United States Court of Appeals for the Federal Circuit

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

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.

Rohit K. Singla, Munger, Tolles & Olson LLP, of San Francisco, California, argued for plaintiffs-appellants. With him on the brief were Jason A. Rantanen; and Donald W. Ward, of Los Angeles, California.

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Appealed from: United States District Court for the Northern District of California

Judge William H. Alsup

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Appeals from the United States District Court for the Northern District of California in consolidated case nos. 04-CV-2123, 04-CV-3327, 04-CV-3732, and 05-CV-3117, Judge William H. Alsup.

DECIDED: January 25, 2010

Before LINN, FRIEDMAN, and DYK, Circuit Judges.

Opinion for the court filed by Circuit Judge DYK. Opinion concurring-in-part and dissenting-in-part filed by Circuit Judge LINN.

DYK, Circuit Judge.

Therasense, Inc. (now Abbott Diabetes Care, Inc.) and Abbott Laboratories appeal from a final judgment of the United States District Court for the Northern District

of California. Following a bench trial, the district court determined that claims 1–4 of U.S. Patent No. 5,820,551 ("the '551 patent") were invalid due to obviousness and that the entire '551 patent was unenforceable due to inequitable conduct. See Therasense, Inc. v. Becton, Dickinson & Co., 565 F. Supp. 2d 1088 (N.D. Cal. 2008) ("Trial Opinion"). The district court also granted summary judgment of noninfringement of all asserted claims in U.S. Patent Nos. 6,143,164 ("the '164 patent") and 6,592,745 ("the '745 patent"). See Therasense, Inc. v. Becton, Dickinson & Co., 560 F. Supp. 2d 835 (N.D. Cal. 2008) ("Summary Judgment Order"). Finally, it found nearly all of the asserted claims of the '745 patent invalid due to anticipation. Id. We affirm.

BACKGROUND

I

The Centers for Disease Control and Prevention estimates that 23.6 million Americans have diabetes. Ctrs. for Disease Control & Prevention, National Diabetes Fact Sheet, 2007, at 5 (2008). Diabetes mellitus, generally referred to simply as diabetes, is a disorder of the carbohydrate metabolism in which the body either does not produce enough or does not properly utilize insulin, a hormone produced in the pancreas. Insulin regulates blood sugar levels by facilitating the absorption of glucose into cells. In diabetics, this failure of the body to produce or utilize insulin causes glucose to build up in the blood, leading to potentially serious complications, such as comas, blindness, kidney damage, cardiovascular disease, and lower-limb amputations. Diabetics today rely on inexpensive and accurate home blood glucose meters to help them manage their condition.

The patents-in-suit claim technology in the area of disposable blood glucose test strips. These single-use strips work in conjunction with glucose meters and employ electrochemical biosensors to measure the level of glucose in a sample of blood, usually a single drop. When blood is introduced to a test strip, the glucose in the blood reacts with an enzyme present on the strip, transferring electrons to the enzyme. A mediator, also incorporated on the strip, transfers the electrons from the enzyme to the sensor's "active electrode." The electrons then flow from the strip into the meter, which calculates the glucose concentration based on the current flow. While common test strips measure glucose levels in samples of whole blood (blood that contains all of its components, including red blood cells), electrochemical sensors are also capable of measuring glucose levels in a variety of other sample types, such as blood plasma (blood without red blood cells), interstitial fluid (fluid between cells in the skin and organs), and buffer solutions (test solutions that simulate blood). They are also capable of measuring samples in vivo—inside the body—such as live blood. We describe below the various patents involved here.

II

Abbott Diabetes Care, Inc., the successor to Therasense, Inc. and a subsidiary of Abbott Laboratories, is the owner of the patents-in-suit. For convenience we will use the single designation "Abbott" to refer to any and all of the foregoing. In March 2004, Becton, Dickinson and Co. ("BD") sued Abbott in the United States District Court for the District of Massachusetts seeking a declaratory judgment of noninfringement of the '164 and '745 patents. The two products involved were the BD Latitude Diabetes Management System and the BD Logic Blood Glucose Monitor. Both products featured

BD's blood glucose test strip, the BD Test Strip. Two months later, Abbott countersued BD in the Northern District of California alleging infringement of the '164, '745, and '551 patents. The action in the District of Massachusetts was subsequently transferred to the Northern District of California. Shortly thereafter, Abbott also initiated an infringement action against Nova Biomedical Corp. ("Nova"), BD's supplier, alleging infringement of the '164, '745, and '551 patents asserted in Abbott's suit against BD.[1] In August 2005, Abbott sued Bayer Healthcare LLC ("Bayer") alleging that its Microfill and Autodisc blood glucose strips infringed the '551 and '745 patents.

All of the cases were consolidated, with the defendants asserting that their products did not infringe Abbott's patents and that the patents were invalid. On April 3, 2008, the court issued a summary judgment order finding that BD/Nova's products did not infringe any of the asserted claims of the '164 or '745 patents. It also found claims 1–5, 8, 21–23, 28, 31, and 34 in the '745 patent anticipated. Summary Judgment Order, 560 F. Supp. 2d at 880. Issues relating to the '551 patent were considered in a bench trial from May 27–June 3, 2008. After trial the district court determined that claims 1–4 of the '551 patent were invalid due to obviousness and that the entire '551 patent was unenforceable due to inequitable conduct. Trial Opinion, 565 F. Supp. 2d at 1127.[2] The district court entered Rule 54(b) judgments, and we have jurisdiction over this appeal pursuant to 28 U.S.C. § 1295(a)(1).

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[1] Because Abbott accuses BD and Nova of infringement based on the same BD products, BD and Nova will hereinafter be referred to collectively as "BD/Nova."

[2] Abbott also sued BD/Nova alleging that the BD Test Strip infringes U.S. Patent No. 5,628,890. That patent was the subject of a separate jury trial in which the jury found that the BD Test Strip did infringe the patent, but that the patent was invalid. After entry of judgment, Abbott appealed, and that judgment is the subject of a separate

DISCUSSION

I Obviousness of the ’551 Patent

We first address the district court’s holding that claims 1–4 of the ’551 patent would have been obvious in light of U.S. Patent Nos. 4,545,382 (“the ’382 patent”) and 4,225,410 (“the ’410 patent”). Obviousness is a question of law based on underlying questions of fact. Daiichi Sankyo Co., Ltd. v. Apotex, Inc., 501 F.3d 1254, 1256 (Fed. Cir. 2007) (citing Winner Int’l Royalty Corp. v. Wang, 202 F.3d 1340, 1348 (Fed. Cir. 2000)). We therefore review the ultimate determination of obviousness by a district court de novo and the underlying factual inquiries for clear error. Id.

A Membraneless Sensor

The claims of the ’551 patent describe a test strip with an electrochemical sensor for testing whole blood without any membrane over the electrode.[3] Some sensors in

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appeal in Therasense, Inc. v. Becton, Dickinson & Co., Nos. 2009-1008, -1009, -1010, -1034, -1035, -1036, -1037 (Fed. Cir. Jan. 25, 2010).

[3] Claim 1 of the ’551 patent is representative. It provides:

> 1. A single use disposable electrode strip for attachment to the signal readout circuitry of a sensor to detect a current representative of the concentration of a compound in a drop of a whole blood sample comprising:
>
> a) an elongated support having a substantially flat, planar surface, adapted for releasable attachment to said readout circuitry;
>
> b) a first conductor extending along said surface and comprising a conductive element for connection to said readout circuitry;
>
> c) an active electrode on said strip in electrical contact with said first conductor and positioned to contact said whole blood sample;
>
> d) a second conductor extending along said surface comprising a conductive element for connection to said read out circuitry; and
>
> e) a reference counterelectrode in electrical contact with said second conductor and positioned to contact said whole blood sample,
>
> wherein said active electrode is configured to be exposed to said whole blood sample without an intervening membrane or other whole blood

the prior art had employed diffusion-limiting membranes to control the flow of glucose to the electrode because the slower mediators of the time could not deal with a rapid influx. Other prior art sensors employed protective membranes to prevent "fouling"—when red blood cells stick to the active electrode and interfere with electron transfer to the electrode, resulting in an inaccurate measurement. In addition, sensors injected into the human body for in vivo measurements used protective membranes as a safety measure to prevent the chemistry from dissolving into the body and because fouling was a particular problem with respect to long-term in vivo implants.

The central question with respect to obviousness is whether the prior art disclosed a glucose sensor without a membrane for use in whole blood. The district court found after trial that the prior art '382 patent disclosed electrochemical sensors in which "a protective membrane was optional in all cases except the case of live blood, in which case the protective membrane was preferred—but not required." Trial Opinion, 565 F. Supp. 2d at 1103. Whether the '382 patent disclosed a membraneless sensor is

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> filtering member and is formed by coating a portion of the first conductor with a mixture of or layers of an enzyme which catalyzes a redox reaction with said compound in whole blood and a mediator compound which transfers electrons from said redox reaction to said first conductor to create a current representative of the concentration of said compound in said whole blood sample; and wherein said active electrode which is formed on a portion of said conductor is not in electrical contact with said reference counterelectrode but these electrodes are so dimensioned and positioned that they can be simultaneously completely covered by a single drop of whole blood such that this drop provides an electrical path between these electrodes to support said current representative of the concentration of said compound in said whole blood sample.

'551 patent col.13 l.29–col.14 l.17 (emphasis added).

a question of fact which we review for clear error. See Graham v. John Deere Co., 383 U.S. 1, 17 (1966).

Initially filed in 1981 by one of Abbott's predecessors, the '382 patent represented an early achievement in the field of electrochemical sensors for measuring glucose levels. The '382 patent disclosed a faster-acting ferrocene mediator chemistry that allowed for better response times and quicker test results. The first two named inventors on the '382 patent are also the first two named on the '551 patent.

At the outset, it is important to understand the scope and context of the '382 patent. The claims of a prior art patent are part of its disclosure. In re Brenno, 768 F.2d 1340, 1346 (Fed. Cir. 1985) ("[I]t is true . . . that 'a claim is part of the disclosure' . . . ."); In re Smolak, 88 F.2d 838, 841 (CCPA 1937) ("[T]he disclosures in [prior art] specifications . . . include the claims, the written specification, and the drawings." (quotation omitted)); see also Gabrielidis v. Prince Sports Group, Inc., Nos. 99-1469, 99-1490, 2000 WL 1648134, at *7 (Fed. Cir. Nov. 1, 2000). The claims of the '382 patent are plainly directed in part to sensors without a membrane, as is made clear by the dependent claims that specifically include a membrane as an additional feature of the device. For example, claim 1 claims a sensor electrode utilizing an enzyme and a ferrocene mediator for generating an electrical current representative of the level of a substance in a sample liquid, see '382 patent col.10 ll.52–63, while dependent claim 12 adds "an outermost protective membrane permeable to water and glucose molecules, said membrane covering said enzyme located upon said ferrocene layer," id. col.11 ll.29–32. One embodiment described in the patent involves a membraneless sensor for testing interstitial fluid, see id. col.3 l.53–col.4 l.2, and Example 8 of the patent

specifically describes tests on strips using a buffer solution both with and without membranes, see id. col.9 ll.22–30.

Abbott appears not to contest that the '382 patent broadly claims membraneless strips and that the specification discloses such membraneless strips. It contends, however, that in the case of blood—as opposed to other fluids—a membrane is required. In this respect it is significant that none of the claims in the '382 patent explicitly distinguishes between blood and other fluids. Also pertinent is the difference between in vivo sensors and in vitro sensors. In vivo sensors test live blood or other fluids inside the body, while in vitro sensors test fluids such as blood after they have been extracted from the body. Claims 1–17 of the '382 patent cover both in vivo and in vitro sensors; additional claims 18–19 are limited to in vivo sensors, though again those claims do not distinguish between sensors for blood and other fluids.

Thus, as the district court found, the difficulty with Abbott's position that membranes are required for blood testing is that the claims covering membraneless sensors do not exclude blood and that other fluids are described as being tested by sensors without membranes. Most significantly, the specification addresses blood directly, stating that:

> 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.

