

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WISCONSIN

ILLUMINA, INC.,

Plaintiff,

v.

AFFYMETRIX, INC.,

Defendant.

OPINION AND ORDER

09-cv-277-bbc

09-cv-665-bbc

These cases for patent infringement are before the court for construction of several terms in U.S. Patents Nos. 7,510,841 and 7,612,020, patents related to a method and an apparatus for conducting genetic testing using microarrays, or “an array of arrays.” The parties dispute the meaning of three terms: “second substrate,” “bioactive agent” and “discrete sites.” Because the two patents share the same specification, the parties agree that the terms have the same meanings for both patents. Their disagreements focus on different passages in the specification that seem to point in different directions.

After considering the parties’ arguments in the briefs and at the claim construction hearing, I conclude that the terms have the following meanings:

- “second substrate” means “a material that can be modified to contain discrete individual sites appropriate for the attachment or association of beads and is amenable to at least one detection method”;
- a “bioactive agent” is “any molecule that can be attached to a microsphere”;
and
- “discrete sites” are “sites that do not touch another site.”

OPINION

A. Independent Claims

Claim 1 of the ‘841 patent reads:

A method of detecting the presence or absence of a plurality of different target analytes, comprising

(a) providing a first substrate with a surface comprising a plurality of assay wells, wherein said assay wells contain sample solutions each having a plurality of different target analytes;

(b) providing a second substrate comprising a plurality of array locations, each array location comprising a plurality of discrete sites on a projection, wherein said sites comprise different bioactive agents;

(c) dipping the projections of said second substrate into said assay wells such that each array location of said second substrate contacts sample solution in a different well of said first substrate under conditions suitable for binding of said different target analytes to said different bioactive agents, thereby processing said sample solutions in parallel; and

(d) detecting the presence or absence of said target analytes.

Claim 1 of the '020 patent reads:

An array of arrays comprising:

(a) a first substrate with a surface comprising a plurality of assay wells comprising samples; and

(b) a second substrate comprising a plurality of projections, each projection comprising an array location, each array location comprising a plurality of discrete sites, wherein said sites comprise different bioactive agents, and wherein said first substrate and said second substrate are arranged such that projections of said second substrate are fitted into assay wells of the first substrate.

B. Second Substrate

Plaintiff's Proposed Construction: a support

Defendant's Proposed Construction: a material that is modified to contain discrete individual sites appropriate for the attachment or association of beads (small discrete particles) and is amenable to at least one detection method

With respect to each of the terms in dispute, the parties said little in their briefs or at the claim construction hearing about plaintiff's proposed constructions; instead, they focused almost exclusively on whether defendant's proposed constructions are correct. The issue in dispute for the term "second substrate" is whether the definition includes a requirement that the substrate's surface allows "for the attachment or association of beads." Beads are "small discrete particles" that represent one way to detect the "target analyte." The patents use the words "bead" and "microsphere" interchangeably. '841 patent, col. 8,

ln. 36.

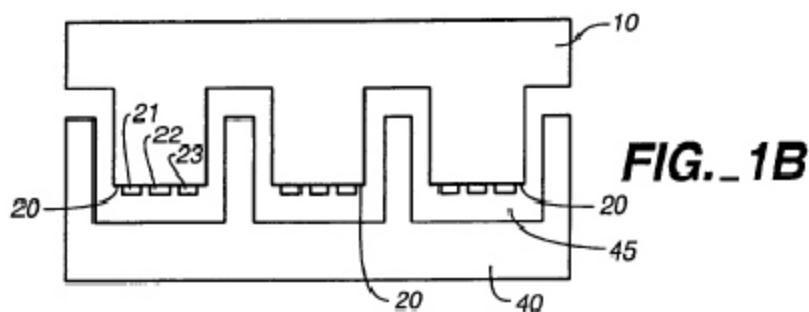
Defendant relies primarily on one passage from the specification, which it says represents a definition of the word “substrate” in the context of the patent:

By "substrate" or "solid support" or other grammatical equivalents herein is meant any material that can be modified to contain discrete individual sites appropriate for the attachment or association of beads and is amenable to at least one detection method.

