2008-1511, -1512, -1513, -1514, -1595

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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,

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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BRIEF FOR DEFENDANT-APPELLEE BAYER HEALTHCARE LLC

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UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Therasense v. Becton

No. 2008-1511

CERTIFICATE OF INTEREST

Counsel for the (petitioner) (appellant) (respondent) (~~appellee~~) (amicus) (name of party) Bayer HealthCare LLC certifies the following (use "None" if applicable; use extra sheets if necessary):

1. The full name of every party or amicus represented by me is:

Bayer HealthCare LLC

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

None

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

Bayer AG

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

See attachment

10/21/08
Date

Parisa Jorjani
Signature of counsel

Parisa Jorjani
Printed name of counsel

Please Note: All questions must be answered

cc: _____

CERTIFICATE OF INTEREST ATTACHMENT

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

MORRISON & FOERSTER LLP	Rachel Krevans Wesley E. Overson Jason R. Bartlett Marcelo O. Guerra Parisa Jorjani
AMSTER ROTHSTEIN & EBENSTEIN	Morton Amster Joseph M. Casino Kenneth P. George Matthew Fox Reiko Kaji

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

Therasense v. Becton, 2008-1511, -1512, -1513, -1514, -1595

Affidavit of Authority

District of Columbia, ss:

Judith A. Jackson, being duly sworn, deposes and says that Parisa Jorjani, after reviewing Certificate of Interest, authorized me to sign this document on her behalf.

Judith A. Jackson
Litigation Docket Coordinator

Subscribed and sworn before
me on this 21st day of October 2008.

Notary Public, D.C.

My commission expires MY COMMISSION EXPIRES JULY 30, 2013

sf-2593694

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STATEMENT OF RELATED CASES

No appeal in or from this civil action was previously before this court or any other appellate court.

Abbott Laboratories and Abbott Diabetes Care, Inc. (collectively, "Abbott") has appealed two other judgments related to this case: (1) the appeal relating to United States Patent Nos. 6,592,745 and 6,143,164, which Appellants moved to consolidate with the current appeal, and (2) the appeal relating to U.S. Patent No. 5,628,890 (Appeal Nos. 2008-1511, -1512, -1513, -1514, -1595, 2009-1035, -1036, -1037, and -1050).

I. INTRODUCTION

Abbott's appeal as to Bayer concerns three issues: (1) invalidity of the '551 patent, (2) unenforceability of the '551 patent, and (3) invalidity of the '745 patent. Faced with two detailed and well-reasoned opinions from the district court, Abbott uses blanket generalizations and strained interpretations of the record in a futile attempt to meet the high burden required to overturn a district court's findings of fact and ultimate determinations.

According to Abbott, the district court "made the same kind of fundamental error" with respect to both the '551 and '745 patents and "often acted as its own expert," ignoring the evidence. Nothing could be further from the truth. The "district court" was in fact two separate judges, who separately presided over the summary judgment and trial and issued two separate opinions. Consistency in their findings suggests that *both* were proper.

Abbott's main argument, that the district court judges "ignored the evidence," is plainly wrong. Both opinions contain thorough discussions of the evidence presented at summary judgment and trial. Where evidence was not credited by the district court, it was because it was found to be not credible — a finding that is entirely within the discretion of a trial court. Each judge thoroughly reviewed the record before him, and made findings that Abbott does not like.

Abbott has not presented evidence or law sufficient to overturn the district court's findings.

II. STATEMENT OF THE ISSUES

1. Whether the district court clearly erred in finding that the '551 patent was obvious in view of the '382 (which disclosed that the use of membranes with whole blood was optional), the Pace '410 patent, and the understanding of persons of skill in the art in 1983.

2. Whether the district court abused its discretion in finding that the '551 patent was unenforceable because Abbott submitted misleading statements designed to overcome the only remaining prior art rejection and at the same time knowingly and deliberately failed to disclose prior inconsistent statements regarding the same point of alleged novelty, in violation of the explicit provisions of 37 C.F.R. §1.56(b).

3. Whether the '745 patent is invalid as anticipated by the '225 reference, which disclosed the claimed subject matter but taught away from it.

III. STATEMENT OF THE CASE

Although Bayer generally does not dispute Abbott's description of the procedural history, Abbott's brief is silent on certain points. The four actions referenced in Abbott's statement of the case were originally assigned to the Honorable Martin Jenkins. (JA00060-61.) Judge Jenkins presided over the cases

from inception through summary judgment, at which point he left the federal bench to join the California Court of Appeals. Judge Jenkins's summary judgment order, dated April 3, 2008, led to the appeal relating to the '745 patent. *Therasense, Inc. v. Becton, Dickinson & Co.*, 560 F. Supp. 2d 835 (N.D. Cal. 2008). After Judge Jenkins left the federal bench, all four cases were assigned to the Honorable William Alsup, who presided over the trial. All parties waived their rights to have a jury determine invalidity. Judge Alsup's findings of fact and conclusions of law are detailed in his order of June 24, 2008. *Therasense, Inc. v. Becton, Dickson & Co.*, 565 F. Supp. 2d 1088 (N.D. Cal. 2008).

IV. STATEMENT OF FACTS

Bayer generally does not dispute Abbott's description of the facts. Abbott's statement, however, ignores contrary evidence presented at trial by defendants and accepted by the district court, and is silent on certain critical events, discussed below.

A. Invalidity of the '551 Patent

1. Background of the Technology

Bayer disputes certain of Abbott's characterization of the state of the art.

Colorimetric systems were not "unreliable and inconvenient." Colorimetric systems were home testing kits which used disposable strips with a drop of whole

blood from a user's finger, and were the predominant devices for home testing of blood glucose in the early 1980s. (JA02524 at 211:5-212:14.)

There is no evidence that Medisense's Exactech product was "revolutionary." (Br. at 6.) In particular, there is no evidence that the Exactech product was any more commercially successful than other glucose sensor products on the market, or that its commercial success, if any, was due to the absence of a filter as claimed in the '551 patent. During prosecution of the '551, Medisense submitted declarations attempting to establish commercial success of its Exactech product, but did not attribute Exactech's commercial success either to the presence of a filter or to a faster test time, instead attributing it to the use of mediated electrochemistry on a disposable sensor. (JA06490-93; JA06969-70; JA06982-86; JA07001-02.) The examiner nonetheless rejected the declarations, finding that there was no nexus. (JA07598-99; JA07011-14.) The use of mediated electrochemistry on disposable sensors is disclosed by the '382 patent, which covers the Exactech product. (JA06508 at 4:8-12; JA02624 at 357:9-14; JA02752-53 at 549:18-552:18.)

2. The Prior Art '382 Patent: Disclosure of Membraneless Disposable Sensors for Use in Whole Blood.

The '382 discloses membraneless disposable sensors for use in whole blood. In so finding, the district court undertook a thorough review of the entire patent, as detailed below. (JA00068-73; JA06504-13.)

a. Background and Summary of the Invention.

The district court first reviewed the general disclosures of the '382 patent, including the "Background of the Invention" and the "Summary of the Invention." (JA00068-69.) As the district court noted, the '382 discloses ferrocene, which was faster than previous electrochemical systems, as the preferred mediator. (JA00068.) The '382 discloses that ferrocene gave "electrodes with improved linearity, speed of response and insensitivity to oxygen." (JA06504 at Abstract.)

The '382 also discloses that the electrodes of the invention could be used in small, disposable *in vitro* diabetic home kits for use with whole blood. (JA06509 at 5:26-33; JA02525 at 215:19-216:22; JA02755 at 559:19-561:7.) Abbott's statement that the '382 is limited to "tabletop devices" and "implantable glucose sensor[s]" (Br. at 8) is therefore incorrect.

The '382 patent does not require a "'protective' or 'permeable' membrane" for use in whole blood as Abbott states. (Br. at 9.) The '382 discloses that "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." (JA06508 at 4:63-66 (emphasis added).) Abbott's brief ignores *live blood*, explicitly referred to in this sentence, which is another category of liquids

that such sensors may be used to test.[1] While the '382 states that a membrane is *preferred* for use with live blood, it does not state that a membrane is preferred, let alone required, to test whole blood. (JA02748-49 at 533:8-11, 535:22-536:5.) The district court analyzed the sentence's structure, and found that it refers to two circumstances: the "preferable" circumstance applies only to *in vivo* testing in live blood, while the "optional" circumstance applies to other testing liquids, including whole blood. (JA00074.) The district court considered the entire disclosure of the '382 patent and the understanding of persons of skill in the art at the relevant time. (JA00074-75.) This finding is supported by ample evidence. (JA02531 at 238:22-241:23; JA02748-49 at 534:3-537:5; JA02618-19 at 333:18-338:6; JA03076; JA03695-98.)

Abbott's statement that "[w]itnesses *on both sides* agreed that terms like 'optionally' and 'preferably' are not always read literally" is not supported by the evidence. (Br. at 19 (emphasis in original).) Abbott first cites Mr. Pope, whose testimony is irrelevant on invalidity, as he was not a person of skill in the art. (JA02975 at 612:18-14:15; JA03296.) Abbott then cites testimony from Dr. Turner, elicited in response to a hypothetical question by Abbott's counsel

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[1] Live blood is blood that is inside the body, while whole blood is blood that is extracted from the body but which has not been filtered into its components. (JA02531-32 at 239:23-240:3 & 245:5-14; JA02748-49 at 534:18-535:18.)

regarding the "preferable" use of a second electrode in a two-electrode system. (JA02623 at 352:9-353:18.) However, a second electrode is always necessary in a two-electrode system, otherwise the system will not function under the laws of physics. (*Id.*) In contrast, the use of a membrane is not always necessary in a sensor to be used in whole blood. (*See* Section IV.A.3, *infra*.) Contrary to Abbott's contention, numerous witnesses of skill in the art — including Dr. Turner, '551 inventors Graham Davis and John Higgins, Abbott scientist Gordon Sanghera, and even Abbott's own corporate representative, Steve Scott — testified that the words "optionally" and "preferably" as used in the '382 would have had their ordinary meaning. (JA02531 at 239:13-22; JA03076; JA03104-05; JA03541-43; JA03008-09 at 747:16-748:5 and 748:13-21.)

b. The Specific Examples.

