IP 04-0358-C M/S Roche v Apex
Judge Larry J. McKinney Signed on 09/26/05

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ROCHE DIAGNOSTICS CORPORATION, ROCHE DIAGNOSTICS OPERATIONS, INC., CORANGE INTERNATIONAL LTD.,	)	
Plaintiffs,	)	
vs.	)	NO. 1:04-cv-00358-LJM-VSS
APEX BIOTECHNOLOGY CORP, HYPOGUARD USA, INC., MEDLINE INDUSTRIES, INC., HOME DIAGNOSTICS, INC.,	)	
Defendants.	)	

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ROCHE DIAGNOSTICS CORPORATION, ROCHE DIAGNOSTICS OPERATIONS, INC., and CORANGE INTERNATIONAL, LTD., Plaintiffs, vs. APEX BIOTECHNOLOGY CORP., HYPOGUARD USA, INC., MEDLINE, INDUSTRIES, INC., and HOME DIAGNOSTICS, INC., Defendants,	)	1:04-cv-00358-LJM-VSS
	)	1:04-cv-01187-LJM-VSS
ROCHE DIAGNOSTICS CORPORATION, ROCHE DIAGNOSTICS OPERATIONS, INC., ROCHE DIAGNOSTICS GMBH, and CORANGE INTERNATIONAL, LTD., Plaintiffs, vs. BIOSITE INCORPORATED, Defendant.	)	1:04-cv-01848-LJM-VSS

ORDER ON CLAIM CONSTRUCTION

On August 1, 2005, the Court held a hearing to assist it with construction of the claim language of the patent at issue in this infringement suit, U.S. Patent No. 5,366,609 (the "'609 patent"). Guided by the Supreme Court's opinion in *Markman v. Westview Inst., Inc.*, 517 U.S. 370, 388-90 (1996) ("*Markman II*"), and by the Federal Circuit's opinions in *Markman v. Westview Inst., Inc.*, 52 F.3d 967 (Fed. Cir. 1995) ("*Markman I*") and *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005), 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 Int'l 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). The parties in these suits, plaintiffs, Roche Diagnostics Corporation, Roche Diagnostics Operations, Inc., Roche Diagnostics GmbH, and Corange International, Ltd. (collectively, "Roche"), and defendants, Apex Biotechnology Corp., Hypoguard USA, Inc., Medline Industries, Inc., (collectively, "Apex Defendants"), Home Diagnostics, Inc. ("HDI") (these defendants collectively, "Apex/HDI"), and Biosite Incorporated ("Biosite") (all defendants collectively "Defendants"), have narrowed the terms in dispute in the only claim at issue, claim 1.

The Court notes that at the claim construction hearing, all the parties referenced certain aspects of the allegedly infringing devices. The Court will not use these references to construe the claims of the '609 patent as to do so is improper. *See SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1118 (Fed. Cir. 1985); *see also Ferguson Beauregard/Logic Controls, Div. of Dover Res., Inc. v. Mega Sys., LLC*, 350 F.3d 1327, 1340 (Fed. Cir. 2003) (citing *SRI International* for the same proposition). In other words, the Court will ascertain what the claims include rather than what they exclude.

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

I. CLAIM CONSTRUCTION STANDARDS

When construing the '269 patent's claims, the Court must determine the meaning of the language used before it can ascertain the scope of the claims Roche asserts are 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 Phillips*, 415 F.3d at 1313; *Innova/Pure Water v. Safari Water Filtration*, 381 F.3d 1111, 1116 (Fed. Cir. 2004). 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 Phillips*, 415 F.3d at 1314; *Ecolab, Inc. v. Envirochem, Inc.*, 264 F.3d 1358, 1366 (Fed. Cir. 2001); *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.

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 (citing 35 U.S.C. § 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 Phillips*, 415 F.3d at 1314; *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 977 (Fed. Cir. 1999); *see also Renishaw PLC v. Marposs Societa' Per Azioni*, 158 F.3d 1243, 1248 (Fed. Cir. 1998). As the Federal Circuit has 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 Phillips*, 415 F.3d at 1314 (citing *Brown v. 3M*, 265 F.3d 1349, 1352 (Fed. Cir. 2001)). 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 Phillips*, 415 F.3d at 1315-17 (discussing the role of the specification in claim construction).

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." *Renishaw*, 158 F.3d at 1250. *See also Phillips*, 415 F.3d at 1316. 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 Phillips*, 415 F.3d at 1313-14; *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. § ¶112, ¶ 1. *See also Phillips*, 415 F.3d at 1312, 1315; *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.

In addition, a patentee may be his or her own lexicographer and use terms in a manner different from their ordinary meaning. *See Phillips*, 415 F.3d at 1316; *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 Phillips*, 415 F.3d at 1316 (citing *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002)). The specification then serves as a dictionary when it defines terms, either expressly or by implication, that are used in the claims.

Although claims must be read in light of the specification, limitations from the specification may not be read into the claims.[1] *See Phillips*, 415 F.3d at 1323; *Comark*, 156 F.3d at 1186. In particular, the Court should not limit the invention to the specific examples or preferred embodiment

[1]An exception to this rule applies when the claim is written in a means- or step-plus-function format under 35 U.S.C. § 112, ¶ 6. The rules of claim construction relative to those types of claims are discussed later herein.

found in the specification. *See Phillips*, 415 F.3d at 1323; *Texas Instruments, Inc. v. United States Int'l Trade Comm'n*, 805 F.2d 1558, 1563 (Fed. Cir. 1986). 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 Corp. v. NEC Corp.*, 163 F.3d 1342, 1348 (Fed. Cir. 1998). *See also Phillips*, 415 F.3d at 1323 (describing how to distinguish between a best mode disclosure and a limitation disclosure in a specification).

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) (further citation omitted by *Intervet* court)). *See also Innova/Pure Water*, 381 F.3d at 1117. 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 Phillips*, 415 F.3d at 1323; *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 Phillips*, 415 F.3d at 1323-24; *Innova/Pure Water*, 381 F.3d at 1117.

The third source of intrinsic evidence is the '269 patent's prosecution history. *See Phillips*, 415 F.3d at 1317; *Desper Prods.*, 156 F.3d at 1336-37; *Vitronics*, 90 F.3d at 1582. 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 Phillips*, 415 F.3d at 1317; *Ecolab*, 264 F.3d at 1368. 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).

In some cases, it may be necessary for the Court to consult extrinsic evidence to aid it in construing the claim language. *See Phillips*, 415 F.3d at 1317; *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 Phillips*, 415 F.3d at 1317. 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, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (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. *See also Phillips*, 415 F.3d at 1318. 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 the only one clearly supported by the intrinsic evidence. *See Digital Biometrics v. Identix*, 149 F.3d 1335, 1344 (Fed. Cir. 1998); *see also Phillips*, 415 F.3d at 1317-19 (discussing the proper use of extrinsic evidence). 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).

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*. The Federal Circuit affirmed this approach in *Phillips*. 415 F.3d at 1322-23.

At least one claim term disputed by the parties is written in means-plus-function format pursuant to 35 U.S.C. § 112, ¶ 6. Claim elements of the '609 patent that are written in a means-plus-function format under 35 U.S.C. § 112, ¶ 6 require special rules of construction. When a patentee uses such an element, he or she is subject to the following statutory provision:

> [a]n element in a claim for a combination may be expressed as a means . . . for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specifications and equivalents thereof.

