United States District Court,
S.D. Indiana, Indianapolis Division.

ROCHE DIAGNOSTICS CORPORATION,
Plaintiff.
v.
INVERNESS MEDICAL TECHNOLOGY, INC., Inverness Medical, Inc., Can-Am Care Corporation, Inverness Medical Limited, a U.K. corporation, and Bayer Corporation,
Defendants.

No. IP 00-1103-C-M/F

Jan. 24, 2002.

Owner of patent for blood glucose testing device sued competitors for infringement. Construing claims of patent, the District Court, McKinney, Chief Judge, held that: (1) "buffer," called for in patent, meant solute that resisted change in pH of reaction solution; (2) requirement that chemical reaction be "substantially completed" before electrical measurement occurred meant that reaction had to be nearly ended in entire sample; (3) "Cottrell current" called for in patent meant rate of charge flow of diffusion controlled reaction at planar electrode when concentrations of reactants in solution were nearly unchanging before controlled potential was applied, with such rate varying over time; and (4) "electrode" called for in patent was any piece of conductive material through which electric current entered or left medium such as liquid solution.

Claims construed.

36,268. Construed.

Donald Knebel, Barnes & Thornburg, Indianapolis, IN, for plaintiff.

Daniel L. Boots, Bingham McHale LLP, Indianapolis, IN, Peter B. Ellis, Foley Hoag & Eliot LLP, Boston, MA, Theresa M. Gillis, Jones, Day, Reavis & Pogue, New York City, Linda Pence, Sommer & Barnard, Indianapolis, IN, for defendants.

CORRECTED ORDER ON CLAIM CONSTRUCTION

McKINNEY**, Chief Judge.**

This cause is now before the Court following a hearing held to assist the Court with construction of the claim language of the patent at issue in this infringement suit, U.S. Patent Reissue No. 36,268 ("'268 patent"). Guided by the Supreme Court's opinion in Markman v. Westview Inst., Inc., 517 U.S. 370, 388-90, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996) (" *Markman II*"), and by the Federal Circuit's opinion in Markman v. Westview Inst., Inc., 52 F.3d 967 (Fed.Cir.1995) (" *Markman I*"), the claim construction rendered herein will not be a "tentative one" subject to change upon receipt of additional information and evidence, but a definitive one based on all of the evidence of record at this point in the litigation. *See* International Comm. Mat'ls, Inc. v. Ricoh Co., Ltd., 108 F.3d 316, 318-19 (Fed.Cir.1997) (noting that district court performed a "tentative construction" of the claim language to facilitate a decision of the preliminary injunction issue).

Having been fully advised by the parties of their relative positions, the Court will discuss the relevant legal rules and application of those rules to the patent in dispute.

I. *CLAIM CONSTRUCTION STANDARDS*

[1] [2] When construing the '268 patent's claims, the Court must determine the meaning of the language used before it can ascertain the scope of the claims Roche alleges are being infringed. *See* Markman I, 52 F.3d at 979. In doing so, the Court's interpretive focus is not the subjective intent of the parties employing a certain term, but the objective test of what one of ordinary skill in the art at the time of the invention would have understood the term to mean. *See* id. at 986. When the Court undertakes its duty to construe the claims, it first must look to the intrinsic evidence: the asserted and unasserted claims, the specification, and the prosecution history. *See* Ecolab, Inc. v. Envirochem, Inc., 264 F.3d 1358, 1366 (Fed.Cir.2001); Watts v. XL Sys. Inc., 232 F.3d 877, 882 (Fed.Cir.2000); Desper Prods. Inc. v. QSound Labs, Inc., 157 F.3d 1325, 1333 (Fed.Cir.1998) (citing Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1581 (Fed.Cir.1996)); Markman I, 52 F.3d at 979. Most of the time, such evidence will provide sufficient information for construing the claims. *See* Vitronics, 90 F.3d at 1583.

[3] The patent claims should " 'particularly point out and distinctly clai [m] the subject matter which the applicant regards as his invention.' " Markman II, 517 U.S. at 373, 116 S.Ct. 1384 (citing 35 U.S.C. s. 112). During claim construction, the appropriate starting point for the court's inquiry is always the words of both the asserted and unasserted claims. *See* Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 977 (Fed.Cir.1999); Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305 (Fed.Cir.1999); Comark Comms., Inc. v. Harris Corp., 156 F.3d 1182, 1186 (Fed.Cir.1998); Vitronics, 90 F.3d at 1582; *see also* Renishaw PLC v. Marposs Societa' Per Azioni, 158 F.3d 1243, 1248 (Fed.Cir.1998). It is the claims, not the written description, that define the scope of the patent and accordingly, the patentee's rights. *See* Laitram Corp. v. NEC Corp., 163 F.3d 1342, 1347 (Fed.Cir.1998); Markman I, 52 F.3d at 970-71. As the Federal Circuit has recently noted, "[c]ommon words, unless the context suggest otherwise, should be interpreted according to their ordinary meaning." Desper Prods., 157 F.3d at 1336 (citing York Prods., Inc. v. Central Tractor Farm & Family Ctr., 99 F.3d 1568, 1572 (Fed.Cir.1996)). *See also* Ecolab, 264 F.3d at 1366; Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 989 (Fed.Cir.1999); Renishaw, 158 F.3d at 1249. Further, when there are several common meanings for a term, "the patent disclosure serves to point away from the improper meanings and toward the proper meaning." Renishaw, 158 F.3d at 1250. *Accord* Desper Prods., 157 F.3d at 1336 (stating that the context of the claims can be found in the specification and drawings).

[4] [5] A claim term will not be given a common dictionary meaning, however, if such a reading would be nonsensical in light of the patent disclosure, or specification. *See* Renishaw, 158 F.3d at 1250. Accordingly, the correct claim construction is also the one that "stays true to the claim language and most naturally aligns with the patent's description of the invention." *Id*. That description, or specification, serves an important purpose. In it, the patentee must provide a written description of the invention that would allow a person of ordinary skill in the art to make and use the invention. *See* Markman I, 52 F.3d at 979. The applicable statute requires that "[t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains ... to make and use the same...." 35 U.S.C. s. para. 112, para. 1. *See also* Johnson Worldwide Assocs., 175 F.3d at 993. Therefore, to discover the correct meaning of a disputed claim term, the court must refer to the specification's description of the invention.

[6] [7] In addition, a patentee may be his or her own lexicographer and use terms in a manner different from their ordinary meaning. *See* Johnson Worldwide Assocs., 175 F.3d at 990; Vitronics, 90 F.3d at 1582. If the patentee chooses to do that, he or she must clearly state the special definition in the specification or file history of the patent. *See id*. The specification then serves as a dictionary when it defines terms, either expressly or by implication, that are used in the claims. *See id*. Therefore, it is also important to review the

specification to discern whether the patentee has used a term in a way that is inconsistent with its ordinary meaning. *See id*. However, the specification should be used to clarify unclear claim terms, not to "trump the clear meaning of a claim term." Comark, 156 F.3d at 1187 (citing E.I. du Pont de Nemours & Co. v. Phillips Petroleum, 849 F.2d 1430, 1433 (Fed.Cir.1988)).

[8] [9] Claims must be read in light of the specification. *See* Markman I, 52 F.3d at 979. However, limitations from the specification may not be read into the claims. FN1 *See* Comark, 156 F.3d at 1186; *see also* Laitram, 163 F.3d at 1347. In particular, the court should not limit the invention to the specific examples or preferred embodiment found in the specification. *See* Texas Instruments, Inc. v. United States Int'l Trade Comm'n, 805 F.2d 1558, 1563 (Fed.Cir.1986); *see also* Comark, 156 F.3d at 1186. Therefore, the "repetition in the written description of a preferred aspect of a claim invention does not limit the scope of an invention that is described in the claims in different and broader terms." Laitram, 163 F.3d at 1348. *See also* Electro Med. Sys. v. Cooper Life Sciences, Inc., 34 F.3d 1048, 1054 (Fed.Cir.1994).

FN1. An exception to this rule applies when the claim is written in a means- or step-plus-function format under 35 U.S.C. s. 112, para. 6; however, the parties do not dispute any means-plus-function claim terms here.

Interpreting the meaning of a claim term "is not to be confused with adding an extraneous limitation appearing in the specification, which is improper." Laitram, 163 F.3d at 1348 (quoting Intervet Am., Inc. v. Kee-Vet Lab., Inc., 887 F.2d 1050, 1053 (Fed.Cir.1989)). An extraneous limitation is a limitation added "wholly apart from any need to interpret what the patentee meant by particular words and phrases in the claim." Hoganas AB v. Dresser Indus., Inc., 9 F.3d 948, 950 (Fed.Cir.1993). *See also* Renishaw, 158 F.3d at 1249. Although there is a fine line between reading a claim in light of the specification and reading a limitation from the specification into the claim, the court must look cautiously to the specification for assistance in defining unclear terms. *See* Watts, 232 F.3d at 882; Comark, 156 F.3d at 1186-87.

[10] The third source of intrinsic evidence is the patent's prosecution history. *See* Desper Prods., 157 F.3d at 1336-37; Vitronics, 90 F.3d at 1582. "Prosecution history is an important source of intrinsic evidence in interpreting claims because it is a contemporaneous exchange between the applicant and the examiner." Desper Prods., 157 F.3d at 1336-37. In a patent's prosecution history the court will find a complete record of the proceedings before the PTO leading to issuance of the patent. *See* Vitronics, 90 F.3d at 1582. The prosecution history contains both express representations made by the patentee concerning the scope of the patent, as well as interpretations of claim terms that were disclaimed during the prosecution. *See* id. at 1582-83; *see also* Ecolab, 264 F.3d at 1368; Elkay Mfg., 192 F.3d at 978; Southwall Tech. Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed.Cir.), *cert. denied,* 516 U.S. 987, 116 S.Ct. 515, 133 L.Ed.2d 424 (1995). Although the prosecution history is useful for understanding claim language, it "cannot enlarge, diminish, or vary the limitations in the claims." Markman I, 52 F.3d at 979 (quotations omitted).

[11] [12] [13] [14] In some cases, it may be necessary for the court to consult extrinsic evidence to aid it in construing the claim language. *See* Pitney Bowes, 182 F.3d at 1308; Vitronics, 90 F.3d at 1584. Extrinsic evidence is any evidence outside of the patent and prosecution history, "including expert and inventor testimony, dictionaries, and learned treatises." Markman I, 52 F.3d at 980. *See also* Pitney Bowes, 182 F.3d at 1308. It may be used to assist the court's understanding of the patent, or the field of technology. *See* Markman I, 52 F.3d at 980-81. However, "courts [should] not *rely* on extrinsic evidence in claim construction to contradict the meaning of claims discernible from thoughtful examination of the claims, the written description, and the prosecution history-the intrinsic evidence." Pitney Bowes, 182 F.3d at 1308 (emphasis in original) (citing Vitronics, 90 F.3d at 1583). Judges are not usually "conversant in the particular technical art involved," or capable of reading the patent specification and claims as one skilled in the art might. *See* Markman I, 52 F.3d at 986; *see also* Pitney Bowes, 182 F.3d at 1308-09. Therefore,

"consultation of extrinsic evidence is particularly appropriate to ensure that [the court's] understanding of the technical aspects of the patent is not entirely at variance with the understanding of one skilled in the art." Pitney Bowes, 182 F.3d at 1309. When the court relies on extrinsic evidence to assist with claim construction, and the claim is susceptible to both a broader and a narrower meaning, the narrower meaning should be chosen if it is supported by the intrinsic evidence. *See* Digital Biometrics v. Identix, 149 F.3d 1335, 1344 (Fed.Cir.1998). It is entirely proper for the court to accept and admit extrinsic evidence, such as an expert's testimony, to educate itself, but then base its construction solely on the intrinsic evidence. *See* Mantech Envt'l Corp. v. Hudson Envt'l Servs., Inc., 152 F.3d 1368, 1373 (Fed.Cir.1998).

[15] [16] Further, the Federal Circuit has taken special note of the use by courts of a specific type of extrinsic evidence: dictionaries. In its *Vitronics* opinion, the court explained that although technical treatises and dictionaries are extrinsic evidence, judges are free to consult these resources at any time in order to get a better understanding of the underlying technologies. 90 F.3d at 1584 n. 6. The *Vitronics* court stated that judges may rely on dictionaries when construing claim terms as long as the dictionary definition does not contradict the definition found in, or ascertained by, a reading of the patent. *Id*.

II. *DISCUSSION*

The allegedly infringing method in this suit is one that measures glucose using blood samples, test strips, and chronoamperometry. Therefore, in its discussion of the claims and the context of the patent, the Court will often refer to glucose as the substance at issue.

[17] [18] In construing the terms of the '268 patent, the Court will apply the canons it finds relevant and reasonable in each particular instance because claim construction is a question of law, and because no canon of claim construction is "absolute in its application." Renishaw, 158 F.3d at 1248. Of utmost importance to the process of construing claims is a consideration of the language of the claims in the necessary context. To learn that context, the Court will consult the patent specification, the prosecution history, expert reports from those skilled in the art provided by the parties, and other extrinsic evidence, if relevant. *See* Eastman Kodak Co. v. Goodyear Tire & Rubber Co., 114 F.3d 1547, 1552 (Fed.Cir.1997). "Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to develop with the claim." Renishaw, 158 F.3d at 1250 (citing Markman II, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996)).

Therefore, the Court will first review the purpose for the invention as described by the '268 patent's specification, which entails an understanding of the problem identified in the prior art that the inventor sought to solve. *See* Eastman Kodak, 114 F.3d at 1554. "These teachings provide valuable context for the meaning of the claim language." *Id*. Then the Court will examine each of the disputed terms from the '268 patent claims and construe them according to the context and the applicable rules of construction. The result will be a definition for each disputed term and ultimately a determination of the scope of the claim in which it is used.

A. THE '268 PATENT

The Patent & Trademark Office ("PTO") issued the '268 patent on August 17, 1999, to Neil J. Szuminsky ("Szuminsky"), Joseph Jordan, Paul A. Pottgen, and Jonathan L. Talbott ("Talbott") (collectively, the "inventors"), and was assigned to Boehringer Mannheim Corporation ("BMC"), predecessor in interest to the plaintiff, Roche. The '268 patent matured from a continuation of application serial number 08/1776,863, filed December 30, 1993, that was abandoned, and was a reissue of application serial number 07/745,544, filed August 15, 1991, which matured into U.S. Patent No. 5,108, 564 ("'564 patent"). The '564 patent matured from a division of application serial number 07/322,598, filed March 13, 1989, which was a continuation-in-part of an earlier filed application serial number 07/168,295, filed March 15, 1988, now

abandoned.

The '268 patented invention includes the method for using a disposable electroanalytical cell to quantitatively determine the amount of biologically significant compounds, such as glucose, from body fluids. '268 Patent, Abstract; id. col. 1, *ll*. 18-25. The invention was designed to permit both physician and patient self-testing of such compounds with greater reliability than either the colorimetric or enzymatic amperometry methods that existed at the time of the invention. Id. col. 2, *ll*. 40-65.

Colorimetry, a technique used by physicians and patients to determine blood glucose levels, "is based upon visual or instrumental determination of color change produced by enzymatic reactions on a dry reagent pad on a small plastic strip." Id. col. 1, *ll*. 47-49. This method uses oxygen, glucose's natural oxidant, to oxidize the glucose in a sample to gluconic acid and hydrogen peroxide. Id. col. 1, *ll*. 49-55. Then, the hydrogen peroxide is measured either directly or indirectly by color change or by spectroscope, to determine the corresponding amount of glucose in the sample. Id. col. 2, *ll*. 6-12. Problems associated with the colorimetric method include (a) poor precision and accuracy because the steps are dependent upon good and consistent operating technique, id. col. 2, *ll*. 22-27; and (b) wide variation in calibration method, id. col. 2, *ll*. 27-30.

