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

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

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

Plaintiffs-Appellants,

v.

BECTON, DICKINSON AND COMPANY,
and NOVA BIOMEDICAL CORPORATION,

Defendants–Appellees,

and

BAYER HEALTHCARE LLC,

Defendant–Appellee.

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

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BRIEF OF DEFENDANTS-APPELLEES BECTON, DICKINSON AND COMPANY AND NOVA BIOMEDICAL CORPORATION

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UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

TheraSense v. Becton

No. 2008-1511, -1512, -1513, -1514, -1595

CERTIFICATE OF INTEREST

Counsel for the (petitioner) (appellant) (respondent) (appellee) (amicus) (name of party) Becton, Dickinson & Co. and Nova Biomedical Corp certifies the following (use "None" if applicable; use extra sheets if necessary):

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

Becton, Dickinson and Company and Nova Biomedical Corporation

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

None

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

None

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

None

17 December 2008
Date

Signature of counsel

Bradford J. Badke
Printed name of counsel

Please Note: All questions must be answered

cc: Jason Rantanen, Rachel Krevans, Barry Levenstam

CERTIFICATE OF INTEREST – Attachment

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

Ropes & Gray	Bradford J. Badke Sona De Jeanne Curtis Gabrielle Ciuffreda Neal Dahiya Sanjeev Mehta Brian Biddinger Janice Jabido Brandon Stroy Mark D. Meredith Levina Wong Nina Horan Brien Santarlas Nicholas Vogt John O. Chesley Gabrielle Elizabeth Higgins Mark D. Rowland
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Statement of Related Cases

There have been no prior appeals from the District Court proceedings.

Abbott has also appealed the District Court's September 10, 2008 judgment in favor of BD/Nova regarding Patent Nos. 6,592,745 and 6,143,164, respectively. Pursuant to this Court's October 23, 2008 Order, Abbott's brief addressed the issues relating to the '551, '745 and '164 patents. BD/Nova has consented to Abbott's motion to consolidate the appeals of the September 10, 2008 judgment with the instant appeal. This brief addresses issues related to the '551, '745, and '164 patents.

The docket numbers of the '551, '745, and '164 patents are 2008-1511, -1512, -1513, -1514, -1595, 2009-1035, -1036, -1037, and -1050. BD/Nova has moved to dismiss its cross-appeal related to the September 10, 2008 judgment, Docket no. 2009-1050.

Abbott has appealed the District Court's August 8, 2008 judgment in favor of BD/Nova regarding Patent No. 5,628,890. BD/Nova has cross-appealed that Judgment. The docket numbers of the appeals related to the '890 patent are 2009-1008, -1009, -1010, and -1034.

I. STATEMENT OF THE ISSUES

The issues on appeal are:

1. Whether the District Court correctly found the '551 patent invalid for obviousness based on a PHOSITA's (person having ordinary skill in the art) understanding of the disclosure of U.S. Patent No. 4,545,382 ("the '382 patent") in combination with U.S. Patent No. 4,225,410 ("Pace"), in light of their knowledge of the art.

2. Whether the District Court correctly found the '551 patent unenforceable due to inequitable conduct because the prosecuting attorney, Lawrence Pope, and an affiant, ex-Abbott employee Gordon Sanghera, both intentionally withheld statements Abbott made to the European Patent Office ("EPO") that directly contradicted representations Mr. Pope and Dr. Sanghera made to the United States Patent and Trademark Office ("USPTO") in order to secure the issuance of the '551 patent.

3. Whether the District Court correctly construed the term "non-flowing manner" in U.S. Patent Nos. 6,143,164 ("the '164 patent") and 6,592,745 ("the '745 patent"), consistent with the intrinsic evidence, and the claim construction methodology mandated by this Court.

4. Whether the District Court correctly found claims 1-5, 8, 21-23, 28, 31 and 34 of the '745 patent anticipated by WO98/35225 ("the '225 reference").

II. STATEMENT OF FACTS

A. Invalidity Of The '551 Patent

Electrochemical glucose sensors test different types of samples: whole blood, live blood, plasma, and buffer solutions. Whole blood is blood that contains all of its components, including red blood cells. (JA02532 at 245:16 – JA02533 at 246:1.) Live blood, a subset of whole blood, is blood inside the body. (JA02532 at 245:5-9.) Plasma is blood without red blood cells. Buffer is test solution that may simulate blood. (JA02533 at 248:4 – JA02534 at 251:25.)

Testing of whole blood raises concerns. "Fouling", or the accumulation of red blood cells on the active electrode to physically block smaller glucose molecules or mediator from reaching that electrode, may occur. *Therasense, Inc. v. Becton, Dickinson and Co.*, 565 F. Supp. 2d 1088, 1099-1100 (Fed. Cir. 2008); (JA02733 at 472:13-473:2.). This may result in a false low reading. *Therasense*, 565 F. Supp. 2d at 1101. Moreover, when testing live blood, chemicals, including enzyme and mediator, may wash off the electrodes (referred to as the loss of active material) and enter the patient's bloodstream, posing a health risk. *Therasense*, 565 F. Supp. 2d at 1099-1100; (JA02734 at 478:12-25.)

The degree of fouling increases over time as more red blood cells accumulate and foul the active electrode. (JA02531 at 240:18-241:4.) Likewise, the longer a sensor is exposed to live blood, the more time chemicals have to escape the sensor and enter the bloodstream. (JA02532 at 244:18-245:4.) One solution known in the art at the time of the '382 patent to address both fouling and loss of active material was to add a protective membrane on the electrodes. (JA02733 at 473:19-474:6; JA02734 at 478:12 – JA02735 at 479:12.)

1. The '382 Patent

The '382 patent is directed to an electrochemical sensor for testing various analytes in body fluids, particularly for testing glucose in blood. *Therasense*, 565 F. Supp. 2d at 1096; (JA06057 at col. 1:54-68.) One important contribution of the '382 patent was fast-acting ferrocene-based mediators, which accelerated the electrochemical reaction and allowed for a faster test time. *Therasense*, 565 F. Supp. 2d at 1095-6; (JA06057 at col. 2:57 to JA06508 - col. 3:12.) The '382 patent contemplates the use of ferrocene-based mediators in both *in vivo* (in the body) and *in vitro* (outside the body) sensors. *Therasense*, 565 F. Supp. 2d at 1095-96; (JA06510 at Example 7; JA06511 at Example 8.)

The '382 patent explicitly teaches that the use of a protective membrane over the electrodes is at most "preferred" when testing live blood, but "optional" under all other circumstances:

> 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.

(JA6508 at col. 4:63-66.) According to the plain meaning of this sentence, in no circumstance is a membrane *required*. *Therasense*, 565 F. Supp. 2d at 1095; (JA02531 at 239:13-22.) Thus, the '382 patent teaches that a membraneless sensor may be used to test live blood, whole blood outside the body, buffer, or any other solution. *Id*.

Example 8 of the '382 patent describes an actual test done with a membraneless sensor. *Therasense*, 565 F. Supp. 2d at 1100; (JA06510 at col. 8:60 – JA06511 at col. 9:26.) This example tested the oxygen sensitivity of a membraneless sensor and determined the effect of a membrane on response time. *Therasense*, 565 F. Supp. 2d at 1101; (JA06510 at col. 8:60 – JA06511 at col. 9:37.) First, membraneless sensors were tested in buffer solution with oxygen and without oxygen to simulate the varying levels of oxygen in whole blood.[1] (JA06511 at col. 9:14-21; JA02533 at 249:20 – JA02534 at 250:15.) The current generated from these tests were within at least 5% of each other. (*Id*. at col. 9:19-21.)

[1] Whole blood could not be used for this test because the process of deoxygenation would destroy the blood sample. (JA02533 at 249:20 – JA02534 at 250:15.)

Second, sensors were tested in buffer and in whole blood with varying glucose concentrations. Three sets of tests were performed. First, a membraneless sensor was tested in two buffer solutions with different glucose concentrations. (JA06511 at col. 9:24-29.) The response times were 24 seconds and 60 seconds, respectively. (*Id*.) A membrane was then added to the sensor and the same tests were run. The response times increased to 36 seconds and 72 seconds. (*Id*.) Finally, this same sensor (*i.e.*, with the membrane) was tested in whole blood having the same glucose concentrations as the buffer solutions. (*Id*. at 9:29-32.) The response times remained at 36 seconds and 72 seconds. (*Id*.) Example 8 thus is consistent with the teaching that membranes are optional. *Therasense*, 565 F. Supp. 2d at 1100; (JA02534 at 250:16-251:25.)

Claim 1 of the '382 patent encompasses membraneless sensors for whole blood. (JA06511 at col. 10:53-63.) Dependent claim 12 adds the limitation of a protective membrane. (JA06512 at col. 11:29-32.)

Notably, Abbott's ExacTech test strip, a *membraneless* sensor for home-testing whole blood, was marked with the '382 patent. (JA07653-4; JA03005 at 735:8-16.) Abbott's own expert confirmed that claim 1 of the '382 patent covers the ExacTech product. (JA02752 at 549:18 – JA02753 at 552:20.)

2. The ‘382 EPO Counterpart: The ‘636 Patent

The disclosures of the European counterpart ‘636 patent and the ‘382 patent are virtually identical. *Therasense*, 565 F. Supp. 2d at 1108. Both contain the “[o]ptionally, but preferably” sentence. (*Id.*; JA06585; JA06508 at col. 4:63-66.)

The ‘636 patent had been revoked based on a German reference known as D1 that was cited in a European opposition proceeding. (JA06832-52.) Abbott appealed that decision and distinguished the ‘636 patent from D1. (JA06585.) Abbott argued that the ‘636 patent teaches that a membrane was optional, whereas D1 required a membrane. In support of its argument, Abbott pointed specifically to the “[o]ptionally, but preferably” sentence as an important technical teaching. Abbott also argued that the ‘636 patent disclosed a different type of membrane, but acknowledged that this membrane is preferred in live blood to prevent fouling. (JA06585; JA06530-31.)

3. The Pace Reference

The District Court found that the ‘551 patent was obvious based on the ‘382 patent in combination with the Pace reference. *Therasense*, 565 F. Supp. 2d at 1117-18; 52:4-12. Pace teaches the following limitation of claim 1 of the ‘551 patent: “an elongated support having a substantially flat, planar surface, adapted for releasable attachment to said readout circuitry.” *Id.* Pace is directed to

an electrochemical sensor for measuring the concentration of various analytes including glucose. *Therasense*, 565 F. Supp. 2d at 1118; (JA06783 at Abstract.) It taught the use of a disposable cartridge on which the sample is placed. (JA06794 at col. 6:27-67; JA06784 at Figures 1 and 1a.) The cartridge is a flat, elongated device on which the electrodes lie. (*Id*.) The cartridge is inserted into a readout device and the results are displayed on a screen. (*Id*.; JA06785 at Figure 3.)

