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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AGAMATRIX, INC.,
Petitioner,

v.

DEXCOM, INC.,
Patent Owner.

Case IPR2018-01716
Patent 9,724,045 B1

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

HORNER, *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 16–20, 23–25, 37, 38, and 41–43 of U.S. Patent No. 9,724,045 B1 (Ex. 1001, "the '045 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 16–20, 23–25, 37, 38, and 41–43 of the '045 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*

[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.

the Matter of Certain Electrochemical Glucose Monitoring Systems And Components Thereof, Inv. No. 337-TA-1075 (USITC) ("the related ITC proceeding"). Paper 2, 63; Paper 4, 1. Additionally, AgaMatrix challenges the '045 patent on different grounds in IPR2018-01715 and challenges related U.S. Patent No. 9,750,460 B2 in IPR2018-01717 and IPR2018-01718. Paper 2, 63–64; 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. Paper 2, 63. 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. 24. 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 '045 Patent

The '045 patent relates to systems for detecting and replacing transient non-glucose related signal artifacts in a glucose sensor data stream.

[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.

Ex. 1001, 1:24–28. Specifically, the systems detect and replace signal noise caused by substantially non-glucose reaction rate-limiting phenomena, such 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 '045 patent, which is reproduced below.

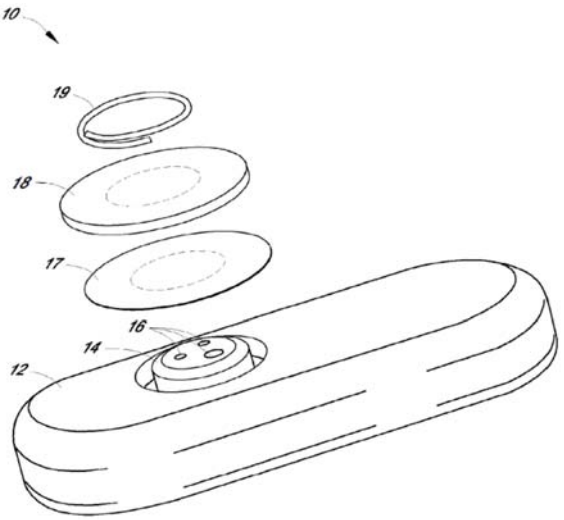

FIG. 1

Figure 1 shows an exploded view of implantable glucose sensor 10 that utilizes amperometric electrochemical sensor technology to measure glucose concentration. *Id.* at 20:19–22. In sensor 10, body 12 and head 14 house three electrodes 16 and sensor electronics. *Id.* at 20:22–23. Electrodes 16 are covered by sensor membrane 17 and biointerface membrane 18, which are attached to body 12 by clip 19. *Id.* at 20:25–28. Electrodes 16 include a working electrode, a counter electrode and a reference electrode. *Id.* at 20:29–32. 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 20:32–37. The

glucose oxidase catalyzes the conversion of oxygen and glucose to hydrogen peroxide and gluconate. *Id.* at 20:45–47. 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 20:50–53. A potentiostat monitors the electrochemical reaction by applying a constant potential to the working and reference electrodes to determine a current value. *Id.* at 20:60–63. The current produced at the working electrode is proportional to the amount of hydrogen peroxide that diffuses to the working electrode. *Id.* at 20:63–66. Thus, a raw signal is produced that is representative of the concentration of glucose in the user's body. *Id.* at 20:67–21:1.

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 21:4–13. The '045 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 to Berner et al. *Id.* at 27:55–66. The 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 28:19–25. The '045 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 29:46–51. The system replaces transient non-glucose related

signal artifacts in the data stream that have a higher amplitude than system noise. *Id.* at 21:14–17.

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 44:54–55. At block 152, a sensor data receiving module receives sensor data, e.g., a data stream, from the glucose sensor. *Id.* at 44:56–60. 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 44:61–45:1. 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 45:1–3.

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 31:48–51. The '045 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 31:51–56.

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 45:28–31. For example, a first filter is applied during low signal artifacts and a second filter is applied during high signal artifacts. *Id.* at 45:45–49.

D. Challenged Claims

Of the claims challenged in the Petition, claims 16 and 37 are independent. Challenged claim 16 is illustrative of the subject matter at issue in the asserted grounds. Claim 16 is reproduced below.

