IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OXFORD GENE TECHNOLOGY LIMITED,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 02-1695-KAJ
	)	
MERGEN LTD., et al.,	)	
	)	
Defendants.	)	

MEMORANDUM OPINION

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Wilmington, Delaware
November 19, 2004

JORDAN, District Judge

I. INTRODUCTION

This is a patent infringement case. Presently before me are several motions filed by plaintiff, Oxford Gene Technology Limited ("OGT"), and defendant, Mergen Limited ("Mergen"). Those filed by OGT include a Motion for Partial Summary Judgment of Patent Validity and Enablement (Docket Item ["D.I."] 177; the "Motion for Validity"), a Motion for Partial Summary Judgment of Infringement (D.I. 179; the "Motion for Infringement"), and a Motion to Strike Mergen's Newly Identified Non-Enablement Defense (D.I. 202; the "Motion to Strike"). Those filed by Mergen include a Motion for Summary Judgment of Invalidity of the Asserted Claims of U.S. Patent No. 6,054,270 (the "'270 patent") (D.I. 181; the "Motion for Invalidity"), a Motion for Summary Judgment of Non-Infringement of Claims 1, 9 and 10 of U.S. Patent No. 6,054,270 (D.I. 185; the "Motion for Non-Infringement"), and a Motion for Summary Judgment of Invalidity of Claim 1 of U.S. Patent No. 6,054,270 (D.I. 190; the "Motion for Invalidity of Claim 1").

Jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338. For the reasons that follow, OGT's Motion for Validity will be denied, OGT's Motion for Infringement will be granted with respect to claims 9 and 10 and denied with respect to claim 1,[1] OGT's Motion to Strike will be denied as moot,[2] Mergen's Motion for Invalidity will be denied,

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[1] Based on my construction of claim 1, OGT has stipulated to: "(a) the denial of OGT's Motion for Partial Summary Judgment of Infringement (D.I. 179, 180) with respect to claim 1 only ... and (b) the grant of Mergen's Motion for Summary Judgment of Non-infringement (D.I. 185, 186) with respect to claim 1 only ...." (D.I. 240.)

[2] Based on OGT's stipulation regarding claim 1 of U.S. Patent No. 6,054,270 (the "'270 patent") (D.I. 240; *see* footnote 1), OGT's Motion to Strike is denied as moot

Mergen's Motion for Non-Infringement will be granted with respect to claim 1 and denied with respect to claims 9 and 10,[3] and Mergen's Motion for Invalidity of Claim 1 will be denied without prejudice.[4]

II. BACKGROUND

The background related to the '270 patent is set forth in my November 16, 2004 Order and Opinion (D.I. 242, 243) and will not be repeated here. Claim 1 of the patent states, 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, ll. 47-53.) I have construed "through a computer-controlled printing device" to mean "through a computer-controlled printing device using monomer by monomer synthesis of oligonucleotides." (D.I. 238 at 14-18.) In short, claim one covers only *in situ* synthesis of oligonucleotides.

Claim 9 reads as follows:

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because it relates only to the issue of the validity of claim 1.

[3] Based on OGT's stipulation regarding claim 1 of the '270 patent (D.I. 240; *see* footnote 1), Mergen's Motion for Non-Infringement will be granted with respect to claim 1.

[4] Based on OGT's stipulation regarding claim 1 of the '270 patent (D.I. 240; *see* footnote 1), I exercise my discretion to dismiss without prejudice Mergen's counterclaim of declaratory judgment of invalidity with respect to claim 1. *See Liquid Dynamics Corp. v. Vaughan Co., Inc.*, 355 F.3d 1361, 1371 (Fed. Cir. 2004) ("A district court judge faced with an invalidity counterclaim challenging a patent that it concludes was not infringed may either hear the claim or *dismiss it without prejudice*, subject to review only for abuse of discretion.") (internal citation omitted) (emphasis added).

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 different known regions on the surface, and
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, ll. 44-56.) I have construed the terms of claim 9 as follows:

CLAIM TERM	MEANING
"to an array of oligonucleotides"	"to two or more oligonucleotide sequences located at different regions on a single support"
"under hybridisation conditions"	"under conditions suitable for hybridization"
"a support having an impermeable surface"	"a solid having a non-porous surface that does not permit diffusion through its substance"
"are attached"	"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"	"by observing the regions where the polynucleotide or fragment thereof hybridizes and the regions where the polynucleotide or fragment thereof does not hybridize"

Oxford Gene, 2004 WL 2211971, at *9-*11.

Claim 10 reads 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, ll. 57-65.) I gave the claim terms which also appear in claim 9 the same construction I gave them with respect to claim 9. I determined that the only new limitation, namely "observing the differences between the patterns of hybridisation," can be understood in accordance with its plain and ordinary meaning and requires no further construction. *Id.* at *12-*13.

III. STANDARD OF REVIEW

Pursuant to Federal Rule of Civil Procedure 56(c), a party is entitled to summary judgment if a court determines from its examination of "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any," that there are no genuine issues of material fact and that the moving party is entitled to judgment as a matter of law. In determining whether there is a triable issue of material fact, a court must review the evidence and construe all inferences in the light most favorable to the non-moving party. *Goodman v. Mead Johnson & Co.*, 534 F.2d 566, 573 (3d Cir. 1976). However, a court should not make credibility determinations or weigh the evidence. *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000). To defeat a motion for summary judgment, Rule 56(c) requires that the non-moving party "do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87 (1986) (internal citation omitted). The non-moving party "must set forth specific facts showing that there is a genuine issue for trial." Fed. R. Civ. P. 56(c). "Where the record taken as a whole could not lead a rational trier of fact to find for the

non-moving party, there is no genuine issue for trial." *Matsushita Elec. Inds. Co., Ltd.*, 475 U.S. at 587 (internal citation omitted). Accordingly, a mere scintilla of evidence in support of the non-moving party is insufficient for a court to deny summary judgment. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986).

A. Patent Validity

When a party challenges a patent's validity, the starting point for analyzing that challenge is the statutory presumption of validity. *See* 35 U.S.C. § 282 ("A patent shall be presumed valid."). Accordingly, "[t]he burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity." *Id.* Invalidity must be shown by clear and convincing evidence. *Robotic Vision Sys. v. View Eng'g, Inc.*, 189 F.3d 1370, 1377 (Fed. Cir. 1999). This presumption of validity is never weakened, and the burden of proving invalidity does not shift from the party asserting invalidity. *Imperial Chem. Indus., PLC v. Danbury Pharmacal, Inc.*, 745 F.Supp. 998, 1004 (D. Del. 1990) (citing *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1574-75 (Fed. Cir. 1984) (other citations omitted)). The burden of going forward with evidence rebutting invalidity may shift to the patentee only after the party asserting invalidity has demonstrated a legally sufficient *prima facie* case of invalidity. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 291 (Fed. Cir. 1985) (internal citations omitted). If the party asserting invalidity has established a legally sufficient case of invalidity, the court then examines all of the evidence of invalidity together with all of the evidence rebutting invalidity, and determines whether there is clear and convincing evidence of invalidity. *Id.* at 291-92.

B. Infringement

A patent infringement analysis involves two steps: claim construction and then the application of the construed claim to the accused process or product. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). The first step, claim construction, has been held to be purely a matter of law. *See Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1454 (Fed. Cir. 1998) (en banc). The second step, application of the claim to the accused product, is a fact-specific inquiry. *See Kustom Signals, Inc. v. Applied Concepts, Inc.*, 264 F.3d 1326, 1332 (Fed. Cir. 2001) (Patent infringement, "whether literal or under the doctrine of equivalents, is a question of fact."). Summary judgment is appropriate in patent infringement suits when it is apparent that only one conclusion regarding infringement could be reached by a reasonable jury. *See Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1323 (Fed. Cir. 2001).