‘841 pat., col. 7, lns. 32-36. Defendant cites case law in which the Court of Appeals for the Federal Circuit has held that “a definition set forth in the specification governs the meaning of the claims.” Sinorgchem Co., Shandong v. International Trade Commission, 511 F.3d 1132, 1136 (Fed. Cir. 2007). See also Martek Biosciences Corp. v. Nutrinova, Inc., 579 F.3d 1363, 1380 (Fed. Cir. 2009) (“When a patentee explicitly defines a claim term in the patent specification, the patentee's definition controls.”); Phillips v. AWH Corp., 415 F.3d 1303, 1321 (Fed. Cir. 2005) (en banc) (“[T]he specification ‘acts as a dictionary when it expressly defines terms used in the claims.’”) (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)).

To support its view, plaintiff cites a passage from the specification stating that “[i]t should be noted that while the disclosure herein emphasizes the use of beads, beads need not be used in any of the embodiments of the invention; the bioactive agents can be directly coupled to the array locations.” ‘841 patent, col. 5, lns. 3-4. In addition, plaintiff cites other

passages discussing “non-bead” embodiments. *E.g., id.* at col. 8, lns. 25-29 (“In these embodiments, at least one surface of the substrate is modified to contain discrete, individual sites for later association of microspheres (or, when microspheres are not used, for the attachment of the bioactive agents”). Figure 1B represents one such embodiment:



In this figure, “beads are not used; rather, array locations 20 have discrete sites 21, 22, 23, etc. that may be formed using spotting, printing, photolithographic techniques, etc.” ‘841 pat., col. 3, lns. 33-36.

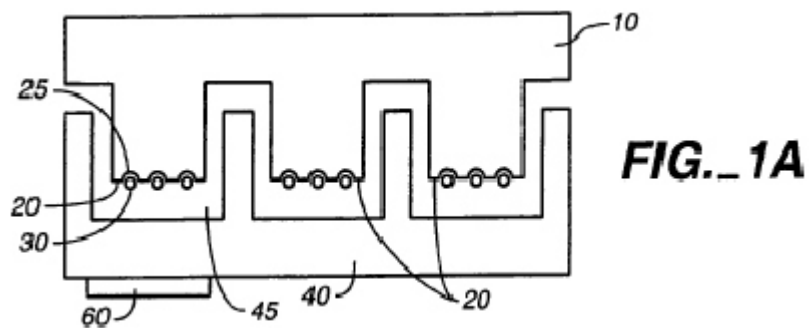
How can these different passages be reconciled? Plaintiff’s answer is to characterize defendant’s cited passage as the description of an embodiment rather than of the invention as a whole. Defendant’s answer is to disregard all references to non-bead embodiments on the ground that the claims do not cover them. However, neither party cites anything in the patent to support its view of the limited scope of the other side’s cited passages. Plaintiff

cites no authority for the view that a court may disregard a passage in the specification that puts a term in quotation marks and states unequivocally what “is meant” when that term is used “herein.” Sinorgchem, 511 F.3d at 1136 (quoting Abbott Labs. v. Andrx Pharms., Inc., 473 F.3d 1196, 1210 (Fed. Cir. 2007) (“[When a term] is set off by quotation marks” and is followed immediately by the word “is,” these are “strong indicat[ors] that what follows is a definition” and “may ‘signify that a patentee is serving as its own lexicographer.’”) Similarly, defendant cites no cases in which a court disregarded a similarly unequivocal statement in the specification that the invention did not require a particular limitation.

There may be a simple resolution to the parties’ seemingly contradictory views. It lies in the small but important difference between defendant’s proposed construction and the passage it cites in support of that construction. Defendant changed the phrase in the specification from “material that *can be* modified to contain discrete individual sites appropriate for the attachment or association of beads” to “material that *is* modified to contain discrete individual sites appropriate for the attachment or association of beads.” If the actual passage from the patent is adopted as the construction, it keeps the emphasis on beads, but allows for the possibility of embodiments that do not involve the use of beads.

