IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

SHIRE LLC, SUPERNUS PHARMACEUTICALS, INC.

Plaintiffs,

v. // **CIVIL ACTION NO. 1:11CV55**
LEAD CASE
(Judge Keeley)

MYLAN PHARMACEUTICALS INC. and MYLAN INC.,

Defendants.

SHIRE LLC, SUPERNUS PHARMACEUTICALS, INC., SHIRE DEVELOPMENT INC.

Plaintiffs,

v. // **CIVIL ACTION NO. 1:11CV201**
MEMBER CASE
(Judge Keeley)

MYLAN PHARMACEUTICALS INC. and MYLAN INC.,

Defendants.

MEMORANDUM OPINION AND ORDER CONSTRUING PATENT CLAIMS

This patent infringement case involves two United States Patents issued to the plaintiffs, Shire L.L.C., Supernus Pharmaceuticals, Inc., and Shire Development, Inc. ("Shire"), specifically U.S. Patent Nos. 6,287,599 ("the '599 patent"), and 6,811,794 ("the '794 patent") (collectively, the "patents-in-suit"). Shire uses the pharmaceutical compositions and methods described in these patents to produce INTUNIV®, an extended-

release, guanfacine-based drug for treating Attention Deficit Hyperactivity Disorder ("ADHD"). Currently pending before the Court is the construction of two disputed terms or phrases found in the asserted claims of the patents-in-suit. After careful consideration of the parties' submissions and the arguments at the Markman hearing,[1] the Court construes the disputed terms as follows.

I. BACKGROUND

In a letter dated February 8, 2011, Mylan notified Shire that it had filed an Abbreviated New Drug Application ("ANDA") seeking United States Food and Drug Administration ("FDA") approval to market a generic version of the 4 mg dosage form of INTUNIV® in the United States. In addition to filing its ANDA, Mylan filed a "paragraph IV certification" with the FDA alleging that the two patents issued to Shire for the 4 mg dosage form of INTUNIV® are invalid and would not be infringed by Mylan's manufacture, use or

[1] In addition to considering the parties' briefs and oral arguments, the Court has also had the benefit of reviewing several decisions by other district courts that have construed many of the same terms and phrases in the patents-in-suit. Specifically, the District of Delaware issued a construction opinion in Shire LLC v. Teva Pharm. USA Inc. et al, No. 10-329, 2012 WL 975694 (D. Del. Mar. 22, 2012), on March 22, 2012. Shortly thereafter, on June 1, 2012, the Northern District of California issued a construction decision in Shire LLC v. Impax Labs Inc. et al., No. 10-5467, 2012 WL 1980803 (N.D. Cal. June 1, 2012). Most recently, on November 13, 2012, the District of Colorado issued a construction opinion in Shire LLC v. Sandoz Inc., No. 1:11-01110, 2012 WL 5494944 (D. Colo. Nov. 13, 2012).

sale of the new drug described in its ANDA. In response, Shire filed the first of two patent infringement actions pursuant to the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2)(A), Civil Action No. 1:11CV55, contending that the product described in Mylan's ANDA infringes claims in the two patents-in-suit.

More than six months later, in a letter dated October 31, 2011, Mylan notified Shire that it had amended its ANDA to include 1 mg, 2 mg, and 3 mg dosage forms of INTUNIV®. Mylan further advised Shire that it had filed Paragraph IV certifications for the '599 and'794 formulation patents directed to these new dosages. In response, Shire filed the second patent infringement action, Civil Action No. 1:11CV201, alleging that Mylan's new 1 mg, 2 mg, and 3 mg ANDA products infringed the patents-in-suit.[2] By Order entered on February 21, 2012, the Court consolidated Shire's two cases against Mylan.

The parties have agreed that any claim term that appears in the claims of both the '599 and the '794 patents should have the same meaning in each patent. Prior to the Markman hearing, the parties also submitted five agreed claim constructions, (dkt. no.

[2] This suit originally included claims for infringement of U.S. Patent No. 5,854,290, which have since been dismissed by consent decree. (Dkt. No. 138).

115), and reached an agreement on two terms that were originally identified as disputed. Two terms and phrases from the asserted claims remain in dispute: (1) the phrase "polymer that swells at a pH in excess of 5.5," which appears in Claim 2 of the '599 patent and Claims 4 and 9 of the '794 patent; and (2) the term "about," which appears in Claims 18-23 of the '599 patent.

