IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

ROCHE DIAGNOSTICS OPERATIONS, : INC. and CORANGE :

INTERNATIONAL LIMITED,

Plaintiffs,

v. : Civil Action No. 07-753-JJF

ABBOTT DIABETES CARE and ABBOTT DIABETES CARE SALES CORPORAITION, et al.,

Defendants.

Daniel A. Boehnen, Esquire and Grantland G. Drutchas, Esquire of MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP, Chicago, IL. Philip A. Rovner, Esquire of POTTER ANDERSON & CORROON LLP, Wilmington, DE.

Attorneys for Plaintiffs.

Bradford J. Badke, Esquire; Sona De, Esquire; and Michael P. Kahn, Esquire of ROPES & GRAY, LLP, New York, NY.
Mary W. Bourke, Esquire and R. Eric Hutz, Esquire of CONNOLLY BOVE LODGE & HUTZ LLP, Wilmington, DE.
Rodger D. Smith II, Esquire of MORRIS, NICHOLS, ARSHT & TUNNELL LLP, Wilmington, DE.

Attorneys for Defendants.

MEMORANDUM OPINION

September 5, 2009
Wilmington, Delaware

Farnan, District Judge

This is a patent infringement case brought by Roche
Diagnostics Operations, Inc. and Corange International Limited
against Abbott Diabetes Care, Inc., Abbott Diabetes Care Sales
Corporation, Bayer Healthcare, LLC, Diagnostic Devices, Inc.,
Lifestan, Inc., and Nova Biomedical Corporation alleging
infringement of U.S. Patent Nos. 7,276,146 ("the '146 patent")
and 7,276,147 ("the '147 patent"), which pertain to methods for
rapidly determining the concentration of an analyte in a liquid
sample using small sample volumes. The parties briefed their
respective positions on claim construction, and the Court
conducted a Markman hearing on the disputed terms. This
Memorandum Opinion provides constructions for the disputed terms.

BACKGROUND

The patents-in-suit pertain to the use of microelectrodes for the rapid determination of the concentration of an analyte in a liquid sample. The patents-in-suit focus on the determination of glucose concentration in a blood sample, an application of particular interest to individuals suffering from diabetes.

Briefly, the disclosed methods involve the application of a blood sample to a disposable test strip having (1) a capillary chamber, (2) a working electrode, (3) a reference electrode, and (4) a reagent. See, '146 patent 3:40-52. "The reagent includes an enzyme and a mediator, and reacts with glucose [in the blood] to provide an electroactive reaction product." Id. at 3:45-46.

"This electroactive reaction product can be electronically detected, measured, or quantified by applying a potential difference between the electrodes and measuring the current generated by the electrooxidation of the mediator at the working electrode. By calibrating the system's behavior using known substances and concentrations, the electrical behavior of the system in the presence of a sample substance of unknown composition can be determined by comparison to the calibration data." Id. at 7:32-40.

DISCUSSION

I. The Legal Principles of Claim Construction

Claim construction is a question of law. Markman v.

Westview Instruments, Inc., 52 F.3d 967, 977-78 (Fed. Cir. 1995),

aff'd, 517 U.S. 370, 388-90, 116 S. Ct. 1384, 134 L. Ed. 2d 577

(1996). When construing the claims of a patent, a court

considers the literal language of the claim, the patent

specification and the prosecution history. Markman, 52 F.3d at

979. Of these sources, the specification is "always highly

relevant to the claim construction analysis. Usually it is

dispositive; it is the single best guide to the meaning of a

disputed term." Phillips v. AWH Corporation, 415 F.3d 1303,

1312-17 (Fed. Cir. 2005) (quoting Vitronics Corp. v. Conceptronic,

Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)). However, "[e]ven

when the specification describes only a single embodiment, the

claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction.'" <u>Liebel-Flarsheim Co. v. Medrad, Inc.</u>, 358 F.3d 898, 906 (Fed. Cir. 2004) (quoting <u>Teleflex</u>, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1327 (Fed. Cir. 2002)).

