UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

DEPOMED, INC.,

Plaintiff,

v.

LUPIN PHARMACEUTICALS, INC., et al.,

Defendants.
_____/

No. C 09-5587 PJH

ORDER CONSTRUING CLAIMS

Plaintiff Depomed, Inc. ("Depomed") asserts three patents against defendants Lupin Pharmaceuticals, Inc. and Lupin Limited (collectively, "Lupin"). The patents at issue involve or relate to orally-administered drug formulations.

Depomed, which is based in California, is a specialty pharmaceutical company, which was founded in 1995 to design, develop, and market pharmaceutical products utilizing optimized drug delivery technologies. Depomed focused its early research efforts on the development of a gastric-retentive drug delivery system designed as a conventionally-sized pill, which swells over time in the stomach, thus providing continuous and controlled drug to the patient's upper gastrointestinal ("GI") tract.[1]

U.S. Patent Nos. 6,340,475 ("the '475 patent") and 6,635,280 ("the '280 patent"), both entitled "Extending the Duration of Drug Release Within the Stomach During the Fed Mode," were issued to Depomed as assignee of the inventors on January 22, 2002, and October 21, 2003, respectively. The invention of the '475 and '280 patents relates

[1] The upper GI tract includes the stomach, the duodenum, and the upper small intestine.

generally to oral formulations for drugs, also known as "drug dosage forms."

Oral drug dosage forms typically contain one or more "excipients" in addition to a biologically active ingredient ("the drug"). Excipients are biologically inactive components that provide desirable characteristics to the dosage form. Some excipients, such as binders, disintegrants and lubricants, do not contribute to the control of release of the drug from the dosage form. Others, termed "release controlling excipients," contribute to or actually control the release of the drug from the dosage form.

Dosage forms are directed to a variety of routes of administration including, for example, intravenous or intramuscular injections, tablets or capsules for oral administration, patches that adhere to the skin for administration of drugs across the skin, and suppositories. The invention of the '475 and '280 patents relates to an oral drug dosage form (a dosage form that is swallowed or ingested – typically, one or more tablets), which benefits from a prolonged period of controlled release in the upper GI tract, and from an enhanced opportunity of absorption in the upper GI tract rather than in the lower portions of the GI tract.

The '475 and '280 patents arise out of a common application filed in June 1997. The '280 patent is a continuation of the '475 patent, which itself is a continuation-in-part of an application now abandoned. Thus, the '475 and '280 patents provide substantively identical disclosures, the specifications differing only by cross-references made to related applications.[2]

The primary objectives of the invention of the '475 and '280 patents are to control the duration of drug release and to determine the location of delivery in the patient's body (where the active ingredient is released from the dosage form). "Controlled release" dosage forms, such as those described in the '475 and '280 patents, are different from "immediate release" dosage forms. With respect to immediate release dosage forms, the patents explain that "drugs that are administered in the form of conventional tablets or

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[2] Thus, in citing to the specification of the '475 patent in this order, the court for the most part also intends citations to the specification of the '280 patent.

capsules become available to body fluids at a rate that is initially very high, followed by a rapid decline." '475 Patent, Col. 1:30-33. The problem with conventional immediate release dosage forms is that they can result in a transient overdose, followed by a long period of underdosing to the patient. Id., Col. 1:33-35.

A variety of controlled release dosage forms have been developed since the 1970's. The controlled release oral dosage form described in Claim 1 of the '475 and '280 patents, comprises a drug dispersed within a polymeric matrix. Id., Col. 17:48-50. A polymer is a very large molecule made up of many repeating subunits. The polymeric matrix described in the patents-in-suit has a special property of being able to absorb or imbibe water, thereby causing the dosage form to increase in size and, in turn, retard the rate of release of drug from the swollen dosage form. Id., Col. 17:51-55.

U.S. Patent No. 6,448,962 ("the '962 patent"), entitled Tablet Shapes To Enhance Gastric Retention of Swellable Controlled-Release Oral Dosage Forms," was issued to Depomed as assignee of the inventors on December 3, 2002, and arises out of an application filed in June 2000. The invention of the '962 patent discloses an improvement over the '475 and '280 patents, by extending gastric retention of a dosage form by using particular shapes, sizes, and swelling properties. The particular shape of these dosage forms and the minimum dimensions of the dosage form increase gastric retention over the dosage forms of the '475 and '280 patents.

Lupin Pharmaceuticals, Inc. is located in Maryland, and is a wholly-owned subsidiary of Lupin Limited, an Indian company. Lupin is in the business of making and selling generic pharmaceutical products.

Depomed commercialized Glumetza® – a once-daily treatment for adults diagnosed with type-2 diabetes. Glumetza® contains the drug metformin HCL, formulated in extended controlled-release 500 mg. and 1000 mg. tablets. In 2009, Lupin submitted Abbreviated New Drug Application ("ANDA") No. 91-664 to the FDA pursuant to 21 U.S.C. § 355(j), seeking approval to market generic Glumetza® metformin HCL extended-release tablets in the 500mg and 1000mg dosage strengths.

