# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

OXFORD GENE TECH	NOLOGY LIMITED	, )	
	Plaintiff,	)	
٧.		)	Civil Action No. 02-1695-KAJ
MERGEN LTD., et al.,		)	
	Defendants.	)	
	MEMORANI	DUM	OPINION

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Wilmington, Delaware September 29, 2004

#### **JORDAN**, District Judge

#### I. INTRODUCTION

This is a patent infringement case. Before me are the parties' requests for construction of the disputed claim language of U.S. Patent No. 6,054,270 (issued April 25, 2000) ("the '270 patent"), pursuant to *Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370, 116 S. Ct. 1384, 134 L. Ed. 2d 577 (1996). Plaintiff in this case is Oxford Gene Technology Ltd. ("OGT"). The defendant is Mergen Ltd. ("Mergen"). The parties have fully briefed and argued their positions. Jurisdiction is proper under 28 U.S.C. § 1338.

#### II. BACKGROUND

#### A. Procedural Background

OGT filed a complaint for patent infringement against defendant Mergen on December 23, 2002.<sup>1</sup> (Docket Item ["D.I."] 1.) Mergen filed a counterclaim against OGT on February 19, 2003. (D.I. 25.) OGT and Mergen are scheduled to try this case to a jury beginning on February 7, 2005.

<sup>&</sup>lt;sup>1</sup> Originally, OGT filed a complaint against Mergen; Clontech Laboratories, Inc., doing business as BD Biosciences Clontech; Genomic Solutions Inc.; PerkinElmer Life Sciences, Inc.; Axon Instruments, Inc.; and BioDiscovery, Inc. (D.I. 1.) OGT having settled with the others, the only remaining defendant in this dispute is Mergen.

#### B. The Disclosed Technology

The '270 patent discloses technology related to the making and using of microarrays in the study of DNA (deoxyribonucleic acid) and RNA (ribonulceic acid). See '270 patent, col. 1, II. 30-48.

#### 1. DNA and the Genetic Code

Genes, which provide the basic information for the operation of living organisms, are made up of DNA. (D.I. 174 at 1; D.I. 175 at 4.) Human genes act as the blueprint (the genetic code) for proteins involved in the function or structure of the human body. (*Id.*) DNA is a chain or strand comprising various combinations of four different nucleotides. (*Id.*) Each of the four nucleotides consists of a phosphate, a sugar (deoxyribose), and an organic base. (D.I. 175 at 4.) There are four different organic bases: adenine ("A"), cytosine ("C"), guanine ("G"), and thymidine ("T.")<sup>2</sup> (D.I. 174 at 1; D.I. 175 at 4.) Any one of these organic bases can be a component of a nucleotide. (D.I. 174 at 1; D.I. 175 at 4.) A nucleotide is distinguished by the organic base it contains. (D.I. 174 at 1.) The particular sequence of nucleotides in a strand of DNA determines what proteins will be made for the carrying out of functions in the human body. (See D.I. 174 at 1-2; D.I. 175 at 5.) DNA containing two or more nucleotides is referred to as a "polynucleotide." (See D.I. 175 at 4.) Usually, however, shorter polynucleotides are referred to as "oligonucleotides." (See D.I. 175 at 4.)

<sup>&</sup>lt;sup>2</sup> In an RNA nucleotide, there are also four different organic bases. They include the first three listed above and uridine, which replaces thymidine. (D.I. 175 at 4, n.2). The sugar in an RNA molecule is ribose rather than deoxyribose. (*Id.*)

When two strands of DNA are brought together under particular conditions, interactions may occur to hybridize, or bind the two strands together. (D.I. 174 at 2; D.I. 175 at 5.) Hybridization can only occur between complementary bases. (*Id.*) A is complementary to T, so A can only bond with T and vice versa. (*Id.*) C is complementary to G, so C can only bond with G and vice versa. (*Id.*) This is also referred to as "base-pairing." (D.I. 174 at 2.) When two complementary strands of DNA hybridize, they form the now famous double-helix structure. (*Id.*) Two perfectly complementary sequences of DNA will form the strongest bonds and be the most stable when hybridized. (D.I. 174 at 2; D.I. 175 at 5.) Two DNA sequences that are not perfect complements may still hybridize, but bonds will only form between bases that are matched with their complements. (*Id.*) Thus hybridization between two DNA sequences that are not perfect complements is less stable.<sup>3</sup> (*Id.*)

The process of hybridization is used as a tool to learn information about a sample of DNA. (D.I. 174 at 2; D.I. 175 at 6.) In a typical experiment, a known sample of DNA is placed near an unknown sample of DNA under particular conditions to promote hybridization. (*Id.*) The conditions can be controlled such that perfect complements can hybridize, but imperfect complements cannot. (D.I. 175 at 6.) The interaction of the complements thus provides useful information about the unknown sample of DNA.<sup>4</sup>

<sup>&</sup>lt;sup>3</sup> A DNA sequence of AAAA will be more stable when hybridized with its perfect complement, TTTT, than with a sequence such as TTCT, which is not a perfect complement. This is because the third A will not form a bond with the C in the latter sequence. (See D.I. 174 at 2; D.I. 175 at 5.)

<sup>&</sup>lt;sup>4</sup> If hybridization occurs, the unknown sample's sequence is learned. If hybridization does not occur, the complement to the known sample is ruled out as a possible sequence for the unknown. (See D.I. 174 at 2-3; D.I. 175 at 6.)

This technique has utility in a variety of applications, including the detection of genetic disorders where mutations may alter the base sequence in a strand of DNA. (See id.)