IV. DISCUSSION

A. VALIDITY[5] OF CLAIMS 9 AND 10

1. Anticipation

[5] As noted, *supra* note 1, I have chosen to decline an examination of the validity of claim 1, since the parties have agreed that, under my construction of that claim, Mergen does not infringe that claim.

Mergen moves for summary judgment on the basis that claims 9 and 10 of the '270 patent are invalid as anticipated by European Patent Application No. 235 726 A2 (the "'726 application"). (D.I. 182 at 14-16.) OGT moves for summary judgment that claims 1, 9, and 10 are not anticipated and therefore, not invalid. (D.I. 178 at 11-13.) Anticipation requires that each and every element of the claimed invention be disclosed in a single prior art reference. *In re Paulsen*, 30 F.3d 1475, 1478-79 (Fed. Cir. 1994). In other words, if any claimed element is missing from the prior art reference, it cannot anticipate the claimed invention. *Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565, 1571 (Fed. Cir. 1986) (citation omitted), *overruled on other grounds by Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337 (Fed. Cir. 2004).

Even in considering the evidence in the light most favorable to Mergen, there is no material issue of fact to preclude a finding on summary judgment that the '726 application does not anticipate claims 9 and 10 of the '270 patent. A common limitation of claims 9 and 10 is that each requires the support to which the oligonucleotides are attached to have an impermeable surface. Claim 9 states: "... wherein the array comprises a support having an *impermeable surface* ...." ('270 patent, col. 16, ll. 48-49 (emphasis added).) Claim 10 states: "... on an *impermeable surface* of a support ...." ('270 patent, col. 16, ll. 62-63 (emphasis added).) The '726 application, however, does not disclose an impermeable surface of a support, and therefore cannot anticipate. Additional evidence makes this perfectly clear.

First, Mergen admits that "... the '726 application does not specifically disclose impermeable surfaces ...." (D.I. 217 at 16.) Second, while Mergen argues that impermeable surfaces were somehow inherent in the "solid sheets" disclosed in the

‘726 application, neither OGT’s expert, Dr. Vrana, nor Mergen’s own expert, Dr. Purdue, agreed. (*See* D.I. 151, Vrana Validity Report at 5-7; D.I. 193, Ex. 5, 186 at 14:01:03 12-4:01:37 25, Dep. Dr. Perdue, July 14, 2004.) On the contrary, the ‘726 application describes the method of “blotting,” which requires the use of permeable surfaces, as expressly disclosed in that reference. (D.I. 151, Vrana Validity Report at 5-7.) Third, the only evidence offered by Mergen in support of its Motion for Invalidity based on anticipation is the deposition testimony of Dr. Vrana, OGT’s validity expert, who concluded that no prior art reference anticipated the patent-in-suit. When asked whether the ‘726 application disclosed impermeable supports, he replied, “I couldn’t, I couldn’t say that.” (D.I. 218, Ex. G at 280.) In addition, Mergen’s own expert, Dr. Purdue admitted in deposition testimony that in his opinion, none of the prior art references invalidates any of the claims.

> Q: ... Do you have opinions as to whether or not any prior art reference invalidates any claim of the ‘270 patent for any reason? ...
> A: You’re asking me whether right now I believe that a single piece of prior art invalidates any of the claims?
> Q: That’s correct, the anticipation as a test. ...
> A: We’ve covered this ground before, and none of them do on their own.

(D.I. 193, Ex. 5 at 186, 14:01:03 12-4:01:37 25, Dep. Dr. Purdue, July 14, 2004.) Finally, Mergen’s own concluding argument on this issue sets forth premises that admit the lack of anticipation. Mergen argued: “If the Court construes claims 9 and 10 to include arrays where oligonucleotides are attached to a surface of a support that is *permeable*, and via a method of attachment that does not require *in situ* synthesis, then the ‘726 application discloses each and every element of the invention claimed in claims 9 and 10 of the ‘270 patent ....” (D.I. 182 at 16 (emphasis added).) Thus, even Mergen

concludes that the court would have to find that claims 9 and 10 included a permeable surface to find that the '726 application anticipates. But, of course, claims 9 and 10 contain the opposite limitation, an impermeable surface of a support.

Because the '726 application does not anticipate the '270 patent, Mergen's Motion for Invalidity with regard to anticipation will be denied. And while OGT's Motion for Validity cannot be granted on this basis alone,[6] Mergen will not be permitted to argue that the '270 patent is invalid because it is anticipated by the '726 application.

2. Obviousness

Mergen moves for summary judgment on the basis that claims 1, 9, and 10 of the '270 patent are invalid for obviousness. (D.I. 182 at 19-21.) OGT moves for summary judgment that these three claims are not obvious and therefore, not invalid. (D.I. 178 at 12-23.) A patent is invalid for obviousness under 35 U.S.C. § 103, "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a). The ultimate determination of obviousness is a question of law based on underlying factual inquiries. *See Rockwell Int'l Corp. v. United States*, 147 F.3d 1358, 1362 (Fed. Cir. 1998) (citation omitted). These inquiries include determining (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the pertinent art; and (4) secondary

[6] To say a patent is not anticipated does not mean that there can be no other basis for invalidity. In this case, there are other arguments for invalidity which cannot be resolved on summary judgment. (*See infra* section IV.A.2.)

considerations, which include objective evidence of nonobviousness such as a long-felt but unsolved need which the invention addresses, the failure of others to formulate the invention, and the commercial success of the invention. *Graham v. John Deere Co. of Kansas City,* 383 U.S. 1, 17-18 (1966).[7] The existence of each element of a claim in the prior art, however, does not, by itself, demonstrate obviousness. *See Moore N. Am., Inc. v. Poser Bus. Forms, Inc.*, No. Civ.A. 97-712-SLR, 2001 WL 253117, at *5 (D. Del. Mar. 8, 2001). Instead, there must be a "reason, suggestion, or motivation in the prior art that would lead one of ordinary skill in the art to combine the references, and that would also suggest a reasonable likelihood of success." *Smiths Indus. Med. Sys., Inc. v.. Vital Signs, Inc.*, 183 F.3d 1347, 1356 (Fed. Cir. 1999) (internal citation omitted).

In its Motion for Invalidity, Mergen makes two arguments regarding obviousness as it relates to claims 9 and 10 of the '270 patent. The first is that claims 9 and 10 are obvious in light of the '726 application in combination with what would have been known by one of ordinary skill in the art, specifically the alleged common knowledge of using glass supports for hybridization. (D.I. 183 at 14-16.) Mergen's second argument is that claims 9 and 10 are obvious in light of the '726 application in combination with the '373 patent. (*Id.* at 19-21.) As support for both arguments, Mergen relies on Dr. Purdue's

[7] A district court cannot make a proper obviousness determination without undertaking an analysis under *Graham. See Greenwood v. Hattori Seiko Co., Ltd.,* 900 F.2d 238, 241 (Fed. Cir. 1990) ("Since the proper *Graham* analysis was not made by the district court, the summary judgment of obviousness under 35 U.S.C. § 103 must be vacated."); *Loctite Corp. v. Ultraseal Ltd.,* 781 F.2d 861, 872-73 (Fed. Cir. 1985) ("In patent cases, the need for express *Graham* findings takes on an especially significant role because of an occasional tendency of district courts to depart from the *Graham* test ...."), *overruled on other grounds by Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059 (Fed. Cir. 1998).

