

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

THERASENSE, INC.,
Plaintiff,

v.

BECTON, DICKINSON AND COMPANY,
Defendant.

No. C 04-02123 WHA

Consolidated with

No. C 04-03327 WHA
No. C 04-03732 WHA
No. C 05-03117 WHA

**FINDINGS OF FACT AND
CONCLUSIONS OF LAW**

AND CONSOLIDATED CASES.

INTRODUCTION

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

THE PROCEDURAL HISTORY OF THE CASE

Abbott Laboratories filed the first of these actions on May 28, 2004. Three subsequent actions were filed. All concerned four United States patents owned by Abbott and Therasense,

1 Inc.¹ U.S. Patent No. 5,820,551 is the subject of this order. These actions were originally
2 assigned to The Honorable Martin J. Jenkins. Judge Jenkins issued a first claim construction
3 order for certain other patents and a separate claim construction order for the '551 patent.
4 He also issued three separate summary judgment orders. The final one, dated April 3, 2008,
5 involved all parties and all patents in suit. While the final summary judgment order did
6 eliminate several infringement counts, several other claims were still viable. Immediately after
7 issuing the final summary judgment order, Judge Jenkins left the federal bench, and all four
8 cases came to the undersigned.

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

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

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

27
28 ¹ Therasense is a wholly-owned subsidiary of Abbott Laboratories, and the exclusive owner of two of
the other patents in suit.

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

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

21 **THE UNITED KINGDOM WORK**

22 United States Patent No. 4,545,382 (and its European counterpart) is a decisive item of
23 prior art in this decision. Here is its story. In the late 1970's and early 1980's, two research
24 groups at the University of Oxford and the University of Cranfield in the United Kingdom were
25 working on electrochemical sensors to detect the concentration of specific components in
26 solutions. In particular, they were interested in developing electrochemical sensors that could
27 be used to test glucose levels in human blood. Doctors Irving Higgins, Hugh Hill, and Elliot
28 Plotkin were part of these research groups. In 1981, both groups teamed with a newly founded

1 company, Genetics International, which was co-founded by James McCann. One goal was to
2 create the first commercial electrochemical sensor for glucose.²

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

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

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

26
27 ² Dr. Anthony Turner, the defense invalidity expert, was also involved in the initial research efforts that
28 took place in the United Kingdom. He joined Dr. Higgins' team at the University of Cranfield in 1981 as a
research officer. He later became a project director in 1983 after Genetics International began working with the
group. Dr. Gordon Sanghera, as stated in more detail below, was also involved with the research efforts by the
two groups.

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

6 The '551 patent was in prosecution for over fourteen years. During this period,
7 Genetics International changed its name to Medisense, Inc. Various claims were rejected
8 twelve times by the PTO examiner, David Shay. Eleven out of the twelve rejections relied on
9 the '382 patent or its European counterpart, the '636 patent. During this prolonged prosecution,
10 Medisense amended the proposed claims several times to overcome rejections by Examiner
11 Shay — all without success. At times, Medisense also submitted declarations from persons of
12 ordinary skill in the art to distinguish its claims from the prior art. None of the proposed
13 amendments ever included a limitation for a sensor without a filter or a membrane.

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

17 In 1996 — while the '551 patent was still pending before the PTO — Medisense was
18 purchased by Abbott Laboratories. After the acquisition, Abbott brought in one of its in-house
19 patent attorneys to take over the prosecution of the '551. That attorney was Lawrence Pope.
20 Attorney Pope worked in conjunction with several technical employees at Medisense, including
21 Dr. Gordon Sanghera, to “brainstorm” various arguments regarding the patentability of the
22 '551. Dr. Sanghera had worked at Medisense since 1990. As of 1997, he was its director of
23 research and development in the United States. His responsibilities included running
24 competitive analysis in conjunction with the marketing department and supervising Abbott's
25 patent portfolio. Dr. Sanghera had also previously worked for Dr. Hill at his laboratory at
26 Oxford University. He had researched electrochemical sensors, but he had not been involved in
27 the research that led to any patents involved herein. Dr. Sanghera had, however, attended the
28

1 European opposition hearings and had been active in crafting the submissions made in that
2 appeal.

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

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

10 To address this problem, Abbott decided to assert, as a matter of extrinsic fact, that in
11 1983 skilled artisans would have believed that a membrane was essential even in the face of the
12 '382 disclosure, *i.e.*, they would not have taken the quoted sentence literally.

13 Attorney Pope then held an interview with Examiner Shay on November 4, 1997.

14 Examiner Shay summarized the interview as follows (TX 469):

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

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

23 THAT based on his historical knowledge he is confident that on
24 the filing date of the earliest application leading to the present
 application on June 6, 1983 and for a considerable time thereafter
25 one skilled in the art would have felt that an active electrode
 comprising an enzyme and a mediator would require a protective
26 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
27 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
28 optionally [sic] or merely preferred.

1 The entire submission was aimed at overcoming the “optionally, but preferably” sentence in the
2 ’382 patent.

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

9 **INVALIDITY**

10 In this action, the central axis of contention concerns membranes and, more
11 particularly, their use as a permeable layer surrounding the chemistry coated onto the active
12 electrode. Late in the fourteen-year prosecution, as stated, Abbott advanced the theory that the
13 ’551 specification revealed a sensor without a protective membrane. However, a key prior art
14 reference — the inventors’ own ’382 patent — had already stated that such membranes were
15 optional and at most preferred in certain circumstances, as quoted above. This ’382 sentence
16 was raised by the examiner as having already taught that membranes were merely optional or
17 preferred. In response, as stated, Abbott took the position (and still maintains) that the
18 sentence would *not* have been understood in 1983 by those skilled in the art to have modified a
19 supposed conventional wisdom that a membrane was necessary for testing in whole blood.³
20 Defendants disagree. They point out that the ’382 sentence expressly stated that even for live
21 blood, a membrane was merely “preferred” and that for all other cases it was “optional.” In no
22 case was it said to be “required.”

23 With this introduction of the central invalidity issue, this order will go back to square
24 one. It will begin by setting forth the basic technology. It will then review the ’382 patent,
25 focusing on its entire disclosure, including the sentence in question, so as to place that sentence
26

27
28 ³ Live blood is inside the body and can only be tested *in vivo*. Whole blood is blood with all its
constituent parts and can be in or outside the body. *In vitro* refers to tests outside the body, which must, in our
context, be performed on whole blood, not live blood.

1 in full context, all from the point of view of one skilled in the art at the time of the alleged
2 '551 invention (in 1983).

3 * * *

4 Although this summary of the technology is now stated in the present tense, this
5 summary was all known in the prior art. The electrochemistry involves an electrode coated
6 with an "enzyme" catalyst. The enzyme is particularly selected to react with glucose or
7 whatever the test substance might be. Again, the substance being tested for is sometimes, as
8 used by Medisense in the EPO proceedings, called a "substrate."⁴ The enzyme-substrate
9 chemical reaction generates electrons. The electrons are passed via yet another chemical called
10 a "mediator," also coated onto the electrode, to the active electrode itself. The electrons then
11 flow as a tiny but measurable electrical current down the active electrode through an ammeter
12 and back to the other uncoated electrode. The blood droplet or other solution under test
13 provides an electrical path completing the circuit between the electrodes. The word "sensor" is
14 sometimes used interchangeably with the active electrode, *i.e.*, the electrode painted with the
15 active chemistry.

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

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

25 * * *

26
27
28 ⁴ The word substrate is used in the '551 patent in a second sense, namely to describe the base on which
the electrode is formed (*see, e.g.*, col. 2:27, 33; col. 3:23). This is a second, different meaning.

1 One of the contributions of the '382 patent — which was concededly prior art to the
2 '551 patent — was a faster-acting ferrocene mediator coated onto an active electrode along
3 with an enzyme. Faster acting meant faster response times and quicker test results.

