

IN THE  
**United States Court of Appeals  
for the Federal Circuit**

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THERASENSE, INC. (now known as Abbott Diabetes Care, Inc.)  
and ABBOTT LABORATORIES,  
*Plaintiffs-Appellants,*

v.

BECTON, DICKINSON AND COMPANY,  
and NOVA BIOMEDICAL CORPORATION,  
*Defendants-Appellees,*

and

BAYER HEALTHCARE LLC,  
*Defendant-Appellee.*

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*Appeals from the United States District Court for the Northern District of  
California in Consolidated Case Nos. 04-CV-2123, 04-CV-3327, 04-CV-3732,  
and 05-CV-3117, Judge William H. Alsup*

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**LAWRENCE S. POPE'S MOTION FOR LEAVE  
TO INTERVENE ON APPEAL**

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October 3, 2008

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Lawrence S. Pope respectfully moves for leave to intervene in this appeal, which concerns a district court's findings that Mr. Pope, along with his technical advisor, committed inequitable conduct while prosecuting the patent-in-suit. Mr. Pope meets the criteria for intervention in this appeal because of the significant and unique detrimental consequences he faces as a result of the district court's inequitable conduct findings that explicitly focus on him by name, and because his challenges to those findings derive from questions of law and fact common to this appeal. In further support of this motion, Mr. Pope states as follows:

**I. Mr. Pope Has A Substantial Interest In The Outcome Of This Appeal.**

1. This appeal concerns a June 24, 2008 judgment of the U.S. District Court for the Northern District of California holding U.S. Patent No. 5,820,551 ("the '551 patent") unenforceable due to inequitable conduct.<sup>1</sup> The appellants, Abbott Diabetes Care, Inc. (formerly Therasense, Inc.) and Abbott Laboratories (collectively, "Abbott"), filed their Notice of Appeal on July 21, 2008, and their opening brief is currently due on October 14, 2008.

2. Lawrence S. Pope was the Abbott attorney responsible for the prosecution of the '551 patent beginning in the fall of 1997 until the U.S. Patent and Trademark Office ("the PTO") issued the patent on October 13, 1998. (Decl. of Lawrence S. Pope ¶ 5 (attached hereto).) Active in patent practice since

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<sup>1</sup> The district court also held the patent invalid. Mr. Pope's proposed intervenor's brief would concern only the inequitable conduct findings.

becoming a patent trainee in 1972 and then a registered patent attorney in December 1973, Mr. Pope has prosecuted and supervised the prosecution of hundreds of patent applications before the PTO, including many for Abbott after he joined that company as a supervisory patent attorney in 1990. (*Id.* ¶¶ 2-4.) He is licensed to practice before the PTO and in Illinois, Pennsylvania, and the District of Columbia. (*Id.* ¶ 1.) In his 35 years of practice – indeed, until this case – Mr. Pope has never been accused of inequitable or other improper conduct during legal proceedings. (*Id.* ¶ 6.)

3. Mr. Pope’s conduct before the PTO during the prosecution of the ‘551 patent is at the heart of the district court’s inequitable conduct findings. Poignantly, the court found that: “Attorney Pope had no plausible reason for consciously withholding [an item the district court determined should have been disclosed] and that he acted with specific intent to deceive [the examiner] and the PTO.” *Therasense, Inc. v. Becton, Dickinson & Co.*, Nos. C 04-02123, C 04-03327, C 04-03732, C 05-03117, 2008 WL 2558001, at \*23 (N.D. Cal. June 24, 2008) (attached hereto as Exhibit 1).

4. That finding and similar findings, described in more detail below, have had an immediate and devastating impact on Mr. Pope’s legal career. As a direct result, Mr. Pope is being compelled to answer to professional disciplinary bodies. (Pope Decl. ¶ 7.) Yet he was not a party or separately represented by

counsel below (*id.* ¶ 8), and thus he had only a limited opportunity to ensure his interests were adequately protected.

**A. The District Court’s Findings Were Specifically Directed To Mr. Pope’s Conduct.**

5. The district court’s findings (though clearly erroneous) include many that were specifically directed against Mr. Pope and further findings that target both Mr. Pope and his technical advisor and former Abbott employee, Dr. Gordon Sanghera.

6. Before Abbott acquired Medisense, Inc. in May 1996, Dr. Sanghera was a Medisense employee responsible for the technical supervision of Medisense’s patent portfolio, a role he continued to occupy after the acquisition. *Therasense, Inc.*, 2008 WL 2558001, at \*3 (N.D. Cal. June 24, 2008). While at Medisense, Dr. Sanghera had been involved in Medisense’s submissions to the European Patent Office (“EPO”) in relation to the European counterpart to U.S. Patent No. 4,545,382 (“the ‘382 patent”). *Id.* The proper characterization of the ‘382 patent was central to the district court’s inequitable conduct findings. Mr. Pope was not involved in any proceedings regarding either the ‘382 patent or its European counterpart.

7. These prior patents and the ‘551 patent all concern electrochemical sensors used to detect the concentration of glucose in liquid solutions such as human blood. *See id.* at \*2-4. The district court found that when Mr. Pope

assumed responsibility for the '551 prosecution, he and Dr. Sanghera engaged in “brainstorming sessions” that were “motivated, in part, . . . to find a claim to suppress competition” and that eventually produced a new non-obviousness argument as to the meaning of a phrase in the '382 patent. *Id.* at \*15. Mr. Pope then presented this argument, supported by Dr. Sanghera’s sworn declaration, to the PTO. *Id.*

8. That presentation to the PTO formed the basis of the district court’s inequitable conduct ruling. The court found that at the time Mr. Pope made this submission, he was “well aware” of what the court found was an inconsistent characterization of the same phrase in the '382 patent made by Medisense before the EPO. *Id.* at \*17, \*19. Medisense’s statements before the EPO were not brought to the attention of the examiner during the '551 prosecution. *Id.* at \*15.

9. The court then found that “Attorney Pope and Dr. Sanghera . . . made a conscious and deliberate decision to withhold disclosure to the PTO of these prior statements”; “[b]oth knew that Dr. Sanghera’s declaration would be submitted to the PTO without disclosing the EPO submissions to the contrary”; and “[b]oth knew that the EPO materials made affirmative statements inconsistent with the declaration and the attorney remarks concerning the '382 sentence in question.” *Id.* at \*17, \*20.

10. Further, the court found that Mr. Pope acted with specific intent to deceive: “With respect to intent, Attorney Pope read the entire EPO appeal and made a conscious decision to withhold the contradictory material from the PTO [during the ‘551 prosecution]. . . . Attorney Pope had no plausible reason for consciously withholding the contradictory material from the PTO . . . .” *Id.* at \*23.

11. Ultimately, the district court found: “Having searched for any credible explanation for the conduct (and found none) and having taken into account all possible inferences of good faith (and found none), this order finds and holds that Attorney Pope and Abbott were guilty of inequitable conduct . . . .” *Id.* at \*24.

**B. Given Their Specificity, The District Court’s Findings Have Caused Direct And Substantial Injury To Mr. Pope.**

12. Thus, beyond merely concluding that the ‘551 patent was unenforceable, the district court directly and specifically targeted Mr. Pope, and its comments and findings are filled with (erroneous) characterizations of his motivations, knowledge, intent, and actions before the PTO. Given the court’s focused commentary and the seriousness of the charges it levels, its opinion amounts to a public reprimand of Mr. Pope. As a result, the district court’s opinion has tarnished Mr. Pope’s long-standing and previously unblemished professional record.

13. For example, the district court's findings about Mr. Pope have been the subject of several unfavorable articles in professional publications. (*See, e.g.*, Ex. 2, Zusha Elinson, *Judge Kills IP Claim, Blames Lawyer*, LAW.COM, June 26, 2008; Ex. 3, Amy Miller, *Preferable Isn't Required: Abbott Loses a Patent Thanks to Its Lawyer's Creative Wordplay*, CORPORATE COUNSEL, Sept. 2008, at 17-18.)

14. In addition to the general public damage to his reputation for integrity – professional and personal – resulting from the court's findings, Mr. Pope also faces disciplinary inquiries from both the Illinois Attorney Registration and Disciplinary Commission and the PTO's Office of Enrollment and Discipline. (Pope Decl. ¶ 7.)

15. The district court's opinion thus has had a dramatic and substantial impact on Mr. Pope's professional reputation and career prospects, indeed his very ability to earn a living. In these circumstances, he has a very substantial and direct interest in this appeal.

## **II. Mr. Pope Should Receive Leave To Intervene In This Appeal.**

16. Intervention in this appeal should be governed by standards analogous to those found in Federal Rule of Civil Procedure 24. Most recently, in *Elliott Industries Ltd. Partnership v. BP American Product Co.*, the Tenth Circuit held Rule 24 applicable in a similar context: “Although the Federal Rules of Civil

Procedure apply only in the district court, ‘the policies underlying intervention may be applicable in appellate courts.’” 407 F.3d 1091, 1102 (10th Cir. 2005) (quoting *UAW Local 283 v. Scofield*, 382 U.S. 205, 216 n.10 (1965)). This Court’s predecessor agreed, and used Rule 24 as guidance for determining the propriety of intervention on appeal. *Canadian Tarpoly Co. v. U.S. Int’l Trade Comm’n*, 649 F.2d 855, 856 (C.C.P.A. 1981).

17. Courts grant permissive intervention under Rule 24(b) where, as here, the intervenor “has a claim or defense that shares with the main action a common question of law or fact” and the intervention will not “unduly delay or prejudice the adjudication of the original parties’ rights.” FED. R. CIV. P. 24(b).

**A. Though Mr. Pope’s Arguments Are Similar To Abbott’s, His Brief Would Focus On Those Factual And Legal Nuances Specific To His Conduct.**

18. Mr. Pope more than meets Rule 24(b)’s criteria. As Rule 24(b) requires, he shares with Abbott a common opposition to the district court’s inequitable conduct findings and judgment. Indeed, inequitable conduct is the key issue in this appeal – and one this Court must address, given the district court’s subsequent and soon-to-be-appealed award of attorneys’ fees based on that conduct. *See Therasense, Inc. v. Becton, Dickinson & Co.*, Nos. C 04-02123, C 04-03327, C 04-03732, C 05-03117, 2008 WL 3915967 (N.D. Cal. Aug. 21, 2008).



19. Mr. Pope also would bring a unique perspective to this appeal by focusing on those factual and legal issues specific to his alleged inequitable conduct. For instance, Abbott will be constrained to defend the substance of Dr. Sanghera's advice. Mr. Pope, however, to eliminate the adverse impact on him, will be able to address his reliance on this advice. Thus, given the district court's heavy focus on his actions before the PTO, Mr. Pope himself – now represented by his own counsel – should be allowed to present the pertinent legal and factual issues in the manner he sees fit.

**B. Mr. Pope's Intervention Will Not Cause Undue Delay Or Unfair Prejudice.**

20. Intervention also will not unduly delay these proceedings or otherwise prejudice the adjudication of the parties' rights. Abbott's brief is currently due October 14, 2008. Mr. Pope requests that this Court set a filing date for his brief ten days after this Court grants this motion or, if Abbott obtains an extension of time in which to file its opening brief, Mr. Pope will file on the date Abbott's brief is due.

21. Furthermore, Mr. Pope will raise no issues that will unfairly prejudice the appellees. Although Mr. Pope's arguments will vary from Abbott's in that he will focus on factual and legal nuances unique or specific to his conduct, and he will not address invalidity issues, Mr. Pope's participation in discovery and as a trial witness at the district court, and the fact that his legal arguments are similar to

Abbott's, mean there is no risk of prejudice to the appellees. In other words, "[b]ecause the district court already confronted [the proposed intervenors'] arguments in rendering its decision, there is no reason to fear 'issue proliferation,' 'confusion,' 'extra cost,' or 'an increased risk of error,' if [Mr. Pope is] allowed to appeal . . . ." *Massachusetts v. Microsoft Corp.*, 373 F.3d 1199, 1236 (D.C. Cir. 2004) (citation omitted).

**C. Mr. Pope's Substantial Interest In This Appeal Supports Intervention.**

22. The direct impact of the district court's opinion on Mr. Pope further supports his intervention in this appeal. Although the court did not issue formal sanctions, its adverse findings regarding Mr. Pope's conduct amount to a public reprimand, without the protections an attorney is usually accorded in professional disciplinary processes. The serious nature of the district court's findings, as well as the continued and long-term professional consequences Mr. Pope confronts as a result, dictate that Mr. Pope, in fairness, be allowed to participate directly in this appeal, with counsel of his own.

23. Indeed, it is not uncommon for courts of appeals to grant motions to intervene where, as here, the party seeking intervention has a unique interest in the outcome of the appeal and that interest is not fully represented by the named parties to the appeal. For example, in *In re EchoStar Communications Corp.*, this Court granted leave to intervene on appeal to a law firm that created documents

that were affected by a district court order compelling their production. 448 F.3d 1294, 1296-97 (Fed. Cir.), *cert. denied sub nom. TiVo, Inc. v. EchoStar Commc'ns Corp.*, 127 S. Ct. 849 (2006). Analogous to Mr. Pope's situation, in *Penthouse Int'l Ltd. v. Playboy Enterprises, Inc.*, 663 F.2d 371, 373 (2d Cir. 1981), the Second Circuit allowed an attorney to intervene in the appeal of a district court order that included findings of misrepresentation and other misconduct by the attorney. *Cf. Elliott Indus. Ltd. P'ship*, 407 F.3d at 1103-04 (granting intervention as of right on appeal where parties no longer had an interest in litigating issue that affected intervenor's interests).

24. Further, the significance of the district court's charges against Mr. Pope warrants this Court's fullest consideration of this appeal, and Mr. Pope's intervention would assist the Court in that process. In other contexts, this Court has recognized that assertions of attorney misconduct in judicial opinions, like those lodged against Mr. Pope here, can seriously affect a lawyer's reputation and livelihood – and that such an injury can be worthy of careful appellate review. “A lawyer's reputation is one of his most important professional assets. Indeed, such a reprimand may have a more serious adverse impact upon a lawyer than the imposition of a monetary sanction.” *Precision Specialty Metals, Inc. v. United States*, 315 F.3d 1346, 1352-53 (Fed. Cir. 2003) (finding jurisdiction to hear an attorney's appeal from a court's reprimand issued in an unpublished opinion).

25. Most recently, in *1-10 Industry Associates, LLC v. United States*, this Court noted that because “the most precious asset of an attorney is his professional reputation,” “it is our duty on appeal to review the facts of such a case with great care to determine whether a sanction has been properly imposed.” 528 F.3d 859, 861 (Fed. Cir. 2008). *Accord Walker v. City of Mesquite*, 129 F.3d 831, 832-33 (5th Cir. 1997) (“[T]he importance of an attorney’s professional reputation, and the imperative to defend it when necessary, obviates the need for a finding of monetary liability or other punishment as a requisite for the appeal of a court order finding professional misconduct.”). Mr. Pope’s intervention in this appeal is necessary to give him the chance to restore his previously unblemished professional reputation.

### **III. Statement Of Consent Or Opposition To This Motion.**

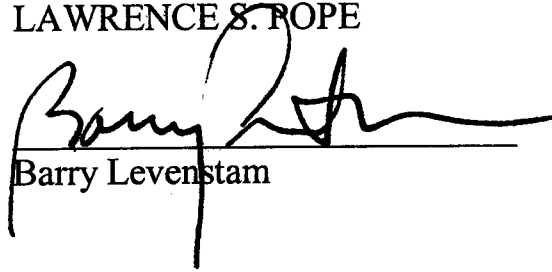
26. Counsel for Mr. Pope has contacted counsel for Abbott, who stated that Abbott consents to this motion. Counsel for Abbott contacted counsel for Becton, Dickinson, & Company and Nova Biomedical Corporation, who stated that those parties oppose this motion. Counsel for Abbott also contacted counsel for Bayer HealthCare LLC, who took the matter under advisement but has not indicated that party’s position regarding this motion as of the time of filing.

WHEREFORE, Mr. Pope respectfully requests that this Court permit him to intervene in this action.

Dated: October 3, 2008

LAWRENCE S. POPE

By:



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## DECLARATION OF LAWRENCE S. POPE

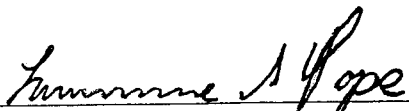
I, Lawrence S. Pope, pursuant to 28 U.S.C. § 1746, declare as follows:

1. I am an attorney licensed to practice before the U.S. Patent and Trademark Office (“the PTO”) and in Illinois, Pennsylvania, and the District of Columbia.
2. I first became involved in patent practice as a patent trainee in 1972. I became a registered patent attorney in December 1973.
3. Since becoming a registered patent attorney, I have prosecuted and supervised the prosecution of hundreds of patent applications before the PTO.
4. In 1990, I accepted employment with Abbott Laboratories as a supervisory patent attorney. In that capacity, I continued to prosecute or supervise the prosecution of patent applications.
5. From the fall of 1997 until the patent issued on October 13, 1998, and in my capacity as an Abbott employee, I was responsible for the prosecution of the application that led to U.S. Patent No. 5,820,551 (“the ‘551 patent”).
6. Before this case, I had never been accused in any legal proceeding of any inequitable or other improper conduct in my professional career.
7. As a direct result of the district court’s conclusions that I committed inequitable conduct during the prosecution of the ‘551 patent, I have received

inquiries from both the Illinois Attorney Registration and Disciplinary Commission and the PTO's Office of Enrollment and Discipline.