In their briefs both sides largely ignored the possibility of adopting a construction that is identical to the passage on which defendant relies. In its opening brief, defendant acknowledged only in a footnote that it had altered the wording in the passage. Dft.’s Br.,

dkt. #25, at 8 n.9. However, in its responsive brief, defendant seemed to concede that its altered version could not be adopted for the term “substrate” generally because at least one of the substrates in a “two component system” is not associated with beads. Figure 1A provides an example:



In this figure the areas identified as 10 and 40 are both substrates, ‘841 pat., col. 3, lns. 29-31, but “first substrate 10” is the only one that has beads. Defendant says that “first substrate 10” in the figure is actually the “second substrate” identified in the claims and that “second substrate 40” in the figure is consistent with the definition of “substrate” in the specification because second substrate 40 “can be” modified to allow the attachment of beads. However, defendant says that the “second substrate” in the claims “is” modified. Dft.’s Br., dkt. #31, at 6. The argument becomes even more convoluted when defendant says that its proposed construction should apply to the term “‘substrate,’ standing alone,” but only in one instance in the context of claim 20 of the ‘020 patent. Dft.’s Br., dkt. #25,

at 7 n.7.

These arguments hurt defendant's position more than they help. The patent's treatment of the adjectives "first" and "second" as interchangeable when they are used to modify "substrate" supports a reading that the terms "first substrate" and "second substrate" do not have different meanings. 3M Innovative Properties Co. v. Avery Dennison Corp., 350 F.3d 1365, 1371 (Fed. Cir. 2003) ("The use of the terms 'first' and 'second' is a common patent-law convention to distinguish between repeated instances of an element or limitation."). Further, if, as defendant concedes, the proper construction for one of the substrates is that it "can be" modified to allow the attachment of beads, this is more support for the view that both substrates should be defined this way. Defendant's only argument to the contrary in its briefs is a sentence in a footnote that the definition should be changed from "can be" to "is" in the context of the "second substrate" because "every . . . claim [disclosing a 'second substrate'] expressly states that the second substrate has discrete sites." Dft's. Br., dkt. #25, at 7 n.9. However, defendant fails to explain why "discrete sites" are synonymous with beads. Tellingly, defendant's proposed construction for the term "discrete sites" does not include a bead limitation.

Finally, even if defendant had a plausible basis for distinguishing the "first substrate" from the "second substrate," defendant's view would still require adopting inconsistent meanings for "substrate." In particular, defendant argues that the term "substrate" in claim

20 of the '020 includes the same bead limitation as the term “second substrate,” even though defendant asserts that “substrate” and “second substrate” have different meanings elsewhere. Defendant does not explain or justify that inconsistency. Fin Control System Pty., Ltd. v. OAM, Inc., 265 F.3d 1311, 1318 (Fed. Cir. 2001) (courts apply “presumption that the same terms appearing in different portions of the claims should be given the same meaning unless it is clear from the specification and prosecution history that the terms have different meanings at different portions of the claims”).

At the claim construction hearing, when I suggested adopting a construction of “second substrate” that was identical to the definition in the specification, neither party raised a persuasive objection. Although plaintiff did not embrace that construction, counsel’s only concern was that the construction should be clear that “that the second substrate in the claims does not require beads.” Trans., dkt. #34, at 35. However, that is simply a restatement of plaintiff’s legal position rather than an argument for rejecting the definition.

Defendant objected on the ground that adopting the definition as is “would allow [plaintiff] to game the system” by “get[ting] everything in the expressed definition,” but then “us[ing] the word[s] ‘can be’ . . . as an escape hatch.” Id. at 110. However, it is difficult to see the logic in an argument that it allows plaintiff to “game the system” by adopting a construction that incorporates language used in the patent; plaintiff does not “get away

with” anything if it is held to the words it chose. If a reader interpreted “can be” to mean “is,” that is not plaintiff’s fault, particularly because there are other passages in the specification rejecting the view that beads are always required.

