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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 IPR2018-01717
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), 325(d)

I. INTRODUCTION

AgaMatrix, Inc. ("AgaMatrix" or "Petitioner") filed a Petition requesting *inter partes* review of claims 14–69 of U.S. Patent No. 9,750,460 B2 (Ex. 1001, "the '460 patent"). Paper 2 ("Pet."). 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." The statute also provides, "[i]n determining whether to institute or order a proceeding under this chapter, chapter 30, or chapter 31, the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office." 35 U.S.C. § 325(d).

Upon consideration of the Petition and the Preliminary Response, we exercise our discretion under 35 U.S.C. § 325(d) and do not institute *inter partes* review because the same prior art previously was presented to the Office.

[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. § 325(d), we do not reach the issue of real party in interest in this proceeding.

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 Components Thereof*, Inv. No. 337-TA-1075 (USITC). Pet. 70–71; Paper 4, 1. Additionally, AgaMatrix challenges the '460 patent on different grounds in IPR2018-01718 and challenges related U.S. Patent No. 9,724,045 B1 in IPR2018-01715 and IPR2018-01716. Pet. 71; 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. 70. 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. 35. Because we deny institution under 35 U.S.C. § 325(d), we do not reach the issue of real party in interest.[2]

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[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

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 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.

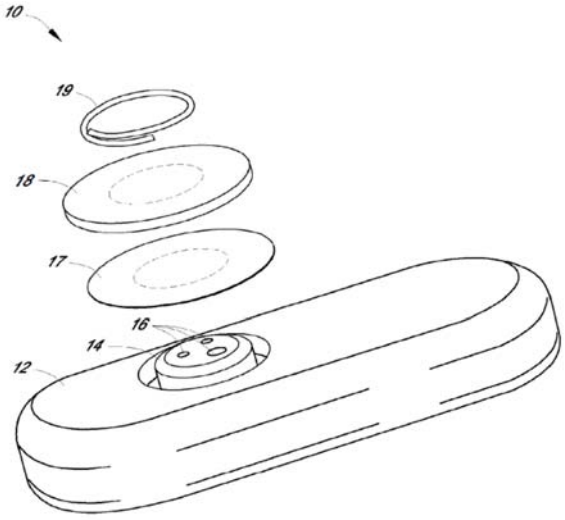

FIG. 1

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.

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not have any conflicts with AgaMatrix Holdings and WaveForm Technologies.

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, 44, 50, 56, and 62–69 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. References

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

a) *Berner*: U.S. Patent No. 6,233,471 B1, issued May 15, 2001, filed in the record as Exhibit 1005.

b) *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 14–69 of the '460 patent on the following grounds (Pet. 12):

Ground	Statutory Basis	Reference(s)	Claims
1	§ 103	Berner	14–61
2	§ 103	Berner and Schulman	62–69

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

III. ANALYSIS

Section 325(d) of Title 35 of the United States Code provides, in relevant part: "In determining whether to institute or order a proceeding under this chapter, chapter 30, or chapter 31, the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office." In *Becton, Dickinson and Co. v. B. Braun Melsungen AG*, Case IPR2017-01586, 2018 WL 2671360 (PTAB Dec. 15, 2017) (designated informative Mar. 21, 2018), the Board set forth six non-exclusive factors that previous panels had considered in evaluating whether to exercise discretion under § 325(d) to deny a petition:[3]

(1) the similarities and material differences between the asserted art and the prior art involved during examination;

(2) the cumulative nature of the asserted art and the prior art evaluated during examination;

(3) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection;

(4) the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art;

(5) whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art; and

[3] There is no requirement that each factor be considered in every case, and there is no limitation to the consideration of other factors that may be relevant to the application of § 325(d).

(6) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the prior art or arguments.

Id. at *6. We first discuss the prosecution history of the '460 patent and then consider the *Becton Dickinson* factors as applicable to the references relied upon by Petitioner.

A. Prosecution History

Applicants filed U.S. Patent Application No. 15/488,190 ("the '190 application"), which eventually issued as the challenged '460 patent, on April 14, 2017. Ex. 1002, 3–118. The '190 application[4] contained original prosecution claims 1–20. *Id.* at 78–80. Shortly after the application filing, Applicants submitted two Information Disclosure Statements that listed the Berner and Schulman references among over 1,200 prior art references. *Id.* at 119–200.

About six weeks later, Applicants initiated an interview with the Examiner to discuss potential amendments "with respect to" the parent '069 patent and U.S. Patent Application No. 15/481,347 ("the '347 application"), which had been recently allowed at the time of the interview.[5] *Id.* at 207. A week later, Applicants initiated a second interview with the Examiner to

[4] The '190 application was filed as a continuation of U.S. Patent Application No. 15/197,349 ("the '349 application"), issued as U.S. Patent No. 9,649,069 B2 ("the '069 patent"), which is a continuation of U.S. Patent Application No. 13/181,341, issued as U.S. Patent No. 9,427,183 B2, which is a continuation of U.S. Patent Application No. 10/648,849, issued as U.S. Patent No. 8,010,174 B2. Ex. 1002, 86.