#### 2. The '270 Patent

The '270 patent discloses methods of making and using arrays of oligonucleotides. (D.I. 174 at 3.) Oligonucleotides of known sequence, called probes, are immobilized by attaching them to particular locations on a solid material forming an array. (D.I. 174 at 3; D.I. 175 at 7.) For a given experiment, an unknown sample, referred to as a polynucleotide, is applied to the oligonucleotide array. (D.I. 174 at 4; D.I. 175 at 7.) Under suitable conditions, the unknown polynucleotide may hybridize with one or more of the oligonucleotide probes, and information may thereby be gained regarding the unknown polynucleotide's sequence.<sup>5</sup> (*Id.*)

There are two basic methods of making arrays of oligonucleotides. (D.I. 174 at 4.) One method is referred to as "in situ synthesis," which "refers to the process of chemically building the oligonucleotides from smaller units on the array where they will be used." (Id. (emphasis added).) In situ synthesis is also referred to as monomer-by-monomer oligonucleotide synthesis. The other method, called "deposition," refers to the process of "synthesizing the oligonucleotides off of the array and then attaching (depositing) the oligonucleotides to known locations on the array." (Id. (emphasis added).) Either method results in oligonucleotide probes of known sequence, at known

<sup>&</sup>lt;sup>5</sup> The unknown polynucleotide may be labeled in order to observe its hybridization with an oligonucleotide probe. (D.I. 175 at 7.)

regions of an array. (*Id.*) Based on the type of experiment desired, a variety of arrays can be constructed. (*Id.* at 4-5.)

#### III. APPLICABLE LAW

Patent claims are construed as a matter of law. *Markman*, 52 F.3d at 979. A court's objective is to determine the plain meaning, if any, that those of ordinary skill in the art would apply to the language used in the patent claims. *Waner v. Ford Motor Co.*, 331 F.3d 851, 854 (Fed. Cir. 2003) (citing *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342 (Fed. Cir. 2001)). In this regard, pertinent art dictionaries, treatises, and encyclopedias may assist a court. *Texas Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1202-03 (Fed. Cir. 2002). The intrinsic record, however, is the best source of the meaning of claim language. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). Therefore, patent claims are properly construed only after an examination of the claims, the specification, and, if in evidence, the prosecution history of the patent. *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1324 (Fed. Cir. 2003) (citing *Vitronics*, 90 F.3d at 1582).

The intrinsic record is also of prime importance when claim language has no ordinary meaning in the pertinent art, see *Bell Atl. Network Servs., Inc. v. Covad Communications Group, Inc.*, 262 F.3d 1258, 1269-70 (2001) (determining that claim language could only be construed with reference to the written description) (citation omitted), and where claim language has multiple potentially applicable meanings, *Texas Digital, Inc.*, 308 F.3d at 1203.

If patent claim language has an ordinary and accustomed meaning in the art, there is a heavy presumption that the inventor intended that meaning to apply. *Bell Atl. Network Servs., Inc.*, 262 F.3d at 1268 (citing *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 989 (Fed. Cir. 1999)). Thus, unless the inventor has manifested an express intent to depart from that meaning, the ordinary meaning applies. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002) (citation omitted).

To overcome that presumption, an accused infringer may demonstrate that "a different meaning is clearly set forth in the specification or ... the accustomed meaning would deprive the claim of clarity." *N. Telecom Ltd. v. Samsung Elecs. Co., Ltd.*, 215 F.3d 1281, 1287 (Fed. Cir. 2000). However, the presumption may not be rebutted "simply by pointing to the preferred embodiment...." *Teleflex, Inc.*, 299 F.3d at 1327. It may be rebutted, though, where "the patentee ... deviate[d] from the ordinary and accustomed meaning ... by redefining the term or by characterizing the invention in the intrinsic record using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." *Id.* 

If claim language remains unclear after review of the intrinsic record, a court "may look to extrinsic evidence to help resolve the lack of clarity." *Interactive Gift Express, Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1332 (Fed. Cir. 2001). The use of extrinsic evidence in the claim construction process, however, is "proper only when the claim language remains genuinely ambiguous after consideration of the intrinsic evidence." *Id.* (citation omitted). A court may not use extrinsic evidence to contradict the import of the intrinsic record, and if the intrinsic record is unambiguous, extrinsic

evidence is entitled to no weight. *Bell & Howell Document Mgmt. Prods. Co. v. Altek* Sys., 132 F.3d 701, 706 (Fed. Cir. 1997).

#### IV. CLAIM CONSTRUCTION

OGT alleges that Mergen literally infringes independent claims 1, 9, and 10 of the '270 patent. (D.I. 180 at 1.) Further, OGT alleges that Mergen contributorily infringes and/or actively induces others to infringe claims 9 and 10 as well. (*Id.*; D.I. 1 at 4.) Each claim will be discussed in turn, according to the claim terms in dispute.

#### A. CLAIM 1

Claim 1 of the '270 patent is as follows:

1. A method of making an array of oligonucleotides, which comprises: attaching a plurality of oligonucleotides to an impermeable surface of a support, the oligonucleotides having different predetermined sequences and being attached at different known locations on the surface of the support through a computer-controlled printing device.

'270 patent, col. 15, II. 47-53.

- 1. "an array of oligonucleotides"
  - a. The Parties' Proposed Constructions

OGT argues that the preamble (i.e., the phrase "A method of making an array of oligonucleotides, which comprises:") is not limiting and therefore, does not require construction. (D.I. 174 at 9.) If found to be a limitation, OGT proposes that I construe the phrase "an array of oligonucleotides" to mean "two or more oligonucleotide sequences located at different regions on a single support." (*Id.*; D.I. 173 at 1.) Mergen proposes that I construe "an array of oligonucleotides" to mean "a single structured

array of oligonucleotides having related sequences, such that the pattern of binding<sup>6</sup> of the sample polynucleotides to the oligonucleotides reveals the sequence of the sample polynucleotides." (D.I. 175 at 27; D.I. 209 at 5.)

OGT argues that the preamble is not limiting and does not require construction.

(D.I. 174 at 9.) If construed, OGT argues that this term is entitled to its ordinary and plain meaning. (D.I. 174 at 10.) The plain meaning of "an array" is a set of elements with two or more locations. (*Id.*) Mergen argues that the preamble needs to be construed because it gives meaning to the claim. (D.I. 209 at 5; D.I. 175 at 27-30.) Mergen further argues that there are two issues in dispute with regard to this claim term: (1) whether "an array" can be construed to mean more than one array, and (2) whether the "array of oligonucleotides" is a structured array of related sequences for sequencing analysis. (D.I. 175 at 27.) As to the latter, Mergen asserts that the answer is yes, the term is so limited. (*Id.* at 29.) It cites several parts of the specification that it believes support its proposed construction. (*Id.* at 28-29.)