II. LEGAL STANDARDS

The construction of patent claims presents a matter of law governed by federal statutes and the decisions of the Supreme Court of the United States and the United States Court of Appeals for the Federal Circuit. See Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995). When interpreting the meaning of a claim, a court may consider the claims, specifications, and prosecution histories as intrinsic evidence. Id. (quoting Unique Concepts, Inc. v. Brown, 939 F.2d 1558, 1561 (Fed. Cir. 1991)). The invention itself, and the scope of a patentee's right of exclusion, will be defined by the patent's claims. Phillips v. AWH Corporation, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quoting Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1115 (Fed. Cir. 2004)); see also Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("[W]e look to the words of the claims themselves . . . to define

the scope of the patented invention."). The description of an invention in the claims, therefore, limits the scope of the invention. Id.

Claim terms should be construed according to their "ordinary and customary" meaning, which 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." Id. at 1313. Claim construction, therefore, requires a court to determine how a person of ordinary skill in the art would have understood the disputed term or phrase in question. "Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." Id.

When construing patent claims, a court must consider the context of the entire patent, including both asserted and unasserted claims. Id. at 1314. Because a patent will ordinarily use patent terms consistently, "the usage of a term in one claim can often illuminate the meaning of the same term in other claims." Id. at 1314. Accordingly, "[d]ifferences among claims" can provide insight into "understanding the meaning of particular claim terms," and "the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in

question is not present in the independent claim." Id. at 1314-15 (citing Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 910 (Fed. Cir. 2004)).

Aside from the claims themselves, the specification in the patent often provides the "'best source for understanding a technical term.'" Id. at 1315 (quoting Multiform Desiccants,Inc. v. Medzam, Ltd., 133 F.3d 1473, 1478 (Fed. Cir. 1998)). Pursuant to 35 U.S.C. § 112, an inventor must use the specification to describe his claimed invention in "full, clear, concise, and exact terms." As such, "[t]he claims of a patent are always to be read or interpreted in the light of its specifications." Schriber-Schroth Co. v. Cleveland Trust Co., 311 U.S. 211, 217 (1940).

An inventor may alter the "ordinary and customary" meaning of a term, however, by acting as his own lexicographer. This occurs, for example, when the patent specification defines a term in a manner different from its ordinary and customary meaning. Phillips, 415 F.3d at 1316. 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." Id. at 1317.

Nevertheless, a court may not import a limitation into the claims from the specification. Id. at 1323. Moreover, the Federal

Circuit has "repeatedly warned" against limiting the claims to the embodiments specifically described in the specification. Id. In other words, a court should not construe the patent claims as being limited to a single embodiment simply because the patent describes only one embodiment. Id. (citing Gemstar-TV Guide Int'l Inc. v. Int'l Trade Comm'n, 383 F.3d 1352, 1366 (Fed. Cir. 2004)).

The prosecution history of a patent may also provide insight into the meaning of a term or phrase. "Like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent." Id. at 1317. The inventor's limitation of the invention during the patent's prosecution may suggest that a claim has a narrower scope than it otherwise might have. Id.

Finally, when determining the ordinary and customary meaning of a term, a court must be cautious when considering extrinsic evidence, such as expert testimony, dictionaries, and learned treatises. Id. Nevertheless, such sources may be reliable if they were publicly available and show "'what a person of skill in the art would have understood disputed claim language to mean.'" Id. at 1314 (quoting Innova, 381 F.3d at 1116).

It is with these legal principles in mind that the Court now turns to the construction of the two disputed terms or phrases among the asserted claims of the patents-in-suit.

III. ANALYSIS

A. "polymer that swells at a pH in excess of 5.5"

The phrase "polymer that swells at a pH in excess of 5.5" appears in dependent Claim 2 of the '599 patent and dependent Claims 4 and 9 of the '794 patent. The parties dispute the appropriate construction (or lack thereof) applicable to this term:

Mylan's Proposed Construction	**Shire's Proposed Construction**
A molecule with many units joined to each other through chemical covalent bonds, often in a repeating manner, which expands to a greater extent in surrounding media having a pH above 5.5 than in media having a pH of 5.5 or below.	No construction (plain and ordinary meaning) **OR** a molecule with many units joined to each other through chemical bonds, often in a repeating manner, which expands at a pH above 5.5.

The proposed constructions offer substantially similar definitions of the word "polymer." The gravamen of the parties' dispute lies in Mylan's use of comparative language to describe how that polymer "swells."

