IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT LABORATORIES, an Illinois corporation, FOURNIER INDUSTRIE ET SANTÉ, a French corporation, and LABORATORIES FOURNIER S.A., a French corporation, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., a Delaware Corporation, Defendant.	)	Civil Action No. 02-1512-KAJ (Consolidated)
TEVA PHARMACEUTICALS USA, INC., a Delaware corporation, and TEVA PHARMACEUTICAL INDUSTRIES LIMITED, an Israeli corporation, Counterclaim-Plaintiffs, v. ABBOTT LABORATORIES, an Illinois corporation, FOURNIER INDUSTRIE ET SANTÉ, a French corporation, and LABORATORIES FOURNIER S.A., a French corporation, Counterclaim-Defendants.	)	

ABBOTT LABORATORIES, an Illinois corporation, FOURNIER INDUSTRIE ET SANTE, a French corporation, and LABORATORIES FOURNIER S.A., a French corporation,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 03-120-KAJ (Consolidated)
IMPAX LABORATORIES, INC., a Delaware corporation,	)	
Defendant.	)	

MEMORANDUM OPINION

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Wilmington, Delaware
April 22, 2005

JORDAN, District Judge

I. INTRODUCTION

This is a patent infringement case. Presently before me are the parties' requests for construction of the disputed claim language of U.S. Patent No. 6,074,670 (issued June 13, 2000) (the "'670 patent"), U.S. Patent No. 6,589,552 B2 (issued July 8, 2003) (the "'552 patent"), U.S. Patent No. 6,277,405 B1 (issued Aug. 21, 2001) (the "'405 patent"), and U.S. Patent No. 6,652,881 B2 (issued Nov. 25, 2003) (the "'881 patent"), pursuant to *Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). The construction of the disputed claim language of the patents listed above applies to two cases that have been consolidated for all pre-trial issues.[1] (*See* Docket Item ["D.I."] 87, 91, C.A. No. 02-1512-KAJ; D.I. 31, C.A. No. 03-120-KAJ.) The plaintiffs in both cases are Abbott Laboratories, Fournier Industrie et Santé, and Laboratoires Fournier S.A.[2] (collectively, "Abbott"). The defendants in C.A. No. 02-1512-KAJ are Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Limited (collectively, "Teva"). The defendant in C.A. No. 03-120-KAJ is Impax Laboratories, Inc. ("Impax"). The parties have fully briefed and argued their positions. Jurisdiction is proper under 28 U.S.C. § 1338.

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[1] Because this opinion addresses two cases, each containing its own pleadings, citations will be designated by case number as well as docket item number.

[2] Fournier Industrie et Santé and Laboratoires Fournier S.A. are collectively referred to as "Fournier."

II. BACKGROUND

A. Procedural Background

Abbott filed a complaint for patent infringement under 35 U.S.C. § 271(e)(2)[3] against Teva on October 4, 2002, after Teva submitted an abbreviated new drug application ("ANDA") under 21 U.S.C. § 355(j) prior to the expiration of the patents-in-suit. (D.I. 1, C.A. No. 02-1512-KAJ). Teva's ANDA sought approval to sell fenofibrate tablets in 54mg and 160mg dosages. (*Id.*) Teva filed an answer on November 15, 2002 and asserted patent counterclaims for injunctive relief and declaratory judgment of non-infringement of the patents-in-suit, invalidity of the patents-in-suit, and unenforceability of "at least the '726 patent" (D.I. 20 at ¶ 72, C.A. No. 02-1512-KAJ), and antitrust counterclaims for "declaratory judgment and injunctive relief based on [Abbott's] threatened unlawful exclusion of Teva from competition in the manufacture, marketing, and sale of TRICOR® tablets, a cholesterol-lowering drug containing the active pharmaceutical ingredient, fenofibrate, and their generic bioequivalents"[4] (*id.* at ¶ 73). Abbott filed a reply to Teva's counterclaims, denying that the patents at issue are not infringed, invalid, or unenforceable. (D.I. 39 at at ¶ 72, C.A. No. 02-1512-KAJ.) Abbott and Teva are scheduled to try this case beginning on June 20, 2005. (D.I. 91 at 7, C.A. No. 02-1512-KAJ.)

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[3] 35 U.S.C. § 271(e)(2) states in relevant part: "It shall be an act of infringement to submit -- (A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act ... for a drug claimed in a patent or the use of which is claimed in a patent... ." Section 505(j) of the Federal Food, Drug, and Cosmetic Act corresponds to 21 U.S.C. § 355(j).

[4] By stipulation, Teva's antitrust counterclaims were dismissed without prejudice on January 31, 2003. (D.I. 38.)

Abbott filed a complaint for patent infringement under 35 U.S.C. § 271(e)(2) against Impax on January 23, 2003, after Impax submitted an abbreviated new drug application ("ANDA") under 21 U.S.C. § 355(j) prior to the expiration of the patents-in-suit. (D.I. 1, C.A. No. 03-120-KAJ.) Impax's ANDA also sought approval to sell fenofibrate tablets in 54mg and 160mg dosages. (*Id.*; D.I. 172 at 3.) Impax filed an answer on March 10, 2003 and asserted a counterclaim for declaratory judgment that the patents-in-suit are invalid, unenforceable and not infringed. (D.I. 9 at ¶ 13, C.A. No. 03-120-KAJ.) Abbott filed a reply to Impax's counterclaim, denying that the patents at issue are not infringed, invalid, or unenforceable. (D.I. 12 at ¶ 13, C.A. No. 03-120-KAJ.) Abbott and Impax are scheduled to try this case beginning on June 6, 2005. (D.I. 53 at 7, C.A. No. 03-120-KAJ.)

B. The Disclosed Technology

1. The State of the Art

Fenofibrate is a pharmaceutical substance that has long been used for treating certain types of cholesterol problems in adults. (D.I. 237 at 1, C.A. 02-1512-KAJ.) Specifically, it lowers triglyceride (fat-like substances) and LDL cholesterol levels in the blood and increases HDL cholesterol levels.[5] (Plaintiff's *Markman* Presentation at 2.) Fenofibrate has also "proven effective in reducing a person's risk of heart disease." (*Id.*) To be therapeutically effective, fenofibrate must dissolve in a patient's stomach. (*Id.* at 3.) Dissolved fenofibrate is "converted by the body into fenofibric acid," which

[5] LDL cholesterol is commonly referred to as unhealthy or "bad cholesterol," whereas HDL cholesterol is referred to as healthy or "good cholesterol." Plaintiff's *Markman* Presentation at 2.)

can then enter the patient's blood stream. (Plaintiff's *Markman* Presentation at 3.) The major drawback in its usefulness in treating patients is that it has poor hydrosolubility, meaning it does not dissolve easily in water, which makes up the majority of digestive juices in the stomach. (D.I. 237 at 1, C.A. 02-1512-KAJ; Plaintiff's *Markman* Presentation at 4.) Because of this drawback, "only a small percentage of fenofibrate in [prior art] fenofibrate compositions would be absorbed by the body and find its way into the patient's blood stream." (D.I. 237 at 1-2, C.A. 02-1512-KAJ.)

