

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

**PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO.
11,213,204 UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.100 *et seq.***

Table of Contents

I.	Introduction.....	1
II.	Standing, Mandatory Notices, and Fee Authorization	2
	A. Grounds for Standing	2
	B. Real Parties-in-Interest.....	2
	C. Related Matters.....	2
	D. Lead and Backup Counsel Information.....	3
	E. Service Information under 37 C.F.R. §42.8(b)(4).....	3
	F. Payment of Fees Under 37 C.F.R. §42.103.....	4
III.	Summary of Challenge	4
IV.	The '204 patent.....	6
	A. Overview of the '204 Patent.....	6
	B. Prosecution History	8
	C. Challenged Claim Listing.....	10
	1. Claim 1	10
	2. Claim 2.....	11
	3. Claim 3	12
	4. Claim 5.....	12
	5. Claim 6.....	12
	6. Claim 7.....	12
	7. Claim 12.....	13
	8. Claim 13	14
	9. Claim 14.....	14

Petition for *Inter Partes* Review of U.S. Pat. No. 11,213,204

10.	Claim 17	14
11.	Claim 18	14
12.	Claim 19	15
V.	Level of Ordinary Skill	15
VI.	Claim Construction	15
VII.	Overview of the Prior Art	17
A.	Gawlick (Ex-1005)	17
B.	Paterno (Ex-1006)	22
C.	Valdes (Ex-1007)	24
D.	Goodnow (Ex-1008)	26
E.	Aspel (Ex-1009)	27
VIII.	Application of Prior Art to the Challenged Claims	28
A.	Ground I: Claims 1-3 and 12-14 Would Have Been Obvious Based on the Combination of Gawlick and Valdes	28
1.	A POSITA Would Have Been Motivated to Combine Gawlick and Valdes with a Reasonable Expectation of Success	29
2.	Independent Claim 1	33
3.	Claim 2	45
4.	Claim 3	46
5.	Independent Claim 12	48
6.	Claim 13	51
7.	Claim 14	52
B.	Ground II: Claims 5-7 and 17-19 Would Have Been Obvious Based on Gawlick in view of Valdes and Goodnow	52

1.	A POSITA Would Have Been Motivated to Combine Gawlick, Valdes, and Goodnow with a Reasonable Expectation of Success	52
2.	Claim 5	54
3.	Claim 6	58
4.	Claim 7	60
5.	Claim 17	60
6.	Claim 18	61
7.	Claim 19	61
C.	Ground III: Claims 7 and 19 Would Have Been Obvious Based on Gawlick in view of Valdes, Goodnow, and Aspel.....	61
1.	A POSITA Would Have Been Motivated to Combine Gawlick, Valdes, Goodnow, and Aspel with a Reasonable Expectation of Success	62
2.	Claim 7	63
3.	Claim 19	64
D.	Ground IV: Claims 1-3 and 12-14 Would Have Been Obvious Based on Paterno in View of Valdes.....	64
1.	A POSITA Would Have Been Motivated to Combine Paterno and Valdes with a Reasonable Expectation of Success	66
2.	Independent Claim 1	68
3.	Claim 2	77
4.	Claim 3	77
5.	Independent Claim 12	77
6.	Claim 13	79

7.	Claim 14.....	79
E.	Ground V: Claims 5-7 and 17-19 Would Have Been Obvious Based on Paterno in View of Valdes and Goodnow	79
1.	A POSITA Would Have Been Motivated to Combine Paterno, Valdes, and Goodnow with a Reasonable Expectation of Success	80
2.	Claim 5.....	81
3.	Claim 6.....	84
4.	Claim 7.....	85
5.	Claim 17.....	86
6.	Claim 18.....	86
7.	Claim 19.....	86
F.	Ground VI: Claims 7 and 19 Would Have Been Obvious Based on Paterno in View of Valdes, Goodnow, and Aspel	86
1.	A POSITA Would Have Been Motivated to Combine Paterno, Valdes, Goodnow, and Aspel with a Reasonable Expectation of Success	87
2.	Claim 7.....	88
3.	Claim 19.....	89
IX.	No Objective Evidence of Nonobviousness	89
X.	Discretionary Denial Is Not Warranted.....	90
A.	35 U.S.C. § 314(a).....	90
B.	35 U.S.C. § 325(d).....	91
XI.	Conclusion	93

LIST OF EXHIBITS

Exhibit	Description
1001	U.S. Patent No. 11,213,204 (the “’204 patent”)
1002	File History for U.S. Patent No. 11,213,204
1003	Declaration of Mr. Lane Desborough
1004	<i>Curriculum Vitae</i> of Mr. Lane Desborough
1005	U.S. Patent Pub. No. 2011/0202495 (“Gawlick”)
1006	U.S. Patent No. 7,301,463 (“Paterno”)
1007	U.S. Patent Pub. No. 2011/0320130 (“Valdes”)
1008	U.S. Patent Pub. No. 2011/0178717 (“Goodnow”)
1009	U.S. Patent Pub. No. 2008/0154099 (“Aspel”)
1010	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)
1011	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)

I. INTRODUCTION

Abbott Diabetes Care Inc. (“Petitioner”) petitions for *inter partes* review seeking cancellation of claims 1-3, 5-7, 12-14, and 17-19 of U.S. Patent No. 11,213,204 (Ex-1001, “’204 patent”), assigned to DexCom, Inc. (“DexCom” or “Patent Owner”).

The ’204 patent relates to methods and systems for caregivers to remotely monitor health characteristics of patients (i.e., hosts), including an “analyte concentration of a host, such as glucose.” Ex-1001, 4:28-34. The ’204 patent acknowledges that by its earliest alleged priority date of December 31, 2012, the following were known in the art: continuous glucose monitoring (“CGM”) systems; devices for remote monitoring generally; and the ability to wirelessly transmit data from one person or device to another. *See generally* Ex-1003, ¶¶41-54.

The ’204 patent’s claimed methods and systems recite little more than using a remote monitor to identify and modify a set of rules for sending (and receiving) alerts based on a host’s analyte data. The limitations are generic and well-known computer operations of remote monitoring systems. There is nothing inventive in such claims—whether independent or dependent. Indeed, several prior art references related to medical management and glucose-monitoring technology expressly teach the generally claimed system for remote monitoring of a host’s

analyte data wherein the remote monitor can modify the default settings it receives from the host device without changing the settings at the host device. The prior art also discloses the specific details of the '204 system's rules and invitation process.

II. STANDING, MANDATORY NOTICES, AND FEE AUTHORIZATION

A. Grounds for Standing

Pursuant to 37 C.F.R. § 42.104(a), Petitioner certifies that the '204 patent is available for IPR, and that Petitioner is not barred or estopped from requesting an IPR challenging the '204 patent on the grounds identified here.

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 '204 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 '204 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 '204 patent is not infringed.

D. Lead and Backup Counsel Information

Petitioner designates the following counsel:

Lead Counsel	Back-Up Counsel
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Pursuant to 37 C.F.R. § 42.10 (b), Petitioner has filed a power of attorney with the above designation of counsel.

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

- **Ground I:** Claims 1-3 and 12-14 would have been obvious based on Gawlick in view of Valdes under 35 U.S.C. § 103.
- **Ground II:** Claims 5-7 and 17-19 would have been obvious based on Gawlick in view of Valdes and Goodnow under 35 U.S.C. § 103.
- **Ground III:** Claims 7 and 19 would have been obvious based on Gawlick in view of Valdes, Goodnow, and Aspel under 35 U.S.C. § 103.
- **Ground IV:** Claims 1-3 and 12-14 would have been obvious based on Paterno in view of Valdes under 35 U.S.C. § 103.
- **Ground V:** Claims 5-7 and 17-19 would have been obvious based on Paterno in view of Valdes and Goodnow under 35 U.S.C. § 103.
- **Ground VI:** Claims 7 and 19 would have been obvious based on Paterno in view of Valdes, Goodnow, and Aspel under 35 U.S.C. § 103.

The '204 patent was filed on June 8, 2017, and claims priority to a provisional application filed on 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.

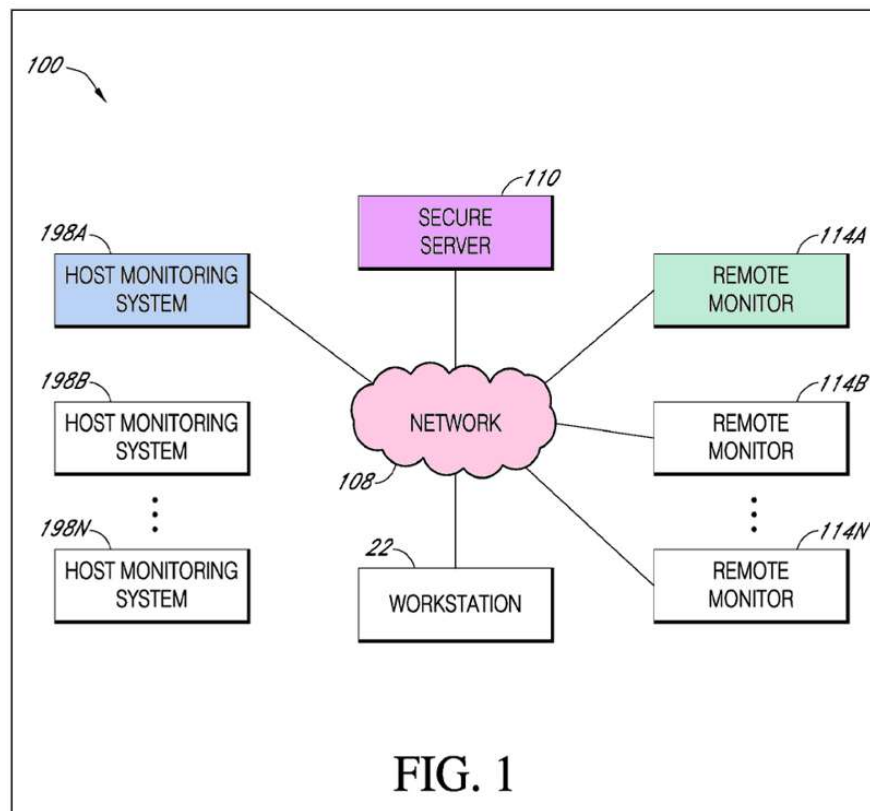
Exhibit	Reference	Date(s)	Availability as Prior Art
Ex-1005	U.S. Patent Pub. No. 2011/0202495 (“Gawlick”)	February 18, 2010 (filed) August 18, 2011 (published)	§§ 102(a), (b), (e)
Ex-1006	U.S. Patent No. 7,301,463 (“Paterno”)	April 13, 2005 (filed) November 27, 2007 (patented)	§§ 102(a), (b), (e)
Ex-1007	U.S. Patent Pub. No. 2011/0320130 (“Valdes”)	June 23, 2011 (filed) December 29, 2011 (published)	§§ 102(a), (b), (e)
Ex-1008	U.S. Patent Pub. No. 2011/0178717 (“Goodnow”)	July 23, 2010 (filed) July 21, 2011 (published)	§§ 102(a), (b), (e)
Ex-1009	U.S. Patent Pub. No. 2008/0154099 (“Aspel”)	November 6, 2007 (filed) June 26, 2008 (patented)	§§ 102(a), (b), (e)

¹ Because the application for the ’204 patent was filed as a continuation of an application that was filed prior to March 16, 2013, the pre-AIA conditions for patentability have been applied.

IV. THE '204 PATENT

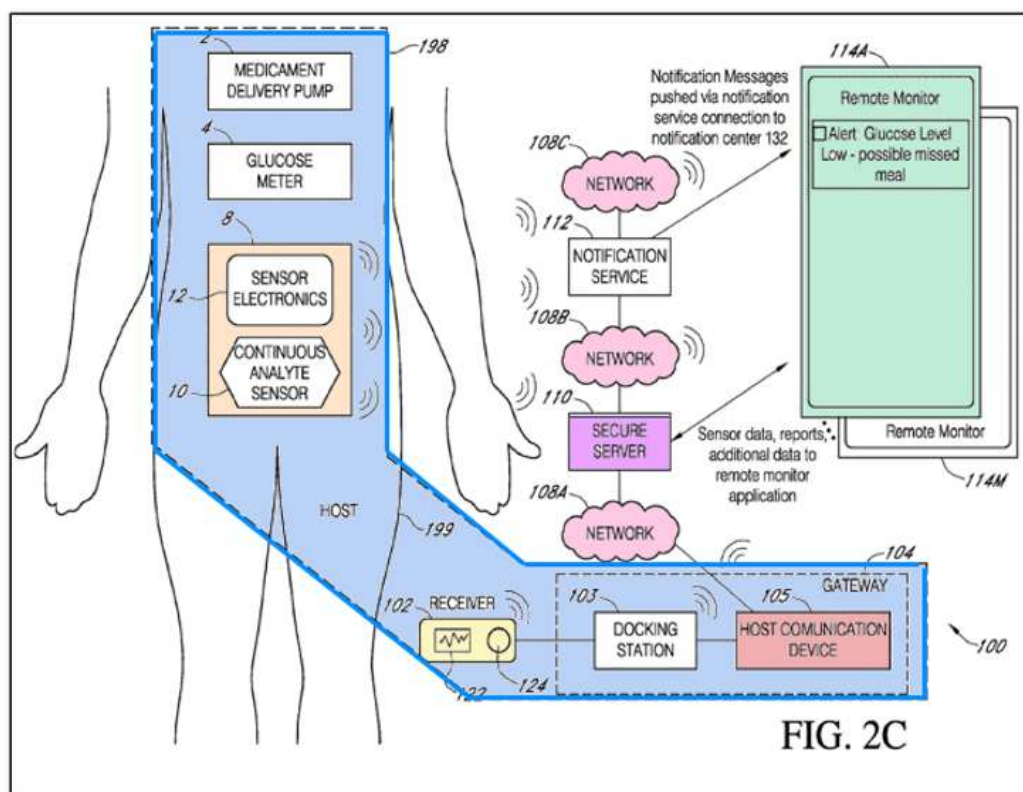
A. Overview of the '204 Patent

The '204 patent is directed to “remote monitoring of analyte data.” Ex-1001, 1:60-62. The patent discusses a “method” for “remote monitoring of analyte data” that “may include receiving, at a remote monitor, a notification message representative of an event detected, by a server, from analyte sensor data obtained from a receiver monitoring an analyte state of a host” and presenting analyte sensor data to the remote monitor. Ex-1001, 1:57-2:4. Figure 1, below, depicts “a high-level system architecture of an implementation of remote monitoring system 100.” Ex-1001, 5:49-50.



Ex-1001, Fig. 1.² Figure 1 includes a plurality of “host monitoring systems 198A-198N connected to a plurality of remote monitors 114A-114M via network 118” and “one or more servers 110 to process the health-related data received from and transmit notifications and data to one or more remote monitors 114A-114M.” Ex-1001, 5:50-53, 5:65-6:5.

Figure 2C depicts a system architecture for an embodiment of remote monitoring system 100, including additional details regarding “host monitoring system 198.” Ex-1001, 3:48-50, 13:37-46; 36:3-12.



² All figure colorization is added by Petitioner.

Ex-1001, Fig. 2C. The “host monitoring system 198” includes a “sensor system 8” attached to “host 199,” Ex-1001, 6:51-63, a “receiver 102,” Ex-1001, 13:43-45, and a “gateway 104” comprising a “docking station 103 and a host communication device 105,”³ Ex-1001, 13:38-41. In this embodiment, “the host communication device 105 is a mobile telephone having a host monitoring application ...” transmitting notifications and data from the receiver to the network and ultimately the remote device. Ex-1001, 13:63-66.

B. Prosecution History

The ’204 Patent was filed as Application No. 15/617,977 (“the ’977 Application”) on June 8, 2017, claiming priority to U.S. Provisional Application No. 61/747,717, filed December 31, 2012. Ex-1001, 1.

After receiving eight examiner rejections over three-plus years, DexCom held an interview on May 20, 2021, during which DexCom “proposed to amend claim 1 with limitations that recite that the modifying of a setting by the remote

³ The Challenged Claims recite a *host device*. The specification refers to the “gateway 104” as including “host device 105,” (e.g., Ex-1001, 22:60-66), sometimes referred to as “host communication device 105,” (e.g., Ex-1001, 13:41-46).

monitor only modifies the setting for the remote monitor.” Ex-1002, 761.

Thereafter, on June 9, 2021, DexCom amended claim 1 as follows:

AMENDMENTS TO THE CLAIMS

1. (Currently Amended) A method comprising:

identifying, by a remote monitor, a set of one or more rules that define conditions for communications between a secure server and the remote monitor, wherein the set of one or more rules are provided to the remote monitor by the secure server and associated with data associated with a receiver configured to monitor an analyte state of a host, ~~and~~ wherein the set of one or more rules are generated according to one or more preferences or settings from a host device, and wherein the host device sets a first setting of the one or more preferences or settings; and

modifying, by the remote monitor, at least one rule of the set of one or more rules wherein the set of one or more rules ~~includes~~ include a first rule defining an alert representative of an event associated with the analyte state of the host, the event being determined by the secure server based on a first measurement of the data associated with the receiver regarding the analyte state of the host at a first time, wherein the alert, when triggered at the first time, causes an alert message to be sent to the remote monitor from the secure server to notify the remote monitor of the event, wherein modifying the at least one rule of the set of one or more rules comprises modifying, by the remote monitor, the first setting set by the host device, and wherein modifying the first setting by the remote monitor modifies the first setting for the remote monitor without changing the first setting at the host device.

Ex-1002, 767.

The Examiner issued a Notice of Allowance on August 30, 2021. Ex-1002, 801-807. Regarding the Reasons for Allowance, the Examiner stated:

In regards to claim 1 and 8, applicant's arguments filed on June 6, 2021, with respect to claim(s) 1 and 8 have been fully considered and are persuasive [see applicant's arguments pg. 8 last paragraph, pg. 9 last paragraph, pg. 10]. Therefore, the claim(s) is/are allowed.

