

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DEXCOM, INC.,
Petitioner,

v.

ABBOTT DIABETES CARE INC.,
Patent Owner.

IPR2024-00521
Patent 11,298,056 B2

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

HARDMAN, *Administrative Patent Judge*.

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

I. INTRODUCTION

Petitioner DexCom, Inc. requests *inter partes* review of claims 13 and 29 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 9 (“Prelim. Resp.”).

We have authority under 35 U.S.C. § 314(a), which provides that an *inter partes* review may not be instituted “unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” After considering the briefing and cited evidence of record, we institute an *inter partes* review.

The following preliminary findings of fact and conclusions of law are made solely for determining whether to institute review. Any final decision will be based on the full trial record.

A. Real Parties in Interest

Petitioner and Patent Owner each identify only themselves as the real parties in interest. Pet. xii; Paper 7 (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) IPR2023-01251. Pet. xii; Paper 7, 1.

C. The ’056 Patent (Ex. 1201)

The ’056 patent, titled “Methods and Systems for Early Signal Attenuation Detection and Processing,” issued on April 12, 2022, from U.S. Application 17/411,154, filed on August 25, 2021, and claims priority (as a continuation) to several utility applications, the earliest of which was

filed on April 28, 2010. Ex. 1201, codes (21), (22), (45), (63). The '056 patent also claims priority to a provisional application filed on April 29, 2009. *Id.* at code (60).¹ The '056 patent relates to devices and methods for analyte monitoring (e.g., glucose monitoring) and therapy management (e.g., using medication infusion devices). *Id.* at 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.

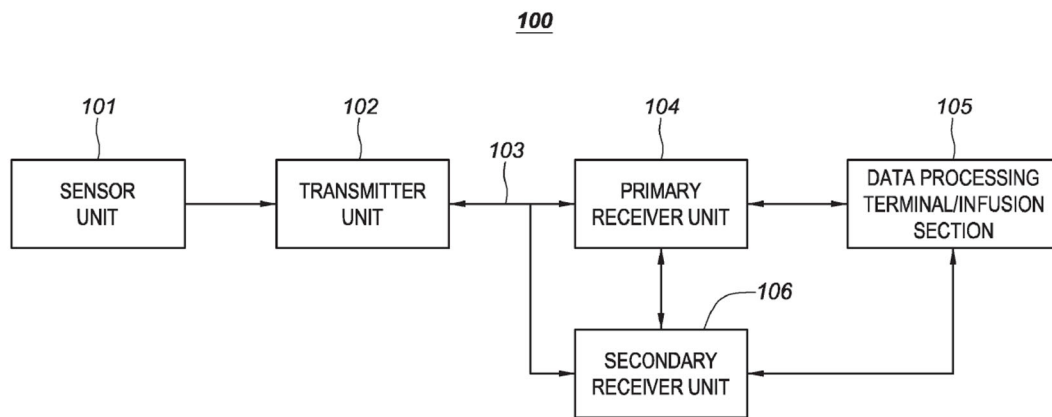


FIG. 1

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

¹ Neither party takes a clear position on the applicable priority date, but Petitioner appears to assume that the priority date falls in the “2009–2010 timeframe,” which appears to correspond to the April 29, 2009 filing date of the provisional application and the April 28, 2010 filing date of the earliest utility application in the familial chain. *See* Pet. 23. For purposes of this Decision, we similarly apply a priority date in the “2009–2010 timeframe.”

embodiments of the '056 patent. *Id.* at 2:65–67, 4:34–37. The block diagram of system 100 includes sensor unit 101, data processing and transmitter unit 102, bi-directional communication link 103, primary receiver unit 104, data processing terminal/infusion section 105, and optional secondary receiver unit 106. *Id.* at 4:56–5:7.

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 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. Data processing and transmitter unit 102 receives analyte level data from sensor unit 101, processes the data, and transmits it to primary receiver unit 104. *Id.* at 5:50–64.

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. 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. “[T]he 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 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.

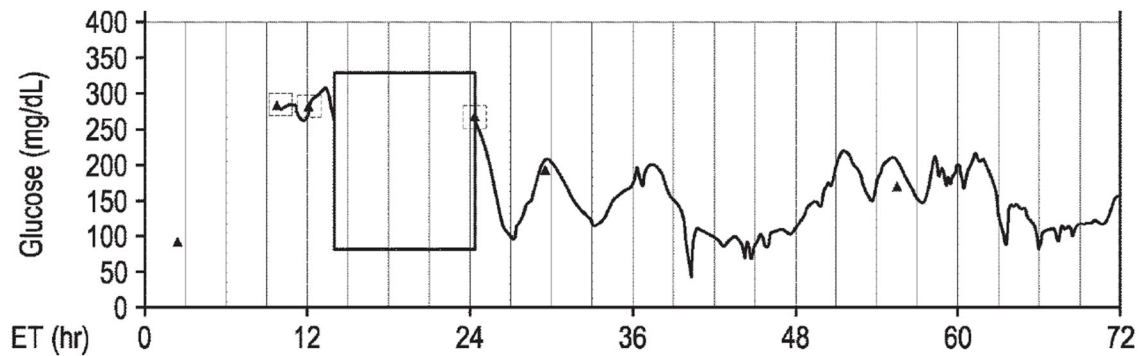


FIG. 7A

Figure 7A illustrates a graphical display of glucose level data in mg/dL over several hours, with a gap in the graphed data (where no glucose measurements appear) 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.

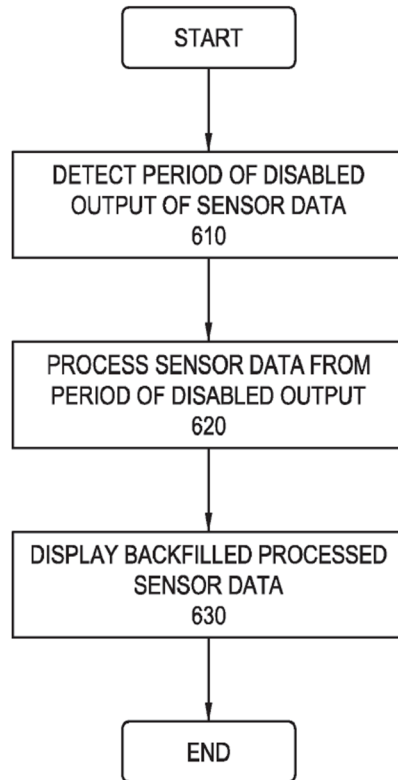


FIG. 6

Figure 6 is a flow chart illustrating a method for backfilling such display gaps in sensor data. *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 as shown in Figure 7B, which is reproduced below. *Id.* at 12:45–47, 12:65–13:2.

