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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. IPR2024-00853
Patent No. 11,213,204

PATENT OWNER'S PRELIMINARY RESPONSE

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	'204 PATENT	4
	A. Disclosed System.....	4
	B. Challenged Claims.....	6
III.	THE GROUNDS FAIL	7
	A. Ground I Fails.....	8
	1. References	9
	a. Gawlick	9
	b. Valdes.....	12
	2. Abbott Alleges Motivation to Use Valdes's Sensor and Receiver in Gawlick's System	13
	3. A POSA Would Not Have Combined Gawlick With Valdes's Receiver Because Modern Medical Institutions Would Never Let a Patient Set Medical Alerts Using Valdes's Receiver.....	14
	4. Abbott Only Alleges Motivation to Use Valdes's Sensor/Receiver in Gawlick's System without Modifying Gawlick's System.....	17
	5. Abbott Fails to Establish That its Gawlick-Valdes Combination Meets Limitation 1[c].....	19
	a. The Petition Fails to Explain How Limitation 1[c] is Allegedly Met with the Required Particularity	21
	b. Valdes Does Not Meet Limitation 1[c].....	22
	c. Gawlick Does Not Meet Limitation 1[c]	23
	i. None of the Petition-Cited Gawlick Disclosures Teach Preferences or Settings "From a Host Device" as Limitation 1[c] Requires	24
	ii. Gawlick's Application Running on the " <i>Host Device</i> " Does Not Help Abbott	27

d. The Petition’s Reasons to Combine with a Reasonable Expectation of Success Do Not Yield a Gawlick-Valdes Combination That Meets Limitation 1[c]	31
e. Conclusion on Ground I’s Failing for Limitation 1[c]	32
6. Abbott Fails to Establish That Its Gawlick-Valdes Combination Meets Limitation 1[g].....	33
7. The Petition Fails to Establish That Its Gawlick-Valdes Combination Meets Limitation 1[h].....	37
8. Abbott Cannot Rely on Expert Testimony to Provide the Limitations That Are Missing from the Prior Art	38
9. Ground I’s Showing for Every Challenged Claim Fails for the Same Reasons as It Fails for Claim 1	41
B. Ground IV Fails	42
1. Paterno	42
2. Abbott’s Assertion That a POSA Would Have Used Paterno’s System to Remotely Monitor Valdes’s CGM System Is Unsupported	43
a. Abbott Mischaracterizes Paterno	43
b. Abbott Established No Supportable Reason to Combine Paterno and Valdes	45
3. Abbott Only Alleges Motivation to Use Valdes’s Sensor/Receiver in Paterno’s System without Modifying Paterno’s System	46
4. Abbott Fails to Establish That a POSA Would Have Implemented a Paterno-Valdes Combination Meeting Limitation 1[c].....	48
a. The Petition Fails to Explain How Limitation 1[c] is Allegedly Met with the Required Particularity	49
b. Valdes Does Not Meet Limitation 1[c].....	50
c. Paterno Does Not Meet Limitation 1[c].....	51
d. Abbott’s Assertion That a POSA Would Have Stored a Setting from Paterno’s Home Unit in the SCMS Is Unsupported	53

i. Neither Paterno nor Valdes Supports Abbott's Assertion	53
ii. Abbott Never Alleges a Reason to Modify Paterno's System in a Manner Required to Meet Limitation 1[c]	54
iii. Abbott's Reliance on Conclusory Expert Testimony to Meet a Missing Claim Limitation Fails.....	55
e. Conclusion on Ground IV's Failing for Limitation 1[c]	57
5. Abbott Fails to Establish That Its Paterno-Valdes Combination Meets Any of Limitations 1[d] and 1[g]-[h]	57
a. Abbott Fails to Establish That Its Paterno-Valdes Combination Meets Limitation 1[d]	58
b. Abbott Fails to Establish That Its Paterno-Valdes Combination Meets Limitation 1[g]	59
c. Abbott Fails to Establish That Its Paterno-Valdes Combination Meets Limitation 1[h]	62
6. Abbott Fails to Establish That Limitation 1[e] Is Met.....	64
7. Ground IV Fails for Every Challenged Claim for the Same Reasons It Fails for Claim 1	66
C. Grounds II-III and V-VI Fall with Grounds I and IV	67
IV. CONCLUSION.....	67

TABLE OF AUTHORITIES

CASES

<i>Apple Inc. v. Mullen Indus. LLC</i> , IPR2023-00087, Paper 10 (May 3, 2023)	39, 40, 41
<i>Arendi S.A.R.L. v. Apple Inc.</i> , 832 F.3d 1355 (Fed. Cir. 2016)	40, 41
<i>Catalent Pharma Solutions Inc. v. Patheon Softgels Inc.</i> , IPR2018-00421, Paper 9 (Aug. 13, 2018)	17
<i>Guardiar Solutions, Inc. v. RSA Protective Technologies, LLC</i> , IPR2019-01161, Paper 8 (Nov. 21, 2019)	64
<i>Henny Penny Corp. v. Frymaster LLC</i> , 938 F.3d 1324 (Fed. Cir. 2019)	16
<i>KSR International Co. v. Teleflex Inc.</i> , 550 U.S. 398 (2007)	passim
<i>Personal Web Technologies, LLC v. Apple, Inc.</i> , 848 F.3d 987 (Fed. Cir. 2017)	31
<i>TQ Delta, LLC v. CISCO Systems, Inc.</i> , 942 F.3d 1352 (Fed. Cir. 2019)	31, 64, 65
<i>Unigene Laboratories, Inc. v. Apotex, Inc.</i> , 655 F.3d 1352 (Fed. Cir. 2011)	passim
<i>Xerox Corp. v. Bytemark Inc.</i> , IPR2022-00624, Paper 9 (Aug. 24, 2022) (precedential)	passim

STATUTES

35 U.S.C. § 312(a)(3)	21, 49
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REGULATIONS

37 C.F.R. § 42.6(a)(3)	55, 66
37 C.F.R. § 42.22(a)(2)	passim

37 C.F.R. § 42.104(b)(4)..... passim

37 C.F.R. § 42.104(b)(5)..... passim

MANUAL OF PATENT EXAMINING PROCEDURE

MPEP § 2143(I)(A).....18

I. INTRODUCTION

The challenged claims relate to remote monitoring of the analyte (e.g., glucose) state of a patient (called a “host”) using a *host device*, a *secure server*, and a *remote monitor*. Alert rules specify alerts to be generated based on the host’s analyte level (e.g., if it is below a threshold value). The *host device* provides alert rule settings to the *secure server*. The *remote monitor* can modify an alert rule setting set by the *host device* without changing the setting at the *host device*. See Limitations 1[c] and 1[g]-1[h] and Limitations 12[e] and 12[j]-12[k].¹ This allows a third-party (e.g., a caregiver) to remotely monitor the host’s analyte level and leverage the alert rule settings set on the *host device*. But it also allows the third-party to customize the alerts at the *remote monitor* in a manner that fits the needs of the user of the remote monitor but does not impact the alerts generated for the patient at the *host device*. This is not taught in the art and Petitioner (“Abbott”) fails to demonstrate that any of its grounds meets these limitations.

Ground I alleges obviousness over Gawlick and Valdes. Gawlick’s system is used in medical institutions (e.g., hospitals) and allows medical personnel to remotely monitor a patient’s vital signs using patient monitoring devices. Medical personnel set alert rules appropriate for the patients they monitor. Abbott alleges

¹ DexCom adopts the Petition’s claim limitation labelling (Petition, 10-14) and its convention of italicizing claim terms.

that Gawlick teaches that an alert rule setting is provided by a patient monitoring device (alleged *host device*) to the medical personnel's computer (alleged *remote monitor*). Not so. Abbott ignores Gawlick's disclosure that setting rules at the medical personnel's remote computer involves **only** what Abbott identifies as the *remote monitor* and *secure server*—Gawlick's alleged *host device* is uninvolved. Thus, Gawlick does not disclose the requirement of every challenged claim that an alert rule provided to the *remote monitor* be based on settings *set by* the *host device*, let alone the other above-noted limitations that require modifying a setting at the *remote monitor without changing the setting at the host device*.

Valdes teaches a patient's **personal** glucose monitoring device. Abbott's assertion that a POSA would have used this in Gawlick's **medical institution** system is baseless. Ground I fails for that reason alone. Additionally, Valdes has no server or server-based remote monitoring at all. Valdes cannot cure Gawlick's deficiencies in failing to meet the above-noted limitations. Abbott never alleges that it does. Abbott also never alleges any reason why a POSA would have modified Gawlick in a manner required to meet the above-noted limitations. Ground I fails for that reason as well.

Ground IV alleges obviousness over Paterno and Valdes. Paterno discloses a system that reminds an individual to perform routine tasks like taking medication and allows a caregiver to remotely monitor the individual's compliance. Paterno

has nothing to do with monitoring a sensor—like Valdes’s glucose monitor—that measures a physical characteristic of a patient’s body. Abbott’s assertion that a POSA would have used Paterno’s system to remotely monitor Valdes’s glucose monitoring device is baseless. Ground IV fails for that reason alone.

But even if the Board finds that a POSA would have used Paterno’s system to remotely monitor a host’s glucose level using Valdes’s device, Abbott fails to establish any reason why a POSA would have combined Paterno and Valdes in a manner that meets any challenged claim. Abbott relies on Paterno to meet the above-discussed claim limitations that require that the *remote monitor* be provided with alert rule(s) generated according to a setting set at the *host device* and modify such a setting *without changing the setting at the host device*. Paterno discloses no such thing. Paterno describes a remote caregiver setting rules for notifications the caregiver receives but never discloses that any of those settings are set at the *host device*.

Valdes does not disclose server-based remote monitoring so it cannot cure Paterno’s deficiencies in failing to meet the above-noted limitations. Abbott never alleges that it does. Abbott also never alleges any reason why a POSA would have modified Paterno in a manner required to meet the above-noted limitations. That is fatal to Ground IV.

Additionally, Limitations 1[e] and 12[h] require that the secure server determine an alert event based on measured data about the host's analyte state. Abbott never alleges any reason why a POSA would have modified Paterno and Valdes in a manner required to meet these limitations. Ground IV fails for that additional reason.

Grounds I and IV are the only grounds challenging the independent claims. Their failings are inherited by the other grounds. Institution should be denied.

II. '204 PATENT

A. Disclosed System

The '204 Patent describes systems and methods for remotely monitoring the analyte state (e.g., glucose level) of a patient called a "host." Ex-1001, Abstract, Figs. 2A-2B (host 199), 6:48-7:3.

Remote monitoring system 100 includes host monitoring systems 198A-198N connected to remote monitors 114A-114M via network 118 and through secure server 110. Ex-1001, 5:49-6:2, Figures 1 and 2A (reproduced below). Host monitoring systems 198 include, *inter alia*, continuous analyte monitoring system 8 that comprises sensor 10, sensor electronics 12 and receiver 102. Ex-1001, 6:48-7:3. The secure server processes "health-related data" from the receiver "and

transmit[s] notifications and data to one or more remote monitors 114A-114M.”

Ex-1001, 5:62-6:2.