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

14 Under “Summary of the Invention,” the '382 inventors stated that they had come to
15 realize that mediator compounds could be associated with the sensor electrode structure itself
16 to make such electrodes available for use by *in vivo* methods. The '382 invention was then
17 described as a sensor electrode composed of a combination of enzyme and mediator
18 (col. 1:60–63). Preferably, the electrode was designed to determine glucose *in vivo*
19 (col. 1:65–66). A long passage then described various mediators and enzymes (col. 2:1 to col.
20 4:55). Again, a significant contribution was the ferrocene chemistry that was faster acting than
21 in the prior art, thus reducing response time.

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

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

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

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

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

17 Then came the main sentence at the heart of this case (col. 4:63–66):

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

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

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

28 Next came a “Description of the Preferred Embodiments.” In total, the ’382 patent
contained thirteen working examples of preferred embodiments of the invention. Some of the
examples described various procedures for producing the working chemistry of the sensor —
i.e., the enzyme and mediator. Other examples described possible configurations of electrodes
and electrochemical sensors. Each was configured slightly differently depending on various test

1 parameters, including the type of solution being tested. Some of the sensors included a
2 membrane and others did not.

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

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

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

21 Example 8 — entitled “*In vitro* sensor” — was the most discussed embodiment at trial
22 (col. 8:63). The example began by describing the construction of a sensor with a glucose
23 oxidase enzyme and a ferrocene mediator. No membrane was applied. The example then
24 explained that the sensor was first tested in “nitrogen-saturated buffer solution” (col. 9:15).
25 The results for the test in buffer solution were then summarized. A cellulose acetate membrane
26 was then applied to the sensor. The example went on to describe response times for that sensor
27
28

1 in buffer and then, in a separate test, in blood. The exact language in the specification stated
2 (col. 9:26–33) (emphasis added):

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

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

15 Example 9 taught the construction of an electrode with a glucose dehydrogenase
16 enzyme and a ferrocene mediator. A dialysis membrane was used to cover the coated electrode.
17 Examples 10 and 11 were minor variations of Example 9. Examples 12 and 13 described
18 further configurations for an electrode with a glucose dehydrogenase enzyme and ferrocene
19 mediator.

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

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

* * *

1 Turning to the '551 patent in suit, its inventor group was virtually the same as for the
2 '382, with slight adjustments.⁵ It was directed to a home-testing kit and more specifically to a
3 two-electrode strip (rather than a three-electrode strip) for one-time, disposable attachment to a
4 handheld readout device. The electrodes were coated with enzymes and mediators (“preferably
5 a ferrocene”) — as in the '382 patent. The strip was described as “elongated” for ready
6 handling and assembly. As with the '382, the active electrode was “preferably formed of
7 carbon.” The inventors went on to say that carbon foil available commercially as GRAPHOIL
8 or PAPYEX was a valuable electrode material. Various “objects” of the invention were
9 described, none of which related to a membrane or lack thereof. Many columns were devoted
10 to construction of the electrodes.

11 The subject of membranes was mentioned only twice in the '551 application.
12 Under “Membrane Cover for Electrode,” the inventors said that “it may be found valuable to
13 exclude the sensor from interfering contact with larger molecules or tissue fluid components”
14 and that this could be done with a “surrounding membrane” (col. 6:67–7:13). That passage
15 briefly described how to make a membrane in situ. Later, a step-by-step constructional
16 sequence was given for an electrode strip. Seven steps were listed. Adding a membrane was
17 *not* listed as a step (col. 8:35–51), an omission since given great weight by Abbott. A later,
18 optional modification stated: “The electrode may then be covered, on both sides, with a
19 semipermeable membrane of cellulose acetate (or polyurethane), not shown, to block large
20 interfering species from contact with the electrode” (col. 9:34–37).

21 Nowhere in the '551 specification or the original claims was there any suggestion that
22 treating the membrane as optional (or omitting it) was an inventive step. Nonetheless, this
23 order appreciates that a legitimate invention may eventually be found lurking in a disclosure
24 even though the inventors missed it themselves for over a decade. *See Newman v. Quigg*, 877
25 F.2d 1575, 1581 (Fed. Cir. 1989). So this order accepts Abbott’s contention, at least for
26 purposes of argument, that the '551 specification disclosed an active electrode *without* a
27

28 ⁵ Drs. Hill, Higgins, and Plotkin are listed as the inventors on the '382 patent. In context, McCann and
Drs. Hill, Higgins, and Davis are listed as inventors on the '551 patent.

1 membrane for use with whole blood (as well as disclosing one *with* a membrane for use with
2 whole blood). The decisive question remains whether or not the same group of inventors (with
3 slight membership changes) had *already* disclosed in the '382 patent that a membrane was
4 merely preferred for use with live blood and was optional in all other cases. This order now
5 turns to resolving that question.

6 * * *

7 This order accepts Abbott's proposition that prior to the '382 patent, those skilled in the
8 art typically employed a membrane on a sensor used with live or whole blood, although one
9 exception was already in print.⁶ That practice, however, was *before* the revelation in the
10 '382 patent. The '382 patent expressly stated that a protective membrane was *optional* in all
11 cases except for live blood, in which case it was *preferred*. In no case did the '382 patent state
12 that a protective membrane was *required*.

13 In context, it seems clear why this was so. The invention specified a faster-acting
14 ferrocene chemistry. This allowed for shorter response times, *i.e.*, measurement times. This, in
15 turn, reduced the *raison d'être* for any membrane. For example, the faster response times
16 reduced the probability of the active chemicals being washed away in the bloodstream and
17 reduced the time within which red blood corpuscles could locate and foul the electrodes.
18 (Fouling refers to the larger red blood cells accumulating on the electrode and blocking the

19
20
21 ⁶ U.S. Patent No. 4,388,166 (Suzuki) issued on June 14, 1983, and was filed on May 15, 1982.
22 Although the various examples of electrochemical glucose sensors recited in the '166 all included some type of
23 membrane, the '166 specification did expressly recognize that a glucose sensor (for blood) could be constructed
24 *without* any membrane as long as the user could tolerate variations in measured values. The specification stated
25 (col. 1:31-43) (emphasis added):

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

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

1 much smaller glucose molecules from reaching the sensor.) The indicated readings took about a
2 minute, even less *without* any membrane. There was, therefore, less need for any membrane.⁷

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

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

7 Italics have been supplied here to illustrate the structure. Ignoring the italicized preferred case,
8 the sentence states: “Optionally, . . . a protective membrane surrounds both the enzyme and the
9 mediator layers” That is the general, optional case. The exception, *i.e.*, the preferred case,
10 is for live blood. That phrase is italicized. The trial record is clear and convincing that persons
11 of ordinary skill in the art understood the words “optionally” and “preferably” in the same way
12 as the rest of us. There is no doubt that those skilled in the art would have understood that the
13 sentence was trying to say exactly what has been laid out in this paragraph.⁸

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

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

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

26 ⁷ Abbott concedes that, for example, the D1 reference in the EPO appeal described below had a
27 response time of five to fifteen minutes.

28 ⁸ The parties agree that in May 1983, a person of ordinary skill in the art would have had a doctoral
degree or postgraduate experience working toward a Ph.D. Such a person would also have had some level of
experience in actually constructing electrochemical sensors or would at least be familiar with them.