> 16. A glucose sensor system, the system comprising:
>
> an electrochemical glucose sensor configured to be in contact with a biological sample for measuring a glucose concentration, wherein the electrochemical glucose sensor comprises a first electrode, a second electrode, and an enzyme-containing film;
>
> sensor electronics comprising a processor for executing a computer program code stored in a memory to cause the sensor electronics to:
>
> apply a voltage to the electrochemical glucose sensor at a first setting,
>
> switch the voltage applied to the electrochemical sensor to a different setting,
>
> measure a signal response of the electrochemical glucose sensor responsive to the switching,
>
> evaluate a severity associated with a signal artifact based on the measured signal response of the electrochemical glucose sensor to the switching, wherein the signal artifact is associated with a non-glucose rate limiting phenomenon, and
>
> generate an estimated glucose concentration value when the severity associated with the signal artifact is evaluated to be under a predetermined threshold, wherein the estimated glucose concentration value accounts for the severity associated with the signal artifact; and
>
> a user interface configured to display the estimated glucose concentration value.

Ex. 1001, 48:15–44.

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, 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 16–20, 23–25, 37, 38, and 41–43 of the '045 patent on the following grounds (Pet. 14):

Ground	Statutory Basis	Reference(s)	Claims
1	§ 103	White and Beaty	16–20, 23–25
2	§ 103	White, Beaty, and Schulman	37, 38, 41–43

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. 15–16 (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.* at 16.

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. 16–18. AgaMatrix stated that "the broadest reasonable interpretation of the [listed] claim terms is *at least as broad as* the listed definitions." *Id.* at 17. 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. 5. 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

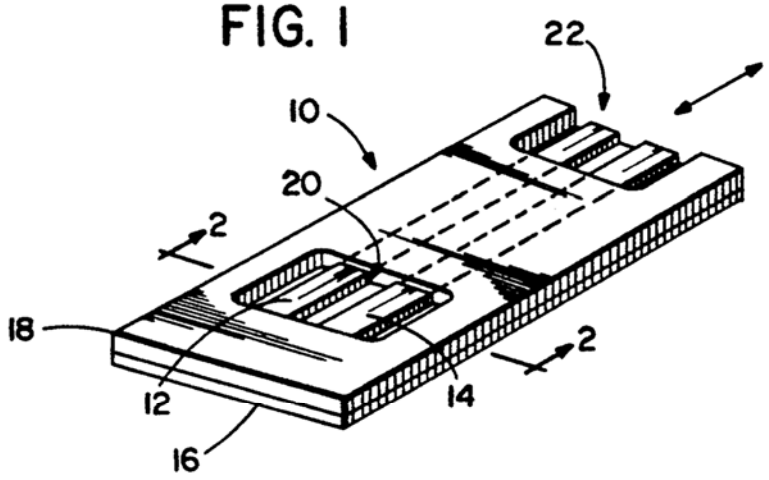

FIG. 2

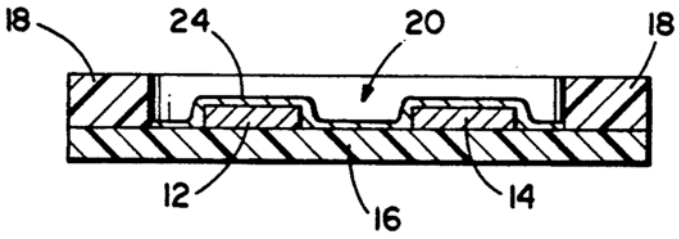

Figure 1 is a perspective view of test cell 10 and Figure 2 is a section taken along line 2–2 in Figure 1. *Id.* at 3:20–22. Test cell 10 includes working electrode 12 and reference electrode 14. *Id.* at 3:35–39. Electrodes 12 and 14 are sandwiched between a pair of polymeric sheet materials 16

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.