Far from relying on a single sentence, the district court then conducted a detailed review of each of the '382 patent's thirteen examples. (JA00069-71.) The '382 patent teaches a series of tests designed to determine whether the sensors in the Examples could be used with whole blood. (JA06509 at 5:15-25; JA06511 at 9:14-21; JA02603 at 272:18-275:2.) According to the '382 patent, devices shown in all Examples offer advantages important for use in blood. (JA06511 at 10:41-50; JA02751-52 at 546:15-547:10.)

The district court particularly focused on Example 8 of the '382 patent, finding that it describes the construction of two versions of an *in vitro* sensor, both with and without a membrane. (JA00070-71; JA02755 at 559:11-14.) Example 8 used the ferrocene chemistry which the '382 described as having a faster response time, and which Abbott's witnesses admitted was faster than previous electrochemical systems. (JA00068; JA06510-11 at 8:60-61&9:4-6; JA06504; JA03003 at 724:6-12.) The membraneless sensor was first tested in a "nitrogen-saturated buffer solution." (JA06511 at 9:15.) "Buffer" is a solution that is commonly used in experiments in the laboratory to test the characteristics of a device, and is formulated to simulate testing in blood.[2] (JA02533-34 at 248:4-251:25.)

Abbott states that Example 8 teaches away from using a membraneless sensor in whole blood, and that there is no evidence that the membraneless sensor of Example 8 would have worked if used with whole blood. (Br. at 11.) Both statements are contrary to the record. As Dr. Turner testified, persons of skill in 1983 would have accepted the buffer results as support for use in blood, and the absence of blood data for the membraneless sensor does not suggest that a

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[2] The "whole" versus "live" blood distinction is not at issue with respect to Example 8, because that Example, as an *in vitro* test, by definition involved whole blood rather than live blood.

membrane was required for use in blood. (JA02533-34 at 248:4-251:25; JA02603 at 272:9-275:2.) Moreover, Abbott's expert, Dr. Johnson, admitted that the membraneless sensor disclosed in Example 8 could be tested in blood without any further modifications, that he had no evidence that it would not work, and that it is a "prototype" of "a sensor that could work in blood." (JA02751-52 at 545:10-546:14; JA02756 at 565:10-21.) Thus, the district court's finding that Example 8 does not require a membrane for use in blood, and that it is consistent with the plain meaning of the "optionally, but preferably" sentence, is supported by the evidence.

Example 8 goes on to discuss "response time" experiments using both versions of the sensor: with a membrane and without. (JA00070-71; JA06511 at 9:22-33.) The response times of both versions of the sensor were tested in buffer solution, while the response time of the sensor with a membrane was also separately tested in blood. (*Id.*) The response time for the membraneless sensor was 12 seconds faster than the sensor with a membrane in buffer, and the sensor with the membrane had the same response time whether tested in buffer or in whole blood. (JA00075; JA06511 at 9:22-33.) Abbott states that the district court erred by finding that the goal of this experiment was to test response times, not whether or not a membrane was required. (Br. at 12.) Yet the '382 says just that, and Abbott has admitted that the '382 "states that the experiments at col. 9:22-33

were done to test 'response times'" and that "[n]othing in that paragraph states that the tests were to see if the membraneless sensor worked with blood." (JA06511 at 9:22-33; JA14459.) Moreover, nothing in Example 8 states that only the version of the sensor with a membrane should be used with blood, or that a membrane is required. (JA06510-11 at 8:60-9:38; JA14459; JA02748 at 533:8-11; JA02988 at 664:5-17.) Thus, the court's finding was amply supported by the evidence.

Abbott says that the district court ignored Dr. Sanghera's testimony that the '382 sensors have higher oxygen sensitivity and thus would not work with oxygen-rich whole blood. (Br. at 14-15.) To the contrary, the district court explicitly considered Abbott's "oxygen sensitivity" argument and correctly rejected it as not supported by the evidence. (JA00080-81.) Defendants pointed out, and the district court agreed, that the '382 sensor shows no more than a 5% current difference between nitrogen-saturated (no oxygen) and air-saturated (with oxygen) tests, as compared to 4% in the '551, such that the latter was "no improvement on that score." (JA00080; JA06511 at 9:19-21; JA03861 at 7:15-22.) Both the '382 and '551 teach the use of glucose dehydrogenase, which can completely eliminate oxygen sensitivity. (JA06507 at 2:9-14; JA03861 at 7:39-40.) Thus, the electrodes disclosed in the '382 exhibited "very low oxygen sensitivity." (JA06509 at 5:15-22; JA02603 at 272:18-275:2.) Finally, it was undisputed that Dr. Sanghera was not a person of skill in the art at the relevant time period and did not consult the

'382 inventors, who were persons of skill at the time, and he was not offered or accepted as an expert witness. (JA14423-24; JA03007 at 742:12-743:6; JA03269; JA03277; JA03004-05 at 728:14-732:24.) Thus, it was within the district court's discretion to disregard Dr. Sanghera's improper opinion testimony as contrary to the intrinsic record, unreliable, and/or irrelevant.

Finally, Abbott's implication that Dr. Sanghera actually performed the experiments discussed in Example 8, while Dr. Turner did not, and thus Dr. Sanghera's testimony should be given more weight, is both irrelevant and unsupported. (Br. at 15.) The issue is what a person of skill in the art would have understood from reviewing the '382 specification, not whether tests were actually performed to try to duplicate its results. Moreover, Abbott presented no experimental data or description of the performance of any such experiments. Dr. Sanghera's testimony regarding Example 8 was limited to his understanding of what the patent described; he said not a word about any experiments that he had personally performed. (JA03001 at 716:2-19.)

3. Knowledge of Persons of Skill in the Art at the Time of Filing the '551 Patent

Bayer disputes Abbott's statement of facts regarding the supposed "conventional wisdom" knowledge of persons of skill in the art. (Br. at 8-10, 12-14.) Abbott focuses on the "conventional wisdom" in the art as of the time the '382 patent was filed, in October 1982, stating that "the critical issue is whether the

'382 taught contrary to that conventional wisdom." (Br. at 10.) As the district court recognized, however, the issue is not what the "conventional wisdom" was *before the '382 patent was filed* — it is what a hypothetical person of skill in the art knew *at the time the '551 patent was filed*, which included knowledge of the prior art '382 patent. (JA00073.)

When the '551 application was filed in May 1983, electrochemical sensors without membranes for testing whole blood were already known in the art. The '382 patent, filed a year earlier, expressly stated, and was understood by persons of skill in the art to disclose, that a protective membrane was *optional* in all cases except for live blood, in which case it was preferred. (JA06508 at 4:63-66; JA02531 at 238:22-239:24; JA02618 at 333:18-25; JA03117-18; JA03156; JA03196-97.) Another patent, the Suzuki '166, filed on May 15, 1982, was part of the prior art and disclosed membraneless sensors for use with whole blood. (JA06514; JA06518 at 1:22-54; JA03076-79.) Those of skill also understood that membranes or filters provided fewer benefits for *in vitro* testing, single-use testing, and fast testing, all characteristics of the '551 claims. (JA02531-32 at 239:13-245:4; JA02604-05 at 279:19-281:20; JA02734-35 at 478:12-479:12; JA03105-07; JA03196-97; JA03696-97; JA03075-76.) Thus, at the time the '551 application was filed, the prior art included membraneless sensors for testing in whole blood, and persons of skill in the art understood that it was preferable to use membranes

when testing live blood but that it was optional when testing buffer, plasma, interstitial fluid, or whole blood. (*Id.*) In no case was it *required.*

According to Abbott, the district court "ignored the uniform testimony from the inventors." (Br. at 12-13.) The inventors' testimony, however, was consistent with the district court's findings. Inventor Davis testified that the "optionally, but preferably" sentence contemplated embodiments without a membrane, and confirmed that the prior art disclosed membraneless devices for use with whole blood. (JA03075-79.) Inventor Hill (1) was unable to place his recollection about the cited testimony at a particular point in time, stating only that he "imagined" that it must have been in '82 or '83, (2) testified that there were occasions during his research when no membranes were used, and (3) stated that protective membranes were not necessary for *in vitro* devices tested with blood. (JA03210; JA03188-89; JA03196-97.) As for Dr. Higgins, he testified that a person of skill in the art reviewing the '382 patent would have understood it to work without a membrane. (JA03117-18; JA03705-10.) Dr. Higgins further testified that membranes were not necessary for measurements using disposable *in vitro* sensors, since fouling was not of much concern. (JA03104-07.) The mere fact that the inventors were experimenting with membranes in early 1983 does not mean that they thought membranes were *required.*

According to Abbott, its notion of the "conventional wisdom" is supported by the '173 patent to Nankai, which Abbott contends the district court ignored. (Br. at 13-14.) The district court did not ignore Nankai: it properly found that Abbott's reliance on a single reference is not determinative of the issue of the knowledge of the hypothetical person of skill in the art, who is presumed to be omniscient. (JA00078.) Moreover, the Nankai reference did not state that a membrane was required for use with whole blood. Nankai disclosed that a membrane allowed the reaction to "proceed more smoothly," and taught that a sensor without a membrane could be coated to mitigate the influence of proteins in samples, "such as blood." (JA06361 at 2:50-53, 58-65.) Defendants' expert, Dr. Turner, testified that the presence of a membrane in Nankai does not suggest that the "optionally, but preferably" language means required. (JA02625 at 361:5-8.)

4. The '551 Patent: Substantially Similar to the '382

Following their filing of the application that led to the '382 patent, the Medisense inventors continued their work on blood glucose sensors. (JA00063.) Two of the '382 inventors, along with two additional Medisense scientists, filed a provisional patent application in the United States in May 1983, which ultimately led to the issuance of the '551 patent. (JA00062-63.)

