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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ABBOTT DIABETES CARE INC.,

Petitioner,

v.

DEXCOM, INC.,

Patent Owner.

Case No. IPR2024-00840

Patent No. 9,119,528

PATENT OWNER'S PRELIMINARY RESPONSE

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	'528 PATENT	3
A.	Background on Real Time and Predictive Alarms	3
B.	The Inventors Discovered That Using Non-User-Settable Criteria Made a Predictive Alarm More Accurate	4
1.	Conventional Predictive Alarms Were Inaccurate	5
2.	Conventional Predictive Alarms Used User-Settable Criteria So They Could Be Adjusted	6
3.	The Inventors Discovered That Fixing the Threshold for a Predictive Alarm Increased Its Accuracy	7
C.	The '528 Patent System Uses Different Functions to Generate a User-Settable Real Time Alarm and a Fixed Predictive Alarm	8
D.	Challenged Claims	11
III.	PETITIONER'S GROUNDS FAIL	12
A.	Ground I's Anticipation Showing Fails	13
1.	Abbott Fails to Establish That Brauker Discloses That Its Predictive Alarm Is Non-User Settable as Required by Limitations 1[b] and 24[d]	13
a.	Abbott Fails to Support Its Assertion That Brauker Teaches That Its Predictive Alarm Threshold Is "Optionally" Non-User Settable	15
i.	"Predetermined" Does Not Mean Non-User Settable	16
ii.	Abbott Mixes Alleged Features of Different Brauker Embodiments Which Fails to Establish Anticipation as a Matter of Law	18
iii.	Brauker Is Explicit That the Predicted Glucose Value Threshold Is User Settable	20
b.	Abbott Obfuscates by Citing Brauker's Clinical Risk Zones	23
c.	The UK High Court Decision Is Irrelevant	27

d. Conclusion – Ground I’s Anticipation Arguments Fail.....	28
B. Ground I’s Obviousness Showing Fails	28
1. The Board Routinely Denies Institution When a Petition Relies on Prior Art That Fails to Disclose a Missing Claim Limitation	29
a. Abbott Relies on Expert Testimony to Supply a Claim Limitation Missing from the Art.....	30
b. Expert Testimony Can Supply a Missing Limitation Only in Rare Circumstances Absent Here	31
c. The Board Routinely Denies Institution Where Petitioners Fail to Justify Reliance on Expert Testimony to Supply a Claim Limitation Missing from the Art.....	33
2. That the Inventors Proceeded Contrary to Accepted Wisdom Evidences Non-obviousness.....	36
3. The Petition Establishes No Supportable Reason to Modify Brauker to Fix the Threshold for its Predicted Glucose Value	37
a. No Prior Art Teaching Would Have Motivated a POSA to Fix the Threshold for Brauker’s Predictive Alarm	38
b. Abbott’s “Obvious to Try” Argument Fails	42
c. Abbott’s “Separate Embodiments” Argument Cannot Save Ground I	43
4. Conclusion – Ground I’s Obviousness Argument Fails.....	44
C. Grounds II-V Fall with Ground I	44
D. Ground VI (Obviousness Over the STS Guide and Brauker) Fails	45
1. Ground VI Seeks to Meet a Claim Limitation Missing from the Prior Art with Unsupported Conclusory Expert Testimony	47
2. That the Inventors Proceeded Contrary to Accepted Wisdom Evidences Non-obviousness.....	49
3. Abbott Establishes No Supportable Reason to Fix the Threshold for the Predicted Glucose Value in the STS Guide-Brauker Combination	49
a. Abbott’s “Known Methods” Yielding “Predictable Results” Rationale Does Not Support Fixing the Threshold for a Predictive Alarm.....	51

b.	Using Real Time and Predictive Alarms Together Provides No Reason to Fix Brauker’s Predictive Alarm	52
c.	No Prior Art Reference Teaches a Fixed Predictive Alarm	54
d.	Abbott’s Assertion That a POSA Had Reason to Fix a Predictive Alarm Threshold in the STS Guide-Brauker Combination Is Unsupported by Any Credible Evidence	55
e.	Abbott’s Hindsight Argument Should Be Rejected.....	60
f.	The UK High Court Decision Is Irrelevant to Abbott’s Failure to Carry Its Burden on Ground VI.....	62
E.	Grounds VII-VIII Fall with Ground VI.....	63
F.	Conclusion	63

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LISTING OF EXHIBITS

Exhibit	Description
2001	U.S. Patent App. Pub. No. 2009/0192380 (“Shariati”)
2002	Declaration of Dr. Barry Keenan from IPR2022-00909 (“Keenan-Dec-00909”)
2003	Deposition Transcript of David Rodbard, taken January 18, 2023 (“Rodbard-Dep.”) in connection with IPR2022-00909
2004	Tsalikian et al., <i>GlucoseWatch® G2™ Biographer (GW2B) Alarm Reliability During Hypoglycemia in Children</i> , <i>Diabetes Technol Ther.</i> 2004 October ; 6(5): 559–566.
2005	Deposition Transcript of David Rodbard, taken May 24, 2023 (“Rodbard-Reply-Dep.”) in connection with IPR2022-00909
2006	A. Kamath, A. Mahalingam and J. Brauker, “Methods of Evaluating the Utility of Continuous Glucose Monitor Alerts”, <i>Journal of Diabetes Science and Technology</i> , Vol. 4, Issue 1, January 2020 (“Kamath”)
2007	U.S. Patent App. Pub. No. 2011/0193704 (“Harper”)
2008	Medtronic User Guide: Guardian Real-Time Continuous Glucose Monitoring System
2009	Transcript of Deposition of Desmond Barry Keenan, Ph.D., MBA, PMP (March 29, 2023) in connection with IPR2022-00909
2010	Excerpt of A Dictionary of Computing, Sixth Edition, Oxford University Press (2008) (“Oxford”)

I. INTRODUCTION

The '528 Patent claims a glucose monitoring system and method that computes a future “*predicted* glucose value” for a patient, determines whether it meets one or more “*non-user settable* criteria” the patient cannot change, and generates an alarm when the predicted glucose value meets the criteria to warn the patient of a potential future glycemic condition warranting attention.¹

Accurately predicting a future glucose value is complex and difficult. Conventional predictive alarms were inaccurate and generated a high rate of false alarms. The '528 Patent inventors made the surprising discovery that fixing (i.e., making non-user settable) the criteria for a predictive alarm increased the alarm's accuracy. That inventive discovery is found nowhere in the prior art and the Petitioner (“Abbott”) never alleges otherwise. Lacking that inventive discovery, a POSA had no reason to fix the criteria for a predictive alarm rather than allowing the patient and their doctor to select customized criteria appropriate for the patient's particular health needs, which is the way every prior art predictive alarm worked.

The '528 Patent's independent claims are only challenged in Grounds I and VI. Ground VI alleges obviousness over the STS Guide and Brauker. Ground I alleges obviousness over Brauker alone but also relies heavily the STS Guide.

¹ Emphasis is added unless otherwise indicated.

Brauker and the STS Guide are both Patent Owner (“DexCom”) references and neither discloses an alarm that is both *fixed and predictive*. Abbott’s assertion that these DexCom references would have motivated a POSA to do something that neither reference describes is based on nothing but hindsight.

Given that the limitation in every challenged claim that requires determining whether a predicted glucose value meets non-user settable criteria is missing from the prior art, Abbott attempts to meet that limitation with nothing but the naked say-so of Abbott’s expert that a POSA would have been motivated to do this. Federal Circuit precedent precludes reliance on expert testimony alone to meet a claim limitation missing from the art, and the Board routinely denies institution when a petitioner seeks to meet a limitation with nothing but expert testimony. Worse yet, the cited testimony does nothing but repeat the Petition’s conclusory assertions *verbatim*. This testimony warrants no weight under the Board’s precedential *Xerox* case.

Proving obviousness requires establishing some supportable *reason why* a POSA would have modified the prior art to arrive at the claimed subject matter. Abbott fails to do so for either obviousness ground. Below, DexCom lays bare Abbott’s failures to establish any supportable reason why a POSA would have fixed the criteria for a predictive alarm. That is fatal to Abbott’s obviousness arguments in Grounds I and VI.

The only remaining challenge to the independent claims is Ground I's argument that certain challenged claims are “*anticipated* and/or obvious based on Brauker.” The anticipation argument is facially deficient because it seeks to piece together disparate teachings that Brauker does not describe as being used together in the manner claimed. That fails to establish anticipation under Federal Circuit law. Additionally, Brauker nowhere discloses a fixed predictive alarm. Abbott's assertion that it does is based on the extraordinary allegation that Brauker's disclosure that a predictive threshold is “user configurable” in one embodiment somehow means there is another embodiment – nowhere described in Brauker – where the threshold is *not* “user configurable.” Abbott fails to establish that Brauker anticipates any challenged claim.

The Petition's remaining grounds only challenge dependent claims and fall with Grounds I and VI. Institution should be denied.

II. '528 PATENT

A. Background on Real Time and Predictive Alarms

At one time, diabetes patients had to test their glucose levels using a self-monitoring blood glucose monitor, “which typically require[d] uncomfortable finger pricks” multiple times daily. Ex-1001, 1:32-39. The '528 Patent describes a different type of device called a continuous glucose monitoring (“CGM”) device. CGM devices are worn on a patient and have a glucose sensor inserted

through the skin. *Id.*, 1:48-54. CGM devices continuously monitor the patient’s glucose levels throughout the day.

Conventional CGM devices generated alarms² that warned the patient in real time when their glucose level was below or above thresholds the patient set to suit their individual needs. *See e.g.*, Ex-1008, 54-55; Shariati (Ex-2001), [0363]-[0364]; Say (Ex-1009), 45:28-31. Thus, alarms could be set by the patient or the patient’s doctor to warn the patient in real time of a hypoglycemic (glucose too low) or hyperglycemic (glucose too high) condition.

Some conventional CGM devices also had alarms that “alert[ed] the diabetic user of hyperglycemic or hypoglycemic events *before they occur.*” Ex-1001, 1:55-58; *see also id.*, 20:53-59. These are called “predictive alarms” because they predict a future condition. Ex-1001, 1:15-17.

B. The Inventors Discovered That Using Non-User-Settable Criteria Made a Predictive Alarm More Accurate

² The ’528 Patent uses the terms “alarm” and “alert” interchangeably. In IPR2022-00909 – which involved another DexCom patent sharing a specification with the ’528 Patent – the experts for Abbott and DexCom agreed on this. Keenan-Dec-00909 (Ex-2002), ¶61; Rodbard-Dep-00909 (Ex-2003), 18:15-20:20.

The specification explains that predictive alarms need to “be accurate, so that a user does not become de-sensitized from their alarm going off, such that they ignore it because it has become a nuisance.” Ex-1001, 1:58-61; *see also* Keenan-Dec-00909 (Ex-2002), ¶¶46-47. A patient de-sensitized from too many false alarms experiences what is known as “alarm fatigue.” Keenan-Dec-00909, ¶¶43-44; Rodbard-Dep-00909 (Ex-2003), 32:13-33:24. Alarm fatigue creates a safety concern because a de-sensitized patient may begin ignoring all alarms, including accurate alarms that warn of a real condition warranting the patient’s attention. Keenan-Dec-00909, ¶47; Rodbard-Dep-00909, 33:13-24; Ex-1001, 19:6-7.