8. During the district court proceedings in this case, I was not separately represented by my own counsel.

I declare under penalty of perjury that the foregoing is true and correct.  
Executed on the 2 day of October, 2008.

  
\_\_\_\_\_  
Lawrence S. Pope



## PROOF OF SERVICE

I, April A. Otterberg, hereby certify that on October 3, 2008, I caused an original and three copies of the foregoing **Lawrence S. Pope's Motion For Leave To Intervene On Appeal** to be transmitted to the Court for filing via hand delivery, and two copies of the same to be served on counsel for the parties listed below via UPS overnight delivery, by depositing same in properly addressed envelopes in an official UPS repository.

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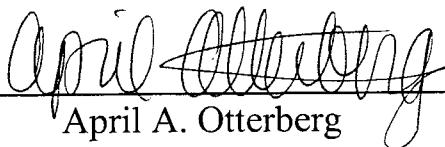
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# **EXHIBIT 1**

**H**Therasense, Inc. v. Becton, Dickinson and Co.  
N.D.Cal.,2008.

Only the Westlaw citation is currently available.

United States District Court,N.D. California.

THERASENSE, INC., Plaintiff,

v.

BECTON, DICKINSON AND COMPANY, Defendant.  
and Consolidated Cases.

Nos. C 04-02123 WHA, C 04-03327 WHA, C 04-03732  
WHA, C 05-03117 WHA.

June 24, 2008.

**Background:** Patentee brought patent infringement action against competitors, alleging infringement of patent for sensor for use in whole blood without any protective membrane. Defendants asserted invalidity defense.

**Holdings:** Following bench trial, the District Court, William Alsup, J., held that:

- (1) patent claims were invalid as obvious;
- (2) patent was unenforceable by reason of inequitable conduct;
- (3) prior art was adequately disclosed in patent specification.

Ordered accordingly.

#### [1] Patents 291 ↪66(1.20)

##### 291 Patents

##### 291II Patentability

##### 291II(D) Anticipation

##### 291k63 Prior Patents

##### 291k66 Operation and Effect

##### 291k66(1.20) k. Measuring, Testing, and

##### Indicating-Devices. Most Cited Cases

Existence of protective membrane around electrode was optional, rather than required, in prior art patent for commercial electrochemical sensor for glucose, and thus patent for sensor for use in whole blood without any protective membrane was invalid for obviousness based on prior art; prior art patent disclosed basic structure of active electrode and faster-acting chemistry, and stated that structure could optionally include protective membrane as an outer layer and that such membrane was

preferable when used with live blood, and those skilled in art would have recognized electrochemistry would still have worked after removal of membrane.

#### [2] Patents 291 ↪16(2)

##### 291 Patents

##### 291II Patentability

##### 291II(A) Invention; Obviousness

##### 291k16 Invention and Obviousness in General

##### 291k16(2) k. Prior Art in General. Most

##### Cited Cases

Broad teachings do not have to be supported by specific experimental examples in order to qualify as prior art in a patent examination.

#### [3] Patents 291 ↪16(3)

##### 291 Patents

##### 291II Patentability

##### 291II(A) Invention; Obviousness

##### 291k16 Invention and Obviousness in General

##### 291k16(3) k. View of Person Skilled in Art.

##### Most Cited Cases

For purposes of patent invalidity based on obviousness, the hypothetical person skilled in the art is presumed to have full knowledge of all prior art in a patent.

#### [4] Patents 291 ↪23

##### 291 Patents

##### 291II Patentability

##### 291II(A) Invention; Obviousness

##### 291k23 k. Omission of Parts. Most Cited Cases

Patent for sensor for use in whole blood without any protective membrane dispensed with function contained in prior art patent, and thus patent did not disclose an invention; patent dispensed with membrane feature contained in prior art patent.

#### [5] Patents 291 ↪23

##### 291 Patents

##### 291II Patentability

##### 291II(A) Invention; Obviousness

##### 291k23 k. Omission of Parts. Most Cited Cases

Deletion of a feature from a prior-art device with a

corresponding deletion of its function is not an invention.

**[6] Patents 291 ↪97**

291 Patents

291IV Applications and Proceedings Thereon

291k97 k. Patent Office and Proceedings Therein in General. Most Cited Cases

Passages from submission by patentee to European Patent Office (EPO) regarding prior art were "material" to prosecution, and thus their disclosure to United States Patent and Trademark Office (PTO) during patent prosecution was obligatory, for purposes of patentee's action against competitor alleging infringement of patent for sensor for use in whole blood without any protective membrane; statements to EPO were inconsistent with statements made to PTO examiner, and centered on precise sentence in question, its meaning, and what it taught. 37 C.F.R. § 1.56(b)(2).

**[7] Patents 291 ↪97**

291 Patents

291IV Applications and Proceedings Thereon

291k97 k. Patent Office and Proceedings Therein in General. Most Cited Cases

Patentee's attorney acted with specific intent to deceive United States Patent and Trademark Office (PTO) and patent examiner during prosecution of patent for sensor for use in whole blood without any protective membrane, and thus patent was unenforceable based on inequitable conduct; attorney had no plausible reason for consciously withholding submissions to European Patent Office (EPO) during prosecution that were inconsistent with statements to PTO, and submissions were material to prosecution. 37 C.F.R. § 1.56(b)(2).

**[8] Patents 291 ↪97**

291 Patents

291IV Applications and Proceedings Thereon

291k97 k. Patent Office and Proceedings Therein in General. Most Cited Cases

Withholding of submission to European Patent Office (EPO) regarding prior art from United States Patent and Trademark Office (PTO) during prosecution of patent for sensor for use in whole blood without any protective membrane by patentee's director of research and development was inequitable conduct, and thus patent was unenforceable based on inequitable conduct; once

director made positive submission to PTO, he was duty-bound to avoid making intentionally misleading submission to PTO, statements were material, and director had no plausible reason for concealing inconsistent EPO submissions from PTO.

**[9] Patents 291 ↪97**

291 Patents

291IV Applications and Proceedings Thereon

291k97 k. Patent Office and Proceedings Therein in General. Most Cited Cases

A declarant who makes a materially false and misleading statement under oath to the United States Patent and Trademark Office (PTO) cannot escape a charge of inequitable conduct on the theory that he advised the lawyer that the statement was misleading and why.

**[10] Patents 291 ↪66(1.20)**

291 Patents

291II Patentability

291II(D) Anticipation

291k63 Prior Patents

291k66 Operation and Effect

291k66(1.20) k. Measuring, Testing, and Indicating-Devices. Most Cited Cases

Patent for sensor for use in whole blood without any protective membrane was invalid as obvious due to prior art; all but one limitation in patent were disclosed expressly by prior patents, and remaining limitation, implementing two-electrode configuration, was well known prior to patent's priority date.

**[11] Patents 291 ↪16.5(1)**

291 Patents

291II Patentability

291II(A) Invention; Obviousness

291k16.5 State of Prior Art and Advancement Therein

291k16.5(1) k. In General. Most Cited Cases

Often, it will be necessary for a court to look to interrelated teachings of multiple patents, the effects of demands known to the design community or present in the marketplace, and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion

claimed by the patent at issue. 35 U.S.C.A. § 103.

**[12] Patents 291 ↪ 16.5(4)**

291 Patents

291II Patentability

291II(A) Invention; Obviousness

291k16.5 State of Prior Art and Advancement

Therein

291k16.5(4) k. Remediating Defects or Solving Problems. Most Cited Cases

Where there is a design need or market pressure to solve a particular problem and there are only a discrete number of predictable solutions that led to the anticipated success of the patent, the patent is likely the product not of innovation but of ordinary skill and common sense. 35 U.S.C.A. § 103.

**[13] Patents 291 ↪ 16(3)**

291 Patents

291II Patentability

291II(A) Invention; Obviousness

291k16 Invention and Obviousness in General

291k16(3) k. View of Person Skilled in Art.

Most Cited Cases

When determining invalidity of a patent, the decisionmaker must forget what he or she has been taught at trial about the claimed invention and cast the mind back to the time the invention was made, to occupy the mind of one skilled in the art who is presented only with the references, and who is normally guided by the then-accepted wisdom in the art.

**[14] Patents 291 ↪ 112.5**

291 Patents

291IV Applications and Proceedings Thereon

291k112 Conclusiveness and Effect of Decisions of Patent Office

291k112.5 k. Sufficiency of Evidence to Offset Effect of Decision in General. Most Cited Cases  
Patent invalidity must be proven by clear and convincing evidence. 35 U.S.C.A. § 282.

**[15] Patents 291 ↪ 99**

291 Patents

291IV Applications and Proceedings Thereon

291k99 k. Description of Invention in

Specification. Most Cited Cases

Specification for patent for sensor for use in whole blood without any protective membrane adequately disclosed limitation "without an intervening membrane or other whole blood filtering membrane," as required to comport with written-description requirement under patent law; those skilled in art would have thought inventors were in possession of electrochemical sensor without a membrane for use in whole blood as of time of application. 35 U.S.C.A. §§ 112, 132.

**[16] Patents 291 ↪ 99**

291 Patents

291IV Applications and Proceedings Thereon

291k99 k. Description of Invention in Specification. Most Cited Cases

To satisfy the written description requirement the disclosure of the prior application must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, the inventor was in possession of the invention. 35 U.S.C.A. § 112.

**[17] Patents 291 ↪ 99**

291 Patents

291IV Applications and Proceedings Thereon

291k99 k. Description of Invention in Specification. Most Cited Cases

In order for a disclosure of prior art to be inherent, the missing descriptive matter must necessarily be present in the original patent application's specification such that one skilled in the art would recognize such disclosure. 35 U.S.C.A. § 112.

**Patents 291 ↪ 328(2)**

291 Patents

291XIII Decisions on the Validity, Construction, and Infringement of Particular Patents

291k328 Patents Enumerated

291k328(2) k. Original Utility. Most Cited Cases

**Patents 291 ↪ 328(2)**


291 Patents

291XIII Decisions on the Validity, Construction, and Infringement of Particular Patents

291k328 Patents Enumerated

291k328(2) k. Original Utility. Most Cited

Cases

Patents 291  328(2)

291 Patents

291XIII Decisions on the Validity, Construction, and Infringement of Particular Patents

291k328 Patents Enumerated

291k328(2) k. Original Utility. Most Cited

Cases

4,225,410, 4,388,166, 4,987,173, 5,682,884. Cited.

4,545,382. Cited as Prior Art.

5,820,551. Unenforceable.

Jason Rantanen, Jeffrey I. Weinberger, John Walter Peck, Ted G. Dane, Esq., Munger, Tolles & Olson LLP, Los Angeles, CA, Rohit K. Singla, Munger Tolles & Olson, San Francisco, CA, David Wille, Matthew A. Hayenga, Baker Botts LLP, Dallas, TX, James W. Cannon, Jr., Maria W. Boyce, William P. Johnson, Baker Botts L.L.P., Austin, TX, Jose E. Rivera, Karen L. Hale, Abbott Park, IL, Steven Mitby, Baker Botts LLP, Houston, TX, for Plaintiff.

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**FINDINGS OF FACT AND CONCLUSIONS OF LAW**

WILLIAM ALSUP, District Judge.

**INTRODUCTION**

\*1 After a bench trial, this order constitutes the findings of fact and conclusions of law. Both sides have submitted lengthy proposed findings and conclusions. Rather than address each and every proposal, this order will find its own way through the evidence and arguments. Any proposal that has been expressly agreed to by the opposing side, however, shall be deemed adopted even if not expressly stated herein. That a proposal has not been expressly covered herein does not necessarily mean it was rejected; it only means that the Court found it unnecessary to reach.

**THE PROCEDURAL HISTORY OF THE CASE**

Abbott Laboratories filed the first of these actions on May 28, 2004. Three subsequent actions were filed. All concerned four United States patents owned by Abbott and Therasense, Inc.<sup>FN1</sup>U.S. Patent No. 5,820,551 is the subject of this order. These actions were originally assigned to The Honorable Martin J. Jenkins. Judge Jenkins issued a first claim construction order for certain other patents and a separate claim construction order for the '551 patent. He also issued three separate summary judgment orders. The final one, dated April 3, 2008, involved all parties and all patents in suit. While the final summary judgment order did eliminate several infringement counts, several other claims were still viable. Immediately after issuing the final summary judgment order, Judge Jenkins left the federal bench, and all four cases came to the undersigned.

All four cases were subsequently consolidated and a trial date was set for May 27, 2008. All defendants were permitted to file one more round of summary judgment motions and each party was allowed motions *in limine*. A technology tutorial for the undersigned was also held. The motions for summary judgment and motions *in limine* were fully briefed. A first omnibus order ruled on the motions for which oral argument was not required. Argument was then heard for the remaining pending motions. In a second omnibus order, the final pending motions were decided. Defendant Roche Diagnostics Corporation subsequently settled on the eve of trial.

During this time, the Court and counsel also addressed the shape of the trial. It was decided that a trial on the '551 patent would be held first with all defendants and would be broken up into three separate phases: (i) invalidity and unenforceability; (ii) infringement (if needed); and (iii) willfulness and damages (if needed). All parties then stipulated that phase one of the '551 trial would be tried to the bench. Defendants raised four issues for phase one: inequitable conduct, obviousness, prosecution laches, and non-compliance with the written-description requirement.

When the trial on the '551 patent began, the remaining defendants were Bayer Healthcare, LLC, Becton Dickinson & Company, and Nova Biomedical Corporation (collectively "BD/Nova"). Before trial began, Abbott made a request to add Attorney Lawrence Pope as a live trial witness in its case-in-chief. During Attorney Pope's deposition, Abbott's counsel had on three separate

occasions insisted to defense counsel that Attorney Pope would *not* appear in person at trial. This was said in aid of repeated instructions not to answer. Attorney Pope was, therefore, scheduled to appear only through video-deposition. Based on Abbott's insistence at deposition that Attorney Pope would not appear live at trial, Abbott's request to have Attorney Pope appear as a live trial witness was initially denied. This denial was on the ground that it would be unfair to defendants, who had relied on the deposition representations to their detriment in not bringing Rule 37 motions. During trial, however, Abbott renewed its motion to allow Attorney Pope to testify in person at trial. The Court then asked Abbott to submit a sworn proffer showing the proposed statement of Attorney Pope's testimony. Abbott submitted a declaration signed by Attorney Pope detailing the facts he would cover in his testimony. Because of the seriousness of the accusation against Attorney Pope, the Court relented and allowed Abbott to call Attorney Pope in its case-in-chief on those topics raised in his declaration.

\*2 After defendants closed their case-in-chief, Abbott moved for partial findings under Rule 52(c) that defendants had failed to meet their burden of proof with respect to their defense of prosecution laches. The motion was granted on the ground that defendants had failed to show any intent to delay prosecution of the '551 patent or that substantial prejudice resulted from any such delay. Abbott also moved for partial findings as to defendants' remaining invalidity defenses. These motions were all denied. Abbott rested its case-in-chief on June 2 and closing arguments were heard on June 3. This order now follows.

### THE UNITED KINGDOM WORK

United States Patent No. 4,545,382 (and its European counterpart) is a decisive item of prior art in this decision. Here is its story. In the late 1970's and early 1980's, two research groups at the University of Oxford and the University of Cranfield in the United Kingdom were working on electrochemical sensors to detect the concentration of specific components in solutions. In particular, they were interested in developing electrochemical sensors that could be used to test glucose levels in human blood. Doctors Irving Higgins, Hugh Hill, and Elliot Plotkin were part of these research groups. In 1981, both groups teamed with a newly founded company, Genetics International, which was co-founded by James McCann. One goal was to create the first commercial electrochemical sensor for glucose.<sup>FN2</sup>

In 1981, the researchers filed their first patent application. This became the '382 patent in the United States and No. 0078,636 B2 in the European Patent Office. The specification taught an improved electrochemical sensor for use in various liquid mixtures. The sensor was an electrode coated with specified chemicals that generated a tiny but detectable flow of electricity in the presence of glucose. The technology itself will be described below. In brief, the chemicals coated onto the electrode combined with glucose or whatever other "substrate" was being tested to generate small currents of electricity, which could then be measured by an ammeter. The higher the concentration of substrate, the higher the electrical current, and the higher the meter reading. The patent disclosed certain ferrocene chemistry that allowed for fasting testing.

Although the United States '382 patent lived out its seventeen years without incident, its EPO counterpart (*i.e.*, the '636) was eventually revoked based on a German prior-art reference that was cited by a third party in a European opposition proceeding. That was in the mid-1990's. The decision to revoke the patent was appealed, however, and the patent was eventually reissued by a technical board of appeal in the European Patent Office. Certain submissions made along the way by Abbott's predecessors, however, have turned out to be important in this proceeding by reason of their non-disclosure to the PTO during prosecution of the '551 patent in suit.

\*3 The research group continued its work on sensors for testing glucose levels in blood. Dr. Hill and his colleagues filed several additional patent applications, which were later combined to form a single United States patent application. All parties herein agree that the resulting U.S. Patent No. 5,820,551-the patent in suit-claims priority to May 1983. James McCann and Drs. Hill, Higgins and Graham Davis were listed as the inventors.

Originally, the claimed invention of the '551 patent was the development of a disposable electrode strip whose electrodes could be covered by a single drop of solution. These one-use strips would be inserted into a convenient unit for digital readout of the level of a target compound (like glucose) in a test liquid mixture (like blood). After a strip was used to generate a readout, it could be thrown away.

