

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ABBOTT DIABETES CARE, INC.,
Petitioner,

v.

DEXCOM, INC.,
Patent Owner.

IPR2024-00840
Patent 9,119,528 B2

Before MITCHELL G. WEATHERLY, JON M. JURGOVAN, and
FREDERICK C. LANEY, *Administrative Patent Judges*.

WEATHERLY, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. Background

Abbott Diabetes Care, Inc. (“Petitioner”) filed a petition (Paper 1, “Pet.”) to institute an *inter partes* review of claims 1–3, 5, 11–13, 16–20, 24–26, 28, 34–36, and 39–43 (the “challenged claims”) of U.S. Patent No. 9,119,528 B2 (Ex. 1001, “the ’528 patent”). 35 U.S.C. § 311.

DexCom, Inc. (“Patent Owner”) timely filed a Preliminary Response. Paper 7 (“Prelim. Resp.”). Institution of an *inter partes* review is authorized by statute when “the information presented in the petition filed under section 311 and any response filed under section 313 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.” 35 U.S.C. § 314(a). Based on our review of the record,¹ we conclude that Petitioner is reasonably likely to prevail with respect to at least one of the challenged claims, and we institute an *inter partes* review.

Petitioner challenges the patentability of claims as follows:

Claim(s) challenged	35 U.S.C. § ²	Reference(s)
1, 2, 11, 12, 16, 18–20, 24, 25, 34, 35, 39, 41–43	102	Brauker ³
1, 2, 11, 12, 16, 18–20, 24, 25, 34, 35, 39, 41–43	103	Brauker

¹ The panel strongly prefers that all text within an evidentiary exhibit should be capable of being found using a search feature and being copied as text. We note that Exhibit 2010 fails to meet this standard. In their papers, the parties should cite evidence by exhibit number in every instance; a short form name may also be used, but not as a substitute for the exhibit number. The panel also prefers that, for every evidentiary exhibit filed in P-TACTS, the party should assign a short, descriptive name in the “Document name” field. Lastly, all briefing should include page numbering, and direct testimony in a declaration should include paragraph numbering. Submissions not meeting these expectations may be refused.

² The Leahy-Smith America Invents Act (“AIA”) included revisions to 35 U.S.C. §§ 102 and 103 that became effective March 16, 2013. The application for the ’528 patent was filed on Jan. 16, 2013. Therefore, we apply the pre-AIA versions of 35 U.S.C. §§ 102 and 103.

³ U.S. Patent Publication No. 2007/0208244 A1 (Ex. 1005, “Brauker”).

Claim(s) challenged	35 U.S.C. § ²	Reference(s)
3, 26	103	Brauker, Guerra ⁴
5, 28	103	Brauker, Guerra, Hughes ⁵
13, 36	103	Brauker, Hughes
16, 17, 39, 40	103	Brauker, STS Guide ⁶
1–3, 11, 12, 16–20, 24–26, 34, 35, 39–43	103	STS Guide, Brauker
5, 28	103	STS Guide, Brauker, Guerra, Hughes
13, 36	103	STS Guide, Brauker, Hughes
16, 39	103	STS Guide, Brauker, Say ⁷

Generally, Patent Owner contends that the Petition should be denied in its entirety. On April 24, 2018, the Supreme Court held that, under 35 U.S.C. § 314, the Office may not institute review of fewer than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018). For the reasons expressed below, we determine that Petitioner has demonstrated a reasonable likelihood of establishing that at all challenged

⁴ Stefania Guerra et al., *A Dynamic Risk Measure from Continuous Glucose Monitoring Data*, DIABETES TECHNOLOGY & THERAPEUTICS, vol. 13, no. 8, 843–852 (Aug. 2011) (Ex. 1006, “Guerra”).

⁵ Colleen S. Hughes et al., *Hypoglycemia Prevention via Pump Attenuation and Red-Yellow-Green “Traffic” Lights Using Continuous Glucose Monitoring and Insulin Pump Data*, JOURNAL OF DIABETES SCIENCE AND TECHNOLOGY, vol. 4, no. 5, 1146–1155 (Sept. 2010) (Ex. 1007, “Hughes”).

⁶ DexCom™ STS™ Continuous Glucose Monitoring System User’s Guide (Ex. 1008, “STS Guide”).

⁷ U.S. Patent No. 6,565,509 B1 (Ex. 1009, “Say”).

claims are unpatentable. In accordance with the *SAS* decision and 37 C.F.R. § 42.108(a), we institute an *inter partes* review of all challenged claims of the '528 patent on all grounds alleged by Petitioner.

B. Related Proceedings

The parties identified the co-pending district court proceeding of *Abbott Diabetes Care Inc. et al v. DexCom, Inc.*, No. 1:23-cv-00239 (D. Del) (the “Delaware Litigation”) in which Patent Owner contends that Petitioner infringes the '528 patent. Pet. 4; Paper 3, 3. Patent Owner identifies as the Board proceedings listed below as related because those proceedings address other patents that Patent Owner contends to be infringed in the Delaware Litigation.

- IPR2024-00797 (U.S. Patent 10,375,222);
- IPR2024-00841 (U.S. Patent 10,709,364);
- IPR2024-00853 (U.S. Patent 11,213,204);
- IPR2024-00859 & IPR20204-00860 (U.S. Patent 11,510,625);
- IPR2024-00861 (U.S. Patent 9,801,541); and
- IPR2024-00890 & IPR2024-00891 (U.S. Patent 11,020,031).

Paper 3, 2.

Both parties identified IPR2020-00909 as a related proceeding in which the Board determined that claims 1–4, 19, and 23 of U.S. Patent 10,702,215 B2 (related to the '528 patent) were unpatentable and which is currently on appeal before the Federal Circuit. Pet. 4; Paper 3, 2–3.

C. The '528 Patent

The '528 patent relates to systems and methods that “allow a user to receive alerts or alarms indicative of glycemic condition in a more accurate and useful way.” Ex. 1001, 2:1–2. Figure 1 is reproduce below.