Id. col.4 ll.63–66. On its face, the specification appears to contradict Abbott's position. It states that when testing with blood—blood in the body (i.e., in vivo testing)—a protective membrane is preferred. The use of the term "preferably" implies that such a membrane is not necessary. See, e.g., Callaway Golf Co. v. Acushnet Co., 576 F.3d

1331, 1346–47 (Fed. Cir. 2009) (holding that despite stating that the outer layers of a golf ball were "preferably" made of ionomer resins, the patent also disclosed the use of other materials such as polyurethane); Halliburton Energy Servs., Inc. v. M-I LLC, 514 F.3d 1244, 1251 (Fed. Cir. 2008) ("[T]he specification states that 'preferably' none of these clays are added; this strongly suggests that absence of clays is simply a preferred embodiment."); Cordis Corp. v. Medtronic AVE, Inc., 339 F.3d 1352, 1357 (Fed. Cir. 2003) ("[U]se of the term 'preferably' makes clear that the language describes a preferred embodiment, not the invention as a whole."). Furthermore, when testing other sample types—which include whole blood outside the body, as well as blood plasma, interstitial fluid, and buffer solutions—the protective membrane is "optional," even more strongly confirming that it is not required for whole blood. The language of the patent thus confirms that a membrane is not necessary when testing live blood in vivo or whole blood in vitro.

Abbott, however, contends that a person having ordinary skill in the art would not have read the '382 specification that way. Abbott asserts that the conventional wisdom of those skilled in the art was that a membrane was necessary when testing with blood, and that skilled artisans would not have read the patent's disclosure literally when it said that a membrane was not necessary with blood.

Abbott may well be correct that for in vivo blood testing—where the sensor is implanted in the body for up to a year—a membrane might sometimes be required for safety and for accurate measurement because of the risk of fouling over the long period

of time that the sensor must operate.[4] The question, however, is whether a membrane was required for in vitro testing of whole blood where the blood stays on the sensor for, at most, a matter of minutes. Dr. Johnson, Abbott's expert, testified that one of ordinary skill in the art in 1983 would have thought that a membrane was required with blood with the '382 patent because of the risk of fouling. He did not specifically address the differences between in vivo and in vitro testing of blood. Bayer's expert witness, on the other hand, specifically addressed both types of testing, recognizing that for in vivo testing of blood a membrane might be necessary to ensure patient safety from the risk of chemicals escaping the sensor and entering the body, and to eliminate the problem of fouling that would occur as the sensor remained in the body for weeks or months. He testified that with in vitro testing a membrane was not necessary because there was no risk of chemicals entering the body and the time period involved in the testing was very short, particularly with respect to the faster chemistry claimed in the '382 patent. The district court plainly found the Abbott testimony not credible and credited the Bayer testimony, stating:

> Skilled artisans would have known that deleting the membrane would simply have deleted their mechanical advantages. They would have known, however, that the electrochemistry would still have worked. They would have known that the degree of fouling would have depended on how long the sensor was exposed to blood. They would have known that the risk of fouling would have been reduced for faster-acting chemistry and reduced even more for sensors used only once, i.e., disposable sensors with no accumulation of residue. They would have known that omitting the filter would have had the further advantage of speeding up the test time even more.

[4] However, one of the inventors of the '382 and '551 patents, Dr. Higgins, testified that even the phrase "preferably when being used on live blood" meant that "you would probably need a membrane, but not definitely." J.A. 3104.

Trial Opinion, 565 F. Supp. 2d at 1101. The district court did not clearly err in crediting Bayer's expert testimony.

Abbott also contends that another portion of the '382 patent's specification beyond the "[o]ptionally, but preferably" sentence demonstrates that a membrane is required when testing whole blood. Abbott in particular points to Example 8 of the patent. Abbott theorizes that the failure of Example 8 (listing test results for a buffer solution with and without a membrane and blood with a membrane) to mention whole blood testing without a membrane somehow demonstrates that whole blood testing required a membrane. We reject this argument. A single example testing whole blood with a membrane does not imply that membranes are required. In fact, there was testimony from Dr. Turner that Example 8's tests with the buffer solution demonstrated that the membraneless sensor would have worked with blood and provided a suggestion to do so, because the pH level of the buffer was apparently deliberately chosen in this example to match the pH of blood. The district court correctly found that "Example 8 in the '382 patent [is] consistent with the plain meaning of [the '[o]ptionally, but preferably'] sentence." Trial Opinion, 565 F. Supp. 2d at 1100. The court thus did not clearly err in finding that the '382 patent disclosed a membraneless sensor for whole blood testing.[5]

[5] Abbott also attempts to rely on U.S. Patent No. 4,897,173 ("the '173 patent") to show that the '382 patent did not disclose a membraneless sensor for whole blood and that the conventional wisdom of those of ordinary skill in the art was that a membrane was necessary when testing whole blood even after the '382 patent. The fact that the '173 patent contained an example in which whole blood was tested using a sensor including a membrane hardly suggests that a membrane was universally required.

B Enablement and Reasonable Expectation of Success

In order to render a claimed apparatus or method obvious, the cited prior art as a whole must enable one skilled in the art to make and use the apparatus or method. Beckman Instruments, Inc. v. LKB Produkter AB, 892 F.2d 1547, 1551 (Fed. Cir. 1989). An individual prior art reference, on the other hand, "need not be enabled; it qualifies as a prior art, regardless, for whatever is disclosed therein." Amgen, Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1357 (Fed. Cir. 2003); see also Symbol Techs., Inc. v. Opticon, Inc., 935 F.2d 1569, 1578 (Fed. Cir. 1991); Beckman Instruments, 892 F.2d at 1551.

Abbott contends that the '382 patent in combination with the '410 patent could not enable the membraneless sensor of the '551 invention because the oxygen sensitivity of the '382 patent renders it ineffective when testing whole blood without a membrane. Oxygen sensitivity is an indicator of the effect that an oxygen-rich sample will have on the ability of a sensor to provide an accurate reading. Example 8 of the '382 patent, for example, notes that tests measuring glucose levels in an oxygen-saturated buffer solution returned a reading 95% of that produced in an oxygen-depleted buffer. '382 patent col.9 ll.19–21. The '382 patent thus displayed a 5% oxygen sensitivity. Both sides' experts agreed that a 5% oxygen sensitivity is tolerable.[6] The dispute between Abbott's expert and the defense experts was whether testing with whole blood would lead to oxygen sensitivity of greater than 5%.

[6] The '551 invention's oxygen sensitivity, characterized as "minimal," is only slightly better at 4%. See '551 patent col.7 ll.18–20.

The district court made no explicit finding that the '382 patent would have enabled one having ordinary skill in the art to make and use a membraneless sensor. The district court did find, however, that the '382 patent exhibits "very low oxygen sensitivity" comparable to that disclosed in the '551 patent, and therefore the '382 patent would not have any issues with oxygen sensitivity. See Trial Opinion, 565 F. Supp. 2d at 1104. This finding is not clearly erroneous. Although there was conflicting testimony on this issue, the district court could properly credit Bayer's expert, Dr. Turner, who testified that Example 8 of the '382 patent showed that there would be no greater than 5% oxygen sensitivity when testing with whole blood because the buffer test showed only 5% oxygen sensitivity and whole blood would necessarily have a lower oxygen sensitivity than the buffer solution. In light of the district court's finding that the '382 patent exhibits "very low oxygen sensitivity" comparable to that of the '551 patent, we reject Abbott's contention that the oxygen sensitivity of the '382 patent does not enable a membraneless sensor.

Abbott also argues that even if the '382 patent disclosed a membraneless sensor for whole blood, the '551 patent would not have been obvious because the '382 patent's disclosure did not provide a reasonable expectation of success. Here, Abbott essentially recycles its contentions regarding the conventional wisdom of those skilled in the art concerning the need for a membrane and the oxygen sensitivity issue.[7] For the

[7] Abbott also relies on two other alleged differences between the '382 and '551 patents: (1) the use of screen printing to make the '551 electrode, and (2) the use of oxidized electrodes on the '382 patent as opposed to the '551 patent's nonoxidized electrodes. However, these distinctions do not relate to any claimed elements in the '551 patent, and they can hardly be relied upon to show the '551 patent's nonobviousness.

reasons discussed above rejecting those contentions, Abbott's claims that there was no reasonable expectation of success similarly fail.

C Motivation to Combine Prior Art References

The district court found that one skilled in the art would have "readily thought to combine" the '382 patent and the '410 patent to create the membraneless sensor for whole blood of the '551 patent. Trial Opinion, 565 F. Supp. 2d at 1123. While the '382 patent discloses a membraneless sensor, the '410 patent teaches the use of a disposable strip-type electrode cartridge that attaches to readout circuitry. Together, these disclose every element of the '551 patent's blood glucose test strip. Abbott argues that there was no motivation to combine these 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 for testing whole blood." Pls.-Appellants' Br. 37–38.

Abbott's characterization of the '382 patent's disclosure of a membraneless sensor as "seemingly inoperative" simply repeats its arguments related to enablement and reasonable expectation of success. In light of our conclusions that the district court did not clearly err in finding that the '382 patent disclosed a membraneless sensor and that those with ordinary skill in the art would have expected such a membraneless sensor to work, we conclude that the district court did not clearly err in finding that those with ordinary skill would have been motivated to combine this sensor in a disposable form (the contribution of the '410 patent). Dr. Turner testified that the field of biosensors in the early 1980s was a "sophisticated field." J.A. 2523. He also testified that at the time, persons with ordinary skill in the art recognized the advantages to the strip-type

format for home testing, which would have motivated a person to put the membraneless sensor on a strip. Abbott failed to present any expert evidence to rebut that expert testimony. Therefore, the district court did not clearly err in finding that a motivation to combine existed.

D Secondary Considerations: Commercial Success

Abbott contends that even if the district court were correct in finding a prima facie case of obviousness, that finding is overcome by evidence of commercial success. The district court concluded that Abbott failed to demonstrate a sufficient nexus between the claims of the '551 patent and the success of Abbott's Exactech product. Trial Opinion, 565 F. Supp. 2d at 1124. This finding is not clearly erroneous.

In order to overcome a finding of obviousness by demonstrating commercial success, "[a] nexus between commercial success and the claimed features is required." Brown & Williamson Tobacco Corp. v. Philip Morris Inc., 229 F.3d 1120, 1130 (Fed. Cir. 2000). "[T]he asserted commercial success of the product must be due to the merits of the claimed invention beyond what was readily available in the prior art." J.T. Eaton & Co. v. Atl. Paste & Glue Co., 106 F.3d 1563, 1571 (Fed. Cir. 1997).

Abbott argues on appeal that the district court erred by requiring Abbott to show that the commercial success of the Exactech product was attributable to the '551 patent, and that Abbott was entitled to a presumption that the commercial success was due to the invention claimed in the '551 patent. Abbott claims that "if the marketed product embodies the claimed features, and is coextensive with them, then a nexus is presumed and the burden shifts to the party asserting obviousness to present evidence to rebut the presumed nexus." Brown & Williamson, 229 F.3d at 1130.

Abbott is incorrect in contending that it was entitled to the presumption of a nexus. This is not a situation where the success of a product can be attributed to a single patent, because Abbott's Exactech product embodied at least two patents: the '382 patent and the '551 patent. Abbott's expert, Dr. Johnson, admitted that the Exactech strips met all of the limitations of claim 1 of the '382 patent. Furthermore, for the fifteen years that the product was on the market—during which the '382 patent was valid and in force for the entire period save for the final three months—Abbott marked the product with the '382 patent, both before and after the '551 patent issued. As such, there is no presumption that the product's success was due only to the '551 patent.

The defendants presented uncontroverted evidence demonstrating that the Exactech product's success was due to features already present in prior art such as the '382 patent. Abbott's primary witness on commercial success conceded that the Exactech product was successful because it offered "fast disposal for whole blood that could directly be put onto the strip, [provided] the reading, and then basically that strip [was] disposable." J.A. 2640. In addition, the defendants presented numerous declarations that Abbott had filed with the PTO during the prosecution of the '551 patent describing the success of the Exactech strips, all of which attested to the product's "ease of use, short user training period, and ability to consistently obtain accurate test results," J.A. 6969, and "[t]he electrode configuration (allowing a small sample size), the size of the test strips, and the ease with which they can be stored, used and disposed of," J.A. 6985. Abbott offered nothing to contradict this evidence and show that the commercial success of the Exactech product was due to the lack of a protective membrane over the sensor electrode. Under these circumstances, the district court did

not err in rejecting Abbott's assertion that commercial success supported a finding of nonobviousness.

* * *

For the reasons stated above, we find no error with the district court's conclusion that claims 1–4 of the '551 patent would have been obvious in light of the prior art.