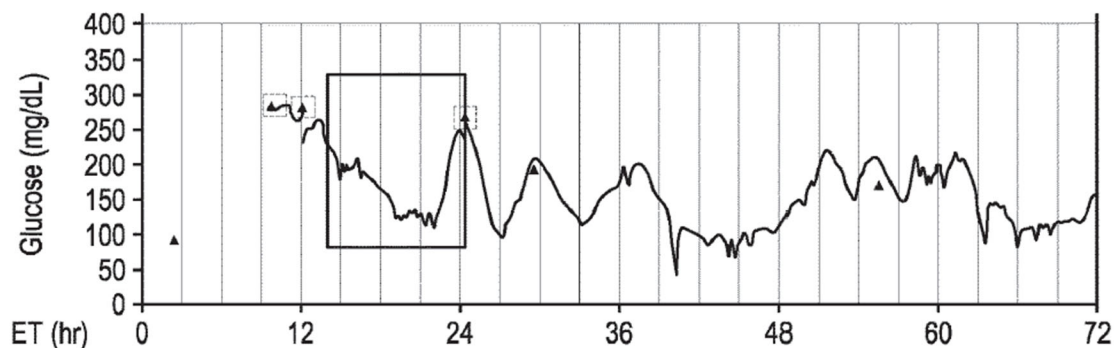


FIG. 7B

Figure 7B illustrates a graphical display of glucose level data in mg/dL over several hours, with backfilled graphically-displayed data indicated by a solid rectangle, now showing a segment of a line graph representing glucose measurements, where the same rectangle in Figure 7A (above) did not. *Id.* at 3:14–15, Fig. 7B. The gap in the data from about hour 14 to hour 24 from Figure 7A has been backfilled according to the method described in Figure 6. *Id.* at 12:65–13:5.

D. The Challenged Claims

Petitioner challenges claims 13 and 29 of the '056 patent. Claims 13 and 29 depend from claim 1, the only independent claim. Claims 1, 13, and 29 are reproduced below with bracketed lettering added to claim 1:²

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

[B] a glucose sensor, a portion of which is configured to be positioned under skin of the user, wherein the glucose sensor

² For ease of reference, we use the same bracketed lettering Petitioner uses in the Petition. *See, e.g.*, Pet. 42–59; *see also* Ex. 1249 (List of Challenged Claims).

is configured to sample a biological fluid of the user to provide sensor data;

[C] 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:

[D] 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

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

[F] 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,

[G] output to the display of the receiver unit, a numerical value representing the processed sensor data,

[H] 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,

[I] 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;

[J] 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;

[K] 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

[L] 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.

13. The glucose monitoring system of claim 1, wherein the adverse condition comprises a sensor misposition error.

29. The glucose monitoring system of claim 1, further comprising a secondary receiver unit, wherein the secondary receiver unit is configured to include a limited number of functions as compared with the receiver unit, wherein the secondary receiver unit is configured to receive processed sensor data from the data processing and transmitter unit and wherein the secondary receiver unit is a watch.

Ex. 1201, 15:24–16:20, 16:56–57, 18:19–24.

E. Asserted Grounds of Unpatentability

Petitioner asserts that claims 13 and 29 are unpatentable on the following grounds:

Ground	Claim(s) Challenged	35 U.S.C. § ³	Reference(s)/Basis
1	13	103(a)	Patel-2009 ⁴ and Paradigm REAL-Time ⁵
2	29	103(a)	Patel-2009, Paradigm REAL-Time, and Goldsmith ⁶

Pet. 5. Petitioner supports its contentions with the Declaration of Brian D. Gross (Ex. 1208), among other evidence.

³ The Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (“AIA”), amended several provisions of 35 U.S.C., including § 103. Given the indicated priority date of the ’056 patent in the 2009–2010 timeframe, for purposes of this Decision we apply the pre-AIA version of § 103; however, our decision would be no different under the AIA version of the statute. *See supra* page 3 n.1.

⁴ Patel et al., U.S. Patent App. Pub. 2009/0085768 A1, published April 2, 2009 (“Patel-2009,” Ex. 1212).

⁵ Petitioner asserts that Paradigm REAL-Time (Ex. 1211) “consists of several pages published on the Medtronic Diabetes Website (www.medtronicdiabetes.com) at least by October 2007.” Pet. 28–29; *see also* Ex. 1210 (Affidavit of Nathaniel E. Frank-White). Patent Owner does not presently challenge Petitioner’s contention that Paradigm REAL-Time qualifies as prior art to the challenged claims. *See generally* Prelim. Resp.

⁶ Goldsmith et al., U.S. Patent App. Pub. 2007/0093786 A1, published April 26, 2007 (“Goldsmith,” Ex. 1251).

II. DISCRETIONARY DENIAL UNDER 35 U.S.C. § 314(a)

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). Patent Owner argues that the Board should deny institution because the Petition is Petitioner’s third challenge to the ’056 patent and is a “follow-on” petition to which *General Plastic*⁷ applies. *See, e.g.*, Prelim. Resp. 1–4.

Under *General Plastic*, we consider the following non-exclusive factors in deciding whether to exercise discretion to deny institution of a follow-on petition:

1. Whether the same petitioner previously filed a petition directed to the same claims of the same patent.
2. Whether at the time of filing of the first petition the petitioner knew of the prior art asserted in the second petition or should have known of it.
3. Whether at the time of filing of the second petition the petitioner already received the patent owner’s preliminary response to the first petition or received the Board’s decision on whether to institute review in the first petition.
4. The length of time that elapsed between the time the petitioner learned of the prior art asserted in the second petition and the filing of the second petition.
5. Whether the petitioner provides adequate explanation for the time elapsed between the filings of multiple petitions directed to the same claims of the same patent.

⁷ *Gen. Plastic Indus. Co., Ltd. v. Canon Kabushiki Kaisha*, IPR2016-01357, Paper 19, 15–16 (PTAB Sept. 6, 2017) (precedential as to Section II.B.4.i) (“*General Plastic*”).