"Enzymatic amperometry methods have been applied to the laboratory based measurement of ... analytes including glucose...." Id. col. 2, *ll*. 49-51. But, this method requires individualistic calibration for each electrode in the device and "meticulous attention to electrode maintenance for continued reliable use," both of which are training intensive and are costly. Id. col. 2, *ll*. 54-58. These characteristics make the method unusable for patients doing self-testing. Id. col. 2, *ll*. 58-62.

The '268 patent professes to address the issues of reliability, ease of maintenance and cost effectiveness so that self-testing by patients is more effective. Specifically, "[e]nzymatic amperometry provides several advantages for controlling or eliminated operator dependant techniques as well as providing a greater linear dynamic range." Id. col. 2, *ll*. 43-46. In addition, the '268 patented invention solves the difficulties of prior art enzyme amperometry methods because it is "based on a disposable sensor that can be produced in a manner that allows it to give reproducible output from sensor to sensor and at a cost well below that of traditional electrodes." Id. col. 2, *ll*. 62-65. Specifically, the '268 patented invention calls for "miniaturized disposable electroanalytic sample cells for precise micro-aliquote sampling, a self-contained, automatic means for measuring the electrochemical reduction of the sample, and a method for using the cell and apparatus...." Id. col. 2, *l*. 67 to col. 3, *ll*. 1-4. In other words, the disposable cell acts both as a precise sample measuring device and as the site for an electrochemical reaction from which the blood glucose level can be ascertained by a reading device. *See* id. col. 4, *ll*. 15-18.

The '268 patent teaches a two-step reaction sequence. Id. col. 3, *l*. 16. The first step is a chemical oxidation, which utilizes an oxidant other than oxygen, preferably in an amount large enough to ensure that the oxidant is not the limiting reagent. Id. col. 3, *ll*. 17-25. Apparently, the test cell is configured such that the sample size is controlled without premeasurement, which adds to the invention's advantages over prior systems for patient self-testing. Id. col. 4, *ll*. 3-9. In the case of glucose, the '268 patent also discloses catalytic oxidation with preferred oxidants "to convert substantially all of the B D glucose to gluconic acid." Id. col. 4, *ll*. 37-41. The patent also contemplates an incubation period, "the length of which is chemistry dependent[,] to allow the enzymatic reaction to reach completion." Id. col. 4, *ll*. 56-58.

In the second step, electro-chemical reduction is used to quantify the reaction production of the first step. Id. col. 3, *ll*. 18-19. The '268 patent states that the second step, for the determination of glucose concentration, "utilizes Cottrell current micro-chronoamperometry in which glucose plus an oxidized electron acceptor produces gluconic acid and a reduced receptor." Id. col. 3, *ll*. 43-47. "Cottrell current micro-chronoamperometry" involves "the measurement of a diffusion controlled current at an accurately specified

time ... after the instant of application of a [controlled] potential...." Id. col. 3, *ll*. 51-54. Measurement of the current due to reoxidation of the acceptors is proportional to the glucose concentration in the sample. Id. col. 3, *ll*. 64-67. Because measurement of the glucose by this method is direct, it is an advantage over prior art. Id. col. 4, *ll*. 1-3. Moreover, the patent teaches that the method of the invention "permits automatic functioning and timing of the reaction allowing for patient self-testing with a very high degree of precision and accuracy," another advantage over the prior art. Id. col. 4, *ll*. 7-9. This method practiced by the preferred embodiment measures glucose in the range of 1 mg of glucose to 1000 mg of glucose per deciliter of sample, a range of "results which have not previously been obtained using other glucose self-testing systems." Id. col. 4, *ll*. 42-46.

[19] In summary, the '268 patent discloses a method for using a disposable chemical reaction cell and an amperometry system to determine the level of biologically significant compounds, such as glucose, from body fluids, such as blood. The system is an advantage over prior colorimetric-based systems because it boasts a controlled sample size, it allows for the reaction to incubate such that the initial reaction is complete or nearly complete, and it measures the biologically significant compound directly. These advantages translate into more precise and accurate results for patients using self-testing. Because meeting these objectives is a requirement for patentability, *see* 35 U.S.C. s. 101, the '268 patent's claim language will be construed in the context of the problems the invention was designed to solve and in a way that renders the claims "capable of being used to effect the object proposed." Stiftung v. Renishaw, 945 F.2d 1173, 1180 (Fed.Cir.1991) (citing Mitchell v. Tilghman, 86 U.S. (19 Wall.) 287, 396, 22 L.Ed. 125 (1873)).

The parties dispute the meaning of four terms in the '268 patent: buffer, substantially to completion (or substantially completed), Cottrell current, and electrode. Roche asserts that Inverness and Bayer infringe twenty-nine claims, however, only four of those claims, claims 1, 12, 43, and 47, are independent claims. The terms at issue are contained in these independent claims. Those claims state, in their entirety:

1. A method of measuring the amount of a selected compound in body fluids comprising:

a) providing a measuring cell having at least a first and second *electrode* and said cell containing an oxidant and a *buffer,*

b) placing a sample of fluid to be tested into said cell,

c) reconstituting said oxidant and *buffer* with said sample fluid to generate a predetermined reaction,

d) allowing said reaction to proceed *substantially to completion,*

e) applying a potential across said *electrodes* and sample, and

f) measuring the resulting *Cottrell current* to determine the concentration of said selected compound present in said sample.

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12. A method of measuring the amount of an analyte in a blood sample, comprising:

a) adding the blood sample to an electrochemical cell that includes an electron transfer agent that will react in a reaction involving the analyte, thereby forming a detectable species;

b) incubating the reaction involving analyte and electron transfer agent in an open circuit until the reaction has *substantially completed;*

c) applying a sufficient potential difference between the *electrodes* of the electrochemical cell, after the incubation step, to readily transfer at least one electron between the detectable species and one of the *electrodes,* thereby resulting in a *Cottrell current;*

d) measuring the *Cottrell current;* and

e) correlating the measured *Cottrell current* to the amount of analyte in the blood sample.

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43. A method for measuring the amount of a selected compound in a blood sample, comprising:

providing a measuring cell having at least first and second *electrodes* for contact with the blood sample introduced into the cell,

applying a potential to the *electrodes* to detect the presence of the blood sample in the cell,

placing the blood sample into the cell,

removing the potential to the *electrodes* after the blood sample is detected in the cell,

selectively oxidizing the compound in the blood sample with an oxidized electron acceptor to produce an oxidized form of the selected compound and a reduced electron acceptor, and

re-applying a potential across the cell *electrodes* after the selective oxidation of the compound in the blood sample has *substantially completed* and measuring the resulting *Cottrell current,* said current being proportional to the concentration of the reduced electron acceptor and the selected compound in the blood sample.

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47. A method for measuring the amount of glucose in blood, comprising:

providing a measuring cell with at least first and second *electrodes* for contact with blood introduced into the cell,

applying a potential across the *electrodes,*

placing a volume of blood into the cell,

removing the potential across the *electrodes* after the volume of blood is placed into the measuring cell,

oxidizing the glucose in the blood with an oxidized electron acceptor in the presence of glucose oxidase to produce gluconic acid and a reduced electron acceptor,

re-applying a potential across the measuring cell electrodes after the oxidation of glucose has *substantially completed,* and

measuring the *Cottrell current* through the cell, the *Cottrell current* being proportional to the glucose concentration in the blood.

Id. col. 13, *ll*. 58-67 to col. 14, *ll*. 1-5; id. col. 14, *ll*. 53-67 to col. 15, *ll*. 1-2; id. col. 17, *ll*. 47-54 to col. 18, *ll*. 1-15; id. col. 18, *ll*. 30-49 (emphasis added in all claims). The Court will construe each of the disputed terms in turn.

B. "BUFFER"

[20] Defendant Bayer disputes the definition of the term "buffer" that is used in claim 1 of the '268 patent. Bayer argues that "buffer," in the context of claim 1 means a solute that maintains the pH of the reaction solution during oxidation. Bayer Br. on Claim Constr. of U.S. Reissue Patent No. 36,268, at 28 ("Bayer Br."). Bayer argues that the plain meaning of buffer is "a dissolved material in a solution that maintains the pH of the solution when acid or base is added." Id. (citing Weber Dep. at 203; Lowe Report para.para. 8-10). Moreover, in the context of the '268 patent, "[t]here is only one solution involved in the method of the '268 patent-that created when the oxidant and buffer dissolve in the sample fluid (*i.e.*, are reconstituted)." Id. at 29. Finally, Bayer argues that the prosecution history confirms that the reconstituted solution is the relevant solution because the inventors "explained that the buffer functioned to maintain pH during the reactions in the cell." Id.

In contrast, Roche urges that "buffer" means "a substance or solution capable of resisting a change in pH." Roche Opening Br. on Claim Constr., at 24-25 (citing VAN NOSTRAND REINHOLD, ENCYCLOPEDIA OF CHEMISTRY 149 (4th ed.1984)) ("Roche Br."). The dictionary definition reads in its entirety:

When acid is added to an aqueous solution, the pH (hydrogen ion concentration) falls. When alkali is added, it rises. If the original solution contains only typical salts without acidic or basic properties, this rise or fall may be very large. There are, however, many other solutions which can receive such additions without a significant change in pH. The solutes responsible for this resistance to change in pH, or the solutions themselves, are known as *buffers*.

ENCYCLOPEDIA OF CHEMISTRY, at 149. Roche avers that this dictionary definition is part of the prosecution history, therefore, it should provide the basis for the definition of buffer in the context of the '268 patent. Moreover, during the *Markman* hearing, Roche argued that the claim language and the patent specification do not require that the buffer perform its function during the oxidation reaction; it could buffer any solution referenced in the claims or the specification, including the solution used to apply the reagents to a substrate.

In the context of the '268 patent, the Court finds that "buffer" means a solute that resists a change in pH of the reaction solution. Apparently the term "buffer," as suggested by Roche, was well known to those skilled in the art at the time of the invention to mean a solute capable of resisting a change in pH. *See* ENCYCLOPEDIA OF CHEMISTRY, at 149 (stating that "[t]he solutes responsible for this resistance to change in pH, or the solutions themselves, are known as *buffers*"). During prosecution of the '268 patent, the inventors described the function of a buffer similarly:

A concise explanation of the general purpose and mechanism of buffers is disclosed by the Encyclopedia of Chemistry (Van Nostrand Reinhold Co., 1984). Buffers keep the pH of the system in a desired range. This is especially helpful for systems which include enzymes. For example, Claim 16 of the reissue application recites a method which employs enzymes.

Respective enzymes have optimum pH ranges for operation as taught by *Biochemical Information,* (J. Keesey, ed., Boehringer Mannheim Biochemicals, 1987). Buffer solution is used to maintain the optimum pH during detection of the sample. This achieves a precise and reliable assay.

Defs.' Joint App. at D124. These explanations also confirm that the buffer must perform its function in a solution. But, the only solution referenced in Claim 1 of the '268 patent is the solution in which the buffer and oxidant are reconstituted-the sample where oxidation takes place.

The Court starts with the language of claim 1, in which the word "buffer" appears. Claim 1 requires that the buffer be contained in the measuring cell along with an oxidant. '268 Patent, col. 13, *ll*. 60-62. The claim also requires that both the buffer and the oxidant reconstitute in the sample fluid "to generate a predetermined reaction." Id. col. 13, *ll*. 64-65. Because the claim requires that the buffer be reconstituted with the oxidant in the sample fluid to generate the oxidation reaction in the cell, it seems clear that the buffer is meant to function during the oxidation reaction.

This interpretation is supported by the '268 patent specification. In the description of the preferred embodiment, the patent states that in experiments run to prove the technology described in the patent, "[t]he electrolyte consisted of a phosphate buffer of pH 6.8 which was about 0.1 molar total phosphate and 0.5M potassium chloride reagent." Id. col. 7, *ll*. 63-66. In addition, the patent teaches that the reagent layer of the preferred embodiment "imbibes" the sample fluid and has those concentrations of buffer and reagent. Id. col. 7, *ll*. 29-30 & 47-53. The patent also teaches that the relevant measurement made by the method is the current in the electrolytic solution containing the sample and the reagent. *See* id. col. 3, *ll*. 43-47; id. col. 3, *ll*. 64-67; id. col. 4, *ll*. 28-31; id. col. 6, *ll*. 31-37; col. 7, *ll*. 63-67 to col. 8, *ll*. 1-12; id. col. 11, *ll*. 11-13. Taken together, these passages identify the buffer as part of the electrolytic solution that contains the sample and the reagent before a potential is applied to measure the current.

Similarly, the disclosure in the specification related to another preferred embodiment for the measurement of cholesterol evidences that the inventors intended for the buffer to perform its function in the solution used to oxidize the cholesterol in the blood sample. For example, the patent states:

Additional examples where CO catalyzes cholesterol oxidation by ferricyanide include a Nocardia source in TRIS buffer with a variety of surfactants.... Furthermore, CO from Nocardia will also catalyze substrate oxidation with ferricyanide in phosphate buffer.... The buffer concentration is from 0.1 to 0.4 molar.

Id. col. 10, *ll*. 47-56. *See also* id. col. 10, *ll*. 26-29 (describing catalyzation of the oxidation reaction of cholesterol with CO in phosphate buffer); id. col. 10, *ll*. 36-46 (describing oxidation of cholesterol with cholesterol oxidase in 0.2 molar TRIS buffer, with ferricyanide in TRIS buffer, and with either ferricyanide or benzoquinone in phosphate buffer). Moreover, the patent teaches that for certain catalyst enzymes used in the oxidation of cholesterol, "[b]uffers acceptable for this reaction to occur with the enzyme include phosphate, TRIS, MOPS, MES, HEPES, Tricine, Bicine, ACES, CAPS, and TAPS." Id. col. 11, *ll*. 1-14.

The prosecution history of the '268 patent confirms that the "buffered" solution in claim 1 is the reaction solution. Claim 1 of the '268 patent is one that appeared in parent application disclosures. *See* Defs.' Joint App. at A18 (File History of U.S. Patent Application No. 07/168,295, Claim 1); id. at B41 (File History of U.S. Patent No. 5,128,015 ("'015 Patent"), Claim 1, that matured from Application No. 07/322,598, a continuation in part of Application No. 07/168,295). In their reissue application for the '268 patent the inventors stated: "All claims of the original patent require the presence of a buffer and oxidant when the claimed methods are practiced." Id. at D40. Moreover, the inventors stated that "[a]lthough Applicants do not view [a] buffer as being absolutely required in the invention, the inclusion of [a] buffer is preferred. To include a buffer when practicing the Applicants' invention, the buffer can either be included in the electrochemical cell when a sample to be analyzed is added to the cell, or the buffer can be in the sample being analyzed." Id. at D41. Therefore, the inventors make clear that if a buffer is necessary, it must be in the electrochemical cell during the oxidation reaction. The plain language of claim 1 requires a buffer in the cell; therefore, the buffer "buffers" the solution in which the oxidation reaction occurs.

For these reasons, the Court finds that "buffer" in the context of the '268 patent means a solute that resists a change in pH of the reaction solution.

C. "SUBSTANTIALLY TO COMPLETION" OR "Substantially completed"

1. *Judicial Estoppel*

As a preliminary matter, the Court finds that judicial estoppel is inappropriate in this case. Inverness argues that judicial estoppel should apply to Roche's proposed claim construction for the term "substantially completed" or "substantially to completion." Inverness Opening Br. on Claim Constr. at 41-46 ("Inverness Br."). Inverness avers that Roche won the issue of the proper construction for this term in a prior proceeding before an arbitrator because the opposing party, Tall Oak Ventures, lost on the claim to which claim construction was an issue (a claim for fraud), and because Tall Oak Ventures stopped pressing its construction in a brief written after the arbitration hearing.

In contrast, Roche argues that judicial estoppel is not appropriate in this case because it did not win the arbitration and because the arbitrator's ruling does not specify the grounds on which it was based. Roche Reply Br. on Claim Constr. at 40-43 ("Roche Reply"). Therefore, any argument that the arbitrator accepted Roche's position on claim construction and not the Tall Oak Ventures' position is speculation.

