IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION

KING PHARMACEUTICALS, INC. ET AL.,	)	
Plaintiffs,	)	Case No. 1:08CV00050
v.	)	**OPINION AND ORDER**
PURDUE PHARMA L.P.,	)	By: James P. Jones Chief United States District Judge
Defendant.	)	

Thomas G. Slater, Jr., Hunton & Williams LLP, Richmond, Virginia, Rodger L. Tate and Robert M. Schulman, Hunton & Williams LLP, Washington, D.C., and Mark T. Hurt, Abingdon, Virginia, for Plaintiffs; Brian C. Riopelle, David E. Finkelson, and Jacob H. Rooksby, McGuireWoods LLP, Richmond, Virginia, Robert L. Florence, McGuireWoods LLP, Atlanta, Georgia, and Wm. W. Eskridge and Wade W. Massie, Penn, Stuart & Eskridge, Abingdon, Virginia, for Defendant.

In this patent infringement action, following a so-called *Markman* proceeding, I construe as a matter of law the disputed claims of the subject patents.

I

The patents at the center of this dispute, U.S. Patent No. 6,696,088 ("the '088 patent") and its continuation, U.S. Patent No. 7,658,939 ("the '939 patent"), are both entitled "Tamper-Resistant Oral Opioid Agonist Formulations" and owned by the defendant, Purdue Pharma L.P. ("Purdue"). In their Supplemental Complaint, the

plaintiffs, King Pharmaceuticals, Inc. and its wholly-owned subsidiary, Alpharma Inc., (collectively "King") request a declaration that the '088 and '939 patents are invalid and that King's product, an oral opioid analgesic named EMBEDA®, does not infringe on either patent. Purdue, in turn, has filed a counterclaim against King for willful infringement of both patents pursuant to 35 U.S.C.A. § 371 (West 2001 & Supp. 2010). Jurisdiction exists under 28 U.S.C.A. §§ 1331, 1338(a), and 2201 (West 2006). The parties have briefed and argued the proper construction of certain claims of the '088 and '939 patents and the issues are ripe for decision.

II

The '088 and '939 patents both put forth inventions engineered to combat abuse of opioid pain prescription medications. "Opioids, also known as opioid agonists, are a group of drugs that exhibit . . . morphine-like properties." '088 patent, col. 1, ll. 9-10; '939 patent, col. 1, ll. 12-13. The most commonly prescribed opioid agonists are morphine, oxycodone, and hydrocodone. These drugs, while highly effective at treating moderate to severe pain, are also widely abused due to their tendency to cause the patient to feel a sense of euphoria and to develop a tolerance — as well as a physical and psychological dependence — to opioids. What magnifies these side effects is the drugs' susceptibility to misuse and abuse. Several types of

opioid tablets or capsules, like OxyContin®, which contains the opioid oxycodone, are designed to release the opioid agonist into the body at a steady rate if ingested correctly, i.e., orally and intact. However, abusers will crush, chew, dissolve, or heat the tablets or capsules and then snort, inject, or otherwise improperly consume the opioid to release all the opioid agonist instantly and achieve an increased high.

Although opioid agonists are classified as Schedule II drugs under the Controlled Substances Act and only legally available by prescription, illegal use is a persistent and severe problem in many communities. *See* 21 U.S.C.A. § 812(b)(2) (West 1999). The illegal distribution of these drugs has become a lucrative business, and many opioid pain medication abusers engage in criminal behavior in order to feed their addiction.

This court is all too aware of the effects that opioid addiction has had on the region of Virginia in which this court sits. In 2006, OxyContin® was prescribed 500% more frequently in Southwest Virginia than the national average. (Pls.' Suppl. Compl., Ex. 10.) That same year in Western Virginia, over 200 people died from prescription drug overdose. (*Id.*, Ex. 9.) One local addiction expert called prescription drug abuse in this region "a public health epidemic." (*Id.*)

In 2008, the Centers for Disease Control and Prevention called upon pharmaceutical manufacturers to "modify opioid painkillers so that they are more

difficult to tamper with and/or combine them with agents that block the effect of the opioid." (*Id.*, Ex. 16 at 5). The inventors of the patents-in-suit followed this directive and developed formulations of opioid analgesics designed in such a way as to prevent the medications from becoming easily manipulated for greater effect by abusers or addicts.

The '088 patent contains forty claims, all of which are different tamper-resistant oral dosage forms containing both opioid agonists and opioid antagonists. Opioid antagonists are chemical substances that block opioid agonists from binding to their receptors in the body, thereby negating or reversing the effect of the agonist. According to the inventors, if the dosage forms of the '088 patent are taken intact, the opioid antagonist is sequestered in such a way that it is substantially not released if dissolved for thirty-six hours in fluids mimicking those present in human digestion. The theory being, if a patient took the oral dosage form, the same result would occur — the antagonist would not be substantially released or absorbed by the patient and the agonist would be able to take effect. On the hand, if the dosage form is tampered with in any way, the antagonist is immediately released and would block the effects of the opioid agonist if taken by a patient.

The '088 patent has only four independent claims, which are nearly identical:

An oral dosage form comprising:

(a) an opioid agonist;

(b) an opioid antagonist; and

(c) means for sequestering the opioid antagonist in an intact dosage form,

wherein the intact dosage form releases [either 36%, 24.6%, 10%, and 6.2%, respectively, depending on the claim] or less of the antagonist after 36 hours based on the in-vitro dissolution of the dosage form in 900 ml of Simulated Gastric Fluid using USP Type II (paddle) apparatus at 75 rpm and 37 degrees C. with a switch to Simulated Intestinal Fluid at 1 hour.