The '551 patent was in prosecution for over fourteen years. During this period, Genetics International changed

its name to Medisense, Inc. Various claims were rejected twelve times by the PTO examiner, David Shay. Eleven out of the twelve rejections relied on the '382 patent or its European counterpart, the '636 patent. During this prolonged prosecution, Medisense amended the proposed claims several times to overcome rejections by Examiner Shay-all without success. At times, Medisense also submitted declarations from persons of ordinary skill in the art to distinguish its claims from the prior art. None of the proposed amendments ever included a limitation for a sensor without a filter or a membrane.

In the meantime, several other companies, including defendants Bayer Healthcare, LLC, and Becton Dickinson & Company, had begun manufacturing and selling disposable electrochemical sensors for diabetic patients.

In 1996-while the '551 patent was still pending before the PTO-Medisense was purchased by Abbott Laboratories. After the acquisition, Abbott brought in one of its in-house patent attorneys to take over the prosecution of the '551. That attorney was Lawrence Pope. Attorney Pope worked in conjunction with several technical employees at Medisense, including Dr. Gordon Sanghera, to "brainstorm" various arguments regarding the patentability of the '551. Dr. Sanghera had worked at Medisense since 1990. As of 1997, he was its director of research and development in the United States. His responsibilities included running competitive analysis in conjunction with the marketing department and supervising Abbott's patent portfolio. Dr. Sanghera had also previously worked for Dr. Hill at his laboratory at Oxford University. He had researched electrochemical sensors, but he had not been involved in the research that led to any patents involved herein. Dr. Sanghera had, however, attended the European opposition hearings and had been active in crafting the submissions made in that appeal.

Dr. Sanghera and Attorney Pope struck upon a new point of possible novelty previously overlooked in the pending prosecution. The new point was that the specification disclosed a sensor for use in whole blood *without* any protective membrane. Trouble was, a passage in the earlier '382 patent already seemed to disclose membraneless sensors. That passage read (col.4:63-66):

\*4 Optionally, but preferably when being used on live blood, a protective membrane surrounds both the enzyme and the mediator layers, permeable to water and glucose molecules.

To address this problem, Abbott decided to assert, as a matter of extrinsic fact, that in 1983 skilled artisans would have believed that a membrane was essential even in the face of the '382 disclosure, *i.e.*, they would not have taken the quoted sentence literally.

Attorney Pope then held an interview with Examiner Shay on November 4, 1997. Examiner Shay summarized the interview as follows (TX 469):

Applicant indicated that he would like to submit claims specifically covering a compound specific electrode with the filtering membrane absent. The Higgins et al. ('382) disclosure was discussed esp[ecially] the paragraph spanning columns 4 & 5. It was determined that since Higgins et al. appear to require the membrane for use with whole blood (see example 8) an affidavit or other evidentiary showing that at the time of the invention such a membrane was considered essential would overcome this teaching.

As arranged in the interview, Attorney Pope submitted a declaration by Dr. Sanghera on December 3, 1997, along with amendments to the claims. The declaration stated in relevant part (TX 443):

THAT based on his historical knowledge he is confident that on the filing date of the earliest application leading to the present application on June 6, 1983 and for a considerable time thereafter one skilled in the art would have felt that an active electrode comprising an enzyme and a mediator would require a protective membrane if it were to be used with a whole blood sample. Therefore he is sure that one skilled in the art would not read lines 63 to 65 of column 4 of U.S. Patent No. 4,545,382 to teach that the use of a protective membrane with a whole blood sample is optionally [sic] or merely preferred.

The entire submission was aimed at overcoming the "optionally, but preferably" sentence in the '382 patent.

Attorney Pope submitted parallel remarks stating that those of ordinary skill in the art believed that the use of a protective membrane was "required" when testing whole blood and that they would have understood the sentence in question as mere patent phraseology, not a technical teaching. Based on Dr. Sanghera's declaration and Attorney Pope's remarks, Examiner Shay finally approved the proposed claims and the patent issued on October 13, 1998. The foregoing findings will be amplified with many



details below.

### INVALIDITY

In this action, the central axis of contention concerns membranes and, more particularly, their use as a permeable layer surrounding the chemistry coated onto the active electrode. Late in the fourteen-year prosecution, as stated, Abbott advanced the theory that the '551 specification revealed a sensor without a protective membrane. However, a key prior art reference—the inventors' own '382 patent'—had already stated that such membranes were optional and at most preferred in certain circumstances, as quoted above. This '382 sentence was raised by the examiner as having already taught that membranes were merely optional or preferred. In response, as stated, Abbott took the position (and still maintains) that the sentence would *not* have been understood in 1983 by those skilled in the art to have modified a supposed conventional wisdom that a membrane was necessary for testing in whole blood.<sup>FN3</sup> Defendants disagree. They point out that the '382 sentence expressly stated that even for live blood, a membrane was merely “preferred” and that for all other cases it was “optional.” In no case was it said to be “required.”

\*5 With this introduction of the central invalidity issue, this order will go back to square one. It will begin by setting forth the basic technology. It will then review the '382 patent', focusing on its entire disclosure, including the sentence in question, so as to place that sentence in full context, all from the point of view of one skilled in the art at the time of the alleged '551 invention (in 1983).

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Although this summary of the technology is now stated in the present tense, this summary was all known in the prior art. The electrochemistry involves an electrode coated with an “enzyme” catalyst. The enzyme is particularly selected to react with glucose or whatever the test substance might be. Again, the substance being tested for is sometimes, as used by Medisense in the EPO proceedings, called a “substrate.”<sup>FN4</sup> The enzyme-substrate chemical reaction generates electrons. The electrons are passed via yet another chemical called a “mediator,” also coated onto the electrode, to the active electrode itself. The electrons then flow as a tiny but measurable electrical current down the active electrode through an ammeter and back to the other uncoated electrode. The blood droplet or other solution under test

provides an electrical path completing the circuit between the electrodes. The word “sensor” is sometimes used interchangeably with the active electrode, *i.e.*, the electrode painted with the active chemistry.

An analogy is to a battery. Battery chemicals generate electrons and thus electricity, which can then be used to do work, such as to drive a meter. In the technology at hand, the active chemistry is the glucose, enzyme, and mediator. Together, they generate the electricity.

Thus, when blood is placed between and across the electrodes, the chemicals coated onto the active electrode go to work, generating electricity or “signal.” The electricity passes through an ammeter, which detects the current. The current will ideally be in proportion to the concentration of glucose. In this way, the meter can be calibrated to progressive concentrations of glucose. The user can then see when the glucose (or other substrate) is too low or too high. All of the foregoing was known in the prior art.

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One of the contributions of the '382 patent'—which was concededly prior art to the '551 patent'—was a faster-acting ferrocene mediator coated onto an active electrode along with an enzyme. Faster acting meant faster response times and quicker test results.

In the “Background of the Invention,” the inventors stated that the '382 invention would have particular value for “in vivo measuring or monitoring of components in body fluids” (col.1:16-17) and said “the determination of glucose in a diabetic human subject” was a primary application (col.1:20-21). The background stated further that the invention lent itself to temporary or permanent implantation. Although “the provision of an implantable glucose sensor [was] a major object of the invention” the inventors noted that “other and broader objects [were] not hereby excluded” (col.1:23-26). A few columns later, for example, the specification called out home-testing kits with disposable sensors. After acknowledging that *in vivo glucose sensors* had already been proposed by others, the inventors stated that they had recently carried out *in vitro* studies.

\*6 Under “Summary of the Invention,” the '382 inventors stated that they had come to realize that mediator compounds could be associated with the sensor electrode structure itself to make such electrodes available for use

by *in vivo* methods. The '382 invention was then described as a sensor electrode composed of a combination of enzyme and mediator (col.1:60-63). Preferably, the electrode was designed to determine glucose *in vivo* (col.1:65-66). A long passage then described various mediators and enzymes (col. 2:1 to col. 4:55). Again, a significant contribution was the ferrocene chemistry that was faster acting than in the prior art, thus reducing response time.

At a few places in this passage, the inventors referenced membranes. For example, two paragraphs stated (col. 3:53 to col. 4:2):

In that form of the invention using polyviologens, as exemplified in the three modifications above, it is an objective to keep loss of active material (enzyme or mediator) to a very low level, i.e., by the surrounding membrane, co-immobilisation or covalent bonding. In a different form of the invention, however, still using glucose oxidase, a rather higher level of loss of active material is tolerated, giving a sensor electrode of reduced but still useful life, coupled with improve [sic] sensitivity and selectivity.

In this form of the invention the electrode is composed of particulate carbon mixed with a low molecular weight mediator disseminated throughout the electrode and glucose oxidase. Chloranil and/or fluoranil are useful mediator substances. It is envisaged to construct from such an electrode a replaceable sensor tip to a needle-type probe for projecting only into the dermis so as to allow ready replacement.

Put differently, after describing a membrane application, the "different form" of the invention dispensed with the membrane and thus "tolerated" a "rather higher level of loss of active material" (due to the absence of the immobilizing membrane). It was envisaged to have replaceable sensor tips for projecting into the dermis.

Another version called out ferrocene-glucose oxidase as "particularly valuable" and stated "the enzyme layer is preferably immobilised at the surface of the underlying mediator, retained in a self-sustaining gel layer" or with "a retention layer thereover permeable to the glucose molecule" (col.4:13-16). "Immobilisation" was a reference to retaining the active chemicals on the electrode so that they would not fall away into the blood or other fluid. Then came the main sentence at the heart of this case (col.4:63-66):

Optionally, but preferably when being used on live blood, a protective membrane surrounds both the enzyme and mediator layers, permeable to water and glucose molecules.

This allowed water and glucose to pass through, kept *in* the chemicals, and kept *out* larger blood constituents like red blood corpuscles.

The "Summary of the Invention" then turned to various applications and specifically called out implanted glucose sensors, digital readout diabetic home-testing kits, devices to take a blood sample from the finger, place it on the sensor, amplify the signal, and give a digital readout, and a watch-type device for monitoring glucose interstitial fluid in the skin with disposable-sensor cartridges in the back, which would plug into the electrodes.

\*7 Next came a "Description of the Preferred Embodiments." In total, the ' 382 patent contained thirteen working examples of preferred embodiments of the invention. Some of the examples described various procedures for producing the working chemistry of the sensor-*i.e.*, the enzyme and mediator. Other examples described possible configurations of electrodes and electrochemical sensors. Each was configured slightly differently depending on various test parameters, including the type of solution being tested. Some of the sensors included a membrane and others did not.

Examples 1 and 2 described purification processes for producing quinoprotein glucose dehydrogenase-an enzyme used to catalyze the chemical reaction. Examples 3 and 4 explained the interaction between glucose oxidase (another enzyme) and ferrocene-the mediator which allowed for much faster and more linear testing than the prior art.

Example 5 described the construction of an *in vitro* sensor with a glucose oxidase enzyme and polyviologen mediator. A dialysis membrane was used. The purpose of the membrane was to block larger molecules from passing through to the working chemistry. The sensor was tested in a buffered electromechanical cell. As the amount of glucose in the test solution was increased, the current generated by the sensor grew, thereby indicating that the electrode was acting as a glucose sensor. This same construction was used in Example 6, except chloranil was used as the mediator.

Example 7 taught a sensor configured with a glucose oxidase enzyme and a dimethyl ferrocene mediator designed for use in interstitial fluid-*i.e.*, skin. Before the sensor was used for testing, the electrode, mediator, and enzyme were dipped into a solution of cellulose acetate, thereby creating a protective membrane over the working chemistry and electrode. The example went on to state: "The small size of such an electrode and its linear response over a large range of glucose concentrations makes it possible to use the electrode for *in vivo* glucose determination on both severely diabetic and normal individuals" (col.8:54-59).

Example 8-entitled "In vitro sensor"-was the most discussed embodiment at trial (col.8:63). The example began by describing the construction of a sensor with a glucose oxidase enzyme and a ferrocene mediator. No membrane was applied. The example then explained that the sensor was first tested in "nitrogen-saturated buffer solution" (col.9:15). The results for the test in buffer solution were then summarized. A cellulose acetate membrane was then applied to the sensor. The example went on to describe response times for that sensor in buffer and then, in a separate test, in blood. The exact language in the specification stated (col.9:26-33) (emphasis added):

With the same buffer, such an electrode *modified* by a cellulose acetate membrane coating (produced as in Example 7) gave response times of 36 seconds (2 mM) and 72 seconds (6 mM). *With blood, this modified electrode* gave response times of 36 seconds (blood with a known 2mM glucose content) and 72 seconds (blood at known 6mM glucose content).

\*8 The sensor constructed in Example 8 was thus tested in two solutions. The example first described was tested in buffer solution. At this point in the specification, no membrane was applied to the sensor. A membrane was then placed on the sensor. The response times of the sensor *with* a membrane were subsequently set forth for the same buffer solution and then, separately, for blood. It is Abbott's contention that this example shows that a membrane was in fact required by the invention of the '382 patent when testing in whole or live blood.

Example 9 taught the construction of an electrode with a glucose dehydrogenase enzyme and a ferrocene mediator. A dialysis membrane was used to cover the coated electrode. Examples 10 and 11 were minor variations of

Example 9. Examples 12 and 13 described further configurations for an electrode with a glucose dehydrogenase enzyme and ferrocene mediator.

Finally, under the '382 claims, Claim 1 covered the sensor electrode coated with the enzyme and mediator. All agree that Claim 1 covered electrodes without limitation to either *in vitro* or *in vivo* use. All agree that Claim 1 covered versions with and without membranes. Indeed, dependent Claim 12 narrowed the claim to sensor electrodes having an outermost protective membrane permeable to water and glucose molecules.

In sum, the '382 disclosed the basic structure of an active electrode and a faster-acting chemistry, stating that the structure could optionally include a protective membrane as an outer layer and stating that such a membrane was preferable when used with live blood, although the examples involving blood employed a membrane.

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Turning to the '551 patent in suit, its inventor group was virtually the same as for the '382, with slight adjustments.<sup>FNS</sup> It was directed to a home-testing kit and more specifically to a two-electrode strip (rather than a three-electrode strip) for one-time, disposable attachment to a handheld readout device. The electrodes were coated with enzymes and mediators ("preferably a ferrocene")-as in the '382 patent. The strip was described as "elongated" for ready handling and assembly. As with the '382, the active electrode was "preferably formed of carbon." The inventors went on to say that carbon foil available commercially as GRAPHOIL or PAPYEX was a valuable electrode material. Various "objects" of the invention were described, none of which related to a membrane or lack thereof. Many columns were devoted to construction of the electrodes.

The subject of membranes was mentioned only twice in the '551 application. Under "Membrane Cover for Electrode," the inventors said that "it may be found valuable to exclude the sensor from interfering contact with larger molecules or tissue fluid components" and that this could be done with a "surrounding membrane" (col.6:67-7:13). That passage briefly described how to make a membrane *in situ*. Later, a step-by-step constructional sequence was given for an electrode strip. Seven steps were listed. Adding a membrane was *not* listed as a step (col.8:35-51), an omission since given great weight by Abbott. A later, optional modification

stated: "The electrode may then be covered, on both sides, with a semipermeable membrane of cellulose acetate (or polyurethane), not shown, to block large interfering species from contact with the electrode" (col.9:34-37).

\*9 Nowhere in the '551 specification or the original claims was there any suggestion that treating the membrane as optional (or omitting it) was an inventive step. Nonetheless, this order appreciates that a legitimate invention may eventually be found lurking in a disclosure even though the inventors missed it themselves for over a decade. See Newman v. Quigg, 877 F.2d 1575, 1581 (Fed.Cir.1989). So this order accepts Abbott's contention, at least for purposes of argument, that the '551 specification disclosed an active electrode *without* a membrane for use with whole blood (as well as disclosing one *with* a membrane for use with whole blood). The decisive question remains whether or not the same group of inventors (with slight membership changes) had *already* disclosed in the '382 patent that a membrane was merely preferred for use with live blood and was optional in all other cases. This order now turns to resolving that question.

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[1] This order accepts Abbott's proposition that prior to the '382 patent, those skilled in the art typically employed a membrane on a sensor used with live or whole blood, although one exception was already in print.<sup>FN6</sup> That practice, however, was *before* the revelation in the '382 patent. The '382 patent expressly stated that a protective membrane was *optional* in all cases except for live blood, in which case it was *preferred*. In no case did the '382 patent state that a protective membrane was *required*.

In context, it seems clear why this was so. The invention specified a faster-acting ferrocene chemistry. This allowed for shorter response times, *i.e.*, measurement times. This, in turn, reduced the *raison d'être* for any membrane. For example, the faster response times reduced the probability of the active chemicals being washed away in the bloodstream and reduced the time within which red blood corpuscles could locate and foul the electrodes. (Fouling refers to the larger red blood cells accumulating on the electrode and blocking the much smaller glucose molecules from reaching the sensor.) The indicated readings took about a minute, even less *without* any membrane. There was, therefore, less need for any membrane.<sup>FN7</sup>

As a matter of sentence structure, the sentence sets up two cases—an optional case and a preferred case:

Optionally, *but preferably when being used on live blood*, a protective membrane surrounds both the enzyme and the mediator layers, permeable to water and glucose molecules.

