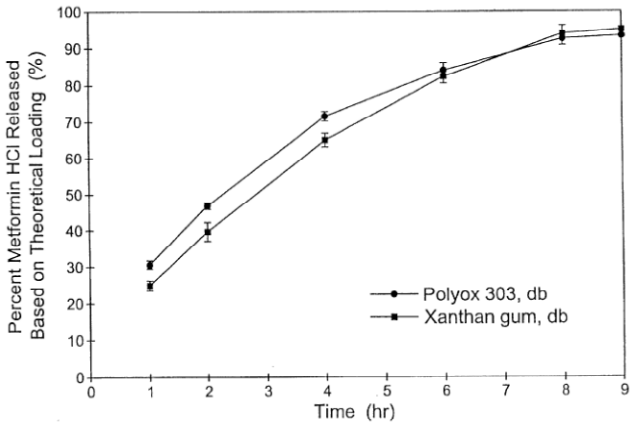
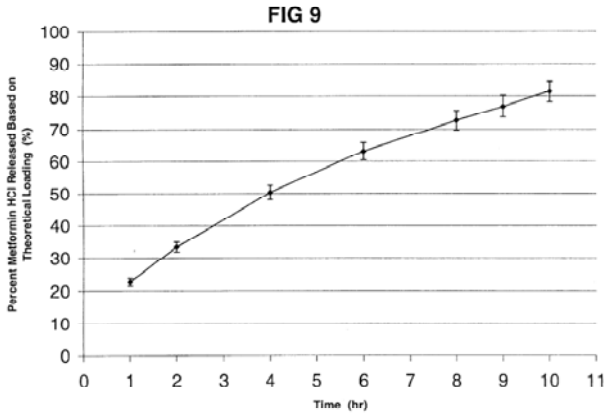


Fig. 7



('475 Patent, Figure 1, Figure 2, Figure 5, Figure 7, and Figure 9.) Each of these figures show the percentage released over time by various oral dosage units comprising polymeric matrices and metformin hydrochloride.[5] (See '475 Patent, Example 1, Example 4, and Example 5.) Figure 1 depicts the release rates for three dosage forms, one of which released 100% of its metformin hydrochloride in six hours, and two of which released only about 90% after nine hours. The dosage forms appearing in Figure 4 released about 100% of their metformin hydrochloride after eight hours. The dosage form appearing in Figure 5 released about 90% of metformin hydrochloride after eight hours. The dosage forms depicted in Figure 7 released just over 90% of their metformin hydrochloride after eight hours. And the dosage form depicted in

[5] Of course, the '475 and '280 Patents are not limited to dosage forms that release metformin hydrochloride. Figures 2, 3, 6, and 8 depict the release rates of other drugs. These figures show release rates anywhere from just over 60% to 100% release after eight hours.

Figure 9 released just over 70% of its metformin hydrochloride after eight hours, and 80% after ten hours.

These results reveal wide, varying release rates at the eight hour mark, thereby making the meaning of "substantially all" unclear. At the very least, the specification demonstrates that the patent applicants meant something other than "about 100%." "In some cases . . . claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words" but in this case, "determining the ordinary and customary meaning of the claim requires examination of terms that have a particular meaning in a field of art." Phillips, 415 F.3d at 1314 (internal citation omitted).

Judge Breyer also recognized the problem with construing "substantially all" based solely on the intrinsic evidence.[6] See Ivax, 2006 U.S. Dist. LEXIS 100311, at *13-14. "[R]oughly two-thirds (21 out of 31) of the formulations reported in the patent released at least 80% of the drug after eight hours" but "only three of the samples actually demonstrated a release between 80% or 90%." Id. Instead of relying on "the degree of testing that the patentee chose to perform—or to report" Judge Breyer sought "[a] firmer foundation, preferably rooted in the science[.]" Id. at *14. Judge Breyer relied upon, and Plaintiffs urge this Court to rely upon, FDA's "Guidance for Industry: Extended Release Oral Dosage Forms: Development, Evaluation, and Application of In Vitro/In Vivo Correlations" published in September 1997 (hereinafter "FDA Dissolution Guidance"). (See Pls.' Ex. 12 to Andre Decl.; DE 45-12.)

