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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. IPR2024-00861
Patent No. 9,801,541

PATENT OWNER'S PRELIMINARY RESPONSE

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I. INTRODUCTION

The challenged claims relate to remote monitoring of the analyte (e.g., glucose) state of a patient (called a “*host*”) using a *receiver* used by the *host*, a *server system* and a *remote monitor*. Rules specify alerts to be generated based on the *host*’s analyte level (e.g., if below a threshold value). The *host* provides alert rule settings to the *server*. The *remote monitor* can modify an alert rule setting *configured by the host*. See e.g., Limitation 1[j].¹ This allows a caregiver to leverage the alert rule settings set by the *host* while also being able to customize alert rule settings at the *remote monitor*. This is nowhere taught in the art and the Petitioner (“Abbott”) fails to demonstrate that any of its grounds meets this requirement.

The challenged claims also require that a *remote monitor* receive *user input indicative of acknowledgment* of an alert, send an acknowledgement message to the server, ***then*** after sending the acknowledgement message, access and receive sensor data relating to the alert. See e.g., Limitation 1[f]-1[g], 1[i]. These limitations are also not met by Abbott’s grounds.

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

Ground I alleges obviousness over Aspel and Gutekunst. Aspel's system allows healthcare professionals to remotely analyze data from various home monitoring devices. Alert messages can be sent to healthcare professionals via wireless devices (e.g., cellphones). Gutekunst discloses a system for remotely monitoring various user devices including glucose monitors having a sensor and receiver. The Petition has a "Motivated to Combine" section that alleges that a POSA would have used Gutekunst's glucose monitor and paired user device as one of the home monitoring devices in Aspel's system. No modification to Aspel's system is alleged other than to receive data from Gutekunst's glucose monitor.

The claims require an alert rule setting *configured by the host* but modifiable by a *remote monitor* user. Abbott fails to demonstrate that Ground I meets this limitation for numerous reasons. Abbott points to Gutekunst's disclosure about how alert rules are set but those teachings are not even used in the Aspel-Gutekunst combination explained in the Petition's "Motivated to Combine" section. The Petition never establishes any reason why a POSA would have modified Aspel to change the way alert rules are set based on Gutekunst. That violates black-letter obviousness law that requires establishing some reason to combine the references in the manner claimed.

Additionally, Abbott only cites Gutekunst disclosures demonstrating that various system users can set and modify their *own* alerts. Neither Aspel nor

Gutekunst teaches that a user of a *remote monitor* can modify an alert setting *configured by the host* as claimed. And Abbott never even alleges, let alone establishes, any reason why a POSA would have implemented the Aspel-Gutekunst combination in a manner that meets this claim requirement. Ground I fails for that reason alone.

The claims also require accessing by the *remote monitor* sensor data for an alert *after* the *remote monitor* receives user acknowledgement of the alert. Abbott admits this is a temporal requirement but fails to establish that it is met by the Aspel-Gutekunst combination. Abbott alleges that Aspel meets this limitation but points to disparate disclosures that, at best, show that an alert can be acknowledged and that data relating to the alert can be received at a *remote monitor*. The temporal (“after”) requirement is not met by the Aspel-Gutekunst combination. Ground I fails for this independent reason.

Ground III alleges obviousness over Paterno, Valdes, and Hanson. Paterno’s system reminds an individual to perform routine tasks like taking medication and sends alerts to a caretaker who can remotely monitor compliance. Hanson’s system sends alerts to a caregiver who remotely monitors whether a patient is taking medication according to a prescribed schedule. Valdes discloses a continuous glucose monitoring system used by a patient with no *server* and without server-based remote monitoring.

Abbott alleges that a POSA would have used Paterno's system to remotely monitor Valdes's glucose monitor and would have added Hanson's alert interface and alert messages. Ground III fails for numerous reasons.

First, the Petition never explains the contemplated workings of its combination because it never identifies *any* alert interface or alert message from Hanson that is actually used in the combination. Ground III fails for that reason alone.

Second, Abbott's assertion that a POSA would have used Paterno's system to remotely monitor Valdes's glucose monitor is based on the false assertion that Paterno's system already remotely monitors a patient's blood sugar. Paterno teaches no such thing. Abbott fails to establish that a POSA would have used Paterno's system to remotely monitor Valdes's glucose monitor.

Third, even if the Board were to find that a POSA would have combined Paterno, Valdes, and Hanson in *some* way, Abbott fails to establish any reason why a POSA would have combined their teachings in a manner meeting any challenged claim for numerous independent reasons.

The claims require that a *server* detect an event based on a *host's analyte concentration* level. This is not taught in any of Ground III's references. Only Valdes teaches an event based on analyte concentration, but Valdes's events are generated locally—not by a *server*. Abbott never even alleges, let alone

establishes, any reason why a POSA would have modified the teachings of the references to detect an analyte concentration event on Paterno's server.

The claims also require receiving *user input indicative of acknowledgement* of an alert. Abbott says this is met by Hanson, but Hanson never mentions acknowledging an alert. Additionally, Hanson's alleged "acknowledgments" relate to a medication alert and allow the remote caregiver to prescribe new medications or change a dosage. This has nothing to do with alerts based on a host's *analyte concentration* level. Abbott never explains how Hanson's alert handling interface would be modified to work with *analyte concentration* alerts in the combination, let alone establish some reason why a POSA would have made those unidentified modifications needed to meet the claims.

Finally, the claims require that an alert setting *configured by the host* be modifiable by the user of a *remote monitor*. The Petition's section addressing the relevant limitation in claim 1 ignores what the claim language requires. Abbott cites separate disclosures from Paterno and Valdes but neither reference meets this claim requirement. And Abbott never even alleges that a POSA had some reason to modify the teachings of the references to meet this claim requirement.

Grounds I and III are the only grounds that challenge the independent claims. Their failings are inherited by the other grounds. Institution should be denied.

II. '541 PATENT

A. Disclosed Methods and System

The '541 Patent describes remotely monitoring a patient's analyte state (e.g., glucose level). Ex-1001, Abstract. The person whose glucose is monitored is a host. Ex-1001, Abstract, Figs. 2A-2B (host 199), 6:48-67.

The “remote monitoring system 100 includes a plurality of host monitoring systems 198A-198N connected to a plurality of remote monitors 114A-114M via network 118” and through secure server 110. Ex-1001, 5:46-50, Figures 1 and 2A (reproduced below). Host monitoring systems 198A-198N include, *inter alia*, continuous analyte monitoring system 8 that comprises sensor 10, sensor electronics 12 and receiver 102. Ex-1001, 6:48-67. 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, 5:62-65.

Using the receiver, the host sets recommended alert rules that are provided to the server. The server uses those alert rules to evaluate the sensor data and identify events requiring attention. Ex-1001, 30:40-43 (“rules may be configured by a user (e.g., using receiver 102...)”), 35:31-33 (low glucose alarm triggered

based on “the threshold *configured by the user*”),² Fig. 13 (threshold 604). In this way the remote monitoring system alerts caretakers, through their respective remote monitors, when the *host*’s glucose (or other analyte) level has reached a predetermined level or otherwise requires attention. The remote monitor user is a “caretaker” such as a parent, caregiver, doctor or nurse. Ex-1001, 6:3-4, 7:11-20, 15:16-21.

The host (using the receiver) configures alert rules settings on the server, but the user of a remote monitor can tailor those alerts for their 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 (describing a parent making “subsequent changes... to the set of rules being used for the child’s receiver... to send notifications to the parent’s remote monitor 114.”). For example, a school nurse monitoring several children might want to limit alerts sent to their remote monitor to those requiring prompt intervention (e.g., the host has a dangerous glucose level that requires an insulin injection). *Id.*, 34:3-35.

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

The remote monitoring system improved upon systems like that described in Patent Owner (“DexCom”)’s Valdes reference used in Ground III. Valdes monitored a host’s glucose level and generated alerts to the host but did not communicate with a server and thus did not allow a remote monitor to receive data and alerts concerning the host’s condition from a server.

The ’541 Patent’s system provides a way for others to help manage the host’s diabetes. The host still sets alert rules tailored to the host’s condition. Ex-1001, 5:62-66. But the ’541 Patent introduces a “remote monitor” that caretakers use to interact with the system. Ex-1001, 5:66-6:9, 7:11-20, 15:16-21. The host can authorize others to receive condition-related alert notifications on the remote monitor. Ex-1001, 31:65-32:12, 32:58-33:5, Fig. 10 (step 1018), Fig. 12.

Rather than forcing a remote user to receive all the alerts the host receives, the ’541 Patent describes a mechanism for a caretaker to tailor the host’s alert settings for the caretaker’s needs. Ex-1001, 33:42-46, 33:60-67, 36:31-33. For example, a school nurse could monitor the condition of several diabetic children while limiting alert notifications to conditions or events with sufficient severity to require intervention. Ex-1001, 34:3-35. A remote user receives the particular settings a host sets to trigger alerts for that host and those settings can vary by host because glucose levels of concern can be different for different people. Ex-1001,

26:48-27:41, 29:8-25, 36:22-37, 36:53-56. The remote user can modify the host settings to customize alerts received at the remote monitor. Ex-1001, 36:31-33.

B. Prosecution History

The Examiner cited Valdes and other references in a final rejection. Ex-1002, 159, 162-164, 171. During an interview the Examiner proposed claim amendments. Ex-1002, 94. The Examiner then entered an amendment that added, *inter alia*, the language in Limitation 1[j]³ that requires that alert rules be configured by the host and modifiable by the user of the remote monitor. Ex-1002, 83, 85. The Examiner thereafter allowed the claims. Ex-1002, 78 and 82. The Examiner's reasons for allowance emphasized that the prior art—including Valdes—failed to meet the amended claim language including the language in Limitation 1[j]. Ex-1002, 89 and 91.

C. Challenged Claims

Petitioner (“Abbott”) challenges claims 1-7, 9, 11, 13, and 15-17 (“Challenged Claims”). Petition, 4. The Challenged Claims include independent claims 1 and 15-17. Claims 1 and 15 recite methods. Claim 16 recites a system. Claim 17 recites a “non-transitory computer readable medium” (“CRM”) comprising executable instructions.

³ DexCom adopts the Petition's claim limitation labelling (Petition, 9-15) and the Petition's convention of italicizing claim language.

Claim 1 recites a method involving a *receiver*, a *wireless mobile remote monitor* (“*remote monitor*”), and a *server system* (“*server*”). The *receiver* monitors an “*analyte state of a host*,” such as glucose level. Limitation 1[b]. The *remote monitor* receives from the *server* “*an alert notification message*” representing a “*detected event*” (Limitation 1[a]) and “*present[s]*” the alert to a *user* at the *remote monitor* (Limitation 1[d]). The “*detected event*” that is the subject of the “*alert notification message*” is “*based on analyte concentration sensor data*” obtained from a *receiver* monitoring the *host*. Limitation 1[b].

Claim 1 further recites the *remote monitor* “*receiving... user input indicative of acknowledgement of the presented alert notification message*” (Limitation 1[f]) and “*sending an acknowledgment message*” from the *remote monitor* to the *server* (Limitation 1[g]). **After** the *remote monitor* sends the acknowledgement, the *remote monitor* “*access[es]*” and “*receives*” “*at least some of the analyte concentration sensor data from the server*” (Limitations 1[h]-1[i]).

Claim 1 further requires that the “*event detected by the server*” is “*based on one or more sets of recommended alert rules settings*” that were “*configured by the host using the receiver*” (Limitation 1[j]). “[A]t least one of the sets of recommended alert rules settings” configured by the *host* can be modified by the *user* of the *remote monitor* (Limitation 1[j]).

Claim 15 recites a method with many of the same steps as claim 1.

Claim 16 recites a “*wireless mobile remote*” system comprising a processor and memory with instructions that configure the processor to perform many of the same steps as claim 1.

Claim 17 recites a CRM with instructions executable by a processor to perform a method having many of the same steps as claim 1.