B. Unenforceability of the '551 Patent

1. Prosecution History

Abbott's in-house counsel, Lawrence Pope, took over the prosecution of the '551 patent in the fall of 1997. By this time, the '551 application had been before the PTO for over thirteen years and had faced eleven rejections over the '382 or '636 patents alone. Further, Medisense's own '382 patent was set to expire in a few years.

In prosecuting the '551, Mr. Pope met with Abbott's Director of Research and Development, Dr. Gordon Sanghera, who, along with others in management positions, participated in brainstorming sessions concerning ways to overcome the rejections. (JA03014 at 769:11-19; 770: 7-9 and JA03016 at 777: 23-778:5.) After developing their strategy, Mr. Pope met with the Examiner. During this interview, Mr. Pope indicated to the Examiner for the first time that he wished to submit new claims covering an electrode with no filtering member.

(JA07639.) They discussed whether the '382 patent already taught electrodes without a filtering member, and specifically the "optionally, but preferably" language spanning columns four and five (lines 63-66 of column 4). (JA07639; JA6508.) The Examiner determined that "an affidavit or other evidentiary showing that at the time of the invention [of the '551 patent] such a membrane was considered essential would overcome this *teaching*." (JA07639) (emphasis added).

In response to this request, in December 1997, Mr. Pope filed the new claims, along with his remarks and a declaration of Dr. Sanghera under 37 C.F.R. §1.132 stating that at the time of the '551 invention, a PHOSITA reading the '382 patent would have considered a membrane essential for use with whole blood. (JA07636-38; JA07640-46.) Mr. Pope's amendments focused on the feature that the active electrode is exposed to whole blood without an intervening membrane. (JA07643-44.) In his remarks, Mr. Pope, *relying on Dr. Sanghera's declaration*, stated that the '382 patent taught an electrode that required a protective membrane when used with whole blood. (JA07644.) He stated that the general teaching to this effect was at lines 63 to 66 of column 4 of the '382 patent (the "optionally, but preferably" language). (*Id.*) Although Mr. Pope and Dr. Sanghera knew of Medisense's contradictory remarks to the EPO, neither disclosed those EPO statements to the PTO. (JA02983 at 647:4-18; JA03016 at 778:10-12.)

At the time of this declaration, Dr. Sanghera was an Abbott employee working, in part, on competitor analysis. (JA03012 at 760:20-22.) Earlier in 1997, Dr. Sanghera led competitive analysis of certain products that he believed to be covered by these newly presented claims of the '551 patent, including a product made by a company called Selfcare. (JA03012 at 763-64:11-10 and JA03013 at 766-67:13-9.) Dr. Sanghera even discussed these tests with Mr. Pope. (JA03013 at 765:3-7.) In fact, at the time of his declaration, Dr. Sanghera believed that the newly amended claims of the '551 patent covered all of the electrochemical blood glucose strips on the market at the time. (JA03015 at 775:1-6.)

In December 1997, Dr. Sanghera submitted his declaration to the PTO directed to how a PHOSITA would read the "[o]ptionally, but preferably" language of the '382 patent. (JA07637-38.) However, Dr. Sanghera did not disclose to the Examiner that he was not a PHOSITA at the time the '551 was filed, nor that he had no involvement in the research that lead to the '382 application. (JA03006 at 737:16 – 738:9, 739:1-3.) Further, although Dr. Sanghera had studied under and remained in contact with '382 patent inventor Dr. Hill, he did not discuss the history of the development of the '382 with Dr. Hill or any other inventors, or how they interpreted the "[o]ptionally, but preferably" language. (JA03007 at 740:12-21.) Nor did Dr. Sanghera review the research records that led to the '382 patent. (JA03007 at 742:22-743:2.) Dr. Sanghera did

little more than read some literature despite the fact that he knew that the patent Examiner would rely on his declaration in allowing these claims. (JA03015 at 775:16-24.)

Dr. Sanghera also failed to disclose in his declaration that he was involved in the EPO appeals relating to the European counterpart to the '382 patent. At the time of the EPO proceedings at issue, Dr. Sanghera was a project manager in Research and Development at Abbott. (JA02995 at 694:12-15, 695:3-15.) As part of this role, Dr. Sanghera reviewed and approved the EPO submissions and attended the oral argument before the EPO regarding the patentability of the '636 patent. (JA03010 at 752:24-753:6; 755:5-7.) Dr. Sanghera was fully aware of the arguments presented to the EPO and understood the difference between whole blood and live blood. Prior to the '551 submissions to the PTO, he reviewed these proceedings with Mr. Pope. (JA02980 at 634:19-21; JA03011 at 757:6 – 758:3.) Indeed, Dr. Sanghera's declaration contained little more than a reference to an irrelevant patent[2] and conclusory statements that "based on his historical knowledge he is confiednt [sic] that . . . one skilled in the art would have felt that an active electrode comprising an enzyme and a mediator

[2] Dr. Sanghera cited to U.S. Patent No. 4,897,173 as evidence of an example later than the time of the filing of the '551 patent that describes the use of a membrane for a blood sensor. This reference, however, does not provide any support regarding what the '382 disclosure taught to a PHOSITA at the time of the '551 filing. (JA07637 at ¶ 6).

would *require* a protective membrane if it were to be used with a whole blood sample." (JA07637.)

Shortly after submission of the amendment and declaration, based on the representations made in the remarks and declaration, the '551 patent issued as amended on October 13, 1998. (JA03014 at 770:13-15.) This came after fifteen years of prosecution and twelve rejections over either the '382 patent or the '636 patent. That *very same day* Abbott filed suit against its competitor, Selfcare, alleging infringement of the '551 patent. (JA03014 at 770:16-771:17.) Both Mr. Pope and Dr. Sanghera were active participants in the case against Selfcare. Mr. Pope was an attorney of record and Dr. Sanghera submitted a technical declaration in support of a preliminary injunction. (JA03014-15 at 771:16-772:11.)

C. Claim Construction of the '164 Patent's "Non-flowing Manner" Limitation

1. Intrinsic Evidence For Claim Construction

The '164 patent's "non-flowing manner" limitation disclaimed any sensors other than those whereby residual motion caused by the filling of a non-flow cell is allowed to dissipate so that there is no manner of convective flow at the measurement time.

Abbott's prosecution of the '164 application is consistent with construing "non-flowing manner" to exclude a non-flow cell's residual motion because Abbott added that limitation to distinguish not just the flow-cell Niwa

reference, but also the Nakajima reference, which Abbott admits is a non-flow cell reference that has a "relatively stationary" sample. *Infra* p. 13.

On June 7, 1999, the Examiner rejected pending claim 148, which ultimately issued as asserted claim 16 of the '164 patent, based on Nakajima in combination with Niwa. The Examiner stated that Nakajima taught all the elements of pending claim 148 except the volume limitation that required a sample size of 500 nL or less. (JA13753.) For that limitation alone, the Examiner turned to Niwa as "teach[ing] an electrochemical detector with an active volume of 70-340 nL (abstract)." (*Id.*) The Examiner acknowledged that Niwa disclosed a flow-cell configuration, but determined that it would have been obvious to disconnect the flow system so that Niwa also disclosed a stop-flow cell with a fixed volume. (JA13748.)

In response to the June 7, 1999 rejection, Abbott attempted to argue that Niwa did not actually disclose the 500 nL sample size limitation of the claim. Specifically, Abbott argued that its claimed sample size was not disclosed by Niwa because "although Niwa discloses a cell volume of less than 70-340 nL, the actual volume of sample interrogated during the measurement process is at least 4 x 10 microliters" in light of Niwa's continuous sample flow through the sensor. (JA13257-8.) Abbott recognized, however, that "[t]he Examiner suggests it would be obvious to operate the Niwa system in a stop-flow method," and never

attempted to rebut that suggestion. (JA13254.) Abbott's failure to do so undermined its attempt to distinguish Niwa, because in a stop-flow system, the 500 nL limitation *is* taught.

Abbott further argued that there was a lack of motivation to combine the non-flow-cell disclosure of Nakajima with the flow-cell disclosed in Niwa. (JA13257.) In so doing, Abbott admitted that "the device of Nakajima receives a sample that is *relatively stationary* during the measurement process," and "is not a flow-cell device." (*Id.* (emphasis added).)

Meanwhile, Abbott attempted to make the same distinction of Niwa based on sample volume during the prosecution of the '164 patent's parent application. (JA13786.) The Examiner there rejected Abbott's distinction of Niwa based on sample volume. (JA13791.) An interview summary indicated that Abbott would "consider introducing a limitation regarding *non-flow-through* measuring." (*Id.* (emphasis added).)

Following this interview, for both the '164 patent application and its parent application, Abbott amended its claims to include "non-flowing manner," and not the proposed "non-flow-through" limitation. (JA13800-01 at pending claim 148; JA13259.26.) Abbott chose "non-flowing manner" to distinguish Nakajima, and not just Niwa. Abbott had already and unsuccessfully attempted to distinguish Niwa for the only claim limitation it disclosed: the sample-volume

limitation. To overcome the prior art, then, Abbott needed to distinguish Nakajima's "relatively stationary" disclosure.

Although, the '164 patent specification discloses both flow cells and non-flow cells, Abbott disclaimed most of these embodiments by its amendment. (JA13234 at 11:38-45.)

The claimed embodiment of the specification excludes more than just flow cells. It also excludes the residual motion created from filling a non-flow cell: "[t]he potential is preferably applied after the sample *has come to rest in the sample chamber* to prevent electrolysis of sample passing through the measurement zone as the sample chamber is filling." (JA13234 at 12:32-35) (emphasis added). Here, sample coming to rest in the sample chamber is contrasted with the motion of the sample that is created when it *fills* the sample chamber, and not the motion of sample continuously *exiting* the sensor as would occur in a flow cell. Therefore the claimed embodiment excludes the motion of the sample prior to it being at "rest in the sample chamber," which is the residual motion created by the momentum of the sample filling a non-flow cell. This is the embodiment that is encompassed by "non-flowing manner." Indeed, Abbott pointed to only this embodiment for support when it added the same "non-flowing manner" limitation to its claims in an amendment to its European application that corresponds to the '164 patent. (JA13259.36.)