Defendants assert that it is improper for any court to rely on the FDA Dissolution Guidance because it was published in September 1997, just after the patentees filed their priority

[6] The defendant in Ivax proposed that "substantially all" meant "at least 90%." Ivax, 2006 U.S. Dist. LEXIS 100311, at *12. Here, Sun proposes "at least 90%" as an alternative construction. (Defs.' Opening Br. at 18; DE 47)

application for the ’475 and ’280 Patents on June 6, 1997. However, the FDA Dissolution Guidance expressly relies upon sources published and information gathered before the priority application date. (See Pls.’ Ex. 12 at 2.) It therefore is unreasonable to argue that a person of ordinary skill in the art at the time of the invention would not have been aware of the principles contained in the FDA Dissolution Guidance simply because it was published three months after the patentees filed their priority application. While the later publication date would prevent its consideration, for example, in an 35 U.S.C. § 103 obviousness analysis, the Court finds that the FDA Dissolution Guidance is properly considered during claim construction as evidence of the understanding of one skilled in the art. Moreover, the FDA Dissolution Guidance does not raise many of the concerns often associated with extrinsic evidence. See Phillips, 415 F.3d at 1318. In particular, the FDA Dissolution Guidance was published at the time of patent prosecution, was written by and for those skilled in the art, and therefore reflects the understanding of a skilled artisan in the field. See id.

The FDA Dissolution Guidance explains that, with respect to in vitro dissolution testing, the same testing reported in the ’475 and ’280 Patents, results should be gathered at a minimum of three time points: the early, middle, and late stages of dissolution). (Pls.’ Ex. 12 at 16-17.) “The last time point should be the time point where at least 80% of drug has dissolved.” (Id. at 17.) In other words, the appropriate end point for testing dissolution of a drug is when 80% of the drug is released. Therefore, the Court agrees with and gives appropriate deference to Judge Breyer’s reliance on the FDA Dissolution Guidance and will adopt Plaintiffs’ proposed construction. The terms “releases substantially all of said drug within about eight hours after such immersion,” “until substantially all of said drug is released,” and “while releasing substantially all of said drug within said stomach where said drug is maintained in an acidic

environment" mean "at least 80% of the drug has been released after eight hours of immersion in gastric fluid."

G. "Until all of said drug is released"

This term is in the '475 Patent. Plaintiffs define the term to mean "until the plateau of the dissolution profile characterizing drug release from the swollen dosage form is reached," and Defendants define it as "until all of the drug has been released into the gastric fluid." Similar to the previous terms, (see Discussion, supra, Part III.F), the parties' dispute focuses on the word "all." Defendants maintain that "all" has the plain and ordinary meaning of 100%, but Plaintiffs disagree, arguing that those words have special meaning in the context of the '475 Patent.

The claim elements in which the term appears require that the polymeric matrix "remain[] substantially intact until all of said drug is released." ('475 Patent, Claim 1, Claim 34; see also '475 Patent, 9:35-36.) Defendants argue, and the Court agrees, that "all of said drug" must have a meaning different than "substantially all of said drug." See Symantec Corp. v. Computer Assocs. Int'l, Inc., 522 F.3d 1279, 1289 (Fed. Cir. 2008)("[W]hen construing terms in the body of a claim, the general assumption is that different terms have different meanings[.]"). The '475 Patent discloses that the dosage form will not always, and often does not, release 100% of the incorporated drug, and therefore, Defendants' construction cannot be correct. (See, e.g., '475 Patent, Figure 1.) But there nothing else in the intrinsic evidence to assist the Court in determining what meaning the patentees intended to give "all of said drug."