#### b. The Court's Construction

A preamble is only limiting where "it recites essential structure or steps, or if it is necessary to give 'life, meaning, and vitality' to the claims." *Intirtool, Ltd. v. Texar Corp.*,

<sup>&</sup>lt;sup>6</sup> Mergen uses the term "hybridization" in the Joint Claim Construction Chart, D.I. 173 at 1, instead of "binding," which it used in its Opening Claim Construction Brief, D.I. 175 at 27, and its Answering Brief, D.I. 209 at 5. The difference is negligible because I consider the terms essentially synonymous for the purpose of construing the phrase "an array of oligonucleotides" in claim 1 of the '270 patent.

369 F.3d 1289, 1295 (Fed. Cir. 2004) (internal quotations and citations omitted). If deletion of the preamble "does not affect the structure or steps of the invention," it should not be considered limiting unless there is "clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art. *Id.* (internal quotations and citations omitted).

While I do not think that the preamble's deletion affects "the structure or steps of the invention," *id.*, to the extent that it is limiting, I agree with OGT's construction. This construction is consistent with the ordinary and plain meaning of "an array." I will not read limitations into the claim from the specification when the term is easily construed according to its ordinary meaning as understood by a person of ordinary skill in the art. See Texas Digital Sys., Inc., 308 F.3d at 1205. Claim 1 states a method of making an array, not what uses that array may have, or what information may be gained by its use. Therefore, I do not accept Mergen's proposed construction. I construe "an array of oligonucleotides" to mean "two or more oligonucleotide sequences located at different regions on a single support."

- 2. "attaching a plurality of oligonucleotides"
  - a. The Parties' Proposed Construction

OGT proposes that I construe "attaching a plurality of oligonucleotides" to mean "fastening (as by tying or gluing) or affixing two or more oligonucleotides." (D.I. 174 at

12; D.I. 173 at 1.) Mergen proposes that I construe "attaching a plurality of oligonucleotides to mean "monomer by monomer synthesis of oligonucleotides on an impermeable surface of a support." (D.I. 175 at 13; D.I. 209 at 9; D.I. 173 at 1.)

The focus of the parties' dispute in this claim term is the word "attaching." OGT argues that "attaching" should be construed according to its ordinary and plain meaning. (D.I. 175 at 12.) Mergen argues that I should read into the term "attaching," the *method* by which the oligonucleotides are attached. (D.I. 175 at 13.) In support of its proposed construction, Mergen relies on a theory of prosecution disclaimer. (D.I. 175 at 16-18.)<sup>8</sup>

#### b. The Court's Construction

"Attaching" is a common, everyday word. As discussed above, I will not read in limitations from the specification when the term is easily construed according to its ordinary meaning as understood by a person of ordinary skill in the art. *See Texas Digital Sys., Inc.*, 308 F.3d at 1205. To construe "attaching a plurality of oligonucleotides," I do not need to find further limitations regarding the *method* of attachment. "Attaching," when read in light of the specification means "affixing." Therefore, I construe "attaching a plurality of oligonucleotides" to mean "affixing two or more oligonucleotides."

3. "to an impermeable surface of a support"

<sup>&</sup>lt;sup>7</sup> It does not appear that the parties contest that the phrase "a plurality of oligonucleotides" means "two or more oligonucleotides." Therefore, I need not construe it further.

<sup>&</sup>lt;sup>8</sup> Mergen, however, has not carried its burden of demonstrating a clear and unambiguous disclaimer with respect to this claim term. *See Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1324 (Fed. Cir. 2003).

#### a. The Parties' Proposed Constructions

OGT proposes that I construe "to an impermeable surface of a support" to mean to "a side of a single, mostly flat solid having a non-porous surface that does not permit diffusion through its substance." (D.I. 175 at 15; D.I. 173 at 1.) Mergen proposes that I construe "to an impermeable surface of a support" to mean either: to "a solid having a non-porous surface that does not permit diffusion through its substance," (D.I. 173 at 1), or to "the surface of the support is a solid, non-porous surface that is impermeable to liquid applied to the surface such that it prohibits diffusion." (D.I. 175 at 10; D.I. 209 at 16.)<sup>10</sup>

#### b. The Court's Construction

The focus of the parties dispute is the term "a support" because both parties propose identical constructions regarding the "impermeable surface." (D.I. 173 at 1.) I find little or no basis for OGT's proposed construction that the support is "a side of a single, mostly flat solid." (Id. (emphasis added).) There is no indication in the specification that the support is "mostly flat." While a "surface" may be considered "a side" of an object, the clear and plain meaning of "surface" is "the exterior or outside of an object or body." Webster's Third New International Dictionary of the English Language 2300 (1986). Even OGT uses the term "surface" in the latter part of its

<sup>&</sup>lt;sup>9</sup> This is the same construction that OGT proposed in litigation against Motorola regarding essentially the same claim term, in the context of claim 9 of the '270 patent. (D.I. 176, Ex. B at 11.)

<sup>&</sup>lt;sup>10</sup> At the *Markman* Hearing, in response to questioning regarding which construction Mergen proposes at the present time, counsel for Mergen responded: "Either construction is fine." (D.I. 269 at 98:1-98:2) (transcript for *Markman* Hearing, August 27, 2004.)

proposed construction, indicating that it does not believe "surface" requires further construction. (D.I. 174 at 15-16; D.I. 173 at 1.) Therefore, I construe "to an impermeable surface of a support" to mean "to a solid having a non-porous surface that does not permit diffusion through its substance."

- 4. "the oligonucleotides having different predetermined sequences and **being attached** at different known locations on the surface of the support"
  - a. The Parties' Proposed Constructions

OGT's proposes that I construe "the oligonucleotides having different predetermined sequences and being attached at different known locations on the surface of the support" to mean "the oligonucleotides having different predetermined sequences and being affixed or fastened to the support surface at different known locations." (D.I. 174 at 16; D.I. 173 at 2.) Mergen proposes that I construe "the oligonucleotides having different predetermined sequences and being attached at different known locations on the surface of the support" to mean "the sequences of the different oligonucleotides are known" and that "the oligonucleotides *themselves* are attached to the impermeable surface such that the different oligonucleotides occupy separate regions of the array." (D.I. 173 at 2; see D.I. 209 at 17-20 (emphasis added).)