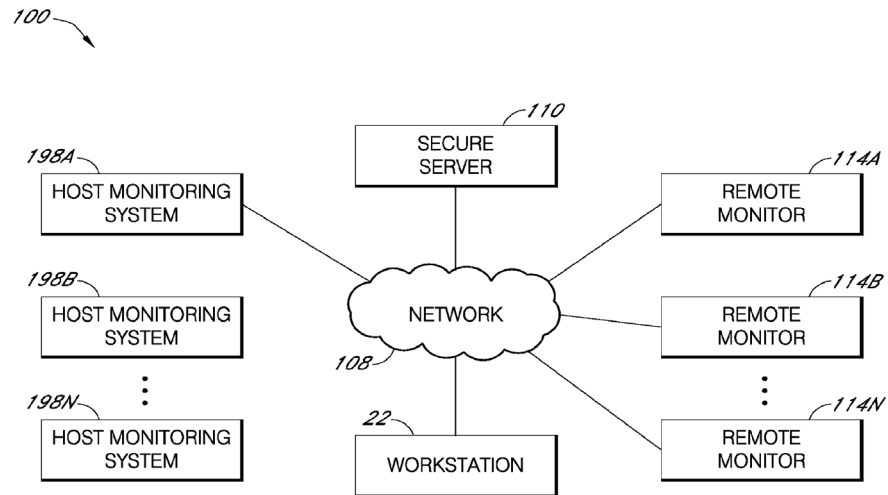


FIG. 1

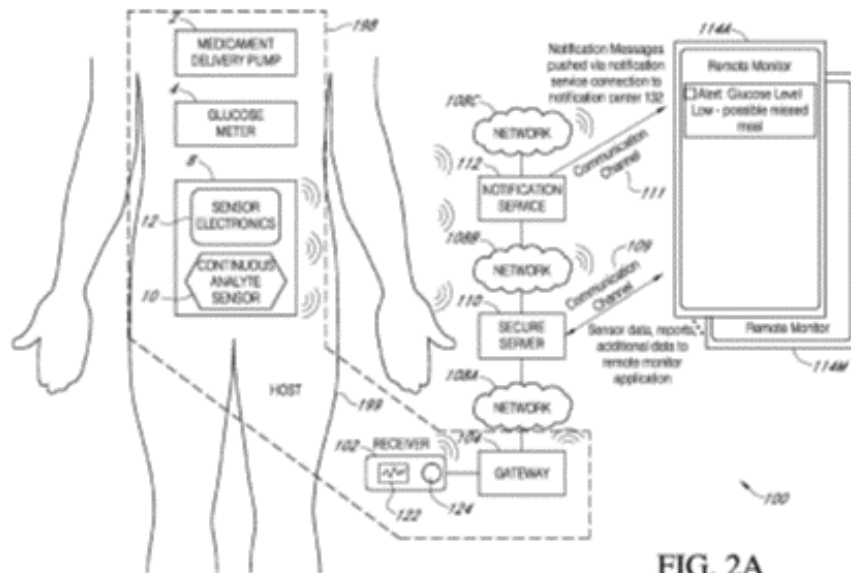


FIG. 2A

Using the receiver, the host sets alert rules provided to the server that the server uses to evaluate sensor data and identify events requiring attention. Ex-

1001, 30:40-43, 36:31-33, Fig. 6. Alerts sent to the remote monitoring system alert caregivers when the host's glucose (or other analyte) level requires attention. Ex-1001, 6:3-4 ("Each remote monitor 114 can be associated with a caretaker, such as parent, spouse, doctor, nurse, hospital[.]"), 7:11-20, 15:16-21.

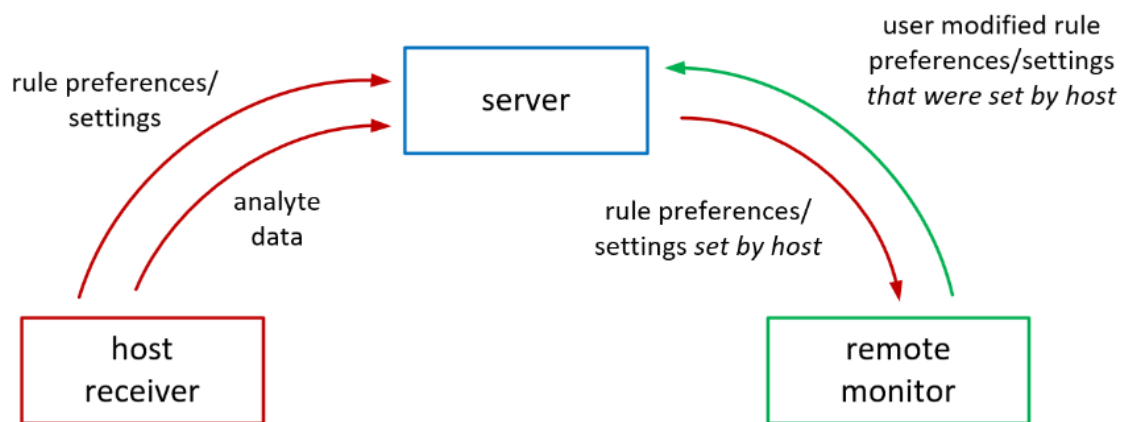
The host sets alert rule settings but remote caregivers can tailor those alert settings for their own needs. Ex-1001, 33:42-46 ("notification messages sent to the remote monitor(s) may be configured to suit the needs of a given remote monitor-user and these needs may be different from the needs of the host-patient."), *id.*, 33:60-67. For example, a school nurse monitoring several children might limit alerts to the nurse's remote monitor to those requiring prompt intervention. *Id.*, 28:40-44, 34:3-35.

B. Challenged Claims

Petitioner ("Abbott") challenges claims 1-3, 5-7, 12-14 and 17-19 ("Challenged Claims"). Petition, 4. The Challenged Claims include independent claims 1 and 12.

Both independent claims relate to a system for monitoring the analyte (e.g., glucose) state of a "host" (e.g., a patient) using a host device, a secure server, and a remote monitor. The host device provides to the secure server preferences or settings for one or more rules, including a first rule defining an alert representative of an event associated with an analyte state of the host. *See* Limitations 1[c] and

1[e] and Limitations 12[d]-[e] and 12[h]. The remote monitor modifies at least one rule by modifying a first setting set by the host device and does so without changing the first setting at the host device. *See* Limitations 1[g]-[h] and 12[j]-[k]. These communications among the server, host receiver and remote monitor are illustrated below.



The server receives analyte data from the host and determines alert events based on the rule settings. *See* Limitations 1[e] and 12[h]. When an alert is triggered based on the remote monitor user settings, the secure server sends an alert message to the remote monitor. *See* Limitations 1[f] and 12[i].

III. THE GROUNDS FAIL

Only Grounds I and IV challenge independent claims 1 and 12. Petition, 4. The remaining Grounds (II-III and V-VI) challenge only dependent claims.

Grounds I and IV fail for reasons explained below. Grounds II-III inherit Ground I's flaws and Grounds V-VI inherit Ground IV's flaws. Thus, if the Board agrees that Abbott fails to carry its burden for Grounds I and IV, institution should be denied.

A. Ground I Fails

Ground I alleges that certain Challenged Claims would have been obvious over Gawlick and Valdes. Petition, 28-64. Abbott fails to establish that Gawlick and Valdes render obvious any Challenged Claim.

As demonstrated below, there are numerous claim limitations that are not disclosed by Gawlick or Valdes, and where the Petition offers no reason why a POSA would have modified the references' teachings in its Gawlick-Valdes combination in a manner that meets these limitations. Indeed, the Petition never even maps the Gawlick-Valdes combination that it purports to support with a "reason to combine" to these limitations. Instead, the Petition confusingly cites to disparate disclosures in both references despite neither reference meeting the limitation.

In the sections below, DexCom addresses the numerous claim limitations that Abbott fails to establish are met by Gawlick, by Valdes, or by the Gawlick-Valdes combination that Abbott purports to establish with a "reason to combine."

1. References

a. Gawlick

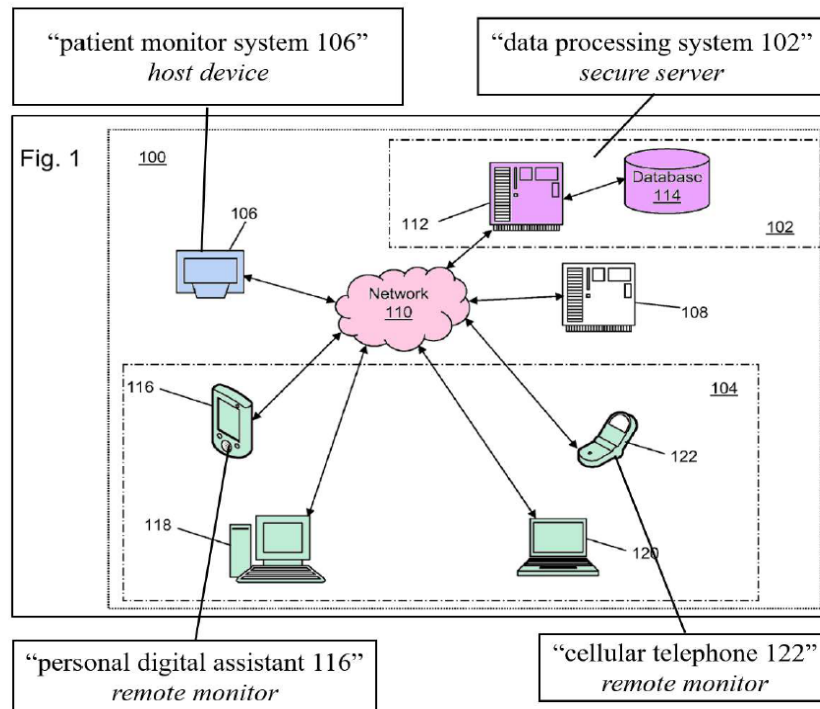
Gawlick is entitled “adjustable alert rules for *medical personnel*” and is used in “[*m*]odern *medical institutions*.” Gawlick, code(54) (Title), [0001].²

Gawlick’s system allows medical personnel, in hospital or other medical institution, to remotely monitor patients using patient monitoring devices that continuously monitor the patient’s “vital signs” (e.g., heart rate, blood pressure, etc.). Gawlick, [0001]-[0005], [0021]. These patient monitoring devices traditionally “trigger alerts for critical values that are above and/or below predefined thresholds.” *Id.*, [0001]-[0005]. The predefined thresholds in the prior art systems were the same for every patient and did not account for differences between patients based on age, health conditions, etc. *Id.* Gawlick’s system allows medical professionals to set alerts based on different thresholds customized for different patients. *Id.*, Title, Abstract, [0006], [0042], [0061], [0075]-[0076].

Abbott annotates Gawlick’s Figure 1 as shown below. *See* Petition, 18. The various patient monitoring devices that monitor the patients’ vital signs are grouped in the “patient monitor system 106” that Abbott maps to the claimed *host device*. Gawlick, [0017] and [0020]. Medical personnel computers (like PDA 116) that

² All emphasis, other than the Petition’s italicizing of claim terms, is added unless otherwise indicated.

are grouped in the “medical personnel alert system 104” that Abbott maps to the claimed *remote monitor*. Gawlick, [0017] and [0020]. Abbott maps the claimed *secure sever* to “data processing system 102” that includes server 112 and database 114 to store patient data and alert rules. Gawlick, [0017]-[0018] and [0039].



Petition, 18.

Gawlick Figure 15 (reproduced below) illustrates a dashboard that provides medical personnel an alert rule list 1500. The dashboard is “presented under control of browser application 311 in combination with second medical alert application 310 and through interaction with medical alert application 210 at medical personnel alert device 104’.” Gawlick, [0068]. Browser 311 and medical alert application 310 run on the medical personnel alert device 104’ that Abbott

maps to the claimed *remote monitor*. See e.g., Gawlick, Fig. 3. Medical alert application 210 runs on the data processing system 102's server 112 that Abbott maps to the claimed *secure server*. See e.g., Gawlick, Fig. 2. The dashboard is for medical personnel and can include alerts for multiple patients. Gawlick, [0074] (an alert rule can apply "to all patients, a specific patient, all patients of a specific physician," etc.).

The patient monitoring devices that Abbott maps to the claimed *host device* are uninvolved in presenting this dashboard with alert rule list 1500.