Ex-1002, 806. The referenced "applicant's arguments" read:

Applicant respectfully submits that the cited references, either alone or in combination, do not disclose, teach, or suggest all of the features of currently amended claim 1. For example, the combination of the cited references does not disclose, teach, or suggest: "identifying, by a remote monitor, a set of one or more rules that define **conditions for communications** between a secure server and the remote monitor, wherein the set of one or more rules are provided to the remote monitor by the secure server and associated with the data associated with a receiver configured to monitor an analyte state of a host, wherein the set of one or more rules are generated according to one or more preferences or settings from a host device, and **wherein the host device sets a first setting of the one or more preferences or settings...**" and "modifying, by the remote monitor, at least one rule of the set of one or more rules, wherein the set of one or more rules include a first rule defining an alert ... when triggered at the first

8

time, causes an alert message to be sent to the remote monitor from the secure server to notify the remote monitor of the event, wherein modifying the at least one rule of the set of one or more rules comprises modifying, by the remote monitor, the first setting set by the host device, and wherein modifying the first setting by the remote monitor modifies the first setting for the remote **monitor without changing the first setting at the host device,**" as recited in claim 1.

Ex-1002, 773-774.

C. Challenged Claim Listing

1. Claim 1

1[Pre]	A method comprising:
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1[a]	identifying, by a remote monitor, a set of one or more rules that define conditions for communications between a secure server and the remote monitor,
1[b]	wherein the set of one or more rules are provided to the remote monitor by the secure server and associated with data associated with a receiver configured to monitor an analyte state of a host,
1[c]	wherein the set of one or more rules are generated according to one or more preferences or settings from a host device, and wherein the host device sets a first setting of the one or more preferences or settings; and
1[d]	modifying, by the remote monitor, at least one rule of the set of one or more rules
1[e]	wherein the set of one or more rules include a first rule defining an alert representative of an event associated with the analyte state of the host, the event being determined by the secure server based on a first measurement of the data associated with the receiver regarding the analyte state of the host at a first time,
1[f]	wherein the alert, when triggered at the first time, causes an alert message to be sent to the remote monitor from the secure server to notify the remote monitor of the event,
1[g]	wherein modifying the at least one rule of the set of one or more rules comprises modifying, by the remote monitor, the first setting set by the host device, and
1[h]	wherein modifying the first setting by the remote monitor modifies the first setting for the remote monitor without changing the first setting at the host device.

2. Claim 2

2[a]	The method of claim 1, wherein the at least one rule is the first rule, wherein modifying the first rule comprises varying a first threshold associated with a low level of glucose at the host, and wherein the event being determined by the secure server is further based on the
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	first measurement indicating an analyte measurement that is lower than the first threshold.
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3. Claim 3

3[a]	The method of claim 1, wherein the at least one rule is the first rule, wherein modifying the first rule comprises varying a second threshold associated with a high level of glucose at the host, and wherein the event being determined by the secure server is further based on the first measurement indicating an analyte measurement that is higher than the second threshold.
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4. Claim 5

5[a]	The method of claim 1, further comprising: receiving, at the remote monitor, an invitation to access the secure server and the data associated with the receiver; and
5[b]	providing, from the remote monitor to the secure server, an acceptance to the invitation.

5. Claim 6

6[a]	The method of claim 5, wherein the invitation is associated with a set of recommended rule settings configured by the host device, and wherein the recommended rule settings are provided to the remote monitor for acceptance or modification.
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6. Claim 7

7[a]	The method of claim 5, wherein accepting the invitation, programmatically establishes an account associated with the remote monitor at the secure server.
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7. Claim 12

12[Pre]	An apparatus for remote monitoring of a host's analyte levels, the apparatus comprising:
12[a]	at least one processor; and
12[b]	at least one memory including code, which when executed by the at least one processor causes the apparatus to:
12[c]	identify, by the apparatus, a set of one or more rules that define conditions for communications between a secure server and the apparatus,
12[d]	wherein the set of one or more rules are provided to the apparatus by the secure server and associated with data associated with a receiver configured to monitor an analyte state of a host,
12[e]	wherein the set of one or more rules are generated according to one or more preferences or settings from a host device, and
12[f]	wherein the host device sets a first setting of the one or more preferences or settings; and
12[g]	modify at least one rule of the set of one or more rules,
12[h]	wherein the set of one or more rules include a first rule defining an alert representative of an event associated with the analyte state of the host, the event being determined by the secure server based on a first measurement of the data associated with the receiver regarding the analyte state of the host at a first time,
12[i]	wherein the alert, when triggered at the first time, causes an alert message to be sent to the apparatus from the secure server to notify the apparatus of the event,
12[j]	wherein modifying the at least one rule of the set of one or more rules comprises modifying, by the apparatus, the first setting set by the host device, and

12[k]	wherein modifying the first setting by the apparatus modifies the first setting for the apparatus without changing the first setting at the host device.
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8. Claim 13

13[a]	The apparatus of claim 12, wherein the at least one rule is the first rule, wherein modifying the first rule comprises varying a first threshold associated with a low level of glucose at the host, and wherein the event being determined by the secure server is further based on the first measurement indicating an analyte measurement that is lower than the first threshold.
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9. Claim 14

14[a]	The apparatus of claim 12, wherein the at least one rule is the first rule, wherein modifying the first rule comprises varying a second threshold associated with a high level of glucose at the host, and wherein the event being determined by the secure server is further based on the first measurement indicating an analyte measurement that is higher than the second threshold.
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10. Claim 17

17[a]	The apparatus of claim 12, wherein the code, when executed by the at least one processor further causes the apparatus to: receive an invitation to access the secure server and the data associated with the receiver; and provide an acceptance to the invitation.
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11. Claim 18

18[a]	The apparatus of claim 17, wherein the invitation is associated with a set of recommended rule settings configured by the host device, and wherein the recommended rule settings are provided to the apparatus for acceptance or modification.
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12. Claim 19

19[a]	The apparatus of claim 17, wherein the apparatus is configured to accept the invitation responsive to user input at the apparatus, and wherein accepting the invitation, programmatically establishes an account associated with the apparatus at the secure server.
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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 that 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-1010, 18-20), and DexCom served an Opening Claim Construction Brief, (*see* Ex-1011). Petitioner therein argues that the “rules”/“settings” terms of the ’204 patent are indefinite, but DexCom argues “plain and ordinary meaning.” For the purposes of this proceeding only, and without waiving its argument, Petitioner adopts DexCom’s explanation of “rules”/“settings” from DexCom’s claim construction brief. Ex-1011, 15-18.

The parties also disagree as to the proper construction of claims 7 and 19, i.e., whether account creation must occur automatically. Ex-1010, 19-20; Ex-1011, 18-20. Petitioner shows below that the claims are invalid under both proposed constructions.

VII. OVERVIEW OF THE PRIOR ART⁴

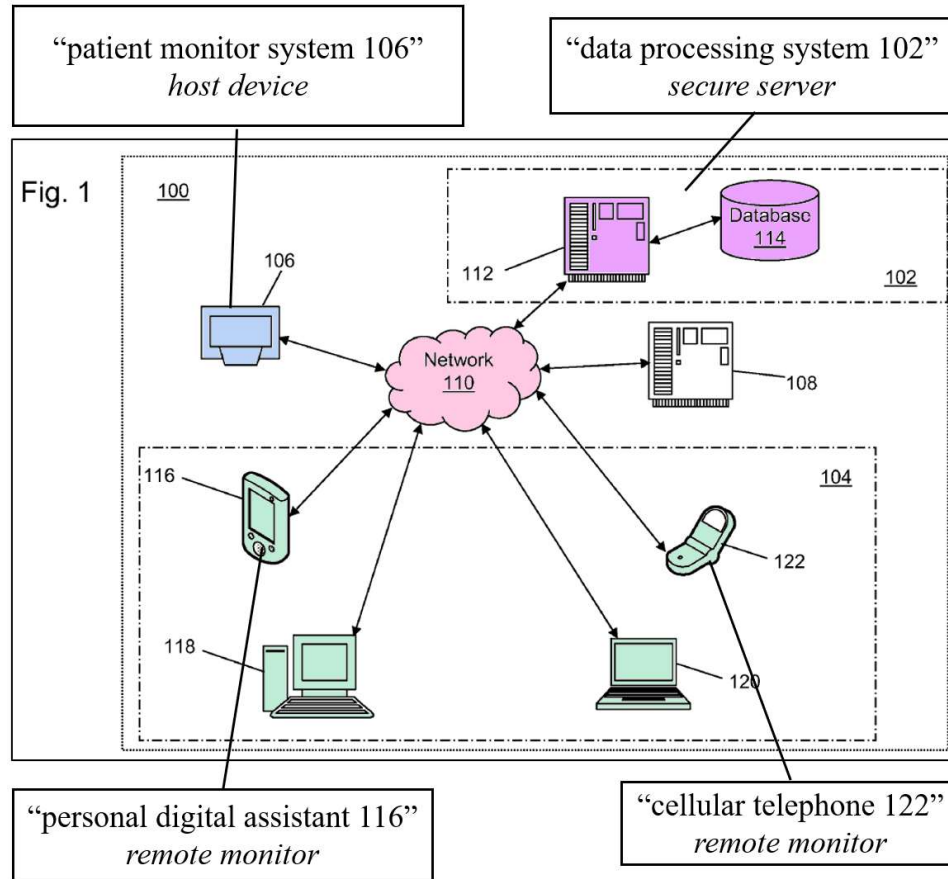
A. Gawlick (Ex-1005)

U.S. Patent Application Publication No. 2011/0202495, titled “Adjustable Alert Rules for Medical Personnel,” to Gawlick (“Gawlick”) was filed February 18, 2010, and published August 18, 2011. Gawlick qualifies as prior art under at least 35 U.S.C. § 102(b).

Gawlick comprehensively discloses a medical alert system and methods for remotely monitoring patient data (including blood glucose data). Gawlick describes system components and functionality to accommodate the unique circumstances of a patient and health care providers. This is reflected in Gawlick’s title and stated purpose, to permit flexibility of alert rules over previous “static” systems that could not be adjusted by patients or caregivers. Ex-1005, [0001]-[0005].

Gawlick’s Figure 1 discloses a medical alert system 100 (claim language in italics).

⁴ Each of the prior art references is analogous art to the ’204 patent, because it is either from the same field of endeavor (e.g., Valdes, Goodnow) or reasonably pertinent to the particular problem purportedly addressed by the ’204 (e.g., Gawlick, Paterno, Aspel). Ex-1003, ¶¶90-95.



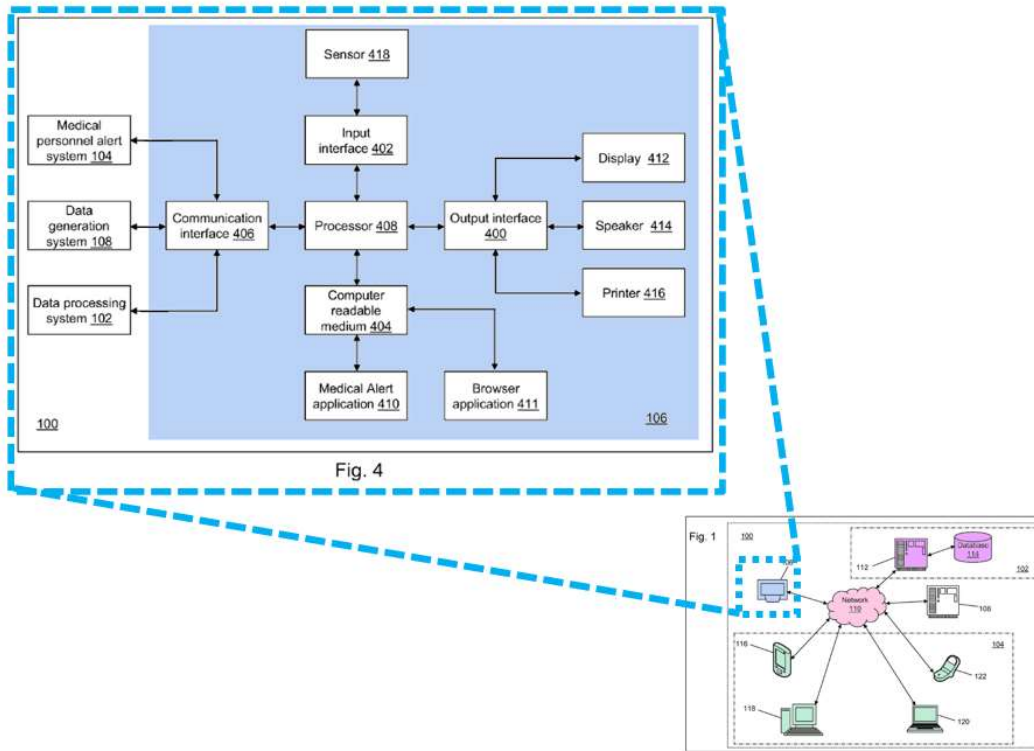
Ex-1005, Fig.1. Medical alert system 100 comprises several subsystems that communicate with each other using “network 110” and perform various functions.

Ex-1005, [0017]. The “data processing system 102” (purple) is a server that collects patient data, stores settings, evaluates rules, and sends alert notifications.

The “patient monitor system 106” (blue) collects data from a patient and sends it to the data processing system, and provides access to the system’s applications. The “medical personnel alert system 104” (green) allows remote caregivers to receive alerts and access the system’s applications using a device such as a cellphone or PDA. Ex-1005, [0017].

Information flow in the system begins at the patient. A sensor “monitors, senses, measures, and/or detects, one or more physiological characteristics of a patient,” including “blood chemistry” and, as shown in the example figures, glucose monitoring. Ex-1005, [0039]. These physiological data are then received by “patient monitor system 106,” which is depicted as a block diagram in Figure 4 below (shown as a call-out from Fig. 1). Ex-1005, [0037]. The “patient monitor system 106” includes “medical alert application 410” and “browser application 411.” Ex-1005, [0037].⁵

⁵ Gawlick explains that the functional blocks in Figure 4 “provide the same or similar functionality as described with reference” to the equivalent block in Figure 2. Ex-1005, [0038]; Ex-1003, ¶67. When explaining Figure 4, the Petition will sometimes cite to relevant explanations regarding Figure 2.



Patient monitoring system 106 provides the data to “[d]ata processing system 102,” which “may include a server computing device 112 and a database 114.” Ex-1005, [0018], [0039]-[0040]. “Server computing device 112” evaluates stored data using “a rules engine” to generate alerts. Ex-1005, [0018]-[0019], [0039]-[0040].

These alerts can be sent to “[m]edical personnel alert system 104,” which includes “one or more computing devices,” for example “a smart phone[.]” Ex-1005, [0020]. Gawlick describes creating, modifying, and receiving alerts using the “one or more computing devices,” including alerts based on blood glucose levels. Ex-1005, Figs. 16-17, [0020], [0086].

636

1600

1504 GENERAL 1506 CARDIAC ARREST 1508 RESPIRATORY FAILURE 1509 RANGES

1604 1 2 3 > LAST

ID	CONDITION
ABG_BE_GUARDED	rtype='ABG_BE' AND (value < -2 OR value > 2)
ABG_BE_SAFE	rtype='ABG_BE' AND (value > = -2 AND value < = 2)
ABG_CA_GUARDED	rtype='ABG_CA' AND (value < 1.1 AND value > 1.3)
ABG_CA_SAFE	rtype='ABG_CA' AND (value > = 1.1 AND value < = 1.3)
ABG_GLUCOSE_CRITICAL	rtype='ABG_GLUCOSE' AND (value < 64 OR value > 160)
ABG_GLUCOSE_GUARDED	rtype='ABG_GLUCOSE' AND (value > 128 AND value < = 140)
ABG_GLUCOSE_SAFE	rtype='ABG_GLUCOSE' AND (value > = 64 AND value < = 128)
ABG_GLUCOSE_SERIOUS	rtype='ABG_GLUCOSE' AND (value > 140 AND value < = 160)
ABG_HCO3_CRITICAL	rtype='ABG_HCO3' AND (value < 14 OR value > 33)
ABG_HCO3_GUARDED	rtype='ABG_HCO3' AND ((value > = 18 AND value < 22) OR (value > 26 AND value < = 30))
ABG_HCO3_SAFE	rtype='ABG_HCO3' AND (value > = 22 AND value < = 26)

1602

1606

1608

1610 1612

FIG. 16

635

1700

GROUP (TIP: LEAVE IN BLANK TO NEW GROUP)

1702 8

PRIORITY

1704 CRITICAL

TYPE

1706 PATIENT UNDER PHYSICIAN

DELAY (TIP: DELAY FORMAT IN DD -HH:MM:SS)

1708

DESCRIPTION

1710

ACTION

1712

OVERRIDES THE FOLLOWING RULES:

1714 ID PRIORITY DESCRIPTION

⊖ 23 CRITICAL ABG: GLUCOSE LEVEL CRITICAL

SEARCH RULES TO OVERRIDE:

1716

1718 ☐ EVALUATE RULE EVERY: 1720 MINUTE 1722

CONDITION (USE < AND > FOR < AND > RESPECTIVELY)

1724

1725 <condition>

<object name='r0'> rtype='ABG_GLUCOSE' AND (value < 64 OR value > 160) </object>

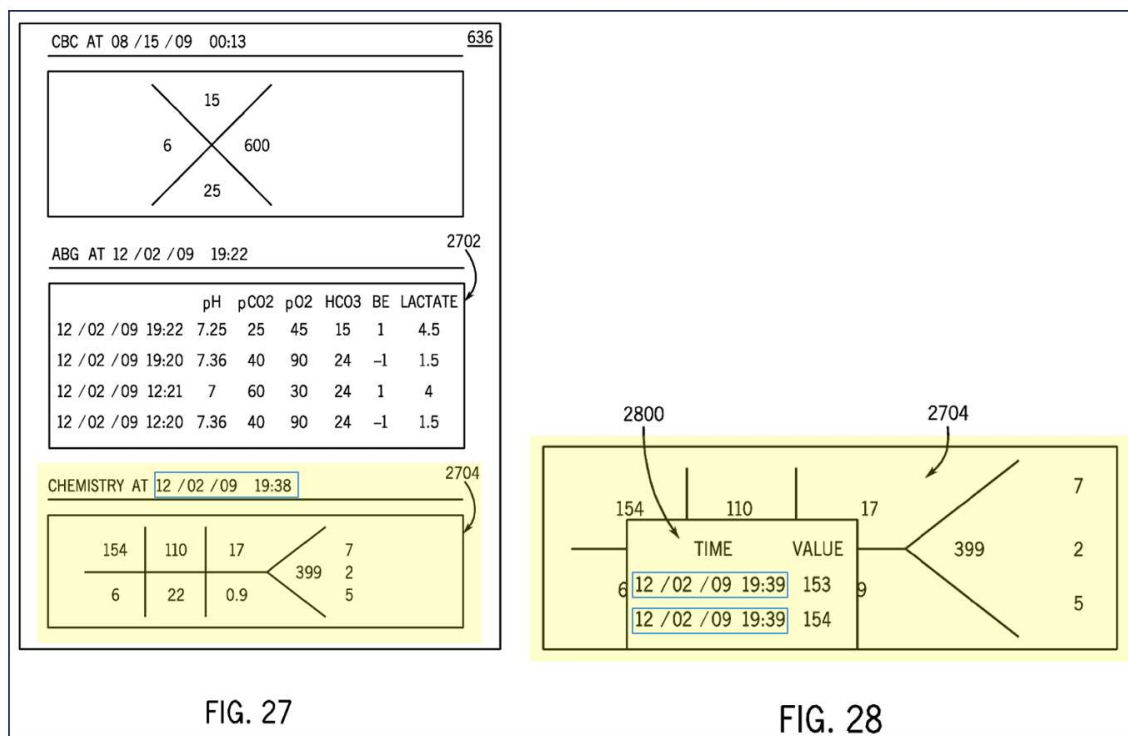
1726

1728

1730 SAVE CANCEL 1732

FIG. 17

The medical alert application includes a “dashboard,” depicted in Figures 27 and 28, showing the results of continuous monitoring of “blood chemistry” including “glucose level.”