III. THE PETITION’S GROUNDS FAIL

Grounds I and III challenge all the independent claims (claims 1 and 15-17) and dependent claims 4-7, 9, 11 and 13 that depend from claim 1. The remaining grounds (Grounds II and IV) challenge only dependent claims 2-3.

Grounds I and III are fatally flawed for reasons explained below. Grounds II and IV inherit the flaws of Grounds I and III, respectively. Thus, if the Board agrees that Abbott fails to carry its burden for Grounds I and III, institution should be denied.

A. Ground I (Aspel and Gutekunst) Fails for Multiple Independent Reasons

1. References

a. Aspel (Ex-1005)

Aspel describes a system for collecting and storing physiological and other personal data from individuals. Aspel, Abstract, [0002]. Aspel’s system transmits physiological data to a secure central storage system for use by healthcare professionals for analysis and intervention. Aspel, [0021]. Aspel’s system also

makes the data available to the patient. *Id.* The system alerts patients, caregivers, medical professionals, and monitoring centers “based on the reception of certain data or the absence of data within a set time.” Aspel, [0089], [0091]. Aspel Fig. 4 (below) depicts the system architecture. Aspel, [0031], [0051].

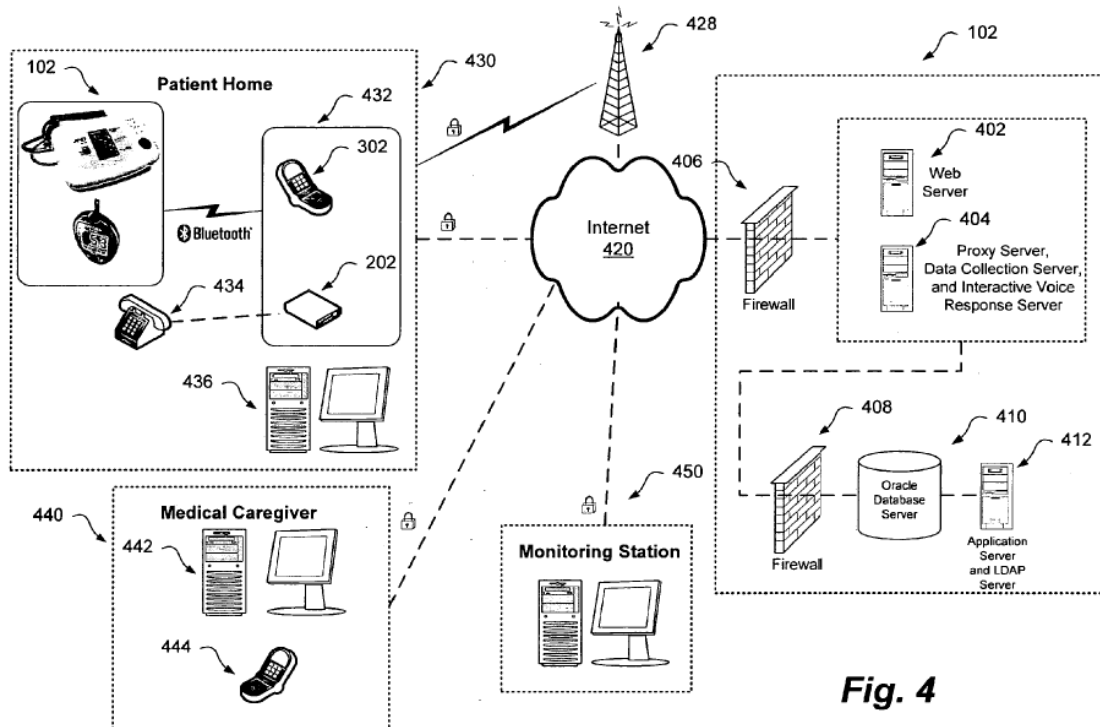


Fig. 4

Aspel describes an “all alerts” report 1900 “for a Caregiver with multiple patients.” Aspel, [0162]. Within the “all alerts” report, “[e]ach event includes a tick box, allowing the user [caregiver] to select particular records so they can be ‘acknowledged’ (1902) *and have them removed from the report.*” Aspel, [0162]-[0163].

Selecting an ‘Overall Summary’ tab causes the system to “collect[] and analyze[] the necessary data, [and] generat[e] the summary report 2000 for the current patient” as shown in Fig. 20. Aspel, [0164].

Marking the “tick box” *removes* an event from the report, while selecting the “Overall Summary” tab generates a “summary report” with patient data for events that *remained* within the report.

b. Gutekunst (Ex-1006)

Gutekunst describes a “medical monitoring and surveillance system” that allows for remote monitoring of a “device 218” which can be an implanted sensor like a glucose monitor. Gutekunst, [0091]. A user device 215 (e.g., a mobile phone in Fig. 2) is provided that communicates with device 218 and a server 220. *Id.* The user device 215 supports a mobile application that communicates with a server. Gutekunst, [0088], [0090]. The server “enables a party... to schedule one or more trigger events” that respond to sensor readings (e.g., from the glucose monitor) meeting predetermined criteria. Gutekunst, [0127] and Abstract. The user or third party “may select from a predefined set of trigger events and build new trigger events.” Gutekunst, [0127].

2. The Petition Only Alleges that a POSA Would Have Been Motivated to Use Gutekunst’s Sensor/Receiver in Aspel’s System Without Modifying Aspel’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 non-hindsight *reason* to combine the prior art in the manner claimed).

Abbott fails to establish a reason to combine teachings from Aspel and Gutekunst in a manner that meets any Challenged Claim.

a. Abbott’s Explanation of the Combination Describes No Modification to Aspel’s System Other than Working with Gutekunst’s Sensor/Receiver

Abbott alleges that Aspel teaches a system for remotely monitoring home medical monitor devices, Gutekunst teaches an implantable glucose monitor, and that a POSA would have used Gutekunst’s glucose monitor as one of the home medical monitor devices remotely monitored by Aspel’s system. Petition, 29-31.

Abbott alleges that Aspel’s central server corresponds to the claimed *system server* and allows “different users [to] receive an alert... on various devices including a ‘wireless device 444 such as a cellphone or smartphone device’” that corresponds to the claimed *remote monitor*. Petition, 29. Abbott notes Aspel’s

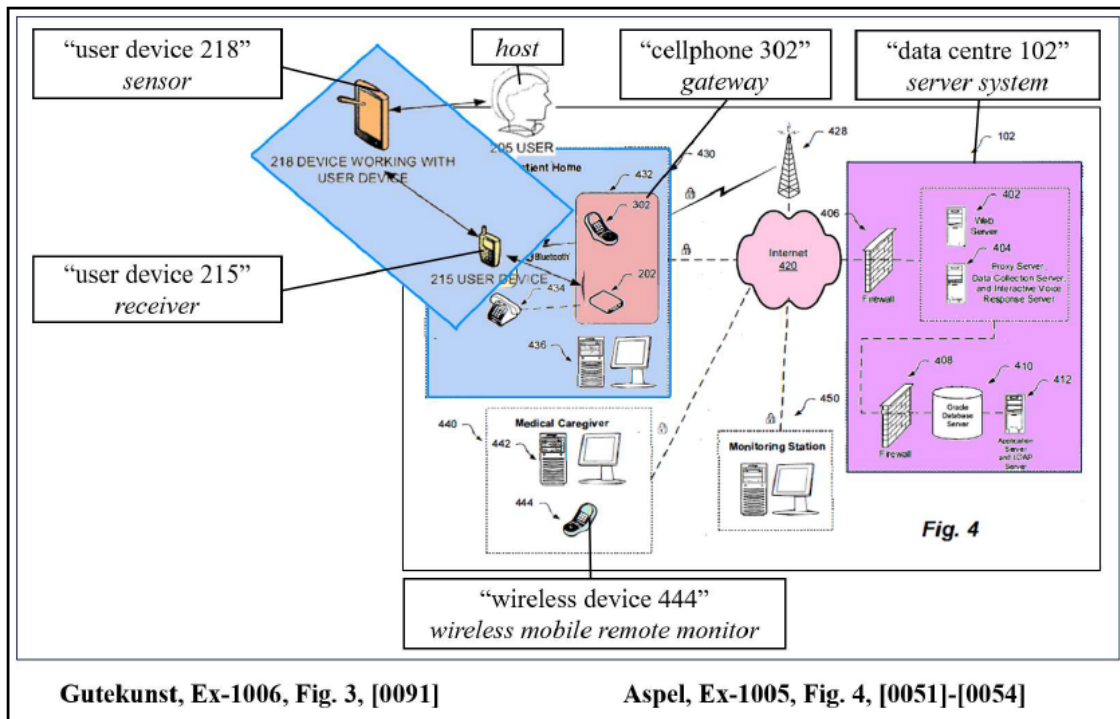
disclosure that a “glucometer” may be among the monitored home medical monitor devices that transfer data “to ‘data centre 106’” in Aspel’s central server. Petition, 29; Aspel, Fig. 1, [0046]-[0048].

Abbott then notes Gutekunst’s disclosure of a device 218 that “facilitate[s] the gathering of the user’s medical information,” “may be implanted into a person’s body” and can be a “glucose monitor.” Petition, 29. Abbott characterizes Gutekunst’s user device 215 as “a *receiver for analyte concentration sensor data* from the glucose monitor (device 218).” Petition, 29.

Abbott asserts that Gutekunst’s “configuration is compatible with Aspel’s disclosed system, substituting Gutekunst’s ‘glucose monitor’ ‘device 218’ which ‘may be implanted’ for the ‘glucometer’ disclosed in Aspel.” Petition, 29-30.

Abbott asserts that “[a] POSITA would have combined these disclosures into the Aspel-Gutekunst combination (below), replacing ‘home medical monitoring devices’ from Aspel with Gutekunst’s user devices 218 and 215.” Petition, 30.

Abbott provides the annotated figure reproduced below of “the Aspel-Gutekunst combination.” *Id.*, 31.



Thus, in describing its Aspel-Gutekunst combination, Abbott does not describe any modification to Aspel’s “server system” or “remote monitor” other than to work with Gutekunst’s glucose sensor and receiver to allow remote monitoring of Gutekunst’s glucose monitor.

b. The Petition’s “Motivated to Combine” Section Alleges No Reason to Modify Aspel’s System Other than to Work with Gutekunst’s Sensor/Receiver

The Petition has a section purporting to establish that a POSA “Would Have Been Motivated to Combine Aspel and Gutekunst with a Reasonable Expectation of Success.” Petition, 31-33. Abbott says that Aspel describes “remote monitoring of health parameters” and recognizes that “**many different user interfaces, functions and health lifestyle and wellness**

parameters may be required.” Petition, 31 (emphasis original). Abbott notes Aspel’s statement that its “invention... can monitor and measure a limitless variety of devices and physiological parameters.” Petition, 31-32 (citing Aspel, [0188]).

Abbott asserts that a POSA “would have recognized Gutekunst discloses devices for monitoring and gathering a ‘user’s medical information’ that would complement the Aspel system.” Petition, 32. Abbott argues that a POSA would have “readily contemplated adapting Gutekunst’s ‘devices’ to provide physiological parameters to Aspel’s monitoring system[.]” *Id.*

As with the above-discussed explanation of its Aspel-Gutekunst combination, Abbott’s reasons to combine Aspel and Gutekunst offer no reason to modify anything about Aspel’s system other than to allow Aspel’s server to remotely monitor and receive data from Gutekunst’s sensor and user device.

Petition, 32. Leaving no doubt, Abbott alleges that:

Combining Aspel and Gutekunst would have involved ***combining prior art elements*** (i.e., ***a glucose monitor sensor*** and mobile application on a user device) ***according to known methods to yield predictable results*** (i.e., receiving glucose data as taught in Gutekunst and ***providing it to the Aspel system, e.g., the Data Center***).

Id.

The Petition thereby invokes *KSR*’s known elements/predictable results rationale which 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) (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).