Key to allowing the sample to "come to rest in the sample chamber" is having a test time that is long enough to allow the residual motion left over from the momentum of the filling process to die down. The '164 patent specification teaches long test times ranging from one to several minutes (JA13235 at 13:35-42) that can allow this residual motion to dissipate so that the sample reaches a non-flowing state.

Thus, by way of the "non-flowing manner" amendment, Abbott limited its claims to a sensor where there was no residual sample movement. Following that amendment, the Examiner allowed pending claim 148 of the '164 patent.

2. The District Court Gave "Non-Flowing Manner" Its Ordinary Meaning

(a) Claim Construction Order

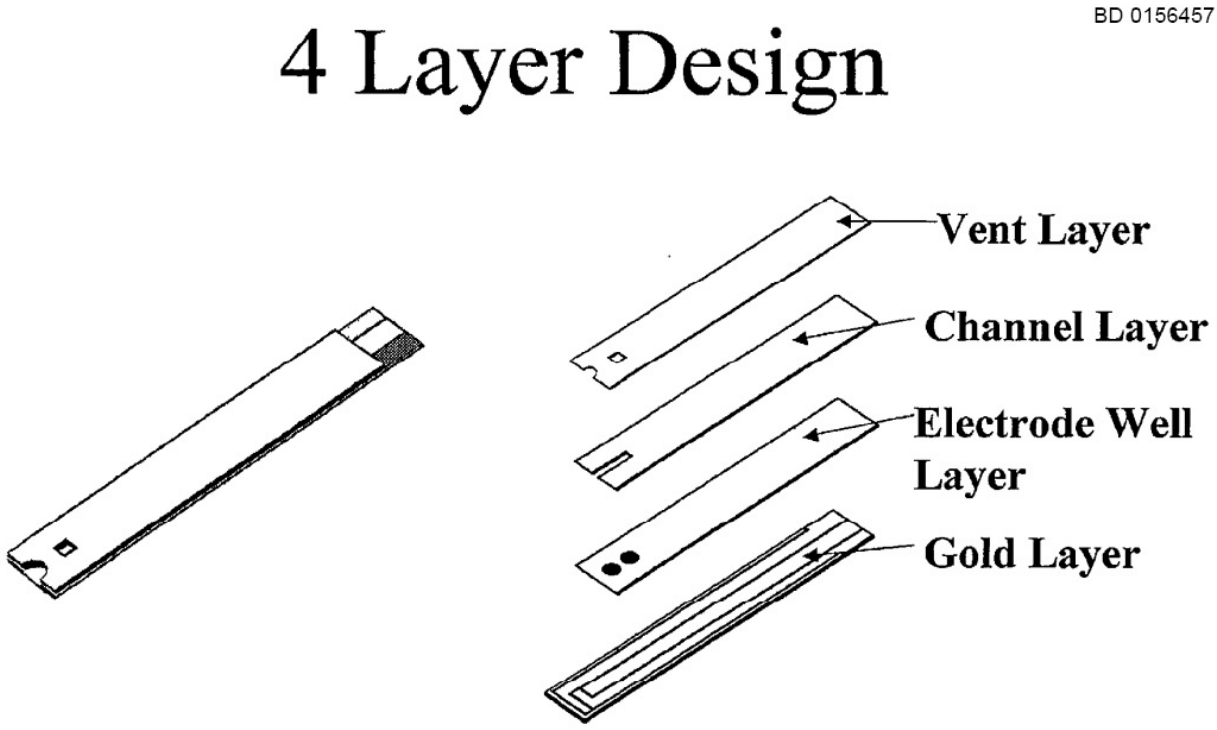
The District Court expressly relied on the plain meaning of "non-flowing manner," and on the '164 patent specification, when construing that term.[3] Rather than simply adopting either party's proposed construction, the Court analyzed the intrinsic evidence to reach its own construction that "the sample is not moving in the sample chamber during the measurement." (JA13833-34.) In its

[3] "Non-flowing manner" is found in independent claim 16 of the '164 patent (and also in independent claims 1, 28 and 34 of the '745 patent). The limitation was first construed for the '164 patent, and then the same construction was applied to both the '164 and '745 patents by all parties and the District Court because the two patents have common inventors and substantially similar disclosures.

Claim Construction Order, the District Court held that "[t]he plain and ordinary meaning of 'non-flowing manner' indicates that the sample must be stopped, rather than moving." (JA13833.) The District Court further relied on the '164 patent specification, finding that "[a]s the specification indicates, it is important to the proper functioning of the sensor that the sample be at least temporarily immobilized during measurement." (*Id.*) Thus, the District Court construed "non-flowing manner" to exclude more than just a flow cell, and required that there be no residual fluid movement in the sample chamber itself.

(b) The BD™ Test Strip Has Blood Movement During Measurement

Below is a depiction of the accused infringing device, the BD™ Test Strip:



(JA13067.)

The BD™ Test Strip has a unique well structure not found in other strips that causes a residual swirling motion of the sample during its 5 second test time. The BD™ Test Strip has two electrodes: a working electrode for measuring current from glucose, and a counter electrode for completing the electrical circuit. (JA12187 at 94:11-95:18.) Each electrode is located at the bottom of a separate well that extends below the channel to form a "working electrode well" and a "counter electrode well." (*Id.*) These wells are shown as the two dark circles in the Electrode Well Layer in the schematic above. Blood entering the strip will first fall into the working electrode well. (JA12080 at ¶ 8.) As blood rushes into the

well, though, it will overshoot the well edge much like a waterfall. (JA12080 at ¶ 10.) The blood that overshoots the well edge will trap air underneath it, creating air bubbles. (*Id.*) Blood will then recirculate back toward the edges of the well to displace that air, resulting in a continuous swirling motion for the test time and causing the air bubbles to move along the sides of the well. (*Id.*) The same waterfall and swirling motion that is happening in the working electrode well then also occurs in the counter electrode well. (*Id.*) This swirling movement extends outside the wells and into the channel itself. (JA12080 at ¶ 10; JA12095-7 at ¶ 7.)

(c) The District Court Found That The BD™ Test Strip Did Not Infringe The '164 And '745 Patents

In granting BD/Nova summary judgment of non-infringement, the District Court began its opinion by applying its prior construction of "non-flowing manner":

> In its August 31, 2006 claim construction order regarding the '164 patent, the Court construed "holding the sample in a non-flowing manner within the sample chamber of the analyze sensor" to mean that "the sample is not moving in the sample chamber during the measurement." The Court determined that a sample that was even "flowing at a very slow rate" is "directly at odds with the plain and ordinary meaning of "non-flowing."

(JA00023.)

Notably, the Court also referenced an earlier summary judgment order where it had consistently applied the same definition of "non-flowing manner" to

deny a different BD/Nova motion for summary judgment that the '164 patent was invalid:

> In its July 10, 2007 summary judgment order, the Court further indicated that this construction meant "something other than preventing the sample from leaving the measurement zone – it requires that 'the sample is not moving in the sample chamber during the measurement."

(*Id.*)

BD/Nova's experts[4] created and analyzed eighteen videos of blood filling the BD™ Test Strip. Those videos were before the District Court as part of BD/Nova's summary judgment briefing. In *each recording*, a flow of the blood sample (including the rotational swirling) can be observed for the entire five-second measurement time. (JA12095-7 at ¶¶ 7-8; JA12126-37; JA14572; JA12081 at ¶ 11.) Also visible in each recording are air bubbles that form only at the circumference of the well, and not in the middle of the well. This confirms that blood is overshooting the edge of the well, trapping air underneath this overflow at the edge of the well, and then swirling as it displaces that air. (JA12126-37; JA14572; JA12081-2 at ¶¶ 11, 13.) Following the test time, however, the residual flow begins to dissipate. (*Id.*) Abbott's expert watched BD/Nova's videos, and conceded at his deposition that he sees "slight swirling in the chamber" that "appears to be a convective flow." (JA12258 at Tr. 475:6-14; JA12270 at Tr.

[4] BD/Nova's fluid dynamics expert, Dr. William Durgin, was the only such expert in the case for any party.

490:2-17.) Abbott's expert characterized this flow as "mass transfer" and as having "a velocity gradient within the solution somewhere." (JA12758 at Tr. 495:7-14; JA12781 at Tr. 98:15-18.)

The Court then granted BD/Nova's motion for summary judgment of non-infringement because both parties' experts agreed that the BD™ Test Strip exhibits a rotational swirling effect (or convective flow) during measurement. (JA00023-4.)

D. Invalidity Of The '745 Patent Claims

1. The '225 Reference Anticipates The '745 Patent Claims

The '225 reference discloses "[a] sensor designed to determine the amount and concentration of analyte [such as glucose] in a sample having a volume of less than about 1 uL." (JA08777.) The '225 reference further discloses diffusible mediators to help measure analyte, which are tabbed as "not desirable," but nonetheless disclosed. (JA08787 at 9:21-32.)

Previous co-defendant Roche's electrochemistry expert, Dr. Weber, analyzed the '225 reference and found that it disclosed every limitation of the pertinent claims of the '745 patent. (JA01863-82.)

Dr. Weber found that the '225 reference disclosed the "diffusible mediator" limitation because, *inter alia*, "the ['225] patent discloses the possibility to use diffusible mediators. Certainly, the preference of the inventors is for non-

leachable mediators, but they disclose that other types, diffusible, can be used." (JA01864-5 (*citing* JA08787-8 at 9:20-33; 10:25).)

After showing calculations of how far a *diffusible* mediator would travel, Dr. Weber further concluded that the '225 reference disclosed the "background signal" limitation because "the '225 patent shows that the distance between the electrodes is larger than the distance a mediator can travel during a certain time, so there is no shuttling. If there is no shuttling as defined by '745, then there is no background as defined by '745." (JA01866-7.)

Dr. Weber's analysis is undisputed. Nowhere in his summary judgment declaration did Abbott's expert Dr. Bard opine that Dr. Weber's analysis of the '225 reference was incorrect or incomplete. Nor did Dr. Bard opine that the '225 reference did not anticipate the '745 patent claims. Indeed, Dr. Bard had already admitted at his deposition that he had not identified anything wrong with Dr. Weber's analysis of the '225 reference. (JA08373 at 158:14-24.) Dr. Bard even agreed that the '225 reference disclosed the "diffusible mediator" limitation of the '745 claims. (JA08367-9 at 141:23-25; 142:9-143:5.)

BD/Nova's expert, Dr. Turner, did *not* opine on whether the '225 reference anticipated the '745 patent claims. (JA09623-9700.) Dr. Turner did opine, however, that at the time of the '745 patent application, a PHOSITA would have known that "background signal due to shuttling of the diffusing mediator

from one electrode to the other has never been a problem in the design of these [analyte sensor] devices." (JA09678.)