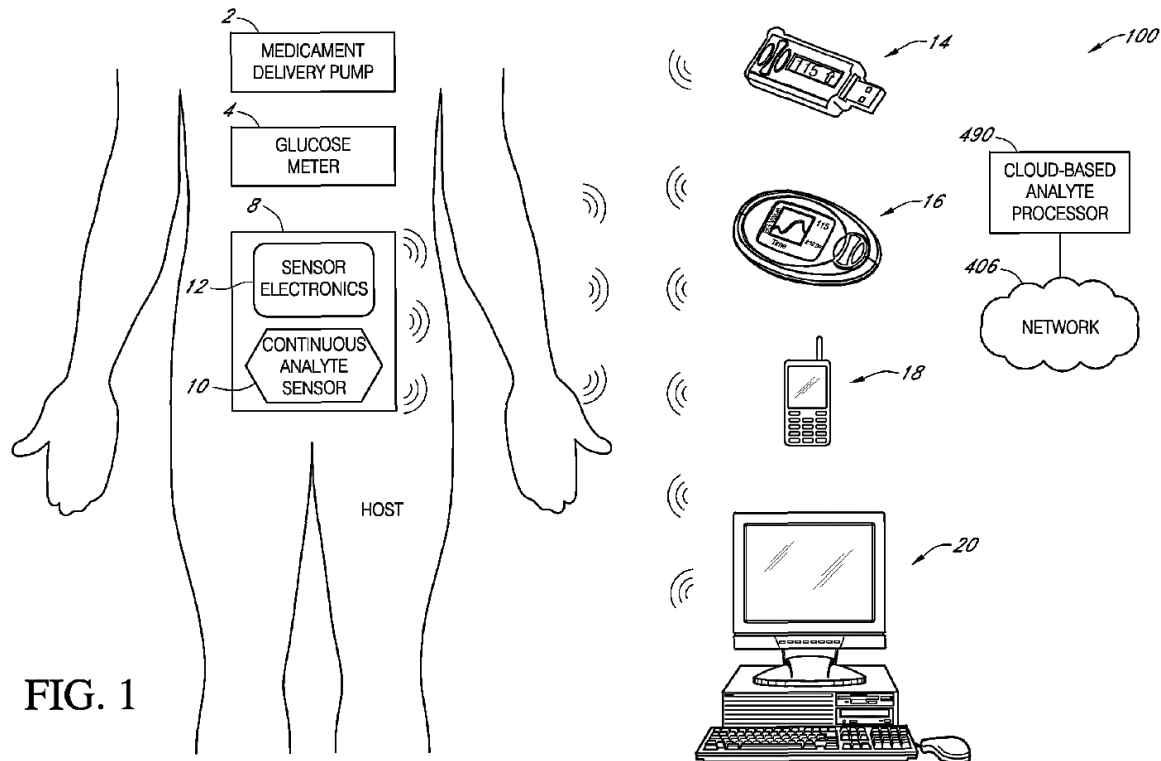


Figure 1 illustrates analyte monitoring system 100 including sensor system 8, sensor electronics 12, and continuous analyte sensor 10. *Id.* at 9:65–10:6. Sensor electronics 12 may couple, wirelessly, with display devices 14, 16, 18, and 20 which “may be configured for presenting information (and/or alarming), such as sensor information transmitted by the sensor electronics 12 for display at the display devices 14, 16, 18, and/or 20.” *Id.* at 10:59–65.

The ’528 patent describes two types of alarms or indicators, “user settable” indicators, and “non-user settable” indicators. *See* Ex. 1001, 21:1–15 (The ’528 patent explaining, for example, that a predictive threshold “ TV_p may not be settable by the user; it may be a fixed value or permanent value set during factory settings.”). A “user settable” threshold

TV_1 may be settable by the user and generally defines the upper limit or upper glucose value that a user may operate at before being alerted by the monitor. Similarly, TV_2 may be settable by

the user and generally defines the lower limit or lower glucose value that a user may operate at before being alerted by the monitor.

Id. at 21:1–6.

Figure 5 is reproduced at right and “is an illustration of a continuous trace of glucose values measured during a time frame in accordance with an embodiment of the disclosure.” *Id.* at 9:26–28.

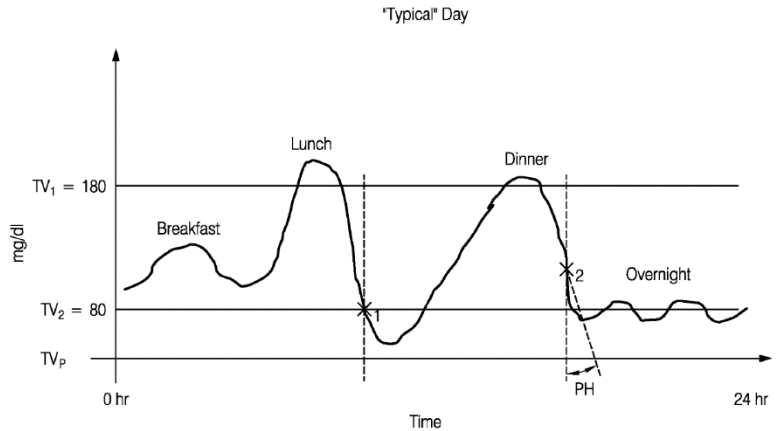


FIG. 5

A threshold flag X_1 coinciding with user settable threshold TV_2 is marked on the trace. *Id.* at Fig. 5. Threshold flag x_2 marks an example of a glucose level at which “the user wants to be notified of when his glucose level hits a certain value, high or low. When the user’s glucose value is determined to meet that predetermined user set value, the user may be notified via an alert or alarm.” *Id.* at 21:36–37.

