

United States District Court,  
N.D. California.

**ALZA CORP,**  
Plaintiff.

v.

**IMPAX LABORATORIES, INC,**  
Defendant.

No. C-03-4032 VRW

**March 10, 2005.**

## **ORDER**

**WALKER, Chief J.**

This suit concerns a single patent, United States Patent No 6,124,355 (the " '355 patent), which claims a time release formulation of oxybutynin (a drug to control urinary incontinence) and related methods of administering the same. The '355 patent is also the subject of a similar suit pending before Judge Irene Keeley in the Northern District of West Virginia, *Alza Corp v. Mylan Laboratories, Inc*, No 1:03CV61. Judge Keeley issued a claim construction order on December 7, 2004 (the "Keeley Order"), which is attached as an exhibit to this order. The parties have framed their claim construction positions in this case in terms of their agreement and disagreement with the Keeley Order. The court appreciates this, for it has focused the issues and allows the court to rule expeditiously.

The principal issues in dispute are whether the composition claims of the '355 patent are written in means-plus-function form under 35 USC s. 112, para. 6, and, relatedly, whether the corresponding method claims are written in step-plus-function form under the same paragraph. As is familiar,

"[a] claim limitation that actually uses the word 'means' invokes a rebuttable presumption that s. 112 para. 6 applies. By contrast, a claim term that does not use 'means' will trigger the rebuttable presumption that s. 112 para. 6 does not apply." *CCS Fitness, Inc v. Brunswick Corp*, 288 F3d 1359, 1369 (Fed Cir2002). The use of the term "means" is "central to the analysis," *Personalized Media Communications, LLC v Int'l Trade Comm'n*, 161 F3d 696, 703 (Fed Cir1998), because the term "means," particularly as used in the phrase "means for," is "part of the classic template for functional claim elements," *Sage Prods, Inc v. Devon Indus, Inc*, 126 F3d 1420, 1427 (Fed Cir1997), and has come to be closely associated with means-plus-function claiming. See *Apex, Inc v. Raritan Computer, Inc*, 325 F3d 1364, 1373 (Fed Cir2003); *York Prods, Inc v Cent Tractor Farm & Family Ctr*, 99 F3d 1568, 1574 (Fed Cir1996).

The presumption that a limitation lacking the term "means" is not subject to section 112 para. 6 can be overcome if it is demonstrated that "the claim term fails to 'recite sufficiently definite structure' or else recites 'function without reciting sufficient structure for performing that function.'" ' *CCS Fitness*, 288 F3d at

1369 (quoting *Watts v. XL Sys, Inc*, 232 F3d 877, 880 (Fed Cir2000)). Our cases make clear, however, that the presumption flowing from the absence of the term "means" is a strong one that is not readily overcome. See, e g, *Al- Site Corp v. VSI Int'l, Inc*, 174 F3d 1308, 1318-19 (Fed Cir1999); *Personalized Media Communications*, 161 F 3d at 703-05.

The task of determining whether the limitation in question should be regarded as a means-plus-function limitation, like all claim construction issues, is a question of law for the court, even though it is a question on which evidence from experts may be relevant. *Linear Tech Corp v. Impala Linear Corp*, 379 F3d 1311 (Fed Cir2004); *Wenger Mfg, Inc v. Coating Mach Sys, Inc*, 239 F3d 1225, 1231 (Fed Cir2001); *Personalized Media Communications*, 161 F3d at 702; see generally *Markman v. Westview Instruments, Inc*, 517 U.S. 370, (1996).

*Lighting World, Inc v. Birchwood Lighting, Inc*, 382 F3d 1354, 1358 (Fed Cir2004) (alteration in original).

Applying these rules, the Keeley Order concludes that the claims of the '355 patent are not drafted in means-plus-function (or step-plus-function) form. The court agrees and, accordingly, adopts the Keeley Order.

Because the court agrees with the reasoning and result of the Keeley Order, it need only address one argument that Impax now makes that Mylan did not make before Judge Keeley. Impax's argument concerns the standard-recited above-for rebutting the presumption that a claim lacking "means" is not subject to s. 112, para. 6: The party seeking to rebut the presumption must "demonstrate[ ] that the claim term \* \* \* recites function without reciting sufficient structure for performing that function." *Lighting World*, 382 F3d at 1358 (quotation marks omitted). Before Judge Keeley, Mylan argued that the claims of the '355 patent supply *no* structure. Implicitly in its papers-and explicitly at the March 10, 2005, hearing on this matter-Impax concedes that the claims of the '355 patent supply some structure, but it notes that Judge Keeley "did not take the next step of analyzing whether that structure *was sufficient* to perform the highly particularized functions recited in the claims." *Impax Br (Doc # 88)* at 3:4-5.

The court agrees with Impax that the Keeley Order does not address this argument. But the court must nonetheless reject the argument. First, as described above, it is Impax's burden to rebut the presumption against construction under s. 112, para. 6. Second, the burden is "a strong one that is not readily overcome," *Lighting World*, 382 F3d at 1358, so strong, indeed, that it "is not surprising that [the Federal Circuit] ha[s] seldom held that a limitation not using the term 'means' must be considered to be in means-plus-function form," *id* at 1362. Third "sufficient structure" does not equate with "specific structure"; rather, the claim term need only "designate structure" to persons of skill in the pertinent art. *Id* at 1359.

To meet its burden, Impax offers an expert declaration, see *Leeson Decl (Doc # 89)* para. 11-34, which "may be relevant," although the claim construction question remains a matter of law, *Lighting World*, 382 F3d 1358. Fatal to Impax's argument is that the Leeson Declaration demands more of the patent than the Federal Circuit would: "Specific structure" is not required, but this is apparently what Dr Leeson contends is missing from the claims in stating that "the rate of release and length of release period depend on the nature, combination(s), proportion(s) and arrangement of excipients (i e, internal structure) of the dosage form or formulation, information that the term "sustained release" does not provide." *Leeson Decl (Doc # 89)* para. 22. Rather, the issue is whether certain phrases of the claims of the '355 patent denote some structure for performing the recited function. There is, in the end, no question that they do.

Moreover, there is a good reason that the presumption against Impax's position is so strong: If it were

significantly weaker, the quantum of structure that claimants would be required to include in their claims to *avoid* s. 112, para. 6 would rival the amount of structure typically found in the specification when a claim is interpreted under s. 112, para. 6. In effect, the weak presumption that Impax urges would compel all claimants to specify in detail (either in the claim or the specification) the structural means for performing their claimed functions. But this is precisely what *Lighting World* rejects, as do all the cases before it rejecting s. 112, para. 6 readings. Claimants may, as Alza has done in the '355 patent, write claims that neither include a structural blueprint nor require construction under s. 112, para. 6. Accordingly, the court interprets the claims of the '355 patent not to invoke s. 112, para. 6.