1 This contortion collapses on its own weight. The sentence in question meant just what it said
2 and the ordinary artisan would have so understood it.⁹

3 Contrary to Abbott, Example 8 in the '382 patent was consistent with the plain
4 meaning of this sentence. Example 8 was one of the preferred embodiments. It described a
5 ferrocene-glucose oxidase electrode. In the experiment described in Example 8, the sensor was
6 tested in a buffer solution with two different glucose concentrations, yielding response times of
7 24 and 60 seconds, depending on the concentration. Then a protective membrane was applied
8 to the sensor. While still testing the buffer concentration, the response times went to 36 and
9 72 seconds, respectively. The same sensor — again with a protective membrane — was tested
10 in blood samples with the same concentration and 36- and 72-second response times were again
11 obtained. It is true that when the sensor was used in blood a protective membrane was used and
12 that a protective membrane was not used with the first buffer solution. Nothing in Example 8,
13 however, stated that a membrane was required for use in blood. That a membrane was added
14 seems to have been little more than a way to investigate the time effect of adding a membrane.

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

21 The '382 sentence was then and remains correct, a fact that even Abbott does not
22 challenge. Membranes were never part of the electrochemistry itself. Rather, they offered
23 certain mechanical advantages, provoked by two different concerns. The first was human safety.
24 For *in vivo* use, toxic materials might break away from the coated sensor and pollute the
25 bloodstream. To protect against this possibility, a membrane immobilized the active ingredients,
26 *i.e.*, retained them in place and thus reduced the risk of breakaway. Reduced response times

27
28 ⁹ This order also rejects Abbott's idea that the word "optionally" referred to use of a membrane as an
alternative in lieu of some other type of whole-blood filtering member.

1 from faster chemistry, however, reduced the breakaway risk — for the sensor could be removed
2 sooner than before. The second concern was the risk of “fouling.” This was the risk that red
3 blood particles would stick to the active electrode and prevent glucose from interacting with the
4 chemicals coated onto the electrodes. If enough “fouling” occurred, the signal would be
5 diminished below an acceptable level and an erroneous readout would occur. Fouling might
6 occur in live blood or whole blood. In these proceedings, the supposed problem of fouling has
7 been exaggerated by Abbott. After the faster chemistry disclosed in the ’382 patent, the risk
8 became more theoretical than practical, especially for one-use, disposable applications.
9 Subsequent diabetic kits using the faster sensors have deleted the membrane with acceptable
10 results. In sum, the ’382 statement in question was then and remains correct.

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

20 To be sure, in making these findings in the preceding paragraph, the Court has relied on
21 trial testimony and materials outside the four corners of the patent and prior-art references.
22 This, however, is because Abbott itself has resorted to extrinsic evidence and “conventional
23 wisdom.” That is, to overcome the ’382 prior-art sentence in question, Abbott has resorted to
24 extrinsic evidence, arguing that skilled artisans would not have understood the sentence in light
25 of prevailing practices. Therefore, it is entirely appropriate for the other side to likewise resort
26 to extrinsic evidence as to how those skilled in the art would have taken the ’382 sentence in
27 question.
28

1 Abbott next argues that one skilled in the art would have read the “optionally, but
2 preferably” passage of the ’382 as mere “patent phraseology.” Notably, the passage in
3 question stated that a membrane was preferable “when being used on *live* blood” (col. 4:63–64).
4 Defense Expert Turner testified that even today’s implantable electrochemical sensors used for
5 testing glucose in live blood would use a membrane to ensure that toxic materials were not
6 released into the blood stream (Tr. 333). He even went as far as saying that the FDA would
7 likely not approve an implantable sensor without a membrane for safety reasons, which was the
8 reason a protective membrane was preferable for live blood. Unlike implantable sensors used to
9 test live blood, however, one-time disposable sensors for *in vitro* testing (as disclosed in the
10 ’551 patent) had no such safety concerns. With *in vitro* testing, a membrane was motivated only
11 by the potential of fouling the electrode. As to them, the ’382 sentence in question taught that
12 the membrane was merely optional.

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

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

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

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

5. THAT based on his historical knowledge he is confiednt
[sic] that on the filing date of the earlist [sic] application leading to

1 the present application on June 6, 1983 and for a considerable time
2 thereafter one skilled in the art would have felt that an active
3 electrode comprising an enzyme and a mediator would require a
4 protective membrane if it were to be used with a whole blood
5 sample. Therefore he is sure that one skilled in the art would not
6 read lines 63 to 65 of column 4 of U.S. Patent No. 4,545,382 to
7 teach that the use of a protective membrane with a whole blood
8 sample is optionally or merely preferred.

9 6. THAT Examples 3 and 4 of U.S. Patent No. 4,897,173
10 provide evidence that this concern about unprotected active
11 electrodes for whole blood samples persisted until at least the
12 June 21, 1985 filing date of the earliest application leading to this
13 patent. The fact that the Example 3 teaching a sensor for use with
14 serum samples has no protective membrane but Example 4
15 teaching a sensor for blood has a polycarbonate membrane is
16 evidence that the authors of this technical disclosure still believed
17 that active electrodes could not be directly exposed to whole blood
18 samples.

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

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

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

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

6 This order finds that the '382 patent taught those skilled in the art that — at least when
7 faster chemistry was employed — a protective membrane was optional in all cases except the
8 case of live blood, in which case the protective membrane was preferred — but not required.
9 The trial evidence and the plain language of the disclosure are clear and convincing on this point.
10 Abbott's "conventional wisdom" evidence is rejected.

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

18 * * *

19 There is a different aspect to Abbott's entire theory that deserves comment. Deletion of a
20 feature from a prior-art device with a corresponding deletion of its function is not an invention.
21 For example, if the prior art already discloses a pencil with an eraser, one may not delete the
22 eraser and claim an eraserless pencil as an invention. The reason is that the deletion of the eraser
23 would also mean a deletion of its function. This would be true even if the conventional wisdom
24 was that all pencils came with erasers. *See Richards v. Chase Elevator Co.*, 159 U.S. 477, 486
25 (1895).

26 Similarly, deletion of the protective membrane was not inventive in the '551 patent
27 because there was a corresponding deletion of its function. The loss of this function was
28 tolerable because the chemistry was fast enough (at least by the time of the '382 prior-art

1 disclosure) to obtain acceptable results without a membrane. But assuming *arguendo* that skilled
2 artisans had uniformly believed that a membrane was necessary (despite the '382 patent), the
3 mere deletion of the membrane with a corresponding loss of its functions would not warrant a
4 patent.

5 It would be different if the '551 patent disclosed a specific configuration that preserved
6 the membrane's function but without the membrane. Exactly what was disclosed in the
7 '551 patent that compensated for the deletion of the membrane and guarded against fouling?
8 The Court asked this question several times during the bench trial. Clearly, the
9 '551 specification and prosecution history were totally silent on this point.

10 At the closing argument, Abbott's counsel argued — for the first time — that the
11 '551 disclosed use of certain materials for constructing the electrodes and that these materials
12 were less sensitive to oxygen. Whereas the '382 patent had taught carbon as a preferred
13 electrode, the '551 patent recommended carbon foil available commercially as GRAPHOIL or
14 POPYEX. The argument emerged that normally red blood cells (and their oxygen content)
15 posed a noise hazard but that the electrodes specified in the '551 were less sensitive to oxygen.
16 Thus, it was said, a membrane could be safely deleted from an electrode constructed from
17 GRAPHOIL.

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

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

27 Given that the '382 had already disclosed "very low oxygen sensitivity," the later
28 statement in the '551 patent was no improvement on that score. The '551 statement was a

1 passing comment on a design consideration (concerning oxygen sensitivity) that had been
2 covered in the earlier patent and was covered again in the later patent. Since the earlier patent
3 had already achieved “very low” oxygen sensitivity, it is far-fetched to argue that the later patent
4 somehow solved that problem, much less solved it in a way that specifically dispensed with the
5 need for a membrane, a nexus nowhere made until at closing argument in 2008.¹⁰

6 To return to the main point, the clear-cut fact remains that to the extent the
7 ’551 dispensed with the membrane, it also dispensed with its function and thus no invention was
8 disclosed at all. This point would hold even if we indulged Abbott’s view of the conventional
9 wisdom about membranes at the time.¹¹

10 * * *

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

15 **INEQUITABLE CONDUCT**

16 Turning to the defense of inequitable conduct, the “optionally, but preferably” sentence
17 remains at center stage. When Abbott acquired the pending application that led to the
18 ’551 patent, its in-house lawyer, Lawrence Pope, took over the prosecution. That was in 1997.
19 He replaced Fish & Richardson, who had been unsuccessful for twelve years in obtaining
20 allowance of any claims. Examiner Shay had repeatedly rejected all proposed claims over the
21 ’382 patent.