[21] [22] [23] Apparently, Seventh Circuit law applies to this procedural issue. Lampi Corp. v. American Power Prods., Inc., 228 F.3d 1365, 1377 (Fed.Cir.2000) (citing U.S. Philips Corp. v. Sears Roebuck & Co., 55 F.3d 592, 596 n. 3 (Fed.Cir.1995)). Judicial estoppel is an equitable doctrine "that prevents a party who prevails on one ground in a lawsuit from then repudiating that ground in order to prevail in another lawsuit." *Id*. (citing McNamara v. City of Chicago, 138 F.3d 1219, 1225 (7th Cir.1998)). Moreover, "[t]he doctrine also applies to administrative proceedings in which a party obtains a favorable order by making an argument that it seeks to repudiate in a subsequent judicial proceeding." *Id*. (citing Chaveriat v. Williams Pipe Line Co., 11 F.3d 1420, 1427 (7th Cir.1993)). Some courts have held that judicial estoppel applies to positions taken before an arbitrator. *See, e.g.,* Lydon v. Boston Sand & Gravel Co., 175 F.3d 6 (1st Cir.1999); Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc., 149 F.Supp.2d 610, 613-14 (S.D.Ind.2001). The Court is persuaded that judicial estoppel may apply to positions taken before an arbitrator. *See* Kale v. Obuchowski, 985 F.2d 360, 362 (7th Cir.1993) (stating that the Seventh Circuit could not find a case that "makes application of judicial estoppel depend on the existence of a judicial opinion adopting the litigant's position; it is enough that the litigant win").

[24] Here, the Court cannot conclude that Roche FN2 obtained a favorable ruling on the appropriate construction of the term "substantially to completion" or "substantially completed" in the ' 268 patent during a prior arbitration proceeding. Claim construction of the '564 and ' 015 patents, parent patents to the ' 268 patent, was a sub-issue in Tall Oak Ventures' claim that Roche fraudulently represented that its glucose meter did not infringe the '564 and '015 patented technology. Inverness avers that Roche argued in its pre-hearing brief that the term "substantially to completion" or "substantially completed" in the '564 and ' 015 patents means "99.9% of the glucose in the entire sample is converted into gluconic acid before the potential is applied." Inv.App., Exh. 10, Pre-Hearing Br. of Respondent, BMC, *Tall Oak Ventures v. Boehringer Mannheim Corp*. Ref. No. 55-199-0078-95, at 33 ("Roche Pre-Hearing Arb. Br."). *But see* Inv.App., Exh. 11, Post Hearing Br. of Respondent, BMC, *Tall Oak Ventures v. Boehringer Mannheim Corp.,* Ref. No. 55-199-0078-95, at 5 (stating that "the evidence of record, all from Tall Oak documents or witnesses, conclusively establishes that the claims of the ' 564 patent require that substantially all of the glucose in the sample or drop is converted to gluconic acid before the potential is applied") ("Roche Post Hearing Arb. Br."). Roche came to this conclusion based on the specification and the file history of the '564 and ' 015 patents. Inv.App., Exh. 10, Roche Pre-Hearing Br., at 33. Inverness argues that the arbitrator's award of $1,100,000 to Tall Oak Ventures evidences that Roche won the issues relevant to Tall Oak Ventures' fraud

claim because Tall Oak Ventures had sought damages of $71,000,000 on that claim. Inv. Br. at 43. In addition, if Tall Oak Ventures had prevailed on the fraud claim, it would have been entitled to rescission of the patent purchase agreement it had with Roche. Id. at 45.

FN2. The Court notes that the entity involved in the arbitration action was Roche's predecessor in interest BMC. To simplify this discussion of a complex matter, the Court refers to the party in the arbitration action as Roche.

Instead, Inverness speculates that the arbitrator's award to Tall Oak Ventures was premised on Roche's breach of its obligation of good faith and fair dealing. Id. Inverness argues that testimony by a Roche representative during the arbitration hearing would support such a finding. Id. (citing Inv.App., Exh. 14, Transcript of Proceedings, Vol. IV, *Tall Oak Ventures v. Boehringer Mannheim,* Ref. No. 55-199-0078-95, at 2659-2660 ("Arbitration Hrg. Tr.")). Further, Inverness opines that "[t]he arbitrator clearly signaled during the hearing that he was moving in this direction." Id. Specifically, Inverness points to the following comments and questions in the arbitration hearing transcript:

THE ARBITRATOR: Suppose that we were to find that there was a trade secret involved and that [Roche] did take the trade secret of Tall Oak's personnel in coming up with the palladium same size, same material, and that's all, and not go into the question of the patents, just-

* * * * * *

THE ARBITRATOR: But suppose that was [Tall Oak Ventures'] trade secret and [Roche] took it and [Roche is] going to pay [Tall Oak Ventures] for it, and as a result of [Roche's] payment for the trade secret, [Roche] now become[s] the owner and [Roche] become[s] the owner of the patent and so therefore [Roche] could work in that fashion, couldn't you?

* * * * * *

THE ARBITRATOR: As a result of the damages, whatever they may be, for the misappropriation of trade secrets, I assume what you're saying is that the trade secret, whatever that property right is, then turns over and becomes the property of [Roche] after [Tall Oak Ventures is] paid and [Roche] has a right to retain the patent.

MR. KLINE [Counsel for Roche]: Yes.

Inv.App., Exh. 14, Arbitration Hrg. Tr., Vol. VI, at 1698 1700. Inverness argues that this commentary indicates that the arbitrator was clearly thinking about an award premised only on Roche's conduct in the 1988-1989 time frame, not for Roche's alleged misrepresentation on infringement in 1992. Inv. Br. at 45-46.

The Court is not convinced that this combination of award amount and arbitration hearing conversation indicate that Roche won the argument on claim construction. There is nothing in the arbitrator's original decision to indicate the basis for the $1,100,000 award to Tall Oak Ventures. It merely orders BMC to pay Tall Oak Ventures that amount and sets forth other rules for the award including that it "is in full settlement of all claims, counterclaims, and all matters submitted to the arbitrator by motion or otherwise." Inv. App, Exh. 15, Award of Arbitrator, *Tall Oak Ventures v. David Giddings, Chief Executive Officer, Boehringer Mannheim Corp.,* Ref. No. 55-199-000078-95, para.para. 1, 6 (Sept. 25, 1996). Therefore, the arbitrator's award could have been predicated on a finding of liability for any of Tall Oak Ventures' claims against Roche. The arbitrator's clarification of the award provides little further clarity. The clarification states in relevant part:

By way of clarification, my award of $1.1 million dollars was to compensate Tall Oak for past liability. The award was not intended to discharge BMC from making the contingency and interest payments due under Section 1.2 of the Patent Estate Purchase Agreement ("PEPA") upon issuance of European Patent Office ("EPO") and Japanese patents.

Moreover, since the basis for Tall Oak's alleged ground for Breach of the PEPA, as mentioned in its October 3, 1996 letter, was not raised at the hearing, there is no basis for Tall Oak's claim of a default rate of 18% interest, as provided by Section 7.2 of PEPA, on the $350,000.00 and $150,000.00 payments that will be due from BMC upon issuance of European and Japanese patents respectively or, in the alternative, for return of the EPO and Japanese patent applications to Tall Oak.

Inv.App., Exh. 15, Clarification of Award of Arbitrator, *Tall Oak Ventures v. David Giddings, Chief Executive Officer, Boehringer Mannheim Corp.,* Ref. No. 55-199-0078-95 (Oct. 9, 1996). The context of this clarification suggests that the $1,100,000 award was based on some type of breach of contract damages because the arbitrator references additional obligations for Roche under the contract at issue. In addition, as Inverness points out, if the arbitrator had found for Tall Oak Ventures on the fraud claim, presumably he would have rescinded the PEPA. However, the clarification still makes no definitive ruling on the fraud claim.

Even if the Court were to accept Inverness' argument that the arbitrator found for Roche on Tall Oak Ventures' fraud claim, there is no evidence that the arbitrator accepted Roche's position on claim construction in making such a ruling. Roche specifically argued that Tall Oak Ventures could not prove three elements of fraud against it. Those elements were: "(1) a misrepresentation made with (2) intent to deceive, and (3) justifiable reliance." Inv.App., Exh. 10, Roche Pre Hearing Br., at 31. Claim construction, as the first step of an infringement analysis, is relevant to only one of these elements, "misrepresentation." Id. Moreover, Roche argued that Tall Oak Ventures could not prove by "clear, precise and convincing" evidence that it justifiably relied upon Roche's assertion that its product did not infringe the patents. Roche based it argument on the fact that one of the principals of Tall Oak Ventures admitted that the $1, 250,000 Roche paid for the patents gave him " 'some comfort should [Tall Oak Ventures] come to a different conclusion [on infringement] regarding the technology embodied in the BMC glucose biosensor, once it becomes available.' " Id. at 37 (quoting Letter, From Dr. Pottgen, To Max Kenemore, Patent Counsel, May 11, 1992). Arguably, then, the arbitrator could have made a ruling for Roche and against Tall Oak Ventures on the fraud claim for reasons completely unrelated to claim construction of the patents at issue. With this finding, the Court is persuaded that judicial estoppel cannot apply in this case.

The cases that Inverness cites for the proposition that judicial estoppel may apply if a party prevails only on a subsidiary issue are not apposite. *See* Bethesda Lutheran Homes & Servs., Inc. v. Born, 238 F.3d 853, 857-58 (7th Cir.2001); In re Cassidy, 892 F.2d 637, 641-42 (7th Cir.1990). In those cases, it was clear that the first court had ruled in favor of the party who changed its position in the second case. *See* Bethesda Lutheran Homes & Servs., 238 F.3d at 857-58 ("The plaintiffs argued in the first suit that the relevant Medicaid regulations and Wisconsin state law were unconstitutional. Having won that suit to the extent of getting the legal obstacles to Medicaid reimbursement removed, they could not turn around and in the next suit seek additional relief by arguing that the regulations and state law were constitutional after all and compelled the defendants to grant them benefits."); In re Cassidy, 892 F.2d at 641 ("[Party] unequivocally urged the [first] court to consider the defense of discharge. His present position is that it was error for the court to give him what he then wanted."). As described above, it is not clear whether the arbitrator ruled in favor of Roche on the fraud claim. Even if the Court accepted Inverness' argument that the arbitrator did rule in favor of Roche on Tall Oak Ventures' fraud claim, it is not clear that the arbitrator ruled in favor of Roche on that claim because he accepted Roche's claim construction over that of Tall Oak Ventures'.

Inverness also argues that Tall Oak Ventures capitulated the issue of claim construction on the "substantially completed" patent term; therefore, judicial estoppel is appropriate for that reason. Inv. Br. at 43-44 (citing Kale v. Obuchowski, 985 F.2d 360, 362 (7th Cir.1993); Inv.App., Exh. 13, Tall Oak Ventures' Post Hearing Br., at 6). In *Kale,* the Seventh Circuit stated that "[p]ersons who triumph by inducing their opponents to surrender have 'prevailed' as surely as persons who induce the judge to grant summary judgment." Kale, 985 F.2d at 362 (citing Maher v. Gagne, 448 U.S. 122, 100 S.Ct. 2570, 65 L.Ed.2d 653 (1980)). Inverness points to a portion of Tall Oak Ventures' post-hearing brief that talks about whether Roche's product might infringe the Tall Oak Ventures patents for its argument that Tall Oak Ventures capitulated the issue of claim construction for the term "substantially to completion." The relevant paragraphs state in part:

On January 2, 1992, Walling of BMC wrote an internal memorandum in which he stated "the Magellan product may infringe patent claims that will issue to [Tall Oak Ventures]." PX 607. Walling stated therein that "utilizing the Magellan product to conduct an assay of an analyte may infringe some of [Tall Oak Ventures'] method claims." Walling further concluded "if the Magellan product measure Cottrell current before the reaction goes substantially to completion, then we have an argument that utilizing the Magellan product to measure an analyte does not infringe [Tall Oak Ventures'] method claims." ... Dr. Kissinger, BMC's own expert electrochemist, testified at the hearing that [tests on the Magellan product] were flawed. TR 3441. Critically, Kissinger was never consulted on this issue prior to the time BMC purchased [Tall Oak Ventures'] patents even though he was consulted by BMC on other issues. TR 3247.... Most importantly, as Dr. Kissinger testified "the reaction always goes to completion." TR 3454. By this, he meant that "99.9 percent of them (glucose molecules) are converted to gluconic acid in this reaction.["] TR 3454; 3459.

The reaction of glucose in the 4 microliter well of the Accu Chek Advantage product has proceeded substantially to completion before the 300 mV potential is applied, and BMC has never had, and does not now have, a reasonable basis for believing otherwise.

Inv.App., Exh. 13, Tall Oak's Post Hearing Br., at 6-7. Inverness avers that with this argument, Tall Oak Ventures failed "to rebut Roche's arguments with respect to the correct interpretation of the 'substantial completion' limitation!" Inv. Br. at 44. But, it is clear that Roche's interpretation of the '564 and '015 "substantial completion" limitation was more narrow than that proposed by Tall Oak Ventures. The passage above, in reference to the Roche glucose meter, describes how the Roche product infringes the "substantial completion" limitation even under Roche's more narrow construction. It follows that if the "substantial completion" limitation in its more narrow interpretation reads on Roche's device, the Tall Oak Ventures' more broad interpretation of that limitation will also read on the device. In other words, the Court does not read Tall Oak Ventures' argument as a capitulation on the construction for the term "substantially to completion." Rather, the argument cleverly uses Roche's expert's testimony about what the Roche product does to prove that Roche's device infringed the '564 and '015 patents, regardless of how the arbitrator resolved the claim construction issue.

In addition, Tall Oak Ventures' post-hearing brief only argues about the accuracy of Roche's assertion that its product did not infringe Tall Oak Ventures' patents. There is no argument that its reliance on such assertions was justified. Applying Inverness' argument to this finding, Tall Oak Ventures capitulated on this issue and lost the fraud claim because the arbitrator found against it on this element. But, there is no more evidence that the arbitrator found against Tall Oak Ventures on the fraud claim because he agreed with Roche's position on this element than there is evidence that the arbitrator found against Tall Oak Ventures on the fraud claim because he agreed with Roche's position on construction for the term "substantially to completion." As discussed above, the arbitrator neither clearly found in favor of Roche on the fraud claim nor clearly accepted Roche's claim construction if he found for Roche on the fraud claim.

The Court finds that any decision to limit Roche's arguments in this Court based on a position it took on the fraud claim during the arbitration would force the Court to speculate on the basis for the arbitrator's decision

in the first action. Because the case law on judicial estoppel supports application of the doctrine only in those cases where the first court accepted the argument of the party sought to be estopped, the Court declines Inverness' invitation to apply judicial estoppel to Roche's arguments about the proper construction for the "substantially completed" limitation in the '268 patent.

2. *Claim Construction*

[25] The "substantially to completion" or "substantially completed" phrase used in the '268 patent is found in all of the independent claims; the step in which it appears requires a reaction between the sample and the reagent to proceed "substantially to completion" or to be "substantially completed" before the next step. *See* '268 Patent, col. 13, *ll*. 66-67; col. 14, *l*. 61; col. 18, *l*. 11; col. 18, *ll*. 45-46. The parties dispute two facets of this phrase: what "substantially completed" actually means and where the reaction must reach "substantial completion."

Roche argues that the common meaning for the term "substantially" as defined in binding precedent, *see* York Products, Inc. v. Central Tractor Farm & Family Center, 99 F.3d 1568, 1572 (Fed.Cir.1996), is the correct meaning in the context of the '268 patent. Specifically, "substantially" means either "largely but not wholly," or "considerable in extent." Id. (quoting from WEBSTER'S COLLEGIATE DICTIONARY and AMERICAN HERITAGE DICTIONARY 2nd COLLEGE EDITION, respectively). Moreover, Roche argues that the predetermined reaction that happens when the sample is placed on the cell "does not have to proceed to completion in the entire sample, but rather only in that portion of the sample in which the re[a]gents have dissolved before the potential is applied." Roche Reply Br. on Claim Constr., at 6 ("Roche Reply"). In other words, the reaction need only go to substantial completion in the "reagent layer." Id. at 10 (citing '268 Patent, col. 7, *ll*. 29-30). *See also* '268 Patent, col. 12, *ll*. 28-32.