In sum, the court adopts the Keeley Order to the extent that it construes claims of the '355 patent, and subject to the foregoing further discussion of Impax's argument regarding interpretation under s. 112, para. 6. To the extent the Keeley Order concerns other matters (such as motions for summary judgment of invalidity), such matters are not now before the court and the court expresses no view on them.

IT IS SO ORDERED.

### ***ORDER CONSTRUING CLAIMS AND DENYING SUMMARY JUDGMENT***

**KEELEY, J.**

This is a patent infringement suit involving a pharmaceutical invention disclosed by U.S. Patent No. 6,124,355 (issued Sept. 26, 2000) ("the '355 patent"). The plaintiff, Alza Corporation ("Alza"), holds title to the '355 patent. The defendants in this case are Mylan Laboratories, Inc. and Mylan Pharmaceuticals, Inc. (collectively "Mylan"). Before the Court are the parties' requests to construe the disputed claim language of the patent pursuant to *Markman v. Westview Instruments*, 52 F.3d 967 (Fed.Cir.1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Five motions for summary judgment, filed by Mylan, are also pending. The parties have fully briefed and argued their respective positions on these matters. As elaborated below, the Court construes the claim terms according to their plain meanings and DENIES Mylan's motions for summary judgment.

#### **I. BACKGROUND**

##### **A. Procedural History**

Alza initiated this infringement action on May 2, 2003. Mylan filed its answer on May 27, 2003, asserting that the '355 patent was invalid or otherwise not infringed. On February 27, 2004, the parties submitted a Joint Claim Construction Report (or "JCCR"), which included numerous stipulated definitions of claim terms. Following the close of discovery, the parties completed three rounds of briefing on claim construction issues. Mylan also filed five motions for summary judgment, which were fully briefed by September 3, 2004. On October 12, 2004, the Court heard extensive oral argument with respect to claim construction and the motions for summary judgment.

##### **B. The Disclosed Invention**

Generally, the '355 patent discloses a sustained-release (or extended release) version of oxybutynin, a drug used for the treatment of urinary incontinence. Before the invention of its sustained-release formulation, oxybutynin was administered two to four times a day to patients. '355 patent, col. 1:63-65. In contrast, the

sustained-release formulation can be administered once a day because it delivers oxybutynin at a controlled rate over a twenty-four hour period. *See id.* at figs. 1 & 2.

## II. CLAIM CONSTRUCTION

### A. Standard of Law

"Claim interpretation requires the court to ascertain the meaning of the claim to one of ordinary skill in the art at the time of invention." *SmithKline Beecham Corp. v. Apotex Corp.*, 365 F.3d 1306, 1313 (Fed.Cir.2004) (citations omitted). The analysis "must begin and remain centered on the claim language itself." *Novartis Pharm. Corp. v. Abbot Labs.*, 375 F.3d 1328, 1334 (Fed.Cir.2004) (citation omitted). As such, there is a " 'heavy presumption' that a claim term carries its ordinary and customary meaning. The ordinary meaning of a claim term may be determined by reviewing a variety of sources, including the claims themselves, other intrinsic evidence including the written description and the prosecution history, and dictionaries and treatises." *Teleflex. Inc. v. Ficoso N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed.Cir.2002) (citations omitted).

Patent claims "must be read in view of the specification, of which they are a part." *Markmen*, 52 F.3d at 979 (citations omitted). It is improper, however, "to read a limitation from the specification into the claims." *Microsoft Corp. v. Multi-Tech Systems, Inc.*, 357 F.3d 1340, 1347 (Fed.Cir.2004). Therefore, "[i]f the claim language is clear on its face, ... consideration of the rest of the intrinsic evidence is restricted to determining if a deviation from the clear language of claims is specified." *Interactive Gift Express. Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1331 (Fed.Cir.2001). "Absent evidence that a 'patentee *unequivocally* imparted a novel meaning to [the] term[ ] or expressly relinquished claim scope during prosecution,' [a court must] give the limitation its full and ordinary meaning." *Akamai Technologies, Inc. v. Cable & Wireless Internet Servs., Inc.*, 344 F.3d 1186, 1194 (Fed.Cir.2003) (quoting *Omega Eng'g. Inc. v. Raytek Corp.*, 334 F.3d 1314, 1323 (Fed.Cir.2003)) (emphasis added) (other citations omitted). Thus, the "heavy presumption" that a claim term carries its ordinary meaning "may be rebutted when: (1) the patentee has chosen to be his own lexicographer, or (2) a claim term lacks such clarity that there is 'no means by which the scope of the claim may be ascertained from the language used.'" *Novartis Pharm.*, 375 F.3d at 1334.

### B. Claims 1 & 2

Claims 1 and 2 of the '355 patent read as follows:

1. A sustained-release oxybutynin formulation for oral administration to a patient comprising a therapeutic dose of an oxybutynin selected from the group consisting of oxybutynin and its pharmaceutically acceptable salt that delivers from 0 to 20% of the oxybutynin in 0 to 4 hours, from 20 to 50% of the oxybutynin in 0 to 8 hours, from 50 to 85% of the oxybutynin in 0 to 14 hours, and greater than 75% of the oxybutynin in 0 to 24 hours for treating incontinence in the patient.

2. A sustained-release oxybutynin formulation for oral administration to a patient in need of treatment for urge incontinence comprising a therapeutic dose of an oxybutynin selected from the group consisting of oxybutynin and its pharmaceutically acceptable salt that delivers from 0 to 1 mg in 0 to 4 hours, from 1 mg to 2.5 mg in 0 to 8 hours, from 2.75 to 4.75 mg in 0 to 14 hours, and 3.75 mg to 5 mg in 0 to 24 hours for treating urge incontinence in the patient.

#### *1. The Parties' Proposed Constructions*

Both claims 1 and 2 recite "a sustained-release oxybutynin formulation for oral administration to a patient comprising a therapeutic dose of oxybutynin" that delivers a specified percentage or milligram amounts of oxybutynin at the end of certain time intervals. Pursuant to the stipulations in the parties' Joint Claim Construction Report, "formulation" means "something that is prepared according to a formula." (JCCR at 2.) Mylan contends that "sustained-release oxybutynin formulation" lacks any meaningful structure, and therefore must be construed as a means-plus-function limitation. *See* 35 U.S.C. s. 112, para. 6. Mylan also maintains that, in the specification, the only described structure that administers the specified amounts of oxybutynin is the bilayer push/pull osmotic pump delivery system ("osmotic pump system" or "osmotic dosage form") disclosed in Examples 15-21. Accordingly, Mylan asserts that the "formulation" claims only cover the osmotic dosage form and its equivalents. *See id.* Alza, on the other hand, argues that "sustained-release oxybutynin formulation" recites sufficient structure and encompasses both osmotic and non-osmotic dosage forms.