* * *

The specific nature of the Aspel-Gutekunst combination that the Petition explains and seeks to support in its “Motivated to Combine” section is important because, as discussed below, there are claim limitations (Limitations 1[j] and 1[h]) that are not met by Aspel, Gutekunst, or the Aspel-Gutekunst combination that would have resulted by combining the features of those references in the manner alleged. Abbott never even alleges, let alone establishes, any “reason” to modify the functionality of Aspel or Gutekunst in a manner that would be required to meet those claim limitations.

3. The Petition Fails to Establish that its Aspel-Gutekunst Combination Meets Limitation 1[j]

Limitation 1[j] requires that the event detected by the server system be “based on one or more sets of recommended alert rules settings *configured by the host*,” where “at least one of the sets of recommended alert rule settings” are

“modifiable by the user of the wireless mobile remote monitor using the wireless mobile remote monitor.” Limitation 1[j] thus requires that at least one of the sets of alert rule settings *“configured by the host using the receiver”* be *“modifiable”* by a user *“using the... remote monitor.”*

Abbott alleges that Aspel’s “data center (*server system*)” creates alerts using *alert rule settings* but relies entirely on **Gutekunst** to purportedly teach settings that *are configured by the host using the receiver* and *modifiable* by a user *using the remote monitor*. Petition, 45 (“Gutekunst discloses the alert rules settings being modifiable by the remote monitor”) and 46 (“Gutekunst additionally” discloses *“alert rule settings by the host using the receiver”*).

Abbott’s showing for Limitation 1[j] fails for multiple independent reasons detailed below.

a. The Petition’s Reasons to Combine Do Not Yield an Aspel-Gutekunst Combination that Meets Limitation 1[j]

As discussed *supra* §III.A.3, in describing the Aspel-Gutekunst combination purportedly supported by the Petition’s “Motivated to Combine... with a Reasonable Expectation of Success” section, Abbott only alleged that a POSA would have “replac[ed] ‘home medical monitoring devices’ from Aspel with Gutekunst’s user devices 218 and 215.” Petition, 30.

Abbott did not allege that a POSA would have modified the way alert settings are established in Aspel's system, let alone allege a reason why a POSA would have modified Aspel's system to allow a user of a *remote monitor* to modify alert rules that had been *configured by the host using the receiver*⁴ as required to meet Limitation 1[j].

Thus, even if Abbott establishes that ***Gutekunst*** teaches that a *remote monitor* can modify alert rules configured by the *host* using the receiver (Gutekunst discloses no such thing as discussed *infra* §III.A.3.c.ii), that would be irrelevant to whether Abbott demonstrates that the Petition's ***Aspel-Gutekunst combination*** meets Limitation 1[j] because no such Gutekunst teachings are used in the Aspel-Gutekunst combination that Abbott purports to support in the Petition's "Motivated to Combine" section.

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 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

⁴ The *receiver* is alleged to be met in the Aspel-Gutekunst combination by Gutekunst's user device 215. Petition, 36.

establishing some non-hindsight reason to modify the prior art *in the manner claimed*); *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’s section addressing Limitation 1[j] does not allege any new or different reason why a POSA would have combined the teachings of Aspel and Gutekunst in any particular way. Petition, 45-47. Instead, Abbott relies entirely on the arguments provided in the Petition’s “Motivated to Combine... with a Reasonable Expectation of Success” section VIII.A.1. Petition, 47 (“A POSITA would have been motivated to combine Aspel and Gutekunst. *See Section VIII.A.1.*”).

But in Section VIII.A.1 (Petition, 31-33), Abbott alleges only that a POSA would have used Gutekunst’s “devices for monitoring and gathering ‘a user’s medical information’” and “to provide physiological parameter’s to Aspel’s monitoring system.” Petition, 32. The Aspel-Gutekunst combination that the Petition alleges a POSA would have been motivated to pursue combines

Gutekunst’s “glucose monitor sensor and mobile application on a user device” with “the *Aspel system*, e.g., the Data Center.” Petition, 32; *see also id.*, 30-31 (“the Aspel-Gutekunst combination... replac[es] ‘home medical monitor devices’ from Aspel with Gutekunst’s user devices 218 and 215).

Section VIII.A.1 makes no mention of **modifying** “the Aspel system” used in the combination (Petition, 32) to change the way alert settings are handled in **any** manner. Section VIII.A.1 indisputably alleges no reason why a POSA would have modified “the Aspel system” to allow a *remote monitor* to modify alert rules that had been *configured by the host using the receiver* (Gutekunst’s user device 215 in the combination) as required to meet Limitation 1[j].

Indeed, as explained *supra* §III.A.2, Abbott alleges that its Aspel-Gutekunst combination involves combining “known elements... to yield predictable results.” Petition, 32. That “known elements” rationale relies on combining prior art according to their established functions “**with no change** in their respective functions.” *KSR*, 550 U.S. at 415-416. This rationale does not support modifying the function of “the Aspel system” to change the way alert settings are handled and the Petition offers no “reason” why a POSA allegedly would have done so.

Thus, the only Aspel-Gutenkunst combination purportedly supported by the Petition’s “Motivated to Combine... with a Reasonable Expectation of Success” section does not modify the way alert rule settings are configured or modified in

“the *Aspel system*, e.g., the Data Center” used in the combination. Petition, 32.

Abbott does not even allege that “the Aspel system” used in the combination allows a *remote monitor* to modify alert rules that had been *configured by the host using the receiver* (Gutekunst’s user device 215 in the combination) as required to meet Limitation 1[j]. Therefore, Abbott fails to establish that the Aspel-Gutekunst combination purportedly supported by the Petition’s “Motivated to Combine... with a Reasonable Expectation of Success” section meets Limitation 1[j].

b. The Petition Never Establishes Any Reason to Modify the Manner in Which Aspel’s System Allows Alert Rule Settings to Be Established

In its section purporting to establish that Limitation 1[j] is met, the Petition focuses on what Gutekunst purportedly discloses about how alert rule settings are set (Petition, 45-47), then alleges in conclusory fashion that “[i]n the Aspel-Gutekunst combination, the Aspel *server system* incorporates Gutekunst’s “trigger events,” which include “trigger-related information” from the *receiver* and the *wireless mobile remote monitor*, to detect events” (*id.*, 47).

Even if the Board were to read the Petition as suggesting—contrary to what was alleged in the “Motivated to Combine... With a Reasonable Expectation of Success” section VIII.A.1—that the Aspel-Gutekunst combination uses *Gutekunst’s* techniques for establishing alert rule settings, Ground I still fails

because the Petition never even alleges—let alone establishes—any *reason why* a POSA would have modified Aspel’s *server system* to “incorporate[] Gutekunst’s ‘trigger events.’” Petition, 47.

Again, establishing obviousness requires establishing not just a reason to combine the prior art in *some* way, but a reason “why a skilled artisan would have combined the elements *in the manner claimed.*” *TQ Delta*, 942 F.3d at 1359; *see also KSR*, 550 U.S. at 418; *Unigene Lab.*, 655 F.3d at 1360 (a reason must be established as to why a POSA “would have selected and combined [the] prior art elements” in a manner that “*yield[s] the claimed invention.*”).

The Petition does not even allege, let alone establish, any reason why a POSA would have modified Aspel’s “server system” to incorporate the manner in which Gutekunst’s “trigger rules” are established. The Petition argues that Aspel’s “data center... create[s] alerts.” Petition, 45. The Petition then cites teachings in Gutekunst that are alleged to meet Limitation 1[j]’s “*sets of recommended alert rules settings being modifiable by the user of the wireless mobile remote monitor.*” Petition, 45-46. Finally, the Petition asserts in conclusory fashion that “*[i]n the Aspel-Gutekunst combination*, the Aspel *server system* incorporates Gutekunst’s ‘trigger events,’ which include ‘trigger-related information’ from the *receiver* and the *wireless mobile remote monitor*, to detect events.” Petition, 47. But the

Petition never alleges, let alone establishes, any *reason why* a POSA would have incorporated Gutekunst’s “trigger events” in “the Aspel *server system*.”

The Petition’s section addressing Limitation 1[j] does not allege new or different reasons why a POSA would have combined the teachings of Aspel and Gutekunst in any particular way. Petition, 45-47. Instead, Abbott relies entirely on the arguments in the Petition’s “Motivated to Combine... with a Reasonable Expectation of Success” section VIII.A.1. Petition, 47 (“A POSITA would have been motivated to combine Aspel and Gutekunst. *See Section VIII.A.1.*”). But as discussed *supra* §III.A.2, the Petition’s “Section VIII.A.1” (Petition, 31-33) alleges only that a POSA would have combined Gutekunst’s “glucose monitor sensor and mobile application on a user device” with “the Aspel system, e.g., the Data Center.” Petition, 32; *see also id.*, 30-31 (“the Aspel-Gutekunst combination... replac[es] ‘home medical monitor devices’ from Aspel with Gutekunst’s user devices 218 and 215”). “Section VIII.A.1” does not allege, let alone establish, any reason why a POSA would have *modified* “the Aspel system” used in the combination (Petition, 32) to change the way alert settings are handled to allow a *remote monitor* to modify alert rules *configured by the host using the receiver* (Gutekunst’s user device 215 in the combination) as required to meet Limitation 1[j]. *Supra* §III.A.2.b. That is fatal to Ground I.

As explained above, Ground I fails because Abbott fails to establish any reason “why a skilled artisan would have combined the [prior art] elements *in the manner claimed.*” *TQ Delta*, 942 F.3d at 1359; *see also KSR*, 550 U.S. at 418; *Unigene Lab.*, 655 F.3d at 1360 (proving obviousness requires establishing some reason why a POSA “would have selected and combined [the] prior art elements” in a manner that “*yield[s] the claimed invention*”).

c. The Petition Fails to Explain With the Required Particularity How and Why the Aspel-Gutekunst Combination Allegedly Meets Limitation 1[j]

Even if the Board were to find that the Petition established some reason why a POSA allegedly would have modified Aspel’s server system to use Gutekunst’s “trigger events” (it did not), Ground I still fails to meet Limitation 1[j] for a second independent reason.

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 has promulgated two rules specifying “content” a petition must have to meet this particularity requirement and be considered. 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)).

In addition, the Federal Circuit has made clear that “a ***prerequisite*** to adequately explaining and supporting a conclusion” of obviousness based on a combination of references is “a ***clear, evidence-supported account of the contemplated workings of the combination.***” *Personal Web Techs. v. Apple*, 848 F.3d 987, 994 (Fed. Cir. 2017).

The Petition fails to comply with these requirements in connection with Limitation 1[j] because the Petition is unclear about how and why the Aspel-Gutekunst combination allegedly meets Limitation 1[j].

As the subsections below address in detail, the Petition cites some disclosure in Aspel but never alleges that Aspel discloses what Limitation 1[j] requires. Petition, 45. The Petition then cites some disclosure in Gutekunst about alert rule trigger events but ignores a specific requirement of Limitation 1[j]—that at least one of the “*sets of recommended alert rules settings configured by the host*” be “*modifiable by the user of the wireless remote monitor*”—and never alleges that Gutekunst meets it. *Id.*, 46-47. Finally, the Petition says that “[i]n the Aspel-Gutekunst combination, the Aspel *server system* incorporates Gutekunst’s ‘trigger events,’ which include ‘trigger-related information’ from the *receiver* and the *wireless mobile remote monitor*, to detect events.” *Id.*, 47. But the Petition never

even maps all of the requirements of Limitation 1[j] to “the Aspel-Gutekunst combination” and never explains how or why the combination allegedly meets everything that Limitation 1[j] requires. Thus, the Petition fails to comply with a requirement it “must” have to be considered because the Petition fails to “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).

Ground I fails for this additional reason because Abbott never even alleges that Aspel, Gutekunst or the Aspel-Gutekunst combination meets what is required to meet Limitation 1[j]—that a set of recommended alert rule settings configured by the *host* be modifiable by a different user, i.e., the user of the *remote monitor*.

i. Abbott does not allege that Aspel teaches a remote monitor user modifying rules settings configured by a host

Abbott alleges that “Aspel discloses a system with a data center (*server system*) that analyzes data and compares data to target values (*alert rules settings*) to create alerts, i.e., *the event is detected by the server system*.” Petition, 45. This does not allege ***anything*** about how alert rule settings are configured or modified.

ii. Abbott does not allege that Gutekunst teaches a remote monitor user modifying rules settings configured by a host

Abbott alleges that Gutekunst’s “user 205” meets the claimed “*host*.” Petition, 46. The *host* is the person whose glucose is monitored. See Limitation

1[b] (“*monitoring an analyte state of a host*” and “*an analyte of the host*”).

