

IN THE 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

**PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,801,541
UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.100 *et seq.***

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LIST OF EXHIBITS

Exhibit	Description
1001	U.S. Patent No. 9,801,541 (the “’541 patent”)
1002	File History for U.S. Patent No. 9,801,541
1003	Declaration of Mr. Lane Desborough
1004	<i>Curriculum Vitae</i> of Mr. Lane Desborough
1005	U.S. Patent Pub. No. 2008/0154099 (“Aspel”)
1006	U.S. Patent Pub. No. 2011/0173308 (“Gutekunst”)
1007	Breen, Christopher, <i>The iPhone Pocket Guide</i> , Sixth Ed. (Nov. 2011) (“Breen”) (scanned excerpt)
1008	U.S. Patent No. 7,301,463 (“Paterno”)
1009	U.S. Patent Pub. No. 2011/0320130 (“Valdes”)
1010	U.S. Patent Pub. No. 2012/0313785 (“Hanson”)
1011	Joint Claim Construction Chart, Doc. 107, <i>Abbott Diabetes Care Inc. et al v. DexCom, Inc.</i> , No. 1:23-cv-00239 (D. Del. Mar. 21, 2024)
1012	DexCom Inc.’s Opening Claim Construction Brief, Doc. 123, <i>Abbott Diabetes Care Inc. et al v. DexCom, Inc.</i> , No. 1:23-cv-00239 (D. Del. Apr. 18, 2024)
1013	Declaration of Sylvia D. Hall-Ellis, Ph.D.
1014	Blank
1015	Scheduling Order, <i>Abbott Diabetes Care Inc. et al. v. DexCom, Inc.</i> , No. 1:23-cv-00239, Dkt. 54 (D. Del. Sept. 19, 2023)

I. Introduction

Abbott Diabetes Care Inc. (“Petitioner”) petitions for *inter partes* review seeking cancellation of claims 1-7, 9, 11, 13, and 15-17 of U.S. Patent No. 9,801,541 (Ex-1001, “’541 patent”), assigned to Patent Owner, DexCom, Inc. (“DexCom”).

The ’541 patent relates to methods and systems for “remote monitoring.” Ex-1001, 1:17-18. The disclosed system purports to enable “one or more caretakers (e.g., parent, spouse, or healthcare practitioner) to remotely monitor health characteristics of hosts,” including an “analyte concentration of a host, such as glucose.” Ex-1001, 4:25-30. The ’541 patent acknowledges that by the time of its earliest possible priority date (December 31, 2012), continuous glucose monitoring systems (“CGMs”) were already known, as were devices for remote monitoring, as well as the ability to easily transmit data from one person to another and one location to another via wireless connectivity. *See generally*, Ex-1003, ¶¶40-53.

The ’541 patent’s claimed methods and systems recite little more than sending analyte data to a server, which sends an alert to a connected remote monitor that is authorized and authenticated, the remote monitor acknowledging the alert and subsequently accessing analyte data. These limitations are generic and well-known computer operations of sending data to authenticated remote devices and/or users. There is nothing novel or inventive in such claims, either independent

or dependent, considering the disclosures of prior art references describing medical management and glucose monitoring technology that expressly teach the generally claimed method and system for remote monitoring of a host's analyte data, and the specific details about the system's method of operation with users of the remote monitoring devices.

II. Standing, Mandatory Notices, and Fee Authorization

A. Grounds for Standing

Pursuant to 37 C.F.R. § 42.104(a), Petitioner certifies that the '541 patent is available for IPR, and that Petitioner is not barred or estopped from requesting an IPR challenging the '541 patent on the grounds identified in this petition.

B. Real Parties-in-Interest

The real parties-in-interest are Abbott Diabetes Care Inc., Abbott Diabetes Care Sales Corp., and Abbott Laboratories. Abbott Diabetes Care Inc. is the Petitioner. Abbott Diabetes Care Inc. is directly owned by Abbott Laboratories. Abbott Diabetes Care Inc. directly owns Abbott Diabetes Care Sales Corp.

C. Related Matters

The '541 patent is asserted against Abbott Diabetes Care Inc. and Abbott Diabetes Care Sales Corp. as a counterclaim for infringement in *Abbott Diabetes Care Inc. et al v. DexCom, Inc.*, No. 1:23-cv-00239 (D. Del). DexCom asserted the '541 patent in its Answer, Affirmative Defenses, and Counterclaims, electronically served on Petitioner Abbott Diabetes Care Inc. on May 12, 2023, and hand-served

on Abbott Diabetes Care Sales Corp. on May 15, 2023. Petitioner asserts that the '541 patent is not infringed.

D. Counsel Information

Lead Counsel	Back-Up Counsel
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E. Service Information under 37 C.F.R. §42.8(b)(4)

Please address correspondence to counsel at the address above. Petitioner consents to electronic service to: Abbott-IPR@cov.com and the email addresses listed above. Service information is provided in the designation of counsel above.

F. Payment of Fees Under 37 C.F.R. §42.103

The Office is authorized to charge the fee set forth in 37 C.F.R. §42.15(a)(1) for this Petition to Deposit Account No. 60-3160 with any shortage or overpayment of fees associated with this Petition and any other fees incurred by Petitioner.

III. Summary of Challenge

Petitioner requests IPR of claims 1-7, 9, 11, 13, and 15-17 of the '541 patent based on the following grounds:

- **Ground I:** Claims 1, 4-7, 9, 11, 13, and 15-17 would have been obvious based on Aspel in view of Gutekunst under 35 U.S.C. § 103.
- **Ground II:** Claims 2 and 3 would have been obvious based on Aspel in view of Gutekunst and Breen under 35 U.S.C. § 103.
- **Ground III:** Claims 1, 4-7, 9, 11, 13, and 15-17 would have been obvious based on Paterno in view of Valdes and Hanson under 35 U.S.C. § 103.
- **Ground IV:** Claims 2 and 3 would have been obvious based on Paterno in view of Valdes, Hanson, and Breen under 35 U.S.C. § 103.

The '541 patent was filed March 15, 2013, and claims priority to a provisional application filed December 31, 2012. Each of the asserted references is

available as prior art under 35 U.S.C. § 102 (pre-AIA),¹ as shown in the following table.

Exhibit	Reference	Date(s)	Availability as Prior Art
Ex-1005	U.S. Patent Pub. No. 2008/0154099 (“Aspel”)	November 6, 2007 (filed) June 26, 2008 (patented)	§§ 102(a), (b), (e)
Ex-1006	U.S. Patent Pub. No. 2011/0173308 (“Gutekunst”)	October 18, 2010 (filed) July 14, 2011 (published)	§§ 102(a), (b), (e)
Ex-1007	Breen, Christopher, <i>The iPhone Pocket Guide</i> , Sixth Ed. (Nov. 2011) (“Breen”)	November 30, 2011 (published)	§ 102(a), (b)
Ex-1008	U.S. Patent No. 7,301,463 (“Paterno”)	April 13, 2005 (filed) November 27, 2007 (patented)	§§ 102(a), (b), (e)
Ex-1009	U.S. Patent Pub. No. 2011/0320130 (“Valdes”)	June 23, 2011 (filed) December 29, 2011 (published)	§§ 102(a), (b), (e)
Ex-1010	U.S. Patent Pub. No. 2012/0313785 (“Hanson”)	April 4, 2011 (provisional) April 4, 2012 (filed) December 13, 2012 (published)	§§ 102(a), (e)

¹ Because the application for the ’541 patent was filed prior to March 16, 2013, the pre-AIA conditions for patentability apply.

IV. The '541 patent

A. Overview of the '541 Patent

As discussed above, the '541 patent (which shares its specification with U.S. Patent. No. 11,213,204) relates to “[m]ethods and apparatus, including computer program products, ... for remote monitoring of analyte data.” Ex-1001 1:57-59.

Figure 2A illustrates an embodiment:

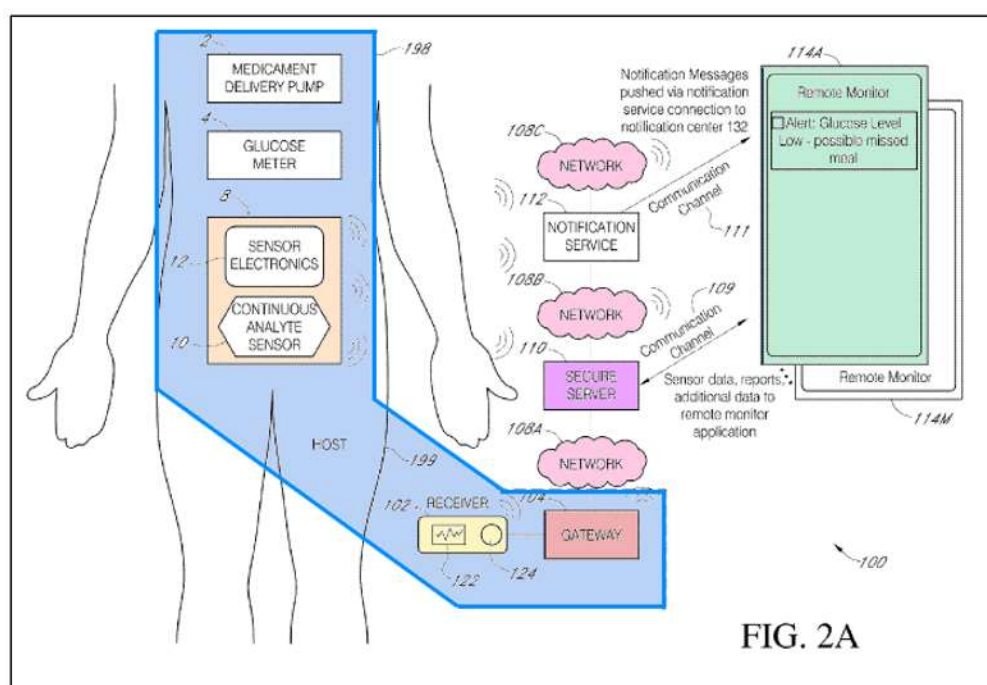


FIG. 2A

Ex-1001, Fig. 2A.² The claims recite methods and systems for receiving and displaying alert notification messages at a remote monitor, reciting generic and

² All patent figures in the Petition that include color have been annotated by Petitioner.

well-known computer operations of sending data to authenticated and authorized remote users, who acknowledge alerts to access and receive data.

B. Prosecution History

The '541 patent issued from Application No. 13/842,679, which was filed March 15, 2013, claiming priority to U.S. Provisional Application No. 61/747,717, filed December 31, 2012. Ex-1001, Cover.

After three office actions rejecting the claims and corresponding responses, the examiner issued a final rejection of the then-pending claims on January 12, 2017. Ex-1002, 158-178. In response, DexCom substantially amended new claim 1 on April 11, 2017, as follows:

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AMENDMENTS TO THE CLAIMS

1. (Currently Amended) A method comprising:
 - receiving, at a wireless mobile remote monitor, an alert notification message from a server system, the alert notification message representative of an event detected by a server, 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, the wireless mobile remote monitor being remote to the host and the server system;
 - presenting, at the wireless mobile remote monitor, the alert notification message, wherein the wireless mobile remote monitor or a user of the wireless mobile remote monitor is configured specifically authorized by the host server to receive the alert notification message to augment the receiver monitoring of the analyte state of the host, wherein the wireless mobile remote monitor or the user of the wireless mobile remote monitor is authenticated by the server system;
 - receiving, at the wireless mobile remote monitor, user input indicative of acknowledgment of the presented alert notification message;
 - 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;
 - after sending the acknowledgment, accessing, by the wireless mobile remote monitor, at least some of the analyte concentration sensor data from the server system, in response to the acknowledgement of the presented alert notification message; and
 - receiving, in response to the accessing, information 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 including at least the analyte sensor data,
 - wherein the alert notification message includes a short message and the receiving the alert notification message is over at least a first wireless connection between the remote monitor and a notification service in communication with the server, the first wireless connection comprising a persistent, encrypted connection configured to carry the short message pushed by the notification service to a notification message center at the remote monitor;
 - wherein the short message is structured by the notification service to be received by the remote monitor over the first wireless connection, and wherein the information is received over at least a second, different wireless connection between the remote monitor and the server, the second wireless connection comprising a momentary, encrypted connection established, in response to the accessing, to provide the information.

Ex-1002,117-118. During a June 6, 2017 interview, DexCom agreed to “include a limitation that recited in part that the event was detected by the server based on one or more set of rules configured by the host using the receiver, and at least one of

the set being modifiable by the user of the remote monitor using the remote monitor.” Ex-1002, 94.

The Examiner allowed the amended claims on June 14, 2017. Ex-1002, 78-93. DexCom filed post-allowance IDSs on August 3, 2017, Ex-1002, 32-77. After two corrected Notices of Allowance (Ex-1002, 9-10), the patent issued on October 31, 2017. DexCom filed a notice of correction on February 7, 2018. Ex-1002, 3-7.

C. Challenged Claim Listing

1. Claim 1

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, 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;
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. Claim 2

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.
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3. Claim 3

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.
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4. Claim 5

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.
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5. Claim 6

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.
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6. Claim 7

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.
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7. Claim 9

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.
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8. Claim 11

11[a]	The method of claim 1, further comprising sending, to the server system, a message acknowledging a receipt of the alert notification message.
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9. Claim 13

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.
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10. Claim 15

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,
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 acknowledgment 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.

11. Claim 16

16[Pre]	A wireless mobile remote system comprising:
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 the 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 acknowledgement of the presented alert notification message;
16[j]	send an acknowledgment message to the server system indicating acknowledgment 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;
16[m]	wherein the event is detected by the server 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 modification by the user of the wireless mobile remote system using the wireless mobile remote system.

12. Claim 17

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:
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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;
17[j]	after sending the acknowledgment, accessing at least some of the analyte concentration sensor data from the server system;
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.

V. Level of Ordinary Skill

A person of ordinary skill in the art (“POSITA”) as of December 2012 would have had a Bachelor’s degree in biomedical engineering, chemical engineering, mathematics, statistics, or computer science (or a related or equivalent field), and two or more years of experience researching, developing, designing and/or evaluating (or supervising the same) systems for measuring and monitoring (including remote monitoring) of a host’s analyte data, or similar data , or equivalent experience. A person with less or different education but more relevant practical experience, or vice versa, may also meet this standard. Each of these POSITAs may be part of an interdisciplinary team with others having the relevant experience set forth above and/or with clinicians involved in diagnosing, treating, monitoring, and managing patients using medical devices.

VI. Claim Construction

In IPR proceedings, claims are construed in accordance with their “ordinary and customary meaning” in light of the specification. 37 C.F.R. § 42.100(b); *see Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005). For purposes of this petition, other than as discussed below, Petitioner does not believe any specialized constructions are necessary. Petitioner also reserves the right to dispute in a different forum whether the Challenged Claims meet the requirements under 35 U.S.C. §§ 101 or 112.

In the copending district court litigation, the parties exchanged proposed constructions, Ex-1011 at.12-13, and DexCom served an Opening Claim Construction Brief, Ex-1012. Petitioner argues in that proceeding that certain terms of the '541 patent are indefinite, but DexCom argues “plain and ordinary meaning.” For the purposes of this proceeding only, and without waiving its argument, the Petitioner adopts DexCom’s explanation of those terms from its claim construction brief. Ex-1012 at.12-18.

VII. Overview of the Prior Art³

A. Aspel (Ex-1005)

U.S. Patent Application Publication No. 2008/0154099, titled “Health Monitoring System and Method,” to Aspel (“Aspel”) was filed November 6, 2007, and published June 26, 2008. Ex-1005, Cover. Aspel qualifies as prior art to the '541 patent under at least 35 U.S.C. § 102(b).

The Aspel system is designed for long-term comprehensive care of patients with chronic illnesses. Ex-1005, [0193]. Aspel’s system “collects data from

³ Each prior art reference is analogous art to the '541 patent, because it is either from the same field of endeavor (e.g., Valdes, Gutekunst) or reasonably pertinent to the particular problem purportedly addressed by the '541 (e.g., Aspel, Breen, Paterno, Hanson). *See generally*, Ex-1003, ¶¶87-93.

medical and measurement devices 102 via an access point 104 ... transmits the data to a data center 106, which securely stores that information,” and then “analyses it and provides interfaces for various users 106 [sic] to receive guidance, view and interact with that data.” Ex-1005, [0046].

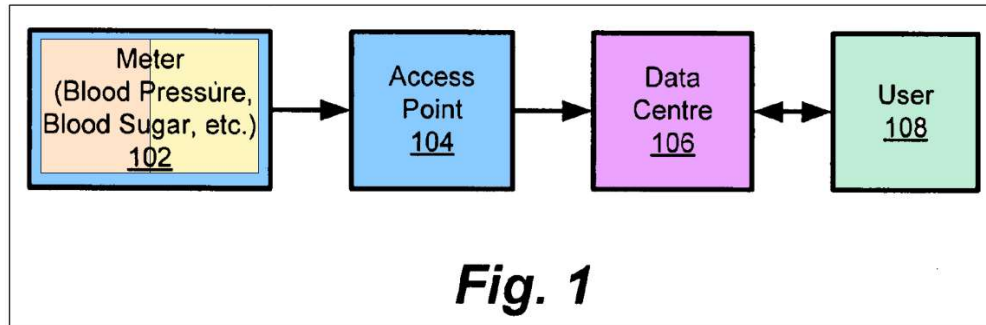
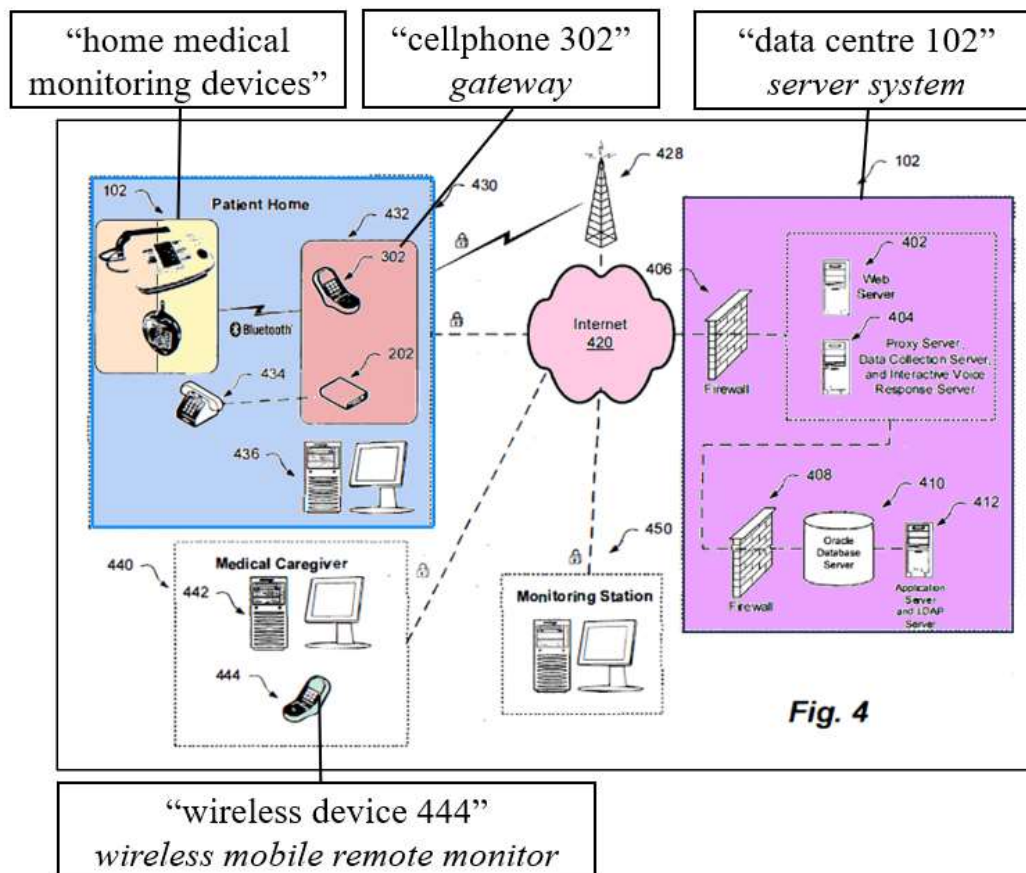


Figure 4 depicts a block diagram of Aspel’s system architecture.