In construing this term, and faced with essentially the same opposing constructions,[7] Judge Hamilton again turned to the FDA Dissolution Guidance document to determine the

[7] Depomed offers the same construction here as it offered in Lupin. See Lupin, 2011 U.S. LEXIS 52839, at *31. The defendant in Lupin argued that "until 100% of the drug is dissolved .

meaning that a person of ordinary skill would give to this term. The FDA Dissolution Guidance explains that "[if] the maximum amount dissolved is less than 80%, the last time point should be the time when the plateau of the dissolution profile has been reached." (Pls.' Ex. 12 at 17.) FDA's "Guidance for Industry: SUPAC-MR: Modified Release Solid Oral Dosage Forms" explains that the endpoint of dissolution testing should occur "until either 80% of the drug from the drug product is released or an asymptote is reached." (Pls.' Ex. 11 to Andre Decl. at 8; DE 45-11.) Put differently, when the plateau or asymptote of the dissolution profile is reached, all of the drug that is going to be released has been released; and it makes sense that the polymeric matrix will remain substantially intact until this occurs in order to carry out the extended, controlled release function. Moreover, unlike Defendants' construction, Plaintiffs' construction would ensure that no embodiment is read out of the claim because not all dosage forms disclosed in the patent release 100% of the drug contained in the dosage form. See Adams Respiratory Therapeutics, Inc. v. Perrigo Co., 616 F.3d 1283, 1290 (Fed. Cir. 2011). Therefore, the Court will construe the term "until all of said drug is released" to mean "until the plateau of the dissolution profile characterizing drug release from the swollen dosage form is reached."

H. "At a weight ratio of drug to polymer of from 15:85 to 80:20", "at a weight ratio of drug to polymer of from 0.1:99.99 to 80:20", and "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"

The terms "at a weight ratio of drug to polymer of from 15:85 to 80:20" and "at a weight ratio of drug to polymer of from 0.1:99.9 to 80:20" both appear in the '280 Patent. Plaintiffs argue that these terms do not need construction as they can be given their plain and ordinary meaning. Defendants do not dispute that Plaintiffs' construction is correct, but they nonetheless

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. . ," id., whereas in this case, Sun argues that the term means "until all of the drug has been released . . . ."

offer a construction that they believe is easier to understand: "the weight of drug is [15 to 80%/0.1% to 80%] relative to the total weight of drug and polymer in the solid polymeric matrix." Indeed the specification confirms that Defendants' construction is simply another way of expressing the claim term. ('280 Patent, 9:50-60.) There is therefore no need to construe these first two terms.

The third term, "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," appears in the '475 Patent. Plaintiffs define the term to mean "a medium comprising polymer that surrounds drug particles at a drug to polymer ratio from 14.4:85.6 to 80.8:19.2." Defendants similarly construe the term to mean "a polymeric matrix at a drug to polymer weight ratio from 14.4:85.6 to 80.8:19.2." The parties thus do not dispute the meaning of "about 15:85 to about 80:20," (see Pls.' Ex. 41), but instead differ only in the definition of "a solid polymeric matrix with said drug dispersed therein." The Court already has construed "a solid polymeric matrix with said drug dispersed therein," and need not define it again here. Therefore, the Court will construe the term "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" to mean "a solid polymeric matrix with said drug dispersed therein at a weight ratio of drug to polymer of from 14.4:85.6 to 80.8:19.2."

I. "Dosage form consisting essentially of a solid monolithic matrix with said drug contained therein"

This term appears in the '962 Patent. Plaintiffs argue that the term does not require construction. Defendants define the term to mean "dosage form with a solid monolithic matrix containing the drug and no other components that restrict swelling of the matrix."

The Court agrees with Plaintiffs that this term does not require independent construction. First, "consisting essentially of" has an accepted meaning in patent law and does not need further

definition. "By using the term 'consisting essentially of,' the drafter signals 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." PPG Indus. v. Guardian Indus. Corp., 156 F.3d 1351, 1354 (Fed. Cir. 1998). Second, the parties have agreed that the phrase "solid monolithic matrix" means "single entire matrix." (See Pls.' Ex. 41.)