#### b. The Court's Construction

In the Joint Claim Construction Chart, the parties agreed that the only disputed claim term in the above quoted claim language is "being attached." (D.I. 173 at 2.) In regards to this claim term, the word "attached" is the focus of attention. (*Id.*) In general, both parties make the same arguments made in section IV.A.2.a., *supra* at 10. Mergen also argues that the oligonucleotides *themselves* are attached to the impermeable surface. (*Id.* (emphasis added).) Mergen, however, does not explain in its Opening Claim Construction Brief or Answering Brief why the term "attached" in this part of claim 1 should include the word "themselves," when Mergen did not introduce that construction when "attached" was to be construed. I do not include the word "themselves" because it is clear from the patent that the oligonucleotides themselves are not attached to the impermeable surface, but rather are attached via a linker which is attached to the surface. (D.I. 174 at 17.) For example, the specification states:

Commercially available microscope slides (BDH Super Premium 76x26x1 mm) were used as supports. These were derivatised with a long aliphatic linker that can withstand conditions used for the deprotection of the aromatic heterocyclic bases, i.e. 30% NH3 at 55 for 10 hours. The *linker*, bearing a hydroxyl group which *serves* as a starting point for the subsequent oligonucleotide, is synthesised in two steps.

'270 patent, col. 8, II. 59-65 (emphasis added). Therefore, I construe "being attached" to mean simply "being affixed."

5. "through a computer-controlled printing device"

<sup>&</sup>lt;sup>11</sup> OGT stated: "The only disputed term included in this phrase is 'attached' ...." (D.I. 173 at 2.) Mergen stated that "the oligonucleotides having different predetermined sequences" was agreed to by the parties to mean "the sequences of the different oligonucleotides are known" and that "at different known locations on the surface of the support was agreed to mean "that the oligonucleotides are bound to the surface of the support, such that the different oligonucleotides occur separate regions of the array." (D.I. 173 at 2.)

#### a. The Parties' Proposed Constructions

OGT provides no proposed construction for "through a computer-controlled printing device" and only repeats the words "through a computer-controlled printing device." (D.I. 174 at 17; D.I. 173 at 2.) Mergen proposes that I construe "through a computer-controlled printing device" to mean "the monomer by monomer synthesis of oligonucleotides *to* known locations on the impermeable surface of the support is done with a computer-controlled printing device." (D.I. 175 at 18 (emphasis added).)

#### b. The Court's Construction

Reading the claim in light of the specification requires me to construe "through a computer-controlled printing device" to mean "through a computer-controlled printing device using monomer by monomer synthesis of oligonucleotides." I reach this conclusion after careful consideration of the claim term and the specification. Although OGT argues that claim 1 covers both the *in situ* and deposition methods of oligonucleotide synthesis (D.I. 174 at 18), the specification does not support the conclusion that a computer-controlled printing device can perform the deposition method.

Specifically, OGT points to three places in the specification for support. First, column 6, lines 51-55 of the '270 patent state: "Laying down very large number of lines or dots could take a long time, if the printing mechanism were slow. However, a low

<sup>&</sup>lt;sup>12</sup> In the parties Joint Claim Construction Chart, Mergen proposed that I construe "through a computer-controlled printing device" to mean "the monomer by monomer synthesis of oligonucleotides *at* known locations on the impermeable surface of the support is done with a computer-controlled printing device." (D.I. 173 at 2 (emphasis added).)

cost inkjet printer can print at speeds of about 10,000 spots per second." OGT uses this as support for the decreased time spent manufacturing an array by using an inkjet printer. (D.I. 174 at 18.)

This example supports the proposition that inkjet printers reduce the time required to manufacture an array. This quotation, however, comes from a section entitled, "5.2 Laying Down the Matrix." '270 patent, col. 6, II. 29-56. The first five lines of this section clearly disclose the *in situ* method of building oligonucleotides on the array. "The method described here envisages that the matrix will be produced by *synthesising oligonucleotides in the cells of an array* by laying down the precursors for the four bases in a predetermined patten, an example of which is described above." (*Id.* at II. 31-35 (emphasis added).) There is no disclosure in this section that supports OGT's proposition that inkjet printers can also be used for depositing *pre-formed* oligonucleotides. Therefore, according to the claim language and the disclosure in the specification, the time advantage referred to above is in the context of the *in situ* method of synthesizing oligonucleotides.

The second place OGT cites to support its argument that the specification discloses the deposition method of oligonucleotide synthesis is Section 5.3 entitled: "Oligonucleotide Synthesis." "Although we know of no description of the direct use of oligonucleotides as hybridisation probes while still attached to the matrix on which they were synthesised, there are reports of the use of oligonucleotides as hybridisation probes on solid supports to which they were attached *after* synthesis." (D.I. 1, Ex.1, col. 6 line 63 through col. 7 line 1 (emphasis added).) This disclosure does refer to the deposition method, but does not provide support for OGT's argument that claim 1

includes this method. If anything, this disclosure seems to support Mergen's argument that: "This patent is a teaching of the new technology.... The only time they mention a deposit method, they talk about the known prior art, which they're just changing their patent from." (D.I. 269 at 72:18-73:3) Therefore, I do not believe that this disclosure gives added support to OGT's argument.

The third place in the specification that OGT cites for its construction is Example 5 which states: "A microcomputer was used to control the plotter and the syringe pump which delivered the chemicals." '270 patent, col. 11, II. 52-53. This example, however, continues: "Filling the pen *successively* with G, T and A phosphoramidite solutions an array of twelve spots was laid down in three groups of four, with three different oligonucleotide sequences." '270 patent, col. 11, II. 57-60 (emphasis added).) Reading Example 5 in full, makes it clear that it discloses the use of a microcomputer to control the *in situ* method of oligonucleotide synthesis because the nucleotides are filled "successively." This is different than depositing a preformed oligonucleotide as would be required in the deposition method.<sup>13</sup>

<sup>&</sup>lt;sup>13</sup> OGT makes another argument in its Answering Brief which seems to suggest that Example 5 does not even apply to claim 1. "Meanwhile, claim 7, contains a limitation to a computer-controlled printing device. Since it depends from claim 3, claim 7 is limited to *in situ* synthesis by its own terms. And because it is limited to *in situ* synthesis, claim 7 recites attaching 'nucleotide *precursors*.' Claim 1 does *not* apply 'nucleotide *precursors*." (D.I. 222 at 15-16 (emphasis added).)