The system is also “designed to alert users and Caregivers...” based on data including glucose readings. Ex-1005, Fig. 17B, [0089].

1702

Fax:
 Hospitalization #:
 Treaty #:

Family Doctor Information
 Name:
 Phone:
 Fax:

Equipment Serial Number
 Blood Glucose Meter Serial Number:
 Blood Pressure Meter Serial Number:
 Note: The serial numbers are case sensitive

Description of Insulins
 Insulin A:
 Insulin B:

Glucose Target Range: (Units are mmol/L)
 Settings for before and after meal ranges will generate the colors in the logbook, graphs, etc.

	Before	After
Hypo:	4.0	4.0
Low:	4.0	5.0
High:	7.0	10.0
Hyper:	9999	9999

Glucose Alerts: (Units are xxxxx/L)
 An alert will be generated if there are readings above within days.
 An alert will be generated if there are consecutive readings above .
 An alert will be generated if there are readings within days.

FIG. 17B

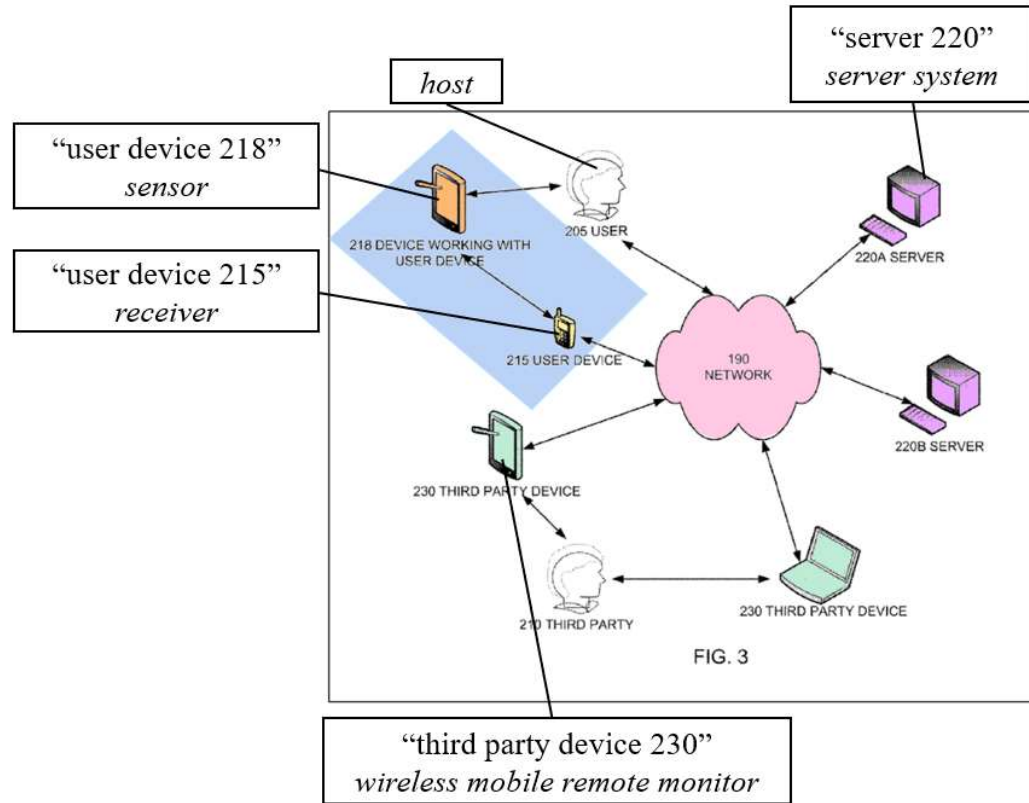
Alerts can be “presented to patients, their Caregivers, designated medical professionals and monitoring centers in the web interface to the system.” Ex-1005, [0091]. While a patient may establish “user defined alerts,” or alerts that initiate when “readings are out of a configurable set of target ranges,” Ex-1005, [0090], a caregiver with the proper access—a “multi-Caregiver”—can also set alert levels that will trigger events based on that patient’s data, Ex-1005, [0128].

B. Gutekunst (Ex-1006)

U.S. Patent Application Publication No. 2011/0173308, titled “System and Method for Medical Surveillance through Personal Communication Device,” to Gutekunst (“Gutekunst”) was filed October 18, 2010, and published July 14, 2011. Ex-1006, Cover. Gutekunst qualifies as prior art to the ’541 patent under at least 35 U.S.C. § 102(b).

Gutekunst discloses a “medical monitoring and surveillance system [that] uses a server communicating with a general-purpose personal device [(e.g., a cellular telephone)] running an application.” Ex-1006, Abstract.

Gutekunst generally discloses configuring alert triggers for use in a medical monitoring system. Ex-1006, [0058],[0059],[0063],[0127]-[0128], Fig. 3 (below). “By accessing the server 220 through the web interface, the user 205 or the third party 210 may select from a predefined set of trigger events and build new trigger events.” Ex-1006, [0127].



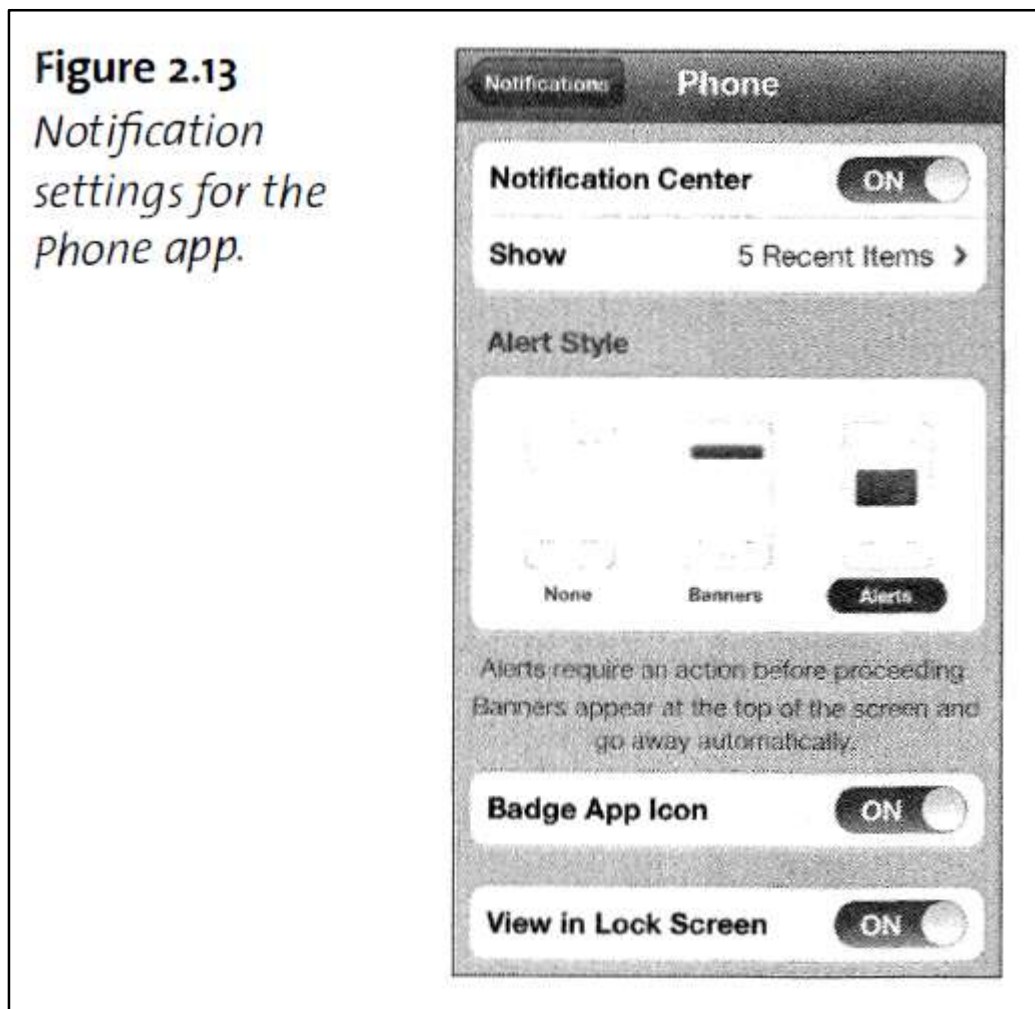
Gutekunst discloses that its device 218 (e.g., implantable glucose monitor) may be configured to communicate with the (user’s) device 215 using a communication standard (such as Bluetooth™). Ex-1006, [0091].

C. Breen (Ex-1007)

The iPhone Pocket Guide, Sixth Edition by Christopher Breen (“Breen”) was published on November 30, 2011, and has a 2012 copyright. Breen was publicly accessible at least by November 30, 2011. Ex-1013, ¶49. Breen qualifies as prior art to the ’541 patent under at least 35 U.S.C. § 102(a), (b).

Breen discloses features of Apple’s iPhone running iOS 5, including its “alert styles.” Ex-1007, 64-65. iOS 5 notifications are available to any “[t]hird-

party applications configured to support notifications[.]” Ex-1007, 63. The iPhone 4S, which was released with iOS 5, is described in the ’541 specification. Ex-1001, 5:3. The Notifications settings, shown below, provide “Alert Style” optionality including “Banners” and “Alerts.” Ex-1007, Fig. 2.13, 65.

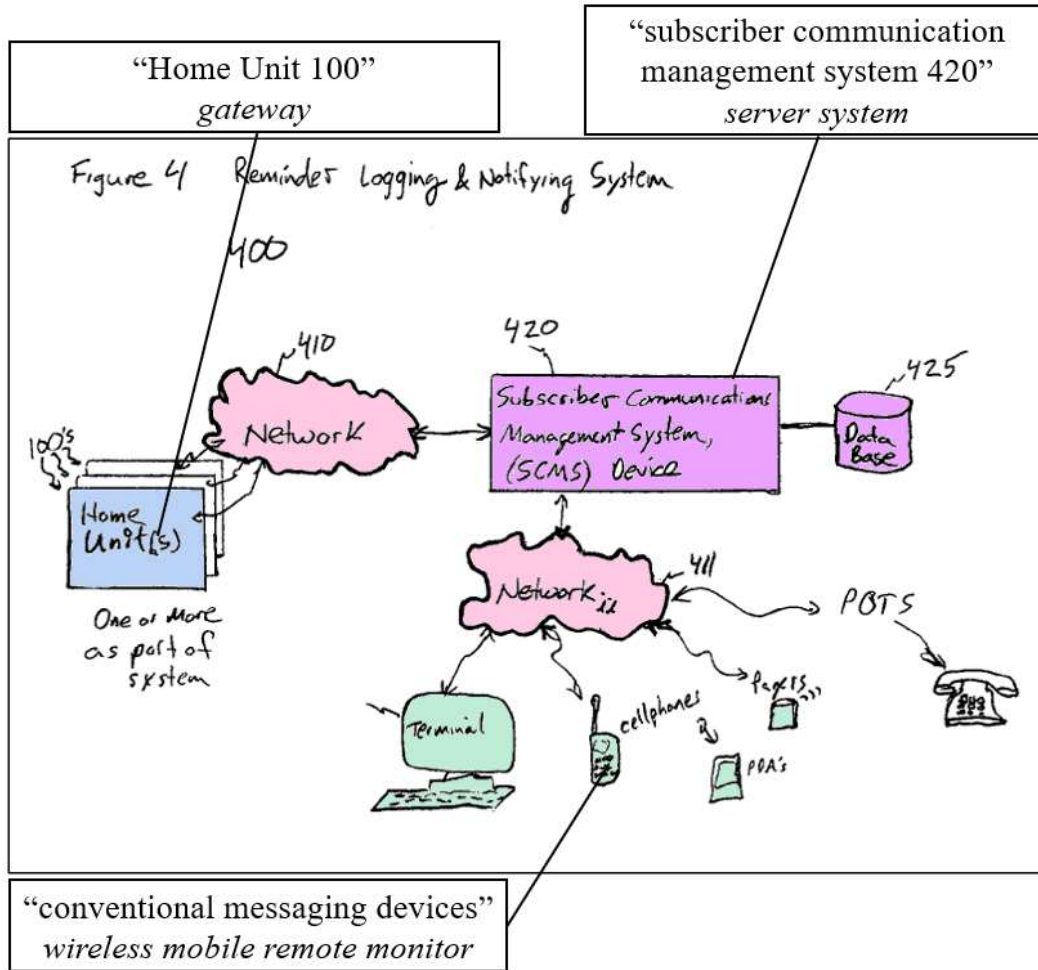


D. Paterno (Ex-1008)

U.S. Patent No. 7,301,463, titled “Assisting and Monitoring Method and System,” to Paterno (“Paterno”) was filed April 13, 2005, and issued November

27, 2007. Ex-1008, Cover. Paterno qualifies as prior art under at least 35 U.S.C. § 102(b).

Paterno broadly discloses an assisting and monitoring method and system including automated notifications (alerts). Ex-1008, 1:66, 2:9-11. The disclosed system includes “two-way communication devices to exchange information between remotely located event logging devices” and a central server, Subscriber Communication Management System (“SCMS”). Ex-1008, 3:30-33, 3:41-42, 16:30-17:26. Paterno further discloses Home Units used by “the individual” being monitored and “conventional messaging devices” (cellphones, PDAs, pagers, computer terminal) used to monitor the individual. Ex-1008, 11:19-20, Fig. 4.



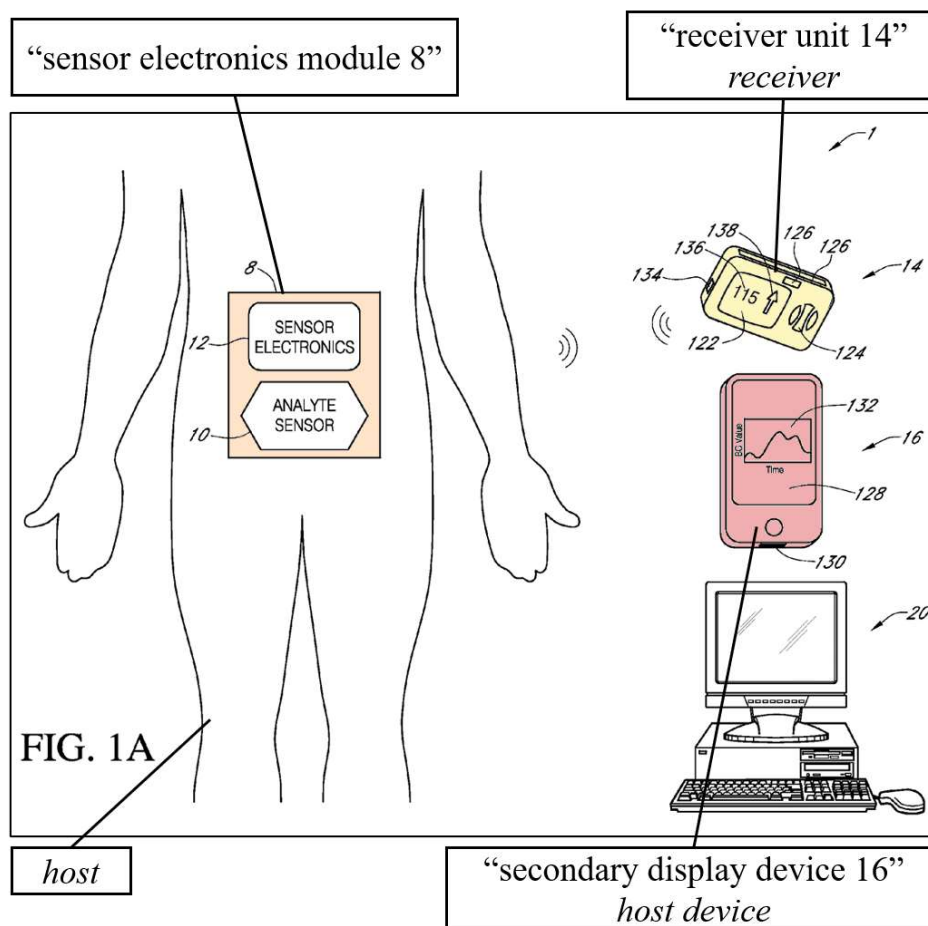
Ex-1008, Fig. 4. The individual can “provide account access to one or more people” (e.g., caregivers) with “customized access permissions” so they can make changes relating to “sending of messages, alerts, ... and for setting what notifications and messages they will receive from the system[.]” Ex-1008, 3:52-63. Remote caregivers can change their monitoring parameters, such as “who, how, and when members of a subscribed account are notified of” different events. Ex-1008, 3:41-42, 16:30-17:26.

Paterno discloses that “in home monitoring of critical health parameters such as blood sugar” was known in the art. Ex-1008, 1:46-48.

E. Valdes (Ex-1009)

U.S. Patent Publication No. 2011/0320130, titled “Systems and Methods for Communicating Sensor Data Between Communication Devices,” to Valdes *et al.* (“Valdes”) was filed June 23, 2011, and published December 29, 2011. Ex-1009, Cover. Valdes qualifies as prior art under at least 35 U.S.C. § 102(b); Ex-1001, 54:27-28.

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. Ex-1009, Abstract, [0002], [0008], [0108]-[0109].