('088 patent, col. 51, l. 48 to col. 52, l. 26). The remaining thirty-six claims are dependent variations of these four.

The '939 patent builds upon the '088 patent by detailing a method of sequestering the opioid antagonist in which a sphere is formed by surrounding an inert core with an opioid antagonist and applying a layer of hydrophobic material on top of the antagonist. (Imagine a peach: the inert core is the pit, the antagonist is juicy fruit surrounding the pit, and the hydrophobic material is the peach's fuzzy skin.) The result, the inventors claim, is a spherical composition that if put in a solution mimicking human digestive fluids for thirty-six hours, will not release more than 15% of the antagonist. The two independent claims of the '939 patent (claims 1 and 2) detail the spherical antagonist composition:

1. An opioid antagonist composition comprising an inert core, a first layer and a second layer, the first layer being between the core and the second layer, the first layer consisting of the opioid antagonist, and the second layer comprising a hydrophobic material,

wherein the hydrophobic material sequesters the opioid antagonist such that

an amount of the antagonist released from the composition which has been administered intact is bioequivalent to 0.125 mg naltrexone or less, based on the in-vitro dissolution at 1 hour of the composition in 900 ml of Simulated Gastric Fluid using a USP Type II (paddle) apparatus at 75 rpm at 37° C., and

less than 15% by weight of the opioid antagonist is released within 36 hours from the intact composition, based on the in-vitro dissolution in a dissolution bath, and the composition is free from an opioid antagonist.

2. An opioid antagonist composition comprising an inert core, a first layer and a second layer, the first layer being between the core and the second layer, the first layer comprising naltrexone, nalmefene, or pharmaceutically acceptable salts thereof, and the second layer comprising a hydrophobic material,

wherein the hydrophobic material sequesters naltrexone, nalmefene or pharmaceutically acceptable salts thereof such that

an amount of the antagonist released from the composition which has been administered intact is bioequivalent to 0.125 mg naltrexone or less, based on the in-vitro dissolution at 1 hour of the composition in 900 ml of Simulated Gastric Fluid using a USP Type II (paddle) apparatus at 75 rpm at 37° C., and less than 15% by weight of the opioid antagonist is released within 36 hours from the intact composition, based on the in-vitro dissolution in a dissolution bath, and the composition is free from an opioid agonist.

'939 patent, col. 52, ll. 22-57. The other dependent claims outline either different versions of the compositions in claims 1 and 2, or oral dosage forms containing one of the antagonist compositions and an opioid agonist.

III

In this Opinion, I undertake the first step in any patent infringement case — to construe the meaning and scope of the patent claims at issue. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd,* 517 U.S. 370 (1996). This process, called claim construction, is a matter of law exclusively for the court. *See id.* at 979, 984. This is distinct from the question of fact of whether the accused product infringes on the patent claims, which is the province of the jury. *See id.* at 976, 984.

In this task of construction, claim terms "are generally given their ordinary and customary meaning." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (citation and internal quotation marks omitted). "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Id.* at 1313. "The inquiry into how

a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation." *Id.* "[T]he claims themselves provide substantial guidance as to the meaning of particular claim terms." *Id.* at 1314. "Other claims of the patent . . . can also be valuable sources of enlightenment as to the meaning of a claim term." *Id.*

The claims must also "be read in view of the specification, of which they are a part." *Id.* at 1315 (citation and internal quotation marks omitted). "[T]he person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Id.* at 1313. "[T]he specification is always highly relevant to the claim construction analysis" as it is the "best source for understanding" the meaning of a disputed term, "informed, as needed, by the prosecution history." *Id.* at 1315 (citations and internal quotation marks omitted).

"The prosecution history is the 'complete record of all the proceedings before the Patent and Trademark Office [(the "PTO")], including any express representations made by the applicant regarding the scope of the claims.'" *Gen. Creation LLC v. Leapfrog Enters., Inc.*, 232 F. Supp. 2d 661, 665 (W.D. Va. 2002) (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). "Like the

specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent." *Phillips*, 415 F.3d at 1317.

The claims, the specification, and the prosecution history are all forms of intrinsic evidence the court may rely on during claim construction. However, the court may also examine extrinsic evidence, but cautiously. "Extrinsic evidence consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. "[W]hile extrinsic evidence can shed useful light on the relevant art, . . . it is less significant [and less reliable] than the intrinsic record in determining the legally operative meaning of claim language." *Phillips*, 415 F.3d at 1317-18 (citation and internal quotation marks omitted).

"Extrinsic evidence is to be used for the court's understanding of the patent, not for the purpose of varying or contradicting the terms of the claims." *Markman*, 52 F.3d at 981. It "is not for the purpose of clarifying ambiguity in claim terminology. It is not ambiguity in the document that creates the need for extrinsic evidence but rather unfamiliarity of the court with the terminology of the art to which the patent is addressed." *Id.* at 986. "[E]xtrinsic evidence cannot add, subtract, or vary the limitations of the claims." *Id.* at 985. Therefore, "[t]he district court's claim

construction, enlightened by such extrinsic evidence as may be helpful, is still based upon the patent and prosecution history." *Id.* at 981.

