UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

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CASE NO.: **CV 16-05947 SJO (ASx)** **DATE:** **August 1, 2017**

TITLE: **Dexcom, Inc. v. AgaMatrix, Inc.**

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PRESENT: THE HONORABLE S. JAMES OTERO, UNITED STATES DISTRICT JUDGE

Victor Paul Cruz	Not Present
Courtroom Clerk	Court Reporter

COUNSEL PRESENT FOR PLAINTIFF:	**COUNSEL PRESENT FOR DEFENDANT:**
Not Present	Not Present

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PROCEEDINGS (in chambers): CLAIM CONSTRUCTION ORDER; ORDER GRANTING DEFENDANT'S MOTION TO EXCLUDE DECLARATION OF DR. WEBER [Docket No. 88]

Plaintiff Dexcom, Inc. ("Dexcom" or "Plaintiff") and Defendant AgaMatrix, Inc. ("AgaMatrix" or "Defendant") have filed claim construction briefs in which they ask the Court to construe four (4) disputed phrases found in the sole patent asserted in this litigation, U.S. Patent No. 7,081,195 ("the '195 Patent"). Dexcom filed its Opening Claim Construction Brief ("Opening Brief") on June 8, 2017. AgaMatrix filed its *Markman* Brief ("Responsive Brief"), under seal, on June 23, 2017.[1] Dexcom filed its Reply *Markman* Brief ("Reply Brief") on June 29, 2017.

Notwithstanding longstanding Federal Circuit precedent requiring district courts to focus on the intrinsic record in construing claim terms and phrases, *see Phillips v. AWH Corp.*, 415 F.3d 1303, 1317-18 (Fed. Cir. 2005) (en banc), Dexcom has chosen to submit a twenty-page declaration from one of its experts, Stephen G. Weber, Ph.D., in which Dr. Weber offers his opinions regarding how a person of ordinary skill would have understood the disputed phrases at the time the '195 Patent was filed. (*See* Decl. Stephen G. Weber, Ph.D., in Supp. Opening Br. ("Weber Opening Decl."), ECF No. 86-12.) AgaMatrix responded by filing a Motion to Exclude Declaration of Dr. Weber ("Motion to Exclude") on June 19, 2017, arguing the Weber Opening Declaration should be excluded both because it is untimely and because it contains inadmissible hearsay. Dexcom opposed the Motion to Exclude ("Exclude Opposition") on June 26, 2017, and AgaMatrix replied ("Exclude Reply") on June 28, 2017.

The Court heard argument from counsel on July 20, 2017.

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[1] AgaMatrix's Responsive Brief and supporting materials were docketed on June 26, 2017 after the Court granted AgaMatrix's application for leave to file these papers under seal. (*See* Order Granting AgaMatrix's Appl. for Leave to File Under Seal, ECF No. 96.)

I. FACTUAL AND PROCEDURAL BACKGROUND

Dexcom initiated the instant patent infringement action against AgaMatrix on August 9, 2016, asserting that AgaMatrix's blood glucose meters using "WaveSense™ technology," including the CVS Health™ Advanced Blood Glucose Meter ("CVS Meter"), infringe one or more claims of the '195 Patent. (*See* Compl., ECF No. 1.) Dexcom filed its First Amended Complaint ("FAC") on September 30, 2016, in which it alleges the following. (*See* FAC, ECF No. 31.)

Dexcom, a corporation organized under the laws of the state of Delaware with its principal place of business in San Diego, California, is a medical device company primarily focused on the design, development, and commercialization of glucose monitoring systems for use by and for the treatment of patients suffering from diabetes. (*See* FAC ¶ 1.) Dexcom has a substantial patent portfolio consisting of more than 700 pending and issued patents worldwide, including the '195 Patent, entitled "Systems and Methods for Improving Electrochemical Analyte Sensors." (FAC ¶¶ 2-3, 9.) Dexcom is the owner and assignee of the '195 Patent, which issued on July 25, 2006 and was the subject of *ex parte* re-examination proceedings before the United States Patent and Trademark Office ("PTO") that concluded with the issuance of an *Ex Parte* Reexamination Certificate on April 24, 2012. (*See* FAC ¶ 9.)

AgaMatrix is a corporation organized under the laws of the state of Delaware with its principal place of business in Salem, New Hampshire that manufactures, distributes, advertises, and/or sells at least the CVS Meter. (*See* FAC ¶¶ 4, 7.) AgaMatrix advertises its blood glucose meters as "featur[ing] its WaveSense™ technology, a proprietary suite of measurement techniques using [the] dynamic electrochemistry® [technology] to correct factors that can impact the accuracy of blood glucose measurements." (*See* FAC ¶ 11, Ex. D.) AgaMatrix's Dynamic Electrochemistry Technology, in turn, is "a sophisticated technology platform for sensing blood glucose, by improving the ability to detect the glucose signal and correct for common sources of interference." (*See* FAC ¶ 10, Ex. C.) AgaMatrix's "WaveSense™ Technology uses Dynamic Electrochemistry® coupled with specific signal processing algorithms to correct for a number of errors that are common in self-monitoring blood glucose (SMBG) systems, resulting in more accurate measurements." (*See* FAC ¶ 12, Ex. D.) More specifically, its WaveSense™ technology uses "[a] time-varying input signal [that] induces an output signal . . ., which can then be exploited by sophisticated digital signal processing algorithms to give an accurate glucose reading." (*See* FAC ¶ 12, Ex. D.)

Dexcom asserts a single cause of action against AgaMatrix for direct infringement of one or more claims of the '195 Patent, literally or under the doctrine of equivalents. (*See generally* FAC.) Specifically, Dexcom alleges that AgaMatrix products using the WaveSense™ technology, including at least the CVS Meter, directly infringe at least claim 53, which is discussed in greater detail in Section II, *infra*. Dexcom alleges the CVS Meter satisfies each element of claim 53, including the preamble, to the extent it is limiting, by pointing to different AgaMatrix webpages and portions of the '439 Patent. (*See* FAC ¶¶ 24-30.) Finally, Dexcom alleges AgaMatrix both induces

infringement of the '195 Patent by instructing its customers how to use its specifically configured products and contributes to infringement of the '195 Patent by offering to sell or selling components that constitute a material part of the invention claimed in the '195 Patent. (*See* FAC ¶¶ 31-32.)

On November 21, 2016, the parties filed their Joint Rule 26(f) Report, in relevant part "agree[ing] that the Northern District of California Patent Local Rules ('P.L.R.') should apply . . . ." (Joint Rule 26(f) Report 2, ECF No. 51.) On December 19, 2016, the Court held a scheduling conference, during which it (1) imposed a trial and pretrial schedule; (2) limited the number of claim terms to be construed and the final number of asserted claims; (3) required the parties to follow the Northern District of California's Patent Local Rules ("P.L.R.") in light of their agreement; and (4) viewed each side's technology tutorials. (*See* Minutes of Scheduling Conference, ECF No. 57; Reporter's Tr. of Mandatory Scheduling Conference 4:12-18, ECF No. 63.)

The parties filed their Joint Claim Construction and Prehearing Statement ("JCCPS") on April 18, 2017. (*See* JCCPS, ECF No. 82.) In this filing, the parties noted that disputes had arisen regarding their anticipated reliance on both extrinsic evidence and expert witnesses for the purpose of claim construction. (*See* JCCPS.) On May 10, 2017, AgaMatrix filed a Supplement to the JCCPS, stating it "will rely on the opinions and testimony of Dexcom expert Dr. David J. Vachon provided at his deposition taken May 4, 2017 in the copending *Inter Partes* Review Nos. 2016-01679 and 2016-01680." (*See* Suppl. to JCCPS, ECF No. 83.) The parties' claim construction briefs and AgaMatrix's Motion to Exclude followed.

II. TECHNOLOGICAL SUMMARY

According to the specification of the '195 Patent, the claimed invention "relates generally to systems and methods involving the electrochemical detection or measurement of analytes." (Opening Br., Ex. B ("'195 Patent") col. 1:17-19, ECF No. 86-2.) The primary "analyte" considered in the '195 Patent is glucose. (*See* '195 Patent at Abstract.)

The '195 Patent states the inventions disclosed therein are designed to overcome problems with known electrochemical sensors, including that these sensors "can electrochemically **react not only with the analyte to be measured** (or by-product of the enzymatic reaction with the analyte), but **additionally can react with other electroactive species** that are not intentionally being measured (for example, interfering species), which causes an increase in signal strength due to these 'interfering species'." ('195 Patent col. 1:43-49 [emphasis added].) "For example, in a conventional . . . glucose sensor wherein the sensor measures hydrogen peroxide, interfering species such as acetaminophen, ascorbate, and urate, are known to produce inaccurate signal strength when they are not properly controlled." ('195 Patent col. 1:53-58.)

