United States District Court,
S.D. Florida, Miami Division.

BIOVAIL LABORATORIES INTERNATIONAL SRL, a corporation of Barbados,
Plaintiff.
v.
ABRIKA, LLLP, a limited partnership; Abrika Pharmaceuticals, Inc., a corporation of Florida; and Abrika Pharmaceuticals, LLLP,
Defendants.

No. 04-61704-CIV

Aug. 24, 2006.

Dennis J. Mondolino, Jason A. Lief, McDermott Will & Emery, New York, NY, Nancy J. Flint, Samuel Alberto Danon, Hunton & Williams, Miami, FL, Thomas G. Slater, Jr., Hunton & Williams, Richmond, VA, for Plaintiff.

Amy S. Manning, Brook A. Clark, Philippe Bennett, Robert E. Hanlon, Thomas Parker, Alston & Bird, Cary S. Kappel, Clifford Marc Davidson, Davidson Davidson & Kappel, New York, NY, Scott Allan Cole, Thomas E. Scott, Jr., Cole Scott & Kissane, Miami, FL, for Defendants.

ORDER ON CLAIM CONSTRUCTION

CECILIA M. ALTONAGA**, District Judge.**

THIS CAUSE came before the Court for claim construction. The Court has carefully considered extensive briefing by the parties, pertinent portions of the record and authorities, and heard argument and received evidence at a *Markman* FN1 hearing held on March 29-30 and April 27, 2006.

FN1. Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed.Cir.1995) (*en banc*), *aff'd,* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996).

PROCEDURAL BACKGROUND

Plaintiff, Biovail Laboratories International SRL ("Biovail"), holds U.S. Patent Numbers 6,096,341 ("the '341 patent") FN2 and 6,143,327 ("the ' 327 patent") FN3 which claim controlled-release tablets containing the active ingredient bupropion hydrochloride, an anti-depressant drug sold under the tradename Wellbutrin XL(R).FN4 The '341 and the ' 327 patents were issued on August 1, 2000 and November 7, 2000, respectively, and expire on October 30, 2018.

FN2. The '341 Patent is entitled "Delayed Release Tablet of Bupropion Hydrochloride."

FN3. The '327 Patent is entitled "Delayed Release Coated Tablet of Bupropion Hydrochloride."

FN4. Both patents list Pawan Seth of Irvine, California, as Inventor and Pharma Pass, LLC of Irvine, California, as Assignee. Biovail is the owner by assignment of each of patent.

On September 23 and October 1, 2004, Defendant, Abrika Pharmaceuticals, LLLP (together with related Defendants Abrika LLLP and Abrika Pharmaceuticals, Inc., collectively "Abrika"),FN5 submitted abbreviated new drug application ("ANDA") No. 77-285 to the United States Food and Drug Administration (the "FDA") seeking approval to market 150 and 300 mg generic versions of Wellbutrin XL(R) to the public. Pursuant to 21 U.S.C. s. 355(j)(2)(A)(vii) (IV) (the "Paragraph IV certification"), Abrika certified to the FDA, and notified Biovail, that the manufacture, use, or sale of its proposed generic formulation would not infringe the '341 and ' 327 patents. In particular, Abrika based its certification of non-infringement on its position that the generic formulation described in its ANDA did not meet the specific dissolution profiles required by all of the claims in the '341 and ' 327 patents as measured under 0.1N HC1, USP 1 @ 75 RPM test conditions ("the 0.1N HC1 test conditions").FN6

FN5. On July 6, 2006, Abrika informed the Court that "Abrika Pharmaceuticals, Inc., a corporation of Florida, was an inactive corporation that has been dissolved. Effective as of April 1, 2006, all of the assets and liabilities of Abrika, LLP were transferred to Abrika Pharmaceuticals, Inc., a Delaware corporation." [D.E. 409].

FN6. Dissolution testing is a type of testing commonly performed in the pharmaceutical industry to measure drug release. The 0.1N HC1 dissolution test simulates the acidic environment of the human stomach ("gastric fluid") and measures the dissolution of substances in that environment.

On December 21, 2004, Biovail Laboratories, Inc. and SmithKline Beecham Corp. FN7 filed the present action alleging that Abrika's paragraph IV certifications constituted infringement of the '341 and ' 327 patents FN8 under the Hatch-Waxman Act, 35 U.S.C. s. 271(e)(2). Section 271(e)(2) provides in pertinent part that "[i]t shall be an act of infringement to submit ... an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent ... if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug ... claimed in a patent or the use of which is claimed in a patent before the expiration of such patent." *See, e.g.,* Teva Pharms. USA, Inc. v. Pfizer, Inc., 395 F.3d 1324, 1328 (Fed.Cir.2005) (Under the Hatch-Waxman Act "a generic drug manufacturer infringes a patent by filing an ANDA to obtain approval for a generic drug product claimed by a valid and unexpired patent"); Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1569 (Fed.Cir.1997) (the statute "provide[s] patentees with a defined act of infringement sufficient to create case or controversy jurisdiction to enable a court to promptly resolve any dispute concerning infringement and validity."). Biovail's suit for infringement has suspended the FDA's consideration and approval of Abrika's ANDA. *See* 21 U.S.C. s. 355(j)(5)(B)(iii).

FN7. Neither of the two original Plaintiffs, Biovail Laboratories, Inc. and SmithKline Beecham Corp., remain parties to this action. The Court dismissed SmithKline Beecham Corp. as a plaintiff by Order dated April 20, 2005 [D.E. 87], and granted Plaintiff's Motion to File Second Amended Complaint, which substituted Biovail Laboratories, Inc. for its successor-in-interest, Biovail Laboratories International SRL [D.E. 151], on June 24, 2005.

FN8. On Biovail's Motion, the Court dismissed Count II of Biovail's Second Amended Complaint ("SAC"), entitled "Abrika's Act of Infringement of the '327 Patent under 35 U.S.C. s. 271(e)(2)," and Counts II and IV of Abrika's Amended Counterclaim, entitled "Noninfringement of U.S. Patent No. 6,143,327" and "Declaratory Judgment of Invalidity and Unenforceability of U.S. Patent No. 6,143,327," respectively. [D.E. 272]. The parties dispute the effect of that Order on the scope of the present claim construction. Biovail contends that claim construction of the '327 patent is inappropriate because all claims alleging infringement of the ' 327 patent have been removed from this action. Abrika correctly maintains, however, that its pending counterclaims alleging antitrust violations and unfair competition require a determination of the validity of the '327 patent. Although there is no longer an infringement allegation with respect to the '327 patent, Abrika's remaining counterclaims place the validity of the patent at issue. [*See* March 16, 2006 Order [D.E. 318] at 3]. Because validity of the '327 patent remains at issue, the undersigned agrees that it is appropriate to construe the claims of the '327 patent. *See* SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp., 225 F.3d 1349, 1355 (Fed.Cir.2000) ("The first step in any invalidity analysis is claim construction ...."); Akamai Techs., Inc. v. Cable & Wireless Internet Servs., Inc., 344 F.3d 1186, 1192 (Fed.Cir.2003); Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456 (Fed.Cir.1998) (*en banc*).

Moreover, because the '327 patent is a continuation-in-part of the '341 patent, the '327 patent is a relevant part of the '341 patent prosecution history. *See* Microsoft Corp. v. Multi-Tech Systems, Inc., 357 F.3d 1340, 1349 (Fed.Cir.2004); Datamize, LLC v. Plumtree Software, Inc., 417 F.3d 1342 (Fed.Cir.2005). Biovail does not dispute that the "same term or phrase should be interpreted consistently where it appears in claims of common ancestry." Epcon Gas Systems, Inc. v. Bauer Compressors, Inc., 279 F.3d 1022, 1030 (Fed.Cir.2002) (citing Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 980 (Fed.Cir.1999)); Abtox, Inc. v. Exitron Corp., 131 F.3d 1009, 1010 (Fed.Cir.1997); Fonar Corp. v. Johnson & Johnson, 821 F.2d 627, 632 (Fed.Cir.1987)). Accordingly, the identical disputed claim terms which apply to both the '341 and '327 patents are construed consistently.

ANALYSIS

A. Claim Construction Standard

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc., 381 F.3d 1111, 1115 (Fed.Cir.2004). The Supreme Court has explained that it is "unjust to the public, as well as an evasion of the law, to construe ... [an invention] in a manner different from the plain import of its terms." White v. Dunbar, 119 U.S. 47, 52, 7 S.Ct. 72, 30 L.Ed. 303 (1886). Therefore, because the public is entitled to rely on claim terms to ascertain the scope of patented inventions, "[c]ourts construe claim terms in order to assign a fixed, unambiguous, legally operative meaning to the claim." Chimie v. PPG Indus., Inc., 402 F.3d 1371, 1377 (Fed.Cir.2005).