Italics have been supplied here to illustrate the structure. Ignoring the italicized preferred case, the sentence states: "Optionally, ... a protective membrane surrounds both the enzyme and the mediator layers ...." That is the general, optional case. The exception, *i.e.*, the preferred case, is for live blood. That phrase is italicized. The trial record is clear and convincing that persons of ordinary skill in the art understood the words "optionally" and "preferably" in the same way as the rest of us. There is no doubt that those skilled in the art would have understood that the sentence was trying to say exactly what has been laid out in this paragraph.<sup>FN8</sup>

\*10 Abbott contends that skilled artisans simply would not have believed the sentence and would have had no reasonable expectation of reliance on it by reason of a prevalent view that membranes were essential when testing in whole blood. A revelation in a public disclosure cannot be erased from the prior art on the theory that it contradicted the conventional wisdom. The whole point of disclosures in patents is to reveal something new. See Atlas Powder Co. v. Ireco, 190 F.3d 1342, 1347 (Fed.Cir.1999).

Abbott has tied itself in knots contorting the grammar to come up with an alternative meaning. One example is Abbott's Proposed Finding No. 90, which reads:

Interpreted in light of the conventional wisdom at the time, the "preferably" language means that the membrane is optional when an *in vivo* sensor does not contact whole blood but that the membrane is required when the sensor contacts red blood cells in whole blood.

This contortion collapses on its own weight. The sentence in question meant just what it said and the ordinary artisan would have so understood it.<sup>FN9</sup>

Contrary to Abbott, Example 8 in the '382 patent was consistent with the plain meaning of this sentence. Example 8 was one of the preferred embodiments. It

described a ferrocene-glucose oxidase electrode. In the experiment described in Example 8, the sensor was tested in a buffer solution with two different glucose concentrations, yielding response times of 24 and 60 seconds, depending on the concentration. Then a protective membrane was applied to the sensor. While still testing the buffer concentration, the response times went to 36 and 72 seconds, respectively. The same sensor-again with a protective membrane-was tested in blood samples with the same concentration and 36- and 72-second response times were again obtained. It is true that when the sensor was used in blood a protective membrane was used and that a protective membrane was not used with the first buffer solution. Nothing in Example 8, however, stated that a membrane was required for use in blood. That a membrane was added seems to have been little more than a way to investigate the time effect of adding a membrane.

[2] It is also true, as Abbott urges, that no test recited in the preferred embodiments included a test on blood without a membrane. There were, however, too few blood examples among the embodiments to warrant any inference from this happenstance. No doubt, the broad teaching of the sentence in question went beyond the specifics of the preferred embodiments. That is often true in patents. Broad teachings do not have to be supported by specific experimental examples in order to qualify as prior art.

The '382 sentence was then and remains correct, a fact that even Abbott does not challenge. Membranes were never part of the electrochemistry itself. Rather, they offered certain mechanical advantages, provoked by two different concerns. The first was human safety. For *in vivo* use, toxic materials might break away from the coated sensor and pollute the bloodstream. To protect against this possibility, a membrane immobilized the active ingredients, *i.e.*, retained them in place and thus reduced the risk of breakaway. Reduced response times from faster chemistry, however, reduced the breakaway risk-for the sensor could be removed sooner than before. The second concern was the risk of "fouling." This was the risk that red blood particles would stick to the active electrode and prevent glucose from interacting with the chemicals coated onto the electrodes. If enough "fouling" occurred, the signal would be diminished below an acceptable level and an erroneous readout would occur. Fouling might occur in live blood or whole blood. In these proceedings, the supposed problem of fouling has been exaggerated by Abbott. After the faster chemistry

disclosed in the '382 patent, the risk became more theoretical than practical, especially for one-use, disposable applications. Subsequent diabetic kits using the faster sensors have deleted the membrane with acceptable results. In sum, the '382 statement in question was then and remains correct.

\*11 Abbott's idea that skilled artisans would have read the sentence in question and disbelieved it in 1983 is not plausible on the trial record. Skilled artisans would have known that deleting the membrane would simply have deleted their mechanical advantages. They would have known, however, that the electrochemistry would still have worked. They would have known that the degree of fouling would have depended on how long the sensor was exposed to blood. They would have known that the risk of fouling would have been reduced for faster-acting chemistry and reduced even more for sensors used only once, *i.e.*, disposable sensors with no accumulation of residue. They would have known that omitting the filter would have had the further advantage of speeding up the test time even more.

To be sure, in making these findings in the preceding paragraph, the Court has relied on trial testimony and materials outside the four corners of the patent and prior-art references. This, however, is because Abbott itself has resorted to extrinsic evidence and "conventional wisdom." That is, to overcome the '382 prior-art sentence in question, Abbott has resorted to extrinsic evidence, arguing that skilled artisans would not have understood the sentence in light of prevailing practices. Therefore, it is entirely appropriate for the other side to likewise resort to extrinsic evidence as to how those skilled in the art would have taken the '382 sentence in question.

Abbott next argues that one skilled in the art would have read the "optionally, but preferably" passage of the '382 as mere "patent phraseology." Notably, the passage in question stated that a membrane was preferable "when being used on *live* blood" (col.4:63-64). Defense Expert Turner testified that even today's implantable electrochemical sensors used for testing glucose in live blood would use a membrane to ensure that toxic materials were not released into the blood stream (Tr. 333). He even went as far as saying that the FDA would likely not approve an implantable sensor without a membrane for safety reasons, which was the reason a protective membrane was preferable for live blood. Unlike implantable sensors used to test live blood, however, one-time disposable sensors for *in vitro* testing

(as disclosed in the '551 patent) had no such safety concerns. With *in vitro* testing, a membrane was motivated only by the potential of fouling the electrode. As to them, the '382 sentence in question taught that the membrane was merely optional.

The examiner was persuaded by Abbott's view as a result of two considerations. One was the presence or absence of a membrane in the '382 examples, particularly in Example 8. This argument is unpersuasive and rejected by this order, for the reasons stated above.

The other reason was based on an extrinsic evidentiary declaration without which the examiner said no allowance would be made. This was the now-controversial declaration of Dr. Gordon Sanghera. Although he was not a co-inventor, he had worked at Medisense and had become an Abbott employee at the time of his declaration. The entirety of his substantive statement to the examiner was as follows (TX 443):

\*12 3. THAT he is familiar with U.S. Patent No. 4,545,382 and with the history of the development of the technology disclosed in this patent. In particular he is familiar with the beliefs and concerns of those skilled in the art in 1981 when the first application leading to this patent was filed as well as in 1983 when the first application leading to the present application was filed.

4. THAT he is familiar with the teachings of U.S. Patent No. 4,987,173 to Nankai et al. and in particular with the teachings of Examples 3 and 4 with regard to the construction of sensors for use with serum and whole blood samples.

5. THAT based on his historical knowledge he is confiednt [sic] that on the filing date of the earlist [sic] application leading to the present application on June 6, 1983 and for a considerable time thereafter one skilled in the art would have felt that an active electrode comprising an enzyme and a mediator would require a protective membrane if it were to be used with a whole blood sample. Therefore he is sure that one skilled in the art would not read lines 63 to 65 of column 4 of U.S. Patent No. 4,545,382 to teach that the use of a protective membrane with a whole blood sample is optionally or merely preferred.

6. THAT Examples 3 and 4 of U.S. Patent No. 4,897,173 provide evidence that this concern about unprotected active electrodes for whole blood samples

persisted until at least the June 21, 1985 filing date of the earliest application leading to this patent. The fact that the Example 3 teaching a sensor for use with serum samples has no protective membrane but Example 4 teaching a sensor for blood has a polycarbonate membrane is evidence that the authors of this technical disclosure still believed that active electrodes could not be directly exposed to whole blood samples.

With the exception of the '173 Nankai patent, the declaration was conclusory and unsupported. The '173 Nankai patent was more specific. It did, indeed, happen to use a filtration layer with whole blood and did not use one with serum, as Abbott states. The Nankai PCT filing date was June 19, 1986. Nankai did tend to support the "conventional wisdom" argument advanced by Abbott.

But Nankai was and remains subject to a very important and overriding caveat. The Nankai specification made no reference to the '382 patent and said nothing about the "optionally, but preferably" sentence. Nankai was silent on the key sentence. Nankai did not purport to construe it.

[3] Although for obviousness purposes, the hypothetical person skilled in the art is presumed to have full knowledge of all prior art, that in no way means that we must presume Nankai knew of the '382 sentence in question. *Nankai was simply one practitioner, not someone presumed to be omniscient.* His patent in no way addressed the meaning of the key sentence. He may have been unaware of the key sentence, for all the record shows. By contrast, for our obviousness purposes, we must presume the hypothetical artisan knew all of the prior art, including the key sentence at issue. See Custom Accessories, Inc. v. Jeffrey-Allan Ind., Inc., 807 F.2d 955, 962 (Fed.Cir.1986).

\*13 The decisive fact remains that those skilled in the art, had they read it, would have understood the '382 sentence as stating that a protective membrane was preferred in the case of live blood and optional in all other cases. They would have understood it as disagreeing with any viewpoint that membranes were necessary when testing whole or live blood. The very purpose of a patent is to disclose new information to persons skilled in the art.

This order finds that the '382 patent taught those skilled in the art that-at least when faster chemistry was employed-a protective membrane was optional in all cases except the case of live blood, in which case the protective membrane was preferred-but not required. The trial evidence and the

plain language of the disclosure are clear and convincing on this point. Abbott's "conventional wisdom" evidence is rejected.

The foregoing is sufficient. To this, it must be said that the information withheld from the examiner, discussed momentarily, eviscerates any vestige of plausibility to Abbott's extrinsic evidence, for that information from the applicants themselves now shows that they knew full well the meaning of the very "optionally, but preferably" sentence at the heart of this suit. This evidence, revealed for the first time in these proceedings, also decidedly supports this order's invalidity conclusion. This order rejects the Sanghera declaration and its supposed conventional wisdom.

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[4][5] There is a different aspect to Abbott's entire theory that deserves comment. Deletion of a feature from a prior-art device with a corresponding deletion of its function is not an invention. For example, if the prior art already discloses a pencil with an eraser, one may not delete the eraser and claim an eraserless pencil as an invention. The reason is that the deletion of the eraser would also mean a deletion of its function. This would be true even if the conventional wisdom was that all pencils came with erasers. See *Richards v. Chase Elevator Co.*, 159 U.S. 477, 486, 16 S.Ct. 53, 40 L.Ed. 225 (1895).

Similarly, deletion of the protective membrane was not inventive in the ' 551 patent because there was a corresponding deletion of its function. The loss of this function was tolerable because the chemistry was fast enough (at least by the time of the '382 prior-art disclosure) to obtain acceptable results without a membrane. But assuming *arguendo* that skilled artisans had uniformly believed that a membrane was necessary (despite the '382 patent), the mere deletion of the membrane with a corresponding loss of its functions would not warrant a patent.

It would be different if the '551 patent disclosed a specific configuration that preserved the membrane's function but without the membrane. Exactly what was disclosed in the '551 patent that compensated for the deletion of the membrane and guarded against fouling? The Court asked this question several times during the bench trial. Clearly, the '551 specification and prosecution history were totally silent on this point.

\*14 At the closing argument, Abbott's counsel argued-for the first time-that the '551 disclosed use of certain materials for constructing the electrodes and that these materials were less sensitive to oxygen. Whereas the '382 patent had taught carbon as a preferred electrode, the '551 patent recommended carbon foil available commercially as GRAPHOIL or PAPYEX. The argument emerged that normally red blood cells (and their oxygen content) posed a noise hazard but that the electrodes specified in the '551 were less sensitive to oxygen. Thus, it was said, a membrane could be safely deleted from an electrode constructed from GRAPHOIL.

Nowhere in the specification, nowhere in the prosecution history, and nowhere in the trial evidence was this point made. It surfaced for the first time at closing argument. Still, the Court has fully considered it. It is easy to see why it has taken so long to invent this line of argument.

Both the '382 and '551 patents disclosed electrodes that exhibited immunity from oxygen. For example, the '382 specification stated that the electrodes exhibited "very low oxygen sensitivity." This would allow "omission of the dilution step involved in blood analysis in current instruments," the '382 specification said (col.5:20-22). For its part, the '551 patent stated that, for carbon foil, "oxygen interference is minimal, there being less than 4% change in signal between anaerobic and fully aerobic samples" (col.7:15-20).

Given that the '382 had already disclosed "very low oxygen sensitivity," the later statement in the '551 patent was no improvement on that score. The ' 551 statement was a passing comment on a design consideration (concerning oxygen sensitivity) that had been covered in the earlier patent and was covered again in the later patent. Since the earlier patent had already achieved "very low" oxygen sensitivity, it is far-fetched to argue that the later patent somehow solved that problem, much less solved it in a way that specifically dispensed with the need for a membrane, a nexus nowhere made until at closing argument in 2008.<sup>FN10</sup>

To return to the main point, the clear-cut fact remains that to the extent the '551 dispensed with the membrane, it also dispensed with its function and thus no invention was disclosed at all. This point would hold even if we indulged Abbott's view of the conventional wisdom about membranes at the time.<sup>FN11</sup>

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The main invalidity issue is the no-membrane limitation. The foregoing resolves that key component. The inequitable-conduct issue is also anchored in the no-membrane limitation. This order, therefore, will now proceed directly to that issue for ease of reader convenience and return later to the less controverted limitations and complete the obviousness analysis.

### INEQUITABLE CONDUCT

Turning to the defense of inequitable conduct, the “optionally, but preferably” sentence remains at center stage. When Abbott acquired the pending application that led to the '551 patent, its in-house lawyer, Lawrence Pope, took over the prosecution. That was in 1997. He replaced Fish & Richardson, who had been unsuccessful for twelve years in obtaining allowance of any claims. Examiner Shay had repeatedly rejected all proposed claims over the '382 patent.

\*15 Abbott “brainstorming” sessions were held to find a way to win claims on the '551 application. These sessions included Dr. Gordon Sanghera. The original inventors were not included. By this point, Abbott's competitors were beginning to sell diabetic home-testing kits in competition with the Exactech, the Medisense- Abbott product. Although Dr. Sanghera denied it at trial, this order finds that Dr. Sanghera and Attorney Pope were motivated, in part, by marketplace developments to find a claim to suppress competition. The very day the '551 patent issued, for example, Abbott asserted it in a patent-infringement action against a home diabetic kit made by Lifescan, Inc. There is, however, nothing wrong with seeking a patent in order to stifle competition, at least under the patent laws, so long as the patent is lawfully obtained.

The brainstorming sessions produced an argument never before advanced by the inventors or by prior counsel, namely that the '551 specification taught that a protective membrane was not necessary when testing whole blood. This argument was then presented to Examiner Shay in an oral interview by Attorney Pope in November 1997. With respect to novelty and the prior art, they expressly discussed the '382 sentence. For convenience, this now-familiar sentence is repeated:

Optionally, but preferably when being used on live blood, a protective membrane surrounds both the enzyme and the mediator layers, permeable to water

and glucose molecules.

More specifically, the Interview Summary (TX 469) referenced the Higgins '382 and Pace '410 patents and stated:

Applicant indicated that he would like to submit claims specifically covering a compound specific electrode with the filtering membrane absent. The Higgins, et al. ('382) disclosure was discussed esp[ecially] the paragraph spanning columns 4 & 5. It was determined that since Higgins et al. appear to require the membrane for use with whole blood (see example 8) an affidavit or other evidentiary showing that at the time of the invention such a membrane was considered essential would overcome this teaching.

A box was checked stating that an agreement had been reached. In short, the examiner agreed to permit an evidentiary showing to overcome the presumed teaching of the “optionally, but preferably” sentence.

To this end, Attorney Pope prepared a sworn declaration for the signature of Abbott's Dr. Sanghera. Although he was skilled in the art by the time of the declaration, Dr. Sanghera had not been skilled in the art at the time of the invention (and, as stated, had not been one of the inventors). This, of course, was not a requirement for a declaration. Dr. Sanghera read, understood, and signed the declaration, knowing its purpose and knowing that it would be submitted to the PTO to overcome the presumed teaching of the sentence. The declaration is quoted above. In brief, it stated that Dr. Sanghera was sure that one skilled in the art at the time of the invention would not have read the sentence in question to teach that the use of a membrane with a whole-blood sample was optional or even preferred. To this end, Dr. Sanghera did not consult with any of the inventors to learn what had been considered optional, preferred, or essential despite the fact he still had a good relationship with at least Inventor Hill. He limited his research to literature.<sup>FN12</sup>

\*16 The declaration was filed for Examiner Shay along with an amendment and remarks by Attorney Pope. The amendment cancelled all prior claims and proposed new claims, soon allowed. The attorney's remarks (TX 470) are now set forth at length with italics on the passages of particular relevance:

At the interview the applicants' undersigned representative explained that a new set of claims would be presented which focus on the feature that the active



electrode is directly exposed to a whole blood sample *without* the intervention of a barrier material such as a membrane or gel which filters out larger molecules or other blood components expected to interfere with the active electrode's operation. It was agreed that this embodiment was one of the options clearly disclosed in the present application. It was also agreed that the art generally taught the use of such protective barriers on the effective filing date of the present application.

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*The applicants' representative pointed out that U.S. Patent No. 4,545,382 to Higgins et al teaches that active electrodes designed for use with whole blood require a protective membrane.* He noted that the general teaching to this effect at lines 63 to 66 of column 4 of this patent was amplified and supported by the specific working examples. In each working example in which an active electrode was prepared for use with a whole blood sample it was provided with a protective membrane by either deposition of a cellulose acetate film or attachment of a dialysis membrane.