According to the specification, two solutions to the aforementioned problem were known to exist at the time the provisional application leading to the '195 Patent was filed. First, "[s]ome glucose sensors utilize a membrane system that blocks at least some interfering species, such as ascorbate and urate," by including in at least one layer of the membrane assembly "a porous structure that has a relatively impermeable matrix with a plurality of 'micro holes' or pores of molecular dimensions, such that transfer through these materials is primarily due to passage of species through the pores," thereby acting as a "sieve." ('195 Patent cols. 1:61-2:3.) But "[i]n other such examples, at least one layer of the membrane assembly defines a permeability that allows selective dissolution and diffusion of species as a solute through the layer." ('195 Patent col. 2:3-6.) "Unfortunately, it is difficult to find membranes that are satisfactory or reliable in use, especially in vivo, which effectively block all interferants and/or interfering species." ('195 Patent col. 2:6-9.)

The invention claimed purports to solve this problem of "interferants" and "interfering species" in analyte-measurement devices by obtaining differential signal measurements based on multiple bias potential settings. ('195 Patent col. 2:13-20.) As the specification explains, a given concentration of an analyte (such as hydrogen peroxide, a marker for glucose) and an interfering species (such as acetaminophen) will produce **different amounts of electric current depending on the voltage** that is applied to two electrodes. ('195 Patent cols. 6:61-7:43.) This effect is displayed graphically in Figure 2, reproduced below:

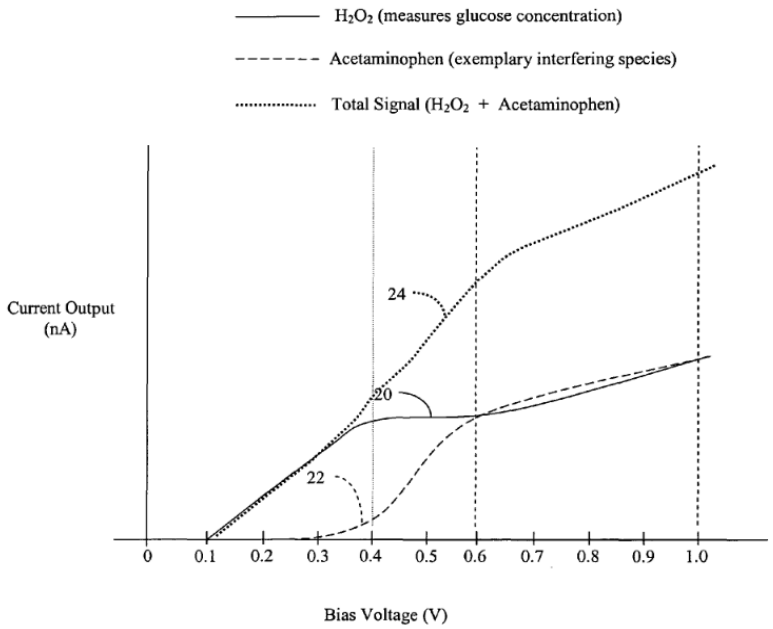

Figure 2 is a schematic graph of current versus bias voltage obtained from cyclic voltammetry for hydrogen peroxide, or H_2O_2, and acetaminophen. Figure 2 illustrates that hydrogen peroxide

produces an electric current in the sample when as little as 0.1 volts are applied to the electrodes, whereas acetaminophen begins producing more than a *de minimis* electric current when approximately 0.3 volts are applied. Figure 2 also shows that the current produced by hydrogen peroxide remains relatively constant when a voltage between approximately 0.4V and 0.6V is applied to the electrodes, while the current output produced by acetaminophen across these voltages increases dramatically. Thus, if measurements of current outputs in a sample containing glucose and acetaminophen are taken at both 0.4V and 0.6V and different signal values are obtained, the difference can be attributed to the presence of acetaminophen. Subtracting the current measurements taken at 0.4V and 0.6V from each other can provide an acetaminophen-free measure of the concentration of glucose in the sample. Or, in the words of the '195 Patent, "the preferred embodiments provide systems and methods for improving the quality of analyte-measuring devices [first] by **identifying interfering species** on an analyte signal" and then "by **obtaining differential measurements** based on **multiple bias potential settings**." ('195 Patent col. 2:13-20 [emphasis added].)

The '195 Patent initially contained 42 claims, of which 3 were independent. (*See* '195 Patent cols. 12-14.) An *Ex Parte* Reexamination Certificate issued on April 24, 2012, which (1) cancelled the three independent claims; (2) confirmed the patentability of other claims; (3) determined other claims are patentable as amended; and (4) added new claims 43 through 62 and determined these claims to be patentable. (*See* '195 Patent col. 1*:16-25.)[2] Among these new claims is independent claim 53, which is asserted in this litigation. This claim is reproduced in its entirety below, with disputed claim terms highlighted in bold text:

> A method for identifying a signal interference in an analyte-measuring device, the method comprising:
> [a] providing at least one electrochemical sensor;
> [b] measuring a first **signal output obtained at a** first **bias potential setting**;
> [c] measuring a second **signal output at a** second **bias potential setting**;
> [d] comparing the first **signal output** with the second **signal output** to determine a differential measurement, thereby identifying **an interference in the signal outputs**; and
> [e] deriving an analyte concentration from the first **signal output** and the second **signal output** to determine an analyte concentration,
> [f] wherein the first **bias potential setting** is at a different bias voltage than the second **bias potential setting**.

('195 Patent col. 4*:1-15.)

[2] The Court cites to columns of the *Ex Parte* Reexamination Certification using asterisks.

According to the specification, "[t]he term '**signal output**,' as used herein, is a **broad term** and is used in its ordinary sense, including, without limitation, an **analog or digital signal** directly related to the measured analyte from the analyte-measuring device. The term encompasses a single point, or alternatively, a plurality of time spaced data points from a substantially continuous glucose sensor, which comprises individual measurements taken at time intervals ranging from fractions of a second up to, for example, 1, 2, or 5 minutes or longer." ('195 Patent col. 4:25-33 [emphasis added].) The term "**bias potential**" is "a **broad term** and is used in its ordinary sense, including, without limitation, the **voltage difference between two points in a circuit**, which is the same cause of the flow of a current, if sufficient analyte is present." ('195 Patent col. 4:61-65 [emphasis added].)

Finally, although the '195 Patent does not expressly define the term "**interference**," it defines "[t]he terms 'interferants' and 'interfering species,' as used herein, [as] broad terms . . . used in their ordinary sense, including, without limitation, **effects and/or species that interfere with the measurement of an analyte of interest** in a sensor to produce a **signal that does not accurately represent** the analyte measurement." ('195 Patent col. 5:3-8 [emphasis added].) According to the specification, one example of "interfering species" would be "compounds with an oxidation or reduction potential that overlap[ ] with the analyte to be measured," while one example of an "interferant" is "local ischemia," which "produces error in the output signal due to lack of sufficient oxygen to react with the enzyme." ('195 Patent col. 5:8-14.) The specification further describes "interfering species" as "compounds with an oxidation or reduction potential that overlaps with the analyte to be measured (or by product of the enzymatic reaction with the analyte)." ('195 Patent col. 1:49-53.)

III. LEGAL STANDARDS

A. Principles of Claim Construction

Before a jury can determine if any of the asserted claims are invalid or if the defendant's technology infringes one or more asserted claims, the court must determine the meaning and scope of the asserted claims through the process of "claim construction." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370, 116 S. Ct. 1384 (1996). Only after the claims have been construed can the jury compare the allegedly infringing device against the claims. *Id.*

In *Phillips v. AWH Corp.*, 415 F.3d 1303, 1311-24 (Fed. Cir. 2005) (en banc), the en banc Federal Circuit set forth a number of principles to guide lower courts through the claim construction process. The general rule is that the words of a claim "are generally given their ordinary and customary meaning," which is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application" *Id.* 1312-13 (citations omitted). "[T]he person of ordinary skill in the art is deemed

to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Id.* at 1313.

"In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Id.* at 1314. "In such circumstances, general purpose dictionaries may be helpful." *Id.* Where, however, "determining the ordinary and customary meaning of the claim requires examination of terms that have a particular meaning in a field of art," courts look to other sources, including "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Id.* (quoting *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004)).

