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Caution

As of: Dec 17, 2010

AFFYMETRIX, INC, Plaintiff and Counterdefendant, v. HYSEQ, INC, Defendant and Counterplaintiff. AFFYMETRIX, INC., Plaintiff and Counterdefendant, v. SYNTENI, INC. and INCYTE PHARMACEUTICALS, INC., Defendants and Counterplaintiffs.

Case No. C 99-21163 JF, Case No. C 99-21164 JF (Consolidated for Claim Construction)

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA, SAN JOSE DIVISION

132 F. Supp. 2d 1212; 2001 U.S. Dist. LEXIS 5935

**January 22, 2001, Decided
January 22, 2001, Filed**

COUNSEL: **[**1]** For AFFYMETRIX, INC., Plaintiff: Morgan Chu, Richard de Bodo, Jeffrey L. Arrington, Marc A. Fenster, Irell & Manella LLP, Los Angeles, CA.

For HYSEQ, INC., defendant: Anthony Nimmo, William K. Merkel, Kevin M. Flowers, Kim A. Jacklin, Anand P. Iyer, Marshall O'Toole Gerstein Murray & Borun, Chicago, IL.

For HYSEQ, INC., defendant: Charles S. Crompton, III, Latham & Watkins, Menlo Park, CA.

JUDGES: JEREMY FOGEL, United States District Judge.

OPINION BY: JEREMY FOGEL

OPINION

[*1216] ORDER ¹ CONSTRUING CLAIMS OF U.S. PATENTS NOS. 5,445,934, 5,744,305, 5,800,992, AND 5,795,716

1 This disposition is not designated for publication and may not be cited.

I. INTRODUCTION

Both of the cases captioned above are patent infringement suits. Affymetrix, plaintiff in both cases, asserts four separate patents against the named defendants. The cases were consolidated for the purpose, *inter alia*, of construing disputed patent claim terms. On November 29 and 30, 2000, the Court conducted a tutorial and hearing to assist it in **[**2]** construing the claims of *United States Patents Nos: 5,445,934 (the '934 patent), 5,744,305 (the '305 patent), 5,800,992 (the '992 patent), and 5,795,716 (the '716 patent)*. After considering the arguments and evidence presented by all

parties, the Court will construe the principal disputed terms as set forth below. Certain of the disputed terms have not been construed. If necessary, the parties may request the Court to construe the remaining terms at a later date. The Court will request supplemental briefing as to the term "substantially complementary."

II. BACKGROUND

Affymetrix's four patents relate to "DNA chip" or "array" technology. Two of the patents, the '934 and the '305 patents, claim "arrays" or "substrates," wherein a high density of different nucleic acids (RNA or DNA) is placed on a solid support, such that users may perform experiments on a large number of different nucleic acids at one time, in a single reaction. The '992 patent claims methods of detecting nucleic acid sequences in the arrays by using labeled complementary nucleic acids that hybridize to nucleic acid sequences in the arrays. The fourth patent, the '716 patent, concerns computer [**3] programs which translate the raw data from the experiments into genetic information about the sample.

In the two cases captioned above, Affymetrix asserts that Defendants Incyte Pharmaceuticals, Inc. and Synteni (collectively, "Incyte") infringe the '934, '305, and '992 patents; and that Defendant Hyseq, Inc. ("Hyseq") infringes the '305, '992, and '716 patents. A brief discussion of each of the patents in suit follows.

A. The '934 Patent, Entitled "Array of Oligonucleotides on a Solid Support."

The '934 patent claims a "substrate," which has a surface comprising at least 1,000 groups of oligonucleotides with different, known sequences covalently attached to the surface in discrete known regions. The 1,000 or more groups of oligonucleotides occupy a total area of less than one square centimeter. The '934 patent was filed on September 30, 1992 and issued on August 29, 1995.

[*1217] Affymetrix accuses Incyte of infringing claims 1, 5, 6, and 7 of the '934 patent. Claims 1 and 7 are independent claims.

B. The '305 Patent, Entitled "Arrays of Materials Attached To A Substrate"

The '305 patent, like the '934 patent, claims a chip apparatus. In this case, the [**4] claims recite an "array

of oligonucleotides" or an "array of polynucleotides." The apparatus is comprised of a solid support and oligonucleotides or polynucleotides attached to the solid support at a density of greater than 400 different oligonucleotides or polynucleotides per square centimeter. The oligonucleotides or polynucleotides are attached to the surface of the solid support in different predefined regions, and the different oligonucleotides have different determinable sequences. The '305 patent was filed on June 6, 1995 and issued on April 28, 1998.

Affymetrix accuses Hyseq of infringing claims 1, 2, 5, 8, 15, 17, and 20 of the '305 patent, and accuses Incyte of infringing claims 1, 3-13, and 15-25. Claims 1 and 15 are the only independent claims.

C. The '992 Patent, Entitled "Method of Detecting Nucleic Acids."

The '992 patent claims a method for detecting nucleic acid sequences that may be used in connection with an array of polynucleotides, where the polynucleotides are comprised of a determinable nucleic acid. The method utilizes the well-known ability of nucleic acid sequences to "hybridize" to complementary sequences. The '992 patent claims a method of simultaneously [**5] detecting the presence of two sets of specific nucleic acid sequences, where one collection of nucleic acids is labeled with one label, and another collection of nucleic acids is labeled with a different label, distinguishable from the first. The two collections of labeled nucleic acids are substantially complementary to a nucleic acid of the array. The collections of labeled nucleic acids are made to contact the arrays so as to detect hybridization of the labeled nucleic acids to complementary nucleic acids in the arrays.

The '992 patent further claims a method of detecting differential expression of each of a plurality of genes in one cell type compared to expression of the same genes in a second cell type. This method involves adding a mixture of labeled nucleic acid from the two cell types to an array of polynucleotides representing genes derived from the two cell types. The labels are distinct fluorescent labels, which are examined under fluorescence excitation conditions. The method is practiced under conditions that allow hybridization to complementary sequence polynucleotides in the array. The '992 patent was filed on June 25, 1996 and issued on September 1, 1998.

Affymetrix [**6] accuses Hyseq of infringing

claims 1 and 3 of the '992 *patent*, and Incyte of infringing claims 1, 3, 4, and 5. Claims 1 and 4 are independent claims.

Although the specifications of the '934, '305, and '992 *patents* differ in many respects, the patents are related in that all three derive from the originally filed U.S. Patent Application No. 362,901 (the '901 Application). Each of the patents is based on separate continuation-in-part applications that are based, either directly or indirectly, on the '901 Application.²

2 A diagram of the complicated relationship among these patents is presented in the Arrington Declaration in Support of Affymetrix' Opening Brief, Exh. E.