ID	GROUP	PRIORITY	DESCRIPTION	DELAY	TYPE
1080	1	GUARDED		IMMEDIATE	PATPHYSICIAN
2	1	SERIOUS	ABG: pH LEVEL SERIOUS	0 12:0:0.0	GENERAL
3	1	CRITICAL	ABG: pH LEVEL CRITICAL	IMMEDIATE	GENERAL
4	2	GUARDED	ABG: PCO2 LEVEL GUARDED	0 12:0:0.0	GENERAL
5	2	SERIOUS	ABG: PCO2 LEVEL SERIOUS	0 12:0:0.0	GENERAL
6	2	CRITICAL	ABG: PCO2 LEVEL CRITICAL	IMMEDIATE	GENERAL
10	3	GUARDED	ABG: BE LEVEL GUARDED	1 0:0:0.0	GENERAL

FIG. 15

Gawlick also discloses an "alert rule window [that] allows the user to adjust the parameters associated with the alert rule." Gawlick, [0075]. Like Figure 15's dashboard with alert rule list 1500, Gawlick's "alert rule window [that allows for adjusting rule parameters] may be presented under control of browser application 311 in combination with the second medical alert application 310 and through interaction with medical alert application 210 at medical personnel alert device

104'." Gawlick, [0075]. As explained above, browser 311 and medical alert application 310 run on the medical personnel alert device 104' (*remote monitor*) and medical alert application 210 runs on the data processing system 102's server 112 (*secure server*). See e.g., Gawlick, Figs. 2-3. Thus, the patient monitoring devices (*host device*) are uninvolved in the presentation of the alert rule window or its use in setting rule parameters.

In short, Gawlick teaches a system whereby medical personnel can use a remote computer to set their own alert rules for patients they monitor in a medical institution. There is no teaching in Gawlick that any alerts generated locally by various patient monitoring devices have any impact on the rules that medical personnel establish on the remote monitoring system.

b. Valdes

As Abbott acknowledges, "Valdes discloses a *continuous* glucose monitoring ('CGM') system and, a '[s]ystem and method for communicating glucose concentration information between devices of a' CGM system." Petition, 24. Valdes's CGM system is not used in medical institutions but instead is used by the patients in their daily life. Valdes, [0004]-[0005].

The CGM system includes sensor electronics module 8 (hereafter "sensor") and receiver unit 14 (hereafter "receiver") that receives and processes data from the sensor to measure the host's analyte (e.g., glucose) level. Valdes, [0002], [0062],

[0097], [0172], [0200]; Petition, 25. The receiver can wirelessly communicate with a secondary display device 16 such as a mobile phone or computer used by the host or by a third party (*e.g.*, a caregiver). Valdes, [0113], [0157]; Petition, 25.

2. Abbott Alleges Motivation to Use Valdes’s Sensor and Receiver in Gawlick’s System

To demonstrate any Challenged Claim obvious, 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 Lab. v. Apotex*, 655 F.3d 1352, 1360 (Fed. Cir. 2011); *KSR Int’l v. Teleflex*, 550 U.S. 398, 418 (2007) (establishing obviousness requires establishing some *reason* to combine the prior art in the manner claimed).

The Petition has a section purporting to establish that a POSA “Would Have Been Motivated to Combine Gawlick and Valdes with a Reasonable Expectation of Success.” Petition, 29-33. In it, Abbott notes that Gawlick discloses a “[p]atient monitoring system” that works with various sensors to measure patient vital signs and Abbott alleges that a POSA would have “understood that one such sensor described by Gawlick ... is a CGM, as disclosed by Valdes.” Petition, 29-30. Abbott says “a CGM offers advantages” because it continuously monitors the patient’s glucose level. *Id.*, 30-31. Abbott then alleges:

A POSITA would have *modified Gawlick’s patient monitor system to accept data from the [Valdes] receiver*, *i.e.*, act as a Valdes secondary

display device, because doing so allows the receiver unit to act as an “intermediary” between the “sensor electronics module 8” and the display device, which in turn allows the display device to obtain data without including an “authentication mechanism” for the sensor. Ex-1007, [0110]. This approach is advantageous for Gawlick’s flexible system with multiple sensors because it *leaves the sensor and receiver devices unchanged* and avoids authentication of each sensor type and manufacturer. Ex-1003, ¶105. This modification could be used to implement embodiments disclosed by Valdes allowing the receiver unit to be “automatically readable by a network system upon entry into a hospital ... via automatic wireless transmission.” Ex-1007, [0118].

Id., 31.

3. A POSA Would Not Have Combined Gawlick With Valdes’s Receiver Because Modern Medical Institutions Would Never Let a Patient Set Medical Alerts Using Valdes’s Receiver

Abbott’s Gawlick-Valdes combination fails because a POSA would not have modified Gawlick by adding Valdes’s receiver for at least two reasons.

First, Abbott contends that in Gawlick-Valdes *alerts are set* using Valdes’s *receiver* that can receive settings from Valdes’s secondary display device.

Petition, 38 (“Valdes includes additional disclosures of configuring ... settings” and “Valdes’s... *receiver*... can be used in combination with a ‘secondary display device’ (Gawlick’s patient monitoring system)”; Valdes, [0119] (secondary device

programs “alert/alarms settings” on the receiver), [0141] (settings from the secondary display device are received by the receiver). But Valdes’s receiver and secondary device are used by the patient or the patient’s parent (Valdez, [0157])—not by *medical personnel* in a *medical institution* like in Gawlick. *Supra* §III.A.1.a; Gawlick, [0001], [0006], [0042], [0046] (describing a patient in “*the intensive care unit (ICU)*.”). Gawlick’s “alert rules are highly customizable such that *medical personnel* can create, edit, and delete rules and/or override other existing rules.” Gawlick, [0042].

A POSA never would have modified Gawlick’s system used in *medical institutions* so that *patients* could create their own settings for alerts that are sent to the *medical personnel* that use Gawlick’s monitoring system. Abbott seeks to inject Valdes’s receiver and its secondary display device into Gawlick’s system in a hindsight attempt to create a *host device* that sets settings as claimed. *See e.g.*, Limitation 1[c]. A POSA never would have done so and that is fatal to Ground 1.³

³ Abbott’s mapping to Limitation 1[c] also alleges that Gawlick teaches that alert settings can be set by the patient monitoring system into which Valdes’s CMG system is allegedly integrated in Abbott’s Gawlick-Valdes combination. Petition, 37-39. That assertion fails for the reasons discussed *supra* §III.A.1.a because Gawlick’s settings are *not* set by the patient monitoring device.

Second, a POSA would have understood there was no reason to use Valdes's receiver and secondary display device in Gawlick's system. Gawlick's "patient monitoring system 106" communicates directly with electronic devices that monitor patient's physiological characteristics in the medical institution. Gawlick, [0021] ("the various electronic devices that makeup patient monitor system 106 may be connected to network 110 for the transmission of data."). Abbott's proposed modification adds needless complexity and decreases efficiency for Gawlick's system that has no use for Valdes's receiver. *Henny Penny v. Frymaster*, 938 F.3d 1324, 1332 (Fed. Cir. 2019) (affirming Board's finding of no motivation to combine because proposed combination would have added "complexity" and "decreased efficiency").

Abbott's assertion that using Valdes's receiver in the combination would have avoided a need for Gawlick's system to authenticate the glucose sensor is obfuscation. Petition, 31. Gawlick's system would have instead needed to authenticate the "intermediary" receiver device instead of the sensor so no authentication step would have been avoided. Abbott's reference to Valdes's teaching that the CGM can be automatically readable by a hospital network (*id.*) never says that the device did not have to first have been registered with, and authenticated by, the hospital system.

Abbott uses the challenged claims as a roadmap to piece together an alleged Gawlick-Valdes combination that adds unnecessary components (Valdes’s receiver and secondary display device) in an attempt to meet the claims. This impermissible hindsight renders the combination improper. *Catalent Pharma Solutions v. Patheon Softgels*, IPR2018-00421, Paper 9 at 12-15 (Aug. 13, 2018) (denying institution where petitioner failed to explain why a POSA “would modify the teachings of [the prior art] to produce the claimed invention”: “Given the unexplained ‘picking-and-choosing’ activity in Petitioner’s analysis, we are persuaded that Petitioner and its expert have impermissibly relied on hindsight[.]”).

4. Abbott Only Alleges Motivation to Use Valdes’s Sensor/Receiver in Gawlick’s System without Modifying Gawlick’s System

Even if the Board finds that Abbott established some reason to combine Gawlick and Valdes (it did not), the *only* “modifi[cation to] Gawlick’s patient monitoring system” that Abbott’s “Motivated to Combine” section alleges is to modify Gawlick’s system “to accept data from the receiver” in Valdes’s CGM “via automatic wireless transmission.”⁴ Petition, 31. Abbott confirms this by alleging that:

⁴ Abbott alleges that if Gawlick’s patient monitoring system did not use “the *same* wireless communication technology” that Valdes uses then modifying the “data-

“Combining Gawlick and Valdes would have *merely involved combining known prior art elements* (i.e., Valdes’s CGM sensor and receiver with Gawlick’s “patient monitor system”) *according to known methods to yield predictable results* (i.e., continuous measurement and monitoring of the blood glucose level of a host). Ex-1003, ¶106. *See KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 415-21 (2007).”

Petition, 31-32.

This *KSR* rationale only applies when known prior art elements are combined without “change in their respective functions.” *KSR*, 550 U.S. 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).

Indeed, Abbott characterizes “[c]ombining Gawlick and Valdes” as requiring “only a *simple addition*” of Valdes’s sensor and receiver into Gawlick’s patient monitoring system. Petition, 32. Abbott states that the combination

receiving components” in Gawlick’s system to do so would be “simple.” *Id.*, 32-33.

“leaves the sensor and receiver devices [of Valdes] ***unchanged***.” Petition, 31.

And again, the only modification to Gawlick’s patient monitoring system that the “Motivated to Combine” section purports to establish that a POSA would have made to accommodate the “simple addition” of Valdes’s sensor and receiver is to the “data-receiving components” in Gawlick’s system to use the “same wireless communication technology” that Valdes uses. *Id.*, 32-33.

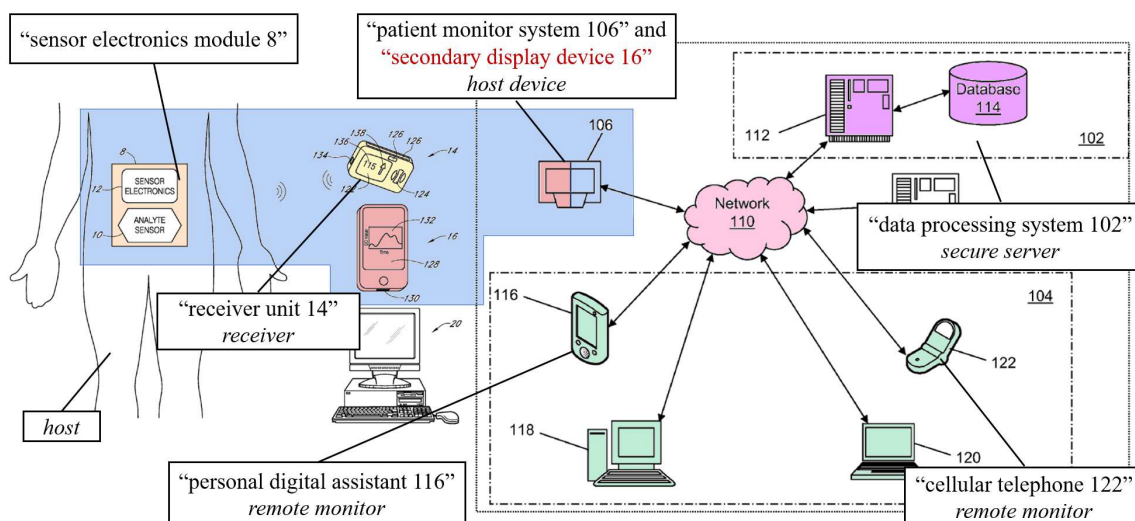
The specific nature of the Gawlick-Valdes combination that the Petition’s “Motivated to Combine... with a Reasonable Expectation of Success” section purports to establish is important because, as discussed below, the combination that would have resulted from combining Gawlick and Valdes in the manner alleged fails to meet numerous claim limitations.

5. Abbott Fails to Establish That its Gawlick-Valdes Combination Meets Limitation 1[c]

Limitation 1[c] requires that “***the set of one or more rules are generated according to one or more preferences or settings from a host device, and wherein the host device sets a first setting of the one or more preferences or settings.***” The antecedent for “*the set of one or more rules*” is in Limitation 1[a] which requires “*identifying, by a remote monitor, a set of one or more rules.*” Limitation 1[b] further requires that “***the set of one or more rules are provided to the remote monitor by the secure server.***”

Thus, Limitation 1[c] requires that the *host device* set a setting that is used to generate one or more rules that are provided to the *remote monitor* by the *secure server*. Abbott fails to establish that its Gawlick-Valdes combination meets this requirement.