In November 2009, Lupin sent Depomed written notification that Lupin had filed the Lupin ANDA, and also asserting that the '475, '280, and '962 patents are invalid or will not be infringed by the commercial manufacture, use, or sale of the Lupin products. Following this notification, Depomed filed the present lawsuit.

The parties now seek an order construing nine disputed terms, and Depomed also seeks an order striking certain statements from Lupin's responsive claim construction brief, and certain portions of one of Lupin's declarations. The court heard argument on January 26, 2011, and now rules as follows, and for the reasons stated at the hearing.

DISCUSSION

A. Legal Standard

Patent infringement analysis involves a two-step process. The court must first determine as a matter of law the correct scope and meaning of disputed claim terms, and must then compare the properly construed claims to the accused device to see whether the device contains all the limitations (literally or by equivalents) in the claims at issue. Markman v. Westview Instruments, Inc., 517 U.S. 370, 384 (1996).

"[T]he 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) (citation and quotation omitted). The court must determine the meaning of disputed claim terms from the perspective of one of ordinary skill in the pertinent art at the time the patent was filed. Chamberlain Group, Inc. v. Lear Corp., 516 F.3d 1331, 1335 (Fed. Cir. 2008).

A patentee is presumed to have intended the ordinary meaning of a claim term in the absence of an express intent to the contrary. See York Prods., Inc. v. Central Tractor Farm & Family Ctr., 99 F.3d 1568, 1572 (Fed. Cir. 1996). 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." Phillips, 415 F.3d at 1313.

The person of ordinary skill in the art is "deemed to read the claim term not only in the context of the particular claim . . . but in the context of the entire patent, including the specification." Id. Indeed, a patent's specification "is always highly relevant to the claim

construction analysis" and claims "must be read in view of the specification, of which they are a part." Id. at 1312-15 (citations and quotations omitted). Because the specification must contain a description of the invention that is clear and complete enough to enable those of ordinary skill in the art to make and use it, the specification is therefore "always highly relevant" to the court's claim construction analysis. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996).

In some cases, the specification may reveal that the patentee has given a special definition to a claim term that differs from its ordinary meaning; in such cases, "the inventor's lexicography controls." Phillips, 415 F.3d at 1316. The specification also may reveal the patentee's intentional disclaimer or disavowal of claim scope. "In that instance, as well, the inventor has dictated the correct claim scope, and the inventor's intention, as expressed in the specification, is regarded as dispositive." Id. Although the court must read the claim in view of the specification, the claims are not limited to preferred embodiments or illustrative examples appearing in the specification. Kraft Foods, Inc. v. International Trading Co., 203 F.3d 1362, 1366 (Fed. Cir. 2000).

The words in the claim may also be interpreted in light of the prosecution history, if in evidence. Teleflex, Inc. v. Ficosa North Am. Corp., 299 F. 3d 1313, 1324-25 (Fed. Cir. 2002) (citations omitted). The prosecution history "can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." Phillips, 415 F.3d at 1317. These components of the intrinsic record are the primary resources in properly construing claim terms.

Finally, after reviewing the intrinsic evidence, if the court is unable to resolve a disputed claim term, it may consider extrinsic evidence, such as expert testimony, inventor testimony, and technical treatises and articles. Vitronics, 90 F.3d at 1584. However, while courts have discretion to consider extrinsic evidence, such evidence is "less significant than the intrinsic record in determining the legally operative meaning of claim language." Phillips, 415 F.3d at 1317–18 (internal quotations omitted).

B. The Disputed Terms

The parties seek an order construing nine disputed terms. Five of the terms appear in Claim 1 of the '475 patent, and similar disputed terms appear in Claim 1 of the '280 patent (for which the specification is the same as for the '475 patent). The remaining two terms appear in Claim 1 of the '962 patent.

Claim 1 of the '475 patent recites (with disputed terms set forth in boldface font):

> 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, Col. 17:45-59.

Claim 1 of the '280 patent recites (with disputed terms set forth in boldface font):

> 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 the 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, Col. 17:45-61.

Finally, two disputed terms appear in Claim 1 of the '962 patent. Claim 1 of the '962 patent recites (with disputed terms set forth in boldface font):

> A controlled-release oral drug dosage form for releasing a drug into at least a portion of a region defined by the stomach and the upper gastrointestinal tract, said dosage form consisting essentially of a **solid monolithic matrix** with said drug contained therein, said matrix being non-circular in shape and

> having first and second orthogonal axes of unequal length, said matrix being one that swells in an unrestricted manner along both such axes upon imbibition of water, the longer such axis having a maximum length of 3.0 cm when said matrix is unswollen, and the shorter such axis achieving a minimum length of 1.2 cm within one hour of immersion of said dosage form in water and wherein said matrix has a shape which when projected onto a plane, is either **an oval** or a parallelogram.

'962 Patent, Col. 11:14-25.

C. The Parties' Proposed Constructions and Arguments

(1) **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)

(2) **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)

The parties agree that these two terms should be given the same construction. Depomed proposes the following construction:

> The polymeric matrix of the drug dosage form 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.