The ’528 Patent relates to an inventive technique for providing *accurate* predictive alarms. Ex-1001, 1:14-17, 1:67-2:4.

1. Conventional Predictive Alarms Were Inaccurate

Unlike real-time alarms that compare a current glucose value to a threshold, predictive alarms conventionally determined the current glucose level (like real-time alarms do) *but also used additional information* to make a prediction about a future glucose value using, for example, complex algorithms based on “polynomial and autoregressive models...Kalman Filtering (KF), artificial neural networks, statistical and numerical logical algorithms, and machine learning.” Ex-1001, 24:15-24; Keenan-Dec-00909, ¶¶92-93; Ex-1009, 54:62-55:5; GlucoWatch (Ex-2004), 2; Rodbard-Reply-Dep-00909 (Ex-2005), 37:14-18,

41:10-15, 41:19-44:1. Making a prediction about a future glucose value is more complicated than simply comparing the current glucose value to a threshold, resulting in conventional predictive alarms being less accurate. Keenan-Dec-00909, ¶¶45-46; Rodbard-Reply-Dep-00909, 44:11-46:2, 52:22-53:9, 59:4-10; GlucoWatch, 1 and 5 (adding a predictive “down alert alarm” increased “the false alarm rate ... from 16% to 62%”).

A study of a conventional predictive alarm showed that 65% of the predictive alarms generated were false alarms. Kamath (Ex-2006), 65. Abbott offers no evidence establishing that a more accurate predictive alarm was known in the art. Indeed, Abbott’s own “Navigator” product had a predictive alarm (called a “projected” alarm), and its manual had a “*Caution*” that warned users to “*NOT* rely solely on the projected glucose alarms” because of accuracy concerns. Ex-1010, 69 (emphasis original); Rodbard-Reply-Dep-00909, 73:3-13 (*Abbott’s* expert admitting same).

2. Conventional Predictive Alarms Used User-Settable Criteria So They Could Be Adjusted

Conventional predictive alarms could serve the useful purpose of warning of an impending hypoglycemic or hyperglycemic condition before it occurred. But if the alarm was too inaccurate and caused high incidences of false alarms, that could create safety issues. Just like the boy who cried wolf had his cries ignored when the threat was real, an inaccurate alarm can dangerously create alarm fatigue that

can cause the patient to ignore *all* alarms – including ones that accurately warn of a dangerous condition. Keenan-Dec.-00909, ¶¶46-47; Ex-1010, 68-69; Kamath, 65.

Every known predictive alarm used user-settable criteria. Brauker, [0697]; Keenan-Dec-00909, ¶¶48-54; Harper (Ex-2007), [0202], [0281]; Say, 45:28-31; Shariati, [0571]; Ex-1010, 67, 70; Guardian (Ex-2008), 32; Rodbard-Reply-Dep-00909, 15:10-16:22 (admitting glucose levels vary so different thresholds are appropriate for different patients). This allowed the inaccuracy of conventional predictive alarms to be managed. Keenan-Dec-00909, ¶¶48-54. If a predictive alarm was generating a prohibitively high number of false alarms for a particular patient, the patient and/or the patient’s doctor could adjust the predictive alarm. Keenan-Dec-00909, ¶¶48-54.

3. The Inventors Discovered That Fixing the Threshold for a Predictive Alarm Increased Its Accuracy

The ’528 Patent inventors did not follow conventional thinking. They developed a predictive alarm that used a *non-user settable* threshold because they surprisingly discovered that it increased the accuracy of the predictive alarm.

As the patent explains, the “[u]se of prediction algorithm parameters...*tuned in advance*” beneficially “minimize[d] the number of nuisance/false alarms.” Ex-1001, 21:53-59. If a prediction algorithm is not tuned in advance, the algorithm may be called upon to make accurate predictions across

a wide range of predicted glucose values that various patients could set.

Conversely, the inventors discovered that by setting prediction algorithm parameters to particular values “in advance” (*e.g.*, during manufacturing), the algorithms can be better optimized to be more accurate and thereby reduce false alarms. Keenan-Dep-00909 (Ex-2009), 199:14-202:11.

Abbott cited no evidence of an appreciation in the art of the unexpected benefit that fixing criteria for a predictive alarm in advance would increase accuracy. The inventors’ approach contravened the conventional thinking that a high false alarm rate was unavoidable for predictive alarms and should be managed via user-settable criteria that allowed a predictive alarm to be adjusted if it generated too many false alarms for a particular patient. Keenan-Dec-00909, ¶¶48-55.

C. The ’528 Patent System Uses Different Functions to Generate a User-Settable Real Time Alarm and a Fixed Predictive Alarm

The patent describes a system having a sensor to detect glucose levels in a patient, electronics that process the sensor data, and a device that generates an alert/alarm. Ex-1001, Figs. 3A-3D, 9:61-10:58, 16:9-18.

Figure 5 (reproduced below) depicts a continuous trace of a patient’s glucose values over a 24-hour period in comparison with three threshold values: TV_1 , TV_2 , and TV_p . Ex-1001, 9:26-28. Figure 5’s glucose levels are in units of

“mg/dL,” which stands for milligrams (of glucose) per deciliter (of body fluid).

Ex-1001, Fig. 5.

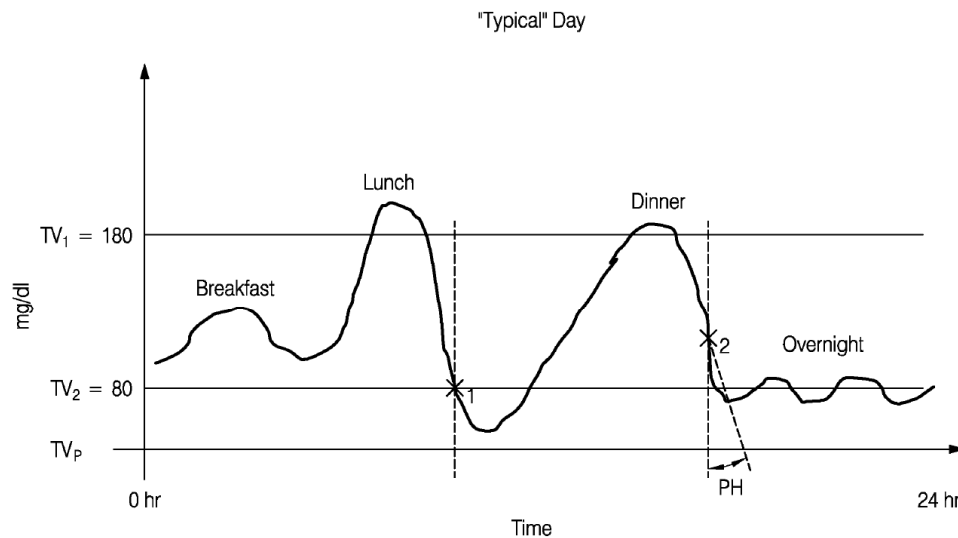


FIG. 5

TV₁ and **TV₂** are user-settable threshold values defining upper (**TV₁**) and lower (**TV₂**) glucose-value thresholds. Ex-1001, 20:66-21:6. If the device detects that the patient’s current glucose level is above upper-threshold **TV₁** or below lower-threshold **TV₂**, it generates an alarm. Ex-1001, 21:29-39.

TV_p is a predictive threshold “against which a predicted value is compared.” Ex-1001, 21:6-8. Whereas **TV₁** and **TV₂** are user-settable thresholds, **TV_p** is “not...settable by the user” – it is “a fixed value or permanent value set during factory settings.” Ex-1001, 21:12-15. When the device predicts that the patient’s glucose level will pass below **TV_p** in the near future (*e.g.*, within 20 minutes), the device generates an alarm. Ex-1001, 21:43-49.

The patent describes two functions for generating alarms. A “*function*” is a software program unit that receives input values and produces an output value. Keenan-Dec-00909, ¶98 (citing Oxford (Ex-2010), 213); Rodbard-Dep-00909, 13:4-16.

The first function provides a “real time” glucose value determination. Ex-1001, Abstract, 2:7-9. The first function may do so by “determin[ing] whether the ‘real time’ glucose value has crossed a [] threshold (80 mg/dL).” *Id.*, 42:52-55.

The second function provides a “predicted” glucose value determination. *Id.*, Abstract, 2:9-11. The second function may use complex algorithms based on “polynomial and autoregressive models... Kalman Filtering (KF), artificial neural networks, statistical and numerical logical algorithms, and machine learning.” *Id.*, 24:15-24; *see also* Keenan-Dec-00909, ¶45.

Figures 4A-F illustrate the difference between alarms/alerts generated based on a first function that determines whether a real-time glucose value meets one or more first criteria, and those generated based on a second function that determines whether a predicted glucose value meets one or more second criteria. Figure 4B illustrates “a low alert screen that can be displayed responsive to a host’s analyte concentration falling below a lower boundary (see boundaries 182). In this example screen, a host’s glucose concentration has fallen to 55 mg/dL, which is below the lower boundary set in FIG. 4A, for

example.” Ex-1001, 16:66-17:4. “[B]oundaries 182” are user settable. *Id.*, 16:50-55.

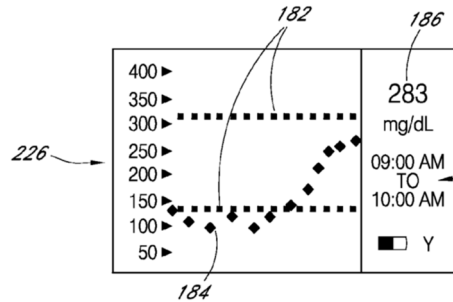


FIG. 4A



FIG. 4B

Figure 4D illustrates “an alert indicting that the user’s blood glucose is dropping and will soon be in a low range” so the alert is generated based on a *predicted* glucose value rather than on the real-time glucose value. *Id.*, 17:31-34.

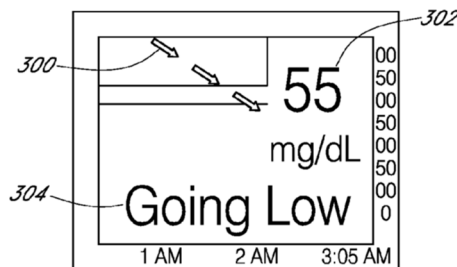


FIG. 4D

D. Challenged Claims

The Petition challenges claims 1-3, 5, 11-13, 16-20, 24-26, 28, 34-36, and 39-43 (“Challenged Claims”). The Challenged Claims include independent claims

1 and 24. Both challenged independent claims require evaluating sensor data using a first function to determine whether a real time glucose value meets one or more user settable criteria, evaluating sensor data using a second function to determine whether a *predicted* glucose value meets one or more *non-user* settable criteria, and activating an indicator if the user-settable or non-user-settable criteria are met. *See* Limitations 1[a]-1[c] and 24[c]-24[e].³

Thus, every Challenged Claim requires evaluating sensor data to determine whether a *predicted* glucose value meets one or more *non-user* settable criteria.⁴ *See* Limitations 1[b] and 24[d].

III. PETITIONER’S GROUNDS FAIL

Only Grounds I and VI challenge the independent claims (claims 1 and 24). Petition, 6. The remaining grounds (Grounds II-V and VII-IX) challenge only dependent claims. Petition, 6-7.

³ DexCom adopts Abbott’s claim limitation labelling for the Board’s convenience. *See* Petition, 9-15.