II Inequitable Conduct in the Prosecution of the '551 Patent

Following the bench trial, the district court also held the '551 patent unenforceable for inequitable conduct based on a failure to disclose statements made to the European Patent Office ("EPO") during a revocation proceeding of the European counterpart to the '382 patent. Trial Opinion, 565 F. Supp. 2d at 1127.

"[I]nequitable conduct includes affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive." Innogenetics, N.V. v. Abbott Labs., 512 F.3d 1363, 1378 (Fed. Cir. 2008) (quoting Pharmacia Corp. v. Par Pharm., Inc., 417 F.3d 1369, 1373 (Fed. Cir. 2005)) (quotation marks omitted). "The party asserting inequitable conduct must prove a threshold level of materiality and intent by clear and convincing evidence. The court must then determine whether the questioned conduct amounts to inequitable conduct by balancing the levels of materiality and intent, 'with a greater showing of one factor allowing a lesser showing of the other.'" Digital Control, Inc. v. Charles Mach. Works, 437 F.3d 1309, 1313 (Fed. Cir. 2006) (quoting Union Pac. Res. Co. v. Chesapeake Energy Corp., 236 F.3d 684, 693 (Fed. Cir. 2001)) (citations omitted).

The ultimate finding of inequitable conduct is reviewed under an abuse of discretion standard. Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 876 (Fed. Cir. 1988) (en banc). We review the underlying factual determinations of materiality and intent for clear error, however. Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1365 (Fed. Cir. 2008).

The penalty for inequitable conduct is severe, as an entire patent is rendered unenforceable. Therefore it is important that courts maintain a high standard. "Just as it is inequitable to permit a patentee who obtained his patent through deliberate misrepresentations or omissions of material information to enforce the patent against others, it is also inequitable to strike down an entire patent where the patentee only committed minor missteps or acted with minimal culpability or in good faith." Star Scientific, 537 F.3d at 1366. This is one of those rare cases in which a finding of inequitable conduct is appropriate, particularly in light of the critical nature of the representations to the PTO in securing allowance of the '551 patent and the district court's careful and thorough findings as to materiality and intent.

A Materiality

There is no question that the PTO rules, in particular Rule 56, require the submission of any known information that contradicts information submitted to the PTO:

> Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the [PTO], which includes a duty to disclose to the [PTO] all information known to that individual to be material to patentability . . . .
>
> (b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and
>
> . . .
>
> (2) It refutes, or is inconsistent with, a position the applicant takes in:

(i) Opposing an argument of unpatentability relied on by the [PTO], or
(ii) Asserting an argument of patentability.

37 C.F.R. § 1.56(a)–(b). These rules are directly relevant to the materiality component of inequitable conduct because "if a misstatement or omission is material under the . . . Rule 56 standard, it is material [for purposes of inequitable conduct]." Digital Control, 437 F.3d at 1316; see also Pharmacia, 417 F.3d at 1373 (affirming a finding of inequitable conduct where a prior article by a declarant contradicted his declaration to the PTO). The district court found that statements made by Abbott's predecessor to the EPO were highly material to the prosecution of the '551 patent because they contradicted representations Abbott made to the PTO regarding the membraneless sensor disclosed in the '382 patent. Trial Opinion, 565 F. Supp. 2d at 1112–13. This finding is not clearly erroneous, and indeed is clearly correct.

1 PTO Representations

The original application that led to the '551 patent was filed in 1984. Over the next thirteen years, Abbott pursued the patent through half-a-dozen continuation applications that were repeatedly rejected for anticipation and obviousness, including repeated rejections over the '382 patent. In 1997, Abbott formulated a new argument for patentability during a brainstorming session attended by Lawrence Pope ("Pope"), Abbott's patent attorney, and Dr. Sanghera, Abbott's Director of Research and Development. Thereafter, new claims were drafted including electrochemical sensors lacking a membrane. During an interview with the examiner, Pope presented the new claims with the argument that the claims of the application were not anticipated or obvious because the claims taught a new glucose sensor that did not require a protective membrane when testing whole blood. Pope and the examiner specifically

discussed the "[o]ptionally, but preferably" language in the '382 patent. In Pope's own summary of the interview, he stated that he "pointed out [to the examiner] that [the '382 patent] teaches that active electrodes designed for use with whole blood require a protective membrane." J.A. 7644. The examiner then agreed that if Abbott produced "an affidavit or other evidentiary showing that at the time of the invention such a membrane was considered essential [for whole blood, it] would overcome [the '382 patent's] teaching." J.A. 7639.

In accordance with that agreement, Dr. Sanghera submitted a declaration to the PTO urging that the language of the '382 patent concerning the membraneless sensor should not be taken at face value. It stated in relevant part:

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

J.A. 7637 (emphases added). Pope, in submitting the affidavit, further represented:

> The art continued to believe [following the '382 patent] that a barrier layer for whole blood sample was necessary for a considerable period. . . .
>
> One skilled in the art would not have read the disclosure of the Higgins patent (U.S. 4,545,382) as teaching that the use of a protective membrane with whole blood samples was optional. He would not, especially in view of the working examples, have read the "optionally, but preferably" language at line 63 of column [4] as a technical teaching but rather mere patent phraseology. This is supported by the Declaration under 37 C.F.R. 1.132 of Gordon Sanghera which accompanies the present amendment.
>
> . . . .
>
> . . . The applicants have established that a new claim limitation supported by the present application provides a patentable distinction over

> U.S. Patent No. 4,545,382, the key reference in the prosecution of the present application and its predecessors. There is no teaching or suggestion of unprotected active electrodes for use with whole blood specimens in this patent or the other prior art of record in this application.

J.A. 7645–46 (emphases added). Shortly thereafter, the PTO allowed the '551 patent with the newly added claims for a membraneless sensor.

2 EPO Representations

The district court found that Abbott had made directly contradictory representations to the EPO concerning the teaching of the '382 patent in European Patent EP 0 078 636 ("the '636 patent")—a counterpart to the '382 patent with virtually identical specifications—and that Abbott had not disclosed those contradictory representations to the PTO.

In 1993, the '636 patent was revoked as obvious. One of the references the EPO relied on was a German reference labeled D1. Abbott[8] argued to the EPO that the D1 reference was distinguishable. On January 12, 1994, Abbott's patent counsel submitted to the EPO a brief distinguishing the '636 patent from the D1 reference, stating:

> Contrary to the semipermeable membrane of D1, the protective membrane optionally utilized with the glucose sensor of the patent is [sic] suit is not controlling the permeability of the substrate (as set forth above under IV.2., in the membrane of D1 the permeability for the substrate must be kept on a low value to achieve a linear relationship between the measures [sic] currency and the substrate concentration in the test solution). Rather, in accordance with column 5, lines 30 to 33 of the patent in suit:
>
> > "Optionally, but preferably when being used on live blood, a protective membrane surrounds both the enzyme and the mediator layers, permeable to water and glucose molecules."

[8] At this time, the party operating before the EPO was Medisense, a predecessor to both Therasense and Abbott. We use the term "Abbott" to include Medisense.

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

J.A. 6530–31 (emphases added).

On May 23, 1995, Abbott's patent counsel submitted another brief to the EPO regarding the D1 reference and the '636 patent. It again discussed the "[o]ptionally, but preferably" language:

> "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."
>
> It is submitted that this disclosure is unequivocally clear. The protective membrane is optional, however, it is preferred when used on live blood in order to prevent the larger constituents of the blood, in particular erythrocytes from interfering with the electrode sensor. Furthermore it is said, that said protective membrane should not prevent the glucose molecules from penetration, the membrane is "permeable" to glucose molecules.

J.A. 6585 (emphases added).

The district court found that the EPO statements contradicted the PTO representations in at least two significant ways. First, the district court found that by describing the "[o]ptionally, but preferably" language as "unequivocally clear," Abbott's EPO representations contradicted Abbott's representations to the PTO that a person having ordinary skill in the art would have understood the phrase as mere "patent phraseology" that did not convey a clear meaning. See Trial Opinion, 565 F. Supp. 2d at 1110. Second, the district court noted that the EPO documents clearly explained that

membranes were merely preferred for live blood. Id. at 1109–10. The documents identified reasons specifically directed toward live blood explaining why a membrane was necessary, supporting the position that these problems did not exist for in vitro testing of whole blood and that a membrane was not necessary for testing whole blood in vitro. See id. at 1109. These findings are not clearly erroneous, and indeed are manifestly correct.

3 Abbott's Arguments

Abbott asserts that the district court erred in finding that the statements it made to the EPO were inconsistent with the PTO statements. It contends that in the EPO, the focus was on distinguishing the semipermeable membrane of the D1 reference from the protective, permeable membrane of the '636 patent. Abbott is correct that such a distinction was made in the EPO submissions. However, that is not the only point Abbott made in the EPO to distinguish the two references. The district court correctly found that Abbott also argued before the EPO that the protective membrane of the '636 patent was optional. The optional nature of the membrane was not irrelevant to the distinction of the D1 reference's semipermeable membrane because the optional nature of the membrane proved that it was not the type of membrane required by the D1 reference, as Abbott appears to recognize.[9] Abbott's representation was particularly clear in the May 1995 submission. In labeling the "[o]ptionally, but preferably" language "unequivocally clear," Abbott emphasized the alleged plain meaning of the language in

[9] In describing the distinction made before the EPO between the '636 patent and the D1 reference, Abbott states in its reply brief, "If that kind of [semipermeable] membrane is needed, it is needed whenever glucose is measured, regardless of the liquid—buffer, blood, or interstitial fluid. Thus, by showing that the '382/'636 did not use

the specification quoted in the immediately preceding sentence and reinforced that meaning in the following sentence, where it stated, "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." J.A. 6585. This sentence clearly was not directed to permeability. There can be no doubt that Abbott was making two assertions in this submission. It first explained that the protective membrane is optional but preferred when used on live blood and that the '382 patent language was "unequivocally clear" on this point. Then, using the transition "furthermore," it expressed its second point about the permeability of the membrane.

The dissent suggests a somewhat different theory to explain Abbott's representations to the PTO—a theory that significantly was not addressed by Abbott itself. Abbott's theory is that the "unequivocally clear" statement of the second EPO submission was directed to the permeability of the membrane to water and glucose. As discussed above, this theory ignores the context of the "unequivocally clear" statement and particularly the sentence immediately following the "unequivocally clear" statement, which says nothing about permeability. The dissent attempts to fill this gaping hole in Abbott's argument by suggesting that it would be reasonable to interpret the sentence following the "unequivocally clear" statement as also directed to how the membrane functioned, i.e., that it was "unequivocally clear" that it protected against fouling, rather than that it was "unequivocally clear" that it was optional. With respect, Abbott's EPO statements cannot possibly be read in this manner.

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a membrane for at least some liquids, [Abbott] proved that it did not use the D1's

The "unequivocally clear" statement is tied directly to the optional nature of the membrane when used with whole blood and other fluids. The three sentences in question read:

> "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."
>
> 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.

J.A. 6585. On its face, the description of the membrane's protective function was itself designed to establish why the membrane was optional with whole blood and other fluids, but preferred with live blood. It was preferred with live blood because it protected against fouling. Both with respect to whole blood and live blood, it was "unequivocally clear" that the membrane was optional (whole blood and other fluids) or preferred (live blood). Necessarily, it was "unequivocally clear" that the membrane was not required for either whole blood or live blood. Thus, this is not a situation such as that referred to in Scanner Technologies Corp. v. ICOS Vision Systems Corp. in which "multiple reasonable inferences" as to the meaning of representations could be drawn from the evidence and there existed an "equally reasonable inference" favorable to Abbott. See 528 F.3d 1365, 1376 (Fed. Cir. 2008).

Indeed, Abbott in oral argument agreed that the EPO statements were a "recharacterization of the sentence that was already before the [PTO] examiner." Oral Argument at 40:40. Pope in his testimony agreed that the plain English reading of what

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glucose-controlling membrane." Pl.-Appellants' Reply Br. 13 (citation omitted).