The Specification states that X_2 is a “predictive flag, and may be configured to alert the user that a second threshold, e.g., TV_p , is predicted to be met within a predetermined or predefined time frame or time horizon PH.” *Id.* at 21:43–46. The Specification further explains that TV_p and PH may be preset or fixed by the manufacturer, “using a variety of historical data using e.g., the user’s historical data, a population historical data, the particular sensor’s historical data, etc.” *Id.* at 21:63–65.

Use of prediction algorithm parameters (e.g., reliance on modeled versus measured data, time-sensitive weighting of past data, prediction horizon PH, and prediction threshold TV_p) tuned

in advance may increase or optimize warning time for patients before a severe event occurs and may minimize the number of nuisance/false alarms heard by user.

Id. at 21:53–59.

Claims 1 and 24 are the independent claims among challenged claims 1–3, 5, 11–13, 16–20, 24–26, 28, 34–36, and 39–43. *Id.* at 47:17–50:52. The other challenged claims depend directly or indirectly from either claim 1 or claim 24. *Id.* Claim 1 is illustrative and recites:

1[pre]. A method of activating a hypoglycemic indicator based on continuous glucose sensor data, the method comprising:

[a] evaluating sensor data using a first function to determine whether a real time glucose value meets one or more user settable first criteria;

[b] evaluating sensor data using a second function to determine whether a predicted glucose value meets one or more non user settable second criteria;

[c] activating a hypoglycemic indicator if either the one or more user settable first criteria or the one or more non user settable second criteria are met; and

providing an output based on the activated hypoglycemic indicator.

Id. at 47:17–29 (with Petitioner’s bracketed labels added to ease discussion).

II. ANALYSIS

A. Claim Interpretation

We interpret claims in the same manner used in a civil action under 35 U.S.C. § 282(b) “including construing 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.” 37 C.F.R. § 42.100(b). When applying that standard, we interpret the claim

language as it would have been understood by one of ordinary skill in the art in light of the specification. *Wasica Fin. GmbH v. Cont'l Auto. Sys., Inc.*, 853 F.3d 1272, 1279–80 (Fed. Cir. 2017). Thus, we give claim terms their ordinary and customary meaning as understood by an ordinarily skilled artisan. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc). Only terms that are in controversy need to be construed, and then only to the extent necessary to resolve the controversy. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017).

Neither party identifies any claim language requiring express interpretation, and we currently discern no such claim language. The parties are free to expressly address the meaning of any claim language during the trial.

B. Legal Standards

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987). The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), reaffirmed the framework for determining obviousness as set forth in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). The *KSR* Court summarized the four factual inquiries set forth in *Graham* that we apply in determining whether a claim is reasonably likely to be unpatentable as obvious under 35 U.S.C. § 103(a) as follows:

(1) determining the scope and content of the prior art, (2) ascertaining the differences between the prior art and the claims at issue, (3) resolving the level of ordinary skill in the pertinent art, and (4) considering objective

evidence indicating obviousness or nonobviousness.⁸ *KSR*, 550 U.S. at 406.

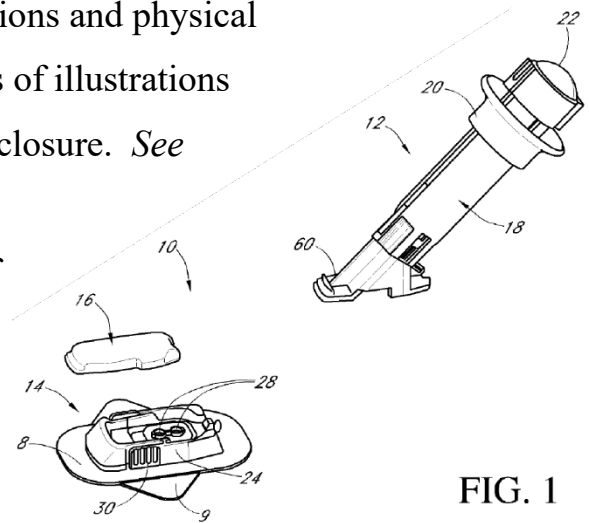
With these standards in mind, we address each challenge below.

C. Claims 1, 2, 11, 12, 16, 18–20, 24–25, 34, 35, 39, and 41–43:

Anticipation by Brauker or Alternatively Obviousness over Brauker

1. Brauker

Brauker describes a “systems and methods for transcutaneous measurement of glucose in a host.” Ex. 1005, code (57). Brauker exhaustively describes a wide array of functions and physical arrangements of such systems over 64 pages of illustrations and 745 numbered paragraphs of textual disclosure. *See generally id.* Figure 1, reproduced at right illustrates many of the major components of the system. Sensor system 10 includes, applicator 12, mounting unit 14, and electronics unit 16. *Id.* ¶ 260. Mounting unit 14 includes base 24 adapted to be mounted on the skin of a patient, a transdermal glucose sensor, and electrical contacts 28 configured to make electrical contact between the sensor and electronics unit 16. *Id.* ¶ 261. Electronics unit 16 gathers and transmits data collected by the glucose sensor to receiver 158, an example of which is illustrated in Figure 41, reproduced below right.



⁸ Currently, no objective evidence of nonobviousness is of record.

Figure 41 illustrates receiver 158 with LCD screen 170 for displaying information about the user's measured (506) and estimated (508) glucose levels.

Id. ¶¶ 696–700. In the example,

receiver 158 also indicates high threshold 500 and low threshold 502 that,

collectively, “represent boundaries between clinically safe and clinically risky” glucose levels. *Id.* ¶ 697. Brauker describes the risky regions above high threshold 500 and below low threshold 502 as danger zones 504. The exemplary dots 508 representing estimated glucose values are shown varying in size to represent a confidence level in the accuracy of each estimated value with smaller dots indicating higher accuracy and larger dots indicated lower accuracy. *Id.* ¶ 700. Receiver 158 also includes speaker 164 for producing “audible signals or alerts for conditions such as present and/or estimated (e.g., predicted) hyperglycemic or hypoglycemic conditions” in the user.