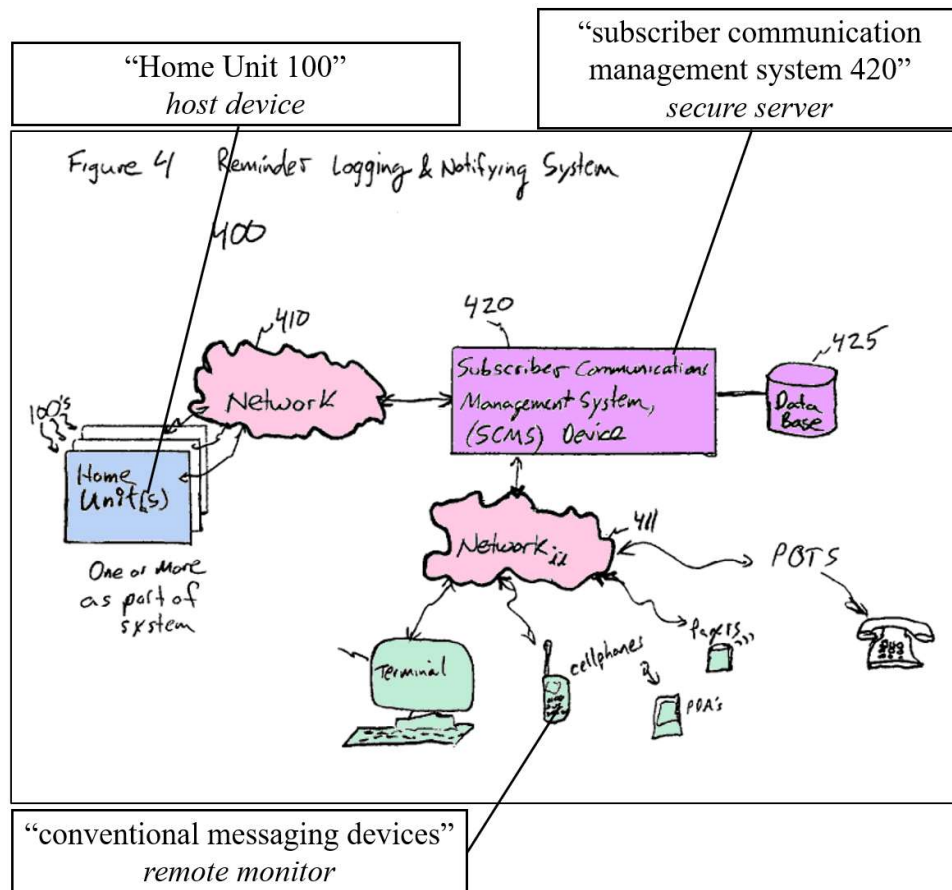


B. Paterno (Ex-1006)

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-1006, 1. 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-1006, 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-1006, 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-1006, 11:19-20.



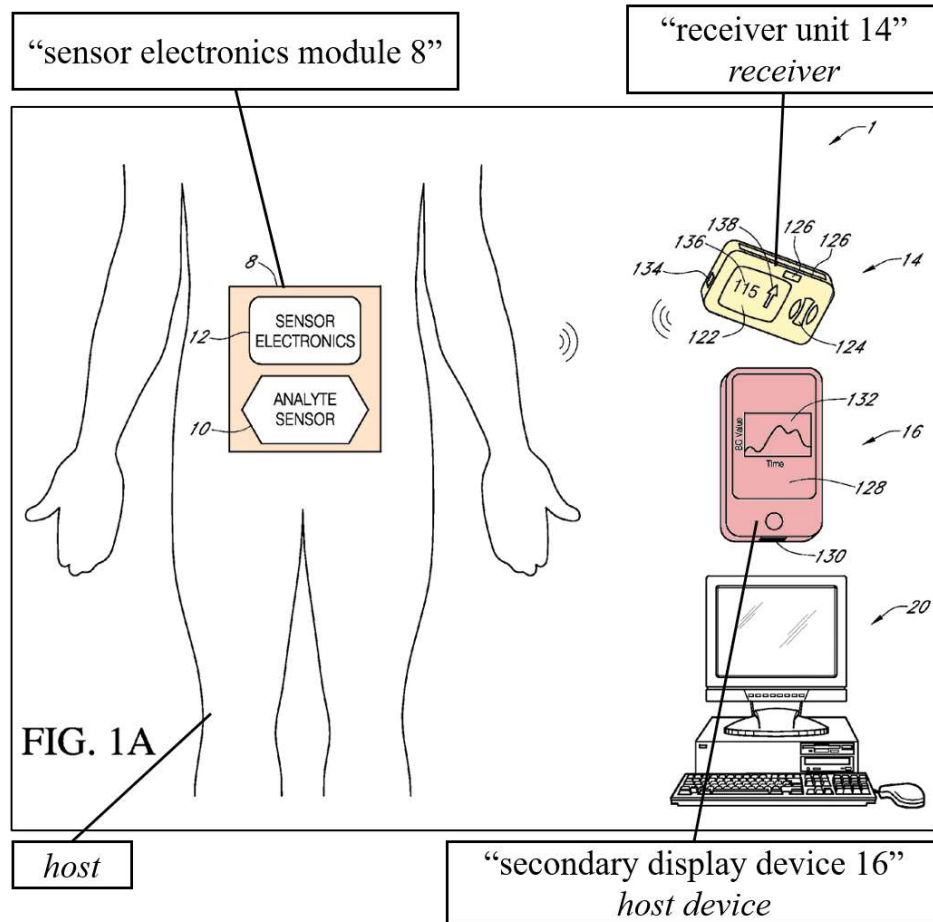
Ex-1006, Fig. 4. The individual can “provide account access to one or more people” (e.g., caregivers) so that they can make changes relating to “sending of messages, alerts, ... and for setting what notifications and messages they will receive from the system[.]” Ex-1006, 3:52-63. Remote caregivers can change their

monitoring parameters, such as “who, how, and when members of a subscriber account are notified of” different events. Ex-1006, 3:41-42, 16:30-17:26.

C. Valdes (Ex-1007)

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-1007, 1. Valdes qualifies as prior art under at least 35 U.S.C. § 102(b). *See also* 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-1007, Abstract, ¶¶ [0002], [0008], [0108]-[0109].



Ex-1007, Fig. 1A.

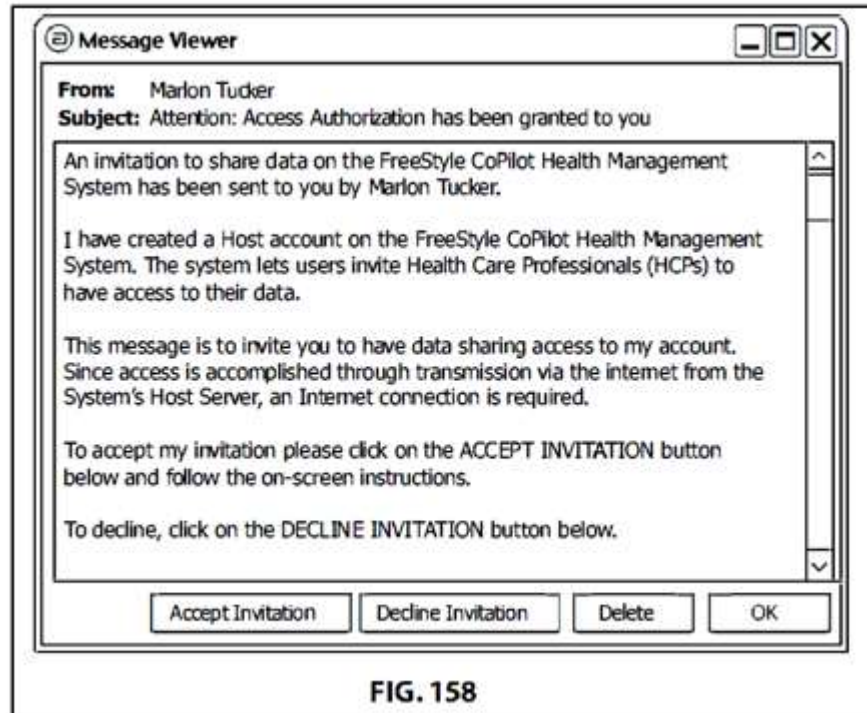
Valdes explains that a “continuous analyte sensor” provides “sensor data” that is “directly related to the measured analyte from an analyte sensor” to a “receiver unit.” Ex-1007, [0062], [0002]. The stand-alone “receiver unit” receives and processes data from the analyte sensor. Ex-1007, [0097]. The “receiver unit” then “wirelessly communicate[s]” with “one or more secondary display devices,” including “a mobile phone” and “a personal computer.” Ex-1007, [0113]. The “secondary display device” can function as a device for use by the host, (Ex-1007, [0098]), or by a third-party caregiver, (Ex-1007, [0157]).

D. Goodnow (Ex-1008)

U.S. Patent Application Publication No. 2011/0178717, titled “Diabetes Care Host-Client Architecture and Data Management System” to Goodnow (“Goodnow”) was filed July 23, 2010, and published July 21, 2011. Ex-1008, 1. Goodnow qualifies as prior art under at least 35 U.S.C. § 102(b).

Goodnow discloses a “software application that enables users to upload, store, and/or analyze glucose readings and other important information for diabetes management.” Ex-1008, [0205]-[0206], [0209]. “For users who want to communicate and share data remotely, the [s]ystem has a host server on the internet that acts as a processing, storage, and routing center for the files of users who choose to use these communication and data access capabilities.” Ex-1008, [0217].

A user can securely synchronize their glucose data with a “Health Care Professional” (“HCP”) by inviting the HCP through the disclosed platform or through email. Ex-1008, [0343]-[0349], [0351]-[0353]. The HCP may choose to accept or decline the invitation. *Id.*



Ex-1008, Fig. 15.

E. Aspel (Ex-1009)

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-1009, 1. Aspel thus qualifies as prior art to the ’204 patent under at least 35 U.S.C. § 102(b).

Aspel discloses a “system for ongoing collection, transmission, storage, analysis, and presentation of physiological and other personal data from individuals” to “authorized system users” like “medical doctors and other Caregivers.” Ex-1009, Abstract. Aspel describes a process for adding new patients to the system. Ex-1009, Figs. 17-18, [0160]-[0161].

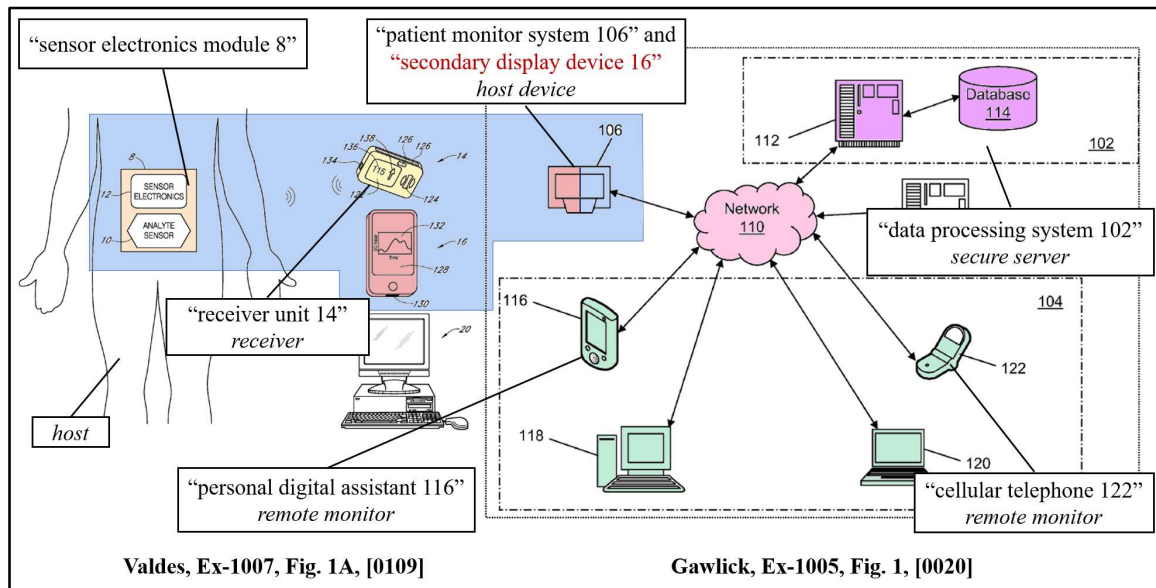
VIII. APPLICATION OF PRIOR ART TO THE CHALLENGED CLAIMS

A. Ground I: Claims 1-3 and 12-14 Would Have Been Obvious Based on the Combination of Gawlick and Valdes

Claims 1-3 and 12-14 would have been obvious based on the combination of Gawlick and Valdes. Gawlick discloses a “medical alert system 100” comprising several subcomponents. The “[m]edical personnel alert system 104” includes “one or more computing devices, ” including “a personal digital assistant 116, a desktop 118, a laptop 120, an integrated messaging device, a cellular telephone 122, a smart phone, a pager, etc.” (*remote monitors*). Ex-1005, [0020].⁶ The system also includes a “data processing system 102” (*secure server*) and a “patient monitor system 106” (*host device*). While Gawlick discloses a system that includes rules for monitoring blood glucose, it does not expressly disclose a CGM *receiver configured to monitor an analyte state of a host*. Valdes expressly discloses a CGM system whose “receiver unit” (*receiver*) receives and processes analyte sensor data. Ex-1007, Abstract, [0059], [0097]. Valdes further discloses a “secondary display device.” Ex-1007, [0177].

⁶ Throughout this Petition, *italics* is used to indicate language from the Challenged Claims.

The annotated figure below illustrates the combination of Gawlick and Valdes. Gawlick's patient monitor system 106 has been shaded partially in red to indicate its capabilities in the combined system to interact with Valdes' "receiver unit" as a "secondary display device." Valdes discloses embodiments in which the receiver would provide data to Gawlick's system. Ex-1007, [0118].



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

Teaching, Suggestion, Motivation

Gawlick discloses glucose measurements as a physiological characteristic and suggests continuous glucose readings. Ex-1005, [0112]-[0113]. Gawlick discloses that "[p]atient monitor system 106 includes one or more electronic devices that continuously, periodically, and/or upon request monitor the physiological characteristics of patients such as ... blood chemistry, etc."

including “glucose level.”⁷ Ex-1005, Fig. 16-17, [0021], [0112]. Gawlick also discloses glucose as one specific physiological characteristic for generating notifications. Ex-1005, Figs. 16,17.

“Patient monitor system 106 **may include a plurality of sensors that use the same or a different sensing/detection technology.**” Ex-1005, [0039].

Gawlick explains that “[d]ifferent and additional components may be incorporated into patient monitor system 106.” Ex-1005, [0037]. Additional sensors to measure “physiological characteristics” enhance monitoring for patients with a specific condition, which aligns with Gawlick’s criticism of static systems that ignore differences between different types of patients. Ex-1005, [0001]. Gawlick discloses exemplary rules for blood glucose monitoring. Ex-1005, Figs. 16-17, [0112]. A POSITA would have readily understood that one such sensor described by Gawlick as using known “sensing/detection technology” is a CGM, as disclosed by Valdes, which is a useful medical device for patients with diabetes mellitus.

Valdes provides an improved method of obtaining “blood glucose” data for use in Gawlick’s system. A POSITA would understand that for patients with diabetes mellitus, a CGM offers advantages, particularly in a monitoring system such as Gawlick. Ex-1003, ¶¶101-04. For example, Valdes explains that when

⁷ All emphasis in quoted text, as indicated by **bold** font, was added by Petitioner.

“time intervals are spread so far apart ... the diabetic will likely find out too late, sometimes incurring dangerous side effects, of a hyperglycemic or hypoglycemic condition.” Ex-1007, [0004].

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

Other Factors and Reasonable Expectation of Success

Combining Gawlick and Valdes would have merely involved combining known prior art elements (i.e., Valdes’s CGM sensor and receiver with Gawlick’s “patient monitor system”) according to known methods to yield predictable results

(i.e., continuous measurement and monitoring of the blood glucose level of a host).