This general claim analysis does not apply, however, if a claim element is deemed to be written in a means-plus-function format. Ordinarily, a claim must recite a sufficient structure, material, or acts to be patentable. 35 U.S.C.A. § 112, para. 2 (West 2001). But if a claim element is written in means-plus-function format the claim need not describe a structure, it need only describe the function that the element performs:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

35 U.S.C.A. § 112, para. 6 (West 2001). Unlike the typical claim analysis, "construction of means-plus-function elements *requires* the court to look beyond the claim language to determine the structure that the claim element takes." *Gen. Creation*, 232 F. Supp. 2d at 666. Whether or not a claim element is in means-plus-function format is a question of law. *Id.*

IV

In this case, the specific claim terms in dispute in the ’088 patent are “dosage form” and “means for sequestering . . .” “Dosage form” is also at issue in the ’939 patent, and the parties concede that the meaning of “dosage form” must be the same in both patents. Also disputed in the ’939 patent are the terms “free from,” “consisting of,” “bioequivalent,” and “effect.” The parties agree that the only term at issue that is subject to means-plus-function analysis is “means for sequestering.” By applying the applicable principles of claim construction, I find the following to be the proper construction of the disputed terms.

A. “DOSAGE FORM” (BOTH PATENTS).

The term “dosage form” is ubiquitous in both the ’088 and ’939 patents. It appears in every claim of the ’088 patent and in seventeen of the claims in the ’939 patent. King argues that the definition of “dosage form” is “a pharmaceutical product having active ingredients (an opioid agonist and an opioid antagonist) that are present in a structural arrangement in which agonist particles and antagonist particles are interspersed in the product and are not isolated from each other in two distinct layers.” (Pls.’ ’088 Opening *Markman* Br. 16; Pls.’ ’939 Opening *Markman* Br. 21.) In contrast, Purdue believes “dosage form” should be construed using its ordinary

meaning, "the physical form of a drug product." (Def.'s '088 Rebuttal Cl. Constr. Br. 2-3; Def.'s '939 Opening Cl. Constr. Br. 21.)

I find that Purdue's definition is indeed the customary and ordinary meaning of "dosage form" ascribed by one skilled in the art of pharmaceutical manufacturing. For example, the Federal Drug Administration (the "FDA") defines "dosage form" as "the physical form in which a drug is produced and dispensed, such as a tablet, a capsule, or an injectable." Drugs@FDA Glossary of Terms, http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm (last visited June 1, 2010). And, nowhere in its briefs does King argue that "the physical form of a drug product" is not the typical meaning of "dosage form." The more pertinent issue is whether the inventors of the patents-in-suit deviated from the ordinary meaning by adding the structural restrictions King cites. I find that they did not.

The first place to look for the definition of a term is within the claims themselves, and this is where King's definition immediately fails. *See Phillips*, 415 F.3d at 1314 ("[T]he use of a term within the claim provides a firm basis for construing the term"). As King conceded at oral argument, "dosage form" must be defined the same for both patents because the '939 patent is a continuation of the '088 patent. Additionally, a term "cannot be interpreted differently in different claims because claim terms must be interpreted consistently." *Southwall Techs., Inc. v.*

Cardinal IG Co., 54 F.3d 1570, 1579 (Fed. Cir. 1995); *see also Phillips*, 415 F.3d at 1314 ("Because claim terms are normally used consistently throughout the patent, the usage of a term in one claim can often illuminate the meaning of the same term in other claims.").

In contradiction to King's definition of "dosage form," claim 4 of the '939 patent states:

> An oral *dosage form* comprising an opioid agonist and the opioid antagonist composition of claim 1, *wherein the hydrophobic material separates the opioid antagonist from the opioid agonist.*

'939 patent, col. 52, ll. 61-64 (emphasis added). In this claim, the opioid antagonist and agonist are not "interspersed" and in fact are isolated from each other in some manner. Thus, to define "dosage form" as including the limitation that "agonist particles and antagonist particles are interspersed in the product and are not isolated from each other in two distinct layers" would mean to limit claim 4 in a way that it is not supported by the language of the claim itself. Because claim terms should be construed consistently throughout both patents, the rest of the claims cannot use that definition of "dosage form" either.

King nonetheless argues that the structural limitations in its definition of "dosage form" are required because throughout the specification of the '088 patent, the inventors repeatedly describe their invention as dosage forms "wherein the

agonist and antagonist are interdispersed[1] and are not isolated from each other in two distinct layers." *See, e.g.*, '088 patent, col. 4, ll.18-30, col. 5, ll. 5-19. However, courts must be careful not to read a limitation into a claim simply because the embodiments contain such a limitation. *Phillips*, 415 F.3d at 1323 ("[A]lthough the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments").

Moreover, while several of the embodiments of the invention in the '088 patent do explicitly require that "the agonist and antagonist are interdispersed and are not isolated from each other in two distinct layers," this is not a characteristic of all the embodiments. *Compare, e.g.*, '088 patent, col. 4, ll. 18-30, *with* '088 patent, col. 4, ll. 31-45. For example, several embodiments of the dosage forms are said to contain an opioid agonist and an opioid antagonists "wherein the antagonist is in the form of multiparticulates individually coated with sequestering material," but these embodiments mention nothing about whether or not the agonist and antagonist are "interdispersed." '088 patent, col. 4, ll. 31-45; *see also id.*, col. 5, ll. 54-59.

Moreover, the section that most comprehensively addresses the meaning of "dosage form" states:

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[1] Based on the definition of "interdispersed" given by the parties at oral argument, I find the word as used here is indistinguishable from "interspersed."

> The oral dosage form containing an opioid agonist in combination with a substantially non-releasable form of an opioid antagonist includes, but are not limited to, tablets or capsules. The dosage forms of the present invention may include any desired pharmaceutical excipients known to those skilled in the art. The oral dosage forms may further provide an immediate release of the opioid agonist. In certain embodiments, the oral dosage forms of the present invention provide a sustained release of the opioid agonist contained therein. Oral dosage forms providing sustained release of the opioid agonist may be prepared in accordance with formulations/methods of manufacture known to those skilled in the art of pharmaceutical formulation, e.g., via the incorporation of a sustained release carrier into a matrix containing the substantially non-releasable form of an opioid antagonist; or via a sustained release coating of a matrix containing the opioid agonist and the substantially non-releasable form of the opioid antagonist.