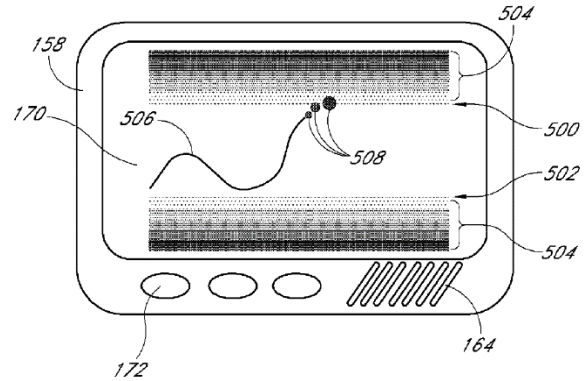


FIG. 41

2. Independent Claim 1

Petitioner contends that Brauker anticipates claim 1 or alternatively renders claim 1 unpatentable as obvious. Pet. 25–31. Patent Owner argues that Brauker fails to describe either of steps 1b and 1c, Prelim. Resp. 15–27, which is where we focus our analysis below to determine whether to institute *inter partes* review.⁹ For the reasons expressed below, we find that

⁹ Based on Petitioner's uncontested arguments supported by the evidence it cites, Pet. 25–26, we find that Petitioner has established a reasonable

Petitioner establishes a reasonable likelihood of demonstrating that Brauker anticipates claim 1 or renders claim 1 unpatentable as obvious.

a. Limitation 1b

Limitation 1b refers to the following text of claim 1: “evaluating sensor data using a second function to determine whether a predicted glucose value meets one or more non user settable second criteria.”

Ex. 1001, 47:22–24.

i. Petitioner’s Arguments and Evidence

Petitioner contends that Brauker describes a “first aspect” of its system that evaluates sensor data using the claimed “second function to determine” when “the estimated glucose data for the future time [i.e., *predicted glucose value*] is below a predetermined threshold.” Pet. 26–27 (citing Ex. 1005 ¶ 15; Ex. 1003 ¶ 74). Petitioner thus argues that Brauker’s reference to a “predetermined threshold” alone establishes that the threshold is not determined (i.e., set) by a user but rather “predetermined” by another entity. *Id.*; *see also id.* at 18 (arguing the “predetermined threshold” refers to “threshold pre-programmed at the factory” and citing Ex. 1003 ¶ 49).

Petitioner concedes that “Brauker does not expressly state whether the ‘predetermined threshold’ of the ‘first aspect’ is user settable or non user settable.”¹⁰ *Id.* at 27. But, Petitioner argues that Brauker teaches that this

likelihood of proving that Brauker describes the subject matter recited in the preamble of claim 1 and limitation 1a.

¹⁰ We do not consider the issue of whether Brauker “expressly state[s]” that its predetermined threshold is non user settable to be dispositive of whether Brauker describes step 1b in an anticipation context. Rather, we seek to determine at trial what Brauker describes to an ordinarily skilled artisan. “An anticipating reference must describe the patented subject matter with sufficient clarity and detail to establish that the subject matter existed in the

“predetermined threshold can optionally be user settable or non user settable” because Brauker describes both types of “predetermined thresholds” elsewhere. *Id.* at 27 (citing Ex. 1005 ¶¶ 35, 697, 698).

Based on the same disclosure, Petitioner also argues that an ordinarily skilled artisan would have found it obvious to make Brauker’s predetermined threshold of its “first aspect” non user settable. *Id.* at 29. Petitioner contends that an ordinarily skilled artisan “would have understood the advantages of using a non user settable low glucose alarm.” *Id.* (citing Ex. 1003 ¶ 77). Petitioner explains that an “alarm based on user settable criteria enables the user to tailor the alarm, but lacks the additional safety of a fixed alarm that is guaranteed to be triggered if the user’s glucose is expected to hit a predetermined serious and potentially life-threatening danger level.” *Id.* (citing Ex. 1013, 725 (“The user should never go below 50 mg / dL at any time without an alarm.”)).

ii. Analysis of Patent Owner’s Responsive Arguments

Patent Owner first argues that Brauker’s “predetermined threshold” does not necessarily refer to a threshold that is “pre-programmed at the factory” (i.e., by a non user). Prelim. Resp. 16–17. As already noted, Petitioner’s argument is based on a plain reading of “predetermined” and Dr. Rodbard’s undisputed testimony. Ex. 1003 ¶¶ 49, 74. Patent Owner argues that we should give “no weight” to Dr. Rodbard’s testimony because it is “conclusory and unsupported.” Prelim. Resp. 17 (citing *Xerox v.*

prior art and that such existence would be recognized by persons of ordinary skill in the field of the invention.” *Crown Operations Int’l, Ltd. v. Solutia Inc.*, 289 F.3d 1367, 1375 (Fed. Cir. 2002). Currently, Petitioner’s showing on this issue is supported by Dr. Rodbard’s undisputed testimony. Pet. 18 (citing Ex. 1003 ¶ 49), 28 (citing Ex. 1003 ¶ 74).

Bytemark, IPR2022-00624, Paper 9, 14–16 (Aug. 24, 2022) (precedential)). However, Dr. Rodbard’s testimony is based on his review of various portions of Brauker that very clearly indicate that Brauker, at least in connection with some versions of its glucose monitoring system, contemplates a “predetermined threshold” for glucose monitoring that is set by a non user (e.g., a manufacturer). Ex. 1003 ¶ 74 (citing Ex. 1005 ¶¶ 697–698). Thus, we do not agree that Dr. Rodbard’s testimony is wholly unsupported or conclusory. Nevertheless, he will be subject to cross examination, and Patent Owner is free to offer countervailing evidence relating to what an ordinarily skilled artisan would have understood from Brauker’s discussion of its predetermined threshold.