Furthermore, "[i]t is well-settled that, in interpreting an asserted claim, the court should look first to the intrinsic evidence of record, i.e., the patent itself, including the claims, the specification and, if in evidence, the prosecution history." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996). The

Federal Circuit has repeatedly emphasized that "intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language." *Id.;* Bell Atlantic Network Servs. Inc. v. Covad Communications Group, Inc., 262 F.3d 1258, 1267 (Fed.Cir.2001); Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1325 (Fed.Cir.2002).

The examination of intrinsic evidence begins with the words of the claims themselves. The words of a claim "are generally given their ordinary and customary meaning." Vitronics Corp., 90 F.3d at 1582. The ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention. *See* Innova/Pure Water, Inc., 381 F.3d at 1116; Verve, LLC v. Crane Cams, Inc., 311 F.3d 1116, 1119 (Fed.Cir.2002) ("Patent documents are written for persons familiar with the relevant field; the patentee is not required to include in the specification information readily understood by practitioners, lest every patent be required to be written as a comprehensive tutorial and treatise for the generalist, instead of a concise statement for persons in the field.").

The presumption that words have their ordinary meanings when used in a patent claim is rebutted, however, where the patentee, acting as his own or her own "lexicographer," has clearly set forth a definition of a claim term that is different from the term's ordinary and customary meaning. Vitronics Corp., 90 F.3d at 1582 ("Although words in a claim are generally to be given their ordinary and customary meaning, a patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history.") (citing Hoechst Celanese Corp. v. BP Chemicals, Ltd., 78 F.3d 1575, 1578 (Fed.Cir.1996) ("A technical term used in a patent document is interpreted as having the meaning that it would be given by persons experienced in the field of invention, unless it is apparent from the patent and the prosecution history that the inventor used the term with a different meaning.")).

The presumption is also rebutted if the inventor has disavowed or disclaimed a scope of coverage by using words or "expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." Teleflex, 299 F.3d at 1324, 1325 ("The patentee may demonstrate an intent to deviate from the ordinary and accustomed meaning of a claim term by including in the specification expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope."). Finally, where the term or terms chosen by the patentee so deprive the claim of clarity that there is " 'no means by which the scope of the claim may be ascertained from the language used,' " the presumption is rebutted. Bell Atlantic Network Servs. Inc., 262 F.3d at 1268 (quoting Johnson v. Worldwide Assoc. Inc. v. Zebco Corp., 175 F.3d 985, 990 (Fed.Cir.1999)).

After the court has determined the ordinary and customary meanings of the terms at issue, it may then look to the rest of the intrinsic evidence, including the patent specification and file history. Teleflex, Inc., 299 F.3d at 1324-26. The Federal Circuit has explained that, in examining the file history, the court may examine the prior art cited therein:

In addition, a court in its discretion may admit and rely on prior art proffered by one of the parties, whether or not cited in the specification or the file history. This prior art can often help to demonstrate how a disputed term is used by those skilled in the art. Such art may make it unnecessary to rely on expert testimony and may save much trial time. As compared to expert testimony, which often only indicates what a particular expert believes a term means, prior art references may also be more indicative of what all those skilled in the art generally believe a certain term means. Once again, however, reliance on such evidence is unnecessary, and indeed improper, when the disputed terms can be understood from a careful reading of the

public record.

Vitronics, 90 F.3d at 1584.

Among the intrinsic evidence, "the specification is always highly relevant to the claim construction analysis." Vitronics, 90 F.3d at 1582; *see also* Markman, 52 F.3d at 979 ("Claims must be read in view of the specification, of which they are a part."). In fact, the specification is "usually ... dispositive ... [and] the single best guide to the meaning of a disputed term." Vitronics, 90 F.3d at 1582. For example, the specification may "reveal a special definition given to a claim term" or "an intentional disclaimer, or disavowal of claim scope by the inventor." Phillips v. AWH Corp., 415 F.3d 1303, 1316 (Fed.Cir.2005) (*en banc*). In those case, the federal Circuit has instructed that "the inventor's invention, as expressed in the specification, is regarded as dispositive." *Id*. (citing SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1343-44 (Fed.Cir.2001).

In addition, the *Phillips* court recognized that "the rules of the [United States Patent and Trademark Office] PTO require that application claims must 'conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description.' " Phillips, 415 F.3d at 1316-17 (quoting 37 C.F.R. s. 1.75(d)(1)). Thus, it is "entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims." Phillips, 415 F.3d at 1317.

Finally, intrinsic evidence includes the patent's prosecution history. *Id.;* Markman, 52 F.3d at 980. Statements made by the applicant during the patent prosecution "regarding the meaning of a claim term are relevant to the interpretation of that term in every claim of the patent absent a clear indication to the contrary." CVI/Beta Ventures v. Tura LP, 112 F.3d 1146, 1155 (Fed.Cir.1997); Southwall Technologies, Inc. v. Cardinal IG Co., 54 F.3d 1570, 1578 (Fed.Cir.1995); *see also* Laitram Corp. v. Morehouse Industries, Inc., 143 F.3d 1456, 1452 (Fed.Cir.1998) (arguments made by the applicant during prosecution, whether or not actually relied upon by the PTO examiner, are relevant to the construction of claim terms). "The purpose of consulting the prosecution history in construing a claim is to 'exclude any interpretation that was disclaimed during prosecution.' " Chimie, 402 F.3d at 1384 (quoting ZMI Corp. v. Cardiac Resuscitator Corp., 844 F.2d 1576, 1580 (Fed.Cir.1988)).

Usually, "intrinsic evidence alone will resolve any ambiguity in a disputed claim term. In such circumstances, it is improper to rely on extrinsic evidence." Vitronics, 90 F.3d at 1583 (citations omitted). The Federal Circuit has consistently emphasized that extrinsic evidence may not be used in claim construction to vary the meaning of claim terms as reflected in the intrinsic public record. *Id*. In particular, "[e]xpert testimony ... may not [be used to] ... diverge from the description of the invention as contained in the patent documents." Aqua-Aerobic Sys., Inc. v. Aerators, Inc., 211 F.3d 1241, 1245 (Fed.Cir.2000). Although the court may rely on the evidence from experts "to educate itself about the patent and the relevant technology, the claims and the written description remain the primary and more authoritative sources of claim construction." Mantech Envtl. Corp. v. Hudson Envtl. Servs., Inc., 152 F.3d 1368, 1373 (Fed.Cir.1998).

The limited utility of extrinsic evidence was recently reemphasized when the Federal Circuit, sitting *en banc,* repudiated the methodology employed in some of its own cases, exemplified by Texas Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193 (Fed.Cir.2002), for placing "too much reliance on extrinsic sources

such as dictionaries, treatises, and encyclopedias and too little on intrinsic sources, in particular the specification and prosecution history." FN9 Phillips, 415 F.3d at 1320. The *Phillips* court cautioned that the court's reliance on extrinsic authorities "will systematically cause the construction of the claim to be unduly expansive." *Id*. at 1321. The more prudent course "focuses at the outset on how the patentee used the claim term in the claims, specification, and prosecution history, rather than starting with a broad definition and whittling it down." *Id*. Guided by these principles, the Court endeavors to construe the disputed claim terms.

FN9. Although the *Phillips* court's discussion of the *Texas Digital Sys., Inc*. methodology directly focused on the inappropriate reliance on dictionaries, the *Phillips* court also reiterated its consistent holding that any extrinsic evidence, including expert testimony, is less reliable than the intrinsic record in claim construction. *See, e.g.,* Phillips, 415 F.3d at 1318 ("conclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court. Similarly, a court should discount any expert testimony 'that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent.' ") (quoting Key Pharms. v. Hercon Labs. Corp., 161 F.3d 709, 716 (Fed.Cir.1998)).

B. Disputed Claim TermsFN10

FN10. Prior to the *Markman* hearing, the parties filed a Joint Stipulation with respect to the construction of four claim terms. Consistent with that Stipulation, the Court construes the following four undisputed claim terms as follows: 1) "lubricant:" A chemical compound that is added to a solid drug formulation, *i.e.*, tablet, that reduces friction with the die wall; 2) "binder:" A chemical compound in a solid drug formulation, *i.e.*, tablet, that acts as an adhesive agent and ensures that the tablet is formed with the required mechanical strength; 3) "plasticizer:" a chemical compound that decreases the softening temperature of the film-forming polymer(s) to which it is added and modifies the properties of the polymer(s) to make it (them) more flexible (*e.g.*, decreasing brittleness); "where the proportion of 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:" this claim term excludes the end points of the claimed ranges.

The parties dispute the proper construction of six terms in claims 1 and 30 of the '341 patent. The relevant claims, with the disputed claim terms highlighted, are as follows:

A delayed release tablet comprising:

(i) a core comprising bupropion hydrochloride and conventional excipients, **free of stabilizer;** and

(ii) a coating **consisting essentially of**FN11 a **water-insoluble, water-permeable film-forming polymer,** a plasticizer and a **water-soluble polymer,** where the proportion of **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**FN12 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.

FN11. Biovail disputes the need to construe this term.