Ex-1003, ¶106. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 415-21 (2007).

Combining Gawlick and Valdes also requires only a simple addition of one known element to a flexible system to obtain a predictable result (i.e., the use of another sensor, already contemplated, with communication capability in a flexible system). Gawlick discloses using various sensors for monitoring a patient. Ex-1005, [0039]. Adding to—or substituting for—one of these sensors for the sensor disclosed by Valdes to continuously monitor the patient's blood glucose level is a simple addition to what is at least suggested by Gawlick. Ex-1003, ¶107. Indeed, Valdes discloses that the receiver can transmit data wirelessly to a secondary display unit. Even if Gawlick's patient monitor system did not include the same wireless communication technology, modifying it to receive the data would require a mere substitution of the data-receiving components of the secondary display unit in Valdes into Gawlick's patient monitor system. Ex-1003, ¶¶107-08.

CGMs, such as Valdes, were known in the art to yield predictable results. Ex-1003, ¶109. In addition, Valdes discloses using well-known “direct wireless communication” protocols to send a “data package” using several standard protocols “including radio frequency, Bluetooth, universal serial bus, any of the wireless local area network (WLAN) communication standards.” Ex-1007, [0092]-[0093]. Gawlick, in turn, states that its “one or more computing devices

communicate using various transmission media that may be ... wireless as known to those skilled in the art,” which would include the communication interfaces used by Valdes. Ex-1007, [0020]. Because the technology used by Valdes was well-known, and in some cases the industry standard, a POSITA would have had a reasonable expectation of success in using routine programming techniques to integrate Valdes’s CGM with Gawlick’s patient monitor system. Ex-1003, ¶109.

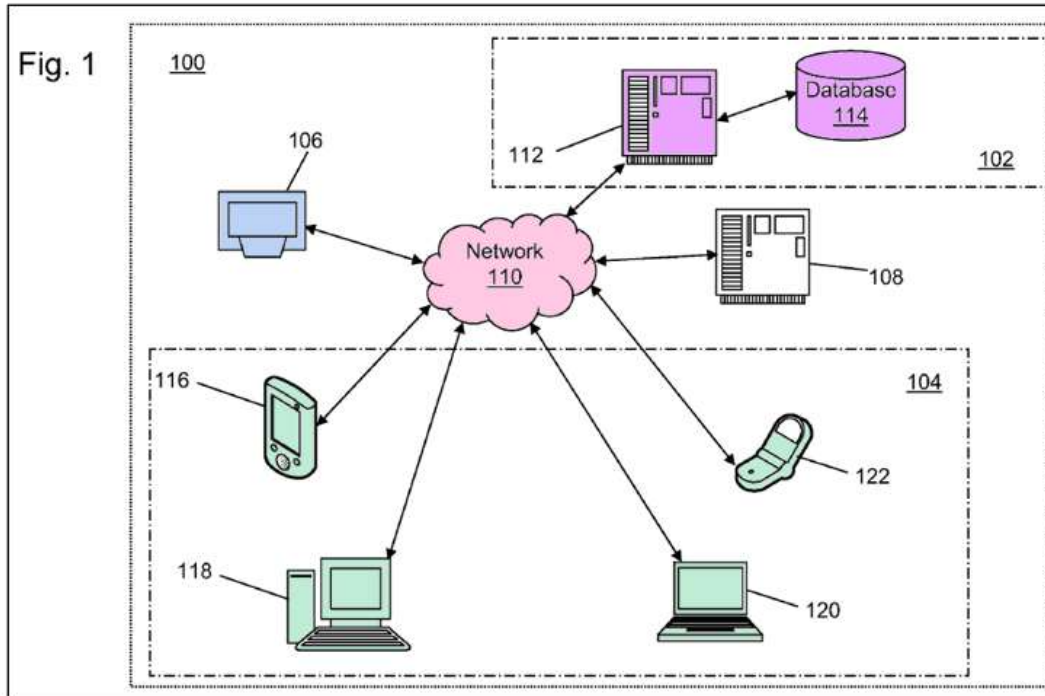
2. Independent Claim 1

a) 1[Pre]: “A method comprising:”

To the extent the preamble is limiting, Gawlick discloses “a method for adjusting an alert rule used to indicate a status of a patient.” Ex-1005, [0006]; Ex-1003, ¶110-11.

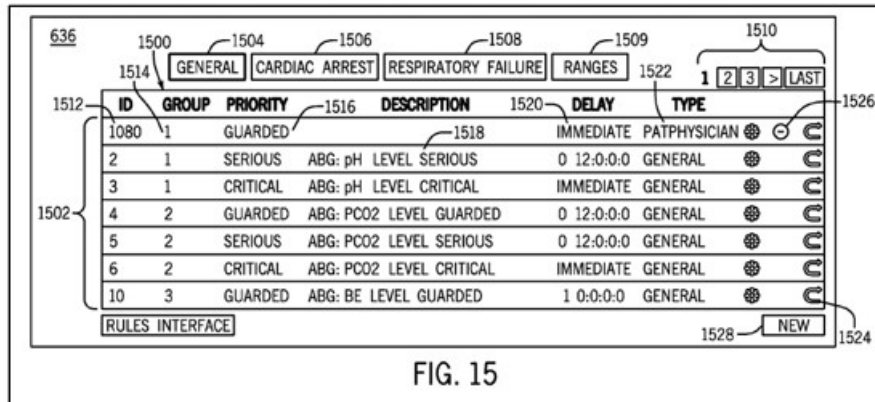
b) 1[a]: “identifying, by a remote monitor, a set of one or more rules that define conditions for communications between a secure server and the remote monitor,”

Gawlick’s medical personnel alert system 104 includes “one or more computing devices” (*remote monitors*). Ex-1005, [0020], [0037]. Gawlick’s system also includes a data processing system 102, comprising server computing device 112 and database 114, which users access using a “username and password.” Ex-1005, [0049], [0059]. Thus, a POSITA would understand the data processing system to be a *secure server*. Ex-1003, ¶¶112-14.



A user of Gawlick’s *remote monitor* identifies a set of one or more rules that define conditions for communications between a secure server and the remote monitor by using an “alert rule list” and associated interfaces. Ex-1003, ¶114.

Gawlick depicts in Figure 15 “an alert rule list 1500 presented under control of browser application 311 in combination with second medical alert application 310 ... at medical personnel alert device 104’.” Ex-1005, [0068]. The alert rules define when alerts are sent from the *secure server* to the *remote monitor*.



- c) 1[b]: “wherein the set of one or more rules are provided to the remote monitor by the secure server and associated with data associated with a receiver configured to monitor an analyte state of a host,”

Gawlick discloses data processing system 102 includes a database 114 that uses a “rules engine.” Ex-1005, [0018]-[0019]. Gawlick’s data processing system stores alert rules in “the alert rules table of database 114” and provides “browser application 311 in combination with second medical alert application 310” (in the *remote monitor*) with the stored “alert rules” (*the set of one or more rules*). Ex-1005, [0068], [0087].

Figure 5 depicts “operations performed using a medical alert application” on a medical personnel alert device. Ex-1005, [0014]-[0015]. Figure 17, below, also depicts *one or more* alert rule settings that the system uses to generate *one or more rules* provided to the *remote monitor*. Ex-1005, [0087]-[0088], [0112]-[0113].

FIG. 17 is a screenshot of a user interface for configuring a rule. The interface is titled "GROUP (TIP: LEAVE IN BLANK TO NEW GROUP)" and contains several input fields and buttons. The fields are labeled with reference numerals: 1702 for the Group field (containing "8"), 1704 for the Priority field (containing "CRITICAL"), 1706 for the Type field (containing "PATIENT UNDER PHYSYSICIAN"), 1708 for the Delay field (containing "DELAY (TIP: DELAY FORMAT IN DD HH:MM:SS)"), 1710 for the Description field, 1712 for the Action field, and 1714 for the Overrides field. The Overrides field contains a table with the following data:

ID	PRIORITY	DESCRIPTION
23	CRITICAL	ABG: GLUCOSE LEVEL CRITICAL

Below the table is a section labeled "SEARCH RULES TO OVERRIDE:" with a search input field (1716). To the right of the search field is a button labeled "EVALUATE RULE EVERY:" (1718) with a dropdown menu (1720) set to "MINUTE" (1722). Below this is a section labeled "CONDITION (USE < and > FOR < AND > RESPECTIVELY)" (1724). The condition editor contains a text area (1725) with the following text:

```
<condition>
<object name='r0'> rtype='ABG_ GLUCOSE' AND (value &lt; 64 OR value &gt; 160) </object>
</condition>
```

The text area is labeled with 1726. Below the text area are two buttons: "SAVE" (1730) and "CANCEL" (1732). The entire interface is labeled with 1700 in the top right corner.

The settings shown above are associated with blood glucose level (*data associated with ... an analyte state of a host*).

Gawlick's system includes a patient monitor system, including recited *host device*, for obtaining data and transmitting it to the data processing system. Ex-1005, [0021]. When combined with Valdes, one of the sources of data is a CGM, which includes a "receiver unit" (*receiver configured to monitor the analyte state of a host*), Ex-1007, Abstract, [0059], and a "continuous analyte sensor" for providing "sensor data" to the receiver unit, Ex-1007, [0062], [0097]. In the Gawlick-Valdes combination, the *rules* implemented by Gawlick's "rules engine," which are *provided to the* "one or more computing devices," are *associated with data associated with Valdes's receiver*. Ex-1003, ¶¶115-21.

It would have been obvious to a POSITA to combine Gawlick's remote monitoring system with the Valdes CGM for at least the reasons explained above and in Section VIII.A.1.

- d) *1[c]: “wherein the set of one or more rules are generated according to one or more preferences or settings from a host device, and wherein the host device sets a first setting of the one or more preferences or settings; and”*

Gawlick discloses a patient monitor system (*host device*) that can be used to configure “an alert rule table 1100” with *preferences or settings* used to generate *the set of one or more rules* for the medical personnel alert devices. The patient monitor system includes, among other things, “a third output interface 400, a third input interface 402, ..., a third medical alert application 410, a second browser application 411, a third display 412 ...” Ex-1005, Fig. 4, [0014], [0037]. These interfaces and applications allow a user to adjust *preferences or settings* using the patient monitor system. Ex-1005, [0038].

These *preferences or settings* are used to generate *one or more rules*, under DexCom's proposed interpretation of settings and rules. Ex-1011, 16-18. For example, Gawlick discloses in Figures 11 and 17, “user interface windows of the medical alert application” that can be accessed from the patient monitor system. Ex-1005, [0014]-[0016]. In Figure 11, “an alert rule table 1100 summarizes a series of alert rule range values for various physiological characteristics in

accordance with an example embodiment.” Ex-1005, [0061]. Figure 17 provides an exemplary “plurality of user interface controls that allow the user to define a new alert rule.” Ex-1005, [0076]-[0087] (explaining the user interface controls).

Ex-1005, Fig. 17 (depicting creation of a rule for “ABG_glucose” values).

Valdes includes additional disclosures of configuring *preferences or settings* for *generating the set of one or more rules*. Valdes’s receiver unit (*receiver*) can be used in combination with a “secondary display device” (Gawlick’s patient monitoring system). Ex-1007, Fig. 4, [0168], [0177]; Ex-1003, ¶¶122-27.

Using the secondary display device, the user may set parameters such as alert/alarm settings (e.g., thresholds). Ex-1007, [0119]. “For example, a hypoglycemic alert may include alert conditions indicating a minimum glucose level.” Ex-1007, [0101]. This is consistent with Gawlick’s disclosure of setting a

first setting of one or more preferences or settings using a patient monitor system.

For example, Figure 17 of Gawlick (shown above), shows a “condition” including glucose thresholds of “64” and “160” mg/dL, which match the glucose thresholds used for alerts in Valdes. Ex-1005, Fig. 17. In the Gawlick-Valdes system, these *preferences or settings* are stored in the data processing system, Ex-1005, [0087], and are used to “trigger actions to alert medical personnel” via the medical alert application in the medical personnel alert device, Ex-1005, [0042].

It would have been obvious to a POSITA to use Gawlick’s patient monitor system to include the functionality to be Valdes’s secondary display device to set hypoglycemic- or hyperglycemic-alert thresholds for at least the reasons explained above and in Section VIII.A.1.

e) *1[d]: “modifying, by the remote monitor, at least one rule of the set of one or more rules”*

Gawlick discloses using a medical alert application on a medical personnel remote device (*remote monitor*) to modify “alert rules,” *at least one rule of the set of one or more rules* set by the patient monitor system (*host device*) for the medical personnel alert devices. Ex-1003, ¶¶128-31. Gawlick explains that “the alert rules are highly customizable such that medical personnel can **create, edit, and delete rules and/or override other existing rules.**” Ex-1005, [0042].

Gawlick discloses that “the user may have logged into ... second medical alert application 310, [t]hus, the information saved through interaction with ...

second medical alert application 310 ... may be associated with the user ...” Ex-1005, [0049]. For example, “**the adjusted alert range values are also associated with the user adjusting the values** based on the account associated with the username and password.” Ex-1005, [0059]. Gawlick explains in detail how to edit an alert rule. For example, “[t]he alert rule window allows the user to adjust the parameters associated with the alert rule.” Ex-1005, [0075].

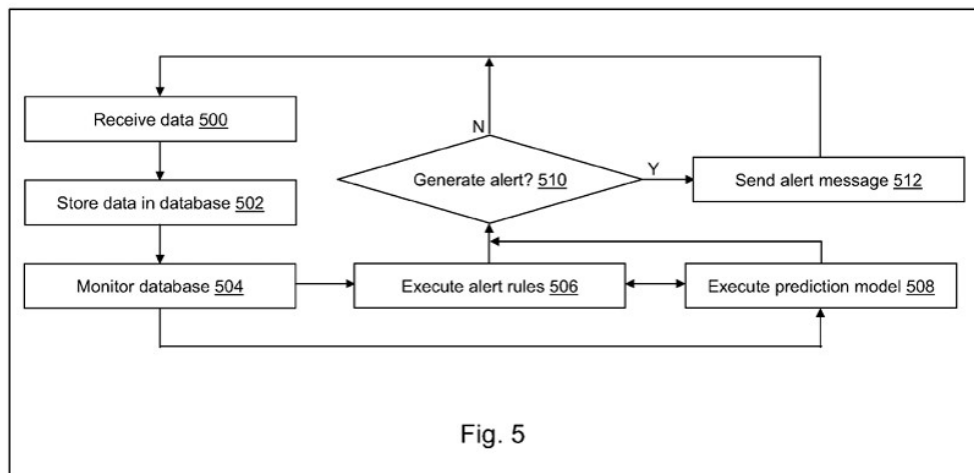
- f) 1[e]: “wherein the set of one or more rules include a first rule defining an alert representative of an event associated with the analyte state of the host, the event being determined by the secure server based on a first measurement of the data associated with the receiver regarding the analyte state of the host at a first time,”

Gawlick Figure 17 depicts a blood glucose alert rule, which is a *first rule* in the set of one or more rules including an alert representative of an event associated with the analyte state of the host. The data processing system (*secure server*) includes a database that stores data, i.e., as received from Valdes’s receiver unit (*receiver*) via the patient monitor system, corresponding to the blood glucose level of the host, or *the analyte state of the host at a first time*. See Section VIII.A.2.c. The data processing system uses this data to “evaluate alert rules,” *the event being determined by the secure server*, to “trigger actions,” i.e., an alert representative of an event associated with the analyte state of the host. Ex-1003, ¶¶132-36.

FIG. 17

Ex-1005, Fig. 17, [0086].

Gawlick discloses that the “alert rule[s] [are] triggered based on receipt of a measured value of a physiological characteristic.” Ex-1005, [0062]. Figure 5 “depicts a flow diagram illustrating example operations performed using medical alert application[.]” Ex-1005, [0015], [0040].



Ex-1005, Fig. 5. “In an operation 506, an alert rule is executed.” Ex-1005, [0042] (the database “evaluates the alert rule or rules and triggers actions to alert medical personnel such as doctors and nurses about a condition of a patient”). It would have been obvious to a POSITA to configure Gawlick’s “alert rules” to set hypoglycemic- or hyperglycemic-alert thresholds based on data received from the Valdes receiver unit for at least the reasons explained above and in Section VIII.A.1.

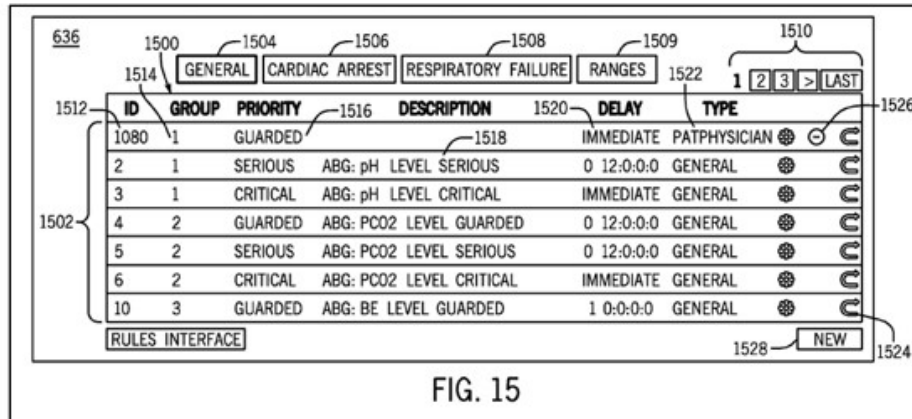
- g) 1[f]: “wherein the alert, when triggered at the first time, causes an alert message to be sent to the remote monitor from the secure server to notify the remote monitor of the event,”

As explained in VIII.A.2.f with reference to Figure 5, Gawlick discloses a process for evaluating data and generating alerts. Ex-1005, [0040]-[0043]; Ex-1003, ¶¶137-38. Gawlick explains that if an “alert is generated,” *when triggered at the first time*, it “may be sent to one or more medical personnel alert device,” i.e., *causes an alert message to be sent to the remote monitor from the secure server to notify the remote monitor of the event*. Ex-1005, [0043].