*Example 8 at columns 8 and 9 was noted as being particularly instructive in this regard.* An active electrode was constructed by successively coating the end of a carbon rod with ferrocene and then glucose oxidase. This unprotected active electrode was first tested in nitrogen saturated buffer and then in an air saturated buffer to establish the impact, if any, of oxygen on the reaction; the impact appears to have been minimal. Then at lines 22 to 33 the effect of a cellulose acetate membrane on response time was investigated when the sample was buffer and when it was blood. In both cases the response time appears to have increased by as much as 50%, e.g., from 24 to 36 seconds for a low level of glucose. Nevertheless all the succeeding examples utilized a protective membrane. *The clear implication is that the use of protective membrane caused a slower response time but nonetheless was needed for a whole blood sample.*

The art continued to believe that a barrier layer for whole blood sample was necessary for a considerable period. For instance, U.S. Patent No. 4,897,173 to Nankai et al (copy accompanies this response), which claims priority from 1985, describes the production of electrodes for the measurement of glucose. In Example 3 at columns 4 and 5 an electrode structure for serum (see line 6 of column 5) is described which does not

involve a protective membrane. In contrast Example 4 at columns 5 and 6 directed to an electrode for use with whole blood (see lines 61-62 of column 5) teaches a filtration layer 21 with a pore size of one micron.

*\*17 One skilled in the art would not have read the disclosure of the Higgins patent (U.S.4,545,382) as teaching that the use of a protective membrane with whole blood samples was optional. He would not, especially in view of the working examples, have read the optionally, but preferably language at line 63 of column 6 as a technical teaching but rather mere patent phraseology.* This is supported by the Declaration under 37 C.F.R. 1.132 of Gordon Sanghera which accompanies the present amendment.

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The Examiner is respectfully requested to indicate the allowability of the currently pending claims and issue a Notice of Allowance. The applicants have established that a new claim limitation supported by the present application provides a patentable distinction over U.S. Patent No. 4,545,382, the key reference in the prosecution of the present application and its predecessors. *There is no teaching or suggestion of unprotected active electrodes for use with whole blood specimens in this patent or the other prior art of record in this application.* Furthermore, the present claims are patentably distinct from the claims of U.S. Patent No. 5,682,884. Therefore, this case is in condition for allowance.

In sum, Attorney Pope's remarks stated that the sentence in question would have been regarded as "mere patent phraseology" rather than a "technical teaching" and that the art believed that a membrane was "required" even for a considerable period after the '382 patent', closing with: "There is no teaching or suggestion of unprotected active electrodes for use with whole blood specimens in this patent or the other prior art of record in this application." In reliance on the submission, Examiner Shay allowed the new claims and the '551 issued.

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At the time of the interview and the submission, Attorney Pope and Dr. Sanghera were well aware of previous representations based on the same "optionally, but preferably" sentence made by Medisense to the European Patent Office in 1994-95. Attorney Pope and Dr.

Sanghera, however, made a conscious and deliberate decision to withhold disclosure to the PTO of these prior statements. This much is conceded. Abbott contends, however, that there was no duty to disclose the earlier statements and that there was no intent to deceive. On these latter points, the following was proven at trial by clear and convincing evidence.

The '636 patent-the European counterpart to the '382-had been revoked in 1993 in an opposition proceeding based on a German prior-art reference called D1. In 1994, Medisense appealed, arguing that D 1 was distinguishable on two grounds. The centerpiece of Medisense's appeal relied on the very sentence in question-the "optionally, but preferably" sentence. Overall, the '636 and '382 specifications were virtually identical. In both, the "optionally, but preferably" sentence and its immediate context were completely identical. Before the EPO, however, Medisense had an incentive to advance the sentence as an important teaching over the D1 reference. Medisense submitted that the "optionally, but preferably" sentence demonstrated that the '382/'636 invention did *not* need a membrane for measuring glucose in blood, whereas the D 1 device had required one.

\*18 Specifically, D1 had disclosed an enzyme electrode usable for glucose and covered by a semipermeable membrane. Before the EPO, Medisense argued that the D1 membrane was essential to the D1 invention. By contrast, Medisense stated that the '382/'636 membrane was merely optional. Medisense relied on the "optionally, but preferably" sentence as follows (TX 311 at AL54151):

10. The above object is solved by a glucose sensor as defined in claim 1 of the patent in suit ['382/'636]. Apart from the important feature of utilizing a ferrocene or ferrocene derivative as mediator, another important difference over D1 resides in that the claimed glucose sensor-contrary to that of D1 which requires a membrane-does not have and **must not** have a semipermeable membrane within the meaning of D1. Contrary to the semipermeable membrane of D1, the **protective membrane optionally** utilized with the glucose sensor of the patent [in] suit is **not** controlling the permeability of the substrate (as set forth above under IV.2), in the membrane of D1 the permeability for the substrate **must** be kept on a low value to achieve a linear relationship between the measures [sic] currency and the substrate concentration in the test solution. Rather, in accordance with column 5, lines 30

to 33 of the patent in suit:

"Optionally, but preferably when being used on live blood, a protective membrane surrounds both the enzyme and the mediator layers, permeable to water and glucose molecules."

See also claim 10 of the patent in suit as granted according to which the sensor electrode has an outermost protective membrane (11) permeable to water and glucose molecules. Finally, see Example 7 in column 10, lines 19 to 26 reporting that by using such a protective membrane the response time did not increase but from 24 to 60 sec. (without membrane) to 36-76 sec. (with membrane). Accordingly, the purpose of the protective membrane of the patent in suit, preferably to be used with *in vivo* measurements, is a safety measurement to prevent any course particles coming off during use but **not** a permeability control for the substrate.

The passage indented the "optionally, but preferably" sentence for emphasis, just as set out above. The bolded words were bolded by Medisense, just as set out above. The foregoing quotation is exactly the way it was made by Medisense in January 1994.

The "safety" purpose stated in the quotation helped to show, it deserves to be said, why a protective membrane was merely "preferred" for live blood, *i.e.*, *in vivo* testing. It was optional in all cases but when placed in a human bloodstream, a membrane was advisable to retain the chemistry aboard the electrode and, thusly, prevent toxic particles from circulating within the patient.

In the same submission (TX 311 at AL54154), Medisense stated that D1 was "strongly teaching away from the subject matter as claimed [in the '382/'636] which not only does not require a membrane but must not have a membrane. In other words, with the claimed subject matter, rather than keeping the permeability for the substrate at a low level, there is free access of the substrate to the electrode without any permeability limitation."

\*19 In May 1995, Medisense further stated in the same EPO appeal, again referring precisely to the "optionally, but preferably" sentence (TX 315):

*It is submitted that this disclosure is unequivocally*

clear. *The protective membrane is optional, however, it is preferred when used on live blood in order to prevent the larger constituents of the blood, in particular erythrocytes from interfering with the electrode sensor.* Furthermore it is said, that said protective membrane should not prevent the glucose molecules from penetration, the membrane is “permeable” to glucose molecules. This teaches the skilled artisan that, whereas the semipermeable membrane of D 1 must be constructed, for example by crosslinking, in such a way that the membrane will in fact control the permeability of the glucose at the required low value, the purpose of the protective membrane in the patent in suit is **not** to control the permeation of the glucose molecules. For this very reason the sensor electrode as claimed does not have (and must not have) a semipermeable membrane in the sense of D1. The fact that the same material (cellulose acetate) may be used both for the semipermeable membrane of D 1 and the protective membrane of the patent in suit is not relevant. The

decisive feature is the modification (crosslinking) of said material to an extent so as to **control** the permeation of the substrate glucose. Finding the semipermeable membranes satisfying the requirements set forth on page 3, lines 24 to 56 of D1 is tedious and involves considerable trial and error work. Reproducibility of such membranes is always a critical factor.

For the immediately quoted passage, italics have been added by this order to draw attention to a particular statement. The bolded words, however, were bolded in the original. Medisense won the EPO appeal, based on the very arguments described above.

The submissions made to the EPO were inconsistent with the submissions made to the PTO in at least two important ways: <sup>FN13</sup>

The PTO was told that the '382 *required* a membrane for use with whole blood and that those skilled in the art would not have understood the “optionally, but preferably” sentence to teach to the contrary.

The EPO was told that under the '382 a protective membrane was merely *preferred* and *not required* when dealing with live blood and specifically quoted the “optionally, but preferably” sentence in support.

The PTO was told that the “optionally, but preferably” sentence would have been understood by skilled artisans as “mere

The EPO was told that the critical sentence was “unequivocally clear” and taught skilled artisans that “the protective membrane [was] optional,

patent phraseology” and not as a “technical teaching.”	however it is preferred when used on live blood....”
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Dr. Sanghera had been much involved in the EPO appeal. He had helped develop the arguments and had even attended the oral argument before the EPO on June 20, 1995. He was completely familiar with the points made in the EPO appeal by Medisense. Dr. Sanghera disclosed all of the EPO submissions to Attorney Pope, who read and understood them.

\*20 Examiner Shay was focused on whether the '382 patent disclosed filterless devices for use with whole blood. This, in truth, was the overriding question. The “optionally, but preferably” sentence was the single roadblock to allowance. Attorney Pope and Dr. Sanghera knew this was so. Both decided to withhold the EPO materials from the PTO. Both knew that Dr. Sanghera's declaration would be submitted to the PTO without disclosing the EPO submissions to the contrary. Both knew that the EPO materials made affirmative statements inconsistent with the declaration and the attorney remarks concerning the '382 sentence in question.

Inasmuch as the EPO submissions centered on the same key sentence at issue in the PTO as well as the key issue before the PTO, a reasonable examiner would have plainly considered the EPO submissions to be highly material, given the contradictory teaching ascribed to the sentence.

3

In the United States, patent prosecutions are *ex parte* and non-public. This means that applicants and their counsel are the only ones able to make presentations to examiners. This one-sidedness persists until an allowance and grant, whereupon the patent is introduced to the public. In all proceedings leading up to a grant, therefore, there is no opponent to state the counter case. Examiners and the integrity of the entire process depend on the candor of counsel and applicants to disclose, if known, material adverse information. The duty of candor is codified at 37 C.F.R. 1.56. At the relevant time, it stated as follows (emphasis added):

§ 1.56. Duty to disclose information material to patentability.

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned.

However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

- (1) prior art cited in search reports of a foreign patent office in a counterpart application, and
- (2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

\*21 (b) *Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and*

- (1) It establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or
- (2) *It refutes, or is inconsistent with, a position the applicant takes in:*

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(i) *Opposing an argument of unpatentability relied on by the Office, or*

(ii) *Asserting an argument of patentability.*

A violation of this rule, if proven in district court, can lead to a bar against enforcement of any claim in the patent. This is the defense of “inequitable conduct.” The Federal Circuit has recently summarized the elements of proof for inequitable conduct in McKesson Info. Solutions, Inc. v. Bridge Med., Inc., 487 F.3d 897, 913 (Fed.Cir.2007):

A patent may be rendered unenforceable for inequitable conduct if an applicant, with intent to mislead or deceive the examiner, fails to disclose material information or submits materially false information to the PTO during prosecution. Digital Control, Inc. v. Charles Mach. Works, 437 F.3d 1309, 1313 (Fed.Cir.2006).

The materiality of information withheld during prosecution may be judged by the “reasonable examiner” standard. See id. at 1316. That is, “[m]ateriality ... embraces any information that a reasonable examiner would substantially likely consider important in deciding whether to allow an application to issue as a patent.” Akron Polymer, 148 F.3d at 1382 (citations omitted). Moreover, “[i]nformation concealed from the PTO may be material even though it would not invalidate the patent.” Li Second Family, 231 F.3d at 1380. “However, a withheld otherwise material [piece of information] is not material for the purposes of inequitable conduct if it is merely cumulative to that information considered by the examiner.” Digital Control, 437 F.3d at 1319. “As this court has previously noted, the scope and content of prior art and what the prior art teaches are questions of fact.” Id.

“The intent element of the offense is ... in the main proven by inferences drawn from facts, with the collection of inferences permitting a confident judgment that deceit has occurred.” Akron Polymer, 148 F.3d at 1384. “However, inequitable conduct requires not intent to withhold, but rather intent to deceive. Intent to deceive cannot be inferred simply from the decision to withhold [information] where the reasons given for the withholding are plausible.” Dayco, 329 F.3d at 1367. In addition, “a finding that particular conduct amounts to ‘gross negligence’ does not of itself

justify an inference of intent to deceive; the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive.” Kingsdown Med. Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867, 876 (Fed.Cir.1988) (en banc in relevant part).

\*22 “The party asserting inequitable conduct must prove a threshold level of materiality and intent by clear and convincing evidence.” Digital Control, 437 F.3d at 1313. “The court must then determine whether the questioned conduct amounts to inequitable conduct by balancing the levels of materiality and intent, ‘with a greater showing of one factor allowing a lesser showing of the other.’” Id. (quoting Union Pac. Res. Co. v. Chesapeake Energy Corp., 236 F.3d 684, 693 (Fed.Cir.2001)). “When, after a trial, the court has made factual findings as to materiality and deceptive intent, those factual findings are reviewed for clear error, and the decision of the ultimate issue of inequitable conduct is reviewed for abuse of discretion.” Digital Control, 437 F.3d at 1313.

#### ATTORNEY POPE

This order will consider the required elements first as to Attorney Pope and then as to Dr. Sanghera.

#### MATERIALITY

[6] Contrary to Attorney Pope and Abbott, the submissions made to the EPO were not only material within the meaning of Rule 56, they were highly material. They were flatly inconsistent with the main point being made by Attorney Pope and Abbott to Examiner Shay. They centered on the precise sentence in question, its meaning, and what it taught. Inconsistency is called out by Rule 56 as a specific indicium of materiality (§ 1.56(b)(2)).

Contrary to Attorney Pope and Abbott, the EPO submissions were not cumulative. While the “optionally but preferably” sentence was, of course, already of record, the supposed issue was what it taught and even whether it constituted a teaching at all insofar as those skilled in the art were concerned. On that score, there was nothing already of record (or being made of record in the PTO) that duplicated the same points made in the EPO appeal or even came close to duplicating them. Thus, the examiner was led to believe that those skilled in the art would have

had no reasonable expectation of success in trying to implement the guidance of the sentence in question by deleting a membrane in whole or live blood. The EPO submissions certainly pointed the other way.

This is unlike the situation where a reference is already before an examiner who can draw his or her own conclusions as to what it teaches and is able to discount spin offered by counsel. See *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1379 (Fed.Cir.2008). Although the key sentence itself was indeed before Examiner Shay, the inquiry had shifted to a point of extrinsic evidence. That is, Examiner Shay had acquiesced to Attorney Pope's request to resort to extrinsic evidence to show that the sentence would have been understood by skilled artisans differently than its words suggested. Having received permission to supply extrinsic evidence, Attorney Pope was duty-bound to present any inconsistent extrinsic information known to him. In the arena of extrinsic evidence, the examiner was unable to fend for himself. He had no way of knowing what, if any, contrary extrinsic information had been left out of the Sanghera declaration. He was completely dependent on Attorney Pope and Dr. Sanghera to fully disclose any extrinsic information, pro and con, known to them on the factual point covered by the submission.

\*23 Abbott contends that most or all of the key passages in the EPO appeal were, in effect, dicta that need not have been raised at all by Medisense before the EPO. Put differently, Medisense could possibly have prevailed in the EPO appeal had it stuck to just one distinction over D 1, namely that D 1 specified a different type of filter than did the '382/'636. It is true that the D1 needed a *diffusion-limiting* filter whereas the '382/'636 referred to a *blood-filtering* membrane, which performed a different function. But the hard fact remains that Medisense did *not* so limit its appeal. It clearly submitted to the EPO that, in addition, the '382/'636 needed no membrane at all, invoking the very "optionally, but preferably" sentence at issue. Regardless of whether or not Medisense *needed* to make the second point in its EPO appeal, Medisense *did* make the point. Since that point was inconsistent with the PTO submission made later, Abbott was obligated to disclose it as part of its extrinsic-fact submission.

In sum, this order finds that the passages quoted above from the EPO submission were material within the meaning of Rule 56, such that their disclosure to the PTO was obligatory.<sup>FN14</sup>

## INTENT

[7] With respect to intent, Attorney Pope read the entire EPO appeal and made a conscious decision to withhold the contradictory material from the PTO. That is not sufficient to prove the intent requirement, of course, but there should be no doubt that conscious withholding occurred. Intent to deceive must be shown. The Court has carefully considered all of the facts and circumstances surrounding the decision to withhold. In this regard, Abbott has asserted the attorney-client privilege. Nonetheless, some direct testimony emerged as to Attorney Pope's rationale for non-disclosure. His stated reason was that the EPO information was cumulative, an argument this order has already solidly rejected. Without a doubt, Attorney Pope knew or should have known that the withheld information would have been highly material to the examiner, given the central question of what, if anything, the "optionally, but preferably" sentence taught those skilled in the art. There was no other information in the PTO record that came close to the clear-cut message of the withheld information.

