UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

ABAXIS, INC., Plaintiff, v. CEPHEID, Defendant.	Case No.: 10-CV-02840-LHK ORDER CONSTRUING DISPUTED CLAIM TERMS

Plaintiff Abaxis, Inc. filed suit against Defendant Cepheid, alleging infringement of four patents. The parties now seek construction of four disputed terms used in the claims of the patents. The Court held a tutorial on June 15, 2011, and a claim construction hearing on June 21, 2011. The Court has reviewed the claims, specifications, and other relevant evidence, and considered the briefing and arguments of the parties. The Court now construes the terms at issue.

I. Background

Plaintiff Abaxis, Inc. develops technology for use in diagnostic medical testing. Such testing frequently involves mixing a biological sample with a chemical reagent and monitoring the chemical reaction that follows. In order to achieve consistent, accurate testing that can be performed efficiently and inexpensively, the reagents used must be provided in precise amounts, with minimal variation, and they must dissolve rapidly. To address this need, Abaxis developed a method for producing freeze-dried reagent beads or spheres that contain precisely measured

amounts of chemical reagents. These reagent beads or spheres are typically formed by preparing an aqueous solution of the reagent, dispensing uniform, precisely measured drops of the solution into a cryogenic liquid, and lyophilizing the frozen drops to form dried beads or spheres.

Various aspects of these bead/sphere compositions and the methods for their preparation are claimed in patents owned by Abaxis, including the following patents-in-suit: Patent Number 5,413,732 (the "'732 patent"), Patent Number 5,624,597 (the "'597 patent"), Patent Number 5,776,563 (the "'563 patent"), and Patent Number 6,251,684 (the "'684 patent"). Each of these patents derives from a patent application filed on August 19, 1991, which issued as the '732 patent. The '597 patent issued from a continuation application from the '732 patent and shares the same specification with the '732 patent. The '563 and '684 patents are child patents of an abandoned continuation-in-part application. They share overlapping subject matter with the specification of the '732 and '597 patents, but are not identical. The first claim of the '732 patent provides an illustration of the types of inventions claimed in the four patents:

> **1.** A method for forming a plurality of uniform, precisely measured reagent spheres, the method consisting essentially of the steps of:
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> forming a homogeneous solution of a reagent;
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> precisely measuring uniform drops of the solution;
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> dispensing the uniform, precisely measured drops into an unagitated cryogenic liquid, whereby the drops are frozen;
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> collecting the frozen drops from the cryogenic liquid; and
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> lyophilizing the frozen drops, thereby forming a plurality of reagent spheres having a coefficient of weight variation less than about 3% and which completely dissolve in an aqueous solution in less than about 10 seconds.

In its First Amended Complaint, Abaxis claims that a number of Cepheid products infringe the four patents-in-suit. Abaxis contends that when it first approached Cepheid regarding its alleged infringement, Cepheid entered into a royalty-bearing license agreement for use of Abaxis's patented inventions and paid fees under that agreement for over four years. Opening Br. at 4, ECF No. 54. Abaxis claims that in late 2009, Cepheid refused to make further payments under the licensing agreement, but has continued to sell infringing products. *Id.* Accordingly, Abaxis's complaint asserts four claims of patent infringement, as well as a claim for breach of the license agreement. Cepheid denies these allegations and asserts counterclaims for declarations of non-

infringement, invalidity, and unenforceability of Abaxis's patents, a declaration as to the term of the '597 patent, and for breach of contract. The Court granted Abaxis's motion to dismiss Cepheid's inequitable conduct defense and counterclaim on March 22, 2011, and a motion to dismiss the amended inequitable conduct defense and counterclaim is pending.

The case is currently before the Court for construction of the following four disputed claim terms:

(1) "dissolves in less than about 10 seconds in water/an aqueous solution";

(2) "about";

(3) "A container holding a dried chemical composition . . . wherein said dried chemical composition comprises a preselected precisely measured aliquot of said dried chemical composition"; and,

(4) "bead."

II. Legal Standard

Claim construction is a question of law to be determined by the Court. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed.Cir. 1995) (en banc), *aff'd* 517 U.S. 370 (1996). "Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed.Cir. 2005) (quoting *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed.Cir. 1998)). Accordingly, a claim should be construed in a manner that "stays true to the claim language and most naturally aligns with the patent's description of the invention." *Id.*

In construing disputed terms, the court looks first to the claims themselves. "It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" *Id.* at 1312 (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). Generally, the words of a claim should be given 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 1312-13. In some instances, the ordinary meaning to a person of skill in the art is clear, and

claims construction may involve "little more than the application of the widely accepted meaning of commonly understood words." *Id.* at 1314. In many cases, however, the meaning of a term to a person skilled in the art will not be readily apparent, and the court must look to other sources to determine the meaning of the term. *Id.*

The meaning of a term may be illuminated by the context in which it is used in an asserted claim, or by usage of the term in related claims. *Id.* Importantly, however, "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.* at 1313. Accordingly, claims "must be read in view of the specification, of which they are a part." *Id.* at 1315 (quoting *Markman*, 52 F.3d at 979). Indeed, the specification is "always highly relevant" and "the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). At the same time, the Federal Circuit has cautioned against limiting claims to the specific embodiments of the invention. *Phillips*, 415 F.3d at 1323. A court "should also consider the patent's prosecution history, if it is in evidence." *Id.* (quoting *Markman*, 52 F.3d at 980).

In addition to such intrinsic evidence, a court may rely on extrinsic evidence, such as dictionaries and treatises, to shed light on the claimed technology. *Phillips*, 415 F.3d at 1317. However, such evidence is considered "less significant than the intrinsic record" and "less reliable than the patent and its prosecution history in determining how to read claim terms." *Id.* at 1317-18 (quotation marks and citation omitted). Ultimately, while extrinsic evidence may be useful in claim construction, "it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1319.