A court may consider extrinsic evidence, including expert and inventor testimony, dictionaries, and learned treatises, in order to assist it in understanding the underlying technology, the meaning of terms to one skilled in the art and how the invention works. Phillips, 415 F.3d at 1318-19; Markman, 52 F.3d at 979-80. However, extrinsic evidence is considered less reliable and less useful in claim construction than the patent and its prosecution history. Phillips, 415 F.3d at 1318-19 (discussing "flaws" inherent in extrinsic evidence and noting that extrinsic evidence "is unlikely to result in a reliable interpretation of a patent claim scope unless considered in the context of intrinsic evidence").

In addition to these fundamental claim construction principles, a court should also interpret the language in a claim by applying the ordinary and accustomed meaning of the words in the claim. Envirotech Corp. v. Al George, Inc., 730 F.2d 753, 759 (Fed. Cir. 1984). If the patent inventor clearly supplies a different meaning, however, then the claim should be interpreted

according to the meaning supplied by the inventor. Markman, 52 F.3d at 980 (noting that patentee is free to be his own lexicographer, but emphasizing that any special definitions given to words must be clearly set forth in patent). If possible, claims should be construed to uphold validity. In re Yamamoto, 740 F.2d 1569, 1571 (Fed. Cir. 1984).

II. The Meaning of the Disputed Terms

Plaintiffs assert that Defendants infringe claims 31-62 of the '146 patent and claims 36-69 of the '147 patent. The following is an illustrative independent claim from the '146 patent, with the disputed terms emphasized:

- 31. A method of determining the concentration of glucose in a blood sample, comprising:
 - providing a disposable biosensor test strip including a capillary chamber having a depth suitable for capillary flow of blood and holding a volume of between about 0.1 µl and about 1.0 µl of the blood sample, a working electrode and a counter or reference electrode disposed within the capillary chamber, and a reagent proximal to or in contact with at least the working electrode, the reagent including an enzyme and a mediator, the reagent reacting with glucose to produce an electroactive reaction product;
 - applying a blood sample containing glucose into the **capillary chamber**, the **capillary chamber** directing capillary flow of the blood sample into contact with the reagent to cause the blood sample to at least partially solubilize or hydrate the reagent;
 - detecting the blood sample in the capillary chamber;
 following said detecting, applying or controlling the
 voltage or current across the working and counter
 or reference electrodes;
 - electrooxidizing the electroactive reaction product
 at the working electrode; and
 within 10 seconds after said detecting, determining

and providing a readout of the glucose concentration in the blood sample, said determining comprising correlating the electrooxidized electroactive reaction product to the concentration of glucose in the blood sample.

Thus, the parties purport to dispute the meaning of the bulk of the language used in the independent claims. However, the disputes that seem to be of greatest interest to the parties concern the claim terms "electrode" and "detecting."

Specifically, with regard to the term "electrode," the parties dispute whether it should be understood to refer only to "microelectrodes," which Defendants contend are electrodes having a width within the range of 15 to 100 µm. With regard to the "detecting" term, the parties dispute whether "detection" of the blood sample must always be followed by a "delay period," during which the voltage between the working electrode and reference electrode is turned off so that the "electroactive reaction product" can build up in advance of the process of "determining" the glucose concentration.

For the reasons that follow, the Court construes the disputed terms as follows:

A. "Working Electrode," "Counter Electrode" and "Reference Electrode"

Claim Term	Plaintiffs' Construction	Defendants' Construction
"reference electrode"	A reference electrode is an electrode that is intended to maintain a known and constant potential.	A reference microelectrode having a width of 15 to 100 μm.
"working electrode"	An electrode in an electrochemical cell at which the reaction of interest occurs.	A working microelectrode having a width of 15 to 100 μm.
"counter electrode"	An electrode that is used to complete an electrical circuit with the working electrode during glucose measurement.	A counter microelectrode having a width of 15 to 100 μm.