2. The Stamm Patents

The four patents-in-suit, the '405, '552, '670, and '881 patents (collectively, "the Stamm patents") are related to each other and all have the same inventors Andre Stamm and Pawan Seth. (D.I. 237 at 2, C.A. 02-1512-KAJ.) The Stamm patents are owned by assignment by Fournier and exclusively licensed in the United States to Abbott. (D.I. 1 at ¶¶ 7-8, C.A. 02-1512-KAJ.) The '405, '552, and '881 patents issued as a series of continuations from the same parent application, which itself issued as the '670 patent. (*Id.*) The Stamm patents claim priority to French patent application FR 97 00479 (filed January 17, 1997), and all have the same specification. (*Id.*; D.I. 223 at 3, C.A. 02-1512-KAJ.) Because of this commonality, they also have many of the same claim terms.

The inventions claimed in the Stamm patents relate to a "novel pharmaceutical composition having high bioavailability through improved dissolution, and a method for preparing it." (*See, e.g.,* '881 patent, Background of the Invention, col. 1 ll. 20-22.) In general, this "novel pharmaceutical composition" is described as "an immediate release

fenofibrate composition." ('881 patent, col. 3 ll. 38-39.) More specifically, the '670 and '552 patents are directed to fenofibrate compositions with particular ingredients that are described in the claims (*see, e.g.,* '670 patent, col. 9 ll. 48-60; '552 patent, col. 9 l. 66-col. 10 l. 4), whereas the '405 and '881 patents are generally directed to fenofibrate compositions with particular dissolution characteristics (e.g., dissolution rates at particular time intervals) that are described in the claims (*see, e.g.,* '405 patent, col. 10 ll. 29-36; '881 patent, col. 10 ll. 44-65).

III. APPLICABLE LAW

Patent claims are construed as a matter of law. *Markman*, 52 F.3d at 979. A court's objective is to determine the ordinary and customary meaning, if any, that those of skill in the art would apply to the language used in the patent claims. *Waner v. Ford Motor Co.*, 331 F.3d 851, 854 (Fed. Cir. 2003) (citing *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342 (Fed. Cir. 2001)). In this regard, pertinent art dictionaries, treatises, and encyclopedias may assist a court. *Texas Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1202-03 (Fed. Cir. 2002). The intrinsic record, however, is the best source of the meaning of claim language. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). Therefore, patent claims are properly construed only after an examination of the claims, the specification, and, if in evidence, the prosecution history of the patent. *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1324 (Fed. Cir. 2003) (citing *Vitronics*, 90 F.3d at 1582).

The intrinsic record is also of prime importance when claim language has no ordinary meaning in the pertinent art, *see Bell Atl. Network Servs., Inc. v. Covad*

Communications Group, Inc., 262 F.3d 1258, 1269-70 (Fed. Cir. 2001) (determining that claim language could only be construed with reference to the written description) (citation omitted), and where claim language has multiple potentially applicable meanings, *Texas Digital, Inc.*, 308 F.3d at 1203.

If patent claim language has an ordinary and accustomed meaning in the art, there is a heavy presumption that the inventor intended that meaning to apply. *Bell Atl. Network Servs., Inc.*, 262 F.3d at 1268 (citing *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 989 (Fed. Cir. 1999)). Thus, unless the inventor has manifested an express intent to depart from that meaning, the ordinary meaning applies. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002) (citation omitted).

To overcome that presumption, an accused infringer may demonstrate that "a different meaning is clearly set forth in the specification or ... the accustomed meaning would deprive the claim of clarity." *N. Telecom Ltd. v. Samsung Elecs. Co., Ltd.*, 215 F.3d 1281, 1287 (Fed. Cir. 2000). However, the presumption may not be rebutted "simply by pointing to the preferred embodiment...." *Teleflex, Inc.*, 299 F.3d at 1327. It may be rebutted, though, where "the patentee ... deviate[d] from the ordinary and accustomed meaning ... by redefining the term or by characterizing the invention in the intrinsic record using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." *Id.*

If claim language remains unclear after review of the intrinsic record, a court "may look to extrinsic evidence to help resolve the lack of clarity." *Interactive Gift*

Express, Inc. v. Compuserve Inc., 256 F.3d 1323, 1332 (Fed. Cir. 2001). The use of extrinsic evidence in the claim construction process, however, is "proper only when the claim language remains genuinely ambiguous after consideration of the intrinsic evidence." *Id.* (citation omitted). A court may not use extrinsic evidence to contradict the import of the intrinsic record, and if the intrinsic record is unambiguous, extrinsic evidence is entitled to no weight. *Bell & Howell Document Mgmt. Prods. Co. v. Altek Sys.*, 132 F.3d 701, 706 (Fed. Cir. 1997).

IV. CLAIM CONSTRUCTION

Abbott alleges that Teva infringes claims of each of the Stamm patents, including: claims 1-3, 5, 7, 9, 15, 19, and 35 of the '670 patent; claims 1-12, 15-22, 25, 27, and 56-57 of the '552 patent; claims 6 and 9 of the '405 patent; and claims 5, 10, 19, 26, 31, and 41 of the '881 patent. (D.I. 223 at 4, C.A. 02-1512-KAJ.) Abbott further alleges that Impax infringes claims of three[6] of the Stamm patents, including: claims 1-8, 11, 25, 27, and 56 of the '552 patent; claims 6 and 9 of the '405 patent; and claims 5, 10, 14, 19, 26, 31, and 41 of the '881 patent. (D.I. 169 at 1, C.A. 03-120-KAJ.) Because the parties have agreed that the disputed claim terms have the same meaning in each of the asserted claims of the Stamm patents, I will construe each term only once and will provide as a reference, a claim which represents how such term is used in the patents. (D.I. 297 at 32:25-33:10, transcript of *Markman* hearing, Feb. 28, 2005.)

[6] Initially, Abbott alleged that Impax infringed claims of the '670 patent, but Abbott has since agreed not to assert the '670 patent against Impax in this litigation. (D.I. 297 at 28:11-14, transcript of *Markman* hearing, Feb. 28, 2005.)

A. "inert hydrosoluble carrier"

Claim 1 of the '670 patent, which is representative of the use of this term in the Stamm patents, is as follows:

> An immediate-release fenofibrate composition comprising:
> (a) an **inert hydrosoluble carrier** covered with at least one layer containing fenofibrate in a micronized form having a size less than 20 µm, a hydrophilic polymer and a surfactant; and
> (b) optionally one or several outer phase(s) or layer(s), wherein, based on the weight of (a), said inert hydrosoluble carrier makes up from 20 to 50% by weight, said fenofibrate makes up from 20 to 45% by weight, said hydrophilic polymer makes up from 20 to 45% by weight, and said surfactant makes up from 0.1 to 3% by weight.