2. Claim Construction Hearing

Abbott had argued earlier in the same litigation that the claims of the '164 patent, which shares the same disclosure as the '225 reference, should not exclude sensors that use a diffusible mediator. Specifically, BD/Nova argued that the claims of the '164 patent could not include electrochemical sensors that used a diffusible mediator because the specification disclosed and then disclaimed such sensors. (JA13295-7.) In response, Abbott argued that "the identification of an option as inferior is not enough to exclude it from the scope of the claim." (JA14257.) The Court adopted Abbott's construction. (JA13832-3.) Abbott then continued to assert the '164 patent claims against the BD™ Test Strip which used a diffusible mediator.

III. SUMMARY OF THE ARGUMENT

Invalidity of the '551 patent claims: The District Court correctly found the '551 patent claims obvious in light of the '382 patent's disclosure, the Pace reference, and a PHOSITA's knowledge of the art.

Unenforceability of the '551 patent: The District Court correctly found the '551 patent to be unenforceable due to both the prosecuting attorney's and affiant's inequitable conduct. They improperly withheld, with an intent to

deceive, submissions to the EPO that were highly material to the patentability of the ‘551 patent because they were inconsistent with Abbott’s arguments and Dr. Sanghera’s declaration to the PTO in favor of patentability.

Summary judgment of non-infringement of the ‘164/’745 patents: The District Court properly construed the “non-flowing manner” term, and correctly found non-infringement based on that construction. The plain meaning of “non-flowing manner,” the patent specification and the prosecution history all support BD/Nova and the District Court’s construction, not Abbott’s. Abbott’s analysis of the prosecution history improperly overlooks the fact that Abbott disclaimed more than just flow-cells with this limitation.

Summary judgment of invalidity of the ‘745 patent claims: The District Court properly found certain claims of the ‘745 patent invalid as anticipated by the ‘225 reference. The only dispute Abbott appears to have is whether the ‘225 reference’s diffusible-mediator disclosure is “part of the invention” or teaches the asserted claims, neither of which is the standard for anticipation. Moreover, the majority of Abbott’s arguments are ones that were never considered or ruled upon by the District Court because Abbott failed to raise those arguments during summary judgment. Those arguments have therefore been waived.

IV. ARGUMENT

A. The District Court Correctly Found The '551 Patent Invalid For Obviousness

The issue of obviousness is a question of law reviewed de novo that is based on underlying findings of fact, which are reviewed for clear error. *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1359 (Fed. Cir. 2007). A finding of clear error is appropriate only where the reviewing court based on the entire record is "'left with the definite and firm conviction that a mistake has been committed.'" *Id*. (citing *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 395 (1948)).

1. The '382 Patent Teaches Membraneless Sensors

(a) The District Court's Finding Was Based On The Entire Disclosure Of The '382 Patent And The Trial Record

The District Court properly found that the '382 patent teaches membraneless sensors based on the entire disclosure of the patent and trial testimony. *Therasense,* 565 F. Supp. 2d at 1101.

The '382 patent expressly teaches that membranes are optional. *Therasense*, 565 F. Supp. 2d at 1099; (JA6508 at col. 4:63-66; JA02531 at 239:13-22.) The Court properly read the "optionally but preferably" sentence to mean that a membrane surrounding the enzyme and mediator layers is optional. *Id*. Further, a membrane is merely preferred when the sensor is in live blood, *i.e.*, inside the

body. *Id*. Under no circumstance is a membrane required. *Id*. Thus, the '382 patent teaches a membraneless sensor for testing whole blood. *Id*.

The Court's interpretation is consistent with the teachings of the '382 patent. As Abbott concedes, one contribution of the '382 patent is the use of ferrocene-based mediators, which speed up reaction time. (Abbott Brf., p. 8.) Membranes reduced fouling. (*Id*.) Since fouling is time-dependent, a PHOSITA would understand the fast-acting mediator taught in the '382 patent reduced this risk such that a membrane for testing whole blood was no longer necessary. *Therasense*, 565 F. Supp. 2d at 1101; (JA02531 at 240:4 – 241:23.)

Thus, a PHOSITA would understand from reading the '382 patent that in the case of testing whole blood outside the body, where fouling is a concern, a membrane is merely optional. In the case of testing live blood inside the body, a membrane would be preferred because the loss of active materials into the bloodstream, although minimized, still presents a risk to the patient. (JA02531 at 240:4-17.) Contrary to Abbott's allegations, the Court's interpretation of the "optionally, but preferably" sentence is grounded in the technical teachings of the '382 patent and in an understanding of the function of a membrane.

(b) Abbott's Argument That The '382 Patent Teaches Away From Membraneless Sensors Is Baseless

Abbott contends that the '382 patent teaches away from membraneless sensors. Abbott's argument has no basis in law or in fact. Abbott's

own expert, Dr. Johnson, admitted that nowhere in the '382 patent does it disclose that a membrane is required for an in vitro sensor. (JA02748 at 533:8-11.) Rather, Abbott relies solely on the lack of an example of a membraneless sensor tested in whole blood. (Abbott Brf., pp. 11-12.)

Revealingly, Abbott marked its membraneless ExacTech test strip with the '382 patent. *Supra* p. 5. Abbott's own expert confirmed that claim 1 of the '382 patent cover this product. (*Id.*) Abbott cannot now run away from this representation.

The absence of an example or experimental data relating to a membraneless sensor does not constitute a teaching away from membraneless sensors, much less overcome the explicit teaching that membranes are just optional. *In re Donohue*, 766 F.2d 531, 533 (Fed. Cir. 1985). In any case, though no experimental data is shown, the '382 patent teaches that the sensors described in the examples, including those without membranes, are in fact intended for use in whole blood. (JA06511 at col. 10:44-50.)

Abbott's argument that Example 8 of the '382 patent somehow teaches against a membraneless sensor similarly fails. Abbott's own expert had no evidence that the membraneless sensor of Example 8 would not work in whole blood. (JA02751 at 545:10 – 546:14.)

The purpose of Example 8 is to measure the oxygen sensitivity of a membraneless sensor and to see the effect of adding a membrane to response time. *Supra* pp. 4-5. Example 8 says nothing to suggest that a membrane would be required to test whole blood.

(c) The Nankai Reference Is Irrelevant

Abbott argues that the addition of a membrane in a sensor used to test whole blood described in the Nankai reference is evidence that the Nankai inventors read the '382 patent teachings to mean that membranes are required. (Abbott Brf., pp. 13-14.) Abbott improperly and without basis overextends the import of one example in Nankai to erase the teachings of the '382 patent. There is no evidence what the Nankai inventors knew or believed about the '382 patent.

(d) Abbott Is Attempting To Rewrite The "Optionally, But Preferably" Teaching

Abbott's interpretation of the "optionally, but preferably" sentence is a distortion of its plain meaning. Abbott argues that a PHOSITA would interpret this sentence to mean that a membrane is optional where there are no red blood cells in the sample in the first place (e.g,. interstitial fluid or buffer). (Abbott Brf., p. 9.) The '382 disclosure, however, suggests no such thing. The plain language states that membranes are optional in general; it does not qualify that they are optional only when testing samples without red blood cells. *Supra* p. 4. Nor can Abbott point to any specific teaching in the patent to support its theory.

Abbott's interpretation of the "optionally, but preferably" sentence is inconsistent with what it told the EPO during opposition proceedings for the '636 patent. Abbott relied on the same "optionally, but preferably" sentence as in the '382 patent to argue that an important difference between the '636 patent and D1 is that the '636 patent teaches a sensor without a membrane. *Supra* p. 6. That is, Abbott's interpretation was exactly what the District Court found here – the '382 patent teaches that membranes are optional. *Id*. Abbott cannot now take the opposite view that the "optionally, but preferably" sentence is merely "patentese" when it relied on this very sentence as an important teaching to distinguish the prior art in the EPO.

Further, BD/Nova's expert Dr. Turner reviewed the "[o]ptionally, but preferably" sentence in the context of the entire '382 patent and its file history, and opined that a membrane is not required when testing whole blood. (JA02523 at 209:1-9.) Dr. Turner's opinion about uses of the word "preferably" in other contexts is irrelevant.

2. Reasonable Expectation Of Success

The teachings of the '382 patent and trial testimony of Dr. Turner clearly establish that a PHOSITA would have had a reasonable expectation of success that the '382 patent membraneless sensor would have worked in whole blood. The District Court credited the testimony of Dr. Turner regarding the

function of a membrane in a sensor. *Therasense*, 565 F. Supp. 2d at 1101. The membrane is not part of the electrochemistry. *Id*.; (JA02531 at 240:4-241:4.) It does not play a role in facilitating the transfer of electrons from glucose to the meter to obtain a reading. Rather, it merely serves as a physical barrier between the sample and the electrodes to prevent fouling. *Id*.

The '382 patent teaches the use of a fast-acting mediator which reduced response time and minimized the risk posed by fouling of the active electrode. *Supra* p. 3; (JA02532 at 244:18-245:4.) The '382 patent examples cite test times within one minute for sensors with a membrane, and less time without a membrane. (*See e.g.*, JA06511 at col. 9:22-37.) For *in vitro* testing with a test time of approximately 60 seconds, one of skill in the art would know that fouling is much less of a concern. (JA02531 at 241:12-23; JA02065 at 280:22-281:11.) Thus, a PHOSITA would have had a reasonable expectation that the '382 patent membraneless sensor would work in whole blood. *Therasense*, 565 F. Supp. 2d at 1100-01.

Abbott's argument that a PHOSITA would not know how to make a membraneless sensor defies logic. Abbott does not dispute that it was known how to construct a sensor with a membrane. A PHOSITA would know how to omit the step of adding a membrane, based on the disclosure of the '382 patent.

3. The ‘382 Sensor Is Enabled

The District Court’s finding that a membraneless sensor would work in whole blood was based on ample evidence in the record. Dr. Turner testified that fouling would still occur but it would not be much of a concern for test times indicated in the ‘382 patent. *Supra* p. 25. Thus, a PHOSITA would understand that a membrane would not be necessary for an *in vitro* sensor of the ‘382 patent to test whole blood. *See id*.

Abbott’s argument that the need for a membrane is not eliminated since fouling would still occur misses the mark. As Dr. Turner testified, fouling occurs over time. (*Supra* p. 3.) He further testified that a sensor of the ‘382 patent, which employs a fast-acting mediator and a test time of 60 seconds, would work despite fouling. (*Supra* p. 25.)