Abbott alleges that Gutekunst’s “third party 210” (e.g., “a caregiver or medical professional”) corresponds to the user of the *remote monitor*. Petition, 46.

Abbott points to disclosure in Gutekunst that the *host* using the *receiver* (user 205) and the user of the *remote monitor* (third party 210) can each build new trigger events and modify trigger events. Petition, 46. These disclosures are consistent with Gutekunst disclosing that *each user can build and modify their own trigger events*. Gutekunst never says that a user of the *remote monitor* can modify trigger events configured by a *different* user like the *host*. Indeed, the Petition never even alleges that Gutekunst discloses this.

In this respect, Abbott alleges that “Gutekunst... explains a method in which a user’s ‘trigger-related information’—*alert rules settings configured by the host using the receiver*— (depicted in Fig. 6, block 605) is *combined and stored with* ‘trigger-related information from third party.’” Petition, 46. “[C]ombin[ing] and stor[ing]” alert rule settings from the *host* using the *receiver*, with those from the user of a *remote monitor*, by storing them together in Gutekunst’s server, does not disclose that any rule setting configured by the *host* is *modifiable* by the user of the *remote monitor*. Abbott does not even allege that it does.

Abbott’s remaining assertion that Gutekunst “teaches *alert rules settings being modifiable by the user of the wireless mobile remote monitor*” because “a

third-party user of a *wireless remote monitor*... [can] modify *recommended alert rule settings*” (Petition, 46) is unremarkable. The cited Gutekunst disclosure is consistent with the user of the *remote monitor* modifying alert rule settings that had been previously configured by that **same user** using the *remote monitor*. Abbott’s assertion that Gutekunst discloses that a user of a *remote monitor* can modify alert rule settings does not even allege that the user of the *remote monitor* can modify any setting **configured by the host** as would be required to meet Limitation 1[j].

Thus, as detailed above, the Petition fails to even **allege** that Gutekunst teaches what Limitation 1[j] requires.

iii. Abbott does not allege any reason why a POSA would have implemented an Aspel-Gutekunst combination in which a remote monitor user can modifying rules settings configured by a host

Abbott asserts that “[i]n the Aspel-Gutekunst combination, the Aspel server system incorporates Gutekunst’s ‘trigger events.’” Petition, 47. But the Petition never asserts that a POSA had any reason to modify the way Gutekunst’s trigger events are configured or modified to achieve a method in which the *remote monitor user* (third party 210) can modify “*sets of recommended alert rules settings*” configured by the *host* (user 205) as required to meet Limitation 1[j].

The Petition’s allegations about the manner in which its Aspel-Gutekunst combination works fail to even allege that the combination meets the requirement

in Limitation 1[j] that an alert setting *configured by the host* is *modifiable* by the user of the *remote monitor*.

d. None of the Cited Disclosures in Aspel or Gutekunst Teach a Remote Monitor User Modifying Rules Settings Configured by a Host

Even if the Board were to find that the Petition alleges that its Gutekunst-Aspel combination meets the requirement in Limitation 1[j] that an alert setting *configured by the host* is *modifiable* by the user of the *remote monitor*, any such assertion would be entirely unsupported by any teaching in Aspel or Gutekunst. Below, DexCom walks through every disclosure in Aspel and Gutekunst that Abbott cites in connection with Limitation 1[j]. None teaches that any setting *configured by the host* is *modifiable* by a different user, let alone by a user of a *remote monitor*.

Abbott cites Aspel, [0089]-[0090] which refer to “user defined alerts.” Petition, 45. But Aspel’s next paragraph makes clear that the “user” is a medical professional who can see alerts for “persons within their care.” Aspel, [0091]. Aspel never discloses that a *patient* (i.e., a *host*) configures alert rule settings.

Next, Abbott cites Gutekunst, [0127], [0142] and Fig. 6 as teaching that the user 205 of the *host* device and the third party 210 user of the *remote monitor* can each build new trigger events and modify trigger events. Petition, 46. As discussed *supra* §III.A.1.b, these disclosures are consistent with Gutekunst

disclosing that each user can build and modify *their own* trigger events. These Gutekunst disclosures never teach that an alert rule setting configured by the *host* is *modifiable* by any other user of the system, let alone a user of a *remote monitor*.

Abbott then cites Fig. 6 as teaching that the server can receive “trigger-related information” from the user of the *host receiver* (block 610) and from a user of a *remote monitor* (block 610), store that information (block 615) and evaluate it using decision block 630. Petition, 46. Abbott’s assertion that this teaches “*alert rules settings being modifiable by the user of the wireless mobile remote monitor*, (depicted in Fig. 6 block 610)” is false. *Id.* Fig. 6 does not disclose modifying “trigger-related information” at all, and certainly does not disclose that a user of a *remote monitor* modifies a setting *configured by the host*.

Abbott then string cites a non-existent “Fig. 65” and *nine* paragraphs from Gutekunst as purportedly supporting that a remote monitor user can “modify” alert rule settings. Petition, 46. None of the cited paragraphs says a *remote monitor* user modifies a setting *configured by the host*.

Gutekunst, [0156] says generically that “server 220 creates or modifies a trigger event.” This does not disclose that a user of a *remote monitor* can modify a setting *configured by the host*.

Gutekunst, [0128]-[0129] say nothing about a “multi-Caregiver” setting “alert levels using ‘generated HTML web pages’” as Abbott erroneously alleges.

Petition, 46. Regardless, disclosure that a *remote monitor* user can set alert levels does not disclose that the user can modify alert settings from a different user of a *host receiver*.

Gutekunst, [0058]-[0059] only teach that a “first application generates data used by a second application,” and vice versa. They teach nothing about modifying alert settings.

Gutekunst [0063]-[0066] also say nothing about modifying alert settings.

Thus, none of the disclosures in Aspel or Gutekunst that Abbott cites in connection with Limitation 1[j] teach that a “*remote monitor*” user can modify “*alert rules settings configured by the host*” as Limitation 1[j] requires.

e. Abbott’s Expert Testimony Cannot and Does Not Remedy the Defects in the Cited Prior Art Disclosures

The only other evidence Abbott cites is Ex-1003, ¶¶138-143. Petition, 47. This testimony is only cited to support that “[i]n the Aspel-Gutekunst combination, the Aspel *server system* incorporates Gutekunst’s ‘trigger events,’ which include ‘trigger-related information’ from the *receiver* and the *wireless mobile remote monitor*, to detect events.” *Id.* As discussed *supra* §§III.A.3-III.A.3.c, that assertion does not even allege that the Aspel-Gutekunst combination meets what Limitation 1[j] requires. The cited testimony cannot save Abbott for three reasons.

First, arguments cannot be incorporated by reference from the expert declaration into the Petition so the expert declaration cannot remedy the Petition’s failure to establish that Limitation 1[j] is met. 37 C.F.R. §42.6(a)(3).

Second, the cited testimony warrants no weight. These paragraphs repeat the Petition’s arguments for Limitation 1[j], often word-for-word, without providing any meaningful analysis or corroborating evidence. This conclusory unsupported testimony warrants no weight. *Xerox v. Bytemark*, IPR2022-00624, Paper 9, 15 (Aug. 24, 2022) (precedential); *id.*, Paper 12, 5 (Dir. Feb. 10, 2023); 37 C.F.R. §42.65(a).

Third, like the Petition, these paragraphs never even allege—let alone establish—that in the Aspel-Gutekunst combination a *remote monitor user* can modify “*alert rules settings configured by the host*” as Limitation 1[j] requires.

f. Conclusion on Ground I’s Failing for Limitation 1[j]

As detailed above, Abbott failed to carry its burden to demonstrate that the Aspel-Gutekunst combination meets Limitation 1[j]. Ground I fails for that additional reason.

4. Abbott Fails to Establish that its Aspel-Gutekunst Combination Meets Limitation 1[h]

Limitation 1[h] requires “*accessing, by the... remote monitor,... analyte concentration sensor data from the server system*” “*after sending the acknowledgment.*” Abbott concedes that “*after*” is a “temporal limitation”

requiring accessing the sensor data “subsequent to sending the acknowledgment.”
Petition, 43.

The “*analyte concentration sensor data*” that must be accessed in Limitation 1[h] finds its antecedent in Limitation 1[b] which requires that this is data on which “*the event*” is based. And Limitations 1[a] and 1[g] make clear that the “*alert notification message*” acknowledged in Limitation 1[h] is “*representative of [the] event.*” Thus, claim 1 makes clear that “*the data*” accessed in Limitation 1[h] “*after sending the acknowledgement*” of the alert notification message is the data upon which the event is based that is represented in the alert notification message that is acknowledged.

a. Abbott Fails to Allege that its Aspel-Gutekunst Combination Meets What Limitation 1[h] Requires.

Abbott only points to teachings in Aspel to meet Limitation 1[h]. Petition, 43-44. Abbott alleges that Aspel, [0163]’s disclosure of a “tick box” that a user can “select” to remove an alert from a report meets the claimed *acknowledgement*. Petition, 43. Abbott also points to separate disclosures in Aspel that a *remote monitor* user can “**access the patient data.**” *Id.* (emphasis original).

Abbott fails to even allege, let alone establish, that Aspel teaches that the *remote monitor* user accesses the sensor data on which the alert was generated *after* selecting the tick box for that alert to remove the alert from the report.

Thus, the Petition’s showing is facially deficient because it does not even allege, let alone establish, that Aspel describes “*accessing...the analyte concentration sensor data*” **after** “*sending the acknowledgement*” as required by Limitation 1[h]. Ground 1 fails for this additional independent reason. 37 C.F.R. §42.104(b)(4) (the petition “must” identify where “each element of the claim is found in the prior art”).

b. No evidence supports that Abbott’s Aspel-Gutekunst Combination Meets Limitation 1[h]

Even if the Board were to find that the Petition *alleges* that its Aspel-Gutekunst combination meets Limitation 1[h]’s temporal (“after”) requirement, Abbott cites no evidence supporting such an allegation.

Abbott never alleges that a POSA would have modified Aspel’s system in any way that would meet Limitation 1[h]. Instead, Abbott simply alleges that Aspel discloses what Limitation 1[h] requires. Petition, 43-44.

Again, Abbott alleges that Aspel, [0163]’s disclosure of a “tick box” that a user can “select” for an alert meets the claimed “acknowledgement.” Petition, 43. But Aspel never teaches that the user accesses data for an alert after selecting its tick box. Indeed, Aspel, [0163] teaches that “[e]ach event... includes a tick box, allowing the user to select particular records so they can be ‘acknowledged’ (1902) *and have them removed from the report.*” Aspel never says that a user accesses data for an alert **after** deciding to remove it from the report and that would make

no sense. Aspel’s next paragraph describes gathering data and “generating the summary report.” Aspel, [0163]-[0164]. But the data gathered for the report does not include data for “acknowledged” events because they were “removed from the report” in response to having their tick boxes selected. Aspel, [0163].

Abbott also cites Aspel, [0054] and [0165]-[0169] to show that a caregiver can “access... patient data through the data centre 102” via “reports.” Petition, 43-44. These disclosures say nothing about what Abbott admits is a “temporal limitation” (*id.*, 43) and never state that a caregiver accesses data for an alert *after* “acknowledging” that alert by marking a “tick box” to remove it from a report.

The only other evidence Abbott cites is Ex-1003, ¶¶131-134. Petition, 44. That expert testimony parrots the Petition without adding meaningful analysis and warrants no weight. *Xerox*, IPR2022-00624, Paper 9, 15. But even if credited, this testimony, like the Petition, fails to address the “temporal requirement” (petition, 43)—“after”—in Limitation 1[h].