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III. Discussion

A. "dissolves in less than about 10 seconds in water/an aqueous solution" ('563 patent, claim 1; '684 patent, claim 6)

Abaxis's Proposed Construction	Cepheid's Proposed Construction
No construction necessary. (*i.e.*, "dissolves" means dissolves)	"completely dissolves in less than about 10 seconds in water/an aqueous solution" (*i.e.*, "dissolves" means *completely* dissolves)

The first claim term in dispute is the phrase "dissolves in less than about 10 seconds in water/an aqueous solution." This term appears in the '563 and '684 patents, as follows:

'563 Patent, claim 1:

> A container holding a dried chemical composition which **dissolves in less than about 10 seconds in water**, wherein said dried chemical composition comprises a pre-selected precisely measured aliquot of said dried chemical composition which chemical composition is in bead form have in [sic] a diameter between 1.5 mm and 10.0 mm. (emphasis added)

'684 Patent, claim 6 (dependent on claim 1):

> **1.** A dried chemical reagent composition comprising a plurality of dried beads having a coefficient of weight variation of less than about 3%, and a diameter of between about 1.5 mm and about 10 mm or the equivalents thereof.
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> ***
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> **6.** The composition of claim **1** wherein the beads **dissolve in less than about 10 seconds in an aqueous solution**. (emphasis added)

Although the parties identify the entire phrase as the disputed term, their briefing is focused solely on the meaning of the word "dissolve." Both parties agree that "dissolve" should be given its plain and ordinary meaning. However, Abaxis argues that the plain and ordinary meaning is readily apparent to a lay person and requires no construction. To the extent that any definition is necessary, Abaxis offers the dictionary definition of "to make a solution of, as by mixing with a liquid: *to dissolve salt in water*," or "to become dissolved, as in a solvent." Reply Br. at 2; Decl. of Adam M. Pivovar in Supp. of Pl.'s Reply Br. Ex. 1. Cepheid, on the other hand, urges the Court to construe "dissolve" to mean "completely dissolve."

In its briefing, Cepheid argues that "dissolve" must be construed to eliminate any ambiguity as to whether "dissolve in less than about 10 minutes" covers beads that only partially dissolve within the prescribed time period. Cepheid appears to be concerned that if the claim is not

construed, Abaxis may later argue that the claim term encompasses beads that merely *start* to dissolve, or *partially* dissolve, in less than about 10 minutes. Cepheid makes a persuasive argument that such an expansive definition of "dissolve" runs contrary to the ordinary meaning of the term and would render meaningless the time limits included in the claims and specifications. Cepheid points out that the patent specifications provide examples of different reagent compositions that dissolve "within" a specified number of seconds. *See, e.g.*, '563 patent at 10:22-23 ("Each reagent bead dissolves . . . within 5 seconds"); *id.* at 11:9-10 ("Each reagent bead dissolves . . . within 3 seconds"); *id.* at 12:20-21 ("The two reagent beads dissolve . . . within 10 seconds"). The Court agrees that it would make little sense to provide such specific dissolution times, or to distinguish between 3-second and 5-second dissolution times, unless those times refer to the time required for the process of dissolution to reach some sort of end state. This reasoning is further supported by the prosecution history of the '732 patent, in which Abaxis distinguished prior art on grounds that Abaxis's claimed compositions dissolved twice as fast as those disclosed in existing patents (that is, in less than about 10 seconds, as compared to the 20-30 seconds disclosed in the prior art). *See* Decl. of Steven C. Carlson in Supp. of Cepheid's Responsive Claim Constr. Br. ("Carlson Decl.") Ex. E at ABAX 019614. This distinction would have little meaning if Abaxis's claimed compositions did not complete the process of dissolution in less than about 10 seconds. *See Wang Laboratories, Inc. v. America Online, Inc.*, 197 F.3d 1377, 1384 (Fed. Cir. 1999) (prosecution history of parent patent is relevant to continuation-in-part patent where the subject matter is common to both patents).

Abaxis does not appear to disagree with this reasoning. Indeed, Abaxis explicitly states that "[n]othing in the claim language or intrinsic record suggests that one of skill in the art would equate beads that 'dissolve in less than about 10 seconds' as meaning beads that '[start to] dissolve in less than about 10 seconds.'" Reply Br. at 1. Abaxis points out that the very fact that Cepheid has to use modifying words such as "start to" in its argument suggests that the ordinary meaning of "dissolve" does not encompass the mere commencement of the dissolution process. Nonetheless, Abaxis opposes Cepheid's proposed construction because it believes that Cepheid seeks to narrow the scope of the claims by insisting that "completely dissolves" requires that dissolution be

"absolute or perfect and that the existence of *any* particulate matter is beyond the scope of the claim." Reply Br. at 3-4. Abaxis suggests that while a person skilled in the art would understand dissolve to mean that the process of dissolution has essentially been completed, such a person would not understand "dissolve" to require perfectly complete dissolution of all particulate matter into solution. Thus, the parties seem to agree that "dissolves in less than about 10 seconds" means that the process of dissolution reaches some measure of completion in less than about 10 seconds. The question is whether the modifier "completely" is required to make this meaning clear, or whether "completely" would impose an unwarranted limitation on the scope of the claim.