## ***2. The Court's Construction***

According to 35 U.S.C. s. 112 para. 6,

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

"Through use of means-plus-function limitations, patent applicants are allowed to claim an element of a combination functionally, without reciting structures for performing those functions." *Apex, Inc. v. Raritan Computer, Inc.*, 325 F.3d 1364, 1371 (Fed.Cir.2003) (citation omitted). As s. 112, para. 6 indicates, however, the scope of means-plus-function claims is limited "to the means specified in the written description and equivalents thereof." *O.I. Corp. v. Tekmar Co.*, 115 F.3d 1576, 1583 (Fed.Cir.1997).

"[A] claim term that does not use 'means' will trigger the rebuttable presumption that s. 112, [paragraph] 6 does not apply. The term 'means' is central to the analysis." *Apex*, 325 F.3d at 1371-72 (quoting *Personalized Media Comm. v. Int'l Trade Comm'n*, 161 F.3d 696, 703 (Fed.Cir.1998)) (citation omitted). The challenger "can rebut this presumption if it demonstrates [by a preponderance of the evidence] that the claim term fails to 'recite sufficiently definite structure' or else recites a 'function without reciting sufficient structure for performing that function.'" *Id.* at 1372 (quotation and internal quotation omitted). "To help determine whether a claim term recites sufficient structure, [a court should] examine whether it has an understood meaning in the art." *Id.* (quoting *Watts v. XL Sys., Inc.*, 232 F.3d 877, 880 (Fed.Cir.2000)).

Here, claims 1 and 2 do not include the term "means." Therefore, Mylan bears the burden of showing that the disputed claim limitations, as understood by one of ordinary skill in the art, rely "on functional terms rather than structure or material to describe performance of the claimed function." *Id.* To determine whether the claim limitations recite sufficient structure, the Court may properly consider extrinsic evidence, including expert testimony. *Personalized Media Comm.*, 161 F.3d at 1374.

The disputed language, "sustained-release oxybutynin formulation," is a preamble in claims 1 and 2. "In general, a preamble limits the invention if it recites essential structure or steps, or if it is 'necessary to give life, meaning, and vitality' to the claim." *Catalina Mktg. Int'l v. Coolsayings.com*, 289 F.3d 801, 808 (Fed.Cir.2002) (quotation omitted). Alza contends that the preamble serves as a limitation to the claims.

Likewise, Mylan's means-plus-function argument presupposes that the preamble is a limitation. In light of this tacit agreement, the Court will construe the preamble accordingly.

Although Mylan suggests otherwise, a claim limitation does not need to "connote a precise physical structure in the minds of those of skill in the art." *Personalized Media Comm.*, 161 F.3d at 705. Indeed, the Federal Circuit has held that a term which conveys "a variety of structures" to a skilled artisan is "sufficiently definite ... to preclude the application of s. 112, [paragraph] 6." *Id.* Moreover, "sustained-release oxybutynin formulation" "is not a generic structural term such as 'means,' 'element,' or 'device'; nor is it a coined term lacking a clear meaning, such as 'widget.'" *Id.* at 704 (footnote omitted). To the contrary, Mylan's expert, Dr. Okerholm, agreed that the term "denotes particular types of structures, a variety of structures." (Alza's Resp. to Mylan's Opening CC Br. at 10.) Mylan offers no evidence that a skilled artisan in September, 2000, would have only understood "sustained-release oxybutynin formulation" in functional terms, as opposed to structural or material terms. Thus, Mylan fails to prove that claims 1 and 2 contain means-plus-function limitations, and the Court will construe the claim language according to the parties' stipulated definitions.

### **C. Claim 3**

Claim 3 of the '355 patent reads as follows:

3. A sustained-release oxybutynin solid dosage form for oral administration to a patient for treating incontinence comprising an oxybutynin selected from the group consisting of oxybutynin and its pharmaceutically acceptable salt that administers up to 2 mg of the member in 0 to 4 hours, from 2 mg to 5 mg of the member in 0 to 8 hours, from 5 mg to 8.5 mg of the member in 0 to 14 hours, and greater than 7.5 mg in 0 to 24 hours for treating incontinence in the patient.

#### ***1. The Parties' Proposed Constructions***

Claim 3 describes a "sustained-release oxybutynin solid dosage form for oral administration to a patient ... comprising an oxybutynin" that delivers certain milligram amounts of the drug at specified time intervals. Mylan contends that the inventors of the '355 patent acted as their own lexicographers by defining "dosage form provided by the invention" as an osmotic pump system in the specification. Therefore, it urges the Court to equate the term "solid dosage form" in claim 3 with "osmotic pump dosage form." Alza advocates a construction of "solid dosage form" that is consistent with the term's plain meaning and stipulated definition.

Mylan also asserts that Alza expressly limited the scope of the '355 patent in a March 29, 1999 continuation-in-part application ("CIP") that matured into U.S. Patent No. 6,262,115 (issued July 17, 2001) ("the '115 patent"). *See Microsoft Corp. v. Multi-Tech Sys. Inc.*, 357 F.3d 1340, 1350 (2004). The '115 patent explicitly discusses several non-osmotic dosage forms for the first time. Mylan emphasizes that the written description of the '115 patent refers to "dosage form s," while the '355 patent only uses the singular "dosage form." It also argues that the '115 patent states that the '355 patent relates only to "osmotic dosage forms." *See '115 patent*, cols. 6:64, 9:7. Thus, Mylan concludes that the March 1999 CIP/'115 patent confirms that the '355 patent only encompassed osmotic dosage forms.

In response, Alza argues that the added non-osmotic dosage forms do not constitute new matter because the '355 patent covers such dosage forms. Further, Alza asserts that the PTO Examiner recognized this scope of coverage because he initially rejected the '115 patent claims (arising from the March 1999 CIP) based on the

doctrine of double patenting vis-a-vis the '355 patent claims. Mylan suggests, however, that the Examiner's double patenting rejection cannot confirm the scope of the '355 patent claims because it would not have considered how the specification limited those claims.

## 2. *The Court's Construction*

As Mylan is well aware, a court cannot import claim limitations from the written description. *Resonate Inc. v. Alteon Websystems, Inc.*, 338 F.3d 1360, 1364 (Fed.Cir.2003). Indeed, "claim terms take on their ordinary and accustomed meanings unless the patentee demonstrated an intent to deviate from [such a] meaning ... by redefining the term or characterizing the invention in the intrinsic record using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1327 (Fed.Cir.2002). As already noted, to act as his own lexicographer, a patentee must "define[ ] the specific terms used to describe the invention 'with reasonable clarity, deliberateness, and precision.'" *Id.* at 1325 (quoting *In re Paulsen*, 30 F.3d 1475, 1480 (Fed.Cir.1994)). Otherwise, there is a "heavy presumption" in favor of a term's ordinary meaning. *Id.* at 1327. In *Teleflex*, for example, the patent specification described only one embodiment of the disputed claim element. Nonetheless, the Federal Circuit refused to limit the claim to that embodiment because the record contained no "clear statements of scope" that compelled such a limitation. *Id.* at 1328.