('670 patent, col. 9 ll. 48-60 (emphasis added).)

1. The Parties' Proposed Constructions

Abbott argues that the specification explicitly defines this claim term as follows: "In the framework of this invention, the expression 'inert hydrosoluble carrier' means any excipient, generally hydrophilic, pharmaceutically inert, crystalline or amorphous, in a particulate form, not leading to a chemical reaction under the operating conditions employed, and which is soluble in an aqueous medium, notably in a gastric acid medium." (D.I. 237 at 6, C.A. 02-1512-KAJ; '670 patent, col. 4 ll. 3-9.) Based on that language, Abbott asserts that "the patentees acted as their own lexicographer[s] by expressly defining the term in the patent specification and by using their definition in a consistent way throughout the patent." (D.I. 237 at 6, C.A. 02-1512-KAJ.) Abbott therefore proposes that I construe "inert hydrosoluble carrier" in accordance with the definition stated in the specification (D.I. 238 at 1, C.A. 02-1512-KAJ; D.I. 167 at 1, C.A.

03-120-KAJ), because "under well-settled law, this express definition 'controls' the meaning of the claim term" (D.I. 237 at 6, C.A. 02-1512-KAJ).

Teva proposes that I construe "an inert hydrosoluble carrier" to mean "any excipient, generally hydrophilic, pharmaceutically inert, crystalline or amorphous, in a particulate form, not leading to a chemical reaction under the operating conditions employed, which is soluble in an aqueous medium, notable in a gastric acid medium, and which functions as a support for particles of micronized fenofibrate and polymer." (D.I. 238 at 1-2, C.A. 02-1512-KAJ.) Teva asserts that the addition of the phrase "and which functions as a support for particles of micronized fenofibrate and polymer" is necessary because "[t]he inert hydrosoluble carrier is a specific material that carries or supports particles of micronized fenofibrate that adhere to the surface of the carrier," and, as such, the meaning of the term should include this functional description in addition to the definition provided in the specification of the Stamm patents. (D.I. 223 at 29-30, C.A. 02-1512-KAJ.) In support, Teva cites several Federal Circuit decisions in which the Court construed disputed claim language to include functional characteristics.[7]

Impax proposes that I construe "an inert hydrosoluble carrier" in essentially the same way, with this slightly different wording: "an excipient, generally hydrophilic, pharmaceutically inert, crystalline or amorphous, in a particulate form, not leading to a

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[7] In support of its argument, Teva cites *Astrazeneca AB, Aktiebolaget Hassle, KBI-E, Inc. v. Mutual Pharm. Co., Inc.*, 384 F.3d 1333, 1338-39 (Fed. Cir. 2004), *Alloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1371-72 (Fed. Cir. 2003), *Networld LLC v. Centraal Corp.*, 242 F.3d 1347, 1352 (Fed. Cir. 2001), and *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1216-17 (Fed. Cir. 1995). (D.I. 268 at 12, C.A. 02-1512-KAJ.)

chemical reaction under the operating conditions employed, which is soluble in an aqueous medium, notably in a gastric acid medium, and having material coated or layered onto the excipient, which acts as a support." (D.I. 167 at 1, C.A. 03-120-KAJ.) Impax asserts that Abbott's proposed construction "fails to account for the meaning of the term 'carrier,' ... [which] must be construed to require that the excipient ... have material coated or layered onto it ... [because] it is acting as the support for the material." (D.I. 169 at 11, C.A. 03-120-KAJ.)

2. The Court's Construction

"[P]atent law permits the patentee to choose to be his or her own lexicographer by clearly setting forth an explicit definition for a claim term that could differ in scope from that which would be afforded by its ordinary meaning." *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342 (Fed. Cir. 2001). A patentee acts as his own lexicographer where he "clearly set[s] forth a definition of the disputed claim term in the specification." *Sunrace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1304 (Fed. Cir. 2003). In so doing, "the specification must have sufficient clarity to put one reasonably skilled in the art on notice that the inventor intended to redefine the claim term." *Merck & Co., Inc. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1370 (Fed. Cir. 2005) (internal citations omitted).

The patentees here acted as their own lexicographers in defining the meaning of the term "inert hydrosoluble carrier." The specification clearly states, "[i]n the context of this invention, the expression 'inert hydrosoluble carrier' means... ."[8] ('670 patent, col. 4

[8] Because each of the Stamm patents has the same written description, citations are directed to the patent specification containing the specific claim chosen to represent

ll. 3-5.) I cannot imagine a clearer way of expressing the intention that a particular term be given a particular meaning. Abbott proposes that such meaning defines the term in its entirety, whereas Teva and Impax argue that the meaning is incomplete because it does not describe the function of the carrier as a support. (D.I. 237 at 6, C.A. 02-1512-KAJ; D.I. 223 at 29-30, C.A. 02-1512-KAJ; D.I. 169 at 11, C.A. 03-120-KAJ.) In acting as their own lexicographers, the patentees identified "inert hydrosoluble *carrier*" as the term they intended to define. ('670 patent, col. 4. ll 3-4 (emphasis added).) Thus, the definition explicitly identified in the specification, was intended to include the term "carrier," and, as such, it does not require its own independent construction based on its intended function.[9] Therefore, I construe "inert hydrosoluble carrier" to mean "any excipient, generally hydrophilic, pharmaceutically inert, crystalline or amorphous, in a

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the context of the disputed claim term at issue.

[9] In support of its argument, Teva cites *Astrazeneca AB, Aktiebolaget Hassle, KBI-E, Inc. v. Mutual Pharm. Co., Inc.*, where the Federal Circuit held that the patentee had acted as his own lexicographer because the specification stated that "[t]he solubilizers suitable according to the invention are defined below" and then stated that "[t]he solubilizers suitable for the preparations according to the invention are semi-solid or liquid non-ionic surface active agents... ." *Astrazeneca*, 384 F.3d 1333, 1339 (Fed. Cir. 2004). Based on this disclosure in the specification, the Court determined that the term "solubilizer" was intentionally limited to "surfactants." *Id.* at 1339-40. Thus, if anything, this case supports Abbott's argument that the patentees acted as their own lexicographers in defining the term "inert hydrosoluble carrier," as expressed in the specification. In *Alloc, Inc. v. International Trade Commission*, 342 F.3d 1361, 1371-72 (Fed. Cir. 2003), *Networld LLC v. Centraal Corp.*, 242 F.3d 1347, 1352 (Fed. Cir. 2001), and *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1216-17 (Fed. Cir. 1995), also cited by Teva, the patentee had not acted as his own lexicographer by explicitly defining a claim term. Those cases therefore do not support the particular arguments asserted by Teva and Impax, that the explicit definition provided by the patentee is somehow deficient because it does not encompass the full meaning of the term as used in the patents, and, therefore, the court should alter the definition provided.

particulate form, not leading to a chemical reaction under the operating conditions employed, and which is soluble in an aqueous medium, notably in a gastric acid medium."