Cepheid argues that the language of the patents supports its proposed construction because the terms "dissolve and "completely dissolve" are used interchangeably throughout the patents. For instance, the patent specification states that in some embodiments, the dried compositions "comprise a chemical lattice to facilitate rapid and *complete* dissolution." '563 patent at 3:41-44 (emphasis added). When describing the same device a few columns later, however, the specification omits the word "complete" and simply states that the chemical lattice facilitates "rapid dissolution of the beads." *Id.* at 7:17-18. Similarly, Cepheid argues that the examples use "completely dissolve" and "dissolved" interchangeably in variations on the following sentences: "It is best to *completely dissolve* each chemical before adding the next chemical. After the last chemical *dissolved*, the solution volume was adjusted . . . ." *Id.* 9:36-39 (emphasis added); *see also id.* at 10:38-42, 11:30-34, 11:50-54. Cepheid also cites similar usages of "dissolve" and "completely dissolve" in the parent patents and notes that those earlier patents actually claimed reagent spheres that "completely dissolve in less than 10 seconds." '732 patent, claim 1; '597 patent, claim 16; *see also* '732 patent 3:7-9, '597 patent 2:66-3:2 ("The reagent spheres of the present invention are capable of quickly and completely dissolving in a solution, typically in less than about 10 seconds.").

On the other hand, Abaxis correctly notes that "dissolve" is repeatedly used without modification in the '563 and '684 patents. "Dissolve," unmodified, is by far the predominant usage, and the references to "complete" dissolution cited by Cepheid do not clearly show that "dissolve" and "completely dissolve" were used interchangeably in the '563 and '684 patents.

Indeed, the reference to compositions "compris[ing] a chemical lattice to facilitate rapid and complete dissolution" describes only "some embodiments" of the invention. '563 patent at 3:40-44. Moreover, because the chemical lattice is described as "facilitat[ing]" complete dissolution, it is not clear that the claims require that complete dissolution actually be achieved. Abaxis thus argues that because "dissolve" is used predominantly without modification and nothing in the claims or specifications provides a specific definition of the term, the ordinary meaning should govern.

Ultimately, the Court finds both parties' positions to be fairly persuasive. On the one hand, the Court agrees that the phrase "dissolves in less than about 10 seconds" must mean that the process of dissolution is, for practical purposes, complete in less than about 10 seconds. Otherwise, the time limitations included in the claims and specifications would have little meaning. On the other hand, "dissolve," rather than "completely dissolves," is by far the predominant usage in the patents, and the intrinsic evidence does not suggest that "dissolve" requires every microscopic particle to go fully into solution. Instead, the patents provide a rather qualitative description of the dissolution process. *See, e.g.*, '563 patent 7:12-14 ("the rapidity of dissolution *gives the impression* that the bead 'explodes' and distributes the dissolving chemicals throughout the reconstituting volume") (emphasis added). This suggests that "dissolve" is used to describe an appearance or other qualitative measure of dissolution, rather than a more technical, molecular-level understanding. At the claim construction hearing, Cepheid acknowledged that the patents do not require complete dissolution at the level of nanoparticles and agreed that some sort of visual or appearance-based test, possibly under weak magnification, would be an appropriate means of determining whether a bead is dissolved for purposes of Abaxis's patents. This suggests that even under Cepheid's understanding of the claims, a bead could be considered "dissolved" if some particulate matter remains at a microscopic level. Thus, both parties seem to agree that although "dissolve" requires some measure of completion, it does not require complete dissolution at a molecular level.

For these reasons, the Court is wary of adopting a construction of "dissolve" that might be understood to require perfect or absolute dissolution of all particulate matter. Cepheid itself has

suggested, and the Court agrees, that "dissolve," as used in the context of a dissolution time, is well-understood to mean that a solid substance has gone fully into solution within the designated time period. Responsive Br. at 9. If this is the case, however, then the addition of "completely" might be understood to require something more, such as absolute or perfect dissolution of all particulate matter. The Court has already found that such a limitation is not supported by the evidence. Accordingly, the Court will not adopt Cepheid's proposed construction of "completely dissolves." Instead, the Court adopts a variation of the dictionary definition offered by Abaxis, using the past tense to indicate that the dissolution process has essentially come to an end, but also clarifying that absolutely or perfectly complete dissolution is not required. Specifically, the Court construes "dissolves in less than about 10 seconds in water/an aqueous solution" to mean "in less than about 10 seconds the bead has gone into solution and become dissolved in the water/ aqueous solution, but absolute or perfect dissolution of all particulate matter is not required." The Court believes that this construction accurately limits the patent claims to beads that essentially complete the dissolution process in less than about 10 seconds, without imposing a further limitation of absolute or perfect dissolution that is not supported by the patents.

B. "about" ('732 patent, claims 1-4; '597 patent, claims 3-5, 16; '563 patent, claims 1, 3-4; '684 patent, claims 1, 6-7, 12-13)

Abaxis's Construction	**Cepheid's Construction**
"approximately"	"within experimental error"

The second term in dispute is the word "about," as used to modify the following values:

(1) The coefficient of weight variation of the reagent spheres, beads, or aliquots ("a coefficient of weight variation [of] less than *about* [3% or 2.5%]," "a coefficient of weight variation of between *about* 0.3% to about 2.5%") ('732 patent, claims 1 and 3; '597 patent, claim 4; '563 patent, claim 4; '684 patent, claims 1 and 7);

(2) The diameter of the reagent spheres or beads ("a [mean] diameter between *about* 1.5 mm and," "a diameter of between *about* 1.5 mm and *about* 10 mm," "a diameter of less than

about 5 mm/3.5 mm") ('732 patent, claim 2; '597 patent, claims 3 and 17; '563 patent, claim 3; '684 patent, claims 1, 12, and 13);

(3) The volume of the uniform, precisely measured drops that are frozen and dried to form the reagent spheres/beads ("a volume between *about* 2.0 µl and *about* 6.5 µl") ('732 patent, claim 4; '597 patent, claim 5);

(4) The amount of time in which the reagent spheres/beads dissolve ("in less than *about* 10 seconds") ('732 patent, claim 1; '597 patent, claim 16; '563 patent, claim 1; '684 patent, claim 6).