This argument by OGT seems to contradict its reliance on Example 5 for disclosing support for the deposition method of oligonucleotide synthesis. Example 5 begins with the phrase, "To test an automated system for laying down the *precursors....*" (D.I. 1, Ex. 1, col. 11, II. 42-43 (emphasis added).) If Example 5 does not pertain to claim 1, as OGT seems to suggest, then OGT has eliminated that example as support for its argument that claim 1 is not limited to *in situ* oligonucleotide synthesis.

Based on the foregoing, I conclude that the language of the claim, when read in light of the disclosures in the specification, supports the conclusion that "through a computer-controlled printing device" means "through a computer-controlled printing device using monomer by monomer synthesis of oligonucleotides."

Even if this construction were not sufficiently clear from the patent itself, the prosecution history also supports this interpretation. Original claims 36 and 37 of what became the '270 patent were as follows:

- 36. A method of making an array of oligonucleotides, which comprises: attaching a plurality of oligonucleotides to an impermeable surface of a support, the oligonucleotides having different predetermined sequences and being attached at different known locations on the surface of the support.
- 37. The method as claimed in claim 36 or 111, wherein the oligonucleotides are synthesized before attachment to the surface of the support.

(D.I. 201, Ex. D at 4.) (Declaration of Philip Rovner.) After amendment, claim 36 became claim 1, as discussed above. The prosecution history provides evidence for the motive behind the amendment to add the language "through a computer-controlled printing device" at the end of the claim. (D.I. 201, Ex. D at 4.) The examiner rejected claim 37 under 35 U.S.C. § 112, first paragraph, as containing "subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." (D.I. 201, Ex. E at 2.) The basis for the rejection was that: "The 'synthesis' *before* attachment of claim 37 has not been found." (*Id.* (emphasis added).) In other words, a claim including the deposition method was not supported by the specification. The applicant cancelled claim 37 in response to this

rejection. (D.I. 201, Ex. F at 1.) And finally, when claim 36 was eventually allowed, the examiner stated: "Stavrianopoulos et al. (U.S. Patent No. 4,994,373) is the closest prior art of record *but neither teaches nor suggests monomer by monomer synthesis of oligonucleotides* on a surface nor the hybridization assay practice of utilizing an array of different oligonucleotide probes on a single surface." (D.I. 201, Ex. H at 4 (emphasis added).)

This prosecution history suggests: (1) that the examiner did not find support in the specification for the deposition method, evidenced by his rejection of claim 37's "synthesis before attachment;" (2) the amendment to original claim 36, adding "through a computer-controlled printing device," limited claim 36 to monomer by monomer synthesis because otherwise, the examiner would have rejected it for the same reason he rejected claim 37; and (3) at least one reason that the examiner allowed the claim is because it taught monomer by monomer synthesis, which distinguished it over the closest prior art. Therefore, the prosecution history supports the conclusion that "through a computer-controlled printing device" means "through a computer-controlled printing device using monomer by monomer synthesis of oligonucleotides."

#### B. CLAIM 9

<sup>&</sup>lt;sup>14</sup> OGT has argued that this statement by the examiner specifically refers to only claims 3 through 8 and not claim 1. When asked to provide a basis for this argument, other than "generalized reasoning," counsel for OGT simply stated, "So my answer is, no, I can't do that, Your Honor." (D.I. 269 at 45:22-23.) Therefore, I do not find any basis for limiting the examiner's comments to only claims 3 through 8.

Claim 9 of the '270 patent is as follows:

different known regions on the surface, and

9. A method of analysing a polynucleotide, which method comprises: applying a labelled polynucleotide to be analysed or fragments thereof to an array of oligonucleotides under hybridisation conditions, wherein the array comprises a support having an impermeable surface to which a plurality of oligonucleotides having different predetermined sequences are attached to

analysing the polynucleotide by observing the regions where the polynucleotide or fragment thereof hybridizes and the regions where the polynucleotide or fragment thereof does not hybridize.

'270 patent, col. 16, II. 44-56.

- 1. "analysing a polynucleotide"
  - a. The Parties' Proposed Constructions

OGT argues that the preamble is not limiting and therefore, does not require construction. (D.I. 174 at 19.) If found to be a limitation, OGT proposes that I construe the phrase "analysing a polynucleotide" to mean "determining information about one or more polynucleotides, which includes detecting the presence or quantity of one or more polynucleotides." (D.I. 173 at 3.) Mergen proposes that I construe the phrase "analysing a polynucleotide" to mean "the process of which determining information about the sequence of a polynucleotide whose identity is incompletely known, as defined by the subsequent steps of the claim." (D.I. 175 at 20; D.I. 173 at 3.)

#### b. The Court's Construction

As earlier noted, *supra* at 9, a preamble is only limiting where "it recites essential structure or steps, or if it is necessary to give 'life, meaning, and vitality' to the claims." *Intirtool, Ltd.*, 369 F.3d at 1295 (internal quotations and citations omitted). If deletion of the preamble "does not affect the structure or steps of the invention," it should not be considered limiting unless there is "clear reliance on the preamble during prosecution to

distinguish the claimed invention from the prior art. *Id.* (internal quotations and citations omitted).

While I do not think that the preamble's deletion affects "the structure or steps of the invention," *id.*, to the extent that the preamble may be viewed as limiting, the parties do not dispute the construction. In its Answering Brief, OGT states that: "If Mergen simply means 'the process of which determining information about the sequence of one or more polynucleotides whose identity is incompletely known' ... OGT has no issue with that construction ...." (D.I. 222 at 21.) This is essentially the same construction Mergen offered. Therefore, even if the preamble were limiting, the term is evidently not in dispute and I will not construe it.

