United States District Court,
C.D. California.

BAXTER DIAGNOSTICS INC,
Plaintiff.
v.
AVL SCIENTIFIC CORP., et al,
Defendants.
And Related Action,
And Related Actions.

No. CV 91-4178 RG (Ex)

April 25, 1996.

Holder of patent for apparatus that measured concentration of gases in a blood sample sued alleged infringer. The District Court, Gadbois, J., held that: (1) failure to disclose prior art did not invalidate patent; (2) attorney had duty to disclose that scientist who submitted affidavit in favor of reissuance of patent was an employee of a licensee under patent, but failure to do so did not invalidate patent; (3) patent was not obvious; (4) single-layer fluorescent sensor infringed patent; (5) double-layer fluorescent sensor did not infringe patent; and (6) infringement was not willful.

Ordered accordingly.

31,879. Valid and infringed.

Christie, Parker & Hale, LLP, Carl Kustin, Thomas J. Daly, John D. Carpenter, Art Hasan, Pasadena, CA, for plaintiff.

Thomas J. Manley, J.B. Kelly, Hunton & Williams, Raleigh, NC, William J. Robinson, David J. Meyer, Graham & James, Los Angeles, CA, for AVL Parties.

Nelson Mullins Riley & Scarborough, Sylvia K. Kochler, Atlanta, GA, for defendantcounterclaimant Frank J. Swenson.

ORDER FOR JUDGMENT

GADBOIS, District Judge.

AVL Scientific Corp. ("AVL") obtained a license to use an optical sensor device that measures the concentration of gases in the blood. It alleges that Baxter Diagnostics Inc. ("Baxter") willfully infringed

United States Patent No. 4,557,900 and United States Reissue Patent No. 31,879 (collectively, "the LUbbers patent"), which cover this device, by developing single- and double-layer optical blood gas sensor devices. In response, Baxter contends that the LUbbers patent is invalid. Alternatively, it contends that its sensor devices do not infringe the patent or are *de minimis* uses of the patented technology. This Court holds that the LUbbers patent is valid. Baxter's single-layer sensor infringes it because it is not a *de minimis* use of the patented technology; however, this infringement was not willful. The double-layer sensor does not infringe the patent either literally or equivalently.

I. VALIDITY OF THE LUBBERS PATENT

Baxter contends that the LUbbers reissue patent is invalid (1) because it was procured through inequitable conduct and (2) because claims in it are obvious.

A. Inequitable Conduct Before the Patent And Trademark Office

Baxter's first invalidity allegation is that the LUbbers applicants conducted themselves inequitably while their reissue application was pending. Specifically, it asserts that Gordon Peterson, one of the attorneys in charge of prosecuting the application, failed to disclose to the Patent and Trademark Office ("the PTO") that a scientist who submitted declarations advocating the patentability of the LUbbers technology was an employee of a company that had a license to use the technology. It also asserts that the applicants failed to disclose material prior art. In light of all the circumstances, the applicants' conduct was not so culpable that the patent should be invalidated.

1. Alleged Failure to Disclose Material Prior Art

Baxter alleges that the applicants did not disclose United States Patent No. 3,612,866 ("the Stevens patent") and British Patent No. 1,190,583 ("the Bergman patent") to the PTO even though this prior art was the focal point in the prosecution of the German counterpart of the LUbbers patent application, and the German patent examiner requested that the drafters of the German application discuss it in the text of that application.

a. History of LUbbers Patent Prosecution

A summary of the factual history of the LUbbers patent prosecution and the LUbbers technology is helpful in understanding Baxter's allegations.

i. Overview of LUbbers Sensor Technology

The LUbbers patent teaches an apparatus that measures the concentration of gases, such as carbon dioxide or oxygen, in a blood sample. A vessel holds the blood sample to be tested. Within the vessel, a silicone diffusion membrane that is selectively permeable by certain gases separates the analyte gas from the blood. If the analyte is carbon dioxide, it reacts with water sealingly embedded in the membrane, changing the pH of the water. The fluorescent indicating dye that is also sealingly embedded in the membrane detects this pH change. To determine the concentration of gas, a technician interrogates the dye with a monochromatic light and reads the wavelength of the light that the dye emits. The wavelength varies according to the pH change.

ii. LUbbers Patent Prosecution Timeline

Max-Planck Institute ("Max-Planck"), the owner of the LUbbers technology, filed the LUbbers patent application in Germany in 1975. It issued as a patent in late 1979. Claiming priority of the German LUbbers patent application, Max-Planck filed the American LUbbers patent application in 1976. The application issued as a patent in 1977. Max-Planck filed a reissue application in the United States on January 8, 1979. This application issued as a patent on May 5, 1985.

iii. Importance of Bergman and Stevens Patents to German Prosecution

During the prosecution of the German application, Dragerwerk AG, a German company, filed an opposition, asserting that the Stevens and Bergman patents made the LUbbers technology unpatentable. It contended that the Stevens and Bergman patents teach an indicator "sealingly embedded" in a diffusion membrane and that a sealingly embedded indicator is an essential feature of some of the claims in the LUbbers application. Responding to the Dragerwerk opposition, Max-Planck narrowed some claims and deleted some claims. (Exs. 1791 & 1792.)

The German patent office ultimately found that the Stevens and Bergman patents did not preclude the patentability of the LUbbers technology. (Ex. 1795.) It distinguished the patents on two grounds. First, it found that, unlike the indicators in the Stevens and Bergman references, the indicator in the LUbbers patent is sealingly embedded in an indicator space that is selectively permeable by the analyte:

While the fluorescent indicator is in contact with the entire measuring cell in case of the known measuring arrangements, individual, selectively determinable components only may penetrate into the indicator space in case of the subject matter of the application. Higher measuring accuracy is thus obtained.

(Id. at 6.) Second, it found that LUbbers' idea of separating the indicating space from the light-measuring means improved upon the Stevens and Bergman patents:

[T]he fact that the indicator space is provided independently of the light-measuring means is to be deemed an advantage according to the application over the known arrangements. Owing to this fact it is, for instance, possible to have the place of measurement shifted into the blood vessels themselves.

(Id.) It emphasized that "[n]either alone nor in combination are these two particularities suggested by prior art." (Id. at 7.) However, it told Max-Planck to discuss the Stevens and Bergman patents in the text of the application. (*See* id. at 9 ("The prior art according [the Stevens and Bergman references], which comes closest to the subject matter of the application ... w [as] incorporated into the introduction to the new specification.").)

iv. History of United States Reissue Application

Shortly after adding the discussion of the Stevens and Bergman patents to its German application, Max-Planck filed a reissue application in the United States to broaden the claims in the original LUbbers patent. The reissue application did not list the Stevens and Bergman patents in its "References Cited" section. (Ex. 331.) However, Max-Planck submitted a copy of the German LUbbers patent that discloses and discusses the Stevens and Bergman patents. (Ex. 221 at A000658.) It did not provide an English translation of this discussion.

Gordon Peterson, the attorney handling the prosecution, did not know about the Stevens and Bergman references. (Testimony of Gordon Peterson, Trial Tr. at 3314:6-10.) He had access to the German LUbbers

patent, but he never obtained a translation of the portion of that patent which discusses them. (Id. at 3326:17-25; Testimony of Harry Weissenberger, Trial Tr. at 3213:9-12.)

However, several other individuals involved in the American prosecution had actual knowledge of the Stevens and Bergman references. AVL became involved in the prosecution after it became an exclusive licensee under the LUbbers patent. Dr. Hermann Marsoner and Dr. H.W. Kroneis, who worked for AVL and who were frequently consulted about the prosecution, published a paper that cited the references in 1983. (Ex. 4195 at 592.) In October 1981, Marsoner and Kroneis of AVL, Dr. Dietrich LUbbers and Dr. Norbert Optiz of Max-Planck, and Dr. Harold Heitzmann of Cardiovascular Devices, Inc., a LUbbers licensee, attended a meeting at AVL. The minutes of the meeting show that they discussed the Stevens patent. (Ex. 387.) All of these scientists were actively involved in the prosecution of the reissue application.

They had many opportunities to inform Peterson and the PTO about the Stevens and Bergman references. He sent every PTO action and response to the scientists and to Dr. Hans Hofman, the agent who prosecuted the German patent. Many of his responses argued that the prior art did not teach sealingly embedding an indicating substance in a diffusion membrane. LUbbers and Hofman commented on these responses. But neither they nor the other scientists informed Peterson of the Stevens and Bergman references.

LUbbers and Opitz were aware of their duty to disclose material prior art to the patent office. They had originally filed declarations with the PTO that did not contain an acknowledgement of their duty as inventors to disclose material prior art. (Ex. 211 at A000529, A00486-87.) The examiner notified them that their declarations were defective and asked that they file new declarations that acknowledged their duty to disclose. (Id. at A000529.) They complied with this request. The other scientists had been involved in prosecutions of patents on technology they had invented, so they were aware of the inventor's duty to disclose material prior art to the PTO.

b. Law Governing Failure to Disclose Prior Art

[1] [2] [3] [4] [5] "The concept of inequitable conduct in patent procurement derives from the equitable doctrine of unclean hands: that a person who obtains a patent by intentionally misleading the PTO cannot enforce the patent." Demaco Corp. v. F. Von Langsdorff Licensing Ltd., 851 F.2d 1387, 1394 (Fed.Cir.), *cert. denied,* 488 U.S. 956, 109 S.Ct. 395, 102 L.Ed.2d 383 (1988). "Inequitable conduct requires proof by clear and convincing evidence." Manville Sales Corp. v. Paramount Sys., Inc., 917 F.2d 544, 551 (Fed.Cir.1990). The party alleging invalidity must make a threshold showing that (1) the applicant or a person substantially involved in the preparation of the application withheld or misrepresented material information and (2) the applicant or a person substantially involved in the preparation of the application intended to deceive the PTO by withholding or misrepresenting the information. Halliburton Co. v. Schlumberger Technology Corp., 925 F.2d 1435, 1439 (Fed.Cir.1991); *see also* 37 C.F.R. s. 1.56; Fox Indus. v. Structural Preservation Sys., 922 F.2d 801, 804 (Fed.Cir.1990) (stating that the duty of candor rests on the inventor and every other individual who is substantially involved in the preparation or prosecution of the application). If the party with the burden of proof makes these threshold showings, the court must balance materiality and intent: "The more material the omission, the less culpable the intent required, and vice versa." Halliburton Co., 925 F.2d at 1439; Manville Sales Corp., 917 F.2d at 551. After receiving this evidence, the court must make an "equitable judgment" about whether "in light of all the particular circumstances, the conduct of the patentee is so culpable that its patent should not be enforced." LaBounty Mfg., Inc. v. United States Int'l Trade Comm'n, 958 F.2d 1066, 1070 (Fed.Cir.1992).