Moreover, "[t]he claims themselves provide substantial guidance as to the meaning of particular claim terms," for example by observing "the context in which a term is used in the asserted claim." *Id.* Comparing the usage of a term across different claims and examining difference among claims can also provide valuable insight into the meaning of claim terms. *Id.*

"The claims, of course, do not stand alone," and the specification provides "the single best guide to the meaning of a disputed term." *Id.* at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). One reason the specification is of paramount importance is that it "may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess." *Id.* at 1316; *see also Markman*, 52 F.3d at 980 ("[A] patentee is free to be his own lexicographer"). That said, "[t]hough understanding the claim language may be aided by explanations contained in the written description, it is important not to import into a claim, limitations that are not part of the claim. For example, a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment." *Superguide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004). Moreover, the prosecution history, which consists of the complete record of the proceedings before the PTO and includes the prior art cited during the examination of the patent, may also shed "decisive light" on the proper construction of a claim term, particularly where an applicant limits her invention to overcome prior art. *Regents of Univ. of Cal. v. Dakocytomation Cal., Inc.*, 517 F.3d 1364, 1372-73 (Fed. Cir. 2008); *Phillips*, 415 F.3d at 1316-17; *N. Am. Container, Inc. v. Plastipak Packaging, Inc.*, 415 F.3d 1335, 1345 (Fed. Cir. 2005); *Seachange Int'l, Inc. v. C-Cor Inc.*, 413 F.3d 1361, 1372-73 (Fed. Cir. 2005).

District courts may also rely on extrinsic evidence, which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises," in construing claims, although such evidence is afforded less significance than the intrinsic record. *Phillips*, 415 F.3d at 1317 (citations omitted). "[W]hile extrinsic evidence 'can

shed useful light on the relevant art,' we have explained that it is 'less significant than the intrinsic record in determining "the legally operative meaning of claim language."'" *Id.* (citations omitted).

In summation, although "there is no magic formula or catechism for conducting claim construction . . . . certain types of evidence are more valuable than others," and "what matters is for the court to attach the appropriate weight" to each piece of evidence. *Phillips*, 415 F.3d at 1324.

B. Exclusion of Untimely Expert Opinions

Rule 16(f)(1) of the Federal Rules of Civil Procedure authorizes courts to "issue any just orders, including those authorized by Rule 37(b)(2)(A)(ii)-(vii), if a party or its attorney," among other things, "fails to obey a scheduling or other pretrial order." Fed. R. Civ. P. 16(f)(1)(C). Moreover, pursuant to Rule 37(b)(2)(A)(ii), when a party "fails to obey an order to provide or permit discovery," the court may "prohibit[ ] the disobedient party from . . . introducing designated matters in evidence." Fed. R. Civ. P. 37(b)(2)(A)(ii).

"When parties seek to exclude evidence based on [FRCP 37], courts [in the 9th Circuit] employ the five factor analysis set forth in *Southern States R[a]ck and Fixture, Inc. v. Sherwin-Williams Co.*, 318 F.3d 592, 597 (4th Cir. 2003)." *Young v. Wolfe*, No. CV 07-03190 RSWL (AJWx), 2017 WL 985632, at *1 (C.D. Cal. Mar. 14, 2017). "The factors are: (1) the surprise to the party against whom the evidence would be offered; (2) the ability of that party to cure the surprise; (3) the extent to which allowing the evidence would disrupt the trial; (4) the importance of the evidence; and (5) the non-disclosing party's explanation for its failure to disclose the evidence." *Id.*

IV. ANALYSIS

The Court begins by resolving AgaMatrix's Motion to Exclude. It then addresses the merits of the parties' claim construction arguments.

A. Dr. Weber's Declaration Should be Excluded as Untimley

In its Motion to Exclude, AgaMatrix argues Dr. Weber's expert declaration should be excluded under Rules 16(f) and 37(b)(2)(A)(ii), both because his opinions are untimely under this Court's scheduling order and the Northern District's Patent Local Rules and because his opinions are inadmissable under the Federal Rules of Evidence. (*See generally* Mem. in Supp. Mot. to Exclude ("Exclude Mem."), ECF No. 89.) With respect to timeliness, AgaMatrix contends that Dexcom's (1) failure to identify Dr. Weber or to produce a summary of his opinions in March; (2) failure to include his opinions in the JCCPS; and (3) decision to identify, for the first time, Dr. Weber's opinions on June 8, 2017 along with its Opening Brief fly in the face of Rules 4-2 and 4-3 of the P.L.R. (Exclude Mem. 1, 7-10.) AgaMatrix's admissibility arguments follow from these same arguments. (Exclude Mem. 10-12.)

Dexcom responds that AgaMatrix misinterprets both the Court's scheduling order and the P.L.R., and further argues that, even if the Weber Opening Declaration were untimely, AgaMatrix cannot credibly claim prejudice. (Exclude Opp'n 1-2, ECF No. 99.) These arguments do not persuade.

Rule 4-2(b) of the P.L.R. provides that, "[a]t the same time the parties exchange their respective 'Preliminary Claim Constructions,' each party shall also . . . designate any supporting extrinsic evidence including, without limitation, dictionary definitions, citations to learned treatises and prior art, and testimony of percipient and expert witnesses." P.L.R. 4-2(b). The rule goes on to provide that "[e]xtrinsic evidence shall be identified by production number or by producing a copy if not previously produced." *Id.* Finally, "[w]ith respect to any supporting witness, percipient or expert, the identifying party shall also provide a description of the substance of that witness' proposed testimony that includes a listing of any opinions to be rendered in connection with claim construction." *Id.*

Rule 4-3 of the P.L.R. mandates that the parties' Joint Claim Construction and Prehearing Statement "shall contain" certain information. P.L.R. 4-3. Rule 4-3(b) provides that one bucket of information required includes:

> Each party's proposed construction of each disputed term, together with an identification of all references from the specification or prosecution history that support that construction, and an identification of any extrinsic evidence known to the party on which it intends to rely either to support its proposed construction or to oppose any other party's proposed construction, including, but not limited to, as permitted by law, dictionary definitions, citations to learned treatises and prior art, and **testimony of percipient and expert witnesses**[.]

P.L.R. 4-3(b). Rule 4-3(e), in turn, requires that the parties include

> Whether any party proposes to call one or more witnesses at the Claim Construction Hearing, the **identity** of each such witness, and for each witness, a **summary of his or her testimony** including, for any expert, **each opinion to be offered related to claim construction**.

P.L.R. 4-3(e) (emphasis added).

Although "there is some ambiguity in the Patent Local Rules regarding the level of detail required to adequately preserve the right to rely on expert testimony," courts in the Northern District have held that Rule 4-3 of the P.L.R. "**does** require the filing of any expert report simultaneously with the JCCPS." *GoPro, Inc. v. C&A Mktg., Inc.*, No. 16-cv-03590, 2017 WL 2335377, at *3 (N.D. Cal. May 30, 2017) (quoting *Tristrata, Inc. v. Microsoft Corp.*, No. 11-cv-03797-JST, 2013 WL 12172909, at *2 (N.D. Cal. May 13, 2013)); *see also HTC Corp. v. Tech. Props. Ltd.*, No. 5:08-cv-

00882 JF/HRL, 2010 WL 4973628, at *2 (N.D. Cal. Dec. 1, 2010) (modifying claim construction schedule to allow the deposition of the plaintiff's expert, Dr. May in light of the plaintiff's disclosure of "only a sparse summary of Dr. May's potential expert testimony," noting that "[i]f HTC delays both the production of documents relevant to Dr. May's opinion and the deposition of Dr. May until after December 9, 2010, TPL will be deprived of the opportunity to conduct discovery with respect to Dr. May's opinion before its opening claim construction brief is due," which "may be grounds for the exclusion of an expert"). Although at least one case has determined that the plaintiff was entitled to rely on expert testimony in connection with its claim construction briefing by including a statement in the JCCPS that it intended to use "[t]he opinion of [the expert] that, to one of ordinary skill in the art in the field of the [asserted patent], the [terms at issue] would have the meaning attributed to it by [Plaintiff]," the court in that case declined to strike the plaintiff's expert's report in part because of "the similarity between Defendant's disclosure and the disclosure which Defendant contends was insufficient," which "support[ed] a finding that Plaintiff adequately disclosed the expert testimony it intended to use in the [JCCPS]." *Reflex Packaging, Inc. v. Lenovo (U.S.), Inc.*, No. C 10-01002 JW, 2011 WL 7295479, at *2-3 (N.D. Cal. Apr. 7, 2011). Here, as noted above, AgaMatrix included substantially more information regarding the opinions of its expert in the JCCPS, and *Reflex Packaging* is therefore distinguishable.[3]

Like the plaintiffs in *GoPro* and *Tristrata*, Dexcom has failed to comply with Rule 4-3 of the P.L.R. because it did not file Dr. Weber's declaration simultaneously with the JCCPS. Indeed, Dexcom dedicates a total of two paragraphs in the JCCPS to Dr. Weber, broadly stating that it "may rely on an expert declaration by Dr. Weber in support of its proposed claim constructions and in opposition to AgaMatrix's proposed constructions." (JCCPS 4.) "For instance, Dr. Weber may provide opinions on the background technology and the meaning of the terms and phrases identified for construction as understood by a person of ordinary skill in the art during the relevant time period." (JCCPS 4.) Meanwhile, AgaMatrix "identified opinions by [its expert] Dr. John Smith that it may rely on in support of its claim constructions," and set forth almost two pages of his opinions. (JCCPS 5-7.) Dexcom's disclosures are insufficient to satisfy Dexcom's obligations under Rule 4-3. "Thus, [Dr. Weber's] declaration should be stricken or excluded unless [Dexcom's] failure was 'substantially justified or harmless.'" *GoPro*, 2017 WL 2335377 at *3 (quoting Fed. R. Civ. P. 37(c)(1)).