- h) 1[g]: “wherein modifying the at least one rule of the set of one or more rules comprises modifying, by the remote monitor, the first setting set by the host device, and”

Gawlick discloses using a medical alert application on a medical personnel alert device (*remote monitor*) for *modifying the first setting set by the host device*. Ex-1005, [0014]-[0015]. As explained above, Figure 15 depicts an “alert rule list

1500” that the user may use to access and “adjust the parameters associated with the alert rule.” Ex-1005, [0071], [0075]-[0076].



For example, Gawlick explains that the “[u]pon receipt of an indication of a user selection of save button 1044, the adjusted alert range values are saved for the patient indicated in patient demographic information 604... Thus, the adjusted alert range values may be customized for the patient and/or medical personnel adjusting the alert values.” Ex-1005, [0059]. A POSITA would understand that the “alert rules list” being accessed using the medical personnel alert device (*remote monitor*) corresponds to the “patient indicated in patient demographic information 604.” Ex-1005, [0062]. Thus, Gawlick discloses or renders obvious, either alone or in combination with Valdes, using the *remote monitor*, to modify the *first setting set by the host device* as understood in DexCom’s proposed construction. Ex-1003, ¶¶139-41; Ex-1011, 16-18.

- i) 1[h]: “wherein modifying the first setting by the remote monitor modifies the first setting for the remote monitor without changing the first setting at the host device.”

Gawlick discloses that a medical personnel alert device (*remote monitor*) allows a user to “override the alert rule” (*modify the first setting by the remote monitor*) “so that the modified alert rule is only associated with the user” of the medical personnel alert device. Thus, Gawlick discloses or renders obvious, either alone or in combination with Valdes, that the *remote monitor modifies the first setting for the remote monitor without changing the first setting at the host device*. Ex-1003, ¶¶142-45.

For example, Gawlick discloses that “**the user may only override the alert rule so that the modified alert rule is only associated with the user, and thus, does not effect [sic] the alert rules of other users.**” Ex-1005, [0075]. Gawlick discloses many fields available for user configuration—shown in detail by Figures 17 and 18. Ex-1005, [0079]. “In the example embodiment of FIG. 17, **rule override control 1714 presents a list of one or more alert rules, if any, which are overridden by the new alert rule.**” Ex-1005, [0083].

3. Claim 2

- a) 2[a]: “The method of claim 1, wherein the at least one rule is the first rule, wherein modifying the first rule comprises varying a first threshold associated with a low level of glucose at the host, and wherein the event being determined by the secure server is further based on the first measurement indicating an analyte measurement that is lower than the first threshold.”

As discussed in Sections VIII.A.2.f,h,i above, Gawlick discloses modifying a rule by overriding a setting for a *remote monitor* including by *varying a first threshold associated with a low level of glucose at the host*. For example, Figure 17 includes an “ABG_GLUCOSE_CRITICAL” alert when “ABG_GLUCOSE” is less than a threshold of 64.

The medical alert application allows the medical personnel alert device to modify this threshold. As discussed in above Sections VIII.A.2.f-g, Gawlick’s

“alert rule engine” in the data processing system will trigger this rule when the measured value is lower than the threshold of 64, i.e., *the event being determined by the secure server is further based on the first measurement indicating an analyte measurement that is lower than the first threshold.*

Similarly, Valdes discloses a rule based on “exceeding a hypoglycemia threshold.” Ex-1007, [0017]; *see also* Ex-1007, [0101] (“hypoglycemic alert”). In the Gawlick-Valdes combination, the *remote monitor* would be able to modify this threshold in the same way it can modify the low-glucose threshold disclosed in Gawlick. Ex-1003, ¶¶146-49. It would have been obvious to a POSITA to configure Gawlick’s “alert rules” to set hypoglycemic-alert thresholds based on data received from the Valdes receiver unit, as explained above and in Section VIII.A.1.

4. Claim 3

- a) 3[a]: “The method of claim 1, wherein the at least one rule is the first rule, wherein modifying the first rule comprises varying a second threshold associated with a high level of glucose at the host, and wherein the event being determined by the secure server is further based on the first measurement indicating an analyte measurement that is higher than the second threshold.”

As discussed above in Sections VIII.A.2.f,h,i, above, Gawlick discloses modifying a rule by overriding a setting for a *remote monitor*, including by *varying a second threshold associated with a high level of glucose at the host*. For

example, Gawlick Fig. 17 includes an “ABG_GLUCOSE_CRITICAL” alert when “ABG_GLUCOSE” is greater than a threshold of 160.

FIG. 17

The medical alert application allows the medical personnel alert device to modify this threshold. As discussed above in Sections VIII.A.2.f,g, Gawlick discloses that the “alert rule engine” in the data processing system will trigger this rule when the measured value is greater than the threshold of 160, i.e., *the event being determined by the secure server is further based on the first measurement indicating an analyte measurement that is higher than the second threshold.*

Similarly, Valdes discloses a rule based on “exceeding a hyperglycemia threshold.” Ex-1007, [0017]; *see also* Ex-1007, [0034] (“hyperglycemic event threshold”). In the Gawlick-Valdes combination, the *remote monitor* would be able

to modify this threshold in the same way it can modify the high-glucose threshold disclosed in Gawlick. Ex-1003, ¶¶150-53. It would have been obvious to a POSITA to configure Gawlick’s “alert rules” to set hyperglycemic-alert thresholds based on data received from the Valdes receiver unit, as explained above and in Section VIII.A.1.

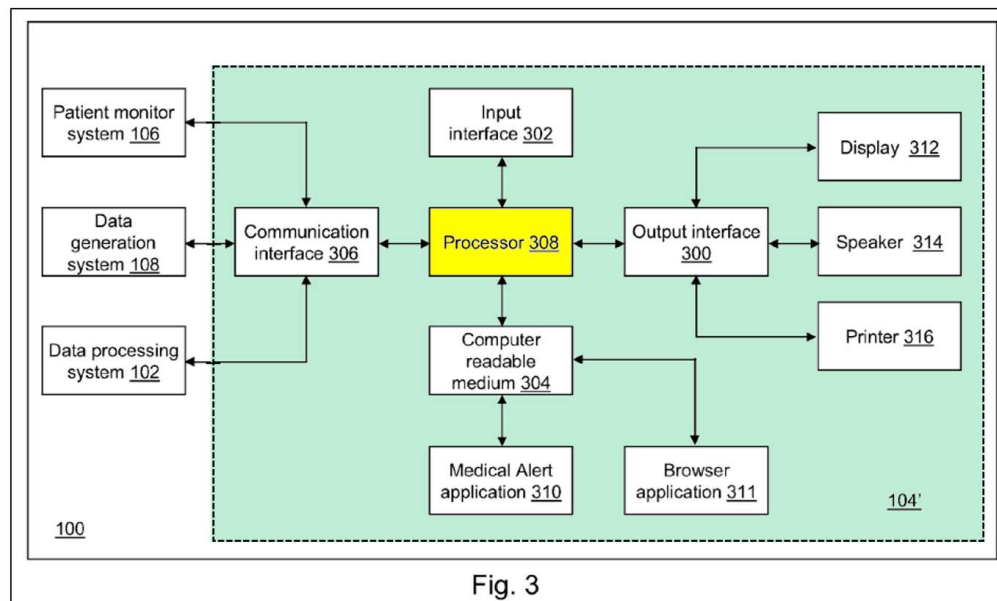
5. Independent Claim 12

- a) 12[Pre]: “An apparatus for remote monitoring of a host’s analyte levels, the apparatus comprising:”

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

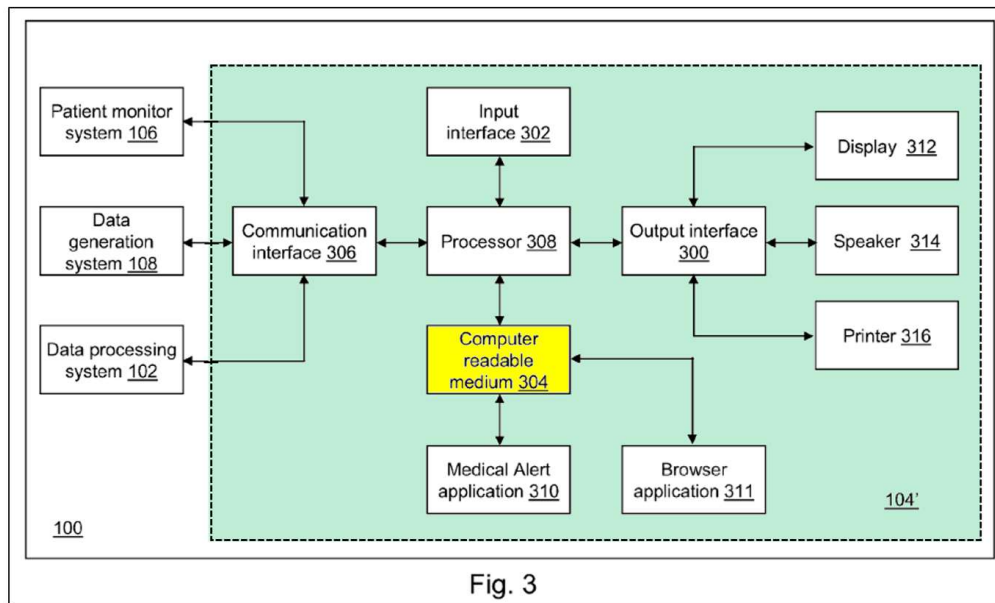
- b) 12[a]: “at least one processor; and”

Gawlick discloses a medical personnel alert device including a “second processor 308” (*at least one processor*). Ex-1005, Fig. 3, [0034]; Ex-1003, ¶¶155-56.



- c) 12[b]: “at least one memory including code, which when executed by the at least one processor causes the apparatus to:”

Gawlick discloses a medical personnel alert device including a “computer readable medium 304” (*at least one memory including code*) that is *executed by the at least one processor*. Ex-1005, Fig. 3, [0034].



Gawlick explains that “computer-readable medium 204 [304] is an electronic holding place or storage for information so that the information can be accessed by processor 208 [308] as known to those skilled in the art. **Computer-readable medium 204 [304] can include, but is not limited to, any type of random access memory (RAM), any type of read only memory (ROM), any type of flash memory, etc. such as magnetic storage devices ... , optical disks ..., smart cards, flash memory devices, etc.**” Ex-1005, [0028]. A POSITA would understand that this explanation applies equally to the “computer-readable medium

304” as expressly referenced by Gawlick, (Ex-1005, [0038]; Ex-1003, ¶159), and that the medical alert application would be implemented as *code* for performing the various operations described by Gawlick when executed by the *processor*. See Ex-1005, [0031]; Ex-1003, ¶¶157-59.

- d) 12[c]: “identify, by the apparatus, a set of one or more rules that define conditions for communications between a secure server and the apparatus,”

See Section VIII.A.2.b.

- e) 12[d]: “wherein the set of one or more rules are provided to the apparatus by the secure server and associated with data associated with a receiver configured to monitor an analyte state of a host,”

See Section VIII.A.2.c.

- f) 12[e]: “wherein the set of one or more rules are generated according to one or more preferences or settings from a host device, and”

See Section VIII.A.2.d.

- g) 12[f]: “wherein the host device sets a first setting of the one or more preferences or settings; and”

See Section VIII.A.2.d.

- h) 12[g]: “modify at least one rule of the set of one or more rules,”

See Section VIII.A.2.e.

- i) 12[h]: “wherein the set of one or more rules include a first rule defining an alert representative of an event associated with the analyte state of the host, the event being determined by the secure server based on a first measurement of the data associated with the receiver regarding the analyte state of the host at a first time,”

See Section VIII.A.2.f.

- j) 12[i]: “wherein the alert, when triggered at the first time, causes an alert message to be sent to the apparatus from the secure server to notify the apparatus of the event,”

See Section VIII.A.2.g.

- k) 12[j]: “wherein modifying the at least one rule of the set of one or more rules comprises modifying, by the apparatus, the first setting set by the host device, and”

See Section VIII.A.2.h.

- l) 12[k]: “wherein modifying the first setting by the apparatus modifies the first setting for the apparatus without changing the first setting at the host device.”

See Section VIII.A.2.i.

6. Claim 13

- a) 13[a]: “The apparatus of claim 12, wherein the at least one rule is the first rule, wherein modifying the first rule comprises varying a first threshold associated with a low level of glucose at the host, and wherein the event being determined by the secure server is further based on the first measurement indicating an analyte measurement that is lower than the first threshold.”

See Section VIII.A.3.

7. Claim 14

- a) 14[a]: “The apparatus of claim 12, wherein the at least one rule is the first rule, wherein modifying the first rule comprises varying a second threshold associated with a high level of glucose at the host, and wherein the event being determined by the secure server is further based on the first measurement indicating an analyte measurement that is higher than the second threshold.”

See Section VIII.A.4.

B. Ground II: Claims 5-7 and 17-19 Would Have Been Obvious Based on Gawlick in view of Valdes and Goodnow

Gawlick discloses a medical alert application requiring users to log into the system using a username and password. Ex-1005, [0049]. Gawlick also explains that different users of its system may have different permissions. Ex-1005, [0059]. But Gawlick does not describe in detail how these disclosed account features would be implemented. Goodnow expressly discloses inviting a new user to access data and how that new user’s account is created. A POSITA would have modified Gawlick’s medical alert application to include Goodnow’s account features. Ex-1005, [0012]-[0016]; Ex-1003, ¶¶171-72.

1. A POSITA Would Have Been Motivated to Combine Gawlick, Valdes, and Goodnow with a Reasonable Expectation of Success

Teaching, Suggestion, Motivation

Gawlick discloses that “[a]s known to those skilled in the art, the user may have logged into [the] medical alert application ... using a user name and

password ... [that] may be associated with an account that is associated with a medical personnel group such as nurse, medical technician, physician, etc. and/or a specific individual.” Ex-1005, [0049]. Gawlick further discloses that different users may have different permissions, e.g., to “adjust the alert values.” Ex-1005, [0059]. Thus, Gawlick assumes a POSITA would understand how to implement these account features.

As of the priority date for the ’204 patent, such features were well-known. Ex-1003, ¶¶173-75. For example, Goodnow discloses creating a “User Profile,” (Ex-1008, Fig. 8, [0222]), and inviting a health care professional to access a patient’s data, (Ex-1008, Fig. 149, [0341]). Goodnow also discloses a compatible access level: “Full Access, which **allows the HCP to view and edit** the data, including event data, **glucose targets**, the user’s prescribed plan, etc.” Ex-1008, [0357].

Other Factors and Reasonable Expectation of Success

Combining Gawlick-Valdes with Goodnow would have required merely combining prior art elements (i.e., Goodnow’s account features with the Gawlick-Valdes remote analyte monitoring system) according to known methods to yield predictable results (i.e., creating new user accounts and inviting those users to share data). Ex-1003, ¶176.

Combining Gawlick-Valdes with Goodnow also would have entailed a simple substitution of one known element for another to obtain predictable results. Gawlick discloses a system requiring usernames/passwords and account permissions. Ex-1005, [0039]. Software systems with user accounts including usernames, passwords, and permissions were pervasive in the prior art. Because the technology disclosed by Goodnow was well-known, a POSITA would have had a reasonable expectation of success in using routine programming techniques to apply Goodnow's account features and invitation protocol with the Gawlick-Valdes system. Ex-1003, ¶177-79.

2. Claim 5

- a) 5[a]: “The method of claim 1, further comprising: receiving, at the remote monitor, an invitation to access the secure server and the data associated with the receiver; and”

As explained above for claim 1, Gawlick discloses a medical alert application that is accessible at a medical personnel alert system, and a data processing system including a database for storing data, such as data from the patient monitor system. The combination of Gawlick and Valdes would result in data from Valdes's “receiver unit,” or *data associated with the receiver*, being sent to the data processing system. Gawlick does not describe the process for inviting a new user to access this information, but Goodnow discloses the process of sending

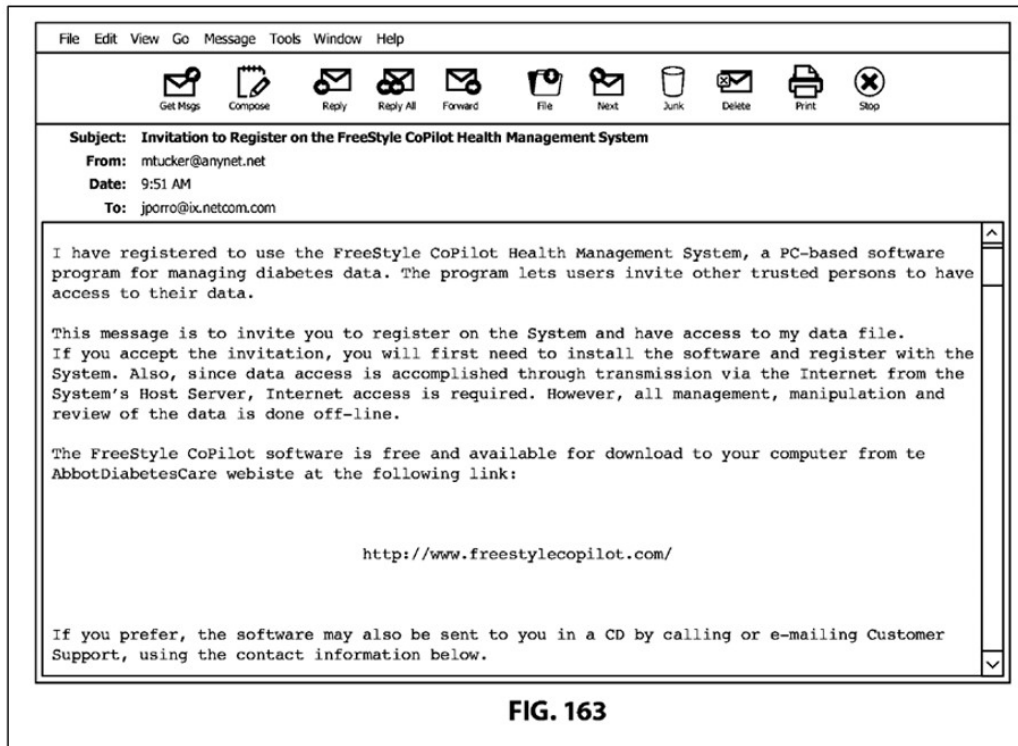
an invitation to access the secure server and the data associated with the receiver.