Abbott cites no evidence establishing that its Aspel-Gutekunst combination “access[es], by the... remote monitor,... the analyte concentration sensor data” *after* “sending the acknowledgement” as required by Limitation 1[h]. Ground I fails for this additional independent reason.

5. Ground I's Challenges to the Remaining Claims Inherit the Failures For Claim 1

Ground I fails for dependent claims 4-7, 9, 11, and 13 that depend from claim 1, for the same reasons Ground I fails for claim 1.

Ground I's showings for independent claims 15-17 also inherit its failings for claim 1. Ground I relies entirely on its showing for Limitation 1[j] to meet Limitation 15[m] (Petition, 58), Limitation 16[m] (*id.*, 61), and Limitation 17[l] (*id.*, 63) that all require a setting *configured by the host* being modifiable by the user of the *remote monitor*. Ground I also relies entirely on its showing for Limitation 1[h] for Limitation 16[k] (*id.*, 60) and Limitation 17[j] (*id.*, 62) that require accessing sensor data *after* an acknowledgment.

B. Ground II Inherits Ground I's Failures

Ground II adds Breen to Ground I's "Aspel-Gutekunst combination" and relies on Breen to purportedly "provide[] additional disclosures regarding sending notifications to a mobile device[.]" Petition, 63-65. Abbott contends that this new Aspel-Gutekunst-Breen combination renders obvious claims 2-3 that each depends from claim 1. Petition, 65-69.

Ground II does not rely on Breen to meet Limitation 1[j] or Limitation 1[h], does not map the Aspel-Gutekunst-Breen combination to either limitation, and relies entirely on Ground I's showing for Limitations 1[j] and 1[h]. Thus,

Ground II inherits Ground I's failures for Limitations 1[j] and 1[h] and fails for the same reasons Ground I fails.

C. Ground III (Paterno, Valdes, and Hanson) Fails

Abbott alleges that Paterno, Valdes, and Hanson render obvious independent claims 1 and 15-17, as well as certain dependent claims.

1. References

a. Paterno (Ex-1008)

Paterno describes “[a] convenient task reminder, compliance logging and monitoring system for *routine activities*.” Paterno, Abstract. Paterno’s “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. Home Unit 100’s “primary function” is “scheduling of future events and logging of events to that schedule.” *Id.*, 5:56-58. Each Home Unit has an associated account record in the SCMS that identifies which individuals can access the account. Paterno, 3:29-39.

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 did so. Paterno, 8:35-37 (“Betty it is time to take your morning medications – please press the OK button after you have done this.”).

Paterno is not directed to a system as claimed that involves alerts “based on analyte concentration sensor data.” *See e.g.*, Limitation 1[b].

b. Valdes (Ex-1009)

As the Petition 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, 25 (citing Valdes, Abstract, ¶¶ [0002], [0008], [0108]-[0109]). Valdes’s CGM system includes a sensor electronics module 8 (hereafter “sensor”) and a receiver unit 14 (hereafter “receiver”) that receives sensor data from the sensor to measure the analyte (e.g., glucose) level of a host. Valdes, [0002], [0062], [0097]; Petition, 26. The receiver can wirelessly communicate with one or more secondary display devices 16, such as a mobile phone or computer, used by either the host or a third party such as a parent or caregiver. Valdes, [0113], [0157]; Petition, 26.

c. Hanson (Ex-1010)

Hanson describes “[m]edication management and reporting technology” that determines whether a patient is taking medication according to a prescribed

schedule. Hanson, Abstract. The system uses a camera that captures images of the patient's medication. *Id.* The system also includes motion sensors "configured to sense physical activity in a building in which medication of a patient is located" and determines whether to take an image of medication based on the motion sensors being triggered. Hanson, Abstract.

Hanson's system includes a "central monitoring station 150" and "one or more user devices 140." Hanson, [0052]-[0053]. The user devices, which can be a cellphone, include "a native medication monitoring and reporting application" that "enables the user devices 140 to receive and process image and sensor data from the monitoring system." Hanson, [0056].

Hanson compares the "state" of the observed medication to an "expected state" determined by evaluating a "schedule by which the medication should be taken by the patient." Hanson, Abstract. The system determines whether "the patient has departed from the [medication] schedule based on the comparison that the detected state does not match the expected state." *Id.* In other words, Hanson determines whether the patient has more pills on hand than should be the case if the medication had been taken as prescribed. Hanson also provides "proactive care recipient guidance, reminders, and refills" such as "preemptively reminding [patients] to take medications prior to their scheduled times." Hanson, [0062].

The system sends an alert message when it determines that a patient has departed from their prescribed medication schedule. *Id.* Alert messages can be sent to a doctor or caregiver who can view patient records. Hanson, [0115]. Hanson also describes providing an alert recipient an option to prescribe new medications (Hanson, [0120]) or to “change a dosage at which the patient is currently taking the medication” (Hanson, [0121]).

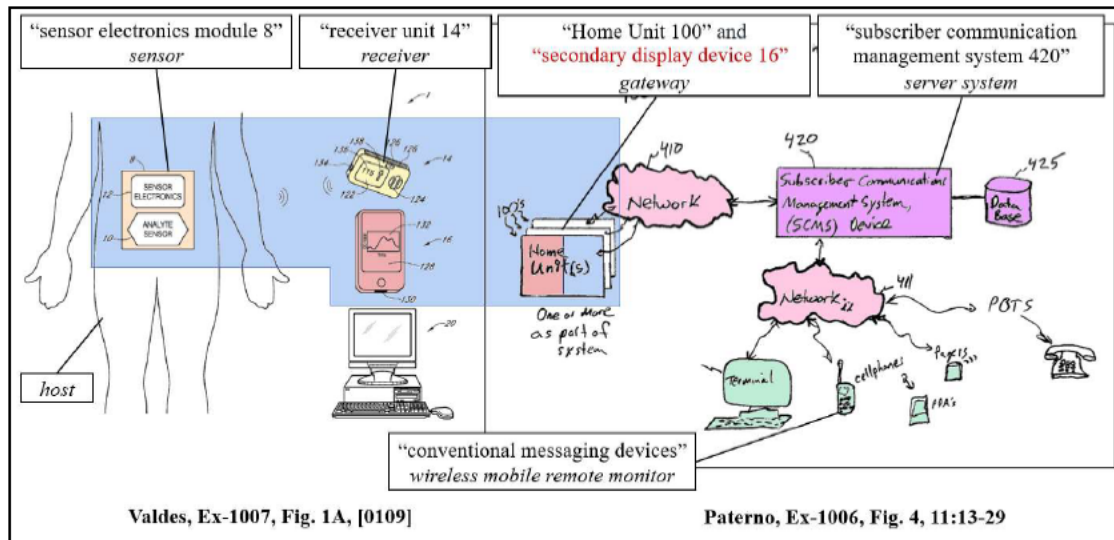
2. Abbott Fails to Explain the Contemplated Workings of its Paterno-Valdes-Hanson Combination

As explained in connection with Ground I, 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 Techs.*, 848 F.3d at 994. Abbott fails to meet this “prerequisite” requirement because the contemplated workings of Abbott’s proposed Paterno-Valdes-Hanson combination are entirely unclear.

a. The Petition’s Section Introducing Ground III Does Not Explain the Contemplated Workings of the Combination

In a section introducing Ground III, the Petition states that “Paterno discloses a monitoring system consisting of a Home Unit 100 at a patient’s location, a server (SCMS 420 and database 425), and ‘conventional messaging devices,’ e.g., cellphones.” Petition, 69. Abbott then states that Valdes “discloses a CGM [continuous glucose monitor] including a sensor” for measuring analyte

concentration and “a receiver unit 14 to gather the data” and that Valdes “describes setting alert rules.” *Id.* Abbott provides an annotated figure, reproduced below, that “depicts the results of combining Paterno (right) with Valdes (left) as in the proposed combination.” *Id.*



Abbott then says that “[i]n the... combination, Hanson’s *disclosures regarding networking communications* would be incorporated into the *server system* and the *wireless mobile remote monitor*.” Petition, 70. No explanation is provided of what these Hanson “networking communications” are that a POSA purportedly would have “incorporated into” the combination.

b. The Petition’s “Motivated to Combine... With a Reasonable Expectation of Success” Section Does Not Explain the Contemplated Workings of the Combination

The Petition has another section purporting to establish that a POSA “Would Have Been Motivated To Combine Paterno, Valdes, and Hanson and With a

Reasonable Expectation of Success.” Petition, 70-72. In that section, Abbott says that Paterno describes monitoring blood sugar⁵ and that the combination uses Valdes’s CGM with Paterno’s system to provide “more efficient and timely glucose level monitoring.” Petition, 70.

Abbott describes Hanson as teaching “medication management and reporting technology” that “incorporate[es] additional alert rules into the *server*” and “provid[es] a remote alert to a remote device” using “notification mechanisms” and “alert interfaces.” Petition, 70-71. Abbott asserts that a POSA “would have considered Hanson’s disclosures regarding alert messages to benefit Paterno’s system by allowing additional notification rules.” *Id.*, 71. But Abbott never identifies a single “notification rule[]” or “alert message[]” in Hanson that a POSA allegedly would have added to Paterno’s system, let alone explain how or why a POSA would have considered those *unidentified* “notification rules” and “alert messages” in Hanson to be beneficial in Paterno’s system.

In a sub-section entitled “Other Factors and Reasonable Expectation of Success,” the Petition states that “[c]ombining Paterno, Valdes, and Hanson would

⁵ As discussed *infra* §III.C.3.a, Abbott’s assertion that “Paterno discloses a system for detecting events... relating to home monitoring of blood sugar” (Petition, 74) is false.

have involved combining prior art elements (i.e., adding Valdes’s CGM for “monitoring of... blood sugar” to Paterno’s system; supplementing Paterno’s alert mechanism based on Hanson’s disclosure) according to known methods to yield predictable results (i.e., continuous measurement of the blood glucose level of a host with alert messages for remote recipients). Petition, 71. Thus, the “prior art elements” from Hanson alleged to be included in the combination are added to “supplement[] Paterno’s alert mechanism based on Hanson’s disclosure.” *Id.* But again, Abbott never identifies or explains any “alert mechanism” in Hanson that a POSA would have purportedly added to Paterno, let alone provide an explanation of how or why a POSA would have added those **unidentified** “alert mechanism(s)” to Paterno’s system. The “contemplated workings” of the combination are entirely unclear. *Personal Web Techs.*, 848 F.3d at 994.

Worse yet, on the next page the Petition again characterizes the combination as merely “combining prior art elements... to yield predictable results” but characterizes the elements added from Hanson in a **different** way. Abbott alleges that “[a]dding Hanson to the Paterno-Valdes combination would have involved combining prior art elements (i.e., **adding Hanson’s mobile application**) according to known methods to yield predictable results (i.e., a **custom mobile application for interacting with a server**).” Petition, 72. Abbott alleges that “Hanson discloses using ‘native applications’ on ‘a mobile device’ to enable more advanced

interactions with the monitoring system” and that a “POSITA would have readily appreciated the convenience and special features of a native application” as compared to “a cross-platform website.” *Id.* The Petition never even explains where in “the Paterno-Valdes combination” Hason’s mobile application allegedly would have been “[a]dd[ed].” Petition, 72. Would it be used on Paterno’s messaging devices alleged to meet the *remote monitor*, on Valdes’s receiver 14 used by the *host*, on both? The “contemplated workings” of the combination are unclear for this additional reason. *Personal Web Techs.*, 848 F.3d at 994.

Finally, Abbott asserts that Hanson discloses “technology” that “incorporate[s] ***additional alert rules*** into the *server*” and that a POSA “would have considered Hanson’s disclosures regarding ***alert messages*** to benefit Paterno’s system by allowing ***additional notification rules***” that a POSA allegedly would have used to “supplement[] Paterno’s ***alert mechanism*** based on Hanson’s disclosure.” Petition, 70-71. Yet, once again the Petition does not identify a single “alert rule,” “alert message,” “notification rule” or “alert mechanism” in Hanson that a POSA purportedly would have added to Paterno’s system.