Finally, neither party offers a specific definition for the phrase "drug contained therein." Defendants' proposed construction does not give any separate meaning to this phrase. Plaintiffs suggest that the phrase is already being defined by the Court, although the Court is construing "drug dispersed therein" as opposed to "drug contained therein." Nevertheless, the '962 Patent, which is an improvement upon the '475 and '280 Patents, adopts similar, and sometimes identical, language to the '475 and '280 Patent with respect to swellable polymers and their use in extended, controlled release technology. (Cf. '962 Patent, 4:48-52, with '475 Patent, 7:54-58; cf. '962 Patent, 3:52-61, with '475 Patent, 5:57-66.) In addition, the '962 Patent uses "dispersed" and "contained" interchangeably when referring to the drug's location in the polymeric matrix. (See id. 7:31-32, 3:52-53.) The Court will therefore will give "drug contained therein" in the term "dosage form consisting essentially of a solid monolithic matrix with said drug contained therein" the same meaning as "drug dispersed therein." (See Discussion, supra, Part III.B.)

J. "Swells in an unrestricted manner along both such axes"

The term "swells in an unrestricted manner along both such axes" is found in the '962 Patent. Plaintiffs argue that this term can be given its plain and ordinary meaning, but alternatively propose that the term means "imbibition of fluid causes an increase in volume of the matrix, wherein the relative length of both axes after imbibition of fluid is substantially the

same as the relative dimensions of the original matrix." Defendants' construction of the term is "no component of the dosage form hinders swelling of the matrix in any dimension (i.e. prevents completely or partially the matrix from swelling)."

For the reasons set forth during the Markman hearing, (see Markman Hearing Tr. 53:2-22), the Court finds that this term does not require construction.

K. "Said matrix has a shape which when projected onto a plane" and "said matrix being non-circular in shape and having a first and second orthogonal axes of unequal length"

Both terms appear in the '962 Patent. Plaintiffs contend both terms can be given their plain and ordinary meaning. Defendants define "said matrix has a shape which when projected onto a plane" to mean "the largest planar projection of the tablet." Defendants construe the term "said matrix being non-circular in shape and having a first and second orthogonal axes of unequal length" to mean "the largest planar projection of the shape has a first and second orthogonal axes of unequal length."

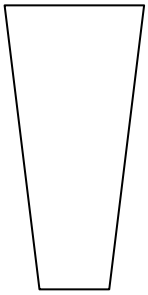
The main dispute concerns Defendants' use of the word "largest" to modify "planar projection." The claim in which these terms appear states in part:

> A controlled-release oral drug dosage form . . . said dosage form comprising a solid monolithic matrix with said drug contained therein, said matrix being non-circular in shape and having a first and second orthogonal axes of unequal length . . . wherein said matrix has a shape which when projected on to a plane, is either an oval or a parallelogram.

('962 Patent, Claim 1.) The specification explains that the shape of the dosage form is important because certain shapes prevent the dosage form from escaping through the pylorus. (Id. 3:22-28.) "The shape that achieves this result is a non-circular and non-spherical shape which, when projected onto a planar surface, has two orthogonal axes of different lengths[.]" (Id. 3:28-31.) The specification lists possible shapes for the dosage form—"oval, triangle, almond, peanut,

'bow tie,' parallelogram, trapezoidal, pentagonal, and hexagonal, provided . . . that the largest planar projection of the shape has at least two orthogonal dimensions, one being larger than the other." (Id. 4:10-12.)

Defendants thus argue that the "planar projection" referred to in Claim 1 of the '962 Patent must be the "largest planar projection." However, Defendants' definition would read out several embodiments. Claim 1 requires that the matrix have "a shape which when projected onto a plane, is either an oval or a parallelogram." (Id., 11:24-25.) But the largest planar projections of several of the shapes listed in the specification are neither an oval nor a parallelogram. For example, the largest planar projection of a trapezoid is neither an oval nor parallelogram, as illustrated below.



The same is true for a triangle, pentagram, bow tie, or hexagon. Therefore, Defendants' construction thus reads out embodiments described in the specification and complicates a term that can be given its plain and ordinary meaning. The Court agrees with Plaintiffs that these terms do not require construction.

L. "An oval"

The term "an oval" appears in the '962 Patent. Plaintiffs' proposed construction is "any curve that is closed and concave towards the center wherein the geometric form bounded by the closed curve has first and second orthogonal axes of unequal length." Defendants define the

term to mean "a shape that has a curve that is closed and concave toward the center and has an overall non-circular shape from all dimensions."