Abbott’s argument that no one had tried to use any ‘382 sensor in whole blood without a membrane is false. Abbott’s own product, the ExacTech test strip, is a membraneless sensor used for testing whole blood that was marked with the ‘382 patent. (*Supra* p. 5.) In any case, enablement does not require that every embodiment of the invention be reduced to practice or tested. *In re Donohue*, 766 F.2d at 533.

Contrary to Abbott’s assertions, the District Court did not find that a PHOSITA “could rip the membrane off the sensor described in the ‘382 patent,

stick in whole blood, and have it work." (Abbott Brf., p. 35.) Rather, the District Court found that a PHOSITA would have readily thought to combine the teaching of the '382 patent, Pace, and knowledge of how to implement a two-electrode configuration to construct a sensor as claimed in the '551 patent. *Therasense*, 565 F. Supp. 2d at 1120.

A PHOSITA would have expected such a sensor to work in whole blood, s*upra* p. 25, and Abbott cannot point to anything in the '382 patent that would suggest otherwise. Abbott relies on the speculation of ex-employee Dr. Sanghera that oxygen sensitivity would prevent a membraneless sensor from working based on his reading of Example 8. (Abbott Brf., p. 35.) There is no basis for his opinion, nor was Dr. Sanghera a PHOSITA at the time the '382 patent was filed. The sensor tested in buffer solution with oxygen compared favorably to the test run on a buffer solution without oxygen. (JA06511 at col. 9:19-21.) The current generated from the test run with oxygen produced a current that was "at least 95% of that produced in the [deoxygenated buffer solution]." (*Id.*) Dr. Sanghera's extrapolation from this data that a membraneless sensor would not work in whole blood is unsupported speculation. Moreover, the Court found that Dr. Sanghera was not a credible witness. *Therasense*, 565 F. Supp. 2d at 1116.

The '382 patent teaches that the sensors described in the examples were intended for use in whole blood. (JA06511 at col. 10:44-48.) The Court

properly credited the testimony of BD/Nova's expert Dr. Turner, who testified that the membraneless sensor of Example 8 would work in whole blood, and that Example 8 tested those sensors in buffer solutions with and without oxygen for the very purpose of simulating tests on whole blood. (JA02533 at 249:20 – JA02534 at 251:25.)

The District Court properly disregarded '382 patent inventor Dr. Hill's testimony about the unavailability of electrodes that could be used to test whole blood without a membrane. The availability of such electrodes does not alter the teachings of the '382 patent.

4. District Court Properly Found Motivation To Combine

The District Court correctly found a motivation to combine based on the persuasive testimony of BD/Nova's expert, Dr. Turner, who testified that the field of biosensors was a "sophisticated field" (JA02523 at 209:16 – JA02524 at 210:1) and had "relatively few references" when the '382 patent issued. (JA02526 at 221:3-5.) He observed that the '382 patent and Pace were concerned with the same subject matter, *id*. at 220:25-221:13, and concluded that "[a]nybody working in this field would have been looking for these two pieces of information." (JA02526 at 220:2-7.)

Finally, Dr. Turner confirmed that a PHOSITA would have understood the desirability of the combination of the industry standard of the strip-

type format of Pace with the teachings of the '382 patent. (JA02526 at 221:9 - JA02527 at 222:1.) As Abbott's own expert confirmed, the '382 patent discloses sensors for home-testing by diabetics. (JA06509 at col. 5:26-29; JA02755 at 559:23-60:18.) Dr. Turner further testified that a PHOSITA would be motivated to modify the three electrode system disclosed in the '382 patent to a two electrode system because it was simpler and more practical. (JA02529 at 231:5-13.)

5. The '551 Is Invalid Because It Merely Deleted A Function

The District Court correctly found the '551 patent to be obvious on the alternative ground that deletion of the membrane is not inventive because it led to the corresponding deletion of the membrane's function. *See Richards v. Chase Elevator Co.*, 159 U.S. 477, 486 (1895).

Abbott presented no evidence at trial that the '551 patent discloses anything to make up for the loss of a membrane. It was during closing argument that Abbott argued for the first time that the '551 sensors showed less oxygen sensitivity and fouling because of the specific electrode preparation disclosed in the '551 patent. *Therasense*, 565 F. Supp. 2d at 1104. Abbott's own expert, Dr. Johnson, testified, however, that the '551 patent does not suggest that its electrode preparation somehow makes the use of a membrane unnecessary. (JA02757 at 567:6-11.) In fact, Abbott could not point to anything in the trial record, '551 patent, or in its prosecution history to support this belated argument.

Abbott argues that using a carbon paste or suspension somehow led to a decrease in oxygen sensitivity in the '551 sensor. The '382 specification, however, teaches that an advantage of electrodes of the '382 invention is "very low oxygen sensitivity [which] would allow omission of the dilution step involved in blood analysis in current instruments." (JA06509 at col. 5:18-22.) The very advantage that Abbott points to in the '551 patent was already a feature of the '382 sensor. *Therasense*, 565 F. Supp. 2d at 1104.

Abbott now argues for the first time in its appeal brief that the decreased oxygen sensitivity of the '551 sensor is superior to that in the '382 sensor. Yet Abbott again fails to point to anything in the '551 patent or its prosecution history that supports this newly concocted theory. Abbott's unsupported attorney argument has no basis in the record.

6. No Commercial Success

The District Court properly found that Abbott failed to show the requisite nexus between the commercial success of the ExacTech product and the asserted claims of the '551 patent.

A nexus may be presumed where the patentee shows that the product embodies the elements of the claim *and* it is coextensive with them. *See Brown & Williamson Tobacco Corp. v. Philip Morris, Inc.*, 229 F.3d 1120, 1130 (Fed. Cir. 2000). Abbott failed to even allege, much less come forward with evidence, that

the ExacTech product is coextensive with the claims. The ExacTech product consists of multiple components which include the ExacTech pen (electrical meter), the calibrator bar, and the test strip. (JA02635 at 403:21 – JA02636 at 404:25.) Abbott's corporate witness repeatedly referred to the ExacTech product as the three components (*See e.g.*, JA02635 at 403:21 – JA02636 at 404:25; JA02639 at 419:10-20), and testified that the ExacTech *product* (as opposed to the test strip) was successful. (JA02637 at 410:25-411:8.) The asserted claims of the '551 patent are directed only to the test strip and thus they are not coextensive with the ExacTech product. *See Demaco Corp. v. F. Von Langsdorff Licensing, Ltd.*, 851 F.2d 1387, 1392-93 (Fed. Cir. 1988).

Even assuming that Abbott can show the requisite nexus between the purported invention of the '551 patent and the sales of the ExacTech product, there is no reliable proof of commercial success. All Abbott presented was uncorroborated testimony of its employee-scientist, Steven Scott. He admitted that he had never held a marketing position and did not consider himself an expert in the blood glucose market. (JA02726 at 443:9-22.) He could not provide testimony on the number of ExacTech test strips sold during the relevant time frame. (JA02727 at 447:1-12.) Furthermore, Mr. Scott did not have a specific recollection of the market share of the ExacTech product. (*Id*. at 447:1-448:3.) His testimony, the only trial testimony on commercial success, should be disregarded.

B. The District Court Correctly Found That The '551 Patent Was Unenforceable Due To Inequitable Conduct

This Court reviews the determination of inequitable conduct under an abuse of discretion standard and reviews the facts underlying issues of materiality and intent supporting such determination for clear error. *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1234 (Fed. Cir. 2003). Further, this Court gives deference to the role of the District Court as fact-finder to assess the demeanor and credibility of witness testimony. *Refac Int'l, Ltd. v. Lotus Dev. Corp.*, 81 F.3d 1576, 1582 (Fed. Cir. 1996).

Despite this clear standard, Abbott incorrectly argues that to the extent that there was ambiguity in the documents found to be highly material by the District Court (there was none), any ambiguities should be resolved in Abbott's favor. (Abbott Brf, p. 41.) For support, Abbott cites to *Scanner Techs. Corp. v. ICOS Vision Sys. Corp. N.V.* and improperly states the rule in that case. 528 F.3d 1365 (Fed. Cir. 2008). First, nowhere in this rule did this Court in *Scanner Techs.* state that ambiguity should be resolved in favor of the patentee. Second, the District Court here correctly considered the inferences proffered by Abbott and even those that Abbott did not advance clearly[5] and found that Attorney Pope was not "a convincing trial witness. To the contrary, his trial explanation for his

[5] The District Court considered and correctly dismissed Mr. Pope's excuse that at the time of his submission to the PTO he was unaware of any difference between live blood and whole blood. *Therasense*, 565 F. Supp. 2d at 1114.

withholding was not plausible and he was not credible. . . . Sadly, this order must find that Attorney Pope had no plausible reason for consciously withholding the EPO submissions. . . ." *Therasense*, 565 F. Supp. 2d at 1113. Further, the District Court clearly "searched for any credible explanation for the conduct (and found none) and . . . [took] into account all possible inferences of good faith (and found none)." *Id*. at 1114. Moreover, Abbott has failed to provide any credible evidence that the statements to the EPO were ambiguous.

1. Mr. Pope And Dr. Sanghera Had A Duty To Disclose Prior Inconsistent EPO Arguments

Every individual associated with the filing or prosecution of a patent application has a duty of candor and good faith in dealing with the PTO, including a duty to disclose information known to the individual to be material to patentability. 37 C.F.R. § 1.56(a). These "individuals" include each attorney who prepares or prosecutes the application, and every other person substantively involved in the prosecution of the application. 37 C.F.R. § 1.56(c). The District Court correctly held that Attorney Pope, as the prosecuting attorney for the '551 patent, and Dr. Sanghera, in his substantive participation in that prosecution and his submission of a declaration under 37 C.F.R. § 1.132, both had a duty of candor and good faith in dealing with the PTO.

2. Materiality

Under Rule 56, information is material to patentability when it is not cumulative to other information already of record and when it refutes or is inconsistent with a position the applicant takes in asserting an argument of patentability. 37 C.F.R. § 1.56(b).

First, as the District Court correctly found, although the '382 and '636 patents themselves were already before the PTO, Abbott's statements to the EPO concerning whether the "optionally, but preferably" language constituted a teaching to a PHOSITA at the time of the invention were not cumulative to the '382 patent or any other information before the Examiner. *Therasense*, 565 F. Supp. 2d at 1112. Indeed, the Examiner specifically required information that was not available to him regarding the "optionally, but preferably" teaching. (JA07639.) Abbott provided Dr. Sanghera's declaration as an evidentiary showing that, at the time of the invention of the '551 patent, a PHOSITA would have believed a membrane to be required when used with whole blood. (JA07637 at ¶ 5.) However, neither Mr. Pope nor Dr. Sanghera provided Abbott's own prior inconsistent statements to the EPO regarding the very same teaching that the use of a membrane was merely "optional," or "preferred" when used with live blood. Thus, the District Court properly found that the withheld information was not

cumulative of any information already in front of the Examiner. *Therasense*, 565 F. Supp. 2d at 1112.