In the joint claim construction statement, Lupin proposed the following construction:

> Unrestricted swelling to a size at least 20% greater than that of the starting tablet due to the ingress of water, resulting in a swollen polymeric matrix that is larger than the diameter of the pylorus in the fed mode.

However, in its responsive claim construction brief, Lupin now proposes the following alternative construction:

> An unrestricted swelling to a size greater than that of the starting tablet due to the ingress of water, resulting in a swollen solid polymeric matrix that is larger than the diameter of the pylorus in the fed mode.

In this revised construction, Lupin has removed the size limitation "at least 20%," and has also added the word "solid" to the phrase "swollen polymeric matrix." Lupin says it eliminated the phrase "at least 20%" in response to Depomed's argument in the opening brief that Lupin's proposed construction is faulty because it requires numerical precision,

and that it added "solid" because it seemed necessary to properly construe the term.

Both Claim 1 of the '475 patent and Claim 1 of the '280 patent recite a "controlled-release oral dosage form." The oral dosage form in Claim 1 of the '475 patent comprises "a solid polymeric matrix" with the drug "dispersed therein," and in Claim 1 of the '280 patent, it comprises "one or more polymers forming a solid polymeric matrix" with the drug "dispersed therein." The dosage form "swells upon imbibition of water" ('475 patent) or is "swollen in a dimensionally unrestricted manner as a result of imbibition of water" ('280 patent).

The specification explains that "[t]he water-swellable polymer forming the matrix in accordance with this invention is any polymer that is non-toxic, that swells in a dimensionally unrestricted manner upon imbibition of water, and that provides for sustained release of an incorporated drug."[3] '475 patent, Col. 7:54-58. As set forth in the parties' briefs, the dispute concerning the construction of these two terms involves whether the polymeric matrix swells in an "unrestricted" manner, and whether the polymeric matrix remains "solid" when it swells. Depomed also asserts that Lupin's alteration of its original proposed construction was improper.

According to the Abstract for the '475 and '280 patents, in the disclosed invention, "[d]rugs are formulated as unit oral dosage forms by incorporating them into polymeric matrices comprised of hydrophilic polymers that swell upon imbibition of water to a size that is large enough to promote a retention of the dosage form in the stomach during the fed mode." The matrix "is a relatively high molecular weight polymer that swells upon ingestion, preferably to a size that is at least about twice its unswelled volume, and that promotes gastric retention during the fed mode." '475 patent, Col. 5:66-6:3.

The swelling of the polymeric matrix achieves two objectives for the administration of

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[3] At the hearing, in response to questions by the court, counsel for Depomed defined "polymeric matrix" as used in the context of "dosage form" in the patents-in-suit as "the amalgamation of the individual polymers that are used." That is, "the polymer matrix is the meshing together of all the polymers to form a matrix." Hearing Transcript, January 26, 2011 ("Tr.") at 8-9; see also Tr. at 78-81.

highly soluble drugs – "(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. at Col. 6:19-24. The drug-containing polymeric matrix "swell[s] in size in the gastric cavity due to ingress of water in order to achieve a size that will be retained in the stomach when introduced during the fed mode." Id. at Col. 9:1-5.

Both parties agree that because of the ingestion of water, the polymeric matrix increases to a size that causes the dosage form to remain in the stomach for some period of time. Depomed argues, however, that Lupin is impermissibly reading limitations into the claim phrases. Depomed asserts that there is no basis in the claims or the specification for construing these terms as including "unrestricted" swelling of the dosage form, or as including the limitation that the resulting "swollen" polymeric matrix will be "solid."

In response, Lupin argues that the limitation "unrestricted swelling" is already part of the claim language, referring to Claim 1 of the '280 patent, which describes the dosage form as "one that when swollen in a dimensionally unrestricted manner as a result of imbibition of water . . . " '280 patent, Col. 17:51-53. Lupin also points to the specification, which explains that "[t]he water-swellable polymer forming the matrix in accordance with this invention is any polymer that is non-toxic, that swells in a dimensionally unrestricted manner upon imbibition of water, and that provides for sustained release of an incorporated drug." '475 Patent, Col. 7:54-58.

Lupin argues that unrestricted swelling is essential for the claimed formulation to avoid passing through the pylorus during the fed mode, citing the following portion of the '962 specification:

> When dosage forms such as [cylindrical tablets elongated in shape to facilitate swallowing] swell due to imbibition of water, one dimension may achieve a length great enough to exceed the pyloric opening while the others may be significantly smaller . . . Accordingly, for a certain percentage of the administered units of these swelling forms, prolonged retention in the stomach is not achieved and the beneficial effect of the swelling is lost.

'962 Patent, Col. 3:8-17.

As the court noted at the hearing, the claim language requires that the dosage form swells or increases in size, and does not place any restriction on that swelling. However, Claim 1 of the '280 patent (the claim where the word "unrestricted" appears) refers to the dosage form being swollen in a "dimensionally unrestricted" manner. It is not the swelling itself that is unrestricted, but the swelling of the dimensions of the dosage form – that is, length, the width, or other dimension of the dosage form – based on the swelling characteristics of the selected polymer.