The Federal Circuit has developed an approach to interpreting the term "about" and similar qualifying words. Under this approach, the "word 'about' does not have a universal meaning . . . the meaning depends upon the technological facts of the particular case." *Ortho-McNeil Pharmaceutical, Inc. v. Caraco Pharmaceutical Laboratories, Ltd.*, 476 F.3d 1321, 1326 (Fed. Cir. 2007) (quoting *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1217 (Fed. Cir. 1995)). Generally, use of the word "about" is understood as a means of "avoid[ing] a strict numerical boundary to the specified parameter." *Ortho-McNeil*, 476 F.3d at 1326 (quoting *Pall Corp.*, 66 F.3d at 1217). The range encompassed by the term "must be interpreted in its technological and stylistic context." *Ortho-McNeil*, 476 F.3d at 1326 (quoting *Pall Corp.*, 66 F.3d at 1217). "In determining how far beyond the claimed range the term 'about' extends the claim," the court must focus on the "criticality" of the numerical limitation and the purpose it serves within the claimed invention. *Cohesive Technologies, Inc. v. Waters Corp.*, 543 F.3d 1351, 1368 (Fed. Cir. 2008). Courts should also consider how the term is used within the patent and the prosecution history, the possible effects of varying its parameters, and extrinsic evidence of meaning and usage in the art. *Ortho-McNeil*, 476 F.3d at 1326. "Although it is rarely feasible to attach a precise limit to 'about,' the usage can usually be understood in light of the technology embodied in the invention." *Modine Mfg. Co. v. United States Int'l Trade Comm'n*, 75 F.3d 1545, 1557 (Fed. Cir. 1996), *abrogated on other grounds by Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 234 F.3d 558 (Fed. Cir. 2000) (en banc).

In some cases, courts have construed "about" narrowly to encompass only a range of experimental or measuring error. *See Lupin Ltd. v. Abbott Laboratories*, 484 F. Supp. 2d 448, 464 (E.D. Va. 2007) (construing "about" to "encompass[] only measurement errors inherently associated with PXRD testing"); *Chiron Corp. v. SourceCF Inc.*, 431 F. Supp. 2d 1019, 1027-30 (N.D. Cal. 2006) (finding trial evidence persuasive that "about" would ordinarily be understood to encompass "the limits of the pharmacy's professional measuring capabilities" and revising a prior ruling that construed "about" as "approximately"); *Motorola, Inc. v. Analog Devices, Inc.*, No. 1:03-CV-131, 2004 WL 5633734, at *5 (E.D. Tex. Mar. 23, 2004) (construing "about" to mean "plus or minus some reasonable measurement error"). *See also BJ Services Co. v. Halliburton Energy Services, Inc.*, 338 F.3d 1368, 1372-73 (Fed. Cir. 2003) (affirming jury finding that patent was not invalid for indefiniteness where "about" was used to encompass "the range of experimental error that occurs in any measurement").[1] In other cases, courts have found that "about" should be construed to mean "approximately" and cautioned against interpreting "about" more narrowly than warranted by the claims and specification. *See Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364, 1369 (Fed. Cir. 2005) (reversing district court's construction of "about" to mean "exactly" and holding that "such term should be given its ordinary meaning of 'approximately'"); *Biopolymer Engineering, Inc. v. Immunocorp*, Civil Nos. 05-536 (JNE/SRN), 05-2972 (JNE/JJG), 2007 WL 4562592, at *9-15 (D. Minn. Dec. 21, 2007) (declining to "arbitrarily construe 'about'" where there was no evidence to specify the intended range and instead giving "'about' its ordinary meaning of 'approximately'"); *Novartis Pharmaceuticals Corp. v. Apotex Corp.*, No. 02Civ.8917(KMW)(HBP), 2006 WL 626058, at *9 (S.D.N.Y. Mar. 13, 2006) (rejecting contention that "about" means "limited to the precise lower and upper limits of the recited range" and construing term to mean "approximately").

Here, Abaxis urges the Court to give "about" its ordinary meaning of "approximately." *See Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005) (identifying "approximately" as the "ordinary and accepted meaning" of "about"). Abaxis points

[1] It appears that the district court in *BJ Services* found it unnecessary to construe the term "about 0.06% percent by weight," and at trial both sides presented evidence regarding the range of experimental error applicable to the claimed invention.

out that the patents provide no definition of "about" and make no reference to "experimental error." Abaxis therefore argues that there is no support in the record for Cepheid's proposed construction of "within experimental error" and that such a construction would improperly "import a limitation into a claim where the limitation has no basis in the intrinsic record." *Seachange Intern., Inc. v. C-COR, Inc.*, 413 F.3d 1361, 1376 (Fed. Cir. 2005). Abaxis also argues that because the term "about" is used in numerous contexts in each patent, it must be given a definition broad enough to apply to each use. *See Acromed Corp. v. Sofamor Danek Group, Inc.*, 253 F.3d 1371, 1381-82 (Fed. Cir. 2001) (a term that appears in multiple claims of the same patent must be given "a meaning broad enough to apply to each" use); *Anchor Wall Systems, Inc. v. Rockwood Retaining Walls, Inc.*, 340 F.3d 1298, 1308 (Fed. Cir. 2003) ("varied use of a disputed term in the written description attests to the breadth of a term rather than providing a limiting definition").

Cepheid, on the other hand, urges the Court to construe "about" to mean "within experimental error." Under Cepheid's proposed construction, a drop that is measured to be 1.95 µl would fall within the claimed method involving "drops hav[ing] a volume between about 2.0 µl and about 6.5 µl," only if the imprecision in measurement was .05 µl or greater. If the Court were to adopt such a construction, the parties could introduce evidence at trial to establish the range of experimental or measuring error. Cepheid argues that such an approach is warranted because precision and "tight tolerances" are critical to Abaxis's claimed invention. Responsive Br. at 16. Cepheid also points out that the specification examples provide precise measurements (such as 1.78 mm, 2.96 µl, 1.8%, 3 seconds, etc.), and that none of these measurements falls outside the ranges claimed in the patents. Cepheid argues that these examples suggest that the claims are intended to encompass only values that come very close to the stated ranges, and therefore "within experimental error" is the appropriate construction. Finally, Cepheid also claims that "within experimental error" is broad enough to encompass all of the claims, for the parties may simply introduce evidence at trial to establish the range of error that applies to each measurement.