Ex-1003, ¶¶180-84.

Specifically, Goodnow discloses that “a user receives an e-mail invitation to share data.” Ex-1008, [0354]. The Gawlick medical personnel alert system includes “one or more computing devices” including “a personal digital assistant 116, a desktop 118, a laptop 120, an integrated messaging device, a cellular telephone 122, a smartphone, a pager, etc.” Ex-1005, [0020], [0037]. A POSITA would understand that these *remote monitors* would be used for *receiving* the email invitation disclosed by Goodnow. Ex-1003, ¶181.

Goodnow explains that “[o]nce the user (Home or HCP) sets up a Host Account, **he or she can authorize one or more HCPs to have access to the data. To do this, the user can initiate an ‘invitation’ to the HCP to share data via the Host.**” Ex-1008, [0341]. For example, “[f]rom the Host menu on the main menu bar, the user can choose Invite to Share Data. FIG. 148 illustrates an Invite to Share Data (Home User Screen, left; HCP User Screen, right).” Ex-1008, [0343]. Goodnow also explains how to set permissions for the HCP. “FIG. 151 illustrates an Assign Access Level Screen. **The user can select Read-Only Access or Full Access (Read and Enter Data), and then click Submit.** The Host then displays the Process Complete screen and sends an invitation to share data to the HCP.” Ex-1008, [0345].

Goodnow describes how the user of the (impending) *remote monitor* receives their e-mail invitation. “When a **user receives an e-mail invitation to share data**, the message will instruct the user to ... set up a user profile, and synchronize with the Host and set up a Host Account.” Ex-1008, Fig. 163, [0354].

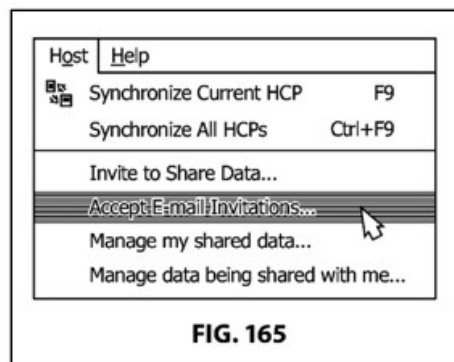


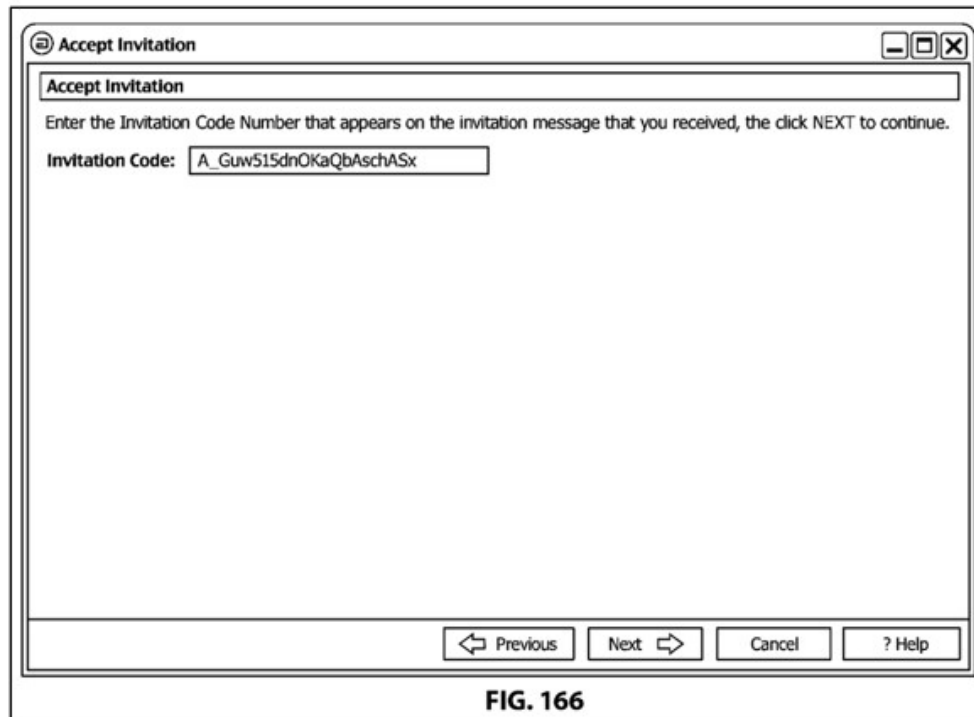
A POSITA would have combined Goodnow with the Gawlick-Valdes system to implement account features for at least the reasons described above in Sections VIII.B.1 and VIII.A.1.

b) 5[b]: “providing, from the remote monitor to the secure server, an acceptance to the invitation.”

Goodnow discloses that the user can choose to “Accept E-Mail Invitation” by entering an “invitation code” for the server, i.e., *providing, from the remote*

monitor to the secure server, an acceptance of the invitation. Goodnow also discloses that the user “can set up a user profile and register with the Host. **From the Host drop-down box on the main menu bar, the user can choose Accept E-Mail Invitation.** FIG. 165 illustrates a HCP: Host Drop-Down List. The system connects to the Host server and the screen illustrated at FIG. 166 displays. The user can enter the Invitation Code in the box provided and click Next. The Host then synchronizes with the user’s system, and the patient’s data is downloaded.” Ex-1008, [0355]; Ex-1003, ¶¶185-187.





A POSITA would have combined Goodnow with Gawlick-Valdes for at least the reasons described above in Sections VIII.B.1 and VIII.A.1.

3. Claim 6

- a) 6[a]: “The method of claim 5, wherein the invitation is associated with a set of recommended rule settings configured by the host device, and wherein the recommended rule settings are provided to the remote monitor for acceptance or modification.”

As explained above in Section VIII.A.2.d, Gawlick discloses *a set of recommended rule settings* associated with a particular patient and configured using a patient monitor system (including the recited *host device*). In Gawlick’s system, the user of the medical personnel alert system sees these *recommended rule settings* in an “alert rule list,” as explained above in Section VIII.A.2.b. The

user of the *remote monitor* can *accept* or *modify* these rule settings, as explained in Sections VIII.A.2.e,h,i. A POSITA would understand that Goodnow's invitation protocol, is thus *associated with a set of recommend rule settings configured by the host device*.

Goodnow describes an invitation to access the patient's "data," including the patient's "glucose targets," or *rule settings configured by the host device*. For example, Goodnow discloses that "[t]he user can choose ... [to] Grant Read-Only Access, which restricts the HCP to viewing your data, or Grant Full Access, which allows the HCP to view and edit the data, including event data, glucose targets, the user's prescribed plan, etc." Ex-1008, [0357]. Goodnow discloses that accepting the invitation would result in synchronizing this "data." Ex-1008, [0355]-[0357]. Thus, a POSITA would understand that Goodnow's invitation protocol is associated with *a set of recommend rule settings configured by the host device*. Ex-1003, ¶¶188-90. A POSITA would have combined Goodnow with Gawlick-Valdes for at least the reasons described above in Sections VIII.B.1 and VIII.A.1.

4. Claim 7

- a) 7[a]: “The method of claim 5, wherein accepting the invitation, programmatically establishes an account associated with the remote monitor at the secure server.”

Gawlick in view of Valdes and Goodnow renders this limitation obvious under DexCom’s proposed construction of “programmatically” in which the establishment of the remote monitor user’s account need not occur automatically or without user intervention. Ex-1011, 18-20. Goodnow discloses a process for accepting an invitation by choosing “Accept E-Mail Invitation” (Fig. 165) and entering “the Invitation Code in the box provided and click[ing] Next” (Fig. 166). Ex-1008, [0355]. “The Host then synchronizes with the user’s system, and the patient’s data is downloaded.” Ex-1008, [0355]; Ex-1003, ¶¶191-92. A POSITA would have combined Goodnow with Gawlick and Valdes for at least the reasons described above in Sections VIII.B.1 and VIII.A.1.

5. Claim 17

- a) 17[a]: “The apparatus of claim 12, wherein the code, when executed by the at least one processor further causes the apparatus to: receive an invitation to access the secure server and the data associated with the receiver; and provide an acceptance to the invitation.”

See Section VIII.B.2.

6. Claim 18

- a) 18[a]: “The apparatus of claim 17, wherein the invitation is associated with a set of recommended rule settings configured by the host device, and wherein the recommended rule settings are provided to the apparatus for acceptance or modification.”

See Section VIII.B.3.

7. Claim 19

- a) 19[a]: “The apparatus of claim 17, wherein the apparatus is configured to accept the invitation responsive to user input at the apparatus, and wherein accepting the invitation, programmatically establishes an account associated with the apparatus at the secure server.”

See Section VIII.B.4.

C. Ground III: Claims 7 and 19 Would Have Been Obvious Based on Gawlick in view of Valdes, Goodnow, and Aspel

Claims 7 and 19 would also have been obvious based on Aspel’s teachings modifying Gawlick in view of Valdes and Goodnow, under Petitioner’s proposed construction of “programmatically” (i.e., automatically, without user log in or other intervention). Ex-1010, 19. As explained above, Gawlick does not describe in detail how its account features would be implemented, and Goodnow discloses inviting a new user to access data and how that new user’s account would be created. Aspel provides additional disclosure about automatically creating a new user account, including creating the username and password. A POSITA would have used Aspel’s disclosures to implement some of the account features discussed

in Gawlick and Goodnow by modifying the medical alert application. Ex-1005, [0012]-[0016]; Ex-1003, ¶196.

1. A POSITA Would Have Been Motivated to Combine Gawlick, Valdes, Goodnow, and Aspel with a Reasonable Expectation of Success

As explained above, the Gawlick-Valdes-Goodnow system includes well-known account features. Ex-1003, ¶197. While Goodnow's teachings provide details regarding account features, Aspel discloses creating a username and password automatically for a new account in a healthcare monitoring system that includes "Glucose Alerts." Ex-1009, Figs.17A-C, [0151]-[0159].

Other Factors and Reasonable Expectation of Success

Combining Gawlick-Valdes-Goodnow with Aspel would have merely combined prior art elements (i.e., Aspel's username and password creation with the Gawlick-Valdes-Goodnow remote analyte monitoring system) according to known methods to yield predictable results (i.e., creating a username and password automatically for a remote analyte monitoring system). Ex-1003, ¶198.

The combination also would entail a simple substitution of one known element for another to obtain predictable results. As explained above, Gawlick-Valdes-Goodnow render obvious a remote analyte monitoring system having usernames and passwords. Because the technology disclosed by Aspel was well-known, a POSITA would have had a reasonable expectation of success using

routine programming techniques to apply Aspel's username and password creation features with the Gawlick-Valdes-Goodnow remote monitoring system. Ex-1003, ¶199.

2. Claim 7

- a) 7[a]: "The method of claim 5, wherein accepting the invitation, programmatically establishes an account associated with the remote monitor at the secure server."

As explained above for claim 5, Section VIII.B.2, Goodnow discloses a process for establishing an account, including a username and password, by receiving and accepting an invitation. Ex-1008, [0355]. It would have been obvious to a POSITA for the user's account to alternatively be established automatically, i.e., *programmatically*, for the convenience of the user. Ex-1003, ¶¶200-02. For example, Aspel discloses a new patient form. Ex-1009, Figs. 17A-C, [0151]-[0160]. Once the form is created, "a confirmation" is shown to the user, as depicted in Figure 18. Ex-1009, [0161]. Figure 18 provides "confirmation ... the new record was created, and reiterates the username and password." Ex-1009, [0161]. A POSITA would recognize that the displayed "Username:" and "Password:" were programmatically (automatically) created, and to maintain an efficient system, the account would be created only after an invitation was accepted. Ex-1003, ¶201. Thus, Goodnow's new user form would be modified to omit the username and password fields.

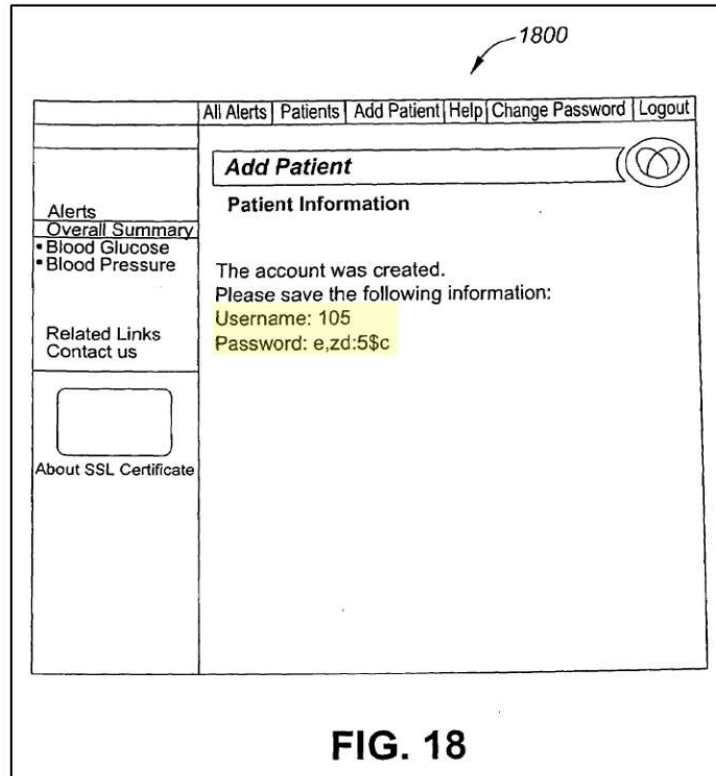


FIG. 18

A POSITA would have combined Aspel with Gawlick-Valdes-Goodnow for at least the reasons described above in Sections VIII.C.1, VIII.B.1, and VIII.A.1.

3. Claim 19

- a) 19[a]: “The apparatus of claim 17, wherein the apparatus is configured to accept the invitation responsive to user input at the apparatus, and wherein accepting the invitation, programmatically establishes an account associated with the apparatus at the secure server.”

See Section VIII.C.2.

D. Ground IV: Claims 1-3 and 12-14 Would Have Been Obvious Based on Paterno in View of Valdes

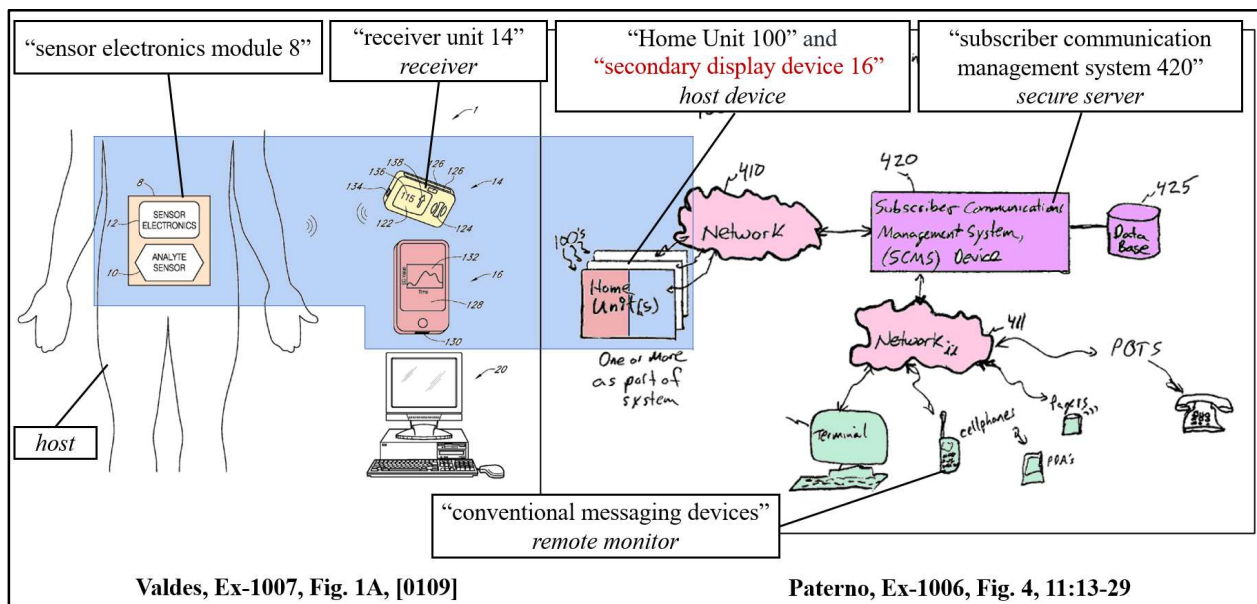
Claims 1-3 and 12-14 would have been obvious based on Paterno in view of Valdes. As described in Section VII.B, Paterno discloses a remote monitoring

system including a “Home Unit” (including a *host device*) at a user’s/patient’s location for providing reminders and logging and an SCMS (*secure server*).

Paterno discloses that data could be obtained from “one or more input devices, which can be within the unit or external to it,” (Ex-1006, 4:22-40), and explains benefits of “captur[ing] valuable data on the health of the individuals[,]” (Ex-1006, 13:48-51). Valdes discloses a system including a “receiver unit” (*receiver*), an analyte sensor, and a “secondary display device.” Ex-1007, [0059], [0097], [0177].

The figure below illustrates the combination of Paterno in view of Valdes.

Paterno’s “Home Unit” has been shaded partially in red to indicate that in the combined Paterno-Valdes system, the modified “Home Unit” would include capabilities to interact with the Valdes “receiver unit” as a “secondary display device.” Ex-1003, ¶¶204-06.