1. Judicial Estoppel

Prior to analyzing these claims, the Court first considers Mylan's argument that Shire should be judicially estopped from

opposing Mylan's construction of the phrase "polymer that swells at a pH in excess of 5.5." According to Mylan, Shire earlier advocated a comparative-swelling construction of this term, substantially similar to Mylan's proposal here, in its Markman briefing before the District of Colorado in Shire LLC v. Sandoz Inc., No. 1:11-01110, (Dkt. Nos. 89, 94) (D. Colo.).[3] Characterizing Shire's current opposition to such a construction as "litigation-inspired" and "inconsistent," Mylan asks the Court to invoke the doctrine of judicial estoppel to prevent Shire from "blowing hot and cold as the occasion demands." (Dkt. No. 130 at 4-5, 7).

The doctrine of judicial estoppel forbids a party from taking a position inconsistent with one successfully asserted by that same party in a prior proceeding. Lowery v. Stovall, 92 F.3d 219, 223 (4th Cir. 1996). The doctrine "can apply to claim construction arguments," Fitness Quest Inc. v. Monti, 330 F. App'x 904, 914 (Fed. Cir. 2009) (citation omitted), and its applicability is "a matter of regional circuit law." Minn. Mining & Mfg. Co. v. Chemque, Inc., 303 F.3d 1294, 1302-03 (Fed. Cir. 2002) (citation

[3] Shire offered the following construction in the District of Colorado action: "molecule with many units joined to each other through chemical covalent bonds, often in a repeating manner, which expands in an environment which has a pH above 5.5 relative to an environment that has a pH of 5.5 or below." (Dkt. No. 116-17 at 36).

omitted). The Fourth Circuit has outlined three prerequisites for judicial estoppel:

> First, the party sought to be estopped must be seeking to adopt a position that is inconsistent with a stance taken in prior litigation. The position at issue must be one of fact as opposed to one of law or legal theory. Second, the prior inconsistent position must have been accepted by the court. Lastly, the party against whom judicial estoppel is to be applied must have intentionally misled the court to gain unfair advantage. This bad faith requirement is the determinative factor.

Zinkand v. Brown, 478 F.3d 634, 638 (4th Cir. 2007) (internal citations and quotation marks omitted).

There is no question that the District of Colorado neither construed nor addressed the phrase "polymer that swells at a pH in excess of 5.5" in its Markman ruling. See Shire LLC v. Sandoz Inc., No. 1:11-01110, 2012 WL 5494944 (D. Colo. Nov. 13, 2012). Thus, Shire's prior position was not "accepted by the court" and does not fulfill the second requirement of judicial estoppel. Zinkand, 478 F.3d at 638 (quoting Lowery, 92 F.3d at 224); see also New Hampshire v. Maine, 532 U.S. 742, 750-51 (2001) ("Absent success in a prior proceeding, a party's later inconsistent position introduces no risk of inconsistent court determinations, and thus poses little threat to judicial integrity." (internal citations and quotations marks omitted)). As the doctrine is inapplicable to this

case, Shire is not precluded from opposing Mylan's proposed construction of the disputed term.

2. The Claims

The Court begins its analysis by looking to the "actual words of the claim," Becton, Dickinson and Co. v. Tyco Healthcare Group, LP, 616 F.3d 1249, 1254 (Fed. Cir. 2010), as well as the context in which the disputed term appears. Phillips, 415 F.3d at 1314. Patent claims come in two general forms: independent and dependent. 35 U.S.C. § 112(c). Independent claims do not refer to any other claim of the patent and are read separately to determine their scope. Intamin, Ltd. v. Magnetar Tech. Corp., 623 F.Supp.2d 1055, 1065 (C.D. Cal. 2009). Dependent claims, in contrast, refer to at least one other claim, include all of the limitations of the claim to which they refer, and specify a further limitation on that claim. 35 U.S.C. § 112(d); see also Monsanto Co. v. Syngenta Seeds, Inc., 503 F.3d 1352, 1357 (Fed. Cir. 2007).

The disputed phrase "polymer that swells at a pH in excess of 5.5" appears in three dependent claims of the patents-in-suit. A representative example of its use appears in Claim 2 of the '599 patent, which is, in turn, dependent on Element (c) of Claim 1:

Claim 1 (Independent):

A pharmaceutical composition, comprising:

(a) at least one pharmaceutically active agent that is pH dependent;
(b) at least one non pH dependent sustained release agent;
(c) <u>at least one pH dependent agent</u> that increases the rate of release of said at least one pharmaceutically active agent from the tablet at a pH in excess of 5.5

Claim 2 (Dependent):

The composition of claim 1 wherein said at least <u>one pH dependent agent</u> is at least one **<u>polymer that swells at a pH in excess of 5.5.</u>**

'599 patent at Cls. 1-2 (emphasis added).

