United States District Court,
C.D. California.

BIOVAIL LABORATORIES INC,
v.
ANCHEN PHARMACEUTICALS INC.

No. SACV 04-1468JVS(RCx)

Jan. 12, 2006.

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Proceedings: (IN CHAMBERS) Order on Claim Construction Hearing

JAMES V. SELNA**, Judge.**

Karl J. Tunis, Deputy Clerk

I. *BACKGROUND*

Plaintiff Biovail Laboratories, Inc. ("Biovail") has instituted the instant patent infringement case against Defendant Anchen Pharmaceuticals, Inc. ("Anchen"). Biovail contends that Anchen has infringed U.S. Patent No. 6,096,341 ("the '341 patent"). Biovail is the owner of the '341 patent. The '341 patent describes a delayed-release tablet formulation of bupropion hydrochloride. Bupropion hydrochloride is an anti-depressant drug which is contained in a prescription medication called Wellbutrin XL.

II. *LEGAL STANDARD*

It is well settled that claim construction is "exclusively within the province of the court." Markman v. Westview Instruments, Inc., 517 U.S. 370, 372, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). Such construction "begins and ends" with the claim language itself, Interactive Gift Express, Inc. v. Compuserve, Inc., 256 F.3d 1323, 1331 (Fed.Cir.2001), but extrinsic evidence may also be consulted "if needed to assist in determining the meaning or scope of technical terms in the claims." Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1216 (Fed.Cir.1995).

In construing the claim language, the Court begins with the principle that "the words of a claim are generally given their ordinary and customary meaning." Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed.Cir.2005) (internal quotation marks omitted). Further, this ordinary and customary meaning "is the meaning that the [claim] 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.) "[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*.)

"In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." (*Id*. at 1314.) "In such circumstances general purpose dictionaries may be helpful." (*Id*.) In other cases, "determining the ordinary and customary meaning of the claim requires examination of terms that have a particular meaning in a field of art." (*Id*.) In those cases, "the court looks to those sources available to the public that show what a person of skill in the art would have understood the disputed claim language to mean." (*Id*.) These sources include "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." (*Id*.*;* internal quotation marks omitted.)

The claim terms are not presumed to have the meaning that a person of ordinary skill in the relevant art would ordinarily attribute to them if (1) the patentee acts as his own lexicographer, or (2) the claim term is too vague for an accurate meaning to be ascertained from the language used. Novartis Pharms. Corp. v. Abbott Labs., 375 F.3d 1328, 1334 (Fed.Cir.2004). All that is required for a patentee to act as his own lexicographer is that a different meaning is set out in the specification in a manner sufficient to provide notice of the meaning to a person of ordinary skill in the art. In re Paulsen, 30 F.3d 1475, 1480 (Fed.Cir.1994).

With these principles in mind, the Court now turns to the construction of the claim language at issue.

III. ***DISCUSSION***

The inside of the tablet of the invention contains the active ingredient, the drug bupropion hydrochloride, which is surrounded by a coating which is designed to slowly release the drug over a prolonged period of time. (Biovail's Opening Claim Construction, Ex. 2, hereinafter "Williams Decl.," para. 9.) Bupropion hydrochloride decomposes in water. (*Id*.*,* para. 6.) In order to slow the decomposition of bupropion hydrochloride, most drug formulations containing bupropion hydrochloride previously needed a stabilizer to prevent or inhibit decomposition.

The '341 patent is a bupropion hydrochloride delayed-release tablet that does not need a stabilizer. Part (i) of claim 1 describes the core of the formulation as being "free of stabilizer."

Part (ii) of claim 1 describes the coating of the delayed release bupropion tablet as consisting essentially of three components; (1) a water-insoluble, water-permeable firm-forming polymer, (2) a plasticizer, and (3) a water-soluble polymer.

Biovail explains that the film-forming polymer forms a coating around the core of the tablet. Further, Biovail states that a polymer is a molecular chain of repeating subunits. A film-forming polymer forms a film upon drying. In order to prevent those films from becoming brittle and cracking, compounds called plasticizers are added to the film-forming polymers to make them more pliable. Biovail states that the plasticizers decrease the softening temperature of the polymer to which the plasticizer is added, thus making the film that results less brittle. (Williams Decl., para.para. 15-17.)

Similarly, Anchen explains that film coating involves the deposition of a uniform film onto the surface of a tablet to regulate the time and/or rate of drug release when it passes through the body. Anchen avers that water-insoluble, water-permeable polymers, like ethylcellulose are often used to extend the release time of a drug over a period of time. (John E. Mooney ("JEM") Decl., Ex. E, Remington: The Science and Practice of Pharmacy 1654 (19th ed. 1995) ("Remington's"); Ex. F, Pharmaceutical Dosage Forms (Tablets), Vol. 3, 216

(2d ed.1990). Anchen states that the films create a partitioning membrane that allows water or other various gastrointestinal fluids to permeate into the core of the tablet, dissolve the drug, and free the drug through diffusion. (JEM Decl., Ex. G, Ho-Wah Hui, et al., Design and Fabrication of Technology Based Controlled Release Drug Delivery Systems, Ch. 9 in Controlled Drug Delivery 392, Fig. 6 (2d Ed.1987); Ex. E, Remington's at 1654; Ex. F, Pharmaceutical Dosage Forms at 211 & 216 .) Anchen concludes that claim 1 requires a water-insoluble polymer like ethylcellulose in a coating. (Anchen's Opening Claim Construction Brief, p. 5.)

A. ***CLAIM LANGUAGE***

There are four disputed claims to be construed in this case; (1) "free of stabilizer," (2) "a plasticizer," (3) "dissolution profile," and (4) "free of pore-forming agent." The disputed terms are used in independent claims 1 and 30.

Claim 1 provides,

A delayed release tablet comprising: (i) a core comprising bupropion hydrochloride and conventional excipients, **free of stabilizer;** and (ii) a coating consisting essentially of a water-insoluble, water-permeable film-forming polymer, **a plasticizer** and a water-soluble polymer, where the proportion of the water-insoluble, water-permeable film-forming polymer varies between 25 and 90% of the coating dry weight, the proportion of plasticizer varies between 5 and 30% of the coating dry weight, and the proportion of water-soluble polymer varies between 10 and 75% of the coating dry weight, exhibiting a **dissolution profile** such that after 1 hour, from 0 up to 30% of the bupropion hydrochloride is released, after 4 hours, from 10 to 60% of the bupropion hydrochloride is released, after 6 hours, from 20 to 70% of the bupropion hydrochloride is released, after 8 hours, more than 40% of the bupropion hydrochloride is released.

(Anchen's Opening Claim Construction Brief, Ex. 1, ('341 patent), hereinafter ("Ex.1"); Disputed terms bolded.))

Claim 30 provides,

A bupropion hydrochloride delayed release tablet, **free of stabilizer** and **free of pore-forming agent,** exhibiting a **dissolution profile** such that after 1 hour, from 0 up to 30% of the bupropion hydrochloride is released, after 4. hours, from 10 to 60% of the bupropion hydrochloride is released, after 6 hours, from 20 to 70% of the bupropion hydrochloride is released, after 8 hours, more than 40% of the bupropion hydrochloride is released.

(Id.)

B. " ***FREE OF STABILIZER*** **"**

Disputed Term	Biovail's Proposed Construction	Anchen's Proposed Construction	The Court's Construction
Free of stabilizer (claim 1)	"Free of stabilizer" means that the core and tablet lack an effective stabilizing amount of an organic or inorganic acid capable of inhibiting the degradation of bupropion hydrochloride, and existing as a solid or	"Free of stabilizer" means free of stabilizer of any kind including those of acidic pH or with antioxidant properties.	"Free of stabilizer" means the core is free of any substance or agent that tends to prevent changes to the chemical or physical integrity of the tablet, or enhances the ability of the tablet to maintain protection against microbiological

	liquid under ambient conditions.		contamination.
		The term "free of stabilizer" means that the core material is not united with, attached to, combined with, or mixed with any substance or agent that tends to prevent changes to the chemical or physical integrity of the tablet, or enhances the ability of the tablet to maintain protection against microbiological contamination.	
Free of Stabilizer (Claim 30)	Same as above	The definition above applied to the tablet, not just the core. In addition, the tablet must be free of any coating that improves stability.	"Free of stabilizer" means the tablet is free of any substance or agent that tends to prevent changes to the chemical or physical integrity of the tablet, or enhances the ability of the tablet to maintain protection against microbiological contamination.