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

Teaching, Suggestion, Motivation

Paterno discloses that “Home Unit(s) 100 are part of a reminding, logging and notification system ...” Ex-1006, 6:6-10. Paterno further discloses “[m]onitoring devices and systems exist that can provide in home monitoring of critical health parameters **such as blood sugar** ...” could be incorporated in a monitoring system to “greatly aid in healthcare management of people with chronic illnesses.” Ex-1006, 1:46-50. Paterno discloses “[t]he SCMS 7000 ... can support numerous data analysis and reporting tools for the information collected by the Home Units, CPTBs [(“Care Provider Tracking Boxes”)], and connected communications tools of the account group members.” Ex-1006, 15:17-27. Paterno refers to monitoring blood sugar (Ex-1006, 1:46-48), but does not explicitly disclose incorporating a “blood sugar” sensor.

A POSITA, however, would have understood that a sensor would be needed to provide in home monitoring of “blood sugar” and that one way to monitor “blood sugar” is with a CGM, as disclosed by Valdes. Ex-1003, ¶¶207-09. As noted in Section VIII.A.1, a POSITA would understand that for patients with diabetes mellitus, a CGM offers several advantages over other types of “blood sugar” monitoring. *See* Ex-1007, [0004]. Thus, a POSITA would understand the

benefits of combining the CGM, and associated predetermined events, disclosed by Valdes, with the monitoring system disclosed by Paterno. Ex-1003, ¶209.

Other Factors and Reasonable Expectation of Success

Combining Paterno and Valdes would have involved merely combining prior art elements (i.e., adding Valdes's CGM to Paterno's remote monitoring system) according to known methods to yield predictable results (i.e., remote monitoring of continuous measurements of the blood glucose level of a host). Ex-1003, ¶210. *KSR Int'l Co.*, 550 U.S. at 415-421.

Continuous glucose monitors, such as Valdes, were well-known in the art to yield predictable results. In addition, Valdes discloses using “direct wireless communication” protocols to send a “data package” using several standard protocols “including radio frequency, Bluetooth, universal serial bus, any of the wireless local area network (WLAN) communication standards.” Ex-1007, [0092]-[0093]. Paterno, in turn, describes communication by “wireless means” or a “wireless network” throughout. *See, e.g.*, Ex-1006, 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 routine programming techniques to integrate Valdes's CGM with Paterno's “Home Unit” for use in Paterno's monitoring system. Ex-1003, ¶211.

2. Independent Claim 1

a) 1[Pre]

Paterno discloses “[a]n Assisting and Monitoring method and system for compliance logging and monitoring system. . .” Ex-1006, 1:66-2:4; Ex-1003, ¶¶212-13.

b) 1[a]

Paterno discloses “conventional messaging devices” (*remote monitors*) that communicate with an SCMS (*secure server*). Ex-1006, 11:13-16. “The SCMS is a computer based system with an internal or external database 425, and it **communicates over wired and/or wireless network(s) 411, with the conventional messaging devices of the caregivers** associated with the Home Unit (reminder & logging) system subscribers.” Ex-1006, 11:16-21. The SCMS includes “account record[s]” with subscriber and other information and provides such **“configuration options through a convenient interface, for example an Internet Portal, ...”** Ex-1006, 3:63-66. A POSITA would thus understand that Paterno’s SCMS, which includes security permissions in the “account record,” is a *secure server*. Ex-1003, ¶¶214-17.

The SCMS provides “conventional messaging devices” with interfaces to allow programming of the Home Unit (*host device*) including an online “Internet web form.” Ex-1006, 3:63-66, 11:27. The SCMS “provides convenient method(s) of updating event schedules, messages, reminder parameters, reminder contents,

and operational parameters of the Home Units,” i.e., *a set of one or more rules that define conditions for communications between a secure server and the remote monitor*. Ex-1006, 15:21-24. A POSITA would understand that modifying these “profile records,” such as “notification parameters 9060” in Figure 14, would require the user *identifying the set of one or more rules* under DexCom’s suggested construction. Ex-1003, ¶216.

The “conventional messaging devices of the caregivers” include cellphones and PDA’s. Ex-1006, Fig.4. Paterno discloses that the conventional messaging devices use the SCMS interface to identify and modify “profile records” including “Event Schedules 9020 (and any other parameters).” Ex-1006, 17:63-66. The “profile records 9000” are used by the SCMS to “determine[] when, how and what notification messages should be delivered to each member or integrated service system of each subscriber account ...” Ex-1006, 16:34-39.

c) 1[b]

Paterno discloses that the conventional messaging devices access rules that are provided by the SCMS via an “Internet Portal,” thus, the *set of one or more rules are provided to the remote monitor by the secure server*. Ex-1006, 15:38-62.

Paterno does not expressly disclose rules *associated with data associated with a receiver configured to monitor an analyte state of a host*. Valdes discloses a “continuous analyte sensor” for providing “sensor data ... related to the measured

analyte from an analyte sensor” to a receiver unit (*receiver*) to *monitor an analyte state of a host*. Ex-1007, [0059],[0062],[0097]. In the Paterno-Valdes combination, Paterno monitors a host’s “blood sugar” through Valdes’s sensor and receiver unit, with the host’s “profile” including “notification parameters,” *rules*, for alerting *remote monitors* based on the host’s blood sugar levels. Ex-1003, ¶¶218-22.

A POSITA would have combined Paterno and Valdes for at least the reasons explained above and in Section VIII.D.1.

d) 1[c]

Paterno discloses that “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 ...” Ex-1006, 3:57-63. Paterno does not describe the specific glucose alert conditions described by Valdes.

A POSITA would understand that the Paterno-Valdes combination would implement Paterno’s Home Unit to include capabilities of a Valdes secondary display device used to modify glucose alert conditions, i.e., *one or more preferences or settings*. Valdes discloses that the user may set user parameters such as alert/alarm settings (e.g., thresholds) using a secondary display device. Ex-1007, [0119]. “For example, a hypoglycemic alert may include alert conditions indicating a minimum glucose level.” Ex-1007, [0101]. Figures 7A-7E depict a “user

interface” for a secondary display device, e.g., 316A, that is used “to input data and to modify settings, among other things.” Ex-1007, [0192]. Valdes explains that this configuration advantageously provides “a larger display,” (Ex-1007, [0098]), than the “small display” provided by the “receiver unit,” (Ex-1007, [0099]). Thus, a POSITA would use the modified Home Unit (*host device*) to set a first setting of the one or more preferences or settings and store them in the SCMS. Ex-1003, ¶¶223-27.

It would have been obvious to a POSITA that Paterno’s Home Unit, operating as Valdes’s secondary device, would be used to set hypoglycemic- or hyperglycemic-alert thresholds, i.e., *rules* generated from the *host device’s first setting*. This configuration would allow the host to retain the *receiver* for local monitoring of blood glucose levels while simultaneously allowing the Home Unit to serve as the gateway to Paterno’s SCMS for the *remote monitor*.

A POSITA would have combined Paterno and Valdes for at least the reasons explained above and in Section VIII.D.1.

e) 1[d]

Paterno discloses that a caregiver’s conventional messaging devices can be used to *modify* “profile records,” i.e., *at least one rule of the set of one or more rules*, in the SCMS. Ex-1003, ¶¶228-31. Paterno discloses that subscribers can “specify specific privileges by group member for both the programming sending of

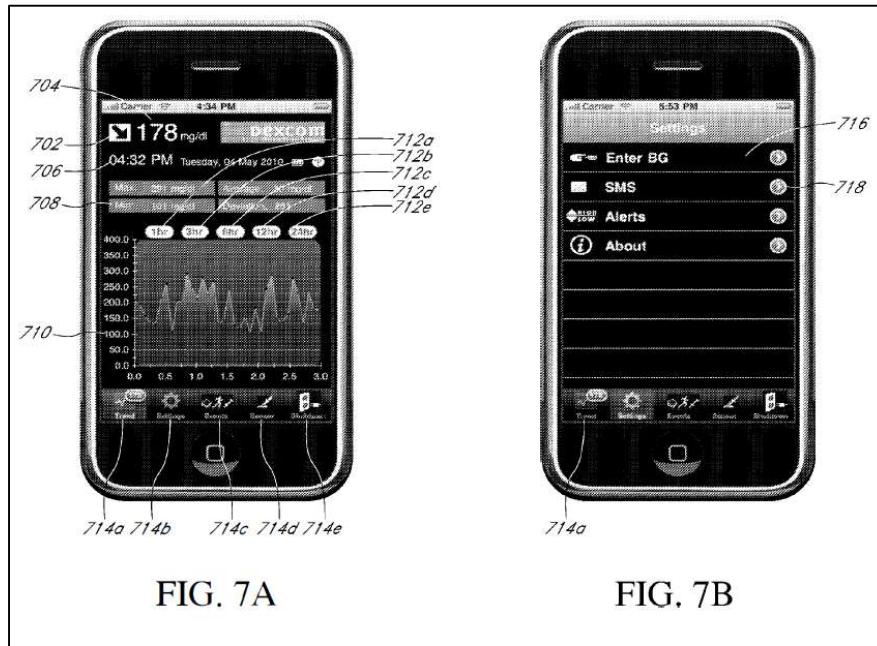
messages, alerts, and alert schedule updates to the Home Unit in that account, and **for setting what notifications and messages they will receive from the system based on the communications from the Home Unit associated with their account.**” Ex-1006, 3:57-66.

A caregiver’s device (*remote monitor*) can use the provided “Internet Portal” to modify *at least one rule*. For example, “[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-1006, 16:50-58. “The subscriber can further request customized access permissions by person in the account group.” Ex-1006, 3:52-63.

f) 1[e]

As explained above, Paterno discloses a system for setting and evaluating notification rules, *a first rule defining an alert representative of an event*. Valdes discloses rules *associated with the analyte state of the host*, such as a rule defining an alert representative of hypoglycemia or hyperglycemia. Ex-1007, [0017], [0101]. A POSITA would incorporate these rules into the “profile records” in Paterno’s system, to monitor “blood sugar” as taught by Paterno. In the combined system, the SCMS would evaluate the notification rules based on data received from Valdes’s receiver unit, i.e., *the event being determined by the secure server*

based on a first measurement of the data associated with the receiver regarding the analyte state of the host at a first time. Ex-1003, ¶¶232-37.



Valdes Figs. 7A and 7B depict user interfaces of its secondary display device. Ex-1007, [0125, 0198], Figs. 1A, 1B. “Further to FIG. 7B, the user interface 700 can include a settings screen that allows a user to select and modify settings of a glucose monitoring system... include[ing] ... modifying settings relating to sending SMS alerts [and] modifying high and low blood glucose threshold alerts . . .” Ex-1007, [0198]. A POSITA would accordingly incorporate the different alert *rules* disclosed by Valdes into Paterno’s remote monitoring system. Ex-1003, ¶234.

It would have been obvious to a POSITA to modify Paterno’s SCMS to incorporate Valdes’s “threshold alerts” and to determine whether the analyte data

from Valdes's receiver unit exceeded those thresholds. Ex-1006, 15:17-27. When that data exceeds either threshold, the SCMS would then notify, *alert*, the *remote monitors*. Ex-1003, ¶¶235-36.

A POSITA would have combined Paterno and Valdes for at least the reasons explained above and in Section VIII.D.1.

g) 1[f]

Paterno discloses that the SCMS is used to “generate and deliver” “notification messages,” or *alert messages*, “to the communications tools of the caregivers.” These notification messages, disclose or render obvious, either alone or in combination with Valdes, *an alert message to be sent to the remote monitor from the secure server to notify the remote monitor of the event*.

Paterno discloses “[t]he second key function of the SCMS device 420 is to **generate and deliver timely notification messages to the communications tools of the caregivers ...**” Ex-1006, 16:30-39. A POSITA would understand that in the combined Paterno-Valdes system, the “profile records 9000” would include the blood glucose alert rules disclosed by Valdes. Ex-1003, ¶¶238-40.

h) 1[g]

Paterno discloses that the Home Unit configures a *first setting*, as explained above in VIII.D.2.d. Paterno further discloses that caregivers with conventional messaging devices use an Internet Portal provided by the SCMS to modify profile

records, or *at least one rule of the set of one or more rules*. In the combined Paterno-Valdes system, the *first setting* by the *host device* is the set of *rules* relating to the “blood glucose” levels disclosed by Valdes, which users would set on Paterno’s Home Unit. Ex-1003, ¶¶241-43.

For example, Paterno discloses a modification by a remote monitor, Jane, to a rule set by a Home Unit for Betty: “one profile 8010 may have an event schedule 9020 of tasks with associated reminder alerts ... **Further, the account member information 9050 contents of this profile 8010 may also include four caregivers associated with the one Home Unit at Betty's house. The 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-1006, 16:42-58.

i) 1/[h]

In the Paterno-Valdes system, a caregiver would use the *remote monitor* to adjust the “notification parameters” in the profile records, *first setting*, which are stored in the SCMS’s database. Ex-1006, 15:27-32. For example, Paterno discloses that the primary caregiver may specify in the “notification parameters” different messages she wishes to receive in response to communication from the Home Unit. Ex-1006, 16:50-58. Figure 14 depicts an “SCMS database profile table record

contents,” (Ex-1006, 2:66-67), which includes “Notification parameters 9060,” (Ex-1006, 15:54-61).

A POSITA would have understood that modifying the notification parameters in the profile record modifies the *first setting* for the *remote monitor*, i.e., data that is stored in database 425 of Fig. 4 (i.e., at the *secure server*)—but does not change the *first setting* at the Home Unit, whose memory record is depicted in Figure 2 (i.e., *at the host device*). Ex-1003, ¶¶244-49. Paterno discloses “memory record contents for a Home Unit.” Ex-1006, 2:43-45, 5:3-5. In Figure 2, the Home Unit’s “memory record” lacks the “notification parameters” of the SCMS database’s profile table record that are used to modify the settings for each *remote monitor*. Ex-1006, Fig. 2.

Thus, a POSITA would understand that Paterno’s disclosure of “memory record contents for a Home Unit,” which include the *first setting*, do not include the same Notification parameters found in the profile records at the SCMS. A caregiver can use a *remote monitor* to adjust the notification parameters in the profile records *without changing the first setting* (Home Unit memory record depicted in Figure 2) at the Home Unit, *the host device*. Ex-1003, ¶248.

3. Claim 2

a) 2[a]

Sections VIII.D.2.h-i explain that Paterno discloses modifying a rule by overriding a setting for a given *remote monitor*. As discussed above in Section VIII.D.2.f, Valdes discloses a rule based on “exceeding a hypoglycemia threshold.” Ex-1007, [0017]; *see also* Ex-1007, [0101] (“**a hypoglycemic alert** may include alert conditions indicating a minimum glucose level”). It would have been obvious to a POSITA to incorporate Valdes’s hypoglycemia threshold in Paterno’s setting, as discussed in Section VIII.D.1 above. Ex-1003, ¶¶249-50.

4. Claim 3

a) 3[a]

Sections VIII.D.2.h-i explain that Paterno discloses modifying a rule by overriding a setting for a given *remote monitor*. As discussed above in Section VIII.D.2.f, Valdes discloses a rule based on “exceeding a hyperglycemia threshold.” Ex-1007, [0017]. It would have been obvious to a POSITA to incorporate Valdes’s hyperglycemia threshold in Paterno’s setting, as discussed in Section VIII.D.1 above. Ex-1003, ¶¶251-52.

5. Independent Claim 12

a) 12[Pre]

To the extent the preamble is limiting, Paterno renders this limitation obvious in view of Valdes. *See* Section VIII.D.2.a.

b) 12[a]

Paterno discloses caregiver devices such as “cellphones” and “PDA’s.” Ex-1006, Fig. 4. A POSITA would readily understand that each of these *remote monitors* includes *at least one processor*. Ex-1003, ¶¶254-55.

c) 12[b]

Paterno discloses caregiver devices such as “cellphones” and “PDAs.” Ex-1006, Fig. 4. A POSITA would readily understand that each of these *remote monitors* includes *at least one memory* and that the methods disclosed by Paterno would have been implemented as *code*. Ex-1003, ¶¶256-57.

d) 12[c]

See Section VIII.D.2.b.

e) 12[d]

See Section VIII.D.2.c.

f) 12[e]

See Section VIII.D.2.d.

g) 12[f]

See Section VIII.D.2.d.

h) 12[g]

See Section VIII.D.2.e.

i) 12[h]

See Section VIII.D.2.f.

j) 12[i]

See Section VIII.D.2.g.

k) 12[j]

See Section VIII.D.2.h.

l) 12[k]

See Section VIII.D.2.i.

6. Claim 13

a) 13[a]

See Section VIII.D.3.

7. Claim 14

a) 14[a]

See Section VIII.D.4.

**E. Ground V: Claims 5-7 and 17-19 Would Have Been Obvious
Based on Paterno in View of Valdes and Goodnow**

Paterno discloses an “Internet portal” provided by the “SCMS” to access the system. Ex-1006, 3:63-66. Paterno discloses that “Each account record ... includes records of **who can access the account, and of the people that can access it, what permissions if any they have to make account profile changes,**” “**as requested by the subscriber.**” Ex-1006, 3:33-39, 3:52-54, 3:63-66. Paterno does not, however, provide a detailed explanation of how new users are invited to the system.

As explained in Sections VII.D and VIII.B, Goodnow explicitly discloses well-known account features for internet applications. A POSITA would have used Goodnow's disclosures to implement Paterno's account features by modifying the "Internet portal" based on Goodnow's disclosure. Ex-1005, [0012]-[0016]; Ex-1008, Figs. 8 & 149, [0222], [0341]; Ex-1003, ¶¶269-271.

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

Teaching, Suggestion, Motivation

Paterno discloses "user accounts." Ex-1006, 3:29-51. At the time of the '204 patent, account features for an "Internet Portal" were well-known. Ex-1003, ¶¶272-73. For example, Goodnow discloses creating a "User Profile," (Ex-1008, Fig. 8, [0222]), and inviting a health-care professional to access a patient's data, (Ex-1008, Fig. 149, [0341]). Goodnow also discloses a compatible patient-data access scheme: "Full Access, which **allows the HCP to view and edit** the data, including event data, **glucose targets**, the user's prescribed plan, etc." Ex-1008, [0357].

