United States District Court
Northern District of California

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

DOMINION ASSETS LLC,

Plaintiff,

v.

MASIMO CORPORATION, et al.,

Defendants.

Case No. 14-cv-03002-BLF

ORDER CONSTRUING CLAIMS

[Re: ECF 37, 40, 42]

Plaintiff Dominion Assets LLC ("Plaintiff") accuses defendants Masimo Corporation and Cercacor Laboratories, Inc. (collectively, "Defendants") of infringing two patents directed toward techniques for non-invasively measuring the concentration of blood analytes. The Court held a tutorial on January 30, 2015 and a *Markman* hearing on February 6, 2015 for the purpose of construing disputed terms in both patents.

I. BACKGROUND

Blood glucose monitors are critical tools in managing diabetes, a condition in which the pancreas secretes little or no insulin. Insulin regulates the manner in which the body utilizes glucose—or, sugar—in the blood and, in the correct concentrations, prevents hyperglycemia (excess glucose) and hypoglycemia (insufficient glucose), both of which can lead to serious complications. A diabetic generally requires regular shots of insulin to supplement his body's short supply, and must monitor his blood glucose levels to avoid large swings in concentration. The most common and reliable method of monitoring blood glucose is to draw blood and measure its glucose concentration directly. This invasive measurement technique can become understandably onerous, particularly if repeated—as is required for effective control—four or more times a day. As such, there is tremendous interest in developing an effective and accurate

non-invasive blood glucose monitor.

Plaintiff is the current owner and assignee of two patents originally issued and assigned to Diasense, Inc., a company in the business of researching and developing such a non-invasive glucose monitor. Pl.'s Br. 1, ECF 37. The fruits of that labor can be seen in the patents-in-suit: U.S. Patent Nos. 5,379,764 (the '764 Patent) and 5,460,177 (the '177 Patent).[1] The patents-in-suit are roughly contemporaneous. The '764 Patent, titled "Non-Invasive Determination of Analyte Concentration in Body of Mammals," was invented by Russell H. Barnes, Jimmie W. Brasch, Sr., David L. Purdy, and William D. Lougheed. The patent has a priority date of December 9, 1992 and was issued on January 10, 1995. The '177 Patent, titled "Method for Non-Invasive Measurement of Concentration of Analytes in Blood Using Continuous Spectrum Radiation," was invented by David L. Purdy, Perry Palumbo, and Mark DiFrancecso. This patent has a priority date of May 7, 1993 and was issued on October 24, 1995. Both patents are now expired.

Both the '764 Patent and the '177 Patent improve upon known methods for non-invasively measuring the concentration of blood components using radiation (or, light). In broad terms, the generally known method takes advantage of interactions between light radiation and blood analytes. Light that enters the body is different from light that exits the body after interacting with components in the blood. That difference can be detected using spectroscopy and compared using mathematical techniques to arrive at the concentration of the analyte of interest. Early methods were imprecise at measuring blood analytes that exist only in relatively low concentrations (such as glucose), due to interference with readings caused by other components in the blood. *See* '764 Patent col. 2:11-47. The '764 Patent recognizes this problem and overcomes it through the use of mathematical techniques of pretreatment and multivariate analysis to respectively "eliminate or minimize the effects of detector offset and optical scattering drift" and determine the concentration of glucose based upon its spectral properties. *Id.* col. 2:63-3:16.

The '177 Patent similarly improves on a known method of non-invasive measurement, this

[1] The claims of the patents, as will be discussed below, are not limited to blood glucose detection. Indeed, as Defendant is quick to point out, no one has yet succeeded in developing a device for the non-invasive measurement of blood glucose concentration. Def.'s Br. 2, ECF 40.

time using infrared radiation across a continuous spectrum, in order to address deficiencies in the prior art when dealing with blood analytes in low concentrations. '177 Patent col. 1:49-2:2. Low concentrations are associated with a general problem of low signal-to-noise ratio when using radiation in the near-infrared portion of the spectrum, as not only is the radiation absorbed by water in the body, but the analyte of interest also contributes little to the total signal intensity. *Id.* The '177 Patent confronts this problem by describing a manner in which intensity-modulated radiation can be used so that the intensity of radiation used on the body can be increased (thereby amplifying the detected signal) without the undesirable consequences normally associated with excess radiation. *Id.* col. 2:13-25.

Defendant Masimo Corporation develops, manufactures, and markets non-invasive monitoring products, including ones that measure a variety of constituents in a patient's blood. Masimo contracted with defendant Cercacor Laboratories to develop a "non-invasive blood constituent monitoring platform that measures hemoglobin, carboxyhemoglobin, methemoglobin and other blood constituents." Compl. ¶ 18, ECF 1. Plaintiff alleges that the resultant platform, which is either known as or incorporated into Masimo's "Rainbox SET" products, infringes the claims of the '764 and '177 Patent.

II. LEGAL STANDARD

Claim construction is a matter of law. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 387 (1996). "It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude," *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (internal citation omitted), and, as such, "[t]he appropriate starting point . . . is always with the language of the asserted claim itself," *Comark Commc'ns, Inc. v. Harris Corp.*, 156 F.3d 1182, 1186 (Fed. Cir. 1998). "The terms used in patent claims are not construed in the abstract, but in the context in which the term was presented and used by the patentee, as it would have been understood by a person of ordinary skill in the field of the invention on reading the patent documents." *Fenner Investments, Ltd. v. Cellco P'ship*, 778 F.3d 1320, 1322-23 (Fed. Cir. 2015). The court thus reads a claim in light of the specification, which is "the single best guide to the meaning of a disputed term," *Phillips*, 415 F.3d at 1315, and accords

a claim term "the meaning it would have to persons in the field of the invention, when read and understood in light of the entire specification and prosecution history," *Fenner Investments*, 778 F.3d at 1323. Furthermore, "the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim." *Phillips*, 415 F.3d at 1316 (quoting *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998)). Therefore, "[a]ny explanation, elaboration, or qualification presented by the inventor during patent examination is relevant, for the role of claim construction is to 'capture the scope of the actual invention' that is disclosed, described, and patented." *Fenner Investments*, 778 F.3d at 1323 (quoting *Retractable Techs., Inc. v. Becton, Dickinson & Co.*, 653 F.3d 1296, 1305 (Fed. Cir. 2011)).

Evidence external to the patent is less significant than the intrinsic record, but the court may also consider such extrinsic evidence as expert and inventor testimony, dictionaries, and learned treatises "if the court deems it helpful in determining 'the true meaning of language used in the patent claims.'" *Phillips*, 415 F.3d at 1318 (quoting *Markman*, 52 F.3d at 980). Indeed, a district court may be called upon to resolve subsidiary factual disputes necessary to a proper construction of the claims such as, for example, what meaning a person of ordinary skill in the art would ascribe to a certain term at the time of the invention. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837-38, 841-42 (2015). However, extrinsic evidence may not be used to contradict or change the meaning of claims "in derogation of the 'indisputable public records consisting of the claims, the specification and the prosecution history,' thereby undermining the public notice function of patents." *Philips*, 415 F.3d at 1319 (quoting *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1578 (Fed. Cir. 1995)).