Defendant points to two other passages to show that a bead limitation should be included:

The present invention is generally based on previous work comprising a bead-based analytic chemistry system in which beads, also termed microspheres, carrying different chemical functionalities are distributed on a substrate comprising a patterned surface of discrete sites that can bind the individual microspheres.

* * *

It should be noted that a key component of the invention is the use of a substrate/bead pairing that allows the association or attachment of the beads at discrete sites on the surface of the substrate, such that the beads do not move during the course of the assay.

‘841 pat. col.5, lns. 34-39; id. at col. 17, lns. 50-54.

Neither of these passages shows persuasively that the invention generally or substrates specifically include a bead limitation. The first passage is a description of the prior art. Even if the invention is “generally based on” prior art that uses beads, that does not mean that the invention is limited to embodiments that use beads.

The second passage is included in a larger discussion of preferred embodiments that use beads. ‘841 pat., col. 17, lns. 20-21 (“In a preferred embodiment, the compositions of the invention further comprise a population of microspheres.”). Thus, in context, the

passage cited by defendant is best read as a description of a preferred embodiment. That is, when beads are used, it is important that they “do not move during the course of the assay.” Although the passage uses the word “invention,” that “does not ‘automatically’ limit the meaning of claim terms in all circumstances . . . [S]uch language must be read in the context of the entire specification and prosecution history.” Netcraft Corp. v. eBay, Inc., 549 F.3d 1394, 1398 (Fed. Cir. 2008). In light of the other passages stating clearly that the invention does not include a bead limitation, I decline to read this passage as suggesting a contrary view.

Finally, defendant has not pointed to anything in the prosecution history that would require this court to adopt a bead limitation. Defendant did not discuss the prosecution history in its briefs, but at the claim construction hearing, it cited one page in which the patent examiner considered three dependent claims that would later become claims 7, 8 and 9 in the ‘841 patent. These claims disclose different densities of “bioactive agents per square centimeter.” Defendant says that the examiner must have believed that beads were required by the invention because the examiner used the phrase “claimed microspheres” in rejecting the claims as obvious under Burbaum, who had “describe[d] the use of beads” at particular densities. Chin Decl., dkt. #26, exh. O, at 14.

This reference is far too ambiguous to require adopting defendant’s proposed construction. If the examiner believed that the invention included a bead limitation, it is

odd that the only context in which the examiner would make this observation is in one phrase when rejecting *dependent* claims. Both Burbaum and claims 7, 8 and 9 address density, so that is most likely the only issue the examiner was considering in rejecting those three claims.

Court's construction: "a material that can be modified to contain discrete individual sites appropriate for the attachment or association of beads and is amenable to at least one detection method"

C. Bioactive Agents

Plaintiff's Proposed Construction: A part that juts out from a portion of a substrate, for example like a finger

Defendant's Proposed Construction: a molecule (e.g., protein, oligopeptide, small organic molecule, coordination complex, polysaccharide, polynucleotide, etc.) attached to an array location that is also attached to a microsphere

The dispute over this term is similar to the dispute over "second substrate": the parties disagree whether bioactive agents must be attached to a bead. Again, defendant relies on a passage from the specification that it says provides a definition of "bioactive agent":

By "candidate bioactive agent" or "bioactive agent" or "chemical functionality" or "binding ligand" herein is meant as used herein describes any molecule, e.g.,

protein, oligopeptide, small organic molecule, coordination complex, polysaccharide, polynucleotide, etc. which can be attached to the microspheres of the invention.

'841 pat., col. 17, lns. 58-63. Again, defendant modifies this definition in its proposed construction by changing the “can be” to “is.” Because defendant provides no justification for that change, I will adopt the definition as it is stated in the specification.