Claim 1 provides that the "core" of the tablet be "free of stabilizer," and Claim 30 requires that the "tablet" be "free of stabilizer."

The term "free" of is a "negative limitation," which defines the claimed invention by what it is not. *See generally* Upsher-Smith Labs., Inc. v. Pamlab. L.L.C., 412 F.3d 1319, 1321-23 (Fed.Cir.2005).

The background of the invention states:

As bupropion hydrochloride is unstable, the product described in the above two patents [U.S. Patent Nos. 5,358,970 (the "'970 patent") and 5,427,798 (the "'798 patent")] requires a **stabilizer** to achieve sufficient stability. This stabilizer is an acidic compound, preferably cysteine hydrochloride.

(Ex. 1, Col. 1, 24-27; emphasis provided)

The summary of the invention states, "[t]he invention thus provides a new bupropion hydrochloride controlled release composition under the form of a tablet **free of stabilizer of any kind** including those with acidic pH or with antioxidant properties ." (Ex. 1, Col. 1:55-56; emphasis provided)

Biovail contends that the term "stabilizer" is defined by reference to certain prior art references in existence at the time of the filing of the '341 patent, specifically the '970 patent and the '798 patent, and that those definitions apply to this term. (Biovail's Preliminary Claim Construction, p. 18.)

Biovail argues that based on the '341 patent specification and the patents cited in the background section of the '341 patent, a person who is skilled in the art would understand free of stabilizer to mean: "lacking an effective stabilizing amount of an organic or inorganic acid capable of inhibiting the degradation of bupropion hydrochloride, and existing as a solid or liquid under ambient conditions." (Williams Decl., para. 14.)

Biovail asserts that "all of the examples of stabilizers contained in the ' 341 patent, the '970 patent and the '798 patent are organic or inorganic acids that exist as solids or liquids under ambient conditions." (Williams

Decl., para. 13; Ex. 1, Col. 1:24-25.)

Moreover, Biovail avers that by virtue of the specific disclosure of the ' 970 patent, "it is clear that a core is free of stabilizer when there is not sufficient stabilizer in the core to stabilize bupropion hydrochloride. Thus, when there is no measurable amount of stabilizer in the core, it is, by definition, 'free of stabilizer.' " (Response to Anchen's Opening Claim Construction Brief, p. 8.)

Anchen contends that the terms "free of" and "stabilizer" are not ambiguous, and therefore there should be no genuine dispute concerning the ordinary meaning of the phrase "free of stabilizer." (Anchen's Opening Claim Construction, p. 11.)

Anchen avers that "free of" is not a term that has a special meaning within the context of pharmaceuticals, and therefore should be defined in a way that is consistent with its ordinary English meaning: "not united with or not present as an element in other substances," "chemically uncombined or readily obtained in an uncombined form." (JEM Decl., Ex. I, Webster's Third New Int'l Dict. of the English Language Unabrid., 904-05 (1981).

Further, Anchen claims that the word "stabilizer" is a concept well understood in the pharmaceutical art as something that may provide stability. (Anchen's Opening Claim Construction Brief, pp. 7, 11.) "The term 'stability,' with respect to a drug dosage form refers to the chemical and physical integrity of the dosage unit, and when appropriate, the ability of the dosage unit to maintain protection against microbiological contamination." (United States Pharmacopeia-National Formulary ("USP"); JEM, Decl., Ex. H at 1940 .)

Anchen avers that its proposed ordinary meaning of the term "free of stabilizer" is supported by and consistent with the specification of the ' 341 patent, and specifically the summary of the invention. As Anchen stresses, the summary of the invention informs the public that the claimed invention is "free of stabilizer of any kind." (Ex. 1, Col.1:55-56.)

However, Biovail avers that Anchen's reliance on Webster's has been rejected by the Federal Circuit in *Phillips*. The Court finds that Biovail's interpretation of *Phillips* is misplaced. In *Phillips,* the court held that when the ordinary meaning of claim language, as understood by a person of skill in the art is readily apparent even to lay judges, and claim constructions involves little more than the application of the widely accepted meaning of commonly understood words, then general purpose dictionaries may be helpful. 415 F.3d at1314. Hence the Court finds that Anchen's reliance on Webster's dictionary is proper in this case.

Further as Anchen points out, Biovail's expert, Dr. Williams, admitted that a person of skill in the art would consider the USP to be a "reliable authority," (11/22/05 Decl. of Don J. Mizerk ("DJM Decl."), Ex. W (11/15/05 Williams Depo.) at 70:13-16) and that the USP is the "first place to go" to determine stability parameters. (*Id*. at 84:7-20.)

Moreover, as Anchen points out Dr. Williams admitted that a person of skill in the art in 1998 who was not aware of the '341 patent would agree with Anchen's proposed definition of the phrase "free of stabilizer." (Id. at 72:25-73:19.) However, the Court notes that Dr. Williams then stated that one of ordinary skill in the art would have been narrowed in the definition of the stabilizer because of the discussion in the background section and the content of the two patents that are discussed there. (Id. at 74:11-17.)

The Court, however, does not find that the discussion in the background section nor the content of the two patents narrows the definition of the claim.

Finally, as Dr. Williams admitted that a certain substance would be in the definition of stabilizer. (Id. at 74:7-10.)

Anchen avers that Biovail has not overcome the heavy presumption in favor of a claim term's ordinary meaning, and that the '341 patent does not incorporate patents '970 and '798. "To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents." Advanced Display Sys., Inc. v. Kent State Univ., 212 F.3d 1272, 1282-83 (Fed.Cir.2000). As Anchen points out, there is nothing in the '341 patent specification that expressly incorporates both of those two patents.

Further, Dr. Williams admits that the '341 patent does not explicitly incorporate any definition of the term 'stabilizer' from the '970 or '798 patents. (DJM Decl., Ex. W at 76:16-77:3.) Importantly, Biovail's proposed definition of "stabilizer" is not found anywhere in the '341 patent, and actually contradicts the summary of the invention.

In addition, the Court does not find that the patentee has acted as his own lexicographer merely by mentioning the '970 or '798 patents in the background of the invention. The Court does not find that the patentee has set out a different meaning in the specification in a manner sufficient to provide notice of the meaning to a person of ordinary skill in the art. In re Paulsen, 30 F.3d 1475, 1480 (Fed.Cir.1994).

For the foregoing reasons the Court finds that Anchen's proposed construction follows the directives in *Phillips*. However, the Court does not find that it is necessary to construe the term "free of."

C. " *PLASTICIZER* "

Disputed Term	Biovail's Proposed Construction	Anchen's Proposed Construction	The Court's Construction
Plasticizer	A "plasticizer" is a composition that decreases the softening temperature of the polymer to which it is added.	No need to construe.	A plasticizer is a substance added to the polymeric solution both to facilitate processing and to increase the flexibility and toughness of the final product by internal modification (solvation) of the polymer molecule.
		A plasticizer is a substance added to the polymeric solution both to facilitate processing and to increase the flexibility and toughness of the final product by internal modification (solvation) of the polymer molecule.	Among other things, a plasticizer is known to lower the glass transition temperature of a high polymer.
			Among other things, a plasticizer is known to lower the glass transition temperature of a high polymer.