In construing claims, a court must overall be cognizant that "[w]ords are symbols, linguistic embodiments of information sought to be communicated, and, as such, can be imperfect at representing their subject." *Fenner Investments*, 778 F.3d at 1323. Judicial "construction" of disputed words describing patented technology thus aims to define the boundaries of a patentee's legal rights, "not to change that which was invented." *Id.*

III. AGREED CONSTRUCTIONS

The parties agree on the construction of two terms in the '177 Patent. *See* JCCS, ECF 32. The Court accordingly approves and adopts the following constructions:

Term	Agreed Construction
plurality of detectors ('177 Patent, Claims 6, 7)	Two or more detectors
a plurality of wavelength ranges within said continuous spectrum ('177 Patent, Claims 1, 7)	Two or more wavelength ranges within the continuous spectrum
intensity-modulated radiation ('177 Patent, Claims 1, 7)	radiation the intensity of which can be adjusted (increased or decreased in level)[2]

IV. TERMS IN THE '177 PATENT

The parties dispute the proper construction of a number of terms found in Claims 1 and 7 of the '177 Patent. By way of example, Claim 7 is an apparatus claim corresponding to the method claimed in Claim 1. Claim 7 provides (with disputed terms in bold):

> 7. An apparatus for non-invasive detection of the concentration of an analyte in the bloodstream of a living animal, comprising:
>
> (a) a source of **intensity-modulated radiation** over a **continuous spectrum** for irradiating a body part of the animal **simultaneously** over the **continuous spectrum**;
> (b) a plurality of detectors for detecting the intensity of radiation emitted by the body part at a plurality of wavelength ranges within said continuous spectrum and providing an output signal representative of the detected radiation intensity; and
> **(c) means for calculating the concentration of the analyte from said detected intensity.**

[2] Although the parties presented competing proposed constructions for this term in their Joint Claim Construction Statement, Defendants did not address this term in their claim construction briefing. At the *Markman* hearing, Defendants indicated that they would accept Plaintiff's proposed construction. The Court therefore adopts Plaintiff's proposal for this term as the parties' agreed construction.

A. "irradiating a body part of the animal with intensity-modulated radiation over a continuous spectrum"

Plaintiff's Proposal	Defendants' Proposal	Court's Construction
irradiating a body part of the animal with intensity-modulated radiation over a continuous spectrum	irradiating a body part of the animal with intensity-modulated radiation ***simultaneously*** over a continuous spectrum	irradiating a body part of the animal with intensity-modulated radiation ***simultaneously*** over a continuous spectrum

The parties dispute whether this phrase can and should be construed to include the word "simultaneously." Plaintiff argues that no construction is needed because the phrase "irradiating a body part of the animal with intensity-modulated radiation over a continuous spectrum" is unambiguous. Pl.'s Br. 6, ECF 37. Defendants argue that the phrase in dispute should always have included the "simultaneously" limitation, as demonstrated by the prosecution history. Def.'s Br. 5-6, ECF 40. Plaintiff replies that injecting a limitation from the prosecution history into the unambiguous claim language runs counter to the general prohibition against importing extraneous limitations. Pl.'s Reply 3-4, ECF 42.

Plaintiff's argument presents a certain appeal because it is a basic tenet of claim construction that limitations from the specification should not be imported into unambiguous claims. *DSW, Inc. v. Shoe Pavilion, Inc.*, 537 F.3d 1342, 1348 (Fed. Cir. 2008); *see also Phillips*, 415 F.3d at 1323. However, it is also fundamental to claim construction that "the interested public has the right to rely on the inventor's statements made during prosecution, without attempting to decipher whether the examiner relied on them, or how much weight they were given." *Fenner Investments*, 778 F.3d at 1325; *see also Microsoft Corp. v. Multi–Tech Sys., Inc.*, 357 F.3d 1340, 1350 (Fed. Cir. 2004); *Laitram Corp. v. Morehouse Indus., Inc.*, 143 F.3d 1456, 1462 (Fed. Cir. 1998). Thus, an express disclaimer of claim scope in the prosecution history is relevant to determining the proper metes and bounds of a claimed invention. For that reason, the Court finds Defendants' construction more compelling.

The prosecution history of the '177 Patent clearly indicates that the phrase "irradiating a body part of the animal with intensity-modulated radiation over a continuous spectrum" in Claim 1 must necessarily embrace the "simultaneously" limitation because the patentees disclaimed a

broader scope. This disclaimer was made in a January 30, 1995 Amendment to overcome an obviousness rejection based the Strobl reference, a prior art patent.[3] Decl. of Bruce J. Wecker, ECF 37-1 Exh. 4 ('177 Patent file history) at January 30, 1995 Amendment. In the Amendment, the patentees requested that the word "simultaneously" be inserted in "Claim 2, line 3, after 'radiation'" and in "Claim 7, line 6, after 'animal.'"[4] *Id.* at p. 2. In conjunction with the requested amendments, the patentees described Claim 1 as including "the steps of irradiating a body part of the animal with intensity-modulated radiation *simultaneously* over a continuous spectrum." *Id.* at p. 3 (emphasis added). Noting that "the simultaneous irradiation of a body part with a continuous spectrum is highly advantageous," *id.*, the patentees proceeded to argue—within the same discussion of Claim 1—that the Strobl reference "does not teach or suggest the *simultaneous* irradiation of a body part with radiation over a continuous spectrum," *id.* at p. 4 (emphasis in original). As such, it is clear that the patentees understood Claim 1 to require that radiation over a continuous spectrum occur "simultaneously"—a requirement not found in Strobl. This conclusion is bolstered by the patentees' argument that Claim 7 was allowable as "an apparatus claim corresponding to claim 1" without any further elaboration to suggest that Claim 7 was intended to have any other limitations not found in Claim 1. *Id.* at p. 5. To the extent Claims 1 and 7 are respective method and apparatus claims with the same limitations, Claim 1 should include the same "simultaneously" limitation as can be found in Claim 7. Finally, there is no discussion in the argument for allowance of Claim 2 regarding the "simultaneously" limitation, suggesting that the limitation was meant for Claim 1. *See id.* The patentees' own statements thus demonstrate that Claim 1 was intended to require radiation simultaneously over a continuous spectrum. To be sure,

[3] U.S. Pat. No. 5,303,026 by Strobl, et al. Decl. of Bruce J. Wecker, ECF 37-1 Exh. 6.

[4] The Amendment actually requests that "simultaneously" be inserted in line 5 of Claim 2, but the examiner crossed out the number "5" by hand and wrote in "3." Clearly, the patentee made some typographical error in the requested Amendment. However, it is likely that the error was not in identifying the wrong line of Claim 2 in which to insert the "simultaneously" limitation, but rather in identifying the fifth line of the wrong *claim* in which the limitation should be inserted. Reading the requested amendment as inserting "simultaneously" into the fifth line of Claim 1 would yield the construction that Defendants advance—one that comports with the argument submitted in conjunction with the Amendment. As it stands, however, the "simultaneously" limitation was inserted into Claim 2, where its relevance is not immediately apparent.

the claim language itself contains no such limitation. However, even had the patentees not sought to amend their claims to add the "simultaneously" limitation to Claims 2 and 7, the public would still be entitled to rely upon their statements in prosecution, where the "simultaneously" limitation is clearly argued to be an important aspect of the claimed invention. It would be inconsistent with the prosecution history to permit Plaintiff to now argue that "simultaneously" was only intended to limit Claims 2 and Claim 7, and *not* independent Claim 1, despite Claim 1 being the principle subject of the patentees' detailed argument with respect to Strobl.[5]

Based on the foregoing, the Court construes the phrase "irradiating a body part of the animal with intensity-modulated radiation over a continuous spectrum" as "irradiating a body part of the animal with intensity-modulated radiation simultaneously over a continuous spectrum."

