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Paper No. 10
Filed: March 13, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AGAMATRIX, INC.,
Petitioner,

v.

DEXCOM, INC.,
Patent Owner.

Case IPR2018-01718
Patent 9,750,460 B2

Before LINDA E. HORNER, LYNNE H. BROWNE, and PATRICK R. SCANLON, *Administrative Patent Judges.*

SCANLON, *Administrative Patent Judge.*

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314(a)

I. INTRODUCTION

AgaMatrix, Inc. ("AgaMatrix" or "Petitioner") filed a Petition (Paper 2, "Pet.") requesting *inter partes* review of claims 14–18, 20–24, 26–30, 32–36, 38–42, 50–54, 62–66, and 68 of U.S. Patent No. 9,750,460 B2 (Ex. 1001, "the '460 patent"). Dexcom, Inc. ("Dexcom" or "Patent Owner") filed a Preliminary Response (Paper 6, "Prelim. Resp."). AgaMatrix filed a Reply to Dexcom's Preliminary Response (Paper 8, "Reply"). Dexcom filed a Sur-Reply (Paper 9, "Sur-Reply").[1]

Under 35 U.S.C. § 314(a), an *inter partes* review may not be instituted "unless . . . the information presented in the petition . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition."

Upon consideration of the Petition and the Preliminary Response, and for the reasons explained below, we determine that AgaMatrix has not shown a reasonable likelihood that it would prevail with respect to at least one of the challenged claims. Thus, we deny the Petition and do not institute an *inter partes* review of claims 14–18, 20–24, 26–30, 32–36, 38–42, 50–54, 62–66, and 68 of the '460 patent.

II. BACKGROUND

A. Related Proceedings

AgaMatrix and Dexcom identify the following related matters: *Dexcom, Inc. v. AgaMatrix, Inc.*, Case No. 1:17-cv-01310 (D. Del.) and *In the Matter of Certain Electrochemical Glucose Monitoring Systems And*

[1] The arguments presented in the Reply and Sur-Reply were limited to the issue of whether AgaMatrix named all the real parties-in-interest in the Petition. Because we deny institution under 35 U.S.C. § 314(a), we do not reach the issue of real party in interest in this proceeding.

Components Thereof, Inv. No. 337-TA-1075 (USITC) ("the related ITC proceeding"). Pet. 2, 71; Paper 4, 1. Additionally, AgaMatrix challenges the '460 patent on different grounds in IPR2018-01717 and challenges related U.S. Patent No. 9,724,045 B1 in IPR2018-01715 and IPR2018-01716. Pet. 2, 72; Paper 4, 1. Dexcom also identifies five pending patent applications as related to this proceeding. Paper 4, 1–2.

B. Real Parties in Interest

AgaMatrix, Inc. identifies itself as the real party-in-interest. Pet. 71. Dexcom, Inc. identifies itself as the real party-in-interest. Paper 4, 1. Dexcom asserts that AgaMatrix failed to identify AgaMatrix's parent holding company, AgaMatrix Holdings, and its sister corporation, WaveForm Technologies as real parties-in-interest. Prelim. Resp. 29. Because we deny institution under 35 U.S.C. § 314(a), we do not reach the issue of real party in interest.[2]

C. The '460 Patent

The '460 patent relates to systems for detecting and replacing transient non-glucose related signal artifacts in a glucose sensor data stream. Ex. 1001, 1:24–28. Specifically, the systems detect and replace signal noise caused by substantially non-glucose reaction rate-limiting phenomena, such

[2] "The core functions of the 'real party-in-interest' and 'privies' requirement [is] to assist members of the Board in identifying potential conflicts, and to assure proper application of the statutory estoppel provisions." Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,759 (Aug. 14, 2012). Because we do not institute review, statutory estoppel provisions do not apply. *See* 35 U.S.C. § 315(e) (statutory estoppel provisions triggered by *inter partes* reviews that result in a final written decision). Although we do not reach the real party-in-interest issue, the panel members have confirmed that they do not have any conflicts with AgaMatrix Holdings and WaveForm Technologies.

as ischemia, pH changes, temperature changes, pressure, and stress. *Id.* at 2:20–25.

An exemplary implantable glucose sensor is shown in Figure 1 of the '460 patent, which is reproduced below.