As the district court found, the disclosures of the '382 and '551 are quite similar. It was undisputed that the '382 and '551 both teach: (1) electrochemical sensors for analyzing glucose in liquids, including blood; (2) glucose oxidase and oxygen dehydrogenase enzymes and ferrocene-based mediators; (3) *in vitro* testing, including home testing kits; (4) small sensors that take blood from a finger; and (5) carbon as a preferred electrode material. (JA14460-61.) Thus, the '551 patent discloses a sensor using the same electrochemistry that formed the basis for the '382 patent.

As to membraneless sensors, the '551 specification is quite similar to the '382 specification. The '382 states that a membrane is "optional;" the '551 states that a membrane "may be found valuable." (JA03860-61 at 6:65-7:13; JA06508 at 4:63-66.) Both disclose membraneless sensors to be used to test whole blood. (*Id.*, JA06510 at 8:60-9:38.) The membraneless sensor of the '382 patent could be used to test whole blood without any modifications, and there is no special structure disclosed in the '551 that makes a membraneless sensor usable with whole blood. (JA02751-52 at 545:10-547:10; JA02756 at 565:10-21; JA02533 at 249:7-15; JA02756-57 at 566:20-567:11.) And Abbott admitted that neither the '382 nor the '551 discloses experimental results for such a sensor. (JA14462.)

Abbott attempts to distinguish the '551 from the '382 by pointing to three alleged differences: (1) the use of carbon rod electrodes in the '382, which show a

5% oxygen sensitivity, versus Graphoil electrodes in the '551, which according to Abbott, show "much less" oxygen sensitivity, (2) the use of screen printing in the '551, and (3) the use of oxidized electrodes in the '382 versus non-oxidized electrodes in the '551. (Br. at 15-18.) None of these alleged differences are claim elements, making it difficult to see how they could support reversal. The district court nonetheless considered those differences which were actually raised by Abbott at trial, giving Abbott every chance to rebut defendants' clear and convincing evidence of obviousness. (JA00068-73; JA00080-81.)

As to the differences in the electrode materials used in the two patents and their effect on oxygen sensitivity, the district court fully considered this point despite the fact that it was made for the first time in closing argument. (JA00080.) Defendants pointed out, and the district court agreed, that the '382 sensor shows no more than a 5% current difference between nitrogen-saturated (no oxygen) and air-saturated (with oxygen) tests, as compared to 4% in the '551, such that the latter was "no improvement on that score." (JA00080; JA06511 at 9:19-21; JA03861 at 7:15-22.) Moreover, both the '382 and '551 teach the use of a glucose

dehydrogenase enzyme, which can completely eliminate oxygen sensitivity.[3] (JA06507 at 2:9-14; JA03861 at 7:39-40.)

Nor did the district court ignore the '551 patent's use of screen printing to make the sensor. As the court found, the only testimony on this issue was from Dr. Sanghera, who merely stated that the Exactech electrode was screen-printed. (JA00081 at n.11; JA03019 at 788:19-25.) The court was within its discretion to discount this testimony, as it did not shed light on the issue of whether screen printing was the reason that the '551 sensors worked without a membrane. (*Id.*) Moreover, the record showed that screen printing was an obvious method for making electrodes: claims directed to screen printing had been rejected by the examiner during the prosecution of the '551 as obvious over the prior art. (JA07603-06; JA07620-27.) Thus, even if screen printing were required to make the membraneless electrodes in the '382 patent for use in whole blood, persons of

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[3] Abbott cites (1) a report from Dr. Turner, dating from early 1983, purporting to "report on [the inventors'] discovery that Graphoil showed much less oxygen sensitivity than the ultracarbon rod," and (2) an entry from Dr. Davis's laboratory notebook, stating that "We can now test whole blood." (Br. at 17.) Abbott failed to examine any witness on either of these documents, and any characterization of the documents' relevance is mere attorney argument. Moreover, nothing about the Davis notebook entry states that it is the first successful experiment with whole blood, or that the sensor used was without a membrane. As noted by Dr. Davis, blood for testing was generally hard to obtain, which may have been related to this remark in his notebook. (JA03089-90.)

skill in the art at the time the '551 patent was filed knew how to apply the method to make the electrodes disclosed in the '382 patent.

Finally, as to oxidation of the electrodes, the '551 patent says nothing about it (let alone provides any teaching on how the lack of oxidation could mean that no membrane or filter would be needed), and the '382 patent teaches both oxidized *and* non-oxidized electrodes. (JA03850-65; JA06510-11 at 8:17-24 & 9:42-49.) Moreover, this alleged difference was never raised by Abbott at trial, and was revealed, for the first time, in its proposed findings of fact *after* trial. During Abbott's closing argument, the district court specifically asked Abbott's counsel to address what, if anything, in the '551 patent allowed the electrodes in that patent to work in whole blood without a membrane. (JA03606 at 847:4-11.) Abbott's counsel made no mention of oxidation of the electrodes.

B. Unenforceability of the '551 Patent

1. Early Prosecution of the '551 Patent: the Applications Are Rejected Repeatedly.

Abbott's description of the file history of the '551 ignores over thirteen years of prosecution, during which the proposed claims were rejected over and over again in view of the '382 patent.

The '551 patent issued in 1998, after a series of applications dating back fifteen years. The original claims, filed in March 1984, were found unpatentable over the '382 patent (referred to by the examiner as "Higgins et al"). (JA07144-

47.) Medisense filed a continuation-in-part application, and in December 1985 added claims having a few additional limitations, such as "elongated support" and "reference electrode." (JA07258-60.) The PTO rejected these claims as well as obvious over U.S. Patent 4,225,410 to Pace in combination with the '382 patent. (JA07274-76.) Pace discloses a "small, handheld computer" coupled to a disposable chip to analyze and display measurements. (JA06783-99 at Abstract, 2:62-65, 3:58-59.)

Medisense filed another CIP in January 1987, and sought claims that added yet another limitation: a "two-electrode strip" for attachment to a sensor. (JA07314; JA07345.) The examiner rejected those claims three times, finding that they were obvious in light of the '382 patent and other prior art. (JA07397-99; JA07420-23; JA07437-41.) Medisense amended its claims again, adding a "single use disposable strip" as a limitation. (JA07474-75.) The examiner again rejected the claims as obvious over the '382 patent in view of Pace. (JA07497-502.)

Medisense filed more continuation applications with similar claims in September 1991, May 1992, and July 1994. (JA07513-15; JA07532; JA07540-47; JA06901-02.) The examiner each time rejected the claims as obvious over the '382 patent in view of Pace. (JA07517-21; JA07590-99; JA07620-27; JA07007-15.) Medisense even submitted declarations attempting to establish commercial success of its Exactech product, but did not attribute Exactech's commercial

success either to the presence of a filter or to a faster test time, instead attributing it to the use of mediated electrochemistry on a disposable sensor. (JA06490-93; JA06969-70; JA06982-86; JA07001-02.) The examiner rejected the declarations, finding that there was no nexus. (JA07598-99; JA07011-14.) Medisense did not give up, filing another continuation application in June 1995. In August 1996, the examiner again rejected the claims as obvious over the '382 patent. (JA04663-67.)

2. Pope and Sanghera Take Over the Prosecution and Introduce the "No Membrane or Other Filtering Member" Limitation

In May 1996, shortly before the last continuation application that led to the '551 patent was filed, Abbott purchased Medisense. (JA02976 at 618:1-4&16-20.) In the fall of 1997, Abbott assigned Lawrence Pope, an Abbott in-house patent attorney, to take over the prosecution of the '551 for its newly-acquired subsidiary. (*Id.*) Abbott also transferred a Medisense scientist, Gordon Sanghera, to the U.S. to manage the company's intellectual property and provide technical advice to Abbott attorneys, including Mr. Pope. (JA02996 at 696:6-9, 698:1-8; JA03011-12 at 759:14-760:5; JA03014 at 769:11-770:9.) Along with several Abbott research and development personnel, Dr. Sanghera "brainstormed" various arguments regarding the patentability of the '551 claims. (JA02999 at 708:2-709:18.) Dr. Sanghera and Mr. Pope worked as "a team" with respect to the prosecution of the '551 patent. (JA03016 at 777:23-778:5.)

In November 1997, Mr. Pope attended an examiner interview about the '551 claims. (JA07639.) In an attempt to overcome the latest rejection over the '382, Mr. Pope suggested for the first time in the lengthy prosecution history that the invention was actually an "electrode with the filtering member absent." (*Id*; JA07640-44.) This argument was wrong on its face. The '382 patent explicitly taught that a filtering member was optional, not required: "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." (JA06508 at 4:63-66.) Focusing on this exact sentence, the examiner stated in the interview summary

> The Higgins *et al.* ('382) disclosure was discussed esp 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.

(JA07639.)

Rather than asking any of the Medisense inventors to submit the required declaration or even consulting them, Mr. Pope and Dr. Sanghera wrote and submitted Dr. Sanghera's declaration. (JA07636-38; JA03381; JA03007 at 742:12-743:6; JA03269; JA03277.) At trial, Dr. Sanghera admitted that he was not

a person of ordinary skill in the art in 1983. (JA03006 at 737:16-738:9.) Yet in his declaration, Dr. Sanghera stated 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 or merely preferred.

(JA07637.) In his Remarks accompanying the declaration, Mr. Pope stated that the "general teaching" of lines 63 to 66 of column 4 is that a membrane is "require[d]" for whole blood, and the "optionally, but preferably" sentence is not a "technical teaching" but "mere patent phraseology." (JA07644-45.)

3. Medisense's Representations to the PTO Regarding the '382 Patent Were Directly Contrary to What It Told the EPO Two Years Earlier.

What Dr. Sanghera and Mr. Pope deliberately failed to tell the PTO was that they knew that their new representations directly contradicted Medisense's own prior representations to the EPO about the exact same "optionally, but preferably" sentence during opposition proceedings involving the European counterpart to the '382 patent, EP0078636 (the "'636 patent"). (JA06540-52.)