[6] Information is material if there is a substantial likelihood that the patent examiner would have considered the omitted information important in deciding whether to allow the application to issue as a patent. 37 C.F.R. s. 1.56; Fox Indus., 922 F.2d at 803. However, an applicant does not have to disclose "an otherwise material reference if the reference is cumulative or less material than those already before the examiner." Halliburton Co., 925 F.2d at 1440.

[7] [8] [9] "Direct proof of [intent to mislead] is rarely available but may be inferred from clear and convincing evidence of the surrounding circumstances." LaBounty Mfg., 958 F.2d at 1076. Proof of gross negligence can be circumstantial evidence of an intent to mislead. Hewlett-Packard Co. v. Bausch & Lomb Inc., 882 F.2d 1556, 1562 (Fed.Cir.1989). However, "the label 'gross negligence' covers too wide a range of culpable conduct to create such an inference in all cases." *Id*. Instead, "[s]uch an inference depends upon the totality of the circumstances, including the nature and level of culpability of the conduct and the absence or presence of affirmative evidence of good faith." *Id*.

[10] [11] The failure to disclose prior art references that invalidated claims in patent applications pending in foreign countries is strong evidence of intent to mislead. J.P. Stevens & Co. v. Lex Tex Ltd., 747 F.2d 1553, 1566 (Fed.Cir.1984). However, filing supporting documents that list the references "does not support a conclusion of intentional withholding." Demaco Corp., 851 F.2d at 1396. For example, in *Demaco Corp*., the patent applicant failed to file a material prior art reference. However, the reference "was listed in the German priority document filed with the PTO" and was part of the file wrapper. *Id*. The *Demaco* court found that the presence of the reference in the file wrapper negated a finding of deliberate concealment.

c. Application of Law to Failure to Disclose Stevens and Bergman References

[12] Although Baxter has proven by clear and convincing evidence that the Stevens and Bergman references are material, it has not proven that the LUbbers applicants intended to mislead the PTO. Thus, the applicants' failure to disclose prior art does not render the LUbbers patent invalid.

i. Materiality of Stevens and Bergman References

There is a substantial likelihood that the patent examiner would have considered the Stevens and Bergman patents important in deciding whether to allow the LUbbers application to issue as a patent. Therefore, these references are material.

The German patent office stated that these references were the most pertinent prior art references it examined in conjunction with the LUbbers patent. (Ex. 1795 at 9.) Clearly, it believed that the references were important even though it ultimately decided that they did not preclude the patentability of the LUbbers technology. The initial German application and the application before the PTO were virtually identical. Arguably, the PTO was likely to agree with the German examiner and to find that the LUbbers claims were valid; however, references that were important to the German office would be important in appraising its work and would allow the PTO to make an independent decision about claim validity.

ii. Intent to Mislead

Although the Stevens and Bergman references are material, the applicants did not intend to deceive the PTO by withholding them. The presence of the references in the file wrapper, albeit not in the "References Cited" section of the application, demonstrates that the applicants were not actively hiding them from the PTO and did not intend to mislead it. *See* Demaco Corp., 851 F.2d at 1396. Furthermore, although the scientists who

were active in helping Peterson with the prosecution had ample opportunity to suggest that he include the references in the "References Cited" section, given the German patent office's determination that the LUbbers technology was patentable over the references, they thought that including the references was unnecessary. A belief that the PTO did not need the references to assess the LUbbers application accurately is not tantamount to an intent to mislead it by withholding information the applicant believes would result in an adverse decision.

iii. Balancing of Materiality and Intent

Balancing materiality and intent to deceive is improper in this case because Baxter has not made a threshold showing of an intent to deceive. *See* Halliburton Co., 925 F.2d at 1439. Nevertheless, the omitted references are not so material that they could offset the nonexistent intent to deceive. While the PTO was likely to have considered them important, they do not render claims in the patent invalid for obviousness. *See infra* Part I.B.3. The PTO would have issued the application as a patent even if it had known about the references. In light of the circumstances, the failure to list the Stevens and Bergman patents in the "References Cited" section of the application was not inequitable conduct that warrants invalidating the LUbbers patent.

2. Failure to Disclose Declarant's Employment with Interested Party

Baxter's other inequitable conduct allegation is that attorney Peterson failed to disclose that a scientist who submitted declarations supporting the LUbbers reissue application was an employee of a company that was a licensee under the LUbbers patent.

a. Peterson's Submission of Interested Declaration

In April 1991, Peterson, who was representing Cardiovascular Devices, Inc., filed a protest to the LUbbers reissue application. (Ex. 209 at 74-80.) The protest does not reveal that Cardiovascular Devices is the protestor. FN1

FN1. No statute or regulation requires a protestor to reveal its identity.

After filing this protest, Cardiovascular Devices obtained a license under the LUbbers patent from AVL. As a result, it began advocating the patentability of the LUbbers technology and became active in the prosecution of the reissue application. Peterson became the attorney responsible for handling the prosecution. (Testimony of Dr. John L. Gehrich, Trial Tr. at 3224:18-21.)

When the patent examiner realized that Peterson had represented both the protestor and the applicants, he requested an explanation. (*See* Ex. 209 at 127 (stating that examiner had suggested that Peterson "file papers clarifying conflicting situation of being protesting attny [sic] and applicants' attny [sic]").) Peterson filed the requested explanation, stating that no conflict of interest existed because the protestor had obtained a license to use the LUbbers technology and had decided to withdraw the protest:

[A]fter filing the protest and upon further evaluation, the protestor took a license on a bundle of technology, including this reissue application. Thus, the former protestor is now a licensee and charged with the responsibility for prosecuting this reissue application. Protestor hereby formally withdraws its protest to the issuance of this reissue application. It can be seen, therefore, that there is no conflict because counsel has represented the same client throughout these proceedings and further because the protest has now been

formally withdrawn.

(*Id*. at 143-44.) He did not reveal the protestor's identity.

Later in the prosecution, the PTO began examining the issue of whether prior art disclosed using fluorescent dyes to detect carbon dioxide. It told Peterson that certain claims could issue if he could show that the dye phenol red does not fluoresce. (Ex. 211 at A000591.) To this end, he obtained a declaration from Dr. William Miller, a scientist who worked for Cardiovascular Devices. The declaration stated that phenol red could not be used as a fluorescent indicator in the device that the LUbbers patent describes. (*Id*. at A000594-95.) Both the declaration and a resume attached to the declaration disclose that Miller is an employee of Cardiovascular Devices. (*Id*. at A000593, A000596.) However, neither discloses that Cardiovascular Devices was the protestor turned licensee.

The Miller declaration did not sway the PTO, so Peterson arranged a telephonic conference between Miller and the patent examiner. (*Id*. at A000634.) He also directed Miller to submit a supplemental declaration, explaining the factual basis for his conclusions about phenol red. (*Id*. at A000645.) The supplemental declaration does not reveal that Cardiovascular Devices was a LUbbers licensee. The interview and declaration apparently satisfied the PTO that phenol red could not fluoresce in the apparatus that the LUbbers patent describes.

b. Legal Standard Governing Duty to Disclose Declarant's Bias

Neither the Manual of Patent Examining Procedure ("MPEP") nor the Code of Federal Regulations affirmatively requires declarants to disclose their interest in a patent's issuance. *See* 37 C.F.R. s. 1.132; U.S. Department of Commerce, Patent and Trademark Office, *Manual of Patent Examining Procedure*.

[13] [14] However, the edition of the MPEP in use during the LUbbers prosecution stated that the PTO could consider the declarant's interest when evaluating his declaration:

Affidavits or declarations should be scrutinized closely and the facts presented weighed with care. The affiant's or declarant's interest is a factor which may be considered, but the affidavit or declaration cannot be disregarded solely for that reason.

U.S. Department of Commerce, Patent and Trademark Office, *Manual of Patent Examining Procedure* s. 716(3). The case law is consistent with the MPEP. The Federal Circuit's predecessor held that an affidavit by an interested person is less persuasive than an affidavit by a disinterested person. In re McKenna, 203 F.2d 717, 720 (C.C.P.A.1953). However, the PTO may not disregard an affidavit solely because an interested person authored it. *Id*. Indeed, the affidavit "may be relied on when sufficiently convincing." *Id.; cf*. Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281, 294 (Fed.Cir.1985), *cert. denied,* 475 U.S. 1017, 106 S.Ct. 1201, 89 L.Ed.2d 315 (1986) (holding that opinion testimony of a party with a direct interest in patent validity litigation is less persuasive than opinion testimony by a disinterested party but that the interested testimony could not be disregarded solely because it was interested).