Abbott told the EPO was contrary to what Abbott told the PTO.[10] To deprive an examiner of the EPO statements—statements directly contrary to Abbott's representations to the PTO—on the grounds that they were not material would be to eviscerate the duty of disclosure. Moreover, if this could be regarded as a close case, which it is not, we have repeatedly emphasized that the duty of disclosure requires that the material in question be submitted to the examiner rather than withheld by the applicant. See LNP Eng'g Plastics, Inc. v. Miller Waste Mills, Inc., 275 F.3d 1347, 1361 (Fed. Cir. 2001) ("[W]hen a question of materiality is close, a patent applicant should err on the side of disclosure."); LaBounty Mfg., Inc. v. U.S. Int'l Trade Comm'n, 958 F.2d 1066, 1076 (Fed. Cir. 1992) ("[A close case] makes it all the more necessary that the [reference] should [be] disclosed to the examiner. Close cases should be resolved by disclosure, not unilaterally by the applicant.").

Abbott nonetheless contends that lawyer argument about prior art is not information material to patentability and that since both the EPO and the PTO representations were merely argument, any inconsistency between the two could not be material. This court has held that representations made to the PTO concerning the content of prior art "amount[] to mere attorney argument and our precedent has made clear that an applicant is free to advocate its interpretation of its claims and the teachings of the prior art." Innogenetics, 512 F.3d at 1379. However, all of the cases Abbott cites involve patentees who simply made representations to the PTO about prior

[10] Pope agreed that "as a matter of normal English construction," the "unequivocally clear" statement "refers to [the '[o]ptionally, but preferably' language] and refers to all of it." J.A. 2990. Thus, according to Pope, "if [the '[o]ptionally, but preferably'] language stood alone, . . . it would definitely indicate that the use of a protective membrane was optional or preferable." J.A. 2988.

art in order to secure the allowance of their patents. See id.; Young v. Lumenis, Inc., 492 F.3d 1336, 1344 (Fed. Cir. 2007); Life Techs., Inc. v. Clontech Labs., Inc., 224 F.3d 1320, 1326 (Fed. Cir. 2000); Azko N.V. v. U.S. Int'l Trade Comm'n, 808 F.2d 1471, 1485 (Fed. Cir. 1986). None of these cases involved a situation in which contradictory arguments made in another forum were withheld from the PTO. They do not speak to the applicant's obligation to advise the PTO of contrary representations made in another forum. Before the EPO, Abbott made statements that contradicted the representations Abbott made to the PTO regarding the '382 patent. An applicant's earlier statements about prior art, especially one's own prior art, are material to the PTO when those statements directly contradict the applicant's position regarding that prior art in the PTO. See 37 C.F.R. § 1.56(b)(2). In any event, the representations to the PTO were not merely lawyer argument; they were factual assertions as to the views of those skilled in the art, provided in affidavit form.

The district court's finding that the EPO statements were highly material because they contradicted the position taken before the PTO was not clearly erroneous and was strongly supported by the uncontradicted record.

B Intent

In determining whether a failure to disclose material information was intentional, "the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive." Kingsdown, 863 F.2d at 876. Because direct evidence of deceptive intent is rarely available, such intent can be inferred from indirect and circumstantial evidence. Star Scientific, 537 F.3d at 1366.

In concluding that Abbott's representatives—Pope and Dr. Sanghera—intended to deceive the PTO by withholding the EPO documents, the district court made five findings: (1) that the statements made to the PTO concerning the prior art '382 patent were absolutely critical in overcoming the examiner's earlier rejections of the claims of the '551 patent; (2) that the EPO statements would have been very important to an examiner because they contradicted the representations made to the PTO; (3) that Pope and Dr. Sanghera both knew of the EPO statements and consciously withheld them from the PTO; (4) that neither Pope nor Dr. Sanghera provided a credible explanation for failing to submit the EPO documents to the PTO; and (5) that Pope's and Dr. Sanghera's explanations for withholding the EPO documents were so incredible that they suggested intent to deceive. See Trial Opinion, 565 F. Supp. 2d at 1113–16. The first of these is undisputed. The second is not clearly erroneous as discussed above. The third is also undisputed; Pope and Dr. Sanghera together evaluated the documents from the EPO proceedings during the prosecution of the '551 patent and made a conscious decision to withhold them from the PTO.

The district court's fourth and fifth findings regarding intent are based on the district court's assessment of witness credibility. "[D]etermination of the credibility of the witnesses is within the discretion of the presiding official who heard their testimony and saw their demeanor," Griessenauer v. Dep't of Energy, 754 F.2d 361, 364 (Fed. Cir. 1985), such that a judge's credibility determinations are "virtually unreviewable," Hambsch v. Dep't of the Treasury, 796 F.2d 430, 436 (Fed. Cir. 1986). As such, "[t]his court may not reassess, and indeed is incapable of reassessing, witness credibility and motive issues on review." LNP Eng'g, 275 F.3d at 1361.

The district court judge had the opportunity to observe both Pope's and Dr. Sanghera's testimony during the bench trial and found their explanations neither plausible nor credible. In fact, the court explicitly noted that "Attorney Pope did not prove to be a convincing trial witness." Trial Opinion, 565 F. Supp. 2d at 1113. The district court similarly found Dr. Sanghera's testimony not to be credible, expressing twice in its opinion that his demeanor was unconvincing. See id. at 1115 ("As a trial witness, it must be said that Dr. Sanghera was impeached on substantive points with his prior inconsistent statements and exhibited an unconvincing demeanor." (citation omitted)); id. at 1116 ("His unconvincing trial demeanor has been a factor in this determination.").

These findings are amply supported. One example will suffice. In attempting to dismiss the EPO statements as merely cumulative, Pope was confronted with the need to explain the May 1995 statement that the "[o]ptionally, but preferably" language was "unequivocally clear." Pope testified that "it was my understanding at the time that what was unequivocally clear was that that the protective membrane, which was sometimes required by the '636 patent was permeable to water and glucose." J.A. 2983. This is contrary to the explicit meaning of the May 1995 statement, as the district court found. When the district court asked Pope to further explain the sentence, "It is submitted that this disclosure is unequivocally clear," Pope responded:

> I would agree with Your Honor that as a matter of normal English construction, the sentence, "it is submitted" refers to what comes immediately before and refers to all of it, but as a patent attorney reading this document and making a judgment call, I was making my judgment call on what was being conveyed, what information was important, what position was being taken. And in that context, I didn't believe that they were trying to convey anything about the optional but preferably language.

J.A. 2990. The district court did not err in finding that Pope's "trial explanation for his withholding [the EPO submissions] was not plausible and he was not credible" and that Pope "acted with specific intent to deceive [the examiner] and the PTO," Trial Opinion, 565 F. Supp. 2d at 1113, particularly in view of Pope's admission that the EPO statement's "normal English construction" directly contradicted his representations to the PTO on a critical issue.

So too Dr. Sanghera testified that he considered it appropriate to withhold from the PTO his own knowledge, reflected in the EPO submission, that "general English usage" contradicted the representations that he had made to the PTO. He testified that "in general English usage, [he] would not use the terms 'optional' or 'preferable' to describe something that is required," and he could not recall "any instance during the course of [his] scientific career in which [he] use[d] the terms 'optional' or 'preferable' to refer to something that was required." J.A. 3009. Yet like Pope, Dr. Sanghera testified that representations to the EPO confirming that the language was "unequivocally clear" could be withheld. The district court did not err in finding bad faith.

The district court's conclusion of intent also finds support in the fact that Pope relied on Dr. Sanghera, who was not a person having ordinary skill in the art at the time of the '382 patent, to provide a declaration to the PTO regarding the teachings of the '382 patent rather than the inventors of the patent, who appear to have had a view quite contrary to Abbott's opinion as to the language of the '382 patent. Dr. Higgins, an inventor on both the '382 and the '551 patents, testified that even the phrase "preferably when being used on live blood" meant that "you would probably need a membrane, but not definitely." J.A. 3104. He felt that Dr. Sanghera's declaration statements

concerning whole blood were simply "wrong." J.A. 3708. "Had [Dr. Sanghera] been around in the field, working in the field in 1983, and he had seen our patent specification, I believe he, as a person skilled in the art, would have concluded that the membrane may not be necessary." J.A. 3707–08.

Finally, Abbott argues that Dr. Sanghera demonstrated a lack of intent to deceive by satisfying his duty to disclose by providing the EPO documents to Pope. See 37 C.F.R. § 1.56(d) ("Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent or inventor."). However, the district court was correct to note that by submitting a declaration to the PTO, Dr. Sanghera was still obligated to avoid intentional deception. See Trial Opinion, 565 F. Supp. 2d at 1115. "Cases involving affidavits or declarations are held to a higher standard." Innogenetics, 512 F.3d at 1379. This court has in the past expected more of declarants before the PTO. In Ferring B.V. v. Barr Laboratories, Inc., we held that the failure to disclose possible biases of the declarants constituted a material omission where the declarations were submitted to overcome a prior art rejection. 437 F.3d 1181, 1190 (Fed. Cir. 2006). Refac International, Ltd. v. Lotus Development Corp. involved similar circumstances in which declarations submitted to establish enablement failed to disclose possible biases. 81 F.3d 1576, 1581 (Fed. Cir. 1996). In this case, it was Dr. Sanghera's duty to avoid intentional deception in his declaration before the PTO, and merely disclosing the EPO documents to Pope did not obviate that duty.

The dissent sets up various straw men that are irrelevant to the district court's finding of intent and the majority's affirmance of the intent issue. Thus, the dissent urges that Pope and Dr. Sanghera were not aware of U.S. Patent No. 4,388,166 to

Suzuki et al.—a prior art reference disclosing advantages and disadvantages of using membraneless sensors with whole blood—and were not aware of Dr. Higgins's contrary interpretation of the "[o]ptionally, but preferably" language. This is undisputed; the district court did not base its finding on intent on the existence of such knowledge. Nor did the district court find that Abbott misrepresented Dr. Sanghera's qualifications before the PTO.

More to the point is the dissent's urging that Pope's and Dr. Sanghera's testimonies reflect a plausible conclusion that the EPO submissions were not material. For the reasons described above, the district court was clearly correct in concluding that the explanations offered by Pope and Dr. Sanghera were not plausible. The dissent's efforts to come up with new theories of plausibility (discussed above in connection with materiality) are both unconvincing and beside the point. Pope's and Dr. Sanghera's intent must be judged by their asserted beliefs at the time, not by some imputed theory that Abbott itself does not even offer on appeal.

Accordingly, the district court did not clearly err in finding that Pope and Dr. Sanghera both intended to deceive the PTO by withholding the EPO documents.

* * *

Because the district court's findings that the EPO submissions were highly material to the prosecution of the '551 patent and that Pope and Dr. Sanghera intended to deceive the PTO by withholding those submissions were not clearly erroneous, the district court did not abuse its discretion in holding the '551 patent unenforceable due to inequitable conduct.

III Noninfringement of the ’164 and ’745 Patents

On summary judgment, the district court concluded that there was no issue of material fact as to whether the BD Test Strip infringes the ’164 and ’745 patents because the BD Test Strip does not satisfy the “non-flowing manner” limitation present in both patents. Abbott contends that the district court’s decision is based on an erroneous claim construction. We review both the district court’s grant of summary judgment and its claim construction de novo. AquaTex Indus., Inc. v. Techniche Solutions, 479 F.3d 1320, 1328 (Fed. Cir. 2007); Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456 (Fed. Cir. 1998) (en banc).

The ’164 patent describes a glucose sensor for blood samples smaller than one microliter. The ’745 patent describes a glucose sensor for blood samples smaller than one microliter that employs diffusible mediators. A limitation in each of Abbott’s asserted claims in the ’164 and ’745 patents requires that the blood sample being analyzed be held within the strip in a “non-flowing manner.” Claim 16 of the ’164 patent is representative in this respect:

> 16. A method for determining a concentration of an analyte [such as glucose] in a body fluid of a patient, comprising the steps of:
> creating an unassisted flow of a body fluid from the patient;
> transporting a portion of the body fluid into an analyte sensor configured and arranged to determine the concentration of the analyte from 500nL or less of body fluid;
> holding the sample in a non-flowing manner within a sample chamber of the analyte sensor; and
> determining the concentration of the analyte in the body fluid from the portion of the body fluid transported into the analyte sensor.

’164 patent col.25 l.66–col.26 l.11 (emphasis added). The district court construed the claim term “holding the sample in a non-flowing manner within the sample chamber of the analyte sensor” to mean that “the sample is not moving in the sample chamber

during the measurement." Summary Judgment Order, 560 F. Supp. 2d at 854. Even a sample "flowing at a very slow rate" is "directly at odds with the plain and ordinary meaning of 'non-flowing,'" the court stated. Id.