D. '716 *Patent*, Entitled "Computer-Aided Visualization and Analysis System for Sequence Evaluation"

The '716 *patent* claims computer program products and systems that identify an unknown base in a sample nucleic acid sequence. The claimed products and systems determine the identity of a particular base by comparing the results from hybridizing [**7] a set of probes to a sample with the results from hybridizing the set of probes [**1218] to a reference nucleic acid, which has a known sequence. Because generally, pairs of completely complementary nucleic acids hybridize more strongly than nucleic acid pairs that have a "mismatch," the identity of the unknown nucleotide can be determined by hybridizing with a set of nucleic acids, each having a different base at the critical complementary site, and comparing the strength of that hybridization with the hybridization to a reference nucleic acid. The '716 *patent* was filed on October 21, 1994 and issued on August 18, 1998.

Affymetrix accuses Hyseq of infringing claims 3, 4, 7, 8, 9, and 10. Claims 3, 4, 7, and 8 are independent claims.

III. LEGAL STANDARD

Claim construction is purely a matter of law, to be decided exclusively by the Court. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 387, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996). Claims are construed from the perspective of a person of ordinary skill in the art at the time of the invention. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 986 (Fed. Cir. 1995). To determine the

meaning of the [**8] claim terms, the Court initially must look to intrinsic evidence, that is, the claims, the specification, and, if in evidence, the prosecution history. *Autogiro v. United States*, 181 Ct. Cl. 55, 384 F.2d 391 (Ct. Cl. 1967). The Court must look first to the words of the claims themselves. See *Vitronics Corp. v. Conceptoronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). These words are to be given their ordinary and customary meaning unless it is clear from the specification and prosecution history that the inventor used the term with a different meaning. *Id.* The claims should be interpreted consistently with the specification. See *Renishaw PLC v. Marposso Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). Arguments and amendments made during prosecution of a patent application limit claim terms so as to exclude any interpretation that was disclaimed during prosecution. *Southwall Tech., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed. Cir. 1995).

Where intrinsic evidence alone resolves any ambiguity in a disputed claim term, it is improper to rely on extrinsic evidence. *Vitronics*, 90 F.3d at 1583, 1585. [**9] However, extrinsic evidence may be considered in the rare instances where the intrinsic evidence is insufficient to enable the court to construe disputed claim terms. *Id.* at 1585.

IV. DISCUSSION

As a preliminary matter, the Court addresses a threshold argument that Incyte repeatedly offers concerning claim construction.³ Incyte relies on the canon of claim construction which states that, "when claims are amenable to more than one construction, they should when reasonably possible be interpreted so as to preserve their validity." *Modine Mfg. v. U.S. Int'l Trade Comm'n*, 75 F.3d 1545, 1557 (Fed. Cir. 1996). Arguing that the '934, '305, and '992 specifications do not enable Affymetrix's claim constructions under 35 U.S.C. § 112, P 1, Incyte urges rejection of Affymetrix's proffered constructions.

3 Hyseq joins Incyte in this line of argument.

Specifically, Incyte asserts that Affymetrix's true invention is the "Very Large Scale Immobilized Polymer [**10] Synthesis" or "VLSIPS" technology. This technology originally involved the use of light sensitive compounds in the stepwise formation, monomer-by-monomer, of polypeptides, not polynucleotides, such that the synthesis occurs on the

solid support, or chip apparatus. Incyte argues that even if, *arguendo*, the specifications of the '934, '305, and '992 patents enable chips with polynucleotides, those chips are only enabled for polynucleotides synthesized monomer-by-monomer directly on the solid support. Accordingly, Incyte imposes the limitation requiring monomer-by-monomer [*1219] synthesis on multiple disputed terms in the claims.

Although the Court acknowledges that it must attempt to *interpret* claims in a manner which will sustain their validity, courts do not have authority to *redraft* claims for this purpose. *Process Control Corp. v. Hydrex Corp.*, 190 F.3d 1350, 1356-57 (Fed. Cir. 1999) (refusing to adopt a construction that would avoid invalidity where there was only one reasonable interpretation of the claim term). Moreover, while the Court may use the specification to interpret words in the claim, it is improper to import extraneous limitations [**11] from the specification into the claim terms. *E.I. Du Pont De Nemours & Co. v. Phillips Petro.*, 849 F.2d 1430, 1433 (Fed. Cir. 1988) (refusing to read limitations into a claim to avoid invalidity due to prior art). The Du Pont court defined "extraneous limitation" as any limitation read into a claim from the specification wholly apart from any need to interpret what the patentee meant by particular words or phrases in the claim. *Id.*

In light of these various doctrines of claim construction, the Court rejects Incyte's arguments to the extent that they purport to limit the claims to only what Incyte asserts is enabled by the specification. Incyte has provided no authority to support its effort to transform claim construction analysis into a full non-enablement and written description analysis. While Incyte cites several cases which demonstrate the Federal Circuit's strict application of the *enablement* requirement to biotechnology inventions-- see *Enzo Biochem v. Calgene*, 188 F.3d 1362 (Fed. Cir. 1999); *Regents of the Univ. of California v. Eli Lilly*, 119 F.3d 1559 (Fed. Cir. 1997); *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200 (Fed. Cir. 1991) [**12] -- none of these cases dictate that the enablement analysis must be incorporated into claim construction.

None of the other cases relied upon by Incyte require limiting the meaning of claim terms solely on the basis of an invalidity analysis. Contrary to Incyte's interpretation, the Federal Circuit in *Schering Corp. v. Amgen Inc.*, 222 F.3d 1347 (Fed. Cir. 2000), limited the meaning of the

term "Interferon alpha" because the patentee had explicitly limited that definition during prosecution. *Id. at 1352-53*. The Federal Circuit expressly disagreed with the district court's rationale that the term should be limited because a broader interpretation would render the claim invalid for improper introduction of new matter. *Id. at 1352-54*. Instead, the court based its claim construction on the established doctrine requiring a court to adopt a patentee's explicit definition of a term. *Id.* Likewise, in *Cultor Corp. v. A.E. Staley Mfg. Co.*, 224 F.3d 1328 (Fed. Cir. 2000), the court construed "water-soluble polydextrose" to be restricted to that prepared with a citric acid catalyst, because the specification explicitly had [**13] limited the term to polydextrose produced using a citric acid catalyst. ⁴ *Id. at 1331*.

4 The patent specification defined "water-soluble polydextrose" as "the water-soluble polydextrose prepared by melting and heating dextrose . . . preferably with about 5-15% by weight of sorbitol present, in the presence of a catalytic amount (about 0.5 to 3.0 mol%) of citric acid." *Cultor*, 224 F.3d at 1330.

Collectively, this Court interprets the cases cited above to instruct that the asserted non-enablement of a proffered claim construction alone is not a proper basis for rejecting that construction. Instead, the Court must conduct the traditional claim construction analysis, looking first to the claim language itself, then to the specification and prosecution history. If the Court concludes from this analysis that a claim term is susceptible to two or more meanings, the Court *then* must, where possible, adopt a meaning which renders the claim valid. Adopting this approach, the [**14] Court now proceeds to construe the disputed terms.