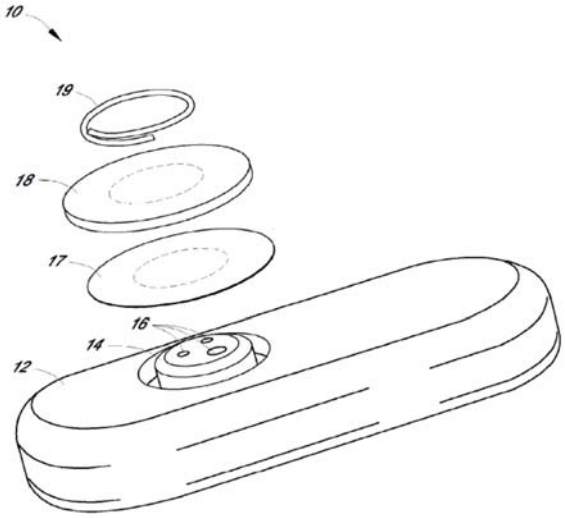

FIG. 1

Figure 1 shows an exploded view of implantable glucose sensor 10 that utilizes amperometric electrochemical sensor technology to measure glucose concentration. *Id.* at 20:21–24. In sensor 10, body 12 and head 14 house three electrodes 16 and sensor electronics. *Id.* at 20:24–26. Electrodes 16 are covered by sensing membrane 17 and biointerface membrane 18, which are attached to body 12 by clip 19. *Id.* at 20:27–30. Electrodes 16 include a working electrode, a counter electrode, and a reference electrode. *Id.* at 20:31–34. Sensing membrane 17 includes an enzyme, e.g., glucose oxidase, which covers an electrolyte phase disposed between sensing membrane 17 and electrodes 16. *Id.* at 20:34–39. The glucose oxidase catalyzes the conversion of oxygen and glucose to hydrogen peroxide and gluconate. *Id.* at 20:47–49. The change in hydrogen peroxide can be monitored to determine glucose concentration because for each

glucose molecule metabolized, there is a proportional change in the production of hydrogen peroxide. *Id.* at 20:52–55. A potentiostat monitors the electrochemical reaction by applying a constant potential to the working and reference electrodes to determine a current value. *Id.* at 20:62–65. The current produced at the working electrode is proportional to the amount of hydrogen peroxide that diffuses to the working electrode. *Id.* at 20:65–21:1. Thus, a raw signal is produced that is representative of the concentration of glucose in the user's body. *Id.* at 21:2–3.

One problem with the raw data stream output of enzymatic glucose sensors is that transient non-glucose reaction rate-limiting phenomena, such as oxygen concentration and temperature and/or pH changes, can produce erroneous signals. *Id.* at 21:6–15. The '460 patent describes improving data output by decreasing signal artifacts on the raw data stream from glucose sensors, such as the sensors described in U.S. Patent No. 6,595,919 B2 to Berner et al. *Id.* at 27:59–28:3. The '460 patent describes that conventional glucose sensors are known to smooth raw data to filter out system noise caused by unwanted electronic or diffusion-related noise that degrades the quality of the signal and thus the data. *Id.* at 28:23–29. The '460 patent explains that because signal artifacts are not mere system noise, but rather are caused by specific rate-limiting mechanisms, methods used for conventional random noise filtration produce data lower or higher than the actual blood glucose levels due to the expansive nature of these signal artifacts. *Id.* at 29:50–55. The system of the '460 patent replaces transient non-glucose related signal artifacts in the data stream that have a higher amplitude than system noise. *Id.* at 21:16–19.

Figure 15 provides a flow chart that illustrates a process of replacing signal artifacts by selectively applying signal estimation based on the

severity of the signal artifacts. *Id.* at 44:61–62. At block 152, a sensor data receiving module receives sensor data, e.g., a data stream, from the glucose sensor. *Id.* at 44:63–67. At block 154, a signal artifacts detection module detects transient non-glucose related signal artifacts in the data stream that have a higher amplitude than system noise and detects a severity of the signal artifacts. *Id.* at 45:1–8. For instance, the signal artifacts detection module may use predetermined thresholds to categorize the severity of the signal artifacts, e.g., low, medium, and high. *Id.* at 45:8–10.

In one embodiment in which the system is aimed at detecting signal artifacts due to ischemia, the system uses pulsed amperometric detection to measure oxygen concentration. *Id.* at 31:54–57. The '460 patent describes that "[p]ulsed amperometric detection includes switching, cycling, or pulsing the voltage of the working electrode (or reference electrode) in an electrochemical system, for example between a positive voltage (e.g., +0.6 for detecting glucose) and a negative voltage (e.g., -0.6 for detecting oxygen)." *Id.* at 31:57–62.

At block 156, a signal artifacts replacement module selectively applies one of a plurality of signal estimation algorithm factors in response to the severity of the signal artifacts. *Id.* at 45:35–38. For example, a first filter is applied during low signal artifacts and a second filter is applied during high signal artifacts. *Id.* at 45:52–56.

D. Challenged Claims

Of the claims challenged in the Petition, claims 14, 20, 26, 32, 38, 50, 62–66, and 68 are independent. Challenged claim 14 is illustrative of the subject matter at issue in the asserted grounds. Claim 14 is reproduced below.