The Court agrees with Abaxis that nothing in the claims or specifications defines "about" or makes any reference to experimental error. Indeed, even in the detailed examples provided in the patents, there is no mention of experimental error. Where, as here, the record provides no support

for a specific range or definition of "about," some courts have declined to "arbitrarily construe" the term and instead applied the ordinary meaning of "approximately." *See Biopolymer Engineering, Inc. v. Immunocorp*, Civil Nos. 05-536 (JNE/SRN), 05-2972 (JNE/JJG), 2007 WL 4562592, at *9-15 (D. Minn. Dec. 21, 2007). There are cases, however, in which courts have construed "about" to mean measuring or experimental error, even in the absence of a specific reference to such error in the intrinsic record. In *Lupin Ltd. v. Abbott Laboratories*, for instance, the court construed "about" to encompass "only measurement errors inherently associated with PXRD [powder X-ray diffraction] testing." 484 F. Supp. 2d 448, 464 (E.D. Va. 2007). In that case, the patent claimed a crystalline form of antibiotic that exhibits peaks at "about" certain specified diffraction angles, as measured through PXRD testing. "About" was not defined anywhere in the claims or prosecution history. *Id.* However, the specification provided a specific diffraction pattern for a "Crystal A" and stated that any form of the antibiotic that exhibited "substantially the same diffraction pattern" would also be identified as Crystal A. Based on the requirement of substantial similarity, the Court concluded that the word "about" referred only to "minor deviations" from a PXRD angle. *Id.* In addition, it seems that experts for both sides agreed that a person skilled in the art would understand "about" in this context to mean the insignificant variations that arise due to minor differences in the PXRD testing process. *Id.* Thus, although "about" was not defined in the patent, the court construed the term to encompass only measuring error.

The question then, is whether the record here supports a construction of "about" to mean "experimental error," in the absence of an explicit definition in the patents. Unlike in *Lupin*, the parties to this case have not produced expert testimony suggesting that a person of ordinary skill in the art would understand "about" as used in the patent to mean "within experimental error." Rather, Cepheid's argument is based primarily upon the criticality of precision to Abaxis's claimed inventions. This argument is strongest in the context of the coefficient of weight variation. The patents emphasize that the reagents must be prepared in "precisely measured quantities" and have a "uniform mass." '732 patent 1:15, 5:39. The coefficient of weight variation is a measurement of the precision of the mass of the reagent spheres/beads: the lower the coefficient of weight variation, the more uniform the mass of the spheres/beads. *See* '732 patent 5:40-47. Abaxis states that

diagnostic testing requires precise amounts of chemical reagents. Opening Br. at 2. This suggests that the upper limit on the coefficient of weight variation is critical to ensuring the uniformity and precision of the spheres/beads. Given this need for uniformity and precision, it is possible that phrases such as "having a coefficient of weight variation less than about 3%" are intended to tolerate only the degree of variation caused by experimental error.

However, "about" is used in other instances to modify numerical limits and ranges for which the precision of the upper and lower limits is not as critical. For instance, with regard to the volume of the drops used to form the dried reagent spheres/beads, the specification indicates that "[t]he exact volume of the drops will depend upon the particular application." '732 patent 6:3-4; '597 patent 5:56-58. The specification identifies particular volumes that are appropriate for different types of tests, ranging from 2.065 µl for glucose tests to 4.0 µl for tests of potassium and creatinine. '732 patent 6:4-12; '597 patent 5:58-65. Presumably, for any particular test, obtaining drops of a precise volume is important, for precise measurement of the liquid drops is critical to obtaining precisely measured spheres/beads of uniform mass. Indeed, the term "about" is not used to modify the values for test-specific volumes. However, the patent does not suggest that the *range* of possible volumes that might be used over a variety of tests must be precisely limited. Rather, the patents indicate that the desired volume of drops will vary depending on the application, and thus the "about 2.0 µl" to "about 6.5 µl" limitation merely specifies an approximate range within which the different desired volumes are expected to fall. There is no indication that a volume that is near the 2.0-6.5 µl range, but not within experimental error, would disrupt the function of the claimed invention or could have no application. *See Cohesive Technologies*, 543 F.3d 1351, 1368 (Fed. Cir. 2008) ("To be clear, it is the purpose of the *limitation* in the claimed invention . . . that is relevant. Thus, we ask what function the 'about 30 µm' low-end limit on particle size plays in the operation of the claimed apparatus and method.").

Similarly, the amount of time it takes a reagent sphere/bead to dissolve does not appear to require precision. It is clear that rapid dissolution is preferable. The patents state that because "speed of analysis is at a premium" and "many clinical diagnostic analyses require that measurements be made within a short time after the sample is added to the reagent," the dried

reagents "must dissolve quickly in the sample solution." '732 patent 1:63-68; '597 patent 1:64-2:1; '563 patent 2:1-5; '684 patent 2:2-6. However, while the patents claim reagent spheres/beads that dissolve in less than about 10 seconds, the specification states that the spheres/beads "typically dissolve in less than about 30 seconds, preferably less than about 10 seconds." '732 patent 6:16-18; '597 patent 6:2-4;'563 patent 7:9-13; '684 patent 7:8-12. Although the Court would not suggest that "about 10 seconds" encompasses a 30-second dissolution time, the wide range of dissolution times described in the specification suggests that "about 10 seconds" tolerates greater variation than "experimental error" would allow.