Abbott alleges that the *host device* is met by Gawlick’s “patient monitor system 106’ and ‘secondary display device 16’” which in the Gawlick-Valdes combination is “Valdes’ receiver unit,” the *remote monitor* is met by a computing device (e.g., “cellular telephone 122”) in Gawlick’s medical personnel alert system 104, and the *secure server* is met by Gawlick’s “data processing system 102.” Petition, 29 (annotating Gawlick Fig. 1 as reproduced below); *see also id.*, 37 (“Gawlick discloses a patient monitor system (*host device*)”); 33 (“Gawlick’s medical personnel alert system 104 includes ‘one or more computing devices’ (*remote monitors*)”).



Valdes, Ex-1007, Fig. 1A, [0109]

Gawlick, Ex-1005, Fig. 1, [0020]

Thus, Abbott’s purported mapping to the claim elements is:

<i>host device</i>	Gawlick patient monitor system 106 including Valdes’s receiver
<i>remote monitor</i>	a computer in Gawlick’s medical personnel alert system 104
<i>secure server</i>	Gawlick’s data processing system 102

Abbott fails to establish that its Gawlick-Valdes combination has a *host device* that sets a setting that is used to generate one or more rules provided to the *remote monitor* by the *secure server* as required to meet Limitation 1[c] for multiple independent reasons detailed below.

a. The Petition Fails to Explain How Limitation 1[c] is Allegedly Met with the Required Particularity

By statute, the Petition “may be considered *only* if” it “identifies... *with particularity*... the grounds... and the evidence that supports the grounds for the challenge to each claim.” 35 U.S.C. §312(a)(3). The Office promulgated two rules specifying “content” a petition must have to meet this particularity requirement. The “petition... must include... a detailed explanation of the significance of the evidence” (37 C.F.R. §42.22(a)(2)), “must specify where each element of the claim is found in the prior art patents or printed publications relied upon” and “must” identify “specific portions of the evidence that support the challenge” (37 C.F.R. §§42.104(b)(4)-(5)).

The Petition fails to comply with these requirements for Limitation 1[c] because the Petition is entirely unclear about how and why the Gawlick-Valdes combination purportedly meets Limitation 1[c]. As detailed below, Limitation 1[c] is not met by Valdes, Gawlick, or the Gawlick-Valdes combination a POSA purportedly would have made based on the Petition’s “Motivated to Combine” section.

b. Valdes Does Not Meet Limitation 1[c]

The alleged *host device* in the Gawlick-Valdes combination is Gawlick’s patient monitor system that is modified to act as a “secondary device” for Valdes’s receiver. Petition, 29, 31 (a “POSITA would have modified ***Gawlick’s patient monitor system to*** accept data from the [Valdes] receiver, i.e., ***act as a Valdes secondary display device***”), 37-38.

Abbott alleges that Valdes’s “receiver would provide ***data*** to Gawlick’s [patient monitor] system” 106 that acts as a “secondary device” for Valdes’s receiver. Petition, 29 (***citing Valdes, [0118]***). The “data” that Valdes, [0118] says its receiver provides to a secondary device is “sensor, drug (e.g., insulin) and other ***medical*** information.” Valdes [0118] says nothing about settings.

Abbott points to Valdes, [0119]’s teaching that a secondary device can be used to program “alert/alarms settings” on the receiver and Valdes, [0101]’s teaching that an “alert may include alert conditions indicating a minimum glucose

level.” Petition, 38. Those cited Valdes paragraphs teach that settings are sent from the “secondary device” *to the receiver*. Valdes does not teach that the “secondary device” sends these settings anywhere else, let alone to a *server* or *remote monitor*.

Thus, nothing in Valdes supports Abbott’s assertion that when Gawlick’s patient monitor system (*host device*) is modified to act as a “secondary device” for Valdes’s receiver (Petition, 29 and 31) that this would yield a *host device* that “sets a [] setting” that is used to generate one or more rules that are *provided to the remote monitor by the secure server* as required to meet Limitation 1[c] and its antecedents in Limitations 1[a]-[b].

c. Gawlick Does Not Meet Limitation 1[c]

Abbott alleges without citation that “Gawlick discloses a patient monitor system (*host device*) that can be used to configure ‘an alert rule table 1100’ with *preferences or settings* used to generate *the set of one or more rules* for the medical personnel alert devices.” Petition, 37. This assertion is entirely unsupported. As explained below, Gawlick does describe rules that are provided by the data processing system 102 (*secure server*) to the medical personnel alert system 104 (*remote monitor*). But none of those rules are “*generated according to one or more preferences or settings from*” *Gawlick’s patient monitoring system*, which

Abbott alleges to be “*a host device*,” as required to meet Limitation 1[c]. Abbott fails to establish otherwise.

i. None of the Petition-Cited Gawlick Disclosures Teach Preferences or Settings “From a Host Device” as Limitation 1[c] Requires

Abbott cites Gawlick, [0014], [0037]-[0038] and Fig. 4 as purportedly disclosing “interfaces and applications [that] allow a user to adjust *preferences or settings using the patient monitor system*” alleged to meet the *host device*.

Petition, 37 (italics original). *None* of the cited sections of Gawlick supports this.

“FIG. 4 depicts a block diagram of the patient monitor system of the medical alert system of FIG. 1 in accordance with an example embodiment.” Gawlick, [0014]. Neither Figure 4, nor Gawlick, [0014]—quoted in its *entirety* above—says anything about rules, let alone preferences or settings for rules.

Gawlick, [0037]-[0038] identify and describe the “functionality” of the components in Figure 4’s “block diagram” and say nothing about rules, preferences, or settings. Abbott’s assertion that Gawlick, [0038] teaches that Figure 4’s “interfaces and applications allow a user to adjust *preferences or*

settings using the patient monitor system” is entirely unsupported. Petition, 37.

Gawlick, [0038]⁵ says no such thing.

Abbott also cites Gawlick, [0061]’s explanation that Fig. 11 shows “an alert rule table 1100 [that] summarizes a series of rule range values.” Petition, 37-38.

Gawlick Fig. 11 and [0061] do not help Abbott because they teach *nothing* about preferences or settings for those rules and how they are set. Gawlick Fig. 11 and [0061] never say that preferences and settings for these rules are “adjust[ed]...

using the patient monitor system” alleged to meet the *host device* as Abbott erroneously alleges. Petition, 37.

Abbott cites Gawlick Fig. 17 and [0076]-[0087] as teaching “an exemplary ‘plurality of user interface controls that allow the user to define a new alert rule.’” Petition, 37-38. But this disclosure has nothing to do with “*preferences or settings from a host device*” as required by Limitation 1[c]. Paragraph [0075], which immediately precedes Abbott’s cited block of paragraphs ([0076]-[0087]), explains that those paragraphs describe “an alert rule window [that] may be presented under control of browser application 311 in combination with the second medical alert application 310 [both running *on the alleged remote monitor*] and through

⁵ To the extent Abbott relies on Gawlick, [0038]’s disclosure of a medical alert application running on the patient monitor system, that fails as discussed in §III.A.5.c.ii below.

interaction with medical alert application 210 [running on the alleged *secure server*] at medical personnel alert device 104' [the alleged *remote monitor*].” This disclosure never mentions Gawlick’s patient monitor system that is alleged to meet the *host device*. This disclosure describes interaction between the alleged *remote monitor* and *secure server* and has nothing to do with “*preferences or settings from a host device*” as required by Limitation 1[c].

“[B]rowser application 311 in combination with the second medical alert application 310” (Gawlick, [0075]) both run on Gawlick’s “medical personnel alert device” 104'. Gawlick, Fig. 3 and [0034]. Abbott alleges that this medical personnel alert device 104' meets the *remote monitor*—not the *host device*.

Petition, 29 and 33. Medical alert application 210 runs on server 112 of Gawlick’s data processing system 102. Gawlick, Figs. 1-2 and [0017]-[0018]. Abbott alleges that this data processing system 102 meets the *secure server* – not the *host device*.
Petition, 29 and 33.

Thus, Gawlick, [0075] is clear that the disclosure in Figure 17 and [0076]-[0087] that Abbott relies on as teaching a user interface to “allow the user to define a new alert rule” (Petition, 37-38) has nothing to do with Gawlick’s patient monitor system 106 that the Petition relies on to meet the *host device* (Petition, 29 and 37). These disclosures do not teach “*preferences or settings from a host device*” as required by Limitation 1[c].

ii. Gawlick’s Application Running on the “*Host Device*” Does Not Help Abbott

Abbott alleges that Gawlick teaches that the “user interface windows” in Figs. 11 and 17 “can be accessed from the patient monitor system” that Abbott maps to the *host device*. Petition, 37 (citing Gawlick, [0014]-[0016]). The cited Gawlick paragraphs are in the “Brief Description of the Drawings” and do not support Abbott’s assertion.

As discussed *supra* §III.A.5.c.i, Gawlick, [0014] merely explains that Figure 4 is a block diagram of patient monitor system 106. Gawlick, [0015] says “FIG. 5 depicts a flow diagram illustrating example operations performed using medical alert application of the server computing device of FIG. 2, the medical personnel alert device of FIG. 3, and/or the patient monitor system of FIG. 4[.]” Gawlick, [0016] says that Figs. 6-31 depict user interface windows for “the medical alert application of Fig. 5.”

None of those cited paragraphs says that Gawlick’s interface in Fig. 11 or Fig. 17 is provided on the patient monitor system (*host device*). Fig. 11 and [0061] that describes it say ***nothing*** about preferences or settings for the rules listed in Fig. 11’s “alert rule table,” let alone teach that preferences or settings for those rules came “*from a host device*” as required by Limitation 1[c].

Figure 17 is the only cited disclosure in Gawlick that even relates to preferences or settings for a rule. But Gawlick is explicit that Fig. 17 illustrates

“an alert rule window [that] may be presented under control of browser application 311 in combination with the second medical alert application 310 [both on the *remote monitor*] and through interaction with medical alert application 210 [on the *secure server*] at medical personnel alert device 104' [the *remote monitor*].”

Gawlick, [0075]; *Supra* §III.A.5.c.i. Fig. 17 does not disclose preferences or settings *from the patient monitor system (host device)*.

Abbott also points to Gawlick Fig. 4 and the description in Gawlick, [0037] of this “block diagram” of the “patient monitor system” 106 (*host device*) which includes output interface 400, input interface 402, “third medical alert application 410” and “second browser application 411.” Petition, 37. Abbott alleges that Gawlick, [0038] discloses that “[t]hese interfaces and applications allow a user to adjust preferences or settings *using the patient monitor system*” (*host device*). Petition, 37. Not so. Gawlick, [0038] says *nothing* about preferences or settings for any rule, let alone “*preferences or settings from a host device*” (Limitation 1[c]) for rules “*provided to the remote monitor by the secure sever*” (Limitation 1[b]).

Gawlick, [0038] says that various components of patient monitoring system 106 (*host device*) can be “the same or similar” as those of server 112, and that “[t]hird medical alert application 410, second medical alert application 310, and/or medical alert application 210 may be the same or different applications or part of

an integrated, distributed application.” Abbott provides **no** explanation (let alone a detailed one) of how and why this allegedly discloses “*preferences or settings from a host device*” (Limitation 1[c]) for one or more rules that “*are provided to the remote monitor by the secure sever*” (Limitation 1[b]). That fails to meet Abbott’s burden to provide a “**detailed** explanation of the significance of the evidence.” 37 C.F.R. §42.22(a)(2); *See also* 37 C.F.R. §§42.104(b)(4)-(5) (“the petition must specify where each element of the claim is found in the prior art patents or printed publications relied upon” and “must” identify “specific portions of the evidence that support the challenge”).

DexCom bears no burden in this proceeding. Neither DexCom, nor the Office, has any obligation to speculate as to theories Abbott failed to advance and explain why various unexplained theories would have failed. Abbott’s failure to meet its burden to explain how and why Gawlick discloses “*preferences or settings from a host device*” (Limitation 1[c]) for one or more rules “*provided to the remote monitor by the secure sever*” (Limitation 1[b]) should end the matter.