14. A glucose sensor system, the system comprising:

an electrochemical glucose sensor configured to be in contact with a biological fluid to obtain a glucose measurement, wherein the electrochemical glucose sensor comprises a first electrode, a second electrode, and an enzyme-containing film, wherein the first electrode comprises an electrode surface; and

sensor electronics comprising a processor for executing computer program code stored in a memory to cause the processor to:

apply a voltage to the electrochemical glucose sensor, wherein applying the voltage comprises at least one process selected from the group consisting of switching, cycling, and pulsing a voltage applied to the electrochemical glucose sensor;

measure a signal response of the electrochemical glucose sensor responsive to the applying,

detect an erroneous signal based at least in part on the signal response of the electrochemical glucose sensor to the applying, wherein the erroneous signal is associated with at least one condition selected from the group consisting of an ischemia, a pH, a temperature associated with the electrochemical glucose sensor, a biochemical species, an available electrode surface area, a local environment associated with the electrode surface of the first electrode, a diffusion transport of glucose or a measured species, and a pressure or a stress associated with the electrochemical glucose sensor,

determine a value associated with a severity of the erroneous signal, and

discard a glucose measurement when the value associated with the severity of the erroneous signal is outside of a predetermined threshold value.

Ex. 1001, 48:23–56.

E. Evidence Relied Upon

AgaMatrix relies on the following prior art references in the asserted grounds of unpatentability:

a) *White*: U.S. Patent No. 5,243,516, issued September 7, 1993, filed in the record as Exhibit 1006.

b) *Beaty*: PCT Application Publication No. WO 99/32881 A1, published July 1, 1999, filed in the record as Exhibit 1007.

c) *Schulman*: U.S. Patent No. 5,497,772, issued March 12, 1996, filed in the record as Exhibit 1008.

F. Asserted Grounds of Unpatentability

AgaMatrix challenges the patentability of claims 14–18, 20–24, 26–30, 32–36, 38–42, 50–54, 62–66, and 68 of the '460 patent on the following grounds (Pet. 12):

Ground	Statutory Basis	Reference(s)	Claims
1	§ 103	White and Beaty	14–18, 20–24, 26–30, 32–36, 38–42, and 50–54
2	§ 103	White, Beaty, and Schulman	62–66 and 68

AgaMatrix supports its challenge with a Declaration of John L. Smith, Ph.D., filed as Exhibit 1003 ("Smith Declaration").

III. ANALYSIS

A. Level of Ordinary Skill

AgaMatrix asserts that a person of ordinary skill in the art at the time of the invention would have had the equivalent of either (i) a bachelor's or master's degree in biology, chemistry, physics, electrical engineering, or related fields, and at least five years of experience developing glucose

sensors or other biosensors; or (ii) a Ph.D. with at least two years of experience in the same fields. Pet. 14 (citing Ex. 1003 ¶¶ 33–36). According to AgaMatrix, additional graduate education could substitute for professional experience, and significant work experience could substitute for formal education. *Id.*

In the related ITC proceeding, Dexcom submitted expert testimony of a slightly different level of ordinary skill in the art, but Dexcom argues in its Preliminary Response that at this stage in this proceeding, the differences between the proposed levels of skill in the art are "not material to the Board's decision whether Petitioner has met its burden for institution of IPR." Prelim. Resp. 5; *see also* Ex. 1016, 5 (Dexcom's level of ordinary skill in the art as submitted in the ITC proceeding).

We adopt AgaMatrix's asserted level of ordinary skill in our determination of whether there is a reasonable likelihood that AgaMatrix would prevail with respect to at least one of the claims challenged in the Petition.

B. Claim Construction

AgaMatrix submitted proposed interpretations for various claim terms based on either claim interpretations made by Judge Bullock in the related ITC proceeding, or claim interpretations stipulated to by the parties in the related ITC proceeding, or interpretations offered by Dexcom in the related ITC proceeding. Pet. 15–16. AgaMatrix stated that "the broadest reasonable interpretation of the [listed] claim terms is *at least as broad as* the listed definitions." *Id.* at 15. Dexcom does not dispute that the stipulated constructions and the constructions ordered by the ITC should control at this stage of the IPR proceedings. Prelim. Resp. 6. For purposes of this decision, we employ the claim constructions ordered by the ITC and

stipulated to by the parties in the related ITC proceeding, as presented in the Petition.

C. First Ground: White and Beaty

1. White

White discloses a biosensing instrument for amperometrically determining the concentration of biological compounds, such as glucose, in a body fluid such as blood. Ex. 1006, 1:5–10. A test cell used with the biosensing instrument is shown in Figures 1 and 2, reproduced below.