B. "continuous spectrum"

Plaintiff's Proposal	Defendants' Proposal	Court's Construction
every wavelength within a range, or a large number of closely-spaced discrete wavelengths within the range	plain and ordinary meaning	every wavelength within a range, or a large number of closely-spaced discrete wavelengths within the range

Plaintiff argues for a broad construction of this term, wherein, as explained in the specification, a "continuous spectrum" can be comprised of a large number of closely spaced discrete wavelengths. Pl.'s Br. 7-8. Defendants submit that the plain and ordinary meaning of the term is sufficient, though they do not precisely explain their understanding of the plain meaning of the disputed term. Def.'s Br. 7-8. Rather, Defendants take issue with Plaintiff's proffered construction on the ground that the patentees did not clearly define "continuous spectrum" as anything different from the ordinary understanding of that term in the art and that the patentees expressly disclaimed discrete wavelengths in prosecution. *Id.* The Court finds Plaintiff's argument more persuasive.

"To act as its own lexicographer, a patentee must clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning." *Thorner v. Sony Computer Entm't*

[5] Nor does the Court perceive any claim differentiation problems between independent Claim 1 and dependent Claim 2 if Claim 1 is construed to include a "simultaneously" limitation.

America, 669 F.3d 1362, 1365 (Fed. Cir. 2012). "It is not enough for a patentee to simply disclose a single embodiment or use a word in the same manner in all embodiments, the patentee must 'clearly express an intent' to redefine the term." *Id.* (quoting *Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1381 (Fed. Cir. 2008)). In cases where a court has found clear lexicography, the patentee generally links a term with a definition by, for example, stating that a term "means" something. *3M Innovative Properties Co. v. Avery Dennison Corp.*, 350 F.3d 1365, 1369 (Fed. Cir. 2003); *see also Sinorgchem Co. v. Int'l Trade Comm'n*, 511 F.3d 1132, 1336 (Fed. Cir. 2007); *Astrazeneca AB, Aktiebolaget Hassle, KBI-E, Inc. v. Mut. Pharm. Co.*, 384 F.3d 1333, 1338-39 (Fed. Cir. 2004).

Here, the '177 Patent states that "[a] source that provides radiation over a continuous spectrum provides radiation at every wavelength within a range, or at a large number of closely-spaced discrete wavelengths within a range." '177 Patent col. 3:15-19. Plaintiff contends that this sentence is clear lexicography by the patentees, and Plaintiff accordingly proposes a construction adopting the language from that sentence. Defendants argue that the quoted sentence "does not indicate the patentees' intent to define 'continuous spectrum.'" Def.'s Br. 7. Contrary to Defendants' assertion, there is more than just one sentence to indicate that the patentee clearly intended "continuous spectrum" to include numerous discrete wavelengths. Continuing from the quoted passage, the written description indicates that the alternative to a tungsten filament bulb that provides radiation at every wavelength within a given range is "a large number of discrete wavelength radiation sources emitting simultaneously and separated in wavelength, preferably equally, across the spectrum." *Id.* col. 3:21-24. As an example, the patent discloses providing "discrete wavelength radiation sources at intervals of about 10-15 nm, to provide radiation over a continuous spectrum." *Id.* col. 3:25-27. As such, the written description is sufficiently clear that the patented invention can be practiced with a source of radiation that provides radiation at a large number of closely-spaced discrete wavelengths within a range.

Moreover, the requirement of clear lexicography often goes hand-in-hand with the "similarly exacting" requirement that a disavowal of claim scope also be clear and unequivocal. *See, e.g.*, *Thorner*, 669 F.3d at 1366. This is because lexicography is generally used by accused

infringers to *narrow* the scope of a claim. *See CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002) (lexicography is one of at least four ways in which "a court may constrict the ordinary meaning of a claim term"). Here, Plaintiff is urging a construction on the theory that the patentee has defined "continuous spectrum" to encompass something a bit broader than what Defendants contend is the plain and ordinary meaning of the term. Neither party cited any case authority addressing lexicography in the present circumstance. In the absence of any authority prohibiting a patentee from describing and claiming a functional equivalent to the disclosed invention, the Court finds Plaintiff's proposed construction to be more persuasive and more consonant with the disclosures in the '177 Patent specification.

Defendants' prosecution history disclaimer argument does not undermine this conclusion. Defendants point to the patentees' response to an obviousness rejection in light of the Chance[6] prior art reference to argue that the patentees "drew an *unqualified* distinction between 'continuous spectrum' and 'discrete wavelengths,' and disavowed coverage of discrete wavelengths by this claim." Def.'s Br. 8 (emphasis added). In arguing for allowance over Chance, the patentees explained that "[i]n the technique of Chance, only two electromagnetic signals, each at a known, discrete wavelength, are generated and coupled to the subject []." Wecker Decl. Exh. 4 ('177 Patent file history) at May 17, 1994 Response p. 2. Thus, the patentees argued that "Chance does not irradiate a body part with radiation over a continuous spectrum, but only at discret[e] wavelengths." *Id.* at p. 3. Contrary to Defendants' assertion, this is hardly an unqualified disavowal of coverage for all discrete wavelengths. Unlike in *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 998 (Fed. Cir. 2006), upon which Defendants rely, the patentees' argument in prosecution cannot reasonably be interpreted as a broad disavowal of more than was needed to overcome a rejection based on Chance. The more reasonable reading of the patentees' statements—in context—is that they disavowed coverage for two discrete wavelengths, which can hardly be argued to fall within the definition of "continuous spectrum" set forth in the written description. *See* Pl.'s Reply 6-7. There is therefore no inconsistency in distinguishing Chance and

[6] U.S. Patent No. 5,187,672 by Chance et al. Claassen Decl. Exh. C.

claiming that a continuous spectrum can comprise a large number of closely-spaced discrete wavelengths within a range, and the Court rejects Defendants' assertion that the patentees' statements in prosecution disavow coverage of the latter.

Defendants argue in the alternative that accepting Plaintiff's proposed construction would render the claim indefinite. Def.'s Br. 8-9. There is only one example disclosed in the '177 Patent of a "large number of closely-spaced discrete wavelengths" to provide radiation over a continuous spectrum. '177 Patent col. 3:25-27. This, Defendants argue, is insufficient to give reasonable notice of the "bounds or ranges" for the words "large number" and "closely-spaced." As such, the patent "fail[s] to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014); *see* Def.'s Br. 9. Plaintiff notes that because Defendants only recently raised this argument, neither party has developed evidence on how one of ordinary skill in the art would interpret Plaintiff's construction. Nevertheless, Plaintiff contends based upon the testimony of its expert that the skilled artisan would not find a "large number of closely-spaced discrete wavelengths" to be indefinite. Pl.'s Reply 7. Although there is no precise definition of what "a large number of closely-spaced discrete wavelengths within the range" means, the patentee defined "continuous spectrum" as such. That is sufficient at this stage in the proceedings, and the Court need not adopt a contrary construction simply to rescue a claim from potential invalidity. On the present record, the Court cannot determine how one of ordinary skill in the art would interpret a "large number of closely-spaced discrete wavelengths" in the context of the patent. The Court must therefore reserve ruling on indefiniteness until the parties can present a more fulsome evidentiary record on the issue.

The term "continuous spectrum" is accordingly construed as "every wavelength within a range, or a large number of closely-spaced discrete wavelengths within the range."

C. "simultaneously"

Plaintiff's Proposal	Defendants' Proposal	Court's Construction
concurrently, or close in time, relative to the frequency of the living animal's pulse cycle	at the same time	concurrently, or close in time, within a single heartbeat

This term demonstrates the imprecision of words used to describe concepts of time and speed for which science attributes great significance to mere fractions of a second. Defendants here argue that "simultaneously" must be construed to require that radiation over a continuous spectrum must occur at exactly the same time. They rest their argument primarily upon embodiments disclosed in the '177 Patent and on the patentees' statements made to overcome a rejection based on the same Strobl reference discussed above. Def.'s Br. 10-11.