35 U.S.C. § 112, ¶ 6. *See also Mas-Hamilton Group v. LaGard, Inc.*, 156 F.3d 1206, 1211 (Fed. Cir. 1998).

For an element in a means-plus-function format, the "means" term "is essentially a generic reference for the corresponding structure disclosed in the specification." *Chiuminatta Concrete Concepts v. Cardinal Indus.*, 145 F.3d 1303, 1308 (Fed. Cir. 1998). *See also Mas-Hamilton Group*, 156 F.3d at 1211 (quoting *Chiuminatta Concrete Concepts*, 145 F.3d at 1308). By using this format, a patentee is allowed to claim a function without expressing all of the possible means of

accomplishing that function. *See O.I. Corp. v. Tekmar Co.*, 115 F.3d 1576, 1583 (Fed. Cir. 1997). "The price that must be paid for use of that convenience is limitation of the claim to the means [or acts] specified in the written description and equivalents thereof." *Id.*

Thus, a claim expressed in means-plus-function language constitutes an exception to the rule that prohibits reading limitations from the specification into the claims. *See Valmont Indus., Inc. v. Reinke Mfg. Co.*, 983 F.2d 1039, 1042 (Fed. Cir. 1993). When dealing with a means-plus-function claim, specific alternative structures to accomplish the function mentioned in the specifications, and equivalents thereto, delineate the scope of the patent claim. *See Mas-Hamilton Group*, 156 F.3d at 1211; *Serrano v. Telular Corp.*, 111 F.3d 1578, 1583 (Fed. Cir. 1997). The alternative structures must be specifically identified, not just mentioned as possibilities, in order to be included in the patent claim's scope. *See Fonar Corp. v. Gen. Elec. Co.*, 107 F.3d 1543, 1551 (Fed. Cir.), *cert. denied*, 522 U.S. 908 (1997).

Having set forth the proper claim construction standards, the Court construes the disputed terms as follows:

II. DISCUSSION

The '609 patent is entitled "Biosensing Meter with Pluggable Memory Key." The patent cites three objects, or purposes: 1) "provide a biosensing meter with a pluggable memory module that enables substantial reconfiguration of test procedures and parameters employed by the meter," '609 Patent, col. 3, *ll.* 19-22; 2) "provide a biosensing meter with a pluggable memory module that enables threshold potentials, test times, delay periods and other pertinent test procedures and constants to be inserted and/or altered," *id.* col. 3, *ll.* 23-27; and 3) "provide a biosensing meter with a pluggable read only memory wherein data read from the read only memory at sequential times

during the use of the meter enables a determination to be made as to whether the read only memory has been switched during a test procedure." *Id.* col. 3, *ll.* 28-33.

Claim 1 of the '609 patent is the only claim at issue.[2] It reads:

> 1. A biosensing meter for receiving a sample strip that includes a sample well with an analyte reactant therein, said biosensing meter comprising:
>
> sense means for outputting signals indicative of manifestations of a reaction in said sample well between an analyte-containing fluid and said analyte reactant;
>
> pluggable memory key means for insertion into an electrical receptacle in said meter, said pluggable memory key means including a plurality of stored parameter values and procedure routine specifications that are employed in controlling execution of an algorithm performed by said meter that enables determination of an analyte concentration value, said procedure routine specifications including stored values from which time values can be determined for controlling said sense means during execution of said algorithm; and
>
> processor means coupled to said memory key means and responsive to parameter values and procedure routine specifications accessed from said pluggable memory key means, for controlling operation of said sense means in accordance with said algorithm and for calculating from signal outputs from said sense means a concentration value of an analyte in said analyte-containing fluid in said sample well.

'609 Patent, col. 8, *l.* 54 to col. 9, *l.* 11. The disputed terms in claim 1 are: "sample well," "sense means," "pluggable memory key means," "parameter values," "procedure routine specifications," and "processor means coupled to." The Court addresses each in turn.

A. "SAMPLE WELL"

Roche contends that "sample well" means: "the reaction zone, *i.e.*, a reservoir, or other structure or area, that receives a sample fluid." The crux of Roche's argument that the "sample well" is simply the reaction zone is because that is how "sample well" is referred to in the

[2]Roche asserts claim 2 against Biosite, however, there is no dispute about the terms therein.

specification of the '609 patent. The patent states in the Background of the Invention section: "Biosensing instruments used for the detection of analyte levels in blood (such as glucose and cholesterol) often employ disposable sample strips that include a well or reaction zone for receiving a blood sample." *Id.* col. 1, *ll.* 13-16. Moreover, the patent teaches: "Sample strip **18** contains a well **20** (i.e., a reaction zone) . . . ." *Id.* col. 4, *ll.* 31-32.

Although Apex Defendants take no position on this term, HDI contends that "sample well" means: "a well, *i.e.*, an open-topped container or reservoir into which an analyte-containing fluid is emplaced." HDI finds support for the "sample well" to have an open top in Figure 3, and in the following passage from the specification: "[A] glucose determination is made by initially emplacing in well **20**, a sample of blood." *Id.* col. 5, *ll.* 48-50. Figure 3 shows an example of a sample strip inserted into a meter. HDI also supports its construction for the term "sample well" with the testimony of its expert, Professor Anthony P.F. Turner ("Dr. Turner"), who opines about the difference between a "well," which requires only one opening, and "contemporary capillary-fill devices," which require a second aperture to allow air to escape. Turner Rep. ¶ 36. Dr. Bruce K. Gale ("Dr. Gale"), also testified that he would not describe a "microfluidic channel" as a "well," apparently to distinguish one of the allegedly infringing devices. Gale Dep. at 148.

Similarly to HDI, Biosite contends that "sample well" means: "a chamber or other discrete space in a device defining a container or reservoir into which an analyte-containing fluid sample is emplaced." Biosite also wants to include other parameters in this definition: "In claim 1 of the '609 patent, the sample well is required to contain an analyte reactant, and further required to be the location in which reactions occur between the analyte-containing fluid sample and the analyte reactant." In other words, Biosite contends that the proper construction for "sample well" includes the specification that the "sample well" "must contain an analyte reactant and be the location where

reactions occur." Biosite Br. at 35 n.13. The Court finds that the later requirements are unnecessary given the recitation of these elements in claim 1 itself. In other words, "sample well" need not be further defined by what occurs there or what is contained there, because the remainder of claim 1 has elements that explicitly state what is required. Moreover, other claims also use the term and also clearly state the requirements of the "sample cell." *See* '609 Patent, claims 4 & 6.

The Court finds that the proper definition for "sample well" is "a container or reservoir for the sample," which best comports with the plain meaning of the term in the '609 patent. Beginning with the claims of the '609 patent the term "sample well" appears in four independent claims of the patent, claims 1, 4, 6, and 12. The plain meaning of the term in the context of those claims is a reservoir or container for a sample. There is no reason to interpret the term "sample well" to include limitations that appear otherwise in the claims. All of the independent claims particularly describe the contents of or the purpose for the "sample well" of that claim. For example, claim 4 states, that the sample strip "includes a sample well with an analyte reactant therein" and that a current output occurs at a second electrode on the sample strip "when an analyte containing fluid is present in said sample well . . . ." '609 Patent, col. 9, *ll.* And, claim 6 requires that the sample strip include "excitation and sense electrodes and a sample well bridging thereacross [sic], said sample well including an analyte reactant . . . ." *Id.* col. 10, *ll.* 7-9. *See also,* col. 11, *l.* 23 to col. 12, *l.* 6 (claim 12). In other words, adding to the plain meaning of "well" what must also be included therein or what must happen therein is redundant.

The specification also supports a plain meaning definition for "sample well." The '609 patent teaches that the invention includes a meter that "is enabled to receive a sample strip that includes a sample well . . . ." '609 Patent, Abstract. Further, in the abstract the '609 patent teaches that the meter senses a current from the sample strip "when an analyte containing fluid is present

in the strip's sample well." *Id.* Both usages are repeated in the Summary of the Invention section of the patent. *See id.* col. 3, *ll.* 36-45. Neither one of these usages require that the sample well have an open top nor do they require that the sample be "emplaced" therein. Both merely require that the well exist and that the meter sense when fluid or a sample is present in the well.

Another section of the '609 patent that describes the "sample well" states: "Sample strip **18** contains a well **20** (i.e. reaction zone) that encompasses a pair of conductive electrodes **24** and **26**. A layer (not shown) of enzymatic reactants overlays electrodes **24** and **26** in well **20** and provides a substrate on which an analyte-containing fluid sample may be emplaced." *Id.* col. 4, *ll.* 31-36. The '609 patent also teaches that "a glucose determination is made by initially emplacing in well **20**, a sample of blood." *Id.* col. 5, *ll.* 48-50. A similar description is also found later in another section of the Detailed Description of the Invention. That description states, in relevant part:

> If the leakage current (sensed by sense amplifier **50** and fed to microprocessor **59** via A/D converter **52**) is found to be less than a threshold (key), microprocessor **59** indicates via display **12**, that the user may apply a drop of blood to well **20**. . . .
>
> . . . Time delay d enables the drop of blood to entirely wet the enzyme layer within well **20**. If the voltage senses at time **70** is below a sample size threshold **72** (key), the test is aborted as the volume of blood is determined to be insufficient to assure complete hydration of enzymatic reactants within well **20**.