FIG. 1

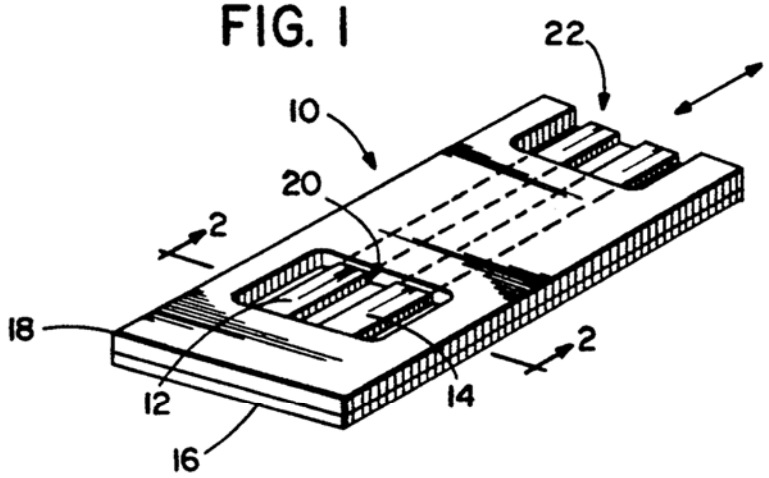

FIG. 2

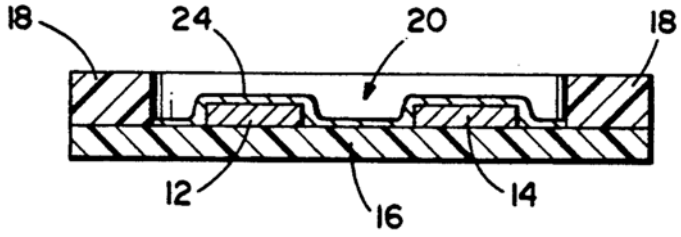

Figure 1 is a perspective view of test cell 10 and Figure 2 is a section taken along line 2–2 in Figure 1. *Id.* at 3:20–22. Test cell 10 includes working electrode 12 and reference electrode 14. *Id.* at 3:35–39. Electrodes 12 and 14 are sandwiched between a pair of polymeric sheet materials 16 and 18. *Id.* at 3:41–42. Sheet material 18 has openings 20 and 22 that

expose electrodes 12 and 14. *Id.* at 3:42–44. Opening 20 creates a reaction well wherein a sample of body fluid is placed to enable a reaction to occur. *Id.* at 3:44–46. Opening 22 exposes electrodes 12 and 14 so that test cell 10 can be plugged into a female connector that makes electrical connections to the electrodes. *Id.* at 3:46–49. Reaction layer 24 is placed in well 20 and provides reactants, such as a glucose oxidase enzyme and a gelatin and propiofin film former, for the biosensing reaction. *Id.* at 3:50–61.

A high level block diagram of the biosensing instrument is illustrated in Figure 4, reproduced below.

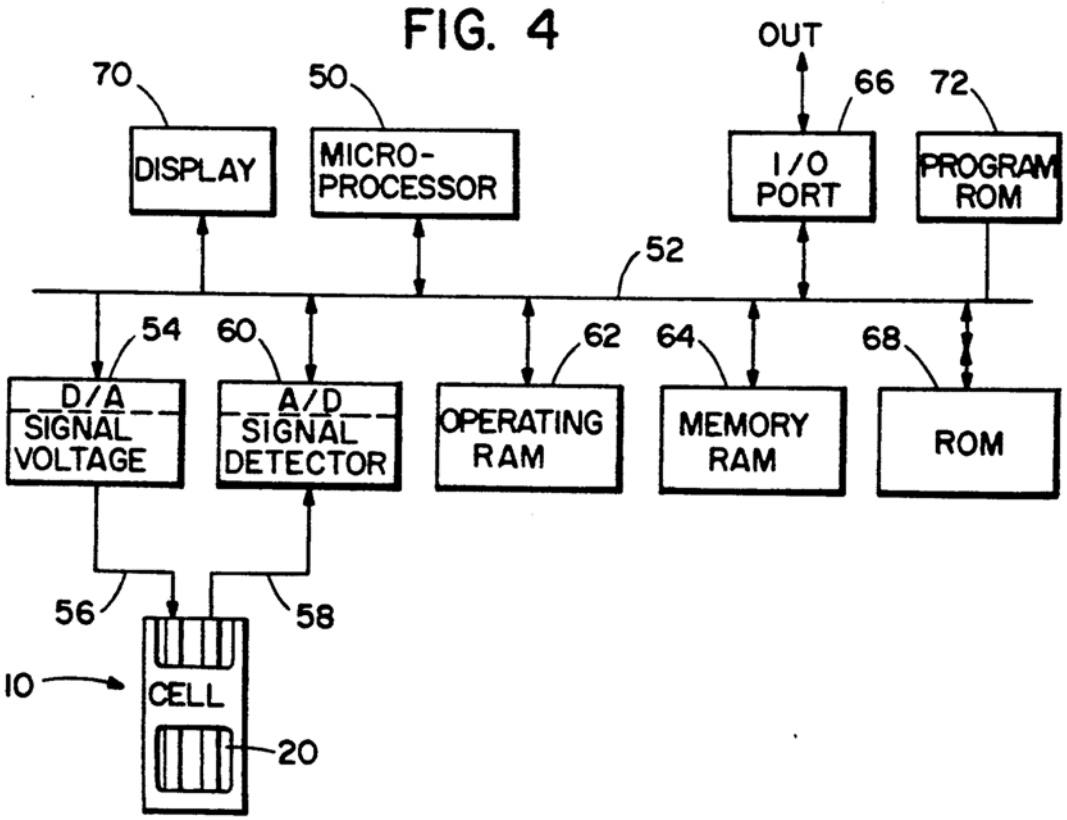

Figure 4 shows a block diagram of the test system used to determine the concentration of an analyte in a fluid sample. *Id.* at 3:26–28. Microprocessor 50 implements system control via bus 52 and communicates with signal voltage module 54, which converts digital commands from

microprocessor 50 into analog outputs that are then applied to test cell 10 via line 56. *Id.* at 5:27–34. Current flow is returned through test cell 10, via conductor 58, by signal detector 60 which, in turn, measures the current on a continuing basis and converts the readings to digital outputs. *Id.* at 5:38–41. Display 70 enables the user to see the results of a concentration measurement. *Id.* at 6:2–3.