In the EPO proceeding, the '636 patent had been revoked in 1993 based on a prior art reference referred to as "D1." (JA00085; JA06833.) In 1994, Medisense appealed, arguing that D1 was distinguishable on two grounds. Relying on the identical "optionally, but preferably" sentence at issue in the '551 prosecution, Medisense argued that

> the claimed glucose sensor — contrary to that of D1 which requires a membrane — does not 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.

(JA06530-31 (emphasis in original).) Thus, according to Medisense, (1) while the D1 reference *required* a membrane, in the '636 patent the membrane was *optional* and (2) the '636 patent's optional membrane was a "protective membrane," not a membrane for controlling the permeability of the substrate. (*Id.*; JA03432-33; JA03322; JA03015 at 773:17-25.) In a subsequent submission in 1995, Medisense affirmatively used the "optionally, but preferably" sentence as a scientific point of novelty over the prior art, stating, after quoting the sentence:

> 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.

(JA06585 (emphasis added).) At trial, Mr. Pope admitted that Medisense had used this sentence as a technical teaching before the EPO. (JA02986 at 658:19-659:20.)

Dr. Sanghera was a full participant in the EPO proceedings. He crafted the statements submitted to the EPO, and attended the hearing as Medisense's representative. (JA03002 at 723:16-23; JA03009-11 at 750:11-753:9, 755:5-757:11; JA03016 at 778:8-10.) Mr. Pope admits that he was fully aware of the conflicting statements. (JA03286-90.) Yet both Mr. Pope and Dr. Sanghera withheld the contradictory statements from the PTO.

Abbott states that its EPO and PTO submissions were not inconsistent, because they were both directed to "membranes being optional for fluids other than blood, but required for blood." (Br. at 24.) Abbott ignores the fact that Medisense affirmatively used the "optionally, but preferably" sentence as a technical teaching to overcome prior art in Europe, while as discussed above, Mr. Pope later told the PTO that it was "mere patent phraseology." Thus, Abbott's EPO and PTO submissions were clearly inconsistent. Moreover, Abbott is ignoring the difference between "whole blood" and "live blood." As the '382/'636 patent states and the district court found, a membrane is *preferred* for use with *live* blood, while it is optional for use with other liquids, which would include whole blood. (JA00094; JA02748-49 at 533:8-537:5; JA02531 at 238:22-241:23; JA02618-19 at 333:18-338:6; JA03076; JA03695-98.)

Abbott states that in 1997, Mr. Pope thought "whole blood" and "live blood" were synonymous. (Br. at 24-25 & n.4.) But as the district court found, the EPO statements would have been *even more* material had Mr. Pope thought that live and whole blood were the same, since Medisense had explicitly told the EPO that a membrane was *optional but preferred* when used with live blood. (JA00094.) Thus, if Mr. Pope truly did not know the difference, he would have thought that a membrane was optional, but preferred when used *either* with live or whole blood — not that a membrane was required for whole blood. The fact remains that Medisense used the word "preferred," which does not mean "required." (JA02990-91 at 675:18-677:12; JA00094.)

According to Abbott, there was no evidence of bad faith because Mr. Pope testified that he had understood the EPO submissions "to address an entirely different issue: whether the membrane disclosed in the '382/'636 specification was the same as the semi-permeable membrane of the D1 reference." (Br. at 25.) As the district court found (and as both Mr. Pope and Dr. Sanghera admitted), however, Medisense's submissions were plainly not so limited. (JA00092; JA03432-33; JA03322; JA03015 at 773:17-25.) Medisense *also* distinguished D1 because while D1 *required* a membrane, the '382/'636 needed no membrane at all, invoking the "optionally but preferably" sentence. (*Id.*) The district court found this argument to be clearly inconsistent with Dr. Sanghera and Mr. Pope's later

submissions to the PTO, and thus highly material. (JA00092; JA00095-97.) The district court found Mr. Pope and Dr. Sanghera's explanations for withholding the information not "plausible" and "disingenuous." (JA00092-93, JA00097.) In making this factual finding, the district court, in its discretion, took into account the demeanor of Mr. Pope and Dr. Sanghera at trial, and found each to be an unconvincing witness. (*Id.*)

C. '745 Anticipation

The district court found that the '745 patent is anticipated by WO98/35225, a published patent application which shares two inventors with the '745 patent. (JA00049-53.) The '225 reference was published on August 13, 1998, before the earliest filing date of the '745 patent, and contains the same disclosure as the '164 patent. (JA08777-859; JA09914-47; JA08518.) Because of this identity, the references will be referred to as "'225/'164" for convenience.

It is undisputed that the '225/'164 reference states that "a diffusing or leachable (*i.e.* releasable) redox mediator is not desirable when the working and counter electrodes are close together." (JA08787 at 9:25-29; Br. at 60.) Defendants' expert, Dr. Weber, opined that this reference disclosed the use of diffusible mediators to persons of skill in the art. (JA01863-67.) Abbott's expert, Dr. Bard, did not dispute this disclosure. Instead, when discussing the identical '164 specification, he stated that "reasonable minds can differ about whether the

'164 patent discloses the use of diffusible mediators." (JA08518.) Moreover, Dr. Bard stated that "One of ordinary skill in the art could make a sensor with diffusible mediators using the teachings of the '164 Patent whether the '164 Patent explicitly discloses them or not." (*Id.*) At his deposition, Dr. Bard also admitted that the '225/'164 reference discloses that diffusible mediators can be used, although they are not preferred. (JA08367-69 at 141:23-25, 142:9-143:5.)

Moreover, Abbott itself took the position earlier in these proceedings that the '225/'164 disclosure supports the use of diffusible mediators. During the Markman proceedings in the related cases against BD and Nova, Abbott argued that the '164 patent — which has a specification identical to the '225 reference — was not limited to immobilized mediators. (JA14257-58; JA08861-62, JA08909-11; JA08924.) Abbott argued this because it wanted the '164 patent claims to capture BD/Nova's devices, which included diffusible mediators. In ruling in Abbott's favor on this point, the court relied on the same sentence from the '225/'164 reference that Abbott now says does not disclose diffusible mediators. (JA13832.)

V. SUMMARY OF THE ARGUMENT

As to the invalidity of the '551 patent, the district court's finding that the patent is invalid was amply supported by the evidence and was not clearly erroneous. If Abbott's predecessor, Medisense, indeed invented the first

disposable electrochemical blood glucose sensor for home use, that was not the '551 patent. Medisense disclosed and claimed that invention in the expired, prior art '382 patent. The district court's detailed determination that the '551 patent was invalid over the '382 combined with other prior art clearly demonstrates that it was not based on "one sentence," but on an analysis of the entire '382 patent, in view of the understanding of persons of skill in the art. Abbott's "commercial success" argument is also unavailing, as Abbott did not point to any evidence that the alleged commercial success of Medisense products was related to the invention claimed in the '551 patent.

As to unenforceability, Abbott points to nothing that would warrant finding that the district court abused its discretion. In the 14th year of prosecution, Medisense finally convinced the examiner to allow the '551 patent after it introduced the "no filter" limitation. The examiner had expressed concern that the "optionally, but preferably" sentence in the '382 patent taught a filterless sensor, but Medisense persuaded him, with argument and a declaration, that that sentence was not a "technical teaching," and should be ignored. Medisense never told the examiner that it had already told the EPO that the same sentence was "unequivocally clear," and that it had used the sentence as a technical teaching in order to distinguish prior art to the '382 European counterpart during opposition proceedings. No matter what spin Abbott tries today to give the scientific meaning

of this sentence, one thing is plain — it could not be both a scientific teaching providing novelty over prior art in Europe, and "mere patent phraseology," to be ignored in the United States.

As to the invalidity of the '745 patent, Abbott argues that the '225 prior art reference did not disclose or enable the use of diffusible mediators. But Abbott fails to tell this court that its own expert admitted that diffusible mediators were disclosed and enabled in the '225 reference, though their use was not preferred. It is well settled that a reference anticipates an invention even if it "teaches away" from it. Thus, the '225 reference invalidates the '745 patent.

VI. ARGUMENT

A. '551 Obviousness

Abbott's brief disputes the district court's obviousness findings on only one element of the '551 claims: namely, the requirement that the "active electrode is configured to be exposed to said whole blood sample without an intervening membrane or other whole blood filtering member." Thus, Abbott has conceded that the remaining limitations of the '551 claims were found in the prior art combination relied upon by defendants at trial. The only issues on appeal are: (1) did the '382 patent, together with what was known to one of skill in the art in May 1983, disclose that membranes were not required for use with whole blood; (2) did

the district court properly combine the '382 with the other references; and (3) was the district court's alternative rationale correct.

1. Legal Standard

A patent is invalid if the "differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains." 35 U.S.C. § 103(a). This is a legal question, based on the underlying factual determinations, including: (1) the scope and content of the prior art; (2) the differences between the claimed invention and the prior art; (3) the level of ordinary skill in the art; and (4) secondary considerations such as commercial success. *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1359 (Fed. Cir. 2007), *cert. denied*, 128 S. Ct. 1655 (2008). This court "reviews the trial court's conclusions of law de novo and its findings of fact for clear error." *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1359 (Fed. Cir. 2007). "A factual finding is clearly erroneous if, despite some supporting evidence, the reviewing court on the entire evidence is left with a definite and firm conviction that a mistake has been committed." *Id.*

2. The District Court Viewed the '382 Patent as a Whole.

Abbott argues that the district court erred by exclusively focusing on the "optionally, but preferably sentence" which according to Abbott is not a technical

teaching at all, and that it ignored the patent as a whole. (Br. at 30-31.) Nothing could be further from the truth. These facts, as found by the district court, plainly were not clearly erroneous.