[3] To the extent a conflict exists between *Reflex Packaging* and those cases reaching the opposite conclusion, the Court finds the latter line of cases to be persuasive. Moreover, the exemplary JCCPS referenced on page 9 of Dexcom's Exclude Opposition and included as Exhibits I, J, and K to the Declaration of Erik Carlson submitted in support of the Exclude Opposition ("Carlson Exclude Declaration") are of little help, as there is no indication that a court ruled on the sufficiency of these disclosures. (*Cf.* Exclude Opp'n 9; Carlson Exclude Decl., Exs. I-K, ECF No. 100.)

Dexcom's primary argument as to why the Court should not strike Dr. Weber's declaration is that the "language" of Rule 4-3 "appears nowhere" in the Court's scheduling order. (Exclude Opp'n 1, 3.) This is nonsensical. In their Joint Rule 26(f) Report, the parties expressly "agree[d] that the Northern District of California Patent Local Rules ('P.L.R.') should apply" subject to certain deadline-related disputes not at issue here. (Joint Rule 26(f) Report 2.) During the scheduling conference, the Court noted the parties' agreement to abide by the Patent Local Rules, and imposed the schedule suggested under these rules. (*See* Minutes of Scheduling Conference; Reporter's Tr. of Mandatory Scheduling Conference 4:12-18.) At no point did Dexcom seek clarification as to which of the Northern District's Patent Local Rules it was required to follow, even after AgaMatrix notified Dexcom in March of this year that a dispute on this front had arisen. Dexcom was not "substantially justified" in failing to disclose Dr. Weber's declaration before filing its Opening Brief.

Nor was Dexcom's failure "harmless." Under the Court's scheduling order, claim construction discovery closed on May 18, 2017, several weeks before Dexcom first disclosed Dr. Weber's opinions. (*See* Minutes of Scheduling Conference.) This is highly inappropriate given Dr. Weber "did not finalize and sign" his declaration until June 8, 2017. (Exclude Opp'n 16.) Dexcom's submission that because its Joint Claim Chart "gave AgaMatrix ample notice that Dexcom would rely on Dr. Weber to support its proposed constructions" and because "AgaMatrix had a full month thereafter to notice his deposition and probe his opinions on these subjects if needed . . . [i]t chose not to" is highly disingenuous. (Exclude Opp'n 1.) It would be highly irregular for a party to depose the other side's expert where the expert had not yet disclosed his opinions. *See VIA Techs., Inc. v. Asus Comp. Int'l*, No. 14-cv-03586-BLF, 2016 U.S. Dist. LEXIS 63677, at *8 (N.D. Cal. May 13, 2016) ("In his declaration, however, Gomez explained for the first time how the unit might be implemented and why the term 'unit' would not confuse a POSITA. Without this explanation, Defendants had no guidance on how to conduct a useful deposition; by the time they received it, the window for discovery had long since closed. And, of course, VIA's initial disclosure made no mention of the fact that Gomez intended to offer pages of opinions on the background of the technology."); *see also Friskit, Inc. v. RealNetworks, Inc.*, No. C 03-5085 FMS, 2005 WL 6249309, at *1 (N.D. Cal. Mar. 22, 2005) ("Further, without the necessary disclosures required by Local Rule 4-3(d), Friskit's deposition of Real's expert would have been meaningless and time consuming."). The Court declines to sanction AgaMatrix for making this sound strategic choice.

For the foregoing reasons, the Court **GRANTS** AgaMatrix's Motion to Exclude Declaration of Dr. Weber. The Court will not consider the Weber Opening Declaration in connection with any proceeding, including claim construction, and Dexcom is prohibited from presenting expert testimony based on Dr. Weber's late-filed declaration.

B. Definition of "Person of Ordinary Skill in the Art" at the Time of the Invention

Dexcom argues that a person of ordinary skill in the art in the context of the '195 Patent would be a "skilled individual with at least a bachelor's degree in chemistry, physics, or engineering (including electrical engineering), and at least three years of experience relating to electrochemical systems." (Opening Br. 3 n.3 [citing Weber Opening Decl. ¶ 11].) AgaMatrix does not offer a competing definition in its briefs, but appears to argue that the artisan must be skilled in the field of "electrochemical sensors." (Responsive Br. 9.)

At oral argument, counsel for AgaMatrix clarified that AgaMatrix believes "a person with ordinary skill in the art would have a degree in chemistry and experience in electrochemical engineering." (Reporter's Tr. of Markman Hr'g & Mot. to Exclude ("Tr.") 9:10-13, ECF No. 117.) When pressed as to how these two proposed definitions were in conflict, AgaMatrix stated it "do[esn]'t think it actually makes a difference" and stated it was "willing to accept [Dexcom's] construction for today." (Tr. 10:1-18.)

Given the nature of the technology at issue and the apparent lack of any dispute regarding the definition of "person of ordinary skill in the art," the Court adopts Plaintiffs' proposed definition.

C. "Bias Potential Setting"

The parties' first dispute centers on the meaning of the term "bias potential setting," which is recited four times in claim 53 and is also recited in twenty three other claims and throughout the specification. Their claim construction positions are provided below:

Dexcom's Proposed Construction	AgaMatrix's Proposed Construction
"circuit state that impacts voltage difference between two electrodes"	"the application of a [predetermined or set] voltage difference between two electrodes in a sample, which is the cause of the flow of a current, if sufficient analyte is present"

Both parties submit that their proposed constructions are consistent with the plain and ordinary meaning of the term "bias potential." They agree that the two points in the circuit of the electrochemical sensors at issue are two electrodes, such that "bias potential" implicates the "voltage difference between two electrodes." (Opening Br. 10; Responsive Br. 9-11.) Their disputes center around (1) the meaning of the word "setting;" (2) whether the "bias potential setting" can be created through an "open circuit," in which a switch is flipped to "break" one part of the circuit; and (3) whether the term "bias potential" is limited to one definition provided in the specification. (*See* Opening Br. 13; Responsive Br. 10 n. 3.)

Dexcom argues the term should be construed broadly as a circuit state that impacts a voltage difference, relying on the schematic depicted in Figure 1 of the '195 Patent and on the Weber

Declaration. (Opening Br. 10-11; *see also* Weber Decl. ¶¶ 25-28, 31-33.) Dexcom also argues a skilled artisan "would have known of circuit states that do not necessarily apply voltage, yet impact voltage difference between electrodes," such as "open circuits" wherein a switch is flipped to break one part of the circuit, and cites to U.S. Patent No. 5,620,579 ("Genshaw"), which discusses open circuitry and which was considered in the prosecution of the '195 Patent. (Opening Br. 12-13.)

AgaMatrix proposes that the term should be limited to settings that result in the application of a set voltage, relying on language in the specification and on extrinsic evidence tending to show that voltage differences are "applied" to electrodes. (Responsive Br. 9-10.) AgaMatrix also argues that because the words "circuit state" referenced in Dexcom's proposed construction do not appear in the claims or anywhere else in the '195 Patent, Dexcom's proposal is confusing and inappropriate. (Responsive Br. 10.) Finally, AgaMatrix challenges Dexcom's suggestion that an "open circuit" constitutes a "circuit state" capable of creating a "bias potential" within the meaning of the '195 Patent, offering evidence that a skilled artisan would not consider an "open circuit" a "circuit."