Second, Patent Owner argues that Petitioner cannot establish anticipation by “mixing and matching features what the Petition itself characterizes as different ‘embodiments’ of Brauker.” Prelim. Resp. 19 (citing *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008)). We agree that Petitioner cites different parts of Brauker that refer to different “aspects” and “exemplary” embodiments and the Petition and Dr. Rodbard’s testimony describe certain cited parts of Brauker as relating to “another embodiment.” E.g., Pet. 27; Ex. 1003 ¶ 74. However, Petitioner contends that the plain meaning of Brauker’s “predetermined threshold” as it is used in connection with Brauker’s “first aspect”¹¹ refers to a threshold that

¹¹ It is unclear whether Brauker’s use of “first aspect,” “second aspect,” “third aspect,” etc. constitutes a description of distinct embodiments. These phrases appear as introductory tags to single-sentence statements that read like claim language and may or may not refer to distinct versions Brauker’s sensor system 10. We also note that Brauker’s use of “embodiment” is not entirely clear as a way of setting out distinct embodiments of its sensor system 10. For example, Brauker appears to refer to its receiver 158

is determined by a non user, and Dr. Rodbard, who offers the perspective of an ordinarily skilled artisan, reads Brauker the same way. Ex. 1003 ¶¶ 49, 74. Patent Owner proffers no evidence to the contrary. Thus, on the current record, Petitioner’s position is sufficiently persuasive.

Third, Patent Owner argues that “Brauker only describes the predetermined threshold for the predicted glucose value as being set by the user.” Prelim. Resp. 20 (citing Ex. 1005 ¶¶ 35, 697). Although we agree with Patent Owner regarding Brauker’s disclosure at paragraph 35, we disagree regarding Brauker’s paragraph 697, which states: “the normal glucose threshold is between about 80 and about 200 mg/dL, between about 55 and about 220 mg/dL, or other threshold that can be set *by the manufacturer*, physician, patient, computer program, or the like.” Ex. 1005 ¶ 697 (emphasis added). This passage from Brauker expressly provides that the manufacturer is among the entities that can set glucose thresholds. And, Brauker describes these thresholds as applying to both real time (506) and predicted glucose data (508). Ex. 1005 ¶¶ 698, 702, Fig. 41. On the current record, Petitioner’s position is sufficiently persuasive.

For all the reasons expressed above, we find that Petitioner has established a reasonable likelihood of proving that Brauker discloses or suggests limitation 1b.

generally as part of any and all “embodiments.” By our count, Brauker uses “embodiment” or “embodiments” 954 times, which surely does not convey that Brauker discloses 954 distinct systems. It appears to us that Brauker uses “aspect” and “embodiment” in atypical ways that an ordinarily skilled artisan may understand differently than as referring to distinct versions of Brauker’s sensor system 10.

b. Limitation 1c

Limitation 1c refers to the following text of claim 1: “activating a hypoglycemic indicator if either the one or more user settable first criteria or the one or more non user settable second criteria are met; and providing an output based on the activated hypoglycemic indicator.” Ex. 1001, 47:25–29.

i. Petitioner’s Arguments and Evidence

Petitioner contends that Brauker describes limitation 1c because Brauker describes signaling the user when either the real time glucose value or an estimated future glucose value are below the lower glucose threshold or the lower predetermined threshold. Pet. 31 (citing Ex. 1005 ¶¶ 11, 15, 246; Ex. 1003 ¶ 79).

ii. Analysis of Patent Owner’s Responsive Arguments

Patent Owner proffers three arguments in response to Petitioner’s argument that Brauker describes limitation 1c, none of which overcomes Petitioner’s showing.

First, Patent Owner argues that Petitioner impermissibly combines teachings from distinct embodiments when making its showing for limitation 1b and “does not even allege that Brauker’s clinical risk zones are part of Brauker’s ‘first aspect.’” Prelim. Resp. 23. We have already addressed Petitioner’s showing for limitation 1b in Part II.C.2.a above and found it to be sufficiently persuasive.

In arguing that Brauker describes limitation 1c, Petitioner relies upon Brauker’s paragraphs 11 and 15, which are among the disclosures relating to Brauker’s “first aspect.” Pet. 31 (citing Ex. 1005 ¶¶ 11, 15).

Brauker states:

In an embodiment of the first aspect, the system further comprises an alarm configured to provide at least one of a visual

signal, an audible signal, and a tactile signal *when the calibrated signal is below the lower glucose threshold.*

Ex. 1005 ¶ 11 (emphasis added). We find that this passage describes activating a hypoglycemic indicator if a user settable first criteria is met.

Brauker further states:

In an embodiment of the first aspect, the system further comprises an alarm configured to provide at least one of a visual signal, an audible signal, and a tactile signal *when the estimated glucose data for the future time is below a predetermined threshold.*

Id. ¶ 15 (emphasis added). We find that this passage describes activating a hypoglycemic indicator if a non user settable second criteria is met.

Accordingly, we disagree with Patent Owner's first argument.

Second, Patent Owner argues that Petitioner never maps limitation 1c "to any indicator and output activated when the alleged non-user settable criteria of Brauker's clinical risk zones are met." Prelim. Resp. 24. To the extent that Patent Owner's argument rests upon Petitioner's alleged failure to prove that Brauker describes limitation 1b (while relying, in part, on Brauker's risk zone), we find Petitioner's position to be sufficiently persuasive for the reasons expressed in Part II.C.2.a above.

Third, Patent Owner argues that Petitioner's reading of Brauker as describing a manufacturer setting its predetermined threshold (for acceptable estimated glucose levels) in a manner that precludes a user from resetting that predetermined threshold is "unreasonable." Prelim. Resp. 24–27. We disagree.