22 _____
23 ¹⁰ Interestingly, the Exactech product (the same product Abbott contends embodies the ’551 product for
24 secondary consideration purposes) does *not* use GRAPHOIL as its electrode material, meaning whatever
25 purported benefit that was captured as a result of the GRAPHOIL was not present in the Exactech product.
In fact, the Exactech product used carbon paste as its electrode material — the same material disclosed in the
’382 patent (Tr. 780).

26 ¹¹ Similarly, at the closing argument, Abbott’s counsel argued that the ’551 patent disclosed a method
27 for placing the working chemistry onto the substrate — *i.e.*, screen printing — that may have contributed to the
28 purported success of the Exactech product. The only evidence on the record pertaining to this subject is the
testimony of Dr. Sanghera, who stated that the Exactech’s electrode was screen printed (Tr. 788). Other than
that, there is no evidence indicating that screen printing helped eliminate the need for a membrane or that it was
somehow novel over the prior art. Accordingly, counsel’s argument is rejected.

1 Abbott “brainstorming” sessions were held to find a way to win claims on the
2 ’551 application. These sessions included Dr. Gordon Sanghera. The original inventors were
3 not included. By this point, Abbott’s competitors were beginning to sell diabetic home-testing
4 kits in competition with the Exactech, the Medisense-Abbott product. Although Dr. Sanghera
5 denied it at trial, this order finds that Dr. Sanghera and Attorney Pope were motivated, in part, by
6 marketplace developments to find a claim to suppress competition. The very day the ’551 patent
7 issued, for example, Abbott asserted it in a patent-infringement action against a home diabetic kit
8 made by Lifescan, Inc. There is, however, nothing wrong with seeking a patent in order to stifle
9 competition, at least under the patent laws, so long as the patent is lawfully obtained.

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

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

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

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

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

27 To this end, Attorney Pope prepared a sworn declaration for the signature of Abbott’s
28 Dr. Sanghera. Although he was skilled in the art by the time of the declaration, Dr. Sanghera

1 had not been skilled in the art at the time of the invention (and, as stated, had not been one of
 2 the inventors). This, of course, was not a requirement for a declaration. Dr. Sanghera read,
 3 understood, and signed the declaration, knowing its purpose and knowing that it would be
 4 submitted to the PTO to overcome the presumed teaching of the sentence. The declaration is
 5 quoted above. In brief, it stated that Dr. Sanghera was sure that one skilled in the art at the time
 6 of the invention would not have read the sentence in question to teach that the use of a
 7 membrane with a whole-blood sample was optional or even preferred. To this end, Dr. Sanghera
 8 did not consult with any of the inventors to learn what had been considered optional, preferred,
 9 or essential despite the fact he still had a good relationship with at least Inventor Hill. He limited
 10 his research to literature.¹²

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

15 At the interview the applicants' undersigned representative
 16 explained that a new set of claims would be presented which focus
 17 on the feature that the active electrode is directly exposed to a
 18 whole blood sample *without* the intervention of a barrier material
 19 such as a membrane or gel which filters out larger molecules or
 20 other blood components expected to interfere with the active
 21 electrode's operation. It was agreed that this embodiment was one
 22 of the options clearly disclosed in the present application. It was
 23 also agreed that the art generally taught the use of such protective
 24 barriers on the effective filing date of the present application.

25 * * *

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

¹² The Suzuki '166 patent, however, which had expressly discussed deleting the membrane in blood tests, was *not* included in the Sanghera declaration (*see* note 6, *supra*). This order assumes that Dr. Sanghera was unaware of Suzuki.

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

16 The art continued to believe that a barrier layer for whole blood
 17 sample was necessary for a considerable period. For instance, U.S.
 18 Patent No. 4,897,173 to Nankai et al (copy accompanies this
 19 response), which claims priority from 1985, describes the
 20 production of electrodes for the measurement of glucose. In
 21 Example 3 at columns 4 and 5 an electrode structure for serum (see
 22 line 6 of column 5) is described which does not involve a
 23 protective membrane. In contrast Example 4 at columns 5 and 6
 24 directed to an electrode for use with whole blood (see lines 61–62
 25 of column 5) teaches a filtration layer 21 with a pore size of one
 26 micron.

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

* * *

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

46 In sum, Attorney Pope's remarks stated that the sentence in question would have been
 47 regarded as "mere patent phraseology" rather than a "technical teaching" and that the art
 48 believed that a membrane was "required" even for a considerable period after the '382 patent,

1 closing with: “There is no teaching or suggestion of unprotected active electrodes for use with
2 whole blood specimens in this patent or the other prior art of record in this application.” In
3 reliance on the submission, Examiner Shay allowed the new claims and the ’551 issued.

4 * * *

5 At the time of the interview and the submission, Attorney Pope and Dr. Sanghera were
6 well aware of previous representations based on the same “optionally, but preferably” sentence
7 made by Medisense to the European Patent Office in 1994–95. Attorney Pope and Dr. Sanghera,
8 however, made a conscious and deliberate decision to withhold disclosure to the PTO of these
9 prior statements. This much is conceded. Abbott contends, however, that there was no duty to
10 disclose the earlier statements and that there was no intent to deceive. On these latter points, the
11 following was proven at trial by clear and convincing evidence.

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

22 Specifically, D1 had disclosed an enzyme electrode usable for glucose and covered by a
23 semipermeable membrane. Before the EPO, Medisense argued that the D1 membrane was
24 essential to the D1 invention. By contrast, Medisense stated that the ’382/’636 membrane was
25 merely optional. Medisense relied on the “optionally, but preferably” sentence as follows
26 (TX 311 at AL54151):

27 10. The above object is solved by a glucose sensor as defined
28 in claim 1 of the patent in suit [’382/’636]. Apart from the
important feature of utilizing a ferrocene or ferrocene derivative as
mediator, another important difference over D1 resides in that the

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

claimed glucose sensor — contrary to that of D1 which requires a membrane — does not have and **must not** have a semipermeable membrane within the meaning of D1. Contrary to the semipermeable membrane of D1, the **protective** membrane **optionally** utilized with the glucose sensor of the patent [in] suit is **not** controlling the permeability of the substrate (as set forth above under IV.2), in the membrane of D1 the permeability for the substrate **must** be kept on a low value to achieve a linear relationship between the measures [sic] currency and the substrate concentration in the test solution. Rather, in accordance with column 5, lines 30 to 33 of the patent in suit:

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

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

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

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

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

1 In May 1995, Medisense further stated in the same EPO appeal, again referring precisely
2 to the “optionally, but preferably” sentence (TX 315):

3 *It is submitted that this disclosure is unequivocally clear. The*
4 *protective membrane is optional, however, it is preferred when*
5 *used on live blood in order to prevent the larger constituents of*
6 *the blood, in particular erythrocytes from interfering with the*
7 *electrode sensor. Furthermore it is said, that said protective*
8 *membrane should not prevent the glucose molecules from*
9 *penetration, the membrane is “permeable” to glucose molecules.*
10 *This teaches the skilled artisan that, whereas the semipermeable*
11 *membrane of D1 must be constructed, for example by*
12 *crosslinking, in such a way that the membrane will in fact control*
13 *the permeability of the glucose at the required low value, the*
14 *purpose of the protective membrane in the patent in suit is **not** to*
15 *control the permeation of the glucose molecules. For this very*
16 *reason the sensor electrode as claimed does not have (and must*
17 *not have) a semipermeable membrane in the sense of D1. The*
18 *fact that the same material (cellulose acetate) may be used both*
19 *for the semipermeable membrane of D1 and the protective*
20 *membrane of the patent in suit is not relevant. The decisive*
21 *feature is the modification (crosslinking) of said material to an*
22 *extent so as to **control** the permeation of the substrate glucose.*
23 *Finding the semipermeable membranes satisfying the*
24 *requirements set forth on page 3, lines 24 to 56 of D1 is tedious*
25 *and involves considerable trial and error work. Reproducibility*
26 *of such membranes is always a critical factor.*

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

19 The submissions made to the EPO were inconsistent with the submissions made to the
20 PTO in at least two important ways:¹³

- 21 • The PTO was told that the '382 *required* a membrane for use with whole blood and that those
22 skilled in the art would not have understood the “optionally, but
23 preferably” sentence to teach to the contrary.
- 24 • The EPO was told that under the '382 a protective membrane was merely *preferred* and *not required*
25 when dealing with live blood and specifically quoted the “optionally,
26 but preferably” sentence in support.