'609 Patent, col. 6, *ll.* 41-68 to col. 7, *l.* 1. These descriptions also use the term "well" to mean a container or reservoir for the sample.

In the first description, the patent provides an example description of the well - "a reaction zone" - however, this is just an example, as indicated by the "i.e." before the term "a reaction zone." *Id.* col. 4, *l.* 32. Moreover, there is no indication in the claims or elsewhere in the patent that the construction of the term "sample well" should be narrowed to "reaction zone." The same section also uses the word "emplaced," which both HDI and Biosite contend limits the term "sample well,"

similarly to the requirement at column 5 where the process of measurement requires emplacing blood int the well. There is nothing in these descriptions, however, that limit the term "well" to require what is put inside the well. In other words, adding a phrase defining what is emplaced in the well to the definition of well unnecessary imports a requirement from the specification into the claim.

Moreover, a close reading of the specification teaches that the sample may be emplaced on a substrate in the well, *id.* col. 4, *ll.* 35-36, not that the sample is emplaced in the well. In other words, it is possible for the sample to be carried to the well, container, or reservoir, through a substrate or other means that wicks the fluid to the well. Furthermore, the patent clearly teaches that the emplacement is not mandatory by using "may" rather than "shall." Similarly, in the last passage quoted above, it is clear that the sample reaches some reactant layer within the well, however, there is no language that would limit the plain meaning of the term well either to have an open top or to have the sample emplaced therein.

For these reasons, there is nothing in these passages that convinces the Court that the inventors intended to limit the plain meaning of the term "sample well." The Court finds that the term "sample well" means: a container or reservoir for the sample.

B. SENSE MEANS

The second term disputed by the parties is "sense means," which the parties agree is written in means-plus-function language. The entire phrase that includes the disputed terms reads: "sense means for outputting signals indicative of manifestations of a reaction in said sample well between an analyte-containing fluid and said analyte reactant . . . ." The parties agree on the essential

function of the "sense means:" to output[3] signals indicative of the manifestation of a reaction in the sample well between an analyte-containing fluid and said analyte reactant. The Court does not disagree with this analysis. Although the parties agree on some structure of the "sense means" including the electrical contact 48, and the sense amplifier 50, the parties disagree on several other aspects of the structure of the sense means. Defendants contend that in addition to electrical contact 48 and sense amplifier 50, the "sense means" includes sense electrode 26, and must include the structure of sense amplifier 50 that is described in Figure 7 and no equivalents. Biosite argues that in addition to those requirements, the "sense means" includes excitation voltage source 44. In contrast to Defendants' contentions, Roche argues that the "sense means" includes electrical contact 48 and sense amplifier 50 as well as the A/D converter 52.

The Court finds that the structure that corresponds to the function "to output signals indicative of manifestations of a reaction in said sample well . . ." of the "sense means" is: electrical contact 38, sense amplifier 50, and the A/D converter 52, and equivalents thereof. The specification teaches that "[a] sense amplifier is . . . provided . . . [to] produce[] an output signal indicative of sensed currents when an analyte containing fluid is present in the strip's sample well." '609 patent, col. 3, *ll.* 40-45. The specification also teaches that a "microprocessor controls the sense amplifier to provide a plurality of signal outputs over a predetermined duration, the sense amplifier being operated under control of specific parameter values . . . ." *Id.* col. 3, *ll.* 54-58. The specification continues: "A contact **48** enables a potential appearing on electrode **26** to be fed to a sense amplifier **50** whose output, in turn, is fed to an analog-to-digital converter (A/D) **52**." *Id.* col. 4, *ll.* 63-65.

[3]Roche also construes the term "output," and defines it as "to put out" or "produce." Pl.'s Cl. Constr. Br. at 29. None of the defendants dispute this definition, however, the Court finds there is no reason to further define the function because the term "output" is clear.

These passages clearly link the electrical contact and the sense amplifier to the function of outputting signals of sensed currents from the sample strip. In addition, the specification teaches that after an excitation voltage is applied to the sample strip and causes a reverse reaction, the current produced "is sensed at sense electrode **26** by sense amplifier **50**. . . . The sense current measurements enable a glucose determination to be made . . . ." *Id.* col. 7, *ll.* 12-28. In other words, the output from the sense amplifier allows the meter to calculate the amount of glucose in the sample. This passage connects the current produced by the reverse reaction to the sense amplifier as the means for outputting the data necessary to determine the analyte concentration in the sample.

The other claims of the '609 patent also support the Court's construction for the structure of the "sense means" as three other independent claims clearly identify the "sense amplifier means" as the structure that produces output indicative of current at the second, or sense, electrode. *See id.* col. 9, *ll.* 41-46 (claim 4); *id.* col. 10, *ll.* 13-18 (claim 6); *id.* col. 12, *ll.* 1-4 (claim 11).

Apex/HDI would have the Court limit the structure of the "sense means" to the description of the sense amplifier found at column 7, lines 51 to 65, and drawn in Figure 7. The patent reads:

> In FIG. **7**, a circuit diagram is shown of sense amp **50** and includes an operational amplifier **100** having an input connected via contact **48** to sense electrode **26**. A feedback resistance **102** provides normal gain control for operational amplifier **100** and is shunted by a much lower resistance **104** and a switch **106**. During the delay measurement interval (key), a microprocessor **59** causes switch **106** to be closed thereby shunting amplifier **100** with resistor **104**. This action prevents saturation of amplifier **100** during the period when the Cottrell current exceeds a maximum measurable current level (key). Subsequent to the delay measurement times, microprocessor **59** causes switch **106** to open so that operational amplifier **100** exhibits its normal gain characteristic and enables measurements **82**, **84**, etc. to be taken.

Id. col. 7, *ll.* 51-65. Apex/HDI rely upon cases that require a clear link in the specification between the structure of a means-plus-function term and the function to support its argument. *See* Apex

Defs.' Br. at 26-27 (citing *Med. Instr. & Diag. Corp. v. Elekta AB*, 344 F.3d 1205, 1212 (Fed. Cir. 2003); *Tex. Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1213 (Fed. Cir. 2002); *B. Braun Med. Inc. v. Abbott Labs.*, 124 F.3d 1419, 1424 (Fed. Cir. 1997)). Although the Court agrees that the sense amplifier and its corresponding description in the '609 patent is the structure that is clearly linked to the function of the "sense means" the Court is unwilling to limit the structure to that disclosed by Figure 7, without equivalents. There is nothing in the cases cited by Apex/HDI, or the prosecution history of the '609 patent, that would support eliminating "equivalents" from a proper construction of the disputed term. Those cases focus on the complete absence of a disclosed structure or the failure of a court to correctly limit the structure to the one disclosed in the patent specification, not whether or not equivalents should be eliminated. Section 112, ¶ 6, allows a patentee to include structural equivalents in the scope of a means-plus-function term. *See* 35 U.S.C. § 112, ¶ 6 (stating that means-plus-function terms "shall be construed to cover the corresponding structure, material, or acts described in the specifications *and equivalents thereof*" (emphasis added)); *Tex. Digital Sys.*, 308 F.3d at 1213-14 (discussing the correct structure for a particular term as described in the relevant specification including "equivalents thereof"). For this reason, to the extent that Apex/HDI mean to exclude equivalents from the structure of the "sense means," the Court rejects their argument.