The parties have stipulated, and the Court agrees, that Element (c) of Claim 1, the independent claim, should be construed as:

> [Ingredient] that is neither the non-pH dependent sustained release agent [Element (b) of Claim 1] nor the pharmaceutically active agent [Element (a) of Claim 1] and that increases the rate of release of the pharmaceutically active agent from a tablet more in an environment that has a pH above 5.5 than in an environment that has a pH of 5.5 or below.

(Dkt. No. 115 at 2 (first alteration in original)).[4]

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[4] Each district court that has construed this term has adopted a variation of this stipulated construction. <u>Shire LLC v. Sandoz Inc.</u>, No. 1:11-01110, 2012 WL 5494944, at *4 (D. Colo. Nov. 13, 2012) ("agent that increases the rate of release of the pharmaceutically active agent from a tablet in an environment that has a pH above 5.5 relative to an environment that has a pH of 5.5 or below"); <u>Shire LLC v. Impax Labs Inc. et al.</u>, No. 10-5467, 2012 WL 1980803, at *7 (N.D. Cal. June 1, 2012) ("Substance that is not the non-pH dependent sustained release agent, and that increases the rate of release of the drug from the

According to Mylan, the claims support its proposed construction because the "polymer that swells" must be a "pH dependent agent." '599 patent at Cl. 2. The "pH dependent agent," in turn, must "increase[] the rate of release of the pharmaceutically active agent from a tablet more in an environment that has a pH above 5.5 than in an environment that has a pH of 5.5 or below." (Dkt. No. 115 at 2). Mylan therefore deduces that, in order to achieve this intended purpose, the polymer itself must swell to a greater extent in an environment with a pH above 5.5 than in an environment with a pH of 5.5 or below. In essence, then, Mylan urges the Court to find that polymer's role as a "pH dependent agent" imparts a separate, individualized pH-dependency limitation into the phrase "polymer that swells."

Shire, on the other hand, contends that, under the plain terms of the patent, the only requirement for an ingredient to qualify as a "pH dependent agent" is that it release the active pharmaceutical

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composition in an environment having a pH above 5.5, as compared to when the composition is an environment of pH 5.5 or below."); Shire LLC v. Teva Pharm. USA Inc. et al, No. 10-329, 2012 WL 975694, at *7 (D. Del. Mar. 22, 2012) ("agent that is neither the non-pH dependent sustained release agent nor the pharmaceutically active agent, and that increases the rate of release of the pharmaceutically active agent from a tablet more in an environment that has a pH above 5.5 than in an environment that has a pH of 5.5 or below"). For the reasons more fully described in those opinions, the Court **ADOPTS** the parties' agreed construction of this term.

ingredient in a pH-dependent manner. In other words, as long as the polymer in question increases the rate of release of the pharmaceutically active agent more in an environment that has a pH above 5.5 than in an environment with a pH of 5.5 or below, as required by Claim 1, and expands at a pH in excess of 5.5, as required by Claim 2, it is irrelevant whether that polymer exhibits pH-dependent swelling. Shire contends that Mylan's proposed construction imports an unwarranted limitation into the unambiguous language of the claims.

The relevant claims are fairly straightforward. In keeping with ordinary rules of construction for dependent claims, Claim 2 of the '599 patent "contain[s] a reference to a claim previously set forth and then specif[ies] a further limitation of the subject matter claimed." 35 U.S.C § 112(d). In patent parlance, Claim 2 first uses the definite article "said" to refer to the antecedent element of the "at least one pH dependent agent" described in Element (c) of Claim 1. See generally Robert C. Faber, Landis on Mechanics of Patent Claim Drafting § 3:11 at 3–49 (2007) (discussing "reference-back word[s]" such as "said," which must be followed by "the actual antecedent which the reference-back word implies"); see also SanDisk Corp. v. Kingston Technology Co., Inc., 695 F.3d 1348, 1360 (Fed. Cir. 2012). Claim 2 then specifically

limits the "at least one pH dependent agent" of Claim 1 to "at least one polymer that swells at a pH in excess of 5.5." '599 patent at Cl. 2.

