

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DEXCOM, INC.,
Petitioner,

v.

ABBOTT DIABETES CARE INC.,
Patent Owner.

IPR2023-01252
Patent 11,298,056 B2

Before JEFFREY N. FREDMAN, RYAN H. FLAX, and
CYNTHIA M. HARDMAN, *Administrative Patent Judges*.

HARDMAN, *Administrative Patent Judge*.

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

I. INTRODUCTION

Petitioner DexCom, Inc. requests *inter partes* review of claims 1–30 of U.S. Patent No. 11,298,056 B2 (“the ’056 patent,” Ex. 1201). Paper 3 (“Pet.”). Patent Owner Abbott Diabetes Care Inc. filed a Preliminary Response. Paper 7 (“Prelim. Resp.”).

We have authority to determine whether to institute an *inter partes* review. *See* 35 U.S.C. § 314; 37 C.F.R. § 42.4(a). For the reasons provided below, we exercise our discretion under 35 U.S.C. § 314 to deny institution of an *inter partes* review.

A. Real Parties in Interest

Petitioner and Patent Owner each identify only themselves as the real party in interest. Pet. ix; Paper 6 (Patent Owner Mandatory Notices), 1.

B. Related Matters

The parties identify as related the following matters involving the ’056 patent: (i) *Abbott Diabetes Care Inc. et al. v. DexCom, Inc.*, No. 1:23-cv-00239 (D. Del.), filed March 3, 2023; and (ii) IPR2023-01252. Pet. ix; Paper 6, 1.

C. The ’056 Patent (Ex. 1201)

The ’056 patent, titled “Methods and Systems for Early Signal Attenuation Detection and Processing,” relates to devices and methods for analyte monitoring (e.g., glucose monitoring) and therapy management (e.g., using medication infusion devices). Ex. 1201, code (54), 1:52–54.

The Specification describes continuous analyte monitoring systems, discrete analyte monitoring systems, and therapy management systems. *Id.* at 1:57–59. One embodiment of a data monitoring and management system is depicted in Figure 1 of the ’056 patent, reproduced below.

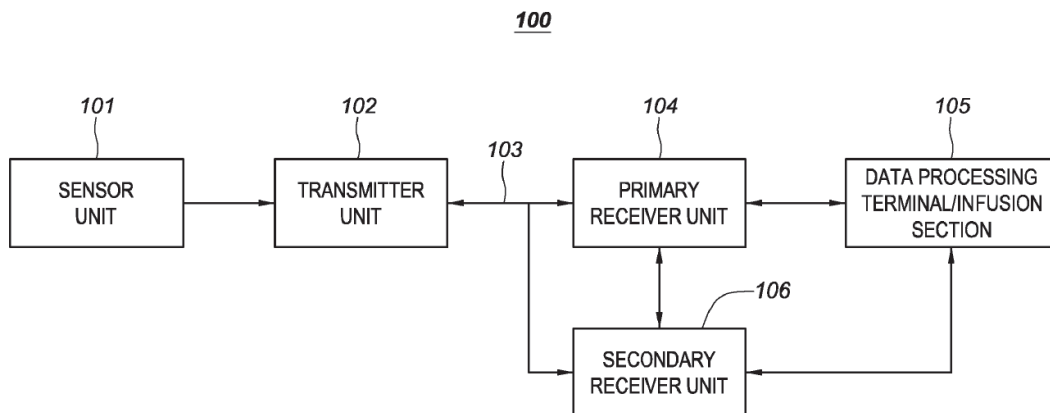


FIG. 1

Figure 1 of the '056 patent is a block diagram of system 100, such as an analyte (e.g., glucose) monitoring system, for practicing one or more embodiments of the '056 patent. *Id.* at 2:65–67, 4:34–37. The block diagram of system 100 includes a sensor unit 101, a data processing and transmitter unit 102, a bi-directional communication link 103, a primary receiver unit 104, a data processing terminal/infusion section 105, and an optional secondary receiver unit 106. *Id.* at 4:56–5:7.

The sensor unit 101 may be positioned in or on a user's body, and may be configured to continuously sample an analyte level of the user and convert the sampled analyte level into a corresponding data signal for transmission by the data processing and transmitter unit 102. *Id.* at 5:48–54. “[T]he data processing and transmitter unit 102 may be physically coupled to the sensor unit 101 so that both devices are integrated in a single housing and positioned on the user's body.” *Id.* at 5:54–58. The data processing and transmitter unit 102 receives analyte level data from the sensor unit 101, processes the data, and transmits it to the primary receiver unit 104. *Id.* at 5:50–64.