The Petition never provides “a ***clear, evidence- supported account of the contemplated workings of the combination***” because, as demonstrated above, the Petition provides no account—let alone a clear one—of what alert rule(s), message(s) or mechanism(s) from Hanson a POSA allegedly would have used in

the Paterno-Valdes-Hanson combination. *Personal Web Techs.*, 848 F.3d at 994. That is fatal to Ground III because providing a clear explanation of the contemplated workings of the combination is a “*prerequisite*” to establishing obviousness. *Id.*

As explained in connection with Ground I, to establish obviousness 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 (a reason to combine in the manner claimed is required); *TQ Delta*, 942 F.3d at 1359 (same). Without even explaining what alleged features from Hanson a POSA allegedly would have added to Paterno-Valdes system, Abbott cannot meet its burden to establish a *reason why* a POSA would have added these *unidentified* Hanson features to the Paterno-Valdes system. *Personal Web*, 848 F.3d at 994 (a clear explanation of the combination is “a prerequisite to adequately explaining and supporting a conclusion that a relevant skilled artisan *would have been motivated to make the combination* and reasonably expect success in doing so.”).

Ground III is not stated with the required “particularity.” 35 U.S.C. §312(a)(3). The failure to provide a clear explanation of the “contemplated workings” of the Paterno-Valdes-Hanson combination is fatal to Ground III. *Personal Web*, 848 F.3d at 994.

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

Ground III also fails because Abbott's assertion that a POSA would have used Paterno's system to monitor Valdes's continuous glucose monitor (CGM) is entirely unsupported. Petition, 69-72.

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.C.1.a. Paterno never discloses using its system to monitor any device (like a CGM) with a sensor for measuring something about a patient's body.

Abbott's suggestion that Paterno teaches that its system monitors "blood sugar" is false. Petition, 70. Paterno's reference to "blood sugar" is in the "BACKGROUND" and describes *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. Paterno describes these *prior art* systems as "BACKGROUND" and distinguishes them from Paterno's "invention." Paterno, 1:40-60. Paterno never describes its "invention" as monitoring blood sugar or any other of the other "health parameters" Paterno refers to in its "BACKGROUND."

The only other Paterno disclosures Abbott cites in its "Motivated to Combine Paterno, Valdes and Hanson" section are cited to establish that Paterno's

Home Units can communicate “wireless[ly]” so a POSA would reasonably expect success in having Valdes’s CGM wirelessly transmit data “to Paterno’s Home Unit.” Petition, 71 (citing Paterno, 6:10-12, 20:28-34).

None of the cited disclosures in Paterno support Abbott’s suggestion that Paterno teaches using its system to “monitor[] blood sugar.” Petition, 70.

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 alleges for combining Paterno and Valdes is that “Paterno refers to monitoring blood sugar but does not specifically disclose incorporating a ‘blood sugar’ sensor with its Home Unit. A POSITA would have understood that *one way to monitor ‘blood sugar’* is using a CGM, as disclosed by Valdes” and a “POSITA would have understood the advantages of a CGM in Paterno’s monitoring system, for

more efficient and timely glucose level monitoring.”⁶ Petition, 70. Abbott’s alleged “reason” is entirely 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.C.3.a.

A POSA would not have understood Valdes’s CGM to be a “more efficient and timely” “way” to achieve Paterno’s “monitor[ing] of blood sugar” (Petition, 70) because Paterno’s system does not monitor blood sugar at all. Thus, the Petition’s only “reason” to combine Paterno and Valdes is unsupported. Ground III fails for this additional reason.

4. The Petition Fails to Establish That Its Paterno-Valdes-Hanson Combination Meets Several Limitations in Claim 1

a. Limitation 1[b]

Limitation 1[b] requires that the event represented by Limitation 1[a]’s “alert notification message” be “*based on analyte concentration sensor data obtained from a receiver.*” Elsewhere, claim 1 requires that “*the event is detected by the server system.*” See Limitation 1[j]. Thus, claim 1 recites a method in

⁶ If the Board considers Abbott’s assertion that its combination 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.C.4.

which the event is not generated by the receiver but by the *server* that obtains the sensor data *from the receiver*.

“The petition must specify where each element of the claim is found in the prior art.” 37 C.F.R. §42.104(b)(4). The Petition fails to do so for Limitation 1[b]. The Petition never maps its Paterno-Valdes-Hanson *combination* to Limitation 1[b]. Instead, in its section addressing “1[b],” the Petition simply characterizes various alleged disclosures in Paterno and Valdes separately. Petition, 74-75. None of these disclosures meet Limitation 1[b].

The Petition asserts that “Paterno discloses a system for detecting events, including relating to home monitoring of blood sugar.” Petition, 74. The Petition cites no evidence to support this assertion because nothing in Paterno can support it. As discussed *supra* §III.C.3.a, Paterno only references “blood sugar” in describing prior art devices in its “BACKGROUND.” Paterno does not disclose “detecting events... relating to home monitoring of blood sugar” as the Petition erroneously alleges. Petition, 74. Paterno does not meet Limitation 1[b] because it does not generate an “*event... based on analyte concentration sensor data*.”

Next, the Petition alleges that “Valdes... discloses software to receive glucose sensor data, process the received sensor data, display an indication of the sensor data and transmit the displayable data to a secondary device.” Petition, 74 (citing Valdes, [0008]). That cited passage describes software that *runs on*

Valdes's receiver 14. Valdes, [0008] (“the receiver unit comprising... a software program”). The Petition alleges that this same software—“[t]he software”—“recognizes a predetermined event... and initiates an alert.” Petition, 74. Thus, the Petition cites Valdes’s disclosure of detecting an event *on the receiver*. That does not meet Limitation 1[b]’s requirement that the event be “based on sensor data obtained from a receiver” because Valdes’s receiver does not obtain sensor data from itself.

Thus, neither Paterno nor Valdes meets what Limitation 1[b] requires. And the Petition never offers any *reason why* a POSA would have *modified* Paterno, Valdes, or both so that an “event [] based on analyte concentration sensor data” is generated anywhere other than on Valdes’s receiver as taught by Valdes. Indeed, the only combination that Abbott sought to establish that a POSA would have made is one that merely “combin[es] prior art elements... according to known methods to yield predictable results.” Petition, 71 and 72. This *KSR* rationale only applies when known prior art elements are combined without “change in their respective functions” and would not support modifying the function of Paterno, Valdes, or both to have Paterno’s server evaluate sensor data and generate events based on the patient’s analyte concentration levels. *KSR*, 550 U.S. at 415-16; *supra* §III.A.2.b.

To establish obviousness of claim 1, Abbott needed to establish some ***reason why*** a POSA would have ***modified*** Paterno, Valdes, or both so that an “*event [] based on analyte concentration sensor data*” is generated somewhere other than on Valdes’s receiver to meet what Limitation 1[b] requires. *TQ Delta*, 942 F.3d at 1359 (Abbott needed to establish a “***reason why*** a skilled artisan would have combined the elements ***in the manner claimed.***”); *KSR*, 550 U.S. at 418 (same); *Unigene Lab.*, 655 F.3d at 1360 (Abbott needed to establish that a POSA would have combined the prior art elements in a manner that “yield[s] the claimed invention.”). The Petition did not even allege, let alone establish, any such reason.

Abbott fails to establish that its Paterno-Valdes-Hanson combination meets Limitation 1[b]. Ground III fails for this separate independent reason.

b. Limitation 1[f]

Limitation 1[f] requires “*receiving, at the wireless mobile remote monitor, user input indicative of acknowledgment of the presented alert notification message.*”

The Petition cites disclosures from both Paterno and Hanson. Petition, 77-78. None of the cited disclosures discloses “*user input indicative of acknowledgment*” as required by Limitation 1[f]. Abbott alleges that a POSA would have “adapted” Hason’s teachings for receiving medication alerts to Paterno’s system but never establishes any reason why a POSA would have done

so and never explains what the resulting combination would have looked like and how it allegedly would have met Limitation 1[f].

i. Paterno does not disclose “*user input indicative of an acknowledgment*”

Abbott cites Paterno’s disclosure of an automated *device*-generated acknowledgment that “the desired receiving device or system has been reached.” Petition, 77 (citing Paterno, 9:63-10:14). The cited passage describes a “controller module 110” performing a “communication task” at “step 6040” that “includes... receiving acknowledgment that the desired receiving device or system has been reached... and receiving confirmation that the transmitted data was received and deemed complete by embedded data consistency checks.” Paterno, 10:7-14, Fig. 10.

Nothing in Paterno’s automated *device*-generated acknowledgment involves any *user input* at all, let alone “*user input indicative of acknowledgment of the presented alert notification message*” as required by Limitation 1[f].

ii. Hanson does not disclose “*user input indicative of an acknowledgment*”

Abbott cites Hanson as providing “input controls” that “receive input” relating to “alerts for medication.” Petition, 77. This is not an alert of the type required by claim 1 which is an alert representative of an event “*based on analyte concentration sensor data*” per Limitations 1[a]-1[b]. Petition, 77. Indeed,

Abbott never alleges that Hanson teaches the type of alert required by claim 1. Instead, Abbott alleges that Hanson’s medication alerts would be “readily adapted” to other alert types. Petition, 77. That assertion fails for the reasons discussed *infra* §III.C.4.b.iii because Abbott never even alleges, let alone establishes, any reason why a POSA would have “adapted” Hanson’s alerts.

But the Petition’s reliance on Hanson also fails for an additional reason: Abbott’s assertion that Hanson discloses a remote monitor that receives *user input indicative of an acknowledgment* is false. Petition, 77. The Petition quotes Hanson’s disclosure of “**user input controls that help a recipient... evaluate and handle the alert.**” Petition, 77 (emphasis original). A user “evaluat[ing] and handl[ing]” an alert is not an acknowledgment of the alert. The ’541 specification distinguishes “acknowledg[ing] the triggered alert” from both “indicat[ing] what corrective action was taken in response to the alert” (Ex-1001, 47:18-20) and contacting the patient (*Id.*, 47:18-43), which is among Hanson’s examples of “evaluat[ing] and handl[ing] the alert” (Hanson, [0114]).

None of the cited Hanson sections describe an acknowledgment. Hanson, [0120]-[0121] (cited Petition, 77) explain what Hanson means by input controls that help a recipient “evaluate and handle the alert.” Hanson’s input controls provide an “alert interface... includ[ing]... input control 1221 that allows the recipient of the alert to prescribe a new medication” and a separate “change dosage

input control” that allows the recipient to change the dosage. *Id.* Prescribing medication, or changing a dosage, are “corrective action [] taken in response to the alert” which the specification distinguishes from an acknowledgement of the alert. Ex-1001, 47:18-20. They do not meet “*receiving... user input indicative of acknowledgment of the presented alert notification message*” as Limitation 1[f] requires.

Hanson, [0112] (cited Petition, 77) describes **sending** an alert. It says nothing about receiving an alert, let alone receiving user acknowledgement of a received alert.

Hanson does not disclose “***user input indicative of acknowledgment of the presented alert notification message***” as required by Limitation 1[f].

iii. Abbott fails to establish that its Paterno-Valdes-Hanson combination meets Limitation 1[f]

Abbott alleges that “[i]n the Paterno-Valdes-Hanson combination, Hanson’s ‘alert interface’ would be used on Paterno’s” *remote monitor* and “*receive user input indicative of acknowledgment of the presented alert notification message*” as required by Limitation 1[f]. Petition, 77-78. That fails for three reasons.

(1) Abbott establishes no reason why a POSA would have adapted Hanson’s alert interface to Paterno’s alerts

Abbott acknowledges that Hanson’s medication alerts are not of the type claimed but alleges that “a POSITA would have ***readily adapted*** Hanson’s

teachings for use with the types of alerts discussed above.” Petition, 77. But Abbott never even alleges, let alone establishes, any *reason why* a POSA would have “adapted” Hanson’s alerts in that way.