The Court must construe dependent claims "to incorporate by reference all the limitations of the claim to which it refers." 35 U.S.C. § 112(d). Here, as Claim 2 covers iterations of the claimed composition in which the "pH dependent agent" of Claim 1 is a "polymer that swells," the relevant polymer must satisfy the limitations of that antecedent claim. In other words, per the parties' agreed construction of Element (c) of Claim 1, the polymer must be an "[ingredient] that . . . increases the rate of release of the pharmaceutically active agent from a tablet more in an environment that has a pH above 5.5 than in an environment that has a pH of 5.5 or below." (Dkt. No. 115 at 2 (alteration in original)). As this construction shows, the independent claim does not require the relevant "ingredient" to exhibit any specific, individual characteristics. To the contrary, the only limitation is that the "pH dependent agent," whatever its individual properties, "increase[] the rate of release of the pharmaceutically active agent" in a pH-dependent way. Id.

As for the actual phrase "polymer that swells at a pH in excess of 5.5," Claim 2 - unlike Claim 1 and even dependent Claim

4[5] - does not explicitly invite a comparison by describing an "increase[]" in swelling at a pH greater than 5.5. Compare '599 patent at Cls. 1, 4, with id. at Cl. 2. To the contrary, it provides only that the polymer "swell[] at a pH in excess of 5.5." Id. at Cl. 2. Notably, then, although the patentees used the definite term "increases" to create a comparative limitation in Claims 1 and 4, they omitted any similar words of comparison in Claim 2. See Phillips, 415 F.3d at 1314 ("Differences among claims can . . . be a useful guide in understanding the meaning of particular claim terms."). Indeed, the disputed phrase appears to mean just what it says: namely, that the polymer must swell at a pH greater than 5.5. The claims themselves do not further suggest that the swelling be more than, less than, or the same as that which occurs at a pH of 5.5 and below.

Mylan does not dispute the meaning a person of ordinary skill in the art would ascribe to any of the individual words or phrases of these claims. Rather, it paints its proposed construction as the natural result of the polymer's role as the independent claim's "pH dependent agent." Relying on the opinion of its expert, Dr. Kinam

[5] Claim 4 of the '599 patent provides: "The composition of claim 1 wherein said at least one pH dependent agent is at least one agent that increases the solubility of said at least one pharmaceutically active agent at a pH of greater than 5.5." '599 patent at Cl. 4 (emphasis added).

Park, Ph.D. ("Dr. Park"),[6] it contends that polymers, as a general rule, release more active agents the larger they swell. (Dkt. No. 116-1 at 9). In light of this scientific principle, Mylan argues, the claimed polymer, in order to release the pharmaceutically active agent in the relative manner required by the independent claim, would have to swell to a greater extent at a pH above 5.5 than it would at a pH of 5.5 and below. (Dkt. No. 116 at 19). Mylan thus concludes that "[a] person of ordinary skill in the art therefore would understand that the [disputed] phrase . . . refers to a polymer that exhibits pH-dependent swelling." (Dkt. No. 130 at 10-11).

The Court may rely on expert testimony as necessary to assist it in understanding the underlying technology of a patent. Pitney Bowes, Inc. v. Hewlett–Packard Company, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing Vitronics Corp., 90 F.3d at 1582); see also Phillips, 415 F.3d at 1317-18. It is clear, however, that such evidence may not be used "for the purpose of varying or contradicting the terms of the claims." Markman, 52 F.3d at 981. Expert reports and other extrinsic evidence, in other words,

[6] Mylan submitted Dr. Park's declaration in conjunction with its briefing and declined to call him live at the Markman hearing. The Court notes that it was therefore unable to make credibility determinations or evaluate Dr. Park's report in light of cross-examination.

"cannot add, subtract, or vary the limitations of the claims." Id. at 985; see also Bell Atl. Network Servs., Inc. v. Covad Comm'n Group, Inc., 262 F.3d 1258, 1269 (Fed. Cir. 2001) ("[A]dditional extrinsic evidence [such] as expert testimony . . . may not be used to vary, contradict, expand, or limit the claim language from how it is defined, even by implication, in the specification or file history.").

Mylan's reliance on Dr. Park's opinion is unpersuasive. As an initial matter, Mylan presents its proposed construction as one of basic scientific truths, i.e., that "polymers release [] active agents via swelling," and consequently, that the claimed polymer "must" swell in a pH-dependent manner. (Dkt. No. 130 at 10). Dr. Park, however, does not speak in such definite terms: without specific citation to independent authority, he states only that polymers, "generally speaking," release more active ingredients the greater they swell. (Dkt. No. 116-1 at 9). At this stage of the case, this general statement of scientific principle alone does not warrant a finding that those skilled in the art would generally restrict the definition of "polymer[s] that swell[] at a pH in excess of 5.5" within the context of these patents to those polymers that swell in a pH-dependent manner.