"Claims 'must be read in view of the specification, of which they are a part.'" Phillips v. AWH Corp., 415 F.3d 1303, 1315 (Fed. Cir. 2005) (citing Markman v. Westview Instruments, Inc., 52 F.3d 967, 978 (Fed. Cir. 1995)). Here, the written description repeatedly confirms that the invention, and hence the claims, are directed to methods utilizing microelectrodes. See, e.g., '146 patent at Title ("Electrodes, methods, apparatuses comprising micro-electrode arrays"); id. at Abstract ("Described are micro-arrays of electrodes . . . "); id. at 1:13-16 ("The present invention relates to arrays of micro-electrodes . . . "); id. at 2:20-28 ("[I]t has now been discovered that micro-electrode arrays for example, IDAs, can be advantageously useful

when disposed on flexible substrates."); id. at 2:41-50 ("The micro-electrode arrays of the invention"); id. at 3:3-9 ("An aspect of the invention relates to micro-electrodes used in combination with a flexible substrate."); id. at 3:16-18 ("Another aspect of the invention relates to an electrochemical sensor comprising an array of micro-electrodes disposed on a flexible substrate."); id. at 3:21-23 ("Yet another aspect of the invention relates to a method of detecting an analyte using an array of micro-electrodes of the invention"); id. 3:26-28 ("A sensor is provided which comprises micro-electrodes proximal to a flexible substrate . . . "); id. at 3:26-27 ("Still another aspect of the invention relates to a method of preparing a microelectrode . . . "); id. at 4:22-48 (describing the invention in terms of micro-electrodes and stating, inter alia, that "[m]icroelectrodes, as distinguished from other electrodes generally, are understood in the electronic and biosensor arts").

Furthermore, a patentee may disavow claim scope "by clearly characterizing the invention in a way to try to overcome rejections based on prior art." Computer Docking Station Corp. v. Dell, Inc., 519 F.3d 1366, 1374 (Fed. Cir. 2008). In response to the examiner's obviousness rejections under 35 U.S.C. § 103, the patentee specifically noted that the prior art Morales and Mizutani III references used macro electrodes, and that Mizutani I and Ripshon references "also do not describe a test sensor that

includes a capillary fill chamber having two or more microelectrodes and a concomitantly small sample receiving cavity" (D.I. 360, Exh. J at 6-7.) Thus, the patentee distinguished the prior art, in part, on the basis of its use of macroelectrodes as opposed to microelectrodes. In light of the above evidence in both the specification and prosecution history, the Court concludes that the claims should, as Defendants contend, be limited to microelectrodes.

With regard to the dimensions of the microelectrodes, the patents-in-suit set forth a broad range for the preferred dimensions of microelectrodes. See, '146 patent at 3:3-15. To the extent the patents-in-suit disclose examples using macroelectrodes having dimensions outside this range, the Court concludes such examples cannot pertain to claimed embodiments because, although the claims are limited to blood samples, the examples include a capillary depth insufficient for the flow of blood. See, id. at 19:45-50 (explaining that capillary depths greater than 100 μm allow "fast fill of blood" and that smaller capillary depths can be used with other biological fluids). However, the specification, unlike Defendants' proposed construction, does not describe the upper limit of the range as a strict cutoff. Rather, the specification explains that the "preferred dimension" is "from 15 or 20 or 25 μ m, up to about 100 um . . . " (Id. at 3:7-15.) Accordingly, the Court will

construe these "microelectrode" terms to refer to microelectrodes having a width of 15 μ m up to approximately 100 μ m. This construction illuminates the size of a microelectrode to one of skill in the art without improperly excluding microelectrodes that are slightly larger than the preferred dimensions.

B. "Capillary Chamber"

Claim Term	Plaintiffs' Construction	Defendants' Construction
"capillary chamber"	A receptacle which draws in blood by capillary action, and with a volume equaling its depth multiplied by width multiplied by length.	A space or channel that is defined over the electrodes that directs flow of the blood sample over the electrode.

On reviewing the parties' briefing, the Court concludes that the essential dispute between the parties is whether the term "capillary chamber" refers only to rectangular chambers (Defendants' position) or chambers of any shape (Plaintiffs' position). The specification explains that a "microchannel or capillary more specifically refers to a space or channel that is defined over the array to allow the flow of a fluid over the array," and does not make any reference to a particular capillary shape. '146 patent at 18:43-48. To the extent the specification discloses rectangular capillary chambers, the Court concludes that these are mere examples that should not be imported into the claims. Accordingly, the Court will construe the term "capillary

chamber" to mean, as Plaintiffs contend, "a space or channel that is defined over the electrodes that directs flow of the blood sample over the electrodes."