FN12. The parties disagree as to whether "dissolution profile" or "exhibiting a dissolution profile" should be construed.

'341 patent, col. 9, ll. 49-67 (Claim 1) (emphasis added).

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., at col. 12, ll. 3-11 (Claim 30) (emphasis added).

At the outset, the undersigned acknowledges that two other federal district courts have had occasion to construe some of the same claim terms contested by the parties here. *See* Biovail Labs. Intern. SRL v. Impax Labs., Inc., 433 F.Supp.2d 501 (E.D.Pa.2006) (the " *Impax* court") (construing, *inter alia,* "dissolution profile," "free of stabilizer," and "free of pore forming agent"); *Biovail Labs. Inc. v. Anchen Pharm. Inc.,* No. SACV 04-1468 (C.D.Cal. Feb. 8, 2006) (the "*Anchen* court") (construing, *inter alia,* "dissolution profile," "free of stabilizer," and "free of pore forming agent"). While the Court is not required to defer to constructions of the '341 patent adopted by other district courts, *see, e.g.,* Texas Instruments, Inc. v. Linear Technologies Corp., 182 F.Supp.2d 580, 586 (E.D.Tex.2002), persuasive deference is given to these reasoned judgments. *See* V-Formation, Inc. v. Benetton Group SpA, 401 F.3d 1307, 1312 (Fed.Cir.2005) ("The district court properly referred to a related, non-binding judicial opinion to support its independent conclusion in this case.").

1. ***The "Dissolution Profile" Claim Limitation***

The parties devote the majority of their briefing and argument to the construction of the patents' dissolution profile limitation. The '341 and ' 327 patents each recite that the "tablets of the invention exhibit specific dissolution profiles." '341 patent, col. 1, ll. 58-59; '327 patent, col. 2, ll. 5-6. The claim language in which the dissolution profile limitation appears recites a set of numerical ranges that demonstrate the release of bupropion hydrochloride at various time intervals during a dissolution test. The claim language, however, does not reference the test conditions used to obtain the recited profile.

The parties are in agreement that dissolution profiles vary depending on the dissolution medium and test selected. [3/29 Hr'g. Tr. 90:24-91:10 (Williams); 3/29 Hr'g. Tr. 144:3-22 (Sinko)].FN13 Therefore, knowing the test condition applied to the claims of the patent is essential to determining whether or not one is practicing the claimed invention. Accordingly, Abrika maintains that when a claim term recites a characteristic or value that varies substantially based on the methodology used to obtain it, and the methodology is not in the claim, the claim term is interpreted to incorporate the specific methodology under which it was obtained. Employing this rule, Abrika concludes that the "dissolution profile" limitation is properly construed to incorporate the only test conditions disclosed in the patent specification, that is, the

0.1N HC1 test conditions. Abrika proffers the following construction of "exhibiting a dissolution profile:" exhibiting the recited percentage of bupropion HC1 released over time as determined under 1000 ml 0.1 N HC1, 75 rpm, USP Apparatus 1.FN14

FN13. Biovail presented expert testimony from Robert O. Williams III, Ph.D. ("Williams"), Professor of Pharmaceutics at the College of Pharmacy, University of Texas at Austin. Abrika presented expert testimony from Patrick J. Sinko, Ph.D. ("Sinko"), Chair of the Department of Pharmaceutics and Parke-Davis Professor of Pharmaceutics and Drug Delivery at the Ernest Mario School of Pharmacy, Rutgers University.

FN14. In the alternative, Abrika argues that if the dissolution profile claim limitation were not limited to the 0.1N HC1 test identified in the specification, the claims of the '341 and '327 patents would be invalid as indefinite. *See* 35 U.S.C. s. 112, para. 2 ("The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention"); Honeywell Int'l. Corp. v. Int'l. Trade Comm'n, 341 F.3d 1332, 1340 (Fed.Cir.2003) (holding that the asserted patent was invalid because "the claims, the written description, and the prosecution history fail to give us, as the interpreter of the claim term, any guidance as to what one of ordinary skill in the art would interpret the claim to require.").

In support of its construction, Abrika explains that the Federal Circuit has consistently held that a claim reciting a highly variable test result incorporates the methodology under which the result was obtained. *See* Chimie, 402 F.3d at 1377; J.T. Eaton & Co. v. Atlantic Paste & Glue Co., 106 F.3d 1563 (Fed.Cir.1997); Genentech, Inc. v. Wellcome Found., 29 F.3d 1555, 1563 (Fed.Cir.1994). In *Chimie,* for example, the court held that the claim limitation "dust-free and non-dusting" was properly construed as measured under the DIN 53 583 standard, the only standard referenced in the two examples contained in the specification that constituted a product of the issued claims. 402 F.3d at 1378. The *Chimie* court held that even though

the pour test and the stabilized fluid bed test may provide alternative means for assessing dust production, it remains that the only articulation of the dustiness of the claimed invention is made with reference to the DIN 53 583 standard.... [The Inventor] chose to define the [claim] term 'dust-free and non-dusting' solely by reference to characteristics of the prior art and the only comparison of those characteristics was explained according to the DIN 53 583 standard. It was not improper for the district court to limit the scope of this relative term to the only disclosure on the subject made in the patent.

Id. at 1379-80. Abrika argues that the DIN test referenced in *Chimie* is analogous to the 0.1N HC1 test. Because the patentee here chose to define the "dissolution profile" claim limitation solely by reference to the 0.1N HC1 test in the '341 and '327 patent specifications, the Court should construe the scope of that claim limitation to incorporate that test.

Biovail maintains that Abrika's construction impermissibly imports limitations from the specification into the claims, one of the "cardinal sins" of claim construction. Phillips, 415 F.3d at 1320. *See also* Callicrate v. Wadsworth Mfg., Inc., 427 F.3d 1361, 1367-68 (Fed.Cir.2005) ("The claim itself ... does not include the specific language limiting the pivotally mounted "lever" to a particular embodiment."); *N*. Am. Container, Inc. v. Plastipak Packaging, Inc., 415 F.3d 1335, 1348 (Fed.Cir.2005) ("The [district] court erroneously imported the specification's recommended dimensions for a commercial embodiment of the bottle shown in

figure 12 into the claims.... While we appreciate the court's effort to distinguish the present invention from the prior art ... it was improper for the court to make that distinction by importing the preferred embodiment's physical dimensions into the claims."). Instead, Biovail argues for a broader construction of the dissolution profile limitation-one that is not limited to any particular dissolution test condition.

Both parties agree that one skilled in the art would generally look to the United States Pharmacopoeia ("USP") FN15 to determine the parameters to be used in conducting a dissolution test. [3/29 Hr'g. Tr. 65:11-74:6 (Williams); 3/30 Hr'g. Tr. 22:2-25:10 (Sinko)]. Accordingly, Biovail posits that one skilled in the art would understand the "dissolution profile" limitation of the claims to require different dissolution mediums, dependent upon the specific performance characteristics of the bupropion hydrochloride product at issue, in accordance with the USP. Because Abrika's ANDA product contains an enteric coaling designed to prevent dissolution in a gastric fluid environment (simulated by the 0.1N HC1 dissolution test), Biovail contends that the test referenced in the preferred embodiment of the patent is inapplicable. Furthermore, Biovail argues that enteric coated formulations are encompassed by the claimed dissolution profile, and that a person of ordinary skill in the art would employ a "pH-switch test" to evaluate the dissolution profile of an enteric coated formulation. Biovail thus proposes the following definition for "dissolution profile:" "A quality control assay conducted according to instructions found in the United States Pharmacopoeia." FN16

FN15. "Congress recognizes the United States Pharmacopoeia ("USP"), a nonprofit corporation which develops drug product standards with the help of professionals from academia, the medical community, the pharmaceutical industry and the FDA, as an official compendium." United States v. Barr Laboratories, Inc., 812 F.Supp. 458, 465 (D.N.J.1993). Both parties agree that the USP is a compendium that describes industry standard methods for the dissolution testing of pharmaceutical products. [3/29 Hr'g. Tr. 65:11-17 (Williams); 3/30 Hr'g. Tr. 22:6-9 (Sinko)].

FN16. The Court rejects Biovail's suggestion that the construction of "dissolution profile" should be limited to "a quality control assay." As Biovail's expert testified, the 0.1N HC1 test was employed in the '341 patent specification as "either as a product characterization test or as a quality control test." [*See* Williams Dep. at 137:15-16].

Construction of the "dissolution profile" claim limitation requires the Court to walk the "fine line between reading a claim in light of the specification, and reading a limitation into the claim from the specification." Phillips, 415 F.3d at 1323 (quoting Comark Communications, Inc. v. Harris Corp., 156 F.3d 1182, 1186-87 (Fed.Cir.1998)); Impax, 433 F.Supp.2d at 516 ("there is a difference between reading a limitation from the specification into the claims, which is improper, and reading the claims 'in view of the specification, of which they are a part,' Markman, 52 F.3d at 979, which is not only proper but required."). Experience dictates that determining whether a given claim construction falls on one side of this line or the other is difficult in practice. *See* Phillips, 415 F.3d at 1323.