'088 patent, col. 10, ll. 40-57; '939 patent, col. 10, ll. 30-46. None of this section contradicts the ordinary meaning of "dosage form" derived from the claims.

However, King cites the '088 patent's abstract, which states, "Disclosed is an oral dosage form . . . wherein said agonist and antagonist are interdispersed and are not isolated from each other in two distinct layers." '088 patent, Abstract. This is the strongest argument for altering the ordinary definition of "dosage form" because "the location [of a statement] can signal the likelihood that the statement will support a limiting definition of a claim term. Statements that describe the invention as a whole [such as the abstract], rather than statements that describe only preferred embodiments, are more likely to support a limiting definition of a claim term." *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 864 (Fed. Cir. 2004). Yet, the

abstract alone is not enough to show that the ordinary meaning, which is supported by the claims and the remainder of the specification, should be abandoned. *See id.* ("[C]ertain sections of the specification are more likely to contain statements that support a limiting definition of a claim term than other sections, although what import to give language from the specification must, of course, be determined on a case-by-case basis"). Importantly, the abstract for the '939 patent mentions "dosage form" but does not say the agonist and antagonist are interspersed. The prosecution histories of the patents-in-suit also offer nothing to suggest a meaning of "dosage form" different from the ordinary and customary meaning. Therefore, I do not find that the definition of "dosage form" requires the antagonist and agonist be interspersed.

Beyond the structural limitations King proposes, it also asserts that "dosage form" must be defined as "having active ingredients (an opioid agonist and an opioid antagonist)" because throughout both patents, the oral dosage forms invented are described as comprising an opioid agonist and antagonist. However, the court concluded in *Phillips* that when a claim refers to "steel baffles," rather than simply "baffles," it "strongly implies that the term 'baffles' does not inherently mean objects made of steel." 415 F.3d at 1314. Similarly, the fact that the claims of the patents-in-suit continually recite that dosage forms contain agonists and antagonists, strongly

implies that these ingredients are not inherently included in the meaning of "dosage form."

Consequently, I find the proper definition of "dosage form" is its ordinary and customary meaning: "the physical form of a drug product."

B. "MEANS FOR SEQUESTERING . . ." ('088 PATENT).

"Means for sequestering . . ." appears in claims 1, 2, 3, 4, and 39 of the '088 patent. Claims 1-4 provide

> (c) *means for sequestering* the opioid antagonist in an intact dosage form,
>
> wherein the intact dosage form releases [36%, 24.6%, 10%, or 6.2%, respectively] or less of the antagonist after 36 hours based on the in-vitro dissolution of the dosage form in 900 ml of Simulated Gastric Fluid using a USP Type II (paddle) apparatus at 75 rpm and 37 degrees C. with a switch to Simulated Intestinal Fluid at 1 hour.

'088 patent, col. 51, ll. 48-67, col. 52, ll. 1-26 (emphasis added). Claim 39 states, "The oral dosage form of any of claims 1-4, wherein the *means for sequestering* comprises a layer comprising a hydrophobic material." *Id.*, col. 54, ll. 38-40 (original emphasis omitted, new emphasis added).

Both parties concede that "means for sequestering . . ." as used in claims 1-4 is in means-plus-function format, but King alleges that the term is also in means-plus-

function format in claim 39, while Purdue asserts that in that claim, the term is in the conventional format.

1. Claims 1-4.

The first step in means-plus-function analysis is to determine the function of the "means for sequestering . . ." element. Purdue argues that in claims 1-4, the function of "means for sequestering . . ." is simply "sequestering," which Purdue defines as "maintaining the opioid antagonist in a substantially non-releasable form." ('088 Def.'s Opening Cl. Constr. Br. 15.) In contrast, King contends that the functions for claims 1-4 include the "wherein" clauses in the claims

> sequestering the opioid antagonist in an intact dosage form, wherein the intact dosage form releases [36%, 24.6%, 10%, or 6.2%] or less of the antagonist after 36 hours based on the in-vitro dissolution of the dosage form in 900 ml of Simulated Gastric Fluid using a USP type II (paddle) apparatus at 75 rpm and 37 degrees C. with a switch to Simulated Intestinal Fluid at 1 hour.

(Pls.' '088 Opening *Markman* Br. 18-19.)

It is clear that the function of this element at least includes "sequestering the opioid antagonist in an intact dosage form." Although Purdue omits "opioid antagonist in an intact dosage form" from its proposed interpretation, it gives no basis for doing so.

> In identifying the function of a means-plus-function claim, a claimed function may not be improperly narrowed or limited beyond the scope of the claim language. Conversely, neither may the function be

> improperly broadened by ignoring the clear limitations contained in the claim language. The function of a means-plus-function claim must be construed to include the limitations contained in the claim language.

Lockheed Martin Corp. v. Space Sys./Loral, Inc., 324 F.3d 1308, 1319 (Fed. Cir. 2003) (internal citation omitted). To omit the phrase between "sequestering" and "wherein" improperly broadens the scope of the claim and ignores the clear inventive portion of the claim. The sequestering function is being patented specifically because of its ability to simultaneously prevent the release of opioid antagonists in intact dosage forms and allow the release of opioid antagonists when the dosage forms are tampered with. If the function were as broad as Purdue desires, then the opioid antagonist could remain sequestered even when the dosage form is tampered with, thwarting the whole purpose of the invention.