But as explained above, the **only** disclosure in Gawlick that Abbott cites relating to preferences or settings for rules is the disclosure in Fig. 17 and [0076]-[0087] that Gawlick expressly (in [0075]) describes as being performed on medical personnel alert system 104 (*remote monitor*) and server 112 of data processing system 102 (*secure server*)—not on patient monitor system 106 (*host device*). To

the extent the Petition implicitly argues that ***all*** of Gawlick’s disclosure about the functionality of the medical alert application running on medical personnel alert system 104 and/or server 112 should be understood as also describing functionality of the medical alert application that runs on patient monitor system 106 (*host device*), that fails because Gawlick describes functionality of the application running on medical personnel alert system 104 (*remote monitor*) that simply cannot also be performed on patient monitor system 106 (*host device*).

For example, FIG. 15’s above-discussed dashboard that includes alert rule list 1500 is “presented under control of browser application 311 in combination with second medical alert application 310 [both on the *remote monitor*] and through interaction with medical alert application 210 [on the *server*] at medical personnel alert device 104’ [*remote monitor*].” Gawlick, [0068]. This dashboard is for medical personnel and can include alerts for ***multiple*** patients. Gawlick, [0074] (referring to an alert rule “applied to ***all patients***, a specific patient, all patients of a specific physician,” etc.). A POSA would have understood that this functionality cannot be provided on one of the devices in patient monitor system 106 (*host device*) because each of those devices is associated with a ***particular*** patient and a patient has no reason to receive alerts about ***other patients***. Indeed, providing a patient with alerts about the health conditions of ***other*** patients would violate the privacy rights (e.g., under HIPAA) of those other patients. Abbott does not—

because it cannot—credibly argue that ***all*** the functionality that Gawlick describes as being performed on medical personnel alert system 104 (*remote monitor*) and *server* 112 is also somehow performed on patient monitor system 106 (*host device*) in the Gawlick-Valdes combination.

To demonstrate that its Gawlick-Valdes combination meets Limitation 1[c] based on Gawlick’s disclosure of how rule preferences and settings are set, Abbott needed to point to some teaching in Gawlick of “*preferences or settings from a host device*” (Limitation 1[c]) for one or more rules that “*are provided to the remote monitor by the secure sever*” (Limitation 1[b]). The Petition fails to carry Abbott’s burden to do so.

d. The Petition’s Reasons to Combine with a Reasonable Expectation of Success Do Not Yield a Gawlick-Valdes Combination That Meets Limitation 1[c]

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.” *Personal Web Technologies v. Apple*, 848 F.3d 987, 994 (Fed. Cir. 2017); *see also TQ Delta v. CISCO Sys.*, 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 no reason why a POSA would have ***modified*** Valdes so that its receiver provides a rule set thereon to a secure server. Nor does the Petition allege any reason why a POSA would have ***modified*** Gawlick to allow patient monitor system 106 (*host device*) to set preferences or settings for rules provided to medical personnel alert system 104 (*remote monitor*) by data processing system 102 (*secure server*) as required by Limitation 1[c].

Indeed, no such modification to Gawlick or Valdes would be supported by the Petition’s “Motivated to Combine... with a Reasonable Expectation of Success” section which relies on *KSR*’s known elements/predictable results rationale. That rationale only applies when no change is made to the function of any of the combined prior art elements. *See supra* §III.A.4.

e. Conclusion on Ground I’s Failing for Limitation 1[c]

As detailed above, Abbott fails to carry its burden to demonstrate that the Gawlick-Valdes Combination meets Limitation 1[c]’s requirement that “*the host device sets a first setting of the one or more preferences or settings*” that, pursuant to the antecedents in Limitations 1[a]-[b], are used to generate the *set of one or more rules* [that] *are provided to the remote monitor by the secure server*. Neither Gawlick nor Valdes teaches what Limitation 1[c] requires and Abbott establishes

no reason why a POSA would have modified Gawlick’s system in a manner that meets Limitation 1[c].

Ground I fails for claim 1 for this reason alone.

6. Abbott Fails to Establish That Its Gawlick-Valdes Combination Meets Limitation 1[g]

Limitation 1[d] requires “*modifying, by the remote monitor, at least one rule of **the** set of one or more rules*” and Limitation 1[g] more specifically requires doing so by “*modifying, by the remote monitor, the first setting set by the host device.*” “[**T**]*he set of one or more rules*” in Limitations 1[d] and 1[g] is the same set of one or more rules “*generated according to one or more preferences or settings from a host device*” per Limitation 1[c].

As discussed *supra* §III.A.5, Abbott fails to establish that its Gawlick-Valdes combination meets Limitation 1[c]’s requirement that “*the host device sets a first setting of the one or more preferences or settings*” that, pursuant to the antecedents in Limitations 1[a]-[b], are used to generate the *set of one or more rules* [that] *are provided to the remote monitor by the secure server* in the first place. Abbott’s showing for Limitation 1[g] fails to remedy that failing and further fails to establish that its Gawlick-Valdes combination meets the additional requirements of Limitation 1[g].

Abbott alleges that “Gawlick discloses using a medical alert application on a medical personnel alert device (*remote monitor*) for *modifying the first setting set*

by the host device.” Petition, 42 (citing Ex-1005, [0014]-[0015]). The two cited paragraphs of Gawlick ([0014]-[0015]) are in the “Brief Description of the Drawings” and do not even mention rules or settings, let alone support Abbott’s conclusionary assertion that they teach that the “medical personnel alert device (*remote monitor*)” is “for *modifying the first setting set by the host device.*” Petition, 42.

Abbott cites Gawlick Fig. 15, [0071] and [0075]-[0076] for its disclosure of Gawlick’s “alert rule list.” Petition, 42-43. Abbott quotes the statement in [0075] that the user can “adjust parameters associated with the alert rule.” *Id.* But Abbott cites no disclosure in Gawlick that the “parameters associated with the alert rule” that the user can “adjust” were ever set by patient monitor system 106 (*host device*), as would be required to meet Limitation 1[g]’s “*first setting set by the host device.*” Indeed, the sections of Gawlick that Abbott cites only disclose settings set by the user of medical personnel alert system 104 (*remote monitor*). The “users” of the “***medical personnel*** alert system 104” in these paragraphs are medical personnel—not the patient. *See also* Gawlick, [0020] (“***[m]edical personnel*** may use” Gawlick’s system), [0046] (“user” selection shows diagnosis for multiple patients), Fig. 6.

As discussed *supra* §III.A.5.c.ii, Gawlick describes FIG. 15’s dashboard as including an alert rule list 1500 “presented under control of browser application

311 in combination with second medical alert application 310 [both on the *remote monitor*] and through interaction with medical alert application 210 [on the *server*] at medical personnel alert device 104' [*remote monitor*]" ***without mentioning the patient monitor system 106 (host device)***. Gawlick, [0068].

Abbott quotes Gawlick for disclosure that the alert rule window “allows the ***users*** to adjust the parameters associated with the alert rule.” Gawlick, [0075] (cited at Petition, 43). But Gawlick, [0075] uses virtually identical language to [0068] to describe functionality performed only on the medical personnel alert system 104 (*remote monitor*) and data processing system 102 (*secure server*) and not on patient monitor system 106 (*host device*). Specifically, as discussed *supra* §III.A.5.c, Gawlick, [0075] says the “alert rule window may be presented under control of browser application 311 in combination with the second medical alert application 310 [both on the ***remote monitor***] and through interaction with medical alert application 210 [on the ***server***] at medical personnel alert device 104' [***remote monitor***]" without mentioning patient monitor system 106 (*host device*). Again, the “users” in Gawlick, [0075] are users of the “***medical personnel*** alert system 104” and are medical personnel—not the patient. Gawlick, [0020], [0046], Fig. 6.

None of the Gawlick disclosures that Abbott cites about the alert rule list in Fig. 15 ever say that the user, *i.e.*, medical personnel, can adjust rules generated

based on a setting set by the patient monitor system 106 (*host device*) as required to meet Limitation 1[g]’s modifying a “*first setting set by the host device.*”

The remaining disclosures in Gawlick that Abbott cites ([0059] and [0062]) are only cited to teach that the user of medical personnel alert device 104' (*remote monitor*) can save the adjusted alert range values and customize them for the patient and/or medical personnel, and that the patient is identified in patient demographic data. Petition, 43. These disclosures say nothing about how the settings for the alert rules were established in the first place, let alone disclose that any setting was set by patient monitor system 106 (*host device*) as would be required to meet Limitation 1[g]’s modifying a “*first setting set by the host device.*”

Thus, Abbott’s allegation that “***Gawlick discloses*** using a medical alert application on a medical personnel alert device (*remote monitor*) for *modifying the first setting set by the host device*” (Petition, 42) fails because Gawlick discloses no such thing.

Neither Gawlick nor Valdes teaches what Limitation 1[g] requires and Abbott establishes no reason why a POSA would have modified Gawlick’s system in a manner that meets Limitation 1[g]. Thus, Abbott fails to establish that its Gawlick-Valdes combination meets Limitation 1[g]’s requirement of “modifying,

by the remote monitor, the first setting *set by the host device*.” Ground I fails for claim 1 for this additional independent reason.

7. The Petition Fails to Establish That Its Gawlick-Valdes Combination Meets Limitation 1[h]

Limitation 1[h] requires “*modifying the first setting by the remote monitor... without changing the first setting at the host device*.” If the Board agrees that Abbott fails to show that its Gawlick-Valdes combination meets Limitation 1[g]’s requirement of “*modifying, by the remote monitor, the first setting set by the host device*,” then Abbott clearly fails to show that its Gawlick-Valdes combination does so “*without changing the first setting at the host device*” as required by Limitation 1[h]. But Abbott’s showing for Limitation 1[h] also fails for an additional independent reason.

Abbott alleges that Gawlick discloses Limitation 1[h] because it “discloses that a medical personnel alert device (*remote monitor*) allows a user to ‘override the alert rule’ (*modify the first setting by the remote monitor*) ‘so that the modified alert rule is only associated with the user’ of the medical personnel alert device” and “**does not effect [sic] the alert rules of other users.**” Petition, 44 (emphasis original).

What is conspicuously absent from Abbott’s showing is any reference to patient monitor system 106 that Abbott alleges meets the *host device*. As the Petition itself acknowledges, the disclosure Abbott cites relates to a “‘user’ of the

medical personnel alert device” (Petition, 44)—which is what Abbott maps to the *remote monitor* (see e.g., Petition, 29 and 39). The cited disclosure says a user of a ***medical personnel*** alert device (*remote monitor*) can modify an alert rule associated with that user without affecting the alert rules for ***other users of medical personnel alert devices (remote monitors)***. This never even mentions Gawlick’s patient monitor system 106 (*host device*).

The “petition must specify where ***each element of the claim is found in the prior art*** patents or printed publications relied upon” and “must” identify “specific portions of the evidence that support the challenge.” 37 C.F.R. §42.104(b)(4)-(5). Abbott fails to do so for the “element of the claim” in Limitation 1[h] that requires modifying the first setting “*without changing the first setting at the host device*” because Abbott’s showing ignores the alleged “*host device*” entirely.

Thus, Abbott fails to demonstrate that its Gawlick-Valdes combination meets Limitation 1[h]’s requirement that the first setting be modified “*without changing the first setting at the host device*.” Ground I’s showing for claim 1 fails for this additional independent reason.

8. Abbott Cannot Rely on Expert Testimony to Provide the Limitations That Are Missing from the Prior Art

The Board’s rules are clear that “[t]he 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). Above-discussed Limitations 1[c] and

1[g]-[h] require setting (by a *host device*) and modifying (by a *remote monitor*) a rule setting in a highly specific way that is not taught by Gawlick, Valdes, or any other prior art reference.

The risk of hindsight bias is apparent when a petitioner alleges that a combination of references renders a claim obvious despite none of the references teaching one or more claim limitations. As a result, the Board routinely denies institution when a petition—like Abbott’s—relies only on an expert’s say-so to meet a limitation missing from the art. *Xerox v. Bytemark*, IPR2022-00624, Paper 9, 14-16 (Aug. 24, 2022) (precedential) (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.