⁴ For simplicity, DexCom at times uses “fixed” instead of “non-user settable” and “criteria” or “threshold” rather than “one or more ... criteria.” This is not meant to limit the scope of the Challenged Claims which recite “one or more non-user settable criteria.”

Grounds I and VI are fatally flawed for reasons explained below. Grounds II-V inherit Ground I's fatal flaws and Grounds VII-IX inherit Ground VI's fatal flaws. If the Board agrees that Abbott fails to carry its burden in connection with Grounds I and VI institution should be denied.

A. Ground I's Anticipation Showing Fails

Ground I alleges that certain Challenged Claims – including independent claims 1 and 24 – “would have been anticipated and/or obvious based on Brauker (Ex-1005).” Petition, 6. The failings of Ground I's obviousness showing are addressed *infra* §III.B. This section III.A deals with the Petition's failure to prove that Brauker anticipates either independent claim.

1. Abbott Fails to Establish That Brauker Discloses That Its Predictive Alarm Is Non-User Settable as Required by Limitations 1[b] and 24[d]

Brauker is DexCom's application. Petition, 16 and 63. The premise of Abbott's Ground I anticipation argument is that DexCom pursued the '528 Patent in error because DexCom failed to appreciate that it had already invented and described the claimed invention in DexCom's earlier Brauker application. That strains credibility. Brauker does not disclose a fixed predictive alarm.

Every Challenged Claim requires “evaluating sensor data using a second function to determine whether a *predicted* glucose value meets one or more *non-user* settable criteria” (Limitations 1[b] and 24[d]) and “activating a hypoglycemic indicator if ... the one or more non user settable second criteria are met” (Limitations 1[c] and 24[e]).

To prove anticipation of any Challenged Claim based on Brauker, Abbott bears the burden to show that Brauker discloses all the elements of the claim arranged as required by the claim. *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008) (an anticipatory reference must disclose “within the four corners of the document not only all of the limitations claimed but also *all of the limitations arranged or combined in the same way as recited in the claim*”). Abbott fails to carry that burden because it fails to establish that Brauker discloses determining whether a *predicted* glucose value meets one or more *non-user settable* criteria (Limitations 1[b] and 24[d]) in any embodiment, let alone in the embodiment that Abbott relies on to purportedly anticipate some of the Challenged Claims.

In the sections below, DexCom focuses on the Petition’s showing for Limitation 1[b] because the Petition makes no separate showing for Limitation 24[d]. Petition, 43 (for Limitation 24[d] – “See Section VIII.A.1.c above for limitation 1[b].”).

a. Abbott Fails to Support Its Assertion That Brauker Teaches That Its Predictive Alarm Threshold Is “Optionally” Non-User Settable

Brauker’s “Summary of the Invention” describes nine different “aspects” of the invention. Brauker, [0005]-[0103] (describing a “first aspect” through a “ninth aspect”). Abbott alleges that Brauker’s “*first aspect*” anticipates claim 1. Petition, 25 (mapping Limitation 1[pre] to the “first aspect”), 26 (mapping Limitations 1[a]-1[b] to the “first aspect”), 31 (mapping Limitation 1[c] to the “first aspect”).

To establish anticipation, Abbott must show that Brauker discloses all the claim elements used together and arranged in the manner claimed. *Net MoneyIN*, 545 F.3d at 1371. Thus, to establish anticipation based on Brauker’s “first aspect,” Abbott must establish that Brauker discloses that its first aspect determines whether a predicted glucose value meets one or more non-user settable criteria as required by Limitation 1[b]. Brauker discloses no such thing. Indeed, Brauker does not disclose that *any* of its nine “aspects” meets Limitation 1[b].

Abbott points to Brauker’s disclosure in [0015] that an embodiment of the first aspect provides a signal “when the estimated glucose value for the future time is below a predetermined threshold.” Petition, 26-27. For purposes of this POPR, DexCom does not dispute that Brauker’s “estimated glucose value for the future time” is a “predicted glucose value” as claimed. But Brauker never teaches that the “predetermined threshold” for this predicted glucose value is non-user settable.

Brauker [0015] says nothing about how the predetermined threshold for the predicted glucose value is set. Abbott admits this. Petition, 27 (“Brauker does not expressly state whether the ‘predetermined threshold’ of the ‘first aspect’ is user settable or non user settable[.]”).

Abbott alleges that “Brauker teaches that the predetermined threshold can optionally be user settable or non user settable” based on three *different* Brauker paragraphs – “Ex-1005, [0035], [0697]-[0698].”⁵ Petition, 27. As detailed below, none of the cited paragraphs – or anything else in Brauker – support’s Abbott’s assertion that the predicted glucose threshold is “optionally ... non user settable.”

i. “Predetermined” Does Not Mean Non-User Settable

In its “Overview” of Brauker, Abbott suggests that the reference to a “predetermined threshold” means the threshold is “pre-programmed at the factory.” Petition, 18 (“the ‘predetermined threshold’ (i.e., threshold pre-programmed at the factory)”). That assertion is unsupported by any credible evidence. Abbott cites nothing in Brauker to support this assertion. *Id.* The Petition only cites “Ex-1003 ¶49” which is testimony from Abbott’s expert.

⁵ Brauker, [0697]-[0698] relate to “clinical risk zones” which are discussed in Section III.A.1.b below.

Worse yet, the cited testimony simply parrots the Petition’s conclusory assertion verbatim without citing any disclosure in Brauker or other *documentary* evidence to support it. Ex-1003 ¶49 (“unlike the user settable “lower glucose threshold,” the “predetermined threshold” (i.e., threshold pre-programmed at the factory) is not limited to being user settable.”) (*citing nothing*). This testimony warrants no weight under the Board’s precedential decision in *Xerox v. Bytemark*, IPR2022-00624, Paper 9, 14-16 (Aug. 24, 2022) (precedential) (“*Xerox*”) (“[T]he cited declaration testimony is conclusory and unsupported, adds little to the conclusory assertion for which it is offered to support, and is entitled to little weight.”) (citing 37 C.F.R. §42.65(a) (“Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight”))).

Additionally, even if “predetermined” meant pre-programmed at the factory (it does not), that does not make Brauker’s threshold non-user settable. CGM devices were well-known to have thresholds that were set to a default by the manufacturer (“pre-programmed at the factory”) but could be overridden by being set to a different value by a user such as the patient or the patient’s doctor. Keenan-Dec-00909, ¶149; Rodbard-Dep-00909, 137:23-139:5, 140:23-142:18; Ex-1008, 51. A non-user settable threshold is one the user cannot set. Petition, 28 (“can be set by a manufacturer *only* (i.e., non user settable.)”). Thus, Abbott’s

suggestion that Brauker's threshold can be "pre-programmed at the factory" (Petition, 18) does not even allege that the threshold is non-user settable as claimed.

Finally, any suggestion that Brauker's use of the term "predetermined threshold" (Brauker, [0015]) describes a threshold that is not settable by the user is directly refuted by Brauker. Brauker explicitly describes a "predetermined threshold [that] is *user configurable*." Brauker, [0035].

Thus, Abbott's suggestion that "predetermined" means non-user settable is unsupported by any credible evidence and directly refuted by Brauker.

ii. Abbott Mixes Alleged Features of Different Brauker Embodiments Which Fails to Establish Anticipation as a Matter of Law

Brauker, [0035] appears in Brauker's "Summary of the Invention." It says in its entirety: "In an embodiment of the *fourth* aspect, the predetermined threshold *is user configurable*." Abbott's assertion that this disclosure somehow "suggests" that the threshold for the predicted glucose value in Brauker's *first* aspect is *not* user settable is based on the convoluted assertion that: "[i]n describing *another embodiment*, Brauker discloses that the predetermined threshold of the 'fourth aspect' is user settable, *which suggests that the predetermined threshold of the 'first aspect' can optionally be user settable as well*. Ex-1005, [0035]." Petition, 27-28.

Abbott's assertion that Brauker's disclosure of a feature of the fourth aspect "suggests" that this feature "can ... as well" be a feature of "another embodiment" (i.e., Brauker's first aspect) is entirely unsupported. This is baseless naked attorney argument that is unsupported by citation to Brauker or any other evidence. Petition, 27-28. Abbott's failure to substantiate that Brauker teaches that its "**first** aspect" has a fixed predicted glucose value is fatal to Ground I's anticipation theory because it is Brauker's "first aspect" that Abbott maps to claim 1's other limitations. Petition, 25 (mapping Limitation 1[pre] to the "first aspect"), 26 (mapping Limitations 1[a] and 1[b] to the "first aspect"), 31 (mapping Limitation 1[c] to the "first aspect"). Anticipation cannot be established by mixing and matching features from what the Petition itself characterizes as different "embodiments" of Brauker. Petition, 27-28 (Brauker's "fourth aspect" is [a]nother embodiment" that differs from the "first aspect"). *Net MoneyIN*, 545 F.3d at 1371 (for anticipation, "it is not enough that the prior art reference discloses ... multiple, distinct teachings that the artisan might somehow combine to achieve the claimed invention").

Thus, even if Brauker disclosed a fixed predicted glucose value threshold for Brauker's "**fourth** aspect" (it does not as discussed *infra* §III.A.1.a.iii immediately below), Abbott fails to establish anticipation because Abbott fails to establish that Brauker's allegedly anticipatory "**first** aspect" determines whether a

predicted glucose value meets one or more non-user settable criteria as required by Limitations 1[b] and 24[d].

iii. Brauker Is Explicit That the Predicted Glucose Value Threshold Is User Settable

Even if Brauker taught that its disclosure in [0035] applies to the “first aspect” alleged to anticipate claim 1 (Brauker says no such thing), there is a second independent reason why Abbott’s assertion that Brauker, [0035] “suggests that the predetermined threshold of the ‘first aspect’ can *optionally be user settable* as well” fails. Petition, 27-28.

Brauker’s paragraph [0035] says the “predetermined threshold” for the predictive alarm is “user configurable.” Abbott’s assertion that this should be read as disclosing precisely the opposite – that the threshold is fixed and non-user settable – is nonsensical.

Brauker only describes the predetermined threshold for the predicted glucose value as being set by the user. Brauker, [0035] and [0697]. That makes eminent sense because it is undisputed that glucose levels vary by patient, and that a glucose level that might be considered problematic and warrant an alarm for one patient may not be of concern for another. Rodbard-Reply-Dep-00909, 15:10-16:22 (*Abbott’s* own expert Dr. Rodbard admitting glucose levels vary so different thresholds are appropriate for different patients).

There is no disclosure in Brauker that the alarm threshold for a predicted glucose value is fixed, let alone an explanation of *why* that threshold would be fixed. It should not be lost on the Board that fixing the predicted glucose value threshold would remove any ability of the patient and the patient's doctor to customize the threshold to suit the patient's personal health needs. In the absence of the inventive discovery that this would increase the accuracy of the predictive alarm (*see supra* §II.B), there was no reason why a POSA would have done this. A POSA would not read disclosure of a fixed threshold into Brauker which nowhere describes it. Additionally, Brauker never identifies any value that the threshold would allegedly be fixed at. Abbott never alleges otherwise. According to Abbott, Brauker teaches that the threshold is fixed, thereby removing the ability to customize the alarm for the patient, but Brauker never even identifies some value that the threshold is allegedly fixed at. That strains credibility.