Roche argues, and the Court agrees, that the A/D converter is part of the structure of the "sense means." Roche contends that because the specification requires that the output of the sense amplifier be sent to the A/D converter such that the A/D converter may transform the signal into something with which the "processor means" may communicate, the A/D converter is necessary structure to perform the "outputting" function. The patent reads: "A contact **48** enables a potential appearing on electrode **26** to be fed to a sense amplifier **50** whose output, in turn, is fed to an analog-

to-digital converter (A/D) **52**. . . . The output[] from A/D converter[] **52** . . . are applied to a bus **58** which provides communications between modules contained within biosensing meter **10**." *Id.* col. 4, *ll.* 62-68 to col. 5, *ll.* 1-2. Although the Court does not agree with Roche that the added function of "communicating" is necessary to properly interpret the structure for the "sense means," it is clear from the passage above, that the A/D converter **52** "outputs" the manifestation of the reaction that is fed to it by the sense amplifier. This connection is enough for the Court to conclude that the A/D converter is part of the structure of the "sense means."

Biosite would add elements to the structure of the "sense means" that are not clearly linked to the function of "outputting" in the specification. Biosite argues that without the excitation voltage source and the electrodes of the sample strip there would be no signal for the sense amplifier to output. Although the Court does not disagree that the system described by the '609 patent depends upon the excitation voltage to create the reaction in the sample that produces current, the specification does not require those structures for the "outputting" function of the sense means. In other words, those structures may play a role in creating the measured effect, however, the patent does not identify them as part of the structure that outputs "signals indicative of manifestations of a reaction in said sample well . . . ." As discussed by the *B. Braun Medical* court, only the structure that is clearly linked to the function recited in the claim is "corresponding structure" for purposes of § 112, ¶ 6. *B. Braun Med.*, 124 F.3d at 1424. In the '609 patent, the only structure clearly linked to the function of "outputting signals indicative of manifestations of a reaction in said sample well . . ." is the sense amplifier. The other structures identified by Biosite may "manifest[]" the reaction identified in the function, but they are not clearly linked in the specification to "outputting signals indicative" of such reaction as required by the claimed function. For this reason, the Court is unwilling to add the excitation voltage source and the electrodes of the sample strip to the structure

of the "sense means."[4]

In summary, the Court finds that "sense means" in the '609 patent is a means-plus-function term. The function of the "sense means" is: to output signals indicative of the manifestation of a reaction in the sample well between an analyte-containing fluid and said analyte reactant. The corresponding structure of the "sense means" is: the electrical contact 48, the sense amplifier 50 and the A/D converter 52, and equivalents thereof.

C. PLUGGABLE MEMORY KEY MEANS, PARAMETER VALUES & PROCEDURE ROUTINE SPECIFICATIONS

The Court construes the next three terms in a group because they all appear in the same element of claim 1 of the '609 patent. The element reads:

> pluggable memory key means for insertion into an electrical receptacle in said meter, said pluggable memory key means including a plurality of stored parameter values and procedure routine specifications that are employed in controlling execution of an algorithm performed by said meter that enables determination of an analyte concentration value, said procedure routine specifications including stored values from which time values can be determined for controlling said sense means during execution of said algorithm

'609 Patent, col. 8, *ll.* 61-68, to col. 9, *ll.* 1-3. Roche and Apex/HDI dispute whether the term "pluggable memory key means" is a means-plus-function term,[5] therefore the Court turns to that term first.

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[4]Biosite also argues that the '609 patent's passing reference to "other reaction sensing implementalities, e.g., optical means," '609 Patent, col. 8, *ll.* 48-49, is insufficient to identify the optical structural equivalent of the "sense means" identified by its construction for the term. Because the Court did not accept Biosite's construction for the term "sense means," the Court does not reach the merits of this argument; the construction of the term "sense means" as the Court has construed it clearly identifies the structure necessary to perform the function of that claim element.

[5]Biosite takes no position on the meaning of the term "pluggable memory key means."

1. Pluggable Memory Key Means

Roche contends that the term "pluggable memory key means" connotes sufficient structure such that § 112, ¶ 6 should not apply. Roche would construe the term as: a module containing memory that is "pluggable" (i.e., capable of repeatedly establishing and breaking electrical contact by insertion and removal). Roche Br. at 36. Apex/HDI contend that the term is written in means-plus-function language and should be construed using § 112, ¶ 6. Apex/HDI assert that the term's functions are 1) mating with an electrical receptacle in the meter and 2) storing parameter values and procedure routine specifications. Apex/HDI argue that the structure that corresponds to this function is: a ROM that is received by a meter that includes a programmable Read Only Memory chip containing stored parameter values and procedure routine specifications. Apex/HDI point to evidence that Roche intended for the PTO to interpret the term as a means-plus-function term in claim 5 to bolster their argument that Roche has failed to rebut the presumption that the language used for the term makes it a term subject to § 112, ¶ 6.

To determine whether or not a term that uses the word "means" should be construed pursuant to § 112, ¶ 6, "the focus is on whether the claim term recites no function corresponding to the means or recites sufficient structure or material for performing that function." *Apex Inc. v. Raritan Computer, Inc.*, 325 F.ed 1364, 1372 (Fed. Cir. 2003) (citing *Rodime PLC v. Seagate Tech., Inc.*, 174 F.3d 1294, 1302 (Fed. Cir. 1999)). The Court finds that the term "pluggable memory key means" has sufficient structure to fall outside the ambit of § 112, ¶ 6. There is no dispute between the parties that the term "pluggable" allows the memory key to be alternatively inserted and removed from the meter. Furthermore, there is no dispute between the parties that the "memory key" is a chip or module that contains data.

Apex/HDI contend that the prosecution history makes clear that the "pluggable memory key

means" is a means plus function term. However, as pointed out by Roche in its reply brief, the references cited by Apex/HDI all refer to claim 5. The prosecution history reads:

> Claim 5 specifically recites the operation of the processor means performing certain functions in relation to a CRC value read from the pluggable key means. . . . Applicants are unable to comprehend the basis for the inclusion of claims 5 and 16 in the rejection under 35 USC 112 [sic], fourth paragraph. Applicants respectfully submit that claims 5 and 16 are clearly proper dependent claims and fall well within the bounds of paragraph 6 of 35 USC 112 [sic]. Applicants further submit that the Examiner's statement at the bottom of page 6 of the official Office Action is in clear error when considering the recitations contained in the presently pending claims. For the record, the Examiner indicated as follows:
>
> > "The dependent limitations with respect to how the processor or pluggable memory key means is to be sued have not been given any patentable weight with respect to the apparatus limitations. Patentability of apparatus claims are dependent upon features not on how the particular feature is to be used. The claimed feature only need to be capable of performing the function". [sic]
>
> 35 USC 112 [sic], sixth paragraph provides a statutory basis for means plus function claims. Function recitations is [sic] means plus function claims limit how the "means" are to be used. Thus, by definition, the functional recitations contained in the pending claims are entitled to be given "patentable weight" and to be considered as defining Applicants [sic] invention in full conformance with 35 USC [sic]. Applicants respectfully submit the Examiner was in error in taking the above-noted position. Withdrawal of the rejection of claims 5 and 6 under 35 USC 112 [sic], fourth paragraph is respectfully requested.
>
> * * *
>
> . . . Claim 5 recites that the pluggable key means stores a cyclic redundancy check value (CRC). Claim 5 further recites a function performed by the processor means in combination with the CRC values. No such teaching is present in Keiser et al. . . .

Apex Defs.' Exh. 2, at A70-A73. In summary the patentees stated:

> In view of the above, Applicants respectfully submit that claims 1, 2, 5, 15, and 16 clearly differentiate over any teaching of Keiser et al. or any teaching which one skilled in the art might derive from Keiser et al. Applicants respectfully submit that the functional statements contained in the rejected claim must be considered in determining the patentability thereof in conformance with 35 USC 112 [sic], sixth paragraph. Reconsideration and withdrawal of the rejection of claims 1, 2, 5, 15 and

16 under 35 USC 102(b) [sic] is respectfully requested.

Id. at A73. These sections indicate that the patentees argued for evaluation of at least original claims 5 and 16 pursuant to § 112, ¶ 6, however, there is no connection between these arguments and claim 1.