The primary receiver unit 104 processes the data from data processing and transmitter unit 102 by performing data decoding, error detection and correction, data clock generation, and data bit recovery. *Id.* at 6:28–33. Primary receiver unit 104 contains an analyte (e.g., blood glucose) test strip interface and may be configured to integrate or otherwise couple to an infusion device to administer insulin therapy to patients for administering and modifying basal profiles or determining appropriate boluses for administration based on the detected analyte levels. *Id.* at 6:65–7:5, 9:42–57.

Data processing terminal 105 communicates with and receives analyte level data from data processing and transmitter unit 102 and primary receiver unit 104, including data for managing the patient's insulin therapy. *Id.* at 4:61–5:1, 6:59–65, 7:20–25. The data processing terminal 105 may include a personal computer, a portable computer such as a laptop or a handheld device (e.g., a personal digital assistant (PDA)), or an infusion device such as an insulin infusion pump (external or implantable). *Id.* at 6:50–65, 7:20–25.

The '056 patent explains that periodic calibration of sensor unit 101 may be required for accurate calculation of a user's analyte level and “is used to ensure the analyte related data signals received at a transmitter unit 102 (and further transmitted to a receiver unit, such as the primary receiver unit 104) are correctly converted to corresponding analyte levels.” *Id.* at 10:59–66. “The primary receiver unit 104 determines whether the sensor is calibrated and is in acceptable condition for further data processing.” *Id.* at 11:44–49. If the sensor is calibrated and in condition for further data processing, the sensor data is further processed and output for display on a

display unit of primary receiver unit 104 as a graphical representation or as numerical values, visual indicators, auditory outputs, or combinations thereof. *Id.* at 11:50–58, 12:15–20.

If the sensor conditions are unsuitable for calibration, the analyte sensor data is stored in a memory in the primary receiver unit 104 and display of the sensor data is temporarily disabled until the sensor is calibrated again. *Id.* at 11:46–49, 12:5–15, 12:26–32. When the sensor data is displayed again, there may be a gap in the graphical display, as shown in Figure 7A. *Id.* at 12:32–39.

Figure 7A is reproduced below.

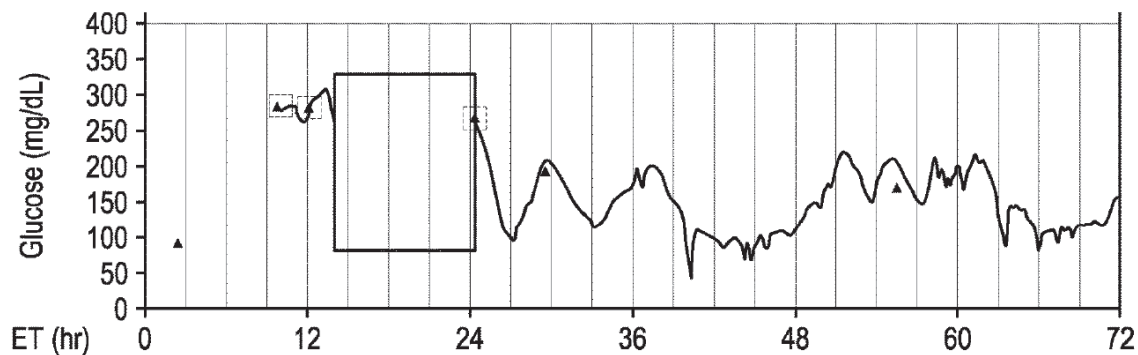


FIG. 7A

Figure 7A illustrates a graphical display of glucose level data in mg/dL over a span of several hours, with a gap caused by a period of uncalibrated sensor data indicated by a solid rectangle from about hour 14 to hour 24. *Id.* at 3:14–15, Fig. 7A. The '056 patent describes a method for filling such a gap in Figure 6, which is reproduced below.