The more difficult question is whether the limitations following the "wherein" clause are included as part of the function. Purdue concedes that the "wherein" clauses of claims 1-4 are necessary claim limitations, but argues these claim limitations are separate and apart from the function of the "means for sequestering . . ." element.

Differentiating between what is merely a claim limitation and what is part of the function is an important task because only the limitations that are part of the function have to adhere to the requirements of 35 U.S.C.A. § 112, para. 6. Yet, "[t]he

Federal Circuit . . . has [had] difficulty teasing out the function within a means-plus-function limitation from a separate [claim] limitation not subject to the constraints of 35 U.S.C. § 112, ¶ 6." *Joovy L.L.C., v. Baby Trend, Inc.*, 3:06-CV-0616-P, 2007 WL 5688725, at *3 (N.D. Tex. July 31, 2007).

Sometimes phrases beginning with words like "wherein," "whereby," or "thereby" are deemed part of the means-plus-function elements and sometimes they are not. For example, the *Lockheed Martin* court ruled that if a "whereby" clause "merely states the result of the limitations in the claim [and] adds nothing to the substance of the claim," then "[t]he function is properly identified as the language after the 'means for' clause and before the 'whereby' clause." 324 F.3d at 1319. On the other hand, the court in *Intergraph Hardware Technologies v. Toshiba Corp.*, 508 F. Supp. 2d 752, 769 (N.D. Cal. 2007), found the "wherein" clause to be a necessary part of the function, and the court in *Competitive Technologies v. Fujitsu Ltd.*, 286 F. Supp. 2d 1161, 1188 (N.D. Cal. 2003), *aff'd*, 185 F. App'x 958 (Fed. Cir. 2006) (unpublished), included a claim's "thereby" clause in its definition of the disputed element's function.

Thus, whether a "wherein" clause is part of the function of a claim is a fact-specific question. *See Griffin v. Bertina*, 285 F.3d 1029, 1034 (Fed. Cir. 2002). "Accordingly, the court cannot consider the word 'wherein' in isolation, but must

determine whether the 'wherein' clause in [the claims] expresses an inventive component or merely the result of the delineated limitations." *Intergraph*, 508 F. Supp. 2d at 769. However, the *Integraph* court improperly conflated the question of whether the "wherein" clause imposes a limitation on the claim, with the question of whether the "wherein" clause is part of the means-plus-function element. *See id.* at 768-69. On the other hand, while the court in *Competitive Technologies* distinguished the two questions, it was circular logic that led it to determine the claim limitation was part of the function: "[The language of the claim limitation] describes the function of the switch means . . . . As such, this language should be considered to be part of the function." 286 F. Supp. 2d at 1188.

Examining claims 1-4, I find that the structure of the claims is instructive. The "wherein" clause is separated from the rest of the claim by a comma, it is in a new paragraph, and its placement indicates it is outside the purview of part (c) of the claim — where the "means for sequestering . . ." element begins. This indicates the function stops at the comma and does not include the "wherein" clause. Furthermore, although the "wherein" clause is clearly an "inventive" limitation, it is also stating a "result" of "sequestering the opioid antagonist in an intact dosage form," not the method for sequestering the antagonist. Accordingly, I reject both parties'

interpretations of the function of the "means for sequestering . . ." element, and define the function to be "sequestering the opioid antagonist in an intact dosage form."

The next step is to determine the structure clearly linked to this function. The court must look to the specification to find the structures or methods corresponding to a means-plus-function element in a claim, and not the claim itself. *See Atmel Corp. v. Info. Storage Devices, Inc.*, 198 F.3d 1374, 1381-82 (Fed. Cir. 1999). In order for a structure to be "corresponding," the specification or prosecution history must clearly link or associate the structure to the function. *Default Proof Credit Card Sys., Inc. v. Home Depot U.S.A., Inc.*, 412 F.3d 1291, 1298 (Fed. Cir. 2005). The structure must be described in the specification "in such a manner that one skilled in the art will know and understand what structure corresponds to the means limitation." *Atmel*, 198 F.3d. at 1382. The structure must also be "capable of performing the function claimed by the means-plus-function limitation." *Default Proof*, 412 F.3d at 1299. "The specification must be read as a whole to determine the structure capable of performing the claimed function." *Id.* at 1298 (citation and internal quotation marks omitted).

Purdue argues the clearly linked structures are "a (1) coating; (2) matrix; or (3) layer comprising a hydrophobic material."[2] (Def.'s Opening Cl. Constr. Br. 15.) I find this construction of the structure lacks sufficient detail for one skilled in the art to identify the structure from the description and inaccurately includes hydrophobic material as an independent structure. As a result, these three proposed structures do not correspond to the function. *See Atmel*, 198 F.3d at 1382.

Reviewing the specification, the section of the patent entitled "Preparation of Opioid Antagonist in a Substantially Non-releasable Form" explains two methods of sequestering an opioid antagonist in an intact dosage form: (1) coating opioid antagonist particles with one or more hydrophobic materials and (2) dispersing an opioid antagonist in a matrix comprising one or more hydrophobic materials. *See* '088 patent, col. 19, ll. 19-29. These two methods qualify as structures because the examples from the '088 patent demonstrate that these structures are successful at sequestering the antagonist when intact and releasing the antagonist when crushed, and how to combine antagonists in these structures with an agonist to create an intact dosage form.

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[2] King provides no interpretation of the requisite structure. Instead, King asserts that there is no corresponding structure to be found in the specification if the function includes the release criteria. Because I found that the function did not include the release criteria, King's argument necessarily fails.