[*1220] A. '934 Patent

Claim 1 of the '934 patent reads:

A substrate with a surface comprising 10<3> or more groups of *oligonucleotides* with different, *known sequences covalently attached* to the surface in *discrete known regions*, said 10<3> or more groups of oligonucleotides occupying a total area of less than 1 cm<2> on said substrate, said groups of oligonucleotides having different

nucleotide sequences.

Claim 7 of the '934 patent reads:

An *array* of more than 1,000 different groups of oligonucleotide molecules with known sequences *covalently coupled* to a surface of a substrate, said groups of oligonucleotide molecules each in discrete known regions and differing from other groups of oligonucleotide molecules in monomer sequence, each of said discrete known regions being an area of less than about 0.01 cm² and each discrete known region comprising oligonucleotides of known sequence, said different groups occupying a total area of less than 1 cm².

1. *oligonucleotides* is construed to mean polymers of nucleotides ranging in length from 2 to about [**15] 100 nucleotides.

Affymetrix contends that "oligonucleotides" means polymers, or small polymeric stretches, of nucleotides, ranging in length from 2 to about 100 nucleotides.

Incyte contends that "oligonucleotides" means single-stranded polymers of nucleotides synthesized monomer by monomer and less than about 20 nucleotides in length.⁵

⁵ This is the construction originally proffered by Incyte and provided in the Joint Claim Construction Statement. Incyte later attempted to modify its construction in its Opening Brief in support of its claim construction. Affymetrix objected, and the Court granted Affymetrix's Ex Parte Request for an Order Prohibiting Defendants from Asserting Claim Construction Definitions not in the Parties' Joint Claim Construction Statements. (Order of November 9, 2000). The Court nevertheless notes that Incyte's attempted revised construction agrees with Affymetrix to the extent that oligonucleotides range in length from 2 to 100 nucleotides.

The Court looks to the plain meaning of the [**16] term, which suggests small polymers of nucleotides. At

the time of the hearing, the parties agreed that oligonucleotides range from 2 to 100 nucleotides in length. The Court rejects Affymetrix's assertion that the term also encompasses small polymeric stretches, given that such a definition would effectively expand "oligonucleotides" to include polynucleotides of unlimited length. A patentee may be his own lexicographer, provided the definition is clearly set forth in the specification. *Beachcombers v. Wildewood Creative Prods., Inc.*, 31 F.3d 1154, 1158 (Fed. Cir. 1994). However, Affymetrix fails to cite any intrinsic evidence to support its unconventional interpretation.

The Court rejects Incyte's argument that the term, "oligonucleotides," must be limited to single stranded synthetic nucleotides made monomer by monomer. Incyte has failed to cite any portion of the specification or prosecution history indicating that patentee intended the specific term, "oligonucleotide," to be limited in this manner.⁶ Instead, Incyte relies exclusively on the argument that, without this limitation, the claim would be invalid for non-enablement. The Court rejects this argument [**17] for the reasons discussed above. Further, the Court finds that in this case, "oligonucleotide" is not reasonably amenable to a definition restricting it to single stranded synthetic nucleotides [**1221] made monomer by monomer. In such a case, the Court cannot rewrite the claims, even if necessary to avoid a finding of invalidity. *Process Control*, 190 F.3d at 1357.

⁶ The Court disagrees with Incyte's characterization of the 9/30/92 Information Disclosure Statement (Livornese Decl., Exh. 11 at 2-3) as limiting the meaning of "oligonucleotides." Although the cited portion of the IDS states that the prior art does not disclose light directed techniques of oligonucleotides and the resulting claimed arrays, the Court discerns no explicit limitation of the term "oligonucleotide" from this passage.

2. *known sequences* is construed to mean sequences of monomers identified prior to attachment to the surface.

Affymetrix contends that "known sequences" means sequences of identified or identifiable monomers.

[**18] Incyte contends that "known sequences" means a polymer synthesized monomer by monomer, and whose sequence is determined by the monomer by

monomer synthesis process used to generate it.

The Court adopts the plain and ordinary meaning of the words, "known sequences," as there are no statements in the specification or prosecution history which indicate that the inventors intended the words to have a meaning inconsistent with the ordinary meaning. Accordingly, the Court finds that Affymetrix's assertion that unknown but *identifiable* sequences are encompassed by the ordinary meaning of "known sequences" is untenable, as this definition contradicts the ordinary meaning of "known."

Furthermore, for the reasons previously discussed, the Court finds that "known sequences" cannot be restricted only to those sequences which Incyte asserts are enabled by the specifications. "Known sequences" is not reasonably amenable to a definition restricting it to polymers synthesized monomer by monomer, whose sequence is determined by a monomer by monomer synthesis process, and the Court will not import this extraneous limitation into the claim.

3. *covalently attached* is construed to mean [**19] directly secured or joined to the solid surface such that every chemical bond between the oligonucleotide and the surface is a covalent bond. Affymetrix contends that "covalently attached" means secured to the solid surface through a covalent bond, either directly or indirectly. Affymetrix's definition requires that only the bond at the point of attachment to the surface, whether to the oligonucleotide or to the linker, be a covalent bond. (Markman hearing transcript at 413:9-415:26).

Incyte contends that "covalently attached" means the oligonucleotide is covalently bonded to the surface by the 3' end of the oligonucleotide. Incyte's definition requires that, if a linker molecule is used to covalently attach the oligonucleotide to the surface, every bond between the surface and the oligonucleotide must be a covalent bond. (Id. at 416:14-18).

The Court adopts the plain and ordinary meaning of the words, "covalently attached" to determine that the oligonucleotide is secured or joined to the solid surface by covalent bonding. The Court rejects Affymetrix's suggestion that the oligonucleotide may be "indirectly" covalently attached to the surface via a non-covalent bond between [**20] the oligonucleotide and a linker molecule, as long as a covalent bond exists between the linker and the surface. Such an interpretation contradicts the plain language of the claim, which requires covalent

attachment between the oligonucleotide and the surface, not merely between a linker and the surface. Affymetrix has failed to point to any intrinsic evidence to suggest that it intended "covalent attachment" to have any meaning other than this conventional meaning.

4. *discrete known regions* are construed to mean identified localized areas on a surface which are, were, or are intended to be activated for formation of a polymer, where the activation is accomplished through exposure of the localized area to an energy source adapted to render a group active for synthesis of the polymer on the surface or for immobilization of a pre-existing polymer on a surface.