Abbott's incredible argument appears to be based on the assertion that because Brauker describes "an embodiment" of the fourth aspect where the threshold for a predicted glucose value is "user configurable," this somehow refers to a different embodiment of the fourth aspect – nowhere described in Brauker – where the threshold is *not* user configurable. Nothing supports this strained reading. Every paragraph in Brauker's Summary of the Invention that describes a feature of one of Brauker's "aspects" describes it as a feature of "an embodiment"

of that aspect. Brauker, [0005]-[0103]. The term “embodiment” appears 377 times in Brauker and “embodiments” (plural) appears another 578 times. Disclosure of an “embodiment” that works in a particular way is in no way a disclosure of some unexplained and undescribed different “embodiment” that works a different way.

Abbott’s citation to *Upsher-Smith Lab’ys, Inc. v. Pamlab, L.L.C.*, 412 F.3d 1319, 1322 (Fed. Cir. 2005) is inapposite. Petition, 27. As Abbott itself admits, “[i]n *Upsher-Smith*, a prior art reference disclosed a vitamin that ‘**optionally includes**’ antioxidants” which “taught both a vitamin including antioxidants and a vitamin excluding antioxidants.” Petition, 27. The disclosure that the vitamin “optionally” included antioxidants is indeed a disclosure of a vitamin without antioxidants, in much the same way that disclosure of a car with an option to have heated seats discloses a car without heated seats. But Brauker does not disclose that the threshold for the predicted glucose value is “optionally” user configurable. Brauker discloses that the “threshold **is** user configurable.” Brauker, [0035]. *Upsher-Smith* does not help Abbott and cannot inject into Brauker disclosure of a fixed threshold for a predicted glucose value that is not disclosed anywhere in Brauker.

To anticipate a Challenged Claim, Brauker must **unambiguously** disclose that the threshold for the predicted glucose value is non-user settable. *Wasica Fin.*

GMBH v. Cont'l Auto. Sys., Inc., 853 F.3d 1272, 1284 (Fed. Cir. 2017)

(“*ambiguous references do not, as a matter of law, anticipate.*”). Abbott fails to establish that Brauker discloses this unambiguously. Thus, “as a matter of law,” Brauker does not anticipate any Challenged Claim. *Wasica*, 853 F.3d at 1284.

b. Abbott Obfuscates by Citing Brauker’s Clinical Risk Zones

As noted *Supra* §III.A.1.a, Abbott alleges that its assertion that “Brauker teaches that the predetermined threshold can optionally be user settable or non user settable” is also supported by Brauker, [0697]-[0698]. Petition, 27-28. But as the Petition admits, these Brauker paragraphs relate to “clinical risk zones.” *Id.* Abbott’s assertion that Brauker’s clinical risk zones support Abbott’s anticipation argument fails for multiple reasons.

First, as mentioned above, Abbott alleges that claim 1 is anticipated by Brauker’s “first aspect.” Petition, 25 (mapping Limitation 1[pre] to the “first aspect”), 26 (mapping Limitations 1[a]-1[b] to the “first aspect”), 31 (mapping Limitation 1[c] to the “first aspect”). Abbott does not even allege that Brauker’s clinical risk zones are part of Brauker’s “first aspect” that the Petition itself characterizes as an “embodiment” of Brauker. Petition, 27-28 (the fourth aspect is “another embodiment”). Abbott’s reliance on Brauker’s clinical risk zones to meet one feature of Limitation 1[b], despite relying on Brauker’s “first aspect” to meet the remainder of claim 1, fails to establish anticipation because Abbott fails to

even allege, let alone establish, that Brauker's clinical risk zones are present in Brauker's "first aspect." Abbott thus fails to establish that Brauker discloses "all of the limitations *arranged or combined in the same way as recited in*" *claim 1*. *Net MoneyIN*, 545 F.3d at 1371.

Second, Limitation 1[c] requires activating a hypoglycemic indicator if the non-user settable criteria are met and providing an output based on the hypoglycemic indicator. Abbott never even attempts to map Brauker's clinical risk zones to Limitation 1[c]. Petition, 31. Thus, even if Brauker taught that its clinical risk zones were non-user settable and part of Brauker's "first aspect" (it teaches neither), the Petition fails to establish anticipation because it never maps Limitation 1[c] to any indicator and output activated when the alleged non-user settable criteria of Brauker's clinical risk zones are met. Once again, Abbott fails to establish anticipation because it fails to establish that Brauker discloses all the claimed elements *arranged as required by any Challenged Claim*. *Net MoneyIN*, 545 F.3d at 1371.

Third, Abbott cites Brauker's disclosure that "[c]linical risk zones 504 can be set by a manufacturer, customized by a doctor, and/or set by a user via buttons 172." Brauker, [0698] (cited Petition, 28). According to Abbott, this allegedly discloses "[o]ne option" where the clinical risk zones "can be set by a

manufacturer **only** (i.e., non user settable).” Petition, 28. Brauker says no such thing.

Abbott does not dispute that if the clinical risk zones can be set by the manufacturer **and** also by a “doctor” or “user” then the zones are **not** non-user settable. Petition, 28 (“can be set by a manufacturer **only** (i.e., non user settable)”); Ex-1001, 16:53-55 (“user” is a “host or a care provider”), claims 20 and 43 (both reciting “the user is a host or a healthcare provider”). CGM devices were known to have thresholds set to a default value by the manufacturer but that could be overridden by the user by setting the threshold to a different value. Keenan-Decl-00909, ¶149; Rodbard-Dep-00909, 137:23-139:5, 140:23-142:18; Ex-1008, 51. Abbott does not dispute that such a threshold would not meet the claimed non-user-settable requirement because it is settable by a user. Petition, 28 (“non user settable” means “can be set by a manufacturer **only**”).

Abbott does not read the “and/or” in Brauker, [0698] to mean that there is one system where clinical risk zones are settable by any and all of the manufacturer, doctor and user. Instead, Abbott reads “and/or” to mean that Brauker describes multiple different and distinct systems. Petition, 28. According to Abbott, the “and/or” means that Brauker describes “one option” in which the clinical risk zones are fixed by the manufacturer so that neither the “doctor” nor

“user” can change them, and “other options” where the risk zones “can be set by a doctor or a user.” *Id.* That is an unreasonable reading of Brauker.

But even if the Board were to find Brauker’s “and/or” sentence to be subject to two possible alternative meanings – one describing a single system where the clinical risk zones are settable by any and all of the manufacturer, doctor and user and another describing different “options” including one where the clinical risk zones are set just by the manufacturer and not user settable – Brauker does not anticipate because the Federal Circuit is clear that “***ambiguous references do not, as a matter of law, anticipate.***” *Wasica*, 853 F.3d at 1284. The use of “and/or” has been criticized as ambiguous. *See, e.g.*, William Strunk Jr & EB White, *The Elements of Style*, 4th ed. (New York: Longman, 1999) at 40 (“And/or. A device, or shortcut, that damages a sentence and often leads to confusion or ambiguity.”); Bryan A Garner (with Jeff Newman and Tiger Jackson), *The Redbook: A Manual on Legal Style* (St. Paul, MN: West Group, 2002), Rule 1.80 at 43 (“The slash... is best known as the star character in two grammatical abominations: and/or and he/she. It is especially unfit for legal writing because it is inherently ambiguous.”).

Abbott fails to establish that Brauker unambiguously discloses that the clinical risk zones are set by the manufacturer and cannot be changed by the patient or doctor using “buttons 172” that Brauker expressly describes for that

purpose. Brauker, [0698]. Thus, Abbott fails to establish anticipation for this additional reason. *Wasica*, 853 F.3d at 1284 (“ambiguous references do not, as a matter of law, anticipate.”).

As explained above, Brauker’s clinical risk zones do not help Abbott because (1) Abbott fails to establish that they are included in Brauker’s “first aspect” alleged to anticipate claim 1, (2) the Petition does not map Limitation 1[c] to anything relating to the clinical risk zones, and (3) Abbott fails to establish that Brauker unambiguously discloses that the clinical risk zones cannot be set by a user using Brauker’s “buttons 172.” Brauker, [0698].

c. The UK High Court Decision Is Irrelevant

Abbott alleges that the UK High Court found a “similar” claim of a European counterpart anticipated by Brauker. Petition, 27 (footnote 4). Abbott relegates this to a footnote for good reason. The UK High Court Decision cannot save Abbott from its failure to carry its *burden in this proceeding* to prove any Challenged Claim anticipated by Brauker.

The UK High Court Decision says the “central dispute” was whether Brauker’s disclosure of clinical risk zones set by the manufacturer and/or by others meant the zones were fixed. Ex. 1028, 123 (¶552). Under UK law – which has different patentability standards – the High Court read this ambiguous disclosure as teaching that the zones are fixed so that Brauker anticipated the claims. The

same result is not possible under United States law because “ambiguous references do not, as a matter of law, anticipate.” *Wasica*, 853 F.3d at 1284. The UK High Court Decision also cannot save Abbott from its failure to establish that the clinical risk zones are included in Brauker’s “first aspect” that is alleged to anticipate claim 1, nor from the Petition’s failure to map Limitation 1[c] to anything relating to the clinical risk zones. *See supra* §III.A.1.b.

d. Conclusion – Ground I’s Anticipation Arguments Fail

For the reasons stated above, Abbott fails to demonstrate that any Challenged Claim is anticipated by Brauker. Ground I’s anticipation arguments fail.

B. Ground I’s Obviousness Showing Fails

Abbott alternatively alleges that the requirement in Limitations 1[b] and 24[d] of determining whether a *predicted* glucose value meets one or more *non-user-settable* criteria is rendered obvious by Brauker. Petition, 29.

While styled as being based on Brauker alone, Ground I relies heavily on another DexCom reference (“STS Guide,” Ex-1008) that discloses a fixed *real-time* low glucose alarm that is an *additional* alarm in addition to a user-settable low glucose alarm. Neither Brauker nor the STS Guide teaches a fixed threshold for a *predictive* alarm. Abbott’s assertion that a POSA would have been motivated by these references to implement a fixed *predictive*

alarm – despite neither reference disclosing this – is unsupported and based on nothing but hindsight.

It is undisputed that neither Brauker, the STS Guide nor any other prior art reference taught fixing the threshold for a predictive alarm *for the purpose of improving its accuracy*. This inventive discovery of the '528 Patent inventors appears nowhere in the art. *See Supra* §II.B.2. In the absence of that inventive discovery, there was simply no reason why a POSA would have fixed the threshold for a *predictive* alarm. Abbott's attempts to establish some non-hindsight reason why a POSA would have done so fail for the reasons detailed below.

1. The Board Routinely Denies Institution When a Petition Relies on Prior Art That Fails to Disclose a Missing Claim Limitation

The Board's rules are clear that "the petition *must* specify where *each element* of the claim is *found in the prior art patents or printed publications relied upon*." 37 C.F.R. §42.104(b)(4). Neither Brauker nor the STS Guide discloses the limitation in every Challenged Claim that requires "using a second function to determine whether a predicted glucose value meets one or more non user settable criteria." Limitations 1[b] and 24[d]. Abbott's assertion that a POSA would have been motivated by the teachings of these DexCom references to arrive at this claim limitation – despite it being absent from *both* references – is based on

nothing but an unsupported assertion from Petitioner’s expert. The risk of hindsight bias in such circumstances is apparent. As a result, the Board routinely denies institution when a petition relies on an expert’s say-so to meet a limitation missing from the art. *Xerox*, Paper 9, 14-16 (denying institution due to “a limitation missing from the prior art”); *Apple v. Mullen Indus.*, IPR2023-00087, Paper 10, 19-20 (May 3, 2023) (“*Apple*”) (same). The Board should do the same here.

a. Abbott Relies on Expert Testimony to Supply a Claim Limitation Missing from the Art

It is true that the STS Guide discloses “a CGM system with *both* user settable and non user settable alarms.” Petition, 29 (emphasis original). But the STS Guide uses a non-user settable threshold for a *real-time alarm – not for a predictive alarm*. Ex-1008, 56; Petition, 23. The STS Guide does not support Abbott’s assertion that a POSA would have fixed the threshold for Brauker’s *predictive* alarm.