27 ¹³ Defendants have further made a plausible case that the two submissions were also inconsistent as to
28 their use of Example 8 (Example 7 in the '636). This inconsistency requires extended argument to develop and, while plausible, is not as facially and directly inconsistent as the above two points of conflict. This order does not rely on the alleged Example 8 inconsistencies.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

- The PTO was told that the “optionally, but preferably” sentence would have been understood by skilled artisans as “mere patent phraseology” and not as a “technical teaching.”
- 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”

Dr. Sanghera had been much involved in the EPO appeal. He had helped develop the arguments and had even attended the oral argument before the EPO on June 20, 1995. He was completely familiar with the points made in the EPO appeal by Medisense. Dr. Sanghera disclosed all of the EPO submissions to Attorney Pope, who read and understood them.

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

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

* * *

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

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

§ 1.56. Duty to disclose information material to patentability.

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

* * *

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

(1) prior art cited in search reports of a foreign patent office in a counterpart application, and

(2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

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

(1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or

(2) *It refutes, or is inconsistent with, a position the applicant takes in:*

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

(ii) *Asserting an argument of patentability.*

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

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

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

* * *

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

“The intent element of the offense is . . . in the main proven by inferences drawn from facts, with the collection of inferences permitting a confident judgment that deceit has occurred.” *Akron Polymer*, 148 F.3d at 1385. “However, inequitable conduct requires not intent to withhold, but rather intent to deceive. Intent to deceive cannot be inferred simply from the decision to withhold [information] where the reasons given for the withholding are plausible.” *Dayco*, 329 F.3d at 1367. In addition, “a finding that particular conduct amounts to ‘gross negligence’ does not of itself justify an inference of intent to deceive; the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive.” *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) (en banc in relevant part).

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

* * *

ATTORNEY POPE

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

3 **MATERIALITY**

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

9 Contrary to Attorney Pope and Abbott, the EPO submissions were not cumulative.
10 While the “optionally but preferably” sentence was, of course, already of record, the supposed
11 issue was what it taught and even whether it constituted a teaching at all insofar as those skilled
12 in the art were concerned. On that score, there was nothing already of record (or being made of
13 record in the PTO) that duplicated the same points made in the EPO appeal or even came close
14 to duplicating them. Thus, the examiner was led to believe that those skilled in the art would
15 have had no reasonable expectation of success in trying to implement the guidance of the
16 sentence in question by deleting a membrane in whole or live blood. The EPO submissions
17 certainly pointed the other way.

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

1 any extrinsic information, pro and con, known to them on the factual point covered by the
2 submission.

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

14 In sum, this order finds that the passages quoted above from the EPO submission were
15 material within the meaning of Rule 56, such that their disclosure to the PTO was obligatory.¹⁴

16 INTENT

17 With respect to intent, Attorney Pope read the entire EPO appeal and made a conscious
18 decision to withhold the contradictory material from the PTO. That is not sufficient to prove the
19 intent requirement, of course, but there should be no doubt that conscious withholding occurred.
20 Intent to deceive must be shown. The Court has carefully considered all of the facts and
21 circumstances surrounding the decision to withhold. In this regard, Abbott has asserted the
22 attorney-client privilege. Nonetheless, some direct testimony emerged as to Attorney Pope's
23 rationale for non-disclosure. His stated reason was that the EPO information was cumulative,
24 an argument this order has already solidly rejected. Without a doubt, Attorney Pope knew or
25 should have known that the withheld information would have been highly material to the
26 examiner, given the central question of what, if anything, the “optionally, but preferably”
27

28 ¹⁴ The defense presented an experienced patent attorney and former examiner, Thomas Smegal, to explain why the EPO items were material. Abbott did not present a counter expert.

1 sentence taught those skilled in the art. There was no other information in the PTO record that
2 came close to the clear-cut message of the withheld information.

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

18 Attorney Pope testified that his motive was to obtain a strong patent. Therefore, he
19 said he had no motive to conceal and to thus undermine the enforceability of the patent.
20 This argument conveniently overlooks the fact that he consciously chose to withhold.
21 Counsel who steer a course toward obtaining a strong patent should err on the side of disclosure,
22 not nondisclosure. And, it must be said, after so many rejections over so many years, it seems
23 clear that Abbott’s primary goal was to eke out some claim, saving a fight over enforceability
24 for a later day.

25 Attorney Pope also said that patent prosecutors often write specifications broadly so as
26 to support broad claims, cutting back on their claims as they go along as necessary to avoid the
27 prior art or as is otherwise necessary. Being aware of this alleged practice, he testified that he,
28 therefore, read “optionally, but preferably” as an overblown way for a prior patent prosecutor to

1 have said “optionally, but always.” This is unconvincing. *First*, there is no authority for this
2 secret-code theory. Words are supposed to mean what they say. Otherwise, our
3 patent-disclosure system would collapse. *Second*, since the claims of the ’382 covered
4 *membraneless* sensors used in blood, as both sides agree, the specification *must* have been
5 sufficient to support the membraneless sensors.¹⁵

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

17 **BALANCING**

18 Turning to the final step, this order must determine whether the questioned conduct
19 amounts to inequitable conduct by balancing the levels of materiality and intent, with a greater
20 showing of one factor allowing a lesser showing of the other, as set forth above. In doing so,
21 the undersigned is very mindful that patent prosecutors must make judgment calls about what
22 is and is not material. We must take care to respect their judgments without second-guessing
23 them and to penalize only clear-cut violations of Rule 56.

24 The withheld extrinsic evidence here was richly material. And, intent to deceive,
25 not just to withhold, was clearly in the mind of Attorney Pope, hard as it is to so conclude
26 as to a professional. Both showings are strong. The balance is decidedly against Abbott.

27
28 ¹⁵ Of course, it is true, as Abbott states, that specifications teach and claims claim. *SRI Int’l, Inc. v. Matsushita Elec. Corp.*, 775 F.2d 1107, 1121 n.14 (Fed. Cir. 1985) (*en banc*). Still, the specification must support the claims.

1 If concealment of extrinsic information as close to the heart of the prosecution as was involved
2 here is allowed to pass, then we would in effect be issuing licenses to deceive patent examiners
3 in virtually all cases. Having searched for any credible explanation for the conduct (and found
4 none) and having taken into account all possible inferences of good faith (and found none), this
5 order finds and holds that Attorney Pope and Abbott were guilty of inequitable conduct in
6 advancing the Sanghera declaration and attorney remarks without also disclosing the inconsistent
7 EPO submissions as to the meaning of the “optionally, but preferably” sentence. This has been
8 proven by clear and convincing evidence.