The term "simultaneously" is used consistently in the written description and claim language of the '177 Patent, but it is nowhere defined. Defendants rely on the following use of the term to advance their construction: "Alternatively, there could be provided a large number of discrete wavelength radiation sources emitting *simultaneously* and separated in wavelength, preferably equally, across the spectrum." '177 Patent col. 3:21-24 (emphasis added). Because this disclosure does not set out a time frame for simultaneity, Defendants argue that the term must have its plain and ordinary meaning of "at the same time." Def.'s Br. 10. The term "simultaneously" is also used elsewhere in the written description in the context of simultaneous readings: "[t]his may be done by taking two readings *simultaneously* at blood rich and blood poor portions of the skin." '177 Patent col. 4:25-27 (emphasis added). While the term is not used here in the context of radiation across a continuous spectrum, there is nothing to suggest that the same word is meant to convey different timeframes. To Defendants' point, both uses of the word "simultaneously" in the written description require actions to occur at the same time. However, although "simultaneously" and "at the same time" may mean "at exactly the same instant in time" to a layperson, it is clear from the disclosures in the '177 Patent that the simultaneous actions do not need to coincide instantaneously. Indeed, it may be physically impossible to take two readings at *exactly* the same instant. Rather, as argued by Plaintiff, even Defendants' proposed construction may be imprecise to one of skill in the art because it does not define a time interval for simultaneity and therefore does not distinguish between events that occur close in time during the same interval and events that occur instantaneously, or at the exact same moment in time. Pl.'s Br. 8, n.3; Pl.'s Reply 8. It is not clear, for example, what Defendants' construction of "at the same time" means if "time" can be defined in intervals of seconds, centiseconds, milliseconds,

nanoseconds, or even picoseconds.

Defendants argue that the patentees, in arguing for allowance over Strobl, disclaimed sequential radiation, or radiation at different times. Def.'s Br. 10-11. This is, again, an overly broad reading of the prosecution history. As discussed above, the patentees distinguished Strobl on the ground that Strobl did not teach "the *simultaneous* irradiation of a body part with radiation over a continuous spectrum." January 30, 1995 Amendment at p. 4 (emphasis in original). The patentees elaborated further: "[t]he Strobl reference teaches the irradiation of the body part over a continuous sequence of very narrow wavelength ranges. As a result, data relating to different wavelength ranges is collected at different times. Accordingly, variations in, for example, blood volume, over time as a result of the pulse cycle, cannot be compensated for." *Id.* The patentees thus distinguished simultaneous radiation from radiation carried out in a sequence of narrow wavelength ranges at different times. As Plaintiff argues (and the Court agrees), the most that can be read into this prosecution history is the disclaimer of radiation at different times with regard to the pulse cycle. Pl.'s Reply 9-10. Because the intrinsic record is ambiguous as to the proper time interval in which radiation across a continuous spectrum is to be simultaneous, the Court must examine external sources.

Plaintiff urges that "simultaneously" can mean that the radiation occurs within the same pulse cycle (or, heartbeat) of a living animal. Plaintiff would have "simultaneously" mean "nearly instantaneously" in that the radiation across a continuous spectrum need not be exactly instantaneous so long as readings are made "at points close enough in time to not be impacted by the physiological changes related to the pulse cycle." Pl.'s Br. 12. In fact, Plaintiff suggests that the near simultaneity it proposes would be understood by one of skill in the art to encompass non-instantaneous radiation "so long as the readings are made sufficiently close in time, that is substantially shorter than the heart cycle—*on the order of a hundred samples per heart beat*."[7] Pl.'s Reply 10 (emphasis added). Plaintiff principally relies on the testimony of its expert, Dr.

[7] To a layperson, two actions taken concurrently within the span of a single heartbeat would certainly appear to be simultaneous, or at the same time. Of course, claim construction must be accomplished from the standpoint of one of ordinary skill in the art.

Elvir Causevic, as evidence of how one of ordinary skill in the art would interpret the term in the context of the '177 Patent. Pl.'s Br. 11-2; Pl.'s Reply 9-10. Dr. Causevic's report states that "[o]ne skilled in the art would understand that the reference to proper multivariate analysis and to the changes in blood volume over the pulse cycle mean that the measurements of intensity would need to be made at points close enough in time to not be impacted by the physiological changes related to the pulse cycle." Wecker Decl. Exh. 5 (Causevic Report) ¶ 81. Moreover, Dr. Causevic asserts that at least one embodiment in the patent specification requires time modulation—the pulsing of light sources at different instants—and construing "simultaneously" to mean instantaneously would impermissibly exclude that disclosed embodiment.[8] *Id.* ¶ 84; *see In re Katz Interactive Call Processing Patent Litig.*, 639 F.3d 1303, 1324 (Fed. Cir. 2011) ("there is a strong presumption against a claim construction that excludes a disclosed embodiment"). Dr. Causevic's testimony thus reinforces the conclusion that one of skill in the art would understand that radiation over a continuous spectrum that is carried out within a single heartbeat would be "simultaneous" within the teaching of the '177 Patent.

In sum, the art clearly demands a greater degree of precision than can be conveyed with mere words. The term "simultaneously," as used in the specification, does not require that simultaneity be instantaneous, though it also does not define the applicable time interval. Likewise, the prosecution history disclaims only sequential radiation over a long enough period of time that blood volume can change as a result of the pulse cycle. In the space between, the Court finds, based on the testimony of Plaintiff's expert, that "simultaneously" within the context of the '177 Patent can encompass radiation that is very close in time, or nearly but not exactly instantaneous.[9] Plaintiff's proposed construction, however, is overly technical and unlikely to be of assistance to a lay jury. At the *Markman* hearing, Plaintiff acknowledged that the applicable

[8] The Court has only an excerpt of Defendants' expert report in the record, and Defendants' expert opines only in regard to claim construction based upon the intrinsic record, which this Court has already found to be ambiguous. Pologe Report ¶¶ 43-54. Notably, Dr. Pologe does not explain what meaning one of ordinary skill in the art would ascribe to the term "simultaneously."

[9] Both parties also cited to a number of cases in which the term "simultaneous" has been construed by the Federal Circuit. *See* Pl.'s Br. 10; Def.'s Br. 12-13. The breadth of ways in which that term has been construed only demonstrates that claim construction is a very patent-specific exercise.

time interval could be defined as a heartbeat. As such, the Court construes "simultaneously" to mean "concurrently, or close in time, within a single heartbeat."

V. TERMS IN THE '764 PATENT

The parties dispute the proper construction of two terms in Claim 1 of the '764 Patent. Claim 1 reads (with disputed limitations in bold):

> 1. A method of non-invasive determination of the concentration of at least one analyte in the blood of a mammal, comprising the steps of:
>
> (a) projecting near infrared radiation on a portion of the body of the mammal, said radiation including a plurality of wavelengths;
> (b) sensing the resulting radiation emitted from said portion of the body;
> (c) deriving from the sensed resulting radiation a first **expression for the magnitude of said sensed radiation as a function of wavelength of the sensed radiation**;
> (d) pretreating said first expression to minimize the influence of instrument offset and drift to obtain a second **expression for the magnitude of said sensed radiation as a function of wavelength**; and
> (e) performing **multivariate analysis** of said second expression to obtain a value for the concentration of said analyte.