The Court begins by noting that the parties agree a "thermostat setting" is analogous to the "bias potential setting" at issue here. (Opening Br. 10; Responsive Br. 9-10.) Thus, just like a user can set a thermostat to a particular level to affect the temperature in the room, a user can configure the circuit state of an electrochemical sensor in a particular way to affect the voltage differences between two electrodes. Moreover, there is no dispute that skilled artisans would have understood that circuit states can "apply" voltage differences between two electrodes to create a bias potential at a desired level.

In light of these principles and for the reasons referenced below, the Court rejects Dexcom's arguments that it would be inappropriate to limit the term "bias potential setting" to circuit states that are both "set" and "applied." (*Cf.* Opening Br. 14.) As stated in the abstract of the '195 Patent, the claimed inventions function by "measuring current values at multiple bias potential settings to assess the quality of the analyte measurement, identify interference in the signal, and calculate substantially interference-free analyte concentration measurements." ('195 Patent at Abstract.) A skilled artisan reading the '195 Patent would have understood that, in an electrochemical sensor such as the one claimed, "current values" or perhaps other values are measured after voltage differences are **applied** between two electrodes. (*See* '195 Patent col. 6:14-21 [describing how, in Figure 1, voltage is applied to both the working and reference electrodes such that the bias potential applied between these electrodes is set at a constant value]; Opening Br. 12; Responsive Br. 10; Decl. Erik J. Carlson in Supp. Opening Br. ["Carlson Opening Decl."], Ex. C ¶¶ [0211], [0262], [0342], [0344], [0385], [0390], ECF No. 86-3; Ex. H ["Genshaw"] at Abstract, cols. 6:47, 9:49, 10:21, ECF No. 86-8; Ex. I at 19, 24, 32-34, 43, ECF No. 86-9.)

Similarly, the Court concludes that a skilled artisan likewise would have understood that the term "bias potential setting" refers to voltage differences that are "set" beforehand, rather than voltage differences that are randomly applied. Claim 53 requires that the first and second bias potential settings be at "different bias voltage[s]," suggesting that the person practicing the claimed method must determine these two bias potential settings beforehand. ('195 Patent col. 4*:14-15.) Otherwise, there would be a non-zero possibility that the settings would be identical. Claim 53 further requires that, in order to "identif[y] a signal interference," the person practicing the claimed method "compar[e]" and "deriv[e] an analyte concentration from" the first and second signal outputs that are "measur[ed]" at the first and second bias potential settings. ('195 Patent col. 4*:1-13.) These differential measurements are only meaningful if the person practicing the claimed method knows what the "signal output" for both the analyte and the cause of the signal interference should be at a particular bias potential setting. Thus, the intrinsic record reveals the voltage difference to be applied to the sample must be determined beforehand.

The next dispute concerns whether a person of ordinary skill reading the '195 Patent would understand that an "open circuit" can be used to create a "bias potential setting." An "open circuit" is one in which no current is permitted to flow between the circuit elements. For the reasons that follow, the Court answers this question in the negative.

To begin, as AgaMatrix correctly points out, Dexcom agrees "that the plain meaning of the term [bias potential setting] implicates voltage difference between two points **in a circuit**" such that "the **two relevant points are electrodes**." (Opening Br. 10 [emphasis altered] [citing '195 Patent col. 4:61-65].) Figure 1, the sole circuit schematic included in the specification of the '195 Patent, defines "bias potential" in reference to two electrodes located in a circuit that is "closed;" i.e., there are no "breaks" in the circuit that prevent current from flowing through it. ('195 Patent col. 6:9-21, FIG. 1; Decl. John L. Smith, Ph.D., in Supp. Responsive Br. ("Smith Responsive Decl.") ¶¶ 24-25, ECF No. 94.) The specification describes the circuit diagram depicted in Figure 1 as that "of a conventional potentiostat." ('195 Patent col. 6:9-12.) Given the inventions claimed in the '195 Patent do not purport to improve the circuitry of such conventional potentiostats, but instead are methods that are said to improve the ability of such potentiostats to detect and measure analytes and interferences, it is reasonable to infer that a person of skill in the art reading the '195 Patent would understand that "bias potentials" are to be generated between the working and reference electrodes of closed circuits similar to the exemplary one described in Figure 1.

This understanding is bolstered by the fact that the specification defines the term "potentiostat" as something that "**forces whatever current is necessary to flow** between the working and counter electrodes **to keep the desired potential**, as long as the needed cell voltage and current do not exceed the compliance limits of the potentiostat." ('195 Patent col. 4:51-60 [emphasis added].) Given this reference to current flowing through the potentiostat—an exemplary component of an "electrochemical sensor," ('195 Patent col. 4*:3)—to keep desired potentials, and given the opening sentence of the Abstract describes the invention as "[a]n analyte-measuring

device, particularly an electrochemical sensor, [to] measur[e] current values at multiple bias potential settings," the Court concludes that using an open circuit to create a bias potential setting would make little sense in the context of the '195 Patent. *See Trs. of Columbia Univ. v. Symantec Corp.*, 811 F.3d 1359, 1363 (Fed. Cir. 2016) ("The only meaning that matters in claim construction is the meaning in the context of the patent.").

The admissible extrinsic evidence offered by AgaMatrix supports this understanding. AgaMatrix's expert, Dr. John L. Smith, Ph.D. ("Dr. Smith"), opines that a skilled artisan reading the '195 Patent would understand that a "circuit" must be complete or continuous so that current can flow. (*See* Smith Responsive Decl. ¶¶ 24-25.) In reaching this opinion, he relies on the following two definitions from technical dictionaries: (1) "A **closed** path followed or capable of being followed by an electric current;" and (2) "1. A path or group of interconnected paths capable of carrying electric currents. 2. An arrangement of one or more complete, **closed** paths for electron flow." (*See* Smith Responsive Decl., Ex. 1, ECF No. 94-1; *see also* Decl. Nika Aldrich in Supp. Responsive Br. ("Aldrich Responsive Decl.") ¶ 6, Ex. G, ECF Nos. 92-2, 95-2.) He then disagrees with Dexcom's assertion that an "open circuit" is a "circuit state" because an "open circuit" is not a "closed path" for electrons to flow. (Smith Responsive Decl. ¶ 25.) Dr. Smith further opines that although a "bias potential setting" includes applying a voltage difference of zero (0) volts—because "[e]ven when a bias potential of zero volts is applied between the electrodes, certain electrochemical reactions," such as that of ascorbate, identified as an "interfering species" in the '195 patent, can occur at the surface of the electrodes, generating an electric current"—"'[o]pening the circuit' is categorically different from applying a potential of zero volts between the electrodes" because "[w]hen the circuit is opened, no potential difference is applied to the electrodes, and no current is generated." (Smith Responsive Decl. ¶¶ 26-28.)

Dexcom, meanwhile, relies on the inadmissible opinions of its expert, Dr. Weber, regarding both (1) Genshaw, a separate patent cited and discussed during prosecution of the '195 Patent; and (2) portions of a particular treatise to support its position that an open circuit can create a "bias potential setting." Even if the Court were to consider Dr. Weber's opinions, it would nevertheless disagree that an "open circuit" can generate a "bias potential setting" in the context of the inventions claimed in the '195 Patent.

The Court first considers Genshaw. As AgaMatrix points out, the phrase "bias potential" does not appear in Genshaw, and Dexcom offers no evidence that the examiner of the '195 Patent considered Genshaw in determining whether an open circuit generates a "bias potential." (*See generally* Carlson Opening Decl., Ex. H ("Genshaw").) Moreover, the invention claimed in Genshaw, about which Dr. Weber opines, operates in a manner meaningfully different than the one claimed in the '195 Patent. Genshaw makes clear that after a first potential is applied to a sample, "the circuit is switched to an open circuit **or to a potential that substantially reduces the current** to minimize the rate of electrochemical potential at the working electrode," after which "[a] second potential is applied between the electrodes and the current generated in the fluid test

sample is measured to determine analyte concentration. (*See* Carlson Opening Decl., Ex. H at Abstract.) The use of the disjunctive word "or" implies that a person of skill in the art understands an "open circuit" is **distinct** from an applied "potential that substantially reduces the current." In any event, according to the specification, the purpose of this step is to "allow[ ] sufficient time for the reaction to build up sufficient ferrocyanide to allow the current resulting from the reoxidation of the ferrocyanide to be measured without difficulty." (Carlson Opening Decl., Ex. H at 6:1-10.) Thus, although it is true that "switching to an open circuit" can "cause the rate of the electrochemical reaction to minimize," this fact has little meaning in the context of the '195 Patent, which operates using a different mechanism: subtracting from the total signal output the known signal output for interferants and interfering species to obtain an accurate concentration for the measured analyte. (*Cf.* Opening Br. 13.) In short, Genshaw sheds no light on whether a person of ordinary skill would consider an "open circuit" a permissible means of generating a "bias potential setting."