C. "Detecting"

Claim Term	Plaintiffs' Construction	Defendants' Construction
"detecting"	Discovering or ascertaining the presence of.	Applying a DC voltage potential across the working and counter electrodes and then going to an open circuit or delay period, during which no potential is applied, after a blood sample contacts the working and counter electrodes and gives rise to a current response.

The dispute between the parties is whether the "detecting" step of the claims requires the use of a "DC voltage potential" followed by a "delay period" (Defendants' position) or not (Plaintiffs' position). Every embodiment disclosed in the patents-in-suit sets forth a detection step involving the application of a DC potential followed by a delay period. See, e.g., '146 patent at 23:60-24:23. However, this does not justify limiting the claims. See, Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 906 (Fed. Cir. 2004) ("Even when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or

expressions of manifest exclusion or restriction.") (quotations omitted).

As noted above, a patentee may disavow claim scope "by clearly characterizing the invention in a way to try to overcome rejections based on prior art." Computer Docking Station Corp., 519 F.3d at 1374. Defendants contend that Plaintiffs did this by arguing during prosecution that, in an obviousness analysis, prior art disclosing amperometric detection methods could not be combined with prior art disclosing coulometric because the former methods require a delay period while the latter methods do not. (See, D.I. 359 at 25-27.) On reviewing the relevant sections of the prosecution history (see, D.I. 362, Exh. U at 12, 20; id., Exh. V at 24; <u>id.</u>, Exh. W at 8; <u>id.</u>, Exh. Z at 21), the Court concludes that while the patentee argued that coulometric methods and amperometric were distinguishable on the basis of amperometric methods requiring a delay period, the patentee did not state that the invention was limited to only amperometric methods. Accordingly, the patentee did not limit the claims to only detection methods that require a delay period.

In addition, the Federal Circuit has explained that "[d]ifferences among claims can also be a useful guide in understanding the meaning of particular claim terms." Phillips v. AWH Corp., 415 F.3d 1303, 1314 (Fed. Cir. 2005). As Plaintiffs note, dependent claims of both the '146 and '147

patent include an explicit "delay period" requirement. <u>See</u>, '146 patent at Claim 58; '147 patent at Claim 64. Thus, the doctrine of claim differentiation counsels against limiting all the claims of the patents-in-suit to the use of a delay period.

Accordingly, the Court will construe the term "detecting" to mean, as Plaintiffs contend, "discovering or ascertaining the presence of."

D. "An Electroactive Reaction Product"

Claim Term	Plaintiffs' Construction	Defendants' Construction
"electroactive reaction product"	A chemical compound produced during a reaction that is capable of donating or receiving electrons to an electrode under appropriate conditions.	The product resulting from the reaction of the glucose and the reagent [an enzyme and a mediator] during the open circuit or delay period.

For two reasons, the Court will not adopt Defendants' proposed construction. First, for the reasons set forth above, the Court will not construe the claims to require a "delay period." Second, to the extent Defendants' proposed construction requires that the "electroactive reaction product" arise from the "reaction of the glucose and the reagent," the Court concludes that this language is superfluous in light of the explicit claim language calling for "the reagent reacting with glucose to produce an electroactive reaction product." See, e.g., '146 patent at Claim 1. Likewise, with regard to Plaintiffs' proposed

construction, the Court sees no evidence that the phrase "under appropriate conditions" would illuminate the meaning of this claim term to one of skill in the art. Accordingly, the Court will construe the term "electroactive reaction product" to mean "a chemical compound produced during a reaction that is capable of donating or receiving electrons to an electrode."

E. "Following Said Detecting, Applying Or Controlling The Voltage"

Claim Term	Plaintiffs' Construction	Defendants' Construction
"following said detecting, applying or controlling the voltage"	No construction necessary.	Re-applying the DC voltage [after an open circuit or delay period].

Defendants' proposed construction is, in part, another effort to introduce a "delay period" limitation into the claims. However, for the reasons stated above, the Court concludes that the claims are not limited to the use of a "delay period."