Abbott alleges that the STS Guide would have motivated a POSA to modify Brauker to make an alarm non-user settable. But Abbott does not allege that a POSA would have modified Brauker to do what the STS Guide actually teaches, which is adding a fixed *real-time* low glucose alarm. Instead, Abbott alleges that the STS Guide would have motivated a POSA to fix the threshold for Brauker’s *predictive* alarm. Petition, 29-31. That is based on nothing but a blatant attempt to

reconstruct the claims in hindsight. Abbott attempts to meet with expert testimony claim limitations (Limitations 1[b] and 24[d]) that are entirely missing from the prior art. The Federal Circuit has made clear that it is a rare case where a missing claim limitation can be met by expert testimony alone, and Abbott fails to establish the factual predicate needed to do so.

b. Expert Testimony Can Supply a Missing Limitation Only in Rare Circumstances Absent Here

The Federal Circuit has repeatedly held that for expert testimony to supply a claim limitation missing from the prior art, “the limitation in question [must be] unusually simple and the technology particularly straightforward.” *Arendi S.A.R.L. v. Apple Inc.*, 832 F.3d 1355, 1362 (Fed. Cir. 2016); *see also DSS Tech. Mgmt., Inc. v. Apple Inc.*, 885 F.3d 1367, 1374 (Fed. Cir. 2018) (“we have invoked common sense to fill in a *missing* limitation only when the limitation in question was unusually simple and the technology particularly straightforward.”) (internal quotes and citations omitted) (emphasis original).

In *Arendi*, the Federal Circuit reversed the Board’s finding of obviousness when not all limitations were disclosed by the prior art. 832 F.3d at 1366. The claimed technology related to a method of identifying duplicate entries in a database and the prior art disclosed a computerized address book. *Id.*, 1358-59. The Board reasoned that “it would have been obvious to ... search for duplicate telephone entries when entering a telephone number in an electronic address

book.” *Id.*, 1360. The Federal Circuit disagreed, noting that the prior art reference did “not mention or imply that a search of any kind is involved with the ‘Add to address book’ function.” *Id.*, 1363. The “only documentary support the Board recited was the declaration of ... Appellees’ expert.” *Id.*, 1364. The Federal Circuit found that the Board erred by relying on “conclusory statements and unspecific expert testimony regarding searches in general,” which was “particularly problematic considering the fact that a key limitation of the [patent – identifying duplicate entries –] was missing from the prior art.” *Id.*, 1366.

In *DSS Tech.*, the Federal Circuit again reversed the Board’s finding of obviousness when not all limitations were disclosed by the prior art. 885 F.3d at 1375. The claimed technology related to a communication network with a single base station and multiple peripheral devices, where each was “energized in low duty cycle RF bursts” intermittently. *Id.*, 1369-70. The prior art taught *peripheral devices* that operated in this manner, but *not the base station*. *Id.*, 1373. The Board found that it would have been obvious “to have the base station operate in an analogous manner” to the peripheral devices. *Id.* The Federal Circuit disagreed because the limitation at issue was “not ‘unusually simple,’ and the technology is not ‘particularly straightforward.’” *Id.*, 1375 (quoting *Arendi*).

The Federal Circuit has only sanctioned supplying a missing limitation through expert testimony in the rare circumstance where the prior art discloses every claimed element, but not the **repetition** of a known prior art element as required by a claim. For example, in *B/E Aerospace*, the Federal Circuit found that the claimed technology (“lavatory enclosures”) was not complex and that the claimed “second recess” simply involved “**repetition** of an existing element” (a disclosed first recess), and thus was obvious despite the prior art not having two recesses. *B/E Aerospace, Inc. v. C&D Zodiac, Inc.*, 962 F.3d 1373, 1380 (Fed. Cir. 2020). Another oft-cited example is *Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324 (Fed. Cir. 2009). The Federal Circuit has characterized *Perfect Web* as a case where the patented invention related to a 3-step process of sending marketing emails where the “missing claim limitation” “was nothing more than an instruction to **repeat** [the three] steps A, B, and C until a particular quantity of email was sent in accordance with the claim.” *Arendi*, 832 F.3d at 1362. The Federal Circuit has made clear that “the facts in *Perfect Web* ... ought to be treated as the **exception, rather than the rule.**” *Id.*

c. The Board Routinely Denies Institution Where Petitioners Fail to Justify Reliance on Expert Testimony to Supply a Claim Limitation Missing from the Art

Abbott does not even attempt to establish that its reliance on expert testimony to supply a claim limitation missing from the cited prior art is

consistent with Federal Circuit precedent. That is reason enough to deny institution.

The Board’s *Xerox* decision involved a “mobile ticketing system for detecting fraudulent activity” and the claimed method required a step of “stor[ing] in a data record associated with the account a data value indicating the fraudulent activity.” *Xerox*, IPR2022- 00624, Paper 9, 6. While the prior art (“Terrell”) taught that “the purchaser of the ticket could be blocked from further use of the system,” the petitioner did not allege that Terrell disclosed storing a data value indicating the fraudulent activity as claimed. *Id.*, 14. Instead, petitioner alleged that POSAs “‘would find it obvious’ that ‘blocking the account of the purchaser’ would includ[e] ‘storing a data value indicating the fraudulent activity in a data record associated with the user account.’” *Id.* “Petitioner’s only evidence in support of its assertion ... [was] the opinion of its Declarant, Dr. Jones.” *Id.*, 15.

In denying institution, the Board not only found that Dr. Jones failed to adequately support his opinions, but that petitioner ran afoul of the Federal Circuit’s *Arendi* decision. *Xerox*, 16. The Board noted that “[p]etitioner has not alleged” that “the limitation in question [is] unusually simple and the technology particularly straightforward,” “much less provided support for such an allegation.” *Id.* (quoting *Arendi*).

The Board reached a similar result in *Apple*, IPR2023-00087, Paper 10, 19-20. That case involved “systems and methods for determining a device’s location” (*id.*, 3) and the claims required the “device to display indicia of two locations other than its own” (*id.*, 15). The prior art (“Sheha”) disclosed “displaying the location of a caller and a called device on a screen, but [did] not disclose displaying multiple locations of other users.” *Id.*, 17. Petitioner alleged “it would have been obvious to display the locations of second and third devices simultaneously.” *Id.* Petitioner’s only evidence was “the opinion of its Declarant, Mr. Williams.” *Id.*, 17-18.

In addition to finding that Mr. Williams failed to adequately support his opinions (*id.*, 18), the Board found that petitioner ran afoul of *Arendi*. *Id.*, 19. The Board noted that “[p]etitioner has not alleged” that “the limitation in question [is] unusually simple and the technology particularly straightforward,” “much less provided support for such an allegation” (*id.*, 19-20). The Board denied institution at least in part on that basis. *Id.* (quoting *Arendi*).

Just like the petitioners in *Xerox* and *Apple*, Abbott did not even allege that the missing claim limitation of “determining whether a predicted glucose value meets one or more non user settable criteria” is unusually simple or that the claimed technology is particularly straightforward. Neither is true. Predictive alarms use complex algorithms like Kalman filters or autoregressive

models. Ex-1001, 24:15-24. Fixing the threshold for a predictive alarm would require choosing a threshold that is appropriate for *every* patient because the alarm could not be adjusted by any patient. It is undisputed that what particular glucose levels are worrisome and warrant an alarm vary from patient to patient. Rodbard-Reply-Dep-00909, 15:10-16:22 (admitting glucose levels vary so different thresholds are appropriate for different patients). Abbott never even identifies any particular threshold that a POSA allegedly would have chosen that would be suitable for every patient, let alone substantiate *with evidence* a reason why a POSA would have chosen that (unidentified) threshold for predictive alerts.

Petitioner's failure to establish that this is one of the rare exceptions to the rule forbidding reliance on expert testimony alone to meet a claim limitation missing from the prior art is reason enough why Ground I's obviousness argument fails.

2. That the Inventors Proceeded Contrary to Accepted Wisdom Evidences Non-obviousness

The extraordinary nature of Abbott's hindsight obviousness argument should not be lost on the Board. *Every* prior art system that used a predictive alarm used a *user-settable* predictive alarm. *Supra* §II.B.2. That is for good reason. As Abbott's own expert Dr. Rodbard has admitted, glucose levels vary by patient so different thresholds are appropriate for different patients. Rodbard-

Reply-Dep-00909, 15:10-16:22; *see also* Ex-1008, 51 (referring to a patient’s “*personal* diabetes goals”).

In addition, the evidence is overwhelming that conventional predictive alarms were inaccurate. *Supra* §II.B.1. Because conventional predictive alarms were user-settable, the patient or the patient’s doctor could adjust a predictive alarm that generated too many false alarms to avoid the patient developing alarm fatigue which could dangerously cause the patient to overlook an accurate alarm warning of a condition warranting the patient’s attention. *Supra* §II.B.2.

The inventors took a different approach based on their unexpected discovery that fixing the threshold for a predictive alarm increased accuracy and reduced the false alarm rate. That is strong evidence of non-obviousness. *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 668 (Fed. Cir. 2000) (“[P]roceeding contrary to the accepted wisdom ... is ‘strong evidence of unobviousness.’”) (citations omitted).

To demonstrate obviousness, Abbott needed to provide some *evidence-based* reason *why* a POSA would have modified a predictive alarm to make it non-user-settable. As explained below, the Petition failed to do so.

3. The Petition Establishes No Supportable Reason to Modify Brauker to Fix the Threshold for its Predicted Glucose Value

Establishing obviousness requires establishing some non-hindsight reason to modify the prior art ***in the manner claimed***. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007); *TQ Delta, LLC v. CISCO Sys., Inc.*, 942 F.3d 1352, 1359 (Fed. Cir. 2019) (reversing the Board’s obviousness determination; “a conclusory assertion with no explanation is inadequate to support a finding that there would have been a motivation to combine because ‘this type of finding, without more, tracks the *ex post* reasoning KSR warned of and ***fails to identify any actual reason why a skilled artisan would have combined the elements in the manner claimed***.’”) (internal citation omitted).

The Petition alleges a handful of reasons why a POSA allegedly would have fixed the threshold for Brauker’s predictive alarm. Petition, 29-31. None is supportable.

a. No Prior Art Teaching Would Have Motivated a POSA to Fix the Threshold for Brauker’s Predictive Alarm

Abbott alleges that a user of Brauker’s system could set “unsafe values for the ***real time***, user settable low glucose alarm” which could lead to “an adverse event for the user.” Petition, 29-30. To address this concern, Abbott alleges a POSA would have been motivated to modify Brauker to achieve the benefit of “using a non user settable low glucose alarm” to “provid[e] a ‘safety net’ of non user settable criteria.” *Id.* But the motivation Abbott identifies would not have led a POSA to fix Brauker’s ***predictive*** alarm. Rather, the “safety net” benefit that

Abbott alleges would have motivated a POSA to modify Brauker would have been achieved by simply adding to Brauker a fixed *real-time* low glucose alarm precisely as taught by the STS Guide.