Baxter contends that in order for the patent examiner to consider an applicant's interest, the applicant must first disclose his interest. It argues that the case law and the MPEP effectively create a duty to disclose a declarant's bias. No court has squarely addressed the issue. FN2

FN2. The Federal Circuit's opinion in Paragon Podiatry Lab., Inc. v. KLM Labs., Inc., 984 F.2d 1182 (Fed.Cir.1993) examines a similar issue but does not clearly suggest how the Federal Circuit would rule on the novel issue before this Court. In *Paragon,* Paragon Podiatry Laboratory applied for a patent on a low profile functional orthotic. The patent examiner expressly required it to submit affidavits by disinterested parties in order to avoid an obviousness rejection. It submitted affidavits by three people who owned stock in it and who had been paid consultants for it. Their affidavits each stated that they "ha[d] not been in the past employed by ... by Paragon Podiatry Laboratories...." *Id.* at 1191. The Federal Circuit found that "[t]he representation to the PTO that the affiants were not employed presents a classic example of a half truth.... None was a 'disinterested' party in any recognized sense of the word." *Id.* at 1192. "The natural consequence of [Paragon's] acts was to lead the examiner to believe that the affiants were 'disinterested' parties, and the patentees were successful in that effort." *Id.* at 1191. Therefore, the Federal Circuit held that Paragon intended to mislead the PTO.

[15] This Court holds that the combination of Peterson's duty of candor under Rule 56 of the Practice Rules in Patent Cases and section 716(3) of the MPEP created a duty to disclose Miller's interest. Rule 56 provides:

A duty of candor and good faith toward the Patent and Trademark Office rests on ... each attorney ... who prepares or prosecutes the application.... All such individuals have a duty to disclose to the Office information they are aware of which is material to the examination of the application. Such information is material where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent.

37 C.F.R. s. 1.56. There is a substantial likelihood that a patent examiner will consider a declarant's interest important to the examination of the application because section 716(3) of the MPEP lists interest as a factor he may consider as he evaluates the contents of a declaration disputing the obviousness of a claim. FN3 The MPEP guides his work, so he is very likely to adhere to the section 716(3) factors when examining declarations even though these factors are advisory, not mandatory. His decisions about obviousness determine whether the application will issue as a patent.

FN3. Indeed, the most recent edition of the MPEP states that the patent examiner must consider the declarant's interest:
In assessing the probative value of an expert opinion, the examiner *must* consider the nature of the matter sought to be established, the strength of any opposing evidence, *the interest of the expert in the outcome of the case,* and the presence or absence of factual support for the expert's opinion.

U.S. Department of Commerce, Patent and Trademark Office, *Manual of Patent Examining Procedure* s. 716.01(c) (6th ed. 1995) (emphasis added).

c. Application of Law to Peterson's Submission of Interested Declaration

[16] While Baxter has made a threshold showing that Peterson intended to mislead the PTO and that the Miller declarations were material to the PTO's decision to allow claims in the LUbbers patent, this Court makes the equitable judgment that, in light of all the particular circumstances, the conduct of the patentee and its attorney was not so culpable that the patent should be invalidated.

i. Peterson's Intent to Deceive the PTO

[17] The patent attorney's duty to ensure that the declarant discloses his interest creates a presumption that unless an interest is disclosed, the declarant is disinterested. Peterson's failure to see that Miller disclosed his interest misled the PTO because it presumed that Miller was disinterested. Thus, the declaration was deceptive. When patentees submit deceptive declarations, an inference of an intent to deceive arises from the "affirmative acts of submitting [the declarations], their misleading character, and the inability of the examiner to investigate the facts [set forth in the declarations]." Paragon Podiatry Lab., Inc. v. KLM Labs., Inc., 984 F.2d 1182, 1191 (Fed.Cir.1993). Neither Peterson nor Miller have stated "facts supporting a plausible justification or excuse for the misrepresentation." *Id*.

ii. Materiality of Miller Declarations

The parties do not dispute that these declarations were material to the PTO's decision to allow certain claims. The PTO stated that it needed to make a determination that phenol red would not fluoresce in the LUbbers apparatus before it could allow some of the claims to stand. (Ex. 221 at A000591.) The information in the declarations allowed it to make this determination.

iii. Equitable Judgment About Submission of Interested Declarations

Despite the threshold showings of materiality and intent to mislead, after evaluating the circumstances surrounding the LUbbers prosecution, this Court's equitable judgment is that Peterson's conduct was not so culpable that the patent should be invalidated. Baxter admits that the patent examiner did not expressly request that Peterson procure a disinterested declaration. (Testimony of Patrick Bright, Trial Tr. at 3488:7-10.)

Additionally, Peterson was not trying to dress faulty information in respectable clothes in order to fool the PTO. Baxter does not quibble with the content of the declarations and provides no evidence that suggests they were not scientifically sound. Its expert witness, Patrick Bright, stated that Miller did not lie about the properties of phenol red. (*Id*. at 3489:18-21.) Furthermore, it does not contend that the content of Miller's declaration was scientifically inaccurate or that a disinterested witness would have disagreed with him. Instead, its expert witness merely speculates that if the patent examiner had been skeptical of Miller's statement, the patent might not have issued. (*Id*. at 3444:16-11.)

Finally, the PTO could not have disregarded the Miller declarations solely because he was an interested person, and it could have relied on them if they were sufficiently convincing. If, as Baxter concedes, Miller's statements are scientifically sound, the PTO would have found them sufficiently convincing. Invalidating the LUbbers patent because Miller did not disclose his affiliation with Cardiovascular Devices would be inequitable.

B. Obviousness of LUbbers Patent Claims

Baxter's second invalidity allegation is that prior art renders claims 31-35 of the LUbbers patent obvious. In response, AVL argues that the patent describes a novel means for measuring the concentration of carbon dioxide in the blood. It asserts that no prior art teaches (1) a semi-permeable diffusion membrane that isolates carbon dioxide from other blood components; (2) a pH-sensitive fluorescent dye sealingly embedded in the membrane; and (3) using a fluorescent dye to measure the concentration of carbon dioxide.

1. Legal Standard Governing Obviousness

[18] A patent claim is invalid "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. s. 103. The party asserting obviousness must prove it by clear and convincing evidence. Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 796 F.2d 443, 446 (Fed.Cir.1986), *cert. denied,* 484 U.S. 823, 108 S.Ct. 85, 98 L.Ed.2d 47 (1987).

[19] [20] In an obviousness analysis, the court must consider " 'what the combined teachings of the references would have suggested to those of ordinary skill in the art.' " Cable Elec. Prods., Inc. v. Genmark, Inc., 770 F.2d 1015, 1025 (Fed.Cir.1985) (*quoting* In re Keller, 642 F.2d 413, 425 (C.C.P.A.1981)). However, "[o]bviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination." In re Geiger, 815 F.2d 686, 688 (Fed.Cir.1987).

[21] [22] Secondary considerations, such as evidence of commercial success or copying, may indicate obviousness or non-obviousness. Cable Elec. Prods., 770 F.2d at 1026-27. The party asserting non-obviousness has the burden of establishing a " 'nexus between the merits of the claimed invention and the evidence of secondary considerations....' " Id. at 1026 (*quoting* Simmons Fastener Corp. v. Illinois Tool Works, Inc., 739 F.2d 1573, 1575 (Fed.Cir.1984), *cert. denied,* 471 U.S. 1065, 105 S.Ct. 2138, 85 L.Ed.2d 496 (1985)).

a. Parties' Dispute Over Prior Art

Baxter argues that United States Patent No. 4,041,932 ("the Fostick patent"), United States Patent No. 3,114,610 ("the Gafford patent"), the Stevens patent, the Bergman patent, a 1928 article entitled "Volumetric Analysis Using Umbelliferone as A Fluorescent Indicator" by Volmar and Widder, and an unpublished doctoral dissertation entitled "A Corrected Spectrofluorometer for Analysis of Turbid Media" by Boldt are prior art and render claims 31-35 obvious. AVL agrees that the Volmar and Widder article as well as the Fostick, Gafford, Stevens, and Bergman patents are prior art. However, it disputes the contention that the Boldt dissertation is prior art.

i. Overview of Boldt Dissertation

Dr. Michael Boldt presented his doctoral dissertation, "A Corrected Spectrofluorometer for Analysis of Turbid Media," to Philipps University in Marburg, Germany in 1971. (Ex. 1801.) Dr. LUbbers supervised the preparation of the dissertation.

Baxter adduced hearsay testimony from its expert Donald Barbeau that the German Bibliothek Index states that the Philipps University Library had catalogued the dissertation by 1974. (Testimony of Donald Barbeau, Trial Tr. at 3350:18-3351:6.) He admits that he has not obtained affidavits from the library, explaining when it catalogued the dissertation. (Id. at 3361:21-25.) However, he obtained statements from library personnel who discussed when they catalogued the dissertation. (Id.)

ii. Legal Definition of Prior Art

[23] [24] Inventions that were "patented or described in a printed publication in this or a foreign country ...

more than one year prior to the date of the application for the patent in the United States" are prior art. 35 U.S.C. s. 102(b). "Because there are many ways in which a reference may be disseminated to the interested public, 'public accessibility' has been called the touchstone in determining whether a reference constitutes a 'printed publication.' " In re Hall, 781 F.2d 897, 899 (Fed.Cir.1986). A single catalogued doctoral dissertation is sufficiently accessible to one interested in the art to constitute a printed publication. Id. at 899-900; *see also* In re Cronyn, 890 F.2d 1158, 1160-61 (Fed.Cir.1989) (holding that three undergraduate student theses that were listed alphabetically by author on index cards in a shoebox in the chemistry department library at Reed College in Oregon were not catalogued in a meaningful way and were not prior art). "[C]ompetent evidence of the general library practice may be relied upon to establish an approximate time when a thesis became accessible." Hall, 781 F.2d at 899.

[25] [26] Section 102 does not state the only sources of prior art. In re Fout, 675 F.2d 297, 300-01 (C.C.P.A.1982). An inventor's admission that he "had actual knowledge of [a] prior ... invention constitutes an admission that it is prior art to" him. Id. at 301; *see also* Constant v. Advanced Micro-Devices, Inc., 848 F.2d 1560, 1570 (Fed.Cir.1988) (holding that inventor who admitted reading an article before he conceived of his invention could not claim that the article was not prior art).

iii. Application of Definition of Prior Art to the Boldt Dissertation

[27] The Boldt dissertation is prior art. Barbeau's hearsay about the Bibliothek Index is arguably incompetent evidence and therefore an unreliable basis for establishing the time when the dissertation was publicly available. However, as the professor supervising Boldt's dissertation, LUbbers knew about Boldt's scientific analysis and research by 1971 when he presented the dissertation to Philipps University. (*See* Ex. 1801 at 121 (thanking LUbbers "for the numerous discussions about the overall definition of the problem and for many valuable suggestions during construction of the spectrofluorometer").)