B. "hydrosoluble carrier"

Claim 1 of the '405 patent, which is representative of the use of this term in the Stamm patents, is as follows:

> A composition comprising a **hydrosoluble carrier** and micronized fenofibrate having a dissolution of at least 10% in 5 minutes, 20% in 10 minutes, 50% in 20 minutes and 75% in 30 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopoeia, in a dissolution medium constituted by water with 2% by weight polysorbate 80 or with 0.025M sodium lauryl sulfate.

('405 patent, col. 10 ll. 29-36 (emphasis added).)

1. The Parties' Proposed Constructions

The parties propose the same meanings for the term "hydrosoluble carrier" as they did for "inert hydrosoluble carrier," except without it being "pharmaceutically inert." (*See* D.I. 238 at 4, C.A. 02-1512-KAJ; D.I. 167 at 3, C.A. 03-120-KAJ.) Thus, Abbott proposes that I construe "hydrosoluble carrier" to mean "any excipient, generally hydrophilic, crystalline or amorphous, in a particulate form, and which is soluble in an aqueous medium, notably in a gastric acid medium." (D.I. 238 at 4, C.A. 02-1512-KAJ.) Teva and Impax have not specifically set out their proposed meanings for this term, but I understand that their proposals would contain the same functional descriptions following the meaning proposed by Abbott. (*See* D.I. 238 at 4, C.A. 02-1512-KAJ; D.I. 167 at 3, C.A. 03-120-KAJ.)

2. The Court's Construction

Based on my construction of "inert hydrosoluble carrier," *supra* Part IV.A.2., and for the same reasons expressed therein, I construe "hydrosoluble carrier" to mean "any excipient, generally hydrophilic, crystalline or amorphous, in a particulate form, and which is soluble in an aqueous medium, notably in a gastric acid medium."

C. "hydrophilic polymer"

Claim 1 of the '670 patent, which is representative of the use of this term in the Stamm patents, is as follows:

> An immediate-release fenofibrate composition comprising:
> (a) an inert hydrosoluble carrier covered with at least one layer containing fenofibrate in a micronized form having a size less than 20 µm, a **hydrophilic polymer** and a surfactant; and
> (b) optionally one or several outer phase(s) or layer(s), wherein, based on the weight of (a), said inert hydrosoluble carrier makes up from 20 to 50% by weight, said fenofibrate makes up from 20 to 45% by weight, said hydrophilic polymer makes up from 20 to 45% by weight, and said surfactant makes up from 0.1 to 3% by weight.

('670 patent, col. 9 ll. 48-60 (emphasis added).)

1. The Parties' Proposed Constructions

Abbott proposes that I construe the term "hydrophilic polymer" to mean "any high molecular weight compound of repeating molecular units having an affinity towards water." (D.I. 238 at 5, C.A. 02-1512-KAJ; D.I. 167 at 4, C.A. 03-120-KAJ.) Abbott asserts that its proposed construction is consistent with the ordinary and customary meaning of the term. (D.I. 237 at 8, C.A. 02-1512-KAJ.) Teva and Impax each propose that I construe "hydrophilic polymer" to mean "any high molecular weight substance (greater, for example, than 300) having sufficient affinity towards water to dissolve

therein and form a gel." (D.I. 238 at 5, C.A. 02-1512-KAJ; D.I. 167 at 4, C.A. 03-120-KAJ.) Teva and Impax allege that the patentees acted as their own lexicographers because the specification clearly defines this term when it states, "[t]he expression 'hydrophilic polymer' in the invention should be taken to mean any high molecular weight substance (greater, for example, than 300) having sufficient affinity towards water to dissolve therein and form a gel." ('670 patent, col. 4 ll. 14-17; *see* D.I. 238 at 5, C.A. 02-1512-KAJ; D.I. 268 at 11, C.A. 02-1512-KAJ; D.I. 167 at 4, C.A. 03-120-KAJ.)

Abbott asserts that the construction proposed by Teva and Impax rests on a selective reading of the specification and is at odds with a passage in the specification which states "[d]epending on polymer solubility, [the hydrophilic polymer] *either* dissolves in the solution *or* forms a gel *or* a suspension having varying degrees of thickness." (D.I. 270 at 13, C.A. 02-1512-KAJ; '670 patent, col. 6 ll. 25-27 (emphasis added).) Abbott argues that the definition provided in the specification is inconsistent with the usage of the term in the passage just quoted, because the definition requires that the hydrophilic polymer both dissolve in water *and* form a gel. (D.I. 270 at 12-13, C.A. 02-1512-KAJ.) Because of this alleged inconsistency, Abbott argues that the term should be construed according to its ordinary meaning. (*Id.*)

Teva and Impax assert that Abbott's alleged inconsistency is not an actual inconsistency at all. They argue that the sentence quoted by Abbott is consistent with the specification's definition of "hydrophilic polymer" because it states that the hydrophilic polymer can either dissolve or form a gel or a suspension "in the solution,"

which is a suspension of the active ingredient in a solvent, where the solvent can be aqueous or organic. (D.I. 268 at 10-11, C.A. 02-1512-KAJ; D.I. 205 at 10, C.A. 03-120-KAJ.) Thus, Teva and Impax argue that because PVP, the identified hydrophilic polymer, is known to be soluble in water, but insoluble in many organic solvents, such as hydrocarbons or mineral oil, the term "hydrophilic polymer" is used consistently throughout the specification. (*Id.*) Therefore, they assert that "hydrophilic polymer" should be construed as explicitly defined in the specification and Abbott's proposed construction should be rejected. (*Id.*)

2. The Court's Construction

For the same reasons expressed *supra* Part IV.A.2., I find that the patentees acted as their own lexicographers and specifically defined "hydrophilic polymer" in the specification to mean "any high molecular weight substance (greater, for example, than 300) having sufficient affinity towards water to dissolve therein and form a gel." Furthermore, because I find that the specification uses this term consistently, I agree with Teva and Impax that the presumption, stating that a term should be construed according to its ordinary meaning, is overcome.