Affymetrix originally argued that "discrete known regions" are physically distinguishable [**1222] and known regions. However, during its rebuttal argument, Affymetrix embraced the definition, provided in the specification, that "region" is a localized area on a surface which is, was, or is intended to be activated for formation [**21] of a polymer. (Markman hearing transcript at 374:22-23). Affymetrix then asserted that "formation" is not limited to synthesis of the polymer on the surface. Affymetrix argued that formation encompasses both synthesis on the surface and immobilization of preexisting polymers on a surface.

Incyte contends that a "discrete known region" is a localized area on a surface which is, was, or is intended to be activated for synthesis of a polymer, and which is also spatially addressable for activation of monomer by monomer synthesis.

Both parties accept the definition of "regions" that the patentee explicitly offers in the specification. In defining "predefined region," the '934 specification states:

A predefined region is a localized area on a surface which is, was, or is intended to be activated for formation of a polymer. The predefined region may have any convenient shape, e.g., circular, rectangular, elliptical, wedge-shaped, etc. For the sake of brevity herein, *"predefined regions" are sometimes referred to simply as "regions."*

('934 patent, col. 8:5-10). The remaining dispute thus concerns the meaning of "activated for formation of a

polymer" within this [**22] definition.

After accepting the '934 patent's definition of "regions" and acknowledging that the parties' real dispute now is as to the meaning of the definition (Markman hearing transcript at 375:9-18), Affymetrix did not present any definition of "activated." Affymetrix noted simply that the disclosed embodiment which uses caged binding members ('934 patent at col. 30:6-col. 31:3), is a "clear example" of activation. (Markman hearing transcript at 376:12-18).

The '934 patent likewise does not provide an explicit definition of "activated." However, it does describe "radiation, electric fields, electric currents" as examples of "activators" which expose a functional group which has been provided with a protective group. ('934 patent at col. 8:65-col. 9:2). Based on this description in the specification, the Court interprets "activated" to mean exposed to an energy source adapted to render a group active for formation of the polymer. This definition is consistent with Affymetrix's observation that the caged binding member embodiment demonstrates an example of activation. In that case, the caged binding members (which are not active) are attached to the surface of a solid support. [**23] (Id. at col. 30:35-39). "Upon application of a suitable energy source, the caging groups labilize, thereby presenting the activated binding member." (Id. at col. 30:43-46). Neither party has provided any evidence to contradict this meaning of "activated."

The Court now turns to the meaning of "formation of a polymer." The plain and ordinary meaning of this term would appear to define formation as equivalent to synthesis of a polymer, in contrast to attachment of a preformed polymer onto the surface. However, Affymetrix argues persuasively that, if "predefined region" is limited to the localized area on a surface which is, was, or is intended to be activated for synthesis of a polymer only, the caged binding member embodiment and the discussion thereof is made nonsensical. The '934 patent states:

According to this alternative embodiment, the invention provides methods for forming predefined regions on a surface of a solid support, wherein the predefined regions are capable of immobilizing receptors. The methods

make use of caged binding members attached to the surface to enable selective activation of the predefined regions. . . . ***The activated binding members [**24] are then used to immobilize specific molecules such [*1223] as receptors on the predefined region of the surface.***

(col.30:14-26). The specification therefore uses the term "predefined regions" to encompass a localized area on a surface which is, was, or is intended to be activated for attachment of a preformed polymer to the surface. In the caged binding member example, the polymer is a polypeptide receptor. In light of this disclosure, the Court finds that the specification uses "formation of a polymer" to mean both synthesis and immobilization of preformed polymers. However, the inquiry does not end with the specification. The Court must consider the prosecution history to determine whether the patentee relinquished any part of this definition to obtain allowance of the patent.

Incyte points to one statement in the prosecution history of the '934 patent to argue that "formation of polymer" should be limited to synthesis of the polymer on the surface, monomer by monomer, to the exclusion of attachment of a preformed polymer. In response to a rejection for obviousness based on prior art, Affymetrix stated:

Lowe et al. teaches directly away from the invention claimed herein. [**25] As recited herein, the present invention ***provides for the fabrication of many sites wherein different oligonucleotides are formed.*** Lowe et al. suggests the formation of a biochemical MOSFET, a commonplace device in the semiconductor industry. However, when those of skill in the art fabricate semiconductor devices such as those of Lowe et al., thousands or millions of the same thing are fabricated on a single substrate. Diversity is abhorred. Hence, the teachings of Lowe et al. would lead one directly away from combination with the admittedly non-enabling teachings of Southern et al.

(Livornese Decl., Exh. 57 (10/26/94 Amendment/Response) at 10). The Court does not agree

that this statement limits the meaning of "formation of a polymer" or "predefined regions" in the manner Incyte suggests. The Amendment/Response characterizes the '934 invention as providing for "fabrication of many sites wherein different oligonucleotides are formed," but does not specify that formation is limited to synthesis of the oligonucleotide on the surface. Instead, the emphasis is on formation of *different* oligonucleotides by way of the invention. As explained in the specification, **[**26]** "formation" by immobilization of polymers also allows creation of many sites wherein different polymers are formed. ('934 patent, col. 30:26-34). Therefore, Affymetrix's characterization of the invention does not exclude formation of different polymers by immobilization.

Furthermore, the Court concludes that the '305 prosecution history does not limit "formation of a polymer" to synthesis, to the exclusion of immobilization of polymers.⁷ Incyte cites an Amendment/Response during the prosecution of the '305 patent, in which Affymetrix stated:

Applicants respectfully point out that it is not the density of individual polymer sequences within a particular predefined region that is recited within the claim, but the density of "different polymer sequences" on the surface of the substrate, i.e. the number of different polymers that one can synthesize in a given area.

(Livornese Decl., Exh. 24 (9/23/96 Amendment/Response) at 6). The Court does not agree that this statement disclaims a definition of "predefined region" that encompasses a localized area on a surface which is, was, or is intended to be activated for immobilization of a polymer. Although Affymetrix mentions **[**27]** synthesis of polymers in this Response, it does so in the context **[*1224]** of emphasizing the density of "different polymer sequences" on the surface, as distinguished from the density of individual polymer sequences. The question of immobilized polymer sequences is not at all at issue in this exchange with the PTO, and the Court declines to use this excerpt as a basis for narrowing the meaning of "formation of a polymer" which is clearly discernable from the specification, as discussed above.

⁷ Because the Court finds that the statements in

the '305 prosecution history do not limit the meaning of "discrete known regions," the Court need not reach the question of whether statements made during prosecution of the '305 patent, which was filed after the issuance of the '934 patent, serve to limit the terms in the '934 patent.

Lastly, for the reasons previously discussed, the Court rejects Incyte's argument that the construction of "discrete known regions" should be limited to only those embodiments which Incyte asserts **[**28]** are enabled by the specification.

5. *array* is construed to mean a plurality of polymers arranged on a solid support.

Affymetrix contends that "array" is a plurality of polymers arranged on a substrate.

Incyte contends that "array" means single stranded polymers synthesized monomer by monomer on spatially addressable regions of a solid support.