In use, a sample of blood is placed in well 20, glucose within the sample causes a forward reaction with the reactants in the well to convert potassium ferricyanide to potassium ferrocyanide. *Id.* at 4:3–7. When the forward reaction is completed, voltage is applied across electrodes 12 and 14 to cause creation of a small current between them that results from the reverse reaction of the potassium ferrocyanide back to potassium ferricyanide. *Id.* at 4:7–12; *see also id.* at 6:5–23. The flow of electrons during the reverse reaction is sensed and measured and bears a known relationship to glucose concentration levels. *Id.* at 4:12–15; *see also id.* at 6:24–44. According to White, the current resulting from the reverse reaction is known as the Cottrell current, which is proportional to the concentration of the analyte and inversely proportional to the square root of the measurement time. *Id.* at 1:65–2:34. An additional feature of the biosensing system is determining whether a measured current is varying in accordance with a predetermined Cottrell current relationship. *Id.* at 2:62–64; *see also id.* at 6:40–44.

2. Beaty

Beaty describes an apparatus for improving the accuracy of measurements made with instruments of the type described in, for example, White. Ex. 1007, 1:4–6. Beaty describes that biosensors for measurement of concentrations of biologically significant components, such as glucose,

are known to be susceptible to variations in the temperature of the biological fluids and to interference by the presence in the biological fluids of other components, known as interferrents. *Id.* at 6:30–7:11. Beaty describes that measurement of the real component or the imaginary component, or both, of the AC impedance of an appropriately designed biosensor provides insight into sample temperature and concentration of interferrents, such as hematocrit, bilirubin, uric acid, and oxygen. *Id.* at 7:28–8:4. This measurement also provides insight into the volume and identity of a sample with which the biosensor is doped. *Id.* at 8:4–7. Specifically, Beaty describes that sample temperature, the concentrations of interferrents, the identity of the sample, and the sample volume can be ascertained at judiciously selected AC frequencies. *Id.* at 8:9–12. For example, Beaty teaches employing, in biosensors of the type described in White, a low-magnitude AC signal at about 1300 Hz to determine the adequacy of the sample volume and the identity of the sample. *Id.* at 8:23–9:4. Beaty also teaches, that once the adequacy of the sample volume for the test has been established, frequencies in the range of from about 2 KHz to about 10 KHz can be used to determine components of impedance of the biosensor/sample system to arrive at a glucose concentration compensated for the combined effects of sample temperature and hematocrit. *Id.* at 9:8–18. Beaty describes that these determinations are made before the amperometric determination of the glucose concentration of the blood sample. *Id.* at 9:19–20; *see also id.* at 11:9–10 (describing that the glucose concentration can be determined using the amperometry techniques described in White).

An embodiment of the apparatus is illustrated in Figure 2, reproduced below.