In the context of Claim 1, where the term appears, "an oval" is two-dimensional since the oval is a projection onto a plane. ('962 Patent, 11:24-25.) It therefore is improper for Defendants to define the term in a three-dimensional context because "an oval," as it is used in the claim, is only two-dimensional rather than three-dimensional. (See Markman Hearing Tr. 74:12-18.) Apart from this reference to "all dimensions," there is no material difference between the two proposed constructions since both use the language a "curve that is closed and concave towards the center." In addition, there can be no serious dispute that the shapes contemplated by the '962 Patent, including an oval, require axes of unequal length. (See, e.g., '962 Patent, Claim 1; Claims 2-9 (requiring the "shorter" axis to be of a particular length).)

Finally, the construction proposed by Plaintiffs was the construction agreed upon in Lupin. See 2011 U.S. Dist. LEIXS 52839, at *42-43. Plaintiffs assert that, for the sake of consistency, the Court should adopt this construction. The Court agrees, Markman, 517 U.S. at 391, and will define "an oval" to mean "any curve that is closed and concave towards the center wherein the geometric form bounded by the closed curve has a first and second orthogonal axes of unequal length."

M. "First solid polymeric matrix"

The term "first solid polymeric matrix" is from the '667 Patent. Plaintiffs propose that this term can be given its plain and ordinary meaning. Defendants define the term to mean "a solid polymeric formulation containing a sufficient amount of a suitable polymer or polymer mix to provide extended, controlled release of a drug dispersed throughout the formulation." Defendants explain, and the Court agrees, that this term is not materially different than the term

"polymeric matrix" appearing in the '475 and '280 Patents. The only difference is that the polymeric matrix of the '667 Patent is in a "dual-matrix configuration, one matrix forming a core of polymeric material in which the drug is dispersed and the other matrix forming a casing that surrounds and fully encases the core, the casing being of polymeric material." ('667 Patent 7:8-10.) There is, for this reason, a "first" and "second" polymeric matrix required in the '667 Patent, (id. 21:41-41, 43), but there is no difference in the "polymeric matrix" among the '667, '475, and '280 Patents.

Consequently, the Court will apply the same reasoning to "first solid polymeric matrix" here as it did for "polymeric matrix" above. (See Discussion, supra, Part III.A.) Specifically, Defendants' proposed construction uses language that is unhelpful in furthering the understanding of term and that repeats elements already in the claim language. (See '667 Patent, 21:36-41.) However, it is not necessary to define the term this way because it would render the claim language redundant and more confusing than the term itself. The Court will therefore define "first solid polymeric matrix" to mean "a first medium comprising polymer."

N. "A core comprising a first solid polymeric matrix with said drug dispersed therein"

This term is found in the '667 patent. Plaintiffs propose that the term means "a core comprising a first medium comprising polymeric materials that surrounds drug particles." Defendants define the term to mean "the core of a drug dosage form comprising a drug dispersed throughout a first solid polymeric matrix."

The dispute between the parties is whether "drug dispersed therein" means that the drug is located "throughout" the matrix or whether the matrix simply "surrounds" the drug. Although the Court has resolved the dispute over the meaning of "drug dispersed therein," as it appears in the '475 and '280 Patents, (see, Discussion, supra, Part III.B.), the claim term "a core comprising

a first solid polymeric matrix with said drug dispersed therein" is in a different patent—the '667 Patent. Still, the parties advance the same arguments. In particular, Plaintiffs argue that Defendants' construction excludes embodiments where the drug is localized in the dosage form, the drug is a core, or the drug is in clusters.

In advancing this argument, Plaintiffs essentially suggest that the drug may be a core, within the first polymeric matrix core, within the polymeric matrix shell. But the '667 Patent forecloses this possibility because the '667 Patent contemplates a dual-matrix configuration rather than a triple configuration. The specification explains the invention is "a dual-matrix configuration, one matrix forming a core of polymeric material in which drug is dispersed and the other matrix forming a casing that surrounds fully and encases the core . . . , the shell and core being configured such that the drug contained in the core is released from the dosage form by diffusion through the shell." ('667 Patent 7:9-17.) Consequently, the '667 Patent does not provide for a drug to be dispersed in the dosage form such that the drug must first diffuse out of its own core, second out of the polymeric matrix core, and third out of the polymeric matrix shell. In fact, this would be contrary to the required "zero-order drug release," which means a constant drug release. ('667 Patent, 7:3-6.)