9 **DR. SANGHERA**

10 The analysis is largely similar for Dr. Sanghera but differs in some ways from that for
11 Attorney Pope.

12 **MATERIALITY**

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

14 **INTENT**

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

21 The problem is that he then made direct representations to the PTO — representations
22 that were materially misleading by omission. He did not have to take this extra step.
23 Having done so, he was obligated to avoid intentional deception. His sworn statements to the
24 PTO about the meaning of the “optionally, but preferably” sentence were known by him to be
25 inconsistent with his own company’s statements to the EPO — statements he had himself helped
26 craft. A declarant who makes a materially false and misleading statement under oath to the PTO
27 cannot escape a charge of inequitable conduct on the theory that he advised the lawyer that the
28 statement was misleading and why. (In this regard, no claim of good faith reliance on the advice

1 of counsel was raised by Dr. Sanghera, a step that would have waived any assertion of the
2 privilege.) In sum, given the fact that Dr. Sanghera made a positive submission to the PTO,
3 he was himself duty-bound to avoid making an intentionally misleading submission, whether or
4 not he told Attorney Pope about the inconsistency.

5 Although Abbott has not raised it, the Court has, on its own, considered the possibility
6 that Dr. Sanghera somehow believed that Attorney Pope would disclose the EPO material in
7 some other way and, thus, there was not a necessity for his declaration to do so. Dr. Sanghera
8 testified at trial at Abbott's behest (despite the fact that much trial time was earlier spent on
9 video excerpts from his deposition). His trial testimony was clear and convincing that he
10 affirmatively participated in the group discussion *not* to disclose the EPO submission, *i.e.*, that
11 he knew all along that no one was going to disclose the EPO submissions (Tr. 757–58, 774,
12 776–78). As a trial witness, it must be said that Dr. Sanghera was impeached on substantive
13 points with his prior inconsistent statements and exhibited an unconvincing demeanor (*e.g.*,
14 Tr. 764–67, 772–73).¹⁶

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

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

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

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

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

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

¹⁶ Contrary to his *trial* testimony, at his *deposition* Dr. Sanghera tried to distance himself from the decision of what was disclosed to the PTO by repeatedly stating that he merely turned over to counsel all relevant information and let counsel decide what would be disclosed (Sanghera Dep. 60, 62, 360–61).

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

A. We did not disclose those, no.

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

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

As Dr. Sanghera stated (Tr. 777):

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

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

Taking into account all possible inferences of good faith, this order concludes that Dr. Gordon Sanghera had no plausible reason for concealing the inconsistent EPO submissions and that he consciously made sworn statements to the EPO that were deliberately misleading by reason of the omission of the inconsistent EPO submissions. His unconvincing trial demeanor has been a factor in this determination.

BALANCING

Once again, both materiality and intent have been proven on the strong end of the scale, so the overall balance is decidedly against Abbott and Dr. Sanghera. And, it should be said that sworn statements to the PTO ought to be regarded with a reasonable degree of reverence and

1 candor rather than as an opportunity to tailor-make convenient extrinsic “facts” to assuage a key
2 point of concern to the examiner.

3 * * *

4 This Court is well aware that inequitable conduct has become a knee-jerk and often-abused
5 response by those accused of patent infringement. Judges ought to view such defenses with
6 skepticism, as has Judge Rader in a recent dissent. *See Events Pharma. v. Amphastar*, 525 F.3d
7 1334, 1349 (Fed. Cir. 2008) (Rader, J.). We should insist on every inch of the
8 clear-and-convincing standard. Here, however, that standard has been met. The present defense
9 is not an abuse — far from it. If the conduct here proven were blessed, then the duty to provide
10 inconsistent information under Rule 56 would be a dead letter.

11 **INVALIDITY CONCLUDED**

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

16 **CLAIM 1**

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

- 18 1. A single use disposable electrode strip for attachment to the
19 signal readout circuitry of a sensor to detect a current
20 representative of the concentration of a compound in a drop of a
21 whole blood sample comprising:
- 22 a) an elongated support having a substantially flat, planar
23 surface, adapted for releasable attachment to said readout
24 circuitry;
 - 25 b) a first conductor extending along said surface and
26 comprising a conductive element for connection to said
27 readout circuitry;
 - 28 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 concentration to said
readout circuitry;

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

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

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

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

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

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

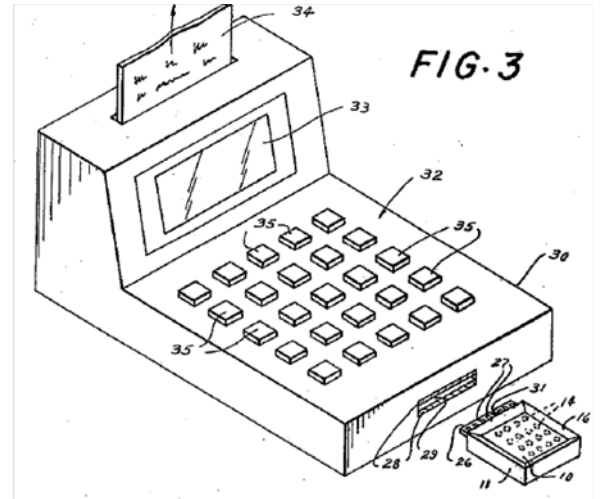
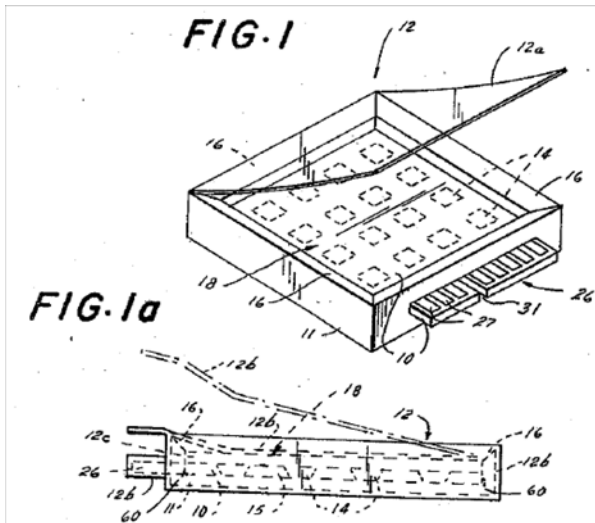
These paragraphs are now considered in turn.

* * *

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;

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



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

* * *

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

This claim limitation merely referred to the actual conductive wires that connect the electrodes (where the electrochemistry occurs) to the readout circuitry. The wires carried electricity and simply allowed current to flow to the readout circuitry. Both the '410 and '382 patents readily disclosed this limitation. For example, the '410 specification stated (col. 7:37-43):

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

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

4 * * *

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

7 The term “an active electrode” has been construed herein to mean “an electrode that
8 incorporates conductive material, and a mixture of or layers of an enzyme and mediator.”

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

17 In a particularly valuable form of the invention, however, the
18 electrode comprises a carbon core, a layer of ferrocene or a
19 ferrocene derivative at a surface thereof and a layer of glucose
20 oxidase or glucose dehydrogenase at the surface of the ferrocene
21 layer.

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

24 * * *

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

27 For the same reasons set forth under element (b), this limitation was disclosed in both the
28 '410 and '382 patents.

* * *

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

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

6 an electrode that (1) is used to complete an electrical circuit with
7 the active electrode during the glucose measurement; (2) is
8 positioned or connected in such a way that electricity can flow
9 between the second conductor and the electrode; (3) has a known
10 potential relative to a standard; and (4) maintains its potential with
11 only insignificant variation during the measurement.

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

19 Although both the ’410 and ’382 patents disclosed the use of reference electrodes and
20 counter electrodes, they only did so in the context of a *three*-electrode configuration: one
21 electrode served as the active electrode, one electrode served as the counter, and one electrode
22 served as the reference. For instance, the ’382 patent stated that the “[active] electrode was
23 connected to a potentiostat, together with a suitable counter electrode and calomel reference
24 electrode and placed in a solution containing glucose” (col 8:35–38). Accordingly, in the
25 ’410 and ’382 patents there was no single electrode that served as both the reference and
26 counter to the active electrode.