6. The finite resources of the Board.

7. The requirement under 35 U.S.C. § 316(a)(11) to issue a final determination not later than 1 year after the date on which the Director notices institution of review.

General Plastic at 15–16.

A. Overview of Prior Petitions

On August 1, 2023, Petitioner filed two petitions for *inter partes* review of the '056 patent. As Petitioner succinctly explains, “Petition 1 (IPR2023-01251) assumes a 2009 effective filing date and challenges claims 1–12, 14–28, and 30, while Petition 2 (IPR2023-01252) argued a later effective filing date, and challenged claims 1–30.” Paper 2, 1 (emphasis omitted).

We granted institution on Petition 1, but discretionarily denied institution of Petition 2, finding that “Petitioner has not sufficiently justified the need for two petitions against the '056 patent.” IPR2023-01252, Paper 9, 14.

B. Analysis of General Plastic Factors

1. Whether the Same Petitioner Previously Filed a Petition Directed to the Same Claims of the Same Patent (Factor 1)

General Plastic Factor 1 is directed to whether a “petitioner previously filed a petition directed to ***the same claims*** of the same patent.” *General Plastic* at 9 (emphasis added). As between Petitions 1 and 3, we find that Factor 1 weighs against discretionary denial because different claims are at issue in Petitions 1 and 3.

Patent Owner notes that the claims challenged in Petition 3 depend from an independent claim that is challenged in Petition 1, and thus Patent Owner argues that the overlap between the two petitions favors discretionary

denial. *See* Prelim. Resp. 6 (citing *Apple, Inc. v. Immersion Corp.*, IPR2017-01369, Paper 7 at 10 (PTAB Nov. 21, 2017)). We find this argument unavailing because *General Plastic* Factor 1 is directed to whether a “petitioner previously filed a petition directed to *the same claims* of the same patent.” *General Plastic* at 9 (emphasis added). Although some panels (in non-precedential decisions) have analyzed the overlap between claims challenged in the serial petitions, we do not read such a requirement in *General Plastic*.

As between Petitions 2 and 3, Patent Owner is correct that Petition 3 addresses claims that were also challenged in Petition 2. Prelim. Resp. 17–18. Petition 2, however, “was not instituted on discretionary grounds, leaving no common claims between the present Petition and any instituted proceeding.” Pet. 9. As the Director explained in a precedential case,

“allowing [a petitioner] the opportunity to pursue a decision on the merits” in a second-filed petition, when the first-filed petition was not evaluated on the merits, “best balances the desires to improve patent quality and patent-system efficiency against the potential for abuse of the review process by repeated attacks on patents.”

Code200, UAB v. Bright Data Ltd., IPR2022-00861, Paper 18, 4–5 (PTAB Aug. 23, 2022) (precedential) (quoting *Intel Corp. v. VLSI Tech. LLC*, IPR2022-00366, Paper 14, 9–10 (PTAB June 8, 2022)). Accordingly, we find that under the circumstances here, the fact that Petitioner previously challenged the claims at issue in Petition 3 does not favor discretionary denial.

For the above reasons, we find that Factor 1 weighs against discretionary denial.

2. Whether at the Time of Filing of the First Petition Petitioner Knew of the Prior Art Asserted in the Second Petition (Factor 2); Whether at the Time of Filing of the Second Petition Petitioner Already Received Patent Owner's Preliminary Response to the First Petition or the Board's Decision on Whether to Institute Review in the First Petition (Factor 3)

Regarding Factors 2 and 3, there is no dispute that Petitioner knew of the prior art asserted in Petition 3 at the time it filed Petition 1, and had in hand both Patent Owner's preliminary response to Petition 1 and the Board's institution decision on Petition 1. *See, e.g.,* Pet. 9; Prelim. Resp. 7–8. Nevertheless, we find that factors 2 and 3, considered in combination with factor 1, do not favor discretionary denial. *See Code200*, Paper 18, 5 (“*General Plastic* factor 1 must be read in conjunction with factors 2 and 3.”).

We agree with Petitioner that

the grounds and arguments presented by Petition 3 are not informed by the Board decisions or Patent Owner arguments in the first two IPRs. Petitioner's arguments are unchanged as to the overlapping claim elements found in claim 1, from which challenged claims 13 and 29 depend. As to those overlapping elements, Petitioner repeats without substantive modification the mapping from Ground 1 of Petition 1 and is using neither the Petition 1 POPR [Patent Owner Preliminary Response] nor the institution decision to modify arguments that were previously unsuccessful, nor shifting its prior art arguments for this petition.

Pet. 11. Stated differently, we find no “road-mapping” concerns or “shifts in the prior art asserted and the related arguments” in the later petition, like those found in *General Plastic*. *See General Plastic* at 17.

Patent Owner suggests that it is irrelevant whether Petitioner *actually* changed its arguments from Petition 1 to Petition 3, because *General Plastic* looks only to whether Petitioner had *access* to a Board decision and thus was *in a position to gain a benefit*. Prelim. Resp. 8–9 (asserting that “factor 3 is directed to Petitioner’s *potential benefit* from receiving and having the *opportunity* to study Patent Owner’s Preliminary Response” and the institution decisions; citing *Apple Inc. v. Uniloc, 2017 LLC*, IPR2020-00854, Paper 9, 17 (PTAB Oct. 28, 2020)). Patent Owner’s position is inconsistent with the Director’s recent explanation that

“road-mapping” concerns are minimized when . . . a petitioner files a later petition that raises unpatentability challenges substantially overlapping with those in the previously-filed petition and ***the later petition is not refined*** based on lessons learned from later developments.

Code200, Paper 18, 5 (emphasis added). As in *Code200*, we find that the later petition (Petition 3) is not refined based on lessons learned from Petition 1, thus, “there is no evidence of ‘road-mapping’ related to factor 3 or other concerns of fairness related to factor 2.” *Id.* at 6.

For the above reasons, we find that Factors 2 and 3 weigh against discretionary denial.