Moreover, the '667 Patent does not recite an embodiment requiring a drug-impregnated matrix, but this embodiment was Plaintiffs' justification, with regard to the '475 and '280 Patents, for disagreeing with the word "throughout." In fact, all examples listed in the '667 Patent disclose dosage forms in which the core was prepared by "mixing together" or "blending" the drug and polymer or polymer mix. (See, e.g., '667 Patent, 13:46-50; 18:64-67.)

In addition, the Court is satisfied that Defendants' use of "throughout" would not exclude embodiments where the drug dispersed in the polymeric matrix core is dispersed unevenly.

Defendants' construction does not require that the drug be incorporated homogenously or evenly throughout a first solid polymeric matrix. Nor would the specification support such a construction. The Court will therefore construe "a core comprising a first solid polymeric matrix with said drug dispersed therein" to mean "the core of a drug dosage form comprising a drug dispersed throughout a first solid polymeric matrix."

O. "A second solid polymeric matrix that swells upon imbibition of water to a size large enough to promote retention in the stomach while the stomach is in the fed mode"

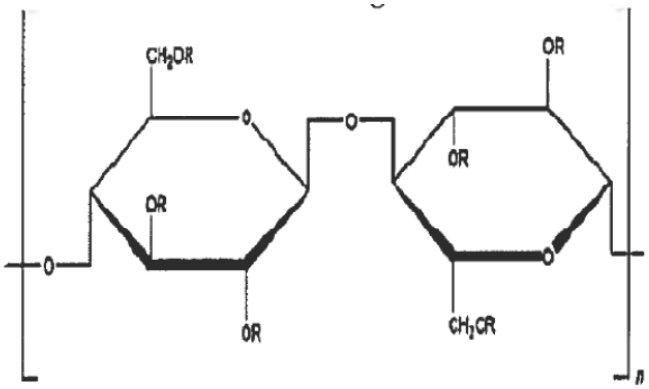
This term is found in the '667 Patent. Plaintiffs assert that the term does not require construction, but they alternatively suggest it should be construed to mean "a second medium comprising polymeric materials which increases in size such that when the dosage form is introduced into the stomach in the fed mode, the dosage form remains in the stomach for several hours." Defendants define the term to mean "a second, solid polymeric formulation comprised of a water-swellable polymer that surrounds and fully encases the core, is of a sufficient thickness and strength that it is not disrupted by the swelling and remains intact and of a size large enough to promote gastric retention; the 'shell.'"

Except for the word "second," the Court has already construed this term as it appears in the '475 Patent, and there is no reason to depart from that construction. The claim language is the same between the two patents, (cf. '667 Patent, 21:43-45, with '475 Patent, 17:50:53), as are the specifications' disclosures with respect to this aspect of both inventions, (see '667 Patent, 8:19-23; '475 Patent, 7:54-58). The Court will therefore construe the term "a second solid polymeric matrix that swells upon imbibition of water to a size large enough to promote retention in the stomach while the stomach is in the fed mode" to mean "a second solid polymeric matrix which increases in size due to the ingress of water such that when the dosage

form is introduced into the stomach in the fed mode, the dosage form remains in the stomach for several hours."

P. "Hydroxyalkyl-substituted cellulose"

The term "hydroxyalkyl-substituted cellulose" appears in the '667 Patent. Plaintiffs believe the term does not require construction because the term has a plain and ordinary meaning to those skilled in the art. Defendants define the term to mean "a cellulose derivative having the structure



which dissolves in the GI tract in a predictably delayed manner wherein at least one R has a free hydroxyl group and is represented by –(AO)mH wherein A is a straight chain or branched alkyl."