The Board’s precedential *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*, 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.* But “[p]etitioner’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 principles articulated in the Federal Circuit’s decision in *Arendi S.A.R.L. v. Apple*, 832 F.3d 1355, 1362 (Fed. Cir. 2016). *Xerox*, Paper 9, 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*, 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 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 the principles

articulated in *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 limitations are unusually simple or that the claimed technology is particularly straightforward. Abbott thus failed to establish that this is one of the rare cases where a claim can be shown to be obvious despite the claim including limitations that are absent from the prior art.

9. Ground I’s Showing for Every Challenged Claim Fails for the Same Reasons as It Fails for Claim 1

The Petition’s showing for the other independent claim (claim 12) inherits the above-discussed failings regarding claim 1 because Abbott makes no separate showing for claim 12 and instead relies entirely on its showing for claim 1.

Petition, 50-51 (for Limitations 12[c]-[k] citing “*See* Section VIII.A.2.b” through “Section VIII.A.2.i” addressing Limitations 1[a]-[h]).

Ground I’s showing for dependent claims 2-3 inherits the failings for claim 1. And Ground I’s showing for dependent claims 13-14 inherits the failings for claim 12 which in turn inherit the failings for claim 1. Thus, Ground I fails for all claims for the same reasons it fails for claim 1.

B. Ground IV Fails

Ground IV alleges that certain Challenged Claims—including independent claims 1 and 12—would have been obvious over Paterno and Valdes. Petition, 64-79. Abbott fails to establish that Paterno and Valdes render any Challenged Claim obvious.

1. Paterno

Paterno describes “[a] convenient task reminder, compliance logging and monitoring system for *routine activities*.” Paterno, Abstract. “The principle objective... is to provide reminders and messages to an individual, track the individual’s responses to the reminders and messages, and relay the individual's responses to [others]... to help an individual and select caregivers... *track the individual’s performance of routine tasks*.” Paterno, 2:5-11.

Paterno’s system includes Home Units 100 and a “Subscriber Communications Management System, (SCMS).” Paterno, 3:29-39 and Fig. 4. The Home Unit 100’s “primary function” is “scheduling of future events and logging of events to that schedule.” *Id.*, 5:55-57. Each Home Unit has an associated account record in the SCMS that identifies which individuals can access the account. *Id.*, 3:33-39.

Paterno’s system is “for compliance logging and monitoring” of “*routine activities*” and provides “an automated communications/notification system that can relay the activity and/or inactivity recorded by a Home Unit device to other

systems and/or specifically designated people.” Paterno, 3:15-20. Routine activities include reminders to take medication and confirming to the caregiver that the patient has done so. Paterno, 8:35-37 (“Betty it is time to take your morning medications – please press the OK button after you have done this.”).

2. Abbott’s Assertion That a POSA Would Have Used Paterno’s System to Remotely Monitor Valdes’s CGM System Is Unsupported

Abbott asserts that a POSA would have used Paterno’s system to monitor Valdes’s CGM system. Petition, 64-67. Nothing supports that.

a. Abbott Mischaracterizes Paterno

Paterno’s system is for scheduling the taking of medication and other routine tasks, reminding the patient of those tasks and logging compliance. *Supra* §III.B.1. Paterno never discloses using its system to remotely monitor devices (like a CGM) that measure some characteristic of the patient’s body. Valdes does not remedy this deficiency because it has no server providing alerts to remote monitors and discloses nothing about server-based remote monitoring.

Abbott’s assertion that Paterno teaches that its system monitors “blood sugar” is false. Petition, 66. Abbott cites (*id.*) disclosure in Paterno’s “BACKGROUND OF THE INVENTION” describing *prior art* systems that “exist” and do various things, including monitoring “health parameters” like “blood sugar, pressure, heart rate and weight.” Paterno, 1:40-53. These *prior art*

systems are described as “BACKGROUND” and distinguished from Paterno’s “invention.” Paterno, 1:40-60. Paterno never describes its “invention” as monitoring blood sugar or any other of what Paterno calls “health parameters.”

Abbott also obfuscates by selectively quoting out-of-context snippets from Paterno to suggest that it teaches obtaining “data” from “input devices” and “captur[ing] valuable data on the health of the individual.” Petition, 65 (*citing* Paterno, 4:22-40 and 13:48-51). These citations—nine columns apart—are unrelated and fail to support Abbott’s assertion.

Paterno, 4:22-40 describes “input devices [that] can include sensors that automatically acquire input *from their environment*, such as motion detectors, water flow meters, and pressure sensors, as well as user interfaces that provide a means for an individual to directly enter information.” This says nothing about sensors that measure blood sugar or any other characteristic of the patient’s physiological parameters.

Paterno, 13:48-51 describes use of Paterno’s system to “administer depression surveys” which thereby “*captures valuable data on the health of the individuals* that the care coordinators are currently not staffed to collect.” Paterno, 13:32-51. The above-emphasized language about “data on the health of the individuals” that Abbott quotes (Petition, 65) refers to a survey and has nothing to do with a sensor to measure any characteristic of the patient’s body.

The only other Paterno disclosures Abbott cites in its “Motivated to Combine Paterno and Valdes” section are cited to establish that Paterno’s Home Units “are part of a reminding, logging and notification system” (6:6-10) and that Paterno’s SCMS can collect and analyze data from the Home Units (15:17-27). Petition, 66. Neither disclosure is even alleged to teach that Paterno’s system monitors any type of device that monitors a physical characteristic of the patient’s body.

b. Abbott Established No Supportable Reason to Combine Paterno and Valdes

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 Lab.*, 655 F.3d at 1360; *see also KSR*, 550 U.S. at 418 (establishing obviousness requires a *reason* to combine the references in the manner claimed).

The only “reason” that Abbott’s “Teaching, Suggestion, Motivation” section provides is that “Paterno refers to monitoring blood sugar (Ex-1006, 1:46-48), but does not explicitly disclose incorporating a ‘blood sugar’ sensor. A POSITA... understood that *a sensor would be needed to provide in home monitoring of ‘blood sugar’*” and that Valdes’s CGM teaches “one way to monitor ‘blood

sugar.’”⁶ Petition, 66. Abbott’s alleged “reason” is unsupported because Paterno’s reference to “blood sugar” describes prior art systems that “exist” and not Paterno’s monitoring system. Paterno, 1:45-50; *supra* §III.B.2.a. No blood sugar sensor is “needed” in Paterno’s system (Petition, 66) because Paterno’s system does not remotely monitor blood sugar.

Thus, the Petition’s only “reason” to combine is unsupported. Ground IV fails to establish obviousness of any Challenged Claim for this reason alone.

Unigene Lab., 655 F.3d at 1360; *KSR*, 550 U.S. at 418.

3. Abbott Only Alleges Motivation to Use Valdes’s Sensor/Receiver in Paterno’s System without Modifying Paterno’s System

Even if Abbott establishes a reason to combine Paterno and Valdes in *some* way (it did not), Abbott fails to establish any reason why a POSA would have combined them in a manner meeting any challenged claim. Abbott alleges that “[c]ombining Paterno and Valdes would have involved *merely combining prior art elements* (i.e., adding Valdes’s CGM to Paterno’s remote monitoring system) *according to known methods to yield predictable results* (i.e., remote monitoring

⁶ If the Board considers Abbott’s assertion that its combination merely combines known elements to yield predictable results to allege a separate “reason” to combine, that rationale fails to yield a combined system meeting any Challenged Claim as discussed *infra* §III.B.4.

of continuous measurements of the blood glucose level of a host).” Petition, 67 (citing *KSR*). As discussed *supra* §III.A.4, this *KSR* rationale ***only*** applies when known prior art elements are combined without “change in their respective functions.” *KSR*, 550 U.S. at 415-16.

The specific nature of the Paterno-Valdes Combination that Abbott’s “Motivated to Combine” section purports to establish is important because, as discussed below, numerous claim limitations are not met by a system that would have resulted from “merely combining” these references to “provide in home monitoring of ‘blood sugar’” using Valdes’s CGM by “combining [Valdes’s] CGM... with the monitoring system disclosed by Paterno.” Petition, 66-67.

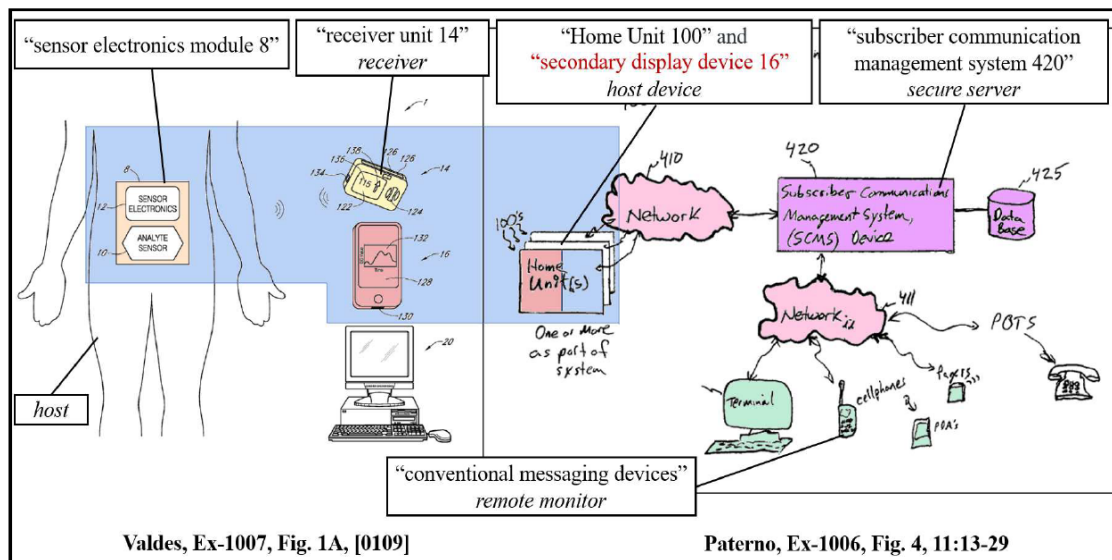
In attempting to map its purported Paterno-Valdes combination to various claim limitations, Abbott is repeatedly forced to modify the functionality of the “known elements” of Paterno, Valdes or both. But Abbott never provides any “reason” why a POSA would have made those modifications and only purports to “support” its Paterno-Valdes combination by referring back to its “Motivated to Combine” section. That section supports no such modifications and indeed relies on *KSR*’s known elements/predictable results rationale that ***precludes*** such modifications to the functions of the combined prior art elements.

Abbott fails to establish any reason why a POSA “would have selected and combined [the] prior art elements” in a manner that “*yield[s] the claimed invention.*” *Unigene Lab.*, 655 F.3d at 1360.

4. Abbott Fails to Establish That a POSA Would Have Implemented a Paterno-Valdes Combination Meeting Limitation 1[c]

Limitation 1[c] requires that the *host device* set a setting used to generate one or more rules provided to the *remote monitor* by the *secure server*. *Supra* §III.A.5.

Abbott alleges that the *host device* is met by Paterno’s Home Unit, the *remote monitor* is met by Paterno’s caregiver messaging devices (e.g., cellphones and PDAs) and the *secure server* is met by Paterno’s Subscriber Communications Management System (SCMS). Petition, 65 (with annotated figure reproduced below) and 68-69. Abbott further alleges that “[i]n the Paterno-Valdes combination, Paterno monitors a host’s ‘blood sugar’ through Valdes’s sensor and receiver unit, with the host’s ‘profile’ including ‘notification parameters,’ *rules*, for alerting *remote monitors* based on the host’s blood sugar levels.” Petition, 70.