[5] The '347 application was filed as a continuation of the '349 application, which issued as the above-mentioned related U.S. Patent No. 9,724,045 B1. *See supra* n.4.

discuss proposed claim amendments and filing a terminal disclaimer to overcome obviousness-type double-patenting rejections over the '069 patent and U.S. Patent No. 7,998,071 and a provisional obviousness-type double-patenting rejection over the '347 application. *Id.* at 241, 262.

After these interviews, Applicants submitted a Preliminary Amendment canceling original prosecution claims 1–20 and adding new prosecution claims 21–89. *Id.* at 220–246. Applicants also filed a terminal disclaimer over the '374 application and the '071 and '069 patents. *Id.* at 212–214.

The Examiner subsequently issued a Notice of Allowance of claims 21–89. *Id.* at 257. In the Notice, the Examiner stated that the Information Disclosure Statements had been considered in full and the Examiner accepted the Terminal Disclaimers. *Id.* at 258. The Examiner also provided Reasons for Allowance that specifically addressed how the independent claims are patentable over Desai[6] and Berner.[7,8] *Id.* at 258–259. Specifically, with respect to prosecution claims 34, 40, 46, 52, 58, 64, 70, 76, and 82–89, which correspond to challenged independent claims 14, 20, 26, 32, 38, 44, 50, 56, and 62–69, the Examiner explained:

> As to claims 34, 40, 46, 52, 58, 64, 70, 76, and 82–89, the prior art of record fails to teach the applying of a voltage to the electrochemical sensor at a first setting, the applying comprising at least one of switching, cycling, or pulsing, and detecting an erroneous signal based on at least in part on the measured signal response of the sensor to the applying, and

[6] U.S. Patent Application Publication No. US 2003/0050546 A1.
[7] U.S. Patent No. 6,233,471 B1.
[8] The Examiner cited and applied Desai and Berner in rejections of the claims during prosecution of the parent '069 patent. Ex. 2003, 8–13.

> discarding a glucose measurement when the value associated with the erroneous signal is outside of a predetermined threshold value. In particular, *Berner (incorporated into Desai) teaches the switching of a voltage to the electrodes, but disclosed such a feature as part of an iontophoretic electrodes embodiment for collection purposes.* It is noted that while the claims are directed to an abstract idea, with the non-generic nature of the data collection along with all the recited limitations, when considered as a whole amounts to significantly more than the abstract idea.

Id. at 259 (emphasis added).

B. Challenges based on Berner

Both grounds asserted by AgaMatrix in the Petition are based on Berner as the primary reference. The Petition asserts that Berner discloses "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." Pet. 26. The Petition explains, "Berner describes applying voltages to different sets of electrodes of the biosensor" and "alternating the polarities of the voltage applied to one pair of electrodes, i.e., *cycling* the applied voltage, and applying voltages to different pairs of electrodes at different times, i.e., *switching* the applied voltage." *Id.* (citing Ex. 1005, 16:7–26, Fig. 2; Ex. 1003 ¶¶ 159–160). Specifically, the Petition asserts that Berner discloses applying an electric potential between iontophoretic electrodes 12, 14, wherein the polarity of the iontophoretic electrodes is alternated periodically. *Id.* (citing Ex. 1005, 16:7–26, Fig. 2). The Petition further asserts that Berner discloses

> [t]he general operation of an iontophoretic sampling system is the ***cyclical repetition of two phases***: (1) a reverse-iontophoretic

> phase, followed by a (2) sensing phase. ***During the reverse iontophoretic phase, the first bimodal electrode*** (FIGS. 4, 40) ***acts as an iontophoretic cathode and the second bimodal electrode*** (FIGS. 4, 41) ***acts as an iontophoretic anode*** to complete the circuit. * * * ***During the sensing phase***, in the case of glucose, ***a potential is applied between the reference electrode*** (FIGS. 4, 44) ***and the sensing electrode*** (FIGS. 4, 42). The chemical signal reacts catalytically on the catalytic face of the first sensing electrode (FIGS. 4, 42) producing an electrical current, while the ***first bi-modal electrode (FIGS. 4, 40) acts as a counter electrode to complete the electrical circuit***.

Id. at 26–27 (quoting Ex. 1005, 17:6–22). Thus, according to the Petition, "Berner describes applying a voltage across the first and second bimodal electrodes during the reverse-iontophoretic phase, and then switching the applied voltage during the sensing phase by applying a voltage between the reference and sensing electrodes." *Id.* at 27 (citing Ex. 1003 ¶¶ 161–163).