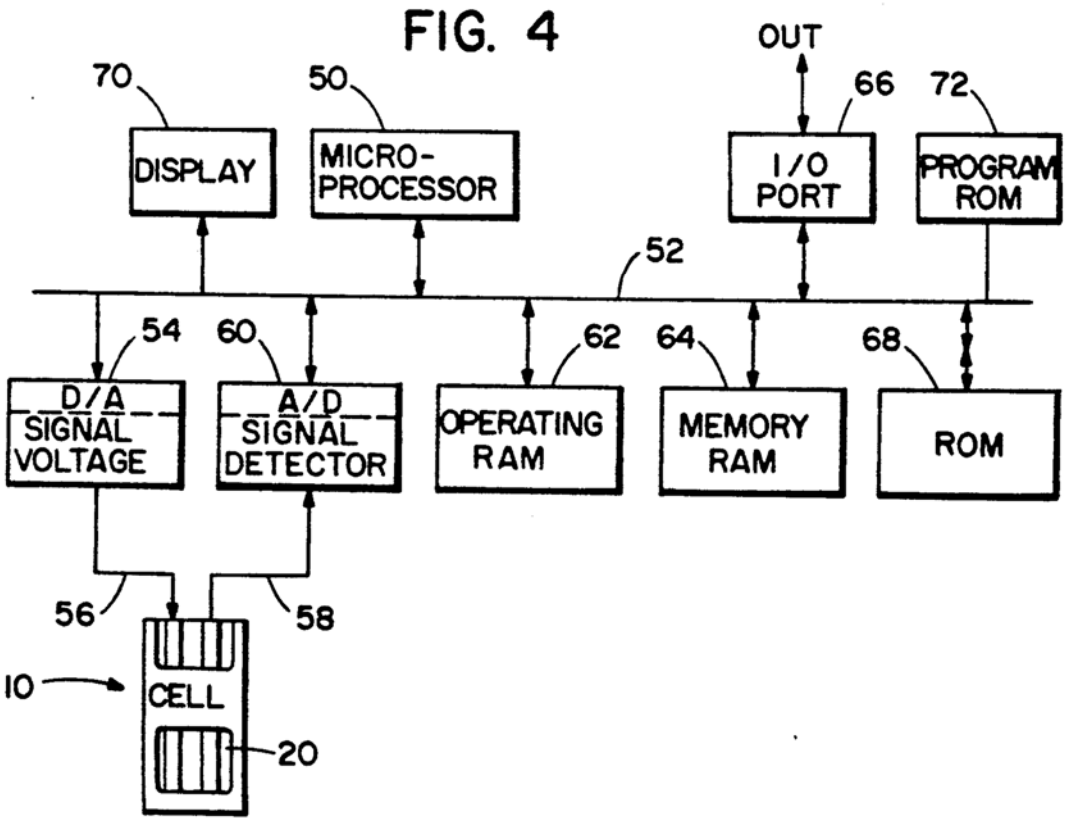

Figure 4 shows a block diagram of the test system used to determine the concentration of an analyte in a fluid sample. *Id.* at 3:26–28.

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 4:27–34. 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 4:38–41. 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.

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.

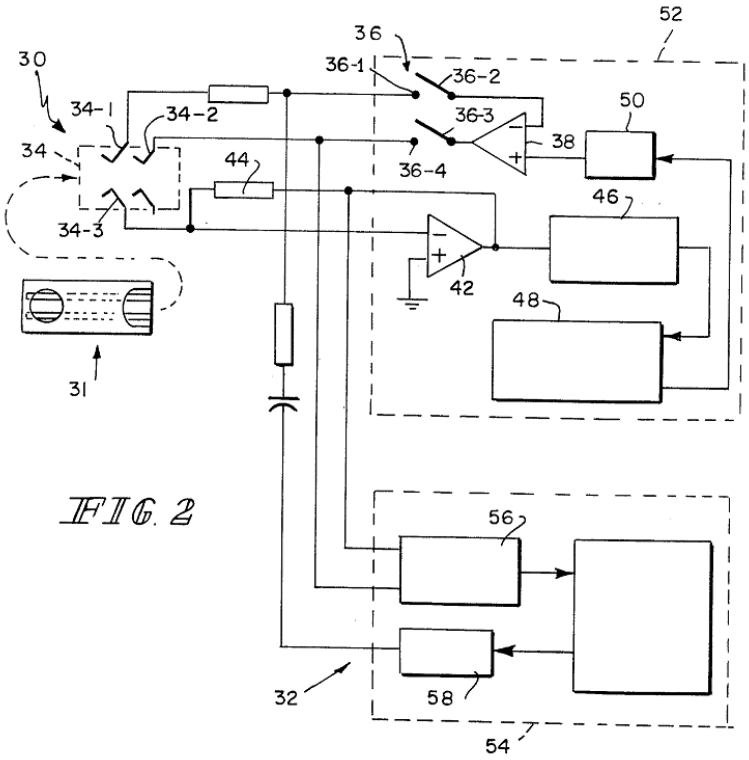

FIG. 2

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 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 16

We focus our discussion on the Petition's showing of element 16(d) ("switch the voltage applied to the electrochemical sensor to a different setting") and element 16(e) ("measure a signal response of the electrochemical glucose sensor responsive to the switching") in the combined teachings of White and Beaty.