In contrast, Bayer asserts that "[t]he glucose/oxidant reaction has gone 'substantially to completion' when at least 99.9% of the glucose in the sample placed in the cell is oxidized [before the potential is applied]; the reaction is not substantially completed when substantially all of the analyte in only a thin layer of the sample placed in the cell has been oxidized." Bayer Br. at 22. Bayer contends that this construction is consistent with the specification and the prosecution history of the '268 patent. Id. at 23-28. In particular, the fact that this step must be "substantially completed" before measurement of the Cottrell current implies that the concentration of the sample is constant before the potential is applied. *See* id. at 23-24. In addition, Bayer contends that the PTO specifically allowed these claims in the '268 patent over prior art because the inventors argued that in their invention the entire sample in the well had to react in order for the Cottrell equation to accurately predict that amount of biological compound in the sample. *See* id. at 12-13 (citing Defs.' Joint App. at B78-79, B276-78, B280, B284); id. at 24 (citing Defs.' Joint App. at 73, 82, D183).

Similarly, Inverness argues that the "substantially completed" limitation means "the reaction involving the glucose in the entire sample must proceed as far as it can, at which point, the specification teaches, '99.9+ percent' of the glucose in the sample has been converted to gluconic acid." Inverness Br. at 21. Inverness avers that "substantial" is an open-ended word or a "word of degree" that would render the claims meaningless without quantification. Id. at 21-22. Moreover, Inverness relies upon the portion of the specification that states, "Gluconic acid yields of 99.9+ percent were attained in the presence of glucose oxidase," for the proposition that "substantially" must mean "99.9+ percent." Id. at 23 (citing '268 Patent, col. 8, *ll*. 23-25). In addition, like Bayer, Inverness argues that the prosecution history confirms that the inventors distinguished their invention on the basis that the "entire well volume" was reacted. Id. at 23-24. Therefore, substantial completion requires that the "entire well volume" react before a potential is applied.

In the context of the '268 patent, including the disputed claims, the undisputed claims, the specification and the prosecution history, the Court finds that "substantiallyto completion" or "substantially completed" means nearly to the end or nearly ended. With respect to where the reaction must be substantially completed, the

Court finds that the reaction must be substantially completed in the entire sample.

a.) The Meaning of "Substantially Completed"

The Court starts with the plain meaning of the claim language. Claim 1 uses the term "substantially to completion" in the context of what happens to the reaction between the sample fluid and the oxidant. *See* '268 Patent, col. 13, *ll*. 63-67. Similarly, the other independent claims at issue, claims 12, 43, and 47, talk about a reaction or an oxidation that has "substantially completed." Id. col. 14, *ll*. 59-61; id. col. 18, *ll*. 10-11; id. col. 18, *ll*. 45-46. The non-asserted independent claims also teach reactions that have "substantially completed." Id. col. 16, *l*. 6; id. col. 16, *l*. 33; id. col. 16, *l*. 65; id. col. 17, *l*. 21. In the context of the claim language where the focus is on what happens to a chemical reaction or oxidation (a special type of chemical reaction), the term "substantially to completion" or "substantially completed" likely means that the reactants are nearly all used up and there is little transformation continuing. This understanding is more succinctly phrased by consulting a dictionary, keeping in mind the context of a reaction between two or more chemicals.

The term "substantially" in normal usage implies considerable in amount or extent. *See* WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 2280 (Unabridged 1981) ("WEBSTER'S UNABRIDGED"); AMERICAN HERITAGE DICTIONARY (3d Ed. SoftKey Int'l Inc. 1994). Or, as suggested by Roche, largely but not wholly. *See* Roche Br. at 28 (citing York Prods., 99 F.3d at 1572 (quoting WEBSTER'S COLLEGIATE DICTIONARY)). Completed, or completion, in normal usage implies finished, done or ended. This common language definition comports with the dictionary definition for complete: "brought to an end or to a final or intended condition." WEBSTER'S UNABRIDGED, at 465. In the context of the claims, where the subject at issue is a reaction between chemicals, "substantially completed" likely means considerably or largely finished.

In contrast to the claim language where the extent of the reaction is qualified by the word "substantially," the '268 patent's specification rarely makes such qualification. Specifically, the patent teaches that a preferred embodiment "involves a two-step reaction sequence utilizing a chemical oxidation step using other oxidants than oxygen, and an electro-chemical reduction step suitable for quantifying the reaction production of the first step." '268 Patent, col. 3, *ll*. 16-19. There are no words of limitation here on the extent of the oxidation reaction. Moreover, the patent teaches the importance of a chemical reaction system that uses an oxidant other than oxygen "in a large excess of the analyte" to "ensure that the oxidant is not the limiting reagent" because the inventors wanted "a quantitative conversion of the analyte." Id. col. 3, *ll*. 19-25. Therefore, it appears that largeness in quantity of the oxidized chemical is important to the invention. Moreover, in the preferred embodiment where the analyte is glucose, the patent reads that the "chemical oxidation reaction has been found to precede to completion in the presence of an enzyme...." Id. co. 3, *ll*. 29-30. Similarly, the patent teaches: "The first reaction is an oxidation reaction which proceeds to completion in the presence of the enzyme glucose oxidase." Id. col. 4, *ll*. 26-28. Again, there are no words qualifying the extent of the oxidation reaction in these descriptions of the preferred embodiment, implying that the reaction is fully complete. This conclusion follows from the earlier emphasis on the importance of the quantity of the oxidized reaction product.

In another description of the preferred embodiment, the patent teaches:

The main difference between these two techniques consists of applying the appropriate controlled potential after the glucose-benzoquinone reaction is complete....

It should be noted that Cottrell chronoamperometry of metabolites needs the dual safeguards of enzymatic catalysis and controlled potential electrolysis. Gluconic acid yields of 99.9+ percent were attained in the presence of glucose oxidase.

Id. col. 8, *ll*. 13-25. Again, there are no words of limitation on the extent of completeness of the oxidation reaction. In fact, the patent teaches that when the catalyst glucose oxidase is used in the method described, experiments showed that 99.9+ percent of the glucose was converted to gluconic acid. All of these descriptions, however, specifically refer to a preferred embodiment of the invention where glucose is the analyte and glucose oxidase is used as the catalyst.

In addition, the patent also states that "[i]t has now been discovered that the preferred oxidants described [in the patent for glucose, ferricyanide, ferricinium, cobalt III orthophenanthroline and cobalt (III) dipyridyl,] have sufficiently positive potentials to convert substantially all of the B D glucose to gluconic acid." Id. col. 4, *ll*. 38-41. Here, even with reference to the preferred embodiment of oxidation of glucose to gluconic acid, the patent qualifies the extent of the reaction using "substantially." However, it seems that the patent teaches the importance of allowing the reaction between the analyte and the oxidant to proceed as close to completion as reasonably possible. As described above, the description of the preferred embodiments for glucose make this apparent. Therefore, a definition for "substantially to completion" or "substantially completed" that incorporates the concept that the reaction has nearly ended best captures the intent of the claims.

Both Bayer and Inverness argue that "substantially" is a word of degree, which in the context of the '268 patent is specifically defined as "99.9+ percent." Bayer Br. at 23; Inverness Br. at 23, 37-38; Inverness Surreply Br. on Claim Constr. at 20-22 ("Inverness Surreply"); Inverness Reply to "Roche's Resp. to Inverness' Surreply Br. on Claim Constr.", at 7 ("Inverness Reply to Roche Resp."). But, the defendants ignore the plain language of the claims themselves and the context in which the value "99.9+ percent" appears. The language of the claims disclose no special meaning for the term "substantially." In addition, independent claims 1, 12, 30, 37, and 43, are generic as to analyte or type of compound to be measured. *See* '268 Patent, col. 13, *ll*. 58-59 ("A method of measuring the amount of a selected compound in body fluids ...."); id. col. 14, *ll*. 53-54 ("A method of measuring the amount of an analyte in a blood sample ...."); id. col. 15, *ll*. 61-62 ("A method of measuring the amount of an analyte in a blood sample ...."); id. col. 16, *ll*. 51-52 ("A method of measuring the amount of an analyte in a blood sample ...."); id. col. 17, *ll*. 47-48 ("A method for measuring the amount of a selected compound in a blood sample...."). Yet, all the claims contain the "substantially completed" limitation.

In addition, the limit of "99.9+ percent" in the specification refers to the description of the preferred embodiment for detection of glucose concentration. The specification reads:

In order to prove the application of the technology according to the present invention, a large number of examples were run in aqueous solution at 25 (deg.) C.... In these tests it was found that any potential between approximately +0.8 and 1.2 volt (vs NHE) is suitable for the quantification of hydroquinone when benzoquinone is used as the oxidant.

* * * * * *

It should be noted that Cottrell current chronoamperometry of metabolites needs the dual safeguards of enzymatic catalysis and controlled potential electrolysis. Gluconic acid yields of 99.9+ percent were attained in the presence of glucose oxidase. Concomitantly, equivalent amounts of benzoquinone were reduced to hydroquinone, which was conveniently quantitated in quiescent solutions, at stationary palladium thin film anodes or sample cells.

The results of these many tests demonstrates the micro-chronoamperometric methodology of the present invention and its practicality for glucose self-monitoring by diabetics.

Id. col. 7, *ll*. 61-67 to col. 8, *ll*. 1-31. The reference to gluconic acid yields in this passage is to the results of a specific set of experiments run by the inventors to prove the application of the method for determination of glucose concentration, one of the preferred embodiments of the invention. There is nothing in the specification that incorporates this yield value for different analytes. This is made clear by reading the portion of the specification that describes an alternative preferred embodiment for determination of cholesterol concentration. No language in that portion of the specification requires that the reactions described yield 99.9+ percent of the oxidized form of cholesterol. The Court is not persuaded that the specification only supports a definition for "substantially completed" of 99.9+ percent.

Based on the language of the claims and the specification, the Court finds that "substantially to completion" or "substantially completed" means nearly to the end or nearly ended.

b.) Where the Reaction Must Proceed "Substantially to Completion"

This finding does not complete interpretation of the "substantially completed" limitation. Both Bayer and Inverness argue that in the context of the asserted and unasserted claims, the reaction must be substantially completed in the entire sample or throughout the entire well volume. Bayer Br. at 12-13, 25-28; Inverness Br. at 23-24, 32-37; Inverness Reply to Roche's Resp. at 5-6. Further, the defendants argue that during prosecution of the '015 patent application, the inventors differentiated their invention on the basis of where the reaction must go substantially to completion. Bayer Br. at 11-13, 25-28; Inverness Br. at 23-24; Inverness Surreply, at 12-13. Bayer and Inverness aver that the arguments made to secure issuance of the '015 patent were expressly incorporated into prosecution of the '564 application, upon which the '268 patent is based; therefore, the prosecution history of the '015 patent is relevant to interpretation of the claim language in the '268 patent. Bayer Br. at 14; Inverness Br. at 23-24, 24 n. 13.

In contrast, Roche argues that the claim language, the specification and the prosecution history support a construction of the "substantially completed" limitation requiring the reaction to proceed substantially to completion "only in that portion of the sample in which the re[a]gents have dissolved before the potential is applied." Roche Reply, at 6. In other words, the reaction must proceed substantially to completion "in the relevant region." Roche Resp. at 9. Roche avers that this construction is supported by the language of claim 1, which requires the oxidant and buffer to reconstitute in the sample fluid. Id. at 6-7. In addition, Roche argues that the specification provides that the reaction takes place in a " 'reagent layer' which contains the reconstituted or dissolved reagents." Id. at 8 (citing '268 Patent, col. 7, *ll*. 12-25; id. col. 7, *ll*. 29-31; id. col. 12, *ll*. 28-32). Further, Roche states that the reaction must only go substantially to completion in a fixed amount of the sample, not the entire sample, because the method must operate independently of sample volume. Id. at 10-11. Roche also argues that the prosecution history of the '015 patent is irrelevant to construction of the "substantially completed" limitation in the '268 patent because the claim limitations are completely different. Id. at 3-6; Roche Reply, at 11-14. Finally, Roche argues that the extrinsic evidence supports its claim construction that the reaction may proceed only where there are reactants.

The Court finds that in the context of the '268 patent claims, specification and prosecution history, the reaction must proceed "substantially to completion" in the entire sample. Starting with the language of the independent claims, the Court finds no language that indicates the reaction goes substantially to completion in only a portion of the sample or in only a reagent layer. Claim 1 states that the method provides for a "measuring cell" into which "a sample of fluid" is placed, then an oxidant and buffer is "reconstitut[ed] ... with said sample fluid to generate a predetermined reaction." '268 Patent, col. 13, *ll*. 59-65. Once the reaction has proceeded substantially to completion, "a potential is applied across said electrodes and sample." Id. col. 14, *l*. 1. These references in claim 1 support a finding that the reaction takes place throughout the sample because there is no limitation on where the potential is applied or where the predetermined reaction takes place.

Similarly, claim 12 teaches "adding [a] blood sample to an electrochemical cell that includes an electron transfer agent that will react in a reaction involving the analyte, thereby forming a detectable species[,]" then "incubating the reaction involving the analyte and electron transfer agent." Id. col. 14, *ll*. 54-60. There is no suggestion in this claim that the incubated reaction occurs only in a small portion of the sample that was added to the cell. The language in independent claims 30, 33, 37, 38 use similar language to claim 12. *See* id. col. 15, *ll*. 63-67 to col. 16, *ll*. 1-6; id. col. 16, *ll*. 23-33; id. col. 16, *ll*. 53-65; id. col. 17, *ll*. 9-21. The language in independent claims 43 and 47 is slightly different. Those claims read in pertinent part:

43. A method for measuring the amount of a selected compound in a blood sample, comprising:

providing a measuring cell having at least first and second electrodes for contact with the blood sample introduced into the cell,

* * * * * *

placing the blood sample into the cell,

* * * * * *

selectively oxidizing the compound in the blood sample with an oxidized electron acceptor to produce an oxidized form of the selected compound and a reduced electron acceptor, and

re-applying a potential across the cell electrodes after the selective oxidation of the compound in the blood sample has substantially completed....

* * * * * *

47. A method for measuring the amount of glucose in blood, comprising: providing a measuring cell with at least first ant second electrodes for contact with blood introduced into the cell,

* * * * * *

placing a volume of blood into the cell,

* * * * * *

oxidizing the glucose in the blood with an oxidized electron acceptor in the presence of glucose oxidase to produce gluconic acid and a reduced electron acceptor,

re-applying a potential across the measuring cell electrodes after the oxidation of glucose has substantially completed,....

Id. col. 17, *ll*. 47-53 to col. 18, *ll*. 1-46. The first step in these methods suggests that there is some area of the blood sample that contacts the electrodes, but some that does not, which could lead to an inference that the relevant area is that closest to the electrodes. However, the remainder of the claim language is not limiting. Particularly in claim 43, the language describing where the oxidation reaction is occurring is broad because it refers to "selectively oxidizing the compound in the blood sample" and "re-applying a potential across the cell electrodes after the selective oxidation of the compound in the blood sample has substantially completed...." Id. col. 18, *ll*. 4-11. This claim language talks about the reaction occurring in the entire sample, not just the portion of the sample nearest the electrodes.

The remaining language in claim 47 is no less broad. That claim teaches "placing a volume of blood into the cell" and "oxidizing the glucose in the blood," then "re-applying a potential across the measuring cell electrodes after the oxidation of glucose has substantially completed...." Id. col. 18, *ll*. 36-46. This claim does not refer to oxidizing the blood closest to the electrodes; it teaches "oxidizing the glucose in the blood." Id. col. 18, *ll*. 40. In the context of the claim, "the blood" can only refer to the "volume of blood" that was earlier placed in the measuring cell. Id. col. 18, *l*. 36.