A. "expression for the magnitude of said sensed radiation as a function of wavelength of the sensed radiation"

Plaintiff's Proposal	Defendants' Proposal	Court's Construction
an array of values representative of the magnitude of the sensed radiation at each measured wavelength	a relationship between the magnitude of the sensed radiation and the wavelength of the sensed radiation which does not include determining ratios of discrete light intensity	an array of values (such as is used to represent a curve, function, or graph) representative of the magnitude of the sensed radiation at each measured wavelength

The central dispute here is whether the "expression" limitation includes determining ratios of discrete light intensity. Defendants argue that the determination of ratios of discrete light intensity was disclaimed in prosecution. Def.'s Br. 13-16. Plaintiff contends that there was no such disclaimer and that, even if there was, the most that the patentee disclaimed was the use of a ratio analyzer to determine the concentration of the analyte of interest, and not the use of ratios generally. Pl.'s Reply 12. The Court agrees with Plaintiff to the extent that its construction does

not encompass use of a ratio analyzer.

"Expression" is mentioned only twice in the '764 Patent. In the "Summary of Invention," the example of a graph is given for an "expression . . . of the concentration of glucose in blood as a function of the wavelengths over which an analysis is carried out." '764 Patent col. 2:57-60. In the written description, an expression is mentioned in connection with the pretreatment step: "the step of pretreatment may also include deriving a new function, the nth derivative with respect to wavelength of the *expression* defining the concentration of glucose as a function of wavelength." *Id.* col. 3:3-7 (emphasis added). Furthermore, Figures 2 and 3 are graphical representations of data from a test subject rabbit, with Figure 2 representing "the absorption for the subject, as a function of the wavelength in the near infrared." *Id.* col. 4:55-62; Figs. 2, 3. These references indicate that an "expression" is a continuous function, such as a graph, comprised of numerous data points that can be manipulated through derivation or other mathematical techniques at the pretreatment step. *Accord id.* col. 6:23-34. This characterization of an "expression" is consistent with the patentee's statements in the prosecution history.

In overcoming an obviousness rejection based on a combination of two prior art references—Clarke[10] and Rosenthal[11]—the patentee stated with respect to Clarke:

> Clarke, et al., discloses a method in which the body is irradiated with radiation at, at a minimum, a reference and a data wavelength. Analysis of the signal obtained from converting detected light into electrical signals consists of using a ratio analyzer []. The ratio analyzer derives a ratio for at least two of the detected wavelengths, such that the ratio can be compared with predetermined values to non-invasively detect the concentration of glucose in a subject's circulatory system []. It will be understood that Clarke, et al. does not obtain and analyze a *continuous expression* for the magnitude of the emitted radiation.

Decl. of Bruce J. Wecker, ECF 37-1 Exh. 3 ('764 Patent File History) at June 3, 1994 Response to Official Action p. 3 (emphasis added). Furthermore, the patentee argued that one of ordinary skill in the art would not be motivated to combine Clarke with Rosenthal:

[10] U.S. Patent No. 5,222,495 by Clarke et al. Claassen Decl. Exh. D.

[11] R.D. Rosenthal, "An Introduction to Near Infrared Quantitative Analysis" (1978). Claassen Decl. Exh. E.

> Clarke, et al. discloses a method involving determining ratios of discrete values of light intensity. Rosenthal discloses a method for treating *continuous expressions*, relating to light intensity values. It would not be possible to apply the pretreatment techniques of Rosenthal to the discrete values employed in Clarke, et al.

Id. pp. 3-4 (emphasis added). Defendants argue based upon these passages that the patentee distinguished between discrete values (which can't be pretreated) and continuous functions (which can) and, as such, disclaimed "determining ratios of discrete light intensity." Def.'s Br. 15. The Court agrees with Plaintiff that this argument overstates the argument that the patentee used to distinguish Clarke. *See* Pl.'s Reply 12-13.

The quoted passages from the prosecution history indicate that the "expression" described in the '764 Patent must be continuous in order for pretreatment and multivariate techniques to be properly applied. Those techniques—such as taking the nth derivative—cannot be applied to discrete values or ratios of discrete values. As such, an "expression" as a continuous function stands in contrast to a "ratio[] of discrete values of light intensity" derived from the detected wavelengths of at least a reference and a data wavelength. Defendants' expert similarly opined that the '764 Patent "claims methods and systems involving 'continuous expressions' as opposed to *a small number of discrete, distinct values* from more than one light source." Wecker Decl. Exh. 7 (Amended Expert Report of Jonas A. Pologe, or "Pologe Report") ¶ 41 (emphasis added). As Plaintiff argues, however, this does not mean that the patentee disclaimed use of ratios or determination of ratios entirely. Pl.'s Reply 12. Rather, the prosecution history simply indicates that the "expression" cannot be *just* a ratio (or even a small number of ratios) of discrete values of light intensity. There is no indication in the prosecution history or the specification that an "expression" cannot be comprised of multiple ratios of discrete values of light intensity or other discrete data points that, when sufficiently numerous, form a continuous function that represents the relationship between the magnitude of the sensed radiation at each measured wavelength. The Court therefore agrees with Plaintiff that Defendants' construction is overly limiting.

Plaintiff's construction, however, is somewhat problematic in the use of "array of values," a term of art that may be unknown to a lay jury. *See* Def.'s Br. 15. Plaintiff asserts that "[t]he aggregation of the data points representing a curve or a function are often referred to as arrays or

matrices in mathematics and computer science." Pl.'s Reply 13. That description is certainly consistent with the example of an "expression" as a graph given in the "Summary of the Invention" and seen in Figures 2 and 3. As such, the Court adopts Plaintiff's construction with a modification to clarify the meaning of "array of values." The term "expression for the magnitude of said sensed radiation as a function of wavelength of the sensed radiation" is accordingly construed as "an array of values (such as is used to represent a curve, function, or graph) representative of the magnitude of the sensed radiation at each measured wavelength."

B. (performing) "multivariate analysis"

Plaintiff's Proposal	Defendants' Proposal	Court's Construction
multivariate analysis is the analysis of two or more independent variables. It is used to find patterns and relationships between several variables simultaneously. It permits the estimation of the effect of a change in one variable on other variables.	determining a model that defines the relationship between two or more independent variables (pretreated transmittance or reflectance values as a function of wavelength) and invasively measured analyte concentrations, and employing the model to analyze the second expression to predict the concentration of the analyte	determining a model that defines the relationship between two or more independent variables (pretreated transmittance or reflectance values as a function of wavelength) and invasively measured analyte concentrations, and employing that model to analyze the second expression to predict the concentration of the analyte, wherein the model can be re-used after it is determined.

The parties dispute the proper construction of "multivariate analysis," which is a well-known technique for analyzing and determining a relationship among multiple variables. By way of background, both parties' experts appear to agree that "multivariate analysis" comprises a calibration step and a prediction step. *See* Causevic Report ¶¶ 120, 122; Pologe Report ¶¶ 31-32. Dr. Causevic's report quotes a chemometric textbook describing the two steps as such: "Calibration is the process of constructing a mathematical model to relate the output of an instrument to the properties of samples. Prediction is the process of using the model to predict properties of a sample given an instrument output." Causevic Report ¶ 122 (quoting Wecker Decl. Exh. 5 (Beebe, Pell, and Seaholtz, John Wily & Son, *Chemometrics, A Practical Guide* (1998))); *see also* Claassen Decl. Exh. F (Beebe & Kowalski, *An Introduction to Multivariate Calibration*

and Analysis, 59 Analytical Chemistry 1007 (1987)) at 1007. The dispute is over whether "multivariate analysis," as used in the claim language, requires the performance of both calibration *and* prediction.