3. The Length of Time Between When Petitioner Learned of the Prior Art Asserted in the Second Petition and Filed the Second Petition (Factor 4); Whether Petitioner Adequately Explains the Time Elapsed Between the Filings of Multiple Petitions Directed to the Same Claims of the Same Patent (Factor 5)

We also consider Factors 4 and 5 together. These Factors (together with Factor 2) “allow[] us to assess and weigh whether a petitioner should

have or could have raised the new challenges earlier.” *General Plastic* at 18. Regarding Factor 4, as noted above in connection with Factor 2, Petitioner admits that it knew of the prior art asserted in Petition 3 at the time it filed Petition 1. Pet. 9. Accordingly, a minimum of six months elapsed between when Petitioner learned of the prior art asserted in Petition 3 and filed Petition 3. Regarding Factor 5, Petitioner explains the delay by arguing that “[t]he need for Petition 3 only arose after the Patent Owner formally asserted new claims 13 and 29 (based on unforeseen apparent claim interpretations) over 4 months after Petitioner filed Petitions 1 and 2, and just seven weeks before the present Petition was filed.”⁸ *Id.* at 11–12.

Patent Owner suggests that Petitioner’s reliance on when Patent Owner asserted claims 13 and 29 is pretext, because (1) at the time Petitioner filed Petition 1, Patent Owner had not yet identified all asserted claims, and thus “that same label [i.e., ‘non-asserted claims’] applies to all 27 originally challenged dependent claims in Petition 1;” and (2) Petitioner included claims 13 and 29 in Petition 2, even though they were not asserted at that time. Prelim. Resp. 10–11, 13. Patent Owner also suggests that Petitioner’s reliance on alleged “unforeseen apparent claim interpretations” is also pretext, because “Patent Owner simply applies the plain and ordinary meaning to both terms.” *Id.* at 12.

There is no dispute that in the related litigation, Patent Owner first specifically asserted infringement of claims 13 and 29 *after* Petitioner had already filed Petition 1. Although Petitioner could have challenged these

⁸ Patent Owner identified the asserted claims in its December 20, 2023 initial infringement contentions. *See* Prelim. Resp. 17; Pet. 11.

claims (and did so, in Petition 2) even in the absence of Patent Owner specifically asserting them in the related litigation, we find that Patent Owner's formal assertion of claims 13 and 29 in the related litigation to be an adequate explanation for the time elapsed between Petitioner's filing of Petitions 1 and 3.

For the above reasons, we find that Factors 4 and 5 weigh against discretionary denial.

4. The Finite Resources of the Board (Factor 6)

Regarding Factor 6, we find that "the Board's mission 'to improve patent quality and restore confidence in the presumption of validity that comes with issued patents' outweighs the impact on Board resources needed to evaluate the merits of [this] petition." *Code200*, Paper 18, 6 (quoting *Cuozzo Speed Techs., LLC v. Lee*, 579 U.S. 261, 272 (2016)).

Accordingly, we find that Factor 6 weighs against discretionary denial.

5. Requirement to Issue a Final Determination Not Later Than 1 Year After the Institution Date (Factor 7)

The parties presently agree that "due to the over six-month time gap in the filing of Petition 1 and Petition 3, it is not feasible to consolidate the cases into a single IPR proceeding." Prelim. Resp. 16; Pet. 13 ("[I]t may not be possible to consolidate the cases into a single IPR proceeding."). Thus, the only consideration for Factor 7 is whether we can complete the instant proceeding within one year of the institution date. On this record, we see no impediment to doing so.

Accordingly, we find that Factor 7 weighs against discretionary denial.

C. Conclusion – Discretionary Denial

For the foregoing reasons, we decline to exercise our discretion to deny institution under *General Plastic*.

III. ANALYSIS

A. Principles of Law

In an *inter partes* review, “the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.” *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify “with particularity . . . the evidence that supports the grounds for the challenge to each claim”)). Petitioner ultimately bears the burden of persuasion to prove unpatentability of each challenged claim by a preponderance of the evidence. 35 U.S.C. § 316(e). This burden never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). The Board may authorize an *inter partes* review if we determine that the information presented in the Petition and Patent Owner’s Preliminary Response shows a reasonable likelihood that Petitioner will prevail with respect to at least one of the challenged claims. 35 U.S.C. § 314(a).

Under pre-AIA 35 U.S.C. § 103(a), a claim is unpatentable as obvious if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. 35 U.S.C. § 103(a); *see also KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved based on underlying factual determinations including: (1) the scope

and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art;⁹ and (4) any objective indicia of obviousness or nonobviousness.¹⁰ *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). An obviousness determination requires finding a reason to combine accompanied by a reasonable expectation of achieving what is claimed in the challenged patent. *See Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016). “[A]ny need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.” *KSR*, 550 U.S. at 419–20.

B. Level of Ordinary Skill in the Art

We consider the grounds of unpatentability in view of the understanding of a person of ordinary skill in the art at the time the invention was made.¹¹ *See Graham*, 383 U.S. at 17–18. Petitioner contends that a person of ordinary skill in the art (sometimes abbreviated herein as “POSITA”) would have had:

a Bachelor of Science degree in biomedical engineering, or a similar field, such as electrical, or software, or computer engineering, and two years of industry experience or research working with medical devices and systems for measuring biomedical signals. Such systems might include those for determining levels of blood analytes, such as glucose, in a

⁹ *See infra* Section III.B.

¹⁰ Patent Owner does not presently assert any objective indicia of nonobviousness. *See generally* Prelim. Resp.

¹¹ For purposes of this Decision, we apply a priority date in the 2009–2010 timeframe. *See supra* page 3 n.1. On the present record, it does not appear that the level of ordinary skill changed during this timeframe.

patient and transmitting indications of such levels to a receiving device for reporting the measurements. Additional education, such as a Master's degree could substitute for the industry experience, or vice versa.

Pet. 23 (citing Ex. 1208 (Gross Decl.) ¶ 51).

Petitioner also posits that “[t]he POSITA may be part of an interdisciplinary team with others having relevant experience and/or with clinicians involved in diagnosis, treatment, and patient management relevant to the use of medical devices for monitoring physiological signals” and “would have been aware of commercially available glucose monitoring systems (e.g., the Medtronic Paradigm® REAL-Time) through scientific journals and magazines,” “would have known the importance of data reliability to glucose monitoring, including anticipating that errors (e.g., communication or calibration failures) would result in missing or inaccurate glucose data,” and

would have accounted for missing data using technical concepts known at the time, including programming glucose monitoring systems to detect failures that result in data being unavailable for display (e.g., due to a calibration error or loss of communication), preserving this data in memory, regenerating it once the system recovered, and displaying regenerated data.