The Court adopts the plain, ordinary meaning of the term "array." For the reasons previously discussed, the Court rejects Incyte's attempt to limit the term to arrays which Incyte argues are enabled by the specification. Incyte has failed to identify any intrinsic evidence suggesting that Affymetrix intended "array" to have any meaning other than the plain meaning of the term.

6. *X% Pure* is construed to mean that X percentage of polymers within a predefined region have identical sequences.

Affymetrix contends that this term means polymers within a localized region wherein a given percentage of said polymers exhibit characteristics which distinguish them from other localized regions. Typically, purity will be measured in terms of biological activity or functions as a result of uniform sequence. Such characteristics typically **[**29]** will be measured by way of binding with a selected ligand or receptor.

Incyte contends "pure" means polymers within a predefined region have uniform monomer sequence and length.

The '934 specification presents a definition of "substantially pure:"

A polymer is considered to be

"substantially pure" within a predefined region of a substrate when it exhibits characteristics that distinguish it from other predefined regions. Typically, purity will be measured in terms of biological activity or functions as a result of uniform sequence. Such characteristics will typically be measured by way of binding with a selected ligand or receptor.

('934 patent at col. 8:12-19). Although the Court ordinarily would accept this express definition of "pure," the Examiner determined that this meaning was indefinite, unclear and confusing. (Livornese Decl., Exh. 41 (6/2/93 Office Action) at 4). In response, Affymetrix amended the claims to recite specific percentages of purity, and characterized the claims as "now referring to a **purity (i.e., identical sequences)** of greater than 50%." Given the clear prosecution history that modifies the definition presented in the specification, [**30] the Court adopts the modified definition as recited above.

7. **covalently coupled** is construed to mean directly joined to the solid surface such that every chemical bond between the oligonucleotide and the surface is a covalent bond.

Affymetrix contends that "covalently coupled" means covalently joined, directly or indirectly to the surface.

Incyte contends that "covalently coupled" means covalently bonded to the surface by the 3' end of the nucleotide or nucleotide polymer.

The Court adopts the plain meaning of "covalently coupled." Coupled means joined, and "covalently" indicates joining [**1225] via covalent bonding. For the reasons stated above in the construction of "covalently attached," the Court finds that every chemical bond which effectuates coupling of the oligonucleotide sequence and the surface must be a covalent bond.

B. '305 Patent

Claim 1 of the '305 patent reads:

An **array of oligonucleotides**, the array comprising [(1)] a planar nonporous solid support having at least a first surface; and [(2)] a plurality of different

oligonucleotides attached to the first surface of the solid support at a **density exceeding 400 different oligonucleotides [**31] per square centimeter**, [(3)] wherein each of the different oligonucleotides is attached to the surface of the solid support in a different **predefined region**, has a different **determinable sequence**, and is at least 4 nucleotides in length.

Claim 15 of the '305 patent is identical to claim 1, except that the word "oligonucleotides" is replaced throughout the claim with the word "**polynucleotides**."

1. **array of oligonucleotides** is construed to mean a plurality of polymers of nucleotides ranging in length from 2 to about 100 nucleotides, arranged on a solid support.

Affymetrix and Incyte assert that "array" and "oligonucleotide" as used in the '305 patent have the same meanings as respectively proffered by the parties for the '934 patent.

Hyseq contends that "array of oligonucleotides" means a two-dimensional arrangement of oligonucleotides covalently attached to a surface in positionally defined and distinguishable predefined regions, wherein each of the predefined regions includes a mixture of single stranded oligomers of nucleotides synthesized monomer by monomer on each predefined region by stepwise attachment of a nucleotide to a [**32] surface-bound growing oligomer, where the mixture includes synthesis failures and full-length synthesis products.

For essentially the same reasons discussed in its construction of the terms, "array" and "oligonucleotides" in the '934 patent, the Court adopts the construction recited above. Hyseq's proffered definition is unsupported by any portion of the '305 specification or prosecution history indicating that the patentee intended that the specific terms, "array" and "oligonucleotide" be limited in this manner. Hyseq's additional limitations thus would constitute impermissible importation of limitations from the specification to the claims.

2. **attached** is construed to mean secured or joined to the solid surface.

Affymetrix contends that "attached" means secured to the solid surface.

Incyte contends that "attached" means covalently bonded to the surface by the 3' end of the nucleotide or nucleotide polymer.

Hyseq contends that "attached" means synthesized at a predefined region on the first surface of the solid support by bonding of the 3' end of the first monomer in the oligonucleotide to the predefined region on the first surface of the solid support prior to monomer-by-monomer [**33] synthesis of the oligonucleotide at that predefined region.

The Court adopts the ordinary and customary meaning of the term, "attached." Incyte argues that, during prosecution of the '934 patent, the PTO indicated that the claims were only enabled for arrays in which the oligonucleotides are covalently coupled to the surface. (Livornese Decl. Exh. 19 (7/12/94 Office Action) at 3). Consequently, Affymetrix withdrew claims to noncovalently attached oligonucleotides in order to obtain allowance. (See Markman hearing transcript at 402: 21-25). Affymetrix concedes that there is no new teaching added to the '305 specification compared to the '934 specification to support a non-covalent attachment. (Id. at 403:11-14). [**1226] Because the Examiner's comments suggest that claims to non-covalently attached oligonucleotides would not be enabled, Incyte argues that "attached" must be construed to exclude non-covalent attachment, to avoid a claim construction that renders the claims invalid.

In this case, however, "attached" is not reasonably susceptible to a definition that restricts it to covalent attachment. *Process Control*, 190 F.3d at 1357. The specification and prosecution [**34] history clearly show that Affymetrix used the term, "attached," to mean encompassing both covalent and non-covalent attachment. ('305 patent, col. 5:19-21 (stating, "Receptors may be attached, covalently or noncovalently, to a binding member, either directly or via a specific binding substance.")). The Court cannot rewrite the claims, even if necessary to avoid a finding of invalidity. *Process Control*, 190 F.3d at 1357. Thus, the Court rejects Incyte's importation of "covalently" to the definition of the term. Likewise, the Court declines to impose the monomer-by-monomer synthesis and 3' attachment limitations on the definition of attachment to avoid invalidity based on non-enablement.

3. *at a density exceeding 400 different oligonucleotides per square centimeter* is clear and does not require interpretation.

Affymetrix contends that "exceeding 400 different oligonucleotides per square centimeter" does not require interpretation.

Hyseq contends that "exceeding 400 different oligonucleotides per square centimeter" means that oligonucleotides must be attached to the solid support at more than 400 different predefined regions per square centimeter.

Incyte [**35] offered no proposed construction in the Joint Claims Construction Statement, but agreed with Hyseq's definition during the hearing.