The detailed description of the invention states that "[t]he plasticizer can be an ester such as a citrate ester, an oil such as castor oil, a polyalkyleneglycol such as polyethyleneglycol of various MWs. The preferred plasticizer is polyethyleneglycol." (Ex. 1, Col.2:62-65.) Further the detailed description of the invention states:

The proportion of plasticizer (e.g.polyethyleneglycol) in the coating may vary between 5 and 30% of the coating dry weight. The relative proportions of ingredients, notably film-forming polymer to water-soluble polymer, can be varied depending on the release profile to be obtained (where a more delayed release is generally obtained with a higher amount of water-insoluble, water-permeable film-forming polymer), [para.] The coating process can be as follows, ethylcellulose and polyethylene glycol (e.g. PEG 1450) are

dissolved in a solvent such as ethanol; polyvinylpyrrolidone [Povidone or "PVP"] is then added. The resulting solution is sprayed onto the tablet cores, using a coating pan or a fluidized bed apparatus.

(Ex. 1, Col.3:9-21)

Biovail contends that the term "plasticizer" has its ordinary and customary meaning. (Biovail's Preliminary Claim Construction Brief, p. 12.) Biovail avers that to a person skilled in the pharmaceutical arts, the term "plasticizer" refers to a composition that decreases the softening temperature of the polymer to which it is added. (Williams Decl., para. 16.) Further, Biovail asserts that the language in the detailed description of the '341 patent cited above is entirely consistent with the ordinary meaning for the term "plasticizer" to one skilled in the art. (Id., para. 17.)

Anchen avers that there is no need to construe the meaning of the term "plasticizer," because Biovail has not claimed that any ingredient in Anchen's coating meets the plasticizer limitation. (Anchen's Opening Claim Construction Brief, p. 16; JEM Decl. Ex. C, at 4.) "[A]lthough the claims are construed objectively and without reference to the accused device, only those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy." Vivid Technologies, Inv. v. American Science & Engineering, Inc., 200 F.3d 795, 803 (Fed.Cir.1999).

Anchen contends that because Biovail only alleges that "oil from the core" may be a plasticizer, the only dispute is whether oil from the *core* can satisfy the claim limitation requiring a plasticizer in the *coating*. (Anchen's Opening Claim Construction Brief, p. 16; emphasis provided; JEM Decl. Ex. C, at 4.)

As recited in claim 1 of the '341 patent, the plasticizer must be an ingredient in the coating material that is mixed and sprayed onto the tablet cores. (Ex. 1, '341 patent, claim 1.) The term "plasticizer" is an ingredient in the coating preparation, which has a dry weight that may be calculated as a certain percentage of the total dry weight of the coating ingredients dissolved or mixed to prepare the coating composition, which is then applied to the tablet cores. (Ex. 1, '341 patent, claim 1; Anchen's Opening Claim Construction Brief, p. 17.) Anchen therefore concludes that the term "plasticizer" should not be construed to extend to oil used in the core of the tablet as lubricant. (Anchen's Opening Claim Construction Brief, p. 17.)

Biovail, however, avers that "Anchen has stonewalled Biovail in discovery on this issue," and that discovery is likely to explain the function of the various excipients in Anchen's proposed formulation. (Response to Anchen's Opening Claim Construction Brief, p. 17.) For this reason the court finds that it is necessary to construe the term "plasticizer."

Anchen's proposed definition is taken from the *Chemical Dictionary* and treatises. (DJM Decl., Ex, X, The *Chemical Dictionary* 822 (10th ed.1981). As discussed above, reliance on extrinsic evidence is proper under *Phillips*. The *Chemical Dictionary* defines a plasticizer as:

[a]n organic compound added to a high polymer both to facilitate processing and to increase the flexibility and toughness of the final product by internal modification (solvation) of the polymer molecule. The later is held together by secondary valence bonds; the plasticizer replaces some of these with plasticizer-to-polymer bonds, thus added movement of the polymer chain segments.

(*Id*.)

Anchen additionally asserts that Biovail's proposed definition of plasticizer is based solely on the declaration of Williams. (Anchen's Responsive Claim Construction Brief, p. 6.) Further, Anchen asserts, and the Court agrees, that Williams admits that Biovail's proposed definition is incomplete. Anchen points out in response to the question, "is the softening temperature the only feature of composition that defines it as a plasticizer? " Williams responded, "there would be other attributes of a plasticizer with a polymer that one could also

refer to plasticizers as." (DJM Decl., Ex. W, Williams Depo. at 92:1-11.) Williams further admitted that such things would be lowering the glass transition temperature of the polymer. (*Id*.)

Hence the Court finds that pursuant to *Phillips,* Anchen's proposed construction embodies the ordinary and customary meaning of the term "plasticizer."

D. " *DISSOLUTION PROFILE* "

Disputed Term	Biovail's Proposed Construction	Anchen's Proposed Construction	The Court's Construction
Dissolution profile	A quality control construe.	No need to assay conducted according to instructions found in the United States Pharmacopoeia.	A quality control assay conducted according to instructions found in the United States Parmacopoeia.
	The ranges of bupropion hydrochloride released after one hour, four hours, six hours and eight hours as determined by a dissolution study conducted according to instructions found in the United States by Pharmacopoeia.		The ranges of bupropion hydrochloride released after one hour, four hours, six hours and eight hours as determined by a dissolution study conducted according to instructions found in the United States by Pharmacopoeia.

A dissolution test is a type of 'in vitro' (i.e., test tube test) quality control test commonly used in the pharmaceutical industry to characterize the performance of a drug product, specifically to measure drug release over time. (Williams Decl., para. 19.)

Biovail explains that in this context dissolution testing involves adding a quantity of a bupropion hydrochloride tablet, the drug product, to a water-based fluid or dissolution medium. (*Id*., para. 19.) Further, after the bupropion hydrochloride is added to the fluid or dissolution medium, samples of the fluid are removed and tested at various times to determine how much of the bupropion hydrochloride is in the fluid. (*Id*.) A dissolution profile is obtained by determining the amount of bupropion hydrochloride that is released from the drug product at various times. (*Id*.)

Anchen asserts that the "dissolution profile" limitation of claims 1 and 30 is indefinite because it does not specify the conditions under which it should be measured. (Anchen's Opening Claim Construction Brief, p. 8.) Anchen avers that dissolution testing can be conducted by using a number of different testing apparatuses, under a number of different agitation conditions, and using a number of different dissolution media with different pH vales. (*Id*.) Anchen contends that "[c]hanges in the variable aspects of a dissolution method will often change the resulting dissolution profile measure for the same drug product." (*Id*.)

Anchen avers that Biovail is attempting to brief the invalidity issue in connection with the *Markman* hearing, and asks the Court to defer resolution of this dispute until after Anchen has conducted additional discovery. (*Id*.)

According to Biovail, the '341 patent does not specify any specific dissolution conditions because the dissolution conditions will depend on the particular performance characteristics of the bupropion hydrochloride product at issue. (Williams Decl., para. 20.) Biovail avers that a person of ordinary skill in the

art would know that. Biovail explains that some drug formulations are designed to release in the stomach, and others are designed to release the active ingredient in the small intestine. (Id., para. 22-25.) Biovail contends that one skilled in the art would look to the USP to determine which parameters should be used in conducting a dissolution test. (Id., para. 22.)

The Court agrees with Biovail, and that the term "dissolution profile" is not indefinite. In addition, the Court finds that Biovail's reliance on the USP is proper and adopts Biovail's construction of the term "dissolution profile."

E. " *FREE OF PORE-FORMING AGENT* "

Disputed Term	Biovail's Proposed Construction	Anchen's Proposed Construction	The Court's Construction
Free of Pore-Forming Agent	"Free of pore-forming agent" means lacking a particulate non-polymeric water soluble species capable of being eluted from a coating to form a pore therein.	"Free of pore-forming agent" means the tablet does not contain a substance that dissolves or leaches out of a coating to create minute openings or interstices in the barrier membrane to enhance diffusion through the coating.	"Free of pore-forming agent" means the tablet does not contain a non-polymeric water-soluble substance that dissolves or leaches out of a coating to create minute openings or interstices in the barrier membrane to enhance diffusion through the coating.

The background of the invention states:

U.S. Pat. No. 4,687,660 (the "'660 patent") and EP-A 017457 (the "'457 patent") disclose a tablet formed of a core and a coating, where the core comprises bupropion hydrochloride together with excipients(a) and optionally as osmotic enhancing agent and where the coating compromises a water-insoluble, water-permeable film-forming polymer (such as cellulose acetate), a **pore-forming agent** (such as impalpable lactose and sodium carbonate), and optionally a so-called water-permeability enhancing agent (such as polyethyleneglycol) and again optionally a plasticizer.