The district court's order included a lengthy discussion of the entire patent, including pages devoted to discussing Example 8 alone. (JA00068-76.) The court's detailed discussion of the specification, including the "optionally, but preferably" sentence, demonstrates that the court considered the '382 patent in its entirety, in view of the understanding of persons of skill in the art. (*Id.*) In particular, after examining Example 8 in detail, the district court found that nothing in it stated that a membrane was required for use in blood, and that it was in fact consistent with the plain meaning of the "optionally, but preferably" sentence. (JA000015.)

The district court's order was entirely proper; it is Abbott's desire to erase the "optionally, but preferably" sentence from the '382 patent that is improper. "[A]ll of the disclosures in a reference, including non-preferred embodiments, must be evaluated for what they fairly teach one of ordinary skill in the art." *In re Inland Steel Co.*, 265 F.3d 1354, 1361 (Fed. Cir. 2001) (citations omitted). Abbott's own subsidiary Medisense relied on the very same language and represented to the EPO that it was a technical teaching. (Section IV.B.3, *supra*.)

Plainly, the district court did not err by considering the disclosure of the "option" of *not* including a membrane to be a teaching. (*Id.*)

Abbott relies heavily on its "conventional wisdom" argument. As discussed above, however, as of the filing date of the '551, sensors using enzymes and mediators without membranes for testing whole blood were already known in the art, including disclosure of such membraneless sensors in the '382 patent and the Suzuki '166 patent. (*Supra,* Section IV.A.3.) Abbott's reliance on a single reference, Nankai, is unavailing, as that reference is silent on whether or not a membrane is required, and there was no evidence that the Nankai inventors were actually aware of the '382 patent or the "optionally, but preferably" sentence. Even if Nankai had specifically discredited the use of membraneless sensors in whole blood, which it does not, that still would not erase the '382 patent's disclosure from the scope of the prior art. *In re Young*, 927 F.2d 588, 591 (Fed. Cir. 1991). Thus, the district court's findings on this issue were supported by the evidence, and were not clearly erroneous.

3. There Was Reason to Combine the References.

Abbott argues that there was no motivation to combine the prior art references because persons of skill in the art would not have combined "a sensor that they did not believe would work in whole blood with the other components to

produce a 'seemingly inoperative' test strip." (Br. at 37.) Abbott applies the wrong legal standard and ignores the facts.

In its recent *KSR* decision, the Supreme Court explained how courts should evaluate whether patent claims are obvious. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741-43 (2007). While there must be a reason to combine references, that reason need not be found in the prior art. Common sense, creativity, and predictability guide the inquiry. The *KSR* Court held that "any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id.* at 1742. "When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field, or a different one." *Id.* at 1727.

Abbott relies on two legal propositions, neither of which is the proper inquiry under *KSR*, and then improperly applies them to a single reference — namely, the '382 patent. First, Abbott argues that defendants had to present evidence of "a finite number of identified, predictable solutions" in order to prove obviousness. (Br. at 37.) Such a showing, however, relates to proof of obviousness using an "obvious to try" analysis, on which neither the defendants nor the district court relied. *KSR*, 127 S. Ct. at 1742. Second, Abbott argues that a motivation to combine could not have existed if a combination was "seemingly

inoperative." (Br. 37-38.) Nothing in *KSR* supports such a bright line rule. Abbott then applies these legal propositions to the '382 reference *alone*, and concludes that there is no motivation to combine. Abbott does not even mention the Pace reference with which the '382 reference was combined. The proper analysis, however, is focused on reasons for *combining* more than one reference. Thus, Abbott's argument makes no sense.

Moreover, Abbott's argument is factually wrong. The combination of the '382 and Pace was not "seemingly inoperative," since as discussed above, there was evidence that persons of skill in the art would have believed that the membraneless sensor tested in buffer would have worked in blood. Moreover, it was plainly proper to combine the Pace and '382 references in an obviousness analysis. Both references relate to the exact same, narrow field: measurement of blood glucose using small electrochemical devices. Defendants' expert, Dr. Turner, testified that a person of skill in the art would have been motivated to combine the references to form the electrochemical test strip described in the '551 patent. (JA02524 at 210:9-14; JA02526-27 at 220:2-222:1; JA02606 at 284:14-18

& 287:10-14.) Abbott offered no evidence at all on this issue.[4] The district court was persuaded by Dr. Turner's uncontroverted testimony, "given the strong overlap between the subject matter of the references," and its findings were not clearly erroneous. (JA00103.)

4. Defendants Proved Reasonable Expectation of Success.

Abbott next argues that there was no evidence of reasonable expectation that a membraneless sensor would have worked in blood. (Br. at 32-33.) The evidence is to the contrary.

Whether there was a reasonable expectation of success is a question of fact, and this court reviews the district court's findings on this issue for clear error. *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006). "[O]bviousness cannot be avoided simply by a showing of some degree of unpredictability in the art so long as there was a reasonable probability of success." *Pfizer,* 480 F.3d at 1364.

As discussed in Section IV.A.2 above, there was ample evidence that membraneless sensors would work in blood, and Abbott's citations to the record do not show any error, let alone clear error. Abbott's expert, Dr. Johnson, admitted on

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[4] Plaintiff's expert, Dr. Johnson, did not testify about motivation to combine. His opinions were focused on the '382 patent, and in particular, anticipation. (JA02736 at 485:6-13.)

cross-examination that the membraneless sensor disclosed in Example 8 is a "prototype" of "a sensor that could work in blood," and that he had no evidence that it would not so work. (*Id.*) Abbott's argument that the "oxygen sensitivity" of the membraneless sensor in Example 8 would have rendered it ineffective in whole blood (Br. at 32-33) is not supported by the evidence, as the uncontroverted evidence was that the electrodes in the '382 patent exhibited "very low oxygen sensitivity," and the '382 patent also teaches the use of glucose dehydrogenase, which can completely eliminate oxygen sensitivity. (Section IV.A.2.b, *supra.*) Abbott's citation to the inventor testimony is also unavailing, as it was consistent with the district court's findings. (Section IV.A.3, *supra,*.) Finally, Abbott's argument that the "many differences" between the '382 and '551 sensors, such as the electrode material, would have resulted in undue experimentation (Br. at 33) is belied both by the law — as the differences Abbott cites are all unclaimed — and by the facts — because the Exactech product, which Abbott alleges embodies the both the '551 and the '382 patents, uses carbon paste electrodes, the same material disclosed in the '382 patent. (JA000081 at n.10; JA06508 at 3:19-23; JA02638 at 412:19-414:11; JA03016-17 at 779:23-781:1.)

Thus, there was indeed evidence that persons of skill in the art would have had a reasonable expectation of success in using the membraneless sensor disclosed in Example 8 with blood. There were not numerous parameters to vary:

the only issue was whether or not to use a membrane. *See Medichem*, 437 F.3d at 1167. That a person of skill in the art may have had to conduct some experiments is not determinative, and there was ample evidence that there was a reasonable probability that the experiments would have been successful. *Pfizer*, 480 F.3d at 1364. The district court's factual finding on this point was supported by the evidence, and was not clearly erroneous.

5. The '382 Patent Enabled Persons of Skill in the Art to Make and Use a Membraneless Sensor in Blood.

Abbott next recasts this exact same argument as an enablement argument that the '382 patent does not enable the '551 invention, because there is allegedly no evidence that the membraneless sensor of Example 8 would have worked if used with whole blood. (Br. at 34-37.) Abbott's argument misapplies the law and ignores the facts.

Abbott cites several cases purporting to hold that a single prior art reference used in an obviousness analysis must enable the claimed invention. (Br. at 34-35.) The proper analysis, however, is focused on whether the prior art *as a whole* is enabling, including the knowledge of persons of skill in the art at the relevant time. *See Amgen Inc. v. Hoechst Marion Roussel*, 314 F.3d 1313, 1357 (Fed. Cir. 2003) ("[E]nablement of the prior art is not a requirement to prove invalidity under § 103."); *Medichem*, 437 F.3d at 1166 ("the prior art must be considered as a whole for what it teaches"). Otherwise, the obviousness analysis — which necessarily

involves the combination of one reference with other references and the knowledge of persons of skill in the art — would collapse into an anticipation analysis, based on a single reference.

Moreover, even assuming that Abbott's view of the law is correct, Abbott's argument fails. It is Abbott's burden to prove that the prior art was not enabled. *Impax Labs., Inc. v. Aventis Pharms., Inc.*, 545 F.3d 1312, 1312 (Fed. Cir. 2008). Abbott failed to meet its burden. For the reasons discussed above, and in Section IV.A.2, there was ample evidence from which the district court could properly conclude that the '382 enabled membraneless sensors for use with blood. Thus, the district court's finding was supported by the evidence, and was not clearly erroneous.

Finally, even the case law on which Abbott relies does not support its argument. *See Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 1471 (Fed. Cir. 1997). In *Motorola*, the Federal Circuit rejected the patentee's argument that the prior art reference could not anticipate or render obvious the asserted claims because it was too "vague" to be enabling. *Id.* In *Motorola*, like this case, there was sufficient evidence to support the jury's implicit determination that the reference was enabling because the reference provided disclosure "at a level of detail similar to those contained in the patent [in-suit]." *Id.*; *see* Section IV.A.4, *supra*. Moreover, like this case, there was testimony from defendants' expert

regarding his understanding of the reference, from which the jury could have concluded that one of skill in the art understood the reference sufficiently to be able to practice it. *Id.* Thus, as in *Motorola*, there was no error in the district court's implicit finding that the '382 patent was enabling.

6. The '551 Patent Involves an Unpatentable Deletion of Function, and Is Merely Directed to an Intended Use for an Old Product.

Abbott takes issue with the court's alternative conclusion that the '551 claims are unpatentable because they involve a mere deletion of function. (Br. at 38.)