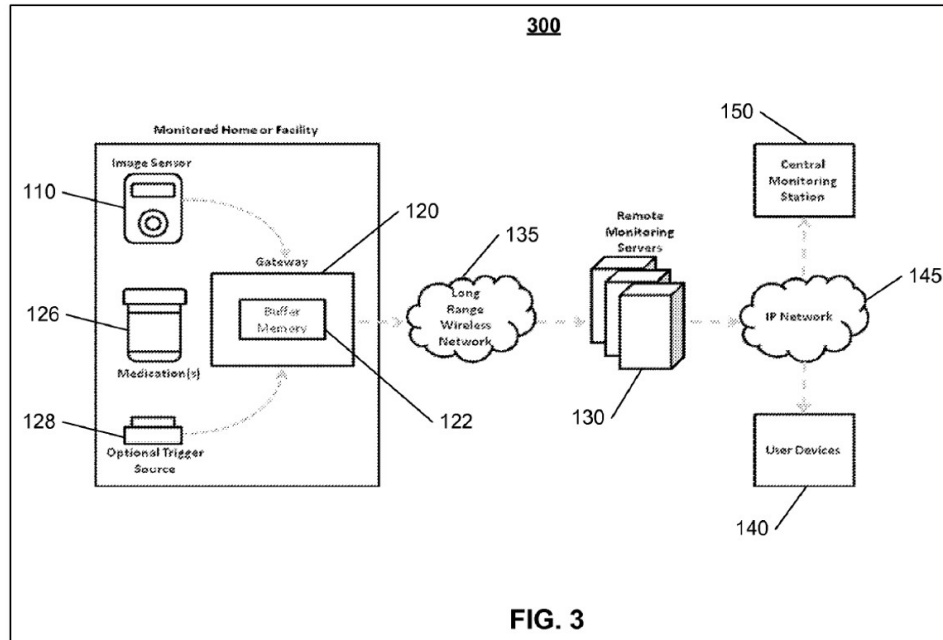
Ex-1009, Fig. 1A.

Valdes explains a “continuous analyte sensor” provides “sensor data” that is “directly related to the measured analyte from an analyte sensor” to a “receiver unit.” Ex-1009, [0062], [0002]. The stand-alone “receiver unit” receives and processes data from the analyte sensor. Ex-1009, [0097]. The “receiver unit” then “wirelessly communicate[s]” with “one or more secondary display devices,” including “a mobile phone” and “a personal computer.” Ex-1009, [0113]. The “secondary display device” can function as a device for use by the host, (Ex-1009, [0098]), or by a third-party caregiver, (Ex-1009, [0157]).

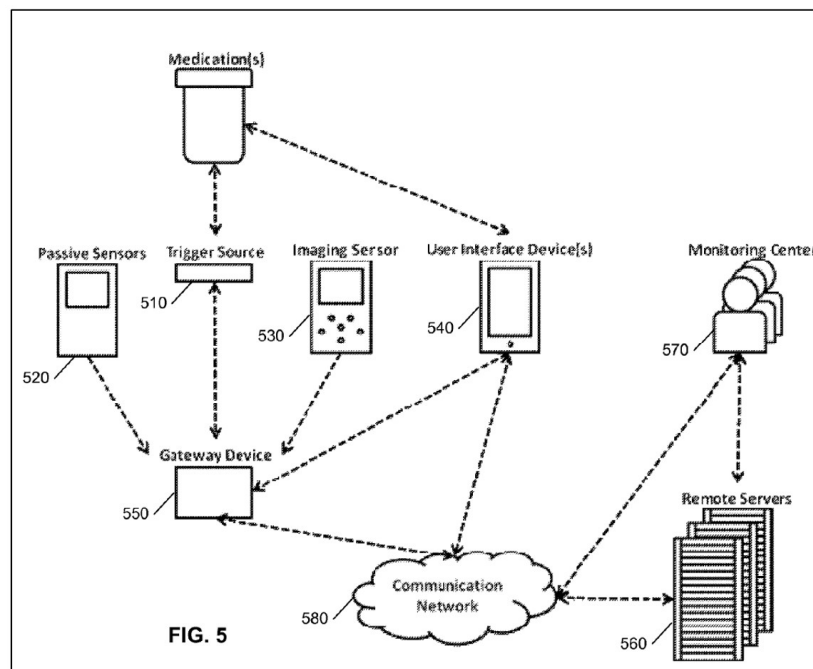
F. Hanson (Ex-1010)

U.S. Patent Publication No. 2012/0313785, titled “Medication Management and Reporting Technology,” to Hanson *et al.* (“Hanson”) was filed April 4, 2012, from an April 4, 2011 provisional application, and published December 13, 2012. Hanson qualifies as prior art to the ’541 patent under at least 35 U.S.C. § 102(a), (e).

Hanson generally discloses a “medication management and reporting technology” with “at least one sensor,” which includes “a blood sugar sensor.” Ex-1010, [0002], [0061], [0081]. The system’s control panel processes sensor data and may then send an “alert to an intermediary monitoring server that processes the alert and, potentially, relays the alert to other devices.” Ex-1010, [0037]. Such devices include “a remote device operated by a caregiver ... that is located outside of the home,” and “a mobile device operated by the person ... or a mobile device operated by a family member of the person.” Ex-1010, [0037].



Ex-1010, Fig. 3.



Ex-1010, Fig. 5. Hanson's system allows alert recipients to "receive information regarding the records of the patient" after "the recipient of the alert ... provide[s] identification information (e.g., a user name and a password) that verifies that the

recipient of the alert is authorized to view the medical records of the patient[.]” Ex-1010, [0115].

VIII. Application of Prior Art to the Challenged Claims

A. Ground I: Claims 1, 4-7, 9, 11, 13, and 15-17 Would Have Been Obvious Based on Aspel in View of Gutekunst

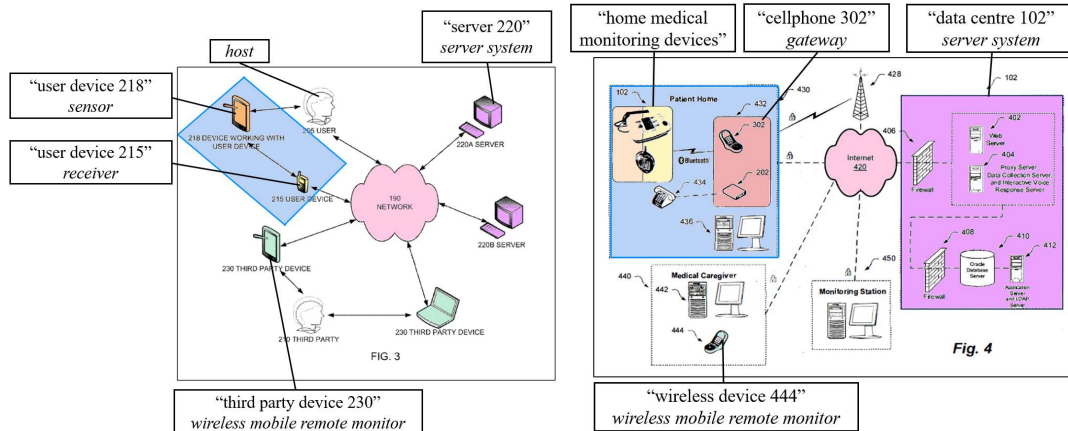
Aspel discloses a “central storage server,” or *server system*, so different users can receive an alert, or *alert notification messages*, on various devices including “wireless device 444 such as a cellphone or smartphone device,” *mobile remote monitors*.⁴ Aspel further discloses “medical and measurement devices 102,” e.g., a “glucometer,” that transfer data via a “mobile device such as cellphone 302” to “data centre 106.”

Gutekunst discloses a general-purpose personal device, “user’s device 215” communicating with “a dedicated device [218] designed to facilitate the gathering of the user’s medical information,” and that “the device 218 may be implanted into a person’s body” and may be “a glucose monitor.” The “user’s device 215 may receive data from the device 218.” Ex-1006, [0091]. Thus, the “user’s device 215” is a *receiver for analyte concentration sensor data* from the glucose monitor (device 218). This configuration is compatible with Aspel’s disclosed system,

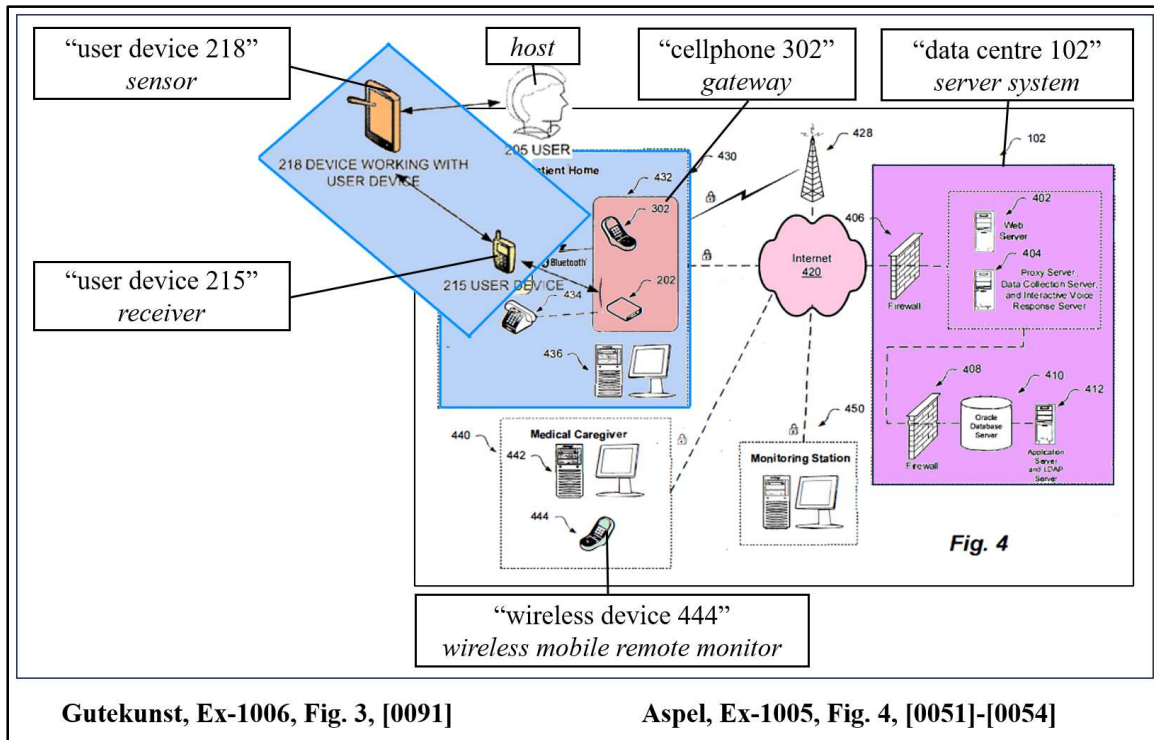
⁴ Throughout this Petition, *italics* is used to indicate language from the Challenged Claims.

substituting Gutekunst's "glucose monitor" "device 218" which "may be implanted" for the "glucometer" disclosed in Aspel.

The two annotated figures below illustrate the disclosure from Gutekunst (left) and Aspel (right), standing alone.



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.



1. A POSITA Would Have Been Motivated to Combine Aspel and Gutekunst with a Reasonable Expectation of Success

a) Teaching, Suggestion, Motivation

Aspel and Gutekunst are from the same field of endeavor: remote monitoring of health parameters. Aspel discloses that “[t]he requirements of healthcare professionals and patients vary greatly ... As a result, **many different user interfaces, functions and health lifestyle and wellness parameters may be required.** The invention can support all of these variations” and “can monitor and

measure a limitless variety of devices and physiological parameters ...”⁵ Ex-1005, [0188].

A POSITA would have recognized Gutekunst discloses devices for monitoring and gathering a “user’s medical information” that would complement the Aspel system. Ex-1006, [0085], [0091], [0093], [0112]-[0013], [0189]; Ex-1003, ¶¶94-100. A POSITA would thus have readily contemplated adapting Gutekunst’s “devices” to provide physiological parameters to Aspel’s monitoring system with reasonable expectation of success.

b) Other Factors and Reasonable Expectation of Success

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). Ex-1003, ¶101. At the time of the alleged invention, mobile applications that interact with server systems were well-known, and both Aspel and Gutekunst disclose the use of cellular phones and the Internet to transmit data to a server. The ’541 specification also references their wide use. Ex-1001, 5:2-4. Thus, a POSITA

⁵ All emphases in quoted text, as indicated by a **bold** font, were added by Petitioner.

would have had a reasonable expectation of success in combining Aspel and Gutekunst in a remote health monitoring system. Ex-1003, ¶101.

2. Independent Claim 1

a) 1[preamble]: “A method comprising:”

Aspel discloses that its invention relates to a “method of collecting and managing physiological and lifestyle information for use by individuals, familial and personal Caregivers, and medical profession[als]...” Ex-1005, [0002]; Ex-1003, ¶¶102-103.

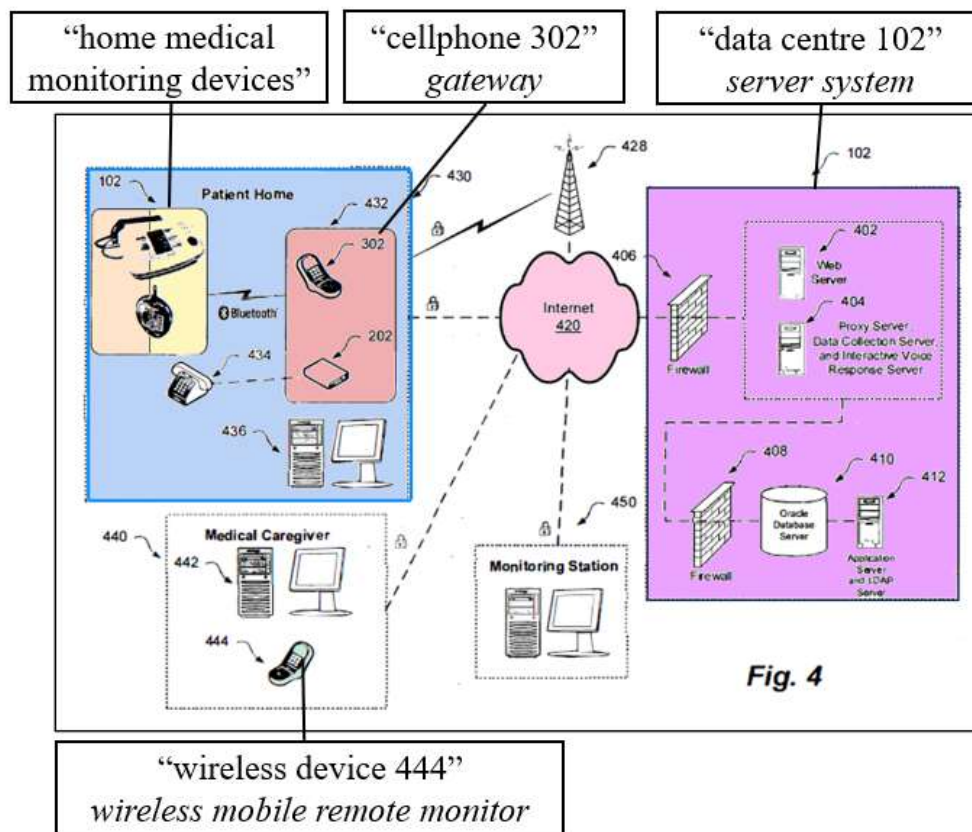
b) 1[a]: “receiving, at a wireless mobile remote monitor, an alert notification message from a server system, the alert notification message representative of a detected event,”

Aspel discloses a “central storage server” (*server system*) so different users can receive an alert (*alert notification messages*) at various devices including “wireless device 444 such as a cellphone or smartphone device” (*wireless mobile remote monitor*). Ex-1003, ¶¶104-108. Alerts are generated and sent by the server when certain conditions are met such as when “readings are out of a configurable set of target ranges,” i.e., the *alert notification message representative of a detected event*. Ex-1005, [0090], [0156] (“Glucose Target Range”).

Aspel explains that “[p]atient physiological data such as ... blood sugar levels... is **collected and transmitted to a secure central storage server.**” Ex-1005, [0021]. “The described system has the necessary communication protocols

to enable the patient to use home medical monitoring devices such as ... a **glucometer.**” Ex-1005, [0044].

As shown in Figure 4 below, Aspel discloses the generation and presentation of alerts through internet sites on wireless devices. Ex-1005, [0054], [0090]-[0091].



Ex-1005, Fig. 4.

Aspel explains that alerts can be delivered by email, text, telephone or fax.

Ex-1005, [0092], [0094], Fig. 10, [0127].

- c) 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,”

Aspel discloses that its system for sending alerts when data is outside a target range, an *event* based on the *analyte state of a host*, is compatible with “all other devices capable of collecting physiological and lifestyle data,” which a POSITA would have understood to include well-known CGMs comprising a *receiver* and *analyte sensor*. Thus, a POSITA would have understood that Aspel would send alerts based on detecting that the *analyte concentration data*, which is *indicating a concentration of an analyte of the host*, is outside a target range (*detected event*). Ex-1003, ¶¶109-112.

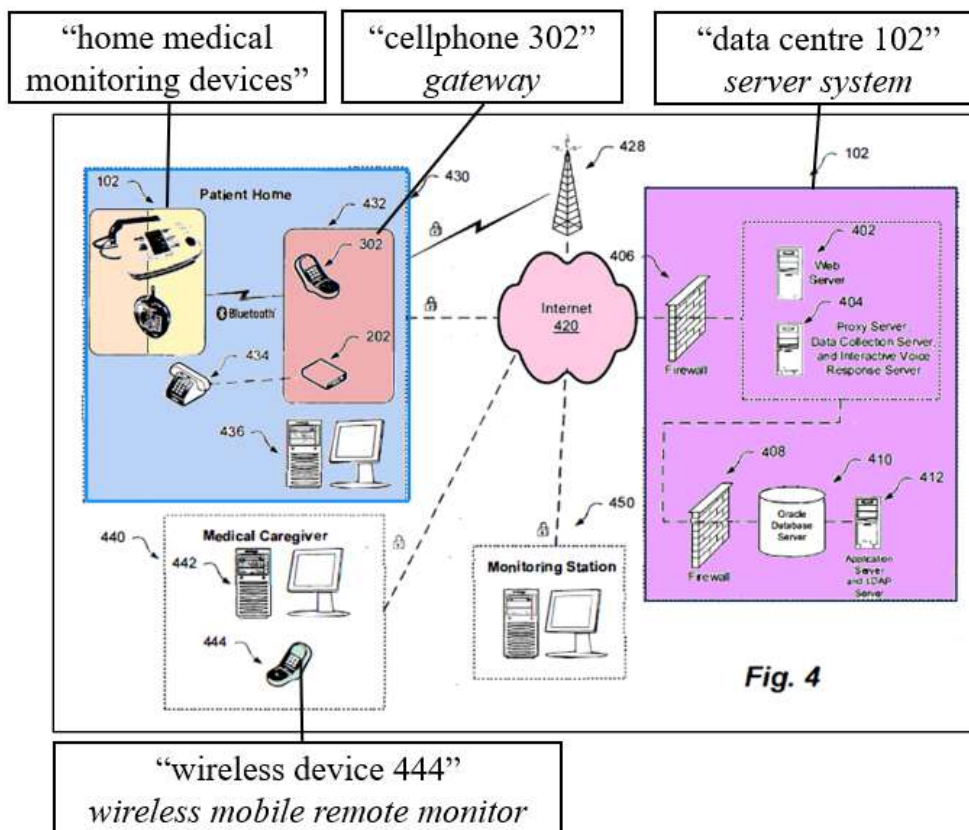
Aspel explains, “[p]atient physiological data such as ... **blood sugar levels**, ... is collected and transmitted to a secure central storage server ...” Ex-1005, [0021]. Aspel’s system contemplates “home medical monitoring devices such as ... **a glucometer**.” Ex-1005, [0044], [0046]. Aspel further discloses sending alerts, *events*, based on blood sugar levels, *an analyte state of a host*, being outside of “target ranges.” Ex-1005, [0090], [0156]-[0157], [0166].