Furthermore, as Plaintiffs note, dependent claims of both the '146 and '147 patent include an explicit limitation that calls for "reapplying a potential." See, '146 patent at Claim 58; '147 patent at Claim 64. Thus, as above, the doctrine of claim differentiation counsels against limiting all claims of the patents-in-suit to "re-applying the DC voltage." Finally, Defendants' proposed construction ignores that the claim language specifically refers to "applying or controlling" the voltage.

In other words, in proposing that the claims be limited to a "reapplication" of the DC voltage, Defendants are, in the Court's view, asking the Court to disregard that the claims specifically allow for "controlling" of the voltage in addition to "applying" of the voltage. Having concluded that the claims should not be limited in the manner proposed by Defendants, the Court further concludes that this term requires no further construction.

F. "Correlating The Electrooxidized Electroactive Reaction Product To The Concentration Of Glucose In The Blood Sample"

Claim Term	Plaintiffs' Construction	Defendants' Construction
"correlating the electrooxidized electroactive reaction product to the concentration of glucose in the blood sample"	Using a relationship between the electrooxidized reaction product and the concentration of glucose in blood.	Accurately determining the concentration of glucose in the blood sample.

Defendants contend that this claim term should be limited to the "accurate" determination of glucose concentration in the blood sample. However, the independent claims already specifically include the step of "determining . . . the glucose concentration in the blood sample." The Court sees no basis for introducing the vague and extraneous limitation that this process be done "accurately," whatever that might mean. Indeed, as Plaintiffs note, the term "accurately" has "no interpretive frame of reference in the specification, is too vague for

consideration, and would create new problems," including the possibility of a party attempting to introduce some statistical or commercial standard of "accuracy." (See, D.I. 380 at 26-27.) In these circumstances, Defendants' proposed limitation is not appropriate. See, Allen Eng'g Corp. v. Bartell Indus., 299 F.3d 1336, 1346-47 (Fed. Cir. 2002) (declining to interpret the preamble term "fast steering" as a claim limitation because it was a "relative term, and no interpretive frame of reference [was] provided in any of the claims or in the specification").

To the extent Defendants criticize Plaintiffs' construction for "cover[ing] only the 'relationship' between current and the result, but omit the 'result,'" (D.I. 379 at 21), the Court notes again that the claims specifically recite "determining . . . the glucose concentration in the blood sample." Thus, it is not necessary to, as Defendants request, construe this term to require "determining the concentration of glucose in the blood sample."

Accordingly, the Court will construe the claim term "correlating the electrooxidized electroactive reaction product to the concentration of glucose in the blood sample" to mean, as Plaintiffs contend, "using a relationship between the

electrooxidized reaction product and the concentration of glucose in blood."

G. "Providing A Readout Of The Glucose Concentration In The Blood Sample"

Claim Term	Plaintiffs' Construction	Defendants' Construction
"providing a readout of the glucose concentration in the blood sample"	An output indicating the concentration of glucose in the blood sample.	Displaying the blood glucose concentration on a device that can be read by the user.

Plaintiffs contend that Defendants are attempting to improperly "impose a 'display' and 'read by user' requirement."

(D.I. 397 at 32:21-23.) Plaintiffs assert - and the Court agrees - that "[t]he specification of the patents in suit does not expressly define the term 'readout.'" (D.I. 357 at 31.)

Accordingly, Plaintiffs purport to draw their proposed construction from a number of general purpose dictionary definitions, which is not inappropriate. See, Mass. Inst. of

Tech. v. Abacus Software, 462 F.3d 1344, 1351 (Fed. Cir. 2006)

(where the specification failed to define a claim term, explaining that "it is appropriate . . . to look to dictionary definitions of the terms").