The disputed claim language in claim 3 is "solid dosage form." The parties stipulated to the meaning of these terms, defining "dosage form" as "a pharmaceutical preparation in which doses of medicine are included" and "solid dosage form" as "a dosage form that is neither liquid nor gaseous." (JCCR at 2.) Despite its agreement with these definitions, Mylan now asserts that the '355 patent implicitly limits the definition of "solid dosage form" to "osmotic dosage form." It maintains that "every time the 'dosage form provided by the invention' is referenced in the patent specification, it describes only an osmotic pump release mechanism." (Mylan's Opening CC Br. at 15) (citing several examples). FN1

FN1. The credibility of Mylan's position on this issue is questionable. Nine months after filing its answer in this case, Mylan stipulated to the definition of "solid dosage form." It could not have been prepared to reach such an agreement without having read the specification thoroughly. Nonetheless, Mylan now posits a different definition of "solid dosage form" based primarily on the specification.

As used in the '355 Patent, however, the term "dosage form" comports with its broad stipulated definition. In the section entitled "Objects of the Invention," the patent qualifies the term in numerous ways: "sustained-release dosage form," "solid-oral dosage pharmaceutical form," "drug delivery dosage form," "controlled-release dosage form," and, most notably, "an osmotic dosage form." '355 Patent, cols. 2-3. The examples in the written description also indicate that the invention encompasses more than one dosage form. *See generally* *id.* at 10:66-15:23 (referring to the manufacture of "a dosage form" or "dosage forms"); *see* *Johnson Worldwide Assocs. v. Zebco Corp.*, 175 F.3d 985, 991 (Fed.Cir.1999) ("Varied use of a disputed term in the written description demonstrates the breadth of the term rather than providing a limited definition.") (citation omitted). Moreover, the patent refers to both osmotic and non-osmotic dosage forms. *See, e.g., id.* at 4:2-5, 38-52; *id.* at 5:25-40; *id.* at 6:6-20. Thus, in the examples cited by Mylan, the osmotic dosage form is merely a preferred embodiment, which, by itself, cannot limit claim 3. *Johnson Worldwide*, 175 F.3d at 992.

Although "dosage form" is used in describing an osmotic pump delivery system, the specification does not

manifestly or consistently equate "dosage form" with "osmotic dosage form." *See* Bell Atl. Network Servs., Inc. v. Covad Comm. Group. Inc., 262 F.3d 1258, 1271 (Fed.Cir.2001). The patent also does not criticize or affirmatively exclude non-osmotic dosage forms. *See* SciMed Life Systems, Inc. v. Advanced Cardiovascular Systems, Inc., 242 F.3d 1337, 1343-44 (Fed.Cir.2001). Therefore, Mylan fails to persuade the Court that the specification unequivocally limits the term "solid dosage form" to mean "osmotic dosage form."

The March 1999 CIP/'115 patent also broadly defines "dosage form ." Indeed, the '115 patent expressly states that "[d]osage form denotes a drug delivery system for administering a therapeutically effective dose of drug, for example oxybutynin to a patient in need of therapy." FN2 '115 patent, col. 2:57-60. By inclusively defining "dosage form" while adding other examples of non-osmotic dosage forms, the '115 patent confirms that the term "dosage form" should not be limited to only osmotic dosage forms. Moreover, insofar as the March 1999 CIP/ '115 patent suggests that the '355 patent *specification* describes only osmotic dosage forms, as Mylan argues, the CIP cannot restrict *claim 3* in the '355 patent to osmotic dosage forms. Such a construction would indirectly and erroneously import a limitation from the specification. Accordingly, since neither the specification nor the March 1999 CIP clearly narrows the scope of claim 3's coverage to osmotic dosage forms, the Court broadly construes "solid dosage form" pursuant to the parties' stipulated definitions.

FN2. This definition differs from the parties' stipulated definition of "dosage form," i.e., "a pharmaceutical preparation in which doses of medicine are included." Accordingly, the two meanings appear to embrace discrete structures. As used in the '355 patent, "dosage form" is a pharmaceutical preparation that contains a drug. In the '115 patent, the term is defined as a drug delivery system. To the extent that this distinction is relevant to the claim construction at hand, it supports a broad reading of "dosage form."

#### **D. Claims 11, 13, and 14**

Claims 11, 13, and 14 of the '355 patent read as follows:

11. A method for treating incontinence in a patient, wherein the method comprises administering orally to the patient a therapeutic dose of an oxybutynin selected from the group consisting of oxybutynin and its pharmaceutically acceptable salt that is delivered from 0 to 20% of the dose in 0 to 4 hours, from 20 to 50% of the dose in 0 to 8 hours, from 50 to 85% of the dose in 0 to 14 hours, and greater than 75% of the dose in 0 to 24 hours for treating incontinence in the patient.

13. A method for treating incontinence in a patient, wherein the method comprises administering orally to the patient a therapeutic dose of an oxybutynin selected from the group consisting of oxybutynin and its pharmaceutically acceptable salt which oxybutynin is administered in from 0 to 1 mg in 0 to 4 hours, from 1 mg to 2.5 mg in 0 to 8 hours, from 2.75 to 4.75 mg in 0 to 14 hours, and 3.75 mg to 5 mg in 0 to 24 hours for treating incontinence in the patient.

14. A method for treating incontinence in a patient, wherein the method comprises administering orally to the patient a therapeutic dose of an oxybutynin selected from the group consisting of oxybutynin and its pharmaceutically acceptable salt, which oxybutynin is administered in up to 2 mg of the member in 0 to 4 hours, from 2 mg to 5 mg of the member in 0 to 8 hours, from 5 mg to 8.5 mg of the member in 0 to 14 hours, and greater than 7.5 mg in 0 to 24 hours for treating incontinence in the patient.



## ***1. The Parties' Proposed Constructions***

Claims 11, 13 and 14 each describe a method for treating incontinence in which the patient receives an oral administration of a "therapeutic dose" of an oxybutynin. The claims also enumerate the percentage or milligram amounts of oxybutynin that are either "delivered" (claim 11) or "administered" (claims 13 and 14) at the end of specific time intervals. The parties have stipulated that "therapeutic dose" means "a quantity of a drug that is useful in treating a particular disease or condition" and that "administer" and "deliver" mean "to release; to dispense; to mete out; to liberate." (JCCR at 2-3.)

Mylan contends that the term "therapeutic dose" is a means-plus-function limitation insofar as Alza argues that "therapeutic dose" is the device or means that performs the function of administering the specified percentages/amounts of oxybutynin at the specified time intervals. As such, Mylan argues that therapeutic dose covers only the osmotic pump system. Alza, however, does not assert that the "therapeutic dose" delivers or administers amounts of oxybutynin at certain times. In its opening claim construction brief, Alza observes that such a construction "would make no sense: The 'therapeutic dose of oxybutynin' is not the structure that delivers the drug according to the claimed rates; it is simply the therapeutically effective amount of [the] drug...." (Alza CC Br. at 12.)

Alza also argues that method claims only invoke the "step-plus-function" arm of s. 112, para. 6, not the "means-plus-function" aspect of the statute. Alza contends that the claim unambiguously describes an act-"administering orally to a patient a therapeutic dose" of oxybutynin-which renders s. 112, para. 6 inapposite.