Though Purdue claims that another qualifying structure is "a layer comprising a hydrophobic material," I do not find that "a layer comprising hydrophobic material," is an independent structure, but rather it is used as part of the coating and matrix to sequester the antagonist. "A layer comprising hydrophobic material" does not describe a structure in such a manner that one skilled in the art would know how to sequester the antagonist without using the coating or matrix methods. Consequently, I find the structures that correspond to the function "sequestering the opioid antagonist in an intact dosage form" are (1) a coating of opioid antagonist particles with one or more hydrophobic materials and (2) a matrix in which an opioid antagonist is dispersed with one or more hydrophobic materials.

2. Claim 39.

A claim element is presumed to be in means-plus-function format if the claim element uses the word "means." *Gen. Creation*, 232 F. Supp. 2d at 666; *see Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1366 (Fed. Cir. 2008). A party can overcome that presumption if it shows by a preponderance of the evidence that the claim recites a sufficient structure within the claim itself to entirely perform the claimed function. *See Apex Inc. v. Raritan Computer, Inc.*, 325 F.3d 1364, 1371-72 (Fed. Cir. 2003). Because claim 39 uses the term "means," there is the presumption that it is in means-plus-function format. *See Gen. Creation*, 232 F. Supp. 2d at 666.

Purdue contends that claim 39 recites a specific structure, however, thereby rebutting the presumption that it is in means-plus-function format. King counters that the structure in claim 39 is not definite enough to overcome the presumption. I agree with King.

"In deciding whether [the] presumption has been rebutted, the focus remains on whether the claim as properly construed recites sufficiently definite structure to avoid the ambit of § 112, P 6." *Personalized Media Commc'ns, LLC, v. Int'l Trade Comm'n*, 161 F.3d 696, 704 (Fed. Cir. 1998). To be sufficient the structure must perform entirely the claim's recited function. *Net MoneyIN*, 545 F.3d at 1366. As explained above, the structure described in claim 39, "a layer comprising a hydrophobic material," is not a definite structure capable by itself of performing entirely the recited function. Therefore, claim 39 must be construed as in the means-plus-function format.

C. "FREE FROM" ('939 PATENT).

King proposes that the phrase "an opioid antagonist composition . . . *free from* an opioid agonist" in claims 1 and 2 of the '939 patent be construed as "a multi-layered particle containing opioid antagonist and completely free of opioid agonist at all times." (Pls.' '939 Opening *Markman* Br. 14.) Purdue, on the other hand, argues that it should mean simply, "the opioid antagonist composition does not

contain an opioid agonist." (Def.'s '939 Opening Cl. Constr. Br. 4.) I find King's interpretation is without merit.

First, there is no basis for including the phrase "at all times." The text of claims 1 and 2 describe the opioid antagonist composition as "comprising an inert core, a first layer and a second layer" and that "the composition is free from an opioid agonist." '939 patent, col. 52, ll. 22-23, 39-40. Thus, there is no question that the entire antagonist composition — the inert core, the first layer, and the second layer — is "free from" any opioid agonist. However, King asserts that "free from" covers more than just these three parts of the antagonist composition. King admits that the antagonist particles can be "interdispersed with agonist-containing particles" in a dosage form but argues that when the antagonist composition is combined in dosage form with an agonist, "the agonist and antagonist *must* be contained in separate particles." (Pls.' '939 Opening *Markman* Br. 20.) I do not agree with this limitation.

Nothing in the claims or the specification supports such a requirement. Over a dozen of the remaining twenty-two claims state the opioid antagonist composition is to be combined with opioid agonists to create working dosage forms of opioid analgesics, and none of them imply that the two must be in separate particles. Several claims require that the opioid agonist and antagonist must be separated by the second layer of the composition, the hydrophobic material, but notably, they do not add that

the agonist and antagonist are in different particles when separated. *See, e.g.*, '939 patent, col. 52, ll. 61-64, ("An oral dosage form comprising an opioid agonist and the opioid antagonist composition of claim **1**, wherein the hydrophobic material separates the opioid antagonist from the opioid agonist."); *id.*, col. 53, ll. 24-29 (same). Additionally, the specification states broadly, "Once the opioid antagonist in a substantially non-releasable form is prepared, it may be combined with an opioid agonist, along with conventional excipients known in the art, to prepare the oral dosage form of the present invention." ('939 patent, col. 20, ll. 64-67.)

There is also nothing that King points to in the prosecution history that supports its position that "at all times" should be part of the definition of "free from." The inventors wrote to the patent examiner, "Applicants respectfully submit that because the claims [1 and 2] explicitly recite a disclaimer that 'the opioid antagonist composition is free from an opioid agonist,' the claims make it clear that opioid agonists are not part of the opioid antagonist compositions of claims [1] and [2]." (Pls.' '939 Opening *Markman* Br., Ex. 13 at 11.) King asserts that this implies that the opioid agonist must be in separate particles. However, that is a strained reading of the statement, and I find the statement actually conveys a meaning of "free from" closely analogous to the definition Purdue presently puts forth.

Also, King's proposal to define opioid antagonist composition as a multi-layered particle containing opioid antagonist is unnecessary, as the composition is defined fully, and more accurately, by claims 1 and 2. King's clarification of the phrase "free from" to "completely free of" seems even less necessary as the modifier "completely" is redundant. If the inventors intended "completely free of," they could have used that phrase just as easily, but they chose "free from."

Purdue's definition on the other hand conveys the customary and ordinary meaning of "free from," and it is supported by the claims, specification, and prosecution history of the '939 patent. Therefore, I accept its definition and construe "free from" as "does not contain."