First, the specification clearly and explicitly defines the term "hydrophilic polymer," when it states "[t]he expression 'hydrophilic polymer' in the invention should be taken to mean... ." ('670 patent, col. 4 ll. 14-15.) Second, the portion of the specification identified by Abbott, discussing polymer solubility, does not establish an inconsistency with regard to how the patentees used this term in the patent. This paragraph states in its entirety:

> The significant starting product is the suspension of the active ingredient. This suspension is prepared by putting the micronized active ingredient into suspension in a solution comprising the hydrophilic polymer and, optionally, a surfactant, in solution in a solvent. If a surfactant is employed, it is put into solution in the solvent (beaker+magnetic or vane stirrer). Next, the hydrophilic polymer (PVP) is dispersed, while stirring, in the solution previously obtained. *Depending on polymer solubility, this either dissolves in the solution or forms a gel or a suspension* having varying degrees of thickness. While still stirring, the micronized active ingredient is dispersed in the form of a fine shower into the above solution or suspension, to form a homogenous suspension. The order of these steps can be reversed. *The solvent employed can be aqueous or organic* (for example ethanol). For example demineralized water can be used.

('670 patent, col. 6, ll. 16-32 (emphasis added).)

As noted by Abbott, this portion of the specification states that the hydrophilic polymer "either dissolves in the solution or forms a gel or a suspension," but does not both dissolve and form a gel, as the portion of the specification defining the term requires. Counsel for Abbott, however, was unable to articulate for the court why the statement "[t]he solvent employed can be aqueous or organic" does not relieve any perceived inconsistency in the use of the term hydrophilic polymer. (*See* D.I. 297 at 60:24-72:3, transcript of *Markman* hearing, Feb. 28, 2005.)

It is quite clear that when the polymer either dissolves or forms a gel or suspension, it is doing so in "the solution." "The solution" thus referred to is the suspension, which consists of the micronized active ingredient, the hydrophilic polymer, optionally a surfactant, and a solvent. Thus, the suspension contains a solvent. Further, the penultimate sentence in the paragraph makes clear that the solvent can be aqueous or organic. As noted by Teva, PVP, the hydrophilic polymer discussed in the quoted paragraph, "is known to be soluble in water but insoluble in many organic solvents." (D.I. 268 at 10, C.A. 02-1512-KAJ.) Thus, I agree with Teva and Impax, that

if the suspension contained an aqueous solvent, the polymer would be affected differently than if the suspension contained an organic solvent. Such a difference would explain why this portion of the specification states that the hydrophilic polymer "either dissolves in the solution *or* forms a gel *or* a suspension," rather than stating that the hydrophilic polymer dissolves *and* forms a gel, as its definition requires it to do in water. Thus, the specification does not use the term "hydrophilic polymer" in a manner inconsistent with the explicit definition provided by the patentees acting as their own lexicographers, and, therefore, I construe it to mean "any high molecular weight substance (greater, for example, than 300) having sufficient affinity towards water to dissolve therein and form a gel."

D. "granuate"

Claim 1 of the '552 patent, which is representative of the use of this term in the Stamm patents, is as follows:

> A fenofribrate composition comprising **granulates**, wherein the **granulates** comprise micronized fenofibrate having a particle size below 20 µm, inert hydrosoluble carrier particles and at least 20% by weight of at least one hydrophilic polymer, wherein the weight ratio of fenofibrate to hydrophilic polymer is from 1/10 to 4/1.

('552 patent, col. 9 l. 66-col. 10 l. 4 (emphasis added).)

1. The Parties' Proposed Constructions

Abbott proposes that I construe the term "granulate" to mean "a small grain or pellet, or small particles forming a larger unit." (D.I. 238 at 6, C.A. 02-1512-KAJ; D.I. 167 at 5, C.A. 03-120-KAJ.) Abbott argues that its proposed construction is consistent with the ordinary and customary meaning of "granulate." (D.I. 237 at 11.) Teva

proposes that I construe "granulate" to mean "the carrier to which the hydrophilic polymer and fenofibrate are adhered as single particles or as agglomerates, forming a coated-core structure." (D.I. 238 at 6, C.A. 02-1512-KAJ.) Impax proposes that I construe "granulate" to mean "the product generated from a granulation process having structures consisting of an inert hydrosoluble carrier coated with micronized fenofibrate and a hydrophilic polymer or (the remnants of) some solvent for fenofibrate. (D.I. 167 at 5-6, C.A. 03-120-KAJ.) Teva and Impax each assert that based on disclosures in the specification, the "very character of the invention" is the coated-core structure, and, as such, it should be a part of every embodiment. (D.I. 223 at 35-36, C.A. 02-1512-KAJ; D.I. 169 at 12-13, C.A. 03-120-KAJ.)

2. The Court's Construction

As earlier noted, if patent claim language has an ordinary and accustomed meaning, there is a heavy presumption that the inventor intended that meaning to apply. *Bell Atlantic*, 262 F.3d at 1268. The ordinary meaning of "granulate," as a verb, is "to form ... into ... granules." Webster's Third New International Dictionary 989 (3d ed. 1986). In the context of the Stamm patents, however, the patentee clearly intends to use the term "granulate" as a noun, synonymous with "granule," whose ordinary and plain meaning is "one of a number of particles forming a larger unit." *Id.*

Neither Teva nor Impax has presented sufficient evidence to demonstrate that the patentee intended another meaning to apply. First, as noted in the foregoing discussion, *see supra* Parts IV.A. and IV.C., when the patentees intended to give a word or phrase a particular meaning, rather than simply relying on an ordinary and customary meaning, they did so in unmistakable terms. Second, Impax's proposed

construction includes structural features of the preferred embodiment formed by the preferred process described in the specification. Specifically, Impax cites two statements in the specification regarding "[t]he composition according to the invention," which refer to methods of preparing the composition. (*See* D.I. 169 at 13, C.A. 03-120-KAJ (citing D.I. 170, Ex. 4 at 6:3-7; 6:43-47).) Each of these statements, however, is part of the detailed description of the preferred embodiment. Further, product claims are generally not limited to the process by which the product is made. *See Vanguard Prods. Corp. v. Parker Hannifin Corp.*, 234 F.3d 1370, 1372 (Fed. Cir. 2000) (noting that product claims are not generally limited to the process by which such product is made); *3M Innovative Props. Co. v. Avery Dennison Corp.*, 350 F.3d 1365, 1374 (Fed. Cir. 2003) (construing the term "embossed" as referring to an embossed pattern without "limit[ing] how the embossed pattern, as defined in the specification, is created") (emphasis omitted). Third, "granulate" is a "general descriptive term," defined subsequently in the claim which does not impose the limitations Teva and Impax seek to impart. Therefore, I construe the term "granulate," synonymously with granule, to mean "one of a number of particles forming a larger unit."