Despite the insistence by Abbott (and Attorney Pope) during deposition and pretrial that he would *not* be presented as a trial witness, the Court allowed Abbott to reverse field and to present him as a live trial witness. Abbott and Attorney Pope were relieved from this representation due to the seriousness of the misconduct charge and to give Attorney Pope every opportunity to explain his conduct. Attorney Pope did not prove to be a convincing trial witness. To the contrary, his trial explanation for his withholding was not plausible and he was not credible. When, for example, Attorney Pope was shown the EPO appeal language quoting the sentence in question and immediately stating that "[i]t is submitted that this disclosure is unequivocally clear," he testified that he had understood the "unequivocally clear" characterization to refer only to the last six words of the 26-word sentence—that is, to the concluding phrase "permeable to water and glucose molecules" and not to its other twenty words. Sadly, this order must find that Attorney Pope had no plausible reason for consciously withholding the EPO submissions and that he acted with specific intent to deceive Examiner Shay and the PTO. In making this finding, this Court has taken into account the demeanor of Attorney Pope during his trial testimony.

\*24 Attorney Pope testified that his motive was to obtain a strong patent. Therefore, he said he had no motive to conceal and to thus undermine the enforceability of the

patent. This argument conveniently overlooks the fact that he consciously chose to withhold. Counsel who steer a course toward obtaining a strong patent should err on the side of disclosure, not nondisclosure. And, it must be said, after so many rejections over so many years, it seems clear that Abbott's primary goal was to eke out some claim, saving a fight over enforceability for a later day.

Attorney Pope also said that patent prosecutors often write specifications broadly so as to support broad claims, cutting back on their claims as they go along as necessary to avoid the prior art or as is otherwise necessary. Being aware of this alleged practice, he testified that he, therefore, read "optionally, but preferably" as an overblown way for a prior patent prosecutor to have said "optionally, but always." This is unconvincing. *First*, there is no authority for this secret-code theory. Words are supposed to mean what they say. Otherwise, our patent-disclosure system would collapse. *Second*, since the claims of the '382 covered *membraneless* sensors used in blood, as both sides agree, the specification *must* have been sufficient to support the membraneless sensors.<sup>FN15</sup>

Although Abbott has not advanced the point clearly, the Court has considered the possibility that Attorney Pope was confused over the difference between live blood and whole blood. At trial, he stated that he did not appreciate (until recently) that "live blood" referred to *in vivo* tests whereas "whole blood" referred to *in vitro* tests on blood removed from the body. Even if he had thought the two were synonymous, the materiality of the EPO statements would still have been manifest. In some ways, the EPO statements would have been even more material, for those EPO statements represented that a membrane was merely optional when used with blood. At all events, even if the sentence and the EPO statements had said that a membrane was preferred for both live and whole blood, the fact remains that "preferred" does not mean "required," which was a point made in the EPO appeal. In sum, this point of possible confusion offers no excuse.

#### BALANCING

Turning to the final step, this order must determine whether the questioned conduct amounts to inequitable conduct by balancing the levels of materiality and intent, with a greater showing of one factor allowing a lesser showing of the other, as set forth above. In doing so, the undersigned is very mindful that patent prosecutors must make judgment calls about what is and is not material. We must take care to respect their judgments without

second-guessing them and to penalize only clear-cut violations of Rule 56.

The withheld extrinsic evidence here was richly material. And, intent to deceive, not just to withhold, was clearly in the mind of Attorney Pope, hard as it is to so conclude as to a professional. Both showings are strong. The balance is decidedly against Abbott. If concealment of extrinsic information as close to the heart of the prosecution as was involved here is allowed to pass, then we would in effect be issuing licenses to deceive patent examiners in virtually all cases. Having searched for any credible explanation for the conduct (and found none) and having taken into account all possible inferences of good faith (and found none), this order finds and holds that Attorney Pope and Abbott were guilty of inequitable conduct in advancing the Sanghera declaration and attorney remarks without also disclosing the inconsistent EPO submissions as to the meaning of the "optionally, but preferably" sentence. This has been proven by clear and convincing evidence.

#### DR. SANGHERA

\*25 The analysis is largely similar for Dr. Sanghera but differs in some ways from that for Attorney Pope.

#### MATERIALITY

For the reasons stated above, the nondisclosed items were material.

#### INTENT

[8] Here, the intent analysis diverges somewhat from that for Attorney Pope, although it reaches the same conclusion. Once Dr. Sanghera disclosed the inconsistent EPO information to Attorney Pope, he ordinarily would have done all that Rule 56 required. A specific Rule 56 proviso stated that "[i]ndividuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent or inventor." Dr. Sanghera did so. He did disclose the EPO materials based on the very same sentence to Attorney Pope.

[9] The problem is that he then made direct representations to the PTO-representations that were materially misleading by omission. He did not have to take this extra step. Having done so, he was obligated to

avoid intentional deception. His sworn statements to the PTO about the meaning of the “optionally, but preferably” sentence were known by him to be inconsistent with his own company's statements to the EPO-statements he had himself helped craft. A declarant who makes a materially false and misleading statement under oath to the PTO cannot escape a charge of inequitable conduct on the theory that he advised the lawyer that the statement was misleading and why. (In this regard, no claim of good faith reliance on the advice of counsel was raised by Dr. Sanghera, a step that would have waived any assertion of the privilege.) In sum, given the fact that Dr. Sanghera made a positive submission to the PTO, he was himself duty-bound to avoid making an intentionally misleading submission, whether or not he told Attorney Pope about the inconsistency.

Although Abbott has not raised it, the Court has, on its own, considered the possibility that Dr. Sanghera somehow believed that Attorney Pope would disclose the EPO material in some other way and, thus, there was not a necessity for his declaration to do so. Dr. Sanghera testified at trial at Abbott's behest (despite the fact that much trial time was earlier spent on video excerpts from his deposition). His trial testimony was clear and convincing that he affirmatively participated in the group discussion *not* to disclose the EPO submission, *i.e.*, that he knew all along that no one was going to disclose the EPO submissions (Tr. 757-58, 774, 776-78). As a trial witness, it must be said that Dr. Sanghera was impeached on substantive points with his prior inconsistent statements and exhibited an unconvincing demeanor (*e.g.*, Tr. 764-67, 772-73).<sup>FN16</sup>

At trial, the only explanation Dr. Sanghera gave for his nondisclosure of the EPO proceedings and the arguments made by Medisense therein was that both he and Attorney Pope thought that they were all irrelevant (Tr. 777:23-778:10):

Q. It's your position, is it not, Dr. Sanghera, that you had no responsibility to disclose to the U.S. Patent and Trademark Office anything about the European Patent Office proceedings?

\*26 A. It was my responsibility to disclose to the U.S. Patent Office everything that we deemed as a team, the technical people, the Abbott counsel, that was relevant to that case for the U.S. patent office. I don't know if that answers your question, but ...

Q. But you didn't disclose the information, correct?

A. We didn't disclose lots of nonrelevant information.

Q. And in particular, you did not disclose the European Patent Office proceedings to the U.S. Patent Office?

A. We did not disclose those, no.

As stated, however, the unambiguous and clear-cut statements made to the EPO were clearly relevant to the only issue before Examiner Shay, namely whether the “optionally, but preferably” sentence was a teaching and, if so, what it taught. It plainly should have been disclosed to Examiner Shay for his independent consideration.

Dr. Sanghera testified that he did think the statements made to the EPO and PTO were inconsistent. According to Dr. Sanghera, the statements made to the EPO were specifically directed at distinguishing the D1 reference on the sole issue of whether or not the '382/636 patent required a diffusion-limiting membrane—a point not at issue with the '551 patent. As Dr. Sanghera stated (Tr. 777):

The European proceedings revolved around the use of a diffusion limiting membrane because we were making arguments about novelty and inventiveness over the La Roche prior art, and we discussed the first chemistry and the, therefore the lack of a requirement of a diffusion-limiting membrane. This the U.S. case. We were talking about blood separation membranes and filters and the two are completely separate pieces of technology.

Nonetheless, the statements made to the EPO regarding the '636 patent plainly went beyond this point of distinction and submitted that it was “unequivocally clear” that the '382/636 needed no membrane at all for use with blood. Whether or not Medisense *needed* to make the point to the EPO, it *did* make the point. Dr. Sanghera knew the point had been made. His effort at trial to excise that part of the EPO proceeding and to pretend it never happened was disingenuous.

Taking into account all possible inferences of good faith, this order concludes that Dr. Gordon Sanghera had no plausible reason for concealing the inconsistent EPO submissions and that he consciously made sworn statements to the EPO that were deliberately misleading



by reason of the omission of the inconsistent EPO submissions. His unconvincing trial demeanor has been a factor in this determination.

### BALANCING

Once again, both materiality and intent have been proven on the strong end of the scale, so the overall balance is decidedly against Abbott and Dr. Sanghera. And, it should be said that sworn statements to the PTO ought to be regarded with a reasonable degree of reverence and candor rather than as an opportunity to tailor-make convenient extrinsic "facts" to assuage a key point of concern to the examiner.

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\*27 This Court is well aware that inequitable conduct has become a knee-jerk and often-abused response by those accused of patent infringement. Judges ought to view such defenses with skepticism, as has Judge Rader in a recent dissent. See *Aventis Pharma. v. Amphastar*, 525 F.3d 1334, 1349 (Fed.Cir.2008) (Rader, J.). We should insist on every inch of the clear-and-convincing standard. Here, however, that standard has been met. The present defense is not an abuse far from it. If the conduct here proven were blessed, then the duty to provide inconsistent information under Rule 56 would be a dead letter.

### INVALIDITY CONCLUDED

[10] To complete the obviousness analysis, this order now resumes with the remaining limitations, *i.e.*, all limitations other than the no-membrane analysis. In brief, this order finds that the differences between the other limitations and the prior art were paper thin and readily apparent to skilled artisans at the time of the alleged invention.

### CLAIM 1

Claim 1 is the only independent claim of the '551 patent. It recited (col.13:29-17):

1. A single use disposable electrode strip for attachment to the signal readout circuitry of a sensor to detect a current representative of the concentration of a compound in a drop of a whole blood sample comprising:

a) an elongated support having a substantially flat,

planar surface, adapted for releasable attachment to said readout circuitry;

b) a first conductor extending along said surface and comprising a conductive element for connection to said readout circuitry;

c) an active electrode on said strip in electrical contact with said first conductor and positioned to contact said whole blood sample;

d) a second conductor extending along said surface comprising a conductive element for connection to said readout circuitry;

e) a reference counterelectrode in electrical contact with said second conductor and positioned to contact said whole blood sample.

wherein said active electrode is configured to be exposed to said whole blood sample without an intervening membrane or other whole blood filtering membrane

and is formed by coating a portion of the first conductor with a mixture of or layers of an enzyme which catalyzes a redox reaction with said compound in whole blood and a mediator compound which transfers electrons from said redox reaction to said first conductor

to create a current representative of the concentration of said compound in said whole blood sample

and wherein said active electrode which is formed on a portion of said conductor is not in electrical contact with said reference counterelectrode but these electrodes are so dimensioned and positioned that they can be simultaneously completely covered by a single drop of whole blood such that this drop provides an electrical path between these electrodes to support said current representative of the concentration of said compound in said whole blood sample.

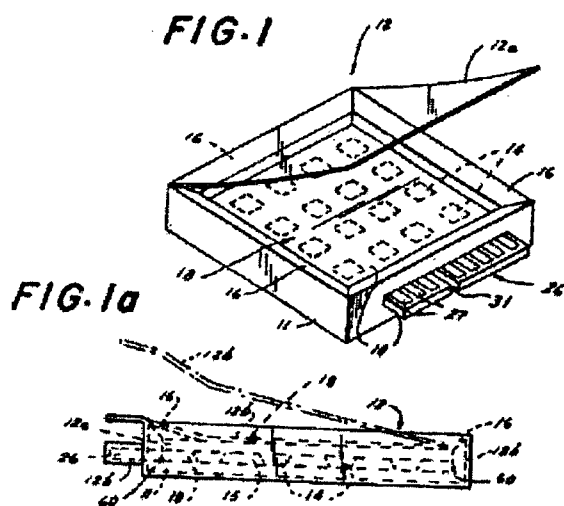
\*28 These paragraphs are now considered in turn.

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A single use disposable electrode strip for attachment to the signal readout circuitry of a sensor to detect a

current representative of the concentration of a compound in a drop of a whole blood sample comprising:

a) an elongated support having a substantially flat, planar surface, adapted for releasable attachment to said readout circuitry;



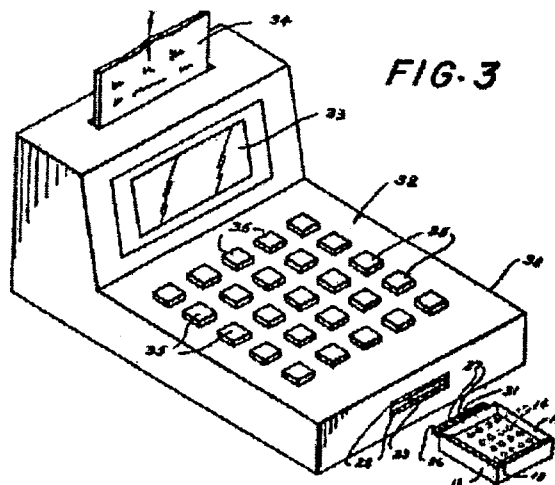
The cartridge 10 shown in Figure 1 (an alternative design is shown in Figure 1 a) contained a matrix of sensors 14. Users would place their finger above the sensor matrix of the circuitry in cartridge 10 and dispense a drop of blood. The cartridge 10 could then be connected to the readout device shown in Figure 3 through a socket connection, and the results of the test could be read out across screen 33. After the test was complete, the user could take out the cartridge and throw it away. The cartridge was flat and elongated so as to more readily allow the user to connect and remove it from the readout device. The ' 410 patent further described the use of enzyme electrodes for detection of glucose in blood.

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b) a first conductor extending along said surface and comprising a conductive element for connection to said readout circuitry;

This claim limitation merely referred to the actual conductive wires that connect the electrodes (where the electrochemistry occurs) to the readout circuitry. The wires carried electricity and simply allowed current to flow to the readout circuitry. Both the '410 and '382

U.S. Patent No. 4,225,410 (Pace) taught the use of a disposable-electrode cartridge that attached to readout circuitry to measure the levels of a target substance in a solution-e.g., glucose in blood-by detecting current. The figures below are from the '410 patent.



patents readily disclosed this limitation. For example, the '410 specification stated (col.7:37-43):

The interconnectors each terminate in an electrical connection projecting from the end of the chip which is adapted to mate with a snap-in electrical connector disposed in a slot of [the readout circuitry]. The connection of the chip overhangs the tray ... and includes a slot for keying into connector of [the readout circuitry].

Likewise, the '382 patent disclosed conductive wires connecting an electrode to readout circuitry (col.8:35). It was elementary that no circuit could be completed without a conductor between the readout circuitry and the electrode.

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c) an active electrode on said strip in electrical contact with said first conductor and positioned to contact said whole blood sample;

The term "an active electrode" has been construed herein to mean "an electrode that incorporates conductive material, and a mixture of or layers of an enzyme and

mediator.”The phrase “in electrical contact with said first conductor” was construed to mean “such that the active electrode is connected or positioned in such a way that electricity can flow between the active electrode and the first conductor.”As stated above, the active electrode was essentially where all of the actual electrochemistry occurs in the sensor. A mediator and enzyme covered the electrode and collectively act to transfer electrons between the glucose molecules in blood to the active electrode to the conductors. A faster-acting chemistry that generated more electrons more quickly was, in effect, a principal invention in the '382 patent. The '382 specification recited (col.4:8-12):

\*29 In a particularly valuable form of the invention, however, the electrode comprises a carbon core, a layer of ferrocene or a ferrocene derivative at a surface thereof and a layer of glucose oxidase or glucose dehydrogenase at the surface of the ferrocene layer.

The '382 specification, among others, plainly already revealed active electrodes: a conductive material (*i.e.*, a carbon core), an enzyme (*i.e.*, glucose oxidase), and a mediator (*i.e.*, ferrocene).

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d) a second conductor extending along said surface comprising a conductive element for concentration to said readout circuitry;

For the same reasons set forth under element (b), this limitation was disclosed in both the '410 and '382 patents.

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e) a reference counterelectrode in electrical contact with said second conductor and positioned to contact said whole blood sample;

At its simplest level, this limitation supplied the completion of the electrical circuit, the blood itself being the last link in the electrical path. There were no chemicals on the reference counterelectrode. Judge Jenkins construed the term “a reference counterelectrode in electrical contact with said second conductor and positioned to contact said whole blood sample” as follows:

an electrode that (1) is used to complete an electrical

circuit with the active electrode during the glucose measurement; (2) is positioned or connected in such a way that electricity can flow between the second conductor and the electrode; (3) has a known potential relative to a standard; and (4) maintains its potential with only insignificant variation during the measurement.

The reference counterelectrode must thus meet four separate requirements. The first two requirements relate to the electrode's function to “counter” the active electrode and complete the circuit. The last two requirements relate to the electrode's function to serve as a “reference” to the active electrode by maintaining a known potential relative to a standard-*e.g.*, ground. The '551 specification described the reference electrode as a “coating applied to the elongated support ... formed by screen printing” and consisting of a silver-silver chloride layer (Ag/AgCl) (col. 2:6-11 and col. 4:57).

Although both the '410 and '382 patents disclosed the use of reference electrodes and counter electrodes, they only did so in the context of a *three*-electrode configuration: one electrode served as the active electrode, one electrode served as the counter, and one electrode served as the reference. For instance, the '382 patent stated that the “[active] electrode was connected to a potentiostat, together with a suitable counter electrode and calomel reference electrode and placed in a solution containing glucose” (col. 8:35-38). Accordingly, in the '410 and '382 patents there was no single electrode that served as both the reference and counter to the active electrode.