Even if there were such a connection, there is no distinguishable difference between the structure identified by a plain-meaning interpretation of the term "pluggable memory key means" and a means-plus-function interpretation of the term. The clear meaning and/or structure for the term "pluggable memory key means" in the '609 patent is: a removable and/or reinsertable read-only-memory ("ROM") chip and/or module. The parties apparently agree that the '609 patent specification repeatedly refers to interchangeably a "removably, pluggable memory module" or a "pluggable read only memory(ies)" or a "pluggable memory key" or "pluggable ROM key" or simply a "ROM key." *See, e.g.*, '609 Patent, col. 1, *ll.* 9-10; *id.* col. 3, *ll.* 13-33; *id.* col. 3, *ll.* 46-64; *id.* col. 4, *ll.* 40-56; *id.* col. 5, *ll.* 5-17. It is the reinsertable, ROM or memory key/module that is inserted into an electrical receptacle of the meter, and stores parameter values and procedure routine specifications (or procedure routines), throughout the '609 patent's specification.

For the foregoing reasons, the Court finds that the "pluggable memory key means" is: a removable and/or reinsertable read-only-memory ("ROM") chip and/or module.

2. Parameter Values & Procedure Routine Specifications

The parties dispute the definition of the terms "parameter values" and "procedure routines specifications" in claim 1. At its core, the parties' argument turns on whether the terms are numbers or software code. Roche contends that both terms refer to numbers or data values of different types. Defendants contend that "parameter values" are numbers, while "procedure routine specifications"

are code. The Court agrees with Roche.

Although the parties dispute the proper construction for the term "parameter values," their definitions for the term are very similar. Roche contends that the term means "data values used in the algorithm," while Apex/HDI argue that the term means "constants and variables that are critical to the operation of the meter," and Biosite avers that the term means "constant values that are assigned to variables for a specified application." The Court finds the term "parameter values" has its ordinary meaning of "constants that are assigned to variables."

The ordinary meaning for the term "parameter" is a constant or value associated with a particular value or variable. *See, e.g.*, WEBSTER'S THIRD NEW INT'L DICTIONARY at 1638; IEEE Std. Glossary of Software Eng'g Term., IEEE St. 610.12-1990, at 55; Biosite Exh. 5, Louder Rep. ¶ 15; Roche Exh. 5, Dunsmore Dep. at 55. The other claims of the '609 patent confirm that the ordinary meaning of the term should apply in this instance. Claim 4 is perhaps the most revealing claim with respect to the varied types of constants or data intended to be included as a "parameter:"

> . . . pluggable memory key means including a plurality of stored parameter values for controlling operations of said meter; and
>
> processor means . . . wherein the processor means is responsive to parameter values accessed from said pluggable memory key means, to cause said excitation supply means to apply a plurality of voltages to said first electrode, each said voltage having a potential and being applied for a duration that is determined by said processor means from parameter values accessed from said pluggable memory key means, and to further control said sense amplifier means to provide a plurality of signal outputs over a set duration and to further calculate from said signal outputs a value equivalent to a concentration of an analyte in said analyte-containing fluid in said sample well, all in conformance with parameter values accessed from said memory key means.

'609 Patent, col. 9, *ll.* 48-68. Likewise, claim 5 also designates that control values, or parameters, are accessed on the pluggable memory key means, including "values of said first and second excitation potentials and the number of signal outputs from said sense amplifier means controlled

by parameter values accessed from said memory key means." *Id.* col. 10, *ll.* 31-35.

The specification also indicates that the plain meaning of "parameter values" should apply to the term in the context of the '609 patent. The summary of the invention teaches that "[a] microprocessor is responsive to a procedure routine and parameter values accessed from the pluggable memory key to cause the excitation supply to apply a plurality of potentials for preset durations, both the values of the potentials and the time duration of their application determined from parameter values derived from the memory key." *Id.* col. 3, *ll.* 49-55. Similarly, the '609 patent reads: "the sense amplifier [is] operated under control of specific parameter values derived from the pluggable memory key." *Id.* col. 3, *ll.* 57-60. From these passages alone, it is clear that a "parameter value" is a constant or data that is assigned to a variable in the programs that are run by the microprocessor. This is also consistent with the language used to describe the interaction between the microprocessor and the ROM key: "When ROM key **30** is inserted into meter **10**, a plurality of flexible contacts . . . enable a microprocessor within meter **10** to access data stored in ROM chip **32**." *Id.* col. 4, *ll.* 52-56.

The most compelling support for the ordinary meaning of "parameter value" in the '609 patent specification, however, is found in the more detailed descriptions of the contents of the ROM key. The '609 patent reads, in pertinent parts:

> A microprocessor **59** . . . provides overall control of the operation of biosensing meter **10** in combination with data read from ROM key **30**. ROM key **30** is pluggable into biosensing meter **10** and contains non-volatile memory that includes constants and other data required to carry out analyte-determination procedures. In general, a ROM key **30** will accompany each batch of disposable sample strips **18** and will contain constants and procedure code that enable meter **10** to adjust its measurement parameters to match the specific batch characteristics of disposable sample strips **18**. Further, ROM key **30** will also contain a large number of additional variable values that control the operation of microprocessor **59** in performing the actual analyte determination tests.

* * *

> As above indicated, the operation of a biosensing meter **10** is substantially controlled by data contained in ROM key **30**. ROM key **30** will contain a variety of data values that are critical to the proper operation of meter **10**. Those values encompass measurement delay times, an incubation time, the number of measurements to be taken during a measurement period, various thresholds against which voltage levels are to be compared, values of excitation voltage levels to be applied to sample strip **18** during a test procedure, glucose value conversion factors, and a variety of failsafe test threshold values.

Id. col. 5, *ll.* 3-18; *id.* col. 5, *ll.* 66-68, to col. 6, *ll.* 1-8. These passages indicate that "parameter values" must be "constants or data" because the same language is used to describe how those "constants or data" are used to control the microprocessor of the meter that is used in claim 1 to describe what the "parameter values" do to control the processor means. *Compare id.* col. 5, *ll.* 3-18 and *id.* col. 5, *ll.* 66-68 to col. 6, *ll.* 1-8 (the passages listed here), *with* col. 9, *ll.* 4-11 (describing the interaction between the processor means and the parameter values and procedure routine specifications on the memory key).

Roche contends that there are two types of constants, "parameter values" and "procedure routine specifications," where "parameter values" are constants used in the algorithm, but "procedure routine specifications" are data values or numbers used to control execution of the algorithm. Roche asserts that the first passage above teaches "constants and other data" and "additional variable data," which is two different types of data. Roche argues that the former type of data is "parameter values" and that the latter type of data is "procedure routine specifications." Furthermore, Roche argues that because dependent claim 2 specifically requires that the pluggable memory key means contain "procedure routines," which Roche agrees with Defendants must be code, the only way to differentiate claim 2 from claim 1 is if "procedure routine specifications" is not code, but numbers or data. In addition, Roche asserts that in the prosecution history, the

inventors clearly intended to include two types of data: parameters and specifications. Roche Br. at 45-46. Defendants do not really address this reference in the prosecution history.

Although the Court does not agree with Roche's argument in its entirety, the three sources of intrinsic evidence indicate that "procedure routine specifications" are data rather than code. The Court looks to the claims first. Claim 1 uses the term "procedure routine specifications" three times:

> . . . said pluggable memory key means including a plurality of stored parameter values and *procedure routine specifications* that are employed in controlling execution of an algorithm performed by said meter that enables determination of an analyte concentration value, said *procedure routine specifications* including stored values from which time values can be determined for controlling said sense means during execution of said algorithm; and
>
> processor means . . . responsive to parameter values and *procedure routine specifications* accessed from said pluggable memory key means, for controlling operation of said sense means in accordance with said algorithm and for calculating from signal outputs from said sense means a concentration value of an analyte in said analyte-containing fluid is said sample well.

Id. col. 8, *ll.* 62-68, to col. 9, *ll.* 1-11 (emphasis added). It is clear from the second usage of the term that "procedure routine specifications" must include "stored values from which time values can be determined for controlling said sense means during execution of said algorithm," therefore, to that extent, "procedure routine specifications" include values, or numbers. No other claims of the '609 patent uses the term "procedure routine specifications." Instead, the remainder of the claims use the term "parameter value" to describe all types of data values, including ones that Roche asserts are "procedure routine specifications."