At summary judgment, the district court applied its construction, concluding that the limitation is not satisfied even if the only motion present in the sample is convective flow. See id. at 856. Abbott argues that such an expansive reading is unwarranted because all liquids have at least a minor amount of convective flow, pointing to the uncontroverted testimony of its expert that "[t]here is always . . . at least a minor amount of convection occurring within any liquid." J.A. 10553. We agree with Abbott. Here any reasonable construction must allow for certain types of motion that are inherent within liquids, including convective flow and Brownian motion.[11]

Even though we reject the district court's broad reading of the "non-flowing manner" limitation, we also reject Abbott's alternative construction. Abbott contends that "flow" means to move in a stream and that the proper construction of the "non-flowing manner" limitation should be that the sample is not moving through the sample chamber during measurement. Abbott analogizes to a river or stream that stops flowing when dammed. However, the plain meaning of "flow" is not so limited. A dammed river or stream may no longer flow along the same path as it once did, but the water will continue to flow within the lake behind the dam—a flow that is more than mere convective flow. The sample chamber on the BD Test Strip is no different. Blood can flow through the sample chamber or it can flow within the sample chamber. In either

[11] The district court did not decide whether Brownian motion would be covered by the claim construction. Summary Judgment Order, 560 F. Supp. 2d at 856.

case the blood is still flowing. We construe a "non-flowing manner" to mean that a sample "is not moving in the sample chamber during the measurement," other than motion attributable to convective flow, Brownian motion, or other qualities inherent to all liquids.

Under the correct claim construction, summary judgment of noninfringement was still appropriate. Abbott on appeal does not contend that the BD Test Strip does not evidence flow under the claim construction that we have adopted, and indeed Abbott's expert admitted that there is a "slight swirling in the chamber." J.A. 12258. BD/Nova presented uncontradicted evidence that the BD Test Strip does not infringe Abbott's '164 and '745 patents because the blood sample flows within the strip's measurement zone during the entire measurement period. Expert testimony and numerous video recordings showed that blood samples on the BD Test Strip exhibit a swirling motion. The evidence also showed that the swirling motion persists during the entire five-second measuring time of the BD Test Strip. Therefore, on this record, summary judgment of noninfringement of the '164 and '745 patents by the BD Test Strip was proper.

IV Anticipation of '745 Patent Claims

On summary judgment, the district court also concluded that there was no material issue of fact as to the anticipation of claims 1–5, 8, 21–23, 28, 31, and 34 of the '745 patent because PCT application WO 98/35225 ("the '225 reference") already disclosed diffusible mediators. Summary Judgment Order, 560 F. Supp. 2d at 875. "This court reviews a ruling of summary judgment de novo. Although anticipation under 35 U.S.C. § 102 is a question of fact, it may be decided on summary judgment if the

record reveals no genuine dispute of material fact." Golden Bridge Tech., Inc. v. Nokia, Inc., 527 F.3d 1318, 1321 (Fed. Cir. 2008) (citation omitted).

The '225 reference contains the same disclosure as the '164 patent. Summary Judgment Order, 560 F. Supp. 2d at 874. It describes a glucose sensor for blood samples smaller than one microliter. The primary improvement of the '745 patent over the '225 reference and the '164 patent is the use of diffusible or leachable mediators with such sensors. Claim 1 of the '745 patent reads:

> 1. A method for determining a concentration of glucose in a sample, comprising the steps of:
>
> (a) contacting a sample with an electrochemical sensor comprising:
>
> (i) an electrode pair comprising a working electrode and a counter electrode, wherein the working electrode and counter electrode are separated by a closest distance in a range of 200 to 1000 μm;
>
> (ii) a measurement zone positioned adjacent to the working electrode and the counter electrode, wherein the measurement zone is sized to contain a volume of no more than about 1 μL of the sample; and
>
> (iii) an analyte-responsive enzyme and a diffusible redox mediator disposed in the measurement zone;
>
> (b) holding the sample within the measurement zone in a non-flowing manner;
>
> (c) generating a sensor signal at the working electrode within a measurement period of no greater than about 5 minutes, wherein a background signal that is generated by the redox mediator is no more than five times a signal generated by oxidation or reduction of 5 mM of glucose; and
>
> (d) determining the concentration of the glucose using the sensor signal.

'745 patent col.61 ll.39–63 (emphases added).

On appeal, Abbott challenges only whether the '225 reference disclosed the "diffusible redox mediator" limitation and the "background signal" limitation. However, Abbott did not argue the "background signal" issue to the district court in its opposition to summary judgment. See Summary Judgment Order, 560 F. Supp. 2d at 871–72.

Therefore, Abbott can not do so now on appeal and has waived the issue. See Fresenius USA, Inc. v. Baxter Int'l, Inc., 582 F.3d 1288, 1296 (Fed. Cir. 2009) ("If a party fails to raise an argument before the trial court, or presents only a skeletal or undeveloped argument to the trial court, we may deem that argument waived on appeal . . . .").

Thus, the only remaining issue is the "diffusible redox mediator" element. The district court concluded that there was no genuine issue of material fact on whether the '225 reference disclosed the "diffusible redox mediator" element of the '745 patent because the '225 reference "acknowledge[s] the possibility of using a leaching or diffusing mediator, although clearly the drafters preferred those that did not leach or diffuse." Summary Judgment Order, 560 F. Supp. 2d at 873. Abbott argues that the district court focused on a single passage out of context. However, the plain language of the '225 reference does disclose diffusible or leachable mediators.

The '225 reference 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. More preferably, the redox mediators of the present invention are bound or otherwise immobilized on the working electrode 22 to prevent undesirable leaching of the mediator into the sample. A diffusing or leachable (i.e., releasable) redox mediator is not desirable when the working and counter electrodes are close together . . . .

'225 reference at 9. The plain meaning of the passage implies that diffusible mediators are contemplated, though they are not preferred. This conclusion is reinforced by the claims of the '225 reference. Claim 127 of the reference describes a method calling for a "redox mediator." It does not specify whether this mediator is a leachable or a non-leachable mediator—that is, diffusible or non-diffusible. Claim 128, however,

encompasses "[t]he method of claim 127, wherein the redox mediator is a non-leachable redox mediator," i.e., a non-diffusible mediator. '225 reference at 63. "[T]he presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." Phillips v. AWH Corp., 415 F.3d 1303, 1315 (Fed. Cir. 2005) (en banc). Here, where the dependent claim adds only the non-leachable (non-diffusible) mediator limitation, this principle of claim construction compels the conclusion that the '225 reference claims diffusible as well as non-diffusible mediators in claim 127. As discussed above, the claims here must be considered part of the disclosure.

Moreover, not a single expert in the case challenged the fact that the '225 reference disclosed diffusible mediators, either explicitly or implicitly. While the witnesses argued that the '225 reference at least to some extent taught away from their use, "[a] reference is no less anticipatory if, after disclosing the invention, the reference then disparages it. . . . [T]he question whether a reference 'teaches away' from the invention is inapplicable to an anticipation analysis." Celeritas Techs., Ltd. v. Rockwell Int'l Corp., 150 F.3d 1354, 1361 (Fed. Cir. 1998). Therefore, there was no triable issue of material fact left for a jury to consider on the issue of whether the '225 reference disclosed diffusible mediators. As such, summary judgment on anticipation of the '745 patent was proper.

CONCLUSION

For the aforementioned reasons, we affirm the district court's judgment that claims 1–4 of the '551 patent are invalid due to obviousness and the entire patent is unenforceable because of inequitable conduct. We also affirm the district court's grant

of summary judgment of noninfringement of the ’164 and ’745 patents and invalidity of claims 1–5, 8, 21–23, 28, 31, and 34 of the ’745 patent due to anticipation.

AFFIRMED

COSTS

No costs.

United States Court of Appeals for the Federal Circuit

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

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.

LINN, Circuit Judge, concurring-in-part and dissenting-in-part.

I am pleased to join Part III of the majority opinion affirming the judgment of noninfringement, but I respectfully dissent from Part II affirming the district court's inequitable conduct ruling. With regard to Parts I and IV, I concur in the result and with much of the majority's reasoning in affirming the judgments of obviousness and anticipation, but I write separately to express my disagreement with the majority's unnecessary, and in my view improper, reference in this case to the claims of the prior art as a measure of what the prior art discloses.

I. Inequitable Conduct

This case involves attorney arguments submitted to the EPO in the '636 patent (the European counterpart of the '382 patent) over its interpretation, which allegedly refute, or are inconsistent with, arguments submitted to the PTO in the '551 patent over the interpretation of the same language. The question for purposes of materiality here is not whether Abbott's arguments to the PTO were meritorious (i.e., that the word "preferably" in the '382/'636 patent would actually have been interpreted by a skilled artisan to mean "required"); rather, the question is whether anything in Abbott's EPO submissions "refutes, or is inconsistent with," its arguments to the PTO. 37 C.F.R. § 1.56(b)(2) (2009). Even if this information were material, however, the individuals who owed a duty of disclosure to the PTO produced a good faith explanation as to why they withheld the EPO submissions. Far from a mere blanket denial of deceptive intent, the individuals' explanation includes specific, detailed reasons as to why they subjectively believed that the withheld information was immaterial during prosecution. Such an explanation will defeat a charge of inequitable conduct if it is "plausible." The question, thus, is not whether it is plausible that the information is immaterial—a question asked under the objective materiality prong—but rather, whether it is plausible that the individuals subjectively believed that the reference was immaterial at the time they withheld it—a question presented under the subjective intent prong.

I address these questions in turn.

A. Materiality

In Scanner Technologies Corp. v. ICOS Vision Systems Corp., 528 F.3d 1365 (Fed. Cir. 2008), we stated:

> Whenever evidence proffered to show either materiality or intent is susceptible of multiple reasonable inferences, a district court clearly errs in overlooking one inference in favor of another equally reasonable inference. All reasonable inferences must be drawn from the evidence, and a judgment then rendered on the evidence as informed by the range of reasonable inferences. Where the rule is breached, no inequitable conduct may be found. The rule is necessary, for without it findings of inequitable conduct, with the punishment of unenforceability of the entire patent, could wrongly stand.

Id. at 1376 (footnote omitted). In that case, an applicant asked the PTO to expedite the handling of its application in view of an allegedly infringing device on the market. The applicant told the PTO that it had made a "rigid comparison" of the device with the claims of the application, and that the device was on "open display" at a trade show. Id. at 1372. The district court found these statements materially misleading. It inferred from these statements that the applicant had actually seen the accused device when, in fact, the device was in a black sealed box and an inspection of it would not have revealed how the device meets the limitations of the claims. Although we acknowledged that the district court's interpretation of this language was "not unreasonable," we ultimately reversed, holding that, under an equally reasonable favorable interpretation, a "rigid comparison" would not require physical inspection, and that the device was on "open display" in the sense that the black box was located in a public, as opposed to private, setting. Id. at 1376-77.

Accordingly, a district court "overlooks" a favorable inference, within the meaning of Scanner Technologies, not simply when it ignores or fails to mention the possibility of such an inference, but when it actually "adopt[s] an unfavorable inference . . . over an equally reasonable favorable inference." Id. at 1377. Citing this rule, we have stated that an unfavorable inference "must not only be based on sufficient evidence and be

reasonable in light of that evidence, but it must also be the single most reasonable inference able to be drawn from the evidence to meet the clear and convincing standard." Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., 537 F.3d 1357, 1366 (Fed. Cir. 2008) (emphasis added) (citing Scanner Techs., 528 F.3d at 1376).

I believe that the "rule" of Scanner Technologies has been breached in this case. The submissions made by Abbott to the EPO are susceptible of multiple reasonable inferences and, depending on the inference drawn, may or may not be material. In each instance, the district court inferred one meaning from the EPO submissions, rendering them material, when an equally reasonable (if not more reasonable) inference renders them immaterial.

The district court found that Abbott's "submissions made to the EPO were inconsistent with the submissions made to the PTO in at least two important ways." Trial Opinion, 565 F. Supp. 2d at 1109.[1] First, in the district court's words, "The EPO was told that under the '382 a protective membrane was merely preferred and not required when dealing with live blood and specifically quoted the 'optionally, but preferably' sentence in support." Id. at 1109-10 (emphases in original). Second, "The EPO was told that the critical sentence was 'unequivocally clear' and taught skilled artisans that 'the protective membrane [was] optional, however it is preferred when used on live blood . . . .'" Id. at 1110 (alteration and omission in original).