The customary and ordinary meaning of this claim term does not require an absolute minimum number of nucleotides. To read it as such would ignore the meaning of the term "density," which denotes a concentration of nucleotides per unit area. Hyseq's definition would impose the unfounded limitation of an absolute minimum of 400 oligonucleotides and consequently would impose the limitation of a minimum surface area of one centimeter.⁸ There is no basis for such limitation, and the Court therefore rejects Hyseq's and Incyte's interpretation.

8 In arguing that this claim term must require a minimum of 400 different predefined regions per square centimeter, Incyte proposed a hypothetical situation where any array having as few as two different polymers would infringe if the polymers were placed closely enough together. (Markman hearing transcript at 227:6-18; 242:8-243:5). However, as Incyte itself recognized ultimately, even this extreme hypothetical example is not necessarily precluded by the prior art when this term is read in the context of the entire claim. (See id. at 247:15-248:4).

[**36] 4. *predefined region* is construed to mean a localized area on a surface which is, was, or is intended to be activated for formation of a polymer, where the activation is accomplished through exposure of the localized area to an energy source adapted to render a group active for synthesis of the polymer on the surface or for immobilization of a pre-existing polymer on a surface.

Affymetrix and Incyte assert that "predefined region" as used in the '305 *patent* has the same meaning as the parties respectively proffered for "discrete known regions" in the '934 *patent*.

Hyseq contends that "Predefined regions" is a localized area on a surface which is, was, or is intended to be activated for the formation of a polymer.

The Court notes that Hyseq's arguments parallel Incyte's arguments and accordingly adopts the same construction for "predefined regions" as it did for "discrete known regions" in the '934 *patent*.

[*1227] 5. *determinable sequence* is construed to mean a polymer of known sequence or of sequence that can be determined using conventional methods.

Affymetrix contends that "determinable sequence" means a nucleic acid polymer "of known sequence or of sequence that [**37] can be determined using conventional methods.

Incyte contends that "determinable sequence" means a polymer synthesized monomer by monomer and whose sequence is determined by the monomer by monomer synthesis process used to generate it.

Hyseq contends that "determinable sequence" means a spatially addressable polymer synthesized monomer-by-monomer whose sequence is determined by the process of monomer-by-monomer synthesis used to generate it.

The Court adopts the plain and ordinary meaning of the term "determinable sequence," that is, a sequence that can be determined. Incyte and Hyseq attempt to limit this definition to the VLSIPS technology which they allege is the only enabled type of determinable sequence. For the reasons previously discussed, the Court will not limit the claim term based solely on putative non-enablement. Moreover, Incyte and Hyseq have failed to produce, any intrinsic evidence to establish that Affymetrix intended the term to have any meaning other than its conventional meaning. "Determinable sequence" thus is not susceptible to the definitions proffered by Incyte and Hyseq. The Court cannot import extraneous limitations into a claim, even to avoid invalidity. [**38] The Court therefore rejects Incyte's and Hyseq's constructions.

6. *polynucleotides* is construed to mean a polymer of

nucleotides of length two or more.

Affymetrix contends that "polynucleotides" means a polymer of nucleotides of length two or more.

Incyte contends that "polynucleotides" means a strand of DNA longer than an oligonucleotide, and often naturally occurring or cloned from naturally occurring DNA.

Hyseq contends that "polynucleotides" means a polymer of nucleotides that is longer than twelve nucleotides in length.

The Court adopts the plain and ordinary meaning of the term. As with its construction of "oligonucleotides," the Court rejects the attempts by Incyte and Hyseq to import limitations into the meaning of the term without citing any portion of the specification or prosecution history to indicate that Affymetrix intended to use "polynucleotide" in a way other than the conventional meaning. For the reasons previously discussed, the Court will not limit the claim term based solely on putative non-enablement.

C. '992 Patent

Claim 1 of the '992 *patent* reads:

A method for detecting nucleic acid sequences in two or more collections [**39] of nucleic acid molecules, the method comprising: (a) providing an *array of polynucleotides* bound to a solid surface, each said polynucleotide comprising a *determinable nucleic acid*; (b) contacting the array of polynucleotides with: (i) *a first collection of labelled nucleic acid* comprising a sequence substantially complementary to a nucleic acid of said array, and (ii) at least *a second collection of labelled nucleic acid* comprising *a sequence substantially complementary* to a nucleic acid of said array; wherein the first and second labels are distinguishable from each other, and (c) detecting hybridization of the first and second labelled complementary nucleic acids to nucleic acids of said arrays."

Claim 4 of the '992 *patent* reads:

A method of detecting *differential expression* of each of a plurality of genes in a first cell type with respect to expression [*1228] of the same genes in a second cell type, said method comprising:

[1] *adding a mixture of labeled nucleic acid from the two cell types to an array* of polynucleotides representing a plurality of known genes derived from the two cell types, under [**40] *conditions that result in hybridization to complementary-sequence polynucleotides* in the array; and

[2] examining the array by fluorescence under fluorescence excitation conditions in which polynucleotides in the array are *hybridized to labeled nucleic acid* derived from one of the cell types give a distinct fluorescence emission color and polynucleotides in the array that are hybridized to labeled nucleic acid derived from the other cell types give a different fluorescence emission color.

1. *A method for detecting nucleic acid sequences* is construed to mean a method for determining the presence or absence of two or more nucleic acid molecules.

Affymetrix and Hyseq contend that this term means determining the presence or absence of two or more nucleic acid molecules.

Incyte contends that this term means a method for determining the sequence of nucleic acids as opposed to fingerprinting and mapping applications.

The parties agree that the preamble is a limitation of the claim. Incyte argues that the preamble limits claims 1 and 3 to applications involving determining the nucleotide sequence of nucleic acids. The Court agrees with Affymetrix and [**41] Hyseq that the ordinary meaning of the term does not restrict the term to sequencing applications. "Detecting nucleic acid sequences" may be plainly interpreted to mean "detecting the presence or absence of nucleic acid sequences." This

meaning is fully supported by the specification, which is entitled "Method of Detecting Nucleic Acids" and expressly characterizes the invention as encompassing more than sequencing:

The present invention provides improved methods useful for de novo sequencing of an unknown polymer sequence, for verification of known sequences, for fingerprinting polymers, and for mapping homologous segments within a sequence.

('992 *patent*, col. 2:26-29). Incyte fails to provide persuasive evidence that Affymetrix intended to use the term "detecting nucleic acid sequences" in a manner that excludes all applications other than sequencing. Finally, for the reasons previously discussed, the Court rejects Incyte's attempt to limit the claims to only those embodiments which Incyte asserts are enabled by the specification.

2. *array of polynucleotides* is construed to mean a plurality of polymers of nucleotides of length two or greater, arranged on [**42] a solid support.

See the discussion of the definitions of "array" in the '934 *patent* and "array of oligonucleotides" and "polynucleotides" in the '305 *patent*.