Roche contends that two different types of data are referred to in the specification: "measurement parameters" and "additional variable values." *Id.* col. 5, *ll.* 12-15. The former, Roche argues, are "parameters" and the latter are "procedure routine specifications." However, several of the "additional variable values," described in more detail later in the specification, are

identified by other claims as "parameter values." *Compare, e.g.*, *id.* col. 5, *ll.* 3-18 and *id.* col. 5, *ll.* 66-68 to col. 6, *ll.* 1-8 (describing particularly the "additional variable values"), *with* col. 9, *ll.* 55-68 (describing the interaction between the processor means and the parameter values in claim 4). This evidence points away from a definition of "procedure routine specifications" that would limit the type of values that could serve as "parameter values," and suggests that an argument for an arbitrary distinction between the two types of data is flawed.

Roche also argues that the doctrine of claim differentiation supports its argument that "procedure routine specifications" are data. Apex/HDI contend that this is unworkable given the strong evidence that "procedure routine" is code and that the '609 patent specifically identifies that the pluggable memory key means has both procedure and code. *See id.* col. 5, *ll.* 9-11. To varying degrees, Roche and Biosite urge the Court to look to the plain meaning of the term "specification" to resolve the parties' dispute. The Court agrees that this approach helps illuminate the difference between "procedure routine specifications" and a "procedure routine" as those terms are used in the '609 patent. The plain meaning for specification is to make something more specific, or to identify something in greater detail. *See* WEBSTER'S NEW INT'L DICTIONARY at 2187; WEBSTER'S COLLEGIATE DICTIONARY (10th Ed.). Claim 1 already teaches that "procedure routine specifications" include "stored values from which time values can be determined for controlling said sense means during execution of said algorithm," '609 Patent, col. 9, *ll.* 1-3, therefore, it is not a stretch to combine the plain meaning of "specification" with "procedure routine" to decide that a "procedure routine specification" is something that identifies a procedure routine, or an identifier for something within the procedure routine. But, how is type of data distinguishable from a parameter value?

A definition for "procedure routine specification" that is data is consistent with the '609 patent specification's apparent reference to at least two different inventions, one in which there are

two types of data on the pluggable memory key means, *see id.* col. 5, *ll.* 5-9 ("ROM key **30** is pluggable into meter **10** and contains non-volatile memory that includes constants and other data required to carry out analyte-determination procedures."), and one in which there are both "constants and procedure code." *See id.* col. 5, *ll.* 10-11 (stating "a ROM key **30** . . . will contain constants and procedure code"); *id.* col. 6, *ll.* 8-13 ("In addition, ROM key **30** may contain either a portion of or the entire code listing that controls the procedures of meter **10** so that, by substitution of a new ROM key, test procedures performed by meter **10** can be altered accordingly."). Moreover, it is the only definition that is consistent with the use of the term "specification" in the prosecution history. The prosecution history reads:

> Claims 1-5, 15 and 16 were rejected under 35 USC [sic] 102(b) in view of Keiser et al. Prior to considering the rejection, it is worthwhile to briefly review Applicants' invention. Applicants biosensing meter resembles the meter of Keiser et al. in several respects, but departs therefrom in such a manner as to provide substantial functional improvements. Applicants' biosensing meter receives a pluggable memory key that contains a memory chip which stores *(1) plural parameters, (2) specification values which are used to control the operation of an algorithm that analyzes a sample to determine the presence of analyte* and (3) further contains in certain configurations, the actual procedure to be used by the meter. By inserting these parameters, values and procedures into the meter via a pluggable key, Applicants have enabled the meter to be reprogrammed at any time there is an improvement in the algorithm (e.g. an improvement which enables a faster or more accurate analysis procedure to be performed). Prior art biosensing meters were incapable of being modified to accept an improved algorithm for the performance of a test function. As a result, prior art biosensing meters had to be <u>structurally</u> altered so as to accommodate a revised algorithm, test procedure or other improvement.
>
> * * *
>
> Keiser et al. include no teaching that the pluggable memory chip contain parameters which define "procedure routine specifications that are employed in <u>controlling execution</u> of an algorithm performed by said meter . . . said procedure routine specifications including stored values from which are determinable time values used to control said sense means during execution of said algorithm" (see claim 1 [as then amended]). Claim 2 is dependent upon claim 1 and indicates that the pluggable key means includes "a procedure routine that when executed by said processor means,

> enables execution of said algorithm". [sic] Keiser et al. have no such data in their pluggable memory key.

Defs.' Exh. 2, at A71-A73 (emphasis added).

This section of the prosecution history teaches two things. First, that the inventors saw a distinction between "plural parameters" and "specification values." *Id.* at A71. Second, that in distinguishing their invention from that of the prior art, the inventors seemed to refer to the language of claim 1 regarding "procedure routine specifications" as a subset of "parameters" within the context of claim 1. *Id.* at A72 ("Keiser et al. include no teaching that the pluggable memory chip contains parameters which define 'procedure routine specifications that are employed in controlling execution of an algorithm performed by said meter . . .' (see claim 1)."). It is this piece of information, in conjunction with the lack of evidence in the other claims or in the '609 patent's specification as to how to distinguish between data that comprises "parameter values" and data that comprises "procedure routine specifications," that convinces the Court that "procedure routine specifications" should be limited to the definition given it by claim 1 itself: "procedure routine specifications including stored values from which time values can be determined for controlling said sense means during execution of said algorithm." '609 Patent, col. 8, *l.* 68, to col. 9, *ll.* 1-3.

Roche's expert, Dr. H.E. Dunsmore ("Dr. Dunsmore"), an Associate Professor of Computer Science at Purdue University in West Lafayette, Indiana, opines that "procedure routine specifications" means "values that determine what the algorithm is," and distinguishes "procedure routine specifications" from "parameter values" by stating that the "parameter values" in claim 1 are narrower than the "parameter values" referenced in the remaining claims. Roche's Exh. 5, Dunsmore Rep. ¶ 41. But, the Court sees no real way to distinguish between what is a "parameter value" and what is a "procedure routine specification" under this analysis. Yes, Dr. Dunsmore's

report explains that a procedure routine specification could refer to numbers that change the formula for calculating a particular unknown, while parameter values are constants in the same formula, but there is nothing in the claims, the specification or the prosecution history that supports this distinction. *Compare id.* ¶¶ 15-22 *with id.* ¶¶ 23-41. In other words, this is an arbitrary differentiation between the two types of values that is only resolved by consultation with the description for "procedure routine specification" contained in claim 1.

The Court recognizes that limiting the definition of "procedure routine specification" to that found in the claim itself is extraordinary, however, the Court finds no better way to reconcile the clear meaning of the term "parameter value," the lack of evidence to support a more clear distinction between "parameter values" and "procedure routine specifications," and the evidence of two types of values in the prosecution history.

For the foregoing reasons, the Court finds that "parameter values" means: constants that are assigned to variables; and the term "procedure routine specifications" means: stored values from which time values can be determined for controlling a sense means during execution of an algorithm.

C. PROCESSOR MEANS

1. Whether or Not the Term is a Means-Plus-Function Term

The next term disputed by the parties is "processor means." Apex/HDI[6] contend that "processor means" is a means-plus-function term that should be construed pursuant to § 112, ¶ 6. Specifically, Apex/HDI argue that there are three functions performed by the "processor means:" accessing, as needed, parameter values and procedure routine specifications from the pluggable memory key means; controlling the sense means in accordance with the algorithm; and calculating the concentration of the analyte in the sample from the signals output from the sense means. Apex/HDI argue that "processor means" does not connote sufficient structure to perform at least two of the specified functions - those that require an algorithm. Apex/HDI rely upon the case *WMS Gaming, Inc. v. Int'l Game Tech.*, 184 F.3d 1339 (Fed. Cir. 1999), to support their position that in this case, where the processor must carry out a specific algorithm, "the disclosed structure is not the general purpose computer, but rather the special purpose computer programmed to perform the disclosed algorithm." *Id.* at 1349. Here, Apex/HDI argue, the "processor means" must perform a specific algorithm, therefore, the corresponding structure for the "processor means" is: a microprocessor programmed to: (1) couple to the memory key means to be responsive to parameter values and procedure routine specifications accessed on an as needed basis in real time during execution of the algorithm directly from the pluggable memory key means; (2) open and close the switch of the sense means to change the gain of the amplifier while the output current from the reaction is being measured to prevent saturation of the sense amplifier; (3) calculate the analyte concentration value by comparing the current flow measured by the sense means to a Cottrell curve.