Court's Construction: any molecule that can be attached to a microsphere

D. Discrete Sites

Plaintiff's Proposed Construction: sites that are sufficiently distinct to permit individual detection

Defendant's Proposed Construction: sites that are non-contiguous with other sites

The parties dispute whether the word “discrete” means non-contiguous, that is, whether each site must not touch another site. In its briefs, defendant relied on several lay dictionary definitions, but, at the claim construction hearing, defendant conceded that some of those definitions support a view that “discrete” can be defined to mean “distinct,” as plaintiff suggests. In addition, plaintiff gave a number of examples of things that are touching, such as the squares on a chess board, but are still “discrete” because they are

individually identifiable.

The question is whether the patent has chosen a more specific meaning for the word “discrete.” Unlike the other two terms, the specification does not include an explicit definition of this term. The figures in the patent seem to support defendant’s proposed construction because all of the “discrete sites” depicted in the figures are spaced apart, but that is not necessarily dispositive because the figures represent embodiments rather than the invention as a whole. E.g., *Lighting World, Inc. v. Birchwood Lighting, Inc.*, 382 F.3d 1354, 1365 (Fed Cir. 2004).

The most substantial discussion of the term appears in column 8 of the patent:

The sites may be a pattern, i.e. a regular design or configuration, or randomly distributed. A preferred embodiment utilizes a regular pattern of sites such that the sites may be addressed in the X-Y coordinate plane. "Pattern" in this sense includes a repeating unit cell, preferably one that allows a high density of beads on the substrate. However, it should be noted that these sites may not be discrete sites. That is, it is possible to use a uniform surface of adhesive or chemical functionalities, for example, that allows the attachment of beads at any position. That is, the surface of the substrate is modified to allow attachment of the microspheres at individual sites, whether or not those sites are contiguous or non-contiguous with other sites. Thus, the surface of the substrate may be modified such that discrete sites are formed that can only have a single associated bead, or alternatively, the surface of the substrate is modified and beads may go down anywhere, but they end up at discrete sites.

‘841 pat., col. 8, lns. 42-53.

Both parties rely heavily on this paragraph, but each focuses on a different portion. Defendant cites the following passage: “it should be noted that these sites may not be

discrete sites. . . . That is, the surface of the substrate is modified to allow attachment of the microspheres at individual sites, whether or not those sites are contiguous or non-contiguous with other sites.” I agree with defendant that the passage is as close as the specification comes to defining what the inventor means by “discrete.” By stating that the sites “may not be discrete sites” and then following that with the explanatory phrase “[t]hat is, . . . those sites [may be] contiguous or non-contiguous with other sites,” the specification seems to be equating the word “discrete” with the word “non-contiguous.” If the phrase is not a definition, plaintiff fails to identify another purpose for the phrase. In fact, plaintiff ignores the phrase entirely in its argument.

Plaintiff does not argue that the passage is not controlling because it is a discussion of an embodiment. Further, plaintiff does not point to any portion of the passage or any other part of the specification that uses its proposed construction. Instead, plaintiff’s argument is devoted to showing that defendant is reading the passage incorrectly. Plaintiff focuses on the last two clauses in the paragraph: “beads may go down anywhere, but they end up at discrete sites.” Plaintiff interprets this to mean that there is no limitation on where one site is in relation to another, but one problem with this interpretation is that it conflates the site with the bead sitting on the site. The specification does not state that the *sites* may be “anywhere,” only that the beads “may go down anywhere.” The use of the phrase “end up at discrete sites” suggests that the beads may not “end up” where they

started. That is, one interpretation is that the beads discussed in the last sentence must “end up” at non-contiguous sites regardless where they “go down.”

Although the last sentence of the passage could favor plaintiff’s or defendant’s proposed construction, plaintiff’s proposal becomes more problematic when viewed with the rest of the paragraph. The passage makes it clear that, in some instances, sites “may not be discrete sites” and, in other instances sites are discrete. Under defendant’s view of the passage, this simply means that the sites may be contiguous in some instances and non-contiguous in other instances. Plaintiff’s view is more complicated. According to plaintiff, even if sites do not start out as discrete sites, they all “end up” that way once the beads go down. However, plaintiff does not explain how a site may be transformed from “non-discrete” to “discrete” with the introduction of a bead. In particular, plaintiff points to nothing in the specification suggesting that a bead changes the character of the site. To the extent plaintiff means to argue that the site can be detected individually because a bead has been placed on it, this seems to be another example of conflating the bead and the site.