On the one hand, the Federal Circuit has stated and reiterated that "[t]he descriptive part of the specification aids in ascertaining the scope and meaning of the claims inasmuch as the words of the claims must be based on the description. The specification is, thus, the primary basis for construing the claims." Standard Oil Co. v. Am. Cyanamid Co., 774 F.2d 448, 452 (Fed.Cir.1985). On the other hand,"[i]t is established that 'as a general rule claims of a patent are not limited to the preferred embodiment ... or to the examples listed within the patent specification.' " Glaxo Wellcome, Inc. v. Andrx Pharms., Inc., 344 F.3d 1226, 1233

(Fed.Cir.2003) (quoting Dow Chem. Co. v. United States, 226 F.3d 1334, 1342 (Fed.Cir.2000)).

The *Phillips* court provided needed direction to district courts seeking to construe claims in harmony with these two lines of precedent. To properly construe claims in the context of the specification while avoiding the importation of limitations from the specification into the claims,

it is important to keep in mind that the purposes of the specification are to teach and enable those of skill in the art to make and use the invention and to provide a best mode for doing so. *See* Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1533 (Fed.Cir.1987). One of the best ways to teach a person of ordinary skill in the art how to make and use the invention is to provide an example of how to practice the invention in a particular case. Much of the time, upon reading the specification in that context, it will become clear whether the patentee is setting out specific examples of the invention to accomplish those goals, or whether the patentee instead intends for the claims and the embodiments in the specification to be strictly coextensive. *See* SciMed Life Sys., 242 F.3d at 1341.

Phillips, 415 F.3d at 1323.FN17 After considering the parties' extensive briefing and thorough arguments, the undersigned is persuaded that Abrika's construction falls on the right side of the "fine line" while Biovail's construction of this limitation is unacceptable.FN18

FN17. *See also,* SciMed Life Sys., Inc., 242 F.3d at 1344 (holding that "[w]here the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question.").

FN18. Both the *Impax* and *Anchen* courts adopted a USP-based construction of the dissolution profile limitation similar to the one urged here by Biovail. See Impax, 433 F.Supp.2d at 522 ("I adopt Biovail's proposed construction of 'dissolution profile,' a nearly identical version of which was approved by the *Anchen* court: 'A quality control assay conducted according to guidance and instructions found in the United States Pharmacopoeia, i.e., 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 guidance and instructions found in the United States Pharmacopoeia.' "). Neither of these courts, however, considered the arguments raised by Abrika in this litigation. In fact, neither *Impax* nor *Anchen* proposed an alternative construction of the limitation. *See* Texas Instruments, Inc., 182 F.Supp.2d 580, 589 ("Where defendants have new arguments to bring to the attention of the court, defendants' rights to fully litigate their claims are particularly persuasive.") (citing KX Indus., L.P. v. PUR Water Purification Prods., Inc., 108 F.Supp.2d 380, 387 (D.Del.2000) ("to the extent parties do not raise new arguments, the court will defer to its previous construction of the claims")).

The Court begins its construction of this disputed term with an examination of the patent specification. The specification of the '341 patent teaches two dissolution profiles.FN19 The first dissolution profile provides "that after 1 hour, from 30 to 60% of the bupropion hydrochloride is released, after 2 hours, from 55 to 80% of the bupropion hydrochloride is released, after 3 hours, from 75 to 95% of the bupropion hydrochloride is released, after 4 hours, from 80 to 100% of the bupropion hydrochloride is released." The second dissolution profile provides that "after 1 hour, from 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." The specification describes eleven examples that illustrate the invention. Of these, examples 1-6 and 8 correspond to the first dissolution profile and examples 7 and 9-11 correspond to the second dissolution profile.

FN19. The inventor filed two identical patent specifications with the USPTO on October 30, 1998. The first dissolution profile taught in the specification was claimed in the application that ultimately issued as U.S. Patent No. 6,033,686 ("'686 patent"). The second dissolution profile taught was claimed in the '341 patent. While the two patents share the same specification, it is clear that the inventor did not intend the dissolution profiles claimed in the patents to overlap. In an Office Action dated April 28, 1999, thepatent examiner rejected the '341 patent application on the ground that the subject matter claimed in that application was an obvious variation of the subject matter claimed in the co-pending '686 patent application. In response dated August 11, 1999, the inventor replied that the claims of the '341 patent application "deal [t] with a bupropion tablet having a *delayed* release profile," while the claims of the '686 patent application "deal[t] with a bupropion tablet having a *controlled* release profile." ['341 Prosecution History, August 11, 1999 Amendment, p. 4]. Hence, the inventor argued that the applications contained "two distinct release profiles," [Id.], and that the "dissolution rates are not essentially the same...." [Id. at 5].

Example 1 teaches that the first dissolution profile claimed in the invention was obtained under the 0.1N HC1 test conditions. '341 patent, col. 5, ll. 12-13 ("Medium: 1000 ml 0.1N HC1. Method: 75 rpm USP Apparatus I"). Examples 2-11 state that both the dissolution profiles expressed are "identical," "similar" or "correspond[ ] substantially" to the profile disclosed in Example 1. *See* Id., at col. 5, ll. 30-31 (example 2) ("The dissolution profile is identical to the one disclosed in example 1"); Id., at col. 5, ll. 62-63 (example 3) ("The dissolution profile is similar to the one disclosed in example 1"); Id., at col. 6, ll. 28-29 (example 4) ("The dissolution profile is similar to the one disclosed in example 1"); Id., at col. 7, ll. 13-16 (example 5) ("The dissolution profile is the result of the combination of two profiles, where the first one is an immediate release profile and the second one corresponds substantially to the one disclosed in example 1"); Id., at col. 7, ll. 62-63 (example 6) ("The dissolution profile is similar to the one disclosed in example 1"); Id., at col. 8, ll. 14 (example 7) ("Dissolution conditions: identical to example 1"); Id., at col. 8, ll. 45-46 (examples 8 and 9) ("The dissolution profiles are similar to the ones disclosed in examples 1 and 7, respectively"); Id., at col. 9, ll. 25-26 (example 10) ("The dissolution profile is similar to the one disclosed in example 1"); Id., at col. 9, ll. 43-44 (example 11) ("The dissolution profile is similar to the one disclosed in example 7"). Thus, although the specification teaches two different dissolution profiles (associated with two different patents' claims), the specification consistently discloses a single set of dissolution test conditions.

The '327 patent recites that the inventive tablet includes a "second coating compris[ing] an enteric polymer," '327 patent, col. 3, l. 54, which "is aimed at protecting the component from coming into contact with the gastric juice and to avoid the food effect." Id., at col. 3, ll. 50-52. This "enteric polymer, notably of the methacrylic type can be for example methacrylic acid co-polymer type C, and is available under the tradename Eudragit (e.g. of the grade L30D-55)." Id., at col. 3, ll. 56-59. The dissolution profile provisions of the first eleven examples disclosed in the ' 327 patent specifications mirror the examples of the '341 patent. In addition, the '327 patent specification includes a twelfth example related specifically to the enteric coated tablet disclosed in the patent. Importantly, this example reiterates that the claimed dissolution profile was determined under the 0.1N HC1 test conditions, Id., at col. 11, ll. 58-60 ("Dissolution conditions are the same as above, i.e. simulated gastric buffer with pH 1.5 at 37 (deg.)C"), even though the formulation at issue contained an enteric coating.

Despite the fact that "[t]here is nothing in the context [of the specification] to indicate that the patentee contemplated any alternative" to the 0.1 N HC1 test conditions, Snow v. Lake Shore & Mich. S. Ry. Co., 121 U.S. 617, 629-30, 7 S.Ct. 1343, 30 L.Ed. 1004 (1887), Biovail mounts a valiant, though ultimately unsuccessful, effort to persuade that the USP should be considered intrinsic evidence with respect to the dissolution profile limitation. In support of its construction, Biovail notes that the USP is explicitly cited as a source of testing conditions in the '341 patent.

Specifically, the '341 patent specification contains three references to the USP. *See* '341 patent, col. 3, ll. 28-31 ("Stability studies were conducted in oven, under the storage test conditions described in the U.S. pharmacopoeia 23rd edition page 1961"); *Id.,* at col. 4, ll. 65-67 ("Storage conditions: conforms to USP 23 guideline (25 (deg.) C. and 60% relative humidity and 40 (deg.) C. and 75% relative humidity"); *Id.,* at col. 5, ll. 11-13 ("Dissolution conditions: Medium: 1000 ml 0.1N HC1. Method: 75 rpm USP Apparatus I"). These specific citations to the USP, however, do not direct the public to the USP generally to craft dissolution tests at variance with the 0.1N HC1 test disclosed in the specification. The first two references are explicitly directed to storage conditions, not to dissolution testing. The only USP reference applicable to dissolution testing conditions relates to the designation of a specific piece of equipment, the USP Apparatus I, not to dissolution test conditions generally.