As Depomed asserts, the specification does not qualify the rate of swelling for the polymeric matrix, as Lupin's construction does, but simply addresses the dimensional swelling characteristics of a selected polymer. Since there are no restrictions placed on the size by either the claim language or the specification, the addition of the limitation "unrestricted" to the construction of these two terms is unnecessary.

Moreover, the patent specification describes the swelling in a broadly functional manner not tied to "unrestricted" swelling. See '475 Patent, Col. 6:19-24; id., Col. 9:1-7. It is improper to read "unrestricted" into Claim 1 of the '475 patent because of the broad, functional description of swelling in the specification. See Prima Tek II, L.L.C. v. Polypap S.A.R.L., 318 F.3d 1143, 1151 (Fed. Cir. 2005) ("varied use of a disputed term in the written description demonstrates the breadth of the term rather than providing a limited definition").

Because Claim 1 of '280 patent contains the express language "when swollen in a dimensionally unrestricted manner," the dosage form in Claim 1 of the '280 patent must be in a state where it has swollen in all dimensions. Lupin's proposed construction appears to be an attempt to alter this limitation on the swollen state to a restriction on the swelling process itself.

Similarly, there is no need to include the limitation "greater than that of the starting tablet." It is inherent in the meaning of "swell" that the dosage form will increase in size. All that is necessary is that the polymeric matrix that comprises the dosage form must swell to a size large enough so that the dosage form is retained in the stomach for some period of

time. The specification states only that the matrix is a polymer that "swells upon ingestion, preferably to a size that is at least about twice its unswelled volume . . . ." '475 patent, Col. 5:66-6:2 (emphasis added).

Indeed, the specification describes the size of the dosage form in functional terms – that is, a size that promotes retention – rather than in terms of absolute size. See id., Col. 5:66-6:3 (the matrix "swells upon ingestion, preferably to a size that . . . promotes gastric retention during the fed mode"); id. at Col. 6:19-24 ("the tablet swells to a size large enough to cause it to be retained in the stomach during the fed mode" and "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. at Col. 9:1-7 ("the drug-containing matrices . . . swell in size in the gastric cavity due to ingress of water in order to achieve a size that will be retained in the stomach when introduced during the fed mode").

With regard to its proposal that the result of the swelling is a "swollen solid polymeric matrix," Lupin relies on the statement in the specification that the claimed formulation "remains undissolved in (i.e., is not eroded by) the gastric fluid for a period of time sufficient to permit the majority of the drug to be released by the solution diffusion process during the fed mode." Id., Col. 6:10-15. In other words, Lupin argues, the polymeric matrix remains solid when swollen to a size large enough to block the pylorus, thus enabling the release of the drug to be "controlled diffusion . . . rather than erosion, dissolving, or chemical decomposition." Id., Col. 6:15-18. However, Lupin does not explain why it has added "solid" to this proposed construction, when the construction it originally proposed in the joint claims construction statement did not include the word "solid."

Moreover, the addition of the term "solid" is contrary to the specification, which reads as follows:

> Upon swelling, the matrix may also convert over a prolonged period of time from a glassy polymer to a polymer that is rubbery in consistency, or from a crystalline polymer to a rubbery one. The penetrating fluid then causes release of the drug in a gradual and prolonged manner by the process of solution diffusion, i.e., dissolution of the drug in the penetrating fluid and diffusion of the dissolved drug back out of the matrix. The matrix itself is solid prior to administration and, once administered, remains undissolved in (i.e., is

> not eroded by) the gastric fluid for a period of time sufficient to permit the majority of the drug to be released by the solution diffusion process during the fed mode. The rate-limiting factor in the release of the drug is therefore controlled diffusion of the drug from the matrix rather than erosion, dissolving or chemical decomposition of the matrix.

Id., Col. 6:3-17. While the polymeric matrix is clearly "solid" at the time the dosage form is ingested, and remains "undissolved" for a period of time thereafter, as it imbibes water and swells, the polymer will become rubber, spongy, or gel-like (that is, less than "solid").

Accordingly, "**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**" 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 "**[t]he 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**."

(3) **gastric fluid** ('475 and '280 patents)

Depomed proposes the following construction for this term:

> Both the fluid in the stomach and simulated or artificial fluids recognized by those skilled in the art as a suitable model for the fluid of the human stomach.

Lupin proposes the following construction:

> Fluid that maintains the essential characteristics of gastric fluid (such as low pH or enzymes) and is recognized by a person of ordinary skill in the art as a suitable model for the fluid of the human stomach.

At the hearing, the court noted that the two proposed constructions are the same, except that Lupin's proposed construction includes examples of "essential characteristics of gastric fluid," and stated that it would accept Depomed's proposed construction.

Accordingly, "**gastric fluid**" means "**[b]oth the fluid in the stomach and simulated or artificial fluids recognized by those skilled in the art as a suitable model for the fluid of the human stomach**."

(4) **dissolution and diffusion** ('475 and '280 patents)

Depomed proposes the following construction for this term:

> 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.