1. *Similarities and Material Differences Between the Asserted Art and the Prior Art Involved During Examination*

   Cumulative Nature of the Asserted Art and the Prior Art Evaluated During Examination

   Extent to Which the Asserted Art Was Evaluated During Examination, Including Whether the Prior Art Was the Basis for Rejection

   Both Berner and Schulman were before the Examiner during prosecution of the '460 patent. Ex. 1002, 124, 129. The Examiner explicitly considered Berner during prosecution of the '460 patent. For instance, the Examiner cited Berner when applying it in a rejection in the parent '069 patent. Ex. 2003, 8–13. Applicants, thereafter, cited Berner in an Information Disclosure Statement during prosecution of the challenged '460 patent. Ex. 1002, 129. Then, the Examiner provided specific reasons for allowance of the claims over Berner. *Id.* at 259.

Thus, the prior art to Berner and Schulman asserted in the Petition is identical to the prior art involved during examination of the challenged patent. As to Berner, the primary prior art reference asserted in the Petition, the Examiner considered this reference and commented on the patentability of the claims of the challenged patent over this reference. Based on these facts, the first three *Becton Dickinson* factors weigh in favor of dismissing the Petition under § 325(d).

2. *Extent of the Overlap Between the Arguments Made During Examination and the Manner in Which Petitioner Relies on the Prior Art or Patent Owner Distinguishes the Prior Art*

As discussed above, during prosecution of the challenged patent, the Examiner found that the prior art, including Berner, failed to disclose applying a voltage to the electrochemical 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. Ex. 1002, 259. The Examiner explicitly found that Berner "teaches the switching of a voltage to the electrodes, but disclosed such a feature as part of an iontophoretic electrodes embodiment for collection purposes." *Id.* AgaMatrix now relies on the same disclosure in Berner of application of a voltage to the iontophoretic electrodes as evidence of disclosure of the applying and the switching, cycling, and pulsing claim elements that the Examiner found missing in Berner.

Dexcom argues that Berner does not apply a voltage to the *electrochemical glucose sensor* and does not switch, cycle, or pulse the voltage applied to the *electrochemical glucose sensor*. Prelim. Resp. 23–30 (arguing that Berner's iontophoretic electrodes are for sampling/collecting

and are not used for sensing glucose). Thus, substantial overlap exists between the reasons for allowance provided by the Examiner during examination and the arguments Dexcom raises in its Preliminary Response. Based on these facts, the fourth *Becton Dickinson* factor weighs in favor of dismissing the Petition under § 325(d).

3. *Whether Petitioner Has Pointed Out Sufficiently How the Examiner Erred in the Evaluation of the Asserted Prior Art*

As explained above, the manner in which AgaMatrix relies on Berner is directly contrary to the findings made by the Examiner about Berner. AgaMatrix does not point out how the Examiner erred in evaluation of Berner. In fact, AgaMatrix does not even acknowledge in the Petition that the Examiner considered Berner during examination of the challenged patent. Pet. 13–14 (acknowledging that Berner and Schulman were among the references cited in an Information Disclosure Statement, but incorrectly asserting that "neither patent was discussed by the examiner and there is no evidence in the prosecution history regarding how closely these two references out of the 1,200 cited references were analyzed by the examiner, if at all"). AgaMatrix's expert appears to share the same mistaken understanding as to the Examiner's consideration of Berner. Ex. 1003 ¶ 90 (incorrectly stating, "[w]hile Berner is cited on the face of the '460 patent, I understand that Berner was not specifically discussed by the examiner or applicant during the prosecution of the '460 patent"). Thus, the Petitioner has not pointed out how the Examiner erred in the evaluation of Berner or provided us with any reason to revisit the Examiner's consideration of Berner. Based on these facts, the fifth *Becton Dickinson* factor weighs in favor of dismissing the Petition under § 325(d).

4. Extent to Which Additional Evidence and Facts Presented in the Petition Warrant Reconsideration of the Prior Art or Arguments

The Petition seeks to have us interpret electrochemical glucose sensor to include iontophoretic electrodes used for sampling, not sensing. Pet. 26–27. Yet the Petition does not address why these iontophoretic electrodes are encompassed by the claim language "electrochemical glucose sensor" and does not propose a definition of the claimed "sensor" that would encompass means for sampling. These additional facts emphasize how the Petition lacks any basis on which to reconsider the prior art already considered by the Examiner.

5. Summary

As discussed above, AgaMatrix in its Petition relies on the same references that were before the Examiner during prosecution of the challenged patent, relies on disclosure in Berner as evidence of certain claim elements, which same disclosure was explicitly considered and rejected by the Examiner as disclosing these claim elements, and fails to explain how the Examiner erred in the evaluation of Berner's disclosure or provide any other evidence that would warrant reconsideration of Berner. Thus, we find that consideration of the *Becton Dickinson* factors supports the exercise of our discretion to reject the Petition under § 325(d).

IV. CONCLUSION

For the reasons provided above, we exercise our discretion under 35 U.S.C. § 325(d) and deny Petitioner's petition for *inter partes* review because the same prior art previously was presented to the Office.

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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