The Court first observes that although the parties present the disputed term as "multivariate analysis," Defendants' proposed construction appears to be aimed at the entire phrase "performing multivariate analysis of said second expression to obtain a value for the concentration of said analyte." From the briefing, it appears that the dispute really lies in where infringement occurs—that is, whether a device that "perform[s] multivariate analysis" must be capable of both calibrating a model *and* applying that model. *See* Pl.'s Br. 16; Def.'s Br. 17. When the parties raise an actual dispute regarding the proper scope of asserted claims, "the court, not the jury, must resolve that dispute." *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008). As such, the Court must construe "performing multivariate analysis" to properly delimit the scope of the claimed invention.

Plaintiff's proposed construction, while it may be technically correct, must be rejected because it offers only an abstract explanation of what multivariate analysis is intended to accomplish, which neither delineates the scope of the claimed method and apparatus nor helps a jury in deciding whether Defendants' accused devices infringe the asserted claims of the '764 Patent. *Sulzer Textil A.G. v. Picanol N.V.*, 358 F.3d 1356, 1366 (Fed. Cir. 2004); *see also Power-One, Inc. v. Artesyn Techs., Inc.*, 599 F.3d 1343, 1348 (Fed. Cir. 2010). To the extent "[t]he designation of an analysis as multivariate draws a contrast from univariate techniques," Pl.'s Br. 16, simply claiming the performance of a multivariate analysis on the "second expression" does not inform, with reasonable certainty, the skilled artisan about the steps that would constitute infringement of the claimed method.

Defendants' proposed construction, in contrast, is consistent with the disclosures in the specification but overly limiting. As Defendants properly note, the '764 Patent only ever describes "multivariate analysis" as a two-step process of developing a model and employing it. As such, the construction of the term should include both steps. Def.'s Br. 17. As explained in the summary of the invention, following the step of pretreatment:

> The nth derivative with respect to wavelength is then used as an input for multivariate analysis. Using multivariate analysis techniques, the glucose concentration is then determined. As is conventional in the use of multivariate techniques in chemical analysis, the multivariate analysis *uses a model* developed by comparing predicted concentrations of the species to be measured in specimens to the known concentrations of the species in that specimen.

'764 Patent col. 3:8-16 (emphasis added). In the more detailed written description, the patent states: "The pretreated data is then subjected to multivariate analysis. The result of the step of multivariate analysis is the glucose concentration." *Id.* col. 6:35-37. These disclosures relate to step (e) of the method of Claim 1: pretreated data is input and predicted analyte concentration is output; in the middle, there is multivariate analysis. As the '764 Patent sets forth: "Various techniques of multivariate analysis are known in the chemical arts." *Id.* col. 6:37-38. "The first step in using multivariate techniques is the development of a model. The model relates various values of pretreated transmittance and reflectance with respect to wavelength and analyte concentrations." *Id.* col. 6:60-64. "In developing the model, the device of the invention is employed," along with invasively collected data. *Id.* col. 6:64-65. Indeed, in an example of the technique described, the written description discloses a model developed using a rabbit test subject wherein pretreated data is used to develop a model. *See id.* col. 7:50-8:9. There is no disclosure or suggestion that "performing multivariate analysis of the second [pretreated] expression" can be accomplished without first developing a model. Even Plaintiff's expert agrees that "[o]ne skilled in the art, reading the specification, and familiar with standard multivariate analysis techniques, would understand that *such analysis* involves a multi-part process." Causevic Report ¶ 120 (emphasis added).

In an effort to rescue its construction, Plaintiff proposes in its reply brief that "[t]he specification is quite clear that this final step of the 'analysis' is employing the model on real patient data . . . . It makes sense to call this final step of taking the measured intensities at various wavelengths, and using mathematics to calculate the concentration as 'performing' 'multivariate analysis.'" Pl.'s Reply 14. To the extent Plaintiff asserts that "performing multivariate analysis" is *just* the application of an already determined model, that interpretation conflicts with Plaintiff's

proffered construction. The mere application of an existing model is not the use of multivariate analysis to "find patterns and relationships between several variables simultaneously"—the *model* contains the already found patterns and relationships.[12] *See* Pl.'s Br. 17-18. In construing a disputed claim limitation, the Court must discern "the meaning it would have to persons in the field of the invention, when read and understood in light of the *entire* specification and prosecution history." *Fenner Investments*, 778 F.3d at 1323 (emphasis added). The entire specification discloses that a model must first be developed using readings from the claimed device before it can be applied to predict the concentration of blood analytes using non-invasively collected data. Thus, consistent with Plaintiff's own definition, the term "multivariate analysis," as used in the claim language and explained in the specification, embodies both the development and application of a model using multivariate techniques.

This conclusion is reinforced by dependent Claims 3-4 and 7-8, which Defendants argue "would make no sense if 'performing multivariate analysis' did not require developing a model." Def. Br. 18. For example, Claim 3 reads: "The method of claim 1, wherein step (e) comprises the step of using the technique of partial least squares." '764 Patent, col. 8:55-57. As disclosed in the written description, "A preferred multivariate analysis technique is partial least squares (PLS). . . . Those skilled in the art of constructing models using these techniques will be able to do so using appropriate commercial software packages." *Id.* col. 6:37-56. The technique of partial least squares, as with all multivariate techniques, begins with the development of a model. *Id.* col. 6:60-61; *see also* Claassen Decl. Exh. F at 1015-16. "Performing multivariate analysis" in step (e) of Claim 1 using the technique of partial least squares thus requires the development of a model. The Court therefore agrees with Defendants' argument—unrebutted by Plaintiff—that a construction of "multivariate analysis" that excludes the calibration step would be inconsistent

[12] Plaintiff's expert opines that "[o]ne skilled in the art would not understand that the multivariate analysis would be artificially divided between the calibration and prediction steps in order to require that both be performed after the collection of patient data." Causevic Report ¶ 126. While this statement was made in the context of whether the '764 Patent requires patient-specific calibration, the Court notes that the artificial division between calibration and prediction is precisely what Plaintiff is arguing for when it asserts that "multivariate analysis" can be just the application of a model to collected data.

with the language of the other claims in the '764 Patent.

The trouble with adopting Defendants' proposed construction entirely, however, is that such a construction could render the patented invention useless for its stated purpose. Developing a model for multivariate analysis requires calibrating the model using more accurate data obtained through contemporaneously drawn blood samples and measuring the concentration of blood analytes in that blood. If that calibration has to occur every time multivariate analysis is performed, it would defeat the purpose of a non-invasive technique for measuring blood analyte concentration. Pl.'s Br. 19. To be sure, the Court cannot "redraft claims to contradict their plain language in order to avoid a nonsensical result." *Haemonetics Corp. v. Baxter Healthcare Corp.*, 607 F.3d 776, 782 (Fed. Cir. 2010); *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357 (Fed. Cir. 1999); *see also* Def.'s Br. 17-18. As Plaintiff and Plaintiff's expert note, nothing in the '764 Patent requires that a model be developed *each time* a patient needs to take a measurement. Pl.'s Br. 19; Causevic Report ¶ 126. Indeed, the written description itself provides that "[a]fter an acceptable model has been iteratively developed, the model is *employed* in analyzing real data to obtain analyte concentrations," '764 Patent col. 7:22-24 (emphasis added), suggesting that a properly calibrated model can be used for subsequent measurements. Furthermore, the model constructed using rabbit data is used to develop "weighting factors or calibration values" that can then be used to obtain the concentration value for the analyte of interest through simple multiplication with pretreated absorbance data at each wavelength and addition of the products of that calculation. *Id.* col. 8:18-26. These disclosures, although not sufficient to support a construction that "performing multivariate analysis" constitutes *only* the application of a model, suggests that the claimed invention is intended to cover both the development and application of a model developed through multivariate techniques as well as the application of that model in subsequent measurements.