Declaration, in which he restates the opinions expressed in his expert report. (*See* D.I. 182 at 16 (referring to Dr. Purdue's Declaration (D.I. 183) at ¶ 7 for the proposition that it was well known in the field to use glass supports for hybridization); D.I. 182 at 20 (referring to Dr. Purdue's Declaration (D.I. 183) at ¶¶ 8-9 for the proposition that the '373 patent in combination with the '726 application renders claims 1, 9, and 10 obvious to one skilled in the art).)

Because I have already concluded that Dr. Purdue's opinion lacked sufficient support for the proposition that one of ordinary skill in the art would know to use glass supports for hybridization (D.I. 242 at 1; D.I. 243 at 11-13), Mergen's first argument must fail. Therefore, Mergen's only obviousness argument with evidentiary support is that the '270 patent is obvious based on the '726 application in view of the '373 patent.

a. The Scope and Content of the Prior Art

A proper inquiry into the first *Graham* factor should focus on the claims in suit, the art the PTO applied to the claims, and the nature of the problem confronting the inventor. *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 449 (Fed. Cir. 1986). In this case, there are two prior art references that must be considered: the '726 application and the '373 patent.[8]

[8] Neither party disputes that both references constitute prior art under 35 U.S.C. § 102. The '726 application was filed in Europe on February 24, 1987. (D.I. 184, Ex. 3 at PR 000241, '726 application at 1.) The '373 patent was filed on July 20, 1989 as a continuation, and claims a priority date back to at least May 9, 1985. (D.I. 184, Ex. 4 at

The ‘726 application teaches a method of making an oligonucleotide array that includes immoblizing or attaching one or more oligonucleotides of known sequence to a solid support at different known locations on its surface. It also discusses what is now called the “reverse dot blot” technique. In this technique, as taught by the ‘726 application, oligonucleotide probes of known sequence are attached to a support surface by “blotting” them to the surface and are then hybridized with a liquid sample containing labeled polynucleotides of unknown sequence. It teaches a variety of approaches for attaching oligonucleotide probes to a support, including both non-covalent and covalent attachment to permeable supports such as nitrocellulose and nylon. It also teaches to observe the locations where hybridization has occurred, by observing the labeled areas. This method can be used to detect certain genetic disorders. (‘726 application; D.I. 212, Ex. A at 6, Expert Report of Dr. Purdue; D.I. 193, Ex. 8 at 4, Rebuttal Expert Report of Dr. Vrana.)

The ‘373 patent teaches a method of analyzing polynucleotide sequences by attaching the polynucleotides to a solid support, and hybridizing them with labeled oligonucleotide or polynucleotide probes of known sequence. It teaches that non-porous and transparent supports, such as glass, are preferred over porous materials, such as nitrocellulose filters. (‘373 patent, col. 5, ll. 46-52.) It discloses a product for performing the disclosed detection of a polynucleotide sequence, which contains a portion for retaining a fluid in which the immobilized polynucleotide sequence is located. According to the ‘373 patent, the portion of the product for containing the fluid is

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PUR 000232, ‘373 patent at 1.)

preferably a well, a tube, or a cuvette. Any resulting hybridization then occurs within this fluid. ('373 patent; D.I. 212, Ex. A at 7-8, Expert Report of Dr. Purdue; D.I. 193, Ex. 8 at 17-18, Rebuttal Expert Report of Dr. Vrana.)

b. The Differences Between the Claimed Invention and the Prior Art

With respect to this second *Graham* factor, the court must view the claimed invention *as a whole*. *Bausch & Lomb*, 796 F.2d at 449 (citation omitted) (emphasis in original); *see also Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc.*, 98 F.3d 1563, 1570 (Fed. Cir. 1996) ("[T]he determination of obviousness, *vel non*, requires that all the evidence be considered together.").

Although Mergen argues that the '726 application on its own teaches all of the limitations of claims 9 and 10 of the '270 patent, (D.I. 217 at 21) -- an argument I have already rejected (*see supra* section IV.A.1.) -- Mergen also argues in the alternative that the '726 application teaches all of the limitations of those claims except an impermeable surface. (D.I. 217 at 21.) OGT apparently does not disagree with that alternative assertion, and neither do I.

Turning then to the only other prior art source available to Mergen to demonstrate the use of an impermeable support for hybridization, I review the '373 patent. There are two differences between the '373 patent and the claimed invention as a whole. The first, is that the '373 patent teaches a method of analysis involving attachment of unknown polynucleotides to a solid support followed by hybridization with labeled oligonucleotide or polynucleotide probes of known sequence. ('373 patent, col 1, ll. 25-45, col. 5, ll. 15-67.) This method was known as a "dot blot" technique. (*See*

D.I. 193, Ex. 8 at 4, Rebuttal Expert Report of Dr. Vrana.) The invention disclosed in the patent-in-suit, on the other hand, teaches the "reverse dot blot" technique, in which the known oligonucleotide probes are attached to the surface of an impermeable support, rather than the unknown polynucleotides being attached. The second difference is that the '373 patent teaches that the hybridization be detectable in solution and that, therefore, the analysis be performed on a solid support that "is desirably a well, a tube, or a cuvette." ('373 patent, col. 7, ll. 49-50.) The invention described in the '270 patent does not require the sample to be in a solution for detection and therefore does not utilize wells, tubes, or cuvettes, but utilizes instead simply "an array of oligonucleotides."[9]

The focus of Mergen's argument is that the '373 patent teaches an impermeable surface of support, the one claim limitation that the '726 application is missing. (D.I. 217 at 21-22.) In the Notice of Allowability for the '270 patent, the examiner stated two features of the invention that the '373 patent did not teach: "monomer by monomer synthesis of oligonucleotides on a surface ... [and] the hybridization assay practice of utilizing an array of different oligonucleotide probes on a single surface." (D.I. 193, Ex. 8, Dr. Vrana's Rebuttal Expert Report, Ex. F at 4.)[10] Because claims 9 and 10 were not limited to monomer by monomer synthesis (*see Oxford Gene*, 2004 WL 2211971, at

[9] "An array of oligonucleotides" was construed to mean "two or more oligonucleotide sequences located at different regions on a single support." *Oxford Gene*, 2004 WL 2211971, at *4, *10, *12.

[10] It is not entirely clear whether the examiner's statements relate to all of the allowed claims. To the best of my understanding, however, they do relate at least to claims 9 and 10, as well as to claim 1.

*14), the only remaining difference is that the '373 patent did not utilize "an array of different oligonucleotide probes on a single surface." (D.I. 193, Ex. 8, Dr. Vrana's Rebuttal Report, Ex. F. at 4.) That difference was apparently noted because the invention practices the "reverse dot-blot" technique while the '373 patent teaches the "dot-blot" technique, the examiner having observed that the '373 patent taught that it was the unknown polynucleotides which were attached to the surface, not the known oliogonucleotide or polynucleotide probes.

c. The Level of Ordinary Skill in the Art

The *Graham* test for obviousness of a claimed invention "includes a factual determination of the level of ordinary skill in the art." *Custom Accessories, Inc. v. Jeffrey-Allan Industries, Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986). Without this information, the court cannot properly assess obviousness because the critical question is whether a claimed invention would have been obvious, at the time it was made, to one of ordinary skill in the art. *Id.* "The person of ordinary skill is a hypothetical person who is presumed to be aware of all the pertinent prior art."[11] *Id.* (internal citation omitted). Factors that may be considered in determining the level of skill include: "the type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field." *Id.* (internal citation omitted).

[11] At least one commentator has asserted that, "in the context of a summary judgment motion, the trial judge is really resolving the question by reference to the skill of the layperson, which is, except in rare circumstances, the most favorable view for the patentee." Robert L. Harmon, Patents and the Federal Circuit § 4.3, at 168 (6th ed. 2003) (citing *Union Carbide Corp. v. Am. Can Co.*, 724 F.2d 1567 (Fed. Cir. 1984)).