Pet. 23–24 (citing Ex. 1208 (Gross Decl.) ¶¶ 52, 54–61).

Patent Owner does not specifically comment on or dispute Petitioner's proposal. *See generally* Prelim. Resp.

Because Petitioner's proposed level of ordinary skill in the art appears to be consistent with the cited prior art and is undisputed on this record, we adopt it for purposes of this Decision. *See Okajima v. Bourdeau*, 261 F.3d

1350, 1355 (Fed. Cir. 2001) (indicating that the prior art itself may reflect an appropriate skill level).

C. Claim Construction

In AIA proceedings we interpret a claim “using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b).” 37 C.F.R. § 42.100(b). Under this standard, we construe the claim “in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” *Id.*

Petitioner expressly addresses two claim terms: “sensor misposition error,” recited in claim 13; and “receive processed sensor data from the data processing and transmitter unit,” recited in claim 29, and asserts that the “ordinary meaning” is applied to all other claim terms. *See* Pet. 24–27. As for the terms “sensor misposition error” and “receive processed sensor data from the data processing and transmitter unit,” Petitioner contends it applies Patent Owner’s “apparent interpretations” of these terms based on Patent Owner’s infringement contentions in the related district court litigation, “without agreeing that these terms are correctly construed.” Pet. 24.

Specifically, as to the claim term “sensor misposition error,” Petitioner argues that Patent Owner construes this term “to be satisfied by a signal loss / communication issue between the ‘data processing and transmitter unit’ and ‘receiver unit’ recited in claim 1.” *Id.* at 25. As to the claim term “receive processed sensor data from the data processing and transmitter unit,” Petitioner argues that Patent Owner construes this term to be “satisfied by a watch that receives data from a device other than the ‘data processing and transmitter unit’ recited in claim 1.” *Id.* at 26. Petitioner

adopts both of these apparent constructions for purposes of its Petition. *Id.* at 25–26.

Patent Owner does not expressly address the construction of any claim terms in this proceeding, although it characterizes its claim constructions in the related litigation as “the plain and ordinary meaning.” *See* Prelim. Resp. 12.

Having reviewed the arguments and evidence of record, we determine that no construction of any claim term is needed to decide whether to institute this Petition. *See Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1375 (Fed. Cir. 2019) (“The Board is required to construe ‘only those terms . . . that are in controversy, and only to the extent necessary to resolve the controversy.’”) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

Any final written decision entered in this case may include express claim constructions, or may include discussion of claim scope that differs from that provided in our analysis below. Any final claim constructions will be based on the full trial record. Should the parties argue for any specific claim interpretations at trial, they should do so in a separately designated section of their briefing to highlight their proposed claim interpretations. *See, e.g.*, Consolidated Trial Practice Guide (Nov. 21, 2019), 44–49.¹² Claim construction arguments should not be merely asserted within arguments over the merits of patentability challenges.

¹² Available at <https://www.uspto.gov/TrialPracticeGuideConsolidated>.

D. Overview of Asserted Prior Art

1. Patel-2009 (Ex. 1212)

Patel-2009, titled “Glucose Sensor Transceiver,” is the April 2, 2009 published version of U.S. Application 12/056,651, filed on March 27, 2008, and “relates to telemetered subcutaneous sensor devices and, more particularly, to devices for wireless communication between an implantable subcutaneous sensor set at a selected insertion site within the body of a user and at least one of a plurality of remotely located therapy-related devices.” Ex. 1212, code (54), ¶ 2. There is presently no dispute that Patel-2009 is prior art. *See generally* Prelim. Resp.

Figure 2 of Patel-2009 is reproduced below.

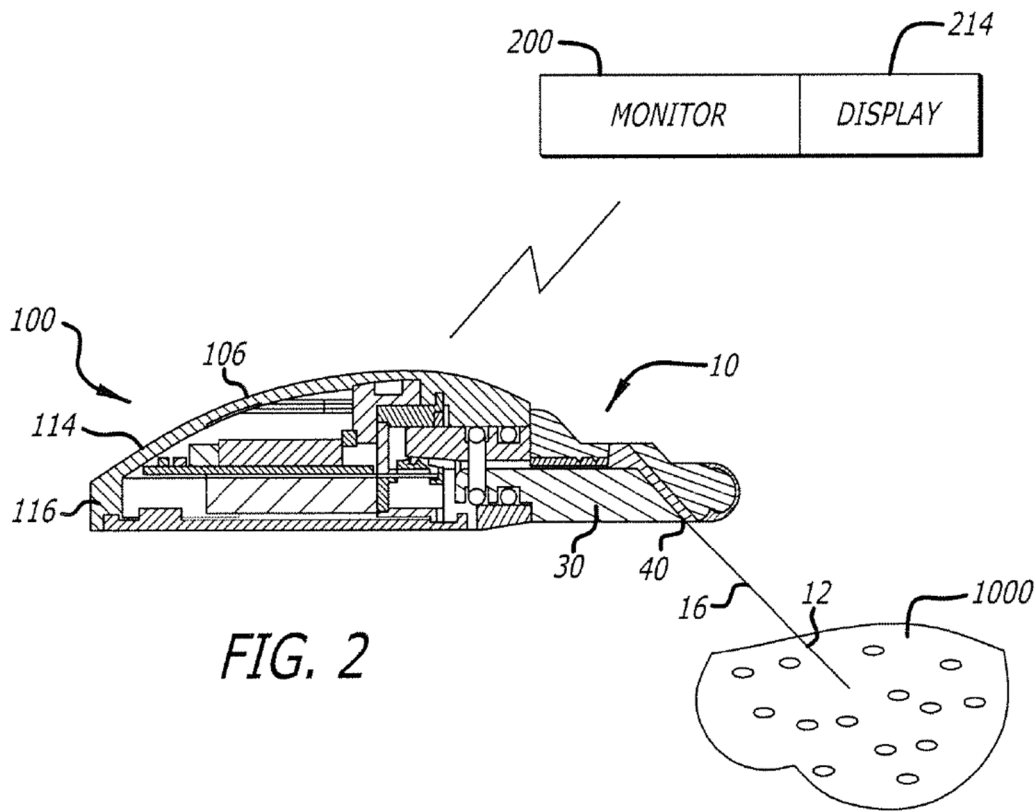


Figure 2 depicts a longitudinal vertical section of a subcutaneous sensor insertion set and telemetered characteristic sensor transceiver device.