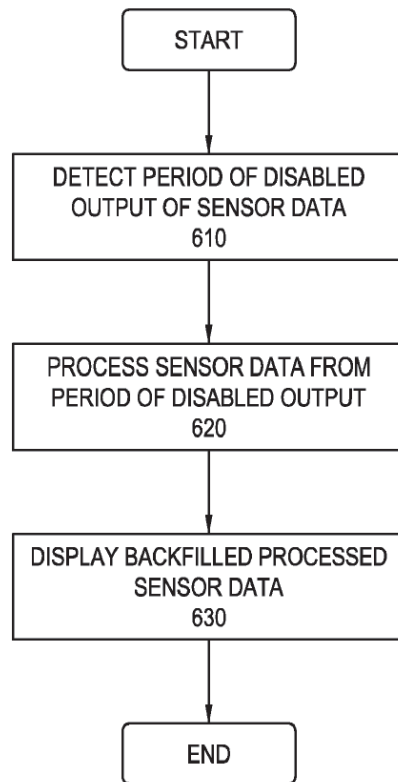


FIG. 6

Figure 6 is a flow chart illustrating a method for backfilling gaps in sensor data in one embodiment of the '056 patent. *Id.* at 3:12–13. According to the '056 patent, “when a scheduled calibration event fails and the associated grace period for calibration does not occur, the output display of the processed, calibrated sensor data is disabled (610).” *Id.* at 12:41–45. Once the system recovers after a successful calibration event, the previously unprocessed data during the display time out period (i.e., the data in the period of the gap) may be retrieved from storage and processed using the new calibration data 620. *Id.* at 12:47–54, 12:62–65. The newly-processed (“backfilled”) sensor data is then displayed and stored 630 as shown in Figure 7B, which is reproduced below. *Id.* at 12:45–47, 12:65–13:2.

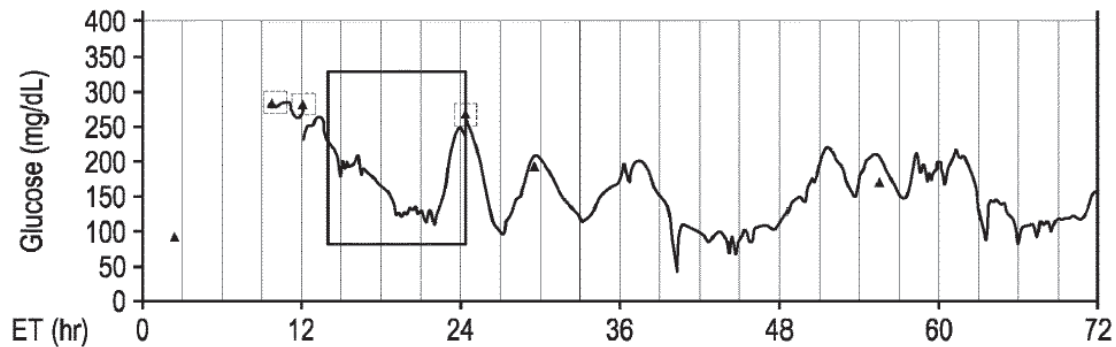


FIG. 7B

Figure 7B illustrates a graphical display of glucose level data in mg/dL over a span of several hours, with backfilled data indicated by a solid rectangle. *Id.* at 3:14–15, Fig. 7B. The gap in the data from about hour 14 to hour 24 shown in Figure 7A (above) as a blank box has been backfilled to graphically show collected data according to the method described in Figure 6. *Id.* at 12:65–13:5.

D. The Challenged Claims

Petitioner challenges the patentability of claims 1–30 of the '056 patent. Claim 1, the only independent claim, is reproduced below:

1. A glucose monitoring system for backfilling data gaps that occur while a user monitors glucose levels, the glucose monitoring system comprising:

a glucose sensor, a portion of which is configured to be positioned under skin of the user, wherein the glucose sensor is configured to sample a biological fluid of the user to provide sensor data;

a data processing and transmitter unit coupled to the glucose sensor, the data processing and transmitter unit comprising a power supply, a processor of the data processing and transmitter unit, memory of the data processing and transmitter unit, and a radio frequency transceiver of the data

processing and transmitter unit, wherein the data processing and transmitter unit is configured to:

- receive the sensor data from the glucose sensor and store the sensor data in the memory of the data processing and transmitter unit;

- process the sensor data using calibration data to provide processed sensor data, wherein the calibration data comprises data associated with a sensitivity of the glucose sensor, and wherein the processed sensor data is stored in the memory of the data processing and transmitter unit; and

- transmit the processed sensor data over a Bluetooth wireless communication link using the radio frequency transceiver of the data processing and transmitter unit; and

a receiver unit comprising a processor of the receiver unit, memory of the receiver unit, a radio frequency transceiver of the receiver unit, an antenna, and a display, wherein the receiver unit is configured to:

- receive, using the antenna and the radio frequency transceiver of the receiver unit, the processed sensor data over the Bluetooth wireless communication link,
- output to the display of the receiver unit, a numerical value representing the processed sensor data,

- output to the display of the receiver unit, a first line graph that is a substantially continuous depiction of the processed sensor data over time,

wherein the glucose monitoring system is configured to detect an adverse condition, wherein the adverse condition results in the receiver unit displaying a data gap such that the first line graph displayed on the receiver unit has an end corresponding to a time associated with a start of the adverse condition;

wherein, during a time period corresponding to the adverse condition, sensor data, processed sensor data, or both,

are stored in the memory of the data processing and transmitter unit;

wherein the receiver unit is configured to output to the display, after the adverse condition is corrected, processed sensor data for the time period corresponding to the adverse condition such that the data gap is backfilled, and

wherein the processed sensor data for the time period corresponding to the adverse condition that is outputted to the display after the adverse condition is corrected comprises a second line graph having a first end corresponding to the time associated with the start of the adverse condition and a second end corresponding to a time associated with an end of the adverse condition.