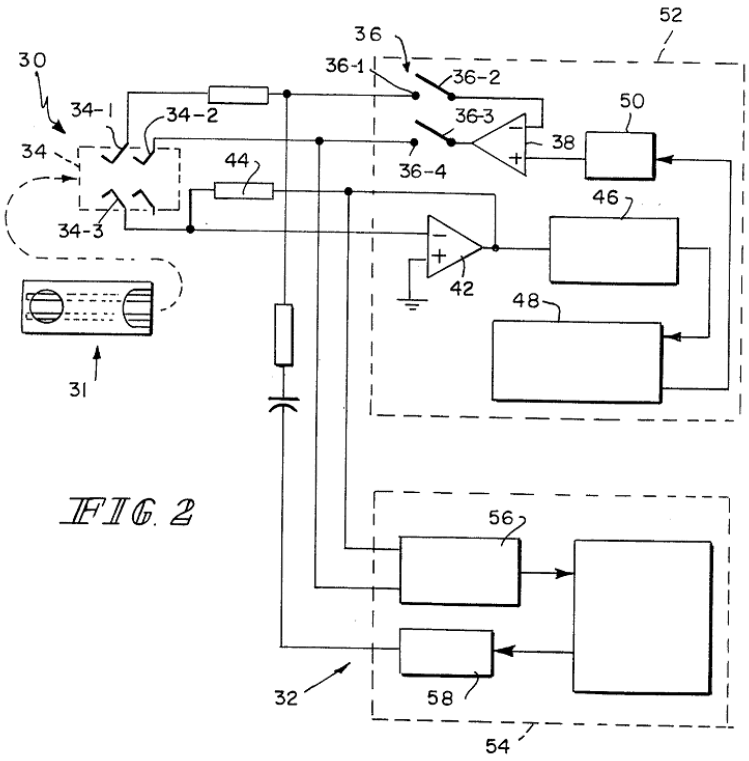

FIG. 2

Figure 2 shows a partly block and partly schematic diagram of an instrument constructed according to Beaty. *Id.* at 6:16–17. Beaty describes that strip connector 30 of the general type illustrated in White makes contact between disposable amperometric sensor cell 31 of the general type illustrated in White and instrument 32. *Id.* at 11:20–23. Beaty further describes that processor 48 has supporting functions which perform glucose measurement functions as described in White. *Id.* at 12:13–15. Processor 48 communicates with cell 31 via D/A converter 50 and A/D converter 46. *Id.* at 12:11–20. Microprocessor 54, which also has input A/D and output D/A capabilities 56 and 58, respectively, performs the hematocrit compensating and sample volume determining functions of instrument 32. *Id.* at 12:20–23. Instrument 32 excites terminal 34-2 of connector 34 at the desired frequency, e.g., 1300 Hz or 10 KHz, to determine the parameter of interest. *Id.* at 12:31–13:6.

In operation, a sample of blood is applied to biosensor 31, and after instrument 32 detects the deposit of a sample on the biosensor 31, an AC signal having a frequency of 1300 Hz is applied across terminals 34-2 and 34-3 of connector 34, and microprocessor 54 indirectly samples the resulting current by measuring excitation and response voltages and using the scale factor to obtain current. *Id.* at 15:1–7. The impedance magnitude and phase angle are calculated, and using these values, microprocessor 54 determines the identity of the sample, e.g., blood, and the adequacy of the sample volume for use in glucose determination. *Id.* at 15:7–11. If it is determined that there is not sufficient volume in the blood sample to proceed with the glucose determination phase of the assay, then the assay is terminated. *Id.* at 15:10–11. If the sample volume is sufficient, an AC signal at 10 KHz is applied across terminals 34-2 and 34-3 of connector 34, and microprocessor 54 samples the resulting current. *Id.* at 15:12–15. The impedance magnitude and phase angle are calculated at this second frequency, and using these values, microprocessor 54 determines a glucose-to-actual glucose correction factor. *Id.* at 15:15–17. The correction is stored and the determination of the glucose concentration proceeds generally as described in White. *Id.* at 15:21–23. The glucose correction factor is applied to the indicated glucose concentration to arrive at the actual glucose concentration. *Id.* at 15:23–26.

3. Analysis of Challenged Independent Claim 14

We focus our discussion on the Petition's showing of element 14(h) ("discard a glucose measurement when the value associated with the severity of the erroneous signal is outside of a predetermined threshold value") in the combined teachings of White and Beaty.

The Petition provides three theories for how the combined teachings of White and Beaty meet the claim limitation of "discard a glucose measurement when the value associated with the severity of the erroneous signal is outside of a predetermined threshold value." Pet. 40–43 (discussing Case 1, Case 2, and Case 3). Under the first theory ("Case 1"), the Petition asserts that White discloses that read-only memory 68 contains precalculated comparison constants ($x_{1,2}$, $x_{2,3}$, etc.) for the batch of test cells from which test cell 10 is taken. *Id.* at 40 (citing Ex. 1006, 5:55–59). The Petition further asserts that White discloses comparing the ratio of the current values measured at measurement times t_n and t_{n+1} to the prestored comparison constant $x_{n, n+1}$, where the ratios not being "similar" indicates that the measured current values are not following a predetermined Cottrell current relationship and an error condition is reported. *Id.* (citing Ex. 1006, 6:6–7:17, Figs. 5, 6).[3] According to the Petition, White thus "describes discarding a glucose measurement if a ratio of two measured current values (i.e., *a value associated with the severity of the erroneous signal*) is substantially different from, (i.e., *outside of*), a corresponding prestored comparison constant ($x_{1,2}$; $x_{2,3}$; etc., and $x_{n, n+1}$, in general), i.e., a *predetermined threshold value*." *Id.* at 41 (citing Ex. 1003 ¶¶ 361–362).

As to this first theory, Dexcom argues in its Preliminary Response that the Petition lacks an identification of what in White allegedly satisfies the claimed "glucose measurement" that is discarded, and asserts that White does not use the terms "glucose measurement" or "discard." Prelim. Resp. 8. According to Dexcom, the Petition does not provide any

[3] The Petition cites to the passage beginning at line 6 of column 6 in White, but it appears the quoted passage actually begins at line 64 of column 6.

substantive analysis or explanation tying the quoted portions of White to discarding a glucose measurement. *Id.* Dexcom also argues that the Petition discusses "a ratio of measured current values," but does not allege this ratio is the claimed glucose measurement. *Id.* Last, Dexcom argues that White describes reporting an error condition, but the Petition does not allege that this error reporting involves discarding a glucose measurement, much less explain why it would. *Id.*