This term appears in the '667 Patent only once. Claim 1 requires that the "second polymeric matrix comprise a polymer independently selected from the group consisting of poly(ethylene oxide), a cross-linked polyacrylic acid, and a hydroxyalkyl-substituted cellulose." ('667 Patent, 21:61-65.) While the specification does not use the term "hydroxyalkyl-substituted cellulose" it lists as examples of "suitable "cellulose polymers and their derivatives," which include hydroxyalkyl-substituted celluloses such as "hydroxymethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, [and] hydroxypropylmethyl cellulose." ('667 Patent, 8:31-35.) Further, the specification explains that "[p]referred cellulosic polymers are

alkyl-substituted cellulosic polymers that ultimately dissolve in the [gastrointestinal] tract in a predictably delayed manner." ('667 Patent, 8:62-64.)

At the very least, the Court cannot read into the term the phrase "dissolves in the GI tract in a predictably delayed manner" since this is from a preferred embodiment. The patent expressly states that "preferred" cellulose polymers are those that are alkyl-substituted and ultimately dissolve in the gastrointestinal tract in a predictably delayed manner. (Id. 8:63-65.) Defendants offer no basis for including this phrase in their construction, other than that the phrase appears in the specification. However, Defendants cannot lift a characteristic from a preferred embodiment and insert into the claim. Seachange Int'l, 413 F.3d at 1377.

As to Defendants' proposed chemical structure and formula for "hydroxyalkyl-substituted cellulose," the parties offer vastly different expert opinions. "It is permissible, and often necessary, to receive expert evidence to ascertain the meaning of a technical or scientific term or term of art so that the court may be aided in understanding . . . what [the instruments] actually say." Markman, 52 F.3d at 981 (quoting U.S. Indus. Chems., Inc. v. Carbide & Carbon Chems. Corp., 315 U.S. 668, 678 (1942)). Plaintiffs' expert, Dr. Hopfenberg, states in his expert report that in his opinion, the term does not need construction because a person of ordinary skill in the art would readily understand the meaning of "hydroxyalkyl-substituted cellulose." (See Hopfenberg Decl. § 145.)

Defendants' expert, Dr. Umesh Banakar, does not expressly disagree that a person of ordinary skill in the art would readily understand the term. Instead, he responds to deposition testimony given by Dr. Hopfenberg, in which Dr. Hopfenberg discounts Defendants' proposed construction. Dr. Banakar and Dr. Hopfenberg do agree on two things. Both recognize the structure in Defendants' construction as the basic structure for cellulose, where the "Rs" are

hydrogens making the "ROs" hydroxyl groups (one hydrogen + one oxygen) attached to the glucose backbone (appearing in Defendants' construction as the repeating hexagon shape). (See Banakar Decl. ¶ 24, DE 53-1; Hopfenberg Dep. 256:2-4, 257:8-16.) Dr. Banakar and Dr. Hopfenberg both explain that all cellulose derivatives have a hydroxyl group attacked to the glucose backbone.

What is disputed, however, is what the "Rs" stand for in the hydroxyalkyl-substituted cellulose. In particular, the experts disagree as to whether the glucose backbone must have at least one hydroxyl group in addition to the straight chain or branched alkyl group, or whether the hydroxyl and the straight chain or branched alkyl are together off of the glucose backbone. Dr. Hopfenberg states that the "R" can either be a hydroxyl group or straight chain or branched alkyl group, but not both. (Hopfenberg Dep. 251:7-9 ("It's incorrect to say R has a free hydroxyl group. R is either a hydrogen or it's an alkyl group.").) But Dr. Banakar states that a person skilled in the art "would understand that a hydroxyalkyl-substituted cellulose [] has an R group that has a straight chain or branched alkyl that has a free hydroxyl group," where "$–(AO)_mH$ represents a straight chain or branched alkyl with a hydroxyl group," and where "there will be the same number of hydroxyl groups as the number for 'm.'" (Banakar Decl. ¶ 24.) Accordingly, Dr. Banakar supports the view that requires the hydroxyl and straight chain or branched alkyl to be together off of the glucose backbone. And it is Dr. Banakar's view that is described in Defendants' construction.