The Petition’s section on Limitation 1[f] offers no new or different reasons to combine the references and instead alleges that a POSA “would have combined Paterno, Valdes, and Hanson” for the reasons in “Section VIII.C.1.” Petition, 78. “Section VIII.C.1” is Ground III’s above-discussed “Motivated to Combine” section which never offers any *reason why* “a POSITA would have readily *adapted Hanson’s teachings* for use with” other types of alerts like this in Paterno. Petition, 77. Indeed, the only combination Abbott sought to establish that a POSA would have made is one that merely “combin[es] prior art elements... according to known elements to yield predictable results.” Petition, 71-72. This *KSR* rationale only applies when known prior art elements are combined without “change in their respective functions” and would not support modifying the function of Hanson’s “alert interface” (Petition, 77) to somehow “adapt” it to for use with Paterno’s different types of alerts. *KSR*, 550 U.S. at 415-16; *supra* §III.A.2.b.

Thus, Abbott’s argument for Limitation 1[f] relies on a way of combining the teachings of Paterno, Valdes and Hanson that is unsupported by any purported *reason why* a POSA would have combined the teachings of those references in the manner alleged to meet Limitation 1[f]. Ground III fails for that reason alone.

KSR, 550 U.S. at 418 (a reason is required to combine the references in the manner claimed); *TQ Delta*, 942 F.3d at 1359 (same); *Unigene Lab.*, 655 F.3d at 1360 (Abbott needed to establish that a POSA had a reason to combine the prior art elements in a manner that “yield[s] the claimed invention”).

(2) Abbott never explains the contemplated workings of the combination

Hanson’s “alert interface” that Abbott cites for “handling” an alert allows the recipient to prescribe medication or change a dosage. *Supra* §III.C.1.c; Hanson, [0120]-[0121]. Abbott never explains how this “alert interface” would be adapted for alerts based on “analyte concentration sensor data” (Limitation 1b)) as required to meet claim 1. Ground III fails for this additional reason because it fails to meet the “prerequisite” requirement of explaining “the contemplated workings of the combination.” *Personal Web Techs.*, 848 F.3d at 994.

(3) Hanson’s alert interface does not provide *user input indicative of an acknowledgment*

Even if the Board were to find that Abbott established some reason to adapt “Hanson’s ‘alert interface’” to Paterno’s system (Petition, 77) and adequately explained the combination, Abbott fails to establish Hanson’s alert interface “*receiv[es]... user input indicative of acknowledgment*” as discussed *supra* §§III.C.4.b.ii-III.C.4.b.iii(2).

c. Limitation 1[g]

As with Limitation 1[f], the Petition relies on Hanson, [0121] and its “change dosage input control” to meet Limitation 1[g]. Petition, 78. The Petition asserts that a POSA “understood” that Hanson’s “change of prescription... *could* be applied to glucose alerts in Paterno’s system.” *Id.* This argument fails for several reasons.

i. Abbott fails to establish any reason why a POSA would have modified Paterno to apply Hanson’s change of prescription

Abbott’s assertion that Hanson’s “change of prescription... *could* be applied to glucose alerts in Paterno’s system” (Petition, 78) is facially deficient because it never alleges any reason why a POSA *would* have done so. “[O]bviousness concerns whether a skilled artisan not only *could* have made *but would* have been motivated to make the combinations or modifications of prior art to arrive at the claimed invention.” *Belden v. Berk-Tek*, 805 F.3d 1064, 1073 (Fed. Cir. 2015); *see also Adidas AG v. Nike*, 963 F.3d 1355, 1359 (Fed. Cir. 2020) (“The obviousness inquiry does not merely ask whether a skilled artisan *could* combine the references, but instead asks whether ‘they *would* have been motivated to do so.’”). “Without any explanation as to how or *why* the references would be combined to arrive at the claimed invention, we are left with only hindsight bias that *KSR* warns against.” *Metalcraft of Mayville v. Toro*, 848 F.3d 1358, 1367 (Fed. Cir. 2017).

Abbott never even alleges, let alone establishes, any *reason why* a POSA would have “applied” “Hanson’s acknowledgement (change of prescription)... to glucose alerts in Paterno’s system.” Petition, 78. Abbott only alleges a “POSITA would have combined Paterno, Valdes and Hanson” for the reasons in “Section VIII.C.1.” *Id.* “Section VIII.C.1” is Ground III’s “Motivated to Combine” section which *never even mentions* Hanson’s “change of prescription.”

The “Motivated to Combine” section alleges that (1) “Hanson’s disclosures regarding alert messages [would] benefit Paterno’s system by allowing additional notification rules” (Petition, 70-71); (2) a POSA would have “add[ed] Hanson’s mobile application” to “the Paterno-Valdes combination” to achieve “the convenience and special features of a native application” (*id.*, 72); and (3) the Paterno-Valdes-Hanson combination is nothing but combining known elements to yield predictable results (*id.*, 71-72).

The Petition’s failure to even allege, let alone establish, some *reason why* a POSA would have “applied” “Hanson’s acknowledgement (change of prescription)... to glucose alerts in Paterno’s system” (Petition, 78) is fatal to Ground III.

ii. Abbott fails to explain the contemplated workings of its combination

Even if the Board were to find that Abbott alleged some reason why a POSA would have “applied” Hanson’s “acknowledgement (change of prescription)... in

Paterno's system" (Petition, 78), Abbott fails to explain the contemplated workings of the resulting combination which is a "prerequisite" to establishing obviousness. *Personal Web Techs.*, 848 F.3d at 994.

Abbott never explains **how** a POSA would have "applied" Hanson's "change of prescription" functionality "to glucose alerts" in the Paterno-Valdes-Hanson combination. Abbott needed to state its grounds with particularity and needed to explain the "contemplated workings" of its combination. *Personal Web Techs.*, 848 F.3d at 994. Abbott's failure to do so is another independent reason why Ground III fails.

iii. Expert testimony cannot save Abbott

The Petition cites Ex-1003 ¶¶259-261 to support its argument regarding Limitation 1[g]. Petition, 78. The required showing of a reason why a POSA would have added Hanson's "acknowledgement (change of prescription)" to Paterno's system and the required explanation of the contemplated workings of the combination both needed to be in the Petition and cannot be incorporated by reference from the declaration. 37 C.F.R. §42.6(a)(3). Regardless, the cited testimony does nothing but parrot the language in the Petition at 78 virtually word-for-word without adding analysis or factual support so it warrants no weight. *Xerox*, Paper 9, 15. This testimony also has the same deficiencies as the Petition language it parrots and cannot save Ground III.

d. Limitation 1[j]

Limitation 1[j] requires that “*the event is **detected by the server system***” where the antecedent for “the event” is that it is “*based on analyte concentration sensor data obtained from a receiver*” per Limitation 1[b].

Limitation 1[j] further requires that the detected event be “*based on one or more sets of recommended alert rules settings **configured by the host***,” where “*at least one of the sets of recommended alert rule settings*” are “***modifiable by the user of the wireless mobile remote monitor***.” Limitation 1[j] thus requires that at least one set of alert rule settings “*configured by the host using the receiver*” be “*modifiable*” by a user “*using the... remote monitor*.”

Abbott’s “analysis” of Limitation 1[j] is facially deficient because it ignores the language of this limitation and what it requires. The Petition has one paragraph citing disclosure in Paterno, another citing disclosure in Valdes, and a third saying that Ground III’s references would be combined for the reasons in the Petition’s “Motivated to Combine” section. Petition, 81-82.

The Petition never even alleges, let alone establishes, how or why the Paterno-Valdes-Hanson **combination** meets Limitation 1[j]. That is facially deficient. *See e.g., Carecloud v. AthenaHealth*, CBM2014-00143, Paper 36 at 34-35 (November 18, 2015) (rejecting obviousness showing where the petitioner “merely mapped the claim requirements to elements disclosed individually in the []

references”—including mapping “disparate disclosures from several references... to the same claim limitation”—“without providing an adequate rationale to explain why or how the disparate [prior art] elements predictably would have been combined by a POSA to meet every aspect of any particular claim limitation at issue”).

As explained below, none of the cited disclosures from Paterno or Valdes meet Limitation 1[j]. Abbott does not rely on any Hanson disclosure for this limitation. Petition, 81-82. The Petition offers no reason why a POSA would have modified the teachings of Paterno, Valdes, or both in a manner that would be required to meet Limitation 1[j].

i. Abbott’s reliance on Paterno fails

Abbott cites Paterno as disclosing that “subscribers can specify specific privileges by group member for... programming sending of... alerts... and for setting what notifications... they will receive.” Petition, 81 (citing Paterno, 3:57-63). This does not meet Limitation 1[j] for two reasons.

First, Abbott does not even allege that Paterno teaches an “*event [] detected by the server system*” where “*the event*” is “*based on analyte concentration sensor data obtained from a receiver*” (Limitation 1[b]) as required to meet Limitation 1[j].

Second, Abbott also does not even allege that Paterno teaches that the *remote monitor* user (Paterno’s “subscriber”) modifies “*one or more sets of recommended alert rules settings configured by the host*” as required by Limitation 1[j].

ii. Abbott’s reliance on Valdes fails

Abbott cites Valdes as disclosing that recommended alert settings can be “configured *by the host using the receiver.*” Petition, 81 (citing Valdes, [0129]). This does not meet Limitation 1[j] for two reasons.

First, Limitation 1[j] requires that a “*user of the wireless mobile remote monitor*” — not a user of the *receiver* as in Valdes — can modify “*settings configured by the host.*”

Second, Valdes does not teach an “*event [] detected by the server system*” as required by Limitation 1[j]. Indeed, Valdes does not disclose a *server* that receives recommended alert rules settings configured by the host, evaluates analyte data, or sends an alert notification message to a remote monitor, as claim 1 requires.

iii. Abbott establishes no reason to modify Paterno, Valdes, or both in a manner required to meet Limitation 1[j]

The Petition’s “mapping” for Limitation 1[j] ignores the language of the limitation and fatally never explains how the Paterno-Valdes-Hanson **combination** allegedly meets it. *Carecloud*, CBM2014-00143, Paper 36 at 34-35.

The Petition separately cites disclosures in Paterno and Valdes (Petition, 81-82) but as just explained *supra* §§III.C.4.d-III.C.4.d.ii, none of the cited disclosures meet Limitation 1[j].

The Petition does not even allege that a POSA would have modified Paterno, Valdes or both in a manner that would have been required to meet Limitation 1[j], let alone establish with evidence some *reason* why a POSA would have done so. For example, the Petition never alleges any reason why a POSA would have modified: (1) the function of Valdes to send to a *server* alert rule settings *configured by the host using the receiver*; (2) the function of Paterno's *server* to generate alerts based on *analyte concentration sensor data*; or (3) the function of Paterno's *server* to allow a *remote monitor* user to *modif[y]* any *alert rule settings configured by the host*.

Abbott only alleges that a "POSITA would have combined Paterno, Valdes and Hanson. *See* Section VIII.C.1." Petition, 82. "Section VIII.C.1" is Ground III's "Motivated to Combine" section which alleges that its Paterno-Valdes-Hanson combination is nothing but combining known elements to yield predictable results. *Id.*, 71. As discussed *supra* §§III.A.2.b, III.C.2.b, that rationale precludes modifying the function of any of the elements of Paterno or Valdes that are combined to make the combination.

Regardless, the Petition never alleges that a POSA had *any reason* to make any of the three above-listed changes to the functions of Paterno and Valdes, or to otherwise combine the features of the references in a manner that meets Limitation 1[j]. Ground III fails for this additional reason. *TQ Delta*, 942 F.3d at 1359 (Abbott needed to establish a “reason why a skilled artisan would have combined the elements in the manner claimed.”); *KSR*, 550 U.S. at 418 (same); *Unigene Lab.*, 655 F.3d at 1360 (Abbott needed to establish that a POSA would have combined the prior art elements in a manner that “yield[s] the claimed invention”).