\*30 During the earlier stages of prosecution, Medisense argued that the two-electrode configuration in the '551 specification was a point of novelty over the prior art. Specifically, in an information disclosure statement received by the PTO on June 30, 1988, Medisense contended (TX 5):

Claim 1 now features a two-electrode strip in which the active current-measuring electrode is an enzyme deposit on the same strip that includes a second reference electrode. This two-electrode strip is far more convenient, and cheaper to make, than the prior art current-measuring devices. None of those devices discloses a simple dry two-electrode strip and nothing in those references would render such a simple strip obvious.

In the subsequent office action signed on October 28,

1988, Examiner Shay rejected this point of novelty:

ASAH, Kurita, Miyawaki, MITS, Huet et al, Smith et al, a Fromowitz et al, Takinishi et al, Brown et al, and Higgins et al all teach various electrode and/or amplifies [sic] configurations.

In fact, two-electrode configurations were common in the prior art. For instance, the Wingard reference (published in February 1983) disclosed a sensor with a platinum active electrode (*i.e.*, the electrode coated with the enzyme) connected to a reference counterelectrode. As with the '551 patent, the reference counterelectrode was silver-silver chloride (Ag/AgCl). Wingard stated (TX 480):

The basic design of the amperometric glucose oxidase-oxygen electrode sensor for in vivo glucose determination is essentially that of Updike and Hick.... In the oxygen electrode an external potential is applied to hold the platinum cathode 0.6-.0.8V more negative than the silver-silver chloride anode and thus to produce a current that is related to the concentration of oxygen that reaches the platinum surface.

Defendants cited to other prior art references (including an undergraduate textbook) that contained similar disclosures. At trial, Dr. Turner persuasively testified that a person having ordinary skill in the art would have been motivated to combine the teachings of two-electrode systems with the sensors described in the '382 and '410 patents. This is not surprising given the strong overlap between the subject matter of the references.

Abbott argues that defendants have failed to show that the prior art cited aligns with Judge Jenkins' claim construction for a reference counterelectrode. Not so. As stated, the reference counterelectrode must primarily serve two functions: (i) to provide a reference voltage for the active electrode and (ii) to counter the active electrode and complete the circuit. It is clear from the language cited above from Wingard that its electrode served as a reference voltage to the active electrode—"an external potential is applied to hold the platinum cathode 0.6-.0.8V more negative than the silver-silver chloride anode."As to the second function, the prerequisite to serve as a counter electrode was that the same current pass through it and the active electrode. The counter electrode (and the blood added by the user) collectively act to close the circuit so that current can thereby flow. The electrode in the sensor circuit disclosed in Wingard met this criterion. Current was passed from it to the active electrode to complete the

circuit ("amperometric" as stated in Wingard).<sup>FN17</sup>

\*31 This order therefore finds that "a reference counterelectrode in electrical contact with said second conductor and positioned to contact said whole blood sample" was disclosed in Wingard. This order further finds that a person having ordinary skill in the art would have had a motivation to combine Wingard with the teachings of the '382 and '410 patents.

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wherein said active electrode is configured to be exposed to said whole blood sample without an intervening membrane or other whole blood filtering membrane;

For the reasons set forth above and which will not be reviewed again here, the no-membrane limitation was taught by the '382 patent (col.4:63-66).

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and is formed by coating a portion of the first conductor with a mixture of or layers of an enzyme which catalyzes a redox reaction with said compound in whole blood and a mediator compound which transfers electrons from said redox reaction to said first conductor;

For the same reasons detailed in the section above relating to the active electrode, this limitation was disclosed by the prior art-in particular, the '382 patent.

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to create a current representative of the concentration of said compound in said whole blood sample;

The '382 expressly taught this limitation. It recited (col. 8:41-42), "[a] current is produced which is proportional to the glucose concentration."This current was then measured and subsequently extrapolated to yield a measure of the amount of glucose in the target blood sample.

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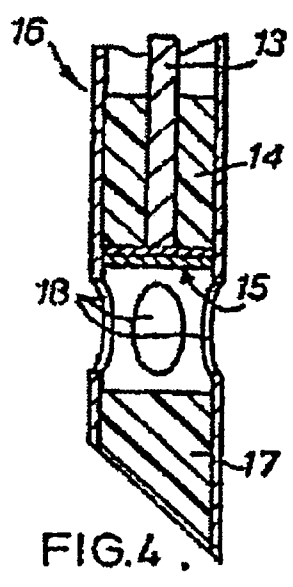
and wherein said active electrode which is formed on a

portion of said conductor is not in electrical contact with said reference counterelectrode but these electrodes are so dimensioned and positioned that they can be simultaneously completely covered by a single drop of whole blood such that this drop provides an electrical path between these electrodes to support said current representative of the concentration of said compound in said whole blood sample.

This limitation required that the active electrode and reference counter electrode be positioned in such a manner so that a single drop of blood could cover both. The two electrodes, however, could not be in electrical

contact with one another. As described above, the '410 patent disclosed a disposable cartridge comprising a matrix of sensors. The user would prick their finger and place a drop of blood over the cartridge. In so doing, the sensors in the matrix would be covered by the user's single drop of blood.

In addition, one of the preferred embodiments disclosed in the '382 patent was a needle electrode that could be used for tests within the body-*i.e.*, *in vivo*. This embodiment was as follows:



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The user could prick themselves with the needle 16. Blood would then enter through the side windows 18 and come into contact with the electrodes in the device. In this way, current was generated and could subsequently be measured. In the same fashion, because the needle electrode was so small, the user could have easily applied a drop of blood to the side windows 18 outside of the body instead of placing the needle in the body. Dr. Turner testified that if a drop of blood were applied in this manner, the device would still function properly. Abbott has offered no evidence to the contrary.

#### CLAIM 2

\*32 Claim 2 stated: "The electrode strip of claim 1 wherein the compound is glucose and the enzyme is

glucose oxidase or glucose dehydrogenase" (col.14:18-20). As previously discussed, there were multiple references and teachings in the '382 patent to testing glucose levels in blood using a glucose oxidase or glucose dehydrogenase enzyme (col.1:66-68) ("The enzyme is therefore preferably a glucose oxidase, or possibly a glucose dehydrogenase, for example a bacterial glucose dehydrogenase.")

#### CLAIM 3

Claim 3 stated: "The electrode strip of claim 1 wherein said conductive elements of the first and second conductors for connection to the readout circuitry are positioned toward one end of said elongated support and said active electrode and reference counterelectrode are positioned remote from said end" (col.14:21-25). Claim 3

required that the active electrode and reference counterelectrode both be positioned on the opposite end of the strip from the portion of the conductors that connect to the readout circuitry. As illustrated in Figure 1a of the '410 patent (shown above), the sensors 14 were placed on one end of the cartridge while the electrical connections 27 for the readout circuitry were at the other end. The '410 patent thus disclosed this limitation.

#### CLAIM 4

Claim 4 stated: "The electrode strip of claim 1 wherein said conductive elements of said first and second conductors are configured to allow reasonable attachment with a socket on a read out meter which carries said signal readout circuitry" (col.14:26-29). For the same reasons set forth above, the '410 patent disclosed this further limitation to claim 1 (col.7:37-43).

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[11][12] Under 35 U.S.C. 103, a patent may not be obtained if the differences between the claimed invention and the prior art would have been "obvious" at the time the invention was made to a person having ordinary skill in the art to which the patent is directed. The Supreme Court recently addressed the issue of obviousness in *KSR Int'l Co. v. Teleflex Inc.*, ---U.S. ---, 127 S.Ct. 1727, 167 L.Ed.2d 705 (2007). There, the Supreme Court reversed the Federal Circuit's rejection of summary judgment of obviousness. In so doing, the Supreme Court emphasized that the obviousness inquiry is pragmatic and flexible: "A person of ordinary skill is also a person of ordinary creativity, not an automaton." *Id.* at 1742. The Supreme Court further stressed that if a person having ordinary skill in the art would have been able to implement a predictable variation of the prior art to yield the claimed invention, Section 103 would likely bar patentability. As the Supreme Court stated in *KSR Int'l Co.*, 127 S.Ct. at 1740-41.:

Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.

\*33 Where there is "a design need or market pressure" to

solve a particular problem and there are only a discrete number of predictable solutions that led to the anticipated success of the patent, "[the patent] is likely the product not of innovation but of ordinary skill and common sense." *Id.* at 1742.

Under this practical approach, this order finds all asserted claims of the ' 551 patent to be obvious in light of the prior art. All but one limitation was disclosed expressly by the '382 and/or '441 patents. The remaining limitation, implementing a two-electrode configuration, was well known prior to the '551 patent's priority date. Each reference relied on above to show obviousness was expressly aimed at the specific subject matter covered by the ' 551 patent-i.e., construction of electrochemical sensors that could be used to measure glucose levels in blood. One skilled in the art would therefore have readily thought to combine these references.

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The Federal Circuit has held that "secondary considerations, when present, must be considered in determining obviousness." *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 667 (Fed.Cir.2000); see also *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed.Cir.1983) ("evidence of secondary consideration may often be the most probative and cogent evidence in the record. It may often establish that an invention appearing to have been obvious in light of the prior art was not. It is to be considered as part of all the evidence, not just when the decisionmaker remains in doubt after reviewing the art"). Originally, three factors were regarded as secondary considerations: commercial success, long-felt but unsolved needs, and failure of others. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966). Since then, several additional factors have been taken into account by the Federal Circuit, including: copying by others, praise of the invention, unexpected results, disbelief of experts, general skepticism of those in the art, commercial acquiescence, and simultaneous development.<sup>FN18</sup>

Evidence of secondary considerations, however, only has probative value where there is "a nexus between the merits of the claimed invention and the secondary consideration." *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 306 n. 42 (Fed.Cir.1985). The burden of proof as to this connection or nexus resides with the patentee. *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392

(Fed.Cir.1988).

Here, Abbott has primarily offered three grounds to support its showing of secondary considerations: (i) the commercial success of the Medisense- Abbott-Exactech product; (ii) a long-felt need for the Exactech product; and (iii) an alleged attempt to design around the '551 patent' by a competitor.

Steven Scott, the former project manager for Abbott's Exactech, testified that over one billion test strips were sold over the lifetime of the Exactech product. He further testified that at the time the Exactech was released in September 1987, no other competitor had an electrochemical strip on the market. According to Abbott, before the Exactech product was released, diabetic patients had to use colormetric test strips that were far less convenient because they required the user to follow precise instructions that could easily be botched to produce inaccurate results.

\*34 This order assumes all of Abbott's representations regarding the Exactech product were true. Nonetheless, Abbott has failed to show that the success of the Exactech product was attributable to the '551 patent'. Significantly, the Exactech product was released in September 1987- two years after the '382 patent' issued and over seven years before the '551 application was filed. Both Dr. Sanghera and Scott testified that Medisense marked the Exactech product packaging with the '382 patent' before and after the '551 patent' issued. Abbott's expert, Dr. Jay Johnson, admitted that the Exactech product was covered by claim 1 of the '382 patent' (Tr. 552:15-18):

Q: But all these limitations that you see in the Claim 1 of the Higgins ' 382 patent are met by the Exactech strip. We just walked through them.

A. Yes.

Dr. Sanghera acknowledged on multiple occasions the novelty behind the invention of the '382 patent-an invention for which Abbott received the full term of a patent. Nothing on the record demonstrates that the purported novelty behind the '551 patent' contributed to the success of the Exactech product. Abbott has therefore failed to show the requisite nexus between the claims of the '551 patent' and the Exactech product. The record instead demonstrates that the success of the Exactech product was more attributable to the fast-working chemistry disclosed in the '382 patent'.

Abbott next proffers the testimony of James McCann (Genetics International's former founder) to support its showing of secondary considerations. McCann is currently employed at Cambridge Sensors Ltd., a company also engaged in the manufacture of glucose sensors. At his deposition, McCann testified that Cambridge Sensors redesigned one of its sensors in an attempt to design around the '551 patent' by placing a mesh layer on the active electrode and moving the enzyme above the mesh layer. He stated (McCann Dep. 140-41):

Q. Was that version created in an effort to design around the '551 patent'?

A. Yes.

Q. Okay you made that redesign in an effort to avoid the claims of the '551?

A. Yes.

It is not clear exactly how much weight McCann's testimony should be given. Both parties have been unable to cite to any decision where such evidence was considered or discounted when assessing secondary considerations. Cambridge Sensor's design-around efforts could show nothing more than its desire to avoid the threat of litigation, meaning it would shed little light on the validity or novelty of the '551 patent'. On the other hand, the redesign may be relevant to show that the industry regarded the '551 patent' as likely valid and enforceable. In any case, however, this evidence by itself is not enough to tip the scales. Given the absence of other factors weighing in favor of secondary considerations, it would be a far leap to preclude a finding of obviousness based on such scant evidence.

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\*35 [13] Many inventions seem obvious after the fact but that, of course, is not the test for invalidity:

It is difficult but necessary that the decision maker forget what he or she has been taught at trial about the claimed invention and cast the mind back to the time the invention was made (often as here many years), to occupy the mind of one skilled in the art who is presented only with the references, and who is normally

guided by the then-accepted wisdom in the art.

W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 1553 (Fed.Cir.1983).

[14] A patent is presumed valid, and the burden of establishing invalidity as to any claim of a patent rests upon the party asserting such invalidity. 35 U.S.C. 282. Invalidity must be proven by clear and convincing evidence. Although not susceptible to precise definition, "clear and convincing" evidence has been described as evidence which produces in the mind of the trier of fact "an abiding conviction that the truth of [the] factual contentions are highly probable." Buildex, Inc. v. Kason Indus., Inc., 849 F.2d 1461, 1463 (Fed.Cir.1988).

Viewing the prior art in whole, one skilled in the art would have deemed the ' 551 patent as a necessary and logical result of the teachings already a part of the public domain. The main claim elements at issue in trial were the deletion of the membrane and the implementation of a two-electrode system. On the former element, the '382 patent expressly disclosed that a membrane was optional but preferred on live blood. It was *not* required. On the latter element, two-electrode configurations were common and even disclosed in an undergraduate electrochemistry textbook. The remaining elements of claims 1-4 were not novel either; they were readily taught by the prior art. Those in the field would have appreciated that combining these elements was a predictable variation on the prior art.

#### WRITTEN DESCRIPTION

[15][16][17] Pursuant to 35 U.S.C. 112 ¶ 1, a patent specification is required to "contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." The written-description requirement and its corollary, the new-matter prohibition of 35 U.S.C. 132, serve to ensure that the patent applicant was in full possession of the claimed subject matter at the time the original application was filed. "To satisfy the written description requirement the disclosure of the prior application must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, [the inventor] was in possession of the invention." PowerOasis, Inc. v. T-Mobile USA, Inc., 522 F.3d 1299, 1306 (Fed.Cir.2008) (emphasis in original).

Any disclosure relied on must be actual or inherent. In order for a disclosure to be inherent, "the missing descriptive matter must necessarily be present in the [original] application's specification such that one skilled in the art would recognize such disclosure." Tronzo v. Biomet, Inc., 156 F.3d 1154, 1159 (Fed.Cir.1998).

\*36 Defendants contend that the '551 specification fails to comport with the written-description requirement. In particular, defendants argue there was no adequate written description in the '551 specification to support the claim limitation "without an intervening membrane or other whole blood filtering membrane." It is true that the no-membrane idea was not expressly called out in the specification and, indeed, was at most lurking in its penumbra. Nonetheless, the relevant inquiry is whether those skilled in the art would have thought the inventors were in possession of an electrochemical sensor without a membrane for use in whole blood as of May 1983. Contrary to the defense, this order finds that those skilled in the art would have recognized such disclosure in the '551 specification. Plaintiff's Expert Johnson gave a detailed description of an embodiment disclosed in the '551 specification describing a membraneless sensor that could be used in whole blood (col.8:27-52). On direct examination, defense Expert Turner admitted that the '551 disclosed a glucose sensor without a membrane that could be used in blood (Tr. 249):

Q. Did you find anything in the '551 patent that specially adapted that sensor disclosed? And we've looked at Claim 1, but claims 1 through 4, is there anything in those claims that shows that these sensors are specially adapted for use with blood?

A. No. The '551 describes the same structures and approach, effectively, as here. *So the '551 could be used with and without a membrane;* the '382 could be used with and without a membrane.

Accordingly, this order finds that the '551 specification adequately disclosed the contested limitation.

That said, it is certainly true that the '382 specification had already announced a description of a glucose sensor without a membrane for use in blood that was as good or better. After all, the '382 specification expressly recited, "[o]ptionally, but preferably when being used on live blood, a protective membrane surrounds both the enzyme and the mediator layers ..." (col.4:63-65). The only affirmative passage in the '551 specification on this



specific point stated (col.6:66-7:2):

Although the enzyme electrode should be in electrical contact with the liquid, it may be found valuable to exclude the sensor from interfering contact with larger molecules or tissue fluid components. This can be done by a covering or surrounding membrane, depending on the electrode geometry.

As such, while the '551 patent adequately disclosed the membraneless limitation, it only did so after such disclosure in the '382 patent.

### CONCLUSION

For the foregoing reasons, claims 1-4 are invalid as obvious and U.S. Patent No. 5,820,551 is unenforceable by reason of inequitable conduct in procuring its allowance. This order concludes all proceedings in the district court on the merits of the '551 claims. Before a Rule 54(b) judgment is entered, counsel shall advise the Court whether any further proceedings are needed. Please do so by **NOON ON JULY 2, 2008**.