Max-Planck filed the original American LUbbers patent application in 1976. Because LUbbers knew about the dissertation by 1971, more than a year before Max-Planck filed the application, it is prior art to him.

b. Parties' Dispute Over Analogous Prior Art

[28] A court may not use a prior art reference in an obviousness analysis unless it is analogous to the art at issue. Wang Labs., Inc. v. Toshiba Corp., 993 F.2d 858, 864 (Fed.Cir.1993). AVL argues that neither the Boldt dissertation nor the Volmar and Widder article is relevant prior art.

[29] [30] When determining whether prior art is analogous, a court follows a two-step inquiry: "(1) whether the art is from the same field of endeavor, regardless of the problem addressed, and (2) if the art is not within the same field of endeavor, whether it is still reasonably pertinent to the particular problem to be solved." Id. at 864. "A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem." In re Clay, 966 F.2d 656, 659 (Fed.Cir.1992). To determine whether a reference would have logically come to an inventor's attention, the court should analyze the invention's purpose. "If a reference disclosure has the same purpose as the claimed invention, the reference relates to the same problem, and that fact supports the use of that reference in an obviousness rejection. An inventor may well have been motivated to consider the reference when making his invention." *Id*. However, "[i]f it is directed to a different purpose, the inventor would accordingly have had less motivation or occasion to consider it." *Id*.

i. Application of Definition to the Boldt Dissertation

The Boldt dissertation is analogous prior art because it is from the same field of endeavor as the LUbbers patent. The dissertation discusses using spectrofluorometers to measure redox potentials in turbid media. A spectrofluorometer is not a sensor. (Testimony of Dr. Otto Wolfbeis, Trial Tr. at 1811:16-17.) However, fluorometry is part of the optical sensor field. (*Id*. at 1812:9-12.)

ii. Application to the Volmar and Widder Article

The Volmar and Widder article, "Volumetric Analysis Using Umbelliferone As A Fluorescent Indicator," is not analogous prior art. It is a two page discussion of the use of B methyl umbelliferone, a pH-sensitive dye, as a fluorescent indicator in alkalimetry and acidimetry. (Ex. 1748.) In layman's terms, it describes the dye's ability to measure the pH change in solutions. It notes that the dye was effective in measuring the pH change of a solution when carbonic acid was introduced. It does not, however, mention using the dye to detect gases.

Measuring the pH change in solutions is not the same field of endeavor as creating optical sensors, so the issue is whether the article is still reasonably pertinent to the particular problem that the LUbbers patent solves. The purpose of the article is to discuss a fluorescent dye that accurately reflects pH change in solutions. The purpose of the LUbbers invention is measuring the concentration of gases in a sample. These purposes are dissimilar. An inventor wishing to create a device that would accurately measure carbon dioxide in the blood is not likely to have considered an article that does not even mention gas detection. Therefore, the Volmar and Widder article is not analogous prior art.

2. Obviousness of Claims 31, 32, 34, and 35

[31] Baxter argues that the Fostick patent, the Gafford patent, the Boldt dissertation, and the Volmar and Widder article make claims 31, 32, 34, and 35 obvious. Because the Volmar and Widder article is not analogous prior art, the Court will not consider it in the obviousness analysis.

a. Overview of Claims 31, 32, 34, and 35

Claims 31, 32, 34, and 35 are virtually identical. They describe a method and an apparatus for measuring the concentration of carbon dioxide in a sample. These claims are very similar to claims in the Fostick patent. However, that patent teaches a method for measuring oxygen concentration while the LUbbers patent teaches using a pH-sensitive fluorescent dye to detect both oxygen and carbon dioxide. Baxter contends that the Gafford patent and the Boldt dissertation make this alleged innovation obvious.

b. Description of Prior Art

i. Description of the Gafford Patent

The Gafford patent teaches a method for detecting carbon dioxide by using a pH-sensitive absorbance dye suspended in an aqueoussolution. (Ex. 486.) Carbon dioxide reacts with the aqueous solution to form carbonic acid. The dye then reacts to this pH change. (*Id*. at col. 1, lines 61-68.) To measure the carbon dioxide concentration, a technician interrogates the dye with a light. The dye absorbs some of the light energy, lessening the intensity of the interrogating light. The degree of lessening varies according to the pH change. The technician measures the change in light intensity at the wavelength of the interrogating light.

(Testimony of Glenn Enscoe, Trial Tr. at 2802:1-6.) FN4

FN4. When measuring gas concentration using a fluorescent dye, the measurement of light intensity is made at the wavelength of the emitted light which may differ from the wavelength of the interrogating light. (Testimony of Glenn Enscoe, Trial Tr. at 2802:1-6.)

ii. Description of the Boldt Dissertation

The Boldt dissertation discusses a method for correcting spectrofluorometer data when this data is obtained from turbid media. In simplistic terms, turbid media is akin to "cloudy water." The dissertation argues that fluorometry is an advance over absorption spectrometry because it is more specific and sensitive. (Ex. 1801 at 6.) The thesis does not teach a method for obtaining accurate carbon dioxide measurements. Indeed, it does not mention carbon dioxide or any other gas. (Testimony of Donald Barbeau, Trial Tr. at 3420:14-20.)

c. Application of Prior Art to Claims 31, 32, 34, and 35

Baxter has argued an elaborate obviousness theory. It contends that the Fostick patent mentions using infrared techniques to detect carbon dioxide. (Ex. 210 at col. 7, line 48 through col. 8, line 11.) The Gafford patent states that it improves upon infrared measurement techniques. (Ex. 486 at col. 1, lines 31-45.) It teaches using an absorbent dye to detect carbon dioxide after it passes through a semi-permeable membrane. The Boldt dissertation allegedly states an incentive for replacing an absorbent dye with a fluorescent dye when it notes that fluorescent indicators are more sensitive than absorbent indicators.

While there is a fairly clear incentive to combine the teachings of Fostick and Gafford, the incentive to combine Fostick, Gafford, and Boldt is much less compelling. Gafford specifically states that absorbent sensors are an improvement over the infrared techniques that Fostick describes. However, while the Boldt dissertation notes that fluorometry is an improvement over absorbent spectrometry, it does not state that fluorescent dyes are more accurate than absorbent dyes in an optical sensor. A scientist reading the dissertation would not necessarily infer that a dye that works well in a fluorometer would work well in an optical sensor because a fluorometer is not a sensor. (Testimony of Dr. Otto Wolfbeis, Trial Tr. at 1811:16-17.) Indeed, the dissertation does not state that fluorescent dyes are superior indicators in all situations.

Other possible incentives to combine the references are missing. The dissertation does not discuss using fluorometry to detect gases, so someone reading it would not necessarily infer that fluorescent dyes are superior to absorbent dyes in detecting carbon dioxide or oxygen. Furthermore, it does not teach a semi-permeable membrane, which teaching could conceivably inspire a researcher to combine Gafford and Boldt.

The Boldt dissertation discusses an invention too disparate from the LUbbers technology to suggest or teach combining it with the Gafford and Fostick references. The Court notes that Dr. Otto Wolfbeis, an expert testifying at trial, stated that combining the Boldt dissertation with the Gafford patent might be obvious to a modern-day optical sensor developer with twenty-twenty hindsight. However, the combination would not have been obvious when scientists, like Dr. LUbbers, first began developing the field of optical sensor technology. (Testimony of Dr. Otto Wolfbeis, Trial Tr. at 1812:13-19.)

3. Obviousness of Claim 33

Baxter also argues that the Fostick, Stevens, and Bergman patents make claim 33 obvious. Except for the

limitations that relate to sealingly embedding the indicator in a silicone membrane, claim 33 is virtually identicalto the Fostick patent. Baxter contends that the Stevens and Bergman patents teach sealingly embedding the indicator in a silicone membrane. At first blush, the prior art seems to render claim 33 invalid for obviousness. However, construing the term "sealingly embedded" in the context of claim 33, demonstrates that its use is novel.

a. Overview of Stevens and Bergman Patents

The Stevens and Bergman patents teach mixing a fluorescent dye into a supporting matrix in order to detect oxygen in the blood. The Stevens patent states: "It will be readily understood that in the various embodiments above described, the transparent substrates employed to support the fluorescent material can be omitted if the fluorescent material is mixed with a suitably rigid transparent oxygen-permeable supporting matrix material, such as polyethylene or the like." (Ex. 200 at col. 3, lines 30-35.) The Bergman patent states: "According to the present invention, a gas detector comprises a material capable of being excited to luminescence ... [and] a permeable or porous supporting matrix into which the excitable material has penetrated and been retained...." (Ex. 205 at p. 1, lines 25-34.)

b. General Definition of "Sealingly Embedded"

The Stevens and Bergman patents teach a general concept of sealingly embedding a dye when they discuss mixing fluorescent material with a matrix material. Taken out of context, "sealingly embedded" is "not a real specific type of term." (Testimony of Dr. Harold Heitzmann, Trial Tr. at 2991:20.) Without any limitations or clarifying language, "sealingly embedded means ... that you have a construction of the sensor where the indicator dye is mixed in somehow in the layer with the semipermeable membrane." (*Id*. at 2978:24-2979:1.) If claim 33 does no more than teach embedding a fluorescent dye in a membrane or matrix, it is invalid for obviousness.

c. Understanding "Sealingly Embedded" in the Context of the LUbbers Patent

[32] Because the LUbbers technology detects blood gases other than oxygen, the term sealingly embedded necessarily means more than merely mixing a dye in a silicone membrane. Claim 33 is not invalid for obviousness.