E. "composition"

Claim 1 of the '670 patent, which is representative of the use of this term in the Stamm patents,[10] is as follows:

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[10] I note, however, what appears to be an inconsistency in the prosecution history of the '405 and '881 patents. Claim 1 of the '405 patent, as originally submitted to the patent and trademark office, and claim 1 of the '881 patent, as issued, are identical. (D.I. 170, Ex. 7 at 055, C.A. 03-120-KAJ, Response and Amendment, date stamped Jan. 26, 2001; '881 patent, col. 10, ll. 44-65.) In the prosecution history of the '405 patent, the examiner required, and the applicants acquiesced in, adding the term

> An immediate-release fenofibrate **composition** comprising:
> (a) an inert hydrosoluble carrier covered with at least one layer containing fenofibrate in a micronized form having a size less than 20 µm, a hydrophilic polymer and a surfactant; and
> (b) optionally one or several outer phase(s) or layer(s), wherein, based on the weight of (a), said inert hydrosoluble carrier makes up from 20 to 50% by weight, said fenofibrate makes up from 20 to 45% by weight, said hydrophilic polymer makes up from 20 to 45% by weight, and said surfactant makes up from 0.1 to 3% by weight.

('670 patent, col. 9 ll. 48-60 (emphasis added).)

1. The Parties' Proposed Constructions

Abbott proposes that I construe the term "composition" to mean "a combination of various elements or ingredients." (D.I. 238 at 8, C.A. 02-1512-KAJ; D.I. 167 at 6, C.A. 03-120-KAJ.) Abbott argues that this meaning comports with "its ordinary meaning to a person of skill in the art." (D.I. 237 at 14, C.A. 02-1512-KAJ.) Teva proposes that I construe "composition" to mean "a fenofibrate composition, wherein the inert carrier (as described above) is a support for the micronized fenofibrate (as described below) and hydrophilic polymer (as described above), and which can take the form of granulates, tablets and capsules." (D.I. 238 at 8, C.A. 02-1512-KAJ.) Teva makes the same

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"hydrosoluble carrier" to the claim in order to clearly define the composition. (D.I. 235, Ex. 7 at 118, C.A. 02-1512-KAJ, Interview Summary dated Mar. 21, 2001 (stating that "to clearly define the composition ... [it] must comprise the micronized fenofibrate and a hydrosoluble carrier to give the claimed dissolution profile [and that w]ithout the hydrosoluble carrier (i.e. drug alone), the dissolution profile would be different.") However, in prosecuting the '881 patent, a second examiner allowed claim 1 without requiring the addition of the "hydrosoluble carrier" term. ('881 patent, col. 10, ll. 44-65.) This would suggest that the term "composition," as used in claim 1 of the '405 patent, was understood by at least one examiner to include a hydrosoluble carrier. Thus, there seems to be an inconsistency in the decisions rendered by the two examiners, because claim 1 of the '405 patent and claim 1 of the '881 patent each claim the same dissolution profile, yet the applicants were not required to amend claim 1 of the '881 patent to include the hydrosoluble carrier as well.

argument in support of its proposed construction for "composition" that it made for its proposed construction of "granulates," *see supra* Part IV.D.1., namely, that it must be construed to cover the coated-core structure. (D.I. 223 at 34-36.) Impax proposes that I construe "composition" to mean "a structure wherein an inert hydrosoluble carrier is coated with micronized fenofibrate and a hydrophilic polymer or (the remnants of) some solvent for fenofibrate." (D.I. 167 at 6, C.A. 03-120-KAJ.) Impax makes the same argument in support of its proposed construction for "composition" as it made for its proposed construction of "granulates," *see supra* Part IV.D.1., namely, that it must be construed to include the structural limitation of a coating. (D.I. 169 at 12-13, C.A. 03-120-KAJ; D.I. 205 at 11-14; C.A. 03-120-KAJ.)

2. The Court's Construction

For the same reasons expressed in construing the term "granulate," *see supra* Part IV.D.2., I find that the term "composition" should be construed according to its ordinary meaning and thus means "an aggregate, mixture, mass, or body formed by combining two or more elements or ingredients." Webster's Third New International Dictionary 466 (3d ed. 1986). As seen in claim 1 of the '670 patent, the elements which combine to form the "composition" are specifically identified. Thus, I agree with Abbott that "composition," is used "as a general descriptive term" (D.I. 270 at 6, C.A. 02-1512-KAJ) and thus I give it the ordinary meaning of "an aggregate, mixture, mass, or body formed by combining two or more elements or ingredients."

F. "tablet"

Claim 15 of the '670 patent, which is representative of the use of this term in the Stamm patents, is as follows:

The composition according to claim 1, under the form of a **tablet**.

('670 patent, col. 10, ll. 46-47 (emphasis added).)

1. The Parties' Proposed Constructions

Abbott proposes that I construe the term "tablet" to mean "an oral dosage form consisting of a small mass of medication." (D.I. 238 at 7, C.A. 02-1512-KAJ; D.I. 167 at 8, C.A. 03-120-KAJ.) Teva proposes that I construe "tablet" to mean something "made from the compression of granulates (as described below) together with an outer phase." (D.I. 238 at 7, C.A. 02-1512-KAJ.) Teva agrees that the meaning of the term encompasses an "oral dosage form." (D.I. 268 at 15, C.A. 02-1512-KAJ ("Solely insofar as this is concerned, Teva does not oppose this construction... .").) Impax proposes that I construe "tablet" to mean "an oral dosage form made from compressed structures wherein an inert hydrosoluble carrier is coated with micronized fenofibrate and a hydrophilic polymer or (the remnants of) some solvent for fenofibrate." (D.I. 167 at 8-9, C.A. 03-120-KAJ.)

Abbott argues that the term "tablet" should be construed according to its ordinary meaning to a person of skill in the art, and that the term is used in a manner consistent with its ordinary meaning. (D.I. 270 at 7, C.A. 02-1512-KAJ.) Teva and Impax make essentially the same arguments they made with regard to "composition" and "granulate," namely that the tablets are a type of "composition" which requires the coated-core structure. (*See* D.I. 268 at 15, C.A. 02-1512-KAJ; D.I. 205 at 15-16, C.A.

03-120-KAJ.) Additionally, Teva and Impax propose that the term should be construed to include the method by which it is made (i.e. compression) and the elements which comprise it (i.e., granulates with an outer phase, as proposed by Teva, or an inert hydrosoluble coated carrier, etc., as proposed by Impax). (*See* D.I. 238 at 7, C.A. 02-1512-KAJ; D.I. 167 at 8-9, C.A. 03-120-KAJ.)

2. The Court's Construction

I agree with Abbott that the term "tablet" should be accorded its ordinary and customary meaning in the art as "an oral dosage form consisting of a small mass of medication." (*See* Webster's Third New International Dictionary 2325 (3d ed. 1986) (defining "tablet" as "a small mass of medicated material").) The term "tablet" itself should not be construed to include a form of "compression" because subsequent claims in the '670 patent include this limitation. For example, claim 19 of the '670 patent is as follows:

> The composition according to claim 15 under the form of a tablet resulting from the compression of elements (a) together with an outer phase.