Second, the District Court correctly found that the submissions to the EPO were "flatly inconsistent" with the main points advanced by Mr. Pope and Dr. Sanghera in support of the '551 claim amendments. *Id*. Whereas to the EPO, Abbott argued that "[c]ontrary to the semipermeable membrane of D1, the **protective** membrane **optionally** utilized with the glucose sensor of [the '636 patent] is **not** controlling the permeability of the substrate," (JA06530-31 (emphasis in original)) Mr. Pope argued to the PTO, based on the Sanghera declaration, that "[o]ne skilled in the art would <u>not</u> have read the disclosure of the ['382 patent] as teaching that the use of a protective membrane with whole blood samples was optional." (JA07645.)

Abbott's argument that the submissions to the EPO were not inconsistent because it was arguing a "completely different point" in the EPO proceeding is inaccurate. (Abbott Brf., p. 42.) Abbott represented to the EPO that:

> Column 5, lines 30-34 of the patent in suit provides the following information:
>
> "Optionally, but preferably when being used on live blood, a protective membrane surrounds both the enzyme and the mediator layers, permeable to water and glucose molecules."
>
> It is submitted that this disclosure is ***unequivocally clear***. The protective ***membrane*** is ***optional***, however, it is

> ***preferred when used on live blood in order to prevent the larger constituents of the blood, in particular erythrocytes from interfering with the electrode sensor.*** Furthermore, it is said, that said protective membrane should not prevent the glucose molecules from penetration, the membrane is "permeable" to glucose molecules.

(JA06585) (emphasis added).

Abbott now neglects to acknowledge that it argued two separate points before the EPO: 1) that the protective membrane of the '636 patent was used optionally in *all* cases and *preferably* in the case of live blood *and* 2) that the protective membrane in the '636 patent was a different *type* of membrane (permeable versus diffusion-limiting) than that of the prior art D1 reference, but that it is preferred in live blood to prevent fouling. Indeed, when testifying, Mr. Pope incredibly attempted to collapse these statements into one argument, stating that the use of the word "furthermore" in the above EPO quotation did not indicate a second argument. The District Court, however, correctly found that while Abbott argued the point of the different *type* of membrane, it nevertheless *also* argued that the protective membrane was "optional".

Abbott argued to the EPO that with respect to the "optionally, but preferably" disclosure, the "protective membrane is optional". (JA07685.) Abbott later argued to the PTO that "one skilled in the art would not read [the "[o]ptionally, but preferably" language] to teach that the use of a protective

membrane with a whole blood sample is optionally [sic] or merely preferred." (JA07637.) Abbott's arguments to the PTO are thus clearly and wholly inconsistent with its argument to the EPO. (C*ompare* JA06585 with JA07637.)

Abbott also attempts to argue that inequitable conduct should not turn on subjective phrases such as "unequivocally clear". (Abbott Brf., p. 46.) However, there is nothing subjective about the phrase "unequivocally clear," and Abbott provides no credible explanation or interpretation of the phrase to mean anything other than what it says. Further, as this Court has repeatedly held, close cases of interpretation of information should be resolved by disclosure of that information by the applicant to the PTO. *Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1367 (Fed. Cir. 2007); *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1386 (Fed. Cir. 2001).

Materiality also "embraces any information that a reasonable Examiner would substantially likely consider important in deciding whether to allow an application to issue." *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, 487 F.3d 897, 913 (Fed. Cir. 2007); *see also Cargill*, 476 F.3d at 1364. Here, it is uncontroverted that the Examiner focused on whether the '382 patent already disclosed membraneless sensors for use with whole blood. (JA07639.) Abbott's submissions to the EPO indisputably went to the heart of the question; the Examiner searched for evidence regarding whether the "optionally, but preferably"

language taught membraneless sensors, and these EPO statements discussed the very same language. (JA07639; JA06585; JA06530-31.) Thus, the submissions made to the EPO would be information that a reasonable Examiner would substantially likely consider important to the patentability of the '551. *See Therasense*, 565 F. Supp. 2d at 1110.

Further, information is highly material, where, as here, the material information is known to the declarant making a declaration to the PTO and it conflicts with that declaration. *Pharmacia Corp. v. Par Pharm., Inc.*, 417 F.3d 1369, 1373 (Fed. Cir. 2005). In *Pharmacia*, the district court found inequitable conduct for failing to disclose to the PTO an article written by the declarant that conflicted with his declaration to the PTO. *Id*. There, as here, the declaration made in support of patentability went to the very point of novelty over the piece of prior art relied on by the Examiner. *Id.* Similarly, here, Dr. Sanghera had approved the technical statements included in the EPO submissions that were inconsistent with his declaration to the PTO. (JA03009 at 750:11-21.) In both the *Pharmacia* case and here, the district court correctly found that the declaration to the PTO was misleading for failing to disclose the prior information and inconsistent with the undisclosed information. *See Therasense*, 565 F. Supp. 2d, at 1110.

Moreover, Dr. Sanghera knew at the time of his declaration, but did not disclose to the PTO, that Abbott was marking (and continued to mark) its membraneless ExacTech product with the '382 patent. (JA03006 at 736:24-737:1; JA03017 at 782:3-6.) Thus, Abbott's marking of its membraneless ExacTech product directly refutes and is inconsistent with Abbott's argument (and Dr. Sanghera's declaration) that the '382 patent did not disclose membraneless sensors for use with whole blood.

Abbott also incorrectly attempts to argue that the submissions to the EPO did not contain material information in the "usual sense" and that lawyer argument about prior art is not material to patentability. (Abbott Brf., p. 47.) First, this Court has never limited Rule 56 to any particular "type" of information, and indeed has stated that it "embraces any information that a reasonable Examiner would substantially likely consider important." *McKesson Info.*, 487 F.3d at 913. While it is true that that an applicant is free to advocate its interpretation of prior art that the Examiner is free to accept or reject, those cases are inapposite here. As the District Court correctly held, this case is unlike other cases where the Examiner can come to his own conclusions and discount any "spin" offered by counsel. *Therasense*, 565 F. Supp. 2d at 1112. At issue here is information that the Examiner was unable to investigate on his own, and as such, he relied solely on Mr. Pope and Dr. Sanghera to fully disclose any information known to them on the

point offered by the submission, including Dr. Sanghera's declaration. *See Paragon Podiatry Laboratory, Inc. v. KLM Laboratories*, 984 F.2d 1182, 1191 (Fed. Cir. 1993) (finding information material where the Examiner was unable to research extrinsic evidence).

3. The District Court Correctly Found An "Intent To Deceive"

(a) Inference Of Intent

The element of intent is rarely proven by direct evidence and is typically inferred from the facts. *Bristol-Myers*, 326 F.3d at 1239. Further, this Court has held that absent a credible reason for withholding the information, intent may be inferred where the patentee knew, or should have known, that the information it withheld would be material to the PTO's consideration of the application. *Monsanto Co. v. Bayer Bioscience N.V.*, 514 F.3d 1229, 1241 (Fed. Cir. 2008) (*citing Bruno Independent Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348, 1354 (Fed. Cir. 2005)).

First, it is undisputed that both Mr. Pope and Dr. Sanghera knew about the EPO submissions. (JA02980 at 635:2-10; JA03009 at 750:11-21.) And, as discussed above, the District Court correctly found that Mr. Pope and Dr. Sanghera knew or should have known that the submissions to the EPO were highly material to the patentability of the '551 patent. *Therasense*, 565 F. Supp. 2d at 1113, 1116. Indeed, the EPO submissions related to the very language of the prior

art about which the Examiner required a showing to overcome its teaching from Abbott. (JA07639; JA06530-31; JA06585.)

The District Court found that neither Mr. Pope nor Dr. Sanghera provided a credible or plausible explanation for the omission of the EPO submissions. *Therasense*, 565 F. Supp. 2d, at 1113, 1115-16. Furthermore, the district court found that neither Mr. Pope nor Dr. Sanghera were credible witnesses. Indeed, Dr. Sanghera was impeached numerous times on the stand. (*See, e.g.*, JA03012 at 763:25-JA03013 at 765:7; JA03013 at 766:13-767:9.) The District Court also found that Mr. Pope was not credible, citing numerous examples of Mr. Pope's testimony. *Therasense,* 565 F. Supp. 2d at 1113. This Court has held that a determination as to whether there was an intent to mislead may involve credibility determinations by the district court. *Refac Int'l*, 81 F.3d at 1582. And that it is the district court that is best suited for making such credibility determinations. *Id.* (*citing Anderson v. City of Bessemer City*, 470 U.S. 564, 575 (1985)).

Abbott argues that the District Court erred in stating that in ambiguous circumstances patent counsel "should err on the side of disclosure, not nondisclosure." (Abbott Brf., p. 51.) This statement is not in error. Indeed, this Court has held that "[c]lose cases should be resolved by disclosure, not unilaterally by the applicant." *Cargill*, 476 F.3d, at 1367. That rule is based on the policy that

applicants should submit information for consideration by the PTO "rather than making and relying on their own determinations of materiality." *Id.*

Moreover, where, as here, the information is material and the patentee knew or should have known of its materiality, it is much more difficult for him to overcome such an inference by establishing his subjective good faith. *Bristol-Myers Squibb*, 326 F.3d at 1239 (citation omitted); *see also Cargill*, 476 F.3d at 1368; *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1191 (Fed. Cir. 2006). Further, where there is such a high degree of materiality as is the case here – the omitted information went directly to the heart of the Examiner's question regarding patentability – a strong inference of intent to deceive is created. *Cargill*, 476 F.3d at 1367.

(b) Motivation To Deceive

Both Mr. Pope and Dr. Sanghera were highly motivated to deceive the PTO. Abbott was desperate to obtain a patent to replace the expiring '382 patent. This motivation is evidenced by numerous meetings involving high level management to brainstorm ways to obtain allowance of the '551 patent. (JA03012 at 760:20-761:1; JA03014 at 769:11-19.) Dr. Sanghera also led competitive analysis in the blood glucose testing market. (*Id.*) As part of that analysis, Dr. Sanghera directed the testing of many competitor glucose sensors and believed that the newly crafted claims presented to the Examiner covered all competitive

products that were on the market at the time the '551 patent issued. (JA03012 at 763:17-JA03013 at 767:9; JA03015 at 775:1-6.) This motivation is further evidenced by Abbott's suit against a competitor alleging infringement of the '551 patent on the *very day the patent issued*, a case in which Mr. Pope was of counsel and Dr. Sanghera submitted a technical declaration regarding infringement for a preliminary injunction.