[6]Biosite takes no position on the processor means per se, however, argues about the "coupled to" limitation within the claim element.

Roche argues that "processor means" has a well-understood meaning in the art and is simply a microprocessor or central processing unit ("CPU"). Roche contends that the presumption that the term is a means-plus-function term because of its language is overcome by the fact that the term has enough structure to perform the function without more. Moreover, Roche asserts that even if the term is a means-plus-function term, Apex/HDI have added an additional functional limitation to the claim, "accessing data from the memory key means," that is unsupported in the claim.

Unlike with the "pluggable memory key means" element, the Court finds that there is not enough structure defined by claim 1 to rebut the presumption that "processor means" is subject to interpretation under § 112, ¶ 6. As already discussed, the use of the term "means" "creates a presumption that section 112, paragraph 6 [sic] has been invoked, but that presumption may be rebutted if the properly construed claim limitation itself recites sufficiently definite structure to perform the claimed function." *Kemco Sales, Inc. v. Control Papers Co.*, 206 F.3d 1352, 1361 (Fed. Cir. 1361) (citing *Personalized Media Commc'ns LLC v. ITC*, 161 F.3d 696, 704 & nn. 9 &10 (Fed. Cir. 1998)). The focus is on whether the claim "recites sufficiently definite structure to avoid the ambit of § 112, ¶ 6." *Personalized Media Commc'ns*, 161 F.3d at 704 (citing *Sage Prods. v. Devon Indust., Inc.*, 126 F.3d 1420, 1427-28 (Fed. Cir. 1997)). A term with a well-known meaning in the art may also connote enough structure to fall outside the ambit of § 112, ¶ 6. *See id.* at 704-05 (discussing a term "detector" without the qualifier "means" after it). Here, Roche contends that "processor" has a well-known meaning in the art, which rebuts the presumption that § 112, ¶ 6 applies. There is no dispute that this is true. However, here it is clear that the "processor" of claim 1 is not a generic one, but one that runs a particular algorithm to control a sense amplifier and to calculate the concentration of an analyte. In such a case, the Federal Circuit has suggested that "[i]n a means-plus-function claim in which the disclosed structure is a computer, or microprocessor,

programmed to carry out an algorithm, the disclosed structure is not the general purpose computer, but rather the special purpose computer programmed to perform the disclosed algorithm." *WMS Gaming*, 184 F.3d at 1349 (citing *Alappat*, 33 F.3d at 1545). *See also Tehrani v. Hamilton Med., Inc.*, 331 F.3d 1355, 1362 (Fed. Cir. 2000) (remanding the case for determination of the algorithm that "forms part of the structure of the 'means for processing' limitation of" the disputed claim).[7]

There are other clues that the Court should construe the "processor means" term as a means-plus-function term. *See Rodime PLC v. Seagate Tech., Inc.*, 174 F.3d 1294, 1302 (Fed. Cir. 1999) (instructing to look for the term "means" first, then look "to whether the element specifies a function for performing the claimed means" next). As the Court just eluded to in the prior discussion, the element itself specifies functions for the "processor means," namely "controlling operation of said sense means" and "calculating . . . a concentration value of an analyte." '609 Patent, col. 9, *ll.* 7-10. For these reasons, the Court concludes that the "processor means" limitation must be construed according to § 112, ¶ 6.

Although the Court has identified the two functions clearly outlined by the "processor means" limitation, Apex/HDI contend that there is an additional function, although their corresponding structural definitions imply that they think there are two additional functions performed by the "processor means." Specifically, Apex/HDI argue that the "processor means" also performs the function of accessing parameter values and procedure routine specifications from the pluggable memory key means. To support this argument Apex/HDI cite *In re Donaldson*, 16 F.3d

[7]The Court recognizes the difference in the claim term in *Tehrani* and the one at issue in this case because "processing" in *Tehrani* is actually part of the function rather than the means, however, there is little difference between the term at issue in *WMS Gaming* and the one in this case, and the *Tehrani* court clearly relied upon *WMS Gaming* to determine that the district court in the *Tehrani* case had erred by not more particularly describing the relevant algorithm that corresponded to the means.

1189 (Fed. Cir. 1994), and *Ferguson Beauregard/Logic v. Mega Sys.*, 350 F.3d 1327 (Fed. Cir. 2003). Those cases refer to disputed terms that contain the word "responsive." *Ferguson Beauregard/Logic*, 350 F.3d at 1333; *In re Donaldson*, 16 F.3d at 1195.

The Court disagrees with Apex/HDI's' analysis and the applicability of those cases to the instant claim. *In re Donaldson* never refers to the "responsive" phrase as a functional limitation; it merely includes it as part of the means. *In re Donaldson*, 16 F.3d at 1198 (repeating the phrase as part of the means, but never referring to it as an additional function). In the *Ferguson Beauregard/Logic* case, the Federal Circuit sidestepped the claim construction question because the dispute on appeal centered around an additional function that neither the lower court nor the appellate court found in either the claim or the allegedly infringing device. *Ferguson Beauregard/Logic*, 350 F.3d at 1344 (stating that the argument presented was based on a factual comparison of the allegedly infringing device to the claim rather than claim construction).

In the instant case, the Court sees no reason to include an "accessing" function to the processor means. The phrase "and responsive to parameter values and procedure routine specifications accessed from said pluggable memory key means" only describes the interface of the "processor means" with the memory key, it does not describe a functionality of the "processor means." The "accessed from" language is merely descriptive of where the "processor means" finds certain data. To the extent that the phrase "responsive to" can be construed as a function, the only disclosure in the specification for a structure that corresponds to that function is a microprocessor, without more. '609 Patent, col. 3, *ll.* 49-51.

Having determined the functions associated with the "processor means,"namely to control the sense means and to calculate the concentration of an analyte, the Court must now determine the algorithm associated with those functions disclosed by the '609 patent. *See WMS Gaming*, 184 F.3d

at 1348. With respect to the "controlling the sense means" function, Apex/HDI contend that the microprocessor is programmed to open and close the switch of the sense means to change the gain of the amplifier while the output current from the reaction is being measured to prevent saturation of the sense amplifier. Roche argues that this is not the only manner in which the microprocessor controls the sense means as disclosed by the specification.

The Court agrees with Roche that there is more to the algorithm that controls the sense means. The '609 patent teaches that a "microprocessor controls the sense amplifier to provide a plurality of signal outputs over a predetermined duration . . . ." '609 Patent, col. 3, *ll.* 55-57. This is the first, and perhaps most important, function performed by the microprocessor to control the sense means. This part of the algorithm is also described later in the specification: "Trace **78** is either displaced upwardly or downwardly in the plot of **FIG. 66** depending upon glucose concentration. During the period of trace **78**, microprocessor **59** causes a plurality of current measurement values to be sampled. . . . The sense current measurements enable a glucose determination to be made . . . ." *Id.* col. 7, *ll.* 19-28. This shutting on and off of the sense amplifier is further described in the more specific description of the sense means and its controls:

> A further delay measurement interval value is also derived from ROM key **30** and represents a count of a number of measurement intervals during which current measurements are inhibited after reapplication of excitation potential **76** to excitation electrode **24**.
>
> * * *
>
> During the delay measurement interval (key), microprocessor **59** causes switch **106** to be closed thereby shunting amplifier **100** . . . . This action prevents saturation of amplifier **100** during the period when the Cottrell current exceeds a maximum measurable current level (key). Subsequent to the delay measurement time, microprocessor **59** causes switch **106** to open so that operational amplifier **100** exhibits its normal gain characteristics and enables measurements **82**, **84**, etc. to be taken.

Id. col. 7, *ll.* 46-65. The '609 patent also teaches that "sense amplifier **50** receive[s] [its] commands from microprocessor **59** . . . . Sense amplifier **59** is controlled to have two different levels of gain so as to avoid a saturation condition upon an initial application of an excitation voltage to sample strip **18**." *Id.* col. 5, *ll.* 19-26. This seems to the be algorithm referenced by Apex/HDI.