[1] These were the only two ways in which Abbott's submissions were found to be "inconsistent" and thus material under 37 C.F.R. § 1.56(b)(2). Thus, it is these two findings that must be reviewed for clear error. Although the district court cited the "reasonable examiner" standard and found that Abbott's EPO submissions would have been "highly material" to such an examiner, the district court made this finding only to the extent that the submissions were "contradictory" or inconsistent. Trial Opinion, 565 F. Supp. 2d at 1110.

In my view, the district court arrived at these two findings in error. I address these findings in turn.

1. "merely preferred and not required"

The first clearly erroneous finding inappropriately attributes to Abbott statements that it did not make. Abbott never said that the membrane was "merely preferred" or "not required" when dealing with blood. Such a statement would be devastating to Abbott and would clearly be material. Instead, Abbott's EPO submissions simply quoted the "[o]ptionally, but preferably" sentence from the '382/'636 patent and, tracking closely the just-quoted language, stated that the protective membrane is "preferably to be used with in vivo measurements" and is "preferred when used on live blood." J.A. 6531, 6585. The word "preferably" is the very same word used in the '382/'636 patent. Abbott never said "merely preferred," and it certainly never said "not required." Nor did Abbott ever use any synonym that might have shed some light on the meaning of the word as used in the patent. Instead, Abbott used the very same word (preferably) in the very same context (blood) as the word appears in the '382/'636 patent. Because Abbott's submissions to the EPO tracked the very language of the '382/'636 patent, they add nothing to the meaning of the word "preferably" beyond what was already before the examiner in the '382/'636 patent.[2]

[2] See Trial Tr. 647, Jun. 2, 2008 (Attorney Pope testifying that the EPO submissions were "redundant of information already before the examiner" because "[t]hat quote appears precisely in the '382 patent"), 653 ("[T]hey paraphrased the quote that they use, and in so doing, they picked up the language 'preferable.' That was, in my mind, simply because they were tracking the quote . . . ."); 677 ("I understand they used the word 'preferred' in their argumentation because they were simply tracking and paraphrasing the quote that they were discussing.").

If anything, the EPO submissions bolster, rather than refute, Abbott's argument to the PTO that a protective membrane was thought by persons of ordinary skill to be required for use in blood. One of the EPO submissions explains that the protective membrane serves to "prevent the larger constituents of the blood, in particular erythrocytes, from interfering with the electrode sensor." J.A. 6585. Indeed, it is this very function that makes it a "protective" membrane: the membrane protects the electrodes from fouling caused by the larger constituents found in blood.[3] The EPO Board itself, upon reviewing Abbott's submissions, recognized as much when it held: "The Board can therefore agree with the Appellant that by a protective membrane is meant exercising a filtering function, preventing the grosser components of blood from reaching the electrode . . . ." J.A. 6570-71. Given that the Board itself recognized that the protective membrane serves an important "filtering function" in blood, it cannot be said that Abbott's EPO submissions somehow denigrated the role of a protective membrane when used on blood.[4]

It is important to appreciate that, aside from testing on "blood," the sensor recited in claim 1 of the '636 patent is also claimed for testing on "interstitial fluid." Interstitial fluid does not contain those larger constituents in blood that cause fouling of the sensor's electrodes. Because the larger constituents are absent in interstitial fluid, all parties agree that a protective membrane is optional when the sensor is used to test

[3] See Trial Tr. 676 (Attorney Pope testifying that the '382/'636 patent "doesn't give any reason why it says 'preferably when being used on live blood,' whereas, when we look down to the sentence [in the EPO submission], they give a reason why you want the protective membrane.").

[4] See Trial Tr. 647 (Attorney Pope testifying that "[t]he decision at the [EPO] Technical Board of Appeals was entirely consistent with my understanding at the time" that "preferably" meant "required").

interstitial fluid.[5] It is therefore reasonable to interpret the word "optionally," in the phrase "[o]ptionally, but preferably when used on live blood," as governing those situations in which the fluid being tested is something other than blood, such as interstitial fluid.[6]

Abbott's submissions to the EPO do not contradict this interpretation. Abbott never said that the membrane is optional all the time, in all fluids, or under all conditions. Rather, Abbott said that the membrane is "optionally utilized with the glucose sensor of the patent in suit," J.A. 6530-31 (emphasis added), more specifically, "claim 1 of the patent in suit," J.A. 6530 (emphasis added). Claim 1 of this patent recites, in the disjunctive, "blood or interstitial fluid." No claim is directed to blood alone.[7] Abbott's EPO submissions can therefore be interpreted, consistent with the quoted "[o]ptionally, but preferably" sentence, to mean that a protective membrane is used "preferably" on blood, and "optionally" on fluids other than blood, such as interstitial fluid. And again, the word "preferably" is not defined in the EPO submissions or otherwise explained, except to say that the membrane serves to "prevent the larger constituents of the blood, in particular erythrocytes, from interfering with the electrode

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[5] See Trial Tr. 674 (Attorney Pope testifying: "The protective membrane was definitely optional. It depended -- the option depended on what was being analyzed.").

[6] See Trial Tr. 690 (Attorney Pope testifying: "My understanding was it was optional for any fluid other than blood."); Trial Opinion, 565 F. Supp. 2d at 1100 (Abbott's Proposed Finding No. 90: "the 'preferably' language means that the membrane is optional when an in vivo sensor does not contact whole blood but that the membrane is required when the sensor contacts red blood cells [i.e., erythrocytes] in whole blood.").

[7] See Trial Tr. 661-62 (Attorney Pope testifying that "the claims encompassed a sensor that could be used on a variety of analytes. So the claim scope didn't speak to th[e] issue" of whether a membraneless sensor could be used in blood).

sensor"—a statement that tends to support, rather than refute, Abbott's argument to the PTO. J.A. 6585.

But instead of giving Abbott the benefit of a reasonable favorable interpretation, in which the words "optionally" and "preferably" are directed to interstitial fluid and blood, respectively; the district court drew a negative inference by extending the word "optionally" to govern both interstitial fluid and blood, collectively. In this way, the district court inferred from Abbott's EPO submissions that a membrane was "not required when dealing with live blood"—language that Abbott itself never used in its submissions. Trial Opinion, 565 F. Supp. 2d at 1109 (emphasis in original). By adopting one inference (i.e., "optionally" governs both blood and interstitial fluid) over an equally reasonable favorable inference (i.e., "optionally" governs interstitial fluid, and "preferably" governs blood), the district court, in my view, clearly erred.

2. "unequivocally clear"

The second clearly erroneous finding concerns Abbott's submission to the EPO that "[i]t is submitted that this disclosure is unequivocally clear." J.A. 6585. The district court found this statement to be inconsistent with Abbott's argument to the PTO that the word "preferably," as used in the patent's "[o]ptionally, but preferably" sentence, was not being used in a colloquial sense (to express a mere preference) but rather constituted "patent phraseology" (to express a requirement). Because Abbott had told the EPO that "this disclose is unequivocally clear,"[8] the district court inferred from this submission that

[8] The full paragraph of the EPO submission dated May 23, 1995 reads:

> It is submitted that this disclosure is unequivocally clear. The protective membrane is optional, however, it is preferred when used on live blood in order to prevent the larger constituents of the blood, in particular erythrocytes from interfering with the electrode sensor. Furthermore it is

that each and every word of the "[o]ptionally, but preferably" sentence must carry its plain and ordinary meaning.

While plausible, the district court's inference is not the only inference that can reasonably be drawn from Abbott's submission. Abbott did not say that any specific word is unequivocally clear. Rather, what was said to be unambiguously clear is "this disclosure"—i.e., the full quoted sentence from the '382/'636 patent, which reads:

> 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.

This sentence sets forth two functional characteristics of the membrane: (1) it is "protective," and (2) it is "permeable to water and glucose molecules." It is these two functional characteristics that Abbott, in its argument, went on to describe immediately after calling this disclosure "unequivocally clear."[9] First, with regard to the membrane

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> said, that said protective membrane should not prevent the glucose molecules from penetration, the membrane is "permeable" to glucose molecules. This teaches the skilled artisan that, whereas the semipermeable membrane of D1 must be constructed, for example by crosslinking, in such a way that the membrane will in fact control the permeability of the glucose at the required low value, the purpose of the protective membrane in the patent in suit is **not** to control the permeation of the glucose molecules. For this very reason the sensor electrode as claimed does not have (and must not have) a semipermeable membrane in the sense of D1. The fact that the same material (cellulose acetate) may be used both for the semipermeable membrane of D1 and the protective membrane of the patent in suit is not relevant. The decisive feature is the modification (crosslinking) of said material to an extent so as to **control** the permeation of the substrate glucose. Finding the semipermeable membranes satisfying the requirements set forth on page 3, lines 24 to 56 of D1 is tedious and involves considerable trial and error work. Reproducability [sic] of such membranes is always a critical factor.

J.A. 6585-86 (emphases in original).

[9] See Trial Tr. 672 (Attorney Pope testifying that the "unequivocally clear" statement is directed to "the nature of the membrane"; "And in my understanding, I

being "protective," Abbott told the EPO that its membrane serves "to prevent the larger constituents of the blood, in particular erythrocytes from interfering with the electrode sensor." J.A. 6585. Second—or in Abbott's words "[f]urthermore"[10]—the membrane is "permeable" to glucose molecules because it "should not prevent the glucose molecules from penetration." J.A. 6585. These two concepts, as articulated in Abbott's submission, flow directly from the quoted sentence of the '382/'636 patent, in the same order that they appear in that sentence. It is reasonable to read Abbott's argument as saying no more than what is "unambiguously clear," in the quoted sentence, is that the membrane serves the dual roles of preventing larger constituents in blood from interfering with the electrode sensor, while also allowing smaller water and glucose molecules to pass through.

The district court believed that only this second function, glucose permeability, was necessary to distinguish the D1 reference in the EPO proceeding, and that Abbott's argument to the EPO "plainly went beyond this point of distinction and submitted that it was 'unequivocally clear' that the '382/'636 needed no membrane at all for use with blood." Trial Opinion, 565 F. Supp. 2d at 1116. But Abbott never told the EPO that the '382/'636 patent "needed no membrane at all for use with blood." Those are the district court's words, not Abbott's. Moreover, the fact that the '382/'636 patent can optionally

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believed that the reason the entire quote appears [in the EPO submission] is that is the only clear disclosure in the '382 patent or the '636 patent with regard to the nature of the protective membrane"; "There isn't another sentence, another clear disclosure in the '636 patent that talks about the nature of the protective membrane." (emphases added)).

[10] See Trial Tr. 658 (Attorney Pope testifying: "I would disagree with the fact that the mere use of the word 'furthermore' means that it's a second argument," rather than "simply being a transitional word.").

be used with or without a "protective" membrane in some glucose-containing fluids, like interstitial fluid, was indeed an important point of distinction that ultimately convinced the EPO Board that the '382/'636 patent did not possess a "diffusion-limiting" membrane like that of the D1 reference.[11] The D1 reference requires a diffusion-limiting membrane because its sensor cannot handle a rapid influx of glucose molecules. The pores of this membrane are small enough to partially reduce the flow of glucose molecules and to completely block the much larger blood constituents, like erythrocytes. The '382/'636 patent, by contrast, has no problem with a rapid influx of glucose molecules, so it does not need a diffusion-limiting membrane, only a protective membrane to protect against fouling by larger blood constituents. But the fact that the '382/'636 patent even discloses the use of a protective membrane shows that no diffusion-limiting membrane was present in the '382/'636 patent. If it were present, then the diffusion-limiting membrane would itself block larger blood constituents, thus rendering a protective membrane entirely redundant and unnecessary. The EPO Board understood this exact point, stating: "Common sense dictates moreover that the optional presence of a protective membrane would be unnecessary if a diffusion controlling membrane was present." J.A. 6571. In other words, the presence of a protective membrane, which performs the erythrocyte-filtering function of a diffusion-limiting membrane, implies the absence of a diffusion-limiting membrane. The EPO Board therefore agreed with Abbott that the '382/'636 patent did not possess a diffusion-limiting membrane like the one in the D1 reference, which was precisely the point Abbott was trying to make.