The task of the Court is to "define[] the claim with whatever specificity and precision is warranted by the language of the claim and the evidence bearing on the proper construction." PPG Indus. v. Guardian Indus. Corp., 156 F.3d 1351, 1355 (Fed. Cir. 1998). The claim language itself is silent as to the pH-dependent or independent nature of the relevant polymer's swelling; consequently, Mylan's restrictive construction finds no foothold in the "actual words of the claim." Becton, 616 F.3d at 1254. The Court is thus reluctant to, as Mylan suggests, rely on extrinsic evidence to adopt a construction that might define the disputed term with greater specificity than is warranted by the claim language.

3. The Specifications

Having concluded that the plain language of the claims does not explicitly include the limitation that the "polymer that swells" do so to a greater extent in an environment with a pH above 5.5 than in an environment with a pH of 5.5 or below, the Court turns to the specifications for guidance. Phillips, 415 F.3d at 1317. The specification of the '599 patent, which again serves as a representative example, identifies "polymers that swell at a pH in excess of 5.5" as one of three non-exclusive categories of

"pH-dependent agents that increase the rate of release of the at least one pharmaceutically active agent from the tablet at a pH in excess of 5.5." '599 patent at col. 2, ll. 8-11.[7] Although the specification does not provide an express definition of the disputed term, it sets forth several examples: "Polymers that swell at a pH in excess of 5.5 include, but are not limited to, acrylic acid copolymers, sodium alginate, carrageenan, alginic acid, pectin, and sodium carboxymethyl cellulose." '599 patent at col 2, ll. 19-22.

Mylan relies on extrinsic sources to argue that the examples from the specification provide support for its proposed construction. Through Dr. Park, it contrasts the listed examples of "polymers that swell at a pH in excess of 5.5" with the listed examples of "non pH dependent sustained release agents." '599

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[7] In full, this section states:

> pH-dependent agents that increase the rate of release of the at least one pharmaceutically active agent from the tablet at a pH in excess of 5.5 include, but are not limited to, polymers that swell at a pH in excess of 5.5, and enteric agents, and/or agents that increase the solubility of the at least one pharmaceutically active agent at a pH greater than 5.5, by maintaining an acidic microenvironment in the tablet, e.g., an organic acid. The at least one pH-dependent agent is present in the composition in an amount of from about 0.5 wt. % to about 40 wt. %, preferably from about 1 wt. % to about 20 wt. %.

'599 patent at col. 2, ll. 8-18.

patent at col. 1, ll. 58-67, col. 2, ll. 19-22. Mylan contends that the examples in the former category consist of polymers with carboxyl functional groups, which swell more at higher pH values, or sulfate functional groups, which can be "readily complexed" to exhibit pH-dependent swelling. (Dkt. No. 116-1 at 9). Conversely, the latter category of "non pH dependent sustained release agents," i.e., ingredients that slow the release of the pharmaceutically active agent irrespective of pH,[8] includes at least one polymer, hydroxypropylmethylcellusose, that exhibits pH-independent swelling. Id. at 10. According to Mylan, the juxtaposition of these two categories establishes that the inventors were "clearly aware" that pH-independent polymers existed and deliberately elected to identify them as "non pH dependent [] agents" but not "polymers that swell at a pH in excess of 5.5." (Dkt. No. 116 at 20-21).

The specification is often described as "'the single best guide to the meaning of a disputed term.'" Phillips, 415 F.3d at 1315 (quoting Vitronics, 90 F.3d at 1582). Nevertheless, "the scope of patent protection" is defined by "[t]he claims, not

[8] The parties have stipulated that the phrase "non-pH dependent sustained release agent" means "[ingredient] that slows release of the pharmaceutically active agent over an extended period of time regardless of gastrointestinal pH, and that is not the pH dependent agent." (Dkt. No. 115 at 2 (alteration in original)). The Court **ADOPTS** this construction.

specification embodiments." Kara Technology Inc. v. Stamps.com Inc., 582 F.3d 1341, 1348 (Fed. Cir. 2009). The specification may only narrow the meaning of a claim term in certain limited circumstances, SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1340-41 (Fed Cir. 2001), and a claim generally will not be confined to its embodiments "unless the patentee has demonstrated a 'clear intention' to limit the claim's scope with 'words or expressions of manifest exclusion or restriction.'" I4I Ltd. P'ship v. Microsoft Corp, 598 F.3d 831, 843 (Fed. Cir. 2010) (quoting Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 907-08 (Fed. Cir. 2004)).