We agree with Dexcom that the Petition falls short in explaining how White discloses discarding a glucose measurement. As noted above (*see supra* Section III.C.1.), White's biosensing system determines whether a measured current is varying in accordance with a predetermined Cottrell current relationship. Ex. 1006, 2:62–64; *see also id.* at 6:40–44. This determination is made by comparing the ratio of the current values measured at measurement times t_n and t_{n+1} to the prestored comparison constant $x_{n, n+1}$. *Id.* at 6:64–67; *see also id.* at Fig. 6 (depicting the comparison at block 120). If the ratios[4] are not "similar" (i.e., do not differ by more than a predetermined error value), then it is known that the measured current values are not following a predetermined Cottrell current relationship, at which point an error condition is reported as depicted by box 122 of Figure 6. *Id.* at 6:67–7:7.

White does not describe, however, what happens as a result of an error condition being reported. More to the point, White does not specify that any signal or measurement, much less a glucose measurement, is discarded when an error condition is reported. In fact, according to the flow diagram in

[4] The prestored or precalculated comparison constant is expressed as a ratio of the square roots of two measurement times. Ex. 1006, 3:4–8, 6:46–47, Fig. 5 (box 100).

Figure 6, the process terminates once an error condition is reported. *Id.*, Fig. 6, box 122. The determination of a glucose measurement occurs in a different branch of the flow diagram that is not reached if the error condition occurs. *Id.* Thus, the Petition's assertion that White describes discarding a glucose measurement if the compared ratios are not similar (Pet. 41) is a conclusory statement not supported sufficiently by objective evidence or analysis. This unsupported, conclusory assertion does not satisfy AgaMatrix's burden of demonstrating obviousness. *See In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016) ("To satisfy its burden of proving obviousness, a petitioner cannot employ mere conclusory statements. The petitioner must instead articulate specific reasoning, based on evidence of record, to support the legal conclusion of obviousness."). The testimony in the Smith Declaration relied on in the Petition for support (Ex. 1003 ¶¶ 361–362) merely parrots the Petition's conclusory assertion and, thus, also is not supported sufficiently by objective evidence or analysis. For this reason, we do not credit the testimony of Dr. Smith on this issue. *See* 37 C.F.R. § 42.65(a) ("Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight.").

Under the second theory ("Case 2"), the Petition asserts that the passage at lines 1–12 on page 15 of Beaty "describes terminating an assay and discarding a glucose measurement when a computed cell impedance value (i.e., *a value associated with the severity of the erroneous signal*) is different from (i.e., *outside of*) the corresponding value stored in a look-up table in memory (i.e., *a predetermined threshold value*)." Pet. 41 (citing Ex. 1003 ¶¶ 363–364).

Dexcom argues that the Petition points to nothing in the quoted portion of Beaty as the alleged "glucose measurement" and fails to even attempt to explain how or why Beaty teaches discarding a glucose measurement. Prelim. Resp. 10. Dexcom also argues that Beaty describes a two-step process including a first measurement that is not a glucose measurement, but determines whether a sample is blood and in sufficient quantity, and a second measurement that occurs as part of a later "glucose determination phase," but does not occur in Beaty's "terminating an assay" scenario posited by the Petition. *Id.* at 10–11 (citing Ex. 1007, 15:1–27).

We agree with Dexcom. The portion of Beaty relied on by the Petition discloses applying an AC signal having a frequency of, for example, 1300 Hz across terminals 34-2 and 34-3 of connector 34 to ascertain whether a sample of blood is of sufficient volume *to proceed with the glucose determination phase* of the assay, where the assay is terminated if the sample is not a sufficient volume. Ex. 1007, 15:1–12. Thus, this portion of Beaty's process does not measure glucose. Rather, Beaty discloses that only "[i]f there is sufficient volume [of the sample] to continue with the glucose determination," is an AC signal at another frequency, 10 KHz for example, applied across terminals 34-2 and 34-3 in a procedure to arrive at the actual glucose concentration. *Id.* at 15:12–27.

Neither the Petition nor the Smith Declaration states explicitly what disclosure in Beaty corresponds to discarding a glucose measurement. But, even assuming for the sake of argument that the Petition alleges that Beaty's disclosure of terminating the assay if the sample has insufficient volume is equivalent to the claimed discarding, such termination cannot result in discarding a *glucose measurement* because Beaty does not measure glucose until *after* the determination of whether the sample has sufficient volume is

made. *Id.* at 15:12–27. In other words, as Dexcom correctly argues (Prelim. Resp. 11), if the assay is terminated in Beaty because of insufficient volume, then the glucose concentration is never measured and the non-existent measurement cannot be discarded at the time of termination.

Under the third theory ("Case 3"), the Petition asserts that

> in light of White's and Beaty's express teachings, a POSITA would have understood that an error condition can be reported and a glucose measurement can be discarded if an impedance value and/or the corresponding correction factor indicative of the effect of temperature, hematocrit, and/or another interfe[r]rent (i.e., *the value associated with the severity of the erroneous signal*) is too high (i.e., *outside of*) compared to a predetermined threshold value, such as that stored in a second look-up table in memory.