D. "CONSISTING OF" ('939 PATENT).

King asserts that "the first layer *consisting of* the opioid antagonist" in claim 1 should be construed as limiting the first layer to that which is specifically recited and nothing more. In other words, the first layer is made solely of an opioid antagonist. Purdue counters that, "consisting of" is a term of art that has already been defined by the Federal Circuit and should be given its ordinary meaning. I agree with Purdue.

While King is correct that the term "consisting of," as opposed to comprising or containing, "is a term of restriction, the restriction is not absolute." *Conoco, Inc.*

v. Energy & Envtl. Int'l, L.C., 460 F.3d 1349, 1360 (Fed. Cir. 2006). "'Consisting of' is a term of patent convention meaning that the claimed invention contains only what is expressly set forth in the claim. However, while 'consisting of' limits the claimed invention, it does not limit aspects unrelated to the invention." *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1331 (Fed. Cir. 2004) (citation omitted). Therefore, the ordinary meaning of "the first layer consisting of opioid antagonist" is "the first layer contains only the opioid antagonist and other ingredients unrelated to the invention." Because nothing in the patent or its prosecution history shows that the inventors departed from this customary definition, it is the proper way to construct the term.

E. "BIOEQUIVALENT" ('939 PATENT).

In the '939 patent, claims 1 and 2 state that "an amount of the antagonist released from the composition which has been administered intact is *bioequivalent* to 0.125 mg naltrexone or less." '939 patent, col. 52, ll. 29-31, 48-50 (emphasis added). King contends the term "bioequivalent" is indefinite within the context of the '939 patent claims because the common definition of "bioequivalent" used by those skilled in pharmaceutical manufacturing only applies to compounds with the same active ingredient, such as brand-name and generic drugs, but the '939 patent seeks to compare naltrexone with antagonists containing distinct active ingredients,

such as naloxone and nalmefene. Purdue admits that the '939 patent does not use the traditional, FDA definition of "bioequivalent." It asserts instead that "bioequivalent" is used to mean "equivalent antagonistic effect" (also termed as "equiantagonistic effect"). (*See* Def.'s '939 Rebuttal Cl. Constr. Br. 17.) Reading the term in the context of patent, I find the '939 patent and its prosecution history support Purdue's interpretation.

A claim is prohibited from being indefinite under 35 U.S.C.A. § 112, para. 2, which requires that a claim "particularly point[] out and distinctly claim[ ] the subject matter which the applicant regards as his invention." The burden is on King as the challenging party to prove that "bioequivalent" is indefinite as a matter of law by "clear and convincing" evidence. *See Gen. Creation*, 232 F. Supp. 2d at 675. In general, "[b]ioequivalency is a regulatory and medical concern aimed at establishing that two compounds are effectively the same for pharmaceutical purposes." *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1298 (Fed. Cir. 2009). Federal regulations for the FDA define bioequivalent as "the absence of a significant difference in the rate and extent to which *the* active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study." 21 C.F.R. § 320.1(e) (2009) (emphasis added). This

definition demonstrates that the FDA assumes bioequivalent drugs have the *same* active ingredient.

Even though the typical definition used by those skilled in the art is a baseline at which to start interpreting claim terms, "a patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning." *Vitronics*, 90 F.3d at 1582. Though perhaps not the most common use, in some instances, "bioequivalent" is used more broadly by those skilled in the art of pharmaceuticals than as defined by the FDA. For example, in *Taber's Cyclopedic Medical Dictionary* 220 (18th ed. 1997), bioequivalence is defined as "[t]he property of having the same biological effects of that to which a medicine was compared," with no requirement that the medicines compared contain the same active ingredient.

The language of the patent supports Purdue's assertion that the inventors were in fact using "bioequivalent" to compare different opioid antagonists rather than drugs with the same active ingredient. Both the specification and claim 22 state "0.025 mg of naltrexone or a bioequivalent dose of another antagonist." ('939 patent, col. 6, ll. 2-3, col. 54, ll. 63-64.) The prosecution history also demonstrates that one skilled in the art could understand "bioequivalent" to mean "equinantagonistic effect." The patent examiner himself used "bioequivalent" synonymously with "equiantagonistic effect" writing in reference to another patent,

> [The] Palermo [patent] teaches that the combinations of opioid antagonists/opioid agonists which are orally administered in ratios which are equivalent to the ratio of e.g., naltrexone to hydrocodone set forth are considered to be within the scope of the [Palermo] invention. For example, in some embodiments, naloxone is utilized as the opioid antagonist, the amount of naloxone included in the dosage form being large enough to provide an *equiantagonistic effect* as if naltrexone were included in the combination (p. 19-31). This demonstrates *bioequivalency* of the dosage forms.

(Def.'s '939 Opening Cl. Constr. Br., Ex. K at 5 (emphasis added).)

Additionally, King's expert, Arthur H. Kibbe, Ph.D., states that this is an acceptable, although non-traditional, use of the term, but faults the inventors for not stating the definition somewhere in the patent. Yet, it is not necessary to define terms explicitly in the specification, if the meaning is clearly implied. *See Gen. Creation*, 232 F. Supp. 2d at 665 ("'The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication.'" (quoting *Vitronics*, 90 F.3d at 1582)). It is plain from the claims and the specification that the inventors were using the non-traditional meaning even though the definition was not expressly stated.