Although neither party made any effort to apply these factors, each has proposed a level of ordinary skill in the art. OGT's proposal is that "a person of ordinary skill in the art at the time of the invention (1988) would have a Ph.D. degree in Biomedical Sciences, Biochemistry, or a relevant sub-discipline of Biology (such as Molecular Biology) or Chemistry, with a few years of experience in or exposure to studies of genomics, gene expression, or nucleic acid hybridization." (D.I. 194, Ex. 3 at 10, Expert Report of Dr. Vrana; D.I. 178 at 15; D.I. 193, Ex. 8 at 25, Rebuttal Expert Report of Dr. Vrana (referring to Dr. Vrana's Expert Report).) Mergen's proposal is that a person of ordinary skill in the art would be one "who had an advanced degree in science working in the field of molecular biology, and/or one with a bachelors degree who has done laboratory work in molecular biology for several years." (D.I. 212, Ex. A at 5, Expert Report of Dr. Purdue.) The parties have merely provided assertions of the level of ordinary skill in the art without explaining the bases for their conclusions. Therefore, Mergen has not satisfied its burden to prove that there is no genuine issue of material fact as to who qualifies as a person of ordinary skill in the art pertaining to the analysis of polynucleotides. Indeed, Mergen has failed to establish even a *prima facie* case of obviousness that would shift the burden of going forward with evidence to OGT.

d. Motivation to Combine

There are also genuine issues of material fact as to whether one of ordinary skill in the art would have been motivated to combine the teachings of the '373 patent and the '726 application. Mergen's only argument in support of finding the necessary motivation is that both references are "in the same field of endeavor and represent different variations of similar experimental techniques involving oligonucleotide and/or

polynucleotide hybridization for the purposes of polynucleotide sequence analysis." (D.I. 182 at 20.)

"[T]he suggestion to combine may be found in explicit or implicit teachings within the references themselves, from the ordinary knowledge of those skilled in the art, or from the nature of the problem to be solved." *Ecolochem, Inc. v. Southern Cal. Edison Co.*, 227 F.3d 1361, 1375 (Fed. Cir. 2000) (quoting *WMS Gaming, Inc. v. Int'l Game Tech.,* 184 F.3d 1339, 1355 (Fed. Cir. 1999)). There still, however, must be evidence that "a skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed." *Id.* (quoting *In re Rouffet,* 149 F.3d 1350, 1357 (Fed. Cir. 1998)); *see also In re Werner Kotzab,* 217 F.3d 1365, 1371 (Fed. Cir. 2000) ("[A] rejection cannot be predicated on the mere identification ... of individual components of claimed limitations. Rather, particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed."). Here, Mergen has not presented any evidence beyond the assertion of its expert that there would have been a motivation to combine. OGT, of course, denies that one of ordinary skill in the art would have selected these components for combination in the manner claimed. (D.I. 178 at 14-15; D.I. 231 at 11-13.) Therefore, a genuine issue of material fact remains on this issue.

e. Secondary Considerations

Because Mergen has failed to establish a *prima facie* case of invalidity of the '270 patent based on obviousness by clear and convincing evidence, and because it is not

until "a *prima facie* case has been established, [that] the burden shifts to the patentee to go forward with rebuttal evidence showing facts supporting nonobviousness," *Ashland Oil*, 776 F.2d at 291-92 (citing *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1573 (Fed. Cir. 1985); *accord, In re Piasecki,* 745 F.2d 1468, 1472 (Fed. Cir. 1984)) any discussion of secondary considerations at this stage would be premature.

The same factual issues that require the denial of Mergen's Motion for Invalidity also require the denial of OGT's Motion for Validity. However, the motions practice on this point has had the effect of demonstrating that Mergen may only challenge the validity of the '270 patent on the issue of obviousness based on the '726 application in view of the '373 patent.

B. INFRINGEMENT

1. Direct Infringement

OGT has moved for summary judgment that Mergen literally infringes claims 1, 9, and 10 of the '270 patent. (D.I. 180 at 1.) OGT argues that Mergen directly infringes claims 1, 9, and 10 of the '270 patent, and indirectly infringes claims 9 and 10. (*Id.*) Mergen has moved for summary judgment of noninfringement of claims 1, 9, and 10 of the '270 patent. (D.I. 186 at 1.) Determining whether an accused product infringes is a two-step process. *Markman*, 52 F.3d at 976. The first step, construing the disputed claim terms, has already occurred in this case. *Oxford Gene*, 2004 WL 2211971. I now proceed to step two, a "comparison of the claim to the accused device, [which] requires a determination that every claim limitation or its equivalent be found in the accused device [or process]." *Transclean Corp. v. Bridgewood Servs., Inc.*, 290 F.3d 1364, 1370

(Fed. Cir. 2002) (citing *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29 (1997)).

In order for OGT to succeed on summary judgment of literal infringement, it must prove that Mergen practices each and every claim limitation of each asserted claim. Mergen, however, only has to prove that it does not practice any one of the limitations and OGT's Motion for Infringement must be denied. Mergen argues that its accused products and services do not infringe the asserted claims of the '270 patent for four reasons:

> (1) Mergen's presynthesized oligonucleotides are attached to a permeable polyacrylamide matrix or gel coating on a glass slide, and are not attached to the impermeable surface of a support, as required by the asserted claims of the '270 patent under either parties' proposed claim construction[;] (2) Mergen uses a deposition method to deposit fully formed oligonucleotides on a coated slide to make its microarray, whereas the '270 patent discloses and the asserted claims require an *in situ* or monomer by monomer synthesis method of making microarrays[;] (3) Mergen's microarrays are and can only be used for gene expression analysis, and not for analysis of polynucleotide sequences, as required by claims 9 and 10 of the '270 patent[; and] (4) [t]he hybridization conditions used in Mergen's methods differ significantly from those disclosed in the '270 patent and required by claims 9 and 10.

(D.I. 186 at 1-2.) With those arguments in mind, I review each of the claims in dispute.

a. Claim 1

Claim 1 is actually no longer in dispute. Based on my construction of claim 1, OGT has stipulated to: "(a) the denial of OGT's Motion for Partial Summary Judgment of Infringement (D.I. 179, 180) with respect to claim 1 only ... and (b) the grant of Mergen's Motion for Summary Judgment of Non-infringement (D.I. 185, 186) with respect to claim 1 only ...." (D.I. 240.) In claim 1, I construed the claim term "through a computer-controlled printing device" to mean "through a computer-controlled printing

device using monomer by monomer synthesis of oligonucleotides." (*See* Background, section II; note 1.) This construction limits the coverage of claim 1 to the *in situ* method of synthesis which OGT admits Mergen does not practice literally or under the doctrine of equivalents. (D.I. 240 at 1.) Therefore, with regard to claim 1, OGT's Motion for Infringment will be denied and Mergen's Motion for Noninfringement will be granted.

b. Claim 9

i. "A method of analysing a polynucleotide"

Claim 9 is a method claim which reiterates many of the limitations of claim 1. (*See* Background, section II.) I have previously construed the limitations of claim 9 and, of course, rely on those constructions in this literal infringement analysis. The meaning of the preamble of Claim 9 was not ultimately disputed during claim construction, and the construction agreed upon by the parties was that, "[a] method of analysing a polynucleotide" means the process of determining information about the sequence of one or more polynucleotides whose identity is incompletely known. *See Oxford Gene*, 2004 WL 2211971, at *9. This preamble is followed by the open-ended transitional term "comprises." It is understood that "comprises," like "comprising" "is open-ended and does not exclude additional, unrecited elements or method steps." *Mars, Inc. v. H.J. Heinz Co., L.P.*, 377 F.3d 1369, 1376 (Fed. Cir. 2004) (quoting MPEP, 8th ed., rev. 1 § 2111.03 (2003); citing *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501 (Fed. Cir. 1997) ("Comprising is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.").