Ex. 1201, 15:24–16:20.

Challenged claims 2–30 depend directly or indirectly from independent claim 1 and recite additional features of the glucose monitoring system. *Id.* at 16:22–18:28.

E. Asserted Grounds of Unpatentability

Petitioner asserts that claims 1–30 are unpatentable on the following grounds:

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1	1–21, 23–30	103	Harper 2019, ¹ Taub/Harper 2012, ² and Hayter/Taub 2013 ³

¹ Harper, U.S. Patent App. Pub. 2019/0216373 A1, published July 18, 2019 (“Harper 2019,” Ex. 1208).

² Taub et al., U.S. Patent App. Pub. 2012/0108931 A1, published May 3, 2012 (“Taub/Harper 2012,” Ex. 1209).

³ Hayter and Taub, U.S. Patent App. Pub. 2013/0127627 A1, published May 23, 2013 (“Hayter/Taub 2013,” Ex. 1210).

Ground	Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
2	22	103	Harper 2019, Taub/Harper 2012, Hayter/Taub 2013, and He/Taub 2014 ⁴

Pet. 3–4. Petitioner asserts that the alleged prior art references qualify as prior art because the grandparent application to the ’056 patent fails to provide adequate written description and enablement support for the challenged claims, such that the priority date of the challenged claims is “April 30, 2021, the filing date of the patent’s immediate parent application.” Pet. 2–3.

Petitioner supports its unpatentability arguments with the Declaration of Morten O. Jensen, Ph.D., Dr. Med. (Ex. 1212), among other evidence.

II. DISCRETIONARY DENIAL

Institution of *inter partes* review is discretionary. *See* 35 U.S.C. § 314(a); *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1356 (2018) (explaining that section “314(a) invests the Director with discretion on the question whether to institute review”) (emphasis omitted). On the same day Petitioner filed the present Petition, Petitioner concurrently filed another petition (IPR2023-01251) directed to the ’056 patent. Accordingly, our decision here whether to institute review takes into consideration guidance in the Patent Trial and Appeal Board Consolidated Trial Practice Guide

⁴ He and Taub, U.S. Patent App. Pub. 2014/0176338 A1, published June 26, 2014 (“He/Taub 2014,” Ex. 1211).

November 2019⁵ (“Trial Practice Guide”) for situations where a petitioner concurrently files parallel petitions challenging the same patent.

The Trial Practice Guide explains:

[b]ased on the Board’s experience, one petition should be sufficient to challenge the claims of a patent in most situations. Two or more petitions filed against the same patent at or about the same time (e.g., before the first preliminary response by the patent owner) may place a substantial and unnecessary burden on the Board and the patent owner and could raise fairness, timing, and efficiency concerns. *See* 35 U.S.C. § 316(b). In addition, multiple petitions by a petitioner are not necessary in the vast majority of cases.

Trial Practice Guide 59 (emphasis omitted). The Trial Practice Guide recognizes that “there may be circumstances in which more than one petition may be necessary, including, for example, when the patent owner has asserted a large number of claims in litigation or when there is a dispute about priority date requiring arguments under multiple prior art references.” The Trial Practice Guide, however, characterizes such circumstances as “rare.” *Id.*

To aid the Board, a petitioner who files parallel petitions should “identify: (1) a ranking of the petitions in the order in which it wishes the Board to consider the merits . . . , and (2) a succinct explanation of the differences between the petitions” *Id.* at 59–60. Pursuant to this guidance, Petitioner files a Ranking Paper, in which it requests that the Board consider the merits of IPR2023-01251 (“Petition 1”) ahead of the present Petition (“Petition 2”). Paper 2 (“Ranking”), 1. To this, Patent

⁵ Available at <https://www.uspto.gov/sites/default/files/documents/tpgnov.pdf>.

Owner filed a response to Petitioner's Ranking Paper. Paper 8 ("PO Ranking Resp.").