Here, the specification contains no language that would unequivocally narrow the claims to require the "polymer that swells" to exhibit pH-dependent swelling. To the contrary, the specification clearly states that the representative examples of "polymers that swell" do not constitute an exhaustive list. '599 patent at col 1, ll. 19-20 ("Polymers that swell at a pH in excess of 5.5 include, but are not limited to . . . ." (emphasis added)). To the extent that Mylan presents the examples as a limit on the disputed claim, then, it runs afoul of settled law. Phillips, 415 F.3d at 1323 ("[W]e have repeatedly warned against confining the claims to those [specific] embodiments."); see, e.g., Cohesive

Techs., Inc. v. Waters Corp., 543 F.3d 1351, 1360 (Fed. Cir. 2008) (declining to limit "rigid" to monomeric particles even though embodiments used only monomeric particles).

Mylan's attempt to find contextual support for its position within the specification examples is likewise unavailing. Three polymers that appear as examples of "polymers that swell at a pH in excess of 5.5" - carrageenan, alginic acid, and sodium carboxymethyl cellulose - are also listed as examples of "non pH dependent sustained release agents." Compare '599 patent at col. 1, ll. 58-67 with '599 patent col. 2, ll. 19-22. These three polymers can thus serve as either "pH dependent agents" or "non pH dependent [] agents" within different iterations of the claimed composition. Inasmuch as these two categories are neither mutually exclusive nor limited to their identified examples, they fail to support Mylan's theory that the patentees deliberately drew a firm line between ph-dependent and ph-independent agents. To the contrary, the overlap of these agents serves to highlight the flexibility of the various ingredients that can serve as components for the claimed composition.

In short, any contrast between the polymers identified as potential "pH dependent agents" or "non pH dependent [] agents" is not as clear-cut or determinative as Mylan would suggest. Even if

it were, however, the Court would not limit the plain language of the claim on the basis of the specification's non-exhaustive sampling of suitable agents.

4. Court's Construction

In sum, the Court will not construe claims that do not specifically recite a pH-dependent swelling limitation to include such a limitation, as such a construction is neither recited in the claim language nor supported by the specification. The Court instead adopts the Northern District of California's well-considered construction of this term, which Shire has offered as an alternative, see Shire LLC, 2012 WL 1980803, at *7, and construes the phrase "polymer that swells at a pH in excess of 5.5" as "a molecule with many units joined to each other through chemical bonds, often in a repeating manner, which expands at a pH above 5.5."

B. "About"

The term "about" appears in Claims 18-23 of the '599 patent. Specifically, each of these claims states that a particular component "is present in the composition in an amount of from about __ wt.% to about __ wt. %," with numerical values ranging between 0.095 to 70. Shire argues that "about" should either be left

unconstrued or interpreted to mean "approximately." Mylan, on the other hand, contends that "about" should be ascribed a precise numerical range, i.e., a plus or minus 5% variation on each corresponding weight percent.[9]

According to the Federal Circuit, the use of a qualifying word such as "about" avoids a "strict numerical boundary to the specified parameter" and the appropriate range "must be interpreted in its technological and stylistic context." Ortho–McNeil Pharm., Inc. v. Caraco Pharm. Labs., Ltd., 476 F.3d 1321, 1326 (Fed. Cir. 2007) (quoting Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1217 (Fed. Cir. 1995)). In order to determine how far beyond a specified range the term "about" extends the claim, courts "must focus . . . on the criticality," or underlying purpose, "of the [numerical limitation] to the invention." Cohesive Techs., Inc. v. Waters Corp., 543 F.3d 1351, 1368 (Fed. Cir. 2008) (alteration in original) (quoting Ortho-McNeil, 476 F.3d at 1327). Courts should also consider the use of the term within the patent, the

[9] Under Mylan's proposal, "about 0.1 wt.% to about 70 wt.%" (claim 18) means "0.095 wt.% to 73.5 wt.%; "about 1 wt.% to about 40 wt.%" (claim 19) means "0.95 wt.% to 42 wt.%;" "about 5 wt.% to about 50 wt.%" (claim 20) means "4.75 wt.% to 52.5 wt.%;" about 10 wt.% to about 30 wt.%. (claim 21) means "9.5 wt.% to 31.5.wt %;" "about 0.5 wt.% to about 40 wt.%" (claim 22) means "0.475 wt.% to 42 wt.%;" "about 1 wt.% to about 20 wt.%" (claim 23) means "0.95 wt.% to 21 wt.%."

prosecution history, and the possible effects of varying its parameters. Ortho–McNeil, 476 F.3d at 1326. Further, "[e]xtrinsic evidence of meaning and usage in the art may be helpful in determining the criticality of the parameter." Id. (quoting Pall Corp., 66 F.3d at 1217).