3. *bound* is construed to mean secured to the solid surface.

There is no dispute among the parties as to the meaning of "bound."

4. *determinable nucleic acid* is construed to mean a nucleic acid of known sequence or whose sequence can be determined using conventional methods.

There is no dispute among the parties as to the meaning of "determinable nucleic acid."

5. *a first [or second] collection of labeled nucleic acid* is construed to mean multiple nucleic acid molecules labeled with a first [or second] label.

Affymetrix contends that this term means multiple nucleic acid molecules labeled with a first [second] label. [*1229] Hyseq contends that this term means multiple non-identical nucleic acid molecules labeled with a first

[second] label.

Incyte originally did not propose a construction of this term.

The Court finds that the plain and ordinary meaning of a "collection of labeled nucleic acid" is merely an aggregation or accumulation of nucleic acid and does not, as Hyseq suggests, require [**43] the labeled nucleic acids to be non-identical. Although the examples from the specification that are cited by Hyseq may reflect embodiments where "collection of labeled nucleic acid" refers to non-identical molecules, the Court finds that these usages do not in any way disclaim the conventional meaning of the word "collection." Hyseq's definition would impermissibly import an extraneous limitation from the specification into the plain meaning of "collection." For the reasons discussed above, the Court cannot rewrite the claims based on asserted non-enablement. The Court thus adopts the construction recited above.

6. *a sequence substantially complementary* is not construed at this time.

Affymetrix contends that this term means a sequence which includes regions that preferably have perfect or substantially perfect homology (i.e. capable of forming a Watson-Crick base pair) to a nucleic acid.

Hyseq and Incyte contend that complementary means two nucleic acid base sequences that can form a double-stranded structure by Watson-Crick matching of each base pair. Hyseq and Incyte further contend that "substantially complementary" is fatally vague and indefinite.

It is well settled [**44] law that terms of degree such as "about," "relatively," "partially," and "substantially" do not automatically brand a claim indefinite. See *Andrew Corp. v. Gabriel Elecs., Inc.*, 847 F.2d 819, 821 (Fed. Cir. 1988); *Amgen, Inc. v. Chugai Pharmaceutical, Inc.*, 927 F.2d 1200 (Fed. Cir. 1991). However, the degree term will be indefinite if the specification offers no guidance as to the scope of the term. *Standard Oil Co. v. American Cyanamid Co.*, 585 F. Supp. 1481, 1490-91 (E. La. 1984), aff'd, 774 F.2d 448 (Fed. Cir. 1985). Affymetrix has provided no support from either the specification or prosecution history to elucidate the limits of the term, "substantially." Moreover, the definition Affymetrix provides merely

incorporates "substantially" into the definition without defining the term. Based on the arguments and evidence presented to date, the Court is inclined to find the term "substantially complementary" indefinite under 35 U.S.C. § 112, P 2. However, before taking the drastic step of finding this term too indefinite to construe, the Court will request that the parties provide further briefing [**45] as to the proper construction of "substantially complementary."

7. *detecting differential expression* is construed to mean the assessment of relative levels of gene activity.

Affymetrix contends that this term means the assessment of the relative levels of gene activity, where the concept of relative levels includes assessment of gene expression above and below the level of detection.

Incyte contends that this term means the assessment of the relative levels of gene activity, where differential gene expression analysis requires the simultaneous and competitive hybridization of samples derived from different cells to an appropriate array and the subsequent quantitation of the resulting relative levels of hybridization.

The Court adopts the plain and ordinary meaning of "differential expression." The Court declines to import further limitations on this preamble term. "A claim preamble has the import that the claim as a whole suggests for it." *Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615 at 615-20 (Fed. Cir. 1995). "If the claim preamble, when read in the context of the entire [*1230] claim, recites limitations of the claim, or, if the [**46] claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999). In this case, the Court finds that the preamble merely states a description of the method that is more fully set forth in the body of claim 4. See *IMS Technology, Inc. v. Haas Automation, Inc.*, 206 F.3d 1422, 1434 (Fed. Cir. 2000). For example, steps [1] and [2] describe the sequence of steps that comprise the method. Because the body of the claim fully and intrinsically sets forth the complete invention, and the preamble merely states the purpose of the invention, the Court finds that "detecting differential expression" in the preamble cannot be construed as a limitation of the claim.

8. *adding a mixture of labeled nucleic acid from the two cell types to an array* is construed to mean adding a mixture of labeled nucleic acid from the two cell types to the array in a single step, wherein "labeled nucleic from the two cell types" means samples of mRNA, DNA, or cellular other nucleic acid obtained from [**47] the two cell types.

Affymetrix contends that this term means adding a mixture, either in a single step or sequentially, of labeled nucleic acid from the two cell types to the array. Affymetrix further states that "nucleic acid from the two cell types" means samples of mRNA, or nucleic acid derived from said mRNA, including, but not limited to cDNA, labeled either before or after isolation from the two cell types.

Incyte contends that this term means the simultaneous and competitive hybridization of samples from different cells to an appropriate array to allow the subsequent quantitation of the resulting relative levels of hybridization. Incyte further asserts that "labeled nucleic acid from the two cell types" means samples of mRNA obtained from the two cell types and then labeled.

The plain language of this claim term requires adding a mixture, or combined sample, to an array in a single step. The Court rejects Affymetrix's proposition that the mixture could be added sequentially, as it is unclear what Affymetrix means when it suggests that a sample containing a mixture of labeled nucleic acids from two cell types could be added sequentially to the array. The plain meaning of adding [**48] a mixture to the array at once is consistent with the Examiner's understanding that the invention suggests "simultaneous hybridization of mixed nucleic acids." (Livornese Decl., Exh. 30 (9/3/97 Office Action) at 8). Affymetrix presents no citation or evidence to contradict the plain meaning in this respect.

The term also requires that the mixture of labeled nucleic acid is "from the two cell types." The Court agrees with Incyte to the extent that this phrase must be limited to nucleic acid samples collected from the two cell types. That is, cDNA, because it is a nucleic acid made in a reaction outside the cell, is not covered by the plain words of the claim. Affymetrix fails to cite to any evidence, intrinsic or extrinsic, that supports its proposition that cDNA and other nucleic acids *derived from* a cell's mRNA, which are never components of a cell, are encompassed by this term. Plainly, cDNA is not

obtained from any cell, but is synthesized based on nucleic acids obtained from the cell.

Finally, the Court rejects Incyte's restriction of the term to mRNA that is labeled after it is obtained from the cell. The term recites "nucleic acids" and plainly covers DNA as well [**49] as any other cellular nucleic acids. Moreover, the claim does not impose any time constraint on when the nucleic acid is to be labeled. Incyte has failed to present any intrinsic or extrinsic evidence to contradict this plain meaning.