Brauker states: "Clinical risk zones 504 can be set by a manufacturer, customized by a doctor, and/or set by a user via buttons 172, for example." Ex. 1005 ¶ 698. Patent Owner's argument focuses on whether "and/or" as

used in this passage is too ambiguous to encompass a manufacturer setting a “predetermined level” that cannot later be changed by a user. Prelim. Resp. 26 (citing manuals of style criticizing the use of “and/or”). The issue for us to decide is not whether Brauker’s use of “and/or” is irreconcilably ambiguous because it runs afoul of advice offered in Strunk & White’s and Bryan Garner’s style guides, but rather, what Brauker’s disclosure reasonably conveys to an ordinarily skilled artisan. Rather than deciding the question presented by Brauker’s allegedly ambiguous use of “and/or” on a partial record, we find that Petitioner’s reading of Brauker, supported by Dr. Rodbard’s testimony, establishes a reasonable likelihood of success in proving that Brauker discloses limitation 1c.

“Clinical risk zones 504” are illustrated in Brauker’s Figure 41 and relate to thresholds that define safe glucose levels whether Brauker’s system is evaluating the patient’s safety based on historical, real time or estimated glucose levels. *Id.* ¶¶ 699–700, 702, Fig. 41 (comparing historical and current glucose data 506, and predicted glucose data 508 to clinical risk zones 504).

For all the reasons expressed immediately above, we find that Petitioner demonstrates a reasonable likelihood of proving that Brauker describes limitation 1c.

c. Summary

For the reasons expressed above, we find that Petitioner establishes a reasonable likelihood of demonstrating that Brauker anticipates claim 1 or renders claim 1 unpatentable as obvious.

3. Independent Claim 24

Independent claim 24 is directed to a system comprising a “sensor” and “sensor electronics” that are configured to perform functions that are defined using substantially identical limitations 1a, 1b, and 1c.¹² *Compare* Ex. 1001, 49:15–31 (claim 24), *with id.* at 47:17–29 (claim 1).

Petitioner contends that Brauker describes all subject matter recited in limitations 24pre, 24a, 24b, and 24c. Pet. 38–43. Patent Owner does not currently contest Petitioner’s arguments relating to these limitations. *See* Prelim. Resp. 13–44 (responding only to Petitioner’s arguments concerning limitations 24d and 24e). Based on our review of Petitioner’s uncontested arguments and the evidence cited in support, we find that Petitioner has established a reasonable likelihood of proving that Brauker describes the subject matter recited in limitations 24pre, 24a, 24b, and 24c.

Petitioner’s and Patent Owner’s arguments relating to claim 24 reflect the substantial overlap between limitations 1b and 1c with limitations 24d and 24e because both parties cross-reference their respective arguments for limitations 1b and 1c when addressing limitations 24d and 24e. Pet. 43; Prelim. Resp. 13–44. For the reasons set forth in Part II.C.2 above, we find that Petitioner has established a reasonable likelihood of proving that Brauker describes or suggests limitations 24d and 24e. Accordingly, we find that Petitioner has established a reasonable likelihood of proving that Brauker anticipates claim 24 or renders claim 24 unpatentable as obvious.

¹² Petitioner labels these substantially identical limitations of claim 24 as limitations 24c, 24d, and 24e respectively. Pet. 12.

4. Dependent Claims 2, 11, 12, 16, 18–20, 25, 34, 35, 39, and 41–43

Petitioner argues that Brauker anticipates or renders obvious dependent claims 2, 11, 12, 16, 18–20, 25, 34, 35, 39, and 41–43.

Pet. 32–37, 44–45. Patent Owner does not currently respond to these challenges. Prelim. Resp. 13–44. For the reasons argued by Petitioner that are supported by the evidence Petitioner cites, we determine that Petitioner has established a reasonable likelihood of proving that dependent claims 2, 11, 12, 16, 18–20, 25, 34, 35, 39, and 41–43 are unpatentable.

D. Dependent Claims 3, 5, 13, 16, 17, 39, and 40:

Obviousness Over Brauker in View of Various References

Petitioner argues that dependent claims 3, 5, 13, 16, 17, 39, and 40 are unpatentable as obvious over the teachings of Brauker combined with teachings from various other references. Pet. 46–59. Patent Owner does not currently respond to these challenges except to argue that they fail for the same reasons that the challenges to independent claims 1 and 24 fail. Prelim. Resp. 44–45.

As stated in Part II.C above, we find Petitioner’s challenges to independent claims 1 and 24 as anticipated or obvious to be sufficiently persuasive to warrant an *inter partes* review. For the reasons argued by Petitioner alleged to be supported by the evidence Petitioner cites, we determine that Petitioner has established a reasonable likelihood of proving that dependent claims 3, 5, 13, 16, 17, 39, and 40 are unpatentable as obvious.

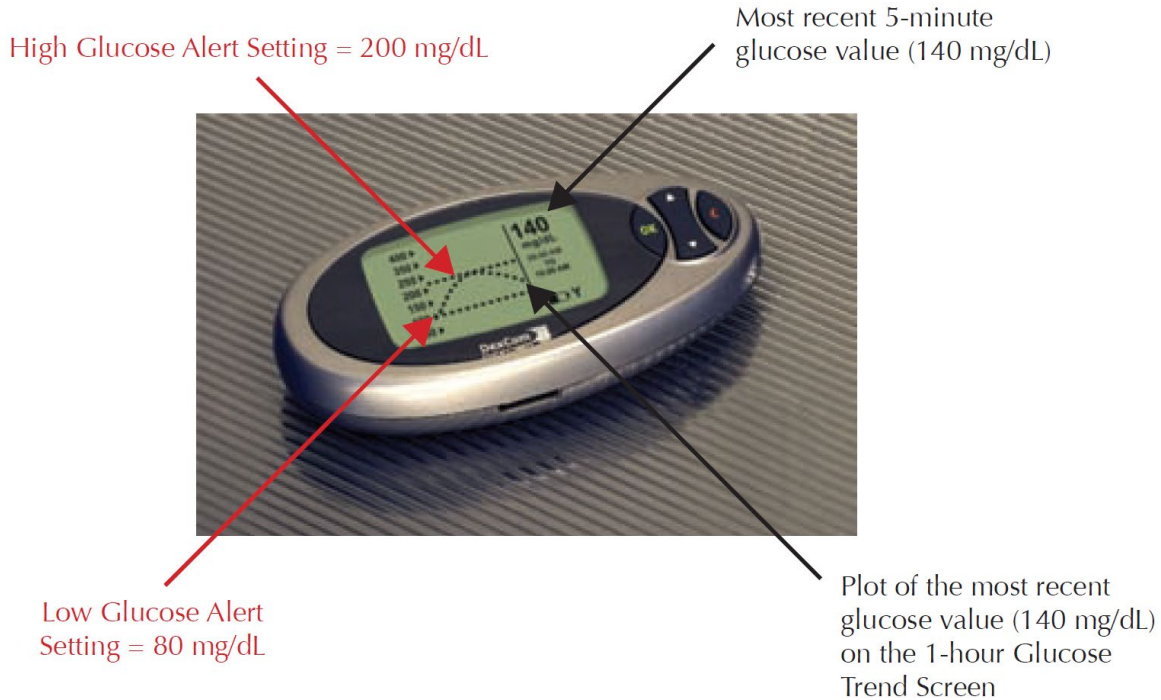
E. Claims 1–3, 11, 12, 16–20, 24–26, 34, 35, and 39–43:
Obviousness in View of STS Guide and Brauker