5. Conclusion on Ground III’s Failings

As detailed above, Ground III fails for numerous independent reasons because Abbott fails to (1) explain the contemplated workings of its Paterno-Valdes-Hanson combination, (2) support that a POSA would have modified Paterno’s system to monitor Valdes’s glucose monitor; and (3) establish that its Paterno-Valdes-Hanson combination meets any of Limitations 1[b], 1[f], 1[g] and 1[j].

6. Ground III’s Challenges to the Remaining Claims Inherit the Failures for Claim 1

Ground III fails for dependent claims 4-7, 9, 11, and 13 that depend from claim 1, for the same reasons Ground III fails for claim 1. As explained below, Ground III’s showing for independent claims 15-17 also inherit its failings for claim 1.

Ground III relies on its showing for Limitation 1[b] to meet Limitations 15[a] and 15[f] (Petition, 91-92), Limitation 16[d] (*id.*, 93), and Limitation 17[c] (*id.*, 94).

Ground III relies entirely on its showing for Limitation 1[f] to meet Limitation 15[i] (Petition, 92), Limitation 16[i] (*id.*, 94), and Limitation 17[h] (*id.*, 95).

Ground III relies entirely on its showing for Limitation 1[g] to meet Limitation 15[j] (Petition, 92), Limitation 16[j] (*id.*, 94), and Limitation 17[i] (*id.*, 95).

Ground III relies on its showing for Limitation 1[j] to meet Limitations 15[a] and 15[m] (Petition, 91-92), Limitation 16[m] (*id.*, 94), and Limitation 17[l] (*id.*, 95).

Thus, Ground III fails for all claims challenged therein for the same reasons it fails for claim 1.

D. Ground IV Falls with Ground III

Ground IV adds Breen to Ground III's Paterno-Valdes-Hanson combination. Petition, 95-96. Abbott alleges that the Paterno-Valdes-Hanson-Breen combination renders obvious claims 2-3 that depend from claim 1. Petition, 96-98.

Nothing in Breen or Abbott's Ground IV analysis remedies any of Ground III's above-discussed defects. The Petition does not map Breen or the Paterno-

Valdes-Hanson-Breen combination to any of Limitations 1[b], 1[f]-1[g] and 1[j].

Ground IV thus inherits Ground III's failures and fails for the same reasons

Ground III fails.

IV. CONCLUSION

The Petition fails to demonstrate that it is reasonably likely to show that any Challenged Claim is unpatentable. The Board should deny institution.

Respectfully submitted,
DexCom, Inc.

Date: August 22, 2024

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V. APPENDIX A: U.S. PATENT NO. 9,801,541 CLAIM LIST

This '541 patent claim list retains the labeling that Abbott applied to asserted claims in the Petition. Unlike the Petition, however, this claim list adds the corrections to claim language propagated by the two Certificates of Correction. And this claim list provides all '541 patent claims (and not just challenged claims).

Ref	Limitation
1[Pre]	A method comprising:
1[a]	receiving, at a wireless mobile remote monitor, an alert notification message from a server system, the alert notification message representative of a detected event,
1[b]	the event being based on analyte concentration sensor data obtained from a receiver monitoring an analyte state of a host, the analyte concentration sensor data indicating a concentration of an analyte of the host,
1[c]	the wireless mobile remote monitor being remote to the host and the server system;
1[d]	presenting, at the wireless mobile remote monitor, the alert notification message,
1[e]	wherein the wireless mobile remote monitor or a user of the wireless mobile remote monitor is specifically authorized by the host to receive the alert notification message to augment the receiver monitoring of the analyte state of the host,
1[e]	wherein the wireless mobile remote monitor or the user of the wireless mobile remote monitor is authenticated by the server system;
1[f]	receiving, at the wireless mobile remote monitor, user input indicative of acknowledgment of the presented alert notification message;

Ref	Limitation
1[g]	sending an acknowledgment message from the wireless mobile remote monitor to the server system indicating acknowledgement of the presented alert notification message to enable the server system to confirm that the alert notification message has been received;
1[h]	after sending the acknowledgment, accessing, by the wireless mobile remote monitor, at least some of the analyte concentration sensor data from the server system; and
1[i]	receiving, in response to the accessing, the at least some of the analyte concentration sensor data including historical data, the at least some of the analyte concentration sensor data being generated by the receiver monitoring the analyte state of the host;
1[j]	wherein the event is detected by the server system based on one or more sets of recommended alert rules settings configured by the host using the receiver, at least one of the sets of recommended alert rules settings being modifiable by the user of the wireless mobile remote monitor using the wireless mobile remote monitor.
2[a]	The method of claim 1, wherein the presenting further comprises inhibiting access to one or more applications at the wireless mobile remote monitor until an action at the wireless mobile remote monitor is detected to indicate an interaction by the user with the alert notification message.
3[a]	The method of claim 1, wherein the presenting further comprises presenting the alert notification message as a momentary message on a display at the wireless mobile remote monitor.
4	The method of claim 1, wherein at least one of the wireless mobile remote monitor and the receiver comprise one or more of a mobile station, a wireless terminal, a tablet, a smart phone, a multi-mode wireless device, and a computer.

Ref	Limitation
5[a]	The method of claim 1, wherein the server system comprises at least one processor configured to receive analyte sensor data from the receiver, process the analyte sensor data to detect the event, and forward, when the event is detected, the alert notification message to the wireless mobile remote monitor based on one or more rules mapping the event to the wireless mobile remote monitor designated to receive alert messages related to the detected event.
6[a]	The method of claim 1, further comprising detecting, based on a first set of rules at the server system, the event, wherein the first set of rules used to generate the alert notification message are different from a second set of rules used to generate alerts to be sent to the receiver coupled to a sensor system at the host.
7[a]	The method of claim 1, wherein the receiver includes, or couples to, a gateway interfacing a wireless connection to a public land mobile network and the server system.
8[a]	The method of claim 1 further comprising configuring a plurality of remote monitors,
8[b]	wherein at least one of the plurality of remote monitors is designated as a primary monitor that is assigned a higher alert priority status,
8[c]	and at least one of the plurality of remote monitors is designated as a secondary monitor that is assigned a lower alert priority status than the primary monitor.
9[a]	The method of claim 1, further comprising configuring, by the wireless mobile remote monitor, at least one rule including a trigger that when triggered causes an alert to be sent by the server system to the receiver.
10	The method of claim 1, further comprising configuring, by the wireless mobile remote monitor, one or more invitations sent to one or more devices to invite the one or more devices to receive future alerts of the host based on at least some of the analyte concentration sensor data from the receiver.

Ref	Limitation
11[a]	The method of claim 1, further comprising sending, to the server system, a message acknowledging a receipt of the alert notification message.
12	The method of claim 1, wherein the alert notification message includes at least one of an indication to the user of a need to calibrate a sensor coupled to the receiver and an acknowledgement message indicating at least one of an action or an acknowledgement sent by the receiver in response to an alarm sent to the receiver.
13[a]	The method of claim 1, wherein the presenting the alert notification message comprises opening a monitoring application on the wireless mobile remote monitor, and the monitoring application initiating the accessing the at least some of the analyte concentration sensor data from the server system.
14	The method of claim 1, further comprising registering, at the server system, at least one of the wireless mobile remote monitor, the receiver, and an analyte sensor coupled to the receiver, wherein the registration includes a code provided by a health care provider.
15[Pre]	A method comprising:
15[a]	providing, by a wireless mobile remote monitor to a server system, one or more sets of alert rules including at least one analyte concentration level threshold, the one or more sets of rules being specifically associated with the wireless mobile remote monitor and a host,
15[b]	wherein the wireless mobile remote monitor or a user of the wireless mobile remote monitor is specifically authorized by the host to receive an alert notification message,
15[c]	wherein the wireless mobile remote monitor or the user of the wireless mobile remote monitor is authenticated by the server system;
15[d]	receiving, at the wireless mobile remote monitor, an alert notification message from the server system,

Ref	Limitation
15[e]	the alert notification message indicating that analyte concentration sensor data associated with the host has exceeded or fallen below the at least one analyte concentration level threshold,
15[f]	the analyte concentration sensor data being received by the server system from a receiver monitoring an analyte concentration state of the host,
15[g]	the wireless mobile remote monitor being remote to the host and the server system;
15[h]	presenting, at the wireless mobile remote monitor, the alert notification message;
15[i]	receiving, at the wireless mobile remote monitor, user input indicative of acknowledgment of the presented alert notification message;
15[j]	sending an acknowledgment message from the wireless mobile remote monitor to the server system indicating acknowledgement of the presented alert notification message to enable the server system to confirm that the alert notification message has been received;
15[k]	accessing, by the wireless mobile remote monitor, the server system using a remote monitoring software application running on the wireless mobile remote monitor; and
15[l]	receiving from the server system, at the wireless mobile remote monitor, information including at least some of the analyte concentration sensor data;
15[m]	wherein at least one of the sets of alert rules is configured by the host using the receiver, said at least one set configured by the host being modifiable by the user of the wireless mobile remote monitor using the wireless mobile remote monitor.
16[Pre]	A wireless mobile remote system comprising:

Ref	Limitation
16[a]	at least one processor; and memory, the memory including instructions to configure the processor to:
16[b]	receive an alert notification message from a server system,
16[c]	the alert notification message representative of a detected event,
16[d]	the event being based on analyte concentration sensor data obtained from a receiver monitoring an analyte state of a host, the analyte concentration sensor data indicating a concentration of an analyte of the host;
16[e]	present the alert notification message,
16[f]	wherein the wireless mobile remote system or a user of the wireless mobile remote system is specifically authorized by the host to receive the alert notification message
16[g]	to augment the receiver monitoring of the analyte state of the host,
16[h]	wherein the wireless mobile remote system or the user of the wireless mobile remote system is authenticated by the server system;
16[i]	receive user input indicative of acknowledgment of the presented alert notification message;
16[j]	send an acknowledgment message to the server system indicating acknowledgement of the presented alert notification message to enable the server system to confirm that the alert notification message has been received;
16[k]	after sending the acknowledgment, access at least some of the analyte concentration sensor data from the server system; and
16[l]	receive the at least some of the analyte concentration sensor data including historical data from the receiver monitoring the analyte state of the host;

Ref	Limitation
16[m]	wherein the event is detected by the server system based on one or more sets of recommended alert rules settings configured by the host using the receiver, at least one of the sets of recommended alert rules settings being modifiable by the user of the wireless mobile remote system using the wireless mobile remote system.
17[Pre]	A non-transitory computer readable medium comprising executable instructions, the executable instructions being executable by a processor to perform a method, the method comprising:
17[a]	receiving an alert notification message from a server system,
17[b]	the alert notification message representative of a detected event,
17[c]	the event being based on analyte concentration sensor data obtained from a receiver monitoring an analyte state of a host, the analyte concentration sensor data indicating a concentration of an analyte of the host;
17[d]	presenting the alert notification message,
17[e]	wherein a digital device executing the instructions or a user associated with the digital device is specifically authorized by the host to receive the alert notification message
17[f]	to augment the receiver monitoring of the analyte state of the host,
17[g]	wherein the digital device or the user of the digital device is authenticated by the server system;
17[h]	receiving user input indicative of acknowledgment of the presented alert notification message;
17[i]	sending an acknowledgment message to the server system indicating acknowledgement of the presented alert notification message to enable the server system to confirm that the alert notification message has been received;

Ref	Limitation
17[j]	after sending the acknowledgment, accessing at least some of the analyte concentration sensor data from the server system; and
17[k]	receiving the at least some of the analyte concentration sensor data including historical data, the at least some of the analyte concentration sensor data being generated by the receiver monitoring the analyte state of the host;
17[l]	wherein the event is detected by the server system based on one or more sets of recommended alert rules settings configured by the host using the receiver, at least one of the sets of recommended alert rules settings being modifiable by the user of the digital device using the digital device.

CERTIFICATE OF WORD COUNT

Pursuant to 37 C.F.R. §42.24, the undersigned certifies that the foregoing **PATENT OWNER's PRELIMINARY RESPONSE** contains 13,995 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 22, 2024

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

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

I certify that on August 22, 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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