[11] See Pl.-Appellants' Reply Br. 13 ("Thus, by showing that the '382/'636 did not use a membrane for at least some fluid, MediSense proved that it did not use the D1's glucose-controlling membranes.").

By adopting one inference (i.e., what is "unambiguously clear" is the meaning of each individual word) over an equally reasonable favorable inference (i.e., what is "unambiguously clear" is the functional role of the membrane), the district court again, in my view, clearly erred.

* * *

The foregoing interpretation of the ambiguous language in Abbott's EPO submission is, in my view, at least as reasonable as the district court's and the majority's. This favorable interpretation, unlike the contrary interpretation, does not rely on individual words or phrases in isolation, but properly views them in context: looking to the surrounding text in which those words and phrases appear, with an eye towards the purpose for which the arguments were submitted during prosecution, and is ultimately consistent with the way the arguments were interpreted by the EPO Board. As shown with regard to each substantive point in the foregoing materiality analysis, and with all due respect to my colleagues in the majority, this favorable interpretation was not invented on appeal; each point was argued to the district court.

The majority concludes that Abbott's EPO statements "cannot possibly be read in this manner," because the "unequivocally clear" statement is "tied directly to the optional nature of the membrane." Maj. Op. 24-25. For this proposition, the majority focuses on the "three sentences in question" in the EPO submission: (1) the "[o]ptionally, but preferably" sentence quoted from the '382/'636 patent; (2) the first sentence of a nine-sentence paragraph that reads, "It is submitted that this disclosure is unequivocally clear"; and (3) the second sentence of this paragraph that reads, "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." There are seven more sentences in this paragraph, overlooked by the majority, that are dedicated to describing the glucose-permeability function of the membrane. See supra note 8. As previously discussed, it is reasonable to read this full paragraph as saying that what is "unambiguously clear" (first sentence) is that the protective membrane performs the dual functions of filtering erythrocytes in blood (second sentence) while allowing glucose to pass through (third through ninth sentences).

Instead of reading the paragraph as a whole, the majority links the paragraph's topic sentence ("unambiguously clear") only to the first five words of the second sentence ("The protective membrane is optional . . . ."). The majority then ascribes the word "optional" to whole blood and the word "preferred" to live blood. It then concludes—"[n]ecessarily"—that "the membrane was not required for either whole blood or live blood." Maj. Op. 25. Each of these three logical steps is based on inference, and at each step, I believe the majority has inappropriately drawn an inference against the patentee.

First, the phrase "[t]he protective membrane is optional" says nothing of blood. As a general statement, moreover, it is factually correct: the membrane is optional in certain fluids, like interstitial fluid, which do not contain erythrocytes. As previously discussed, the fact that the protective membrane is optional in some glucose-containing fluids, like interstitial fluid, shows that the '382/'636 patent does not possess a diffusion-limiting membrane like the one in the D1 reference. The majority entirely misses this point.

Second, live blood is a species of whole blood; both contain all of the larger constituents of blood, including erythrocytes. Because both live and whole blood contain erythrocytes, the latter half of the second sentence describing the membrane's filtering function—i.e., "in order to prevent the larger constituents of the blood, in particular erythrocytes from interfering with the electrode sensor"—applies equally to both types of blood. The majority, however, distinguishes whole blood from live blood and places the former into the "optional" category while retaining the latter under the "preferred" category. But nothing in this paragraph suggests any distinction between whole and live blood, as both contain erythrocytes. Moreover, to the extent that the majority relies on such a distinction for purposes of materiality, it fatally undermines the finding of deceptive intent: Attorney Pope testified that he considered the terms "whole blood" and "live blood" to be synonymous. Trial Tr. 629. The district court made no finding that Attorney Pope did not actually possess this belief, or even that this belief was unreasonable. Instead, the district court dismissed Attorney Pope's mistaken belief because "th[e] EPO submissions represented that a membrane was merely optional when used with blood." Trial Opinion, 565 F. Supp. 2d at 1114 (emphases added). This statement lumps together both live and whole blood under the "optional" category. The majority, however, relies on this distinction and ascribes the word "optional" to whole blood and the word "preferred" to live blood. Maj. Op. 25 ("[T]he membrane was optional (whole blood and other fluids) or preferred (live blood)." (emphases added)). Because the majority relies on this distinction for purposes of materiality, Attorney Pope's honest but mistaken belief would serve as additional exculpatory evidence under the intent prong.

Third, the majority concludes that, irrespective of whether the membrane was "optional" or "preferable" in either whole or live blood, it "[n]ecessarily" follows that the membrane was "not required for either whole blood or live blood." Id. (emphases added). It is unclear how the majority arrives at this conclusion. The question here is not what the word "preferably" means in isolation but whether anything in Abbott's EPO submissions, which quotes and tracks the very language in the '382/'636 patent, contradicts Abbott's argument to the PTO. And again, Abbott never told the EPO that the membrane is "not required" for use in blood; nor did it use any synonym for the word "preferred." Because the EPO submissions explain that the membrane serves to protect the sensor from erythrocytes found in whole blood, these submissions tend to bolster rather than refute Abbott's arguments to the PTO.

A final point deserves brief comment. The majority invokes the familiar adage that "[c]lose cases should be resolved by disclosure." LaBounty Mfg., Inc. v. U.S. Int'l Trade Comm'n, 958 F.2d 1066, 1076 (Fed. Cir. 1992) (emphasis added). It is sage advice, and practitioners should take it to heart, so that they may avoid even being accused of inequitable conduct, much less being found to have committed it. But this adage is not a legal rule. We have never recognized a "close case" standard for materiality. The majority, however, believes that if this is such a case, then the duty of disclosure "requires that the material in question be submitted to the examiner." Maj. Op. 26 (emphasis added). Our circuit already entertains five different standards for materiality. See Digital Control, Inc. v. Charles Mach. Works, 437 F.3d 1309, 1315-16 (Fed. Cir. 2006). I do not think that we need a sixth.

B. Intent

"[I]nequitable conduct requires not intent to withhold, but rather intent to deceive." Dayco Prods., Inc. v. Total Containment, Inc., 329 F.3d 1358, 1367 (Fed. Cir. 2003). The requisite level of intent is "specific intent"—not simple negligence, or even gross negligence. Star Scientific, 537 F.3d at 1368; Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 876 (Fed. Cir. 1988) (en banc) (holding even gross negligence insufficient to prove intent to deceive). As recognized by the Supreme Court and virtually every circuit, "specific intent" denotes a subjective rather than objective standard and is generally associated with actions deliberately and consciously taken to achieve a specific result.[12]

Consistent with this subjective standard, "[i]ntent to deceive cannot be inferred simply from the decision to withhold the reference where the reasons given for the withholding are plausible." Dayco, 329 F.3d at 1367 (emphases added). One "reason" that a reference may legitimately be withheld is that the "applicant did not know of its materiality." FMC Corp. v. Manitowoc Co., 835 F.2d 1411, 1415 (Fed. Cir. 1987) (emphasis added). It is this lack of knowledge, or one's subjective belief that the reference was immaterial, that a court must assess as either plausible or implausible for purposes of specific intent. Thus, when assessing an applicant's reason for withholding a reference that he or she believed was immaterial, the question is not, "Is it plausible

[12] Hartzel v. United States, 322 U.S. 680, 686 (1944); United States v. Philip Morris USA Inc., 566 F.3d 1095, 1118 (D.C. Cir. 2009); Pierre v. Attorney Gen., 528 F.3d 180, 189 (3d Cir. 2008); United States v. Nguyen, 493 F.3d 613, 624 (5th Cir. 2007); United States v. Zunie, 444 F.3d 1230, 1234 (10th Cir. 2006); United States v. Puckett, 405 F.3d 589, 596 (7th Cir. 2005); United States v. George, 386 F.3d 383, 390 (2d Cir. 2004); United States v. De Leon, 270 F.3d 90, 92 (1st Cir. 2001); United States v. Gracidas-Ulibarry, 231 F.3d 1188, 1196 (9th Cir. 2000).

that the reference is immaterial?" That question belongs under the objective materiality prong, to be evaluated "on the evidence as informed by the range of reasonable inferences" both for and against materiality. Scanner Techs., 528 F.3d at 1376. Rather, the question for purposes of specific intent is, "Is it plausible that the applicant subjectively believed that the reference was immaterial?" This inquiry properly focuses on what the applicant knew or believed to be true about the reference at the time that he or she decided to withhold it.

In this case, it is significant that Attorney Pope and Dr. Sanghera were not aware of what the district court called the "one exception" in the prior art—U.S. Patent No. 4,388,166 ("Suzuki")—of a membraneless sensor used on whole blood. Trial Opinion, 565 F. Supp. 2d at 1099 & n.6, 1106 n.12. If they had known of Suzuki, it would have significantly undercut their argument to the PTO that persons of ordinary skill believed that membranes were required for use on whole blood. Moreover, if they had known of Suzuki, it would have made it far more difficult for them to explain why they interpreted the EPO submissions in a manner contrary to Suzuki. But, unlike Suzuki, all prior art of record and all prior art of which Attorney Pope and Dr. Sanghera were aware uniformly showed that "those skilled in the art typically employed a membrane on a sensor used with live or whole blood." Id. at 1099. It is therefore entirely plausible that Attorney Pope and Dr. Sanghera subjectively believed that the EPO discussion of the '382/'636 patent—just like all other prior information known to them—did not contradict the use of membranes for testing on whole blood.

Nor did Attorney Pope or Dr. Sanghera have any knowledge that one of the inventors, Dr. Higgins, held a contrary view of the "[o]ptionally, but preferably" language.

Attorney Pope did not draft the original specification, and the two did not discuss this language with Dr. Higgins when they submitted their argument to the PTO. As we have made clear, "no duty to inquire arises unless counsel is on notice of the likelihood that specific, relevant, material information exists and should be disclosed." Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp., 267 F.3d 1370, 1383 (Fed. Cir. 2001) (emphases added). "The mere possibility that material information may exist will not suffice to give rise to a duty to inquire." Id. at 1382 (emphasis added). Here, the record does not show, and no party has argued, that Attorney Pope and Dr. Sanghera were on notice, at the time of the withholding, of the likelihood that Dr. Higgins held a different view of the "[o]ptionally, but preferably" language. To the contrary, it appears that Dr. Higgins formulated his opinion of this particular language for the first time in the present litigation. Dr. Higgins's personal opinion is therefore entirely irrelevant to what Attorney Pope and Dr. Sanghera subjectively believed at the time of the withholding.

Nor is there any dispute that Dr. Sanghera was perfectly qualified to submit an expert declaration to the PTO as to the meaning of the "[o]ptionally, but preferably" language. As the district court found, "a person of ordinary skill in the art would have had a doctoral degree or postgraduate experience working toward a Ph.D" and "would also have had some level of experience in actually constructing electrochemical sensors or would at least be familiar with them." Trial Opinion, 565 F. Supp. 2d at 1100 n.8. Dr. Sanghera had earned a Ph.D in Electrochemical Biosensors and had worked in the research and development of biosensors for over ten years by the time he submitted his declaration to the PTO in 1997. J.A. 7636. Although he did not possess these qualifications in 1983 (the invention date of the '551 patent), this fact would not

disqualify him from giving a competent opinion in 1995 as to what a hypothetical person of ordinary skill would have known in 1983. See Endress + Hauser, Inc. v. Hawk Measurement Sys. Pty. Ltd., 122 F.3d 1040, 1042 (Fed. Cir. 1997) (stating that the "person of ordinary skill in the art" in § 103 is a "theoretical construct . . . and is not descriptive of some particular individual"). In his declaration, Dr. Sanghera fully disclosed his qualifications and his employment with the assignee, Medisense (now Abbott). J.A. 7636. He also testified that he had thoroughly searched the prior art for any information that might contradict his declaration. Trial Tr. 709-10. There is no suggestion, much less any finding by the district court, that Dr. Sanghera did not actually perform this search or that it was not made in good faith.