Based on the foregoing, "performing multivariate analysis" on the second expression following pretreatment must therefore be construed as "determining a model that defines the relationship between two or more independent variables (pretreated transmittance or reflectance values as a function of wavelength) and invasively measured analyte concentrations, and

employing that model to analyze the second expression to predict the concentration of the analyte, wherein the model can be re-used after it is determined."

VI. MEANS-PLUS-FUNCTION TERMS IN BOTH PATENTS

In addition to the terms already discussed, the parties dispute the definiteness and proper construction of three functional limitations:

1. "means for calculating the concentration of the analyte from said detected intensity." ('177 Patent, Claim 7)

2. "data processing means adapted to (i) pretreat said first expression to minimize the influence of instrument offset and drift to obtain a second expression for the magnitude of said sensed radiation as a function of wavelength and (ii) perform multivariate analysis of said second expression to obtain a value for the concentration of said analyte." ('764 Patent, Claim 5)

3. "data processing means adapted to perform multivariate analysis of said second expression using the technique of partial least squares." ('764 Patent, Claim 7)

The parties' respective arguments are the same regarding each limitation. Defendant argues that each is a means-plus-function term that must satisfy the requirements of 35 U.S.C. § 112(f) and each limitation fails to adequately disclose proper structure. Def.'s Br. 19-25. Plaintiff argues that the terms are not subject to § 112(f) but argues in the alternative that if they are, they adequately disclose a "processor/controller" as the corresponding structure. Pl.'s Br. 19-25; Pl.'s Reply 14-15.

As an initial matter, the Court rejects Plaintiff's contention that these terms are *not* means-plus-function terms. Plaintiff offers scant evidence to overcome the presumption that the terms, in using the specific language of "means," invokes § 112(f). *See* Pl.'s Br. 22. These disputed limitations are properly couched in means-plus-function language, and the proposed construction set forth below accordingly encompass the parties' agreed functions for each term, as stipulated at the Court's request following the *Markman* hearing. *See* ECF 50, 53.

The tradeoff to claiming limitations in functional terms is that § 112(f) requires a patentee to disclose specific structure that corresponds to the claimed function. The "structure disclosed in the specification is 'corresponding' structure *only* if the specification or prosecution history clearly links or associates that structure to the function recited in the claim. This duty to link or associate

structure to function is the *quid pro quo* for the convenience of employing § 112, ¶ 6."[13] *B. Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1424 (Fed. Cir. 1997); *see also Saffran v. Johnson & Johnson*, 712 F.3d 549, 562 (Fed. Cir. 2013). When the corresponding structure is argued, as here, to be a processor, the court must determine whether the claimed function can be achieved on a general purpose processor without special programming. *See Katz*, 639 F.3d at 1316. If it cannot, a "special purpose computer-implemented means-plus-function limitation" requires the disclosure of the algorithm for performing the function. *Function Media, L.L.C. v. Google, Inc.*, 708 F.3d 1310, 1318 (Fed. Cir. 2013). "The specification can express the algorithm in any understandable terms including as a mathematical formula, in prose, or as a flow chart, or in any other manner that provides sufficient structure." *Id.* (internal quotations and citations omitted); *see also Typhoon Touch Techs., Inc. v. Dell, Inc.*, 659 F.3d 1376, 1384 (Fed. Cir. 2011). While the patentee "need not disclose details of structures well known in the art, . . . the specification must nonetheless disclose some structure." *Default Proof Credit Card Sys., Inc. v. Home Depot U.S.A., Inc. (d/b/a The Home Depot)*, 412 F.3d 1291, 1302 (Fed. Cir. 2005). "Stated differently, the testimony of one of ordinary skill in the art cannot supplant the total absence of structure from the specification." *Id.*

Contrary to Plaintiff's assertions, the Court finds that the three disputed means-plus-function terms do not fall within the general purpose processor exception to specific claiming acknowledged in *In re Katz Interactive Call Processing Patent Litigation*. *See* 639 F.3d at 1315-17. Merely using the magic words "data processing means," as in Claims 5 and 7 of the '764 Patent, does not mean that the claimed functions "can be achieved by any general purpose computer without special programming." *Katz*, 639 F.3d at 1316. Indeed, the fact that the "data processing means" must be "adapted" to accomplish the specified function suggests that the corresponding data processor must be specially programmed to accomplish the claimed function. Similarly, the "means for calculating" limitation in Claim 7 of the '177 Patent requires a processor specially programmed to calculate "the concentration of the analyte from said detected intensity."

[13] Before the America Invents Act ("AIA"), Pub. L. No. 112–29, took effect on September 16, 2012, this subsection was designated as 35 U.S.C. § 112 ¶ 6.

As such, it must disclose the specific algorithm for making that calculation. Neither patent sufficiently discloses a specific algorithm for the claimed functions.

A. '177 Patent, Claim 7: "means for calculating the concentration of the analyte from said detected intensity."

Plaintiff's Proposal	Defendants' Proposal	Court's Construction
Function: calculating the concentration of the analyte from the detected intensity Structure: The structure which calculates the concentration of the analyte (substance in the blood) can be a data processor/controller or equivalents.	Function: calculating the concentration of the analyte from the detected intensity Structure: Indefinite under 35 U.S.C. § 112. Alternatively: Data processor and controller 50 programmed to calibrate the apparatus with a partial least squares multivariate analytical technique using data obtained from the apparatus and analyte concentration determined by invasively-obtaining blood samples by lancing a body part to obtain a set of factors and to use the set of factors calculated during the invasive calibration of the instrument to multiply by a given spectra to provide the concentration of the analyte.	Function: calculating the concentration of the analyte from the detected intensity Structure: Indefinite under 35 U.S.C. § 112 (f)

Plaintiff argues that the '177 Patent sufficiently discloses an algorithm to accomplish the required calculation. The specification provides that "[i]n using the calibrated instrument to obtain an analyte concentration, data processor/controller 50 will, in accordance with conventional techniques, calculate the concentration of the analyte in blood, using the set of factors calculated during calibration of the instrument as discussed above." '177 Patent col. 4:47-52. Furthermore, after the device is calibrated and a set of factors developed from that calibration, "[t]he set of factors will, when multiplied by given spectrum, provide the concentration of the desired analyte in the blood." *Id.* col. 4:7-46. Plaintiff contends that these disclosures sufficiently set forth a specific algorithm for "calculating the concentration of the analyte from the detected intensity."

These disclosures are insufficient because they describe how to arrive at an appropriate

algorithm for performing the required the calculation, and not the algorithm for *how* the processor calculates the concentration of the analyte from the detected intensity. *See Function Media*, 708 F.3d at 1318 (disclosures describing a computer program that transmits insufficient to show how program transmits). Had the patentees disclosed the factors used by the processor to calculate concentration, then the assertion that those factors may be multiplied to obtain the concentration may be sufficient structure. As it stands, the fact that various techniques for calibrating the claimed device and obtaining the factors by which the processor calculates concentration from detected intensity are "conventional" and known in the art does not rescue the claim. *Triton Tech of Texas, LLC v. Nintendo of Am., Inc.*, 753 F.3d 1375, 1379 (Fed. Cir. 2014); *see also Biomedino, LLC v. Waters Techs. Corp.*, 490 F.3d 946, 953 (Fed. Cir. 2007) ("a bare statement that known techniques or methods can be used does not disclose structure"). The '177 Patent discloses no algorithm, nor even describes an algorithm (as opposed to a means of obtaining the algorithm) through mathematical formula, prose, or flow chart. As such, Claim 7 of the '177 Patent is indefinite for failure to satisfy the claiming requirements of 35 U.S.C. § 112(f).