Biovail also avers that U.S. Pat. No. 5,427,798 (the "'798 patent") and U.S. Pat. No. 5,681,584 (the "'584 patent"), cited on the face of the '341 patent, constitute prior art and can be considered intrinsic evidence to construe the dissolution profile limitation. *See, e.g., V-* Formation, Inc., 401 F.3d at 1311 ("[t]his court has established that 'prior art cited in a patent or cited in the prosecution history of the patent constitutes intrinsic evidence.' ") (quoting Kumar v. Ovonic Battery Co., Inc., 351 F.3d 1364, 1368 (Fed.Cir.2003)). Biovail places particular reliance on *Kumar* for the proposition that it is appropriate to interpret the '341 patent's dissolution profile limitation in light of that term's usage in prior art cited in the patent. Kumar, 351 F.3d at 1368 (" '[W]hen prior art that sheds light on the meaning of a term is cited by the patentee, it can have particular value as a guide to the proper construction of the term, because it may indicate not only the meaning of the term to persons skilled in the art, but also that the patentee intended to adopt that meaning.' ") (quoting Arthur A. Collins, Inc. v. Northern Telecom. Ltd., 216 F.3d 1042, 1045 (Fed.Cir.2000)).

Kumar, however, also instructs that its holding is limited to circumstances in which the prior art's definition does not contradict the meaning disclosed in the specification or prosecution history of the patent in suit.

Under these circumstances, we conclude that the Polk patent definition is to be preferred over the general dictionary definition relied upon by Ovonic. This Polk patent definition should control *unless the specification clearly states an alternative meaning or this meaning was disclaimed during prosecution.* Here, the specification and prosecution history do not require a different interpretation than the Polk patent's definition of an amorphous alloy....

Kumar, 351 F.3d at 1368 (internal citation omitted) (emphasis added).

Moreover, the fact that the '798 patent and the '584 patent are considered evidence intrinsic to the '341 patent does not, in and of itself, support Biovail's argument that definitions from those prior art patents are relevant to the construction of the dissolution profile limitation. It was significant to the holding in *Kumar* that the prior art at issue in that case was considered at the time of prosecution to be highly relevant to the meaning of the disputed term "amorphous alloy." *See Id.* ("In the present case, the Polk patent is not simply

cited in the '686 patent as pertinent prior art .... Rather the Polk patent was considered by both the applicant and the examiner to be highly pertinent prior art, and there is no indication that the Polk patent's express definition (even if inconsistent with the general dictionary definition) was in any way at variance with the definition that would have been used by those skilled in the art at the time."). Here, by contrast, there is no evidence that either the applicant or the examiner considered the '798 patent or the '584 patent with respect to the dissolution profile limitation.

Considered on its merits, Biovail's reliance on the prior art patents for its construction of the dissolution profile limitation is unpersuasive. With respect to the '798 patent, Biovail focuses exclusively on the statement, found in that patent's specification, that "[t]he test for dissolution (release rates) is performed as specified below in the U.S. Pharmacopoeia under "Drug Release" and the medium is sampled at 1, 4 and 8 hours." '798 patent, col. 3, ll. 58-61. When viewed in broader context, however, the '798 patent does not direct one of ordinary skill in the art to the USP in general for dissolution test conditions. Rather, the patent specification teaches a specific set of dissolution test conditions and procedures, *see* id., at col. 3, l. 49-col.4, l. 68, not a general instruction to look to the USP in determining dissolution test conditions.

Similarly, the '584 patent specifies use of a single dissolution test condition. *See* '584 patent, col. 13, l. 64-col. 14, l.7. Biovail contends that these dissolution test conditions-exposing a tablet to a 0.1 N HC1 dissolution medium for between zero and two hours, and then switching the dissolution medium to a phosphate buffer (pH 7.5) for 2-24 hours-amount to teaching the use of a "pH-switch test" for tablets with enteric coatings. From this disclosure in the '584 patent specification, Biovail's expert witness opined that "one of ordinary skill in the art is going to have the knowledge to understand that they are using the USP Chapter 724 as a general guidance for this pH-switch test." [3/29 Hr'g. Tr. 73:4-18 (Williams)]. The '584 patent, however, does not reference USP Section 724-which also, incidentally, does not correspond to the "pH switch test" disclosed by the '584 patent.FN20 The only reference to the USP in the ' 584 patent is an instruction to use a precise piece of equipment, the "USP Rotating Basket," in conducting the dissolution test. ' 584 patent, col. 13, l. 66.

FN20. Importantly, the modified "pH switch test" indicated by Biovail as an appropriate test to evaluate the dissolution profile of Abrika's ANDA formulation (0.1 N HC1 for two hours followed by a medium of pH 6.8 for 6 hours) does not correspond to either the dissolution test conditions disclosed by the '584 patent or the conditions described by USP Section 724. Thus, even if the USP and the '584 patents are considered intrinsic evidence relevant to construction of the dissolution profile limitation here, they do not provide a foundation in the intrinsic record for application of Biovail's modified "pH switch test."

The prosecution history of the '341 patent FN21 provides further reason to reject Biovail's proposed construction. *See, e.g.,* Southwall Tech., Inc., 54 F.3d at 1576 ("arguments and amendments made during the prosecution of a patent application ... must be examined to determine the meaning ofterms in aclaim."); Ballard Medical Prods. v. Allegiance Healthcare Corp., 268 F.3d 1352, 1359 (Fed.Cir.2001) ("[a]n inventor may use the specification and prosecution history to define what his invention is and what it is not-particularly when distinguishing the invention over prior art."). A review of the patentee's correspondence with the PTO reveals that the patentee relied on the dissolution profile claim limitation-and particularly, the 0.1N HC1 test conditions-to differentiate the invention from prior art.

FN21. Because the '341 patent and the '327 patent " 'derive from the same initial application, the prosecution history regarding a claim limitation in [the '341 patent] ... applies with equal force to

subsequently issued patents that contain the same claim limitation [i.e. the '327 patent].' " Biovail Corp. Int'l v. Andrx Pharms., Inc., 239 F.3d 1297, 1301 (Fed.Cir.2001) (quoting Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 980 (Fed.Cir.1999).

In an Office Action dated April 28, 1999 ("Office Action"), the patent examiner rejected Claims 1, 2 and 4 of the '341 patent under 35 U.S.C. s. 102(b) FN22 for being anticipated by U.S. Patent No. 4,769,027 ("Baker"). The examiner's rejection was based, in part, on the fact that Baker "discloses a controlled release delivery system .... [and] the release rate of th[at] ... delivery system is such that about 60% is released after 2 hours and about 80% is released after four hours (col. 6, lines 47-50)." Office Action at 4.

FN22. "A person shall be entitled to a patent unless-... (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States ...." 35 U.S.C. s. 102(b).

The patentee filed an Amendment to his patent application on August 11, 1999 ("Amendment") to address the examiner's rejection. The patentee replied, in part:

Claim 1 [of the invention] requires a specific dissolution profile for bupropion hydrochloride. While Baker recites this ingredient as a possible active that can be used, it does not provide any dissolution profile for bupropion, but rather for aspirin (at column 6, lines 47-50). Thus Baker cannot anticipate Claim 1 of the invention, since the dissolution profile for aspirin is not necessarily the same as the one for bupropion. Also, *Baker is silent on the dissolution medium and conditions that are used* (it simply refers to example 3 which is absent in Baker, rendering the reproduction of Baker impossible). *The dissolution medium and conditions that are used in the invention is, on the contrary, disclosed in example 1, page 8. (It corresponds to gastric juice.)*

Thus, Baker (1) *fails to teach the dissolution medium and conditions that are used, rendering its disclosure deficient,* and (2) fails to teach the specific dissolution profile for bupropion.

Also, the release profile disclosed in Baker (assuming it might be compared) requires that 80% of the active ingredient be released after 4 hours, while the invention requires that the release after 4 hours be from 10 to 60%, thus far below the 80% disclosed in Baker.

Amendment at 5-6 (italicized emphasis added).