Pet. 42–43 (citing Ex. 1003 ¶ 367). Dexcom disputes this assertion for three reasons. Prelim. Resp. 12–15. First, Dexcom contends "the Petition utterly fails to explain the purported combination or an alleged motivation for creating that combination." *Id.* at 12. Dexcom adds that the Petition's assertion of what "can" be done falls far short of the required showing that one of ordinary skill in the art *would* have been motivated to combine the references in a particular way that *would* have satisfied the claim. *Id.*at 12–13 (citing *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015)).

Second, Dexcom argues that Case 3 fails to identify a "glucose measurement" in the alleged combination or explain how the proposed combination discards a glucose measurement. *Id.* at 13. Third, Dexcom argues that Case 3 rests on the unsupported and conclusory propositions of Case 1 and Case 2, and Case 1 and Case 2 both are deficient for the reasons argued earlier in its Preliminary Response. *Id.* at 14.

We agree with Dexcom that the Petition fails to explain adequately how the proposed combination of White and Beaty would result in a device that discards a glucose measurement. As discussed above, AgaMatrix's arguments that White and Beaty individually disclose discarding a glucose measurement are not persuasive. The Petition does not explain how combining these teachings would overcome those deficiencies. In addition, although the Petition provides a rationale for combining White and Beaty in general (Pet. 43–46), the Petition does not explain adequately why one of ordinary skill in the art would have been led to modify White in view of Beaty in the particular manner proposed for Case 3.

For these reasons, there is not a reasonable likelihood that AgaMatrix would prevail with respect to the challenge to claim 14 in the Petition.

4. Independent Claims 20, 26, 32, 38, and 50

The Petition notes that each of independent claims 20, 26, 32, 38, and 50 is substantially the same as claim 14, with the exception of with which condition the claimed erroneous signal of element 14(f) is associated. Pet. 46–50. The Petition asserts that the combination of White and Beaty teaches all the other elements, including the discarding a glucose measurement limitation, of claims 20, 26, 32, 38, and 50 as discussed in connection with claim 14. *Id.* Thus, AgaMatrix's challenges to claims 20, 26, 32, 38, and 50 are based on the same deficient assertions as to the disclosures of White and Beaty as discussed above in the analysis of the challenge to independent claim 14. For these same reasons, there is not a reasonable likelihood that AgaMatrix would prevail with respect to the challenges to claims 20, 26, 32, 38, and 50 in the Petition.

5. Dependent Claims

AgaMatrix's challenges to dependent claims 15–18, 21–24, 27–30, 33–36, 39–42, and 51–54 are based on the same deficient assertions as to the disclosures of White and Beaty as discussed above in the analysis of the challenge to independent claims 14, 20, 26, 32, 38, and 50. Pet. 51–54. For these same reasons, there is not a reasonable likelihood that AgaMatrix would prevail with respect to the challenges to dependent claims 15–18, 21–24, 27–30, 33–36, 39–42, and 51–54 in the Petition.

D. Second Ground: White, Beaty, and Schulman

1. Analysis of Challenged Claim 62

As noted in the Petition (Pet. 54–55), independent claim 62 of the '460 patent recites limitations identical to limitations recited in independent claim 14 but recites "generate a glucose value for display when the value associated with the severity of the erroneous signal satisfies a predetermined threshold value" and "discard a glucose measurement when the value associated with the severity of the erroneous signal does not satisfy the predetermined threshold value" instead of "discard a glucose measurement when the value associated with the severity of the erroneous signal is outside of a predetermined threshold value" and also adds a "user interface" element. Ex. 1001, 53:9–63.

The Petition relies in large part on the same assertions presented in the challenge of independent claim 14 based on White and Beaty in support of the challenge to the "discard a glucose measurement" limitation in independent claim 62. Pet. 56–61. The Petition presents additional assertions as to how Schulman discloses the additional "user interface" element of claim 62. *Id*. at 61–66. The Petition is insufficient in its showing as to the "discard a glucose measurement" limitation of claim 62, which is

common to the "discard a glucose measurement" limitation of claim 14 discussed above. Thus, there is not a reasonable likelihood that AgaMatrix would prevail with respect to the challenge to independent claim 62 in the Petition

2. Independent Claims 63–66 and 68

AgaMatrix's challenges to independent claims 63–66 and 68 are based on the same deficient assertions as to the disclosures of White and Beaty as discussed above in the analysis of the challenge to independent claim 62. Pet. 69–71. For these same reasons, there is not a reasonable likelihood that AgaMatrix would prevail with respect to the challenges to independent claims 63–66 and 68 in the Petition.

IV. CONCLUSION

For the reasons provided above, AgaMatrix does not show a reasonable likelihood that it would prevail with respect to at least one of the challenged claims.

V. ORDER

Thus, it is hereby:

ORDERED that the Petition is *denied*; and

FURTHER ORDERED that no *inter partes* review is instituted.

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