King contends that even if "bioequivalent" is defined as Purdue suggests, the term is nevertheless indefinite because there is no way to determine how much of an antagonist is "bioequivalent to 0.125 mg naltrexone or less" without undue experimentation. However, Purdue's expert, J. David Haddox, D.D.S., M.D., testified

that to determine the amount of another antagonist "bioequivalent" to 0.125 mg naltrexone, a clinician would go to a standard pharmacological reference book and perform "a relatively simple" calculation. (Def.'s '939 Rebuttal Cl. Constr. Br., Ex. B at 279.) There are indeed reference books that "present pharmacokinetic data in a format that allows the clinician to make rational choices of doses of drugs." Leslie Z. Benet, et al., *Appendix II: Design & Optimization of Dosage Regimens; Pharmacokinetic Data*, *in Goodman & Gilman's The Pharmacological Basis of Therapeutics* 1707, 1707 (9th ed. 1996). One such reference book is Enno Freye, *Opioid Agonists, Antagonists and Mixed Narcotic Analgesics* 43 (1987), which has a table comparing the potency of naltrexone and naloxone, among other opioid antagonists.

Because of this substantial evidence demonstrating that one determining "bioequivalent" doses would not need to perform undue experimentation, I find that King has not shown by clear and convincing proof that "bioequivalent" is indefinite, and I construe "bioequivalent" to mean "equivalent antagonistic effect."

F. "EFFECT" ('939 PATENT).

Finally, King contends the term "effect" as used in claims 14-17 in the '939 patent is "impermissibly vague." (Pls.' '939 Opening *Markman* Br. 27.) "Effect" appears in claims 14 and 16 in the phrase "[an amount of the opioid antagonist]

released . . . insufficient to produce an antagonistic effect" and in claims 15 and 17 in the phrase "[an amount of the opioid antagonist] released . . . will substantially block an effect of the opioid agonist." ('939 patent, col. 54, ll. 1-32.) King's general argument is that for "effect" to have a definite meaning, these claims must give the specific amounts of particular opioid antagonists that are "insufficient to produce an antagonistic effect" and "will substantially block an effect of" a specified opioid agonist. King adds that such a task is virtually impossible because the amount changes from patient to patient and from antagonist to antagonist.

Purdue, in turn, offers "does not rise to a level which significantly impacts or changes the analgesic efficacy of the dose of opioid agonist included in the dosage form" as the definition of "insufficient to produce an antagonistic effect" and asserts that "effect" should be given its plain and ordinary meaning in claims 15 and 17. (Def.'s '939 Opening Cl. Constr. Br. 30.)

I find that "effect" does not need to be defined. It is a term that is relative by nature and widely used in pharmaceutical patents. For example, "'effective amount' is a common and generally acceptable term for pharmaceutical claims and is not ambiguous or indefinite, provided that a person of ordinary skill in the art could determine the specific amounts without undue experimentation." *Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1383-84 (Fed. Cir. 2003).

King argues that "effect" must be precisely defined so as to better analyze the infringement claims, but certain ambiguities are permissible.

> Claims are often drafted using terminology that is not as precise or specific as it might be. As long as the result complies with the statutory requirement to particularly point out and distinctly claim the subject matter which the applicant regards as his invention, that practice is permissible. That does not mean, however, that a court, under the rubric of claim construction, may give a claim whatever additional precision or specificity is necessary to facilitate a comparison between the claim and the accused product.

PPG Indus. v. Guardian Indus. Corp., 156 F.3d 1351, 1355 (Fed. Cir. 1998) (internal citation, quotation marks, and alterations omitted). The *PPG* court held it was proper for the district judge to let the jury decide whether amounts of iron sulfide in the patented glass have a "material effect" on the glass, rather than resolve the issue in claim construction, because the patent was silent about what constituted a material effect on the properties of glass. *Id.* at 1354-55. "[A] sound claim construction need not always purge every shred of ambiguity. The resolution of some line-drawing problems . . . is properly left to the trier of fact." *Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 806 (Fed. Cir. 2007).

King's contention that the amount will differ from patient to patient, while true, is not a basis for finding a pharmaceutical patent indefinite because setting out the amounts of active ingredient necessary for an "effect"in every person is an impossible

task. The '939 patent will require experimentation such as clinical trials to determine "effective amounts," but clinical trials are not considered "undue" experimentation. *See Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1365-66 (Fed. Cir. 2008). One skilled in the art in pharmaceutical manufacturing is certainly accustomed to testing dosages and performing clinical trials to determine the amounts of active ingredients necessary for effect in different population groups, but at the same time, testing will never achieve a precise "effective amount" for every conceivable patient. Thus, the fact that there is no one-size-fits-all "effective amount" dictated in the '939 patent certainly cannot be a reason to find the patent indefinite. Accordingly, I find, as the court in *PPG*, "effect" is definite enough for a jury to determine whether another pharmaceutical product infringes on the '939 patent, and therefore, does not need to be any further defined.

V

For the foregoing reasons, it is **ORDERED** that the following terms in the '088 patent and the '939 patent will have the meanings as indicated:

A. THE '088 PATENT.

1. "Dosage form" means the physical form of a drug product.

2. The proper construction of "means for sequestering . . ." is

(a) a coating of opioid antagonist particles with one or more hydrophobic materials; and

(b) a matrix in which an opioid antagonist is dispersed with one or more hydrophobic materials.

B. THE '939 PATENT.

1. "Dosage form" means the physical form of a drug product.

2. "Free from" means does not contain.

3. "The first layer consisting of opioid antagonist" means the first layer contains only the opioid antagonist and other ingredients unrelated to the invention.

4. "Bioequivalent" means equivalent antagonistic effect.

5. "Effect" means effect.

ENTER: June 22, 2010

/s/ JAMES P. JONES
Chief United States District Judge