B. The '764 Patent

'764 Patent, Claim 5: "data processing means adapted to (i) pretreat said first expression to minimize the influence of instrument offset and drift to obtain a second expression for the magnitude of said sensed radiation as a function of wavelength and (ii) perform multivariate analysis of said second expression to obtain a value for the concentration of said analyte."		
Plaintiff's Proposal	**Defendants' Proposal**	**Court's Construction**
Function: (i) pretreat the first expression to minimize the influence of instrument offset and drift to obtain a second expression for the magnitude of the sensed radiation as a function of wavelength and (ii) perform multivariate analysis of the second expression to obtain a value for the concentration of the analyte. Structure: The structure for data processing means is a data processor/controller or equivalents and can include a	Function: (i) pretreat the first expression to minimize the influence of instrument offset and drift to obtain a second expression for the magnitude of the sensed radiation as a function of wavelength and (ii) perform multivariate analysis of the second expression to obtain a value for the concentration of the analyte. Structure: Indefinite under 35 U.S.C. § 112. Alternatively: Data processor	Function: (i) pretreat the first expression to minimize the influence of instrument offset and drift to obtain a second expression for the magnitude of the sensed radiation as a function of wavelength and (ii) perform multivariate analysis of the second expression to obtain a value for the concentration of the analyte. Structure: Indefinite under 35 U.S.C. § 112(f)

microprocessor	and controller 23 programmed to (i) take the nth derivative, and in particular, the second derivative, of the intensity vs. wavelength function, or, alternatively, subtract the mean of the whole spectrum from each data point in the spectrum and then dividing each data point by the standard deviation of the whole spectrum, and (ii) determine the model that defines the relationship between two or more independent variables (pretreated transmittance or reflectance values as a function of wavelength) and the analyte concentration.	

'764 Patent, Claim 7: "data processing means adapted to perform multivariate analysis of said second expression using the technique of partial least squares."		
Plaintiff's Proposal	**Defendants' Proposal**	**Court's Construction**
Function: perform multivariate analysis of the second expression using the technique of partial least squares Structure: The structure which calculates the concentration of the analyte (substance in the blood) can be a data processor/controller or equivalents.	Function: perform multivariate analysis of the second expression using the technique of partial least squares Structure: Indefinite under 35 U.S.C. § 112. Alternatively: Data processor and controller 23 programmed to determine a model that defines the relationship between two or more independent variables (pretreated transmittance of reflectance values as a function of wavelength) and the analyte concentration using the technique of partial least squares with six factor loadings.	Function: perform multivariate analysis of the second expression using the technique of partial least squares Structure: Indefinite under 35 U.S.C. § 112(f)

For both means-plus-function limitations in the '764 Patent, Plaintiff identifies the disclosure at Column 6, Lines 23-59 as a description of the requisite algorithm. Pl.'s Br. 24-25. The Court agrees—and Defendants do not contest—that this passage sufficiently discloses a specific algorithm for pretreatment in the form of "taking the nth derivative, and in particular, the second derivative, of the intensity vs. wavelength function" or "subtracting the mean of the whole

spectrum from each data point in the spectrum and then dividing each data point by the standard deviation of the whole spectrum." '764 Patent, col. 6:27-34; *see* Def.'s Br. 23. However, in a similar fashion to the '177 Patent, the '764 Patent fails to disclose or describe a specific algorithm for performing multivariate analysis, which this Court has construed to mean both the development of a model representing the relationship between pretreated transmittance/reflectance values as a function of wavelength and invasively measured analyte concentrations, as well as the subsequent and repeated application of that model.

Simply pointing to "[v]arious techniques" of multivariate analysis "known in the chemical arts" is insufficient to demarcate the bounds of the invention, as the indefiniteness inquiry is not merely concerned "with whether one of ordinary skill in the art may find a way to practice the invention," *ePlus, Inc. v. Lawson Software, Inc.*, 700 F.3d 509, 519 (Fed. Cir. 2012), but rather with "whether the disclosed algorithm, from the viewpoint of a person of ordinary skill, is sufficient to define the structure and make the bounds of the claim understandable," *Noah Sys., Inc. v. Intuit Inc.*, 675 F.3d 1302, 1313 (Fed. Cir. 2012). Here, the disclosure identified by Plaintiff amounts to claiming the field of multivariate analysis, along with software that can be used to perform the analysis, and telling the reader to figure out a way to implement the analysis in a processor. There is no specific explanation of how that function is to be achieved, nor is there evidence that one of ordinary skill in the art would know, based on this disclosure, how to program a computer to perform the multivariate analysis claimed in the patent. *Compare id.* at 1317-18 (references to "off the shelf software" and knowledge of individuals with ordinary skill in the art insufficiently specific to satisfy § 112(f)) *with Typhoon*, 659 F.3d at 1386 (descriptive algorithm sufficient where description set out all steps of the method and evidence showed that the steps could be readily implemented by persons of skill in computer programming). Due to the lack of specificity, the Court finds that the '764 Patent does not sufficiently disclose structure to "perform multivariate analysis of the second expression to obtain a value for the concentration of the analyte" or "perform multivariate analysis of the second expression using the technique of partial least squares." As such, Claims 5 and 7 of the '764 Patent are indefinite under § 112(f).

VII. ORDER

For the reasons set forth above, the Court construes the disputed terms as follows:

Claim Terms	Court's Construction
irradiating a body part of the animal with intensity-modulated radiation over a continuous spectrum	irradiating a body part of the animal with intensity-modulated radiation simultaneously over a continuous spectrum
continuous spectrum	every wavelength within a range, or a large number of closely-spaced discrete wavelengths within the range
simultaneously	concurrently, or close in time, within a single heartbeat
expression for the magnitude of said sensed radiation as a function of wavelength of the sensed radiation	an array of values (such as is used to represent a curve, function, or graph) representative of the magnitude of the sensed radiation at each measured wavelength
multivariate analysis (or, performing multivariate analysis of said second expression to obtain a value for the concentration of said analyte)	determining a model that defines the relationship between two or more independent variables (pretreated transmittance or reflectance values as a function of wavelength) and invasively measured analyte concentrations, and employing that model to analyze the second expression to predict the concentration of the analyte, wherein the model can be re-used after it is determined.
means for calculating the concentration of the analyte from said detected intensity	Function: calculating the concentration of the analyte from the detected intensity Structure: Indefinite under 35 U.S.C. § 112(f).
data processing means adapted to (i) pretreat said first expression to minimize the influence of instrument offset and drift to obtain a second expression for the magnitude of said sensed radiation as a function of wavelength and (ii) perform multivariate analysis of said second expression to obtain a value for the concentration of said analyte.	Function: (i) pretreat the first expression to minimize the influence of instrument offset and drift to obtain a second expression for the magnitude of the sensed radiation as a function of wavelength and (ii) perform multivariate analysis of the second expression to obtain a value for the concentration of the analyte. Structure: Indefinite under 35 U.S.C. § 112(f).
data processing means adapted to perform multivariate analysis of said second expression using the technique of partial least squares	Function: perform multivariate analysis of the second expression using the technique of partial least squares Structure: Indefinite under 35 U.S.C. § 112(f).

The Court hereby sets a Further Case Management Conference on May 28, 2015 at 1:30 p.m. in Courtroom 3, 5th Floor, San Jose. The parties shall submit a joint case management statement by no later than May 21, 2015 with a proposed case schedule following claim construction.

IT IS SO ORDERED.

Dated: April 28, 2015

BETH LABSON FREEMAN
United States District Judge

United States District Court
Northern District of California