Although I concluded that the preamble was not limiting, even if it were, Mergen practices it. Mergen uses its products for, *inter alia*, gene expression analysis. (D.I. 195, Ex. 5 at 151: 16-21, Dep. Dr. Love, Apr. 23, 2004.) To determine if a gene is expressed, one would "observe by looking at where there was hybridization, where there was not, you could determine whether – by looking at specific regions for hybridization, you could see whether a gene was expressed." (D.I. 205, Ex. E at 225, 14:52:44 6-14:52:56 10, Dr. Purdue, July 14, 2004.) According to the principles of hybridization experimentation described above (*see* Background, section II), Mergen attaches oligonucleotides of known sequence to specific regions of its array and if hybridization occurs, Mergen learns that the polynucleotide sample applied to that region of the array contains a sequence that is complementary to that of the known oligonucleotide. Thus, it is inherent in the intended use of Mergen's array that one determines information about the sequence of one or more polynucleotides whose identity is incompletely known.

ii. "applying a labelled ploynucleotide to be analysed or fragments thereof"

Claim 9 continues, "applying a labelled polynucleotide to be analysed or fragments thereof." This claim term was not disputed during claim construction and was therefore, not construed. Mergen does not contest that it "applies labelled [sic] polynucleotide fragments to its products." (D.I. 213 at 23.) Mergen's expert, Dr. Purdue, did not discuss this claim limitation in his expert report on infringement. (D.I. 212, Ex. C at ¶ 35.) Mergen's argument is that it does not perform the same type of "analysis" on its products. (Id. at 23-24.) The type of analysis, however, is not at issue

in this claim term. The focus is on the application of a labeled polynucleotide or fragments thereof. The term "to be analysed" refers to a future event, which is construed later in the claim. It is thus effectively undisputed that Mergen practices this limitation of the claim.

iii. "to an array of oligonucleotides"

"[T]o an array of oligonucleotides" was construed to mean "to two or more oligonucleotide sequences located at different regions on a single support." *Oxford Gene*, 2004 WL 2211971, at *4, *9-*10. OGT argues that it is clear that Mergen practices this claim limitation too (D.I. 224 at 1-3, 11) and points to Mergen's written materials which refer to its product as an "array" or "microarray." (*See* D.I. 194, Ex. 1 at 7 (Mergen's website describes its products and services as, "A Full Range of Oligo-based DNA *Microarray* Products and Services.") (emphasis added).) Mergen's argument with regard to this claim limitation is based entirely on its proposed claim construction. (D.I. 213 at 13, 24 (see Mergen's heading for what should be section IV.C.3. (although labeled as section IV.A.3.): "Whether Mergen Practices 'An Array Of Oligonucleotides' Recited In Claim 9 Depends Upon Claim Construction.") In its discussion of claim 9, Mergen references its argument regarding this limitation as it appears in claim 1. (*Id.* at 24.) Mergen argues that its products "do not include a structured array of oligonucleotide probe sequences" that are "closely related" to other oligonucleotides in sequence. (*Id.* at 13-14.) I did not adopt Mergen's proposed construction requiring a structured array of oligonucleotides of related sequence. *Oxford Gene*, 2004 WL 2211971, at *4, *9-*10. Therefore, based on the construction

adopted in this case, Mergen, whose arrays consist of "a plurality of independent oligonucleotide sequences" (D.I. 213 at 13-14), does practice this claim limitation.

iv. "under hybridisation conditions"

"[U]nder hybridisation conditions" was construed according to its ordinary and plain meaning to mean "under conditions suitable for hybridization." *Oxford Gene*, 2004 WL 2211971, at *10. Mergen's argument on this claim limitation is again based solely on its proposed claim construction, which was rejected. Mergen applies polynucleotides to the array for the purpose of hybridization to the oligonucleotides on the array. (D.I. 194, Ex. 3 at 21, Dr. Vrana's Expert Report, Ex. 4 at 10-12.) Under the construction given to this term, it is clear that Mergen practices this claim limitation because it performs its analyses under conditions suitable for hybridization.

v. "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 language "wherein the array comprises" is not argued by either party to have any other meaning than to introduce that the following terms describing components of the array. The following phrase, "a support having an impermeable surface," did generate controversy. I construed it to mean "a solid having a non-porous surface that does not permit diffusion through its substance." *Oxford Gene*, 2004 WL 2211971, at *11. Mergen's arguments regarding this claim limitation, although framed as disputing whether its products have an impermeable surface, are really directed to the attachment limitation of the claim, and not the impermeable surface itself. (D.I. 186 at 13-17.) Mergen's argument seems to be that since the gel is permeable, and is on the surface

of the glass slide, the gel is now the "surface" of the "support" such that the "support" in Mergen's products does not have an "impermeable surface." (*Id.* at 14.) OGT's response is that Mergen's argument "is irrelevant because it is the surface of the *glass slide* to which the oligonucleotides are attached." (D.I. 205 at 7 (emphasis in original).) OGT's argument then focuses on the attachment limitation because that limitation must be considered when determining whether the surface for Mergen's array is impermeable.

Claim 9 continues, "to which a plurality of oligonucleotides having different predetermined sequences are attached to different known regions on the surface." The key inquiry generated by this language is whether the surface of the support, to which the oligonucleotides are said to be attached, is impermeable. To answer that question, one must first decide whether the claim language requires that the oliognucleotides be directly attached to the impermeable surface or whether they can be attached to the surface via some intermediary linking agent.

That issue was resolved when I rejected Mergen's argument that "are attached" means the oligonucleotides must *themselves* be attached to the impermeable surface. (D.I. 173 at 2; *see* D.I. 209 at 17-20 (emphasis added).) The claim, by its terms, is not limited to direct attachment of the oligonucleotide itself to the impermeable surface. In fact, the invention described in the '270 patent did not attach the oligonucleotides directly to the impermeable surface. Instead, the patent describes the attachment of the oligonucleotides to 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, ll. 59-65 (emphasis added).)

Mergen argues that when it constructs its array, it attaches oligonucletodies to a *permeable* surface of a support, not to an *impermeable* surface of a support as required by claim 9. (D.I. 186 at 13-17 (emphasis added).) OGT counters that Mergen's accused products are attached to an impermeable surface of a support through a coating of polyacrylamide, and therefore satisfy this claim limitation. (D.I. 180 at 7-9.)

Mergen's product consists of a glass slide with a polyacrylamide matrix attached. (*See* D.I. 187, Exs. D, E, F.) There is no dispute that the glass slide itself has an impermeable surface. *Id.* The oligonucleotides are attached to the polyacrylamide matrix which is attached to the surface of the glass slide. Thus, the oligonucleotides are attached to the surface of the glass slide via the polyacrylamide matrix. *Id.* The polyacrylamide matrix on Mergen's glass slides functions as a linker between the oliognucloetides and the impermeable surface of the glass slide support. Therefore, the polyacrylamide matrix performs the same function as the linker described in the specification, namely attachment of the oligonucleotides to the impermeable surface of a support.

The other claim term limitations, "a plurality of oligonucleotides having different predetermined sequences are attached to different known regions on the surface" are also practiced by Mergen. First, the oligonucleotides sequences are known. (*See* D.I.