The only prior art teachings Abbott cites in support of its “safety net” argument are the STS Guide’s *real-time* low glucose alarm with a fixed threshold of 55 mg/dL (Ex-1008, 56) and Hayter’s recommendation that “[t]he user should never go below 50 mg / dL at any time without an alarm” (Ex-1013, 725).

Petition, 29-31. A POSA motivated by the STS Guide would have done what the STS Guide teaches and added to Brauker’s system an additional *real-time* low glucose alarm fixed at 55 mg/dL. Doing so would have also achieved Hayter’s recommendation that the user “never go below 50 mg/dL ... without an alarm.” Ex-1013, 725. Adding the STS Guide’s fixed alarm that the user “cannot change or turn off” (Ex-1008, 56) would have ensured that whenever the user’s glucose level fell to 55 mg/dL an alarm would be generated so the user would “never go below 50 mg/dL ... without an alarm” as Hayter recommends (Ex-1013, 725).

Even though the cited prior art teachings would have unambiguously led a POSA to add to Brauker an additional fixed *real-time* low glucose alarm to provide the “safety net” benefit the Petition identifies, Abbott states in conclusory fashion that a POSA would have done something very different. Abbott alleges that a POSA would have instead fixed the threshold for Brauker’s “*predicted* low

glucose alarm” to provide the “safety net” (Petition, 30) of an alarm “guaranteed to be triggered if the user’s glucose is *expected* to hit” a dangerously low level (*id.*, 29). Nothing supports this.

Again, the only *prior art* evidence the Petition cites is the STS Guide and Hayter, neither of which supports the Petition’s hindsight assertion. The only other evidence the Petition cites is three paragraphs of expert testimony (Ex-1003, ¶¶76-78) that *parrot word-for-word* the three paragraphs of conclusory obviousness “analysis” in the Petition. *Compare* Petition, 29-31 *with* Ex-1003, ¶¶76-78. This testimony provides no analysis, and cites no corroborating evidence, to support the naked conclusory assertion that a POSA would have been motivated by safety concerns to fix the threshold for Brauker’s *predicted* alarm rather adding a fixed *real-time* alarm as taught by the STS Guide. As the Board’s precedential *Xerox* case establishes, this conclusory unsupported testimony warrants no weight. *Xerox*, 14-16 (“[T]he cited declaration *testimony is conclusory and unsupported*, adds little to the conclusory assertion for which it is offered to support, and is *entitled to little weight.*”) (citing 37 C.F.R. §42.65(a)).

Even if the Board were inclined to credit Dr. Rodbard’s conclusory unsupported testimony alleging that a POSA would have fixed the threshold for a *predicted* glucose value, this limitation in every Challenged Claim (*supra* §II.D) is entirely missing from the prior art and Abbott fails to establish that this is among

the rare cases where a missing claim limitation can be supplied by expert testimony alone. *See supra* §III.B.1.c.

The blatant hindsight underlying Abbott’s obviousness argument is apparent. It was DexCom’s inventive insight that fixing the threshold for a predictive alarm would increase its accuracy. *Supra* §II.B.3. Lacking that inventive insight found in the ’528 Patent but nowhere in the art, there was no reason why a POSA would have fixed the threshold for Brauker’s *predictive* alarm until DexCom revealed one. *Arkie Lures, Inc. v. Gene Larew Tackle, Inc.*, 119 F.3d 953, 956 (Fed. Cir. 1997) (“Good ideas may well appear ‘obvious’ after they have been disclosed, despite having been previously unrecognized.”). The naked hindsight say-so of Abbott’s expert cannot carry Abbott’s burden to establish a supportable non-hindsight reason why a POSA would have fixed the threshold for Brauker’s *predictive* alarm. *KSR*, 550 U.S. at 418 (a “reason” is required); *TQ Delta*, 942 F.3d at 1359 (same); *Xerox*, 14-16 (conclusory testimony warrants no weight); *supra* §III.B.1.c (expert testimony alone cannot supply a claim limitation missing from the prior art).

Abbott is well aware that the only modification to Brauker supported by the prior art’s teachings is to “add a *real time*, non user settable low glucose alarm” as taught by the STS Guide. Petition, 30 (fn. 5) (emphasis original). In a statement that reveals Abbott’s improper use of hindsight bias, Abbott alleges that

“[a]lthough a POSITA could” have done this, that “is not relevant to this limitation [1[b]], which neither requires nor prohibits such an alarm.” *Id.*

The Federal Circuit has made clear that “a *prerequisite* to adequately explaining and supporting a conclusion” of obviousness is “a clear, *evidence-supported* account of the contemplated workings of the combination.” *Pers. WebTechs., LLC v. Apple, Inc.*, 848 F.3d 987, 994 (Fed. Cir. 2017). What a POSA would have been motivated to do based on the teachings of the art is highly “relevant” (Petition, 30 (fn. 5)) to Abbott’s obligation to provide an “evidence-based” account of its modification to Brauker. While the claims do not “prohibit[]” a fixed real-time low glucose alarm (*id.*), that a POSA would have understood that adding a fixed real-time low glucose alarm to Brauker’s system would have achieved the “safety net” benefits the Petition identifies as motivating the combination is highly “relevant” (*id.*) because it reveals that Abbott’s assertion that a POSA would have done something different than the STS Guide teaches by fixing a *predicted* alarm threshold is unsupported by any credible evidence.

b. Abbott’s “Obvious to Try” Argument Fails

Abbott repeats its erroneous assertion that Brauker discloses that the threshold for its predictive alarm “can optionally be user settable or non user settable,” and then states that it “would have been obvious to try a non user settable” threshold. Petition, 29. Abbott’s argument that Brauker discloses that

the threshold can “optionally” be non-user settable is an *anticipation* argument that fails for the reasons discussed *supra* §III.A.

Abbott offers no meaningful “obvious to try” argument. Abbott simply states the naked conclusion that it “would have been obvious to try a non user settable” threshold. Petition, 29. Abbott fails to even allege, let alone establish, a “reason” why a POSA would have done so. That is fatal to its obvious to try argument because a supportable *reason* to modify the prior art is required to establish obviousness. *KSR*, 550 U.S. at 418; *TQ Delta*, 942 F.3d at 1359.

Abbott’s “obvious to try” argument is also unsupported by any credible evidence. Abbott only cites a paragraph of expert testimony (Ex-1003, ¶76). Petition, 29. That testimony warrants no weight because it merely repeats the Petition’s naked conclusion verbatim with no supporting analysis or corroborating evidence. *Xerox*, 14-16.

c. Abbott’s “Separate Embodiments” Argument Cannot Save Ground I

Abbott’s last Ground I obviousness argument alleges that even if Brauker discloses “a real time glucose alarm and a predicted low glucose alarm only in separate embodiments, it would have been obvious to combine them” to “advantageous[ly]” use them together. Petition, 30-31.

DexCom does not dispute that a POSA would have known to implement a system with both real time and predictive low glucose alarms. But that does not

help Abbott because Brauker’s predictive low glucose alarm is user settable – it is not non-user-settable as required by every Challenged Claim. *See supra* §II.D.

This “separate embodiments” obviousness argument does not even allege that a POSA had any reason to modify Brauker’s predictive glucose alarm to use non-user-settable criteria. Petition, 30-31. Thus, it cannot save Ground I from Abbott’s failure to establish an evidence-based non-hindsight reason why a POSA would have done so. *See supra* §III.B.3.a.

4. Conclusion – Ground I’s Obviousness Argument Fails

The law is clear that to carry its burden of proving obviousness, Abbott had to establish with evidence some supportable non-hindsight *reason why* a POSA would have modified Brauker to determine whether a predicted glucose value meets one or more non-user settable criteria as required by every Challenged Claim. The Petition failed to do so and that is fatal to Ground I’s obviousness showing.

C. Grounds II-V Fall with Ground I

Ground II alleges obviousness of dependent claims 3 and 26. Claim 3 depends from claim 2. Abbott relies on Ground I’s showing to meet claim 2’s limitations in claim 3. Petition, 46 (“Brauker anticipates and/or renders obvious claim 2”). And Abbott relies on claim 3’s showing to meet claim 26. *Id.*, 49 (“See Section VIII.B.1 above for claim 3”). Thus, Ground II fails for the same reasons as Ground I. *Supra* §§III.A-III.B.

Ground III alleges obviousness of dependent claims 5 and 28. Claim 5 depends from claim 1. Abbott relies on Ground I's showing to meet claim 1's limitations in claim 5. Petition, 49 ("Brauker anticipates and/or renders obvious claim 1"). And Abbott relies on claim 5's showing to meet claim 28. *Id.*, 52 ("See Section VIII.C.1 above for claim 5"). Thus, Ground III fails for the same reasons as Ground I. *Supra* §§III.A-III.B.

Ground IV alleges obviousness of dependent claims 13 and 36. Claim 13 depends from claim 1. Abbott relies on Ground I's claim 1 showing in challenging claim 13. Petition, 53 ("Brauker anticipates and/or renders obvious claim 1"). And Abbott relies on claim 13's showing to meet claim 36. *Id.*, 55 ("See Section VIII.D.1 above for claim 13"). Thus, Ground IV fails for the same reasons as Ground I. *Supra* §§III.A-III.B.

Ground V alleges obviousness of dependent claims 16-17 and 39-40. Claims 16-17 depend from claim 1. Abbott relies on Ground I's claim 1 showing in challenging claims 16-17. Petition, 55 ("Brauker anticipates and/or renders obvious claim 1") and 58 (same). For claims 39-40, Abbott relies on its showing for claims 16-17, respectively. Petition, 59 (for claim 39 "See Section VIII.E.1 above for claim 16"), *id.* (for claim 40 "See Section VIII.E.2 above for claim 17"). Thus, Ground V fails for the same reasons as Ground I. *Supra* §§III.A-III.B.

D. Ground VI (Obviousness Over the STS Guide and Brauker) Fails

Ground VI alleges that independent claims 1 and 24 and other Challenged Claims are rendered obvious by the same STS Guide and Brauker references used in Ground I.

Ground VI alleges that Brauker would have motivated a POSA to add a predictive alarm to the STS Guide. But such a modification would not have yielded a system meeting any Challenged Claim because Brauker's predictive alarm is user-settable and not ***non-user-settable*** as claimed. *Supra* §II.D. So Ground VI goes further. Despite the threshold for Brauker's predictive alarm being user-settable, and despite the STS Guide providing no teaching relating to a predictive alarm whatsoever, Abbott alleges that a POSA would have fixed the threshold for the predictive alarm in the STS Guide-Brauker combination. Petition, 62-65. That assertion is based on nothing but hindsight.

DexCom's inventive insight that fixing the threshold for a predictive alarm would increase its accuracy is not taught in the STS Guide, Brauker or any other prior art reference. *See supra* §§II.B.2-II.B.3. Lacking that inventive insight, there was no reason why a POSA would have fixed the threshold for the predictive alarm in the STS Guide-Brauker combination. Abbott relies entirely on the naked say-so of its expert – in testimony that parrots word-for-word the Petition's conclusory assertions – in an attempt to

meet claim Limitations 1[a] and 24[d] that are missing from the prior art.