It is long-standing law that omitting an element with a corresponding omission of its function does not constitute invention. *In re Karlson*, 311 F.2d 581, 584 (C.C.P.A. 1963). In particular, the omission of an element does not result in a patentable invention where the use of the element becomes obviated due to unrelated improvements in the art. *Clark v. Ace Rubber Prods.*, 108 F. Supp. 200, 204-05 (N.D. Ohio 1952) (mere use of a better grade of rubber, which obviated the use of reinforcing fabric, "can hardly be said to constitute invention").

Under this rule, Abbott's omission of the "filtering" element did not result in a patentable invention. According to Dr. Johnson, the only disclosure in the '551 which permitted the removal of a membrane is the use of a different type of carbon, carbon foil, for the '551 electrode than that in the '382. (JA02745-46 at

521:12-524:24.) Thus, according to Dr. Johnson, the need for a membrane became obviated in view of improved materials (such as carbon foil). Moreover, nothing in the '551 patent states that carbon foil functions as a membrane. (JA02756-57 at 566:20-567:11; *see also* JA14463.) Thus, according to Abbott's expert, the use of carbon foil instead of a membrane eliminated the function of the membrane, and the '551 claims are invalid.

The '551 claims are also invalid because they are merely directed to a new intended use for an old product. "It is well-settled that the recitation of a new intended use for an old product does not make a claim to that old product patentable." *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997). It is undisputed that the '382 patent teaches membraneless sensors for analyzing glucose in a liquid containing glucose, such as plasma or buffer. (JA14461.) The '551 is alleged to improve upon the '382 by allowing such use with whole blood. However, as discussed above, there is no special structure that makes the sensor usable with whole blood. (Section IV.A.5, *supra*.) Thus, the '551 claims are invalid, as they are merely an allegedly new use (in whole blood) for an old structure.

7. The District Court Did Not Ignore Commercial Success.

Finally, Abbott argues that the district court ignored evidence of commercial success of its Exactech product. (Br. at 39.) In reality, the district court fully

considered Abbott's evidence and found it insufficient to overcome defendants' clear showing of obviousness. (JA00108-09.)

Evidence of commercial success has probative value only where there is "a sufficient relationship between the commercial success and the patented invention," referred to as "nexus." *Demaco Corp. v. F. von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988). It is not sufficient that commercial embodiments of the claimed invention enjoyed commercial success — the patentee must also link that success to features of the invention that were not disclosed in the prior art. *Asyst Technologies, Inc. v. Emtrak, Inc.*, 544 F.3d 1310, 1316 (Fed. Cir. 2008) (citation omitted). The burden of proof as to nexus resides with the patentee.[5] *Demaco*, 851 F.2d at 1392.

Abbott plainly failed to meet its burden to prove nexus. There was no evidence that sales of Medisense's Exactech related to the "filterless" sensor claimed in the '551 patent. On the contrary, the scant evidence of commercial

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[5]Abbott argues that the district court improperly shifted the burden of proof. (Br. at 39, citing *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1130 (Fed. Cir. 2000).) Unlike *Brown*, however, here there was evidence that the commercial success was due to a feature disclosed in the prior art, and that the product was covered by multiple patents. *Asyst*, 544 F.3d at 1316; *American Standard, Inc. v. York Int'l Corp.*, 244 F. Supp. 2d 990, 996 (W.D. Wis. 2002) (patentee's burden is more difficult to meet when more than one patent covers the allegedly commercially successful product).

success of Medisense's Exactech related to the use of fast, mediated electrochemistry on a disposable sensor, as disclosed in the '382 patent. (*See* Section IV.A.1, *supra*; JA03003 at 724:5-16.) Abbott even had marked the Exactech with the '382 patent number. (JA02728 at 451:2-452:23; JA03005-06 at 734:22-736:23; JA03017 at 781:6-782:6; JA07653-54.)

In view of this uncontroverted evidence, the district court was within its discretion to determine that "secondary considerations did not carry sufficient weight to override a determination of obviousness based on primary considerations." (JA0109); *Ryko Manufacturing Co. v. Nu-Star, Inc.*, 950 F.2d 714, 719 (Fed. Cir. 1991). Thus, the district court's finding was supported by the evidence, and not clearly erroneous.

B. '551 Inequitable Conduct

Defendants presented a single inequitable conduct argument: that Abbott's representatives knowingly withheld highly material information, inconsistent with arguments they were advancing to the PTO on the single point of novelty at issue, with an intent to deceive the examiner. As the district court aptly summarized it, "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." (JA00095.)

1. Legal Standard

A district court's ultimate determination of inequitable conduct is reviewed for abuse of discretion. *Critikon, Inc. v. Becton Dickinson Vascular Access*, 120 F.3d 1253, 1255 (Fed. Cir. 1997). The subsidiary factual questions are reviewed for clear error and are not to be disturbed unless there is a definite and firm conviction that a mistake has been committed. *Id.*

2. Medisense's Arguments to the PTO Were Flatly Inconsistent with Its Arguments to the EPO.

Abbott attempts to paint Medisense's own flatly inconsistent statements to the PTO as merely "ambiguous." (Br. at 41-47.) Not so. Medisense's affirmative representations to the examiner were plainly contradicted by its prior statements to the EPO, which Medisense was required to disclose under Rule 56(b).

This clear inconsistency is demonstrated in detail in Section IV.B.3, above. It is undisputed that during the prosecution of the '551, Mr. Pope and Dr. Sanghera told the examiner that the '382 patent *required* a membrane for use in whole blood. It is also undisputed that the focus of Mr. Pope and Dr. Sanghera's statement was the "optionally, but preferably" sentence in the '382 patent. To persuade the examiner to ignore this sentence, Mr. Pope told him (with help from Dr. Sanghera and full knowledge of prior inconsistent statements to the EPO) that the sentence was not a "technical teaching" but was "mere patent phraseology." Dr. Sanghera, also with full knowledge of the prior inconsistent statements, stated in a declaration

penned by Mr. Pope that a person of skill in the art in 1983 would have felt that a membrane was *required* for use with whole blood. These representations were directly contrary to what Medisense, with Dr. Sanghera's actual participation, had argued only two years before, while attempting to overcome a rejection based on the "D1 reference" in opposition proceedings about the European counterpart of the '382 patent. In Europe, Medisense affirmatively used the "optionally, but preferably" sentence as a scientific point of novelty over the prior art, not "mere patent phraseology," and distinguished the D1 reference because, *inter alia*, its membrane was "required" while the '636 membrane was "optional." Pope and Sanghera disclosed none of this information to the PTO. (Section IV. B.3, *supra*.)

Abbott tries to cloak the inconsistency in these statements with allegations of "ambiguity," but the inconsistencies were plain. The district court undertook a detailed analysis of the relevant facts, and its conclusion that the prior statements were inconsistent is amply supported by the evidence. (JA00081-98.) Unable to explain away such a clear contradiction, Abbott ignores much of the evidence and reinterprets the rest to fit its revisionist history. First, Abbott argues that the submissions were not inconsistent because the membranes discussed in the EPO were a different type than the membrane in the '636. (Br. at 42-43.) Medisense certainly made that argument in Europe. However, Medisense *also* argued to the EPO that the '636 needed no membrane at all, invoking the "optionally, but

preferably" sentence. (JA03432-33; JA03322; JA03015 at 773:17-25.) The district court found this argument to be clearly inconsistent with Dr. Sanghera's declaration and Mr. Pope's submissions to the PTO, and thus highly material. (JA00092.) Taking into account their demeanor, the district court found their explanations for withholding the information not plausible. (JA00092-97.)

Second, the district court did not ignore the distinction between blood and other fluids, as Abbott contends. (Br. at 24.) Medisense's arguments to the EPO were made in the context of Claim 1 of the '636, which specifically claimed measurements of glucose in "blood" or interstitial fluid. (JA06588; JA06525-26.) Medisense told the EPO that one of the advantages of the '636 invention was to provide a device which "takes a blood sample from the finger," which clearly refers to whole blood. (JA06529-31.) Medisense also relied on the response time provided for a membraneless *in vitro* measurement in Example 7 of the '636 (Example 8 in the '382) to support patentability of its claim to a test in blood, demonstrating that the sensor of Example 7[8] was intended for use with blood, not interstitial fluid. (JA06269 at 9:45-10:26; JA06530; JA06578-82.) Indeed, because interstitial fluid involves *in vivo* tests in the skin, all the *in vitro* examples could only be relevant to blood. (JA02992 at 683:4-20; JA02740 at 501:6-12; JA02754 at 555:8-556:19.)

The case law cited by Abbott is inapposite. (Br. at 41, citing *Scanner Techs. Corp. v. ICOS Vision Sys. Corp. N.V.*, 528 F.3d 1365 (Fed. Cir. 2008).) In *Scanner*, the Federal Circuit reversed a finding of inequitable conduct, stating that the falsity or misleading nature of the statements came down to whether certain notes taken by a witness "were indeed 'copious.'" *Id.* at 1378. The court reasoned that "[w]hat constitutes 'copious' note taking is a relative determination, from which subjective inferences, both favorable and unfavorable, can be deduced." *Id.*

Scanner has nothing to do with the facts here. As the district court properly found, Abbott's statements to the PTO were clearly contradicted by the statements to the EPO. Unlike *Scanner*, the issue here was not a non-scientific statement or a "relative" term. Moreover, here the evidence was not susceptible of multiple *reasonable* inferences. Taking into account the demeanor of the witnesses, the district court found Dr. Sanghera and Mr. Pope's explanations to be implausible. (JA00074; JA00093-97.) Moreover, contrary to Abbott's argument, the district court's finding did not focus only on the phrase "it is unequivocally clear": the district court reviewed the entirety of the submissions to the PTO and EPO, and found them to be clearly inconsistent. (JA00081-98.) These factual findings by the district court are amply supported by the evidence and cannot be clear error.

3. Attorney Argument Is Information Material to Patentability Where It Constitutes Inconsistent Statements.

Abbott argues that the district court's findings are "unprecedented," because they are based not on a failure to disclose prior art, but on a failure to disclose attorney argument. (Br. at 21, 47-50.) According to Abbott, such information cannot be material to patentability. (*Id.*) Abbott is wrong on the facts and the law. As to the facts, Dr. Sanghera's declaration, which Abbott's brief virtually ignores, was not attorney argument. As for the law, the district court's finding that the withheld information was "richly material" was based on sound legal precedent. (JA00094.)