The patents also do not suggest that the numerical limitations on the diameter of the spheres or beads requires precision. While the specification refers to a "correct size" for the spheres/beads in a test well, it appears that the "desired" or "correct" size may vary based upon the size of the test well, the type of sample involved, and other factors. *See* '732 patent 7:3-14, '597 patent 6:56-66 ("In order to provide reagent spheres of the correct size in a test well, the components are typically concentrated in the reagent sphere. . . . The ideal concentration for the reagents for a particular assay can be easily determined, depending upon the size of the test well, sample, volume, and the like.");'563 patent 8:25-36, '684 patent 8:25-36 ("The ideal concentration for the reagents for particular assay can be easily determined, depending upon desired size of bead, sample volume, and the like."). Indeed, the '563 and '684 both explicitly state that "[t]he beads of the invention can be made in a wide range of sizes." '563 patent 6:66-67, '684 patent 6:65-67. These patents also specify that the diameter is "typically" less than about 10 mm and that the "minimum size is typically about 1.5 mm." '563 patent 7:1-4, '684 patent 6:67-7:3. The use of "typically" suggests that some embodiments could fall outside the specified range without affecting the function of the invention. It therefore appears that "about" in this context is intended to tolerate variations that may be greater than the range of experimental error.

Finally, Abaxis notes that the word "about" is used throughout claims and specifications of the patents to modify a wide range of values. *See, e.g.*, '732 patent 3:22-24 ("the concentration in the reconstituted reagent is between about 0.08g and about 3.1g per 100 ml"); *id.* 3:28-30 ("filler compounds are typically present in concentration between about 10% and about 50% by dry

weight"); 5:28-29 ("having a normal boiling point below about –75º C."); 5:35-36 ("the frozen drops are lyophilized for about 4 hours to about 24 hours"). Generally, "varied use of a disputed term in the written description attests to the breadth of a term rather than providing a limiting definition." *Anchor Wall Systems, Inc. v. Rockwood Retaining Walls, Inc.*, 340 F.3d 1298, 1308 (Fed. Cir. 2003). This is particularly true where, as here, certain usages seem to require a broader meaning. For instance, "about" is used in the specification to modify a wide time range for lyophilization: "[t]ypically, the frozen drops are lyophilized for about 4 hours to about 24 hours." '732 patent 5:35-36; '597 patent 5:20-21; '563 patent 2:56-58; '684 patent 2:58-60. Given the large range of values provided and the relatively imprecise unit of measurement, it seems unlikely that "about" in this instance means "within experimental error."

The Federal Circuit has recognized that "[c]laims are often drafted using terminology that is not as precise or specific as it might be." *PPG Industries v. Guardian Industries Corp.*, 156 F.3d 1351, 1355 (Fed. Cir. 1998). In such situations, the Federal Circuit has instructed:

> That [imprecision] does not mean, however, that a court, under the rubric of claim construction, may give a claim whatever additional precision or specificity is necessary to facilitate a comparison between the claim and the accused product. Rather, after the court has defined the claim with whatever specificity and precision is warranted by the language of the claim and the evidence bearing on the proper construction, the task of determining whether the construed claim reads on the accused product is for the finder of fact.

Id. In this instance, "about" is used to modify a wide range of values throughout the specification; the term is not defined or limited by the language of the patent; and the parties have not introduced expert testimony or other extrinsic evidence suggesting that a person of ordinary skill in the art would understand "about" in this context to mean "within experimental error." Moreover, while precision is critical to certain aspects of the patents, it is not clear that precision is required in every context in which "about" is used. For these reasons, the Court finds that "about" should be construed to have its ordinary meaning of "approximately."

C. "A container holding a dried chemical composition . . . wherein said dried chemical composition comprises a preselected precisely measured aliquot of said dried chemical composition" ('563 patent, claim 1)

Abaxis's Construction	Cepheid's Construction
No construction necessary	Indefinite

The third term in dispute is the phrase "A container holding a dried chemical composition . . . wherein said dried chemical composition comprises a preselected precisely measured aliquot of said dried chemical composition," which appears in claim 1 of the '563 patent:

> 1. **A container holding a dried chemical composition** which dissolves in less than about 10 seconds in water, **wherein said dried chemical composition comprises a preselected precisely measured aliquot of said dried chemical composition** which chemical composition is in bead form have in [sic] a diameter between 1.5 mm and 10 mm.

Abaxis argues that this term consists of ordinary words that are easily understood as written and therefore contends that the term requires no construction. Cepheid argues that this claim contains circular, nonsensical language that renders the claim indefinite. In addition, the parties have agreed that "aliquot" means "a discrete quantity." Jt. Claim Constr. & Prehearing Statement at 1, ECF No. 46.

The claims of a patent must "particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his invention." 35 U.S.C. § 112. The purpose of this definiteness requirement is to "ensure that the claims delineate the scope of the invention using language that adequately notifies the public of the patentee's right to exclude." *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1347 (Fed. Cir. 2005). The statutory definiteness requirement "does not compel absolute clarity," *id.*, nor does it require that the claims be "plain on their face." *Exxon Research and Engineering Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001). Rather, claims are considered indefinite only if they are "not amenable to construction" or are "insolubly ambiguous." *Datamize*, 417 F.3d at 1347. "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 claim is considered "sufficiently clear to avoid invalidity on indefiniteness grounds." *Exxon Research*, 265 F.3d at 1375.

Because patents are presumed to be valid, "the evidentiary burden to show facts supporting a conclusion of invalidity is one of clear and convincing evidence." *Young v. Lumenis, Inc.*, 492 F.3d 1336, 1344 (Fed. Cir. 2007). Here, Cepheid argues, essentially, that the claim term is indefinite because it is circular. Cepheid reasons as follows:

> According to the claim, the container must hold a "dried chemical composition." The same "dried chemical composition" must then hold an "aliquot" of the same "dried chemical composition." Thus, the claim requires that the "dried chemical composition" comprises an aliquot of itself. This makes no sense.