The extrinsic evidence cited by Dexcom likewise does not support its proposed construction. Although the Bard & Falkner treatise produced by Dexcom indeed discloses that a "potential difference" between electrodes can either be "varied by means of an external power supply" or "when a high impedance voltmeter (i.e., a voltmeter whose internal resistance is so high that no appreciable current flows through it during a measurement) is placed across the cell," a "potential difference" is distinct from a "bias potential difference," and the treatise offers no clarification in this regard. (Carlson Opening Decl., Ex. I at DXCM-0004076-DXCM-0004077.) Moreover, in the very next sentence the treatise expressly describes the latter as the "open-circuit potential of the cell" or the "**zero-current potential**." (Carlson Opening Decl., Ex. I at DXCM-0004076-DXCM-0004077 [emphasis added].) The first sentence of the abstract, however, states that "[a]n analyte-measuring device . . . is provided for **measuring current values at multiple bias potential settings** to assess the quality of the analyte measurement . . .." ('195 Patent at Abstract [emphasis added].) It would be pointless to measure different current values where one of the "bias potential settings" is an "open circuit" because the current resulting from opening the circuit would, by definition, be zero, regardless of the concentration of the analyte or the presence or absence of anything causing a signal interference.

The canons of claim construction provide additional reason to limit the scope of the claims to closed circuits. "If, after applying all other available tools of claim construction, a claim is ambiguous, it should be construed to preserve its validity." *Ruckus Wireless, Inc. v. Innovative Wireless Sols., LLC*, 824 F.3d 999, 1004 (Fed. Cir. 2016) (citing *Phillips*, 415 F.3d at 1327). "Because the specification makes no mention of [open circuits], construing the instant claims to encompass that subject matter would likely render the claims invalid for lack of written description." *Id.* (citing *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1480 (Fed. Cir. 1998), for its holding that a claim "may be no broader than the supporting disclosure"). The canon favoring constructions that preserve claim validity counsels against construing "bias potential setting" to include those created using open circuits.

Finally, the parties dispute whether the voltage difference between the two electrodes must be "the cause of the flow of a current, if sufficient analyte is present." This quoted language comes from the specification, which defines the term "bias potential" as "a broad term [that] is used in its ordinary sense, including, without limitation, the voltage difference between two points in a circuit, which is the cause of the flow of a current, if sufficient analyte is present." ('195 Patent col. 4:61-65.)

Beyond referencing the quoted portion of the specification and arguing that "Dexcom seeks to broaden its construction beyond its own definition, relying on use of the words 'broad' and 'without limitation,'" AgaMatrix does not explain why the Court should construe the term "bias potential setting" to include this language. (*See* Responsive Br. 9-11.) Although the Court disagrees with Dexcom to the extent it argues, without providing any support, that AgaMatrix's proposed requirement is "at odds with the specification," it agrees with Dexcom that the specification uses expressly non-limiting, exemplary language to define "bias potential." (Opening Br. 15.) Thus, absent a compelling explanation by AgaMatrix either that the patentee clearly disavowed other embodiments or that a skilled artisan reading the '195 Patent would understand this portion of the specification to be so limiting—neither of which it provided in its Responsive Brief or at the *Markman* hearing—the Court declines to construe the term "bias potential setting" in this manner. (*Cf.* Smith Responsive Decl.)

The Court construes the disputed claim term "bias potential setting" as follows:

Claim Term	Court's Construction
"bias potential setting"	"the application of a set voltage difference between two electrodes in a sample, in which the electrodes are arranged in a closed circuit"

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D. "Signal Output"

The parties next dispute whether the term "signal output" should be construed to include **any** delivered electrical quantity, as Dexcom proposes, or whether it should instead be tied to the concentration of an analyte, as AgaMatrix suggests. The parties' positions are provided below:

Dexcom's Proposed Construction	AgaMatrix's Proposed Construction
"electric quantity, such as voltage, current, or frequency, delivered by a system or element"	"value or values of a signal indicative of the concentration of an analyte (as affected by any interference) in a sample"

Dexcom argues that because the specification expressly provides that the phrase "signal output" is a "broad term" that is "used in its ordinary sense, including, without limitation, an analog or digital signal directly related to the measured analyte from the analyte-measuring device" and because the words "signal" and "output" have well understood meanings in the context of electrochemical sensors, the Court should adopt its preferred construction. (Opening Br. 5-6.) According to Dexcom and its expert, "signal" in this context means an "electrical quantity," which can be voltage, current, or frequency. (Opening Br. 6 [citing Weber Opening Decl. ¶ 19].) They submit the term "output," meanwhile, indicates that the signal is delivered **by** the system or element, in contrast to being delivered **to** a system or element. (Opening Br. 6 [citing Weber Opening Decl. ¶ 19].) According to Dexcom, nothing in the claims, specification, or prosecution history of the '195 Patent is inconsistent with its preferred broad construction. (Opening Br. 6-8.)

AgaMatrix, meanwhile, argues its proposed construction better captures the context of the '195 Patent and contends that Dexcom's proposal (1) overlooks that the signal output comes from "an electrochemical sensor," not from a random "system or element;" (2) would confuse the jury; (3) is belied by their own expert's testimony in a related proceeding; and (4) is untethered to extrinsic evidence in the field of electrochemistry. (Responsive Br. 14-16.)

AgaMatrix's proposed construction is more in line with the intrinsic evidence and better captures the nature of the inventions claimed in the '195 Patent. To begin, claim 53 includes a limitation under which the user must "derive[ ] an analyte concentration from the first signal output and the second signal output to determine an analyte concentration[.]" ('195 Patent col. 4*:11-13.) In its briefs and at the *Markman* hearing, Dexcom failed to adequately explain how one can "derive" or "determine" an analyte concentration from variables that are not themselves indicative of the concentration of the analyte. (*See, e.g.*, Tr. 50:8-51:12; 57:4-59:1.) The Court is similarly unable to conjure up such an explanation. Claim 53 further requires that the user "compar[e] the first signal output with the second signal output to determine a differential measurement, thereby identifying an interference in the signal outputs[.]" ('195 Patent col. 4*:8-10.) Thus, the claims require that the "interference" be obtained by comparing the signal outputs, similarly suggesting each signal output must in some way be indicative of whether there is an "interference."

This "nexus" between "signal outputs" and both the concentration of the analyte and the presence of an interference is in line with the specification, which in the "Overview" section explains that "[t]he analyte-measuring device [claimed] uses any known method, including invasive, minimally invasive, and non-invasive sensing techniques, to provide an output signal **indicative of the concentration of the analyte**." ('195 Patent col. 5:30-33 [emphasis added].) It is also consistent with the name of the '195 Patent: "systems and methods for improving electrochemical analyte sensors."

AgaMatrix's citation to a portion of the deposition transcript of one of Dexcom's experts, Dr. Vachon, in a parallel litigation offers additional support for its proposed construction. In that litigation, Dr. Vachon testified that "current" that "is reflective of the level of analyte" is "the signal output from the sensor" when one "appl[ies] the bias potential to the two electrodes." (Aldrich Responsive Decl. ¶ 5, Ex. D at 30:6-12.) AgaMatrix's own expert, Dr. Smith, opines that he agrees with the opinions of Dr. Vachon. (Smith Responsive Decl. ¶¶ 22-23.) For the reasons stated at the *Markman* hearing, the Court does not give great weight to either piece of extrinsic evidence. (*See generally* Tr. 43:21-46:17.) However, the opinions of these two experts help clarify how a person of skill in the art would interpret the term "signal output" in the context of electrochemical sensors.

Dexcom's arguments in rebuttal do not persuade. Contrary to Dexcom's submission, AgaMatrix's proposal is not "directly contradicted" by Figure 2 of the '195 Patent. (*Cf.* Opening Br. 9.) Although the data in Figure 2 does show that "current output" is zero (0) when a range of bias potential settings between 0V and approximately 0.1V is applied, this range is not relevant to the claims. (*Cf.* '195 Patent at FIG 2.) Indeed, given the "bias potential settings" are set beforehand, the resulting "signal outputs" are those from which an interference can be identified and a from which an analyte concentration can be both derived and determined. ('195 Patent col. 4*:4-13.) Moreover, the fact that the claims recite first and second "signal outputs," rather than "current output," helps explain why the patentee chose to use the former in the claims and the latter in Figure 2.