4. Balancing Leads To Finding Of Inequitable Conduct

When the elements of materiality and intent have been shown by clear and convincing evidence, it is within the District Court's discretion to weigh the findings of materiality and intent against what the patentee proffered as its reasons for withholding the information. *Cargill*, 476 F.3d at 1368. Such findings of inequitable conduct are reviewed under an abuse of discretion standard. *Bristol-Myers*, 326 F.3d at 1234. And, where the materiality is high, as here, a lesser showing of intent may be sufficient to support a finding of inequitable conduct. *Bruno*, 394 F.3d at 1354.

Careful to consider that patent prosecutors must make judgment calls, and that care must be taken in second-guessing such calls, the District Court correctly held that the balance weighed against Abbott and that the showings of materiality and intent to deceive were strong. *Therasense*, 565 F. Supp. 2d, at 1114, 1116. The information withheld from the PTO was highly material; it went

to the very heart of the Examiner's request for evidence. Neither Mr. Pope nor Dr. Sanghera provided any credible reason for their conscious decision to withhold the information. The District Court searched for and considered all possible inferences from the evidence presented, and found no plausible reason for withholding the EPO submissions and no evidence of good faith in their dealings with the PTO. Thus, it was clearly not an abuse of discretion for the District Court to find the patent unenforceable due to inequitable conduct.

C. The District Court's Grant Of Summary Judgment Of Non-Infringement Of The '164/'745 Patents Was Proper

The Federal Circuit "review[s] a district court's grant of summary judgment *de novo*." *Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1353 (Fed. Cir. 1998). "[A] literal infringement issue is properly decided upon summary judgment when no genuine issue of material fact exists, in particular, when no reasonable jury could find that every limitation recited in the properly construed claim either is or is not found in the accused device." *Id.*

1. The District Court Correctly Construed "Non-Flowing Manner"

As demonstrated by the plain meaning of "non-flowing manner," the '164 patent specification, and the prosecution history, the Court was correct to construe "non-flowing manner" to mean "the sample is not moving in the sample chamber during the measurement" so that residual flow in the sample chamber is

excluded from the scope of the claim. The plain meaning of "holding the sample in a non-flowing manner" is that the sample is held in a way such that there is no flow and nothing that acts like flow. This is consistent with Abbott's disclaimer of any sensors other than those where the sample is at rest. *Supra* pp. 13-14.

The prosecution history demonstrates that Abbott sought to overcome Nakajima, not just Niwa, by the addition of its "non-flowing manner" limitation, where Nakajima was admittedly not a flow cell and held the sample "relatively stationary." *Supra* p. 13. Abbott could not have meant its amendment to only exclude flow cells because Niwa undisputedly also disclosed stop-flow cells.[6] (*Id.*) Moreover, Abbott admitted that Nakajima teaches samples being held "relatively stationary" in a non-flow cell. (*Id.*) Therefore Nakajima still provided the disclosure needed to support the rejection of pending claim 148 if Abbott had meant to only disclaim flow cells. Thus, Abbott's "non-flowing manner" limitation was intended to overcome not only flow cells, but also sensors that have "relatively stationary" flows such as Nakajima.

Notably, Abbott did not choose the Examiner's "non-flow-through" proposal, but instead picked its own, broader language that excluded more than just "flow through." Even assuming "flow" meant "to move in a stream," as Abbott

[6] A stop-flow cell acts like a non-flow cell when it stops the flowing stream.

proposes,[7] "non-flowing manner" would exclude anything with the *manner* of a stream, not just streams themselves. To use Abbott's own analogy, if a stream is abruptly dammed, it does not reach an instant halt because the momentum of its flow will continue for some time before it becomes still. That residual flow between the damming and the eventual stillness is a "flowing manner," even if it were not still an actual stream due to the dam.

Furthermore, Abbott chose to limit the area in the claimed sensor where there must be a non-flowing manner to "*within* a sample chamber," and not "*through* a sample chamber." (JA13800-01 at pending claim 148.) This is significant because Abbott now proposes to change the Court's construction from "not moving *in* the sample chamber" to "not moving *through* the sample chamber." (Abbott Brf., p. 58.) Moreover, Abbott did not amend its claims to say "non-flow-cell," even though they repeatedly used the phrase "flow cell" in the specification and plainly knew how to describe such an embodiment. (JA13239 at 22:43-67.) Abbott should be held to the claim terms it chose.

Abbott's reliance on the Examiner's statement of allowance in the *parent* application that the "prior art is distinguished from applicant's instant invention by disclosing only flow-through embodiments" is unavailing. Even

[7] Abbott's introduction of a dictionary to define "flow" is improper here because no dictionary definitions of "flow" were put before the District Court. Fed. R. App. P. 10(a).

though the District Court's construction of "non-flowing manner" excludes residual motion, it also excludes flow-through embodiments and is therefore consistent with the Examiner's statement.

Thus the swirling, residual motion that lasts for the BD™ Test Strip's entire 5 second test time was properly adjudged to not meet the "non-flowing manner" limitation. *Supra* pp. 18-20.

(a) The District Court's Construction Did Not Exclude All Motion.

The District Court's construction excluded the mass residual flow of a liquid whose filling momentum had not yet stopped when the measurement takes place. Abbott attempts to turn this construction on its head by stretching it to exclude motion on a molecular level. Every liquid has a random movement of particles, such as "Brownian motion." This movement, however, is on a molecular scale much smaller than the overall size of the sensor volume for any sensor, which is the scale of residual flow.

Abbott attempted to convince the District Court that its claim construction that excluded residual (convective) flow is unworkable because that construction would also exclude molecular-scale Brownian motion. Abbott did so even though its expert had admitted that the motion seen in the accused BD™ Test Strip was a residual motion that manifested as swirling (*supra* p. 19), and was not Brownian motion:

> Q. Brownian motion. And this -- this rotational swirling you saw in the BD/Nova strip, is that Brownian motion?
>
> A. That's not Brownian motion.
>
> Q. And is that diffusion?
>
> A. That's not diffusion, no.
>
> Q. Is that a convective flow?
>
> A. It appears to be a convective flow.[8]

(JA12270 at Tr. 490:10-17.)

The District Court directly addressed Abbott's assertion, and held that:

> The Court **need not resolve this [Brownian motion] issue** to resolve the [summary judgment] motion, however, because [Abbott's expert] Dr. Bard has conceded that the motion observed in the active electrode well of the BD test strip is neither Brownian motion or diffusion, but is convective flow. . . . [T]he convective, swirling movement that Bard has conceded exists in the BD test strip is enough to remove the BD test strip from the literal scope of the asserted '164 and '745 patent claims.

(JA00026) (emphasis added). The Court, then, explicitly held that it was *not* expanding its construction to exclude all possible definitions of flow, such as

[8] Abbott's expert defined convection as a "mass transfer" that manifested as "swirling" in the BD™ Test Strip. (*Supra* p. 19.)

Brownian motion, but was instead maintaining its construction that excludes flow such as the residual flow in the BD™ Test Strip. (*Id.*)

Abbott's allegations that the District Court's construction means that no sensor can hold a sample in a "non-flowing manner" are belied by its own admissions. Following the judgment of non-infringement in favor of BD/Nova, prior co-Defendant Roche also moved for the same judgment for its sensor, which lacked the unique well structure of the BD™ Test Strip. In opposition, Abbott argued that "[t]he Court relied heavily upon well structures found only in the BD™ Test Strip when it determined that BD does not infringe claim 11 of the '745 Patent. Roche's Aviva test strip lacks these structures and therefore cannot have 'flow' in the same manner as the BD Test Strips." (JA14547.) Therefore, as Abbott admits, strips that lack the structure to create a residual flow, such as the swirling motion caused by the wells in the BD™ Test Strip, *can* still meet the "non-flowing manner" limitation.[9] Indeed, the Court denied Roche's motion for summary judgment. (JA02201.)

[9] The same is true for strips with a longer test time than the BD™ Test Strip. As discussed above (*supra* p. 19), the videos of the BD™ Test Strip showed the residual flow for the entirety of the 5 second test time, but that flow began to die down by about 15 seconds. So a "non-flowing manner" can also be achieved for a test strip like the ones described in the '164 patent specification where measurement is taken after several minutes (*supra* p. 15), regardless of the strip's design.

Abbott's complaint that the District Court's claim construction is a physical impossibility because it excludes all motion has no merit. The Federal Circuit has applied the plain meaning for terms even if that meaning, when taken to its extreme, could potentially create a physical impossibility. In *K-2 Corp. v. Salomon S.A.*, the Federal Circuit was asked to provide the plain meaning for the term "permanently affixed." 191 F.3d 1356, 1365 (Fed. Cir. 1999). The panel recognized that nothing can be affixed for an infinite amount of time so as to be truly unremovable. *Id.* Likewise, here, no liquid can truly have absolutely zero motion. But the Federal Circuit still applied the plain meaning of "permanently affixed" to require "an unremovable connection" because "we need not wring our hands when considering the implications of a metaphysical analysis of claim terms. Instead, we need only recognize that claim construction is firmly anchored in reality by the understanding of those of ordinary skill in the art." *Id.* For the same reasons, the Court's construction of "non-flowing manner" should be upheld because one of ordinary skill would not consider Abbott to have been claiming the impossible, but would have understood "non-flowing manner" in light of the specification and prosecution history to exclude residual flow.

(b) Abbott Is Attempting To Rewrite The Claim

Abbott is seeking to rewrite, not construe, the "holding the sample in a non-flowing manner within a sample chamber" element to read "holding the

sample in a non-flow cell." But Abbott cannot undo its decision to narrow its claim to exclude sensors, even if not flow-cell sensors, whose sample has a "manner" of flow "within" a sample chamber.

If Abbott had simply attempted to add a "non-flow cell" amendment instead of "non-flowing manner," it could not have overcome Nakajima. *Supra* pp. 49-50. But even if that were not the case, the fact "[t]hat the applicant could possibly have added terms other than ['non-flowing manner'] to create a patentable distinction with the asserted prior art is simply irrelevant to [the Court's] claim construction task. Courts do not rewrite claims; instead, [they] give effect to the terms *chosen by the patentee*." *K-2 Corp.*, 191 F.3d at 1364 (emphasis added). This is because even if "patentees surrender more through amendment than may have been absolutely necessary to avoid particular prior art," this Court "held the patentees to the scope of what they ultimately claim, and [has] not allowed them to assert that claims should be interpreted as if they had surrendered only what they had to." *Norian Corp. v. Stryker Corp.*, 432 F.3d 1356, 1361-2 (Fed. Cir. 2005). Abbott must therefore abide by the "non-flowing manner" limitation that it selected to overcome the prior art.