Ex. 1212 ¶ 22. According to Patel-2009, the telemetered characteristic sensor system provides better treatment and glycemic control in an outpatient or home-use environment because it can provide glucose levels, hypoglycemia/hyperglycemia alerts, and outpatient diagnostics. *Id.* ¶ 40. The telemetered characteristic sensor system includes percutaneous sensor set 10, telemetered characteristic sensor transceiver device 100, and characteristic monitor 200. *Id.* Percutaneous sensor set 10 is placed subcutaneously on a user and contains flexible sensor 12, a hollow, slotted insertion needle (not labeled), and cannula 16, which contains a sensing portion with sensor electrodes (not labeled). *Id.* ¶ 49.

The telemetered characteristic sensor transceiver device 100 receives a calibration value (e.g., from a blood glucose meter), converts raw sensor signals into calibrated processed glucose values using stored algorithms, and then transmits the calibrated glucose values to the characteristic monitor 200. Ex. 1212 ¶¶ 42–43, Fig. 9. The characteristic monitor may have a display to show the calibrated glucose values, may be a bed-side monitor for monitoring body characteristics of a patient, or may be a data receiver, storage, and/or transmitting device for later processing of the transmitted data or programming of the telemetered characteristic sensor transceiver device 100. *Id.* The telemetered characteristic sensor transceiver device 100 maintains multiple two-way communication links with other devices, such as infusion pumps, monitors, personal computers, PDAs, cellular phones, blood glucose meters, or hospital system devices. *Id.*; *see also id.* ¶ 76, Fig. 11.

2. Paradigm REAL-Time (Ex. 1211)

Paradigm REAL-Time comprises web pages, brochures, and user manuals for the Medtronic MiniMed Paradigm REAL-Time System, which Petitioner alleges were “published on the Medtronic Diabetes Website (www.medtronicdiabetes.com) at least by October 2007.” Pet. 28–29. Petitioner asserts that these materials were recorded in October 2007 by the Internet Archive’s Wayback Machine. *See id.* at 29–32; Ex. 1210 (Frank-White Affidavit). There is presently no dispute that Paradigm REAL-Time is prior art. *See generally* Prelim. Resp.

The Paradigm REAL-Time System includes the REAL-Time Continuous Glucose Monitoring System, MiniLink REAL-Time Transmitter, and MiniMed Paradigm 522/722 Insulin Pump. Ex. 1211, 23–24. The REAL-Time Continuous Glucose Monitoring System has a glucose sensor that is inserted through the skin and sends an electronic signal measuring the amount of glucose in the user’s interstitial fluid. Ex. 1211, 23.

The MiniLink REAL-Time Transmitter receives and processes signals from the glucose sensor and wirelessly sends glucose values to the insulin pump. *Id.*

The MiniMed Paradigm 522/722 Insulin Pump displays glucose trend graphs, monitors glucose levels, shows the degree and direction of glucose trends, and can provide alarms when glucose levels go out of range, when calibration is due, and when there is a failed reception of sensor data from the transmitter to the pump. *Id.* at 24, 44–49.

3. Goldsmith (Ex. 1251)

Goldsmith, titled “Watch Controller for a Medical Device,” is the April 26, 2007, published version of U.S. Application 11/496,606, filed on July 31, 2006. Ex. 1251, codes (21), (22), (43), (54). Goldsmith relates to “infusion systems and methods for delivering fluids into an individual’s body and monitoring systems and methods for monitoring analyte levels in an individual’s body.” *Id.* ¶ 2. There is presently no dispute that Goldsmith is prior art. *See generally* Prelim. Resp.

Goldsmith’s infusion system includes a controller device and a therapy/diagnostic device, such as an infusion device, and allows for the control of the delivery of a fluid or medication. Ex. 1251 ¶ 6. The controller device may be hand-held and separate from the infusion device to allow the user to communicate with the infusion device without actually handling it. *Id.* For example, Goldsmith describes a combined watch and controller device in Figure 10. *Id.* ¶ 32.

Goldsmith’s Figure 10 is reproduced below.