The patentee's response is significant as "[t]he prosecution history constitutes a public record of the patentee's representations concerning the scope and meaning of the claims, and competitors are entitled to rely on those representations when ascertaining the degree of lawful conduct, such as designing around the claimed invention." Hockerson-Halberstadt, Inc. v. Avia Group Int'l., Inc., 222 F.3d 951, 957 (Fed.Cir.2000); *see also,* Biogen, Inc. v. Berlex Labs., Inc., 318 F.3d 1132, 1139 (Fed.Cir.2003) ("The court correctly viewed the prosecution history not for the examiner's or the applicant's subjective intent, but as an official record that is created in the knowledge that its audience is not only the patent examining officials and the applicant, but the interested public.") (citing *Markman,* 52 F.3d at 1334-35). As such, competitors (such as Abrika) are entitled to rely on the patentee's representation as to the scope of his invention. *See, e.g.,* Honeywell Intern., Inc. v. ITT Industries, Inc., 452 F.3d 1312, 1318 (Fed.Cir.2006) ("The public is

entitled to take the patentee at his word and the word was that the invention is a fuel filter.").FN23

FN23. *See also,* Inpro II Licensing, S.A.R.L. v. T-Mobile USA, Inc., 450 F.3d 1350, 1355 (Fed.Cir.2006) ("Although claims need not be limited to the preferred embodiment when the invention is more broadly described, 'neither do the claims enlarge what is patented beyond what the inventor has described as the invention.' ") (quoting Netword, LLC v. Central Corp., 242 F.3d 1347, 1352 (Fed.Cir.2001)); SciMed Life Sys., Inc., 242 F.3d at 1343 ("the characterization of [a limitation] as part of the 'present invention' is strong evidence that the claims should not be read to encompass the opposite structure."); Watts v. XL Sys., Inc., 232 F.3d 877, 884 (Fed.Cir.2000), Wang Labs., Inc. v. America Online, Inc., 197 F.3d 1377, 1383 (Fed.Cir.1999); Modine Mfg. Co. v. United States Int'l. Trade Comm'n, 75 F.3d 1545, 1551 (Fed.Cir.1996).

Accordingly, based on the file history of the '341 patent, a reasonable competitor of Biovail would surmise that the patentee would measure satisfaction of the "dissolution profile" claim limitation by testing the accused formulation in 0.1N HC1 test conditions. *See, e.g., J.T. Eaton & Co.,* 106 F.3d 1567-68 (construing "plastic flow temperature" claim limitation to include the test conditions relied on by the patentee during prosecution in order to overcome a s. 103 rejection); Genentech, Inc., 29 F.3d at 1563 (holding that because the patentee specifically employed the bovine fibrin plate assay to distinguish the claimed product from prior art during prosecution, the 500,000 figure in the specific activity limitation of the claim meant "lU/mg. as measured using the bovine fibrin plate assay.").

Biovail contests the import of the patentee's response by attempting to cast it in a different light. According to Biovail, the patentee's response indicated solely that the Baker patent made no reference to any details of dissolution testing, and therefore, provided no context for one of ordinary skill in the art to develop a dissolution test. Biovail's argument on this point is entitled to little weight, however, as it entirely ignores the patentee's unequivocal statement that "[t]he dissolution medium and conditions that are used in the invention" are the 0.1N HC1 test conditions. In fact, Biovail's expert witness acknowledged that he did not reference this portion of the prosecution history when advancing his opinion on the meaning of the claim term. [See 3/29 Hr'g. Tr. 111:6-113:4 (Williams)].FN24

FN24. Furthermore, Biovail's argument here is inconsistent with its general construction of the "dissolution profile" limitation. If one skilled in the art would know to consult the USP generally to determine what dissolution test to employ depending on the formulation of the product at issue, Baker's disclosure would not have been deficient for failing to specify dissolution conditions. The fact that the patentee responded as he did and did not explain to the examiner that the '341 patent directed the public to consult the USP for dissolution test conditions-is revealing.

Given the clear guidance of the specification and prosecution history, it is evident that Biovail's construction of the disputed "dissolution profile" limitation is impermissibly broad.FN25 Biovail's broad construction of the disputed term finds no support in the intrinsic record. *See* Pause Technology, LLC v. TiVo, Inc., 419 F.3d 1326, 1333 (Fed.Cir.2005) (approving the narrow construction of a disputed term, despite the fact that the definition employed words that "did not appear verbatim as claim language." "Because this construction is driven by the use of [disputed term] in the context of the claim and is supported by the written description, a broader construction that lacks support in the intrinsic record must yield."); Curtiss-Wright Flow Control Corp. v. Velan, Inc., 438 F.3d 1374, 1378 (Fed.Cir.2006) ("[the proposed construction] places too much emphasis on the ordinary meaning of [the claim term] without adequate grounding of that term

within the context of the specification of the ... patent."); Phillips, 415 F.3d at 1316 (" 'The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction.' ") (quoting *Renishaw,* 158 F.3d at 1250). Biovail "is not entitled to a claim construction divorced from the context of the written description." Nystrom v. Trex Co., 424 F.3d 1136, 1144-45 (Fed.Cir.2005); Old Town Canoe Co. v. Confluence Holdings Corp., 448 F.3d 1309, 1318 (Fed.Cir.2006).

FN25. To the extent that the Court considers extrinsic evidence, the same conclusion is evident. [*See* Williams Dep. at 150:7-15 (confirming that the '341 patent directs readers to use .1 normal HC1 for both the examples given and for the claims.")]; [3/29 Hr'g. Tr. 92:25-93:12 (Williams) (same)].

Abrika provides a narrower construction of the claim limitation at issue which better reflects the disclosures in the specification and more closely conforms to the patentee's own expressed description of his invention. Accordingly, and based on an exhaustive review of the intrinsic evidence, the Court concludes that "dissolution profile" means "the percentage of bupropion hydrochloride released over time as determined under 1000 ml 0.1N HC1, 75 rpm, USP Apparatus I." FN26

FN26. Biovail's construction must also be rejected because it improperly allows Biovail to gerrymander specific tests for infringement dependent on the characteristics of the accused product at issue. [*See* Biovail's Revised Rebuttal Brief [D.E. 271] at 5 (citing Opening Declaration of Robert O. Williams, Ph.D., para.para. 30, 31) ("While the claims of the '341 patent do not specify any particular dissolution conditions for the claimed dissolution profile, that is because the dissolution conditions will depend on the specific performance characteristics of the bupropion hydrochloride product at issue; and a person of ordinary skill in the art would understand that.")]. As Biovail's expert testified at the *Markman* hearing, one of ordinary skill in the art would "look to see where it's desired for the drug to be released and the particular composition in order to determine what type of dissolution test methodology is appropriate to generate a dissolution profile." [3/29 Hr'g. Tr. 68:16-20 ("Williams")].

As Abrika argues, and Biovail never refutes, claim construction must proceed "without regard to the accused device." Optical Disc. Corp. v. Del Mar Avionics, 208 F.3d 1324, 1333 (Fed.Cir.2000) ("claim scope is determined without regard to the accused device"); *Young Dental Mfg. Co., Inc. v. Q3 Special Prods., Inc.,* 112F.3d 1137, 1141 (Fed.Cir.1997) ("An infringement analysis involves two steps. First, the claim scope is determined without regard for the accused device."); *see also,* Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1580 (Fed.Cir.1991) ("In 'claim construction' the words of the claims are construed independent of the accused product"); SRI Int'l. v. Matsushita Elec. Corp. of Am., 775 F.2d 1107, 1118 (Fed.Cir.1985) ("It is only after the claims have been construed without reference to the accused device that the claims, as so construed, are applied to the accused device to determine infringement.").

2. *The "Free of Stabilizer" Claim Limitation*FN27

FN27. As the *Impax* court noted, " 'Free of stabilizer' and 'free of pore-forming agent' are both 'negative limitations' that define the claimed invention by what it is not. *See* Upsher-Smith Labs., Inc. v. Pamlab, LLC, 412 F.3d 1319, 1321-23 (Fed.Cir.2005). Thus, a nanower construction of these limiting terms results in a broader construction of the claim and vice versa." Impax, 433 F.Supp.2d at 518 n. 19.

The parties dispute the proper construction of the phrase "free of stabilizer." Biovail asserts that "free of stabilizer" means "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." Abrika maintains that the term should be construed to mean "free of any kind of composition that inhibits the decomposition of bupropion HCI."

The '341 patent claims a "core" and a "tablet" that are "free of stabilizer." '341 patent, col. 9, ll.49-51 (claim 1); *id*. at col. 12, ll. 3-4 (claim 30).FN28 The background of the invention describes the use of stabilizers in prior art:

FN28. The "free of stabilizer" limitation appears in claims 1 and 15 of the '327 patent.

U.S. Pat. No. 5,358,970 and U.S. Pat. No. 5,427,798, both to Burroughs Wellcome, describe a sustained release formulation of bupropion hydrochloride based on matrix technology. The term matrix refers to a tablet where the drug is embedded in an excipient that makes a non-disintegrating core called matrix. Drug diffusion occurs through this core. As bupropion hydrochloride is unstable, the product described in the above two patents requires a stabilizer to achieve sufficient stability. This stabilizer is an acidic compound, preferably cysteine hydrochloride. Matrix technology is however not suited for the manufacture of a tablet, since it implies the use of a stabilizer.
'341 patent, col. 1, ll. 16-27. The summary of the invention distinguishes the invention from prior art with reference to the presence of a stabilizer by noting that the invention "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." Id., at col. 1, ll. 53-56. Further, the specification explains that "the above formulation [invention] did not lead to any degradation of bupropion hydrochloride though no stabilizer was present in the formulation." Id., at col. 3, ll. 27-29.
Biovail acknowledges that its definition is "more narrow than the general definition," [Williams Dep. at 130:23-24], and the Court is persuaded that a narrow construction contradicts the express disclosure of the patent that the claimed invention is "free of stabilizer of any kind." Significantly, Biovail's proposed construction has been considered and rejected by both the *Anchen* and *Impax* courts. *See, e.g., Anchen,* slip. op. at 9 ("Biovail's proposed definition of 'stabilizer' is not found anywhere in the '341 patent, and actually contradicts the summary of the invention."). With respect to all of the arguments that Biovail raises here, the *Impax* court's analysis is highly persuasive.