Apex/HDI's description is too narrow because it only accounts for one of the ways in which the microprocessor is programmed to control the sense amplifier. The passages in the specification calls for two different algorithms, one that inhibits current measurement and one that allows for current measurements to be sampled at specific time durations. Therefore, the Court finds that the structure of the "processor means" that performs the "controlling" function is: a microprocessor programmed to open and close the sense means to change the gain of the amplifier alternatively to inhibit current measurements, to avoid saturation, or to take current measurements.

Turning next to the function of "calculating the analyte concentration," Apex/HDI argue that the corresponding structure of the "processor means" is: a microprocessor programmed to calculate the analyte concentration value by comparing the current flow measured by the sense means to a Cottrell curve. The Court also finds this definition too narrow.

The '609 patent teaches that a microprocessor "perform[s] the actual analyte determination tests," using variable values from the pluggable memory key means. *Id.* col. 5, *ll.* 14-17. With respect to glucose determinations specifically, the '609 patent teaches that

> [s]ubsequent to the Cottrell currents being recorded and stored, meter **10** proceeds to determine a glucose concentration by performing conversion of current values to glucose values from a calibration curve defined by values in ROM key **30**; and then performing a temperature compensation correction procedure (key) in accordance with a temperature estimation procedure (key).

Id. col. 7, *ll.* 66-68 to col. 8, *ll.* 1-5. The first passage indicates that the inventors intended to change the type of analyte tested for by the different analyte determination tests employed by the

microprocessor. The algorithm would be determined by the actual "analyte determination test" and the variable values from the pluggable memory key means. Moreover, the second passage indicates an intent for determination of glucose values, specifically, through a comparison of measured current values to a calibration curve defined by values from the pluggable memory key means. This disclosed algorithm is broader than the algorithm proposed by Apex/HDI because it allows for different types of calibration curves to be used. The Court finds that the broader algorithms discussed here are supported by the specification.

For this reason, the Court finds that the structure of the "processor means" for performing the "calculating" function is: a microprocessor programmed to perform an anlyte testing procedure using variable values from a pluggable memory key means or, for glucose values specifically, a microprocessor programmed to compare measured current values to a calibration curve defined by values from a pluggable memory key means.

2. Whether or Not the Processor Means Must be "Coupled to" the Memory Key During a Test

Biosite, and to a certain extent Apex/HDI,[8] contend that the "coupled to" limitation of the "processor means" element necessitates that the processor means be connected to the memory key means during a test. Biosite argues that all the experts in the case agree that the "processor means" accesses data on the pluggable memory key means during the test. Moreover, Biosite continues, the experts agree that the "coupled to" limitation in claim 4 also means that the "processor means" is connected to the pluggable memory key means during the test, therefore, the same meaning should apply the to term in claim 1. To further support its position, Biosite points to language in the specification that implies that the "processor means" must be able to access data during a test: "Because the amount of random access memory (RAM) contained within microprocessor **59** is limited, data from ROM key **30** is loaded into RAM by microprocessor **59** only on an as needed basis, after which it is discarded, with new data taking its place."[9] *Id.* col. 6, *ll.* 14-18.

Roche contends that a continuous connection is not required by the term "coupled to." Roche argues that Biosite takes Dr. Dunsmore's testimony out of context, and that the expert did not opine that the "processor means" has access to the pluggable memory key means during the test. Furthermore, Roche argues that the embodiment of the invention that includes using a cyclic redundancy check ("CRC") indicates that all the necessary data is downloaded to the microprocessor

[8]Apex/HDI contend that the corresponding algorithm for what they have interpreted as an "accessing" function of the "processor means" requires the microprocessor to access parameter values and procedure routine specifications on a real-time basis during execution of the entire algorithm. In effect, this is the same argument that Biosite makes regarding the "coupled to" limitation.

[9]Likewise, Apex/HDI use this language to support their interpretation of the algorithm for the "accessing" function that they would include for the "processor means."

before the test is run. *See id.* col. 8, *ll.* 16-29; *id.* Fig. 8. A definition for "coupled to" that requires the "processor means" to be connected to the pluggable memory key means during the test would obviate this embodiment.

The Court finds that the plain meaning of the term "coupled to" is: joined or connected to during performance of the algorithm. The claim language itself implies that the "processor means" responds to data on the pluggable memory key means during performance of the algorithm that controls the sense means, and calculates an analyte value. Claim 1 states, "processor means coupled to said memory key means and responsive to parameter values and procedure routine specifications accessed from said pluggable memory key means, for controlling operation of said sense means in accordance with said algorithm and for calculating . . . a concentration value . . . ." *Id.* col. 9, *ll.* 4-11. The language of claim 4 is equally persuasive. *See id.* col. 9, *ll.* 52-68 (describing how the processor means uses data from the pluggable memory key means to execute the test procedure).

The specification supports the conclusion that the invention of the '609 patent, as disclosed to one of ordinary skill in the art at the time of the inventions, would have read the limitation "coupled to" to require some connection between the "processor means" and the "pluggable memory key means" during execution of the algorithm. As pointed out by both Biosite and Apex/HDI, the description of the preferred embodiment indicates that the "processor means" is connected to or communicating with the pluggable memory key means during the test. The specification teaches that information is loaded from the pluggable memory key means by the processor "only on an as needed basis." *Id.* col. 6, *ll.* 14-18.

Roche argues that the disclosure of another embodiment that uses a CRC necessitates a different result; the second invention requires all data to be read from the pluggable memory key means at once, the test is run, then the values are read again. The invention described by Figure 8

and the text of the specification that describes the algorithm in Figure 8 suggests that "all data is read from ROM key **30** and a CRC checksum is calculated therefrom . . . [and] the CRC checksum is stored in RAM in microprocessor **59** and the test continues until a glucose value has been calculated . . . ." *Id.* col. 8, *ll.* 19-27. Then, "all data is again read from ROM key **30** and a CRC checksum is again calculated . . . ." *Id.* col. 8, *ll.* 28-29; *id.* Fig. 8. Roche's reading of this passage and Figure 8 ignores the subtlety of this disclosure. It is clear from the passage in column 8 that all the data is read, a CRC value is calculated from the data, but only the CRC value is stored. As taught by the other description of the invention found earlier in the patent, the data is only used as needed, then it is discarded. *Id.* col. 6, *ll.* 16-18. Therefore, all the values are used to calculate the CRC value, but then they are discarded. The claim, however, requires that "processor means" access the parameter values and procedure routine specifications to run the algorithm. If the microprocessor does not store all the values it needs to run the algorithm, and it must access them to run the algorithm, then the "processor means" must be connected to the pluggable memory key means during the test. Roche tries to broaden the claim language too far to insist otherwise.

For the foregoing reasons, the Court concludes that the "coupled to" limitation means: joined or connected to during performance of the algorithm.

IV. CONCLUSION

The Court has construed the disputed terms of U.S. Patent No. 5,366,609, as follows:

TERM	COURT'S CONSTRUCTION
"sample well"	a container or reservoir for the sample.
"sense means"	Is a means-plus-function term. Function: to output signals indicative of the manifestation of a reaction in the sample well between an analyte-containing fluid and said analyte reactant Structure: the electrical contact 48, the sense amplifier 50 and the A/D converter 52, and equivalents thereof
"pluggable memory key means"	a removable and/or reinsertable read-only-memory ("ROM") chip and/or module
"parameter value"	constants that are assigned to variables
"procedure routine specification"	stored values from which time values can be determined for controlling a sense means during execution of an algorithm
"processor means"	Is a means-plus-function term. Function 1: to control the sense means Structure 1: a microprocessor programmed to open and close the sense means to change the gain of the amplifier alternatively to inhibit current measurements, to avoid saturation, or to take current measurements Function 2: to calculate the concentration of an analyte Structure 2: a microprocessor programmed to perform an analyte testing procedure using variable values from a pluggable memory key means or, for glucose values specifically, a microprocessor programmed to compare measured current values to a calibration curve defined by values from a pluggable memory key means
"coupled to"	joined or connected to during performance of the algorithm

IT IS SO ORDERED this 26th day of September, 2005.

_____

LARRY J. McKINNEY, CHIEF JUDGE
United States District Court
Southern District of Indiana

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