## ***2. The Court's Construction***

As discussed above, the absence of the words "means" or "steps for" creates a rebuttable presumption that s. 112, para. 6 is inapplicable. *See Masco Corp. v. United States*, 303 F.3d 1316, 1326 (Fed.Cir.2002). Claims 11, 13, and 14 do not contain such language. Therefore, Mylan has the burden to prove by a preponderance of evidence that, as understood by a person of ordinary skill in the art, the claims lack sufficient structure. *Apex*, 325 F.3d at 1372.

In *O.I. Corp. v. Tekmar Co., Inc.*, 115 F.3d 1576 (Fed.Cir.1997), the Federal Circuit explained that, in s. 112, para. 6, "structure and material go with means, acts go with steps." *Id.* at 1583. Thus, s. 112, para. 6 "is implicated only when means plus function without definite structure are present, and that is similarly true with respect to steps, that the paragraph is implicated only when steps plus function without acts are present." *Id.* Moreover, method claims need not recite structure because they consist of acts. *See, e.g., Dennison Mfg. Co. v. Ben Clements & Sons, Inc.*, 467 F.Supp. 391, 405 (S.D.N.Y.1979) (noting that, under 35 U.S.C. s.s. 100(b) and 101, a method is patentable "in and of itself"). Accordingly, the Federal Circuit recently held that a method claim implicates s. 112, para. 6 "only when steps plus function without acts are present." *Epcon Gas Sys., Inc. v. Bauer Compressors, Inc.*, 279 F.3d 1022, 1028 (Fed.Cir.2002) (citing *O.I. Corp.*, 115 F.3d at 1583) (emphasis added). In its response to Mylan's initial *Markman* brief, Alza persuasively cites *Epcon Gas* and *O.I. Corp.* In its reply, however, Mylan fails to address those plainly relevant cases, choosing instead to characterize Alza's argument as a "red herring" and an "obfuscation." (Mylan's CC Reply at 1-2.) Nonetheless, Mylan admits that "the method claims clearly recite a *specified act*-i.e., 'administering orally to the patient a therapeutic dose of an oxybutynin.'" ( *Id.*) (emphasis in original). Thus, Mylan's position is baseless. The *Epcon Gas* and *O.I. Corp.* decisions unquestionably dictate the construction of method claims in conjunction with s. 112, para. 6. Based on that direction, the Court finds that claims 11, 13, and 14 contain neither means-plus-function limitations nor step-plus-function

limitations.

## **E. Testing Procedures**

The '355 patent claims do not articulate any testing methods for measuring the claimed release rates of oxybutynin. Mylan contends that the specification and prosecution history require the use of in vitro dissolution tests to determine these release rates. Mylan also asserts that the Federal Circuit's holding in *Honeywell v. International Trade Commission*, 341 F.3d 1332 (Fed.Cir.2003), mandates "all methods" of dissolution testing to determine infringement in this case. Alza maintains, however, that testing methodologies need not be included in the claims because they are known to persons of ordinary skill in the art and are adequately discussed within the patent specification.

The Federal Circuit offers clear guidance on this claim construction issue:

*[I]t is manifest that a claim must explicitly recite a term in need of definition before a definition may enter the claim from the written description. This is so because the claims define the scope of the right to exclude; the claim construction inquiry, therefore, begins and ends in all cases with the actual words of the claim. The intrinsic evidence, and, in some cases, the extrinsic evidence, can shed light on the meaning of the terms recited in a claim, either by confirming the ordinary meaning of the claim terms or by providing special meaning for claim terms. However, the resulting claim interpretation must, in the end, accord with the words chosen by the patentee to stake out the boundary of the claimed property.*

*Thus, a party wishing to use statements in the written description to confine or otherwise affect a patent's scope must, at the very least, point to a term or terms in the claim with which to draw in those statements. Without any claim term that is susceptible of clarification by the written description, there is no legitimate way to narrow the property right. The Supreme Court has clearly stated the rationale for this requirement:*

We know of no principle of law which would authorize us to read into a claim an element which is not present, for the purpose of making out a case of novelty or infringement. The difficulty is that if we once begin to include elements not mentioned in the claim in order to limit such claim ..., we should never know where to stop.

*If we need not rely on a limitation to interpret what the patentee meant by a particular term or phrase in a claim, that limitation is "extraneous" and cannot constrain the claim.*

*Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1248-49 (Fed.Cir.1998) (quoting *McCarty v. Lehigh Valley R.R.*, 160 U.S. 110, 116 (1895)) (other citations omitted) (emphasis added).

As Mylan emphasizes, "the claim language in the '355 Patent is silent as to testing procedures and conditions" to measure release rates of the claimed oxybutynin formulations. (Mylan Opening CC Br. at 18.) Indeed, Mylan does not-and cannot-connect its proffered testing methodology claim limitation to any claim language. The claimed inventions of the '355 patent do not include testing methods, and a person of ordinary skill in the art need not refer to such methods to understand the plain meaning of the claim terms. Therefore, a testing methodology requirement is an "extraneous" claim limitation, which the Court refuses to import.

Relying heavily on *Honeywell*, Mylan nevertheless urges the Court to construe the claims to require "all

methods" of in vitro testing to determine oxybutynin release rates. In *Honeywell*, the claim construction dispute "focuse[d] on the method of measuring one claimed feature-the melting point elevation ("MPE")" of a polyester yarn. 341 F.3d at 1335. The claims "require[d] that the yarn produced by the claimed process fall within a specified MPE range at some point in the process." *Id.* The written description identified a test to measure the MPE but failed to explain how to prepare a yarn sample for this test. *Id.* at 1336. The sample preparation method was crucial because "[d]epending upon which sample preparation [was] used, the calculated MPE for a given sample [could] vary greatly." *Id.*

The *Honeywell* court determined that four sample preparation methods were available. Three of the methods were published in the art as of the patent's priority date, and one method was unpublished but known by those of skill in the art. *Id.* Therefore, at issue was whether the claims required "any particular sample preparation method when determining the MPE." *Id.* at 1339. The Federal Circuit found that "the claims, the written description, and the prosecution history fail[ed] to give ... *any* guidance" as to which sample preparation method was necessary to practice the invention. *Id.* at 1340 (emphasis added); *see id.* at 1342. Thus, the court rejected claim constructions that required only one sample preparation method. Moreover, the final possible claim construction, which would require using all four known sample preparation techniques, rendered the invention "inoperable." *Id.* at 1341. As such, in *Honeywell*, the court concluded that the claims were invalid for lack of enablement and for indefiniteness. *Id.*

Here, Mylan asserts that, like the choice of sample preparation methods in *Honeywell*, the choice of testing procedures for its drug is critical to determining infringement. Its accused drug has a polymer matrix release system, which is "critically dependent upon dissolution medium pH, testing apparatus, and agitation speed." Dosage forms utilizing the osmotic pump system, however, have the same dissolution rate irrespective of pH, media, testing apparatus or agitation speed. In light of the importance of testing conditions for its accused drug, Mylan argues that *Honeywell* forbids a claim construction that permits Alza to "gerrymander" specific tests for infringement. Rather, according to Mylan, *Honeywell* compels this Court to construe the claims as requiring all possible methods of in vitro dissolution testing to determine oxybutynin release rates.