The Court also finds support for its conclusion that the language of the independent claims suggests a broader construction for where the reaction must be "substantially completed" than "near the electrode" or "in the reagent layer" in the language of some dependent claims. The only reference in the claim language to a reagent layer occurs in dependent claims 18, 20, 22, and 25. Claim 18, the most generic of the dependant claims, states: "The method of claim 12, wherein the electron transfer agent is included in a reagent layer that is coated directly onto the electrochemical cell or is incorporated into a supporting matrix that is placed into the electrochemical cell." Id. col. 15, *ll*. 16-20. Later dependent claims describe further limitations on claim 18; only some reference the reagent layer specifically. *See, e.g.,* id. col. 15, *ll*. 21-23 ("The method of claim 18, wherein the supporting matrix is filter paper, membrane filter, woven fabric, or nonwoven fabric."); id. col. 15, *ll*. 24-25 ("The method of claim 18, wherein the reagent layer further includes a binder."); id. col. 15, *ll*. 26-28 ("The method of claim 20, wherein the binder is gelatin, carrageenan, methylcellulose, polyvinyl alcohol, or polyvinylpyrrolidone."); id. col. 15, *ll*. 29-30 ("The method of claim 21, wherein a dispersing, spreading, or wicking layer overlays the reagent layer."); id. col. 15, *ll*. 31-34 ("The method of claim 18, wherein adding the blood sample to the electrochemical cell causes a sudden charging current, which automatically initiates incubation step b performed under open circuit."); id. col. 15, *ll*. 37-40 ("The method of claim 24, wherein the reagent layer further includes an enzyme catalyst in sufficient amount to catalyze the reaction involving the analyte and the electron transfer agent."). Arguably, in the method of claim 18, the reaction could only take place in the reagent layer or the supporting matrix; therefore it would only require the reaction to proceed "substantially to completion" in the part of the sample that was adsorbed by or was close to that layer. However, nothing in the '268 patent claim language incorporates this concept into the independent claims. The Court will not import an inferred limitation from a dependent claim into the independent claims.

[26] [27] The Court notes that the independent claim limitations are incorporated into the dependent claims by definition. *See* Robotic Vision Sys., Inc. v. View Eng'g, 189 F.3d 1370, 1376 (Fed.Cir.1999) (citing 35 U.S.C. s. 112). Therefore, the construction of "substantially to completion" cannot exclude the possibility of a limitation in a dependent claim. Moreover, "a claim interpretation that would exclude the inventor's device [or preferred embodiment] is rarely the correct interpretation; such an interpretation requires highly persuasive evidentiary support...." Modine Mfg. Co. v. United States Int'l Trade Comm'n, 75 F.3d 1545,1550 (Fed.Cir.1996), *cert. denied,* 518 U.S. 1005, 116 S.Ct. 2523, 135 L.Ed.2d 1048, *overruled on other grounds,* Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd., 234 F.3d 558, 574 (Fed.Cir.2000). A construction for the substantially completed limitation in the '268 patent that requires a reaction in the entire sample might violate the first maxim and would violate the second. The Court, then, must determine whether the specification or the prosecution history provide "highly persuasive evidentiary support" for the defendants' proposed construction that the reaction must proceed substantially to completion in the entire sample.

The references in the specification to where the reaction in the '268 patent must be "substantially completed" support a construction that refers to a test area that is defined by the measuring cell. One simple reference to the "sample" suggests that the oxidation reaction occurs in the entire sample contained within the sample cell. The patent reads: "In the oxidation reaction, a sample containing glucose, for example, is converted to gluconic acid and a reduction of the oxidant. This chemical oxidation reaction has been found to precede [sic] to completion...." Id. col. 3, *ll*. 27-30.

Other references indicate that the sample cell itself provides the means for determining the test site, but do not disclose the shape or region of that area. The specification states that one of the purposes of the invention is to provide "reproducible output from sensor to sensor...." Id. col. 2, *ll*. 63-64. The specification then states that the invention addresses this requirement "by providing miniaturized disposable electroanalytic sample cells for precise micro-aliquote [sic] sampling...." Id. col. 2, *ll*. 66-67 to col. 3, *l*. 1. This phrase implies that the disposable cells control the sample size, even if it is a fraction or aliquot of the amount of sample available. Further, the patent teaches that the disposable cell is preferably laminated layers of plastic with an opening "designed to provide the sample containing area or cell for the precise measurement of the sample." This language would not require the area in which the reaction would proceed "substantially to completion" to be the entire sample available, merely the amount of sample contained in the "sample containing area" or "sample containing ... cell." Both of these references suggest that the physical parameters of the "measuring cell" defines where the reaction in the method takes place.

Later references also suggest that the "measuring cell" itself provides the means for controlling sample size. The patent reads: "[T]he sample cell according to the [ ] *present* invention, provides the testing of controlled volumes of blood without premeasuring. Insertion of the sample cell into the apparatus thus permits automatic functioning and timing of the reaction allowing for patient self-testing with a very high degree of precision and accuracy." Id. col. 4, *ll*. 3-9 (omission and emphasis in original). Further, in briefly describing the preferred embodiment with respect to glucose, the specification provides that "[t]he sample cell of the invention is used to control the sampling volume and reaction media and acts as the electrochemical sensor." Id. col. 4, *ll*. 15-18. And, "sample cell **20** is a metallized plastic substrate having a specifically-sized opening **21** which defines a volumetric well **21**, when the cell is assembled, for containing a reagent pad and the blood to be analyzed." Id. col. 5, *ll*. 45-49. *See also* id. col. 6, *ll*. 38-43 (describing an alternative embodiment of a sample cell in which "[o]pening **121** is dimensioned to contain the sample for testing"). The patent specification specifically allows for adding reagents to the sample rather than adding a sample to the reagents. The patent reads:

In this embodiment, after a sample has been positioned within well **21**, cell **20** is pushed into window **19** of the front panel to initiate testing. In this embodiment, a reagent may be applied to well **21**, or, preferably, a pad of dry reagent is positioned therein and a sample (drop) of blood is placed into the well **21** containing the reagent.

Id. col. 6, *ll*. 31-37. Again, this suggests that the "measuring cell" itself is used to ensure the proper sample size or volume for the reaction.

The '268 patent specification discloses a reagent layer in the context of the preferred embodiments of the invention. With respect to the preferred embodiment for glucose monitoring, the specification teaches:

[ ] *To* fully take advantage of the above apparatus, the needed chemistry for the sell [sic] testing systems is incorporated into a dry reagent layer that is positioned onto the disposable cell creating a complete sensor for the intended analyte.... The reagent layer is either directly coated onto the cell or preferably incorporated (coated) into a supporting matrix such as filter paper, membrane filter, woven fabric or non-woven fabric, which is then placed into the cell. When a supporting matrix is used, it[s] pore size and void volume can be adjusted to provide the desired precision and mechanical support.... The coating formulation generally includes a binder ... that acts to delay the dissolution of the reagents until the reagent layer has absorbed most of the fluid from the sample....

The reagent layer imbibes a fixed amount of the sample fluid when it is applied to the surface of the layer thus eliminating the need for premeasurement of sample volume.... While the fluid sample could be applied directly to the surface of the reagent layer, to facilitate spread of blood across the entire surface of the reagent layer the sensor preferably includes a dispersing spreading or wicking layer. This layer, generally a

non-woven fabric or adsorbant [sic] paper, is positioned over the reagent layer and acts to rapidly distribute the blood over the reagent layer.

Id. col. 7, *ll*. 6-42 (omission and emphasis in original). The description of the preferred embodiment for measurement of cholesterol uses a similar description. It states: "The concentrations provided are [ ] *those* of the solutions which are coated onto porous supports, filter paper or membranes; [ ] *those* concentrations are reestablished when the membrane imbibes the serum or whole blood specimen." Id. col. 12, *ll*. 28-32. The common definition of "imbibes" is absorb. WEBSTER'S UNABRIDGED, at 1128. The description for the glucose preferred embodiment specifies that only a fixed portion of the sample fluid is absorbed by the reagent layer because such a method ensures that one of the objects of the invention, to eliminate user error due to sample size inaccuracy or inconsistency, is achieved. The "imbibes the ... specimen" language in the description of the cholesterol preferred embodiment suggests the same concept of absorption of the sample fluid in some amount; however, it is not as specific about whether the amount is a portion of or the whole of the sample fluid. These descriptions indicate that the "substantially completed" limitation could occur in something less than the entire sample. However, the area is still defined by the test area of the measuring cell, albeit here, the test area of the measuring cell is the reagent layer.

Analysis of the specification points to a construction of the substantially completed limitation that allows for the reaction to occur in less than the entire sample. Perhaps most persuasive of this point is the description of the preferred embodiment for glucose testing that discloses the use of a reagent layer that "imbibes a fixed amount of the sample fluid." *See* '268 Patent, col. 7, *ll*. 29-30. In context, a fixed amount is less than the entire sample. Moreover, a construction of "substantially completed" that would exclude the preferred embodiment is rarely correct. *See* Modine Mfg., 75 F.3d at 1550. Here, adopting the defendants' construction, that the reaction must proceed substantially to completion in the entire sample, would exclude the preferred embodiment described in the specification for glucose. The defendants primarily rely upon prosecution history for their position that the reaction must occur in the entire sample. Therefore, the Court now turns to the merits of those arguments.

Both Bayer and Inverness argue that the inventors specifically claimed that the reaction must go "substantially to completion" in the entire well volume during prosecution of the '268 patent's parent, the '015 patent. *See, e.g.,* Bayer Br. at 11-13 (citing Joint App. at A18, A34-42, C43, C63, B276-78, B280, B284). The '015 patent and the '268 patent have identical specifications. *Compare* Defs.' Joint App. at 33-46 ('015 patent specification) to id. at 1-15 ('268 patent specification). In addition, claim 1 of the '268 patent originally appeared as claim 1 of the application that matured into the '015 patent, but apparently was withdrawn (along with other method claims) pursuant to the PTO's request under 35 U.S.C. s. 121. *See* Defs.' Joint App. at B71; id. at 108. The defendants focus on what the inventors argued once the method claims were severed from the apparatus claims. Specifically, with reference to what was prosecuted as claims 5 and 12 of the '015 patent application (claims 1 and 2, respectively, in the '015 patent as issued), the inventors distinguished their invention from prior art stating:

By way of summary, Claim 5, as amended, is an independent claim directed towards a sample cell for determining the concentration of a selected compound in a sample aqueous fluid.... [T]he opening [therein] forms a well to receive the sample aqueous fluid and to place the fluid in the known electrode area in contact with the first and second electrode, whereby substantially the entire contents of said well is capable of being substantially simultaneously subjected to a predetermined reaction.

* * * * * *

Claim 12, as amended, is an independent claim directed towards the overall apparatus for measuring compounds in a sample aqueous fluid. This apparatus includes the sample cell of Claim 5....

* * * * * *

In addition, Applicants' device entirely eliminates the need for a diffusion limitinglayer. Diffusion limiting layers are typically used for kinetic measurements and they are analogous to membranes used in an enzyme electrode. Applicants device eliminates this need entirely because it is not a kinetic measurement device. Instead the Cottrell current, as claimed in Claim 12, is what is being measured. As claimed in Claim 5, substantially the entire contents of the well of sample fluid can be reacted simultaneously. This is not true with a sensor which has a diffusion limiting layers [sic].

* * * * * *

[In U.S. Patent No. 7,579,643 and U.S. Patent No. 4,655,901, both to Mase *et al*. (prior art patents),] [t]he diffusion limiting layer determines the rate at which the gas reaches the electrode. In contrast, Applicants['] cell as claimed in Claim 5 is not rate limited and Applicants['] device eliminates the need for a diffusion limiting layer or membrane. The entire well volume, *i.e*. [sic] the entire sample, is reacted in Applicants['] device as claimed in Claim 5 and measured using a Cottrell current rather than a steady state signal.

* * * * * *

Applicants have developed a unique apparatus for measuring the Cottrell current in which the entire well volume, i.e. the entire sample, is reacted and measured.

Def.'s Joint App. at B275-78. Amended claim 5, as referred to above, reads:

5. (Twice Amended) A sample cell for determining the concentration of a selected compound in a sample *aqueous* fluid, comprising

a metallized first electrode which acts as a working electrode,

a metallized second electrode which acts as a reference electrode, said second electrode being operatively associated with said first electrode, and

at least one non-conducting layer member having an opening therethrough [sic], said layer member being disposed in contact with at least one of said electrodes and said layer member being sealed against at least one of said first and second electrodes to form a known electrode area within said opening such that said opening forms a well to receive said sample *aqueous* fluid and to place said fluid in said know electrode area in contact with said first electrode and second electrode, *whereby substantially the entire contents of said well is capable of being substantially simultaneously subjected to a predetermined reaction*.

Def.'s Joint App. at B269-70 (emphasis in original to indicate amendments). Clearly, the inventors specifically limited the invention in the '015 patent to a cell in which the "entire contents of said well" is reacted. Id. at B270. Such a limitation would have been convincing evidence that the inventors intended to exclude the preferred embodiment described in the specification of the '015 patent. *See* Modine Mfg., 75 F.3d at 1550 ("Indeed, a claim interpretation that would exclude the inventor's device is rarely the correct interpretation; such an interpretation requires highly persuasive evidentiary support....").

[28] Bayer and Inverness argue that the '268 patent must also be construed to have this limitation because the '268 patent issued from a division of the '015 patent's original application, the two patents contain nearly identical specifications, the inventors expressly incorporated the prosecution history of the '015 patent into that of the '564 patent (parent of the '268 patent), the patent examiner issued the '015 patent and the '564 patent for essentially identical reasons, and the '268 patent contains the substantially completed limitation in

all but claim 1 in response to the examiner's rejection of those claims without the limitation. But, Roche argues, the language of the '015 patent's claim 1 (prosecuted as claim 5) is not identical to that of the '268 patent. Further, the '015 patent does not contain the substantially completed limitation. Therefore, Roche concludes, the prosecution history of the '015 patent cannot limit the term in the '268 patent.

The Court agrees in large part with the defendants that the evidence establishes the relevance of the '015 patent's prosecution history to the claims of the '268 patent. The Federal Circuit states that "[t]he prosecution history of a related patent can be relevant if, for example, it addresses a limitation in common with the patent in suit." FN3 Advanced Cardiovascular Sys. v. Medtronic, Inc., 265 F.3d 1294 (Fed.Cir.2001). *See also* Watts v. XL Sys., Inc., 232 F.3d 877, 884 (Fed.Cir.2000) (citing Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 980 (Fed.Cir.1999); Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1579 (Fed.Cir.1995)). The focus is on whether the same claim limitation appears in the parent and the subsequent patents. *See* Elkay Mfg., 192 F.3d at 980. Apparently, however, the language of the claim limitation need not be identical. *See* Builders Concrete v. Bremerton Concrete Prods., 757 F.2d 255, 259-60 (Fed.Cir.1985); *see also* Modine Mfg., 75 F.3d at 1551 ("[I]t is incorrect to construe a claim as encompassing the scope that was relinquished in order to obtain allowance of another claim, despite a difference in the words used.").

FN3. The Court notes that the Federal Circuit's use of the phrase "for example" implies that there may be other reasons why the prosecution history of a related patent is relevant to claim construction. Moreover, "the rules of construction must be understood in terms of the factual situations that produce them and applied in fidelity to their origins." Modine Mfg., 75 F.3d at 1551.

At the outset, the Court finds a time line of the pertinent events in the history of the '268 patent important. Application serial number 07/322,598 ("'598 application"), which matured into the '015 patent, was filed on March 13, 1989. Defs.' Joint App. at B2. A preliminary amendment filed June 13, 1990, amended claims 1 and 5 of the '598 application as follows:

1. (Amended) A method for measuring the amount of a selected body compound in body fluids comprising,

a) [placing a sample of fluid to be tested in a sample] *providing a measuring* cell having *at least a* first and second electrode *and said cell containing an oxidant and a buffer;*

b) placing a sample of fluid to be tested in said cell,

[b. mixing said sample with an oxidant and a buffer;]

c) reconstituting said oxidant and buffer with said sample fluid to generate a predetermined reaction,

d) allowing said reaction to proceed substantially to completion,

[c.] *e)* applying a potential across said electrodes and sample; and

[d.] *f)* measuring the resultant *Cottrell* current to determine the concentration of said select compound present in said sample.