- 2. "to an array of oligonucleotides"
  - a. The Parties' Proposed Constructions

OGT proposes that I construe "to an array of oligonucleotides" to mean "to a set of two or more oligonucleotide sequences located at different regions on a single support." (D.I. 174 at 20; D.I. 173 at 3.) Mergen proposes that I construe "to an array of oligonucleotides" to mean to "a single structured array of oligonucleotides having related sequences, such that the pattern of binding<sup>15</sup> of the sample polynucleotides to the oligonucleotides reveals the sequence of the sample polynucleotides." (D.I. 175 at 27; D.I. 209 at 5.)

<sup>&</sup>lt;sup>15</sup> See n.5, supra.

#### b. The Court's Construction

The phrase "to an array of oligonucleotides" is substantively identical to the claim term construed in Claim 1, see *supra*, section IV.A.1.b. Therefore, I construe "to an array of oligonucleotides" to mean "to two or more oligonucleotide sequences located at different regions on a single support."

- 3. "under hybridisation conditions"
  - a. The Parties' Proposed Constructions

OGT proposes that I construe "under hybridisation conditions to mean "under conditions suitable for hybridization." (D.I. 174 at 21; D.I. 173 at 4.) Mergen proposes that I construe "under hybridisation conditions" to mean "conditions that permit discrimination between hybridization of oligonucleotide sequences that are exactly matched and mismatched to the polynucleotide sequence." (D.I. 175 at 23; D.I. 173 at 4.)

#### b. The Court's Construction

OGT argues that this claim term should be construed according to its plain and ordinary meaning. (D.I. 174 at 21.) Mergen encourages me to read in limitations from the specification. (D.I. 175 at 23-24.) I will not read in limitations from the specification when the term is easily construed according to its ordinary meaning as understood by a person of ordinary skill in the art. *See Texas Digital Sys., Inc.*, 308 F.3d at 1205. I conclude that one of ordinary skill in the art would understand that the phrase "under hybridisation conditions" means "under conditions suitable for hybridization." Therefore, I construe the phrase "under hybridisation conditions" to mean "under conditions suitable for hybridization."

4. "wherein the array comprises a support having an impermeable surface to which a plurality of oligonucleotides having different predetermined sequences are attached to different known regions on the surface"

#### a. The Parties' Proposed Constructions

The parties agree that the only claim terms from the quoted language that are in dispute are "a support having an impermeable surface" and "are attached." (D.I. 173 at 4-5.) OGT proposes that I construe this passage to mean "wherein the array comprises a side of a single, mostly flat solid having a non-porous surface that does not permit diffusion through its substance and to which two or more oligonucleotides having different predetermined sequences are fastened or affixed to different known regions on the surface." (D.I. 174 at 23; D.I. 173 at 4.) Mergen refers me back to its proposed constructions of the terms as they previously appeared in claim 1.<sup>16</sup> (D.I. 209 at 28.)

#### b. The Court's Construction

Essentially the same terms have been construed in Claim 1, with insignificant differences.<sup>17</sup> I have construed "attaching a plurality of oligonucleotides" to mean

<sup>&</sup>lt;sup>16</sup> Specifically, Mergen proposes that I construe: (1) "a support having an impermeable surface" to mean "a solid having a non-porous surface that does not permit diffusion through its substance;" (2) "a plurality of oligonucleotides having different predetermined sequences" to mean "the sequences of the different oligonucleotides are known;" (3) "are attached" to mean "that the oligonucleotides themselves are attached to the impermeable surface;" and (4) "to different known regions on the surface" to mean "that the oligonucleotides are bound to the surface of the support, such that the different oligonucleotides occupy separate regions of the array." (D.I. 173 at 4-5.)

<sup>&</sup>lt;sup>17</sup> Two insignificant differences are that claim 1 reads: "being attached at different known *locations* on the surface," '270 patent, col. 15 II. 51-52 (emphasis added), whereas claim 9 reads: "are attached to different known regions on the surface." '270 patent, col. 16, II. 50-52 (emphasis added). These minor differences do not change the claim terms previously construed in any significant way. In addition, the

"affixing two or more oligonucleotides." *See supra*, section IV.A.2.b. I have construed "to an impermeable surface of a support" to mean "to a solid having a non-porous surface that does not permit diffusion through its substance." *See supra*, section IV.A.3.b. And I have construed "being attached" to mean "being affixed." *See supra*, section IV.A.4.b.

- 5. "analysing the polynucleotide"
  - a. The Parties' Proposed Constructions

OGT proposes that I construe "analysing the polynucleotide" to mean "determining information about one or more polynucleotides, which includes detecting the presence or quantity of one or more polynucleotides." (D.I. 174 at 25; D.I. 173 at 5.) Mergen proposes that I construe "analysing the polynucleotide" to mean "the process of which determining information about the sequence of a polynucleotide whose identity is incompletely known." (D.I. 175 at 20; D.I. 173 at 5.)

#### b. The Court's Construction

This is the same claim term discussed above in the preamble of claim 9. See *supra*, section IV.B.1. In its Answering Brief, OGT states that: "If Mergen simply means 'the process of which determining information about the sequence of one or more polynucleotides whose identity is incompletely known' ... OGT has no issue with that construction ...." (D.I. 222 at 21.) As discussed in section IV.B.1., *supra*, this is essentially the same construction Mergen offered. Therefore, because this claim term evidently is not in dispute, I need not construe it.

latter portions of each claim, "at different known locations" and "to different known regions," were not directly disputed. *See supra*, sections IV.A.2. through IV.A.4.

- 6. "by observing the regions where the polynucleotide or fragment thereof hybridizes and the regions where the polynucleotide or fragment thereof does not hybridize"
  - a. The Parties' Proposed Constructions

OGT proposes that I construe the above quoted language to mean "by observing the regions where the polynucleotide or fragment thereof hybridizes and where it does not." (D.I. 174 at 25; D.I. 173 at 5.) Mergen proposes that I construe it to mean "information about more than one polynucleotide sequence is gained by comparing the locations of hybridization and no hybridization." (D.I. 175 at 24-25; D.I. 173 at 5.)