For multiple reasons detailed below, Abbott fails to establish that a POSA would have implemented a Paterno-Valdes combination in which a *host device* sets a setting used to generate a rule provided to the *remote monitor* by the *secure server* as Limitation 1[c] requires.

a. The Petition Fails to Explain How Limitation 1[c] is Allegedly Met with the Required Particularity

The Petition “may be considered *only* if” it “identifies... *with particularity*... the grounds... and the evidence that supports the grounds for the challenge to each claim.” 35 U.S.C. §312(a)(3). The “petition... must include... a detailed explanation of the significance of the evidence” (37 C.F.R. §42.22(a)(2)), “must specify where each element of the claim is found in the prior art” and “must” identify “specific portions of the evidence that support the challenge” (37 C.F.R. §42.104(b)(4)-(5)).

The Petition fails to comply with these requirements because it is entirely unclear about how and why the Paterno-Valdes combination purportedly meets Limitation 1[c]. As detailed below, Limitation 1[c] is not met by Valdes, Paterno or the Paterno-Valdes combination that would have resulted from a POSA motivated to combine Paterno and Valdes in the manner alleged in the Ground IV's "Motivated to Combine" section.

b. Valdes Does Not Meet Limitation 1[c]

Abbott points to Valdes, [0119]'s teaching that a secondary device can be used to program "alert/alarms settings" on the receiver and Valdes, [0101]'s teaching that "a hypoglycemic alert may include alert conditions indicating a minimum glucose level." Petition, 70. In Abbott's Paterno-Valdes combination, Valdes's "secondary device" is implemented by Paterno's Home Unit which is alleged to meet the claimed *host device*. Petition, 70 (the combination "implement[s] Paterno's Home Unit to include capabilities of a Valdes secondary display device used to modify glucose alert conditions, i.e., *one or more preferences or settings*") and 68 ("Home Unit (*host device*)").

Settings from Valdes's secondary device are provided to Valdes's receiver. Petition, 70 (citing Valdes, [0119] ("user parameters *associated with the receiver unit 14* can be programmed into (and/or modified) by... secondary device 16")).

Those settings are implemented on the receiver. They are not sent to a *secure server* or provided to a *remote monitor*.

Valdes does not disclose a *remote monitor* or a *server*. Thus, nothing in Valdes supports Abbott's assertion that when Paterno's Home Unit (*host device*) acts as a "secondary device" for Valdes's receiver (Petition, 70) that this would yield a *host device* that "sets a [] setting" used to generate one or more rules provided to the *remote monitor* by the *secure server* as required by Limitation 1[c] and its antecedents in Limitations 1[a]-[b].

c. Paterno Does Not Meet Limitation 1[c]

Abbott points to Paterno's disclosure that "subscribers can... program[] sending of messages, alerts, and alert schedule updates to the Home Unit" and "set[] what notifications and messages they will *receive from the system*." Petition, 70 (quoting Ex-1006, 3:57-63).

"Subscribers" are users of the "**Subscriber** Communications Management System" (SCMS). Subscribers have subscriber accounts and use "messaging devices" that Abbott maps to the *remote monitor* to program the Home Unit that Abbott maps to the *host device*. Petition, 65 (annotated figure); Paterno, 3:29-46. As Abbott admits, Paterno's SCMS "allow[s] programming of the Home Unit (*host device*)." Petition, 68; *see also id.*, 70 (quoting Paterno's disclosure of "programming... to the Home Unit"). The converse is not true. Paterno does not

disclose that the Home Unit (*host device*) programs any rule on the SCMS (*secure server*).

Rule settings stored in Paterno's SCMS are provided by what Abbott labels as "conventional messaging devices" (*remote monitors*). Petition, 65 (annotated figure). Abbott alleges that "a POSITA would use the modified Home Unit (*host device*) to set a first setting... and store them in the SCMS." Petition, 71. This finds no support in Paterno which never describes using the ***Home Unit*** to set a setting stored in the SCMS.

Thus, even if a POSA would have modified Paterno's Home Unit to act as a secondary device in Valdes and provide alert settings to Valdes's CGM receiver as Abbott alleges (Petition, 70), that does not meet claim 1. Petition, 70. To meet claim 1, Abbott had to establish that the alleged *host device*—Paterno's "modified Home Unit" (Petition, 71)—sets "*a first setting of **the** one or more preferences or settings*" that are used to generate one or more rules (Limitation 1[c]) "***provided to the remote monitor by the secure server***" (Limitation 1[b]). Nothing in Paterno supports this because Paterno does not teach that any setting from its Home Unit is stored in the SCMS (*secure server*) or is used to generate a rule provided by the SCMS to a subscriber messaging device (*remote monitor*).

d. Abbott’s Assertion That a POSA Would Have Stored a Setting from Paterno’s Home Unit in the SCMS Is Unsupported

Abbott alleges in conclusory fashion that “a POSITA would use the modified Home Unit (*host device*) to set a first setting... and *store them in the SCMS*.” Petition, 71.

i. Neither Paterno nor Valdes Supports Abbott’s Assertion

Abbott cites no teaching in Paterno or Valdes to support the assertion that a setting from the Home Unit is stored in the SCMS (Petition, 71) because neither reference supports this.

Paterno - as discussed in Section III.B.4.c, Paterno never teaches that its Home Unit “set[s] a first setting” that is stored “in the SCMS.” Petition, 71. Abbott’s argument is unsupported by anything in Paterno.

Valdes – Abbott alleges that “Paterno’s Home Unit, operating as Valdes’s secondary device, would be used to set hypoglycemic- or hyperglycemic-alert thresholds.” Petition, 71. But that would not meet what claim 1 requires. Valdes’s secondary device sets settings on Valdes’s receiver. Valdes, [0119]. Nothing in Valdes suggests that any setting from the secondary device for an alert on Valdes’s CGM system would be sent to a remote server. Petition, 71. Indeed, Valdes does not even disclose a remote server and Abbott does not allege otherwise.

Thus, neither of Ground IV’s references disclose what Limitation 1[c] requires.

ii. Abbott Never Alleges a Reason to Modify Paterno’s System in a Manner Required to Meet Limitation 1[c]

Abbott seeks to meet Limitation 1[c]’s requirement that the *host device* set a setting used to generate rule(s) provided to the *remote monitor* by the *secure server* by simply alleging that “a POSITA *would* use the modified Home Unit (*host device*) to set a first setting... and store them in the SCMS.” Petition, 71. But Abbott fails to even allege, let alone establish, any *reason why* a POSA would have stored in the SCMS a setting the Home Unit sets.

Abbott only alleges that “[a] POSITA would have combined Paterno and Valdes for at least the reasons explained above and in Section VIII.D.1.” Petition, 71. “Section VIII.D.1” is the “Motivated to Combine” section discussed *supra* §III.B.2.b. Nothing in that section or “explained above” in the Petition ever alleges any reason to *modify* Paterno’s system to store in the SCMS a setting set by the Home Unit. Indeed, as discussed *supra* §§III.A.2 and III.B.2.b, Abbott’s reliance on *KSR*’s known elements/predictable results rationale precludes any such *modification* to the manner in which Paterno’s system functions.

Nothing in the expert declaration could save Abbott from the Petition’s failure to establish a reason why a POSA would have modified Paterno’s system in

the manner Abbott alleges to meet Limitation 1[c]. The **Petition** must demonstrate the Challenged Claims unpatentable and arguments cannot be incorporated by reference into the Petition. 37 C.F.R. §§42.22(a)(2), 42.104(b)(4)-(5), and 42.6(a)(3). But even if the Board waded into the expert declaration, the cited testimony merely parrots the Petition’s “analysis” for Limitation 1[c] virtually word-for-word. *Compare* Petition, 70-71 with Ex-1003, ¶¶223-227. Like the Petition, Abbott’s expert never offers any **reason why** a POSA would have modified Paterno’s system to store in the SCMS a setting set by a Home Unit in the manner Abbott alleges to meet Limitation 1[c].

It is insufficient to establish a reason to combine the prior art references in **some** way. To demonstrate any Challenged Claim obvious, Abbott needed to establish some **reason why** a POSA “would have... combined [the] prior art elements” in a manner that “**yield[s] the claimed invention.**” *Unigene Labs*, 655 F.3d at 1360; *KSR*, 550 U.S. at 418 (a “reason” to combine the prior art in the manner claimed is required). Abbott’s failure to do so for Limitation 1[c] is fatal to Ground IV.

**iii. Abbott’s Reliance on Conclusory Expert
Testimony to Meet a Missing Claim Limitation
Fails**

As demonstrated *supra* §III.B.4.d.ii, Abbott identifies no disclosure in Paterno or Valdes that supports storing a setting from the “modified Home Unit

(*host device*)... in the SCMS.” Petition, 71. Indeed, Abbott identifies no prior art reference that teaches Limitation 1[c]’s requirement that the *host device* set a setting used to generate rule(s) provided to the *remote monitor* by the *secure server*. Abbott seeks to meet this claim limitation solely with expert testimony. Petition, 71(citing Ex. 1003, ¶ 223-227). That fails for three reasons.

First, the rules are clear that “[t]he 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). Abbott failed to meet this requirement.

Second, the risk of hindsight bias is apparent when an expert simply alleges that a POSA would have done what a claim limitation requires despite that limitation being missing from the prior art. Abbott does not even allege, let alone establish, the factual predicate necessary to demonstrate that this is one of the rare cases where Federal Circuit law authorizes reliance on expert testimony alone to meet a claim limitation. *See supra* §III.A.8. The Board routinely denies institution when a petition relies only on an expert’s say-so to meet a limitation missing from the art. *Id.* (citing *Xerox* and *Apple*). The Board should do the same here.

Third, the five paragraphs of expert testimony Abbott cites merely parrot the Petition’s “analysis” for Limitation 1[c] virtually word for word. *Compare* Petition, 70-71 with Ex-1003, ¶¶223-227. This testimony provides no analysis, and

cites no corroborating evidence, to support the naked conclusory assertion that “a POSITA would have used the modified Home Unit (*host device*) to set a first setting... and store them in the SCMS.” Petition, 71. This conclusory unsupported testimony warrants no weight. *Xerox*, Paper 9, 14-16.

Abbott cites no credible evidence establishing any reason why a POSA would have implemented the Paterno-Valdes Combination to use “the modified Home Unit (*host device*) to set a first setting... and store them in the SCMS.” Petition, 71.

e. Conclusion on Ground IV’s Failing for Limitation 1[c]

As detailed above, Abbott failed to carry its burden to demonstrate that a POSA would have implemented a Paterno-Valdes combination that meets claim 1’s requirement that the *host device* set a setting (Limitation 1[c]) used to generate one or more rules provided to the *remote monitor* by the *secure server* (Limitation 1[b]). Ground IV fails for that reason alone.

5. Abbott Fails to Establish That Its Paterno-Valdes Combination Meets Any of Limitations 1[d] and 1[g]-[h]

Limitations 1[d] and 1[g]-[h] require modifying rule settings by the *remote monitor* in specific ways. Abbott fails to establish that its Paterno-Valdes Combination meets any of these limitations.

a. Abbott Fails to Establish That Its Paterno-Valdes Combination Meets Limitation 1[d]

Limitation 1[d] requires “*modifying, by the remote monitor, at least one rule of **the** set of one or more rules,*” where “***the** set of one or more rules are generated according to one or more preferences or settings from a host device*” per Limitation 1[c].

Abbott’s showing for Limitation 1[d] alleges in conclusory fashion that Paterno’s disclosure that a caregiver can “*modify ‘profile records’*” meets Limitation 1[d]. Petition, 71. That assertion cites no disclosure in Paterno. Indeed, the only Paterno disclosure the Petition’s section addressing Limitation 1[d] ever cites demonstrates that *subscribers* can program “**what notifications and messages they will receive... based on communications from the Home Unit**” with an “example” being the caregiver receiving an email “every time the SCMS... receives an update from Betty’s Home Unit.” Petition, 71-72 (emphasis original). This Paterno disclosure does not describe “*modifying*” anything.