Both the Stevens and Bergman patents employ a technique called fluorescence quenching. (*Id*. at 2987:16-19.) Essentially, "fluorescence quenching is the diminution in the fluorescence of the fluorophore caused by the intereaction of oxygen with that fluorophore." (*Id*. at 2987:20-23.) The analyte oxygen molecules collide with the fluorophore. (*Id*. at 2988:1-3.) This collision causes the fluorophore to lose its energy. (*Id*. at 2988:7-11.)

The fluorescence quenching technique differs from detecting a blood gas like carbon dioxide with a pH-sensitive fluorescent dye, as the LUbbers patent teaches. The pH-sensitive fluorescent dye must be dissolved in water. (*Id*. at 2977:6-9; *see also id*. at 2991:21-25; Testimony of Dr. Otto Wolfbeis, Trial Tr. at 1807:8-12.) Carbon dioxide reacts with the water, creating carbonic acid and changing the pH of the water. (Testimony of Dr. Harold Heitzmann, Trial Tr. at 2988:16-20.) This difference in pH affects the pH-sensitive fluorescent dye. (*Id*.)

The LUbbers technology differs from the Bergman and Stevens technology because it involves a two-phase system. The pH-sensitive dye dissolved in water is the aqueous phase. (*Id*. at 2990:17-19.) The silicone

matrix, in which the aqueous phase is sealingly embedded, is the solid phase. (*Id*.) The Bergman and Stevens patents involve only a single, solid phase because the dye is dissolved in the silicone. (*Id*. at 2990:20-2991:11.) The dye interacts with the oxygen, so an aqueous phase is unnecessary. (*Id*. at 2992:1-4.) "[L]ooking at either the Bergman or the Stevens patent, one would not know how to construct a sensor for carbon dioxide with a pH sensitive fluorescent dye." (*Id*. at 2992:5-9.)

This explanation is consistent with the German patent office's findings. It states that "the fluorescent indicator is in contact with the entire measuring cell" in the Stevens and Bergman technologies. (Ex. 1795 at 6.) In the fluorescence quenching technique used in the Stevens and Bergman patents, the oxygen interacts directly with the fluorescent dye, so a membrane that separates the indicating dye and the blood sample is unnecessary. (Testimony of Dr. Harold Heitzmann, Trial Tr. at 2988:21-25.)

In contrast the German patent office noted that "individual, selectively determinable components only may penetrate into the indicator space" in the LUbbers technology. (Ex. 1795 at 6.) In the two-phase system, a semi-permeable membrane is necessary to isolate the reaction between the carbon dioxide and the water from other blood elements. (Testimony of Dr. Otto Wolfbeis, Trial Tr. at 1819:7-15.) If the reaction were not isolated, a false pH reading would likely result.

Because the LUbbers patent states a novel two-phase detection apparatus, claim 33 is not invalid for obviousness.

4. Commercial Success of LUbbers Technology

[33] AVL has argued that the commercial success of the LUbbers technology precludes a finding of obviousness. Even though prior art does not render the LUbbers patent invalid for obviousness, courts must always take evidence of secondary considerations into account, " 'not just when the decisionmaker remains in doubt after reviewing the art.' " Cable Elec. Prods., 770 F.2d at 1026 (*quoting* Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1539 (Fed.Cir.1983)).

a. Commercial Use of LUbbers Technology

Cardiovascular Devices entered a license and technology transfer agreement with AVL in 1981. (Testimony of Dr. John L. Gehrich, Trial Tr. at 3245:4-13.) Its primary goal in entering the agreement was to access the LUbbers technology. (*Id*. at 3261:9-14.) Employing this technology, it was able to develop its GasStat instrument, which was designed to measure blood gases and pH during open heart surgery. (Testimony of Dr. Harold Heitzmann, Trial Tr. at 2958:8-10.) It admits that the GasStat embodies elements of LUbbers patent claims. (*Id*. at 2965:19-21.)

When Cardiovascular Devices began selling the GasStat, it had to compete with the Oxy-Stat, an inexpensive instrument which allows doctors to measure the redness of blood in order to determine its oxygen content. (*Id*. at 3011:3-17.) Customers did not immediately switch to the more expensive, more technologically sophisticated GasStat. (*Id*. at 3010:22-25.)

However, it eventually became a commercial success. (*Id*. at 3261:21-24.) Sales of the GasStat approached $20 million a year in 1991. (Testimony of Dr. Harold Heitzmann, Trial Tr. at 2966:5-8.) Indeed, "the GasStat played a major role" in Cardiovascular Device's financial success. (Testimony of Dr. John L. Gehrich, Trial Tr. at 3261:21-24.)

b. Law Governing Commercial Success Evidence

[34] The party asserting non-obviousness must establish a nexus between commercial success and the merits of an invention. Cable Elec. Prods., 770 F.2d at 1027. This nexus is required because "for commercial success of a product embodying a claimed invention to have true relevance to the issue of nonobviousness, that success must be shown to have in some way been due to the nature of the claimed invention, as opposed to other economic and commercial factors unrelated to the technical quality of the patented subject matter." *Id*.

[35] Comparative, specific evidence, such as market share, growth of market share, or replacing earlier units sold by others, is necessary to establish commercial success. Kansas Jack, Inc. v. Kuhn, 719 F.2d 1144, 1151 (Fed.Cir.1983). Evidence consisting solely of the number of units sold cannot establish commercial success. Cable Elec. Prods., 770 F.2d at 1026-27; Kansas Jack, Inc., 719 F.2d at 1151.

c. Analysis of Commercial Success of GasStat

AVL has established a weak nexus between the commercial success of the GasStat and the merits of the LUbbers technology. It has not introduced any specific evidence about Cardiovascular Devices' market share. However, it showed that the Oxy-Stat had been widely used and accepted when Cardiovascular Devices began marketing the GasStat. In order to garner any market share, it had to displace the Oxy-Stat. It eventually began replacing this device, and it gained a substantial market share.

This weak nexus between the commercial success of the GasStat and the merits of the LUbbers technology bolsters the finding that prior art does not render claims 31-35 of the LUbbers patent invalid.

II. INFRINGEMENT OF THE LUBBERS PATENT

[36] [37] Because Baxter has failed to establish that the LUbbers patent is invalid, the Court must examine AVL's allegation that Baxter infringed it. Analysis of infringement claims proceeds in two phases. First, the court interprets the claims without reference to the accused device. SRI Int'l v. Matsushita Elec. Corp., 775 F.2d 1107, 1123 (Fed.Cir.1985) (*en banc*). Second, it compares the interpreted claims with the accused device to determine whether the device embodies, either literally or figuratively, each limitation specified in the claims. SmithKline Diagnostics, Inc. v. Helena Labs. Corp., 859 F.2d 878, 882 (Fed.Cir.1988). The patentee has the burden of proving infringement by a preponderance of the evidence. SRI Int'l, 775 F.2d at 1123.

A. Legal Standard for Claim Interpretation

[38] [39] [40] [41] [42] Claim interpretation is a question of law. Markman v. Westview Instruments, Inc., 517 U.S. 370, ---- - ----, 116 S.Ct. 1384, 1387-88, 134 L.Ed.2d 577. When interpreting claims, the district court begins by examining the claim language. North American Vaccine, Inc. v. American Cyanamid Co., 7 F.3d 1571, 1575 (Fed.Cir.1993), *cert. denied,* 511 U.S. 1069, 114 S.Ct. 1645, 128 L.Ed.2d 365 (1994). It should construe the language objectively, as "one skilled in the art would construe [it]." SmithKline Diagnostics, 859 F.2d at 882. Testimony by experts skilled in the art can elucidate the meaning of the claim terms. However, testimony by the patentor's attorney "amounts to no more than legal opinion" and co-opts the "process of construction that the court must undertake"; therefore, "it is entitled to no deference." Markman v. Westview Instruments, Inc., 52 F.3d 967, 983 (Fed.Cir.1995) *aff'd,* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577.

[43] [44] If an inventor chooses to give a patent term a definition different from its ordinary meaning to one skilled in the art, "he must set out his uncommon definition in some manner within the patent disclosure." Intellicall, Inc. v. Phonometrics, Inc., 952 F.2d 1384, 1388 (Fed.Cir.1992). Generally, when an inventor claims to have used an uncommon definition, the court examines the specification and patent history to interpret the term. Hormone Research Found., Inc. v. Genentech, Inc., 904 F.2d 1558, 1563 (Fed.Cir.1990), *cert. dismissed,* 499 U.S. 955, 111 S.Ct. 1434, 113 L.Ed.2d 485 (1991); Lear Siegler, Inc. v. Aeroquip Corp., 733 F.2d 881, 889 (Fed.Cir.1984) ("the place to [set forth an uncommon definition] is in the specification").

1. Interpretation of Claims 31, 32, 34, and 35

a. Plain Language of Claims 31, 32, 34, and 35

The parties dispute the interpretation of claims 31-35 of the LUbbers patent. Claim 34 is an apparatus claim that specifies "an arrangement for measuring the concentration of carbon dioxide in a sample." The elements of the claim are:

[1] means for generating a light beam having a predetermined color characteristic;

[2] indicating means for generating light signals from which the concentration of carbon dioxide in a sample to be measured can be determined, including

[2a] a light transmissive surface positioned to be impinged by said light beam,

[2b] a diffusion membrane adapted to be placed in proximity of a sample and being permeable to at least a carbon dioxide component thereof, and

[2c] an indicating substance that is capable of fluorescing positioned to be impinged by said light beam penetrating said light-transmissive surface and by said carbon dioxide component penetrating said diffusion membrane, said indicating substance responding when illuminated by said incident light beam by emitting a resultant light beam having an emitted component which has a color characteristic different from said predetermined color characteristic and is related to the concentration of carbon dioxide in the sample

[3] means for conducting said resulting light beam away from said indicating substance through said light transmissive surface; and

[4] means for discriminating said emitted component from said resultant light beam so that the change in the color characteristic of said indicating substance can be ascertained and

[5] means for correlating the change in the color characteristic with the concentration of carbon dioxide in the sample.