Gutekunst expressly discloses “device 218,” which may be a glucose monitor, an *analyte concentration sensor*, and “device 215,” a *receiver*. Ex-1006, [0091]. A POSITA would have understood that Gutekunst’s “glucose sensor” and

“glucose monitor” provide *analyte concentration sensor data indicating a concentration of an analyte of the host*. Ex-1003, ¶112. In the Aspel-Gutekunst combination, this glucose monitor and its *receiver* (device 215) replaces Aspel’s “glucometer” to monitor the analyte concentration of the host and obtain *analyte concentration sensor data* that is used in determining the *event*. A POSITA would have identified the benefits of substituting Gutekunst’s glucose monitor and receiver to allow for passive, more frequent monitoring and would have been motivated to combine Aspel and Gutekunst. *See* Section VIII.A.1.

d) 1[c]: “the wireless mobile remote monitor being remote to the host and the server system;”

Aspel discloses a medical caregiver’s “wireless device 444 such as a cellphone or smartphone device,” or *wireless mobile remote monitor*, that is remote to the patient, or *host*, and the “central storage server,” or *server system*. Ex-1003, ¶¶113-115.



Ex-1005, Fig. 4.

“Broadly, the system provides a **remote patient monitoring service that enables continuous feedback between patients and their Caregivers.**” Ex-1005, [0193], [0054], [0092], [0094].

e) 1[d]: “presenting, at the wireless mobile remote monitor, the alert notification message,”

As noted above, Aspel discloses presentation of alerts at the wireless remote monitor. Ex-1005, [0091]-[0092].

Aspel further discloses accessing an “All Alerts” report for caregivers, which displays an *alert notification message*, presented at a “wireless device 444

such as a cellphone or smartphone device” (*wireless remote monitor*). Ex-1005, [0054], [0135]; Ex-1003, ¶¶116-119.

1900

All Alerts
Patients
Add Patient
Help
Change Password
Logout

Alerts

Overall Summary

- Blood Glucose
- Blood Pressure

Related Links

Contact us

About SSL Certificate

Alerts (All Patients)

Print

Patients	Date	Time	Description	
3	6 Nov 2006	10:10:41AM	DN: More than 3 days since update (last reading on 01-NOV-2006 07:09:41 AM), (06-NOV-2006 12:00:00AM)	☐
	1 Nov 2006	07:00:18AM	HS: High Systolic: 131mmHg (2006-10-16 12:48:42), (16-OCT-2006 12:48:42 PM)	☐
	1 Nov 2006	07:00:18AM	HD: High Diastolic: 85 mmHg (2006-10-16 12:48:42), (16-OCT-2006 12:48:42 PM)	☐
	24 Oct 2006	09:46:47AM	DN: More than 3 days since update (last reading on 21-OCT-2006 05:59:49AM), (24-OCT-2006 12:00:00AM)	☐
	22 Oct 2006	09:31:23PM	HS: High Systolic: 146mmHg (2006-10-22 23:31:08), (22-OCT-2006 11:31:08PM)	☐
	22 Oct 2006	09:31:23PM	HD: High Diastolic: 95 mmHg (2006-10-22 23:31:08), (22-OCT-2006 11:31:08PM)	☐
	22 Oct 2006	09:22:18PM	HS: High Systolic: 146 mmHg (2006-10-22 23:22:04), (22-OCT-2006 11:22:04PM)	☐
	22 Oct 2006	09:22:18PM	HD: High Diastolic: 88mmHg (2006-10-22 23:22:04), (22-OCT-2006 11:22:04PM)	☐
	22 Oct 2006	09:22:18PM	HD: High Diastolic: 88 mmHg (2006-10-20 09:27:55), (20-OCT-2006 09:27:55 AM)	☐
41	21 Oct 2006	09:51:29AM	FD: Future data: 2006-10-21 11:51:00 4.4 mmol/l (21-OCT-2006 11:51:00 AM)	☐
	21 Oct 2006	07:44:34AM	FD: Future data: 2006-10-21 09:44:32 703 mmol/l (21-OCT-2006 09:44:32AM)	☐

Acknowledge
Select All
Unselect All

1902

FIG. 19

- f) 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, wherein the wireless mobile remote monitor or the user of the wireless mobile remote monitor is authenticated by the server system;”

Aspel discloses “reports and alerts that may be presented through various interfaces to **authorized system users, including patients, medical doctors and other Caregivers.**” Ex-1005, Abstract. In Aspel’s system, “patient data ... is only resolved when **securely accessed** by an **authorized user.**” Ex-1005, [0024]. Aspel explains that the “Web interface allows **authorized users** to add and delete users, view data and delegate access to data based on user roles.” Ex-1005, [0063].

To the extent the language *to augment the receiver monitoring of the analyte state of the host* is a claim limitation, Aspel discloses it.⁶ Aspel’s system “clos[es] the feedback loop between the client (patient) and Caregiver (professional or loved one)” in part by alerting Caregivers. Ex-1005, [0017], [0089]-[0094]. “Closing the feedback loop between the client and the Caregiver improves the efficiency and effectiveness of providing healthcare services [and] ... also provides professional

⁶ Petitioner understands DexCom contends this limitation is met inherently by “merely” using a “remote monitor[] in addition to any monitoring the host is conducting.” Ex-1012, p.15.

Caregivers with the information they require to properly manage their clients' illnesses without actually having to see the patient in person." Ex-1005, [0014]. Thus, Aspel discloses or renders obvious providing *alert notification messages* to *augment the receiver monitoring of the analyte state of the host*.

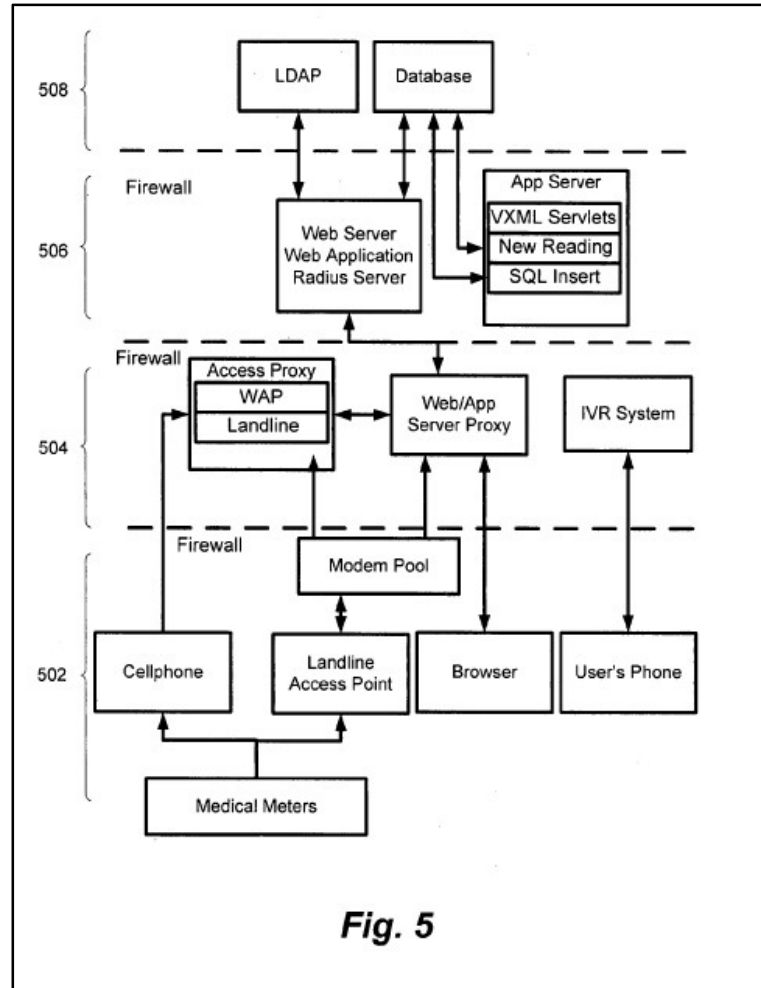
Additionally, as explained above in VIII.A.2.e, a "designated medical professional" uses a "wireless device," *mobile remote monitor*, to receive an alert, *alert notification message*. "The Web interface allows **authorized users** to add and delete users, view data and delegate access to data based on user roles." Ex-1005, [0063]. "The web application is designed for the patient to view their data along with a number of other persons simultaneously. **The persons who are able to view the data in addition to the patient are configurable within the web application.**" Ex-1005, [0065]. "Alerts can be presented to patients, their Caregivers, **designated medical professionals** and monitoring centers in the web interface to the system. **Once logged in, the user may see all alerts pertaining to them and persons within their care.**" Ex-1005, [0091]. A POSITA would have understood that a "designated medical professional" is *specifically authorized by the host to receive the alert notification message to augment the receiver monitoring of the analyte state of the host*. Ex-1003, ¶¶120-123.

- g) 1[f]: “receiving, at the wireless mobile remote monitor, user input indicative of acknowledgment of the presented alert notification message;”

Aspel expressly discloses that “[a]lerts can be delivered by all previously mentioned voice and data delivery systems. This allows the user to be informed of the alerts, **to acknowledge alerts**, and to enter additional information in response to the alerts.” Ex-1005, [0092]; Ex-1003, ¶¶124-125. For example, Aspel explains that “FIG. 19 presents an ‘all alerts’ report 1900 for a Caregiver with multiple patients...” Ex-1005, [0162]. The report “includes a tick box” that allows the user to selectively acknowledge the alerts directly through the interface. Ex-1005, [0163]. The user acknowledges an alert with the interface by clicking the “tick box” corresponding to particular alert records. Ex-1005, [0163].

- h) 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;”

Aspel discloses, with reference to Figure 19, that “[e]ach event also **includes a tick box, allowing the user to select particular records so they can be ‘acknowledged’ (1902) and have them removed from the report.**” Ex-1005, [0163]. Figure 5 depicts the structure and operation of the Aspel system, from which a POSITA would have recognized that Aspel’s acknowledgment is sent from its wireless device (layer 502) to the server (layer 506). Ex-1003, ¶¶126-130.



Ex-1005, Fig. 5, [0056], [0059]-[0060].

A POSITA would have recognized that, for the acknowledgment to result in removing the alert from the report, it would necessitate the recited *sending an acknowledgement message from the wireless mobile remote monitor to the server system indicating acknowledgement of the presented alert notification message to confirm that the alert notification message has been received*. Aspel's acknowledgment would necessarily be sent from "wireless device 444" to the server. Alternatively, it would have been obvious to implement Aspel's system

such that selecting the “tick box” sends an acknowledgement message to the server, which confirms receipt of the message and removes the alert from the alert list. Ex-1003, ¶130.

- i) *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”*

Aspel discloses a system and method that allows caregivers and medical professionals to access blood glucose data (*analyte concentration sensor data*) from the *server system*. The temporal limitation for “after” is being subsequent to sending the acknowledgement, i.e., following clicking the “tick box” in the alert rules list and the removal of the alert from the report (Ex-1005, [0163]; VIII.A.2.h). In Aspel’s system, a medical caregiver would use “wireless device 444,” or *wireless mobile remote monitor*, to access patient data, including *analyte concentration sensor data*, from the data center, or *server system*.

Aspel discloses that a “**medical Caregiver 440 may access the patient data through the data centre 102 by a personal computer 442 or a wireless device 444 such as a cellphone or smartphone device.**” Ex-1005, [0054], [0168].

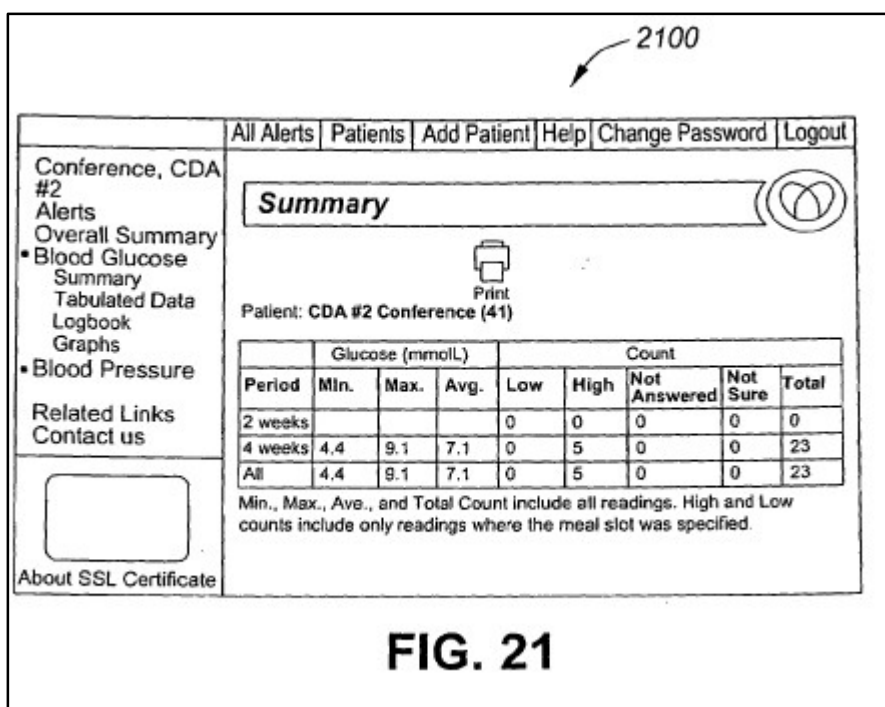


FIG. 21

In Aspel's system a caregiver would access patient data in the form of "reports" provided by the system. Ex-1005, [0165]-[0169]; Ex-1003, ¶¶131-134.

- j) 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;"

Aspel discloses that "[p]atient physiological data such as ... blood sugar levels ... is collected and transmitted to a **secure central storage server which can be accessed by healthcare professionals for analysis and intervention.**" Ex-1005, [0021].

As explained in VIII.A.2.i, different reports are available at the server for viewing. Ex-1005, [0167]. For example, Figure 21 depicts "a screen capture of an exemplary summary report 2100. Clicking on the 'Summary' tab of the 'Blood

Glucose' menu causes the system to collect data for the current patient and generate the report as shown, which includes: title, patient name and a table with minimum, maximum, average glucose levels and counts **for various time periods [i.e., historical data]**." Ex-1005, [0168]. The "Tabulated Data" selection of the "Blood Glucose" menu prompts the user for the parameters to generate a tabulated data report. Ex-1005, [0169], Figs. 14-36. The generated reports are then available for "downloading," (Ex-1005, [0130]), and printing, (Ex-1005, [0170]). Thus, the browser application running on the *wireless mobile remote monitor* downloads, i.e., receives, data in response to *accessing the at least some of the analyte concentration data* and by a request from the *wireless mobile remote monitor*. Ex-1003, ¶¶135-137.

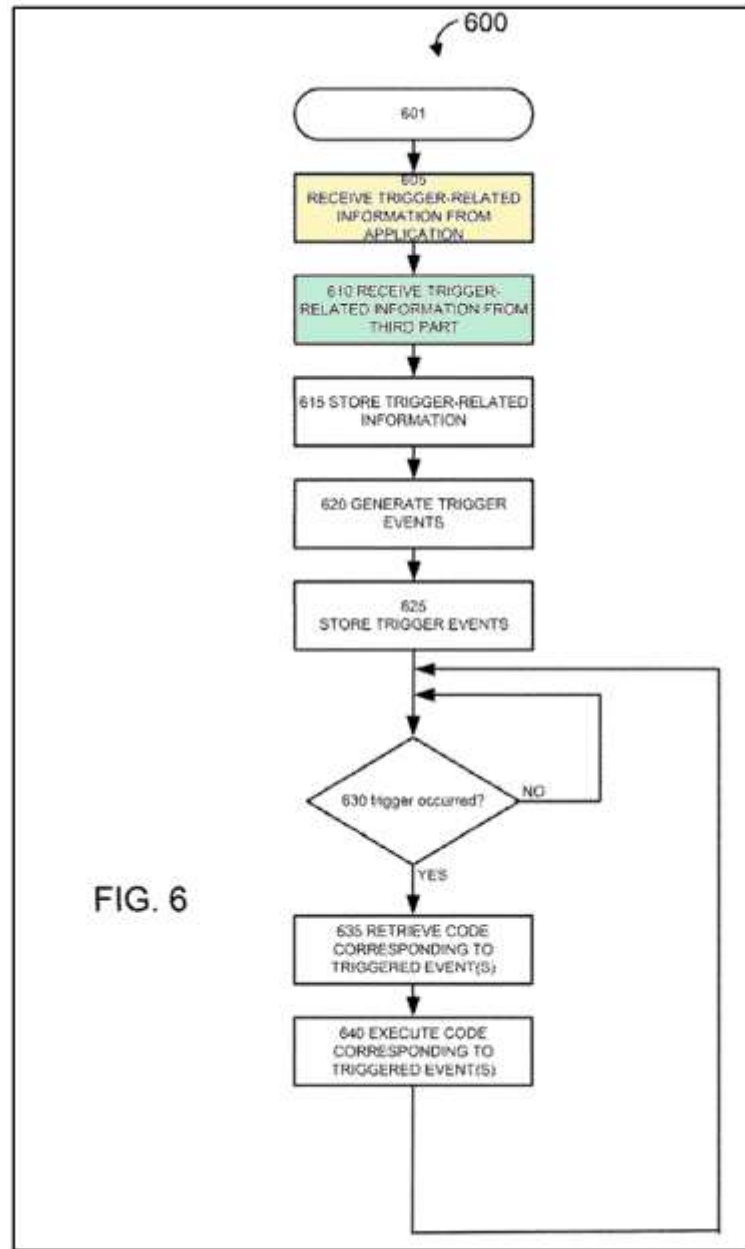
- k) 1[j]: "wherein the event is detected by the server system based on one or more sets of recommended alert rules settings configured by the host using the receiver, at least one of the sets of recommended alert rules settings being modifiable by the user of the wireless mobile remote monitor using the wireless mobile remote monitor."

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*. Ex-1005, [0089]-[0090].

Gutekunst discloses the alert rules settings being modifiable by the remote monitor, explaining that the "user device 215," the *receiver*, includes an application to create or modify trigger events, *alert rule settings*.

Gutekunst's Figure 6 discloses “embodiments [in which] **the server 220 enables a party (e.g., the user 220, 205, the third party 210, or yet another party) to schedule one or more trigger events...** A task may include searching, filtering, or some other evaluation or utilization of data that, if meeting certain parameters, triggers a subsequent (different) task. By accessing the server 220 through the web interface, **the user 205 or the third party 210 may select from a predefined set of trigger events and build new trigger events,**” including by “creat[ing] or modify[ing] a unique trigger event, trigger task, and/or action task.” Ex-1006, [0127], [0142].