With regard to the foregoing, the majority correctly acknowledges: (1) that it is "undisputed" that Attorney Pope and Dr. Sanghera were unaware of the existence of either the Suzuki reference or Dr. Higgins's contrary interpretation, (2) that the district court did not base its finding of intent on the existence of such knowledge, and (3) that it did not find that Dr. Sanghera was unqualified or misrepresented his credentials. Maj. Op. 32. While calling these facts "irrelevant," id. 31, the majority nevertheless "finds support" for the district court's finding of intent based on these very facts, namely, that "Pope relied on Dr. Sanghera, who was not a person having ordinary skill in the art at the time of the '382 patent, . . . rather than the inventors of the patent, who appear to have had a view quite contrary to Abbott's," id. 30. Indeed, far from being "irrelevant," any facts tending to show what Attorney Pope and Dr. Sanghera did or did not know during prosecution are critical to discerning their intent and the plausibility of their explanation. All available evidence regarding an individual's mental state, particularly

facts "point[ing] away from an intent to deceive," must be weighed when assessing culpable intent. Akron Polymer Container Corp. v. Exxel Container, Inc., 148 F.3d 1380, 1384 (Fed. Cir. 1998) (stating that "requisite weight . . . must be given" to evidence of good faith). The fact that these individuals were unaware of any information that would contradict their argument to the PTO, despite having performed a prior art search (a search that they had no obligation to perform) for the specific purpose of ensuring the validity of their argument, is evidence of good faith. But the district court expressly "found no[]" evidence of good faith and dismissed any "possible inferences of good faith." Trial Opinion, 565 F. Supp. 2d. at 1114. It necessarily gave no weight to any favorable inference.

The district court rejected Attorney Pope's and Dr. Sanghera's good faith explanations as "not plausible" and "unconvincing." While considerable deference is owed to a trial court's credibility determinations, this does not mean that a trial court can "cloak the application of an erroneous legal standard in the guise of a credibility determination, and thereby shield it from appellate review." Andreu v. Sec'y of Dep't of Health & Human Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009). Indeed, on closer examination, it becomes apparent that the district court simply disagreed with Attorney Pope's and Dr. Sanghera's interpretation of the EPO submissions. The district court's opinion reflects that what proved "unconvincing" to the court was not the truthfulness of the witnesses' subjective beliefs, but rather the notion that the submissions were not in fact material.

Attorney Pope testified that he believed the EPO submissions to be cumulative of the '382/'636 patent because those submissions quoted and tracked the very same

"[o]ptionally, but preferably" language in the '382/'636 patent, and that the word "preferably," read in context of the entire '382/'636 patent, meant that the protective membrane was required in whole blood. Trial Tr. 640-41, 643, 645-47. As a patent attorney with over thirty years of professional experience, Attorney Pope testified that, when drafting and prosecuting applications, practitioners often use the word "preferred" rather than "required" in order to avoid a disclaimer of claim scope. Trial Tr. 632 (testifying that "[i]f the specification says 'you must,' then you've now precluded yourself from ever claiming more broadly"). See, e.g., Andersen Corp. v. Fiber Composites, LLC, 474 F.3d 1361, 1372 (Fed. Cir. 2007) (construing product claim as product-by-process claim because the specification used "language of requirement, not preference" (emphases added)); Chimie v. PPG Indus., Inc., 402 F.3d 1371, 1385 (Fed. Cir. 2005) (construing claim to require unrecited feature where applicant told examiner that such feature "must be used" (emphasis added)). In his view, the earlier EPO submissions did not contradict his argument to the PTO regarding the meaning of the word "preferably," because those submissions themselves explain why a membrane is "preferred" (i.e., "required") in whole blood: "to prevent the larger constituents of the blood, in particular erythrocytes from interfering with the electrode sensor." Trial Tr. 676-77 (quoting May 23, 1995 EPO submission). Thus, Attorney Pope believed that the EPO submissions were not material because they were both cumulative of the '382/'636 patent and not inconsistent with the PTO submissions.

This explanation is not conclusory. It relies on specific statements and information in the references, and it specifically provides that this was the reason why, at the time, the information was not disclosed to the PTO. Such an explanation is a far

cry from a "mere denial of intent to mislead (which would defeat every effort to establish inequitable conduct)." FMC Corp., 835 F.2d at 1416. Compare Praxair, Inc. v. ATMI, Inc., 543 F.3d 1306, 1317-18 (Fed. Cir. 2008) (affirming finding of deceptive intent where attorney's explanation failed to "suggest that, at the time of the prosecution of the '115 patent, he believed that disclosure of the RFO art would have been cumulative; he also does not actually state that the alleged cumulativeness was the reason he failed to disclose prior art RFO devices to the PTO; and he was unable to identify any specific reference that rendered the RFOs cumulative" (emphases added)), with In re Harita, 847 F.2d 801, 806-07 (Fed. Cir. 1988) (reversing finding of deceptive intent where Japanese patent agent explained that he believed, at the time, there was no duty to disclose to the PTO prior art discovered after filing, as was the practice in Japan).

"Intent to deceive should be determined in light of the realities of patent practice, and not as a matter of strict liability whatever the nature of the action before the PTO." N. Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 939 (Fed. Cir. 1990). Here, the trial court's disagreement with Attorney Pope centered not on his subjective understanding of the facts but rather on the court's normative view of the law. First, in dismissing his explanation that the word "preferably" in the context of the '382/'636 patent means "required," the district court stated, "Words are supposed to mean what they say. Otherwise, our patent-disclosure system would collapse." Trial Opinion, 565 F. Supp. 2d. at 1114. But we have long recognized that "patentees frequently use terms idiosyncratically," which is why persons of ordinary skill must look to the full context in which a term is used. Phillips v. AWH Corp., 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc). The district court's second reason for dismissing Attorney Pope's explanation

was that, "since the claims of the '382 covered membraneless sensors used in blood, as both sides agree, the specification must have been sufficient to support the membraneless sensors." Trial Opinion, 565 F. Supp. 2d. at 1114 (emphases in original). I find this reasoning flawed. It presupposes that the specification of the '382 patent enabled such a "membraneless sensor[] for use in blood"—a fact that Abbott fiercely disputes. See Br. of Pl.-Appellant 14-15. Moreover, it relates to a product that is not specifically claimed in the '382 patent. See '382 patent cl.1 (claiming "[a] sensor electrode for use in a liquid mixture of components"—not specifically blood (emphasis added)). The district court concluded, "At all events, . . . the fact remains that 'preferred' does not mean 'required,' which was a point made in the EPO appeal." Trial Opinion, 565 F. Supp. 2d. at 1114. This statement is circular, and it again shows that the district court anchored its assessment of Attorney Pope's subjective beliefs to the court's previous finding of objective materiality.[13]

The majority does not deny that the district court found the individuals' good faith explanations "not plausible" and "not credible" in light of its prior finding of objective materiality. Moreover, the majority itself rejects these good faith explanations based on the very same "plain English" rationale on which it affirms the materiality finding. Compare Maj. Op. 25-26 (affirming materiality based on "plain English reading" of isolated words), with id. 29-30 (rejecting good faith explanation because it contradicts "normal English" meaning of isolated words).[14] Respectfully, this rationale misses the

[13] The majority states that the district court found the individuals' explanations "so incredible that they suggested intent to deceive." Maj. Op. 28. A review of the district court's opinion reveals no such finding.

[14] By assessing the "plausibility" or "credibility" of an individual's good faith explanation in light of the objectively defined materiality of the withheld information, the

point as it relates to the question of intent. Attorney Pope testified that he read the "[o]ptionally, but preferably" language, not in isolation, but "in the context of the entire document," and that he "would never attempt to understand something drawn out of a document standing alone." Trial Tr. 668. That Attorney Pope actually read these words in context, rather than in isolation, has not been disputed. The isolated "plain English" meaning of those words, therefore, has little bearing on the plausibility of his subjective belief regarding his understanding of the EPO submissions.

In my view, Attorney Pope and Dr. Sanghera's good faith explanations are entirely consistent with the alternative reasonable interpretation of the EPO submissions that renders them immaterial. Indeed, as demonstrated by the myriad footnote citations to the trial record, supra, this alternative reasonable interpretation is the one that the individuals' themselves presented to the district court. Coupled with the fact that these individuals were unaware of the Suzuki patent (or any other contrary teachings), their explanations are certainly plausible.

It bears repeating that what is "plausible" here, for purposes of specific intent, is that the individuals subjectively believed that the withheld information was immaterial when they withheld it. This answers a different question than the one the district court appeared to ask, which was whether it is plausible that the withheld information was not in fact material—a test more appropriately considered under the objective materiality

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majority has, either wittingly or not, tied all three of the Ferring factors to a prior finding of materiality. See Praxair, 543 F.3d at 1313-14 (permitting an inference of deceptive intent to be drawn "when (1) highly material information is withheld; (2) 'the applicant knew of the information [and] . . . knew or should have known of the materiality of the information; and (3) the applicant has not provided a credible explanation for the withholding.'" (quoting Ferring B.V. v. Barr Labs., Inc., 437 F.3d 1181, 1191 (Fed. Cir. 2006) (emphases added))).

prong. To the extent that the district court assessed the plausibility of the individuals' subjective beliefs based on the objective reasonableness of those beliefs, or otherwise required their mistake to be reasonable in order to defeat a finding of specific intent, it did so in violation of Kingsdown, 863 F.2d at 876 (holding even gross negligence insufficient to prove intent to deceive).

* * *

Because I am left with a definite and firm conviction that a mistake has been committed with respect to both materiality and intent, I would reverse the district court's inequitable conduct ruling.

II. Invalidity

I agree with the majority that the prior art '382 patent renders the claims of the '551 patent obvious (Part I of majority opinion) and that the prior art '225 patent anticipates the claims of the '745 patent (Part IV of majority opinion). The descriptive portions of the prior art patents are alone sufficient to invalidate the claims-in-suit. It is therefore unnecessary, and I believe improper in this case, to look to the claims of the prior art patents as a measure of what the prior art discloses for purposes of obviousness and anticipation. See In re Benno, 768 F.2d 1340, 1346 (Fed. Cir. 1985) ("The scope of a patent's claims determines what infringes the patent; it is no measure of what it discloses."). Here, although the claims of the prior art '382 and '225 patents are broad enough to cover a membraneless sensor and a diffusible redox mediator, respectively, those structures are not specifically recited in the claims but instead are disclosed in the descriptive portions of the specification.

The majority quotes Brenno as follows: "[I]t is true . . . that 'a claim is part of the disclosure' . . . ." Maj. Op. 7. But the internal quotation is attributed to the PTO Solicitor and overlooks the more relevant statements made by the court immediately before and after it. The court's full quotation reads:

> Samuel F.B. Morse, the inventor of the telegraph, had a patent thereon, issued in 1840, containing a claim (which the Supreme Court held invalid) which was broad enough to read on the modern Telex. By the board's reasoning, Morse's telegraph patent therefore would have made the Telex obvious. The scope of a patent's claims determines what infringes the patent; it is no measure of what it discloses. A patent discloses only that which it describes, whether specifically or in general terms, so as to convey intelligence to one capable of understanding. While it is true, as the Solicitor suggested at oral argument, that "a claim is part of the disclosure," that point is of significance principally in the situation where a patent application as filed contains a claim which specifically discloses something not disclosed in the descriptive part of the specification (claims being technically part of the "specification," 35 USC 112, 2d par.), in which case the applicant may amend the specification without being charged with adding "new matter," within the meaning of § 132. But that is not the situation here. Danti's claim 1 does not disclose any structure additional to what the Danti specification discloses.

Benno, 768 F.2d at 1346 (emphases added; internal citations omitted). The court went on to reverse the Board's rejections over the prior art Danti patent.

Here, the claims of the '382 and '225 patents do not specifically disclose a membraneless sensor or a diffusible redox mediator; those structures are instead disclosed in the descriptive parts of the specifications. It is also unclear whether the claims on which the majority relies were originally present in the applications that resulted in the '382 and '225 patents or whether they were added during prosecution, which may affect their prior art date.

The other cases cited by the majority to justify its reference to the claims of the prior art patents are not on point. In In re Smolak, 88 F.2d 838, 840 (CCPA 1937), it was appropriate to look to the claims of a reference patent for a disclosure of a "press molded" limitation because, "[t]he words 'press molded' appear only in the claims of the reference." In Gabrielidis v. Prince Sports Group, Inc., 2000 WL 1648134, at *7 (Fed. Cir. Nov. 1, 2000) (nonprecedential), we held that certain elements were not disclosed anywhere in the reference patent, either in the claims or in the remainder of the specification, and therefore affirmed the denial of summary judgment of anticipation.

Thus, while I agree with the majority's conclusion on obviousness and anticipation and with much of the reasoning in Parts I and IV of the opinion, I part company with my colleagues in their unnecessary, and in my view improper, reference to the claims of the prior art patents.