That fails to carry Abbott's burden.

1. Ground VI Seeks to Meet a Claim Limitation Missing from the Prior Art with Unsupported Conclusory Expert Testimony

Ground VI relies on the STS Guide and Brauker. Neither discloses the limitation in every Challenged Claim that requires determining whether a *predicted* glucose value meets one or more *non-user-settable* criteria. As it did in Ground I's obviousness argument (*see supra* §III.B.1.a), Abbott seeks to meet this limitation missing from both of Ground VI's prior art references with nothing but unsupported conclusory testimony from Abbott's expert.

Abbott cites the STS Guide's disclosure of an alarm with a non-user settable threshold, but Abbott acknowledges this is a *real-time* alarm – not a *predictive* alarm. Petition, 61; Ex-1008, 56.

Abbott relies on Brauker to disclose a predictive alarm and alleges that a POSA had reason to add Brauker's predictive alarm to the STS Guide to provide advanced warning of potential hypoglycemia. Petition, 62-63. But adding Brauker's user-settable predictive alarm to the STS Guide would not meet any Challenged Claim. Brauker, [0035]; *supra* §III.A.1.a.iii.

In contrast to Ground I which alleged that Brauker teaches that its predictive alarm can “optionally” be fixed, Abbott never argues this for Ground VI. Petition,

62-65. Yet, Abbott alleges that a POSA would have combined the STS Guide and Brauker to do something that neither discloses – use a fixed threshold for a predictive alarm. *Id.* This is a blatant attempt to reconstruct the claims in hindsight.

The only evidence Abbott cites to purportedly meet the claimed requirement of determining whether a *predicted* glucose value meets one or more *non-user-settable* criteria is three paragraphs of expert testimony. Petition, 62-65 (citing Ex-1003, ¶¶146-148).⁶ As discussed *supra* §III.B.1.b, the Federal Circuit has made clear that a claim limitation absent from the art can rarely be met by expert testimony alone and Abbott failed to establish the factual predicate necessary to demonstrate that this is one of those rare cases. The Board routinely denies institution where a petition relies only on an expert’s naked say-so to meet a limitation missing from the art. *Xerox*, 14-16 (denying institution due to “a limitation missing from the prior art”); *Apple*, 19-20 (same); 37 C.F.R. §42.104(b)(4) (“the petition *must* specify where each element of the claim is found *in the prior art patents or printed publications relied upon*”). The Board should deny Ground VI for this reason alone.

⁶ This testimony parrots the Petition verbatim and warrants no weight. See §III.D.3.d below.

2. That the Inventors Proceeded Contrary to Accepted Wisdom Evidences Non-obviousness

As discussed *supra* §III.B.2, 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. The inventors took a different approach based on their unexpected discovery that fixing the threshold for a predictive alarm increased accuracy and reduced false alarms. *See supra* §II.B.3. That the inventors “proceed[ed] contrary to the accepted wisdom ... is ‘strong evidence of unobviousness.’” *Ruiz*, 234 F.3d at 668 (citations omitted).

Abbott bore the burden to establish some evidence-based reason why a POSA would have used a ***non-user-settable*** predictive alarm in the STS Guide-Brauker Combination. As explained below, Abbott failed to do so.

3. Abbott Establishes No Supportable Reason to Fix the Threshold for the Predicted Glucose Value in the STS Guide-Brauker Combination

Establishing obviousness requires establishing some non-hindsight reason to modify the prior art ***in the manner claimed***. *KSR*, 550 U.S. at 418; *TQ Delta*, 942 F.3d at 1359. It is insufficient to establish a reason to combine the prior art references in ***some*** way. Abbott needed to establish some reason why a POSA “would have selected and combined [the] prior art elements” in a manner that

“yield[s] the claimed invention.” *Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1360 (Fed. Cir. 2011).

Abbott alleges a POSA would have added Brauker’s predictive alarm to the STS Guide to provide “advance[d]” warning of “potential hypoglycemia,” and that this would have been nothing but “combining prior art elements (i.e., STS Guide’s low glucose alarm with **Brauker’s** predicted low glucose alarm) according to known methods to yield predictable results.” Petition, 63-64. Brauker’s predictive alarm is **user-settable**. Brauker, [0035]. Thus, adding Brauker’s **user-settable** predictive alarm to the STS Guide to provide advanced warning of potential hypoglycemia would not have “yield[ed] the claimed invention” (*Unigene Labs.*, 655 F.3d at 1360) because every Challenged Claim requires determining “whether a predicted glucose value meets ... **non user settable** ... criteria” (*see* Limitations 1[b] and 24[d]).

Abbott confusingly alleges that the STS Guide discloses the requirement in Limitations 1[b] and 24[d] of evaluating sensor data using a “second function.” Petition, 61. Those limitations require making a determination about “a **predicted** glucose value” and the Petition admits that the STS Guide’s alleged second function makes a determination about a “**real time** glucose value.” Petition, 61. The STS Guide does not disclose the claimed second function. Instead, Abbott alleges a POSA would have “modified” the STS Guide’s “*second function*” to

“take[] Brauker’s predicted glucose value as input.” *Id.*, 65 (emphasis original).

As detailed below, none of the Petition’s alleged reasons to combine supports combining the STS Guide and Brauker in that manner.

a. Abbott’s “Known Methods” Yielding “Predictable Results” Rationale Does Not Support Fixing the Threshold for a Predictive Alarm

Abbott’s assertion that “combining STS Guide and Brauker would have been combining prior art elements (i.e., STS Guide’s low glucose alarm with Brauker’s predicted low glucose alarm) according to known methods to yield predictable results” (Petition, 64) does not support “modif[ying]” the “STS Guide’s *second function* [to] take[] Brauker’s predicted glucose value as input.” Petition, 65 (emphasis original).

This *KSR* rationale only applies when the elements are combined without “change in their respective functions.” *KSR*, 550 U.S. 398 at 415-16 (describing as obvious “a combination which only unites old elements ***with no change in their respective functions***”); MPEP §2143(I)(A) (Feb. 2023) (proving obviousness based on “Combining Prior Art Elements According to Known Methods To Yield Predictable Results” requires that a POSA “could have combined the [known] elements as claimed by known methods ***with no change in their respective functions***”) (citing, inter alia, *KSR*, 550 U.S. at 416).

Abbott admits the “STS Guide’s *second function*” is “***modified***” in the combination to “take[] Brauker’s predicted glucose value as input” and to provide “an output whether (sic) the ***predicted*** glucose value is below STS Guide’s non user settable threshold.” Petition, 65. That would dramatically change the function of the STS Guide’s alarm.

The STS Guide’s “Low Glucose Alarm” is fixed at 55 mg/dL to provide a fail-safe ***real-time*** alarm that warns the patient that their ***current*** glucose level has reached a dangerous (“very low”) condition. Ex-1008, 56. A POSA never would have replaced this with a less accurate predictive alarm (*supra* §II.B.1) that would warn of a potentially dangerous condition that may, or may not, arise in the future but would not notify the patient when their current glucose level ***actually reaches a dangerous level***. Petition, 63 (admitting a ***real time*** low glucose alarm “helps prevent hypoglycemia by allowing the user to act in view of the ***current*** glucose level.”). Abbott proposes a massive change to the function of the STS Guide alarm. Abbott’s STS Guide-Brauker combination it is not “a combination which only unites old elements ***with no change in their respective functions***” and thus is not supported by the “known methods to yield predictable results” rationale Abbott relies on. *KSR*, 550 U.S. 398 at 415-16.

b. Using Real Time and Predictive Alarms Together Provides No Reason to Fix Brauker’s Predictive Alarm

Abbott's evidence of systems that use "real time and predicted alarms" together provides no support for **fixing** the threshold for the predictive alarm in the STS Guide-Brauker Combination because the identified prior art systems – Brauker and the Navigator Guide – use **user-settable** predictive alarms. Petition, 64; Brauker, [0035]; Ex-1010 ("Navigator Guide"), 67, 70.

DexCom does not dispute that a "POSITA 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" whereas a real-time "low glucose alarm **when potential hypoglycemia is a present risk** helps prevent hypoglycemia by allowing the user to act in view of the current glucose level." Petition, 63 (emphasis original). But that does not help Abbott because these benefits of using a real-time and predictive alarm together are achieved by simply adding Brauker's **user-settable** predictive alarm to the STS Guide. Brauker, [0035].

A motivation to achieve the benefits of using real-time and predictive alarms together provides no reason to **fix** the threshold for the **predictive** alarm. This reason to combine fails to establish obviousness because it establishes no reason to combine the referenced in a manner that would "**yield the claimed invention.**" *Unigene Labs.*, 655 F.3d at 1360.

c. No Prior Art Reference Teaches a Fixed Predictive Alarm

None of Abbott's prior art references teach a fixed predictive alarm.

STS Guide (cited Petition, 61-65) does not disclose a predictive alarm.

Abbott never alleges otherwise.

Brauker (cited *id.*) teaches a *user-settable* predictive alarm. Brauker, [0035]. Ground VI never alleges otherwise and instead relies on the STS Guide to teach a fixed threshold. Petition, 61-65.

Ex-1007, 1149 teaches that “prediction increase[s] our ability to prevent hypoglycemia” and **Ex-1011**, 932 teaches that “glucose can be predicted ahead of time.” Petition, 63. Neither reference discloses a fixed predictive threshold. Abbott never alleges otherwise.

Ex-1010 (“Navigator Guide”), 68 is cited to teach the desirability of using “both the low and high glucose threshold alarms *AND* the projected low and projected high glucose alarms” together. Petition, 64 (emphasis original). The Navigator Guide's predictive (called “projected”) alarm is user-settable. Ex-1010, 67-68 (“[p]rojected alarms use the low and high glucose *threshold* values” from the real-time alarms and the patient “decide[s] the low and high glucose threshold values”) (emphasis original).

Ex-1013 (“Hayter”), 725 is relied on for its recommendation that “[t]he user should never go below 50 mg/dL at any time without an alarm.” Petition, 64.

This provides no motivation to modify the STS Guide’s fixed low glucose alarm to be predictive. The STS Guide’s fixed *real-time* low glucose alarm already achieves Hayter’s recommendation because the STS Guide’s fixed alarm – which the user “cannot change or turn off” (Ex-1008, 56) – ensures that whenever the user’s glucose level falls to 55 mg/dL an alarm is generated so the user would “never go below 50 mg/dL ... without an alarm” (Ex-1013, 725).

Not a single prior art reference teaches any reason to fix a *predictive* alarm threshold.

d. Abbott’s Assertion That a POSA Had Reason to Fix a Predictive Alarm Threshold in the STS Guide-Brauker Combination Is Unsupported by Any Credible Evidence

A POSA following the teachings of the references would have been led to an STS Guide-Brauker system that leaves the STS Guide’s alarms unchanged and adds Brauker’s *user-settable* predictive alarm to achieve the benefit (advanced warning of potential hypoglycemia) Abbott identifies. Petition, 63-65. Despite that, Abbott states in conclusory fashion that a POSA would have done something very different. Abbott alleges a POSA would have instead “modified” the STS Guide’s fixed real-time alarm to take “Brauker’s *predicted* glucose value as input.” Petition, 65. Nothing supports this hindsight assertion.