('670 patent, col. 10, ll. 54-56.) Thus, claim 19 specifically claims a tablet resulting from a compression, and also discloses the specific elements which comprise it. "Elements (a)," refers to the elements listed in claim 1, which include: "an inert hydrosoluble carrier covered with at least one layer containing fenofibrate in a micronized form having a size less than 20 µm, a hydrophilic polymer and a surfactant." ('670 patent, col. 9, ll. 50-53.) Thus, it would be improper to read such limitations into claim 15, when claim 19 expressly contains those precise limitations.

Additionally, Teva cites a portion of the specification which states, "[t]his tablet *preferably* results from the compression of elements (a) (under the form of granules) together with an outer phase." ('670 patent, col. 5, ll. 23-25 (emphasis added).) As indicated by emphasis, this disclosure is of a *preferred* method of making the tablet, not necessarily the only way. Thus, it would be inappropriate to limit the claim term "tablet" to a preferred embodiment. Therefore, in accordance with its customary meaning, I construe the term "tablet" to mean "an oral dosage form consisting of a small mass of medication."

G. "covered"

Claim 1 of the '670 patent, which is representative of the use of this term in the Stamm patents, is as follows:

> An immediate-release fenofibrate composition comprising:
> (a) an inert hydrosoluble carrier **covered** with at least one layer containing fenofibrate in a micronized form having a size less than 20 µm, a hydrophilic polymer and a surfactant; and
> (b) optionally one or several outer phase(s) or layer(s), wherein, based on the weight of (a), said inert hydrosoluble carrier makes up from 20 to 50% by weight, said fenofibrate makes up from 20 to 45% by weight, said hydrophilic polymer makes up from 20 to 45% by weight, and said surfactant makes up from 0.1 to 3% by weight.

('670 patent, col. 9 ll. 48-60 (emphasis added).)

1. The Parties' Proposed Constructions

Abbott proposes that I construe the term "covered" to mean "appearing on or occupying some portion of the surface of." (D.I. 238 at 10.)[11] Teva proposes that I

[11] Because this claim term appears only in the context of the asserted claims of the '670 patent, which Abbott is not asserting against Impax, Impax has not offered a proposed construction for this term and therefore all citations in Part IV.G. are to C.A.

construe "covered" to mean "to lie over; spread over; be placed on or often over the whole surface of; envelop, film, coat." (*Id.*)

2. The Court's Construction

This is a situation where both parties assert that they have proposed the ordinary meaning of the term as understood by a person of skill in the art. (*See* D.I. 237 at 16; D.I. 268 at 15-16.) Each party's proposal finds its origin in a dictionary. In fact, the same dictionary, Webster's Third New International Dictionary 524 (3d ed. 1986), contains both definitions proposed by the parties. Although both proposed constructions may seem equally applicable if viewing the claim term in isolation, it is clear when reading the claim term in the context of the claim itself that the patentees intended to impart the construction as proposed by Teva. The claim language states, "covered with at least one *layer*." ('670 patent, col. 9, ll. 50-51 (emphasis added).) The addition of the word "layer" makes it clear that the patentees did not intend for the hydrosoluble carrier to be covered "here and there" with micronized fenofibrate, but rather they intended it to be "enveloped" with micronized fenofibrate, to the extent that the micronized fenofibrate is discernable as a "layer." A covering "here and there" would not be discernable as a "layer," as that term is used in the '670 patent. Additionally, in the Summary of the Invention section, the specification describes that the granules can be coated "with one or several ... layer(s)." ('670 patent, col. 3, ll. 39-40.) Although in a slightly different context, this disclosure indicates that the patentees intended that the composition could have several layers on the inert hydrosoluble

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02-1512-KAJ.

carrier core. If "covered" were construed to mean that the inert hydrosoluble carrier were coated "here and there," it is difficult to see how that could be described as multiple "layers," in the context of the disclosures in the specification and the claim language. Thus, I find that, in the context of being "covered with at least one layer," the ordinary and customary meaning of the term "covered" is "enveloped," as in "to be placed on or over the whole surface of."

H. "dissolution medium constituted by water with 2% by weight polysorbate 80 or 0.025 M sodium lauryl sulfate"

Claim 1 of the '881 patent, which is representative of the use of this term in the Stamm patents, is as follows:

> A composition comprising micronized fenofibrate, wherein the composition has a dissolution of at least 10% in 5 minutes, 20% in 10 minutes, 50% in 20 minutes and 75% in 30 minutes, as measured using the rotating blade method at 75 rpm according to the European Pharmacopoeia, in a **dissolution medium constituted by water with 2% by weight polysorbate 80 or 0.025 M sodium lauryl sulfate**.

('881 patent, col. 10 ll. 44-65 (emphasis added).)

1. The Parties' Proposed Constructions

Abbott proposes that I construe the term "dissolution medium constituted by water with 2% by weight polysorbate 80 or 0.025 M [i.e. molar] sodium lauryl sulfate" to mean "one of two solutions in water: one with a concentration of 2% by weight polysorbate 80 and one with a concentration of 0.025 molar sodium lauryl sulfate." (D.I. 270 at 13.) Teva proposes that I find that this phrase "is indefinite and incapable of construction." (D.I. 223 at 38.)[12]

[12] Although this term appears in several claims asserted against Impax, Impax has not disputed Abbott's proposed construction of this term in their briefs on claim

Teva asserts that this claim term is indefinite because it means that "an unknown amount of 0.025M sodium lauryl sulfate solution is added to an unknown amount of water." (D.I. 223 at 37.) In support, Teva cites to two disclosures in the specification, one where the dissolution medium is defined as consisting "of 1000 ml of water to which 0.025M sodium lauryl sulfate sodium is added..." ('881 patent, col. 2 ll. 28-30) and one which describes "a dissolution medium constituted by water with 0.025M sodium lauryl sulfate" ('881 patent, col. 3 ll. 56-57). Teva asserts that in each of these disclosures, an unknown amount of 0.025M sodium lauryl sulfate solution is combined with, in the first instance 1000 ml of water, and in the second instance, an unknown amount of water. (D.I. 223 at 28.)

In response, Abbott asserts that a person of skill in the art, would understand the claim language and the disclosures in the specification as designating a particular concentration of sodium lauryl sulfate, specifically 0.025M sodium lauryl sulfate. (D.I. 270 at 14.) Further, Abbott asserts that Teva's own expert, Ms. Gray, interpreted this claim term to require a specific concentration, and that she dissolved a sufficient amount of sodium lauryl sulfate in water to obtain 1 liter of a 0.025 molar solution. (*Id.* at 14-15.)

Teva counters that "Plaintiff's proposed construction ... is legally untenable because it eliminates the term "with" from the claim element... ." (D.I. 268 at 9 (emphasis omitted).) Thus, Teva asserts that the claim term is "fatally ambiguous." (*Id.*)

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construction, and as such, all citations in Part IV.H. are to C.A. 02-1512-KAJ. (*See* D.I. 169, 205.)