Lupin proposes the following construction:

> Dissolution of the drug by the gastric fluid, followed by diffusion of the drug out of the monolithic matrix.

The dispute between the parties involves whether the construction must specify the primary release mechanism, whether it is necessary or appropriate to specify "rapid" dissolution and "slow" diffusion, and whether the patent discloses a "monolithic matrix."

The patent specification states that controlled 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: "[D]rugs that are highly soluble in water can be administered orally in a manner that will prolong their delivery time to spread their release rate more evenly throughout the duration of the fed mode and beyond or not as desired." '475 Patent, Col. 5:31-36.

Depomed argues that a person of ordinary skill in the art would understand that release mechanisms for dosage forms are characterized by their dominant release mechanism, because all dosage forms have multiple mechanisms occurring at the same time. Here, Depomed asserts, a person of ordinary skill would understand "dissolution and diffusion" in the context of water soluble drugs, as recited in Claim 1 and the specification, to mean that the primary release mechanism of the dosage form was "diffusion."

Lupin argues that Depomed's proposed construction is improper, because if the dominant mechanism is "primarily diffusion," it would permit erosion of the dosage form. However, it is not true that the patent does not contemplate the possibility of some erosion. The specification refers to a formulation that "has an erosion rate that is substantially slower than its swelling rate, and that releases the drug primarily by diffusion." Id., Col.

5:57-62.[4]

Lupin also contends that there is no support for a construction specifying that the release of the drug is "rapid" and that the dissolution is "slow;" and that because the term "rapid" is not defined in the patent, its meaning is unknown. Lupin claims that a person of skill in the art would know that the specific dissolution rate is a kinetic property of a drug, which can be manipulated by different factors, including temperature, pH, volume, and salinity.

The specification explains that each of the enumerated beneficial effects "is achieved by using a formulation in which the drug is dispersed in a polymeric matrix that is water-swellable rather than merely hydrophilic, that has an erosion rate that is substantially slower than its swelling rate, and that releases the drug primarily by diffusion." Id., Col. 5:57-62. In other words, while there may be some erosion, the rate of erosion is substantially slower than the rate of swelling.

Further, "[t]he rate limiting factor in the release of the drug is therefore controlled diffusion of the drug from the matrix rather than erosion, dissolving, or chemical decomposition of the matrix." Id., Col. 6:14-17 (emphasis added). Thus, the primary release mechanism of the dosage form is "diffusion." See also id., Col. 6:6-14 (the drug is released "by the process of solution diffusion, i.e., dissolution of the drug in the penetrating fluid and diffusion of the dissolved drug back out of the matrix," while "[t]he matrix itself is solid prior to administration, and . . . remains undissolved in (i.e., is not eroded by) the gastric fluid for a period of time sufficient to permit the majority of the drug to be released by the solution diffusion process").

As for Lupin's inclusion of the term "monolithic matrix" in its proposed construction, Depomed asserts that this term appears nowhere in the language of the '475 or the '280 patents, but only in the '962 patent, and that Lupin appears to be improperly attempting to

[4] At the hearing, counsel for Lupin indicated that Lupin was not disputing that the release is controlled by diffusion, and further agreed that deleting the word "primarily" from Depomed's proposed construction would resolve the objection that Depomed's construction would improperly allow for the drug to be released by erosion (rather than diffusion).

read a limitation from the '962 patent into the '475 and '280 limitation on "diffusion and dissolution."

Lupin disagrees with this assessment, arguing that the polymer formulation disclosed in the '475 patent specification is a monolithic matrix, which it defines as a solid, single unit tablet.

Claim 1 of the '475 patent claims "[a] controlled-release oral drug dosage form . . . , said dosage form comprising a solid polymeric matrix . . . . " Claim 1 of the '280 patent claims "[a] controlled-release drug dosage form . . . , said dosage form comprising one or more polymers forming a solid polymeric matrix . . . ." Neither patent claims a dosage form comprising a "monolithic matrix." Nor does the specification provide any support for including "monolithic matrix" as part of the construction of "dissolution and diffusion."

"**Dissolution and diffusion**" means "**rapid dissolution of the drug, followed by slow diffusion of the drug out of the matrix, such that the drug is released at a rate controlled by the rate of diffusion**."

(5) **releases substantially all of said drug within about eight hours after such immersion** ('475 patent)

Depomed proposes the following construction of this term:

> At least 80% of the drug has been released after eight hours of immersion in gastric fluid.

Lupin argues that the term "substantially" is ambiguous and does not describe the claimed subject matter in such a way that one in the field of the invention would understand the scope of the invention. However, Lupin also proffers the following construction in the event that the court finds the term capable of construction:

> At least 80% of the drug is released from the polymer matrix by solution diffusion within about 8 hours.

The parties agree that "substantially all" means "at least 80 per cent." As indicated at the hearing, since the parties agree to the meaning of "substantially all," there is no dispute. The addition of "solution diffusion" is improper, because the issue of dissolution and diffusion is addressed in the distinct claim term "dissolution and diffusion," and

because "solution diffusion" appears to constitute an attempt to read an additional limitation into the claim. The court adopts Depomed's proposed construction.