(Ex. 1, Col. 1:28-36; emphasis provided)

The summary of the invention indicates that the '341 patent is "free of (monomoeric) pore-forming agent." (Ex. 1, Col.1:57-58.)

Biovail asserts two reasons for adopting its narrower construction which would exclude polymeric water soluble species from the claimed scope of pore-forming agents. First, it looks to the discussion of prior art. Second, it asserts that a construction which failed to exclude polymeric water soluble species would render each of the examples of preferred embodiment outside the scope of the patent. The Court does not find the first argument persuasive, but does find that second argument is persuasive and controlling, particularly in light of the discussion of prior art in the patent.

Prior Art.

Biovail contends that the term "pore-forming agent" is defined by reference to certain prior art references in existence at the time of the filing of the '341 patent, and that those definitions apply to this term. (Biovail's Preliminary Claim Construction, p. 18 .) Specifically, Biovail asserts that one skilled in the art would look to the '660 patent and the ' 457 application, in addition to the '341 patent specification, to comprehend the meaning of the term "pore-forming agent." (Id., p. 16.)

Biovail further contends that the '660 patent provides that a "pore-forming agent" is a particulate, non-polymeric, water soluble species. (JEM Deck, Ex. T, Ex. U.) In addition, Biovail asserts that the '457 application discloses a pharmaceutical composition comprising a formulation containing a water-soluble active ingredient, a semipermeable membrane surrounding the formulation, "and a particulate water-soluble pore-forming material dispersed within the membrane, whereby, in use in an aqueous environment, the pore forming material is dissolved forming pores in the semipermeable membrane ..." (Response to Anchen's Opening Claim Construction, Ex. E, p. 2, para. 2.)

Anchen points out that while Biovail relies on the '660 patent, the term in the '660 documents is "particulate, water-soluble, pore-forming material," and not a "pore-forming agent." (JEM Deck, Ex. T, '660 patent, Claim 1; Ex. U, ' 457 patent, Claim 1.) Anchen contends that while a "particulate, water-soluble, pore-forming material" would be a pore-forming agent, the two terms are not co-extensive. (Anchen's Opening Claim Construction Brief, p. 19.) Anchen states that "[t]he use of the more precise phrase 'particulate, water-soluble, pore-forming materials,' in the prior art patents establishes that the unlimited term 'pore-forming agent' in the '341 patent is not restricted to 'particulate non-polymeric species.' " (Id.) Anchen concludes that if the applicant of the '341 patent wanted to limit the disclaimer of the pore-forming species to a narrow class of particulate non-polymeric materials, the applicant could have done so by using Biovail's proposed definitions. (Id.)

Anchen further points out that Dr. Williams has admitted that the '341 patent does not state anywhere that it is incorporating by reference the definition of poreforming agent in the '660 patent. (DJM Decl., Ex. W, 108:8-15.)

The state of knowledge generally at the time would not lead to the conclusion that polymers should be excluded. Anchen points out that Dr. Williams admitted that in 1998 a person of ordinary skill in the art would have known that water-soluble polymers could be used as pore-forming agents. (DJM Decl., Ex. W, 107:7-20.) Anchen explains that formulators often add a water-soluble component to the coating mixture to increase the permeability of the film, and therefore increase the release rate. (JEM Decl., Ex. F, Pharmaceutical Dosage Forms at 216-17.) Anchen shows that the use of water-soluble additives to create pores in water-insoluble polymeric coatings was a well-established method of increasing the rate of drug release through the coating. (Anchen's Opening Claim Construction Brief, p. 17; JEM Decl., Ex. F.)

At least standing alone, the discussion in the '457 and '660 patents does not support the limitation for which Biovail argues. The Court rejects the incorporation notion for same reason it rejected similar arguments in interpreting the term "free of stabilizer."

Exclusion of Preferred Embodiment.

Biovail argues that because povidone, a pore-forming agent, is included in each of the patent's preferred embodiments, none of the examples would be covered by Claim 30. (Response to Anchen's Opening Claim Construction, p. 15.) Anchen's own showing establishes that water-soluble polymers, including polyvinyl pyrrolidone ("povidone" or "PVP"), and polyethylene glycol ("PEG"), are known pore-forming agents. (JEM Decl., Ex. F, Pharmaceutical Dosage Forms at 216-17.)

Each of the 11 examples in the '341 patent includes the following ingredient in the coating: Kollidon 90F (povidone USP). As a general rule, a claim construction is unlikely to be correct if it excludes the preferred embodiments. Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1349 (Fed.Cir.2003), and cases cited by Biovail in its Post-Hearing Claim Construction Submission, pp. 2-3.)

Anchen, however, counters that '341 patent provides examples and claims coatings using ethylcellulose, PVP, and PEG. That not does erase the point that all 11 examples also include povidone.

To be sure, the case law will entertain constructions which exclude some preferred embodiments. For example, when the claims are narrowed during the prosecution process, the narrowing may remove a preferred embodiments from the scope of the claim in the patent as issued. North American Container, Inc. v. Plastipak, Inc., 415 F.3d 1335, 1346 (Fed.Cir.2005); Elekta Instrument S.A. v. O.U.R. Scientific International, Inc., 214 F.3d 1302, 1308 (Fed.Cir.2000). However, that is not this case.

In this context, it is difficult to believe that one skilled in art reading the patent would not give particular weight to the statement that the invention was "free of (monomeric) pore-forming agent[s]." (Ex. 1, col.1:58.) While the claim 30 might have been drafted with greater clarity, the Court cannot say that the totality of the patent did not put one skilled in the art on notice that a narrowed definition of pore-forming agent was being claimed.

Accordingly, the Court adopts a modified version Biovail's proposed construction.

IV. *CONCLUSION*

For the foregoing reasons, the Court construes the disputed terms as follows.

Disputed Term	The Court's Construction
Free of stabilizer (Claim 1)	"Free of stabilizer" means the core is free of any substance or agent that tends to prevent changes to the chemical or physical integrity of the tablet, or enhances the ability of the tablet to maintain protection against microbiological contamination.
Free of Stabilizer (Claim 30)	"Free of stabilizer" means the tablet is free of any substance or agent that tends to prevent changes to the chemical or physical integrity of the tablet, or enhances the ability of the tablet to maintain protection against microbiological contamination.
Plasticizer	A plasticizer is a substance added to the polymeric solution both to facilitate processing and to increase the flexibility and toughness of the final product by internal modification (solvation) of the polymer molecule.
	Among other things, a plasticizer is known to lower the glass transition temperature of a high polymer.
Dissolution profile	A quality control assay conducted according to instructions found in the United States Parmacopoeia.
	The ranges of bupropion hydrochloride released after one hour, four hours, six hours and eight hours as determined by a dissolution study conducted according to instructions found in the United States by Pharmacopoeia.
Free of Pore-Forming Agent	"Free of Pore-forming agent" means the tables does not contain a non-polymeric water-soluble substance that dissolves or leaches out of a coating to create minute openings or interstices in the barrier membrane to enhance diffusion through the coating.

Biovail Laboratories, Inc. ("Biovail") moves the Court for clarification of the Court's construction of the term "free of stabilizer" in its *Markman* order of January 12, 2006. (Order, Jan 12, 2006, pp. 6, 19.) Biovail contends that the Court's construction exceeded the agreed scope of this term as reflected in the transcript of the *Markman* hearing. (*See* Transcript, Dec. 12, 2005, p.48.) The Court agrees that clarification is appropriate.

In preparing the final order, the Court edited the section of the tentative dealing with the construction of "free of pore-forming agent" substantially, and made other edits, but neglected to adopt a narrowing of the construction for "free of stabilizer." The version of the order which the Court issued does not reflect the Court's intent in construing the term. Accordingly, the Court is issuing an amended *Markman* order this date

reflecting the narrowing construction of "free of stabilizer."