Gutekunst additionally 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,” or *alert rules settings being modifiable by the user of the wireless mobile remote monitor*, (depicted in Fig. 6 block 610) for evaluation by a decision block 630. This allows a third-party user of a *wireless remote monitor*, e.g., a caregiver or medical professional, to modify *recommended alert rule settings*. Ex-1006, Fig. 65, [0156], [0128]-[0129] (multi-Caregiver (doctor or nurse) setting alert levels using “generated HTML web pages”), [0058]-[0059] (explaining how traffic is routed to server applications), [0063]-[0066].



In 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. Ex-1003, ¶¶138-143. A POSITA would have been motivated to combine Aspel and Gutekunst. *See* Section VIII.A.1.

3. Claim 4

- a) “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.”

As explained in Section VIII.2.b, Aspel discloses a *wireless mobile remote monitor* that is “a **wireless device 444 such as a cellphone or smartphone device.**” Ex-1005, [0054]; Ex-1003, ¶¶144-145.

4. Claim 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.”

Aspel expressly discloses that “[t]he embodiments of the invention may be executed by a **computer processor or similar device** programmed in the manner of method steps, or may be executed by an electronic system which is provided with means for executing these steps.” Ex-1005, [0192]. “**Patient physiological data such as ... blood sugar levels ... is collected and transmitted to a secure central storage server** which can be accessed by healthcare professionals for analysis and intervention.” Ex-1005, Fig. 1, [0021], [0046], [0068], [0162]. A

POSITA would have understood that Aspel's system includes *rules for mapping* a user's "account ID" and associated data, including "alerts," to the *wireless mobile remote monitor* of the "Caregiver." Ex-1003, ¶¶146-149. In addition, a POSITA would have understood that the various Aspel described servers include traditional computer components like processors and memory.

Gutekunst explains, in the context of Figure 6, that "the server 220 receives trigger-related information from the third party 205 (or its device 230, or yet another device)." Ex-1006, [0159]. The received information is processed by a "trigger generator" to "generate trigger events" that are used by the server to create an "action task" that may include code for "notifications" for the devices selected to receive the associated event alarms. Ex-1006, [0133]-[0139], [0161]-[0165]. Thus, *the alert notification message to the wireless mobile remote monitor is 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.* Aspel's and Gutekunst's disclosure of these and other claim limitations is discussed above in VIII.A.2.b-d . A POSITA would have been motivated to combine Aspel and Gutekunst. *See* Section VIII.A.1.

5. Claim 6

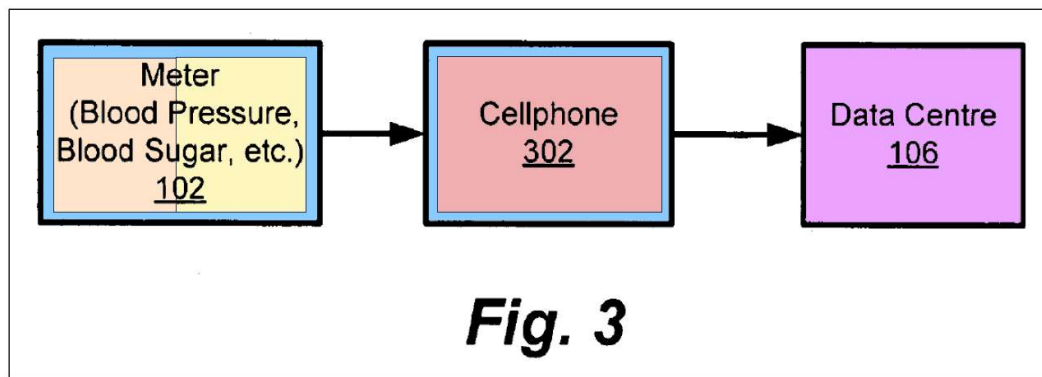
- a) “The method of claim 1, further comprising detecting, based on a first set of rules at the server system, the event, wherein the first set of rules used to generate the alert notification message are different from a second set of rules used to generate alerts to be sent to the receiver coupled to a sensor system at the host.”

Aspel discloses a first set of rules used to generate the alert notification message, as explained above in VIII.A.2.c. These rules can be modified to create a *second set of rules used to generate alerts* as explained in VIII.A.2.k. In addition, Gutekunst discloses that “a party (the user 205, the third party 210, or another entity) may access the server 220 to create or modify a unique trigger event, trigger task, and/or action task.” Ex-1006, [0142]. Gutekunst explains that the server receives “trigger-related information from the application” for “user 205”—*a second set of rules to generate alerts to be sent to the receiver* (user device 215) *coupled to the sensor system* (device 218) *at the host* (user 205)—and in a second step receives “trigger-related information from the third party [210] (or its device 230, or yet another device)” —*the first set of rules used to generate the alert notification message* (for third party 210 and device 230, a *wireless mobile remote monitor*). Ex-1006, [0158]-[0159]; Ex-1003, ¶¶150-151. A POSITA would have been motivated to combine Aspel and Gutekunst. *See* Section VIII.A.1.

6. **Claim 7**

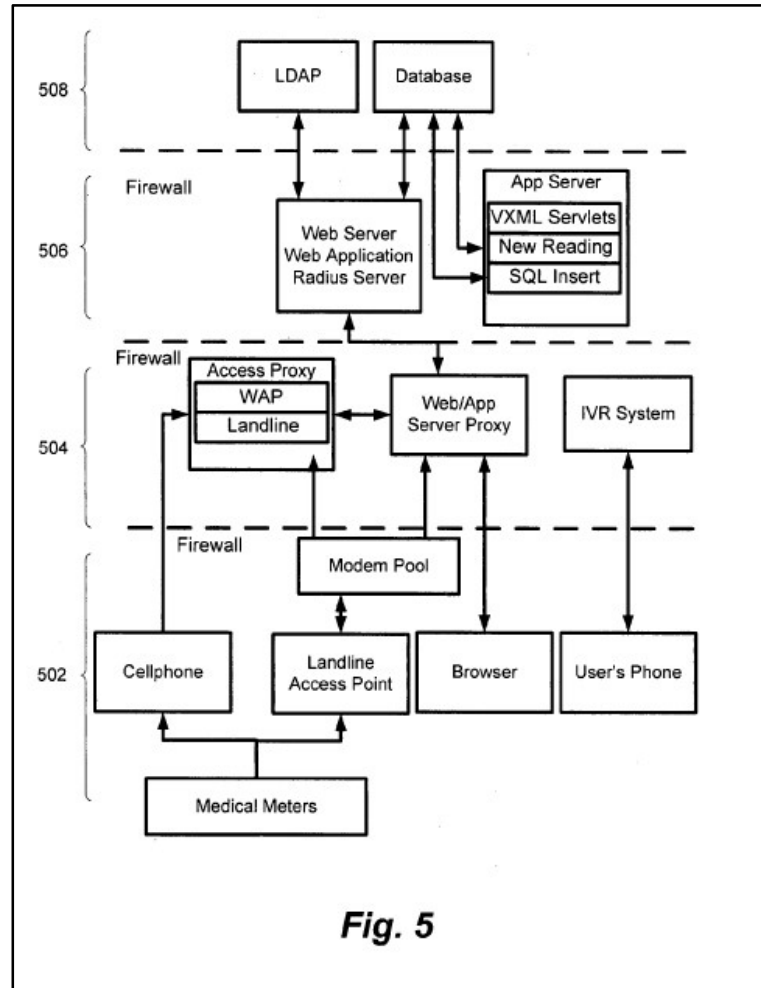
- a) “The method of claim 1, wherein the receiver includes, or couples to, a gateway interfacing a wireless connection to a public land mobile network and the server system.”

Aspel discloses using a cellphone and its wireless cellular network, *a wireless connection to a public land mobile network*, to upload data from the receiver to the *server system*, using a “cellular telephone” and the “WAP gateway,” each of which discloses or renders obvious a *gateway*. Ex-1005, [0119]; Ex-1003, ¶¶152-154. “FIG. 3 presents a process flow diagram of the data transfer from a remote device through to the data centre, via a wireless cellular network, in an embodiment of the invention.” Ex-1005, [0030].



Aspel further discloses “[a]s an alternative to the landline access point, medical device readings may be received and forwarded to the central database via a **Bluetooth-enabled cellular telephone** as presented in the block diagram of FIG. 4.” Ex-1005, [0112]. “The cellular telephone ... **transmits the medical reading to**

the data collection servlet (SQL insert) using the WAP gateway ... at step 816.” Ex-1005, [0119].



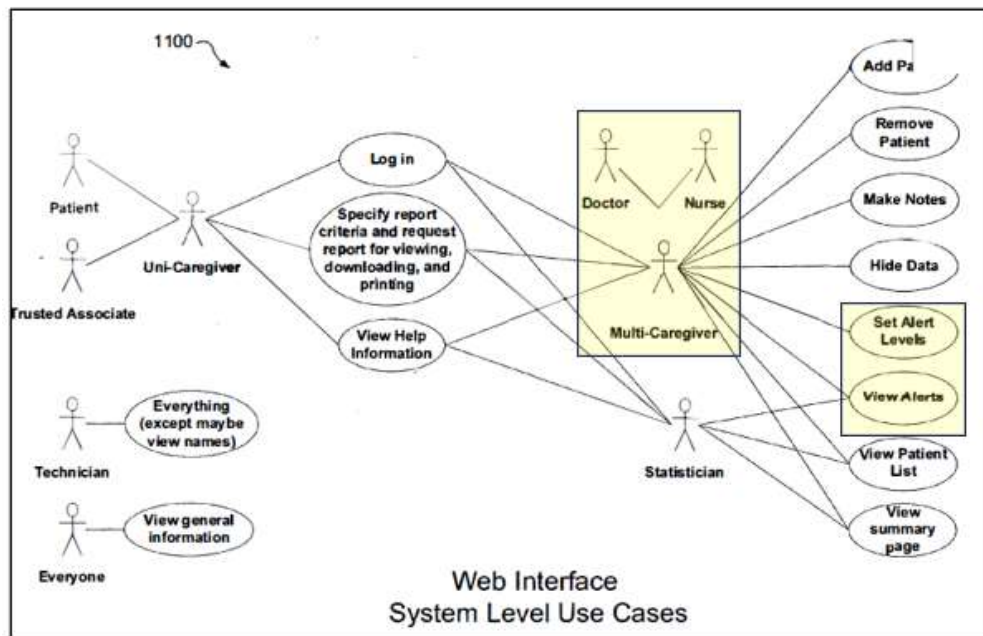
7. Claim 9

- 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.”

Aspel discloses a “web interface” that in combination with Gutekunst, allows a user to set alert levels, or *configuring at least one rule including a trigger*, the alerts are sent by the *server system to the receiver*, as explained above in

VIII.A.2.c,k. The “web interface” can be accessed and used from a “cellphone,” or *wireless mobile remote monitor*, as depicted in Figure 5.

Aspel Figure 11 “presents a web interface structure 1100 showing system level use cases generated by the data centre in connection with FIGS. 14 to 36... The multi-Caregiver has access to functionality such as ... **setting alert levels**, viewing alert levels, view patient list, or view summary page.” Ex-1005, [0128].



Ex-1005, Fig. 11.

Gutekunst discloses a “user device 215,” *receiver*, with a software application that can receive an alert based on a *rule* configured via trigger events configured by a third party, *the wireless remote monitor*, as explained above in VIII.A.2.k; Ex-1003, ¶¶155-160. Gutekunst discloses that “[a] triggering task may be paired with an action task. **The server 220 and/or the device 215 can then**

initiate an action task ..., for example, code for performing **notifications** and other actions, including these:” Ex-1006, [0133]. Notification of a party (e.g., the user 205 and/or the third party 210) in response to change(s) in an application’s configuration,” (Ex-1006, [0134]), including “[n]otification of a party if one or more predetermined results from an application” are above or below a predetermined threshold, within a predetermined range, or otherwise at one or more predetermined criteria. Ex-1006, [0135].

Gutekunst thus discloses “server 220” which has a “triggering task,” *at least one rule* (predetermined results ... are above a predetermined threshold) *including a trigger that when triggered* may be paired with an “action task” including “performing notifications.” This in turn *causes an alert to be sent by the server system to*, “a party (e.g., the user 205 ...),” who has “215 user device,” *the receiver*. See Ex-1006, [0133]-[0135].

A POSITA would have been motivated to combine Aspel and Gutekunst. See Section VIII.A.1.

8. Claim 11

- a) “The method of claim 1, further comprising sending, to the server system, a message acknowledging a receipt of the alert notification message.”

Aspel discloses this limitation as explained above in VIII.A.2.h. Ex-1003, ¶161.

9. Claim 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.”

Aspel depicts an “‘all alert’ report” in Figure 19. Ex-1005, Fig. 19, [0162].

This report includes a “description” for each alert entry in the report. Ex-1005, [0163]. The exemplary alert entries in Figure 19 demonstrate that the “description” field includes at least some of the data used to generate the alert, e.g., “HS: High Systolic: 131 mmHg.” Thus, *presenting* this report includes *the monitoring application initiating the accessing the at least some of the analyte concentration sensor data from the server system*.

Gutekunst further describes a mobile-device-enabled “medical application.” A POSITA would have readily contemplated the *opening* of Gutekunst’s specific application instead of Aspel’s general-purpose web browser. Ex-1003, ¶¶162-164. Gutekunst’s medical application is a monitoring application, in that “[t]he expression ‘**medical application**’ refers to a **software application** (such as an iPhone® application and analogous applications ...) for performing or facilitating [a] ... **medical or health-oriented monitoring protocol**, ... For example, a software application for **monitoring** a person’s ... **serum glucose level** would be both an ‘application’ and a ‘medical application’ as defined herein.” Ex-1006,

[0079]. Thus, Gutekunst discloses that a “medical application,” or *monitoring application*, is “an iPhone® application and analogous applications,” i.e., *on the wireless mobile remote monitor*, an “application for monitoring a person’s ... serum glucose level.”

A POSITA would have been motivated to combine Aspel and Gutekunst.
See Section VIII.A.1.

10. Independent Claim 15

a) 15[preamble]: “A method comprising:”

See Section VIII.A.2.a.

b) 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,”

See Sections VIII.A.7 and VIII.A.2.b-c,k.

c) 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,”

See Section VIII.A.2.f.

d) 15[c]: “wherein the wireless mobile remote monitor or the user of the wireless mobile remote monitor is authenticated by the server system;”

See Section VIII.A.2.f.

- e) 15[d]: “receiving, at the wireless mobile remote monitor, an alert notification message from the server system,”

See Section VIII.A.2.b.

- f) 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,”

See Section VIII.A.2.c. Gutekunst further discloses “[i]n variants, the server 220 transmits the data to the third party 210 in response to **some datum being equal to a trigger, exceeding a trigger, or being less than a trigger ...**,” where the data can be glucose data. Ex-1006, [0126]; Ex-1003, ¶170. A POSITA would have been motivated to combine Aspel and Gutekunst. See Section VIII.A.1.

- g) 15[f]: “the analyte concentration sensor data being received by the server system from a receiver monitoring an analyte concentration state of the host,”

See Section VIII.A.2.c.

- h) 15[g]: “the wireless mobile remote monitor being remote to the host and the server system;”

See Section VIII.A.2.d.

- i) 15[h]: “presenting, at the wireless mobile remote monitor, the alert notification message;”

See Section VIII.A.2.e.

- j) 15[i]: “receiving, at the wireless mobile remote monitor, user input indicative of acknowledgment of the presented alert notification message;”

See Section VIII.A.2.g.

- k) 15[j]: “sending an acknowledgment message from the wireless mobile remote monitor to the server system indicating acknowledgment of the presented alert notification message to enable the server system to confirm that the alert notification message has been received;”

See Section VIII.A.2.h.

- l) 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”

See Section VIII.A.9 and VIII.A.2h.

- m) 15[l]: “receiving from the server system, at the wireless mobile remote monitor, information including at least some of the analyte concentration sensor data;”

See Section VIII.A.2.j.

- n) 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.”

See Section VIII.A.2.k.

11. Independent Claim 16

- a) 16[preamble]: “A wireless mobile remote system comprising:”

See Section VIII.A.2.a,b.

- b) 16[a]: “at least one processor; and memory, the memory including instructions to configure the processor to:”

Aspel discloses “a wireless device 444 such as a cellphone or smartphone device,” or *wireless mobile remote system*, and explains that embodiments can be executed by a “computer processor or similar device,” *processor*, and an “electronic memory medium,” *memory*, “programmed to execute such method steps,” i.e., *including instructions to configure the processor*. Ex-1005, [0054], [0191]-[0192]; Ex-1003, ¶¶180-181.

- c) 16[b]: “receive an alert notification message from the server system,”

See Section VIII.A.2.b.

- d) 16[c]: “the alert notification message representative of a detected event,”

See Section VIII.A.2.b.

- e) 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;”

See Section VIII.A.2.c.

- f) 16[e]: “present the alert notification message,”

See Section VIII.A.2.e.

- g) 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”

See Section VIII.A.2.f.

- h) 16[g]: “to augment the receiver monitoring of the analyte state of the host,”

See Section VIII.A.2.f.

- i) 16[h]: “wherein the wireless mobile remote system or the user of the wireless mobile remote system is authenticated by the server system;”

See Section VIII.A.2.f.

- j) 16[i]: “receive user input indicative of acknowledgement of the presented alert notification message;”

See Section VIII.A.2.g.

- k) 16[j]: “send an acknowledgment message to the server system indicating acknowledgment of the presented alert notification message to enable the server system to confirm that the alert notification message has been received;”

See Section VIII.A.2.h.

- l) 16[k]: “after sending the acknowledgment, access at least some of the analyte concentration sensor data from the server system; and”

See Section VIII.A.2.i.

- m) 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;”

See Section VIII.A.2.j.

- n) 16[m]: “wherein the event is detected by the server 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 modification by the user of the wireless mobile remote system using the wireless mobile remote system.”

See Section VIII.A.2.k.

12. Independent Claim 17

- a) 17[preamble]: “A non-transitory computer readable medium comprising executable instructions, the executable instructions being executable by a processor to perform a method, the method comprising:”

See Section VIII.A.11.b.

- b) 17[a]: “receiving an alert notification message from a server system,”

See Section VIII.A.2.b.

- c) 17[b]: “the alert notification message representative of a detected event,”

See Section VIII.A.2.b.

- d) 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;”

See Section VIII.A.2.c.

- e) 17[d]: “presenting the alert notification message,”

See Section VIII.A.2.e.

- f) 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”

See Section VIII.A.2.f.

- g) 17[f]: “to augment the receiver monitoring of the analyte state of the host,”

See Section VIII.A.2.f.

- h) 17[g]: “wherein the digital device or the user of the digital device is authenticated by the server system;”

See Section [VIII.A.2.f.