194, Ex. 3 at 18, Dr. Vrana's Expert Report, Ex. 4 at 1-2.[12] Second, the oligonucleotides are attached to different known regions on the surface of the support. "The design of the oligonucleotide sequences follows a set of rigorously controlled criteria, including unique match with GenBank's human database, minimal variation ... and consistent position within the gene sequences ...." (Mergen's ExpressChip Instruction Manual at 2, 18-19 in D.I. 194, Ex. 3, Dr. Vrana's Expert Report, Ex. 4 (describing the "Microarray Coordinate System" whereby Mergen or its customers can determine which gene is expressed based on the known location of each oligonucleotide sequence attached to the support).) Therefore, it is also clear that Mergen practices these limitations of claim 9.

vi. "analysing the polynucleotide"

The term "analysing the polynucleotide" uses the same language discussed in the preamble of claim 9 above. (*See* Discussion, section IV.B.1.b.i.) Consistent with that interpretation, "analysing the polynucleotide," therefore means the process of determining information about the sequence of one or more polynucleotides whose identity is incompletely known. *Oxford Gene*, 2004 WL 2211971, at *11. Mergen's argument regarding this claim limitation is focused on what is being accomplished by the analysis, as opposed to whether an analysis occurs. For example, Mergen argues that its products "do not provide sequence information about polynucleotides." (D.I. 213

[12] Mergen's customers can determine which genes are expressed in the polynucleotide sample by knowing which oligonucleotides are attached to the array. (*See* D.I. 194, Ex. 3, Dr. Vrana's Expert Report, Ex. 4 at 1.) Mergen's ExpressChip Instruction Manual directs its customers to its website where it provides "[g]ene information on each arrayed spot and links to NCBI's GenBank/UniGene databases ...." (*Id.*)

at 30.) Mergen's analysis, however, does indeed involve "determining information about the sequence of one or more polynucleotides whose identity is incompletely known" because Mergen admits, "[t]he information obtained using the Mergen slide is limited to gaining an indication of the presence of a sequence [of a polynucleotide] with some degree of similarity ... [to] an oligonucleotide on the slide." (D.I. 186 at 20.) In short, Mergen practices this claim limitation because some information about the sequence of the unknown polynucleotides is determined through its analysis.

vii. "by observing the regions where the polynucleotide or fragement thereof hybridizes and the regions where the polynucleotide or fragment thereof does not hybridize"

I previously construed "by observing the regions where the polynucleotide or fragement thereof hybridizes and the regions where the polynucleotide or fragment thereof does not hybridize" according to its plain and ordinary meaning, to mean exactly what it says. *Oxford Gene*, 2004 WL 2211971, at *11. Mergen argues that it does not practice this claim limitation because "Mergen seeks to analyze the polynucleotides ... not by observing the regions to which each polynucleotide (or fragments thereof) hybridize or do not hybridize (since this is already known), but rather by determining whether hybridization is seen at specific, previously established location [sic]." (D.I. 213 at 30.) OGT argues that Mergen practices this claim limitation because "Mergen

visualizes the results of hybridization, so that one can see where hybridization occurred and where it did not based on the presence or absence of [a] signal at the various spots on an array." (D.I. 180 at 14.)

It is clear that Mergen's arrays are analyzed by observing the regions where the polynucleotide or fragment thereof hybridized and the regions where it did not. Experiments run on Mergen's arrays produce regions with hybridization and regions without hybridization. Mergen and its customers visualize the results of the hybridization and in so doing, they see where hybridization has occurred and where it has not, based on the presence or absence of a signal at the various spots on an array. (*See* D.I. 194, Ex. 3, Dr. Vrana's Expert Report, Ex. 4, Mergen's ExpressChip Instruction Manual at 18.) As Mergen's instruction manual states, "identification of a positive signal is directly dependent upon the abundance of a specific mRNA. ... [T]he vast majority of genes are not highly expressed and signal intensities can vary greatly." (*Id.*) It is only by detecting whether a particular region produces a signal, that Mergen can make a determination regarding whether a particular gene is expressed. This process inherently involves observing the regions where the polynucleotide or fragment thereof hybridizes and the regions where it does not. Mergen states that "[t]he information obtained using the Mergen slide is limited to gaining an indication of the presence of a sequence [of a polynucleotide] with some degree of similarity ... [to] an oligonucleotide on the slide." (D.I. 186 at 20.) Again, by Mergen's own admission, once the presence of the polynucleotide is determined, some information about its sequence is learned. The fact that this information is gained regarding the polynucleotide's

sequence is enough to warrant the conclusion that Mergen practices this final limitation of claim 9.

Based on the foregoing analysis of the limitations in claim 9 and the evidence of record, I conclude that Mergen practices each and every limitation of that claim of the '270 patent and therefore literally infringes. Mergen has not raised a genuine issue of material fact such that summary judgment for OGT is inappropriate. Therefore, OGT's Motion for Infringement will be granted as to claim 9 (D.I. 179) and Mergen's Motion for Noninfringement as to this claim will be denied (D.I. 185).

c. Claim 10

Claim 10 is also a method claim which reiterates many of the limitations of claims 1 and 9. (*See* Background, section II.) I previously held that the preamble, "[a] method of comparing polynucleotide sequences" was not limiting, *Oxford Gene*, 2004 WL 2211971, at *12, and Mergen's arguments to the contrary are not persuasive.

Even if the preamble were limiting, however, Mergen performs "the process of determining relative information about two or more polynucleotide sequences." *See id.* (noting the construction for the preamble of claim 10, were it to be limiting). Mergen uses its products for, *inter alia*, gene expression analysis. (D.I. 195, Ex. 5 at 151: 16-21, Dep. Dr. Love, Apr. 23, 2004.) According to the principles of hybridization experimentation (*see* Background, section II), Mergen attaches oligonucleotides of

known sequence to specific regions of its microarrays and, if hybridization occurs, Mergen learns that the polynucleotide sample applied to that region of the array contains a sequence that is complementary to that of the known oligonucleotide probe. Thus, when more than one polynucleotide sequence is present in a sample, it is inherent in the intended use of Mergen's microarray that the user will determine relative information about the sequences of those polynucleotides whose complement is represented by an oligonucleotide probe. Therefore, as with claim 9, even if the preamble were limiting, Mergen's microarrays are used to practice this limitation.

Nearly all of the limitations of claim 10 are present in claim 9. *See Oxford Gene*, 2004 WL 2211971, at *12. Since I have determined that Mergen literally infringes claim 9 of the '270 patent, it is only necessary to consider the single limitation of claim 10 that differs from claim 9.[13] The last limitation of claim 10, "observing the differences between the patterns of hybridisation," is not present in claim 9. I previously construed "observing the differences between the patterns of hybridisation" to mean exactly what it says. *Oxford Gene*, 2004 WL 2211971, at *12-*13.

OGT argues that Mergen directly practices this claim limitation and hence infringes claim 10. (D.I. 180 at 17-18.) For support, OGT points to three acts by Mergen which OGT alleges are infringing. First, Mergen "compares the hybridization of the target sample sequences to the spots on the array known to serve as "positive

[13] The limitations that are present in both claim 9 and 10, include: (1) "applying the polynucleotides to an array of oligonucleotides," (2) "under hybridizing conditions," (3) "wherein the oligonucleotides have different predetermined sequences and are attached at different known locations," and (4) "on an impermeable surface of a support." *See Oxford Gene*, 2004 WL 2211971, at *12.

controls" in order to determine the difference in intensity between hybridization at various spots on the array." (D.I. 180 at 17.) Second, Mergen practices this claim limitation when it "observe[s] the differences between hybridization expression patterns on two distinct arrays" (*id.*) as it compares the hybridization results of a normal sample to that of a disease sample. (D.I. 195, Ex. 16, Dep. Dr. Hu at 104-05, July 8, 2004.) Third, Mergen offers a "pairwise analysis," such that "Mergen and its customers can visualize side-by-side differences between the patterns of hybridization on two distinct arrays." (D.I. 180 at 18; D.I. 195, Ex. 5, Dep. Dr. Love at 75-76, Apr. 23, 2004.) Mergen counter-argues that "the only reasonable interpretation of the 'observing patterns of hybridization' term to one skilled in the art, would be the spatial distribution over the microarray of regions to which the polynucleotide hybridized and regions to which the polynucleotide did not hybridize." (D.I. 213 at 33 (citing Ex. C, Dec. Dr. Purdue).)