Finally, the Court considers a question central to the parties' briefs: whether the "signal output" must be a "current," or whether it instead can be some other form of electric quantity, such as voltage or frequency. In its brief, AgaMatrix argues that "the only signal that results from applying a voltage to two electrodes is a **current**." (*See* Responsive Br. 12.) At the *Markman* hearing, however, counsel for AgaMatrix suggested that because there was a possibility that some output other than current could be indicative of the concentration of an analyte as affected by an interference, he was "not putting current in [AgaMatrix's] construction" and stated he was "walking away from a claim differentiation problem . . . ." (Tr. 42:25-43:10.) The Court holds AgaMatrix's counsel to his word, and declines to limit "signal output" to "current."

The Court construes the disputed claim term "signal output" as follows:

Claim Term	Court's Construction
"signal output"	"value or values of a signal indicative of the concentration of an analyte (as affected by any interference) in a sample"

E. "Signal Output [Obtained] at a . . . Bias Potential Setting"

The parties next dispute whether the phrases "signal output **obtained** at a . . . bias potential setting" and "signal output at a . . . bias potential setting" should be given the same constructions or should instead be given different constructions because the former includes the word "obtained." (*See* Opening Br. 15-18; Responsive Br. 12-16.) The parties' claim construction positions are provided below:

Disputed Claim Terms	Dexcom's Proposed Constructions	AgaMatrix's Proposed Constructions
"Signal output **obtained** at a . . . bias potential setting"	"electrical quantity **acquired** at a . . . circuit state that impacts voltage difference between two electrodes"	"value or values of a signal indicative of the concentration of an analyte (as affected by any interference), caused by applying a set voltage difference between two electrodes in the sample"
"Signal output at a . . . bias potential setting"	"electrical quantity at a . . . circuit state that impacts voltage difference between two electrodes"	"value or values of a signal indicative of the concentration of an analyte (as affected by any interference), caused by applying a set voltage difference between two electrodes in the sample"

The parties agree the constructions for these two phrases should track those of "signal output" and "bias potential setting," which are addressed above. According to Dexcom's Opening Brief, the parties' dispute regarding these two phrases is narrow, turning on whether the word "obtained" modifies the first phrase. (Opening Br. 16-17.) Dexcom argues that the word "obtained" is not superfluous, and should be construed to mean "acquired." (Opening Br. 16-17.) AgaMatrix appears to submit that the inclusion of the word "obtained" in the first phrase does not alter its meaning, but does not directly address why one phrase contains this word while the other does not. (Responsive Br. 12-16.)

At the *Markman* hearing, the parties clarified that there is no dispute concerning these terms separate and apart from their disputes concerning the interrelated terms "bias potential setting" and "signal output," both of which are discussed above. (*See generally* Tr. 52:17-55:2.) Further construction of these terms is therefore not necessary.

F. "An Interference in the Signal Outputs"

Finally, the parties dispute whether the phrase "an interference in the signal outputs" should be broadly construed to include any "effect" or "species" that can interfere with signal output, or should instead be given a more narrow construction requiring that the interference result from the presence or absence of a substance other than the measured analyte and impact the value of both the first and second signal outputs. The parties' positions are provided below:

Dexcom's Proposed Construction	AgaMatrix's Proposed Construction
"an effect or species that can interfere with signal output"	"the presence or absence of a substance in the sample other than the analyte, which interferes with the measured value of the first and second signal outputs"

Dexcom, relying on the Weber Declaration, argues that "interference" is "a term of art" that a skilled artisan would understand to mean "anything that adds to, subtracts from, or modifies a signal output, such that the signal no longer accurately represents what it is trying to measure." (Opening Br. 18 [citing Weber Decl. ¶ 39].) Dexcom further submits that although "interferences" can include "species" such as acetaminophen, uric acid, or vitamin C, which are compounds often found in blood samples, they can "also include environmental or any other effects that can impede an electrochemical sensor from providing accurate measurements." (Opening Br. 18 [citing Weber Decl. ¶ 39].)

AgaMatrix responds by agreeing that "'[i]nterference' is a well-known term in the field of electrochemistry," but offering its own expert's opinion regarding this term. (Responsive Br. 16 [citing Smith Responsive Decl. ¶¶ 29-35.) According to AgaMatrix and Dr. Smith, "interference" refers to "the presence or absence of a substance in the sample other than the analyte, which causes an error in a measurement." (Responsive Br. 16.) Moreover, AgaMatrix argues that Dexcom's own expert, Dr. Vachon, defined "interference" as "[a] chemical entity that provides an interfering signal. Thus, according to AgaMatrix, the critical question is whether an "interference" must be tethered to the impact of "a substance in the sample other than the analyte" on the measurement of the concentration of the analyte.

At the *Markman* hearing, Dexcom sought to clarify—or perhaps limit—its proposed construction by arguing that the term "interference" should include "environmental factors" such as temperature and pH that are recited in the '849 Application, as well as other conditions that "ha[ve] an impact on the electrochemical reaction or th[at] impact[s] the enzymatic reaction in some way." (Tr. 63:9-24.) Thus, according to Dexcom, a central question with respect to the proper construction of the term "interference" is whether the term includes any condition that impacts the enzymatic reaction rate of the analyte, or instead whether it is limited to conditions that impact the reaction rate through the presence or absence of some substance other than the analyte. To answer this question, the Court must review the specification of the '195 Patent, consider the '849 Application, and examine the admissible pieces of extrinsic evidence.

The Court begins, as it must, with the '195 Patent. The specification expressly refers to two types of "signal interferences": (1) those caused by "**interfering species** such as acetaminophen, ascorbate, and urate;" and (2) those caused by "**effects**, such as **local ischemia, or the like**, which cause the signal to produce erroneous output." ('195 Patent col. 1:53-60 [emphasis added].) Farther down, the specification defines "interferants" and "interfering species" as "broad terms" that are "used in their ordinary sense, including, without limitation, effects and/or species that interfere with the measurement of an analyte of interest in a sensor to produce a signal that does not accurately represent the analyte measurement." ('195 Patent col. 5:3-8.) The specification goes on to state that "[i]n one example of an electrochemical sensor, interfering species are compounds with an oxidation or reduction potential that overlaps with the analyte to be measured." ('195 Patent col. 5:8-11.) But "[i]n another example of an enzyme-based electrochemical sensor, **local ischemia** is an interferant that **produces error** in the output signal **due to lack of sufficient oxygen to react** with the enzyme." ('195 Patent col. 5:11-14 [emphasis added].) Farther down, the specification explains how, by **monitoring and measuring both hydrogen peroxide and oxygen**, "the two measurements can be utilized to determine interference due to transient ischemic conditions, for example." ('195 Patent col. 10:37-42.) The specification explains that "local ischemia can affect sensor performance in vivo due to low O_2 levels that compromise the glucose oxidase reaction and thus signal output of the sensor," such that "[i]f a simultaneous drop of sufficient magnitude and rate are noticed in both signals, an ischemic event is likely occurring." ('195 Patent col. 10:42-47.) By contrast, "[i]f a drop in H_2O_2 (namely, of sufficient magnitude and rate) is noticed without a similar drop in O_2, then no ischemic event is likely, but rather a true glucose concentration change." ('195 Patent col. 10:47-50.) "Conversely, if a drop in O_2 (namely, of sufficient magnitude and rate) is noticed without a similar drop in H_2O_2, then an ischemic event is likely, but not significant enough to compromise the integrity of the H_2O_2 measurement via the glucose oxidation reaction." ('195 Patent col. 10:50-54.) The specification explains that once low O_2 has been detected, one can (1) "cease data output (for example, because the output may be erroneous and result in misdiagnosis)[;]" (2) "trigger a message to the user (for example, to suggest a change of position and/or caution them about the data output)[;]" or (3) "**compensate** for the signal loss due to the effects of local ischemia (for

example, **using algorithms that measure and eliminate the signal error** due to ischemia)." ('195 Patent col. 10:54-63 [emphasis added].)

The specification thus explains that the inventions claimed in the '195 Patent can determine whether ischemia causes an "interference" by "monitoring both H_2O_2 and O_2" as two separate analytes at two different bias potential settings and then examining the "drops" in magnitude for both analytes. It further explains that, if low O_2 has been detected after following these steps, an accurate concentration of the analyte can be measured, as required by claim 53. Dexcom has failed to explain how other so-called "environmental" factors such as pH changes, temperature changes, pressure, and stress lead to the presence of an analyte other than glucose (such as O_2) that can similarly be measured using an electrochemical sensor and the steps recited in claim 53. "Because the specification makes no mention of [interferences caused by factors other than those resulting in the presence or absence of an analyte that can be meaningfully measured at particular bias potential settings], construing the instant claims to encompass that subject matter would likely render the claims invalid for lack of written description." *Ruckus Wireless*, 824 F.3d at 1004 (citing *Gentry Gallery*, 134 F.3d at 1480).