The Petition provides two theories for how the combined teachings of White and Beaty meet the claim limitation of "switch the voltage applied to the electrochemical sensor to a different setting." Pet. 28–30 (discussing Case 1 and Case 2). Under the first theory ("Case 1"), the Petition asserts that Beaty teaches applying AC voltage(s) to the test cell at a first setting to detect the volume of the blood sample and to correct for interferrents, and then teaches switching the voltage applied to a different setting to determine the glucose concentration as described in White. *Id.* at 28–29. According to the Petition, "White's glucose measurement step must involve switching the applied voltage from Beaty's AC voltage(s) to White's 'measurement voltage' which in a typical amperometric measurement would be a DC voltage." *Id.* at 29 (citing Ex. 1003 ¶¶ 304–305).

As to this first theory, Dexcom argues in its Preliminary Response that the Petition fails to provide adequate citation to White to support its allegations as to White's glucose measurement steps and application of a "measurement voltage." Prelim. Resp. 9. Dexcom argues that the Petition fails to provide support or explanation for the conclusion that the transition to White's glucose measurement steps "must involve switching" from Beaty's AC voltage(s) to White's "measurement voltage" which "in a typical amperometric measurement would be a DC voltage." Prelim. Resp. 11 (quoting Pet. 29) (emphasis omitted). Dexcom asserts that the Petition fails to explain why the alleged transition "must involve switching" and why White's voltage "would be a DC voltage." *Id.*

In support of AgaMatrix's allegations, the Petition cites to paragraph 305 of the Smith Declaration, which cites to White. Ex. 1003 ¶ 305 (citing Ex. 1006, 6:59–61, Fig. 5 (step 112)). The cited portion of White states,

"Then, a measurement voltage is applied to cell 10 from signal voltage module 54, and a first current reading is taken at t0 and recorded (box 116)." Ex. 1006, 6:59–61. Step 112 of the flow diagram illustrated in Figure 5 states, "APPLY MEASUREMENT VOLTAGE TO CELL." *Id.*, Fig. 5. Although these portions of White support AgaMatrix's position that a voltage is applied to test cell 10 for purposes of measuring glucose concentration, they do not describe the type of voltage applied, i.e., AC or DC, and do not describe any other aspects or specifications of the voltage applied. Thus, the testimony in the Smith Declaration that White's measurement voltage is DC voltage is not supported by adequate evidence or reasoning. "Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight." 37 C.F.R. § 42.65(a).

Under the second theory ("Case 2"), the Petition asserts that "Beaty teaches, during sample detection and interference correction, AC signals having frequencies of 1300Hz and 10KHz are successively 'applied across terminals 34-2 – 34-3 of connector 34.'" *Id.* at 29 (citing Ex. 1007, 15:3–15). The Petition asserts that Beaty's application of AC signals at a frequency of 1300 Hz is application of voltage "at a first setting" and Beaty's subsequent application of AC signals at a frequency of 10 KHz inherently requires switching the voltage applied from a first setting to a different setting. *Id.* at 29–30 (citing Ex. 1003 ¶¶ 307–309).

Building off of these two theories, the Petition provides that in both Cases 1 and 2, White discloses measuring a raw, glucose-indicating signal as "a signal response of the electrochemical glucose sensor responsive to the switching." Pet. 30–31. The Petition explains that the raw, glucose-

indicating signal obtained during the glucose measurement as described in White "would not have been available but for the switching of the applied voltage from a previous AC setting to the 'measurement voltage' setting and but for Beaty's application of the AC voltage(s)." *Id.* at 31 (citing Ex. 1003 ¶ 312). Dr. Smith explains:

> That is, in order to measure the raw signal, a sufficient volume of the blood sample must be detected, the interferences need to be corrected, and then the measurement voltage must be applied to the electrodes. Therefore, the measurement of the raw signal from White's test cell is indirectly or directly 'responsive to the switching.'"

Ex. 1003 ¶ 312.

Dexcom argues in its Preliminary Response that this position fails because it relies on the unsupported and conclusory assumption that the availability of White's signal requires application of Beaty's AC voltages. Prelim. Resp. 13–14. Dexcom insists that White's raw signal is available and can be measured without application of Beaty's AC voltages. *Id.* at 14. Dexcom asserts that neither the Petition nor the Smith Declaration provides evidentiary support for this assumption. *Id.* We agree with Dexcom that the evidence provided in support of AgaMatrix's "but for" assumption as the basis for a signal response "responsive to the switching" is weak. White describes a test cell and system that is able to obtain current readings in response to application of a measurement voltage without the previous applications of voltages as described in Beaty. Ex. 1006, 6:19–7:17. Although Beaty's disclosed techniques may provide a more accurate glucose concentration value, we do not find adequate support in the evidence

provided by AgaMatrix that Beaty's disclosed techniques are a prerequisite to obtaining a signal response in the system of White.