Anchen Pharmaceutical, Inc. ("Anchen") opposes the request on several grounds. First, Anchen contends that the request is an improper motion for reconsideration. Assuming the request is such, the Court finds that a failure to follow an agreed limitation in the face the parties' agreement and the Court's agreement on the record to do so would amount to a "failure to consider material facts presented to the Court before such decision." *See* Local Rule 7-18(c). Clearly, the parties agreed that for the purpose of the present dispute only chemical stability was in issue, although the, claim could be read more broadly. FN1 (Transcript, Dec. 12, 2005, p. 48.) Moreover, as noted above, the January 12, 2006 order does not reflect the Court's intent.

Second, Anchen objects to Biovail's "stealth[ ]y" request to delete the term "agent' from the construction. The Court declines to strike the term. It appeared in the tentative and the January 12, 2006 order and is carried forward in the amended order.

Accordingly, the Court adopts the following constructions of "free of stabilizer":

Claim 1: "Free of stabilizer" means the core is free of any substance or agent that tends to prevent changes to the chemical integrity of the tablet.

Claim 30: "Free of stabilizer" means the tablet is free of any substance or agent that tends to prevent changes to the chemical integrity of the tablet.

I. ***BACKGROUND***

Plaintiff Biovail Laboratories, Inc. ("Biovail") has instituted the instant patent infringement case against Defendant Anchen Pharmaceuticals, Inc. ("Anchen"). Biovail contends that Anchen has infringed U.S. Patent No. 6,096,341 ("the '341 patent"). Biovail is the owner of the '341 patent. The '341 patent describes a delayed-release tablet formulation of bupropion hydrochloride. Bupropion hydrochloride is an anti-depressant drug which is contained in a prescription medication called Wellbutrin XL.

II. ***LEGAL STANDARD***

It is well settled that claim construction is "exclusively within the province of the court." Markman v. Westview Instruments, Inc., 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577. 372 (1996). Such construction "begins and ends" with the claim language itself, Interactive Gift Express, Inc. v. Compuserve, Inc., 256 F.3d 1323, 1331 (Fed.Cir.2001), but extrinsic evidence may also be consulted "if needed to assist in determining the meaning or scope of technical terms in the claims." Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1216 (Fed.Cir.1995).

In construing the claim language, the Court begins with the principle that "the words of a claim are generally given their ordinary and customary meaning." Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed.Cir.2005) (internal quotation mark; omitted). Further, this ordinary and customary meaning "is the meaning that the [claim] 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.) "[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*.)

"In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." (*Id*. at 1314.) "In such circumstances general purpose dictionaries may be helpful." (*Id*.) In other cases, "determining the ordinary and customary meaning of the claim requires examination of terms that have a particular meaning in a field

of art." (*Id.*) In those cases, "the court looks to those sources available to the public that show what a person of skill in the art would have understood the disputed claim language to mean." (*Id.*) These sources include "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." (*Id.;* internal quotation marks omitted.)

The claim terms are not presumed to have the meaning that a person of ordinary skill in the relevant art would ordinarily attribute to them if (1) the patentee acts as his own lexicographer, or (2) the claim term is too vague for an accurate meaning to be ascertained from the language used. Novartis Pharms. Corp. v. Abbott Labs., 375 F.3d 1328, 1334 (Fed.Cir.2004). All that is required for a patentee to act as his own lexicographer is that a different meaning is set out in the specification in a manner sufficient to provide notice of the meaning to a person of ordinary skill in the art. In re Paulsen, 30 F.3d 1475, 1480 (Fed.Cir.1994).

With these principles in mind, the Court now turns to the construction of the claim language at issue.

III. *DISCUSSION*

The inside of the tablet of the invention contains the active ingredient, the drug bupropion hydrochloride, which is surrounded by a coating which is designed to slowly release the drug over a prolonged period of time. (Biovail's Opening Claim Construction, Ex. 2, hereinafter "Williams Decl.," para. 9.) Bupropion hydrochloride decomposes in water. (*Id.,* para. 6.) In order to slow the decomposition of bupropion hydrochloride, most drug formulations containing bupropion hydrochloride previously needed a stabilizer to prevent or inhibit decomposition.

The '341 patent is a bupropion hydrochloride delayed-release tablet that does not need a stabilizer. Part (i) of claim 1 describes the core of the formulation as being "free of stabilizer."

Part (ii) of claim 1 describes the coating of the delayed release bupropion tablet as consisting essentially of three components; (1) a water-insoluble, water-permeable firm-forming polymer, (2) a plasticizer, and (3) a water-soluble polymer.

Biovail explains that the film-forming polymer forms a coating around the core of the tablet. Further, Biovail states that a polymer is a molecular chain of repeating subunits. A film-forming polymer forms a film upon drying. In order to prevent those films from becoming brittle and cracking, compounds called plasticizers are added to the film-forming polymers to make them more pliable. Biovail states that the plasticizers decrease the softening temperature of the polymer to which the plasticizer is added, thus making the film that results less brittle. (Williams Deck, para.para. 15-17.)

Similarly, Anchen explains that film coating involves the deposition of a uniform film onto the surface of a tablet to regulate the time and/or rate of drug release when it passes through the body. Anchen avers that water-insoluble, water-permeable polymers, like ethylcellulose are often used to extend the release time of a drug over a period of time. (John E. Mooney ("JEM") Decl., Ex. E, Remington: The Science and Practice of Pharmacy 1654 (19th ed. 1995) ("Remington's"); Ex. F, Pharmaceutical Dosage Forms (Tablets), Vol. 3, 216 (2d ed.1990). Anchen states that the films create a partitioning membrane that allows water or other various gastrointestinal fluids to permeate into the core of the tablet, dissolve the drug, and free the drug through diffusion. (JEM Decl., Ex. G, Ho-Wah Hui, et al., Design and Fabrication of Technology Based Controlled Release Drug Delivery Systems, Ch. 9 in Controlled Drug Delivery 392, Fig. 6 (2d Ed.1987); Ex. E, Remington's at 1654; Ex. F, Pharmaceutical Dosage Forms at 211 & 216 .) Anchen concludes that claim 1 requires a water-insoluble polymer like ethylcellulose in a coating. (Anchen's Opening Claim Construction Brief, p. 5.)

A. ***CLAIM LANGUAGE***

There are four disputed claims to be construed in this case; (1) "free of stabilizer," (2) "a plasticizer," (3) "dissolution profile," and (4) "free of pore-forming agent." The disputed terms are used in independent claims 1 and 30.

Claim 1 provides,

A delayed release tablet comprising: (i) a core comprising bupropion hydrochloride and conventional excipients, **free of stabilizer;** and (ii) a coating consisting essentially of a water-insoluble, water-permeable film-forming polymer, **a plasticizer** and a water-soluble polymer, where the proportion of the water-insoluble, water-permeable film-forming polymer varies between 25 and 90% of the coating dry weight, the proportion of plasticizer varies between 5 and 30% of the coating dry weight, and the proportion of water-soluble polymer varies between 10 and 75% of the coating dry weight, exhibiting a **dissolution profile** such that after 1 hour, from 0 up to 30% of the bupropion hydrochloride is released, after 4 hours, from 10 to 60% of the bupropion hydrochloride is released, after 6 hours, from 20 to 70% of the bupropion hydrochloride is released, after 8 hours, more than 40% of the bupropion hydrochloride is released.

(Anchen's Opening Claim Construction Brief, Ex. 1, ('341 patent), hereinafter ("Ex.1"); Disputed terms bolded.))

Claim 30 provides,

A bupropion hydrochloride delayed release tablet, **free of stabilizer** and **free of pore-forming agent,** exhibiting a **dissolution profile** such that after 1 hour, from 0 up to 30% of the bupropion hydrochloride is released, after 4 hours, from 10 to 60% of the bupropion hydrochloride is released, after 6 hours, from 20 to 70% of the bupropion hydrochloride is released, after 8 hours, more than 40% of the bupropion hydrochloride is released.

(Id.)