- i) 17[h]: “receiving user input indicative of acknowledgment of the presented alert notification message;”

See Section VIII.A.2.g.

- j) 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;”

See Section VIII.A.2.h.

- k) 17[j]: “after sending the acknowledgment, accessing at least some of the analyte concentration sensor data from the server system;”

See Section VIII.A.2.i.

- l) 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;”

See Section VIII.A.2.j.

- m) 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.”

See Section VIII.A.2.k.

B. Ground II: Claims 2 and 3 Would Have Been Obvious Based on Aspel in view of Gutekunst and Breen

Aspel and Gutekunst do not expressly describe all implementation details for a medical monitoring system, for example as claimed in claims 2 and 3, that the wireless mobile remote monitor would use for presenting an alert notification message. Breen provides these details. Breen describes a “Notification” settings panel running on iOS 5 on an iPhone device—including the iPhone 4 referenced in the ’541 patent—that allows a user to configure notifications, including “Banners” or “Alerts” alert styles, for “[t]hird-party applications configured to support notifications.”

1. A POSITA Would Have Been Motivated to Combine Aspel, Gutekunst, and Breen with a Reasonable Expectation of Success

A POSITA would have been motivated to combine Aspel with Gutekunst.

Section VIII.A.1. Breen provides additional disclosures regarding sending notifications to a mobile device, which is an important function of the Aspel-Gutekunst combination. Aspel and Gutekunst expressly reference cellular phones, with Gutekunst specifying the iPhone.

a) Teaching, Suggestion, Motivation

As explained above in VII.C, Breen provides “reasonably pertinent” disclosures regarding notifications as used in Aspel and Gutekunst. Aspel discloses “exemplary screen captures of various graphic user interfaces (GUIs)” that are “HTML in a web browser but **may also be implemented in a software application ...**” Ex-1005, [0131]. Similarly, Gutekunst describes a “medical application,” which “refers to a software application” “such as an **iPhone® application.**” Ex-1006, [0079].

A POSITA would have understood Breen’s disclosures regarding the iPhone’s operation to provide details regarding a “software application” with a user interface that implements the features described by Aspel and Gutekunst. Thus, a POSITA would have understood that combining the notification and user interface

elements of Breen with the monitoring system disclosed by Aspel and Gutekunst would enable implementation of their features. Ex-1003, ¶¶207-210.

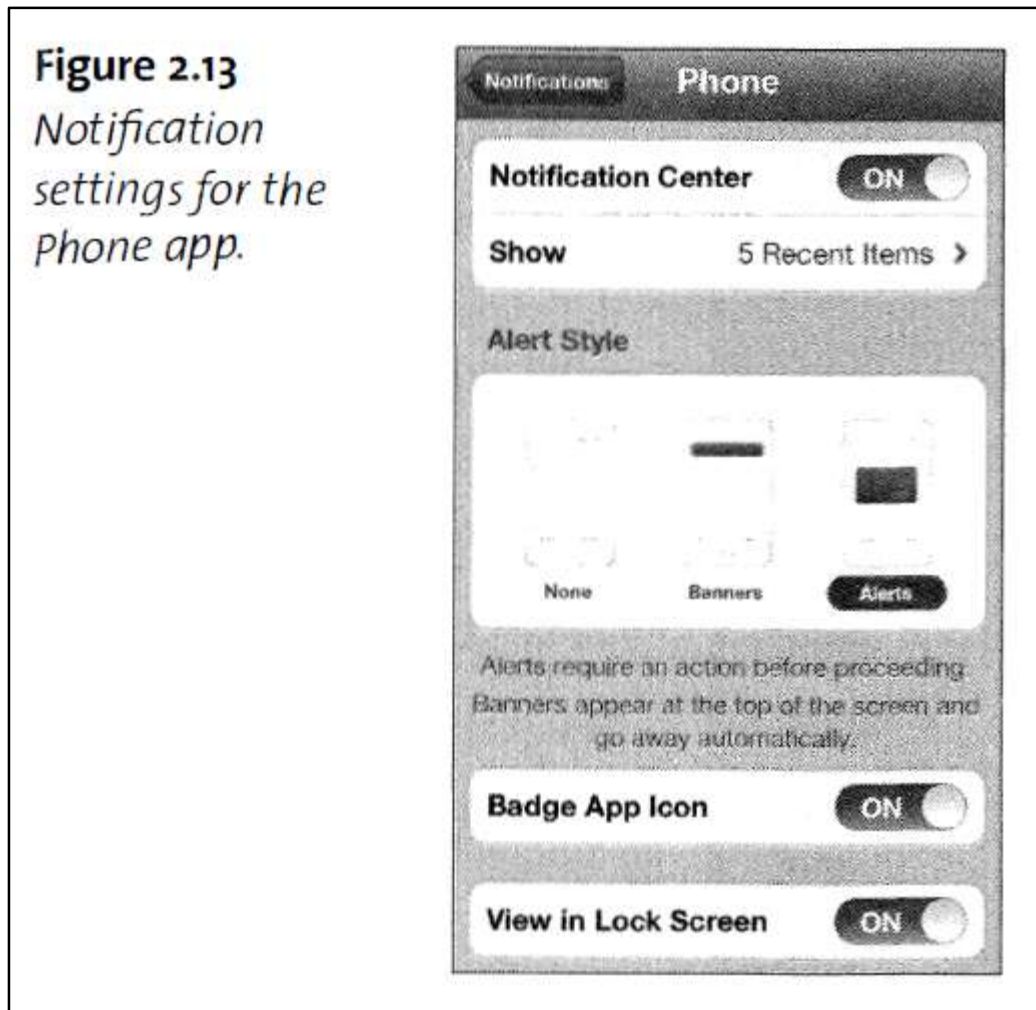
b) Other Factors and Reasonable Expectation of Success

Combining Aspel and Gutekunst with Breen would have involved combining prior art elements (i.e., adding to the Aspel-Gutekunst software application the notification system and user interface elements taught by Breen for iPhone applications) according to known methods to yield predictable results (i.e., an iPhone app for handling notifications and interacting with a server). Ex-1003, ¶211. At the time of the alleged invention, mobile applications that interact with server systems were well-known. Thus, a POSITA would have had a reasonable expectation of success in using Breen’s disclosures regarding notifications with the Aspel-Gutekunst system. Claims 2 and 3 simply claim the two options for “Alert Style” provided by the iPhone Notification settings. Ex-1003, ¶211.

2. Claim 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.”

Aspel describes presenting a list of alerts as explained in VIII.A.2.e. Breen discloses different visual presentations for an alert notification, the “Alert Style.” Ex-1007, 63-65.



Ex-1007, Fig. 2.13. Breen explains that the application can choose to display “Alerts” for notifications, which “require an action before proceeding.” Ex-1007, Fig. 2.13, 64-65. A POSITA would have understood that “requiring an action before proceeding” involves *inhibiting access to one or more applications* until the user performs some *action* such as “tap Accept.” Ex-1003, ¶¶212-215.

In the Aspel-Gutekunst-Breen combination, at least some of the alerts would result in the *wireless mobile remote monitor* (device 230) displaying an “Alert,” (“a window that requires some action from you for it to go away”) which would

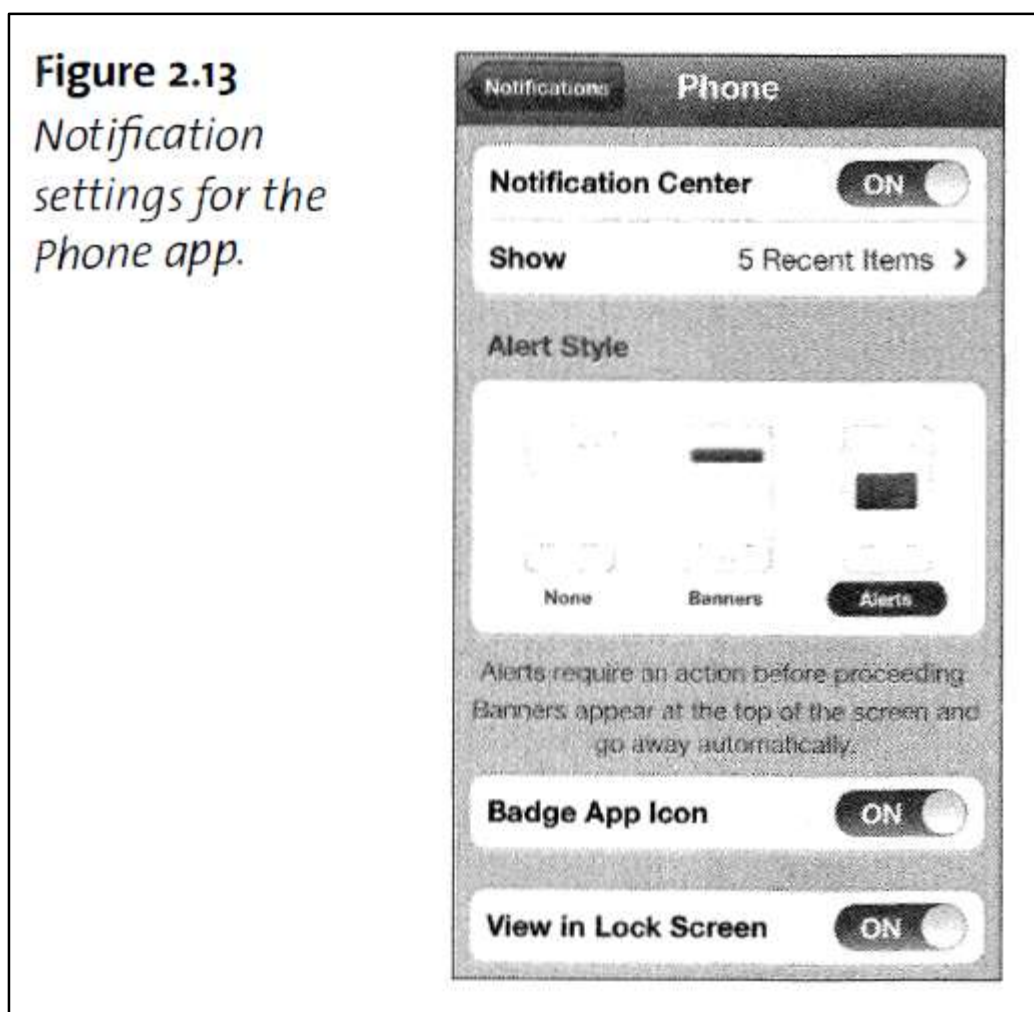
result in the wireless mobile remote monitor *inhibiting access to one or more applications at the wireless mobile remote monitor until an action (“tap Accept”) at the wireless mobile remote monitor is detected to indicate an interaction by the user with the alert notification message.*

A POSITA would have combined Aspel with Gutekunst and Breen. *See* Sections VIII.B.1, VIII.A.1.

3. Claim 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.”

Aspel describes presenting a list of alerts as explained in VIII.A.2.e. Breen discloses the visual presentation of a notification with “Banners” “that appear[] for a few seconds at the top of the device’s screen before disappearing,” i.e., *a momentary message on a display at the wireless remote monitor.*



Ex-1007, Fig. 2.13. Breen explains that the application can choose to display “Banners” for notifications. “A banner appears as a short string of text (preceded by an app’s icon) that appears for a few seconds at the top of your device’s screen before disappearing.” Ex-1007, 64-65.

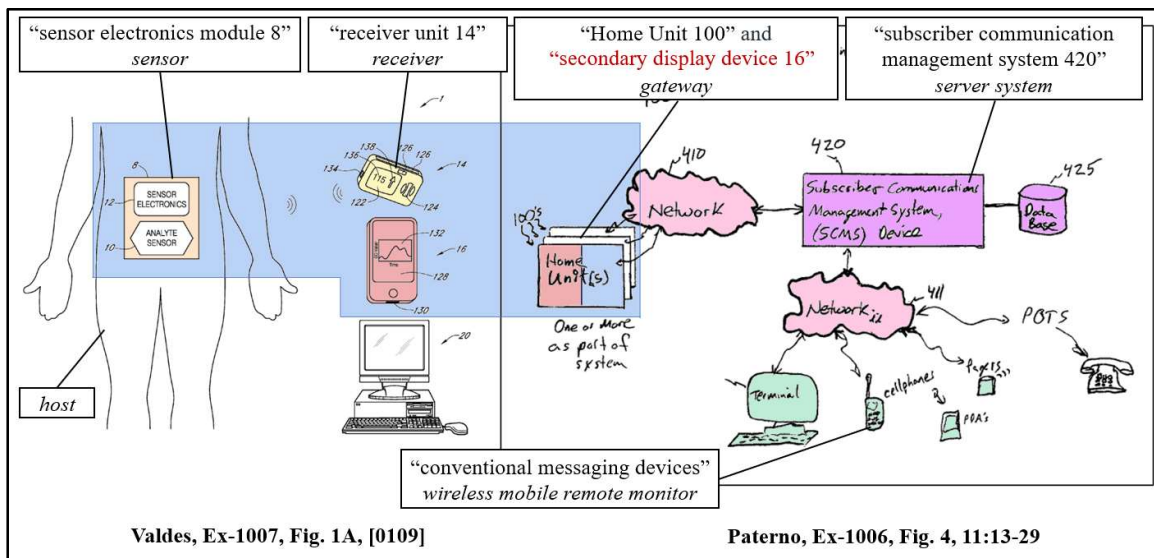
In the Aspel-Gutekunst-Breen combination, at least some of the alerts would result in the *wireless mobile remote monitor* (device 230) displaying a “Banner” that would “appear[] for a few seconds at the top of your device’s screen before disappearing,” which is *a momentary message on a display at the wireless mobile*

remote monitor. This notification and the other type of notification recited in claim 2 are alternatives described in Breen. Ex-1003, ¶¶73,216-219.

A POSITA would have combined Aspel with Gutekunst and Breen. *See* Sections VIII.B.1, VIII.A.1.

C. Ground III: Claims 1, 4-7, 9, 11, 13, and 15-17 Would Have Been Obvious Based on Paterno in view of Valdes and Hanson

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. Valdes discloses a CGM including a sensor for measuring *analyte concentration sensor data* and a receiver unit 14 to gather the data. Valdes also describes setting alert rules based on the data. The figure below depicts the result of combining Paterno (right) with Valdes (left) as in the proposed combination.



In the Paterno-Valdes-Hanson combination, Hanson's disclosures regarding networking communications would be incorporated into the *server system* and the *wireless mobile remote monitor*.

1. A POSITA Would Have Been Motivated to Combine Paterno, Valdes, and Hanson and With a Reasonable Expectation of Success

a) Teaching, Suggestion, Motivation

Paterno discloses “[a]n Assisting and Monitoring method and system for compliance logging and monitoring system” that can remotely deliver messages and scheduled event reminders, and a “Home unit” at a patient's location for providing reminders. Paterno refers to monitoring of 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. A POSITA would have understood the advantages of a CGM in Paterno's monitoring system, for more efficient and timely glucose level monitoring. Ex-1009, [0004]; Ex-1003, ¶¶220-230.

Hanson discloses “medication management and reporting technology,” incorporating additional alert rules into the *server*. Hanson discloses “providing a remote alert to a remote device” using a variety of “notification mechanisms (e.g., IVR, SMS, email, etc.).” Ex-1010, [0018], [0062]. Hanson describes “alert interfaces” that “enable[] a recipient of the alert (e.g., a doctor, a caregiver, etc.) to

receive information regarding the records of the patient.” Ex-1010, [0115]. A POSITA would have considered Hanson’s disclosures regarding alert messages to benefit Paterno’s system by allowing additional notification rules.

b) Other Factors and Reasonable Expectation of Success

Combining Paterno, Valdes, and Hanson would 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). Ex-1003, ¶231.

CGMs, such as Valdes’s, were well-known in the art to yield predictable results. Ex-1003, ¶232. Valdes discloses using well-known “direct wireless communication” protocols to send a “data package” using several standard wireless protocols. Ex-1009, [0092]-[0093]. Paterno, in turn, describes communication by “wireless means” or “wireless network” throughout. Ex-1008, 6:10-12, 20:28-34. Because the technology used by Valdes was well-known and in some cases industry standard, a POSITA would have had a reasonable expectation of success in using Valdes’s CGM to generate data and transmit it to Paterno’s Home Unit. Ex-1003, ¶232.

Adding 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). Ex-1003, ¶233. Hanson discloses using “native applications” on “a mobile device” to enable more advanced interactions with the monitoring system. Ex-1010, [0055]-[0056]. A POSITA would have readily appreciated the convenience and special features of a native application. Ex-1003, ¶233. Because the transition from a cross-platform website to mobile applications was common prior to the priority date of the ’541 patent, a POSITA would have had a reasonable expectation of success. Ex-1003, ¶234.

2. Independent Claim 1

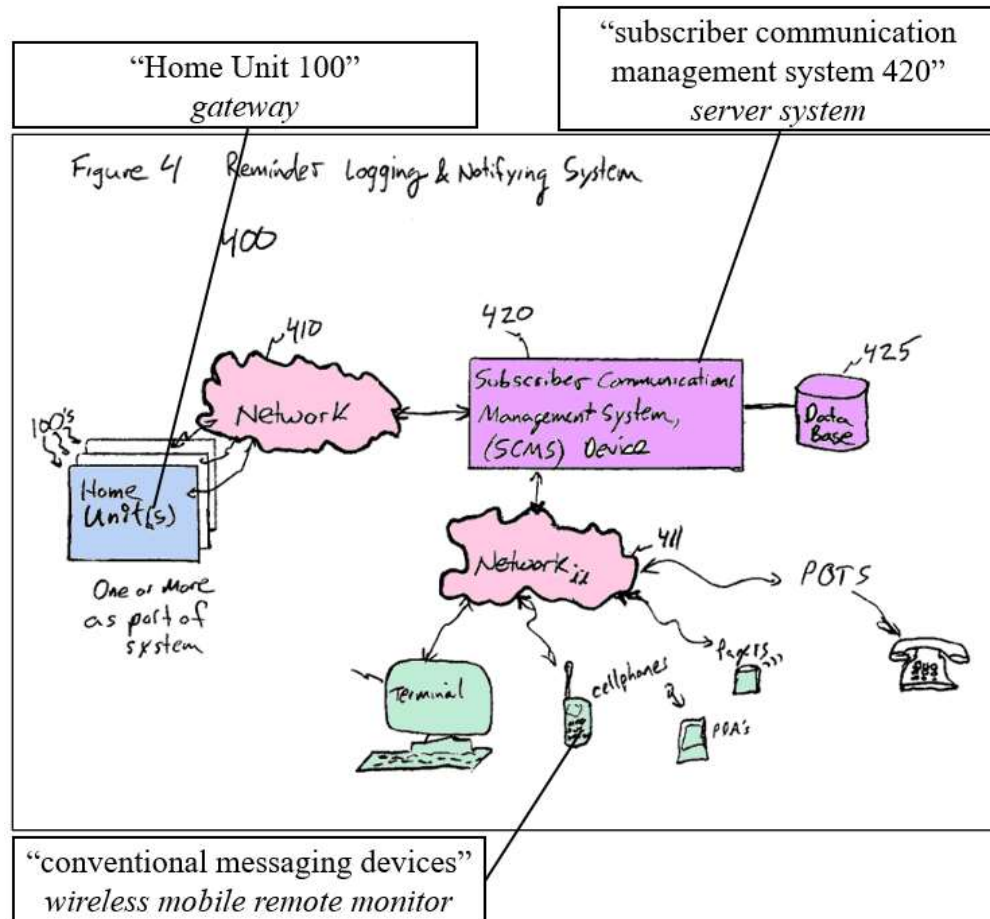
a) 1[preamble]

Paterno discloses “[a]n Assisting and Monitoring **method** and system [and] an automated communications/notification system...” Ex-1008, 1:66-2:4; Ex-1003, ¶¶235-236.

b) 1[a]

Paterno depicts Home Units remotely located from a central Subscriber Communications Management System, (“SCMS”), a computer-based system with an internal or external database 425, communicating over wired and/or wireless network(s) 411, with the conventional messaging devices of caregivers associated with the Home Unit (reminder & logging) system subscribers. Ex-1008, Fig. 4,

11:13-29. A POSITA would have recognized the SCMS—the “central,” “computer based system with an internal or external database” that communicates with remote systems—as a *server system*. Ex-1003, ¶¶237-239.