Responsive Br. at 19. Cepheid also argues that the claim must be found indefinite because the phrase "dried chemical composition" is used in multiple, inconsistent roles within the claim.

The Court agrees that the claim is inelegantly drafted and contains unnecessarily circular language. Nonetheless, the Court has no trouble understanding the meaning of the claim term: that is, the patent claims a container holding a dried chemical composition, which "dried chemical composition" is further specified to be a "preselected precisely measured aliquot" in bead form. "In the face of an allegation of indefiniteness, general principles of claim construction apply." *Datamize*, 417 F.3d at 1347. It is a basic principle of claim construction that "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." *Phillips*, 415 F.3d at 1313. Here, the patent specification describes in detail a method for producing dried chemical compositions in discrete quantities (ie, aliquots) in the form of beads. *See generally* '563 patent. Thus, even if the claim language, taken in isolation, were not clear to a person of ordinary skill in the art, reference to the entire patent would clarify that the claimed invention is a container holding the chemical product described in the specification – that is, a discrete quantity of a dried chemical composition in bead form.

The Court is also unpersuaded by Cepheid's claim that the multiple usages of "dried chemical composition" render the claim indefinite. Cepheid relies on *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350 (Fed. Cir. 1999), for the proposition that a claim is indefinite if

it includes multiple, inconsistent uses of a single claim term. In *Process Control*, the claim included multiple uses of the term "discharge rate," and the Federal Circuit found that each usage had to be given the same meaning. 190 F.3d at 1356. As a result of this construction, the claim covered a method for determining "the material processing rate," which the Federal Circuit found to be identical to the discharge rate, from the discharge rate itself. *Id.* at 1357. Accordingly, the claim "would require 'determining something from some entity which includes what you are trying to measure,' a construction that clearly does not make sense." *Id.* at 1356. Here, in contrast, the meaning of "dried chemical composition" is constant throughout the claim. The use of the term in the modifying clauses simply specifies the physical form – i.e., a bead-shaped, discrete quantity – of the dried chemical composition that is claimed. While the claim might have been more clearly drafted, lack of absolute clarity is not sufficient grounds for finding a claim indefinite. The Court finds the claim readily understandable, and therefore concludes that Cepheid has not shown by clear and convincing evidence that the claim is indefinite and invalid. No construction is required.

D. "bead" ('563 patent, claim 1; '684 patent, claims 1, 2, 6, 7, 10, 12, 13, 14)

Abaxis's Construction	**Cepheid's Construction**
No construction necessary	"a small, rounded mass"

The final term in dispute is "bead" as used in the '563 and '684 patents. The term is used in claim 1 of the '563 patent:

> **1.** A container holding a dried chemical composition which dissolves in less than about 10 seconds in water, wherein said dried chemical composition comprises a preselected precisely measured aliquot of said dried chemical composition which chemical composition is in **bead** form have in [sic] a diameter between 1.5 mm and 10 mm.

The term is also used in numerous claims of the '684 patent, including the following illustrative claims:

> **1.** A dried chemical reagent composition comprising a plurality of dried **beads** having a coefficient of weight variation of less than about 3%, and a diameter of between about 1.5 mm and about 10 mm or the equivalents thereof.
>
> **2.** The composition of claim **1** wherein the **beads** comprise reagents necessary for the analysis of a biological sample.

3. The composition of claim **1**, wherein the **beads** comprise sodium fluoride.

****

10. The composition of claim **1**, wherein the dried **beads** are produced from precisely measured drops of a homogeneous solution.

Abaxis contends that the term "bead" requires no construction because it is used with the "regular meaning it would have to a lay person to simply describe the form of the claimed chemical compositions." Opening Br. at 11. Abaxis appears to argue that the ordinary meaning of "bead" in this context is simply the physical form of the chemical compositions produced using the methods of the patent. *See id.* Cepheid, on the other hand, argues that the term "bead" should be construed to mean "a small, rounded mass."

In its briefing, Cepheid makes much of the fact that the earlier '732 and '597 patents used the term "sphere" instead of bead, and that the '563 and '684 patents replaced most occurrences of "sphere" with the term "bead." Cepheid states that it has presented Abaxis with prior art references disclosing lyophilized compounds having a wide variety of shapes and sizes, Responsive Br. at 4, and suggests that Abaxis may seek to avoid invalidation by narrowing the meaning of "bead" in its later patents to "sphere." Abaxis, however, disavows any intent to limit the shapes encompassed by "bead" to only spherical forms and in fact implies that even the term "sphere" may not be so limited. Instead, Abaxis appears to seek a rather broad construction of "bead" that would "embrace all forms and shapes of beads that can be made using the methods taught in the patent, which are varied." Reply Br. at 12. Thus, the parties appear to agree that "bead" means something broader than a spherical form and can encompass some range of other shapes.

The parties also appear to agree that "bead" should be given its ordinary meaning. The parties diverge, however, with respect to what that ordinary meaning is. Abaxis argues that a person of ordinary skill in the art would read "bead" as simply a "generic descriptor" describing the compositions made from dispensing, freezing, and drying drops of solution. Reply Br. at 11. Presumably, under this definition, "bead" could encompass compositions of any shape, whether rounded or otherwise, so long as the compositions are produced through the methods described in the specification. Cepheid, on the other hand, argues that "bead" should be given the ordinary meaning it has in "common parlance": that is, "a small, rounded mass." Responsive Br. at 4.