"**Substantially all of said drug**" means "**[a]t least 80% of the drug has been released after eight hours of immersion in gastric fluid**."

(6) **(until) substantially all of said drug is released** ('280 patent)

Depomed proposes the following construction for this term:

> At least 80% of the drug has been released after eight hours of immersion in gastric fluid.

As above, Lupin argues that the term "substantially" is insolubly ambiguous, and therefore indefinite, and does not describe the claimed subject matter in such a way that one in the field of the invention would understand the scope of the invention. However, Lupin also proffers the following construction in the event that the court finds the term capable of construction:

> At least 80% of the drug is released from the polymer matrix by solution diffusion within about 8 hours.

The parties' arguments with regard to this term are the same as for term (5), discussed above, and the court's ruling is the same.

"(Until) **substantially all of said drug is released**" means "**[a]t least 80% of the drug has been released after eight hours of immersion in gastric fluid**."

(7) **until all of said drug is released** ('475 patent)

Depomed proposes the following construction of this term:

> Until the plateau of the dissolution profile characterizing drug release from the swollen dosage form is reached.

Lupin proposes the following construction, which it asserts is based on the plain and ordinary meaning:

> Until 100% of the drug is dissolved and released from the polymer matrix by solution diffusion.

As explained by the parties, the dispute regarding the construction of this term involves whether "all of said drug" must be construed so as to distinguish it from "substantially all of said drug" (terms (5) and (6), above); and whether "all of said drug"

means 100%, or something less than 100%.

The court agrees that "until all of said drug is released" as used in Claim 1 of the '475 patent must be construed in such a way that distinguishes it from "until substantially all of said drug is released," as used in Claim 1 of the '475 patent (and in Claim 1 of the '280 patent), which the court has found means simply that "at least 80% of the drug is released after eight hours of immersion in gastric fluid. The question, however, is whether the appropriate construction of "all of said drug is released" is "100% of said drug is released."

The '475 patent describes the invention as a "dosage form" that swells upon imbibition of water to provide gastric retention and allowing the extended release of the drug within the gastric cavity over a prolonged dosing period. '475 Patent, at Abstract; see also id., Col. 5:57-6:17. In addition, the invention provides enhanced absorption of soluble drugs that are absorbed mostly within the stomach or high in the GI tract, such as metformin hydrochloride. Id., Col. 6:38-41.

The patent shows, as preferred embodiments, release profiles for metformin dosage forms in Figs. 1, 4, 5, 7 and 9. Id., Figs. 1, 4, 5, 7, 9. These release profiles show a release plateau for metformin from the dosage forms of the invention that typically does not reach 100%. Id.; see also Declaration of Harold B. Hopfenberg, Ph.D., at ¶ 74-77. Thus, Depomed asserts, the specification of the '475 patent teaches that the dosage form remains intact until the drug release from the dosage form reaches the plateau of its release profile.

Depomed contends that the intrinsic evidence supporting its proposed construction is buttressed by extrinsic evidence contained in the FDA Guidance documents attached to the Declaration of Depomed's counsel William G. Gaede. The FDA recommends a minimum of three time points for a dissolution study: "early, middle and late," the last of which "should be the time point where at least 80% of drug has dissolved," or, "[i]f 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." Gaede Decl., Exh. 3 at 17. The FDA guidance entitled SUPAC-MR: Modified Release Solid Oral Dosage Forms

(September 1997) states the end point of a dissolution assay as "either 80% of the drug from the drug product is released or an asymptote is reached." Gaede Decl., Ex. 4.

Depomed contends that according to these guidelines, a person of ordinary skill in the art would conclude that all drug has been released when the plateau of the release curve is reached, even if the plateau corresponds to a release of less than 80% of the drug loading, within the context of the dosing or bioequivalence schedule being conducted. See Hopfenberg Decl., ¶¶ 77-80.

Depomed asserts that Lupin's proposed construction would exclude from the claim the metformin dosage forms disclosed in the '475 Patent that do not reach 100% drug release, and thus would improperly read out the disclosed embodiments. "A claim construction that excludes a preferred embodiment 'is rarely, if ever, correct and would require highly persuasive evidentiary support.'" Adams Respiratory Therapeutics, Inc. v. Perrigo Co., 616 F.3d 1283, 1290 (Fed. Cir. 2010) (quoting Vitronics, 90 F.3d at 1583). Depomed contends that Lupin's construction would also ignore the understanding of a person of skill in the art as reflected in the FDA Guidance documents.

Lupin, on the other hand, argues that the specification supports a construction of "all" as meaning "100%." Lupin notes that the specification teaches that "because these polymers dissolve very slowly in gastric fluid, the matrix maintains its physical integrity over at least a substantial period of time, in many cases 90% and preferably over 100% of the dosing period," '475 Patent, Col. 9:13-21; and that "[i]n all cases, . . . the drug will be substantially all released from the matrix within about ten hours, and preferably within about eight hours, after ingestion, and the polymeric matrix will remain substantially intact until all of the drug is released, id., Col. 9:32-36

However, Lupin does not dispute that its proposed construction would exclude the specification's metformin examples and the dissolution profiles depicted in Figures 1, 4, 5, 7 and 9 that show a release plateau of less than 100%.