(Ex. 331.) Claim 35 is dependent on claim 34 and merely adds the limitation: "[a] method as defined in claim 34 wherein said indicating substance includes a pH indicating substance."

Claim 31 states "a method of measuring the concentration of carbon dioxide in a sample." It is the method counterpart to apparatus claim 34. The elements of claim 34 are virtually identical to the elements of claim 31. Claim 32 is dependent on claim 31 and adds the limitation: "[a] method as defined in claim 31 wherein

said indicating substance includes a pH indicating substance."

b. Interpretation of Claim 34

Claims 31, 32, and 35 are dependent on or virtually identical to claim 34, so their interpretation is largely dependent on the interpretation of claim 34.

i. Definition of the Term "Indicating Substance"

[45] The parties agree that the key to interpreting claim 34 is determining the definition of the term "indicating substance" and understanding the indicating substance's role in the invention that the LUbbers patent describes. However, they dispute the meaning of the term "indicating substance." AVL contends that the drafters of the LUbbers patent intended to give it an uncommon definition and argues that standing alone, it means nothing. Limitations in the claim define it. In response, Baxter asserts that the drafters did not give it an uncommon meaning, it has an inherent meaning apparent to one skilled in the art, and the "limitations" describe the role of the indicating substance in the invention instead of defining the term.

AVL has not identified where in the specification or patent history the LUbbers applicants set forth the uncommon definition. The Court has examined the specification, patent history, and plain language of the claims and cannot find an uncommon definition.FN5

FN5. The LUbbers applicants do not define the term "indicating substance" in the specification. Instead, they use the term as if persons knowledgeable in the field know what it means. Using the term without defining it assumes that it has inherent meaning and that it does not derive meaning from surrounding limitations or descriptions of its function. The claim language does not define the term either. It gives no indication that the term has a definition that differs from the one that a person skilled in the art would ordinarily attribute to it. Instead, the language describes a method for measuring carbon dioxide concentration in a sample, and it describes the indicating substance's role in measuring this concentration.

Because the specification, patent history, and claim language do not set forth an uncommon definition, the LUbbers applicants did not act as their own lexicographers and did not give the term "indicating substance" an uncommon meaning. Therefore, the Court must construe the term as one ordinarily skilled in the art would. At trial, expert witnesses testified that an indicating substance is a substance that responds to a chemical species by changing its optical properties. (Testimony of Dr. Otto Wolfbeis, Trial Tr. at 1785:16-20.) It "is the substance that undergoes a change in response to the environment." (Testimony of Dr. Dennis Dougherty, Trial Tr. at 3064:14-24; *see also* Testimony of Dr. James Godsey, Trial Tr. at 886:5-11 (same).) This testimony comports with the dictionary definition of an "indicator," which is "[a]n organic substance (usually a dye or intermediate) which indicates by a change in its color the presence or absence or concentration of some other substance, or the degree of reaction between two or more other substances." *Hawley's Condensed Chemical Dictionary* 634 (11th ed. 1987).

A substance is an element or compound that is homogenous. *Id.* at 1102. In a homogenous substance, " 'every part is like every other part.' " *Id.* (*quoting* Black & Conant, *Practical Chemistry*).FN6 The term substance denotes a single compound; a scientist combining multiple compounds would not create a substance. *See also* Miles Labs., Inc. v. Shandon, Inc., 997 F.2d 870, 876 (Fed.Cir.1993), *cert. denied,* 510 U.S. 1100, 114 S.Ct. 943, 127 L.Ed.2d 232 (1994) (suggesting that using the singular form of a word, like "cabinet," to describe an apparatus precludes the assertion that multiple units, like "cabinets," literally

infringe the claim).

FN6. A more "loose" definition of homogenous is "a mixture or solution comprised of two or more compounds or elements that are uniformly dispersed in each other." *Hawley's Condensed Chemical Dictionary* 607 (11th ed. 1987).

ii. The Role of the Indicating Substance

Claim language explains the role of the indicating substance in the invention: (1) it must be capable of fluorescing; (2) it must be positioned to be impinged by a light beam with a predetermined color characteristic that has penetrated a light-transmissive surface; (3) it must be positioned to be impinged by a carbon dioxide component that has penetrated a diffusion membrane; and (4) when illuminated by the light beam, it must be capable of emitting a resultant light beam that has a color characteristic that is related to the concentration of carbon dioxide in the sample and that is different from the predetermined color characteristic of the illuminating light beam.

When an exciting light beam shines on an indicating substance that is capable of fluorescing, the indicating substance reacts "by emitting a new light component." (Testimony of Dr. Dennis Dougherty, Trial Tr. at 3083:6-8.) The new light component has a longer wavelength than the exciting light beam. (Testimony of Dr. Otto Wolfbeis, Trial Tr. at 1777:12-18.)

[46] The light beam that shines on the fluorescent indicator must have a predetermined color characteristic. In simplistic terms, "[f]luorescence measurement techniques ... involve directing light of one color onto a fluorescent indicator, which in turn, emits an output signal of another color. Thus, fluorescence creates a new color...." (Ex. 211 at A000474.) However, "color" is an imprecise term. (Testimony of Dr. Dennis Dougherty, Trial Tr. at 3084:23-25.) The experts construing this term testified that both the wavelength of the light and its intensity are color characteristics. (*Id*. at 3084:8-14; *see also* Ex. 331 at col. 5, lines 49-57 (stating that intensity is a color characteristic).) Thus, the exciting light beam has a predetermined wavelength and/or intensity. The new light component that the indicating substance emits must have a different wavelength and intensity.

[47] Additionally, the indicating substance must be positioned to be impinged by both the exciting light beam and the analyte carbon dioxide. A substance is impinged by light or a gas when it is struck by them or when they collide with it. *Webster's New Collegiate Dictionary* 575 (1973).

2. Interpretation of Claim 33

Claim 33 differs from claims 31, 32, 34, and 35 because it is not limited to carbon dioxide detection. Instead, it is an apparatus claim that teaches a device for measuring any type of gas in a sample.

a. Plain Language of Claim 33

Specifically, claim 33 describes "an arrangement for measuring the concentration of gases in a sample." The elements of claim 33 are:

(1) a combination comprising means for generating a monochromatic light beam having a predetermined color characteristic

(2) indicating means for generating light signals indicative of the concentration of gases in a sample to be measured, including

(a) a light transmissive surface positioned to be impinged by said monochromatic light beam

(b) a diffusion membrane of silicone adapted to be placed in proximity of a sample and being permeable to a selected gas component thereof, and

(c) an indicating substance sealingly embedded throughout said diffusion membrane and positioned to be impinged

(i) by said monochromatic light beam penetrating said light-transmissive surface and

(ii) by said gas component penetrating said diffusion membrane

(3) said indicating substance reacting when illuminated by said incident monochromatic light beam by emitting a resultant light beam having an emitted component which has a color characteristic different from said predetermined color characteristic.

(Ex. 331.)

b. Construction of Terms in Claim 33

The Court has already interpreted most of the important terms in claim 33. *See supra* Part I.B.3.c (interpreting the term "sealingly embedded"); Part II.A.1.b (interpreting the terms "indicating substance," "color characteristic," and "impinge"). Although it has already construed the term "sealingly embedded," it must add some further detail to this construction. It must also decide whether an indicating substance that emits a light beam after a light beam shines on it is luminescent or absorbent.

[48] An indicating substance is sealingly embedded in a silicone membrane when it is " *completely* embedded in the membrane." (Ex. 211 at A000479.) To comply with this description, the entire indicating substance must be embedded in the silicone membrane.

Additionally, an indicating substance that reacts when illuminated by an incident light beam by emitting a resultant light beam is necessarily luminescent. (Testimony of Dr. Dennis Dougherty, Trial Tr. at 3088:10-13.) It cannot be absorbent. (*Id*. at 3088:14-16.) When light energy shines on a luminescent indicator, it releases light energy. (Testimony of Dr. Otto Wolfbeis, Trial Tr. at 1777:12-18.) In contrast, when light energy shines on an absorbance indicator, it absorbs the energy and then releases it as heat energy, which human beings cannot see. (*Id*. at 1776:20-24.) The indicating substance that claim 33 describes emits light energy after a light beam shines on it, so it must be luminescent.

Having interpreted claims 31-35, the Court must now apply them to Baxter's single- and double-layer sensors.

B. Application of Interpreted Claims to Single-Layer Sensor

Baxter has conceded that its single-layer fluorescent sensor, when used to detect carbon dioxide in a sample,

meets all of the limitations of claims in the LUbbers patent. (Pretrial Conference Order para. 40.) However, it asserts that the doctrine of *de minimis non curat lex* makes this infringement unactionable.

1. Development of Single-Layer Sensor

Baxter's Microscan division developed one breadboard instrument for use with a single-layer fluorescent sensor. (Testimony of Liz Jarrard, Trial Tr. at 1074:8-10.) The scientists who developed it ran only fourteen tests on it that successfully detected carbon dioxide. (*Id*. at 2846:14-16.) They dismantled it after running these tests.

Baxter admits that this experimentation was "directed toward coming up with a commercial product that would be acceptable in the marketplace." (Testimony of Dr. James Godsey, Trial Tr. 869:24-870:2; *see also* Testimony of Michael P. Bucklo, Trial Tr. at 2876:19-24 (same).) However, it never sold or attempted to sell the single-layer sensor. (Testimony of Dr. James Godsey, Trial Tr. at 625:20-25.)