9. *conditions that result in hybridization to complementary-sequence polynucleotides* is not construed at this time. [*1231] The Court will construe this term following the parties' supplemental briefing with respect to the term, "substantially complementary," as used in claim 1.

10. *hybridized to labeled nucleic acid* is not construed at this time. The Court will construe this term following the parties' supplemental briefing with respect to the term, "substantially complementary," as used in claim 1.

D. '716 Patent

Claim 3 of the '716 patent is representative in pertinent part of all of the independent claims of the '716 patent at issue in this claims construction. Claim 3 reads:

A computer program product that identifies an *unknown base* in a sample nucleic acid sequence, comprising:

[1] *computer code that receives a first set of signals* corresponding to a *first set* of probe intensities, [**50] each probe intensity in said first set indicating an extent of hybridization of a nucleic acid probe with a reference nucleic acid sequence, and each nucleic acid probe differing from each other by at least a single base;

[2] *computer code that receives a second set of*

signals corresponding to a *second set* of probe intensities, each probe intensity in said second set indicating an extent of hybridization of a nucleic acid probe with said sample sequence, and each nucleic acid probe differing from each other by at least a single base;

[3] *computer code that performs a comparison* of at least one of said probe intensities in said first set and at least one of said probe intensities in said second set;

[4] *computer code that generates a base call* identifying said unknown base according to results of said comparisons said sequence of said nucleic acid probe; and

[5] a computer readable medium that stores said computer codes.

The central issue with respect to construction of the '716 patent claims concerns whether or not the disputed terms should be interpreted as "means-plus-function" terms according to 35 U.S.C. § 112, [**51] P 6. Although the disputed terms are not explicitly recited in "means-plus-function" language, Hyseq argues that claiming "computer code" followed by the function performed by the computer code still subjects these claim terms to 35 U.S.C. § 112, P 6. If § 112, P 6 is applied to the disputed terms, the terms would be limited to the specific structures or steps disclosed in the specification and their equivalents. Upon considering all of the arguments of both Hyseq and Affymetrix, the Court finds that § 112, P 6 does not apply to the terms recited in the form, "computer code that [performs x function]."

Because the disputed claim terms are not expressly recited in "means for" language, there is a presumption that § 112, P 6 does not apply. *Mas-Hamilton Group v. La Gard, Inc.*, 156 F.3d 1206, 1213 (Fed. Cir. 1996). However, this presumption may be overcome if the terms are determined to be purely functional, without the additional recital of specific structure or material for performing the stated function. *Id.*; see also, *Al-Site Corp. v. VSI Int'l, Inc.*, 174 F.3d 1308, 1318 (Fed. Cir. 1999). Hyseq asserts that "a computer [**52] code that receives a first set of signals," "a computer code that receives a second set of signals," "a computer code that performs a comparison," and "a computer code that generates a base call" are all purely functional recitations of claim elements. Specifically, Hyseq argues that "computer code" does not recite any definite structure necessary to escape § 112, P 6.

Although it is a close question, the Court disagrees with Hyseq. To overcome [**1232] application of § 112, P 6, a claim term must identify some specific structure that performs the stated function. *Al-Site Corp.*, 174 F.3d at 1318. In *Mas-Hamilton*, for example, the Court held that "lever moving element" does not recite adequate structure, because a "moving element" could be any device that causes the lever to move. *Mas-Hamilton*, 156 F.3d at 1214. In contrast, the Federal Circuit has found that sufficient structure is recited to escape application of § 112, P 6 when the claim terms identify a type of structure that performs the stated function. See *Greenberg v. Ethicon Endo-Surgery, Inc.*, 91 F.3d 1580, 1583 (Fed. Cir. 1996) (holding "detent mechanism" denotes a type of [**53] device with a generally understood meaning in the mechanical arts); *Personalized Media Communications, LLC v. International Trade Commission*, 161 F.3d 696, 704-05 (Fed. Cir. 1998) (holding "digital detector" connotes structure and 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" or "ram-a-fram").

The Court finds that "computer code" is not a generic term, but rather recites structure that is understood by those of skill in the art to be a type of device for accomplishing the stated functions. Hyseq's own expert, speaking during the tutorial that preceded the Markman hearing, clearly indicated that he understood that "computer code" is a type of device for programming a computer. (Markman hearing transcript at 89:3-24). In this way, "computer code" is more similar to terms like

"detent mechanism" and "digital detector," than "element," "means," or "device." Hyseq has failed to provide any evidence or caselaw to support the proposition that "computer code" is a generic term. Rather, Hyseq has only identified cases in which application of § 112, P 6 was presumed because ****54** the claims had been recited in means-plus-function format. See *WMS Gaming, Inc. v. International Game Technology*, 184 F.3d 1339, 1347 (Fed. Cir. 1999); *Nilssen v. Motorola, Inc.*, 80 F. Supp. 2d 921, 929 (N.D. Ill. 2000).

Furthermore, the Court rejects Hyseq's argument that computer code lacks any structure because it consists of data with no physical dimensions. Hyseq has cited no cases to support this proposition. Moreover, Hyseq's proposition improperly would subject every software patent and many electronics patents to § 112, P 6. When, as here, the "means for" language is absent from a claim, the accused infringer has the burden of overcoming the presumption against application of § 112, P 6. Hyseq has failed to meet its burden. The Court therefore finds that "computer code" has sufficient structure to escape application of § 112, P 6. Hyseq concedes that, if the Court finds that § 112, P 6 does not apply to these terms, the terms should be construed according to their plain and ordinary meaning, and no further construction of these terms is required. Accordingly, the Court adopts the plain and ordinary meaning of these terms.

The final remaining ****55** dispute with respect to the '716 patent concerns the meaning of the term "*set*." Affymetrix contends that "set" means a collection or group. Hyseq contends that "set" has a particular meaning

when used in reference to nucleic acid probes. Hyseq argues that "a set of probes" must include four probes which are coextensive. Consequently, Hyseq argues that "set of signals" indicating the extent of hybridization of the probes and reference nucleic acid sequence is the set of signals from the four probes. Hyseq further asserts that the probes used to obtain the "second set of signals" must be identical in length and sequence to the probes in the first set of signals.

The Court adopts the plain and ordinary meaning of the term, "set," as meaning a collection or group. Hyseq attempts to alter the plain meaning of this term by importing extraneous limitations from embodiments described in the specification. **[*1233]** For the reasons already discussed, the Court rejects this approach.

ORDER

For the foregoing reasons, the Court construes the '934, '305, '992, and '716 patents as set forth above. The parties shall submit supplemental briefs regarding the term "substantially complementary." ****56** " Affymetrix shall file its Opening Supplemental Brief within twenty-one (21) days of the date of this order. Incyte and Hyseq each may file an Opposition Brief fourteen (14) days thereafter. The briefs shall not exceed ten (10) pages in length.

Dated: 1-22-01

JEREMY FOGEL

United States District Judge