* * * * * *

5. (Amended) A sample cell *for determining the concentration of a selected compound in a sample fluid,* comprising

[a. first and second nonconductive substrates, said first substrate having an opening therethrough [sic];]

[b.] a metallized first electrode *which acts as a working electrode,* [positioned on one of said second substrate; and]

[c.] *a metallized second electrode which acts as a reference electrode, said second electrode being operatively associated with said first electrode, and* [a second electrode positioned on said first electrode, whereby said first electrode is positioned over a portion of said second electrode to form a laminate with said first and second electrodes positioned therebetween [sic] and said opening exposing said electrodes to define a sample well.]

at least one non-conducting layer member having an opening therethrough [sic], said layer member being disposed in contact with at least one of said electrodes and said layer member being sealed against at least one of said first and second electrode to form a known electrode area within said opening such that said opening forms a well to receive said sample fluid and to place said fluid in said known electrode area in contact with said first electrode and second electrode.

Id. at B71-72. Although the file history appears incomplete on this issue,FN4 on or about March 1, 1991, the PTO ordered the restriction of the '598 application pursuant to 35 U.S.C. s. 121, to either the method claims, of which claim 1 was a part, or the apparatus claims, of which claim 5 was a part. *See* id. at B108. The patent examiner stated that the method and apparatus claims were distinct because the method could "be performed by a materially different apparatus such as a crystal oscillator for measuring substances within a body fluid." Id. The inventors elected to pursue the apparatus claims under the '598 application. Id.

FN4. The file is obviously incomplete at this point because the document referenced here is numbered page 2, but no page 1 appears in the file. Several documents in the file history are missing pages and/or are not dated or signed. In addition, some documents have their multiple pages separated by other complete documents.

Shortly thereafter, on April 12, 1991, the PTO wrote an office action that was apparently mailed on May 7, 1991. *See* id. at B109-14. In it, the examiner rejected claims 5 and 12 of the '598 application, under 35 U.S.C. s. 103, the statute for obviousness, in light of Mase *et al*. The examiner stated: "Mase et al [sic] teaches a sample cell with first and second metallized electrodes mutually associated with said layer members sealed against at least one electrode and forms a well to receive sample." Id. at B111.

The divisional application containing the method claims from the '598 application was filed on August 15, 1991, application serial number 07/745,544 (the "divisional application"); this application matured into the '564 patent. Defs.' Joint App. at C2. Claim 1 of the divisional application was identical to the original, unamended claim 1 of the '598 application. *See* id. at C43. Contemporaneously with the divisional application, the inventors filed a preliminary amendment that added the substantially to completion limitation to claim 1 in the same way that the preliminary amendment to the ' 598 application had added it. *Compare* id. at B71, to id. at C63.

On September 6, 1991, the inventors filed the amendment to the '598 application in which they modified claim 5 by limitation to a cell "whereby substantially the entire contents of said well is capable of being substantially simultaneously subjected to a predetermined reaction." Defs.' Joint App. at B270.

Apparently, a telephone conversation between the inventors' attorney and the examiner for both the '598 application and the divisional application occurred on October 23, 1991, although there is no formal record of the conversation by the examiner. *See* id. at C68 & C101.FN5 The conversation is referenced in an

amendment to the divisional application filed November 11, 1991. *See* id. at C68 & C101.

FN5. There are two copies of the amendment filed on November 11, 1991. It appears from the file that the one copy was an attachment to a fax, to which the inventors' attorney expected a response from the PTO examiner. *See* Defs.' Joint App. at C67. Only one copy is signed. *See* id. at C73.

It is this amendment that the defendants claim expressly incorporates the prosecution history of the '015 patent into the '564 patent history. The amendment states in pertinent part:

This Amendment is in response to a request from the Examiner to amend the subject case, thereby placing it in condition for allowance. In a telephone conference on October 23, 1991, between the Examiner in the above case, Mr. Bell, and attorney for Applicants, Michael J. Kline, the Examiner sated that the parent case, S.N. 07/322,598 was allowable as is, and that a Notice of Allowance would issue shortly in that case. The Examiner further requested that the subject divisional case be amended to conform with amendments made in the parent case. In view of these conforming amendments, made herein, Applicants respect fully [sic] request early allowance of the subject case.

Please amend the above application as follows:

In the Specification:

* * * * * *

All of the above amendments to the specification conform to amendments made in the parent case. The bases and reasons for the above amendments are adequately set forth in the remarks to the Preliminary Amendment, dated June 13, 1990, and the Amendment, dated September 6, 1991, both in the parent case, which remarks are incorporated by references as if set forth fully herein.

In the drawings:

* * * * * *

In the Claims:

Kindly amend the claims as follows:

In Claim 18, line 13, change "Cattrell" to-Cottrell-.

Please add the following new claim:

22. The method of claim 1 wherein step b) said placing of the blood sample to be tested in the cell generates a current and initiates a timing sequence, and wherein the reaction of step d) is allowed to proceed with an open circuit between said first and second electrode.

Remarks

The amendments presented herein conform the subject case S.N. 07/745,544, to the parent case, S.N. 07/322,598. New claim 22 simply further limits allowable claim 1, requiring that the first and second electrode have an open circuit during step (d). Support for this new claim limitation is on page 10, lines 12-20, page 16, lines 5-11 and page 19, lines 18-21 and Figure 8 of the specification as filed. In view of these

amendments, and the October 23, 1991 telephone conference with the Examiner, the Applicants respectfully request early allowance of the present case.
Id. at C68-73 (excluding page C72, filed out of order).
The examiner allowed the '598 application as the '015 patent on October 28, 1991. Id. at B297-98. The examiner allowed the divisional application as the '564 patent on November 20, 1991. The examiner's reasons for allowance of the two patent applications are remarkably similar. The text is set forth below in a side-by-side comparison.

'**015 Patent Allowance**	'**564 Patent Allowance**
The following is an Examiner's Statement of Reasons for Allowance: The references cited by the examiner fail to teach the key feature of the applicant [sic] invention which is a method for measuring the amount of a selected compound in body fluids whereby providing a measuring cell have [sic] at least two electrodes and the call [sic] contains an oxidant and a buffer. The method used places a sample of fluid in the cell whereby the oxidant and buffer are reconstituted with the sample fluid to generate a reaction whereby the reaction proceeds to completion. A potential is applied across the electrodes and the resulting Cottrell current is measured to determine the concentration of the selected compound present in the sample solution.	The following is an Examiner's Statement of Reasons for Allowance: The prior art cited by the examiner fails to teach the key feature of the applicants [sic] invention which is providing a measuring cell having at least two electrodes wherein the cell contains an oxidant and a buffer and a sample fluid is introduced into the cell thereby reconstituting the oxidant and buffer with a sample fluid to generate a predetermined reaction and allowing the reaction to provide [sic] substantially to completion; and applying a potential across the electrode and sample, then measuring the resulting Cottrell current to determine the concentration of selected [sic] compound present in the sample.
Defs.' Joint App. at B298.	Defs.' Joint App. at C80.

The examiner cited no prior art in the prosecution history on file for the '564 patent.

The same examiner reviewed Roche's reissue application, application serial number 08/679,312 ("'312 application"), filed July 12, 1996, that matured into the '268 patent. Defs.' Joint App. at D2. The '312 application sought to reissue claims 1-6 of the '564 patent, and added claims 12-48. Id. at D27-35. Claims 12-48 did not include the substantially completed limitation. In an office action mailed April 27, 1995, the examiner stated:

Claims 12-48 are rejected under the recapture rule of cancelled subject matter.

The applicants amended their claims to add the limitation that a buffer and oxidant were included in the cell and that the buffer and oxidant were reconstituted with the sample fluid. The limitation with respect to the reaction proceeding to completion or substantially to completion was also added. Applicant now has deleted these aspects from the claims rejected above and therefore, the recapture rule applies.

The amendment filed 12/30/93 is objected to under 35 U.S.C. s. 132 because it introduced new matter into the specification.... The claims also contain new matter because the allowed claims were restricted to allowing the reaction to proceed to completion or substantially to completion before applying the potential across the electrodes and measuring the resulting Cottrell current and the claims presently do not restrict the reaction to having to come to completion.

Applicant is required to cancel the new matter in the response to this Office action.

Id. at D110-11.

Roche tried to convince the examiner that the amendments he referenced for the substantially completed limitation were made voluntarily; therefore, the recapture rule did not apply. However, the examiner rejected its argument. He stated:

Applicants argue in their response that there is support for allowing the incubation reaction to proceed for a specified time period. However, this is not the issue. The issue is whether the applicant is trying to recapture material that was cancelled from the claims in the original application to obtain a patent. By not stating that the reaction has to come substantially to completion in the instant claims, applicant is in fact trying to recapture the cancelled material from the original application. Therefore, the examiner does maintain the rejection.

Id. at D143 & D183. *See also* id. at D215-16, Jan. 22, 1997 (rejecting the applicants' incomplete response to the prior office action and citing the substantially completed limitation again). Roche amended the claims to include the substantially completed limitation and the examiner allowed them as amended.

This history of the substantially completed limitation evidences that the patent examiner allowed the claims of the '268 patent over prior art because of the limitation. However, the only time the examiner cited prior art in reference to this limitation was in the parent application, the '598 application, which matured into the '015 patent. The Court is convinced that the examiner read the substantially completed element in the '564 patent (and the '268 patent by necessity) the same as the "substantially the entire contents of said well is capable of being substantially simultaneously subjected to a predetermined reaction" element of the '015 patent.

A side-by-side comparison of the claims supports this conclusion.

'015 Patent Claim 1 Language	**'268 Patent Claim 1 Language**
A sample cell for determining the concentration of a selected compound in a sample aqueous fluid, comprising	a) providing a measuring cell ... containing an oxidant and a buffer
a metallized first electrode which acts as a working electrode	having at least a first
a metalized second electrode which acts as a reference electrode, said second electrode being operatively associated with said first electrode, and	and a second electrode
at least one non-conducting layer member having an opening therethrough, said layer member being disposed in contact with at least one of said electrodes and said layer member being sealed against at least one of said first and second electrodes to form a known electrode area within said opening such that said opening forms a well to receive said sample aqueous fluid and to place said fluid in said known electrode area in contact with said first electrode and second electrode,	b) placing a sample of fluid to be tested into said cell

whereby substantially the entire contents of said well is capable of being substantially simultaneously subjected to a predetermined reaction.

c) reconstituting said oxidant and buffer with said sample fluid to generate a predetermined reaction,

d) allowing said reaction to proceed substantially to completion

Claim 1 of the '015 patent discloses a sample cell in which a predetermined reaction substantially, simultaneously happens to substantially the entire contents of the well defined by the sample cell. Claim 1 of the ' 268 patent discloses a measuring cell in which a predetermined reaction proceeds substantially to completion. The Court finds these limitations to refer to the same concept as it is presented in the specification of both patents. In other words, in the context of the patents at issue, the claim limitations are the same. *See* Biovail Corp. v. Andrx Pharmaceuticals, Inc., 239 F.3d 1297, 1301-02 (applying a limitation from a parent patent's prosecution history to progeny, in part, because the term was used in the same context in both patents).

Other factors also persuade the Court that the prosecution history of the ' 015 patent is relevant to construction of the substantially completed limitation of the '268 patent. The timing of certain key events in the prosecution of the '015 and '564 patents evidences the close relationship between the two inventions. The divisional application, which matured into the '564 patent, was filed on August 15, 1991, complete with preliminary amendments that included the substantially completed limitation. The inventors' amendments to the '015 patent application that led to issuance of the '015 patent were filed on September 6, 1991. The telephone conference between the inventors' attorney and the examiner occurred on October 23, 1991, at which time the examiner indicated he would allow the '015 patent soon. The '015 patent issued on October 28, 1991.

On November 13, 1991, the inventors filed amendments to the '564 patent application referencing the telephone conference with the examiner and conforming the application to that of the parent. The '564 patent issued a mere seven days later on November 20, 1991. The patent examiner issued the ' 564 patent approximately three months after it was filed. Further, he discussed the content of the '564 patent application with the inventors' attorney asking that it conform to the parent patent, so that he could issue it that quickly. The examiner clearly relied upon his understanding of the invention as disclosed to him during prosecution of the parent application, which issued as the '015 patent, when he issued the '564 patent so quickly. To find otherwise would ignore the presumptive integrity of the patenting process.

In addition, the patent examiner's statement of reasons for allowance of the ' 015 patent and the '564 patent are virtually identical. The statement for the '015 patent reads: "The method used places a sample fluid in the cell whereby the oxidant and buffer are reconstituted with the sample fluid to generate a reaction whereby the reaction proceeds to completion." Defs.' Joint App. at B298. The statement for the '564 patent reads: "[The] invention ... is providing a measuring cell ... wherein the cell contains an oxidant and a buffer and a sample fluid is introduced into the cell thereby reconstituting the oxidant and buffer with a sample fluid to generate a predetermined reaction and allowing the reaction to provide [sic] substantially to completion...." Id. at C80. These statements evidence that the examiner found the substantive invention of the '015 apparatus patent and the '564 method patent identical. The statements also refer to the examiner's cited references or prior art. *Compare* id. at B298 (using "[t]he references cited by examiner fail to teach the key feature ..." language), *with* id. at C80 (using "[t]he prior art cited by the examiner fails to teach the key feature ..." language). But, the examiner never cited prior art in prosecution of the divisional application that matured into the '564 patent.The prior art he cited was discussed during prosecution of the '015 patent approximately two months earlier. The Court finds this strong evidence that the prosecution history of the '015 patent is relevant to construction of the '564 patent or its progeny, the '268 patent.

Further, although the Court is not persuaded that the language of the amendment to the divisional application expressly incorporates into the '564 patent history all of the prosecution history for the '015 patent, the amendment is strong evidence that the patent examiner allowed the '564 patent because it conformed to his understanding of the '015 patented invention. When the amendment to the divisional application was filed, the claims had already been amended in a preliminary amendment, thereby conforming them, in pertinent part, with those the patent examiner had seen in the earlier '015 patent application. The references in the amendment to the divisional application to a conversation with the patent examiner in which he expressed his interest in seeing the divisional application conform to that of the parent, is strong evidence that the examiner viewed the invention in the divisional application as the method version of the '015 patented invention.

Finally, the prosecution history of the '268 patent confirms this understanding of the parent patents. In the application for the '268 patent, only claim 1 (and its dependent claims by incorporation) as originally filed contained the substantially completed element; this claim is identical to claim 1 of the '564 patent. The examiner rejected the other claims, stating:

[They] introduced new matter into the specification.... The claims also contain new matter because the allowed claims were restricted to allowing the reaction to proceed to completion or substantially to completion before applying the potential across the electrodes and measuring the resulting Cottrell current and the claims presently do not restrict the reaction to having to come to completion.

Id. at D110-11. Despite Roche's attempts to circumvent the patent examiner's reasoning, the examiner maintained the objection throughout prosecution of those claims. *See* id. at D143 & D183; id. at D215-16 (rejecting the applicants' incomplete response to the prior office action and citing the substantially completed limitation again). This series of rejections evidence that the patent examiner found the substantially completed element important for patentability of the original claims in the '564 patent. However, the only time the examiner and the inventors discussed that element was during prosecution of the original application that matured into the '015 patent.

The Court finds that the prosecution history of the '015 patent is relevant to construction of the substantially completed element of the '268 patent because that element appears in the '015 patent, albeit using different phrases, the patent examiner relied upon statements made during prosecution of the '015 patent in issuing the original claims of the '268 patent as the '564 patent, and the patent examiner maintained the objection to claims without that element during prosecution of the '268 patent. Although the Court is mindful that claim construction that excludes the preferred embodiment is rarely correct, the Court is convinced that the inventors limited the substantially completed element to overcome the PTO examiner's prior art objections. Therefore, the Court finds that the reaction must proceed substantially to completion in the entire sample.