Paterno’s SCMS “determines when, how, and what notifications to send” based on “customized conditions,” i.e., *detected events*. Namely, Paterno discloses that a “monitoring and notification service provider may offer to subscribers an ability ... to **receive convenient notifications based on customized conditions** related to the logging of activities associated with the scheduled events.” Ex-1008, 11:13-37. In the disclosed system, the “SCMS controller... **determines when, how**

and what notification messages should be delivered to each member or integrated service system of each subscriber account profile.” Ex-1008, 16:34-39. Paterno explains, for example, that a caregiver “may specify in the notification parameters that she wants an email sent to her every time the SCMS device 420 receives an update from [the host’s] Home Unit 100.” Ex-1008, 16:50-58. In the Paterno-Valdes-Hanson combination, the notification may also be based on monitoring *data indicating a concentration of an analyte of the host*, as explained below. A POSITA would have combined Paterno, Valdes, and Hanson. *See* Section VIII.C.1.

c) 1[b]

Paterno discloses a system for detecting events, including relating to home monitoring of blood sugar. Valdes discloses a CGM system where glucose concentration measurement data can be transmitted to further devices including a receiver unit and one or more secondary display devices. Ex-1009, [0002].

Valdes further 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. Ex-1009, [0008]. The software recognizes a predetermined event based on the processed received sensor data (e.g. low glucose value), and initiates an alert. Ex-1009, [0017], [0157]; Ex-1003, ¶¶240-

243. A POSITA would have combined Paterno, Valdes, and Hanson. *See* Section VIII.C.1.

d) 1[c]

Paterno discloses “conventional messaging devices” (*wireless mobile remote monitors*) that are remote to the “Home Unit” located with the *host*, and remote to the SCMS, or *server system*. Ex-1008, Fig. 4, 11:13-29; Ex-1003, ¶¶244-246.

e) 1[d]

Paterno’s Home Unit parameters may include “**how and when members of a subscriber account are notified of Home Unit generated information.**” Ex-1008, 3:29-42.

Paterno discloses the SCMS generates and delivers notification messages to the communications tools of the caregivers. Ex-1008, 16:30-41, 16:50-58. In the Paterno-Valdes-Hanson combination, the “conventional messaging devices of the caregivers” (*wireless mobile remote monitors*) are responsible for *presenting* “notification messages” based on a detected event, or *alert notification messages*. Ex-1003, ¶¶247-249. A POSITA would have combined Paterno, Valdes, and Hanson. *See* Section VIII.C.1.

f) 1[e]

Paterno discloses “subscribers,” the *host*, authorizing “caregivers” to receive “notifications,” or *alert notification message*. Hanson discloses additional details about how the *wireless mobile remote monitor or the user of the wireless mobile*

remote monitor can be given specified privileges, i.e., *authorized to receive the alert notification messages*, for receiving messages. Ex-1008, 3:52-63.

To the extent *to augment the receiver monitoring of the analyte state of the host* is a claim limitation,⁷ a POSITA would have understood from the Paterno-Valdes-Hanson combination that *alert notification messages* sent by the system *augment the receiver monitoring of the analyte state of the host*. Ex-1003, ¶¶250-253. Valdes describes benefits for remotely monitor children with diabetes. Ex-1009, [0107]. Hanson describes an “increase in the [patient’s] monitoring procedures” as a result of a caregiver’s received notification. Ex-1010, [0116].

Hanson discloses how the *remote monitor* user is *authenticated*. For example, Hanson explains that **“the system 300 may require the recipient of the alert to provide identification information (e.g., a user name and a password) that verifies that the recipient of the alert is authorized to view the medical records of the patient.”** Ex-1010, [0115].

A POSITA would have combined Paterno, Valdes, and Hanson. *See* Section VIII.C.1.

⁷ Section VIII.A.2.f; Ex-1012, p.15.

g) 1ff

Paterno discloses “initiating communication, receiving acknowledgement that the desired receiving device or system has been reached, transmitting the appropriate data as specified in the memory parameters 200 and receiving confirmation that the transmitted data was received” Ex-1008, 10:9-14.

Hanson discloses “providing an alert to a remote device” (*wireless mobile remote monitor*) that displays exemplary alert notification dialogs that include “input controls” that “receive input,” *user input indicative of acknowledgement*. The disclosed examples in Hanson relate to alerts for medication, but a POSITA would have readily adapted Hanson’s teachings for use with the types of alerts discussed above, (Section VIII.C.2.b,c), as a POSITA would have understood that the alerts would apply equally to monitored physiological conditions. Hanson discloses “the system 300 may **provide an alert to a remote device (e.g., mobile phone) of the patient’s doctor, the patient’s caregiver**, or a remote monitoring station ...” Ex-1010, [0112]. “[S]econd alert interface 1220 provides several **user input controls that help a recipient of the alert (e.g., a doctor, a caregiver, etc.) evaluate and handle the alert.**” Ex-1010, [0120]-[0121].

In the Paterno-Valdes-Hanson combination, Hanson’s “alert interface” would be used on Paterno’s “conventional messaging devices” (*wireless mobile remote monitor*) to provide *presenting an alert notificaiton message and receiving*

user input indicative of acknowledgment of the message. Ex-1003, ¶¶254-258. A

POSITA would have combined Paterno, Valdes, and Hanson. *See* Section

VIII.C.1.

h) 1/g

Paterno discloses “receiving confirmation that the transmitted data was received and deemed complete by embedded data consistency checks,” after “initiating communication, receiving acknowledgement that the desired receiving device or system has been reached, transmitting the appropriate data as specified in the memory parameters 200.” Ex-1008, 10:9-14.

Hanson, with reference to Fig. 12, further discloses “receiving input selecting the new dosage” and then changing the dosage of the medication in the system (i.e., a form of acknowledgment), namely, “The second alert interface 1220 also includes a change dosage input control 1222 that allows the recipient of the alert to change a dosage at which the patient is currently taking the medication.” Ex-1010, [0121], [0018] (describing “confirmation” from remote device “in response to the local alert”). A POSITA would have understood that Hanson’s acknowledgement (change of prescription) could be applied to glucose alerts in Paterno’s system. Ex-1003, ¶¶259-261. A POSITA would have combined Paterno, Valdes, and Hanson. *See* Section VIII.C.1.

i) 1/h]

Valdes discloses the *analyte concentration sensor data* and Hanson Fig. 12 discloses the user receiving an alert *accessing* records of such data using the first alert interface. Hanson explains that “the recipient of the alert **may select the view records input control 1212** and, based on the selection, the system 300 **retrieves the medical records of the patient from a remote database** and displays the retrieved medical records to the recipient of the alert.” Ex-1010, [0115].

Hanson further discloses that the medical records include blood sugar sensor data. Ex-1010, [0061] (“The sensors further may include ... a blood sugar sensor”).

In the Paterno-Valdes-Hanson combination, the recipient’s selection of the “view records input control” using “conventional messaging devices” (*wireless mobile remote monitor*) is *accessing at least some of the analyte concentration sensor data from the server system*. Ex-1003, ¶¶262-265. A POSITA would have combined Paterno, Valdes, and Hanson. *See* Section VIII.C.1.

j) 1/i]

Paterno renders this limitation obvious in view of Valdes and Hanson under the interpretation DexCom appears to be taking in the District Court litigation, namely that the “accessing... at least some of the analyte concentration sensor data” and the “receiving, in response to the accessing, *the* at least some of the analyte concentration sensor data” can be performed by accessing the server

system (rather than the data itself) and then receiving by rendering the data accessible.

Hanson Fig. 12 discloses *receiving* (“retriev[ing] ... from a remote database”) medical records in response to *accessing* (selecting “view records”) them. “[T]he recipient of the alert may select the **view records** input control 1212 and, **based on the selection, the system 300 retrieves the medical records of the patient from a remote database and displays the retrieved medical records to the recipient of the alert.**” Ex-1010, [0115]. Hanson discloses that the medical records include blood sugar sensor data. Ex-1010, [0061]. A POSITA would have understood that “retrieving” data “from a remote database” comprises sending a request to the remote database and *receiving* the data in response. Ex-1003, ¶¶266-269.

Valdes discloses providing *analyte concentration sensor data* to the server system where it becomes part of the medical records that can be first accessed and then received, as explained above in VIII.C.2.c.

In the Paterno-Valdes-Hanson combination, in response to the recipient’s selection of the “view records input control,” the system “retrieves the medical records of the patient from a remote database,” thereby *receiving information the at least some of the analyte concentration sensor data including historical data*. This data would include *at least some of the analyte concentration sensor data*

being generated by the receiver monitoring the analyte state of the host because the Valdes receiver unit uploads the *analyte concentration sensor* data to the database. Ex-1003, ¶269.

A POSITA would have combined Paterno, Valdes, and Hanson. *See* Section VIII.C.1.

k) 1/jj

Paterno discloses users of wireless remote monitors may modify alert rules settings: “subscribers can specify specific privileges by group member for both the programming sending of messages, alerts, and alert schedule updates to the Home Unit in that account, and for setting what notifications and messages they will receive from the system based on the communications from the Home Unit associated with their account.” Ex-1008, 3:57-63; Ex-1003, ¶270-274. For example, Paterno explains that “[t]he **primary caregiver, daughter Jane, may specify in the notification parameters** that she wants an email sent to her every time the SCMS device 420 receives an update from Betty’s Home Unit 100...” Ex-1008, 16:50-58.

Valdes discloses *one or more sets of recommended alert rules settings* are “configured by the host using the receiver,” as required by this limitation. Valdes discloses that “**the receiver unit 14 has a set of configurable alert settings, wherein the set of alert settings can be initially set to a first, configuration**

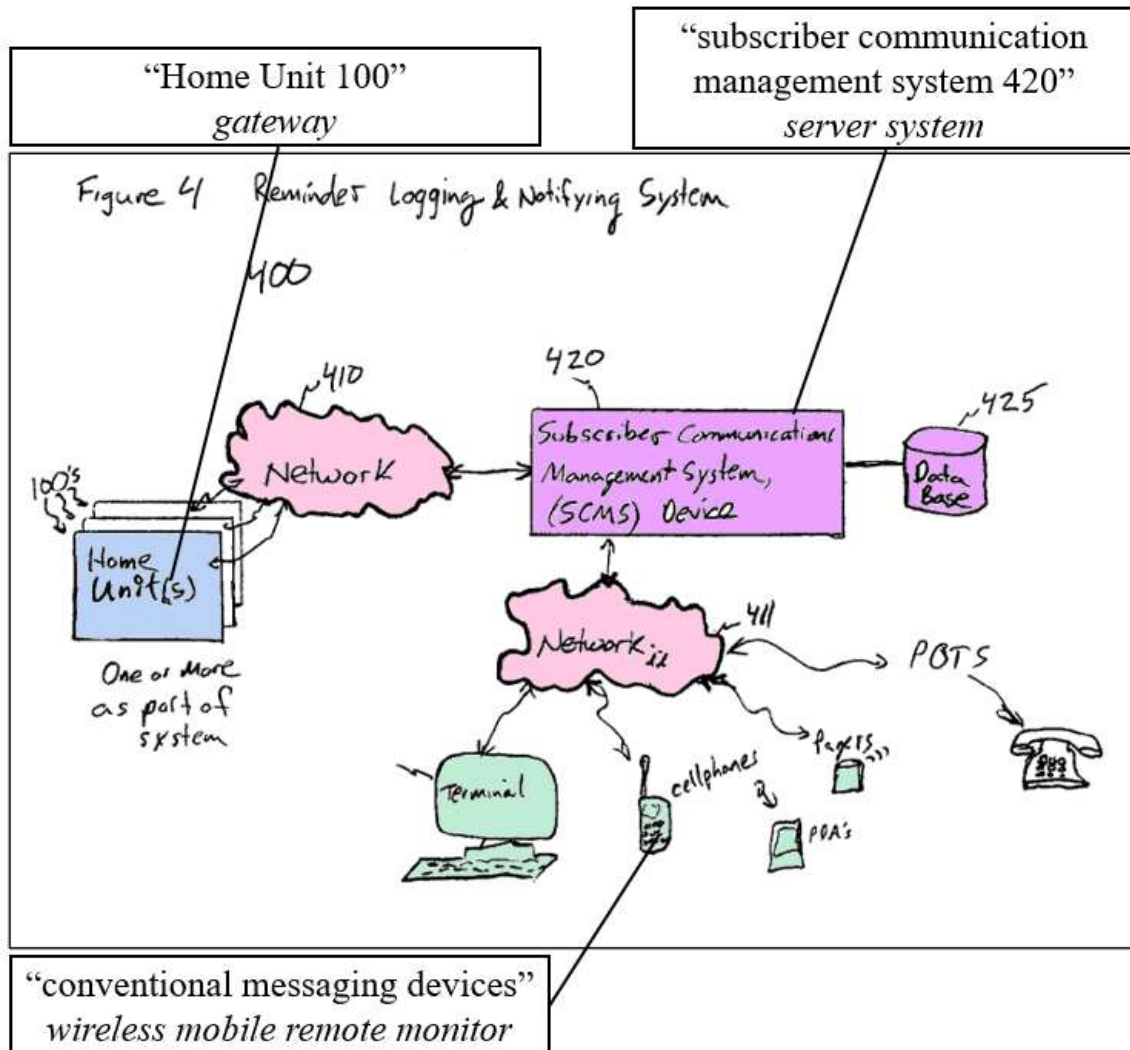
(such as a default configuration set by a manufacturer), but modified to a second, different configuration. Display device 16 or 20 can receive user input via a user interface ... indicative of modifying the alert settings and send a data message to the receiver unit 14 indicative of the modifications. Alternatively, **the receiver unit 14 can allow a user to modify the alert setting using the user interface of the receiver unit. The receiver unit 14 can then modify the current settings according to the user input.** The set of settings can include a hypoglycemic setting, a hyperglycemic setting, a rate-of-change setting and a calibration setting.” Ex-1009, [0124].

A POSITA would have combined Paterno, Valdes, and Hanson. *See* Section VIII.C.1.

3. Claim 4

a) 4[a]

As explained above in VIII.C.2.b, Paterno discloses “conventional messaging devices” (*wireless mobile remote monitors*), such as cellphones, PDAs, and pagers. Ex-1008, Fig. 4; Ex-1003, ¶¶275-276.



4. Claim 5

a) 5[a]

Paterno discloses an SCMS (*server system*). The SCMS communicates with Home Units, generates custom notification messages to the communications tools of the caregivers, and provides method(s) of updating event schedules, messages, reminder parameters, reminder contents, and operational parameters of the Home Units. Ex-1008, 15:44-53. A POSITA would have understood that the SCMS

performs the functions of and includes a *processor*. *See, e.g.*, Ex-1008, 4:32-36 (“**processed** according to pre-configured logical operations”); Ex-1003, ¶¶277-279. As explained above, in VIII.C.2.b-d, the SCMS is configured to perform these limitations in combination with Valdes’s CGM.

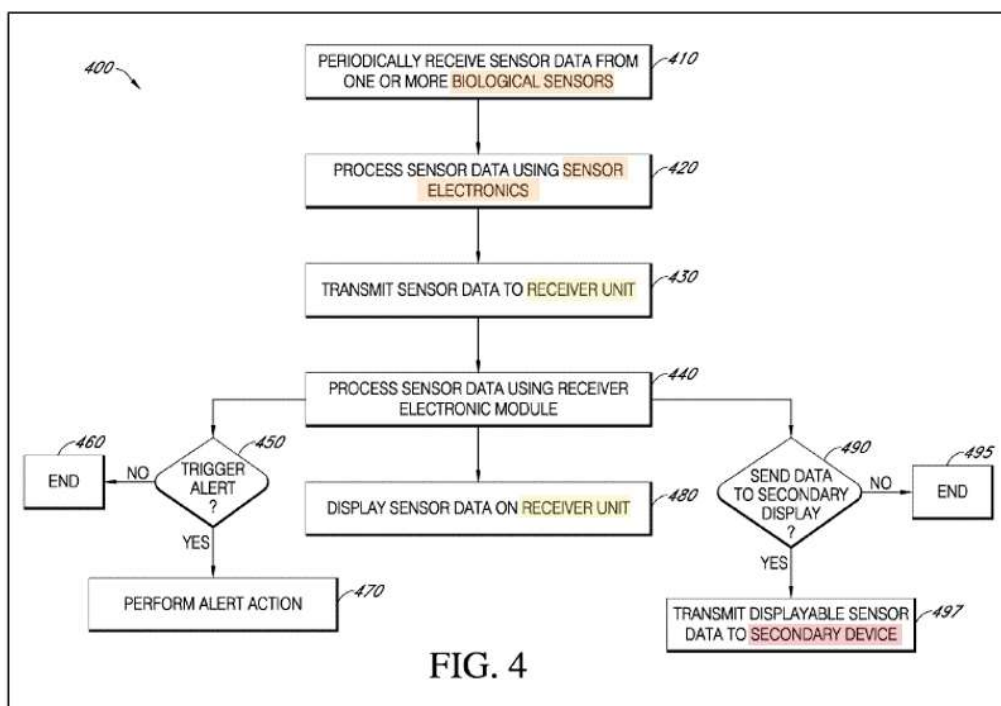
A POSITA would have combined Paterno, Valdes, and Hanson. *See* Section VIII.C.1.

5. Claim 6

a) 6[a]

Paterno discloses an SCMS (*server system*), that processes a *first set of rules used to generate the alert notification message* to the remote monitor. “[T]he SCMS generate[s] and deliver[s] timely notification messages to the communications [to] ... associated with each of the Home Unit/subscriber account profiles.” Ex-1008, 16:30-16:58. Paterno also discloses the use of a different—i.e., a *second—set of rules* for different *alert notification message* recipients.

Valdes further discloses a *second set of rules used to generate alerts to be sent to the receiver coupled to a sensor system at the host*.