Mylan's argument oversimplifies *Honeywell*'s holding and factual context. Unlike the case at bar, the claim construction dispute in *Honeywell* focused on the meaning of an *identified claim term*, i.e., "melting point elevation." The MPE was a limitation of the claimed processes; therefore, the sample preparation method was integrated *within the claim* because it was necessary to calculate the MPE. In contrast, the '355 patent claims make no reference, implicitly or explicitly, to testing methods. Moreover, unlike the sample preparation method in the *Honeywell* patent, no particular dissolution test is required to manufacture the claimed drug. *Id.* at 1341 ("Because the sample preparation method is critical in determining MPE, processes utilizing different sample preparation methods *will produce different varns.*" ) (emphasis added). Thus, a skilled artisan could read the '355 patent, create an infringing drug (assuming enablement), and never employ any testing to determine the release rates of that drug.

In conclusion, despite Mylan's argument to the contrary, *Honeywell* does not hold as a black letter rule that claims must establish testing parameters for infringement. There the sample preparation method was an implicit element of the claim. In the '355 patent, by contrast, testing is a means to *confirm* the properties of the claimed invention. Therefore, in this case, testing methodology is solely an issue of infringement because it is not necessary to an understanding of what the claims mean. Accordingly, the Court refuses to apply any claim limitation that mandates certain testing procedures or conditions.

### III. MOTIONS FOR SUMMARY JUDGMENT

## **A. Standard of Law**

A moving party is entitled to summary judgment "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(c). A genuine issue of material fact exists "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). In considering a motion for summary judgment, the court is required to draw reasonable inferences from the facts in a light most favorable to the nonmoving party. *Id.* at 255.

The moving party has the burden of initially showing the absence of a genuine issue concerning any material fact. *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 159 (1970). Once the moving party has met its initial burden, the burden shifts to the nonmoving party to "establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial ." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). To discharge this burden, the nonmoving party cannot rely on its pleadings but instead must have evidence showing that there is a genuine issue for trial. *Id.* at 324.

In patent infringement actions, summary judgment is inappropriate if expert testimony "is required to explain the nature of the patented invention or the accused product or to assist in their comparison." *Amhil Enterprises Ltd. v. Wawa, Inc.*, 81 F.3d 1554, 1557 (Fed.Cir.1996) (citations omitted); *see also Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1562-63 (Fed.Cir.1991).

## **B. Priority and Inherent Anticipation FN3**

FN3. On November 2, 2004, Mylan filed a supplemental brief on "*Kennecott* and Alleged 'Inherent Written Description.'" ' The Scheduling Order indicates that the briefing deadline for dispositive motions in this case expired in September. The Local Rules do not permit the submission of this briefing, and Mylan did not request leave of court to file it. Therefore, the Court will not consider the supplemental material submitted by the defendants.

In its first two motions for summary judgment, Mylan claims that the '355 patent is invalid because it was inherently anticipated by prior art more than one year before the patent application was filed.

### ***1. Background***

On May 2, 1995, Alza filed what eventually became the '355 patent for its invention of a sustained release version of oxybutynin. Over the years, Alza filed CIPs to disclose improvements made to the invention. Alza filed CIPs on September 5, 1996, February 26, 1997, and May 13, 1998. Each of these applications resulted in a new patent being issued. Meanwhile, on November 28, 1996, Alza's original 1995 '355 patent application was published as an "International Application" under International Publication No. WO 96/37202 ("the November 1996 WO Publication").

### ***2. Analysis***

Under 35 U.S.C. 102(b), "a patent application fails if it is filed more than one year after the invention was described in a written publication. (A publication that thus pre-dates patent claims is called 'anticipatory.')" *Affvmetrix, Inc. v. PE Corp.* (N.Y.), 306 F.Supp.2d 363, 369 (S.D.N.Y.2004). Once the subject matter of a

claimed invention is placed into the public domain by an enabling published disclosure, it cannot be recaptured by rewriting new claims in a new application filed more than one year later. 35 U.S.C. s. 102(b); *see also* *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1158 (Fed.Cir.1998); *Lockwood v. Am. Airlines*, 107 F.3d 1565, 1570 (Fed.Cir.1997).

Therefore, prior art that arose after the filing date of the original patent application but before the filing date of the CIP can be cited against the CIP. However, any material in the CIP application that is in common with an earlier application gets the benefit of the original application's filing date. 35 U.S.C. s. 120. Only new material has the filing date of the CIP itself.

### **a. Inherent Anticipation**

A prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference. *Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1377 (Fed.Cir.2003), *reh'g en banc denied*, 348 F.3d 992 (Fed.Cir.2003). The patent challenger bears the burden of establishing this fact by clear and convincing evidence. *Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co.*, 308 F.3d 1167, 1188 (Fed.Cir.2002).

Regarding Alza's May 13, 1998 CIP application, Mylan argues that the 1996 WO Publication constitutes prior art that enables a bilayer push/pull osmotic pump oxybutynin dosage form. Thus, Mylan contends that the 1996 WO Publication inherently anticipates the "4, 8, 14, and 24 hour release" limitations added by the 1998 CIP. Alza's position is that the material in the 1998 CIP application is not new, but rather recites and reinforces material disclosed in the '355 patent, prior to the November 1996 WO Publication.

Mylan's argument depends on this Court finding, by clear and convincing evidence, that the 1998 CIP application is not entitled to the priority data of the parent application. *See Ralston Purina Co. v. Far-Mar-Co. Inc.*, 772 F.2d 1570, 1573-74 (Fed.Cir.1985). Therefore, the merits of Mylan's summary judgment motion on the threshold issue of priority must be analyzed first.

### **b. Threshold Priority Issue**

Under 35 U.S.C. s. 112, a patent application must:

contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

"Compliance with the written description requirement is essentially a fact-based inquiry that will 'necessarily vary depending on the nature of the invention claimed.'" *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed.Cir.2003) (quoting *Enzo Biochem v. Gen-Probe, Inc.*, 296 F.3d 1316, 1324 (Fed.Cir.2002)); *see also* *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320 (Fed.Cir.2000).