D. "COTTRELL CURRENT"

[29] The third term of the '268 patent in dispute is "Cottrell current." Roche avers that "Cottrell current" means "diffusion controlled current which decays substantially in accordance with one over the square root of time." Roche Reply Br. at 28-31. Roche argues that the intrinsic evidence establishes that the current measured by the method must be "diffusion controlled." Id. at 28 (citing '268 Reissue Patent, col. 3, *l*. 52). Moreover, the patent provides that "Cottrell current" should decay in accordance with the square root of time. *See* id. at 29 (citing '268 Patent, col. 8, *ll*. 9-12). But, not all the conditions for application of the Cottrell equation are necessary for the current to be "Cottrell current" in the context of the '268 patent. According to Roche, only these requirements are consistent with the statements of Dr. Weber during prosecution of the '268 patent application. Id. (citing Defs.' Joint App. at 72, 76).

Generally, the defendants assert that the patent specification requires Cottrell current to vary in accordance

with the Cottrell equation; therefore, Cottrell current is produced only if the method employed controls all the variables in the Cottrell equation including: (1) a planar electrode; (2) the only available approach to the surface of the electrode is from the front; (3) the chemical entities must move by diffusion only; (4) there must be no movement of the fluid; (5) the concentration of the analyte in the solution when the potential is applied must be uniform; and (6) there must be no wall opposite the electrode. *See* Bayer Br. at 25 (citing Lowe Report para. 29; Weber Report, at 7); *see also* Inverness Br. at 51; Inverness Surreply, at 23. Based on this understanding, Bayer argues that "Cottrell current" should be construed to mean "a current that conforms to the Cottrell equation and is measured under the six conditions required by Cottrell[,] including being measured in a solution in which the concentration of the reduced oxidant is wholly unchanging when the measurement begins." Bayer Br. at 25 (citing Defs.' Joint App. at 73, 82). Bayer avers that Roche's definition truncates the Cottrell equation and modifies the degree of compliance with the equation required by the '268 patent and its prosecution history. Id. (citing ' 268 Patent, col. 8; Defs.' Joint App. at 73, 82; Jeneric/Pentron, Inc. v. Dillon Co., Inc., 205 F.3d 1377, 1381-82 (Fed.Cir.2000)).

Similarly, Inverness argues that "Cottrell current" means "the measured current conforms to the Cottrell equation and that the conditions of the Cottrell equation are satisfied." Inverness Br. at 47. Inverness points to the '268 patent's disclosure of the entire Cottrell equation in its specification as evidence that the patent calls for strict adherence to the conditions for use of the Cottrell equation. Id. at 47-48 (citing '268 Patent, col. 3, *ll*. 43-66; id. col. 3, *ll*. 44-57; id. col. 3, *ll*. 51-57). Further, Inverness cites to passages in the prosecution history that suggest that the term contemplates strict compliance with the requirements of Cottrell equation behavior, particularly the requirements that the reaction in the solution have stopped and that the ferrocyanide concentration in the sample be constant or homogeneous. Id. at 48-50 (citing Inv.App. 8, Protest, Oct. 27, 1995, at 6-7; id. Exh. B, at 6; id. at 10, 15; Inv.App. 9, Office Action, Jan. 22, 1996, at 5).

In the context of the '268 patent, the specification and the prosecution history, the Court finds that "Cottrell current" means the rate of charge flow of a diffusion controlled reaction at a planar electrode when the concentrations of the reactants in the solution are nearly unchanging before a controlled potential is applied, and such rate varies with time according to $t^{-1/2}$ within experimental error.

The Court notes at the outset that apparently there is no "plain meaning" for the phrase "Cottrell current." However, based on the background information on electrochemistry supplied by the parties, equally apparent are two things: that "Cottrell" refers to Frederick Cottrell, an electrochemist who determined the mathematical equation for predicting the current in a reaction controlled by diffusion at a planar electrode when a controlled potential, or a step potential, is applied, Roche Br. at 7-8; Pl.'s Exh. 12, PETER J. KISSINGER & WILLIAM R. HEINEMAN, LABORATORY TECHNIQUES IN ELECTROANALYTICAL CHEMISTRY 57-58 (Marcel Dekker, Inc., 1984) ("KISSINGER & HEINEMAN"), and that "current" has the plain meaning of "[t]he amount of electric charge flowing past a specified circuit point per unit of time." AMERICAN HERITAGE DICTIONARY. *See also* KISSINGER & HEINEMAN, at 57 ("Current is physically defined as the rate of charge flow...."). Arguably then, a simple grammatical construction for the phrase "Cottrell current" leads to a definition where Cottrell's equation defines the amount of electric charge flowing past a specified circuit point per unit of time. Or, "Cottrell current" could mean the amount of electric charge at a planar electrode in a diffusion controlled reaction that varies with time according to the Cottrell equation. But, the parties argue that the Court must make the definition of Cottrell current more specific with respect to how closely the current must follow the Cottrell equation.

Starting with the claim language, all of the independent claims of the '268 patent refer to measurement of the "Cottrell current" after the oxidation reaction has been "substantially completed" or has gone "substantially to completion." '268 Patent, col. 13, *ll*. 66-67 to col. 14, *ll*. 1-5; id. col. 14, *ll*. 60-67; id. col. 16, *ll*. 5-12; id. col. 16, *ll*. 64-67 to col. 17, *ll*. 1-4; id. col. 18, *ll*. 9-12; id. col. 18, *ll*. 44-47. That current

then either "determines," "is correlated to," or "is proportional to" the amount of biologically significant compound in the sample. Id. col. 14, *ll*. 3-5; id. col. 15, *ll*. 1-2; id. col. 16, *ll*. 13-14; id. col. 17, *ll*. 5-6; id. col. 18, *ll*. 11-15; id. col. 18, *ll*. 47-49. Two of the claims refer to the concept that the Cottrell current is proportional to the concentration of the biologically significant compound. Id. col. 18, *ll*. 11-15 ("measuring the resulting Cottrell current, said current being proportional to the concentration of the reduced electron acceptor and the selected compound in the blood sample"); id. col. 18, *ll*. 47-49 ("measuring the Cottrell current through the cell, the Cottrell current being proportional to the glucose concentration in the blood"). This proportionality is confirmed for glucose in the specification. The patent reads: "Proportionality between glucose concentrations and Cottrell currents (recorded at t = 30 seconds after the application of potential) is shown in FIG. 7." Id. col. 8, *ll*. 18-20 (showing a straight line).

However, other claims suggest that the relationship between Cottrell current and concentration is not "proportional to" but "correlates with." Claims 12, 30 and 37 require "correlating the measured Cottrell current to the amount of analyte in the blood sample." Id. col. 15, *ll*. 1-2; id. col. 16, *ll*. 13-14. Similarly, Claim 33 requires "correlating the measured Cottrell current to the amount of cholesterol in the blood sample." Id. col. 16, *ll*. 41-42. This difference may have significance in light of the parties' argument about whether all of the conditions of the Cottrell equation must be satisfied for the current described by the '268 patent's method to be "Cottrell current." The Cottrell equation predicts that the current would be proportional to the concentration of the biologically significant compound at any point in time after the potential is applied. *See* Pl.'s Reply App. Exh. 2, ALLEN T. BARD & LARRY R. FAULKNER, ELECTROCHEMICAL METHODS: FUNDAMENTALS & APPLICATIONS 144 (John Wiley & Sons, Inc., 1980) ("BARD & FAULKNER").

The specification teaches several things about "Cottrell current." The ' 268 patent "utilizes Cottrell current micro-chronoamperometry" to quantify the amount of biologically significant compound in the sample. '268 Patent, col. 3, *ll*. 43-47. The patent states that

[i]n this method of quantification, the measurement of a diffusion controlled current at an accurately specified time (e.g. 20, 30, or 50 seconds, for example) after the instant of application of a potential has the applicable equation for amperometry at a controlled potential (E=constant) of:

$$\mathbf{i(t) = nFAC_{metabolite}(D)^{0.5}((tau)(omega)t)^{-0.5}}$$

where i denotes current, nF is the number of coulombs per mole, A[ ] is the area of the electrode, D is the diffusion coefficient of the reduced form of the reagent, t is the preset time at which the current is measured, and C is the concentration of metabolite. Measurements by the method according to the present invention of the current due to the reoxidation of the acceptors were found to be proportional to the glucose concentration in the sample.
Id. col. 3, *ll*. 51-67. The equation set out in this portion of the patent is the Cottrell equation for measuring the current in a diffusion solution using a single planar electrode. *See* KISSINGER & HEINEMAN, at 58; BARD & FAULKNER, at 143. This part of the specification supports a definition for "Cottrell current" that requires the current to follow the Cottrell equation because it specifically identifies the Cottrell equation as the "method of quantification" required by the invention. Moreover, this description identifies one of the parameters for the Cottrell equation: a diffusion controlled reaction. This requirement is likely well known to one skilled in the art because a basic electrochemistry text teaches that "[t]he important concept in [chronoamperometry] is *diffusion-controlled* oxidation or reduction." KISSINGER & HEINEMAN, at 52. Furthermore, according to the specification, Figure 8 of the '268 patent "is a graphical representation of Cottrell current as a function of glucose concentration." Id. col. 5, *ll*. 28-29. On that graph, under the words "Cottrell Current" the equation $i_t=nFAD_{HQ}^{1/2}(tau)(omega)^{-1/2}t^{-1/2}$ appears. Id. at 6, Fig. 8. Again, the label of the graph suggests that "Cottrell current" is current that varies in accordance with the Cottrell

equation. However, the graph also shows that for a sample containing zero millimoles of glucose, there is a measurable current. Id. Roche argues that this suggests that the invention method is less than an "ideal" one because for zero millimoles of glucose, the Cottrell equation produces a result of zero microamperes of current. According to KISSINGER & HEINEMAN there is a "background response to the excitation signal for a solution containing supporting electrolyte only. This current decays rapidly when the electrode has been charged to the applied potential." KISSINGER & HEINEMAN, at 57. *See also* '268 Patent, col. 12, *ll*. 3-9 (discussing the occurrence of a background signal in some circumstances that must be accounted for); Bard Dep. at 173, 268 (discussing how to account for background currents); Defs.' Joint App. at 76, Protest Under 37 C.F.R. s. 1.291 on Behalf of Tall Oak Ventures ("Protest"), Weber Aff. para. 8.13 (describing background processes that occur during chronoamperometry and that produce measurable current). This phenomenon, then, is apparently known to one skilled in the art of chronoamperometry. Therefore, Figure 8 in the specification suggests that there is some predictable variation from the Cottrell equation based on practical or experimental error in the method practicedby the '268 patent. *See* Bard Dep. at 173 (discussing the results predicted by the Cottrell equation and accounting for experimental error); id. at 268 (discussing subtracting out the background current and determining experimental error around the Cottrell equation); *see also* Defs.' Joint App. at 76, Protest, Weber Aff. para. 8.13 (discussing deviations from the Cottrell equation in practice).

Roche also argues that the lines representing Cottrell current in Figure 8 deviate from the Cottrell equation because they show the current reaching a plateau short of zero for each glucose concentration. Roche Br. at 30; Roche Reply, at 25. Apparently it is well known to those skilled in the art of electrochemistry that the Cottrell equation, applied strictly, would not generate the plateaus in current that are represented on the "Cottrell current" graph of Figure 8; both of the defendants' experts testified as such. *See* Lowe Dep. at 171-73; Bard Dep. at 185, 190. Dr. Bard testified that such plateaus could be consistent with results obtained because of convection (movement of the sample fluid by external means rather than diffusion) or because of a non-planar electrode. Bard Dep. at 185. The KISSINGER & HEINEMAN basic electrochemistry textbook teaches that variations from the Cottrell equation could happen for these reasons as well. It states, in relevant part:

The Cottrell equation states that the product it $^{1/2}$ should be a constant K for a diffusion-controlled reaction at a planar electrode. Deviation from this constancy can be caused by a number of situations, including nonplanar diffusion, convection in the cell, slow charging of the electrode during the potential step, and coupled chemical reactions.

KISSINGER & HEINEMAN, at 58. *See also* BARD & FAULKNER, at 143-44 (discussing experimental limitations of "Cottrell conditions"). But, again, it seems these responses are predictable and do not change the fundamental decay of the current with respect to time. *See* KISSINGER & HEINEMAN, at 58-60; BARD & FAULKNER, at 143-46 Bard Dep. at 186 (discussing the relevant region of the lines in Figure 8 of the '268 patent); Defs.' Joint App., at 76, Protest, Weber Aff. para. 8.13 (discussing practical considerations and variations of the current measurement therefrom). Therefore, the patent specification does teach, to one skilled in the art, some predictable variation from the Cottrell equation parameters. The Court must use the clues in the '268 patent claims, specification and prosecution history to clarify which Cottrell equation parameters are necessary for "Cottrell current."

The patent specification teaches that the system measures the "diffusion controlled" current and uses a "controlled potential." '268 Patent, col. 3, *ll*. 51-55. *See also* id. col. 8, *ll*. 21-23 (stating that "Cottrell chronoamperometry of metabolites needs the dual safeguards of enzymatic catalysis and *controlled potential* electrolysis" (emphasis added)). These factors are described by the ENCYCLOPEDIA OF CHEMISTRY, and would be well known to those skilled in the art:

[The potentiostatic chronoamperometry] technique consists of maintaining a constant potential without

convection. When a reducing potential is imposed instantaneously on a stationary working electrode in quiescent solution, current will rise sharply and then decay as the electroactive species in the electrode vicinity is depleted by electrolysis. The magnitude of the current is proportional to the bulk concentration of electroactive species and is related to the electrode potential through the Nernst equation, Eq. (2). If the potential is sufficiently beyond *E* (deg.)' [the formal standard potential], the Nernst equation demands complete conversion to the reduced form. Thus, under these conditions the current is diffusion-controlled and decays with $1/t^{-1/2}$. This is shown by Eq. (3) [the Cottrell equation] where *F* is the faraday, *A* is the

$$I = nFAC^* [D^{1/2}(\text{tau})(\text{omega})^{-1/2} t^{-1/2}] \quad (3)$$

electrode area, *D* is the diffusion coefficient for the electroactive species, and *C* * is the bulk concentration of electroactive species.

Pl.'s Exh. 11, SYBIL P. PARKER, MCGRAW-HILL ENCYCLOPEDIA OF CHEMISTRY 312 (2d ed.) ("ENCYCLOPEDIA OF CHEMISTRY"). *See also* KISSINGER & HEINEMAN, at 52-58 ("The important concept in [chronoamperometry] is *diffusion-controlled* oxidation or reduction.... The Cottrell equation states that the product $it^{1/2}$ should be a constant K for a diffusion-controlled reaction at a planar electrode."). The '268 patent specification also teaches a planar electrode, although the claims do not require that the electrode be of a specific shape. *See, e.g.,* id. col. 3, *ll*. 5-9 (teaching "laminated" electrodes); id. col. 5, *ll*. 45-67 to col. 6, *ll*. 1-57 (teaching "laminated" electrodes, electrode strips or ribbons of electrodes all with known area); *but see, e.g.,* col. 13, *ll*. 60-61 ("providing a measuring cell having at least a first and second electrode"); id. col. 14, *ll*. 54-63 (referring to an "electrochemical cell" and "applying a sufficient potential difference between the electrodes of an electrochemical cell").

The ENCYCLOPEDIA OF CHEMISTRY describes the importance of a solution that is quiescent, or "marked by a state of inactivity or repose." WEBSTER'S UNABRIDGED, at 1865. *See also* '268 Patent, col. 8, *ll*. 25-28 (describing experiments used to verify the method as taking place in "quiescent solutions"). Apparently, a solution approaching such a condition is also necessary to generate "Cottrell current." The claims of the '268 patent teach that "Cottrell current" is the result that occurs after a potential is applied to a solution in which an oxidation reaction has proceeded "substantially to completion." *See, e.g.,* '268 Patent, col. 13, *ll*. 66-67. As discussed above, this is clearly supported by the specification describing the preferred embodiments that require the oxidation reaction to proceed to completion or substantially to completion before the potential is applied and describing experiments run on "quiescent solutions." FN6 *See, e.g.,* id. col. 3, *ll*. 29-33; id. col. 4, *ll*. 55-58; id. col. 8, *ll*. 13-17; *see* id. col. 8, *ll*. 25-28. In other words, to practice the method of the ' 268 patent the concentrations of the reactants in the solution are nearly unchanging or are at equilibrium before the potential is applied. Therefore, the ' 268 patent teaches the importance of this Cottrell equation parameter.