2. Law Governing De Minimis Defense

[49] [50] [51] "An experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement is not an infringement of the rights of the patentee." Poppenhusen v. Falke, 19 F.Cas. 1048, 1049 (C.C.S.D.N.Y.1861) (No. 11,279). However, as this Court has previously noted, "[t]he *de minimis* exception ... is a very narrow one that does not apply to acts of infringement committed by a business in furtherance of some commercial purpose." Baxter Diagnostics, Inc. v. AVL Scientific Corp., 798 F.Supp. 612, 620 (C.D.Cal.1992); *see also* Roche Prods., Inc. v. Bolar Pharmaceutical Co., 733 F.2d 858, 863 (Fed.Cir.1984) (holding that courts should not "construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of 'scientific inquiry,' when that inquiry has definite, cognizable, and not insubstantial commercial purposes"). Indeed, the manufacture of one infringing device generally constitutes infringement even if the manufacturer does not use or sell it. Neff Instrument Corp. v. Cohu Elec., Inc., 269 F.2d 668, 673 (9th Cir.1959). Courts have required infringers interposing a *de minimis* defense to establish "not only that the manufacture or sale be insignificant in amount but also that the alleged infringing activity ... terminated at the *de minimis* stage." Imperial Chem. Indus., PLC v. Henkel Corp., 545 F.Supp. 635, 657 (D.Del.1982).

3. Application of the Law to Development of Single-Layer Sensor

[52] Baxter urges that the *de minimis* defense applies because the manufacture of a single breadboard was insignificant in amount and because it terminated its experimentation with the breadboard at the *de minimis* stage. The Court disagrees and holds that Baxter may not invoke the defense because it did not terminate its experimentation with the breadboard at the *de minimis* stage.

Experimentation with the single-layer breadboard surpassed the *de minimis* stage when Baxter had a cognizable commercial purpose for the experimentation. It admits to having the intent to develop a blood culture product that it could sell; the single-layer breadboard was such a blood culture product. The fact that Baxter never actually marketed the breadboard does not change the fact that it developed the device in furtherance of a commercial purpose, not to gratify its philosophical taste or curiosity.

Furthermore, although Baxter discontinued its experimentation with the single-layer device, developing a blood culture device was an ongoing project. (Testimony of Michael Bucklo, Trial Tr. at 2877:13-16.) It used design concepts and other experimental data to construct the breadboard for its double-layer sensor and

commercial blood culture instrument. (Testimony of Glenn Enscoe, Trial Tr. at 2824:19-2825:2.) It did not terminate its experimentation at the *de minimis* stage if it employed data from the single-layer breadboard to make its commercial instrument.

C. Application of Interpreted Claims to Double-Layer Sensor

[53] After it abandoned its work on the single-layer sensor that infringed the LUbbers patent, Baxter began developing a double-layer sensor. This sensor does not infringe the patent either literally or equivalently.

1. Description of the Double-Layer Sensor

In contrast to the single-layer sensor, which uses one fluorescent dye, the double-layer sensor uses two dyes. One layer is an absorbance dye sealed in a gas permeable membrane. The other layer is a fluorescent dye sealed in acrylic.

The absorbance dye is bromothymol blue. In Baxter's device, it is suspended in an aqueous solution. It is pH-sensitive. When carbon dioxide reacts with the aqueous solution, changing its pH, the dye reacts to the pH change by altering its light absorbance properties. (Testimony of Dr. James Godsey, Trial Tr. at 768:21-22.)

The fluorescent dye is oxazine perchlorate. It is inert, so it does not respond to gases or other chemical species by changing its fluorescent properties. (Testimony of Dr. Otto Wolfbeis, Trial Tr. at 1792:13-16.) The acrylic layer that surrounds it is impermeable to carbon dioxide and other gases. (Testimony of Liz Jarrard, Trial Tr. at 2851:22-24.) The double-layer sensor is affixed to the bottom of a sample bottle.

To measure the concentration of carbon dioxide in a blood sample, technicians put the sample in the bottle. (Testimony of Dr. James Godsey, Trial Tr. at 841:15-18.) They then direct a light beam through the bottom of the bottle. It passes through the absorbance layer until it hits the fluorescent layer. (*Id*. at 768:11-24.) The fluorescent layer then emits light energy that passes through the absorbance layer. (*Id*.) The absorbance layer might absorb some of the emitted light. (*Id*.) The amount of absorption depends upon the pH of the absorbance dye. At neutral pH, it has high absorbance. As the pH drops, the absorbance also drops.

2. Literal Infringement of LUbbers Patent

The Court holds that the double-layer sensor does not literally infringe the LUbbers patent because its indicating substance does not perform the functions that the claim language requires.

a. Law Governing Literal Infringement

[54] [55] [56] [57] A device literally infringes a patent when it embodies every limitation of the patent claims. Transmatic, Inc. v. Gulton Indus., Inc., 53 F.3d 1270, 1277 (Fed.Cir.1995). A court cannot import structural limitations from the preferred embodiment into the claims. *Id*. (holding that the district court erred when it imposed on the claim term "light housing" a configuration disclosed in the preferred embodiment when the claim, itself did not disclose such a configuration). However, when the plain meaning of a claim discloses a structural limitation, a court may not ignore this limitation. Miles Labs., Inc. v. Shandon Inc., 997 F.2d 870, 876 (Fed.Cir.1993), *cert. denied,* 510 U.S. 1100, 114 S.Ct. 943, 127 L.Ed.2d 232 (holding that district court that had interpreted the term "cabinet" to mean a single enclosure could not find that a device consisting of three modules collectively formed a cabinet and literally infringed the patent in issue because

"three does not equal one"). Furthermore, when a claim specifies that an apparatus contains a single unit, a court may not find that several parts collectively form the single unit. *Id*.

b. Literal Application of Claims to Double-Layer Sensor

AVL argues that the two layers of the double-layer sensor collectively form the indicating substance. It contends that, together, the layers embody every limitation of the LUbbers claims. The Court rejects these arguments and holds that the absorbance dye is the indicating substance and that it does not embody every limitation in the claims.

i. Bromothymol Blue is Indicating Substance

If the Court found that the two dyes collectively formed the indicating substance, it would be making the same error that the district court in *Miles Laboratories* made. Having determined that under the claim language, an indicating substance must be homogenous and is necessarily a single compound, it cannot combine the two layers and call them the indicating substance. Thus, the issue is which of the two dyes is the indicating substance.

The experts testifying at trial agreed that bromothymol blue is the indicating substance. (Testimony of Dr. James Godsey, Trial Tr. at 886:12-14; Testimony of Dr. Otto Wolfbeis, Trial Tr. at 1822:2-6; Testimony of Dr. Dennis Dougherty, Trial Tr. at 3062:12-17.) They reasoned that it is "the only substance that changes its properties as a response to changing properties in the environment surrounding it." (Testimony of Dr. James Godsey, Trial Tr. at 886:15-19.) Specifically,it reacts to carbon dioxide by changing its light absorbance properties.

The fluorescent dye oxazine perchlorate cannot be the indicating substance because it does not change its properties in response to its environment. (*Id*. at 887:19-888:7.) It is inert, and its fluorescent properties do not change as a result of changes in pH or carbon dioxide levels. (Testimony of Dr. Otto Wolfbeis, Trial Tr. at 1792:13-16.) It merely acts as a light bulb or light source. (Testimony of Dr. James Godsey, Trial Tr. at 887:21-888:1; Testimony of Liz Jarrard, Trial Tr. at 2850:1-2; Testimony of Dr. Dennis Dougherty, Trial Tr. at 3060:7-10.)

ii. Bromothymol Blue Does Not Embody Every Claim Limitation

Having determined that bromothymol blue is the indicating substance, the Court must decide whether it embodies every limitation in the LUbbers patent claims. It does not because it is not capable of fluorescing or luminescing. (Testimony of Dr. James Godsey, Trial Tr. at 887:5-10; Testimony of Dr. Dennis Dougherty, Trial Tr. at 3067:5-7.) FN7

FN7. The Court notes that even if it found that the dyes collectively form the indicating substance, the double-layer sensor would not embody every limitation of the LUbbers patent. When interpreting claim 33, it stated that the indicating substance must be *completely* embedded in the silicone membrane. The oxazine perchlorate is not embedded in the silicone membrane at all.

3. Infringement Under Doctrine of Equivalents

AVL contends that even if the double-layer sensor does not literally infringe the LUbbers patent, it infringes

the patent under the doctrine of equivalents. However, the double-layer sensor and the device described in the LUbbers patent are substantially different.

a. Legal Standard Governing Doctrine of Equivalents

[58] [59] [60] The policy underlying the doctrine of equivalents is that limiting infringement to a literal duplication of a claim "would place the inventor at the mercy of verbalism and would be subordinating substance to form." Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 607, 70 S.Ct. 854, 856, 94 L.Ed. 1097 (1950). Therefore, a patentee may invoke the doctrine of equivalents when an accused device and a patented device have insubstantial differences. Hilton Davis Chem. Co. v. Warner-Jenkinson Co., 62 F.3d 1512, 1517 (Fed.Cir.1995), *cert. granted,* 516 U.S. 1145, 116 S.Ct. 1014, 134 L.Ed.2d 95 (1996). However, while the doctrine of equivalents may be used to establish infringement even though one or more elements of a claim are literally absent, every element must still be present by at least an equivalent in order to sustain a finding of infringement. Pennwalt Corp. v. Durand-Wayland, Inc., 833 F.2d 931, 949 (Fed.Cir.1987), *cert. denied,* 485 U.S. 961, 108 S.Ct. 1226, 99 L.Ed.2d 426 (1988). The trier-of-fact must evaluate the substantiality of the differences from the perspective of one ordinarily skilled in the art. *Id.* at 1519.

[61] To measure the substantiality of the differences, courts often rely solely on the function-way-result test. *Id.* at 1518. This test examines whether the two devices " 'perform substantially the same function in substantially the same way, to obtain the same result.' " Graver Tank, 339 U.S. at 608, 70 S.Ct. at 856 (*quoting* Sanitary Refrigerator Co. v. Winters, 280 U.S. 30, 42, 50 S.Ct. 9, 13, 74 L.Ed. 147 (1929)).