#### \*37 IT IS SO ORDERED.

FN1. Therasense is a wholly-owned subsidiary of Abbott Laboratories, and the exclusive owner of two of the other patents in suit.

FN2. Dr. Anthony Turner, the defense invalidity expert, was also involved in the initial research efforts that took place in the United Kingdom. He joined Dr. Higgins' team at the University of Cranfield in 1981 as a research officer. He later became a project director in 1983 after Genetics International began working with the group. Dr. Gordon Sanghera, as stated in more detail below, was also involved with the research efforts by the two groups.

FN3. Live blood is inside the body and can only be tested *in vivo*. Whole blood is blood with all its constituent parts and can be in or outside the body. *In vitro* refers to tests outside the body, which must, in our context, be performed on whole blood, not live blood.

FN4. The word substrate is used in the '551 patent in a second sense, namely to describe the

base on which the electrode is formed (*see, e.g.*, col. 2:27, 33; col. 3:23). This is a second, different meaning.

FN5. Drs. Hill, Higgins, and Plotkin are listed as the inventors on the '382 patent. In context, McCann and Drs. Hill, Higgins, and Davis are listed as inventors on the '551 patent.

FN6. U.S. Patent No. 4,388,166 (Suzuki) issued on June 14, 1983, and was filed on May 15, 1982. Although the various examples of electrochemical glucose sensors recited in the '166 all included some type of membrane, the '166 specification did expressly recognize that a glucose sensor (for blood) could be constructed *without* any membrane as long as the user could tolerate variations in measured values. The specification stated (col.1:31-43) (emphasis added):

In the prior art electrochemical measuring apparatus, an enzyme electrode provided with a semipermeable-membrane indeed allows for a stable measurement, but the measurement takes a long time due to slow response. On the other hand, an enzyme electrode *free of a semipermeable membrane* makes a quick response, but has the drawback that measurement is accompanied with noise, resulting in noticeable variations in the measured values. Whether provided with a semipermeable membrane or not, the known enzyme electrode has the drawback that it loses stability during lengthy application.

The specification went on to explain that prior art glucose sensors (with and without membranes) could be used in "blood, serum, or urine," but with decreased sensitivity (col.1:48).

FN7. Abbott concedes that, for example, the D1 reference in the EPO appeal described below had a response time of five to fifteen minutes.

FN8. The parties agree that in May 1983, a person of ordinary skill in the art would have had a doctoral degree or postgraduate experience working toward a Ph.D. Such a person would also have had some level of experience in

actually constructing electrochemical sensors or would at least be familiar with them.

FN9. This order also rejects Abbott's idea that the word "optionally" referred to use of a membrane as an alternative in lieu of some other type of whole-blood filtering member.

FN10. Interestingly, the Exactech product (the same product Abbott contends embodies the '551 product for secondary consideration purposes) does *not* use GRAPHOIL as its electrode material, meaning whatever purported benefit that was captured as a result of the GRAPHOIL was not present in the Exactech product. In fact, the Exactech product used carbon paste as its electrode material-the same material disclosed in the '382 patent (Tr. 780).

FN11. Similarly, at the closing argument, Abbott's counsel argued that the '551 patent disclosed a method for placing the working chemistry onto the substrate-*i.e.*, screen printing-that may have contributed to the purported success of the Exactech product. The only evidence on the record pertaining to this subject is the testimony of Dr. Sanghera, who stated that the Exactech's electrode was screen printed (Tr. 788). Other than that, there is no evidence indicating that screen printing helped eliminate the need for a membrane or that it was somehow novel over the prior art. Accordingly, counsel's argument is rejected.

FN12. The Suzuki '166 patent, however, which had expressly discussed deleting the membrane in blood tests, was *not* included in the Sanghera declaration (*see* note 6, supra). This order assumes that Dr. Sanghera was unaware of Suzuki.

FN13. Defendants have further made a plausible case that the two submissions were also inconsistent as to their use of Example 8 (Example 7 in the '636). This inconsistency requires extended argument to develop and, while plausible, is not as facially and directly inconsistent as the above two points of conflict. This order does not rely on the alleged Example 8 inconsistencies.

FN14. The defense presented an experienced patent attorney and former examiner, Thomas Smegal, to explain why the EPO items were material. Abbott did not present a counter expert.

FN15. Of course, it is true, as Abbott states, that specifications teach and claims claim. SRI Int'l. v. Matsushita Elec. Corp., 775 F.2d 1107, 1121 n. 14 (Fed.Cir.1985) (*en banc*). Still, the specification must support the claims.

FN16. Contrary to his *trial* testimony, at his *deposition* Dr. Sanghera tried to distance himself from the decision of what was disclosed to the PTO by repeatedly stating that he merely turned over to counsel all relevant information and let counsel decide what would be disclosed (Sanghera Dep. 60, 62, 360-61).

FN17. In three-electrode configurations, no current would pass through the reference electrode. All the current would be shared between the active electrode and the counter electrode. The reference electrode was merely used to apply a known potential to bias the circuit. Where the parasitic resistance of the closed circuit or the current running through the closed circuit was small, however, a two-electrode configuration was more tolerable because of the small (and unwanted) voltage drop that would result from the parasitic resistance (*i.e.*, Ohm's Law, voltage equals the product of current and resistance). The determination of whether a two-versus-three-electrode system was used therefore centered on whether the system could handle the decreased accuracy of a two-electrode configuration (TX 316).

FN18. *See Ecolochem, Inc. v. Southern California Edison Co.*, 227 F.3d 1361, 1379-80 (Fed.Cir.2000); *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 885 (Fed.Cir.1998); *Advanced Display Systems v. Kent State Univ.*, 212 F.3d 1272, 1285-85 (Fed.Cir.2000); *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1144 (Fed.Cir.1985); *EWP Corp. v. Reliance Universal, Inc.*, 755 F.2d 898, 907 (Fed.Cir.1985).

N.D.Cal., 2008.  
Therasense, Inc. v. Becton, Dickinson and Co.

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# **EXHIBIT 2**



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### Judge Kills IP Claim, Blames Lawyer

Zusha Elinson  
06-26-2008

Finding that an in-house lawyer tried to deceive the U.S. Patent and Trademark Office, a federal judge ruled Abbott Laboratories' patent unenforceable.

Illinois-based Abbott had sued Bayer and other pharmaceutical makers over a patent on strips used by diabetics to test their blood. Judge William Alsup of the Northern District of California made a finding of inequitable conduct on Tuesday, saying that the patent in question had been obtained only because Abbott attorney Lawrence Pope had withheld key information in connection with the patent filing.

"The withheld evidence here was richly material," Alsup wrote in the 54-page ruling. "And, intent to deceive, not just to withhold, was clearly in the mind of attorney Pope, hard as it is to so conclude as to a professional."

Pope declined to comment, referring questions to Abbott Labs, whose spokesperson did not return calls and an e-mail for comment.

Patent defendants often attempt an inequitable conduct argument but are rarely successful, said Michael Barclay, a patent litigator from Wilson Sonsini Goodrich & Rosati who was not involved in the case.

"You have to prove that something that happened in the patent office was improper, and not only that, but it has to be done with a high level of bad intent," Barclay said. "It's very hard to prove that level of intent."

Beginning in 2004, Abbott sued Bayer, Becton, Dickinson and Company and Roche for infringing on its patents with their disposable test strip products. Roche settled on the eve of the bench trial, which began May 27, while Bayer and Becton stayed in, represented by Morrison & Foerster and Ropes & Gray, respectively.

Rachel Krevans, who led the trial team for MoFo with Wesley Overson, declined to comment publicly, but Bayer spokeswoman Susan Yarin said the company was pleased.

"Obviously, we won, and we're gratified by the decision of the court," she said.

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A Ropes & Gray lawyer on the case did not return phone calls for comment. A spokesman for Baker Botts, which represented Abbott Labs, referred questions to the company.

With Tuesday's ruling, Bayer is now in the clear, having previously invalidated another Abbott patent on summary judgment.

Becton still faces a trial with respect to another related Abbott patent.

The patent at issue in Alsup's ruling, known as the '551 patent, was rejected 12 times by the patent office over a period of 14 years, starting in 1983 with a company called Medisense. All but one of those rejections cited U.S. Patent No. 4,545,382, known as the '382 patent, which had been issued previously to the same researchers.

After Abbott bought the company in 1996, it assigned in-house patent lawyer Pope, now counsel at Mayer Brown in Chicago, to work on the '551 patent.

Along with an Abbott researcher, Pope argued that '551 was novel because it didn't require a protective membrane between the sensor on the strip and the blood like the '382 patent had. Even though the '382 patent had stated it was "optionally, but preferably" to be used with the membrane, Pope argued that was patent law speak for "required."

But Alsup found that the company had strenuously argued to European patent officials just the opposite -- that the protective membrane was optional, not required -- in defending the European equivalent of the '382 patent. Alsup ruled that Pope intentionally kept that material information from the patent examiner.

"If concealment of extrinsic information as close to the heart of the prosecution as was involved here is allowed to pass, then we would in effect be issuing licenses to deceive patent examiners in virtually all cases," Alsup wrote.

The judge found Pope, Abbott and the researcher Gordon Sanghera guilty of inequitable conduct, making the '551 patent unenforceable.

Alsup also invalidated some of the patent's claims.

Pope had a chance to explain his side. After initial reluctance, his company put the lawyer on the stand, where he claimed he'd been trying to secure a strong patent for his employer and had no motive to conceal anything and undermine the patent's enforceability. According to the ruling, he also testified that patent prosecutors often write specifications broadly early on, so he had read "optionally, but preferably" as an overblown way of saying "optionally, but always."

"Attorney Pope," wrote Alsup, "did not prove to be a convincing trial witness."

# **EXHIBIT 3**

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- PSEG's interns debate the future.
- Everglades deal swamps the lawyers.
- Stolt beats the Justice Department—again.

## Spotlight



Google's Drummond squares off with other tech GCs at a Senate hearing. page 19

## Preferable Isn't Required

Abbott loses a patent thanks to its lawyer's creative wordplay.

**P**ATENT DISPUTES OFTEN hinge on the interpretation of highly technical words. But it was a simple English phrase that tripped up an in-house lawyer for Abbott Laboratories in 1997. Lawrence Pope told federal regulators that when a patent said a feature on a particular invention could be used "optionally, but preferably," it really meant the feature was required.

For federal district court judge William Alsup, that was the wrong definition. "Words are supposed to mean what they say," Alsup wrote in a June 24 order. Making matters worse, Alsup found that Pope knew that several years earlier, European patent officials had been told the exact opposite: The feature was *not* required.

Pope's actions were a problem, Alsup wrote, because he misled the Patent and Trademark Office about the uniqueness of a second Abbott patent for a similar device—a disposable test strip that diabetics use to measure their blood sugar level. Pope had said the second patent was different from the first because it did *not* require the use of the particular feature (a protective membrane). Because Pope and Abbott had engaged in "inequitable conduct" to get the second patent, Alsup ruled that it wasn't valid.

Michael Barclay, an IP partner at Wilson Sonsini Goodrich & Rosati in Palo Alto who was not involved in the case, says it's very unusual for a judge to find inequitable conduct. "You have to prove that something that happened in

the patent office was improper, and not only that, it has to be done with a high level of intent," Barclay says. "It's very hard to prove that level of intent."

Pope, now a counsel at Mayer Brown in Chicago, referred requests for comment to Abbott. Scott Stoffel, a spokesperson for the Abbott Park, Illinois-based company, says that it is considering an appeal. The patent "was obtained lawfully, and Abbott continues to believe that this patent is valid and enforceable," Stoffel says.

**BEGINNING IN 2004**, Abbott sued Bayer HealthCare Pharmaceuticals Inc. and other companies for infringing on the second patent with their own diabetic test strips. The PTO granted the patent to Abbott in 1998, two years after the company acquired MediSense, Inc., the original developer of the patent.

The PTO had rejected MediSense's application for the second patent—known as the '551 patent—a total of 12 times over 14 years. In all but one of those rejections, the PTO decided that the '551 patent wasn't sufficiently different from a previous MediSense patent for disposable test strips—the '382 patent—which the office approved in 1981.

After purchasing MediSense, Abbott assigned the '551 patent application to Pope. According to Judge Alsup's opinion, Pope told the PTO that the '551 patent was novel because it did *not* require the use of a membrane to protect the strip's sensor from the blood that a diabetic was testing. Pope argued that the '382 patent *did* require a membrane, even though that patent said it could be used "optionally, but preferably." Pope argued that the words were "patent phraseology" for "required."

The PTO accepted Pope's definition and granted the '551 patent. But Abbott's problems started when it tried to enforce the new patent. Bayer and the other companies Abbott had accused of infringement fired back with their own claim—that Abbott had broken the rules to win the '551.

After a monthlong trial, Alsup agreed. "Intent to deceive, not just to withhold, was clearly in the mind of Attorney Pope, hard as it is to so conclude as to a professional," the judge wrote.

It wasn't just Pope's unorthodox interpretation of the phrase "optionally but preferably" that bothered Alsup. The judge wrote that Pope knew MediSense had



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argued previously that “optionally but preferably” did not mean “required” when it defended the European equivalent of the ‘382 patent years earlier. However, Pope didn’t bother to tell this to the PTO, and

infringement trial, testified that he had no motive to conceal information. “In the style of writing patent applications over the years, a common style—and it’s one that I use myself when drafting the patent

ing to Cameron Weiffenbach, an of counsel at Miles & Stockbridge in Baltimore. Weiffenbach, a former director of the disciplinary office, says that it has a five-year statute of limitations for investigating

## Trying to win approval for a new Abbott patent, its lawyer argued that a previous patent’s use of “optionally but preferably” was “patent phraseology” for “required.”

that particularly angered Alsup. “If concealment of extrinsic information as close to the heart of the [patent] prosecution as was involved here is allowed to pass, then we would in effect be issuing licenses to deceive patent examiners in virtually all cases,” Alsup wrote.

Pope, who took the stand during the

application—is to use the word ‘preferably’ instead of using the word ‘required’ or ‘needed,’” Pope told the court.

Judge Alsup was not persuaded, and wrote in his ruling that Pope “did not prove to be a convincing trial witness.”

Pope probably won’t face an inquiry from the PTO’s disciplinary office, accord-

alleged inequitable conduct. But Weiffenbach adds, “That doesn’t mean that [the office] can’t look at other cases Pope has executed between 2003 and 2008, just to see if there are any other inequitable conduct cases that may have arisen.”

—AMY MILLER

With additional reporting by Zusha Elinson.

### A JOB FOR THE INTERNS

Students debate the future of alternative energy at PSEG.

PUBLIC SERVICE ENTERPRISE GROUP INCORPORATED, the parent company of New Jersey’s largest utility, is trying to figure out which alternative energy source is the best bet for the future. This summer PSEG’s law department got its interns involved by asking them to debate the merits of wind and solar power.

The debate was the main event of the week that the eight interns spent at PSEG’s Newark headquarters in June. All of the interns will be sophomores at local high schools this fall.

“We picked a [debate] topic that is a major focus of ours,” says David Falck, PSEG’s senior vice president of law. The company recently began a loan program to spur investment in solar power, and also announced a plan to build a wind farm off the New Jersey coast.

The students who interned at PSEG are all taking part in a college preparatory program run by



PSEG lawyers help the students prepare.

the New Jersey Law & Education Empowerment Project. “We are what’s called a pipeline diversity program,” says NJLEEP executive director Craig Livemore, explaining that one of its main goals is to introduce young minority students to the law. The students in NJLEEP’s program interned at a variety of law offices around the state, including Horizon Blue Cross Blue Shield of New Jersey and Prudential Financial, Inc.

Six of the interns at PSEG were African American, one was a Latina, and another was of Guyanese descent. That was a plus for the company, according to Falck: “We want to attract a diverse group so that the makeup of our employees mirrors the communities we serve.”

More than 20 members of PSEG’s law department helped plan its intern program. Assistant general regulatory counsel Sheree Kelly says that the debate was chosen as the focus because “public speaking is an important part of being a lawyer.” Kelly adds, “Whether you are talking to a client or a judge, it’s essential to have good public speaking skills and be able to convey ideas clearly and concisely.”

The interns were divided into two teams—one arguing for wind power, and one for solar. “We had a lot of presenters explain to the kids about solar and wind projects, and then we explained how as attorneys we support those types of projects,” says senior attorney Kieran

Brown, who advised the wind team.

“They talked to litigators and contract and environmental attorneys in our company, so they really saw and understood how each practice area supports a renewable energy project,” adds Brown.

“The mentors taught us how to work together as a team,” says Faatimah Jafiq, one of the students on the wind team. (Her group won the debate, according to a panel of judges composed of PSEG officials.) “We also found out what our mentors’ jobs were and what role they played,” Jafiq says. “Overall, they talked quite a bit about their careers and what happens in their typical workday.” A 15-year-old resident of East Orange, New Jersey, Jafiq previously interned at the state attorney general’s office and says that she’s interested in becoming a prosecutor.

Solar team member Sabrina Collins says that the internship gave her self-confidence. “When I found out I had to debate, I was scared,” says Collins, a 15-year-old Newark resident. “My teammates and my coaches helped me realize that I am a confident person when I speak. A lot of people told me I should be a lawyer. Here at PSEG and NJLEEP, it made me see I would make a good lawyer.”

—SHERRY KARABIN



Jafiq makes her case.

## The Top 10

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