FN6. The Court notes that the specification also describes an embodiment in which a vibrator is used to agitate the reagents performing the oxidation of the metabolite "to enhance dissolution." '268 Patent, col. 6, *ll*. 64-67 to col. 7, *ll*. 1-2. In the context of the '268 patent, this embodiment appears to focus on making the oxidation reaction occur more quickly. This construction makes sense in light of the patent's teaching that the oxidation reaction must go to completion or substantially to completion before the potential is applied for the method of the invention to work. '268 Patent, col. 13, *ll*. 66-67 to col. 14, *ll*. 1-5; id. col. 14, *ll*. 60-67; id. col. 16, *ll*. 5-12; id. col. 16, *ll*. 64-67 to col. 17, *ll*. 1-4; id. col. 18, *ll*. 9-12; id. col. 18, *ll*. 44-47. The Court cannot construe the reference to vibration in this embodiment to mean that the inventors thought vibration or agitation of the solution after oxidation is desired or necessary.

The prosecution history also reveals the importance of this Cottrell equation parameter, and a few others.

When BMC sought to broaden the claims of the ' 564 patent with an application for reissue, the PTO examiner rejected the claims, in part, because the measurement of "Cottrell current" was anticipated or made obvious by the teachings in "Nankai *et al*. (EPO 0230472)" and Kawaguri *et al*. *See* Defs.' Joint App., at D108, D114-15, Office Action, PTO, Mailed Apr. 27, 1995 ("Apr. 27, 1995, Office Action"). The inventors filed a protest with the PTO on behalf of the reissue application, which matured into the '268 patent. In their protest the inventors specifically addressed the requirements for "Cottrell current." Id. at 48-58; 67; 73; 76, Protest. Most importantly for claim construction purposes, the PTO "dropped the [prior] art rejection in view of the original inventors explanation in their protest as to how Cottrell current is measured, and agree[d] with their assessment of the prior art references." FN7 Id. at D183, Office Action, PTO, Mailed Jan. 22, 1996 ("Jan. 22, 1996, Office Action"). Therefore, the explanation for "Cottrell current" provided by the inventors to the PTO is important for determining the correct construction for the term in the ' 268 patent.

FN7. The Court notes that the inventors' protest does not appear in the official file history of the '268 patent. However, it is clear that the PTO relied upon the protest with respect to the inventors' argument about "Cottrell current" because the first PTO office action in the file dated after the protest specifically refers to it as the reason for dropping the objection to "Cottrell current." Defs.' Joint App., at D183, Office Action, PTO, Mailed Jan. 22, 1996 ("Jan. 22, 1996, Office Action"). The defendants assert that the protest is a legitimate part of the prosecution history, *see* Inverness Br. at 50 n. 33, Roche does not contest this. Based on circumstances here, where it is clear that the PTO was persuaded to allow "Cottrell current" as used in the '268 patent over its own prior art objection because of the inventors' protest, the Court finds that the protest is "intrinsic" evidence and properly considered as part of the prosecution history of the '268 patent.

Specifically, the protest states in pertinent part:

... [B]y measuring the *Cottrell current,* and not being required to measure a peak current, as in *Kawaguri et al*., the measurement of the present invention may take place at any number of points along the Cottrell current v.s. time curve, depicted in Figure 8 of the '564 Patent. The result is far greater range (up to 1000 mg/dl glucose concentration) and far greater precision (much lower coefficients of variation), as set forth in the table, Column 9, Lines 35-55 of the '564 Patent.

* * * * * *

Nankai et al. can likewise not be practicing the measurement of a Cottrell current, as *Nankai et al*. deals with measuring a *variation in concentration* of a substance *during the reaction*. *Nankai et al*. at Page 5, Lines 3-4. *Weber* at Paragraphs 9.6-9.9. As noted in the attached Affidavit, "One of the requirements for obtaining a Cottrell current is that the concentration of the species being oxidized be a constant in the solution before potential is changed to the value that causes the current to flow. If the concentration of the species sought is varying, as is in *Nankai et al*., then the Cottrell equation will not be obeyed, and the current is not a Cottrell current." *Weber* at Paragraph 9.9. See also [sic], *Weber* at Paragraph 8.5:

8.5 Cottrell Current. Cottrell current refers to the first case mentioned and diagrammed [sic] approximately in Fig. 1. Cottrell current is proportional to:

-> $t^{-1/2}$(t=0 is when the step occurs in the applied potential),

-> n, the number of electrons transferred in a single electrode reaction in which one molecule of reagent is converted to one molecule of product. E.g. [sic], n=2 when benzoquinone is reduced to hydroquinone,

-> F, the Faraday constant, about 96,485 coulombs/mole of electrons,

-> A, the electrode area,

-> $D^{1/2}$, where D is the specie's diffusion coefficient,

-> C^{*}, the concentration of the species of interest as it was, unchanging in space and time, before the potential step.

In all of the above cases it is assumed that, except for the changes wrought by the electrode reaction discussed, there is no variation in the concentration of the species of interest. If there is variation of the specie's [sic] concentration, then the current does not fall into any of the common categories of expected electrochemical results, and is certainly not Cottrell current.

Weber, supra, emphasis added.

Id. at 52-54, Protest (quoting id. at 73, Weber Aff. para. 8.5) (emphasis in original). Furthermore, the affidavit of Dr. Weber, filed contemporaneously with the inventors' protest states, in relevant part:

9.9 One of the requirements for obtaining a Cottrell current is that the concentration of the species being oxidized be a constant in the solution before the potential is changed to the value that causes the current to flow. If the concentration of the species sought is varying as it is in Nankai, then the Cottrell equation will not be obeyed, and the current is not a Cottrell current.

* * * * * *

10.1 At issue is whether the earlier published literature anticipates parts of the patent of Szuminsky et al. ('56[4]).

'56[4] teaches how to make a reliable, useful, reproducible measurement of a Cottrell current. The later arises in an electrochemical cell which is initially at equilibrium or open circuit, or held at a potential where no more than a negligible current is drawn, and which is subsequently perturbed by changing the potential on the working electrode to a second, constant value sufficient to oxidize (reduce) each molecule of the desired species that reaches, by diffusion only, the working electrode. In this cell, the working electrode must be planar and large.... Under these conditions the measured current is proportional to: $t^{-1/2}$(t=0 is when the potential is changed from the first to the second value), the number of electrons being transferred in each overall electrochemical reaction on a single molecule, the Faraday constant, the electrode area (it's macroscopic area if it is a composite mimicking a solid electrode), the square root of the diffusion coefficient of the species undergoing reaction, the concentration of that species in solution before the potential step, and a numerical constant. Neither Kawaguri nor Nankai teach all of the requirements for generating the Cottrell response; 56 [4] does so teach these requirements as indicated above.

* * * * * *

10.3 The intrinsic value of the chronoamerometry (as opposed to the voltammetry of Kawaguri) of a reaction that has gone to completion (as opposed to measuring a variation in concentration caused by an enzyme reaction, as in Nankai) is that the Cottrell current is dependent on fewer, and more easily controlled, parameter[s]. None of the rates of chemical reactions influence the signal magnitude in '56[4]. Both Nankai and Kawaguri are making measurements during the enzyme reaction. Further, Kawaguri is using voltammetry, in which the native electron transfer rate constants of the electron transfer agent, and the physical and chemical state of the surface are important. The most reproducible and trustworthy method is chronoamperometry in a solution with unchanging concentration.

Id. at 82-84, Protest, Weber Aff. para.para. 9.9, 10.1 & 10.3.

The inventors and their expert teach that the parameter of paramount importance to obtaining a "Cottrell current" is that the concentration of the solution is unchanging or the solution is at "equilibrium" before the potential is applied. Id. at 83, Protest, Weber Aff. para. 10.1. *See also* id. at 54, Protest ("It is clear that it is the measuring of Cottrell current after the reaction has proceeded to completion which yields the improved results of the subject invention."); id. at 58, Protest (" *Nankai et al*. does not clearly teach taking a reaction to completion i.e. a point at which the concentration of analyte would be constant, and therefore, subject to the possibility of taking Cottrell current measurements...."). They teach that this is important because if the concentration is varying the current will not obey the Cottrell equation. Id. at 82, Protest, Weber Aff. para. 9.9. Specifically, Dr. Weber teaches: "If the concentration of the species sought is varying ..., then the Cottrell equation will not be obeyed, and the current is not a Cottrell current." Id. Moreover, the inventors used this factor to distinguish the Nankai *et al*. prior art reference. *See* id. at 58, Protest. They stated, in part:

Nankai et al. does not clearly teach taking a reaction to completion, i.e. a point at which the concentration of analyte would be constant, and therefore, subject to the possibility of taking Cottrell current measurement, and does not clearly specify what is meant by the 'pulse voltage' being applied; *Nankai et al*. therefore does not inherently teach measuring Cottrell current.

Id. (citing id. at 83, Protest, Weber Aff. para. 10.1).

In addition to the Cottrell equation parameter that the concentration of the analyte be nearly unchanging before the potential is applied, the inventors also discussed other Cottrell equation parameters relevant to their invention. Specifically, Dr. Weber teaches that

[w]hen the electrode is macroscopically planar and large with respect to the time-dependent parameter $(Dt)^{1/2}$ (D is the diffusion coefficient of the species undergoing oxidation or reduction) then the current is generally proportional to $t^{-1/2}$ following a dramatic and rapid rise in current at the actual time of the change in potential (t=0 is the time of the step change in potential).

Id. at 72, Protest, Weber Aff. para. 8.3. Therefore, it is important that the electrode be planar and large. Moreover, "Cottrell current" is proportional to $t^{-1/2}$, but "in a practical cell, where one expects a certain current that is predicted by theory, it is often not exactly what one obtains due to [background processes including capacitance, corrosion of the electrode, or electrolysis of components of the sample that result in other currents]." Id. at 76, Protest, Weber Aff. para. 8.13. Dr. Weber states that

the background processes are a minor component of the total signal in the cells (biosensors) under consideration. No background process would cause the current response ... to be misidentified. For example, current from an experiment that should produce a Cottrell current may be found to be proportional to $t^{-0.45}$ or $t^{-0.55}$rather than exactly $t^{-1/2}$.

Id. In other words, the current will decay with $t^{-1/2}$ to within experimental error.

In summary, the claim language, the specification and the prosecution history of the '268 patent evidence that the method produces "Cottrell current" when: (1) the reaction is diffusion controlled; (2) the electrode is planar; (3) the concentrations of the reactants in the solution are nearly unchanging before the potential is applied; (4) the potential is controlled; and (5) the measured current varies with time according to $t^{-1/2}$ within experimental error. Therefore, "Cottrell current" in the context of the '268 patent means the rate of

charge flow of a diffusion controlled reaction at a planar electrode when the concentrations of the reactants in the solution are nearly unchanging before a controlled potential is applied, and such rate varies with time according to $t^{-1/2}$ within experimental error.

E. "ELECTRODE"

[30] Inverness disputes the breadth of the term "electrode" as it is used in the '268 patent. Inverness argues that the '268 patent does not disclose the use of carbon as a material for the reference electrode disclosed in the patent. Inverness Br., Addendum B, at 3-4. Specifically, Inverness avers that the specification merely teaches that the electrodes should be made from noble metals or metallized plastic. Id. at 4. Further, Inverness argues that prior art does not disclose the use of carbon as a reference electrode material for this type of chemical cell.

In contrast, Roche argues that there is no reason to vary the meaning of electrode from its ordinary meaning: "any piece of conductive material through which an electric current enters or leaves a medium such as a liquid solution." Roche's Reply Br. at 34. Roche avers that the '268 patent need not teach that which was well known in the art. Id. (citing Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384 (Fed.Cir.1986), *cert. denied,* 480 U.S. 947, 107 S.Ct. 1606, 94 L.Ed.2d 792 (1987)). Specifically, the use of carbon electrodes in test strips was well known in the art prior to the '268 patented invention. *Id.* (citing Roche Reply App. Exh. 1, Exh. 313, C.R. Lowe, *Biosensors: Concepts & Applications* (University of Cambridge, U.K.) (undated), at 27 & 34). *See also* Roche Resp. to Inverness' Surreply, at 16-17 (citing U.S. Patent No. 4, 897,173, to Shiro Nankai *et al.,* Jan. 30, 1990, at col. 7, *ll.* 50-53; col. 7, *ll.* 3-5 (the "Nankai patent")) (stating that the Nankai patent discloses in the claims and elsewhere a reference electrode made from carbon). Roche avers that U.S. Patent No. 4,897,173, to Shiro Nankai *et al.,* Jan. 30, 1990 (the "Nankai patent"), discloses the use of carbon for a reference electrode in an electrochemical cell. The Nankai patent was listed as relevant prior art in the '268 patent. '268 Patent, at 2.

The Court finds that in the context of the '268 patent, electrode should be given its ordinary meaning: any piece of conductive material through which an electric current enters or leaves a medium such as a liquid solution. Starting with the language of the claims, there is nothing to suggest that the term "electrode" means anything extraordinary or requires special materials. *See, e.g.,* id. col. 13, *ll.* 60-61; id. col. 14, *ll.* 62-63. The patent specification does state that the "disposable cells according to the present invention are preferably laminated layers of metallized plastic and nonconducting material. The metallized layers provide the working and reference electrodes...." '268 Patent, col. 3, *ll.* 5-8. Further, the specification describes a process for metallizing the "polyimide Kapton" with silver-silver chloride for use as the reference electrode. Id. col. 5, *ll.* 52-67 to col. 6, *ll.* 10. The specification also teaches that "[t]he reference electrode may also be of the type generally known as a 'pseudo' reference electrode which relies upon the large excess of the oxidizing species to establish a known potential at a noble metal electrode." Id. col. 6, *ll* 11-15. But, none of the language in the patent suggests that these are the only materials that would work for the reference electrode. Moreover, the remaining descriptions of the reference electrode do not specify material. *See* id. col. 6, *ll.* 35-61.

As Roche suggests, the '268 patent need not teach what was well known at the time of the invention. Hybritech, 802 F.2d at 1384 (citing Lindemann Maschinenfabrik v. American Hoist & Derrick, 730 F.2d 1452, 1463 (Fed.Cir.1984)). Claims 1 and 2 of the Nankai patent disclose:

1. A biosensor for electrochemically detecting concentration variations of a substrate in a liquid sample, comprising:

an insulating base;

an electrode system provided on said insulating base, said electrode system being primarily made of carbon and comprising, at least, a measuring electrode and a counter electrode ...

* * * * * *

2. A biosensor according to claim 1, wherein said electrode system includes the measuring electrode, the counter electrode and a reference electrode.

Nankai Patent, col. 6, *ll*. 46-53 to col. 7, *ll*. 3-5. These claims teach a reference electrode made from carbon used in a system designed to measure concentration electrochemically. There was no need for the '268 patent to teach carbon as a potential material for the reference electrode of its electrochemical cell; the Nankai patent had already taught it.

For these reasons, the Court finds that "electrode" in the context of the ' 268 patent has its ordinary meaning: any piece of conductive material through which an electric current enters or leaves a medium such as a liquid solution.

III. *CONCLUSION*

For the foregoing reasons, the Court finds that the disputed terms in the ' 268 patent have the following meanings:

"Buffer" means	a solute that resists change in pH of the reaction solution
"Substantially to Completion" or "Substantially Completed" means	nearly to the end or nearly ended in the entire sample
"Cottrell Current" means	the rate of charge flow of a diffusion controlled reaction at a planar electrode when the concentrations of the reactants in the solution are nearly unchanging before a controlled potential is applied, and such rate varies with time according to $t^{-1/2}$ within experimental error
"Electrode"	any piece of conductive material through which an electric current enters or leaves a medium such as a liquid solution