That argument is essentially a claim construction argument which Mergen did not advance during claim construction. The assertion is that the "observing patterns of hybridization" limitation of claim 10 can only be understood to mean that the analysis is practiced on a single array. The sole support offered for that assertion is a "see" citation to the declaration of Mergen's expert, Dr. Purdue. (D.I. 213 at 33.) In his Declaration, Dr. Purdue does state a conclusion as to the meaning of "patterns of hybridization" to one of skill in the art (D.I. 215, Ex. C at ¶ 18, Dec. Dr. Purdue), but he does so without without citing any basis for that conclusion. Thus, this entirely new definition of "pattern," never before articulated in any brief or proposed claim construction, is unsupported by any evidence but the bare assertion of Mergen's expert. I reject

Mergen's belated attempt to shape claim construction and I decline to add further restrictions to the interpretation of claim 10.

At least two of Mergen's activities directly infringe claim 10. First, Mergen "observe[s] the differences between hybridization expression patterns on two distinct arrays" (D.I. 180 at 17) as it compares the hybridization results of a normal sample to that of a disease sample. (D.I. 195, Ex. 16, Dep. Dr. Hu at 104-05, July 8, 2004.) Second, Mergen offers a "pairwise analysis," such that "Mergen and its customers can visualize side-by-side differences between the patterns of hybridization on two distinct arrays." (D.I. 180 at 18; D.I. 195, Ex. 5, Dep. Dr. Love at 75-76, Apr. 23, 2004.) Furthermore, Mergen's ExpressChip Protocol Synopsis and ExpressChip Instruction Manual refer to a comparison of hybridization patterns: "[t]he sample's expression *pattern* is usually compared with that of a control sample for differential analysis." (D.I. 194, Ex. 3, Dr. Vrana's Expert Report, Ex. 9, Mergen's ExpressChip Protocol Synopsis, at 1 (emphasis added); D.I. 194, Ex. 3 at 18, Dr. Vrana's Expert Report, Ex. 4, Mergen's ExpressChip Instruction Manual, at 1 (emphasis added).)

In light of those activities and Mergen's failure to respond to the arguments raised by OGT,[14] I hold that Mergen literally infringes claim 10 because it practices each and every limitation of claim 10 of the '270 patent, as discussed here and in the corresponding discussion involving the claim terms that are also limitations in claim 9.

[14] Mergen's response to the arguments raised by OGT is entirely based on its own claim construction and claim limitations not adopted by this court. (*Compare* D.I. 213 at 31-33, *with Oxford Gene*, 2004 WL 2211971 at *12-*13.) Aside from arguing its claim construction, Mergen has not provided any basis for concluding that these specific activities do not infringe. (*See* D.I. 213 at 31-33.)

Mergen has not raised any genuine issue of material fact such that summary judgment for OGT is inappropriate. Therefore, with respect to claim 10, OGT's Motion for Infringement (D.I. 179) will be granted and Mergen's Motion for Noninfringement (D.I. 185) will be denied.

2. Indirect Infringement

OGT has moved for summary judgment that Mergen indirectly infringes claims 9 and 10. (D.I. 180 at 1.) Whether directly infringing or not, "a party may still be liable for inducement or contributory infringement of a method claim under 35 U.S.C. §§ 271(b), (c) if it sells infringing devices to customers who use them in a way that directly infringes the method claim." *Linear Tech. Corp. v. Impala Linear Corp.*, 379 F.3d 1311, 1326 (Fed. Cir. 2004) (citing *R.F. Del., Inc. v. Pac. Keystone Techs., Inc.,* 326 F.3d 1255, 1267 (Fed. Cir. 2003)).

a. Inducing Infringement

Pursuant to 35 U.S.C. § 271(b), "[w]hoever actively induces infringement of a patent shall be liable as an infringer." Direct infringement is a prerequisite to liability for inducing infringement. *Met-Coil Sys. Corp. v. Korners Unlimited, Inc.,* 803 F.2d 684, 687 (Fed. Cir. 1986). Additionally, the alleged infringer must have knowingly induced infringement. *Manville Sales Corp. v. Paramount Sys., Inc.,* 917 F.2d 544, 553 (Fed. Cir. 1990) (citing *Water Techs. Corp. v. Calco, Ltd.,* 850 F.2d 660, 668 (Fed. Cir. 1988)). "Although section 271(b) does not use the word 'knowing,' the case law and legislative history uniformly assert such a requirement." *Water Techs.,* 850 F.2d at 668 (internal citations omitted). Liability can be established by proving that the party accused of inducement "should have known that its actions would induce actual infringement." *See*

Mentor H/S, Inc. v. Medical Device Alliance, Inc., 244 F.3d 1365, 1379 (Fed. Cir. 2001) (citing *Manville Sales Corp. v. Paramount Sys.*, 917 F.2d 544, 553 (Fed. Cir. 1990)). A patentee may prove intent through circumstantial evidence. *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1365 (Fed. Cir. 2004) (citing *Water Techs.,* 850 F.2d at 668 (noting that "circumstantial evidence may suffice" in proving intent)).

With respect to inducing infringement under 35 U.S.C. § 271(b), I conclude that OGT has met its burden of showing that Mergen's actions induced infringing acts by its customers and that Mergen knew or should have known that its actions would induce actual infringement. In particular, OGT has argued that the following circumstantial evidence establishes Mergen's active inducement of infringement of claims 9 and 10: (1) Mergen designs its microarray kits for a particular use (*see* D.I. 180 at 11; D.I. 195, Ex. 8 at 69-70, Dep. Dr. Love, June 15, 2004); (2) Mergen sells its products as kits, which include all of the necessary components to the perform the directly infringing acts: "a pair of pre-arrayed slides, materials, and reagents sufficient for the processing of two slides" (*see* D.I. 195, Ex. 4 at 2, ExpressChip Instruction Manual); (3) Mergen instructs its customers on how to use its microarray kits in a manner which has been found to be infringing (*see* D.I. 195, Ex. 4, ExpressChip Instruction Manual; Ex. 6, Protocol Synopsis; Ex. 8 at 52-53, Dep. Dr. Love, June 15, 2004); and (4) Mergen's customers follow those instructions and use the microarrays in the same manner as Mergen, which was found, *see supra*, to be directly infringing (*see* D.I. 180 at 11; D.I. 195, Ex. 5 at 64, Dep. Dr. Love, Apr. 23, 2004, Ex. 8 at 70, 107, 161, Dep. Dr. Love, June 15, 2004). Mergen has not disputed the evidence described above, nor argued why a finding of summary judgment of active inducement is unwarranted. Mergen's only response to

OGT's arguments is that, "[s]ince there is no direct infringement of claims 9 (and 10, as set forth in this opposition), there is no indirect infringement." (D.I. 213 at 22 (citation omitted).)