In support of their definition, Defendants point to the structure of hydroxypropyl methylcellulose (one of the '667 Patent's preferred alkyl-substituted celluloses) as it is detailed in an article entitled "Modulation of drug release from hydrophilic matrices." (See Defs.' Ex. 13 to Bogad Decl. at 3; DE 47-14.) The article illustrates the general structure of cellulose ether,

explains that "the R-group can be a single or a combination of substituents, and that hydroxypropyl methylcellulose "contains methoxyl (CH_3-O-) and hydroxypropoxyl ($CH_3CHOHCH_2$-O-) substituents." (Id. at 2-3.)

However, the article's explanation of the structure of hydroxypropyl methylcellulose is not consistent with Defendants' construction. Even if the hydroxypropyl group fits in the –$(AO)_mH$ formula, Defendants' construction would not provide at all for the methyl group. Further, if the Defendants' construction requires the methyl group to also fit in the –$(AO)_mH$ formula, it is wrong because the methyl group does not have a free hydroxyl group. Nor does Defendants' definition explain what atoms and/or groups will replace the "Rs" in the chemical structure not containing an –$(AO)_mH$.

Ultimately, the Court agrees with Dr. Hopfenberg that Defendants' construction is confusing, incomplete, and would not serve to aid the jury in understanding the meaning of "hydroxyalkyl-substituted cellulose." Again, Defendants attempt to complicate a term, whose scope does not appear to be genuinely disputed and that has plain and ordinary meaning to a person of ordinary skill in the art. Therefore, the Court finds that "hydroxyalkyl-substituted cellulose" does not require construction.

Q. "Curing the coated oral dosage form at a temperature of at least 55° C"

This term appears in the '987 Patent. Plaintiffs assert that the term does not need construction. Defendants propose the term means "the coated oral dosage form is raised to a temperature of at least 55° C." The dispute over this term focuses on whether the dosage form must be cured at 55° C or whether the dosage form's internal temperature must reach 55° C.

The claim is itself sufficient to resolve this dispute because the language requires "curing . . . at a temperature of at least 55° C to form the stable controlled release monolithic coating."

('987 Patent, 25:1-3; 26:3-5 (emphasis added).) It does not require that the oral dosage form be cured "to" a temperature of at least 55° C. If there was ever any doubt, however, the specification settles the issue:

> During the coating process, the product temperature range is maintained between about 25° C to about 40° C for about 3-5 minutes at a low pan speed and low air flow . . . . The coated tablet cores are placed onto a tray and cured (post coating thermal treatment) in an electrical or steam oven at a temperature above the temperature of the melting point of polyethylene glycol or derivative thereof [55° C]. . . The curing time is preferably about 2 to about 7 hours. The cured coated tablets are subsequently cooled to room temperature.

('987 Patent, 10:37-53.) Accordingly, it is clear that the patentees distinguished between tablets being cured at a certain temperature and tablets being heated or cooled to a certain temperature.

The 55° C temperature requirement derives from the melting point of poly glycol. "The coat formulation also [comprises] a poly gycol with a melting point of greater than 55°C . . . or a suitable polyglycol derivative[] having a melting point of at least 55 deg C." Accordingly, Defendants argue that the dosage form itself must be raised to a temperature of at least 55° C so that the poly glycol coating will melt. But the '987 Patent never calls for the poly glycol coating to melt; rather, the purpose of the curing is to "form the stable controlled release monolithic coating." ('987 Patent, 25:1-3.)

The embodiments disclosed in the '987 patent further confirm that there is there no requirement that the coating melt. (See, e.g., '978 Patent, 13:21-23 ("After application of the coating the tablets were cured in an oven at 62±2° C for about 2 hours. This temperature is above the melting temperature of the polyethylene glycol 8000.").) Defendants simply assume that because the patent defines the curing temperature with reference to a melting point, the

coating must actually melt. But that assumption finds no support in the intrinsic evidence. Therefore, the Court agrees with Plaintiffs that this term requires no construction.

IV. CONCLUSION

For the reasons stated herein and for the reasons set forth on the record during the Markman hearing, the Court construes the terms of United States Patent No. 6,340,475, United States Patent No. 6,635,280, United States Patent No. 6,488,962, United States Patent No. 7,736,667, and United States Patent No. 7,780,987 as announced in the Order accompanying this Memorandum Opinion.

Dated: August 3, 2012

/s/ JOEL A. PISANO
United States District Judge