2. The Court's Construction

Although Teva's "grammatical savvy" is noted, I believe that any ambiguity created by the word "with" was likely an inadvertent error. *See Merck*, 395 F.3d at 1371 n.8 (finding that the omission of the word "about" was likely an inadvertent error, rather than an intentional product of claim drafting). In the context of the Stamm patents, the claim term is understood by persons of ordinary skill in the art as expressing a concentration, rather than a specific volume. (*See* D.I. 267, Ex. K at 4, 5, Expert Report of Vivian Gray (noting that Ms. Gray used 1200 ml of dissolution medium at a concentration of "0.025 M Sodium Lauyrl Sulfate" to test samples provided by Fournier).) Although Ms. Gray also stated that "the wording describing the 0.025 M Sodium Lauryl Sulfate medium was not clear," she was able to test the samples according the methodology disclosed in the Stamm patents. (*Id.* at 5.) Furthermore, Abbott's expert, Dr. Amidon, stated that it is inconceivable that anyone of skill in the art would interpret the claim term in the manner suggested by Teva.[13] (*See* D.I. 236, Ex. 11 at 339:4-5, Dep. of Dr. Amidon, Nov. 19, 2004.) Thus, the claim term is not indefinite because one of ordinary skill in the art would read the term as requiring a concentration of 0.025 molar sodium lauryl sulfate. Therefore, I construe "dissolution medium constituted by water with 2% by weight polysorbate 80 or 0.025 M sodium

[13] Although at the *Markman* hearing, counsel for Teva argued that Ms. Gray used 0.025 molar sodium lauryl sulfate because the prosecution history discussed testing under those conditions (D.I. 297 at 81:21-82:3, C.A. 02-1512-KAJ), her methodology is persuasive evidence that a person of ordinary skill in the art practicing the invention claimed in the patents would do the same thing, and look to the prosecution history to clarify any perceived ambiguity. Although I do not find that the claim term is ambiguous, I merely note that Ms. Gray and Dr. Amidon's opinions are instructive as to how one of ordinary skill in the art would view the claim term.

lauryl sulfate" to mean "one of two solutions in water: one with a concentration of 2% by weight polysorbate 80 and one with a concentration of 0.025 molar sodium lauryl sulfate."

V. CONCLUSION

For the reasons stated, the terms in dispute are construed as follows:

CLAIM TERM/PHRASE	THE COURT'S CONSTRUCTION
"inert hydrosoluble carrier"	The Court construed the claim term to mean "any excipient, generally hydrophilic, pharmaceutically inert, crystalline or amorphous, in a particulate form, not leading to a chemical reaction under the operating conditions employed, and which is soluble in an aqueous medium, notably in a gastric acid medium."
"hydrosoluble carrier"	The Court construed the claim term to mean "any excipient, generally hydrophilic, crystalline or amorphous, in a particulate form, and which is soluble in an aqueous medium, notably in a gastric acid medium."
"hydrophilic polymer"	The Court construed the claim term to mean "any high molecular weight substance (greater, for example, than 300) having sufficient affinity towards water to dissolve therein and form a gel."
"granulate"	The Court construed the claim term to mean "one of a number of particles forming a larger unit."
"composition"	The Court construed the claim term to mean "an aggregate, mixture, mass, or body formed by combining two or more elements or ingredients."

"tablet"	The Court construed the claim term to mean "an oral dosage form consisting of a small mass of medication."
"covered"	The Court construed the claim term to mean "enveloped," as in "to be placed on or over the whole surface of."
"dissolution medium constituted by water with 2% by weight polysorbate 80 or 0.025 M sodium lauryl sulfate"	The Court construed the claim term to mean "one of two solutions in water: one with a concentration of 2% by weight polysorbate 80 and one with a concentration of 0.025 molar sodium lauryl sulfate."

An appropriate order will issue.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT LABORATORIES, an Illinois corporation, FOURNIER INDUSTRIE ET SANTÉ, a French corporation, and LABORATORIES FOURNIER S.A., a French corporation, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., a Delaware Corporation, Defendant.	)	Civil Action No. 02-1512-KAJ (Consolidated)
TEVA PHARMACEUTICALS USA, INC., a Delaware corporation, and TEVA PHARMACEUTICAL INDUSTRIES LIMITED, an Israeli corporation, Counterclaim-Plaintiffs, v. ABBOTT LABORATORIES, an Illinois corporation, FOURNIER INDUSTRIE ET SANTÉ, a French corporation, and LABORATORIES FOURNIER S.A., a French corporation, Counterclaim-Defendants.	)	

ABBOTT LABORATORIES, an Illinois corporation, FOURNIER INDUSTRIE ET SANTE, a French corporation, and LABORATORIES FOURNIER S.A., a French corporation,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 03-120-KAJ (Consolidated)
IMPAX LABORATORIES, INC., a Delaware corporation,	)	
Defendant.	)	

ORDER

For the reasons set forth in the Memorandum Opinion issued today in this matter,

IT IS HEREBY ORDERED that the disputed claim terms in U.S. Patent No. 6,074,670, U.S. Patent No. 6,589,552 B2, U.S. Patent No. 6,277,405 B1, and U.S. Patent No. 6,652,881 B2 are construed as follows:

CLAIM TERM/PHRASE	THE COURT'S CONSTRUCTION
"inert hydrosoluble carrier"	The Court construed the claim term to mean "any excipient, generally hydrophilic, pharmaceutically inert, crystalline or amorphous, in a particulate form, not leading to a chemical reaction under the operating conditions employed, and which is soluble in an aqueous medium, notably in a gastric acid medium."
"hydrosoluble carrier"	The Court construed the claim term to mean "any excipient, generally hydrophilic, crystalline or amorphous, in a particulate form, and which is soluble in an aqueous medium, notably in a gastric acid medium."
"hydrophilic polymer"	The Court construed the claim term to mean "any high molecular weight substance (greater, for example, than 300) having sufficient affinity towards water to dissolve therein and form a gel."
"granulate"	The Court construed the claim term to mean "one of a number of particles forming a larger unit."
"composition"	The Court construed the claim term to mean "an aggregate, mixture, mass, or body formed by combining two or more elements or ingredients."
"tablet"	The Court construed the claim term to mean "an oral dosage form consisting of a small mass of medication."
"covered"	The Court construed the claim term to mean "enveloped," as in "to be placed on or over the whole surface of."

"dissolution medium constituted by water with 2% by weight polysorbate 80 or 0.025 M sodium lauryl sulfate"	The Court construed the claim term to mean "one of two solutions in water: one with a concentration of 2% by weight polysorbate 80 and one with a concentration of 0.025 molar sodium lauryl sulfate."

UNITED STATES DISTRICT JUDGE

Wilmington, Delaware
April 22, 2005