The other central piece of intrinsic evidence about which the parties argue is the '849 Application, which is incorporated by reference in the '195 Patent and therefore forms part of the intrinsic record. The abstract of the '849 Application references "transient non-glucose related signal noise" such as "ischemia, pH changes, temperature changes, and the like" that "limit[ ]" the electrochemical reaction rate of glucose. (Carlson Opening Decl., Ex. C ["'849 Appl."] at DXCM-0004309.) Dexcom submits that the '849 Application clarifies that other "environmental" factors such as pH, temperature changes, pressure, and stress can cause "interference" because they "impede an electrochemical sensor from providing accurate measurements." (Opening Br. 18-19.) AgaMatrix, meanwhile, argues that the '849 Application is inapposite because it "fails to even use the term 'interference,'" instead characterizing pH, temperature, pressure, and stress as "signal artifacts." (Responsive Br. 16-20.)

AgaMatrix has the better of this argument. To begin, nowhere in the '849 Application does the term "interference" appear, and the sole instance in which a derivation of the term appears is in connection with the definition of the term "biointerface membrance," under which "materials of a few microns thickness or more . . . interfer[e] with the transport of glucose across the tissue-device interface." (*See* '849 Appl. ¶ 0247.) Moreover, the '849 Application separately defines "ischemia" and "signal artifacts," the latter of which is a genus that includes "ischemia" in addition to "pH changes, temperature changes, pressure, and stress, for example." ('849 Appl. ¶¶ 0250, 0252.) The fact that the drafter of the '849 Application chose to separately define "ischemia" and to include it as one possible species of the defined term "signal artifacts" suggests to a person of skill in the art that the inventors of the later-issued '195 Patent would have chosen to use the term "signal artifacts" had they intended pH changes, temperature changes, pressure, and stress to be possible "interferences."

Finally, and perhaps most importantly, the inventions described in the '849 Application purport to eliminate the effects of "signal artifacts" using methods fundamentally distinct from the methods to identify an interference and derive an analyte concentration without the interference that are claimed in the '195 Patent. (*See* '849 Appl. ¶¶ 0279-0284.) Unlike the inventions claimed in the '195 Patent, those described in the '849 Application detect "high spikes" in "signal amplitude" that "correspond to noise [including signal artifacts\ that substantially increases signal amplitude." (*See* '849 Appl. ¶¶ 0325.) Based on these spikes and the preceding troughs of "transient low noise," the inventions described in the '849 Application "provide systems and methods for replacing at least some of the signal artifacts" that lead to "data lower (or in some cases higher) than the actual blood glucose levels" by "estimating glucose signal values" based on data collected at multiple time points. ('849 Appl. ¶¶ 0325, 0328.) Graphical depictions of how certain inventions described in the '849 Application operate are located in Figures 8 and 9 and are described in associated paragraphs 0329 through 0340. ('849 Appl. ¶¶ 0329-0340.) Although the '849 Application in paragraph 0338 describes how one can use "pulsed amperometric detection" between a "positive voltage (e.g., +0.6 for detecting glucose)" and a "negative voltage (e.g., -0.6 for detecting oxygen)" to detect the presence of ischemia in a manner similar to that described in column 10 of the specification of the '195 Patent, there is **no similar disclose** for pH changes, temperature changes, pressure, or stress. (*Compare* '849 Appl. ¶ 0338; *with id.* ¶¶ 0346-0350 [describing how pH, temperature, pressure, and stress can be measured to estimate accurate glucose levels without any reference to applying different voltages].) Simply put, there is no evidence that conditions such as pH changes, temperature changes, pressure, or stress can meaningfully be considered "interferences" in the context of the '195 Patent.

The admissible extrinsic evidence also lends some support to AgaMatrix's proposed construction. First, the International Union of Pure and Applied Chemistry's ("IUPAC") *Compendium of Chemical Terminology*, which experts on both sides agree is a "reliable resource for information in the field of electrochemistry," defines an "interference" as "[a] systematic error in the measure of a signal **caused by the presence of concomitants in a sample**." (Smith Responsive Decl. ¶¶ 29, 40, Ex. 2 at 2 [emphasis added].) The 6th edition of the *McGraw-Hill Dictionary of Scientific and Technical Terms* is in accord, defining an "interference" in the field of "analytical chemistry" as "[a] systematic error in measurement that **occurs when concomitants are present in the sample** being analyzed." (Smith Responsive Decl. ¶ 29; Aldrich Responsive Decl., Ex. H at 3 [emphasis added].) This same dictionary defines a "concomitant" as "[a]ny species in a material undergoing chemical analysis other than the analyte or the solvent in which the sample is dissolved." (Aldrich Responsive Decl., Ex. H at 4.) Furthermore, Dexcom's expert in another patent litigation, Dr. Vachon, testified that the "[b]road[ ] . . . definition of interference" is "[a] chemical entity that provides an interfering signal." (Aldrich Responsive Decl., Ex. D at 31:1-8; Smith Responsive Decl. ¶¶ 34-35.) Although none of these pieces of extrinsic evidence contemplate that **absence** of a substance other than the analyte (such as the absence of oxygen in the case of ischemia), they are nevertheless useful in clarifying that an "interference" in the context of the '195 Patent can

only be created by the presence or absence of a substance other than the analyte that can be detected using an electrochemical sensor.

The Court also finds several aspects of Dexcom's proposed construction at odds both with canons of claim construction and with the intrinsic evidence. First, its proposed construction improperly seeks to define the term "interference" by reference to the ambiguous words "effect or species." (*See* Opening Br. 18.) The proper construction of the term must capture the ability of the invention to "deriv[e] an [accurate] analyte concentration" by "measur[ing]" signal outputs at two different bias potential settings and then subtracting from the total signal output the output indicative of the presence of the "interference" **in the sample**. ('195 Patent col. 4*:1-15.) The Court rejects Dexcom's "hopelessly overbroad" proposal. *Genentech, Inc. v. Wellcome Foundation Ltd.*, 29 F.3d 1555, 1564 (Fed. Cir. 1994).

Next, the Court disagrees with Dexcom's argument that the term "an interference in the signal outputs" should be construed to include "effects and species" that **can** interfere with signal output, as opposed to those that do in fact interfere. Claim 53 requires that the artisan "compar[e] the first signal output with the second signal output to determine a differential measurement, **thereby identifying an interference** in the signal outputs . . . ." ('195 Patent col. 4*:8-10.) "Here, the claim does not require that the [effect or species] be merely 'capable' of [interfering with the signal outputs]; the claim has a structural limitation that the [effect or species in fact interfere with these outputs]." *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1311 (Fed. Cir. 2005).

Finally, the Court disagrees with Dexcom's proposal that the "interference" can impact only one signal output, rather than both signal outputs. The claim requires that the user "identify[ ] an interference in the signal output**s**." ('195 Patent col. 4*:8-10.) Moreover, the invention disclosed in claim 53 simply has no function unless there is an interference in both signal outputs, because as Dr. Smith opines, "[i]f one signal output can be measured without an interference . . . there would be no need for a second measurement at a different bias potential setting." (Smith Responsive Decl. ¶ 39.)

For the foregoing reasons, the Court construes the term "an interference in the signal outputs" as follows:

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Claim Term	Court's Construction

"an interference in the signal outputs"	"the presence or absence of a substance in the sample other than the analyte, which interferes with the measured value of the first and second signal outputs"

V. CONCLUSION

For the foregoing reasons, the Court **GRANTS** Defendant AgaMatrix, Inc.'s Motion to Exclude Declaration of Dr. Weber. The Court construes the disputed claim terms as follows:

1. **"Bias potential setting"** means **"the application of a set voltage difference between two electrodes in a sample, in which the electrodes are arranged in a closed circuit"**
2. **"Signal output"** means **"value or values of a signal indicative of the concentration of an analyte (as affected by any interference) in a sample"**
3. **"the presence or absence of a substance in the sample other than the analyte, which interferes with the measured value of the first and second signal outputs."**

This is not the first time the parties have sought to complicate this patent infringement dispute, and the Court is skeptical that it will be the last. The Court reminds the parties that "an affirmative decision to be less than candid with either the opposing party or with the Court can render a case 'exceptional' within the meaning of 35 U.S.C. Section 285 ('Section 285')." (Order Den. Mot. for Leave to File SAC & Den. Mot. to Transfer 9, ECF No. 77.)