Biovail contends that "free of stabilizer" means "lacking an effective stabilizing amount" of stabilizer. This argument must be rejected. As the Central District of California recognized in the related *Anchen* litigation, the specification of the '341 patent explicitly provides that the invention is "free of stabilizer of any kind." (Col. 1 line 55.) The specification is "the single best guide to the meaning of a disputed term." *Phillips,* 415 F.3dat 1315. Biovail argues that if a stabilizer were not present in the invention in an amount sufficient to stabilize the tablet, then it would not really be acting as a "stabilizer," and the tablet would still be "free of stabilizer." While this argument may be of philosophical interest, it does not comport with the ordinary and accustomed meaning of "free of stabilizer." When construing a claim involves "application of the widely accepted meaning of commonly understood words," general purpose dictionaries may prove helpful in determining a term's ordinary and accustomed meaning. Phillips, 415 F.3d at 1314. As the *Anchen* court noted, there is no reason not to apply the ordinary English meaning of "free of" when construing "free of stabilizer": "not having or using"; "lacking." Webster's Third New Int'l Dict. of the English Language Unabrid. 905 (1993) (hereinafter "Webster's"). If the tablet did in fact contain a compound used for

stabilizing the tablet, but simply not enough o f it, one would not call it "free of stabilizer," but rather "lacking sufficient stabilizer." Nor is this a case where the patentee acted as his own lexicographer in the specification to define "free of," contrary to its ordinary and accustomed meaning, as "lacking an effective amount of." In light of the specification's clear statement that the claimed invention is "free of stabilizer of any kind," I must reject Biovail's proposed construction of "free of stabilizer."

For the same reason, I reject Biovail's arguments that "free of stabilizer" means free of stabilizers that are organic or inorganic acids and are solids or liquids under ambient conditions. Such constructions would interpret the '341 patent to cover tablets containing stabilizers that are not organic or inorganic acids, or are not solids or liquids under ambient conditions, contrary to the specification's directive that the invention is free of stabilizer of any kind.

Because a specialized meaning for "stabilizer" in the '341 patent is not suggested by the claims, the specification, or the prosecution history, I see no reason not to construe "stabilizer" according to its ordinary and accustomed meaning. The Federal Circuit has noted that technical dictionaries can be of use to a court in determining the meaning of claim terms to one of ordinary skill in the art. *See* Phillips, 415 F.3d at 1318 ("We have especially noted the help that technical dictionaries may provide to a court to better understand the underlying technology and the way in which one of skill in the art might use the claim terms.") (citations omitted). Hawley's Chemical Dictionary defines "stabilizer" as "[a]ny substance that tends to keep a compound, mixture, or solution from changing its form or chemical nature." Hawley's Condensed Chemical Dictionary 1042 (13th ed.1997) (hereinafter "Hawley's").

Impax, 433 F.Supp.2d at 519. Accordingly, the Court construes "free of stabilizer" as "lacking any substance or agent that inhibits the decomposition of bupropion hydrochloride."

3. *The "Free of Pore-Forming Agent" Claim Limitation*

The parties also contest construction of the phrase "free of pore-forming agent." Biovail proposes to define the term as "lacking a particulate non-polymeric water soluble species capable of being eluted from a coating to form a pore therein." Abrika argues that the term should be defined as follows: "free of a material that favors the creation of pores or openings, within a coating." The disagreement between the parties centers on whether "pore-forming agent," as defined in the context of the patents at issue, must be particulate and non-polymeric (or monomeric).

The '341 patent claims a "tablet" that is "free of pore-forming agent." '341 patent, col. 12, l. 4 (claim 30).FN29 In the background of the invention, the patentee discussed the use, and limitations, of pore-forming agents in prior art.

FN29. The "free of pore-forming agent" limitation appears in claim 15 of the '327 patent.

U.S. Pat. No. 4,687,660 and EP-A-0171457 disclose a tablet formed of a core and a coating, where the core comprises bupropion hydrochloride together with excipient(s) and optionally an osmotic enhancing agent and where the coating comprises 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. This type of coating, since it requires pore-forming agent, cannot provide a uniform coating and

therefore the release rate cannot be uniform from one tablet to another.
Id., at col. 1, ll. 28-39. To improve on the limitations inherent in prior art, the patentee explained that in the invention, "the controlled release is obtained thanks to a semi-permeable release coating, free of (monomeric) pore-forming agent." Id., at col. 1, ll. 56-58.
Biovail admits that its proposed definition, limiting pore-forming agent to non-polymeric, particulate material, is narrower than the common meaning of "pore-forming agent." [Williams Dep. 120:3-121:14; 168:2-7 (confirming that the common definition of "pore-forming agents" would include both monomers and polymers)]. With respect to limiting the definition of "pore-forming agent" to "particulate" substances, Biovail's definition is unnecessarily constricted. As the *Impax* court explained:

The word "particulate" appears nowhere in the '341 patent. However, Biovail supports its assertion that the "pore forming material" must be "particulate" by pointing to two prior art references cited in the "Background of the Invention" section of the '341 patent, U.S. Pat. No. 4,687,660 ("the '660 patent") and European Published Patent Application No. EP-A-0171457 ("the ' 457 application"), as well as to U.S. Pat. No. 4,769,027 ("the '027 patent"), which was discussed in the '341 patent's prosecution history. According to Biovail, because the patentee referred to these prior art references in the specification and prosecution history in connection with the term "pore-forming agent," and because they involve pore-forming material that is particulate, one skilled in the art would look to these references to determine that "pore-forming agent" necessarily means a particulate substance. It is true that "prior art cited in a patent or cited in the prosecution history of the patent constitutes intrinsic evidence," which a court can consider along with the patent's claims themselves, the specification, and the prosecution history in defining a claim term. Kumar v. Ovonic Battery Co., Inc., 351 F.3d 1364, 1368 (Fed.Cir.2003). However, the prior art references on which Biovail relies do not provide definitions of the term "pore-forming agent," but merely limit the type of pore-forming material to be used in their respective inventions. For instance, the '660 patent and the '027 patent both involve a pore-forming agent and state that "the pore-forming agent must be particulate in nature, with a maximum particle size preferably not exceeding about 500 m ...." ('660 patent, Col. 4, Ins. 28-30; '027 patent, col. 4, Ins. 62-64.) Similarly, the '457 application states that "[t]he particulate water-soluble pore-forming material of use in the composition of the present invention, preferably, has a maximum particle size not exceeding 500 m ...." ('457 application at 5, para. 2.) This is the language of limitation, not definition. Moreover, as Impax points out, the fact that the adjective "particulate" is used to modify "pore-forming material" in the '457 application would seem to indicate that in general, pore-forming agent may be either particulate or non-particulate.

Furthermore, to conclude that the pore-forming agent must be "particulate" would be to say that a tablet need not actually be "free of pore-forming agent" to fall within the scope of claim 30. Under Biovail's proposed construction, claim 30 covers tablets that are not free of pore-forming agent, so long as the pore-forming agent they include is not particulate in nature.

Impax, 433 F.Supp.2d at 520-21 (footnote omitted).

In contrast, Biovail's proposal to limit "pore-forming agents" to non-polymeric materials is supported by the intrinsic record. The Court concurs with the *Anchen* court's observation that "it is difficult to believe that one skilled in the art reading the patent would not give particular weight to the statement that the invention was 'free of (monomeric) pore-forming agent[s].' " *Anchen,* slip. op. at 18; *see also,* Impax, 433 F.Supp.2d at 521 (adopting the *Anchen* court's discussion and explaining that the "patentee acted as his own lexicographer in the specification, explicitly carving out polymeric water-soluble species from the definition of 'pore-forming agent.' ").

Abrika's argument does not compel a different result here. Abrika attempts to account for this disclosure by arguing that the patentee's statement simply advances monomeric agents as an example of a pore-former. [*See* 3/29 Hr'g. Tr. 155:5-155:8 (Sinko) ("I interpreted the parenthetical as an example and, so, based on this information in the specification, I interpreted the inventor acknowledged the pore-forming agent could be monomeric or polymeric or a salt.")]. This reading is not a credible interpretation of the patentee's statement. Were "(monomeric)" interpreted to be merely an example, the patentee would have been advising the public that "the invention is free of both polymeric and monomeric pore-forming agents, for example, monomeric pore-forming agents." Such reading renders the patentee's clear statement meaningless.FN30

FN30. The parties dispute whether impalpable lactose (identified in the specification as a pore-forming agent utilized in prior art) is a polymer and thus excluded under Biovail's proposed definition of pore-forming agent Whether Biovail's proposed definition accounts for the patentee's description of prior art, however, misses the point. The pertinent consideration is whether the definition "stays true to the claim language and most naturally aligns with the patent's description of the invention." Phillips, 415 F.3d at 1316 (internal quotation omitted). In light of the patentee's clear statement limiting the definition of this claim term with respect to the invention, Abrika's argument that Biovail's proposed definition fails to account for "impalpable lactose" is not persuasive.