However, on reviewing Plaintiffs' dictionary definitions, the Court concludes that they actually tend to support

Defendants' proposed construction. For instance, Plaintiffs note

that the Oxford English Dictionary defines "readout" as "[t]he display of data by an automatic device in an understandable form." (Id. (citing Oxford English Dictionary Online, Oxford University Press 2008 (emphasis added)).) Similarly, Plaintiffs point out that WordNet, a lexical database of English, provides that "readout" means "1. the output of a computer in readable form; 2. the information displayed or recorded as an electronic device; and 3. an electronic device the displays information is a visual form." (Id. at 32 (citing WordNet 3.0, http://wordnet.princeton.edu/ (emphasis added)).) Referring to "understandable" and "readable" forms and the use of "devices" that "display," the Court concludes that Plaintiffs' dictionary definitions comport most closely with Defendants' proposed construction for this claim term. And, in the Court's view, these definitions also comport with the plain and ordinary meaning of "readout." Accordingly, the Court will construe the claim term "providing a readout of the glucose concentration in the blood sample" to mean, as Defendants contend, "displaying the blood glucose concentration on a device that can be read by the user."

H. "Providing A Disposable Biosensor Test Strip"

Claim Term	Plaintiffs' Construction	Defendants' Construction
"providing a disposable biosensor test strip including a capillary chamber having a depth suitable for capillary flow of blood and holding a volume of between about 0.1 µL and about 1.0 µL of the blood sample"	Providing a disposable biosensor test strip including a capillary chamber having a depth suitable for (i) directing blood sample by capillary action and (ii) holding between 0.09 µL and about 1.1 µL of blood sample.	No construction necessary.
"providing a disposable biosensor test strip including a capillary chamber having a depth suitable for capillary flow of blood and holding a volume of less than about 1.0 µL of the blood sample"	Providing a disposable biosensor test strip including a capillary chamber having a depth suitable for (i) directing blood sample by capillary action and (ii) holding less than 1.1 µL of blood sample.	No construction necessary.

The Court agrees with Defendants that these terms require no construction. With regard to the "capillary flow of blood" limitation, Plaintiffs' proposed construction simply paraphrases this as "directing blood sample by capillary action" but otherwise offers no insight as to the meaning of this term to one of skill in the art. As to the meaning of the word "about" in

this claim term, the Court notes that it addresses this issue elsewhere in this Memorandum Opinion. See, infra.

I. Claim Terms Using The Word "About"

Claim Term	Plaintiffs' Construction	Defendants' Construction
"less than about 5 seconds"	Less than 6 seconds.	No construction necessary.
"less than about 8 seconds"	Less than 9 seconds.	No construction necessary.
"about 4 seconds"	Between 3 and 5 seconds.	No construction necessary.
"about 3.5 to 8 seconds"	Between 3 and 9 seconds.	No construction necessary.
"about 1.0 µL of the blood sample"	Less than 1.1 µL of blood sample.	No construction necessary.
"between about 0.1 µL and about 1.0 µL of the blood sample"	Between 0.09 µL and about 1.1 µL of blood sample.	No construction necessary.

With respect to claim terms using the word "about" that refer to the volume of the blood sample, Plaintiffs contend that "nothing in the intrinsic evidence suggests either a particularly broad or a particularly narrow construction of the term 'about'". Plaintiffs further contend that "[t]he only real guidance within the specification or claims for any particular range of values for the volumes comes from the structure of the claims themselves and the number places to which the volume is given." (D.I. 357)

at 20.) Thus, as an example, Plaintiffs suggest that it is "reasonable" to extend a claimed range of "about" 0.1 to 1.0 μ L to 0.09 to 1.1 μ L. (See, id.) Plaintiffs do not appear to cite any cases in which either the Federal Circuit or a district court has adopted this mode of analysis to construe the term "about." With regard to the claim terms using the word about that refer to test times, Plaintiffs make similar arguments. (See, id. at 34-36.)

In passing, Plaintiffs do direct the Court to the Federal Circuit decision Ortho-McNeil Pharm., Inc. v. Caraco Pharm.

Labs., Ltd., 476 F.3d 1321, 1327-28 (Fed. Cir. 2007). There the Federal Circuit affirmed a district court that, based in part on the statistical analysis of an expert, construed the claim term "about" to a specific numerical range. However, in the Court's view, Ortho-McNeil is not helpful here, mainly because Plaintiffs do not provide the Court with the type of expert witness testimony that was significant in Ortho-McNeil. Furthermore, in Ortho-McNeil, the Federal Circuit engaged in a careful analysis of the specification and a comparison of multiple claims, which bolstered the construction suggested by the extrinsic evidence.