This is particularly true here, where Abbott seeks to change the District Court's construction to "*through* the sample chamber" instead of "*in* the sample chamber." Abbott cannot go back and adopt the PTO's proposed "non-

flow-through" amendment when it specifically rejected that suggestion to limit the claim to "non-flowing manner *within* a sample chamber." *Supra* p. 13. To rewrite the claim now would be to rewrite history and unfairly prejudice those who relied on the claim language.

Abbott attempts to justify its revision of the claim language based on statements that it made during prosecution, citing to *Bd. of Regents v. BenQ Am. Corp.*, 533 F.3d 1362, 1369 (Fed. Cir. 2008). That decision does not support Abbott's proposition. An examination of the case that the *BenQ* decision cites as support clarifies that the law is that *the amendments themselves*, not the prosecution history statements regarding those amendments, must be given additional weight during claim construction to ensure that they maintain their narrowing effect. *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1333-4 (Fed. Cir. 2003). In any event, the prosecution history here supports the Court's construction and the plain meaning of "non-flowing manner."

D. The District Court Properly Found That The '745 Patent Claims Are Invalid

The Federal Circuit "reviews a ruling of summary judgment *de novo*. Although anticipation under *35 U.S.C. § 102* is a question of fact, it may be decided on summary judgment if the record reveals no genuine dispute of material fact." *Golden Bridge Tech., Inc. v. Nokia, Inc.*, 527 F.3d 1318, 1321 (Fed. Cir. 2008). The District Court's summary judgment that the '225 reference anticipates

claims 1-5, 8, 21-23, 28, 31 and 34 of the '745 patent should be affirmed because there is no dispute about the '225 *disclosure*.[10]

1. The '225 Reference Undisputedly Discloses The "Diffusible Mediator" Limitation

(a) To Anticipate, The '225 Reference Need Only – And Does – Disclose The Use Of Diffusible Mediators

The District Court properly relied on Roche's expert Dr. Weber's *uncontroverted* testimony that the '225 reference disclosed all the elements of the '745 patent claims. (JA00048; *see also supra* pp. 20-21.) The Court then examined the '225 reference and confirmed that it disclosed the elements that Abbott's attorneys – but not its expert – alleged were missing from that reference.

The District Court relied upon the '225 reference's explicit disclosure of the use of a diffusible mediator with a sensor. (JA00049 (*quoting* JA08787 at 9:25-29.)) It noted the '225 reference's disclosure that "'[i]n general, mediators suitable for use in the invention have structures which prevent or substantially reduce the diffusional loss of redox species during the period of time that the sample is being analyzed.'" (JA00050 (*quoting* JA08788 at 10:25-27.)) It thereby determined that this passage discloses that it is also possible to use diffusing mediators. The District Court relied on the principles of claim differentiation to

[10] The "District Court" here actually consists of two different judges, because not only did Judge Jenkins grant summary judgment, but following his retirement from the Federal Bench, Judge Alsup denied Abbott's motion for reconsideration of that ruling.

find that the '225 reference claimed sensors that used any kind of mediator, including diffusible mediators, further supporting its anticipating disclosure. (JA00050; JA08841.) *See In re Dossel*, 115 F.3d 942, 945 (Fed. Cir. 1997).

Abbott's argument that the District Court mistakenly relied on the '225 disclosure that begins by exclusively reciting non-leachable mediators misses the point. As the District Court found, in the very next sentence it discloses the possibility of using a diffusible mediator because only "'*[p]referably*, there is little or no leaching of the redox mediator away from the working electrode.'" (JA00050 (*quoting* JA08787 at 9:22-24 (emphasis added)).)

Abbott essentially concedes that the '225 reference discloses "diffusible mediators," and only argues that it does not do so as part of its claimed invention. This, however, is not the law for anticipation. Abbott does not cite even a single case that supports this proposition. It is black letter law that, to anticipate, a *reference* (as a whole) needs to disclose all the elements of the claim. *MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999); *see also Celeritas Techs., Ltd. v. Rockwell Int'l Corp.*, 150 F.3d 1354, 1361 (Fed. Cir. 1998). Abbott's argument is additionally belied by *Abbott's own* (successful) attempt to construe the '164 patent claims, based on the same '225 disclosure, to include sensors that use a diffusible mediator, which claims Abbott then asserted against such sensors sold by BD/Nova. *Supra* p. 22.

Likewise, Abbott's attempt to manufacture a dispute of fact by relying on the PTO's consideration of the '225 reference is both misplaced and irrelevant. As the District Court properly held, the presumption of validity, which is the manifestation of the deference owed to Examiners' decisions, "'is one of law, not fact, and does not constitute 'evidence' to be weighed against the challenger's evidence.'" (JA00049 (*quoting Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1258-59 (Fed. Cir. 2004)).) In addition, Abbott's arguments over the '225 reference were made in the context of obviousness, not anticipation. Abbott did not argue that the '225 reference did not *disclose* diffusible mediators under a § 102 standard; it argued that there would be no motivation to combine references that teach the use of diffusible mediators with the '225 reference which *teaches away* from using diffusible mediators. (JA00049 at n. 33, *citing* JA09773-4.) In any event, Abbott failed to provide the District Court with any evidence that the PTO actually accepted or relied upon its arguments.[11]

(b) Whether The '225 Reference Teaches Away From Using Diffusible Mediators Is Irrelevant

Abbott's argument that the '225 reference cannot anticipate the '745 patent claims because, even though the '225 reference discloses the use of

[11] Abbott improperly cites to the '745 patent itself as support for what the PTO said or did during prosecution of its parent application. Abbott cannot use that patent to cure its failure to provide the District Court with the portions of the file history which Abbott alleges support its argument. (*See* JA00049 at n. 33.)

diffusible mediators, it "teaches away" from using those mediators with the sensor, is meritless. "A reference is no less anticipatory if, after disclosing the invention, the reference then disparages it. Thus, the question whether a reference 'teaches away' from the invention is inapplicable to an anticipation analysis." *Celeritas Techs., Ltd.*, 150 F.3d at 1361 (citations omitted); *see also Seachange Int'l, Inc. v. C-COR Inc.*, 413 F.3d 1361, 1380 (Fed. Cir. 2005); *Upsher-Smith Labs., Inc. v. Pamlab L.L.C.*, 412 F.3d 1319, 1323 (Fed. Cir. 2005). So long as the '225 reference discloses the use of diffusible mediators – which it does – then "[t]he fact that [this disclosure] is shown to be less than optimal does not vitiate that it is disclosed." *Celeritas Techs., Ltd.*, 150 F.3d at 1361. The '225 reference's disclosure of the use of diffusible mediators as not "preferable" or "desirable," then, is still anticipating. Were it not so, then Abbott would be impermissibly allowed to patent a prior art device solely because it allegedly later discovered that the device *was* desirable. *Upsher-Smith Labs., Inc.*, 412 F.3d at 1323.

2. Dr. Turner's Testimony Is Consistent With The District Court's Findings

Abbott's attempt to resuscitate the '745 patent claims by relying on the testimony of BD/Nova's expert, Dr. Turner, is unavailing. Dr. Turner never opined on the '225 reference's anticipating disclosure. *Supra* p. 22. And Dr. Turner's testimony at most demonstrates that the '225 reference teaches away from, but still *discloses*, the use of diffusible mediators.

To the extent Abbott is making a veiled enablement argument, it likewise fails. Dr. Turner's testimony was in the context of the '225 reference's disclosure alone, and did not include Dr. Turner's opinion regarding the knowledge of one of ordinary skill in the art. *Supra* pp. 22-23. Importantly, this is the standard for enablement under § 102. *In re Donohue*, 766 F.2d 531, 533 (Fed. Cir. 1985); *see also Arthrocare Corp. v. Smith & Nephew, Inc.*, 406 F.3d 1365, 1372 (Fed. Cir. 2005); *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1326 (Fed. Cir. 2005). In any event, as the District Court held, "even if Abbott could point to expert testimony that there is no disclosure of a diffusible redox mediator in the '225 reference (which it cannot), such expert testimony would be directly contrary to the plain language of the reference, and could not create a genuine issue of disputed fact." (JA00051.)

3. Abbott Waived Its '225 Arguments Presented For The First Time On Appeal

Both Abbott's argument that the '225 reference does not disclose diffusible mediators as part of its invention, and its argument that Defendants failed to put forth evidence that the '225 reference disclosed the '745 patent claims' "background signal" limitation, were not before or considered by the District Court at summary judgment, and are thus waived. *Golden Bridge Tech., Inc.*, 527 F.3d at 1323. An examination of JA09324-7 from Abbott's Opposition to Defendants' motion for summary judgment (Abbott's only responsive paper)

shows this to be true. Abbott, at the most, did nothing more than make a passing reference to these arguments during the course of a five-hour-long hearing on several summary judgment motions. That passing reference failed to provide the specificity or cited support that is required to qualify as having substantively raised an argument before the District Court. (*See* JA01537-1617.)

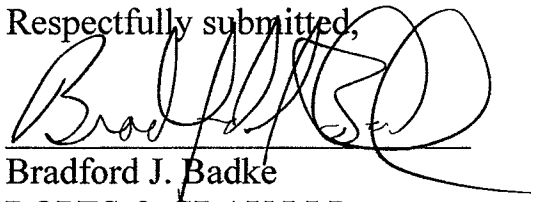
Should this Court consider these arguments, however, then they are meritless in any case. Abbott's argument that the '225 reference does not disclose a diffusible mediator as part of the invention is both irrelevant and irreconcilable with the position it took during construction of the '164 patent claims. *Supra* p. 59. Moreover, Roche's expert Dr. Weber's report, which was before the District Court on summary judgment and went unrebutted by Abbott's expert, opined that the '745 patent's "background signal" limitation was met by the '225 reference even with a diffusible mediator. *Supra* p. 21. Abbott's statement that Defendants failed to offer proof that this limitation was met is therefore meritless.

V. CONCLUSION AND RELIEF SOUGHT

The District Court's finding of inequitable conduct and invalidity of the '551 patent, its finding of non-infringement of the '745 and '164 patents, and

its finding of invalidity of the '745 patent claims were correct and should be affirmed.

Respectfully submitted,



Dated: December 17, 2008

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