#### b. The Court's Construction

OGT argues that the plain and ordinary meaning should be used to interpret this claim, D.I. 174 at 25, and I agree. Observing means looking. This claim term essentially instructs one to look at the regions where hybridization has occurred and the regions where hybridization has not occurred. It is that simple. I do not find that this claim term needs to be limited to what, if any, information is gained by observing. Therefore, I construe "by observing the regions where the polynucleotide or fragment thereof hybridizes and the regions where the polynucleotide or fragment thereof does not hybridize" to mean exacting what it says "by observing the regions where the polynucleotide or fragment thereof does not hybridizes and the regions where the polynucleotide or fragment thereof does not hybridize."

#### C. CLAIM 10

Claim 10 of the '270 patent is as follows:

10. A method of comparing polynucleotide sequences, which method comprises: applying the polynucleotides to an array of oligonucleotides under hybridizing conditions, wherein the oligonucleotides have different predetermined sequences and are attached at different known locations on an impermeable surface of a support, and

observing the differences between the patterns of hybridisation.

'270 patent, col. 16, II. 57-65.

- 1. "comparing polynucleotide sequences"
  - a. The Parties' Proposed Constructions

OGT proposes that I construe "comparing polynucleotide sequences" to mean "determining relative information about two or more polynucleotides." (D.I. 174 at 27; D.I. 173 at 5.)<sup>18</sup> Mergen proposes that I construe "comparing polynucleotide sequences" to mean "the process of determining relative information about two or more polynucleotide sequences, as defined by the subsequent steps of the claim." (D.I. 175 at 26; D.I. 173 at 5.)

<sup>&</sup>lt;sup>18</sup> OGT argues that the preamble should be construed in this claim because the claim language refers back to the phrase "the polynucleotide sequences." (D.I. 174 at 27.) OGT, however, does not suggest that the preamble has to be construed, only that it would be helpful for me to construe it "for legal precision ... although the term could also be construed when it appears in the claim element itself." (*Id.*) When "the body of the claim fully and intrinsically sets forth the complete invention, including all of its limitations ... the preamble is of no significance to claim construction because it cannot be said to constitute or explain a claim limitation." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999) (internal citations omitted). My process for construing the preamble of this claim is consistent with that used to construe the preamble of claims 1 and 9. *See supra* pp. 9 and 19-20.

#### b. The Court's Construction

As earlier noted, *supra* at 9, a preamble is only limiting where "it recites essential structure or steps, or if it is necessary to give 'life, meaning, and vitality' to the claims." *Intirtool, Ltd.*, 369 F.3d at 1295 (internal quotations and citations omitted). If deletion of the preamble "does not affect the structure or steps of the invention," it should not be considered limiting unless there is "clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art. *Id.* (internal quotations and citations omitted).

While I do not think that the preamble's deletion affects "the structure or steps of the invention," *id.*, to the extent that the preamble may be viewed as limiting, I construe "comparing polynucleotide sequences" to mean "the process of determining relative information about two or more polynucleotide sequences."

- 2. "applying the polynucleotides to an array of oligonucleotides under hybridizing conditions, wherein the oligonucleotides have different predetermined sequences and are attached at different known locations on an impermeable surface of a support"
  - a. The Parties' Proposed Constructions

OGT and Mergen each propose that I construe these claim terms in the same manner as they have each proposed with respect to earlier claim language. (D.I. 174 at 28-29; D.I. 209 at 31; D.I. 173 at 6-7.)

#### b. The Court's Construction

I agree with the parties and construe "applying the polynucleotides to an array of oligonucleotides under hybridizing conditions, wherein the oligonucleotides have different predetermined sequences and are attached at different known locations on an

impermeable surface of a support" to be consistent with the earlier constructions. More specifically, I have construed "an array of oligonucleotides" to mean "two or more oligonucleotide sequences located at different regions on a single support." *See supra*, section IV.A.1.b. I have construed "under hybridising conditions" to mean "under conditions suitable for hybridization." *See supra*, section IV.B.3.b. I have construed "attached" (the only term actually in dispute) to mean "affixed." *See supra*, section IV.A.4.b. And I have construed "to an impermeable surface of a support" to mean "to a solid having a non-porous surface that does not permit diffusion through its substance." *See supra*, section IV.A.3.b.

- 3. "observing the differences between the patterns of hybridisation"
  - a. The Parties' Proposed Constructions

OGT proposes that I construe "observing the differences between the patterns of hybridisation" to mean "observing the differences between the patterns of hybridization." (D.I. 174 at 29; D.I. 173 at 7.) Mergen proposes that I construe "observing the differences between the patterns of hybridisation" to mean "information about more than one polynucleotide sequence is gained by analysing patterns of hybridization." (D.I. 173 at 7.)

#### b. The Court's Construction

OGT argues that this claim term should be construed according to its ordinary and plain meaning. (D.I. 174 at 29.) I agree. As earlier noted, the word "observing" has a plain and ordinary meaning which is synonymous with "looking." *See supra*, section IV.B.6.b. Mergen argues that I should read limitations into this claim term from the specification. (D.I. 175 at 32-33.) What, if any, information is gained by observing

the differences between the patterns of hybridisation is not a limitation of this claim term. Therefore, I construe "observing the differences between the patterns of hybridisation" to mean exactly what it says, "observing the differences between the patterns of hybridization."

### V. CONCLUSION

CLAIM TERM/PHRASE	THE COURT'S CONSTRUCTION
Claim 1:	
"an array of oligonucleotides"	The Court construes the claim term "an array of oligonucleotides" to mean "two or more oligonucleotide sequences located at different regions on a single support."
"attaching a plurality of oligonucleotides"	The Court construes the claim term "attaching a plurality of oligonucleotides" to mean "affixing two or more oligonucleotides."
"to an impermeable surface of a support"	The Court construes the claim term "to an impermeable surface of a support" to mean "to a solid having a non-porous surface that does not permit diffusion through its substance."
"the oligonucleotides having different predetermined sequences and <b>being attached</b> at different known locations on the surface of the support"	The Court construes the claim term "being attached" to mean "being affixed."
"through a computer-controlled printing device"	The Court construes the claim term "through a computer-controlled printing device" to mean "through a computer-controlled printing device using monomer by monomer synthesis of oligonucleotides."