See, Ortho-McNeil, 476 F.3d at 1327-28. Here, Plaintiffs have provided no such analysis, but instead, as explained above, appear to suggest that such an analysis would be futile due to a

lack of probative evidence in the internal record. (See, D.I. 357 at 20.)

In these circumstances, the Court concludes that the term "about" should simply be given its ordinary and accepted meaning of "approximately." See, Merck & Co. v. Teva Pharms. USA, Inc., 395 F.3d 1364, 1372 (Fed. Cir. 2005) (where, inter alia, "the patentee did not clearly redefine 'about' in the specification," holding "that the term 'about' should be given its ordinary and accepted meaning of 'approximately.'"); Unigene Labs., Inc. v. Apotex Inc., No. 06 CV. 5571 (RPP), 2008 U.S. Dist. LEXIS 66005, at *26-*27 (S.D.N.Y. Aug. 28, 2008) ("Without evidence, either intrinsic or extrinsic, that would provide a basis for construing the numerical limits of the term 'about 20 mM citric acid' in claim 19 of the '392 patent, the Court gives the word 'about' its ordinary meaning of 'approximately' and construes the claim term no further.").

J. "Determining"

Claim Term	Plaintiffs' Construction	Defendants' Construction
"determining"	Providing an indication of.	No construction necessary.

Plaintiffs contend that although the specification does not define "determining," it provides examples "illustrative of the meaning [of 'determining'] consistent with [its] proposed

definition." (D.I. 357 at 30.) For instance, Plaintiffs point out that the specification explains that electrodes can be used to "indicate the presence or concentration of certain chemical species." (Id. (citing '147 patent at 1:28-31).) Defendants respond that this evidence provides no insight as to the meaning of "determining" to one of skill in the art. In addition, Defendants note that if Plaintiffs' proposed construction is substituted into the claim, the claim would have the following odd reading: "within 10 seconds of said detecting [providing an indication of] and providing a readout of the glucose in the blood sample." (D.I. 379 at 20.) Thus, Defendants contend that Plaintiffs' proposed construction would introduce redundancies into the claim by requiring both "an indication of" and a "readout" of the glucose level.

The Court agrees with Defendants that there is nothing in the intrinsic record suggesting that the word "determining" should be construed according to Plaintiffs' proposed construction. More importantly, in the Court's view, Plaintiffs have not explained how their proposed construction is necessary to assist one of skill in the art in understanding the claims. Rather, Plaintiffs' proposed construction appears to be nothing more than an unnecessary paraphrasing of the ordinary word "determine." Accordingly, the Court agrees with Defendants that this term requires no additional construction. See, U.S.

Surgical Corp. v. Ethicon, Inc., 103 F.3d 1554, 1568 (Fed. Cir. 1997) ("Claim construction is a matter of resolution of disputed meanings and technical scope, to clarify and when necessary explain what the patentee covered by the claims, for use in the determination of infringement. It is not an obligatory exercise in redundancy.").

K. "Electrooxidize"

Claim Term	Plaintiffs' Construction	Defendants' Construction
"electrooxidize"	To cause a molecule or atom to donate at least one electron at an electrode.	

Plaintiffs note that the specifications of the patents-insuit explain that "oxidized" means "donates at least one electron." (D.I. 357 at 29 (citing '147 patent at 7:28-38).)

Thus, according to Plaintiffs, "electro-oxidized" is "merely an oxidation reaction that occurs at an electrode." (Id.)

Defendants agree that "oxidize" means "to donate at least one electron," but object to Plaintiffs' proposed construction as being too broad for its failure to mention the use of a "delay period." Defendants further object to Plaintiffs' proposed construction because "[t]he claims do not recite electrooxidizing 'a molecule or atom'; the claims recite electro-oxidation of the electroactive reaction product."