In 1992, 37 C.F.R. § 1.56 ("Rule 56") was amended to define material information, in part, as noncumulative information that "refutes, or is inconsistent with, a position the applicant takes in . . . [a]sserting an argument of patentability." 37 C.F.R. § 1.56(b)(2) (1992). Rule 56(b) clearly applies here, where the withheld information (the prior characterization of the '382 disclosure) was clearly inconsistent with Abbott's "argument of patentability" to the examiner, and the district court's reliance upon it was entirely proper. (JA00089, JA00091.)

Abbott relies on Federal Circuit cases that have held that applicants do not violate their duty of candor simply by arguing for a particular interpretation of disclosed prior art references. (Br. at 48 and cases cited therein.) The cases cited by Abbott, however, are premised on the notion that the PTO examiner had equal

access to the prior art references and could make up his own mind as to the meaning of the references. None of them involves the deliberate withholding of the applicant's own prior inconsistent statement, characterizing the same reference in the exact opposite way, as prohibited by Rule 56, and as happened here. (JA00091; JA02994 at 689:6-17); *see Pharmacia Corp. v. Par Pharm., Inc.*, 417 F.3d 1369, 1373 (Fed. Cir. 2005) (upholding inequitable conduct based on declarant's failure to disclose prior inconsistent statement in article that declarant had co-authored).

4. Mr. Pope's and Dr. Sanghera's Nondisclosures Were Intentional.

Abbott next argues that the district court improperly relied on a gross negligence standard, and inferred intent from materiality alone. (Br. at 50.) According to Abbott, because Pope's interpretation of the EPO briefs as not inconsistent with the submissions to the PTO was allegedly "plausible," there could have been no inference of intent. (*Id.* at 51-52.) Abbott's arguments fail, as they are inconsistent with the facts as well as the district court's findings.

First, the district court did not apply the wrong standard by stating that Pope "knew or should have known" the materiality of the withheld information. (Br. at 50.) Intent to mislead may be inferred "where a patent applicant knew, or should have known, that withheld information would be material to the PTO's consideration of the patent application." *Critikon*, 120 F.3d at 1256. The district

court did *not* find that a reasonable person in Pope's position should have known of the materiality —it found that *Pope himself* should have known of the materiality. (JA00092-93.) The district court used the proper standard. Moreover, Abbott has no credible argument that Pope was unaware of the materiality of the prior statement about the "optionally, but preferably" sentence: he was present at an examiner interview at which the examiner and he agreed that that exact sentence was the single remaining bar to patentability.

Second, because the withheld information was highly material, a lower level of intent is required to establish inequitable conduct. *Cargill, Inc. v. Cambra Foods, Ltd.*, 476 F.3d 1359, 1364 (Fed. Cir. 2007). Repeated rejections of a claim in view of the same issue put an applicant on notice regarding the high materiality of information relating to that issue. *Id.* at 1366. In order to overcome the repeated rejections over the '382 patent, Mr. Pope specifically discussed the "optionally, but preferably" sentence with the examiner during the interview. When he and Dr. Sanghera submitted the declaration and remarks to the PTO in order to overcome the examiner's sustained rejection over the '382 patent, they were aware that the examiner was focused on a single issue: whether the '382 patent disclosed membraneless sensors. (JA03297-304; JA03311-16; JA03015-16 at 775:16-776:5.) The district court did not clearly err by inferring deceptive intent from Abbott's failure to disclose noncumulative, material information on the very

point of novelty alleged for the '551 patent. *Pharmacia*, 417 F.3d at 1373; *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, 487 F.3d 897, 916, 918 (Fed. Cir. 2007).

Third, this is not a case of "minor missteps," or a case where the attorney offered a plausible explanation for his conduct, as Abbott contends. (Br. at 51-53.) "When an applicant knows or obviously should know that information would be material to the examiner, as was true here, but the applicant decides to withhold that information, 'good faith' does not negate an intent to manipulate the evidence." *Cargill,* 476 F.3d at 1368. The district court found that

> 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. . . . 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.

(JA00093.) Deceptive intent may fairly be inferred absent a "credible explanation" for the nondisclosure. *Bruno Indep. Living Aids v. Acorn Mobility Servs.*, 394 F.3d 1348, 1354-55 (Fed. Cir. 2005). A district court's credibility determination of intent "can virtually never be clear error." *Brasseler U.S.A. L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1381 (Fed. Cir. 2001) (citation omitted).

The district court's finding that Mr. Pope's multiple explanations for withholding the contrary representations to the EPO were not credible was supported by the evidence. One explanation given by Mr. Pope was that he considered the information "cumulative." (JA03290.) But Abbott points to nothing in the record even close to the same points made in the EPO appeal, and the district court so found. (JA00091.) Another explanation by Mr. Pope was that the "optionally, but preferably" sentence was "mere patent phraseology," because words such as "preferably" were used by practitioners to "avoid being unduly restrictive," and therefore would have been disregarded altogether by persons of skill in the art. (JA02979-80 at 631:11-632:11.) The district court properly rejected such a "secret code theory," as it would wreak havoc on the patent system, in which such permissive words are often used as adjectives or adverbs to modify technical teachings. (JA00094.) Yet another explanation by Mr. Pope was his alleged belief that the statement to the EPO that the "optionally, but preferably" sentence was "unequivocally clear" applied only to the last six words of the 26-word sentence. (JA02989-90 at 671:11-673:13.) The district court, in its discretion, found that that explanation lacked credibility as well. (JA00093.) This conclusion was based, in part, on the objective evidence that the claims of the '382 patent covered membraneless sensors that could be used in blood, and that the

specification must have been sufficient to support such claims. (JA00094; JA03072-76; JA02752 at 547:11-552:20.)

Fourth, the district court did not infer intent from materiality alone, as Abbott contends. Abbott cites *Judkins* for the proposition that "intent to mislead may not be inferred, without more, from the failure to disclose to the patent examiner *known*, highly material information." (Br. at 50, citing *Judkins v. HT Window Fashion Corp.*, 529 F.3d 1334, 1343 (Fed. Cir. 2008) (emphasis added).) The *Judkins* court noted that a finding of intent is proper where the patentee commits the "'affirmative act' of submitting deceptive and possibly false affidavits to the patent examiner," and where "the examiner has no way of securing the information on his own." *Id.* Those are exactly the facts here. Thus, the district court's inference was based on much more than materiality alone, and was not clearly erroneous.

Finally, Abbott argues that Pope had no obligation to provide a credible explanation for his conduct. (Br. at 53.) Perhaps he did not, but he and Abbott insisted that he testify, and they cannot now erase his unconvincing excuses.

5. Dr. Sanghera Had a Duty of Candor to the PTO.

Abbott challenges only two aspects of the district court's findings that Dr. Sanghera also committed inequitable conduct: that Dr. Sanghera's declaration was "false and misleading," and that he is not absolved because he disclosed

information about the EPO proceedings to Mr. Pope. (Br. at 53-54.) Abbott's arguments fail on both accounts.

As to the content of Dr. Sanghera's declaration, as discussed above, it contained statements that were clearly contradicted by Medisense's statements to the EPO, and thus were highly material. (Section IV.B.2, *supra*.) Dr. Sanghera knew that his sworn statements to the PTO about the meaning of the "optionally, but preferably" sentence were inconsistent with his own company's statements to the EPO — statements that he himself had helped craft. (*Id.*) The district court properly found his statements to be false and misleading, and in doing so, took into account Dr. Sanghera's demeanor as a witness, which it found to be unconvincing. (JA00096.)

Contrary to Abbott's statement, Dr. Higgins did not agree with Dr. Sanghera's reasoning. (Br. at 54.) Dr. Higgins testified that Dr. Sanghera's conclusion would *not* be reasonable from the point of view of a person of skill in the art at the relevant time who had actually seen the '382 specification — the exact point of view from which Dr. Sanghera's declaration was supposedly written. (JA03705-08; JA03156.) When asked whether he believed that Dr. Sanghera's conclusions were reasonable in light of the literature available in the 1983/84 timeframe, he responded "not really," stating that had Dr. Sanghera reviewed the '382 patent in detail, he would have seen that membraneless sensors would have

worked. (JA03709-10.) In fact, he testified that he viewed Dr. Sanghera's conclusions as being wrong. (JA03707-08.) He was never asked, and did not testify that, Dr. Sanghera's declaration was consistent with the arguments to the EPO.

Abbott nonetheless argues that Dr. Sanghera should be absolved for his failure to disclose this prior position in Europe because he "fully discharged his obligation" under Rule 1.56(d) by providing information to Pope.[6] (Br. at 53-54.) Abbott's interpretation of this rule is incorrect. Rule 1.56(d) is directed at a situation where a person submits accurate information to an attorney or inventor, and has no further involvement in the prosecution. In such a situation, the ultimate decision whether or not to present the information in question rests with the individual responsible for presenting the information. The Manual of Patent Examination and Procedure makes this clear:

> 37 CFR 1.56(d) makes clear that information may be disclosed to the Office through an attorney or agent of record or through a *pro se* inventor, and that other individuals may satisfy their duty of disclosure to the Office by disclosing information to such an attorney,

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[6] Mr. Pope, in his proposed amicus curiae brief, argues just the opposite: that he relied on Dr. Sanghera in determining whether to disclose the EPO submissions. Abbott should not be absolved from a finding of inequitable conduct by allowing its two employees to lay blame on each other.

> agent, or inventor who then is responsible for disclosing the same to the Office. Information that is not material need not be passed along to the Office.

MPEP § 2002.01.