Alternatively, the Petition provides that in Case 2, Beaty describes measuring excitation and response voltages after application of an AC signal having a specific frequency, e.g., 1300 Hz or 10 KHz, as a means to indirectly sample resulting current. Pet. 32 (citing Ex. 1007, 15:3–15). The Petition asserts that a person having ordinary skill in the art would have understood that both the "resulting current" and the "response voltage" are "signal responses" responsive to the AC signal, which inherently involves the switching of voltage levels. *Id.* at 32 (citing Ex. 1003 ¶ 314).

Dexcom argues in its Preliminary Response that this alternative theory fails because the "switching" under Case 2 is "an alleged switch from a 1300Hz AC signal to a 10KHz AC signal" but the Petition fails to explain how either of the alleged "signal responses" is "responsive to" the alleged switch. Prelim. Resp. 16–17. Dexcom argues that the voltage response and resulting current described in Beaty are "measurements made separately during each of these AC voltages." *Id.* at 16. Dexcom asserts that "[t]he cited portions of Beaty do not describe either the 'response voltage' or the 'resulting current' as 'responsive to' a change from 1300Hz AC to 10KHz AC." *Id.* at 17.

We agree with Dexcom that the Petition falls short in explaining how Beaty's measurements, taken after application of, for example, a 10 KHz AC signal, are "responsive to" the asserted switching from 1300 Hz AC to 10 KHz AC. Dexcom does not provide us with a proposed interpretation of "responsive to the switching" as recited in claim 16. *See* Pet. 16–18.

The next element of claim 16 recites "evaluate a severity associated with a signal artifact based on the measured signal response." At this point in the explanation of the asserted ground, the Petition drops its theory about Beaty's signal responses, and relies entirely on White's raw glucose signal as the claimed "measured signal response." Pet. 32–40. Thus, even were the Petition sufficient to show that Beaty's measured signal responses at 1300 Hz AC and at 10 KHz AC are "responsive to the switching," the Petition has not shown where the prior art then evaluates a severity associated with a signal artifact based on this measured signal response.

As to AgaMatrix's theory that White discloses "evaluate a severity associated with a signal artifact based on the measured signal response," for the reasons discussed above, the Petition is not sufficient to show either (1) that application of White's measurement voltage necessarily switches the voltage applied to the electrochemical sensor to a different setting, or (2) that measurement of a signal response in White, i.e., the raw glucose signal, is "responsive to the switching."

For these reasons, there is not a reasonable likelihood that AgaMatrix would prevail with respect to the challenge to claim 16 in the Petition.

4. Dependent Claims

AgaMatrix's challenges to dependent claims 17–20 and 23–25 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 16. Pet. 43–50. For these same reasons, there is not a reasonable likelihood that AgaMatrix would prevail with respect to the challenges to dependent claims 17–20 and 23–25 in the Petition.

D. Second Ground: White, Beaty, and Schulman

1. Analysis of Challenged Claim 37

As noted in the Petition (Pet. 51), independent claim 37 of the '045 patent recites limitations identical to limitations recited in independent claim 16 and adds "wherein the measured signal response is a time-varying voltage response of the electrochemical glucose sensor" to the step of "measure a signal response . . ." and also adds more "user interface" functions. Ex. 1001, 50:4–44. The Petition relies on the same assertions presented in the challenge of independent claim 16 based on White and Beaty in support of the challenge to the common limitations in independent claim 37. Pet. 51. The Petition presents additional assertions as to how Beaty discloses the "time-varying voltage response" and as to how Schulman discloses the additional "user interface" functions of claim 37. *Id*. at 51–58. The Petition is insufficient in its showing as to the limitations of claim 37 which are common to the limitations of claim 16 discussed above. Thus, there is not a reasonable likelihood that AgaMatrix would prevail with respect to the challenge to independent claim 37 in the Petition

2. Dependent Claims

AgaMatrix's challenges to dependent claims 38 and 41–43 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 16. Pet. 62–63. For these same reasons, there is not a reasonable likelihood that AgaMatrix would prevail with respect to the challenges to dependent claims 38 and 41–43 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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