The purpose of the "written description" requirement is to put future inventors on notice of the existence and scope of an invention and to prevent inventors from claiming ownership over more than they rightfully own. This is why the description must "reasonably convey" to one skilled in the art that the inventor possessed the claimed invention at the time of the filing date. *See, e.g.*, *Augusting Medical, Inc. v. Gaymar Indus.*, 181 F.3d 1291, 1302 (Fed.Cir.1999); *Vas-Cath*, 935 F.2d at 1562-631; *Rambus, Inc. v. Infineon Technologies*

"Entitlement to a filing date does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed.... Rather, a prior application must describe an invention, and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought." *Lockwood*, 107 F.3d at 1570; *Tronzo*, 156 F.3d at 1158. Determining the satisfaction of the "written description" standard requires a case-by-case, factual inquiry as to whether information is conveyed clearly enough to enable "one skilled in the art" to realize that the material is part of the patent. While this is a rigorous standard, express statements are not the only way to satisfy it.

A patent's specification may inherently contain a disclosure sufficient to meet the written description requirement if "the missing descriptive matter must necessarily be present in the parent application's specification such that one skilled in the art would recognize such a disclosure." *Tronzo*, 156 F.3d at 1159; *see also* *Kennecott v. Kyocera*, 835 F.2d 1419, 1422-23 (Fed.Cir.1987); *Sulfur-Tech Water Sys., Inc. v. Kohlenberg*, 162 F.Supp.2d 743, 749-50 (N.D.Ohio 2001); *Novo Nordisk A/S v. Becton Dickinson & Co.*, 96 F.Supp.2d 309, 313-14 (S.D.N.Y.2000).

In *Kennecott*, where the term "equiaxed microstructure" was expressly used to describe an invention for the first time in a CIP, the CIP was entitled to the benefit of the filing date of the parent patent because the description was inherent in the structure produced in the original parent patent. Since the additional description was not of a new use, but of the existing physical structure of the product, the appellants had met their burden of showing that this was "the 'necessary and only reasonable construction' " that the disclosure could be given "by one skilled in the art." 835 F.2d 1419, 1423; *see also, e.g.*, *Applied Medical Resources Corp. v. U.S. Surgical Corp.*, 147 F.3d 1374 (Fed.Cir.1998).FN4

FN4. Mylan argues that the precedential value of *Kennecott* is questionable. Counsel suggests that the doctrine of inherency was somehow overruled by the court in *Vas-Cath* and has not been cited as a valid legal proposition since the 1980s. In fact, in *Vas-Cath* the court questioned only one aspect of *Kennecott*. Addressing two sentences in the *Kennecott* case, which state that the "written description" requirement and the enablement requirement are "intertwined" even though they may be viewed separately, the decision in *Vas-Cath* clarified that the enablement and written description requirements are separate. 835 F.2d at 1421.

Thus, *Kennecott* still has value today and has been cited by many courts for the proposition Alza advocates, including the Federal Circuit as recently as 1998—seven years after the *Vas-Cath* decision. *See, e.g.*, *Applied Medical Resources Corp. v. U.S. Surgical Corp.*, 147 F.3d 1374 (Fed.Cir.1998). *See also* *Sulfur-Tech Water Sys., Inc. v. Kohlenberg*, 162 F.Supp.2d 743 (N.D.Ohio 2001), and *Novo Nordisk A/S v. Becton Dickinson & Co.*, 96 F.Supp.2d 309 (S.D.N.Y.2000), two district court cases that fully discuss the doctrine of inherent disclosure as a means of satisfying the written description requirement.

Even in *Lockwood* and *Vas-Cath*, where the written description requirement was rigidly construed, the Federal Circuit did not hold that only express statements could satisfy the standard. *Lockwood* stated that one may fulfill section 112's requirements "by *such descriptive means as* words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention ." 107 F.3d 1565 (emphasis added). Similarly, in *Vas-Cath*, the court found that drawings could be sufficient to satisfy section 112 . FN5 935 F.2d at 1565.

FN5. The *Vas-Cath* court added, parenthetically, that "summary judgment ... [is] inappropriate where [the] resolution of what [the] parent disclosure conveyed to those skilled in the art may require [the] examination

of experts, demonstrations and exhibits." 935 F.2d at 1555 (quotation omitted).

Nor do *PIN/NIP, Inc. v. Platte Chemical Co.*, 304 F.3d 1235 (Fed.Cir.2002), or *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320 (Fed.Cir.2000), support the argument that an inherent limitation in an application does not meet the standard.

In *PIN/NIP*, a claim did not meet the written description requirement where the original application only described a mixture of two chemicals and the later application included a description of applying the two chemicals in a spaced, sequential manner. The Federal Circuit did not deny the existence of a doctrine of inherency, and, significantly, stated that "the originally filed application ... is devoid of any mention *or even implication* that the two chemicals can be applied in a spaced, sequential manner...." 304 F.3d at 1247-48 (emphasis added).

In *Purdue*, the court emphasized that satisfaction of the written description requirement is a factual, case-by-case inquiry. In that case, examples in a patent for a sustained release, twice-a-day oral morphine formulation were not enough to satisfy the requirement where the disclosure did not "even motivate one to calculate the [medication] ratio." 230 F.3d at 1327. The Federal Circuit stated that "one cannot disclose a forest in the original application, and then later pick a tree out of the forest and say 'here is my invention.' ... [T]he blaze marks directing the skilled artisan to that tree must be in the originally filed disclosure." *Id.* at 1326-27. Significantly, however, *Purdue* did not hold that examples set forth in a patent could never satisfy the written description requirement; it held only that the examples in that particular case failed to do so. The district court made the same determination, not on a summary judgment motion, but after hearing expert testimony. Moreover, the Federal Circuit did not comment on what it would have done in the situation, but rather reviewed the district court's decision using a "clearly erroneous" standard.

According to the *Novo Nordisc* court,

[section] 112 does not require the express recitation in the parent application of every feature of the claims in a later continuation-in-part application, but rather calls for a determination on a case-by-case basis of whether a person of ordinary skill in the art would consider the later claimed subject matter to be part of the invention as originally disclosed. In reaching that determination, material which is inherently part of the disclosure, even though not expressly disclosed, must be considered.

96 F.Supp.2d at 314.

In this case, neither party disputes that the oxybutynin release rates are at least suggested by the figures in the original patent application. Whether this implication in the '355 patent is clear enough to satisfy the written description requirement is a factual question that requires the Court to hear expert testimony concerning what one skilled in the art would discern.

Alza expects to proffer two experts who will testify that "one skilled in the art" would have known (1) the percentage or milligram amounts of the oxybutynin that must be released from a product at the end of 4, 8, 14, and 24 hours, and (2) the procedure or procedures to use to determine the amount of oxybutynin released. Certainly the written description requirement is a demanding one; however, regardless of what the expert testimony will ultimately prove, whether the release rates in Alza's '355 patent are "blaze marks" on the trees in the forest of those skilled in the art is a factual matter to be decided at trial. Accordingly,

summary judgment on the threshold priority and inherent anticipation issues must be denied.

### C. Indefiniteness

In its third motion for summary judgment, Mylan contends that the asserted '355 patent claims are indefinite under *Honeywell*. "A claim is indefinite [under 35 U.S.C. s. 112, para. 2] if, when read in light of the specification, it does not reasonably apprise those skilled in the art of the scope of the invention." Amgen, 314 F.3d at 1342.