As to the differences between the petitions, Petitioner states that "Petition 1 (IPR2023-01251) assumes that all claims have an effective filing date in 2009, while Petition 2 (IPR2023-01252) argues that no claim has an effective filing date before 2021." Ranking 1 (emphasis omitted). Petitioner cites the Trial Practice Guide's statement that more than one petition may be necessary "when there is a dispute about priority date requiring arguments under multiple prior art references," and concludes: "[t]hus, even if the Board institutes IPR on Petition 1, it should also consider and institute on Petition 2." *Id.*

On this record, Petitioner's identification of an alleged priority dispute does not demonstrate a genuine need for both petitions. The Trial Practice Guide "does not convey that whenever a priority issue is involved, Petitioner is entitled to file two petitions against the same claims of the same patent." *Square, Inc. v. 4361423 Canada Inc.*, IPR2019-01630, Paper 13 at 9 (PTAB Apr. 2, 2020). "Rather, the operative phrase [in the Trial Practice Guide] is 'may be needed, although this should be rare.'" *Id.* (quoting Trial Practice Guide 59). Petitioner does not persuade us that this is one of the rare instances where more than one petition is needed due to a priority dispute. Indeed, as Patent Owner points out, "Petitioner's first-ranked 1251 petition involves no priority dispute," and "[i]nstead, the alleged priority dispute is raised only in the secondary 'backup' 1252 petition." PO Ranking Resp. 2.

Petitioner states:

If, in its Institution analysis, the Board agrees with Patent Owner that each claim is entitled to be backdated before 2021, then no IPR will be instituted on Petition 2, in which case there

will not be parallel IPR proceedings and no added burden on Patent Owner or the Board after the Institution Decision.

Id. at 1–2. Petitioner also argues that if we institute on Petition 2 based on an effective filing date of 2021, but we or our reviewing court later determine that Patent Owner is entitled to an earlier filing date, “without Petition 1, Petitioner would have forfeited the opportunity to have the Board and its reviewing Court evaluate the patentability of the ’056 claims assuming a 2009 effective filing date.” *Id.* at 2.

We agree with Patent Owner that Petitioner presents “an argument *against*, not for, instituting the 1252 petition.” *See* PO Ranking Resp. 1. We are concurrently instituting Petition 1, which Petitioner’s own arguments suggest renders Petition 2 unnecessary.

Petitioner also argues that “Petition 2 adds little burden to Patent Owner because all four prior art references asserted therein are Patent Owner’s references.” Ranking 2; *see also id.* at 4 (“The burden on the Board to address Petition 2 in addition to Petition 1 is not great.”). Petitioner, however, overlooks that in order to reach its prior-art based arguments in Petition 2, we must first decide the threshold issues of what is encompassed by the “full scope” of the challenged claims and whether that scope is adequately enabled by and described in the ’056 patent’s grandparent application. *See, e.g.*, Pet. 2–3. These questions are highly fact-dependent and involve many considerations, including but not limited to the scope of the claims, the disclosure in the alleged priority applications, the predictability in the art, and the state of the art. *See, e.g.*, Prelim. Resp. 20–22, 26 (raising various legal considerations relevant to Petitioner’s arguments). And, as Petitioner concedes, these additional issues are not at

play in Petition 1, because “[w]hile the effective filing date of the claims is a dispositive threshold issue in Petition 2, it is immaterial to Petition 1.”

Ranking 3; *see also id.* at 4 (“Petition 2 addresses a lack of full-scope written description and enablement support not addressed by Petition 1.”).

Accordingly, Petition 2 adds many unique issues over Petition 1, and thus Petitioner does not persuade us that instituting on Petition 2 adds little burden to Patent Owner and the Board.

Finally, Petitioner contends that “the length and number of claims further warrants multiple petitions.”⁶ Ranking 3–4. However, as Patent Owner correctly notes, there is only one independent claim in the ’056 patent, and most of the dependent claims are short. PO Ranking Resp. 5. Petitioner has not demonstrated anything rare about the length or total number of challenged claims that requires two petitions.

For the foregoing reasons, Petitioner has not sufficiently justified the need for two petitions against the ’056 patent. In light of the totality of the circumstances, including that we are concurrently instituting review in IPR2023-01251 for all claims challenged in that proceeding, we exercise our discretion to decline institution in this proceeding. 35 U.S.C. § 314(a).

⁶ The present petition challenges all 30 claims of the ’056 patent, while the petition in IPR2023-01251 challenges only 28 claims. Both parties acknowledge this difference, but neither argues that it should affect our determination on whether to institute one or both petitions. *See* Ranking 5; PO Ranking Resp. 4–5.

III. CONCLUSION

Pursuant to 35 U.S.C. § 314(a), we exercise our discretion to decline to institute this proceeding.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that the Petition is *denied*, and no trial is instituted.

IPR2023-01252
Patent 11,298,056 B2

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