B. " ***FREE OF STABILIZER*** **"**

Disputed Term	Biovail's Proposed Construction	Anchen's Proposed Construction	The Court's Construction
Free of stabilizer (claim 1)	"Free of stabilizer" means that the core and tablet lack an effective stabilizing amount of an organic or inorganic acid capable of inhibiting the degradation of bupropion hydrochloride, and existing as a solid or liquid under ambient conditions.	"Free of stabilizer" means free of stabilizer of any kind including those of acidic pH or with antioxidant properties.	"Free of stabilizer" means the core is free of any substance or agent that tends to prevent changes to the chemical integrity of the tablet.
		The term "free of stabilizer" means that the core material is not united with, attached to, combined with, or mixed with any. substance or agent that tends to prevent changes to the chemical or physical integrity of the tablet, or enhances the ability of the tablet to maintain protection against microbiological contamination.[	

		FN1]	
Free of Stabilizer (Claim 30)	Same as above	The definition above applied to the tablet, not just the core. In addition, the tablet must be free of any coating that improves stability.	"Free of stabilizer" means the tablet is free of any substance or agent that tends to prevent changes to the chemical integrity of the tablet.

Claim 1 provides that the "core" of the tablet be "free of stabilizer," and Claim 30 requires that the "tablet" be "free of stabilizer."

The term "free of" is a "negative limitation," which defines the claimed invention by what it is not. *See generally* Upsher-Smith Labs., Inc. v. Pamlab, L.L.C., 412 F.3d 1319, 1321-23 (Fed.Cir.2005).

The background of the invention states:

As bupropion hydrochloride is unstable, the product described in the above two patents [U.S. Patent Nos. 5,358,970 (the "'970 patent") and 5,427,798 (the "'798 patent")] requires a **stabilizer** to achieve sufficient stability. This stabilizer is an acidic compound, preferably cysteine hydrochloride.

(Ex. 1, Col. 1, 24-27; emphasis provided)

The summary of the invention states, "[t]he invention thus provides a new bupropion hydrochloride controlled release composition under the form of a tablet **free of stabilizer of any kind** including those with acidic pH or with antioxidant properties ." (Ex. 1, Col. 1:55-56; emphasis provided)

Biovail contends that the term "stabilizer" is defined by reference to certain prior art references in existence at the time of the filing of the ' 341 patent, specifically the '970 patent and the '798 patent, and that those definitions apply to this term. (Biovail's Preliminary Claim Construction, p. 18.)

Biovail argues that based on the '341 patent specification and the patents cited in the background section of the '341 patent, a person who is skilled in the art would understand free of stabilizer to mean: "lacking an effective stabilizing amount of an organic or inorganic acid capable of inhibiting the degradation of bupropion hydrochloride, and existing as a solid or liquid under ambient conditions." (Williams Decl., para. 14.)

Biovail asserts that "all of the examples of stabilizers contained in the ' 341 patent, the '970 patent and the '798 patent are organic or inorganic acids that exist as solids or liquids under ambient conditions." (Williams Decl., para. 13; Ex. 1, Col. 1:24-25.)

Moreover, Biovail avers that by virtue of the specific disclosure of the ' 970 patent, "it is clear that a core is free of stabilizer when there is not sufficient stabilizer in the core to stabilize bupropion hydrochloride. Thus, when there is no measurable amount of stabilizer in the core, it is, by definition, 'free of stabilizer.' " (Response to Anchen's Opening Claim Construction Brief, p. 8.)

Anchen contends that the terms "free of" and "stabilizer" are not ambiguous, and therefore there should be no genuine dispute concerning the ordinary meaning of the phrase "free of stabilizer." (Anchen's Opening Claim Construction, p. 11.)

Anchen avers that "free of" is not a term that has a special meaning within the context of pharmaceuticals, and therefore should be defined in a way that is consistent with its ordinary English meaning: "not united with or not present as an element in other substances," "chemically uncombined or readily obtained in an uncombined form." (JEM Decl., Ex. I, Webster's Third New Int'l Dict. of the English Language Unabrid., 904-05 (1981).

Further, Anchen claims that the word "stabilizer" is a concept well understood in the pharmaceutical art as something that may provide stability. (Anchen's Opening Claim Construction Brief, pp. 7, 11.) "The term 'stability,' with respect to a drug dosage form refers to the chemical and physical integrity of the dosage unit, and when appropriate, the ability of the dosage unit to maintain protection against microbiological contamination." (United States Pharmacopeia-National Formulary ("USP"); JEM, Decl., Ex. H at 1940 .)

Anchen avers that its proposed ordinary meaning of the term "free of stabilizer" is supported by and consistent with the specification of the ' 341 patent, and specifically the summary of the invention. As Anchen stresses, the summary of the invention informs the public that the claimed invention is "free of stabilizer of any kind." (Ex. 1, Col.1:55-56.)

However, Biovail avers that Anchen's reliance on Webster's has been rejected by the Federal Circuit in *Phillips*. The Court finds that Biovail's interpretation of *Phillips* is misplaced. In *Phillips,* the court held that when the ordinary meaning of claim language, as understood by a person of skill in the art is readily apparent even to lay judges, and claim constructions involves little more than the application of the widely accepted meaning of commonly understood words, then general purpose dictionaries may be helpful. 415 F.3d at1314. Hence the Court finds that Anchen's reliance on Webster's dictionary is proper in this case.

Further as Anchen points out, Biovail's expert, Dr. Williams, admitted that a person of skill in the art would consider the USP to be a "reliable authority," (11/22/05 Decl. of Don J. Mizerk ("DJM Decl."), Ex. W (11/15/05 Williams Depo.) at 70:13-16) and that the USP is the "first place to go" to determine stability parameters. (*Id*. at 84:7-20.)

Moreover, as Anchen points out Dr. Williams admitted that a person of skill in the art in 1998 who was not aware of the '341 patent would agree with Anchen's proposed definition of the phrase "free of stabilizer." (Id. at 72:25-73:19.) However, the Court notes that Dr. Williams then stated that one of ordinary skill in the art would have been narrowed in the definition of the stabilizer because of the discussion in the background section and the content of the two patents that are discussed there. (Id. at 74:11-17.)

The Court, however, does not find that the discussion in the background section nor the content of the two patents narrows the definition of the claim.

Finally, as Dr. Williams admitted that a certain substance would be in the definition of stabilizer. (Id. at 74:7-10.)

Anchen avers that Biovail has not overcome the heavy presumption in favor of a claim term's ordinary meaning, and that the '341 patent does not incorporate patents '970 and '798. "To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents." Advanced Display Sys., Inc. v. Kent State Univ., 212 F.3d 1272, 1282-83 (Fed.Cir.2000). As Anchen points out, there is nothing in the '341 patent specification that expressly incorporates both of those two patents.

Further, Dr. Williams admits that the '341 patent does not explicitly incorporate any definition of the term 'stabilizer' from the '970 or '798 patents. (DJM Decl., Ex. W at 76:16-77:3.) Importantly, Biovail's proposed definition of "stabilizer" is not found anywhere in the '341 patent, and actually contradicts the summary of the invention.

In addition, the Court does not find that the patentee has acted as his own lexicographer merely by mentioning the '970 or '798 patents in the background of the invention. The Court does not find that the patentee has set out a different meaning in the specification in a manner sufficient to provide notice of the meaning to a person of ordinary skill in the art. In re Paulsen, 30 F.3d 1475, 1480 (Fed.Cir.1994).

For the foregoing reasons the Court finds that Anchen's proposed construction follows the directives in *Phillips*. However, the Court does not find that it is necessary to construe the term "free of."

C. " *PLASTICIZER* "

Disputed Term	Biovail's Proposed Construction	Anchen's Proposed Construction	The Court's Construction
Plasticizer	A "plasticizer" is a composition that decreases the softening temperature of the polymer to which it is added.	No need to construe.	A plasticizer is a substance added to the polymeric solution both to facilitate processing and to increase the flexibility and toughness of the final product by internal modification (solvation) of the polymer molecule. Among other things, a plasticizer is known to lower the glass transition temperature of a high polymer.
		A plasticizer is a substance added to the polymeric solution both to facilitate processing arid to increase the flexibility and toughness of the final product by internal modification (solvation) of the polymer molecule. Among other things, a plasticizer is known to lower the glass transition temperature of a high polymer.	