Based on the patent specification, the court finds that "all of said drug is released" means "100% or something less than 100% of said drug is released." In most situations,

an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term. In such circumstances, it is improper to rely on extrinsic evidence. Vitronics, 90 Fed. 3d at 1583 (and cases cited therein). Here, however, the court finds that the testimony of Depomed's expert Dr. Hopfenberg, and the relevant evidence from the FDA guidance documents, supports a construction of 100% or something less than 100%.

"**Until all of said drug is released**" means "**until the plateau of the dissolution profile characterizing drug release from the swollen dosage form is reached**."

(8) **solid monolithic matrix** ('962 patent)

Depomed proposes the following construction for this term:

A single entire matrix.[5]

Lupin proposes the following construction:

> A polymeric matrix that is compressed as a single-unit tablet, and not as two or more layers

Lupin objects to Depomed's proposed construction for several reasons. The dispute between the parties centers on whether the "monolithic matrix" is a tablet; whether coatings are allowed under the claim; and whether the "monolithic matrix" must be compressed.

Claim 1 of the '962 patent recites "[a] controlled-release oral drug dosage form . . . consisting essentially of a solid monolithic matrix with said drug contained therein." "Consisting essentially of" is a transition phrase commonly used to signal a partially open claim in a patent. Typically, this transition phrase precedes a list of ingredients in a composition claim or a series of steps in a process claim.

> 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. A "consisting essentially of" claim occupies a middle ground between closed claims that are written in a "consisting of" format and fully

[5] Depomed originally proposed the following construction: "A single entire matrix, not just the upper or lower half of it." At the hearing, however, counsel for Depomed agreed with the court that the addition of "not just the upper or lower half of it" was unnecessary. Counsel stated that he would be "happy with 'the entire matrix,'" so long as the "dosage form" which "consist[s] essentially of a solid monolithic matrix," is not interpreted as "comprising" a solid monolithic matrix, or "a single tablet."

open claims that are drafted in a "comprising" format.

PPG Industries v. Guardian Industries Corp., 156 F.3d 1351, 1254 (Fed. Cir. 1998).

The specification explains that "[t]he dosage form is a swellable body, preferably a polymeric matrix in which a drug is dispersed." '962 Patent, Col. 3:52-53. The specification refers generally to "dosage forms" as "tablets," although it also states that "some other forms are contemplated as well." Id., Col. 4:6-11.

In certain embodiments of the invention, "the dosage form is a multilayered tablet in which one or more of the layers swells while the others do not." Id., Col. 3:62-64. Alternatively, the dosage form may be "a tablet with a core surrounded by a shell, and the core swells while the shell remains relatively dimensionally stable, or vice versa." Id., Col. 3:64-67.

Thus, while the dosage form is referred to in the patent as a tablet, see, e.g., id., Col. 3:22-41, the tablet/dosage form claimed in Claim 1 "consist[s] essentially of a solid monolithic matrix" in which the drug is contained. To construe "solid monolithic matrix" as "a tablet," or to construe said "tablet" as "not hav[ing] two or more layers," as in Lupin's proposed construction, is to confuse the "oral dosage form" element of Claim 1 with the "solid monolithic matrix" element, which is the element being construed. Moreover, as noted above, in certain embodiments of the invention, "the dosage form is a multilayered tablet."

Further, the specification plainly contemplates that coatings are allowed under the claim. "[T]he dosage form may contain an additional amount of the drug in a quickly dissolving coating on the outer surface of the dosage form," which coating "is referred to as a 'loading dose,'" the purpose of which is "to provide immediate release into the patient's bloodstream upon ingestion of the dosage without first requiring the drug to diffuse through the polymeric matrix. . . . A film coating may also be included on the outer surface of the dosage for reasons other than a loading dose." Id., Col. 8:3-19. Lupin's proposed construction would exclude these preferred coatings embodiments of the invention that are disclosed in the specification.

Lupin asserts, however, that the prosecution history of the '962 patent shows that Depomed surrendered all coatings on the monolithic matrix, as it disclaimed any construction of a "solid monolithic matrix" that would include anything other than a tablet "cast as a single piece" – i.e., compressed as a single-unit tablet, and not as two or more layers.

Specifically, Lupin argues that Depomed distinguished its invention from U.S. Patent No, 6,120,803 (Wong, et al.), which disclosed a dosage form that was partially coated with a secondary matrix. According to Lupin, Depomed argued that its claimed tablet was – unlike the tablet taught by Wong – "necessarily comprised of a single monolithic matrix;" and also emphasized that Wong incorporated a "rigid, constraining secondary matrix into the structure of the tablet," whereas Depomed's claimed invention "rel[ied] solely on the unrestricted swelling of a monolithic polymer matrix to maintain the tablet in the stomach for prolonged periods of time." Lupin asserts that the fact that Depomed disclosed coatings in the specification, but argued during the prosecution of the '962 patent that Wong was distinguishable because it was coated with a "secondary matrix," means that coatings are dedicated to the public.