FIG. 10

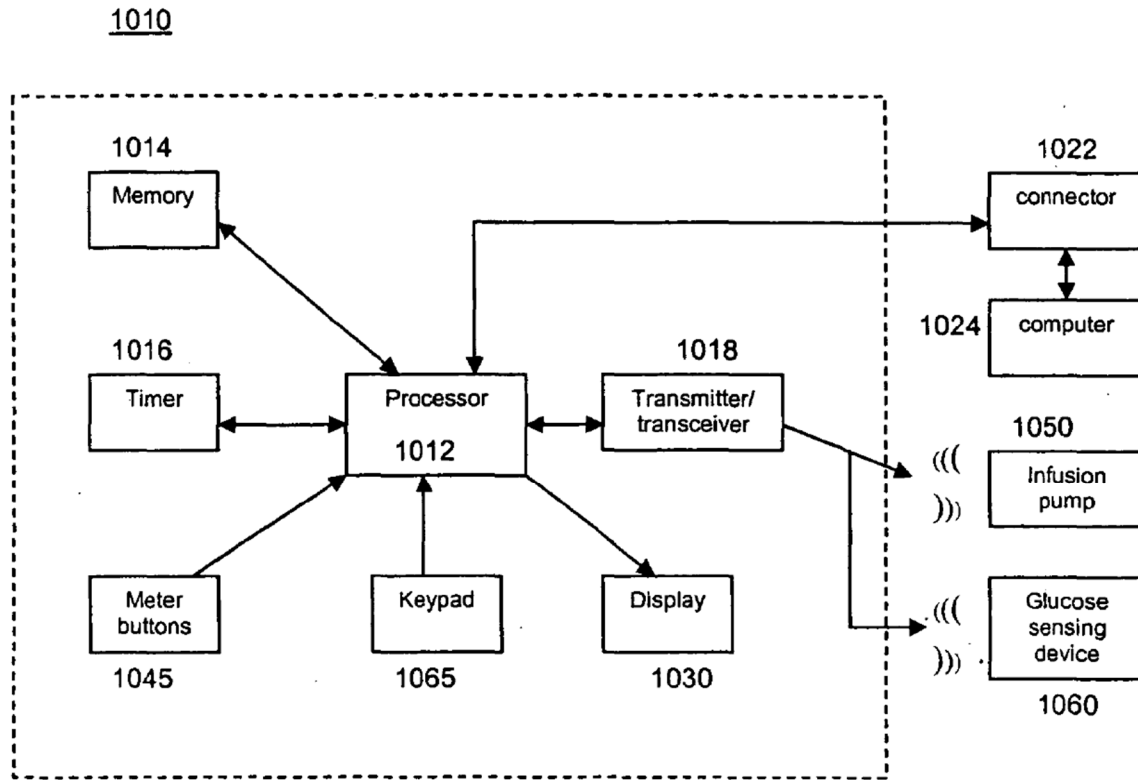


Figure 10 depicts a block diagram of watch controller device 1010 in communication with computer 1024, infusion pump 1050, and glucose sensing device 1060. Ex. 1251 ¶¶ 88–89. Watch controller device 1010 includes housing 1015, which contains processor 1012 “adapted to process data and commands inputted by the user,” transmitter/transceiver 1018, and memory 1014. *Id.* ¶¶ 88, 91. Processor 1012 communicates with infusion pump 1050 through transmitter/transceiver 1018 to transmit “data indicative of the determined concentration of the [blood glucose] in the user,” and communicates with timer 1016, “which is adapted to tell time so that the watch controller device 1010 may act as a watch.” *Id.* ¶ 88. In some embodiments, transceiver 1018 receives information from analyte sensing

device 1060. *Id.* Memory 1014 stores data and controller programs that may be processed by processor 1012 to control infusion pump 1050 and/or analyte sensing device 1060. *Id.* ¶ 91.

The housing of watch controller device 1010 includes display 1030 that shows the current time, a timer, and/or information that mimics the display on infusion pump device 1050 based on communications sent to watch controller device 1010 from infusion pump device 1050. Ex. 1251 ¶ 90. The housing may also include input device(s) 1045 on keypad 1065, such as keys, buttons, and the like, “so that all, or substantially all, viewing and data entry may be performed on the same device without moving the infusion pump device 1050.” *Id.*

E. Ground 1 – Alleged Obviousness of Claim 13 Over Patel-2009 and Paradigm REAL-Time

Petitioner asserts that claim 13 is unpatentable as obvious over the combination of Patel-2009 and Paradigm REAL-Time. *See* Pet. 42–62. At this stage of the proceeding, Patent Owner does not dispute the merits of this obviousness ground. *See generally* Prelim. Resp.

In brief, Petitioner relies on Patel-2009 and Paradigm REAL-Time as each disclosing a continuous glucose monitoring system that teaches or suggests most of the limitations of claim 13. *See generally* Pet. 42–62. For limitations [1.E] and [1.F],¹³ which recite that sensor data is transmitted over a “Bluetooth wireless communication link,” Petitioner asserts that Patel-

¹³ Claims 13 and 29 depend from claim 1, and therefore incorporate all of the limitations of claim 1. The Petition walks through the limitations of claim 1 before turning to the additional limitations recited in claims 13 and 29.

2009 discloses use of two-way wireless communication links and Paradigm REAL-Time discloses “using radio frequency transmission with a six-foot range,” but Petitioner does not assert that either reference expressly discloses use of Bluetooth. Pet. 50–53 (citing, *e.g.*, Ex. 1212 (Patel-2009) ¶¶ 8, 12, 13, 42, 43, 45, 66, 76, 82, Figs. 2, 11; Ex. 1211 (Paradigm REAL-Time), 7–8, 23–26, 37, 43–51, 71; Ex. 1208 (Gross Decl.) ¶¶ 47–49, 54, 56, 61, 98–104). Instead, Petitioner argues that a “POSITA would have found it obvious to configure Bluetooth communication links in order to extend the compatibility, operating range, and usability of the system via a standardized, well-established wireless communication protocol,” and that “Bluetooth would have been chosen for communication with computers, PDAs, and cell phones as disclosed in Patel-2009.” Pet. 52 (citing, *e.g.*, Ex. 1208 (Gross Decl.) ¶¶ 47–49, 54, 56, 61, 100; Pet. 22–23¹⁴).

Claim limitations [1.I]–[1.L] generally relate to a system configured to detect an adverse condition,¹⁵ display a corresponding data gap in a line graph displayed on the receiver, store data during the adverse condition, and 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 in a second line graph. *See* Pet. 54–59. For

¹⁴ At page 52, the Petition cross-references Section IV.A.4, but we understand this to be a typographical error, with Section V.A.4 (found at Petition pages 22–23) being the intended citation.

¹⁵ According to the ’056 patent, “adverse conditions” refers to conditions “associated with the sensor monitoring system,” which may include, by way of example, “one or more of a sensor instability condition, a calibration failure condition, or a monitoring system failure condition.” Ex. 1201, 13:43–62.

these limitations, Petitioner relies on Paradigm REAL-Time, citing for example its disclosure that the “transmitter holds 40 minutes['] worth of memory, so . . . continuous glucose monitoring (CGM) data can be repopulated in the insulin pump.” Pet. 57 (quoting Ex. 1211 (Paradigm REAL-Time), 8). Petitioner asserts that in the Paradigm REAL-Time System, “when transmission is out-of-range for less than 40 minutes, gaps in continuous glucose monitoring (CGM) data are entirely repopulated and do not persist in historical graphs.” *Id.* (citing, *e.g.*, Ex. 1211 (Paradigm REAL-Time), 8; Ex. 1208 (Gross Decl.) ¶¶ 60, 112).

Regarding a reason an ordinarily skilled artisan would have combined Patel-2009 and Paradigm REAL-Time, Petitioner asserts that although Patel-2009 does not provide for backfilled glucose graphs, Paradigm REAL-Time does, and a person of ordinary skill in the art would have been motivated to implement this feature in Patel-2009 to “convey as much accurate glucose information to a user as possible without providing inaccurate information.” Pet. 40–41 (citing Ex. 1208 (Gross Decl.) ¶¶ 55, 59, 60, 79, 80).