The detailed description of the invention states that "[t]he plasticizer can be an ester such as a citrate ester, an oil such as castor oil, a polyalkyleneglycol such as polyethyleneglycol of various MWs. The preferred plasticizer is polyethyleneglycol." (Ex. 1, Col.2:62-65.) Further the detailed description of the invention states:

The proportion of plasticizer (e.g.polyethyleneglycol) in the coating may vary between 5 and 30% of the coating dry weight. The relative proportions of ingredients, notably film-forming polymer to water-soluble polymer, can be varied depending on the release profile to be obtained (where a more delayed release is generally obtained with a higher amount of water-insoluble, water-permeable film-forming polymer), [para.] The coating process can be as follows, ethylcellulose and polyethylene glycol (e.g. PEG 1450) are dissolved in a solvent such as ethanol; polyvinylpyrrolidone [Povidone or "PVP"] is then added. The resulting solution is sprayed onto the tablet cores, using a coating pan or a fluidized bed apparatus.

(Ex. 1, Col.3:9-21)

Biovail contends that the term "plasticizer" has its ordinary and customary meaning. (Biovail's Preliminary Claim Construction Brief, p. 12.) Biovail avers that to a person skilled in the pharmaceutical arts, the term "plasticizer" refers to a composition that decreases the softening temperature of the polymer to which it is added. (Williams Decl., para. 16.) Further, Biovail asserts that the language in the detailed description of the '341 patent cited above is entirely consistent with the ordinary meaning for the term "plasticizer" to one

skilled in the art. (Id., para. 17.)

Anchen avers that there is no need to construe the meaning of the term "plasticizer," because Biovail has not claimed that any ingredient in Anchen's coating meets the plasticizer limitation. (Anchen's Opening Claim Construction Brief, p. 16; JEM Decl. Ex. C, at 4.) "[A]lthough the claims are construed objectively and without reference to the accused device, only those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy." Vivid Technologies, Inv. v. American Science & Engineering, Inc., 200 F.3d 795, 803 (Fed.Cir.1999).

Anchen contends that because Biovail only alleges that "oil from the core" may be a plasticizer, the only dispute is whether oil from the *core* can satisfy the claim limitation requiring a plasticizer in the *coating*. (Anchen's Opening Claim Construction Brief, p. 16; emphasis provided; JEM Decl. Ex. C, at 4.)

As recited in claim 1 of the '341 patent, the plasticizer must be an ingredient in the coating material that is mixed and sprayed onto the tablet cores. (Ex. 1, '341 patent, claim 1.) The term "plasticizer" is an ingredient in the coating preparation, which has a dry weight that may be calculated as a certain percentage of the total dry weight of the coating ingredients dissolved or mixed to prepare the coating composition, which is then applied to the tablet cores. (Ex. 1, '341 patent, claim 1; Anchen's Opening Claim Construction Brief, p. 17.) Anchen therefore concludes that the term "plasticizer" should not be construed to extend to oil used in the core of the tablet as lubricant. (Anchen's Opening Claim Construction Brief, p. 17.)

Biovail, however, avers that "Anchen has stonewalled Biovail in discovery on this issue," and that discovery is likely to explain the function of the various excipients in Anchen's proposed formulation. (Response to Anchen's Opening Claim Construction Brief, p. 17.) For this reason the court finds that it is necessary to construe the term "plasticizer."

Anchen's proposed definition is taken from the *Chemical Dictionary* and treatises. (DJM Decl., Ex, X, The *Chemical Dictionary* 822 (10th ed.1981). As discussed above, reliance on extrinsic evidence is proper under *Phillips*. The *Chemical Dictionary* defines a plasticizer as:

[a]n organic compound added to a high polymer both to facilitate processing and to increase the flexibility and toughness of the final product by internal modification (solvation) of the polymer molecule. The later is held together by secondary valence bonds; the plasticizer replaces some of these with plasticizer-to-polymer bonds, thus added movement of the polymer chain segments.

(*Id*.)

Anchen additionally asserts that Biovail's proposed definition of plasticizer is based solely on the declaration of Williams. (Anchen's Responsive Claim Construction Brief, p. 6.) Further, Anchen asserts, and the Court agrees, that Williams admits that Biovail's proposed definition is incomplete. Anchen points out in response to the question, "is the softening temperature the only feature of composition that defines it as a plasticizer? " Williams responded, "there would be other attributes of a plasticizer with a polymer that one could also refer to plasticizers as." (DJM Decl., Ex. W, Williams Depo. at 92:1-11.) Williams further admitted that such things would be lowering the glass transition temperature of the polymer. (*Id*.)

Hence the Court finds that pursuant to *Phillips,* Anchen's proposed construction embodies the ordinary and customary meaning of the term "plasticizer."

D. " *DISSOLUTION PROFILE* "

Disputed Term	Biovail's Proposed Construction	Anchen's Proposed	The Court's Construction

		Construction	
Dissolution profile	A quality control assay conducted according to instructions found in the United States Pharmacopoeia.	No need to construe.	A quality control assay conducted according to instructions found in the United States Parmacopoeia.
	The ranges of bupropion hydrochloride released after one hour, four hours, six hours and eight hours as determined by a dissolution study conducted according to instructions found in the United States by Pharmacopoeia.		The ranges of bupropion hydrochloride released after one hour, four hours, six hours and eight hours as determined by a dissolution study conducted according to instructions found in the United States by Pharmacopoeia.

A dissolution test is a type of 'in vitro' (i.e., test tube test) quality control test commonly used in the pharmaceutical industry to characterize the performance of a drug product, specifically to measure drug release over time. (Williams Decl., para. 19.)

Biovail explains that in this context dissolution testing involves adding a quantity of a bupropion hydrochloride tablet, the drug product, to a water-based fluid or dissolution medium. (*Id.,* para. 19.) Further, after the bupropion hydrochloride is added to the fluid or dissolution medium, samples of the fluid are removed and tested at various times to determine how much of the bupropion hydrochloride is in the fluid. (*Id.*) A dissolution profile is obtained by determining the amount of bupropion hydrochloride that is released from the drug product at various times. (*Id.*)

Anchen asserts that the "dissolution profile" limitation of claims 1 and 30 is indefinite because it does not specify the conditions under which it should be measured. (Anchen's Opening Claim Construction Brief, p. 8.) Anchen avers that dissolution testing can be conducted by using a number of different testing apparatuses, under a number of different agitation conditions, and using a number of different dissolution media with different pH vales. (*Id.*) Anchen contends that "[c]hanges in the variable aspects of a dissolution method will often change the resulting dissolution profile measure for the same drug product." (*Id.*)

Anchen avers that Biovail is attempting to brief the invalidity issue in connection with the *Markman* hearing, and asks the Court to defer resolution of this dispute until after Anchen has conducted additional discovery. (*Id.*)

According to Biovail, the '341 patent does not specify any specific dissolution conditions because the dissolution conditions will depend on the particular performance characteristics of the bupropion hydrochloride product at issue. (Williams Decl., para. 20.) Biovail avers that a person of ordinary skill in the art would know that. Biovail explains that some drug formulations are designed to release in the stomach, and others are designed to release the active ingredient in the small intestine. (Id., para. 22-25.) Biovail contends that one skilled in the art would look to the USP to determine which parameters should be used in conducting a dissolution test. (Id., para. 22.)

The Court agrees with Biovail, and that the term "dissolution profile" is not indefinite. In addition, the Court finds that Biovail's reliance on the USP is proper and adopts Biovail's construction of the term "dissolution profile."

E. " *FREE OF PORE-FORMING AGENT* "

Disputed Term	Biovail's Proposed Construction	Anchen's Proposed Construction	The Court's Construction
Free of Pore-	"Free of pore-forming agent"	"Free of pore-forming agent" means the tablet does not	"Free of pore-forming agent" means the tablet does not contain a non-

Forming Agent	means lacking a particulate non-polymeric water soluble species capable of being eluted from a coating to form a pore therein.	contain a substance that dissolves or leaches out of a coating to create minute openings or interstices in the barrier membrane to enhance diffusion through the coating.	polymeric water-soluble substance that dissolves or leaches out of a coating to create minute openings or interstices in the barrier membrane to enhance diffusion through the coating.