Lupin argues further that because the patent teaches "multilayered tablets," '962 Patent, Col. 3:63, and because Depomed chose to draft its claims to a "solid monolithic matrix" instead, the public can infer that Depomed knew about multilayered tablets at the time it drafted its claims, but did not intend to claim multilayered tablets, and that those forms were also dedicated to the public.

Lupin also contends that Depomed specified during prosecution what "monolithic" means by citing a dictionary definition in which "monolithic" is defined as "cast in a single piece," adding that in the context of the applicants' "this means the entire matrix, not just the upper or lower half of it," and that "Wong does not teach or suggest a monolithic matrix that swells in an unrestricted manner along both orthogonal axes."

It is true that claim amendments made during prosecution can narrow the meaning of a claim term if there is a clear and unequivocal surrender of subject matter. Phillips, 415

F.3d at 1317; see also Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1324 (Fed. Cir. 2003). Here, however, the prosecution history does not include a clear and unequivocal surrender of coatings that may be around the matrix, as the prosecution history addresses only the matrix itself.

During prosecution, Depomed distinguished the claimed invention from Wong based on the inability of the Wong matrix to swell in an unrestricted manner along both orthogonal axes of the dosage form. See April 25, 2002 Correction and Request for Reconsideration. The Wong unswollen and swollen dosage form was depicted in the Wong patent prior art. The figures in the Wong Patent show a pill form with a band around the center. Because of the banding, the matrix in Wong was unable to swell in a dimensionally unrestricted fashion as claimed in the dosage form of the '962 Patent, which was the basis upon which Depomed overcame the Wong reference during prosecution, as it represented that its invention swelled in all dimensions.

Disclaimers require a clear and unmistakable disavowal of subject matter to which the patentee would otherwise have an exclusive right by virtue of the claim language. Vita-Mix Corp. v. Basic Holding, Inc., 581 F.3d 1317, 1324 (Fed. Cir. 2009). In this case, Depomed disclaimed only the use of bands that restricted the swelling of the monolithic matrix in one section. There is no evidence that Depomed totally disclaimed the use of coatings during prosecution.

Finally, the patent does not require that the monolithic matrix be "compressed." The specification broadly teaches that "[t]ablets in accordance with this invention can be prepared by conventional techniques, including common tabletting methods." The specification provides examples of such methods, which include "[d]irect compression," "[i]njection or compression molding," "[g]ranulation . . . followed by compression," and "[e]xtrusion of a paste into a mold or to an extrudate to be cut into lengths." 962 Patent, Col. 6:39-67. The inclusion of the last example demonstrates that the inventor contemplated manufacture of the monolithic matrix by means other than compression.

Accordingly, "**solid monolithic matrix**" means "**single entire matrix**."

(9) **an oval** ('962 patent)

The parties proposed competing constructions in the joint claim construction statement. In its responsive claim construction brief, however, Lupin asserts that both proposed constructions are legally equivalent, and states that it no longer opposes Depomed's proposed construction.

In view of the fact that the construction is no longer disputed, the court adopts Depomed's proposed construction.

"**An oval**" means "**[a]ny 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**."

(10) **remains substantially intact** ('475 patent)

This term was listed in the claims construction statement as having the following agreed construction:

> A polymeric matrix in which the polymer portion substantially retains its size and shape without deterioration due to becoming solubilized in the gastric fluid or due to breakage into fragments or small particles.

In its responsive claim construction brief, Lupin argues that the term is "insolubly ambiguous" and therefore indefinite because "substantially" is too imprecise. Lupin also assert, however, that if the court is inclined to construe the term, the court should use the agreed-upon construction, above, which appears in the claims construction statement.

The court agrees. The court finds that "**remains substantially intact**" has the meaning agreed by the parties in the joint claim construction statement: "**A polymeric matrix in which the polymer portion substantially retains its size and shape without deterioration due to becoming solubilized in the gastric fluid or due to breakage into fragments or small particles**."

D. Depomed's Motion to Strike

Depomed seeks an order striking Lupin's newly-proposed claim construction for terms (1) and (2). Depomed argues that Lupin's proposed construction differs from that in the claim construction statement in that it omits the phrase "at least 20%" and adds "solid"

to the phrase "swollen polymeric matrix." Depomed also seeks an order striking what it claims is newly-offered evidence to support Lupin's proposed constructions.

As the court indicated at the hearing, neither side's position in this dispute is particularly meritorious. Lupin's problem is that the Local Rules are clear that the joint claim construction statement is a final binding document. Depomed's problem is that it appears to view this motion as providing an opportunity to go through every line of Lupin's opposition brief – in other words, to permit another bite at framing the arguments in reply to Lupin's opposition. The court has considered the motion, to the extent discussed at the hearing, and has determined that it should be DENIED.

IT IS SO ORDERED.

Dated: May 17, 2011

PHYLLIS J. HAMILTON
United States District Judge