No prior art reference describes a fixed predictive alarm. *See supra* §III.D.3.c. The only other evidence cited in Ground VI’s “Motivation to combine”

section is Ex-1003, ¶¶146-148. Petition, 62-65. These three paragraphs of expert testimony parrot word-for-word (with the same emphasis) the three paragraphs of argument in the Petition’s “Motivation to combine” section. *Compare* Petition, 62-65 *with* Ex-1003, ¶¶146-148. This conclusory unsupported testimony warrants no weight. *Xerox*, 14-16 (“[T]he cited declaration ***testimony is conclusory and unsupported***, adds little to the conclusory assertion for which it is offered to support, and is ***entitled to little weight.***”).

Ground VI’s “Motivation to combine” section begins with the conclusory assertion that “[i]t would have been obvious to incorporate Brauker’s predicted glucose alarm in the system of STS Guide so that the modified system would additionally determine whether a ***predicted*** glucose value meets non user settable criteria to provide a low glucose alarm.” Petition, 62-63 (emphasis original) (citing ***only*** Ex-1003 ¶146). The cited testimony simply repeats that conclusory assertion verbatim and never offers any ***reason why*** a POSA would have used “non user settable criteria” for a predictive alarm despite Brauker’s predictive alarm being user-settable and despite the STS Guide’s fixed alarm being a real-time alarm. Brauker, [0035]; Ex-1008, 56.

Abbott then cites Dr. Rodbard’s testimony in Ex-1003 ¶146, as well as the Ex-1007 and Ex-1011 references discussed *supra* §III.D.3.c, to support Abbott’s assertion that a POSA knew to use real-time and predictive alarms together

because a predictive low glucose alarm provides advance notice of potential hypoglycemia whereas a real-time alarm allows a user to “act in view of the current glucose level.” Petition, 63. As discussed *supra* §III.D.3.b, DexCom does not challenge that a POSA knew to use real-time and predictive alarms together in the same system, but this provides no reason to modify the STS Guide’s fixed alarm to convert it into a predictive alarm.

Abbott then notes that Brauker and Navigator Guide both have real time and predictive alarms. Petition, 64. This does not help Abbott because, as discussed *supra* §III.D.3.c, the predictive alarm in both systems is user-settable. Brauker, [0035]; Ex-1010 (Navigator Guide) at 67-68.

Despite every prior art predictive alarm being user-settable, the Petition states in conclusory fashion that:

A POSITA would have been particularly motivated to add a ***predicted, non user settable*** low glucose alarm because a POSITA would have known that non user settable criteria tied to hypoglycemia often relate to clinical danger, Ex-1013 (Hayter), 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.

Petition, 64 (emphasis original).

The only cited ***prior art*** evidence is Hayter. But as discussed *supra* §III.B.3.a, Hayter does not support modifying the STS Guide’s fixed low glucose

alarm to be predictive because the STS Guide’s fixed ***real-time*** low glucose alarm already achieves Hayter’s recommendation by ensuring that whenever the user’s glucose level falls to 55 mg/dL an alarm is generated so the user would “never go below 50 mg/dL ... without an alarm” (Ex-1013, 725).

The only evidence Abbott cites besides Hayter to purportedly support its conclusory assertion that a POSA would have been “particularly motivated” to add a ***non-user settable*** predictive alarm to the STS Guide is Ex-1003 ¶147. Petition, 64. That testimony warrants no weight because it merely repeats the Petition’s conclusory argument verbatim. *Xerox*, 14-16 (“[T]he cited declaration ***testimony is conclusory and unsupported***, adds little to the conclusory assertion for which it is offered to support, and is ***entitled to little weight.***”).

Thus, Abbott’s assertion that a POSA would have been “particularly motivated” to add a ***non-user settable*** predictive alarm to the STS Guide (Petition, 64) is ***not supported by a single piece of credible evidence.***

The Petition then alleges that “combining STS Guide and Brauker would have been combining prior art elements (i.e., STS Guide’s low glucose alarm with Brauker’s predicted low glucose alarm) according to known methods to yield predictable results (i.e., achieving an accurate, advance detection of hypoglycemia, making it possible to reduce the incidence or severity of hypoglycemia). Ex-1003

¶148.” Petition, 64.⁷ This assertion does not help Abbott because combining “Brauker’s predicted low glucose alarm” with the STS Guide system would yield an STS Guide-Brauker system with a *user-settable* predictive alarm as taught by Brauker, [0035].

In its attempt to reconstruct the claims in hindsight, Abbott elsewhere alleges that a POSA would have “*modified*” the function of the STS Guide’s fixed *real-time* alarm to make it predictive. Petition, 65. Thus, *KSR*’s “known methods to yield predictable results” rationale (Petition, 64) provides no support for Abbott’s combination. *See supra* §III.D.3.a; *KSR*, 550 U.S. 398 at 415-16 (describing as obvious “a combination which only unites old elements *with no change in their respective functions*”); MPEP §2143(I)(A) (Feb. 2023) (this rationale “*requires* that a POSA “could have combined the [known] elements as claimed by known methods *with no change in their respective functions*”).

⁷ The only evidence Abbott cites is Ex-1003 ¶148. That paragraph of expert testimony warrants no weight because it merely repeats the Petition’s conclusory argument verbatim without citation to any supporting evidence or analysis. *Xerox*, 14-16.

Finally, the Petition alleges that its STS Guide-Brauker combination “uses a known technique (i.e., Brauker’s predicted low glucose alarm) to improve similar devices in the same way.” Petition, 64-65. This assertion is facially false. Brauker’s “known technique” is a ***user-settable*** “predicted low glucose alarm.” Brauker, [0035]. Alleging that a POSA would have used Brauker’s “known ... predicted low glucose alarm ... in the same way” in the STS Guide’s system (Petition, 65) provides no reason to ***modify*** the alarm’s threshold to make it fixed as required to meet the Challenged Claims. Abbott’s “known technique ... to improve similar devices in the same way” assertion is also unsupported by any credible evidence. The only cited evidence is testimony of Dr. Robard that parrots this conclusory assertion verbatim and warrants no weight. Petition, 65 (citing EX-1003, ¶149); *Xerox*, 14-16.

e. Abbott’s Hindsight Argument Should Be Rejected

Even if the Board were inclined to credit Dr. Rodbard’s conclusory unsupported testimony alleging that a POSA would have modified the STS Guide’s fixed real-time alarm to make it predictive, the limitation in every Challenged Claim that requires comparing a predicted glucose value to one or more non-user settable criteria (*supra* §II.D) is missing from the prior art. Abbott failed to establish that this is among the rare cases where a missing claim

limitation can be supplied solely by the naked say-so of an expert. *See supra* §III.B.1.b.

The blatant hindsight underlying Abbott’s Ground VI obviousness argument is apparent. In the absence of DexCom’s inventive insight that fixing the threshold for a predictive alarm would increase its accuracy (*see supra* §II.B.3), there was simply no reason why a POSA would have fixed the threshold for a ***predictive*** alarm in the STS Guide-Brauker combination. The naked hindsight say-so of Abbott’s expert cannot carry Abbott’s burden to establish a supportable reason why a POSA would have done so. *KSR*, 550 U.S. at 418 (a “reason” is required); *TQ Delta*, 942 F.3d at 1359 (same); *Xerox*, 14-16 (conclusory testimony warrants no weight); *supra* §III.B.1 (expert testimony alone cannot supply a claim limitation missing from the prior art).

Abbott is well aware that the only modification to the STS Guide that is actually supported by Brauker’s teaching of a predictive alarm is to “add a ***predicted, user settable*** low glucose alert” to the STS Guide’s system. Petition, 64 (fn. 10) (emphasis original). In a statement that reveals Abbott’s improper use of hindsight bias, Abbott alleges that “[a]lthough a POSITA could” have done this, that “is not relevant to this limitation [1[b]], which neither requires nor prohibits such an alert.” *Id.* The fact that a POSA would have understood that adding Brauker’s ***user-settable*** predictive alarm to the STS Guide would have achieved

the benefits the Petition identifies as motivating the combination – by providing advanced warning of potential hypoglycemia (Petition, 63) – is *highly* “relevant” (Petition, 64, fn. 10) because it reveals that Abbott’s assertion that a POSA would have done something different than the STS Guide and Brauker teach by fixing a *predictive* alarm threshold is unsupported by any credible evidence.

**f. The UK High Court Decision Is Irrelevant to
Abbott’s Failure to Carry Its Burden on Ground VI**

Abbott alleges that the UK High Court found a “similar claim of a European counterpart” obvious over a different DexCom user guide that “has similar disclosure as STS Guide.” Petition, 63 (footnote 9).

That UK High Court Decision has no bearing on this proceeding in which Abbott bears the burden to prove the claims unpatentable under United States law. The Petition does not even allege that any Challenged Claim would have been obvious based on the STS Guide alone. Ground VI only alleges obviousness over the combination of the STS Guide and Brauker.

Under the law that controls this proceeding, Abbott bore the burden to establish some supportable non-hindsight reason why a POSA would have combined the teachings of the STS Guide and Brauker in a manner that meets the Challenged Claims. *See supra* §III.D.3. Abbott failed to meet that burden for the reasons detailed above. Citation to a decision that applies a *different* country’s law and addresses a *different* theory of obviousness than Ground VI advances cannot

help Abbott avoid the consequence of its failure to establish a supportable reason to combine the STS Guide and Brauker in a manner that meets any Challenged Claim.

E. Grounds VII-VIII Fall with Ground VI

Ground VII alleges obviousness of dependent claims 5 and 28. Claim 5 depends from claim 1. Abbott relies on Ground VI's showing for claim 1 in meeting claim 5. Petition, 80 ("STS Guide in view of Brauker renders obvious claim 1"). And Abbott relies on its showing for claim 5 to meet claim 28. *Id.*, 81 ("See Section VIII.G.1 above for claim 5"). Thus, Ground VII fails for the same reasons Ground VI fails. *Supra* §III.D.

Ground VIII alleges obviousness of dependent claims 13 and 36. Claim 13 depends from claim 1. Abbott relies on Ground VI's showing for claim 1 to meet claim 13. Petition, 81 ("STS Guide in view of Brauker renders obvious claim 1"). And Abbott relies on its showing for claim 13 to meet claim 36. *Id.* ("See Section VIII.H.1 above for claim 13"). Thus, Ground VIII fails for the same reasons Ground VI fails. *Supra* §III.D.

F. Conclusion

Abbott failed to carry its burden to demonstrate any Challenged Claim unpatentable. Institution should be denied.

Respectfully submitted,
DexCom, Inc.

Date: August 23, 2024

/Richard Giunta/

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CERTIFICATE OF WORD COUNT

Pursuant to 37 C.F.R. §42.24, the undersigned certifies that the foregoing **PATENT OWNER'S PRELIMINARY RESPONSE** contains 13,543 words excluding; a table of contents, a table of authorities, a certificate of service or word count, or appendix of exhibits or claim listing. Patent Owner has relied on the word count feature of the word processing system used to create this paper in making this certification.

Date: August 23, 2024

/MacAulay Rush/
MacAulay Rush
Paralegal
WOLF, GREENFIELD & SACKS, P.C.

CERTIFICATE OF SERVICE UNDER 37 C.F.R. §42.6 (e)(4)

I certify that on August 23, 2024, I will cause a copy of the foregoing document, including any exhibits filed therewith, to be served via electronic mail, as previously consented to by Petitioner, upon the following:

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