The background of the invention states:

U.S. Pat. No. 4,687,660 (the "'660 patent") and EP-A 017457 (the "'457 patent") disclose a tablet formed of a core and a coating, where the core comprises bupropion hydrochloride together with excipients(a) and optionally as osmotic enhancing agent and where the coating compromises a water-insoluble, water-permeable film-forming polymer (such as cellulose acetate), a **pore-forming agent** (such as impalpable lactose and sodium carbonate), and optionally a so-called water-permeability enhancing agent (such as polyethyleneglycol) and again optionally a plasticizer.

(Ex. 1, Col. 1:28-36; emphasis provided)

The summary of the invention indicates that the '341 patent is "free of (monomoeric) pore-forming agent." (Ex. 1, Col.1:57-58.)

Biovail asserts two reasons for adopting its narrower construction which would exclude polymeric water soluble species from the claimed scope of pore-forming agents. First, it looks to the discussion of prior art. Second, it asserts that a construction which failed to exclude polymeric water soluble species would render each of the examples of preferred embodiment outside the scope of the patent. The Court does not find the first argument persuasive, but does find that second argument is persuasive and controlling, particularly in light of the discussion of prior art in the patent.

Prior Art.

Biovail contends that the term "pore-forming agent" is defined by reference to certain prior art references in existence at the time of the filing of the ' 341 patent, and that those definitions apply to this term. (Biovail's Preliminary Claim Construction, p. 18 .) Specifically, Biovail asserts that one skilled in the art would look to the '660 patent and the '457 application, in addition to the '341 patent specification, to comprehend the meaning of the term "pore-forming agent." (Id., p. 16.)

Biovail further contends that the '660 patent provides that a "pore-forming agent" is a particulate, non-polymeric, water soluble species. (JEM Decl., Ex. T, Ex. U.) In addition, Biovail asserts that the '457 application discloses a pharmaceutical composition comprising a formulation containing a water-soluble active ingredient, a semipermeable membrane surrounding the formulation, "and a particulate water-soluble pore-forming material dispersed within the membrane, whereby, in use in an aqueous environment, the pore forming material is dissolved forming pores in the semipermeable membrane ..." (Response to Anchen's Opening Claim Construction, Ex. E, p. 2, para. 2.)

Anchen points out that while Biovail relies on the '660 patent, the term in the '660 documents is "particulate, water-soluble, pore-forming material," and not a "pore-forming agent." (JEM Decl., Ex. T, '660 patent, Claim 1; Ex. U, '457 patent, Claim 1.) Anchen contends that while a "particulate, water-soluble, pore-fonning material" would be a pore-forming agent, the two terms are not co-extensive. (Anchen's Opening Claim Construction Brief, p. 19.) Anchen states that "[t]he use of the more precise phrase 'particulate, water-soluble, pore-forming materials,' in the prior art patents establishes that the unlimited term 'pore-forming

agent' in the '341 patent is not restricted to 'particulate non-polymeric species.' " (Id.) Anchen concludes that if the applicant of the '341 patent wanted to limit the disclaimer of the pore-forming species to a narrow class of particulate non-polymeric materials, the applicant could have done so by using Biovail's proposed definitions. (Id.)

Anchen further points out that Dr. Williams has admitted that the ' 341 patent does not state anywhere that it is incorporating by reference the definition of pore-forming agent in the '660 patent. (DJM Decl., Ex. W, 108:8-15.)

The state of knowledge generally at the time would not lead to the conclusion that polymers should be excluded. Anchen points out that Dr. Williams admitted that in 1998 a person of ordinary skill in the art would have known that water-soluble polymers could be used as pore-forming agents. (DJM Decl., Ex. W, 107:7-20.) Anchen explains that formulators often add a water-soluble component to the coating mixture to increase the permeability of the film, and therefore increase the release rate. (JEM Decl., Ex. F, Pharmaceutical Dosage Forms at 216-17.) Anchen shows that the use of water-soluble additives to create pores in water-insoluble polymeric coatings was a well-established method of increasing the rate of drug release through the coating. (Anchen's Opening Claim Construction Brief, p. 17; JEM Decl., Ex. F.)

At least standing alone, the discussion in the '457 and '660 patents does not support the limitation for which Biovail argues. The Court rejects the incorporation notion for same reason it rejected similar arguments in interpreting the term "free of stabilizer."

Exclusion of Preferred Embodiment.

Biovail argues that because povidone, a pore-forming agent, is included in each of the patent's preferred embodiments, none of the examples would be covered by Claim 30. (Response to Anchen's Opening Claim Construction, p. 15.) Anchen's own showing establishes that water-soluble polymers, including polyvinyl pyrrolidone ("povidone" or "PVP"), and polyethylene glycol ("PEG"), are known pore-forming agents. (JEM Decl., Ex. F, Pharmaceutical Dosage Forms at 216-17.)

Each of the 11 examples in the '341 patent includes the following ingredient in the coating: Kollidon 90F (povidone USP). As a general rule, a claim construction is unlikely to be correct if it excludes the preferred embodiments. Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1349 (Fed.Cir.2003), and cases cited by Biovail in its Post-Hearing Claim Construction Submission, pp. 2-3.)

Anchen, however, counters that '341 patent provides examples and claims coatings using ethylcellulose, PVP, and PEG. That not does erase the point that all 11 examples also include povidone.

To be sure, the case law will entertain constructions which exclude some preferred embodiments. For example, when the claims are narrowed during the prosecution process, the narrowing may remove a preferred embodiments from the scope of the claim in the patent as issued. North American Container, Inc. v. Plastipak, Inc., 415 F.3d 1335, 1346 (Fed.Cir.2005); Elekta Instrument S.A. v. O.U.R. Scientific International, Inc., 214 F.3d 1302, 1308 (Fed.Cir.2000). However, that is not this case.

In this context, it is difficult to believe that one skilled in art reading the patent would not give particular weight to the statement that the invention was "free of (monomeric) pore-forming agent[s]." (Ex. 1, col.1:58.) While the claim 30 might have been drafted with greater clarity, the Court cannot say that the totality of the patent did not put one skilled in the art on notice that a narrowed definition of pore-forming agent was being claimed.

Accordingly, the Court adopts a modified version Biovail's proposed construction.

IV. *CONCLUSION*

For the foregoing reasons, the Court construes the disputed terms as follows.

Disputed Term	The Court's Construction
Free of stabilizer (Claim 1)	"Free of stabilizer" means the core is free of any substance or agent that tends to prevent changes to the chemical integrity of the tablet.
Free of Stabilizer (Claim 30)	"Free of stabilizer" means the tablet is free of any substance or agent that tends to prevent changes to the chemical integrity of the tablet.
Plasticizer	A plasticizer is a substance added to the polymeric solution both to facilitate processing and to increase the flexibility and toughness of the final product by internal modification (solvation) of the polymer molecule.
	Among other things, a plasticizer is known to lower the glass transition temperature of a high polymer.
Dissolution profile	A quality control assay conducted according to instructions found in the United States Parmacopoeia.
	The ranges of bupropion hydrochloride released after one hour, four hours, six hours and eight hours as determined by a dissolution study conducted according to instructions found in the United States by Pharmacopoeia.
Free of Pore-Forming Agent	"Free of pore-forming agent" means the tablet does not contain a non-polymeric water-soluble substance that dissolves or leaches out of a coating to create minute openings or interstices in the barrier membrane to enhance diffusion through the coating.

FN1. Of course, if the dispute takes on a broader scope than chemical stability, the Court would revisit the construction.

FN1. At oral argument, the parties agreed that the present dispute does relate to physical integrity or protection from microbial contamination. (Transcript, Dec. 12, 2005, p. 48.) Accordingly, the construction adopted by the Court deals only with chemical stability.

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