Even if the Board were to read Paterno’s disclosure of programming alerts to implicitly suggest that alert rules can be modified after they are initially created, Limitation 1[d] requires “*modifying, by the remote monitor, at least one rule*” that is “*generated according to one or more preferences or settings from a host device*” per Limitation 1[c]. Abbott never even alleges, let alone establishes, that Paterno discloses that the “profile records” alleged to meet the modified *rule* (Petition, 71)

are “*generated according to one or more preferences or settings from a host device*” as required by Limitation 1[c]. Indeed, the only “example” Abbott provides is that a “caregiver... may **specify**... that she wants an email sent to her every time the SCMS device 420 receives an update from Betty’s Home Unit.” Petition, 72 (emphasis original). The *caregiver specifying* a rule about receiving email is not based on a setting from the Home Unit (*home device*) and Abbott cites no disclosure in Paterno that it is.

Abbott’s showing for Limitation 1[d] is facially deficient. Abbott does not even allege that the Paterno-Valdes Combination meets “*modifying, by the remote monitor, at least one rule*” as required by Limitation 1[d] where the modified rule is “*generated according to one or more preferences or settings from a host device*” per Limitation 1[c].

Ground IV fails for claim 1 for this separate independent reason.

b. Abbott Fails to Establish That Its Paterno-Valdes Combination Meets Limitation 1[g]

Limitation 1[g] requires “*modifying... by the remote monitor, the first setting set by the host device.*”

Abbott refers to “VIII.D.2.d” (addressing Limitation 1[c]) to purportedly show that “Paterno discloses that the Home Unit configures a *first setting*.” Petition, 74. Abbott then repeats its assertion that Paterno’s “profile records” meet the claimed “*set of one or more rules*” and again points to the “example” of a

“caregiver” specifying “that she wants an email... every time the SCMS... receives an update from Betty’s Home Unit” to allegedly teach modifying at least one rule. Petition, 75. These assertions fail for the same reasons discussed *supra* §III.B.4 because Abbott fails to establish that Paterno discloses that the Home Unit sets any setting in the subscriber “profile records” in the SCMS.

Abbott then further alleges that “[i]n the combined Paterno-Valdes system, the *first setting* by the *host device* is the set of *rules* relating to the ‘blood glucose’ levels disclosed by Valdes, which users would set on Paterno’s Home Unit.” Petition, 75. This assertion alleges that Paterno’s Home Unit would have been modified in some unexplained way to send the “‘blood glucose’ levels disclosed by Valdes” to the SCMS for inclusion in a “profile record.” *Id.*

The “Motivated to Combine” section Abbott relies on never alleges any reason to *modify* Paterno’s system so that blood glucose levels from Valdes’s CGM would be sent to and stored in Paterno’s SCMS. Petition, 66-67. Indeed, as discussed *supra* §§III.B.2.b, III.B.3, Abbott’s reliance on *KSR*’s known elements/predictable results rationale precludes any such modification to the manner in which Paterno’s system functions.

Unable to find support in either prior art reference (Paterno or Valdes) for the assertion that “[i]n the combined Paterno-Valdes system” the “profile records” stored in the SCMS would include blood glucose levels “set on Paterno’s Home

Unit,” Abbott cites only its expert. Petition, 75 (citing only “Ex-1003, ¶¶241-43”). That fails for three reasons.

First, “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). Abbott failed to meet this requirement.

Second, Abbott fails to even allege, let alone establish, the factual predicate necessary to demonstrate that this is among the rare cases where a missing claim limitation can be met by expert testimony alone. *See supra* §III.A.8 (citing the Board’s *Xerox* and *Apple* decisions denying institution where a petition relied only on an expert’s say-so to meet a limitation missing from the art).

Third, the cited expert testimony merely parrots the Petition’s “analysis” for Limitation 1[g] virtually word for word. *Compare* Petition, 74-75 with Ex-1003, ¶¶241-243. This testimony provides no analysis, and cites no corroborating evidence, to support the naked conclusory assertion that a POSA would have implemented the Paterno-Valdes system to store blood glucose levels “set on Paterno’s Home Unit” in “profile records” stored on the SCMS. Petition, 75. This conclusory unsupported testimony warrants no weight. *Xerox*, Paper 9, 14-16.

Abbott cites ***no*** credible evidence establishing any reason why a POSA would have implemented the Paterno-Valdes combination to store blood glucose levels “set on Paterno’s Home Unit” in “profile records” stored on the SCMS as

alleged to meet Limitation 1[g]. Petition, 75. Ground IV fails for claim 1 for this separate independent reason.

c. Abbott Fails to Establish That Its Paterno-Valdes Combination Meets Limitation 1[h]

Limitation 1[h] requires “*modifying the first setting ... for the remote monitor without changing the first setting at the host device.*”

Abbott alleges that Limitation 1[h] is met in the Paterno-Valdes combination because “a caregiver would use the *remote monitor* to adjust the ***notification parameters*** in the profile records... stored in the SCMS’s database” to specify what “messages” the caregiver “wishes to receive in response to communications from the Home Unit” (Petition, 75) and this allegedly “modifies the *first setting* for the *remote monitor*” (*id.*, 76). That fails for multiple reasons.

First, as discussed *supra* §III.B.4 regarding Limitation 1[c], Abbott identifies no disclosure in Paterno that the caregiver’s “notification parameters” can ever be set by the Home Unit. Thus, those notification parameters cannot meet the claimed *first setting* because “*the host device sets [the] first setting*” per Limitation 1[c].

Second, claim 1 requires that the *first setting* is maintained “*at the host device.*” See Limitation 1[h] (requiring “*modifying the first setting by the remote monitor... without changing the first setting at the host device*”). Abbott never even alleges that Paterno discloses that any of its “notification parameters” are “*at*

the host device.” Indeed, Abbott alleges precisely the opposite—that the “Home Unit [*host device*]... **lacks** the ‘notification parameters’” and does “**not** include” them. Petition, 76. Abbott fails to establish that Paterno’s “notification parameters” are at the Home Unit (*host device*) and thereby fails to establish that Paterno’s “notification parameters” meet the claimed “*first setting at the host device*” as required by Limitation 1[h].

Third, Abbott fails to consistently map anything in the Paterno-Valdes Combination to **all** claim 1’s requirements for “*the first setting.*” In an attempt to meet Limitation 1[g]’s requirement of “*modifying, by the remote monitor, the first setting set by the host device,*” Abbott alleges that the *first setting* is met by “rules relating to the ‘blood glucose’ levels disclosed by Valdes.” Petition, 75. But Abbott switches gears for Limitation 1[h] and alleges that the “*first setting*” is met by “notification parameters in the profile record.” Petition, 76. “[T]he **first setting set by the host device**” in Limitation 1[g] is the same “**the first setting**” modified “*for the remote monitor without changing the first setting at the host device*” in Limitation 1[h].

Abbott fails to demonstrate that its Paterno-Valdes combination “**yield[s] the claimed invention**” because Abbott fails to map anything in the Paterno-Valdes combination to **all** the requirements of “*the first setting*” in claim 1. *Unigene Labs*, 655 F.3d at 1360; *see also Guardian Solutions v. RSA Protective Technologies*,

IPR2019-01161, Paper 8, at 21 (Nov. 21, 2019) (denying institution where Petitioner treated “claim 1 as a list of separate structural requirements and ignores the relationship between the requirements. This approach is fatal to Petitioner’s position with respect to claim 1” because the petitioner pointed to separate structures to meet two claim limitations despite that “the claim requires the same structure to satisfy both of these limitations”).

Abbott fails to establish that its Paterno-Valdes combination meets Limitation 1[h]. Ground IV fails for this additional reason.

6. Abbott Fails to Establish That Limitation 1[e] Is Met

Limitation 1[e] requires a rule defining an alert representative of an event where the event is “*associated with the analyte state of the host*” **and** “*determined by the secure server*” based on measured data.

Abbott alleges in conclusory fashion that “*it would have been obvious* to a POSITA to modify Paterno’s SCMS to incorporate Valdes’s ‘threshold alerts’ and to determine whether the analyte data from Valdes’s receiver unit exceeded those thresholds.” Petition, 73-74. This fails because Abbott never establishes any **reason why** a POSA would have “modifi[ed]” Paterno’s SCMS in this way. *TQ Delta*, 942 F.3d at 1359 (“a conclusory assertion with no explanation is inadequate... because [it]... ***fails to identify any actual reason why a skilled artisan would have combined the elements in the manner claimed.***”) (internal

citation omitted); *KSR*, 550 U.S. at 418 (a **reason** to combine the art in the manner claimed is required).

Abbott alleges that “[a] POSITA would have combined Paterno and Valdes for at least the reasons explained above and in Section VIII.D.1.” *Id.*, 74. “Section VIII.D.1” is the “Motivated to Combine” section discussed *supra* §III.B.2.b, which alleges that “Combining Paterno and Valdes would have involved merely combining prior art elements (i.e., adding Valdes’s CGM to Paterno’s remote monitoring system) according to known methods to yield predictable results.” Petition, 66-67. Nothing in that section or “explained above” ever alleges any reason to “**modify** Paterno’s SCMS... to determine whether [] analyte data... exceeded [] thresholds” as Abbott alleges to purportedly meet Limitation 1[e]. Petition, 73-74. Indeed, Abbott’s reliance on *KSR*’s known elements/predictable results rationale precludes any such modification to the manner in which Paterno’s system functions. *See supra* §§III.A.3, III.B.3.

Even if “Section VIII.D.1” establishes a reason to combine Paterno and Valdes in **some** way, that is insufficient because it establishes no **reason why** a POSA “would have selected and combined [the] prior art elements” in a manner that “**yield[s] the claimed invention.**” *Unigene Lab.*, 655 F.3d at 1360; *see also TQ Delta*, 942 F.3d at 1359; *KSR*, 550 U.S. at 418.

Expert testimony cannot save the Petition from its failure to establish a reason to modify Paterno's SCMS in a manner that meets Limitation 1[e]. Petition, 74 (citing Ex. 1003, ¶ 235-236). The *Petition* must demonstrate the Challenged Claims unpatentable and arguments cannot be incorporated by reference into the Petition. 37 C.F.R. §§42.22(a)(2), 42.104(b)(4)-(5), and 42.6(a)(3).

Additionally, Limitation 1[e]'s requirement that the *secure server* determine an event “*based on a first measurement of [] data... regarding the analyte state of the host*” is not met by either prior art reference. Valdes does not send its analyte data to a remote server at all and, as discussed *supra* §III.B.4.c, Paterno's server does not evaluate any data from a sensor that measures physical characteristics of the monitored individual's body. Abbott fails to establish that this among the rare cases where a claim limitation entirely missing from the art can be met by the naked say-so of an expert. *Supra* §III.A.8 (citing authority).

As demonstrated above, Abbott fails to establish that its Paterno-Valdes combination meets Limitation 1[e]. Ground IV fails for that independent reason.

7. Ground IV Fails for Every Challenged Claim for the Same Reasons It Fails for Claim 1

The Petition's showing for the other independent claim (claim 12) inherits the above-discussed failings for claim 1 because Abbott relies entirely on its showing for claim 1 to meet corresponding limitations in claim 12. Petition, 78-79

(for Limitations 12[c]-[k] arguing only “*See* Section VIII.D.2.b” through “Section VIII.D.2.i” addressing Limitations 1[a]-[h]).

Ground IV’s showing for dependent claims 2-3 inherits the failings for claim 1. And Ground IV’s showing for dependent claims 13-14 inherits the failings for claim 12 which in turn inherit the failings for claim 1. Thus, Ground IV fails for all claims for the same reasons it fails for claim 1.

C. Grounds II-III and V-VI Fall with Grounds I and IV

Grounds II-III and V-VI challenge only dependent claims 5-7 and 17-19. These Grounds rely on the Petition’s showing in Grounds I and IV, respectively, to meet the limitations of the independent claims 1 and 12 that are included in those dependent claims. Petition, 52-64 and 79-89. Thus, Grounds II-III fail for the same reasons that Ground I fails for independent claims 1 and 12, and Grounds V-VI fail for the same reasons that Ground IV fails for independent claims 1 and 12.

IV. CONCLUSION

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

Respectfully submitted,
DexCom, Inc.

Date: August 21, 2024

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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 13,991 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 21, 2024

/MacAulay Rush /
MacAulay Rush
Paralegal
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CERTIFICATE OF SERVICE UNDER 37 C.F.R. §42.6 (e)(4)

I certify that on August 21, 2024, I caused 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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