If Dr. Sanghera had simply conveyed the information from the European proceedings to Mr. Pope and had no other involvement, Section 1.56(d) would apply to Dr. Sanghera's conduct. However, Dr. Sanghera did not stop there. He went on to sign and submit a declaration to the PTO stating that the key sentence in the '382 patent meant that a membrane was *required* for use with whole blood, all the while knowing, because he was there and had crafted the statements, that Medisense had told the EPO the opposite. He had a duty of candor with regard to that declaration that could not be discharged simply by informing Mr. Pope of his (and Medisense's) prior inconsistent statements. 37 C.F.R. § 1.56(a). Moreover, he testified that he and Mr. Pope were "a team" with respect to this prosecution. (JA03016 at 777:23-778:5.)

Dr. Sanghera knew that the examiner needed a sworn statement justifying Abbott's proposal that the examiner disregard the "optionally, but preferably" sentence in order to allow the claim, and he provided such a statement to the PTO. (JA03015 at 775:16-24.) Mr. Pope's knowledge of the inconsistent EPO statement cannot absolve Dr. Sanghera's conduct.

C. Anticipation of the '745 Patent

1. The '225 Patent Discloses Diffusible Mediators.

Abbott argues that the '225 reference does not disclose the use of a diffusible mediator. (Br. at 58-60.) According to Abbott, the district court impermissibly "focused on isolated words, out of context," and ignored the remainder of the '225 specification. (*Id.*)

First, the district court's reading of the '225 specification was consistent with Federal Circuit precedent. It is undisputed that the '225 reference states that "a diffusing or leachable (*i.e.* releasable) redox mediator is not desirable." (Br. at 60.) This sentence plainly discloses diffusible mediators and also teaches away from using them, and Abbott's own expert so admitted. (JA08367-68 at 141:23-25, 142:9-143:5.) Diffusible mediator sensors were well known in the art, and no one believed that using them in a sensor such as the one disclosed in the '225/'164 reference would have been a problem. (JA09683; JA11315; JA11431.) Abbott discounts the '225/'164 disclosure, because it teaches away from the use of diffusible mediators, but it is black letter law that a reference anticipates an invention even if, after disclosing the invention, the reference then disparages it. *Upsher-Smith Labs., Inc. v. Pamlab, L.L.C.*, 412 F.3d 1319, 1323 (Fed. Cir. 2005). Thus, because "the question whether a reference 'teaches away' from the invention

is inapplicable to an anticipation analysis," Abbott's argument is legally irrelevant. *Id.*

Second, Abbott's argument that the remainder of the specification shows that the '225 "invention" does not encompass leachable or diffusible mediators is unavailing. While it may be true that the *invention* disclosed in the '225 reference related to the use of non-diffusible mediators, this does not take away from the fact that the '225 reference *also* discloses diffusible mediators, which were well-known in the prior art. The issue here is not what the inventors of the '225 reference thought they invented — it is what the '225 reference disclosed to persons of skill in the art at the relevant time.

Finally, Abbott's argument is contrary to its own arguments at claim construction. As discussed above, Abbott argued that the '164 patent — which has a specification identical to the '225 reference — was not limited to immobilized mediators, relying on the same portion of the '225/'164 specification which states that a diffusible mediator is not desirable. (Section IV.C, *supra.*) Abbott should not be permitted to contend otherwise now.

2. Dr. Turner's Testimony Did Not Create a Triable Issue of Fact.

Abbott argues that the testimony of Bayer's expert, Dr. Turner, creates a material issue of fact, because Dr. Turner testified that the '164 patent "did not disclose the use of diffusible mediators with the invention and had *no teachings* for

making the invention work with diffusible mediators." (Br. at 60-61 (emphasis in original).) Abbott is wrong.

Dr. Turner never testified that the '164 patent does not disclose diffusible mediators. In each of the quotations cited by Abbott, Dr. Turner's testimony *presumes* disclosure of diffusible mediators in the '164 patent, while at the same time stating that it teaches away from their use: "The '164 patent, according to my reading, *tells you specifically* not to use diffusible mediators"; "Even though *it tells you not to do it . . .*"; "This *clearly tells me* don't use a diffusible mediator." (JA09736-41 (emphasis added).) Moreover, Abbott's argument that the '225/'164 reference must "teach" the use of diffusible mediators is wrong as a matter of law. "The law of anticipation does not require that the reference 'teach' what the subject matter of the patent teaches." *Celeritas Techs., Ltd. v. Rockwell Int'l Corp.*, 150 F.3d 1354, 1361 (Fed. Cir. 1998) (citations omitted). It is sufficient that each limitation is found, either expressly or inherently, in the prior art reference. *Id.* The "diffusible mediator" limitation is expressly disclosed in the '225 reference.

Dr. Turner's testimony finds ample support in the plain language of the '225 reference. As Judge Jenkins found, although the '225 reference teaches that immobilized mediators are preferable, the reference "acknowledge[s] the possibility of using a leaching or diffusing mediator." (JA00050.) For instance, the patent states, "Preferably, there is little or no leaching of the redox mediator

away from the working electrode 22 into the sample during the measurement period, which is typically less than about 5 minutes." (JA08787 at 9:22-25.) As the district court found, while this sentence teaches that less diffusion is *preferable*, it does not preclude the use of diffusible mediators. (JA00050.) Other passages describing diffusible mediators similarly indicate that diffusible mediators are not desirable, but these passages never preclude their use. (*Id.*) The claims of the '225 also disclose that a diffusible mediator may be used in the electrode. (*Id.*)

To the extent Abbott's argument is based on whether the '225 reference is enabling, it is not supported by evidence. Dr. Turner opined that diffusible mediator sensors were well known in the art at the time, and that no one believed that using them in a sensor such as the one disclosed in the '225/'164 reference would have been a problem. (JA09683; JA11315; JA11431.) Abbott's own expert, Dr. Bard, admitted that "[o]ne of ordinary skill in the art could make a sensor with diffusible mediators using the teachings of the '164 Patent, whether the '164 Patent explicitly discloses them or not." (JA08518; JA00052.) He further admitted at his deposition that the '225 reference discloses that diffusible mediators can be used. (JA08367-69 at 141:23-25, 142:9-143:5.) Judge Jenkins properly found this testimony relevant and dispositive.

3. Abbott Waived Its "Background Signal" Argument, and It Is Without Basis in Any Event.

Finally, Abbott argues that the '225 patent did not disclose or enable the "background signal" limitation of the '745 patent. (Br. at 62.) Abbott did not raise this argument at summary judgment — it raised it for the first time in its motion for reconsideration of the district court's summary judgment ruling. (JA09301-34; JA11085-87.) "Raising an issue for the first time in a motion to reconsider is not considered adequate preservation of the issue at a summary judgment stage." *Intercontinental Travel Mktg. v. FDIC*, 45 F.3d 1278, 1286 (9th Cir. 1994). Thus, Abbott has failed to meet its burden to adequately preserve this issue for appeal. *Id.*

Even if Abbott were permitted to advance this argument now, it should be rejected because Abbott and its expert *conceded* that the '225 reference disclosed the background signal limitation. At summary judgment, defendants' expert Dr. Weber provided a detailed analysis of the background signal issue as it related to the '225 reference, which the district court found to be well-supported, constituting a *prima facie* showing that the '225 reference meets all limitations of the '745 claims at issue in this appeal. (JA00048; JA01815-17 (citing Weber expert report, JA01822-84, at JA01863-67).) Abbott did not dispute any element other than the diffusible redox mediator and the non-flowing limitations, and the

district court relied on Abbott's failure of proof in determining that there were no material issues of fact. (JA00048.)

Abbott did not provide any evidence in support of its argument even in its motion for reconsideration. Abbott's only citation was to paragraph 63 of the Bard declaration and to a section of his expert report, neither of which mentions the '225 reference.[7] (JA11085-87; JA01970; JA01988-95.) Dr. Bard offered only a single sentence on the '225 reference in his entire declaration, and that sentence related to the electrode spacing disclosed in the '225 reference, *not* to the background signal limitation. (JA01973.) Neither Dr. Bard nor Abbott challenged Dr. Weber's finding that the background signal limitation was found in the '225 reference, and Abbott's argument fails.

VII. CONCLUSION

For the foregoing reasons, Bayer respectfully requests this court to affirm the judgments invalidating the '745 and '551 patents and finding the '551 patent unenforceable.

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[7] Abbott's appeal brief does not cite to this evidence.

Dated: December 17, 2008

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) or FRAP 28.1(e). The brief contains 13,971 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii). This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) or FRAP 28.1(e) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). The brief has been prepared in a proportionally spaced typeface using Microsoft Word, Version 2003 in 14-point Times New Roman font.

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

Therasense v. Becton, Dickinson and Company
2008-1511, -1512, -1513, -1514, -1595

Affidavit of Authority

San Francisco, CA, ss:

Parisa Jorjani, being duly sworn, deposes and says that Rachel Krevans, after reviewing BRIEF FOR DEFENDANT-APPELLEE BAYER HEALTHCARE, LLC, authorized me to sign this document on her behalf.

Parisa Jorjani

Subscribed and sworn before
me on this 17th day of December 2008.

VIKASHNI POONI
Commission # 1598230
Notary Public - California
San Francisco County
My Comm. Expires Jul 30, 2009

Notary Public

My commission expires July 30, 2009

CERTIFICATE OF SERVICE

I, Christopher Meier, hereby certify that on the 17th day of December 2008, I caused one original and eleven copies of the foregoing document:

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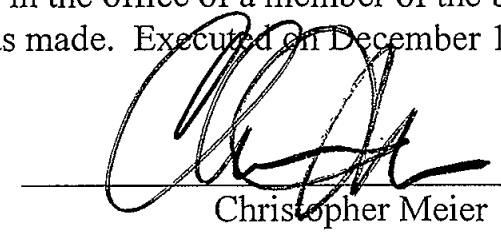
Attorneys for Lawrence S. Pope

I declare I am employed in the office of a member of the bar of this court at whose direction the service was made. Executed on December 17, 2008, at San Francisco, CA.



Christopher Meier