Ex-1010, Fig. 4. “FIG. 4 is a flowchart illustrating one embodiment of a method 400 of using a receiver unit, such as receiver unit 14 or 314, first as a stand alone device and then used in combination with a secondary display device, such as secondary device 16, 20, 316A, 316B or 316C.” Ex-1009, [0168]. “In block 440, the receiver unit 14, 314 processes the **sensor data received from the sensor electronics unit 12, 312.**” Ex-1009, [0172].

“**A first branch proceeds to decision block 450, which decides whether to trigger an alert.** As noted above, each alert can be associated with one or more alert conditions that must be met for the respective alert to trigger. **The alert conditions could be any characteristic of the sensor data**” Ex-1009, [0174].

Valdes further discloses configurations in which its receiver is physically connected to a mobile phone, Ex-1009, [0098].

In the Paterno-Valdes-Hanson combination, Paterno's "SCMS controller 7010," the *server system*, detects events by scanning "profile records 9000," utilizing *a first set of rules at the server system* and an additional *second set of rules*, and Valdes teaches *a second set of rules used to generate alerts to be sent to the receiver* ("receiver unit 14") *coupled to a sensor system* ("sensor electronics 12") *at the host*. Ex-1003, ¶¶280-285. A POSITA would have combined Paterno, Valdes, and Hanson. *See* Section VIII.C.1.

6. Claim 7

a) 7[a]

Paterno discloses an SCMS (*server system*) that is accessible via "Network." Paterno discloses a gateway in its Home Units: "the system includes **network(s) and two-way communication devices to exchange information between ... (Home Units), and ... SCMS.**" Ex-1008, 3:29-33. The SCMS communicates over wired and/or wireless network(s). Ex-1008, 11:13-28. Paterno explains that certain operations by the "Home Unit" are "supported over the existing Cellular Telephone system infrastructure," *a wireless connection to a public land mobile network*. Ex-1008, 20:52-64.

Valdes expressly discloses a *gateway* to access the wireless network. “In some embodiments, **a gateway can be included in the glucose monitoring system 1.**” Ex-1009, [0162]. Valdes further discloses using “a mobile phone ... [to] relay sensor information.” Ex-1009, [0128]. A POSITA would have understood that a “mobile phone” uses *a wireless connection to a public land mobile network*.

In the Paterno-Valdes-Hanson combination, Paterno’s “Home Unit 100” acts as a *gateway* for the Valdes receiver unit to upload data “to a remote storage device or remote computing system,” Paterno’s SCMS (*server system*). Ex-1003, ¶¶286-290. A POSITA would have combined Paterno, Valdes, and Hanson. *See* Section VIII.C.1.

7. Claim 9

a) 9[a]

In the Paterno-Valdes-Hanson combination, Paterno’s notification system allows caregivers to use “conventional messaging devices,” *wireless mobile remote monitors*, to modify notification settings such as a blood glucose alert as taught by Valdes, *at least one rule including a trigger that when triggered causes an alert to be sent by the server system to the receiver*. Ex-1003, ¶¶291-298. Hanson further describes setting the server’s notification settings so that a notification is sent to a patient’s, or *host’s*, “user interface mechanism,” such as Valdes’s “receiver unit

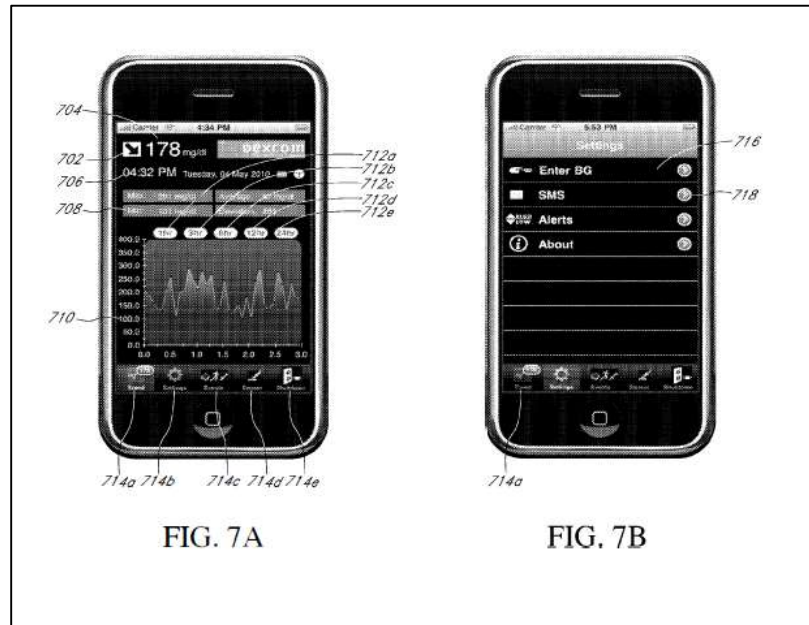
14,” or *receiver*. Paterno discloses that its SCMS communications “generates custom notification messages to the communications tools of the caregivers ... associated with each subscriber account, and provides method(s) of updating event schedules, messages, reminder parameters, reminder contents, and operational parameters of the Home Units” Ex-1008, 15:17-27.

Paterno further discloses that a health care provider (remote mobile monitor) has permission to change the schedule of events and event reminder message contents, and that when any such changes are made, a summary report of the changes is delivered electronically to all caregivers. Ex-1008, 17:27-39. Paterno also describes “input types” with “special influences” on controller function, causing “immediate special action, such as triggering an emergency call.” Ex-1008, 5:39-46.

Hanson discloses storing sensor data on the *server* and using it to generate a message to the host. Ex-1010, [0116]. “The remote servers, monitoring center, or user interface device can **initiate communication to the patient**, caregivers, or other trusted parties... **Communication can be established based on rules established by the patient, caregivers, monitoring center, or set by default.**” Ex-1010, [0129].

Valdes discloses a *receiver* that can display an *alert*. Valdes further discloses “modifying the one or more configurable alert settings in accordance with the user

input into a second configuration that is different than the first, default configuration.” Ex-1009, [0032].



Ex-1009, Figs.7A-B, [0198].

A POSITA would have combined Paterno, Valdes, and Hanson. *See* Section VIII.C.1.

8. Claim 11

a) 11[a]

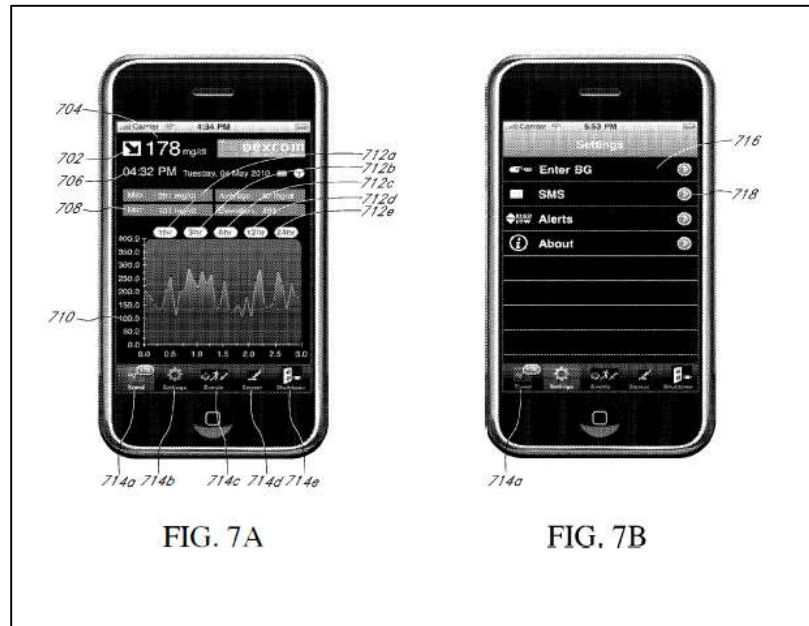
Paterno renders this limitation obvious in view of Valdes and Hanson as explained above in VIII.C.2.h. Ex-1003, ¶299.

9. Claim 13

a) 13[a]

Paterno discloses “cellphones” and “PDA’s” as *wireless mobile remote monitors*.

Valdes discloses its receiver unit “physically and electrically coupled to a **secondary display device having a larger display, such as a mobile telephone.**” Ex-1009, [0098].



Ex-1009, Figs. 7A-B. A software program with a “user interface software module” can be used to review blood glucose readings, i.e., accessing *at least some of the analyte concentration sensor data*. Ex-1009, Figs. 7A-7E, [0192]-[0193]. According to Valdes, a similar user interface could be provided to clinicians for use on their remote devices. Ex-1009, [0206]. Valdes discloses that the sensor data could be sent to the clinician for display on the clinician’s device. Ex-1009, [0209].

Hanson also discloses “user devices” including “a smart phone” that “may include a native medication monitoring and reporting application.” Ex-1010, [0055]-[0056].

In the Paterno-Valdes-Hanson combination, Paterno's "cellphones" as *wireless mobile remote monitors* would enable opening Valdes's disclosed "application," Ex-1009, [0192]-[0193], *monitoring application*, including "user interface 700" that would display Hanson's "Alert" with the ability to "View Records," *initiating the accessing the at least some of the analyte concentration sensor data from the server system*. Ex-1003, ¶¶300-306. A POSITA would have combined Paterno, Valdes, and Hanson. *See* Section VIII.C.1.

10. Independent Claim 15

a) 15[preamble]

See Section VIII.C.2.a.

b) 15[a]

See Sections VIII.C.7 and VIII.C.2.b-c,k.

c) 15[b]

See Section VIII.C.2.f.

d) 15[c]

See Section VIII.C.2.f.

e) 15[d]

See Section VIII.C.2.b.

f) 15[e]

See Section VIII.C.2.c,f. Valdes further discloses "the predetermined event comprises an event selected from the group consisting of exceeding a

hypoglycemia threshold, **exceeding a hyperglycemia threshold, exceeding an approaching hypoglycemia threshold**, exceeding an approaching hyperglycemia threshold, and exceeding a glucose concentration rate-of-change threshold.” Ex-1009, [0017]. *See also* Ex-1009, [0034], [0201]; Ex-1003, ¶312. A POSITA would have combined Paterno, Valdes, and Hanson. *See* Section VIII.C.1.

g) 15[ff]

See Section VIII.C.2.c.

h) 15[g]

See Section VIII.C.2.d.

i) 15[h]

See Section VIII.C.2.e.

j) 15[i]

See Section VIII.C.1.g.

k) 15[j]

See Section VIII.C.2.h.

l) 15[k]

See Section VIII.C.9.

m) 15[l]

See Section VIII.C.2.j.

n) 15[m]

See Section VIII.C.2.k.

11. Independent Claim 16

a) 16[preamble]

See Section VIII.C.2.a,b.

b) 16[a]

Paterno discloses “conventional messaging devices” (*wireless mobile remote monitor*). See Section VIII.C.2.b. A POSITA would have understood that “conventional messaging devices,” for example “cellphones” and “PDA’s,” include a processor, memory, and instructions to configure the processor. Ex-1003, ¶¶322-324.

c) 16[b]

See Section VIII.C.2.b.

d) 16[c]

See Section VIII.C.2.b.

e) 16[d]

See Section VIII.C.2.c.

f) 16[e]

See Section VIII.C.2.e.

g) 16[f]

See Section VIII.C.2.f.

h) 16[g]

See Section VIII.C.2.f.

i) 16[h]

See Section VIII.C.2.f.

j) 16[i]

See Section VIII.C.2.g.

k) 16[j]

See Section VIII.C.2.h.

l) 16[k]

See Section VIII.C.2.i.

m) 16[l]

See Section VIII.C.2.j.

n) 16[m]

See Section VIII.C.2.k.

12. Independent Claim 17

a) 17[preamble]

See Section VIII.C.11.b.

b) 17[a]

See Section VIII.C.2.b.

c) 17[b]

See Section VIII.C.2.b.

d) 17[c]

See Section VIII.C.2.c.

e) 17[d]

See Section VIII.C.2.e.

f) 17[e]

See Section VIII.C.2.f.

g) 17[f]

See Section VIII.C.2.f.

h) 17[g]

See Section VIII.C.2.f.

i) 17[h]

See Section VIII.C.2.g.

j) 17[i]

See Section VIII.C.2.h.

k) 17[j]

See Section VIII.C.2.i.

l) 17[k]

See Section VIII.C.2.j.

m) 17[l]

See Section VIII.C.2.k.

D. Ground IV: Claims 2 and 3 Would Have Been Obvious Based on Paterno in view of Valdes, Hanson, and Breen

Breen supplies user interface details regarding displaying alerts at the *wireless remote monitor* including a “Notification” settings panel running on iOS 5

on an iPhone device—including the iPhone 4 referenced in the '541 patent—that allows a user to configure notifications for “[t]hird-party applications configured to support notifications,” including “Banners” or “Alerts” alert styles.

1. A POSITA Would Have Been Motivated to Combine Paterno, Valdes, Hanson, and Breen with a Reasonable Expectation of Success

a) Teaching, Suggestion, Motivation

Hanson states that its “native medication monitoring and reporting application refers to a software/firmware program running on the corresponding mobile device.” Ex-1010, [0056]. A POSITA would have understood Breen’s disclosures of user interfaces for “notifications” to beneficially provide an application user interface that implements Hanson’s features. Ex-1003, ¶¶350-353.

b) Other Factors and Reasonable Expectation of Success

Combining Paterno, Valdes, and Hanson with Breen would have involved combining prior art elements (i.e., the user interface elements taught by Breen) according to known methods to yield predictable results (i.e., a native monitoring application for handling alerts and interacting with the server). Ex-1003, ¶354. At the time of the alleged invention, mobile applications that interact with server systems, were well-known, for example as explained in Breen. Thus, a POSITA would have had a reasonable expectation of success in using Breen’s disclosures regarding notifications with Paterno, Valdes, and Hanson. Ex-1003, ¶354.

2. Claim 2

a) 2[a]

Paterno discloses sending alerts to a *wireless remote monitor*. Breen discloses notification settings for displaying an “Alert” meeting the limitations of this claim. Ex-1007, 63-65. In the Paterno-Valdes-Hanson-Breen combination, at least some of the alerts would result in the *wireless mobile remote monitor* displaying an “Alert” (“a window that requires some action from you for it to go away”), which would result in the wireless mobile remote monitor *inhibiting access to one or more applications at the wireless mobile remote monitor until an action* (“tap Accept”) *at the wireless mobile remote monitor is detected to indicate an interaction by the user with the alert notification message*. Ex-1003, ¶¶355-357.

A POSITA would have combined Paterno with Valdes, Hanson, and Breen. See Sections VIII.D.1, VIII.C.1.

3. Claim 3

a) 3[a]

Breen discloses a notification with “Banners” meeting the limitations of this claim. In the Paterno-Valdes-Hanson-Breen combination, at least some of the alerts would result in the *wireless mobile remote monitor* displaying a “Banner” that would “appear[] for a few seconds at the top of your device’s screen before disappearing,” which is *a momentary message on a display at the wireless mobile remote monitor*. Ex-1007, 63-65. This notification and the other type of

notification recited in claim 2 are alternative options that are both described in Breen, and thus both equally obvious. Ex-1003, ¶¶358-360.

A POSITA would have combined Paterno with Valdes, Hanson, and Breen. See Sections VIII.D.1, VIII.C.1.

IX. Discretionary Denial Is Not Warranted

A. 35 U.S.C. § 314(a)

The Board should not exercise its discretion to deny institution under 35 U.S.C. § 314(a). No other petitions have been filed against the '541 patent and thus the *General Plastic* factors do not weigh against institution. Under *Apple Inc. v. Fintiv, Inc.*, IPR2020-0019, Paper 11 (March 20, 2020) (precedential), the district court litigation is still in an early stage, and trial on issues including the validity of the '541 patent is scheduled to occur in July 2026, many months after the Board's likely 2025 due date for a final written decision if trial is instituted. See Ex-1015 (Scheduling Order). The other *Fintiv* factors would not justify denying institution. The district court's claim construction process is just underway as of the filing of this Petition. By the time of institution, fact discovery may still be ongoing, but expert discovery and pre-trial motions will not have begun.

Discretionary denial is further inappropriate here because this Petition presents compelling evidence of unpatentability. Both the Aspel and Paterno references—which were not of record during prosecution—directly teach most of

the elements of the Challenged Claims. Thus, the *Fintiv* factors do not apply to this proceeding.

B. 35 U.S.C. § 325(d)

The Board should likewise not deny institution under § 325(d) because neither prong of the two-part *Advanced Bionics* framework is satisfied. *See Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper No. 6 at 8 (P.T.A.B. Feb. 13, 2020) (precedential). Under that framework, when evaluating discretionary denial arguments under §325(d), the Board looks to “(1) whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and (2) if either condition of first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.” *Id.* In applying this test, the PTAB considers the six “*Becton, Dickinson*” factors, *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 (P.T.A.B. Dec. 15, 2017) (precedential as to § III.C.5, first paragraph) (“*Becton, Dickinson*”).

Here, the first part of the *Advanced Bionics* test is not satisfied. Neither of the two primary references, Aspel and Paterno, nor the secondary references, Gutekunst, Hanson, and Breen, is cited art. Of the references argued herein, only Valdes was relied upon or discussed substantively in any office action, and the

combinations involving Valdes in the office actions were different from those asserted in this Petition, and directed at only one dependent claim, and cited Valdes for disclosures different from those cited herein. Thus, the arguments presented here involving Valdes are not the same or substantially the same as those previously presented to the office.

Even were the Board to reach the second prong, it is not met. The Petition reflects the examiner's errors in a manner material to the patentability of the Challenged Claims. For example, under *Becton, Dickinson* factor (f), the examiner erred by overlooking at least the materiality of Valdes to the Challenged Claims during examination (other than for one dependent claim) and by failing to consider the specific and meritorious combinations presented in this petition. As demonstrated herein, the combination of Paterno, Hanson and Valdes (where Valdes's relevant disclosures were overlooked by the examiner) renders the Challenged Claims obvious.

X. Conclusion

Petitioner respectfully requests *inter partes* review and cancellation of claims 1-7, 9, 11, 13, and 15-17 of the '541 patent.

Respectfully submitted,

Dated: May 8, 2024

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Petition for *Inter Partes* Review of U.S. Pat. No. 9,801,541

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CERTIFICATION OF WORD COUNT

Pursuant to 37 C.F.R. § 42.24(d), I certify that the foregoing complies with the type-volume limitation of 37 C.F.R. § 42.24 and contains 13,974 words based on the word count indicated by the word-processing system used to prepare the paper, and excluding those portions exempted by § 42.24(a).

Date: May 8, 2014

/Peter P. Chen/

Peter P. Chen

Registration No. 39,631

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.105, I hereby certify that on May 8, 2024, I caused a true and correct copy of the foregoing Petition for *Inter Partes* Review of U.S. Patent No. 9,801,541, supporting exhibits, and Power of Attorney to be served via Priority Mail Express on the Patent Owner at the following correspondence address of record as listed on the USPTO Patent Center:

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