1. The STS Guide

The STS Guide describes a continuous glucose monitoring (“CGM”) system with a sensor, a transmitter, and a receiver. Ex. 1008, 9.¹³ The sensor is inserted through the skin of a host’s abdomen to continuously monitor glucose levels for up to 3 days. *Id.* at 10. The transmitter is installed on the sensor and wirelessly transmits glucose information measured by the sensor to the receiver every five minutes. *Id.*; *see also id.* Figure at 18 (illustrating transmitter installed on sensor pod).

As shown in the figure from the STS Guide, reproduced below, the receiver displays the user’s most recent glucose value (e.g., 140 mg/dL). A user can set a low glucose alert setting (e.g., 80 mg/dL) such that whenever the glucose value drops below the setting, the receiver vibrates and displays a low glucose alert screen. *Id.* at 54.

¹³ We, like Petitioner, cite the internal page numbering of STS Guide rather than the exhibit page number because the internal page numbering is more granular than the exhibit page numbering and thus increases the precision of each citation.



The STS Guide also describes an “automatic low glucose alarm set at 55 mg/dL” that a user cannot change or turn off. *Id.* at 56. If the real time glucose value falls below 55 mg/dL, the receiver vibrates and displays a low glucose alarm screen. *Id.* Examples of the low alert and low alarm screens displayed on the receiver are reproduced below left and right respectively.



Low Glucose Alert Screen



Low Glucose Alarm

The “Low Glucose Alert Screen” above left indicates that the user’s glucose level has fallen below the user’s setting of 80 mg/dL. *Id.* at 54. The screen above right depicting the “Low Glucose Alarm” indicates that the

user's glucose level has fallen below the manufacturer's setting of 55 mg/dL. *Id.* at 56.

2. Independent Claim 1

a. Petitioner's Arguments and Evidence

Petitioner contends that the STS Guide describes every aspect of claim 1 except for the requirement in limitation 1b that the second function determines whether a “predicted glucose value” meets a criterion that is not set by a user. Pet. 60–66. For this aspect of limitation 1b, Petitioner argues that an ordinarily skilled artisan would have found it obvious to incorporate Brauker's function of determining whether a predicted glucose level meets a threshold into the STS Guide's second function comparing a glucose level to non user settable criteria. *Id.* at 62–65. Petitioner argues that an ordinarily skilled artisan “would have known the advantages of using a predicted low glucose alarm in addition to a real time low glucose alarm, because a ***predicted*** low glucose alarm ***in advance of potential hypoglycemia*** helps prevent hypoglycemia by giving the user more time to act, for example, by eating sugar.” *Id.* at 63 (citing Ex. 1003 ¶ 146; Ex. 1007, 1149; Ex. 1011, 932). Petitioner also contends that prior art establishes the advantages of using alarms based on both real time and predicted glucose values. *Id.* at 64 (citing Ex. 1003 ¶¶ 11, 15; Ex. 1010, 68). Petitioner contends that an ordinarily skilled artisan

would have been particularly motivated to add a ***predicted, non user settable*** low glucose alarm because [an ordinarily skilled artisan] would have known that non user settable criteria tied to hypoglycemia often relate to clinical danger, [Ex. 1013, 725] (“The user should never go below 50 mg / dL at any time without an alarm.”), and that it is particularly beneficial to have an advance warning of a clinical danger. [Ex. 1003 ¶ 147.]

Pet. 64 (internal footnote omitted). Petitioner argues that an ordinarily skilled artisan would have reasonably expected to successfully modify the system described in the STS Guide as proposed because the STS Guide and Brauker both relate to alerts to reduce the severity of hypoglycemia and delivering alarms due to low predicted glucose levels was well known before the alleged invention of claim 1. *Id.* at 65 (citing Ex. 1003 ¶ 149; Ex. 1005 ¶ 15; Ex. 1010, 68; Ex. 1007, 1150; Ex. 1020; Ex. 1021).

b. Analysis of Patent Owner’s Responsive Arguments

Patent Owner first responds that adding Brauker’s user-settable predictive alarm does not meet limitation 1b/1c. Prelim. Resp. 47–48. We disagree because Petitioner does not propose the combination underlying this argument. Rather, Petitioner suggests adding Brauker’s alarm based on comparing predicted glucose level to a threshold, Ex. 1003 ¶ 15, but with a non-user setting the threshold for that alarm in a way that cannot be altered by the user as expressly described by STS, Ex. 1008, 56. Pet. 62–65.