To be sure, the meaning of the passage is not immediately transparent. On one hand, the inventor seems to be saying that sites “may not be discrete sites” if they “allo[w] the attachment of beads at any position”; on the other hand, the inventor says in the same paragraph that beads “end up at discrete sites” even if “beads may go down anywhere.” However, defendant’s understanding of the passage is more internally consistent than

plaintiff's. Further, I agree with defendant that, to the extent ambiguity exists, the notice function of the patent is best served by choosing the narrower construction. Athletic Alternatives, Inc. v. Prince Manufacturing, Inc., 73 F.3d 1573, 1581 (Fed. Cir. 1996).

Plaintiff advances two other arguments, but neither is persuasive. First, plaintiff relies on the specification's use of the word "discrete" in another passage:

In a preferred embodiment, the second substrate is an optical fiber bundle or array, as is generally described in U.S. Ser. Nos. 08/944,850 and 08/519,062, PCT US98/05025, and PCT US98/09163, all of which are expressly incorporated herein by reference. Preferred embodiments utilize preformed unitary fiber optic arrays. By "preformed unitary fiber optic array" herein is meant an array of discrete individual fiber optic strands that are co-axially disposed and joined along their lengths. The fiber strands are generally individually clad. However, one thing that distinguished a preformed unitary array from other fiber optic formats is that the fibers are not individually physically manipulatable; that is, one strand generally cannot be physically separated at any point along its length from another fiber strand.

'841 patent, col. 8, lns. 3-16. Plaintiff argues that "discrete" cannot mean non-contiguous because the passage uses the word "discrete" to describe fiber optic strands that are joined together.

This passage does not provide guidance for two reasons. First, it uses the word "discrete" in a very different context. Although plaintiff argues that the passage shows that defendant's proposed construction is wrong, plaintiff overlooks the fact that its own proposed construction could not apply in the context of this passage. It would make little sense to define a strand in this context as "sufficiently distinct to permit individual

detection” because the strand is not being “detected” by anything. Thus, regardless what the inventor meant by “discrete” in the context of fiber optic strands, that understanding of “discrete” may be different from the one in the context of sites on a projection.

Even if I assume that the inventor meant “discrete” to mean the same thing everywhere in the patent, this passage does not necessarily contradict defendant’s proposed construction. One could read “an array of discrete individual fiber optic strands that are co-axially disposed and joined along their lengths” to include an element of time. That is, the clause could mean that, initially, the strands are “discrete” and *then* they are “joined along their lengths.” Plaintiff is correct that the passage does not require such a reading, but it does not foreclose that reading either.

Finally, plaintiff cites dependent claim 7, in which the array locations contain up to “2,000,000,000 bioactive agents per square centimeter.” Although plaintiff argues that such a densely packed location shows that some sites will be contiguous, plaintiff cites no evidence showing that it would be impossible to have that number of bioactive agents in that amount of space unless the sites were contiguous.

Accordingly, I agree with defendant that the term “discrete sites” is defined in the specification to mean “sites that are noncontiguous.” Because the parties agree that “noncontiguous” means that the sites do not touch another site, I will adopt that as the construction for this term.

Court's construction: sites that do not touch another site

ORDER

IT IS ORDERED that the terms “second substrate,” “bioactive agents” and “discrete sites” are construed as follows:

- (a) “second substrate” means “a material that can be modified to contain discrete individual sites appropriate for the attachment or association of beads and is amenable to at least one detection method”;
- (b) a “bioactive agent” is “any molecule that can be attached to a microsphere”; and
- (c) “discrete sites” are “sites that do not touch another site.”

Entered this 14th day of July, 2010.

BY THE COURT:

/s/

BARBARA B. CRABB
District Judge