Here, there is nothing in the claims, specifications, or prosecution history of the '599 patent that would illuminate the range "about" imparts to the various weight percents. Consequently, to support its proposed construction, Mylan relies heavily on the affidavit of Dr. Park, who opines that, "in the field of formulation science, acceptable variations on weight percents typically consist of variations in the range of 5-10% of the specified weight." (Dkt. No. 116-1 at 10-11). He theorizes that the lowest end of this allowance, a 5% variation, is appropriate in this case because "the patent describes and claims weight percent limits with precision in the tenths of percents," figures which "suggest[] an intent [by the patentees] to provide significant specificity in setting forth the bounds of the claimed ranges." Id. at 11.

Although courts may rely upon extrinsic evidence when the intrinsic evidence is not sufficient to construe the claim, Bell & Howell Document Mgmt. Prods. Co. v. Altek Sys., 132 F.3d 701, 706

(Fed. Cir. 1997), such evidence ranks low on the evidentiary hierarchy. Phillips, 415 F.3d at 1319. Dr. Park's interpretation of "about," in particular, carries little weight. His affidavit on this issue merely recites Mylan's theory without reference to any industry publications or other independent sources. See Network Commerce, Inc. v. Microsoft Corp., 422 F.3d 1353, 1361 (Fed. Cir. 2005) (discounting expert testimony for lack of reference to industry publications or independent sources). To the extent that he attempts to ground his opinion in the fact that the patent includes weight percents "in tenths" (dkt. no. 116-1 at 11), the Court fails to see the logical connection between the mere existence of these fractional numbers and the selection of a 5% - as opposed to a 6, 7, 8, 9, or 10% - variation range. Mylan's proposal, quite simply, appears unmoored from any reliable intrinsic or extrinsic evidentiary foundation.

Recently, the District Court of Colorado construed these same claims and adopted the construction "approximately" for the term "about." Shire LLC., 2012 WL 5494944, at *6. Without any evidence that would provide a basis to specify the permissible deviation from the weight percents in the '599 patent, this Court also concludes that the term "about" should be given its ordinary and accepted meaning of "approximately." See Merck & Co. v. Teva

Pharms. USA, Inc., 395 F.3d 1364, 1372 (Fed. Cir. 2005); see generally Acumed LLC v. Stryker Corp., 483 F.3d 800, 806 (Fed. Cir. 2007) ("[A] sound claim construction need not always purge every shred of ambiguity.").

Thus, the Court construes the term "about" in Claims 18-23 of the '599 patent as "approximately."

IV. CONCLUSION

For the reasons discussed, the Court **CONSTRUES** the contested claim terms and phrases as follows:

1. "**Polymer that swells at a pH in excess of 5.5**" means "A molecule with many units joined to each other through chemical bonds, often in a repeating manner, which expands at a pH above 5.5"; and
2. "**About**" means "Approximately."

Further, the Court adopts the parties' agreed claim constructions and **CONSTRUES** the following terms and phrases as follows:

1. "**Non-pH dependent sustained release agent**" shall be construed as "[ingredient] that slows release of the pharmaceutically active agent over an extended period of

time regardless of gastrointestinal pH, and that is not the pH dependent agent”;

2. “**pH dependent agent that increases the rate of release of said pharmaceutically active agent from the tablet at a pH in excess of 5.5**” shall be construed as “[ingredient] that is neither the non-pH dependent sustained release agent nor the pharmaceutically active agent, and that increases the rate of release of the pharmaceutically active agent from a tablet more in an environment that has a pH above 5.5 than in an environment that has a pH of 5.5 or below”;

3. “**Agent that increases the solubility of said at least one pharmaceutically active agent at a pH of greater than 5.5**” shall be construed as “[ingredient] that increases the amount of the pharmaceutically active agent that will dissolve in a given amount of another substance to a greater extent in an environment which has a pH above 5.5 than in an environment which has a pH of 5.5. or below”;

4. “**reducing the likelihood of side effects associated with the administration of guanfacine**” shall be given its plain and ordinary meaning; and

5. "**binding agent**" shall be given its plain and ordinary meaning.

It is so **ORDERED**.

The Court directs the Clerk to transmit copies of this Order to counsel of record.

DATED: January 14, 2013

/s/ Irene M. Keeley
IRENE M. KEELEY
UNITED STATES DISTRICT JUDGE