The Court will not adopt either parties' proposed construction. To the extent Plaintiffs propose that electrooxidize be limited to "a molecule or atom," the Court will not adopt Plaintiffs' proposed construction. Indeed, the Court sees no reason why a cluster of loosely bound atoms or molecules could not be the subject of an electrooxidation. However, the Court will adopt the remainder of Plaintiffs' proposed construction. As noted, the parties agree that "oxidize" refers to the donation of an electron. Furthermore, the specification indicates that "electrooxidation" does indeed take place at an electrode. See, e.g., '146 patent at 7:35-36 ("electrooxidation of the mediator at the working electrode"); id. at 8:7 ("Mediator electroxidized at the working electrode"); id. at 8:10-12 ("oxidized mediator reduced at the counter electrode can migrate to the working electrode for electrooxidation"). Finally, although Defendants object that Plaintiffs' proposed construction fails to refer to a "delay period," the Court has, as explained above, concluded that the claims do not require a "delay period." Accordingly, the Court will construe the term "electrooxidize" to mean "to donate at least one electron at an electrode."

CONCLUSION

For the reasons discussed, the Court has construed the disputed terms and/or phrases of the patents-in-suit as provided herein. An Order consistent with this Memorandum Opinion will be

entered setting forth the meanings of the disputed terms and/or phrases in the patents-in-suit.

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

ROCHE DIAGNOSTICS OPERATIONS, : INC. and CORANGE :

INTERNATIONAL LIMITED,

Plaintiffs,

v. : Civil Action No. 07-753-JJF

ABBOTT DIABETES CARE and ABBOTT DIABETES CARE SALES CORPORAITION, et al.,

Defendants.

ORDER

At Wilmington, this 10 day of September 2009, for the reasons discussed in the Memorandum Opinion issued this date;

IT IS HEREBY ORDERED that the following terms and/or phrases in United States Patent Nos. 7,276,146 ("the '146 patent") and 7,276,147 ("the '147 patent") are assigned the following meanings:

- 1. The term "working electrode" means "a working microelectrode having a width of 15 μm up to approximately 100 μm ."
- 2. The term "reference electrode" means "a reference microelectrode having a width of 15 μm up to approximately 100 μm ."
- 3. The term "counter electrode" means "a counter microelectrode having a width of 15 μm up to approximately 100

μm."

- 4. The term "capillary chamber" means "a space or channel that is defined over the electrodes that directs flow of the blood sample over the electrodes."
- 5. The term "detecting" means "discovering or ascertaining the presence of."
- 6. The term "electroactive reaction product" means "a chemical compound produced during a reaction that is capable of donating or receiving electrons to an electrode."
- 7. The term "following said detecting, applying or controlling the voltage" requires no further construction.
- 8. The term "correlating the electrooxidized electroactive reaction product to the concentration of glucose in the blood sample" means "using a relationship between the electrooxidized reaction product and the concentration of glucose in blood."
- 9. The term "providing a readout of the glucose concentration in the blood sample" means "displaying the blood glucose concentration on a device that can be read by the user."
- 10. The term "providing a disposable biosensor test strip including a capillary chamber having a depth suitable for capillary flow of blood and holding a volume of between about 0.1 µl and about 1.0 µL of the blood sample" means "providing a disposable biosensor test strip including a capillary chamber having a depth suitable for capillary flow of blood and holding a

volume of between approximately 0.1 μL and approximately 1.0 μL of the blood sample."

- 11. The term "providing a disposable biosensor test strip including a capillary chamber having a depth suitable for capillary flow of blood and holding a volume of less than approximately 1.0 µL of the blood sample" means "providing a disposable biosensor test strip including a capillary chamber having a depth suitable for capillary flow of blood and holding a volume of less than approximately 1.0 µL of the blood sample."
- 12. The term "less than about 5 seconds" means "less than approximately 5 seconds."
- 13. The term "less than about 8 seconds" means "less than approximately 8 seconds."
- 14. The term "about 4 seconds" means "approximately 4 seconds."
- 15. The term "about 3.5 to 8 seconds" means "approximately 3.5 to 8 seconds."
- 16. The term "determining" requires no further construction.
- 17. The term "electrooxidize" means "to donate at least one electron at an electrode."

UNITED STATES DISTRICT JUDGE