Based on the evidence of Mergen's active inducement of claims 9 and 10, as alleged by OGT, and the lack of any rebuttal evidence by Mergen, I find that Mergen actively induced its customers to infringe claims 9 and 10 of the '270 patent. Notably, evidence of sales and instruction manuals supports a finding of induced infringement. *See, e.g., Water Techs.,* 850 F.2d at 668 (affirming inducement finding based on circumstantial evidence including helping customers and providing instructions); *Moleculon Research Corp. v. CBS, Inc.,* 793 F.2d 1261, 1272 (Fed. Cir. 1986) (affirming finding of inducement based on circumstantial evidence such as extensive sales and instruction manual). It is clear that Mergen sold its microarray kit, encouraged its customers to follow the instruction manual describing the intended method of use, and that its customers did so use it, resulting in the direct infringement of claims 9 and 10. Therefore, I will grant OGT's Motion for Infringement based on Mergen's active inducement of its customers' direct infringement of claims 9 and 10 of the '270 patent.

b. Contributory Infringement

The doctrine of contributory infringement is codified at 35 U.S.C. § 271(c):

> Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

This form of infringement is premised on the idea that a defendant who displays sufficient culpability should be held liable as an infringer, even though he may not have made, used, or sold a patented invention. *Hewlett-Packard Co. v. Bausch & Lomb Inc.,* 909 F.2d 1464, 1469 (Fed. Cir. 1990). "Such liability was under a theory of joint tortfeasance, wherein one who intentionally caused, or aided and abetted, the commission of a tort by another was jointly and severally liable with the primary tortfeasor." *Id.* (internal citation omitted).

To prove contributory infringement, a plaintiff must demonstrate the following: (1) an offer to sell, sale, or import; (2) a component or material for use in a patented process constituting a material part of the invention; (3) knowledge by the defendant that the component is especially made or especially adapted for use in an infringement of such patent; and (4) the component is not a staple or article suitable for substantial noninfringing use. *Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co.*, No. Civ. 99-CV-274-SLR, Civ. 99-846-SLR, 2004 WL 1305849, *7 (D. Del. June 9, 2004) (citing 35 U.S.C. § 271(c)). Further, contributory infringement also requires proof of actual direct infringement by a customer of the defendant. *See Novartis Pharms. Corp. v. Eon Labs Mfg., Inc.,* 363 F.3d 1306, 1308 (Fed. Cir. 2004) (internal citations omitted). However, if use of the component by the defendant's customers necessarily infringes the patent, actual proof of an instance of direct infringement is not required. *Dynacore Holdings Corp. v. U.S. Philips Corp.,* 363 F.3d 1263, 1275-76 (Fed. Cir. 2004). "[A] seller of a 'material part' of a patented item may be a contributory infringer if he makes a non-staple article that he knows was 'especially made or especially adapted for use in an infringement of such patent.' " *Husky Injection Molding Sys. Ltd. v. R & D Tool &*

Eng'g Co., 291 F.3d 780, 784 (Fed. Cir. 2002) (quoting 35 U.S.C. § 271(c); *Dawson Chem. Co. v. Rohm & Haas Co.,* 448 U.S. 176, 219 (1980)). Section 271(c) has been interpreted to require not only knowledge that the component was especially made or adapted for a particular use but also knowledge of the patent which proscribed that use. *See Hewlett-Packard*, 909 F.2d at 1469 n.4 (*citing Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 488 (holding that section 271(c) does require a showing that the alleged contributory infringer knew that the combination for which his component was especially designed was both patented and infringing.))

OGT alleges that Mergen is liable for contributory infringement because it contributes to the directly infringing acts of its customers. (D.I. 180 at 11.) Mergen's only response is the same as it was with respect to inducing infringement: "[s]ince there is no direct infringement of claims 9 (and 10, as set forth in this opposition), there is no indirect infringement." (D.I. 213 at 22 (citation omitted).) Because I have found that by following the instructions provided by Mergen, its customers directly infringe claims 9 and 10 (*see supra* section VI.B.2.a.) the question becomes whether OGT has presented sufficient evidence to establish that Mergen contributed to its customers infringement.

First, OGT alleges that Mergen offers to sell and does sell microarray kits, and that Mergen's customers use those microarray kits in a manner that infringes claims 9 and 10 of the '270 patent. (D.I. 180 at 11, 17.) Second, the microarray component is a material part of the invention because it is the support upon which the claimed methods of use are performed. (*See id.*) Third, Mergen knew that the microarray kits were made for a particular use and that such use may be proscribed by the '270 patent. (*See* E-mail from Loretta Tse, Ph.D., Director, Business Development, Mergen, to Drs. Miller

and Shelley (Aug. 10, 2000) (inquiring about a license in the area of DNA microarray technology and noting that Mergen's research has indicated that the '270 patent is relevant to Mergen's "manufacturing and marketing plan"); Instruction Manual, D.I. 195, Ex. 4.) The record shows that by August 10, 2000, Mergen was aware of the '270 patent and that its activities might infringe some of the claims. Finally, OGT has alleged that there is "no substantial non-infringing use of the oligonucleotide arrays except to use them in ... [an infringing] way ...." (D.I. 180 at 11; D.I. 195, Ex. 3 at 23, Dr. Vrana's Expert Report.) Mergen has provided no argument, besides the one sentence quoted above.

Based on the uncontroverted evidence of contributory infringement, Mergen is liable for contributory infringement as "[a] seller of a 'material part' of a patented item ... [who] makes a non-staple article that he knows was 'especially made or especially adapted for use in an infringement of such patent.' " *Husky Injection Molding*, 291 F.3d at 784 (quoting 35 U.S.C. § 271(c); *Dawson Chem. Co. v. Rohm & Haas Co.,* 448 U.S. 176, 219 (1980)). Therefore, OGT's Motion for Infringement will be granted with respect to Mergen's contributory infringement.

V. CONCLUSION

For the foregoing reasons, Accordingly, OGT's Motion for Validity (D.I. 177) will be DENIED; its Motion for Infringement (D.I. 179) will be GRANTED in part, as it relates to direct and indirect literal infringement of claims 9 and 10, and DENIED in part, as it relates to claim 1; and its Motion to Strike (D.I. 202) will be DENIED as moot. Mergen's Motion for Invalidity (D.I. 181) will be DENIED; its Motion for Non-Infringement (D.I. 185) will be GRANTED in part, with respect to claim 1, and DENIED in part, with respect to

claims 9 and 10; and its Motion for Invalidity of Claim 1 (D.I. 190) will be DENIED without prejudice. An appropriate order will follow.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OXFORD GENE TECHNOLOGY LIMITED,	)	
	)	
Plaintiff,	)	
v.	)	
	)	Civil Action No. 02-1695-KAJ
MERGEN LTD., et al.,	)	
	)	
Defendants.	)	
	)	

ORDER

For the reasons set forth in the Memorandum Opinion issued in this matter today, IT IS HEREBY ORDERED that OGT's Motion for Partial Summary Judgment of Patent Validity and Enablement (D.I. 177) is DENIED; OGT's Motion for Partial Summary Judgment of Infringement (D.I. 179) is GRANTED in part, as it relates to direct and indirect literal infringement of claims 9 and 10, and DENIED in part, as it relates to claim 1; and OGT's Motion to Strike Mergen's Newly Identified Non-Enablement Defense (D.I. 202) is DENIED as moot. It is further ORDERED that Mergen's Motion for Summary Judgment of Invalidity of the Asserted Claims of U.S. Patent No. 6,054,270 (D.I. 181) is DENIED; Mergen's Motion for Summary Judgment of Non-Infringement of Claims 1, 9 and 10 of U.S. Patent No. 6,054,270 (D.I. 185) is GRANTED in part, with respect to claim 1, and DENIED in part, with respect to claims 9 and 10; and Mergen's Motion for Summary Judgment of Invalidity of Claim 1 of U.S.

Patent No. 6,054,270 (D.I. 190) is DENIED without prejudice.

Kent A. Jordan
UNITED STATES DISTRICT JUDGE

Wilmington, Delaware
November 19, 2004