[62] However, because technology is becoming increasingly sophisticated, the function-way-result test is not always capable of demonstrating substantial differences. Hilton Davis, 62 F.3d at 1518. When a party presents evidence of substantiality, the court must consider it even if it is not function-way-result evidence. *Id.*

[63] [64] [65] One example of evidence relevant to substantiality is evidence of copying. *Id.* at 1519. "[C]opying suggests that the differences between the claimed and accused products or processes-measured objectively-are insubstantial." *Id.* Another example of relevant evidence is designing around the patent claims. *Id.* at 1520. It weighs against a finding of infringement because it promotes competition and the development of better or cheaper products. *Id.* A third example of relevant evidence is whether a person ordinarily skilled in the art would have known of the interchangeability of the elements of the devices. *Id.* at 1519. "The known interchangeability of the accused and claimed elements is potent evidence that one of ordinary skill would have considered the change insubstantial." *Id.*

b. Application of the Doctrine of Equivalents to Double-Layer Sensor

At trial, the parties presented both function-way-result evidence and other evidence, such as designing around the patent, to describe the substantiality of the differences between the double-layer sensor and the device that the LUbbers patent describes. The Court will examine each type of evidence separately.

The double-layer sensor does not infringe claims 31, 32, 34, and 35 under the doctrine of equivalents. Although it achieves the same function and result as the LUbbers device, it does so in a substantially different way. Furthermore, the findings that Baxter was designing around the patent instead of copying it and that persons ordinarily skilled in the art would not have known about the two-dye sensor militate against a finding of infringement.

i. Function-Way-Result Evidence

The function and result of claims 31, 32, 34, and 35 of the LUbbers patent is producing a fluorescent signal indicative of the concentration of carbon dioxide in the sample. Baxter concedes that the double-layer sensor has this function and result. However, it contends that the double-layer sensor achieves the function and result in a different way.

AVL's expert Dr. Dennis Dougherty conceded that "there is a difference in the *way* Baxter's two-layer sensor operates as compared with the sensors described in LUbbers." (Testimony of Dr. Dennis Dougherty, Trial Tr. at 3088:23-3089:2.) Specifically, "Baxter's sensor uses a pH sensitive dye to modulate the intensity of a fluorescent beam while in LUbbers the pH of the sample solution directly modulates the intensity of the fluorescent light by interacting with the ... fluorophore." (Written Testimony of Dr. Dennis Dougherty at 13:17-21; *see also* Testimony of Dr. Otto Wolfbeis, Trial Tr. at 1822:11-15 (same).) The issue is thus whether this difference is substantial.

AVL argues that despite this difference, the devices are both essentially fluorescent measurement devices because both measure a fluorescent signal in order to determine the concentration of gases in a sample. However, this argument oversimplifies the way that the devices work.

The Baxter double-layer sensor is actually more analogous to an absorbance sensor, such as the sensor that the Fostick patent describes, than to the LUbbers device. The fluorescent layer acts like a light bulb: "the fluorescent dye just-it's just there. It's like a light bulb that's there. And you have this other dye ... [that] would sort of screen out the light coming from that light bulb. So the light bulb is just there as a signal." (Testimony of Harold Heitzmann, Trial Tr. at 3006:13-20.) The fluorescent signal, without more, does not provide any data about the concentration of carbon dioxide in a sample. Instead, the absorbance dye provides the crucial data about carbon dioxide concentration. It absorbs more or less of this fluorescent light energy depending upon the concentration of carbon dioxide in a sample. Although the light source is fluorescent, the Baxter device determines the concentration of carbon dioxide by measuring the amount of fluorescent light that is *absorbed*. Thus, the Baxter two-layer device is essentially an absorbance measurement device.

In the LUbbers device, the fluorescent dye is not a light bulb. Technicians use an external light to interrogate it. By reacting to the pH changes that the carbon dioxide creates, it provides crucial data about the carbon dioxide concentration. The fluorescent light it emits varies according to the pH change. The LUbbers device determines the concentration of carbon dioxide by measuring the intensity of the fluorescent light emitted. Thus, it is essentially a fluorescent measurement device.

Because the devices are based on fundamentally different measurement techniques, the way the devices measure carbon dioxide is substantially different.

ii. Other Evidence of Substantial Differences

Because the technology at issue is very sophisticated, evidence of substantiality other than function-way-result evidence, is particularly helpful in this case. Hilton Davis, 62 F.3d at 1518. Baxter has adduced evidence that scientists ordinarily skilled in the art believed that the two-dye sensor was novel. A 1987 article by Dr. David Jordan, Dr. David Walt, and Dr. Fred Milanovich called the two-dye sensor a "revolutionary design" when they compared it to more traditional sensors such as Cardiovascular Device's

GasStat. (Ex. 4246 at 437; *see also* Testimony of Dr. Otto Wolfbeis, Trial Tr. at 1798:1-20 (stating that the design is not revolutionary but conceding that "it's of some novelty").)

Additionally, Baxter was designing around the LUbbers patent, not copying it. Indeed, the double-layer sensor has commercial benefits that the LUbbers patent does not. Very few dyes function effectively in a single-layer fluorescent sensor because they must have many specific characteristics. However, a broader range of dyes can function effectively in a double-layer sensor. (Testimony of Dr. Otto Wolfbeis, Trial Tr. at 1793:5-12; *see also id*. at 1794:12-18 (same).) The dye need only provide a good fluorescent signal and be inert. Additionally, with a two-dye sensor, a broader range of light sources can be effective. (*Id*. at 1794:24-1795:1.) Thus, a two-dye sensor manufacturer could select less expensive fluorophores and light sources. (Testimony of Dr. Robert Fraatz, Trial Tr. at 1589:24-1591:6 (discussing how different light sources "dramatically impact" the price of a sensor device).)

III. WILLFULNESS

Because the Court has held that Baxter's double-layer sensor does not infringe the LUbbers patent either literally or equivalently, it need only decide whether Baxter willfully infringed the patent when it constructed the single-layer sensor. It finds that Baxter did not willfully infringe the patent.

A. Legal Standard Governing Willfulness

[66] [67] The party asserting willful infringement must prove by clear and convincing evidence that (1) the infringer acted in disregard of the patent and (2) had no reasonable basis for believing it had a right to do what it did. Stickle v. Heublein, Inc., 716 F.2d 1550, 1565 (Fed.Cir.1983). "This is a factual determination to be made after consideration of the totality of the circumstances." American Medical Sys., Inc. v. Medical Eng'g Corp., 6 F.3d 1523, 1530 (Fed.Cir.1993), *cert. denied,* 511 U.S. 1070, 114 S.Ct. 1647, 128 L.Ed.2d 366 (1994).

[68] The infringer's good faith reliance on an attorney's opinion that a reasonable basis for infringing the patent exists tends to negate a finding of willfulness. Read Corp. v. Portec Inc., 970 F.2d 816, 828 (Fed.Cir.1992). "Those cases where willful infringement is found despite the presence of an opinion of counsel generally involve situations where opinion of counsel was either ignored or found to be incompetent." Id. at 828-29.

[69] [70] The infringer's attempts to design around the patent may also negate a finding of willfulness. Westvaco Corp. v. International Paper Co., 991 F.2d 735, 745 (Fed.Cir.1993). Designing around patents promotes healthy competition. State Indus., Inc. v. A.O. Smith Corp., 751 F.2d 1226, 1235-36 (Fed.Cir.1985). Competitors can design better or cheaper functional equivalents of each other's products and benefit consumers. *Id*. This conduct "should not be discouraged by punitive damage awards except in cases where conduct is so obnoxious as clearly to call for them. The world of competition is full of 'fair fights.' " *Id*. at 1237.

B. Application of Legal Standard to Experimentation with Single-Layer Sensor

From June through August or September 1988, a MicroScan employee constructed the infringing single-layer fluorescent sensor. (Testimony of Dr. James Godsey, Trial Tr. at 697:22-698:1.) MicroScan began testing this sensor in August or September 1988. (Testimonyof Dr. Frank Swenson, Trial Tr. at 225:21-22; Testimony of Dr. James Godsey, Trial Tr. at 697:22-25.) It canceled the single-layer sensor project on

October 18 or 19, 1988. (Testimony of Dr. James Godsey, Trial Tr. at 699:22-25.) Thus, the Court must examine Baxter's state of mind between June and mid-October 1988.

[71] After examining the totality of the circumstances at that time, the Court finds that Baxter and MicroScan had a reasonable, good faith belief that the LUbbers patent was invalid. When MicroScan first began working on sensor technology in 1987, it enlisted the aid of Dr. Harold Heitzmann, a scientist who worked for a division of the American Hospital Supply Company, the predecessor of Baxter's parent company. (Testimony of Dr. Harold Heitzmann, Trial Tr. at 2968:12-16.) This division had obtained competent attorney opinion letters stating that the LUbbers patent was unenforceable. (*Id*. at 2969:11-15.) Before MicroScan began working on the sensor technology, it learned about these opinion letters from Heitzmann. (Testimony of Dr. James Godsey, Trial Tr. at 647:13-19.) Knowing that competent attorneys had stated that the LUbbers patent was invalid, MicroScan had a good faith belief that it was not infringing the patent by developing its single-layer sensor project.

Additionally, punitive damages are not warranted because Baxter was experimenting with the single-layer sensor in order to understand sensor technology so that it could eventually design around the LUbbers patent.

IV. CONCLUSION

For the foregoing reasons, the Court holds that the LUbbers patent is valid because Baxter failed to prove either that it was procured through inequitable conduct or that its claims are invalid for obviousness. The Court also holds that Baxter's single-layer sensor device infringes the patent and that it is not a *de minimis* use of the patented technology. However, it finds that this infringement was not willful. Finally, it holds that Baxter's double-layer device does not infringe the patent literally or equivalently.

Counsel for AVL will prepare findings of fact and conclusions of law on these patent issues and file and serve them within twenty days of receiving this Order.