Claim 13 depends from claim 1 and further recites that “the adverse condition comprises a sensor misposition error.” *See* Ex. 1201, 16:56–57. Petitioner asserts that the Patel-2009/Paradigm combination teaches or suggests this limitation because it detects lost communications caused by failed reception of continuous glucose monitoring data (*e.g.*, when the receiver device is not in proximity to the user), displays a data gap on the receiver unit’s glucose graph if the receiver unit fails to receive data for more than a certain amount of time, and displays a new graph with backfilled data when transmission is reestablished. Pet. 59–62 (citing, *e.g.*, Ex. 1211 (Paradigm REAL-Time), 8, 41, 43, 49, 73; Ex. 1212 (Patel-2009)

¶¶ 72, 76, 86, Fig. 11; Ex. 1208 (Gross Decl.) ¶¶ 58, 60, 72, 76–78, 101–03, 108–11, 118).

After considering the arguments and cited evidence of record, we determine that for purposes of institution, Petitioner sufficiently shows that the combination of Patel-2009 and Paradigm REAL-Time teaches or suggests each limitation of claim 13, and that a person of ordinary skill in the art would have had a reason to combine the teachings of Patel-2009 and Paradigm REAL-Time with a reasonable expectation of success. *See, e.g.*, Pet. 27–62. Accordingly, we find for purposes of institution that Petitioner shows a reasonable likelihood of prevailing on Ground 1.

F. Ground 2 – Alleged Obviousness of Claim 29 Over Patel-2009, Paradigm REAL-Time, and Goldsmith

For Ground 2, Petitioner asserts that claim 29 is unpatentable as obvious over the combined teachings of Patel-2009, Paradigm REAL-Time, and Goldsmith. Pet. 63–83. At this stage of the proceeding, Patent Owner does not dispute the merits of this obviousness ground. *See generally* Prelim. Resp.

Claim 29 recites that the system of claim 1 “further compris[es] a secondary receiver unit” that is a watch, configured to “include a limited number of functions as compared with the receiver unit” and “receive processed sensor data from the data processing and transmitter unit.” *See* Ex. 1201, 18:19–25. Petitioner cross-references the arguments it made for Ground 1 (summarized above) as to how the Patel-2009/Paradigm combination would have rendered claim 1 obvious. *See* Pet. 76. Petitioner further asserts that a person of ordinary skill in the art would have found it “obvious to implement a watch controller as ‘a display,’” which “[i]n its

most simplest form, . . . [is] used to show a BG [blood glucose] value and/or graph.” *Id.* at 77 (quoting Ex. 1251 (Goldsmith) ¶¶ 66, 93). Petitioner also asserts that “[t]he size of a watch would lend itself to a reduced number of functions by virtue of its smaller display, reduced memory, and lesser processing power.” *Id.* at 77–78 (citing Ex. 1208 (Gross Decl.) ¶ 140).

Petitioner further argues that

[r]egardless of whether claim 29 is interpreted to mean that the secondary receiver receives data *directly* from the data processor and transmitter unit, or *indirectly* through an intermediary device (*e.g.*, an insulin pump, handheld device, or other larger monitor taught by Patel-2009) it is rendered obvious by the combination of Patel-2009, Paradigm, and Goldsmith.

Pet. 78 (citing Ex. 1208 (Gross Decl.) ¶ 141). Petitioner argues that “Goldsmith teaches both direct and indirect communication between the watch and on-body unit,” and a person of ordinary skill in the art would have recognized benefits of implementing both methods. *Id.* at 79–80 (citing Ex. 1251 (Goldsmith) ¶¶ 6, 10, 11, 49, 58, 85, 87–88, Figs. 7, 10; Ex. 1208 (Gross Decl.) ¶¶ 124–27, 143–44).

As for a reason an ordinarily skilled artisan would have combined Patel-2009, Paradigm REAL-Time, and Goldsmith, Petitioner asserts that the Patel-2009/Paradigm combination system comprises a glucose sensor transceiver that maintains a two-way communication link with one or more remote monitoring devices. Pet. 70. Petitioner argues that a person of ordinary skill in the art would have been motivated to add an additional device for receiving and displaying glucose data and related information (*i.e.*, Goldsmith’s watch) to achieve the benefits taught in Goldsmith, such as

convenience and discrete glucose monitoring. *Id.* at 72–74 (citing, e.g., Ex. 1208 (Gross Decl.) ¶¶ 133–34; Ex. 1251 (Goldsmith) ¶¶ 11, 85, 104); *see also id.* at 76 (“A POSITA would recognize the watch controller as a secondary receiver because, rather than performing the principal functions of the Patel-2009/Paradigm/Goldsmith system, it supplements a sensing device and an infusion device / pump or other analyte monitor to display processed sensor data in a more convenient and discrete manner using a smaller, more compact device.”).

After considering the arguments and cited evidence, we determine that for purposes of institution Petitioner sufficiently shows that the combination of Patel-2009, Paradigm REAL-Time, and Goldsmith teaches or suggests each limitation of claim 29, and that a person of ordinary skill in the art would have had a reason to combine the teachings of Patel-2009, Paradigm REAL-Time, and Goldsmith with a reasonable expectation of success. *See, e.g.*, Pet. 63–83. Accordingly, we find for purposes of institution that Petitioner shows a reasonable likelihood of prevailing on Ground 2.

IV. CONCLUSION

For the foregoing reasons, we determine that the information presented establishes a reasonable likelihood that Petitioner would prevail in showing that at least one of claims 13 and 29 of the ’056 patent is unpatentable.

At this preliminary stage, we have not made a final determination regarding the patentability of any challenged claim or any underlying factual and legal issues. *See TriVascular, Inc. v. Samuels*, 812 F.3d 1056, 1068 (Fed. Cir. 2016) (noting that “there is a significant difference between a petitioner’s burden to establish a ‘reasonable likelihood of success’ at

institution, and actually proving invalidity by a preponderance of the evidence at trial”). Any final decision in this proceeding will be based on the full trial record.

The Board will deem forfeited any issue not raised by Patent Owner in a timely response to the Petition, or as permitted in another manner during trial, even if asserted in the Preliminary Response or discussed in this Decision.

Nothing in this Decision authorizes Petitioner, in a manner not otherwise permitted by the Board’s rules, to supplement the information pertaining to any ground advanced in the Petition.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review is instituted based on all grounds asserted in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial commencing on the entry date of this Decision.

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Patent 11,298,056 B2

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