Accordingly, the Court construes the "free of pore-forming agent" limitation to mean "lacking a monomeric water-soluble species that favors the creation of pores or openings, within a coating."

4. "*Water-Insoluble Polymer*" *and* "*Water-Soluble Polymer*"

The parties contest the definitions of "water-insoluble polymer" and "water-soluble polymer" as used in the patents." FN31 The '341 patent claims a "tablet comprising ... a coating consisting essentially of a water-insoluble, water-permeable film-forming polymer, a plasticizer and a water-soluble polymer." '341 patent, col. 9, ll. 49-54 (Claim 1). The specification provides direction with respect to the meaning of these terms by identifying preferred embodiments of each. *See Id.,* col. 2, ll. 57-62 ("The water-insoluble, water-permeable film-forming polymer can be a cellulose ether, such as ethylcellulose, a cellulose ester, such as cellulose acetate, polyvinylalcohol, etc. The preferred film-forming polymer is ethylcellulose (available from Dow Chemical under the trade name Ethocel (R))"); *Id.,* at col. 2, ll.65-66 ("The water-soluble polymer is preferably polyvinylpyrrolidone.").

FN31. Although the parties initially contested the definition of two larger phrases that appear in the patents, "water-insoluble, water-permeable film-forming polymer" and "water-soluble polymer," they subsequently agreed that their dispute applied solely to their conflicting definitions of the terms "water-insoluble" and "water-soluble."

Both parties acknowledge that these terms have a plain meaning that is understood by those of ordinary skill in the art. The material difference between the parties' respective definitions is the degree to which the claim terms require quantitative specificity. Biovail advances relative definitions for each term, proposing that "water-insoluble" means "substantially insoluble in water," and that "water-soluble" means "soluble in water." Abrika argues for more precise definitions, proposing that "water-insoluble polymer" mean "for every 1 part polymer, there are more than 10,000 parts of water," and that "water-soluble polymer" means

"for every 1 part polymer there are less than 1 part to 30 parts water."

Abrika's numerical restrictions are drawn from a descriptive table of solubility ranges that is well known by those skilled in the art, and reproduced in a number of pharmaceutical references, including "the 1995 and 2000 editions of the United States Pharmacopoeia, both at page 10 (Exhibit 5) ... Remington's Pharmaceutical Sciences (16th ed.1980) at 203 (same) (Exhibit 6), Physical Pharmacy (3d ed. 1983) (Exhibit 7), at 273 (same)." [Expert Claim Construction Report of Patrick J. Sinko, para. 51; *see also,* 3/30 Hr'g. Tr. 11:15-12:9 (Sinko)]. The table correlates commonly used qualitative terms for solubility to corresponding numerical ratios of solvent to solute:

Descriptive Term	Parts of Solvent Required for 1 Part of Solute
Very soluble	Less than 1
Freely soluble	From 1 to 10
Soluble	From 10 to 30
Sparingly soluble	From 30 to 100
Slightly soluble	From 100 to 1,000
Very slightly soluble	From 1,000 to 10,000
Practically insoluble, or Insoluble	10,000 and over

[Expert Claim Construction Report of Patrick J. Sinko, Ex. 5]. Abrika's definition of "water-soluble" encompasses the ranges associated with the descriptive terms "soluble," "freely soluble," and "very soluble," and its definition of the term of the term "water-insoluble" corresponds to the descriptive term "practically insoluble, or insoluble."

Biovail contends that Abrika's definitions of solubility find no support in the intrinsic record and seek to impose quantitative specificity unnecessarily. In place of precise quantitative limitations, Bio vail argues that the '341 patent references solubility terms in a "general sense" [3/29 Hr'g Tr 58:6 (Williams)]. Abrika challenges Biovail's definitions as circular (defining the terms using the terms themselves) and of little use to the public. Moreover, Abrika faults Biovail for qualifying its definition of water-insoluble-substantially insoluble in water-by importing a word for which there is no support in the intrinsic record.

Biovail's inclusion of the modifier "substantially" exposes the limitations of its position. Substantially is admittedly a "subjective" modifier applied by Dr. Williams [3/29 Hr'g. Tr. 89:13-22 (Williams)], and "not one of the descriptive words that [is] typically used" by those skilled in the art to describe insolubility. [3/30 Hr'g. Tr. 15:5-6 (Sinko)]. The inclusion of this imprecise term stems from Biovail's acknowledgment that none of the insoluble polymers listed in the '341 patent are completely insoluble in water. In fact, "the preferred 'water insoluble' polymer of the '341 patent, ethylcellulose, has *some* solubility in water." [Rebuttal Claim Construction Report of Patrick J. Sinko, para. 31]. Imprecision, however, does not prevent overlap between Biovail's definitions of "water-insoluble"-which may be partially (though not "substantially") soluble-and water soluble-which may be only partially soluble. Accordingly, ethylcellulose, the preferred embodiment of the "water-insoluble polymer" in the '341 patent, meets Biovail's definition for both water-soluble and water-insoluble.

Biovail argues that Abrika's definition of "water-soluble polymer" yields similar inconsistency because the preferred embodiment of water soluble polymer in the '341 patent, polyvinylpyrrolidone, "is actually

classified quantitatively as freely soluble" rather than soluble. [3/29 Hr'g. Tr. at 58:10-58:11 (Williams)]. The argument misses the mark as Abrika's quantitative definition for "water-soluble" encompasses substances that are classified as "freely soluble."

Finally, Biovail's critique that Abrika's definition fails to account for a substantial portion of the solubility chart, including all substances that would be described as "sparingly soluble," "slightly soluble," or "very slightly soluble," does not persuade. Nothing in the '341 patent requires that the terms "water-insoluble" and "water-soluble" encompass the entire range of solubility as reflected by the chart. In fact, the patentee's decision to employ descriptive terms with well-known quantitative meanings indicates that he intended "water-soluble" to mean the quantitative value for soluble and above, and "water-insoluble" to mean the quantitative value for practically insoluble and insoluble.

Accordingly, Abrika's definitions are more consistent with the ordinary and customary meanings of the patents' solubility terms. Although the definitions rely on extrinsic evidence, such reliance is appropriate to "educate the court regarding the field of the invention and can help the court determine what a person of ordinary skill in the art would understand claim terms to mean." Phillips, 415 F.3d at 1319. The Court adopts Abrika's construction of "water-insoluble polymer:" for every 1 part polymer, there are more than 10,000 parts of water; and "water-soluble polymer:" for every 1 part polymer there are less than 1 part to 30 parts water.

5. "*Consisting Essentially of*"

"The phrase 'consisting essentially of' in a patent claim represents a middle ground between the open-ended term "comprising" and the closed-ended phrase "consisting of." In view of the ambiguous nature of the phrase, it has long been understood to permit inclusion of components not listed in the claim, provided that they do not "materially affect the basic and novel properties of *the invention*." AK Steel Corp. v. Sollac and Ugine, 344 F.3d 1234, 1239 (Fed.Cir.2003) (emphasis added). Based on the language of Claim 1, however, Abrika seeks to narrow this definition to mean that the coating must include all of the recited elements and must exclude any other ingredient that materially affects the release properties of *the coating*. This proposed definition impermissibly equates the invention with the coating-a reading which is not supported by the intrinsic record. Accordingly, the Court concurs with Biovail that the phrase "consisting essentially of" has a well established legal meaning and does not require construction.

CONCLUSION

For all of the reasons stated herein, it is

ORDERED AND ADJUDGED that the claim terms of U.S. Patent Numbers 6,096,341 and 6,143,327 are construed as follows:

(1) "Dissolution profile" means "the percentage of bupropion hydrochloride released over time as determined under 1000 ml 0.1N HC1, 75 rpm, USP Apparatus I."

(2) "Free of stabilizer" means "lacking any substance or agent that inhibits the decomposition of bupropion hydrochloride."

(3) "Free of pore-forming agent" means "lacking a monomeric water-soluble species that favors the creation of pores or openings, within a coating."

(4) "Water-insoluble polymer" means "for every 1 part polymer, there are more than 10,000 parts of water."

(5) "Water-soluble polymer" means "for every 1 part polymer there are less than 1 part to 30 parts water."

DONE AND ORDERED in Chambers at Miami, Florida this *23* day of August, 2006.

S.D.Fla.,2006.
Biovail Laboratories Intern. SRL v. Abrika, LLLP