The standard of indefiniteness is somewhat high; a claim is not indefinite merely because its scope is not ascertainable from the face of the claims. *Cf., e.g., LNP Eng'g Plastics, Inc. v. Miller Waste Mills, Inc.*, 275 F.3d 1347, 1359-60 (Fed.Cir.2001) (affirming district court finding that patent was not indefinite, despite testimony from a co-inventor that he did not understand what the claim limitation "substantially completely wetted" meant). Rather, a claim is indefinite under s. 112 if it is insolubly ambiguous, and no narrowing construction can properly be adopted.

*Id.* "If the meaning of the claim is discernible, even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree, [the Federal Circuit has] held the claim sufficiently clear to avoid invalidity on indefiniteness grounds." *Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1375 (Fed.Cir.2001).

According to Mylan, the case at bar is "virtually identical" to *Honeywell*. Specifically, Mylan maintains that (1) there are several ways to test an accused drug for infringement; (2) the claims, specification, and prosecution history of the '355 patent do not indicate which test to use; and (3) results vary greatly between the possible tests. Therefore, it concludes that "the claims at issue here are not sufficiently precise to permit a potential competitor to determine whether or not he is infringing." *Morton Int'l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470 (Fed.Cir.1993).

As the Court's claim construction illustrates, *Honeywell* is readily distinguishable from this case. First, as discussed above, the sample preparation method at issue in *Honeywell* acted as a limitation on the disputed claims. Here, testing methods are not integral to the claims but are relevant to infringement. Second, in *Honeywell*, the "claims, written description, and prosecution history d[id] not mention the different sample preparation methods or provide sufficient clues to discern which methods are acceptable." 341 F.3d at 1339. In the '355 patent, however, the written description specifically refers to *The United States Pharmacopeia*, National Formulary 1791-96 (1995), which describes certain procedures for dissolution testing on different extended release drugs. '355 patent, col. 8:44. Moreover, the claims themselves establish the scope of proper testing conditions by indicating that the oxybutynin release rates occur in a "patient," i.e., a human subject.

In essence, Mylan's application of *Honeywell* confuses indefiniteness with infringement. "The test for indefiniteness does not depend on a potential infringer's ability to ascertain the nature of its own accused product to determine infringement, but instead on whether the claim delineates to a skilled artisan the bounds of the invention." *SmithKline Beecham*, 365 F.3d at 1315. Thus, the definiteness inquiry focuses on a skilled artisan's comprehension of disputed claims, not the identification of the most salient infringement tests. Although the parties may wrangle about the proper tests for infringement, the claims of the '355 patent adequately articulate the necessary characteristics and scope of the invention. At the very least, the claims are not "insolubly ambiguous." Accordingly, the Court concludes that, particularly when read in light of the specification, the '355 patent claims reasonably apprise a person of ordinary skill in the art of the scope of



the invention.

## **D. Noninfringement**

In seeking summary judgment for noninfringement, Mylan first argues that, under its asserted claim construction, its accused products do not infringe because they do not utilize osmotic pumps. In the alternative, it asserts that its accused products do not infringe the vast majority of possible testing conditions—assuming an "all methods" infringement testing mandate. Otherwise, Mylan contends that Alza fails to prove infringement "as a matter of law." Alza disagrees, asserting that its experts' testing results indicate that Mylan's accused product infringes the '355 patent.

As an initial matter, Mylan's first two noninfringement theories are contingent upon claim constructions that the Court has rejected; therefore, these arguments fail *a priori*. In its third theory, Mylan attempts to establish that Alza's experts either failed to properly test the accused product or produced results that outrightly demonstrate noninfringement. A protracted analysis of this last contention is unnecessary. As Alza observes, Mylan's motion largely relies on unsupported attorney argument. Mylan argues that "[e]ach of the Alza expert opinions is scientifically baseless and the testing methodologies are admittedly erroneous and/or unsupported by any peer-reviewed papers." (Mylan's Reply to Alza's Resp. to Mot. for Summ. J. on Noninfringement at 5.) Yet Mylan fails to cite any expert opinions to undergird its own conclusions.FN6

FN6. In explaining its lack of expert support for its position, Mylan confidently states: Alza implies that somehow Mylan's unrefuted calculations and charts showing a lack of infringement must be sponsored by an expert witness. Mylan's supporting data is [sic] straightforward applications of deterministic procedures using well-established algorithms. Unlike Alza's need to have its experts interpret and message its infringement with unsupported opinions, the data presented in Mylan's briefs speaks for itself and clearly shows that Alza is unable to prove infringement.

(Mylan's Reply to Alza's Resp. to Mot. for Summ. J. for Nonfringement at 5 n. 2.) Expert testimony, however, is vital to the Court's understanding of the disputed testing methodologies and results. *See* Fed.R.Evid. 702; *cf.* *Carter v. Ball*, 33 F.3d 450, 457 (4th Cir.1994) ("[I]f a [party] offers a statistical comparison without expert testimony as to methodology or relevance to [the] claim, a judge may be justified in excluding the evidence.") (citation omitted).

Further, Alza presents ample evidence to establish numerous issues of fact as to infringement. It cites three experts—Drs. Barr, Lowman, and Peppas—whose respective analyses and testing suggest that Mylan's accused product infringes the '355 patent. Therefore, summary judgment is precluded as to infringement.

## **E. Anticipation**

Finally, Mylan contends that U.S. Patent Nos. 5,399,359 ("the Baichwal patent"), 5,330,776 ("the Morella patent"), 5,082,668 ("the Wong patent"), and 5,498,422 ("the Nakamichi patent") each independently anticipates the '355 patent. To establish patent invalidity by anticipation, a defendant must prove by clear and convincing evidence that *every* limitation of a plaintiff's asserted claims was contained, either expressly or inherently, in a single prior art reference. *Union Carbide Chems. & Plastics Tech. Corp.*, 308 F.3d at 1188. Moreover, "[a]nticipation is a question of fact." *Merck & Co., Inc. v. Teva Pharms. USA, Inc.*, 347 F.3d 1367, 1369 (Fed.Cir.2003).

Again, Mylan's argument relies primarily on conclusions that are unsupported by expert testimony. This

Court is unwilling to accept the assertions of attorneys as to fact-intensive scientific matters. Moreover, Mylan has failed to establish the absence of material factual issues with respect to any anticipation challenge. thus, viewing the evidence in a light most favorable to Alza, and considering the heightened burden of proof borne by Mylan, the Court denies summary judgment as to Mylan's anticipation defense.

#### **IV. CONCLUSION**

Based on the foregoing analysis, the Court CONSTRUES the disputed claim language according to its plain meaning and the parties' stipulated definitions. The Court also DENIES Mylan's motions for summary judgment (dkt. nos.152-156).

It is so ORDERED.

The Clerk shall transmit copies of this Order to counsel of record.

N.D.Cal.,2005.

Alza Corp. v. Impax Laboratories, Inc.

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