27 During the earlier stages of prosecution, Medisense argued that the two-electrode
28 configuration in the ’551 specification was a point of novelty over the prior art. Specifically, in

1 an information disclosure statement received by the PTO on June 30, 1988, Medisense
2 contended (TX 5):

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

10 In the subsequent office action signed on October 28, 1988, Examiner Shay rejected this point of
11 novelty:

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

15 In fact, two-electrode configurations were common in the prior art. For instance, the
16 Wingard reference (published in February 1983) disclosed a sensor with a platinum active
17 electrode (*i.e.*, the electrode coated with the enzyme) connected to a reference counterelectrode.

18 As with the '551 patent, the reference counterelectrode was silver-silver chloride (Ag/AgCl).
19 Wingard stated (TX 480):

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

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

Abbott argues that defendants have failed to show that the prior art cited aligns with
Judge Jenkins' claim construction for a reference counterelectrode. Not so. As stated, the
reference counterelectrode must primarily serve two functions: (i) to provide a reference voltage
for the active electrode and (ii) to counter the active electrode and complete the circuit. It is

1 clear from the language cited above from Wingard that its electrode served as a reference voltage
2 to the active electrode — “an external potential is applied to hold the platinum cathode 0.6-.0.8V
3 more negative than the silver-silver chloride anode.” As to the second function, the prerequisite
4 to serve as a counter electrode was that the same current pass through it and the active electrode.
5 The counter electrode (and the blood added by the user) collectively act to close the circuit so
6 that current can thereby flow. The electrode in the sensor circuit disclosed in Wingard met this
7 criterion. Current was passed from it to the active electrode to complete the circuit
8 (“amperometric” as stated in Wingard).¹⁷

9 This order therefore finds that “a reference counterelectrode in electrical contact with said
10 second conductor and positioned to contact said whole blood sample” was disclosed in Wingard.
11 This order further finds that a person having ordinary skill in the art would have had a
12 motivation to combine Wingard with the teachings of the ’382 and ’410 patents.

13 * * *

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

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

18 * * *

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

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

24

25 ¹⁷ In three-electrode configurations, no current would pass through the reference electrode. All the
26 current would be shared between the active electrode and the counter electrode. The reference electrode was
27 merely used to apply a known potential to bias the circuit. Where the parasitic resistance of the closed circuit or
28 the current running through the closed circuit was small, however, a two-electrode configuration was more
tolerable because of the small (and unwanted) voltage drop that would result from the parasitic resistance
(*i.e.*, Ohm’s Law, voltage equals the product of current and resistance). The determination of whether a
two-versus-three-electrode system was used therefore centered on whether the system could handle the
decreased accuracy of a two-electrode configuration (TX 316).

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

* * *

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

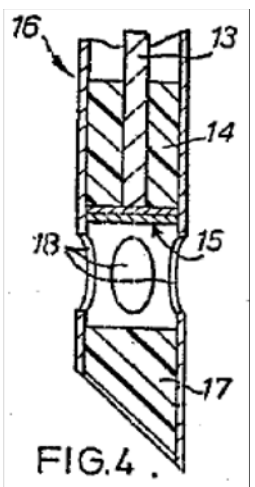
The '382 expressly taught this limitation. It recited (col 8:41-42), “[a] current is produced which is proportional to the glucose concentration.” This current was then measured and subsequently extrapolated to yield a measure of the amount of glucose in the target blood sample.

* * *

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

This limitation required that the active electrode and reference counter electrode be positioned in such a manner so that a single drop of blood could cover both. The two electrodes, however, could not be in electrical contact with one another. As described above, the '410 patent disclosed a disposable cartridge comprising a matrix of sensors. The user would prick their finger and place a drop of blood over the cartridge. In so doing, the sensors in the matrix would be covered by the user's single drop of blood.

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



1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

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

CLAIM 2

Claim 2 stated: “The electrode strip of claim 1 wherein the compound is glucose and the enzyme is glucose oxidase or glucose dehydrogenase” (col. 14:18–20). As previously discussed, there were multiple references and teachings in the ’382 patent to testing glucose levels in blood using a glucose oxidase or glucose dehydrogenase enzyme (col. 1:66–68) (“The enzyme is therefore preferably a glucose oxidase, or possibly a glucose dehydrogenase, for example a bacterial glucose dehydrogenase.”)

CLAIM 3

Claim 3 stated: “The electrode strip of claim 1 wherein said conductive elements of the first and second conductors for connection to the readout circuitry are positioned toward one end of said elongated support and said active electrode and reference counterelectrode are positioned remote from said end” (col. 14:21–25). Claim 3 required that the active electrode and reference counterelectrode both be positioned on the opposite end of the strip from the portion of the conductors that connect to the readout circuitry. As illustrated in Figure 1a of the ’410 patent (shown above), the sensors 14 were placed on one end of the cartridge while the electrical connections 27 for the readout circuitry were at the other end. The ’410 patent thus disclosed this limitation.

CLAIM 4

Claim 4 stated: “The electrode strip of claim 1 wherein said conductive elements of said first and second conductors are configured to allow reasonable attachment with a socket on a

1 read out meter which carries said signal readout circuitry” (col. 14:26–29). For the same reasons
2 set forth above, the ’410 patent disclosed this further limitation to claim 1 (col. 7:37–43).

3 * * *

4 Under 35 U.S.C. 103, a patent may not be obtained if the differences between the claimed
5 invention and the prior art would have been “obvious” at the time the invention was made to a
6 person having ordinary skill in the art to which the patent is directed. The Supreme Court
7 recently addressed the issue of obviousness in *KSR Int’l Co. v. Teleflex Inc.*, 127 S.Ct. 1727
8 (2007). There, the Supreme Court reversed the Federal Circuit’s rejection of summary judgment
9 of obviousness. In so doing, the Supreme Court emphasized that the obviousness inquiry is
10 pragmatic and flexible: “A person of ordinary skill is also a person of ordinary creativity, not an
11 automaton.” *Id.* at 1742. The Supreme Court further stressed that if a person having ordinary
12 skill in the art would have been able to implement a predictable variation of the prior art to yield
13 the claimed invention, Section 103 would likely bar patentability. As the Supreme Court stated
14 in *KSR Int’l Co.*, 127 S.Ct. at 1740–41.:

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

19 Where there is “a design need or market pressure” to solve a particular problem and there are
20 only a discrete number of predictable solutions that led to the anticipated success of the patent,
21 “[the patent] is likely the product not of innovation but of ordinary skill and common sense.”
22 *Id.* at 1742.

23 Under this practical approach, this order finds all asserted claims of the ’551 patent to
24 be obvious in light of the prior art. All but one limitation was disclosed expressly by the
25 ’382 and/or ’441 patents. The remaining limitation, implementing a two-electrode configuration,
26 was well known prior to the ’551 patent’s priority date. Each reference relied on above to show
27 obviousness was expressly aimed at the specific subject matter covered by the ’551 patent —
28

1 *i.e.*, construction of electrochemical sensors that could be used to measure glucose levels in
2 blood. One skilled in the art would therefore have readily thought to combine these references.