CLAIM TERM/PHRASE	THE COURT'S CONSTRUCTION
Claim 9:	
"to an array of oligonucleotides"	The Court construes the claim term "to an array of oligonucleotides" to mean "to two or more oligonucleotide sequences located at different regions on a single support."
"under hybridisation conditions"	The Court construes the claim term "under hybridisation conditions" to mean "under conditions suitable for hybridization."
"wherein the array comprises a support having an impermeable surface to which a plurality of oligonucleotides having different predetermined sequences are attached to different known regions on the surface"	The Court construes the claim term "a support having an impermeable surface" to mean "to a solid having a non-porous surface that does not permit diffusion through its substance."  The Court construes the claim term "are attached" to mean "are affixed."
"by observing the regions where the polynucleotide or fragment thereof hybridizes and the regions where the polynucleotide or fragment thereof does not hybridize"	The Court construes the claim term "by observing the regions where the polynucleotide or fragment thereof hybridizes and the regions where the polynucleotide or fragment thereof does not hybridize" to mean "by observing the regions where the polynucleotide or fragment thereof hybridizes and the regions where the polynucleotide or fragment thereof does not hybridize."

CLAIM TERM/PHRASE	THE COURT'S CONSTRUCTION
Claim 10:	
"comparing polynucleotide sequences"	The Court construes the claim term "comparing polynucleotide sequences" to mean "the process of determining relative information about two or more polynucleotide sequences."
"applying the polynucleotides to an array of oligonucleotides under hybridizing conditions, wherein the oligonucleotides have different predetermined sequences and are attached at different known locations on an impermeable surface of a support"	The Court construes the claim term "an array of oligonucleotides" to mean "two or more oligonucleotide sequences located at different regions on a single support."  The Court construes the claim term "under hybridizing conditions" to mean "under conditions suitable for hybridization."  The Court construes the claim term "are attached" to mean "are affixed."  The Court construes the claim term "on an impermeable surface of a support" to mean "on a solid having a non-porous surface that does not permit diffusion through its substance."
"observing the differences between the patterns of hybridisation"	The Court construes the claim term "observing the differences between the patterns of hybridisation" to mean "observing the differences between the patterns of hybridization."

An appropriate order will issue.

# IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

OXFORD GENE TECHNO	DLOGY LIMITED,	)	
		)	
	Plaintiff,	)	
		)	
V.		)	Civil Action No. 02-1695-KAJ
		)	
MERGEN LTD., et al.,		)	
		)	
	Defendants.	)	

## <u>ORDER</u>

For the reasons set forth in the Opinion issued today, IT IS HEREBY ORDERED that the disputed claim terms in U.S. Patent No. 6,054,270 is construed as follows:

CLAIM TERM/PHRASE	THE COURT'S CONSTRUCTION
Claim 1:	
"an array of oligonucleotides"	The Court construes the claim term "an array of oligonucleotides" to mean "two or more oligonucleotide sequences located at different regions on a single support."
"attaching a plurality of oligonucleotides"	The Court construes the claim term "attaching a plurality of oligonucleotides" to mean "affixing two or more oligonucleotides."
"to an impermeable surface of a support"	The Court construes the claim term "to an impermeable surface of a support" to mean "to a solid having a non-porous surface that does not permit diffusion through its substance."
"the oligonucleotides having different predetermined sequences and <b>being attached</b> at different known locations on the surface of the support"	The Court construes the claim term "being attached" to mean "being affixed."
"through a computer-controlled printing device"	The Court construes the claim term "through a computer-controlled printing device" to mean "through a computer-controlled printing device using monomer by monomer synthesis of oligonucleotides."

CLAIM TERM/PHRASE	THE COURT'S CONSTRUCTION
Claim 9:	
"to an array of oligonucleotides"	The Court construes the claim term "to an array of oligonucleotides" to mean "to two or more oligonucleotide sequences located at different regions on a single support."
"under hybridisation conditions"	The Court construes the claim term "under hybridisation conditions" to mean "under conditions suitable for hybridization."
"wherein the array comprises a support having an impermeable surface to which a plurality of oligonucleotides having different predetermined sequences are attached to different known regions on the surface"	The Court construes the claim term "a support having an impermeable surface" to mean "to a solid having a non-porous surface that does not permit diffusion through its substance."  The Court construes the claim term "are attached" to mean "are affixed."
"by observing the regions where the polynucleotide or fragment thereof hybridizes and the regions where the polynucleotide or fragment thereof does not hybridize"	The Court construes the claim term "by observing the regions where the polynucleotide or fragment thereof hybridizes and the regions where the polynucleotide or fragment thereof does not hybridize" to mean "by observing the regions where the polynucleotide or fragment thereof hybridizes and the regions where the polynucleotide or fragment thereof does not hybridize."

CLAIM TERM/PHRASE	THE COURT'S CONSTRUCTION
Claim 10:	
"comparing polynucleotide sequences"	The Court construes the claim term "comparing polynucleotide sequences" to mean "the process of determining relative information about two or more polynucleotide sequences."
"applying the polynucleotides to an array of oligonucleotides under hybridizing conditions, wherein the oligonucleotides have different predetermined sequences and are attached at different known locations on an impermeable surface of a support"	The Court construes the claim term "an array of oligonucleotides" to mean "two or more oligonucleotide sequences located at different regions on a single support."  The Court construes the claim term "under hybridizing conditions" to mean "under conditions suitable for hybridization."  The Court construes the claim term "are attached" to mean "are affixed."  The Court construes the claim term "on an impermeable surface of a support" to mean "on a solid having a non-porous surface that does not permit diffusion through its substance."
"observing the differences between the patterns of hybridisation"	The Court construes the claim term "observing the differences between the patterns of hybridisation" to mean "observing the differences between the patterns of hybridization."

Kent A. Jordan
UNITED STATES DISTRICT JUDGE

Wilmington, Delaware September 29, 2004