With respect to Abaxis's proposed construction, the Court is not persuaded that the patents support a construction of "bead" to mean the form of the chemical compositions produced using the methods described in the patents. The patents do not define the term "bead" or explicitly limit its meaning to the forms produced by the described methods. Rather, the patents simply describe a dried composition that has the shape or form of a bead. *See* '563 3:19-20; '684 3:20-21 ("The present invention provides dried chemical composition, typically in the form of beads."). Moreover, both the '563 and '684 patents contain a broad, independent claim that includes the term "bead" but does not specify any particular method of production, as well as a dependent claim that is limited to the method of production described in the specification.[2] This strongly suggests that "bead" describes a shape or form that is independent of any method and counsels against reading the process limitation of the dependent claims into a definition of "bead" in the broader, independent claims.

The Court agrees with Cepheid that the reasoning of *Vanguard Products Corp. v. Parker Hannifin Corp.*, 234 F.3d 1370 (Fed. Cir. 2000), applies in this situation. In *Vanguard*, claim 1, the broadest claim of the patent, claimed a gasket with a thick inner layer and a thin outer layer "integral therewith." 234 F.3d at 1371. The defendant argued that "integral therewith" required the two layers of the gasket to be manufactured by "co-extrusion," the only process described in the specification. *Id.* However, claim 10 of the patent specifically described the two layers as "co-extruded," and the district court declined to read this process-based limitation in the broader claim

[2] The '563 patent includes the following dependent claim:

> **4.** The container of claim **1**, wherein said dried chemical composition is produced by a method comprising the steps of:
> forming a solution comprising a desired compound;
> dispensing uniform, precisely measured drops of the solution into a cryogenic liquid, whereby the drops are frozen; and
> drying the frozen drops, thereby forming dried aliquots wherein the dried aliquots comprise a plurality of dried aliquots having a coefficient of weight variation of less than about 3% and wherein said dried chemical composition is a single aliquot selected from the plurality of dried aliquots.

The '684 patent includes the following dependent claim:

> **10.** The composition of claim **1**, wherein the dried beads are produced from precisely measured drops of a homogeneous solution.

1. *Id.* at 1372. The Federal Circuit affirmed, stating that "[t]he method of manufacture, even when cited as advantageous, does not of itself convert product claims into claims limited to a particular process." *Id.* Here, as in *Vanguard*, although the dependent claims of the patents specify a process, the independent claims do not, and it would be inappropriate to import that limitation into the independent claims by construing "bead" as Abaxis proposes. Accordingly, the Court will not adopt Abaxis's construction of "bead" as a generic label for the form of the compositions produced by the methods described in the patents.

As to Cepheid's proposed construction, the Court agrees that "a small, rounded mass" captures the ordinary, common meaning of "bead." *See* Merriam-Webster's Collegiate Dictionary 99 (10th Ed. 1997) (defining "bead" as "as small ball-shaped body").[3] At the claim construction hearing, Abaxis objected to this construction on grounds that the meaning of "rounded" is unclear.[4] However, the parties appear to agree that such a construction would cover a range of shapes that are rounded in some respect. In its opposition brief, Cepheid claimed that "a small, rounded mass" would encompass "a variety of shapes and sizes, such as spherical beads, cylindrical beads, oval beads, and beads that are dome-shaped," Responsive Br. at 4, and at the hearing, Cepheid indicated that its construction would cover any small mass with a rounded aspect. Similarly, Abaxis has stated that "[o]n its face and as it would be applied by the jury, 'a small rounded mass' would not be 'limited to spheres' but would embrace other 'rounded' shapes, such as non-spherical oval, elliptical, or other elongated shapes with rounded surfaces." Reply Br. at 10. Given the parties' apparent agreement as to the ordinary meaning of "rounded," the Court believes that Cepheid's proposed construction can be sufficiently clarified by adding language that reflects the parties' understanding of the range of shapes encompassed by the word "rounded."

[3] The '684 patent was filed on April 24, 1998, and the '563 patent was filed on June 6, 1995. The Court has not been able to locate an edition of Merriam-Webster's Collegiate Dictionary issued prior to the filing of '563 patent. However, Webster's Third New International Dictionary, published in 1981, contains a similar definition, suggesting that there has been little change in the dictionary definition of "bead" over the past three decades. *See* Webster's Third New International Dictionary 190 (1981) (defining "bead" as "a small body shaped like a ball").

[4] One might make the same objection regarding the word "small." However, because the claims of both patents specify the diameter of the claimed beads, the Court does not believe that "small" in this context requires clarification.

Both parties agree that the claims in the '563 and '684 patents are intended to cover a relatively broad range of shapes. Abaxis has not argued that its invention covers "beads" that are not rounded or otherwise would not come within Cepheid's proposed construction. Nor has Abaxis argued that Cepheid's proposed construction would cover a broader range of shapes than the patents support. Indeed, Abaxis has not offered any evidence suggesting that "small, rounded mass" would be an inaccurate construction, other than its contention, rejected by the Court, that "bead" is merely a label for the forms of reagent compositions produced by the methods described in the specification. For these reasons, the Court will adopt Cepheid's construction, with a modification to clarify the meaning of "rounded." To reflect the parties' understanding that "rounded" simply requires some rounded aspect or surface, the Court construes "bead" to mean "a small mass with some rounded aspect or surface, such as a spherical, cylindrical, elliptical, oval, or dome-shaped mass."

IV. Conclusion

For the reasons discussed above, the Court construes the disputed claim terms as follows:

(1) "dissolves in less than about 10 seconds in water/an aqueous solution," means "in less than about 10 seconds the bead has gone into solution and become dissolved in the water/ aqueous solution, but absolute or perfect dissolution of all particulate matter is not required."

(2) "about" means "approximately";

(3) "A container holding a dried chemical composition . . . wherein said dried chemical composition comprises a preselected precisely measured aliquot of said dried chemical composition" is sufficiently definite and requires no construction; and,

(4) "bead" means "a small mass with some rounded aspect or surface, such as a spherical, cylindrical, elliptical, oval, or dome-shaped mass."

IT IS SO ORDERED.

Dated: July 22, 2011

LUCY H. KOH
United States District Judge