3 * * *

4 The Federal Circuit has held that “secondary considerations, when present, must be
5 considered in determining obviousness.” *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 667 (Fed. Cir.
6 2000); *see also Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983)
7 (“evidence of secondary consideration may often be the most probative and cogent evidence in
8 the record. It may often establish that an invention appearing to have been obvious in light of
9 the prior art was not. It is to be considered as part of all the evidence, not just when the
10 decisionmaker remains in doubt after reviewing the art”). Originally, three factors were
11 regarded as secondary considerations: commercial success, long-felt but unsolved needs, and
12 failure of others. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17 (1966). Since then,
13 several additional factors have been taken into account by the Federal Circuit, including:
14 copying by others, praise of the invention, unexpected results, disbelief of experts, general
15 skepticism of those in the art, commercial acquiescence, and simultaneous development.¹⁸

16 Evidence of secondary considerations, however, only has probative value where there is
17 “a nexus between the merits of the claimed invention and the secondary consideration.”
18 *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 306 n.42 (Fed. Cir. 1985).
19 The burden of proof as to this connection or nexus resides with the patentee. *Demaco Corp. v.*
20 *F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988).

21 Here, Abbott has primarily offered three grounds to support its showing of secondary
22 considerations: (i) the commercial success of the Medisense-Abbott-Exactech product;
23 (ii) a long-felt need for the Exactech product; and (iii) an alleged attempt to design around the
24 ’551 patent by a competitor.

27 ¹⁸ *See Ecolchem, Inc. v. Southern California Edison Co.*, 227 F.3d 1361, 1379–80 (Fed. Cir. 2000);
28 *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 885 (Fed. Cir. 1998); *Advanced Display*
Sys. v. Kent State Univ., 212 F.3d 1272, 1285–85 (Fed. Cir. 1988); *Interconnect Planning Corp. v. Feil*, 774
F.2d 1132, 1144 (Fed. Cir. 1985); *EWP Corp. v. Reliance Universal, Inc.*, 755 F.2d 898, 907 (Fed. Cir. 1985).

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

8 This order assumes all of Abbott's representations regarding the Exactech product were
9 true. Nonetheless, Abbott has failed to show that the success of the Exactech product was
10 attributable to the '551 patent. Significantly, the Exactech product was released in
11 September 1987 — two years after the '382 patent issued and over seven years before the
12 '551 application was filed. Both Dr. Sanghera and Scott testified that Medisense marked the
13 Exactech product packaging with the '382 patent before and after the '551 patent issued.
14 Abbott's expert, Dr. Jay Johnson, admitted that the Exactech product was covered by claim 1 of
15 the '382 patent (Tr. 552:15–18):

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

18 A. Yes.

19 Dr. Sanghera acknowledged on multiple occasions the novelty behind the invention of the
20 '382 patent — an invention for which Abbott received the full term of a patent. Nothing on the
21 record demonstrates that the purported novelty behind the '551 patent contributed to the success
22 of the Exactech product. Abbott has therefore failed to show the requisite nexus between the
23 claims of the '551 patent and the Exactech product. The record instead demonstrates that the
24 success of the Exactech product was more attributable to the fast-working chemistry disclosed in
25 the '382 patent.

26 Abbott next proffers the testimony of James McCann (Genetics International's former
27 founder) to support its showing of secondary considerations. McCann is currently employed at
28 Cambridge Sensors Ltd., a company also engaged in the manufacture of glucose sensors. At his

1 deposition, McCann testified that Cambridge Sensors redesigned one of its sensors in an attempt
2 to design around the '551 patent by placing a mesh layer on the active electrode and moving the
3 enzyme above the mesh layer. He stated (McCann Dep. 140–41):

4 Q. Was that version created in an effort to design around the
5 '551 patent?

6 A. Yes.

7 * * *

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

10 A. Yes.

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

20 * * *

21 Many inventions seem obvious after the fact but that, of course, is not the test for
22 invalidity:

23 It is difficult but necessary that the decision maker forget what he
24 or she has been taught at trial about the claimed invention and cast
25 the mind back to the time the invention was made (often as here
26 many years), to occupy the mind of one skilled in the art who is
27 presented only with the references, and who is normally guided by
28 the then-accepted wisdom in the art.

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

A patent is presumed valid, and the burden of establishing invalidity as to any claim of a
patent rests upon the party asserting such invalidity. 35 U.S.C. 282. Invalidity must be proven
by clear and convincing evidence. Although not susceptible to precise definition, “clear and

1 convincing” evidence has been described as evidence which produces in the mind of the trier of
2 fact “an abiding conviction that the truth of [the] factual contentions are “highly probable.”
3 *Builder, Inc. v. Kason Indus., Inc.*, 849 F.2d 1461, 1463 (Fed. Cir. 1988).

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

13 WRITTEN DESCRIPTION

14 Pursuant to 35 U.S.C. 112 ¶ 1, a patent specification is required to “contain a written
15 description of the invention, and of the manner and process of making and using it, in such full,
16 clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or
17 with which it is most nearly connected, to make and use the same.” The written-description
18 requirement and its corollary, the new-matter prohibition of 35 U.S.C. 132, serve to ensure that
19 the patent applicant was in full possession of the claimed subject matter at the time the original
20 application was filed. “To satisfy the written description requirement the disclosure of the prior
21 application must convey with reasonable clarity to those skilled in the art that, as of the filing
22 date sought, [the inventor] was in possession of *the invention*.” *PowerOasis, Inc. v. T-Mobile*
23 *USA, Inc.*, 522 F.3d 1299, 1306 (Fed. Cir. 2008) (emphasis in original). Any disclosure relied on
24 must be actual or inherent. In order for a disclosure to be inherent, “the missing descriptive
25 matter must necessarily be present in the [original] application’s specification such that one
26 skilled in the art would recognize such disclosure.” *Tronzo v. Bioment, Inc.*, 156 F.3d 1154,
27 1159 (Fed. Cir. 1998).

28

1 Defendants contend that the '551 specification fails to comport with the written-description
 2 requirement. In particular, defendants argue there was no adequate written description in the
 3 '551 specification to support the claim limitation "without an intervening membrane or other
 4 whole blood filtering membrane." It is true that the no-membrane idea was not expressly called
 5 out in the specification and, indeed, was at most lurking in its penumbra. Nonetheless, the
 6 relevant inquiry is whether those skilled in the art would have thought the inventors were in
 7 possession of an electrochemical sensor without a membrane for use in whole blood as of
 8 May 1983. Contrary to the defense, this order finds that those skilled in the art would have
 9 recognized such disclosure in the '551 specification. Plaintiff's Expert Johnson gave a detailed
 10 description of an embodiment disclosed in the '551 specification describing a membraneless
 11 sensor that could be used in whole blood (col. 8:27–52). On direct examination, defense
 12 Expert Turner admitted that the '551 disclosed a glucose sensor without a membrane that could
 13 be used in blood (Tr. 249):

14 Q. Did you find anything in the '551 patent that specially
 15 adapted that sensor disclosed? And we've looked at Claim
 16 1, but claims 1 through 4, is there anything in those claims
 that shows that these sensors are specially adapted for use
 with blood?

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

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

22 That said, it is certainly true that the '382 specification had already announced a
 23 description of a glucose sensor without a membrane for use in blood that was as good or better.
 24 After all, the '382 specification expressly recited, "[o]ptionally, but preferably when being used
 25 on live blood, a protective membrane surrounds both the enzyme and the mediator layers . . ."
 26 (col. 4:63–65). The only affirmative passage in the '551 specification on this specific point
 27 stated (col. 6:66–7:2):

28 Although the enzyme electrode should be in electrical contact
 with the liquid, it may be found valuable to exclude the sensor
 from interfering contact with larger molecules or tissue fluid

1 components. This can be done by a covering or surrounding
2 membrane, depending on the electrode geometry.

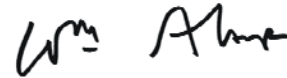
3 As such, while the '551 patent adequately disclosed the membraneless limitation, it only did so
4 after such disclosure in the '382 patent.

5 **CONCLUSION**

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

11 **IT IS SO ORDERED.**

12
13 Dated: June 24, 2008.



14 _____
15 WILLIAM ALSUP
16 UNITED STATES DISTRICT JUDGE
17
18
19
20
21
22
23
24
25
26
27
28