Second, Patent Owner contends that “every prior art predictive alarm used user settable criteria that allowed the patient to personalize the alarm to the patient’s needs and adjust the predictive alarm if it generated too many false alarms.” Prelim. Resp. 49. Even if Patent Owner were to proffer such evidence, Petitioner persuasively argues that an ordinarily skilled artisan would have found it obvious to incorporate a predictive alarm based on a threshold that cannot be altered by the user into a CGM.

Third, Patent Owner argues that Petitioner’s proposed combination is based on hindsight reasoning and criticizes Petitioner’s argument because Brauker’s predictive alarm is user-settable. Prelim. Resp. 50. As explained in II.C.2.a above, we disagree with this description of Brauker’s predictive

alarm. However, even accepting Patent Owner's characterization as true, Patent Owner's argument does not respond to Petitioner's proposed combination, which seeks to modify the STS Guide's non-user settable alarm based on real time glucose measurements by basing that alarm on predicted glucose levels instead. Pet. 62–63. Patent Owner simply does not respond to Petitioner's argument as presented in the Petition. The remaining arguments proffered by Patent Owner at pages 50–55 suffer from the same malady. We also do not find Patent Owner's argument that the proposed combination is the result of impermissible hindsight because no single reference “describes a fixed predictive alarm.” Prelim. Resp. 55–62. Setting aside our preliminary finding otherwise that Brauker describes such an alarm, we are simply persuaded by Petitioner's reliance on undisputed testimony by Dr. Rodbard. We find the proposed combination to involve the rather simple inferential leap of modifying the STS Guide's fixed real time alarm to use the well-known principle of basing a hypoglycemia alarm on predicted glucose levels instead of real time glucose data to increase the likelihood that a patient would not experience a dangerous hypoglycemic condition. *See, e.g.*, Pet. 63.

For all these reasons, we find that Petitioner has established a reasonable likelihood of proving that the combined teachings of the STS Guide and Brauker render claim 1 unpatentable as obvious.

3. Independent Claim 24

Petitioner contends that the STS Guide describes all subject matter recited in limitations 24pre, 24a, 24b, and 24c. Pet. 38–43. Patent Owner does not currently contest Petitioner's arguments relating to these limitations. *See* Prelim. Resp. 46–60 (responding only to Petitioner's

arguments concerning limitations 24d). Based on our review of Petitioner's uncontested arguments and the evidence cited in support, we find that Petitioner has established a reasonable likelihood of proving that the STS Guide describes the subject matter recited in limitations 24pre, 24a, 24b, and 24c.

Petitioner's and Patent Owner's arguments relating to claim 24 reflect the substantial overlap between limitations 1b and 1c with limitations 24d and 24e because both parties cross-reference their respective arguments for limitations 1b and 1c when addressing limitations 24d and 24e. Pet. 79; Prelim. Resp. 46–60. For the reasons set forth in II.E.2 above, we find that Petitioner has established a reasonable likelihood of proving that the combined teachings of the STS Guide and Brauker teaches limitations 24d and 24e. Accordingly, we find that Petitioner has established a reasonable likelihood of proving that the combined teachings of the STS Guide and Brauker renders claim 24 unpatentable as obvious.

F. Dependent Claims 5, 13, 16, 28, 36, and 39:

Obviousness Over STS Guide, Brauker, in View of Various References

Petitioner argues that dependent claims 5, 13, 16, 28, 36, and 39 are unpatentable as obvious over the teachings of the STS Guide combined with teachings from Brauker and various other references. *Id.* at 80–85. Patent Owner argues only that Petitioner's challenges fail for the same reasons that Petitioner's challenge to independent claims 1 and 24 over the combined teachings of the STS Guide and Brauker fails. Prelim. Resp. 63.

As stated in Part II.E above, we find Petitioner's challenge that the combined teachings the STS Guide and Brauker render independent claims 1 and 24 unpatentable as obvious to be sufficiently persuasive to warrant an *inter partes* review. Additionally, for the reasons argued by Petitioner

alleged to be supported by the evidence Petitioner cites, we determine that Petitioner has established a reasonable likelihood of proving that dependent claims 5, 13, 16, 28, 36, and 39 are unpatentable as obvious in view of the combined teachings of the STS Guide, Brauker, and various other references specified by Petitioner.

III. CONCLUSION

For the reasons expressed above, we determine that Petitioner has demonstrated a reasonable likelihood of showing that the challenged claims of the '528 patent are unpatentable. In accordance with the Court's decision in *SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018) and 37 C.F.R. § 42.108(a), we institute an *inter partes* review of all challenged claims of the '528 patent on all grounds alleged by Petitioner.

Patent Owner does not currently proffer any separate argument for the continued patentability of any dependent claim. *See* Prelim. Resp. 44–45, 63 (proffering arguments relating only to patentability of independent claims). Nevertheless, this Decision does not reflect a final determination on the patentability of any claim. We further note that the burden remains on Petitioner to prove unpatentability of each challenged claim. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

IV. ORDER

For the reasons given, it is:

ORDERED that *inter partes* review of claims 1–3, 5, 11–13, 16–20, 24–26, 28, 34–36, and 39–43 of U.S. Patent No. 9,119,528 B2 is *instituted* with respect to all grounds of unpatentability set forth in the Petition; and

IPR2024-00840
Patent 9,119,528 B2

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), *inter partes* review of U.S. Patent No. 9,119,528 B2 is instituted commencing on the entry date of this Order, and pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is given of the institution of a trial.

IPR2024-00840
Patent 9,119,528 B2

PETITIONER:

Peter P. Chen
Scott C. Weidenfeller
David A. Garr
COVINGTON & BURLING LLP
pchen@cov.com
dgarr@cov.com
sweidenfeller@cov.com

PATENT OWNER:

Richard F. Giunta
Elisabeth H. Hunt
Anant K. Saraswat
WOLF GREENFIELD & SACKS, P.C.
rgiunta-ptab@wolfgreenfield.com
ehunt-ptab@wolfgreenfield.com
asaraswat-ptab@wolfgreenfield.com