Other Factors and Reasonable Expectation of Success

Combining Paterno and Valdes with Goodnow would have required merely combining prior art elements (i.e., Goodnow's account features and the Paterno-Valdes remote analyte monitoring system) according to known methods to yield

predictable results (i.e., creating new user accounts and inviting those users to share data). Ex-1003, ¶¶274.

Combining Paterno and Valdes with Goodnow also would entail a simple substitution of one known element for another to obtain predictable results. Paterno discloses a system having “user accounts.” Ex-1006, 3:29-51. Software systems with “user accounts” including usernames, passwords, and permissions were pervasive in the art prior to the ’204 patent. Because the technology disclosed by Goodnow was well-known, a POSITA would have had a reasonable expectation of success in using Goodnow’s account features with Paterno’s remote-monitoring system. Ex-1003, ¶¶275.

2. Claim 5

a) 5[a]

As explained above for claim 1, Paterno discloses an Internet Portal that is accessible at a caregiver device and a SCMS that includes a database for storing “data.” The Paterno-Valdes combination would result in data from Valdes’s “receiver unit,” or *data associated with the receiver*, being sent to the SCMS. Paterno does not describe the process for inviting a new user to access this information, but Goodnow discloses the process of sending an *invitation to access the secure server and the data associated with the receiver*. Ex-1003, ¶¶276-80.

Goodnow explains that “[o]nce the user (Home or HCP) sets up a Host Account, he or she can authorize one or more HCPs to have access to the data. To do this, the user can initiate an ‘invitation’ to the HCP to share data via the Host.” Ex-1008, [0341]. Goodnow explains a process to send the invitation. Ex-1008, [0343]-[0345].

Goodnow explains “[w]hen a user receives an e-mail invitation to share data, the message will instruct the user to ... set up a user profile, and synchronize with the Host and set up a Host Account.” Ex-1008, [0354]. “FIG. 163 illustrates an E-mail Invitation to Register and Share Data.” Ex-1008, [0354].

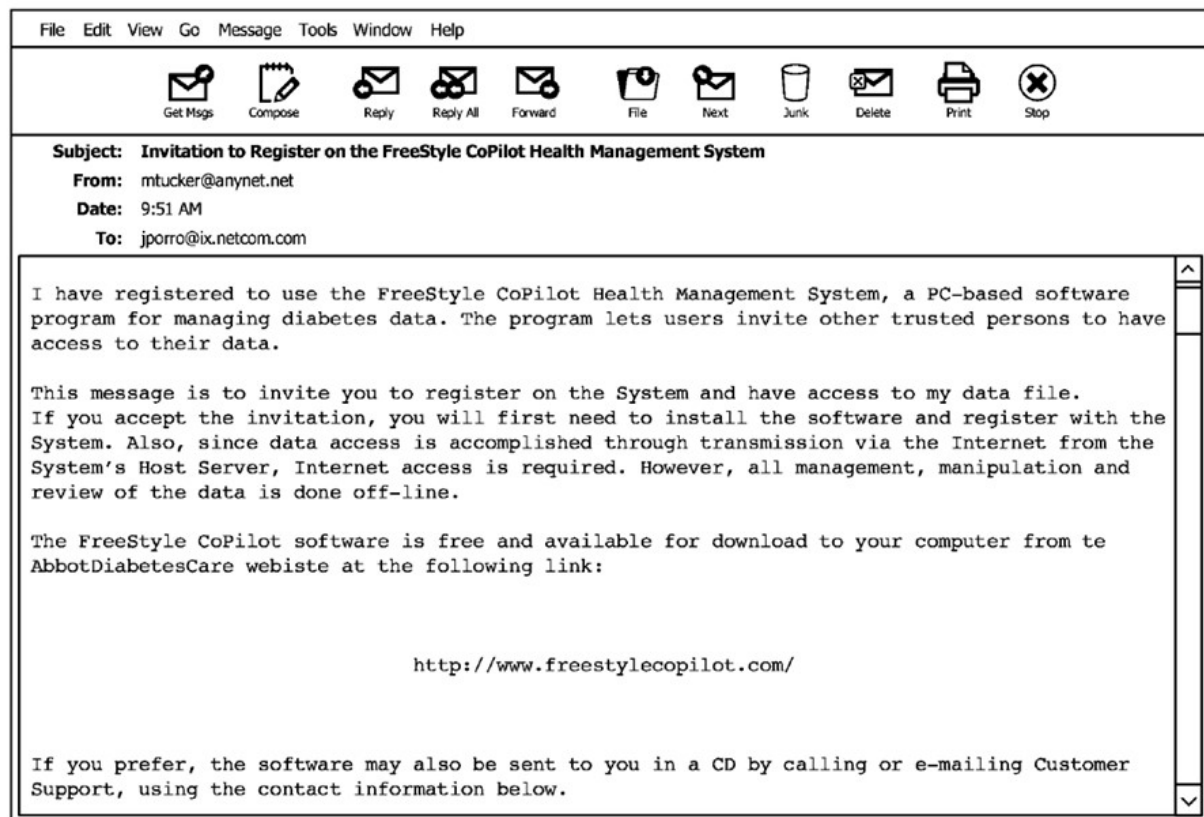


FIG. 163

A POSITA would have combined Paterno, Valdes, and Goodnow for at least the reasons explained above and in Sections VIII.D.1 and VIII.E.1.

b) 5[b]

Goodnow discloses that the user “can set up a user profile and register with the Host.” Ex-1008, [0355]. Goodnow explains the process of accepting invitation including entering the “Invitation Code” as shown in Figures 165 and 166. Ex-1008, [0355]; Ex-1003, ¶¶281-83.

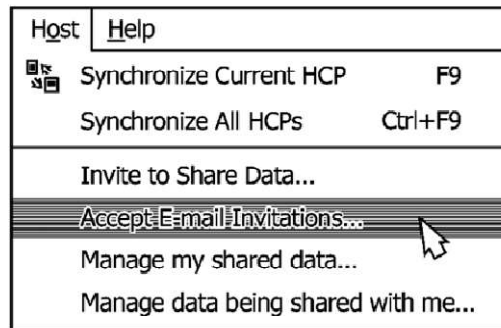


FIG. 165

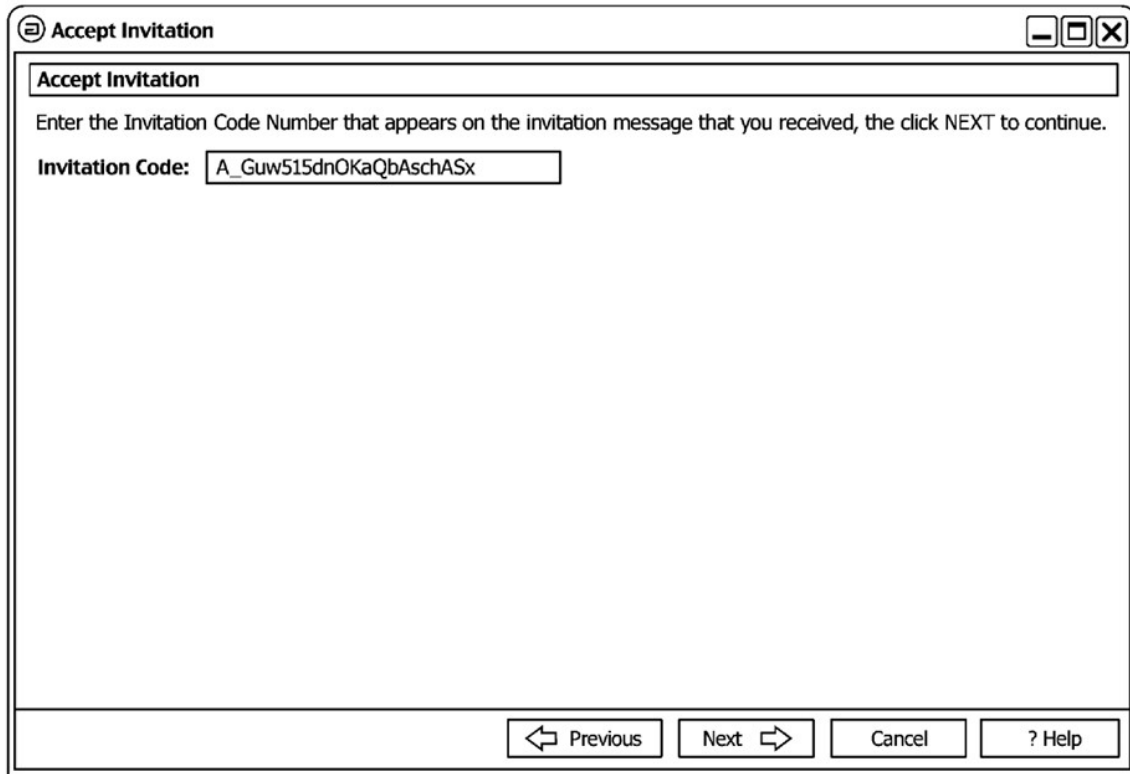


FIG. 166

A POSITA would have combined Paterno, Valdes, and Goodnow for at least the reasons explained above and in Sections VIII.D.1 and VIII.E.1.

3. Claim 6

a) 6[a]

As discussed above in Sections VIII.D.2.f, VIII.D.3, and VIII.D.4, it would have been obvious to a POSITA that the Paterno-Valdes Home Unit would be used to set hypoglycemic- or hyperglycemic-alert thresholds, i.e., rules generated from the host device's first setting of preferences and store them in the SCMS. Ex-1007, [0017], [0101].

Goodnow describes an invitation to access the patient’s “data,” including the patient’s “glucose targets,” or *rule settings*, configured by the *host device*. For example, Goodnow discloses that granting “Full Access” “allows the HCP to view and edit the data, including event data, **glucose targets**, the user’s prescribed plan, etc.” Ex-1008, [0357]. Goodnow discloses that accepting the invitation automatically synchronizes this “data” with the new account. Ex-1008, [0355]. Thus, a POSITA would understand that Goodnow’s invitation is associated with a set of *recommend rule settings* configured by the *host device*. Ex-1003, ¶¶284-88.

As discussed in Section VIII.D.2.h-i, Paterno discloses modifying a *rule* by overriding a setting for a specific *remote monitor*. It would have been obvious to a POSITA to incorporate Goodnow’s invitation with the Paterno-Valdes “Home Unit” to import initial hypoglycemic- or hyperglycemic-alert threshold *settings* that may be modified later using the *remote monitor*. Ex-1003, ¶287.

A POSITA would have combined Paterno, Valdes, and Goodnow for at least the reasons explained above and in Sections VIII.D.1 and VIII.E.1.

4. Claim 7

a) 7[a]

Paterno in view of Valdes and Goodnow renders this limitation obvious under DexCom’s proposed construction in which the establishment of a new account for a remote monitor user need not occur automatically or without user

intervention. Ex-1011, 18-20; Ex-1003, ¶¶289-91. Goodnow discloses a process for accepting an invitation as depicted in Figure 165 and 166. Ex-1008, [0355].

Once accepted, “[t]he Host then synchronizes with the user’s [s]ystem, and the patient’s data is downloaded.” Ex-1008, [0355]. A POSITA would have combined Goodnow with Paterno and Valdes for at least the reasons described above in Sections VIII.E.1 and VIII.D.1.

5. Claim 17

a) 17[a]

See Section VIII.E.2.

6. Claim 18

a) 18[a]

See Section VIII.E.3.

7. Claim 19

a) 19[a]

See Section VIII.E.4.

F. Ground VI: Claims 7 and 19 Would Have Been Obvious Based on Paterno in View of Valdes, Goodnow, and Aspel

Claims 7 and 19 would also have been obvious based on Aspel’s teaching of automatic account creation modifying Paterno in view of Valdes and Goodnow, under Petitioner’s proposed construction of “programmatically.” Ex-1010, 19. As explained above, the Paterno-Valdes-Goodnow system includes an “Internet portal” using Goodnow’s well-known account features. A POSITA would have

used Aspel's automatic creation of a username and password for new accounts. Ex-1003, ¶295.

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

As explained above, the Paterno-Valdes-Goodnow system includes an Internet Portal with "user accounts." While Goodnow's teachings provide important details regarding account features, Aspel discloses creating a username and password automatically for a new account in a healthcare monitoring system that includes "Glucose Alerts." Ex-1009, Fig.17A-C, [0151]-[0159].

Other Factors and Reasonable Expectation of Success

Combining Paterno-Valdes-Goodnow with Aspel would have required merely combining prior art elements (i.e., Aspel's username and password creation with the Paterno-Valdes-Goodnow remote analyte monitoring system) according to known methods to yield predictable results (i.e., creating a username and password automatically for a remote analyte monitoring system). Ex-1003, ¶¶296-97.

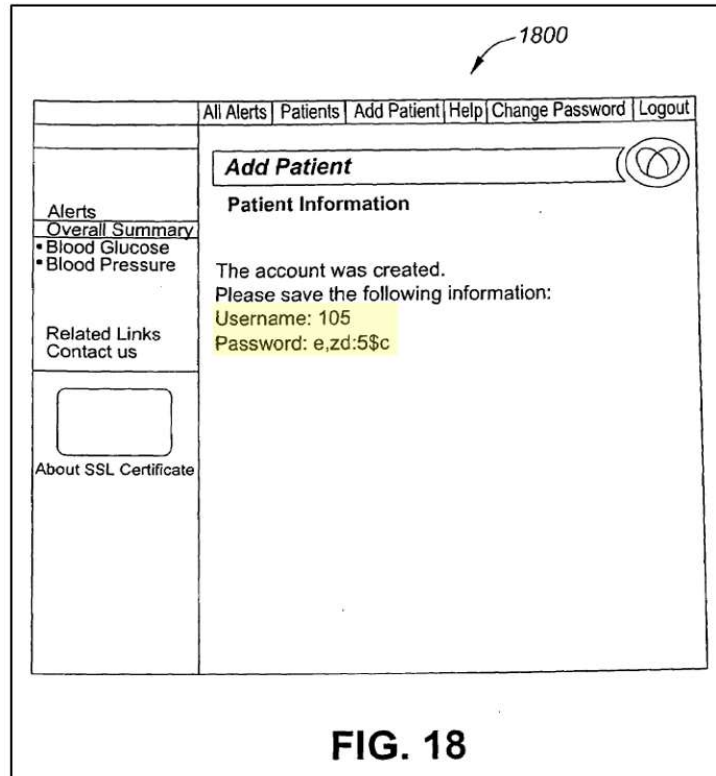
Combining Paterno-Valdes-Goodnow with Aspel also would entail a simple substitution of one known element for another to obtain predictable results. As explained above, Paterno-Valdes-Goodnow render obvious a remote analyte monitoring system having usernames and passwords. Because the technology disclosed by Aspel was well-known, a POSITA would have had a reasonable

expectation of success using routine programming techniques to apply Aspel's username and password creation features to the Gawlick-Valdes-Goodnow remote monitoring system. Ex-1003, ¶298.

2. Claim 7

a) 7[a]

As explained above for claim 5, Section VIII.E.2, Goodnow discloses a process for establishing an account by receiving and accepting an invitation. Ex-1008, [0355]. It would have been obvious to a POSITA for the user's account to alternatively be established automatically, i.e., *programmatically*, for the convenience of the user. Ex-1003, ¶¶299-301. For example, Aspel discloses a new patient form. Ex-1009, Fig. 17A-C, [0151]-[0160]. Once the form is created, "a confirmation" is shown to the user, as depicted in Figure 18. Ex-1009, [0161]. Figure 18 provides "confirmation ... the new record was created, and reiterates the username and password." Ex-1009, [0161]. A POSITA would recognize that the displayed "Username:" and "Password:" were programmatically (automatically) created, and to maintain an efficient system, the account would be created only after the invitation was accepted. Ex-1003, ¶300. Thus, Goodnow's new user form would be modified to omit the username and password fields.



A POSITA would have combined Aspel with Paterno-Valdes-Goodnow for at least the reasons explained above and in Sections VIII.F.1, VIII.E.1, and VIII.D.1.

3. Claim 19

a) 19[a]

See Section VIII.F.2.

IX. NO OBJECTIVE EVIDENCE OF NONOBVIOUSNESS

Petitioner is unaware of evidence of secondary considerations of non-obviousness. Petitioner reserves the right to rebut any purported objective evidence of nonobviousness raised by Patent Owner.

X. 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 '204 patent and thus the *General Plastic* factors for serial petitions do not weigh against institution. Similarly, applying the *Fintiv* doctrine under *Apple Inc. v. Fintiv, Inc.*, IPR2020-0019, Paper 11 (March 20, 2020) (precedential) is also inappropriate for multiple reasons. First, trial in the parallel district court litigation on issues including the validity of the '204 patent is not scheduled to occur until July 2026, many months after this Board's likely 2025 due date for a final written decision if this IPR is instituted. *See Abbott Diabetes Care Inc. et al v. DexCom, Inc.*, No. 1:23-cv-00239, Dkt. 54 (D. Del Sep. 19, 2023) (Scheduling Order). In addition, the other *Fintiv* factors would not justify denying institution. For example, claim construction briefing has just begun as of the filing date of this Petition, and the Rule 16 status conference is not scheduled until July 2024. 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. The primary references Gawlick and Paterno (in combination with Valdes), each directly teach a remote-monitoring

system for the analyte state of a host, including a *host device*, *remote monitor*, and *secure server*, as set forth in the challenged independent claims. Both Gawlick and Paterno also disclose the limitations identified by the Examiner in his reasons for allowance, *see* Section IV.B, including *wherein modifying the first setting by the remote monitor modifies the first setting for the remote monitor without changing the first setting at the host device*. As described above, the dependent claims are also taught by Gawlick and Paterno, along with Valdes, Goodnow, and Aspel. 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 the two-part *Advanced Bionics* framework is not satisfied. *See Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 8 (P.T.A.B. Feb. 13, 2020) (precedential). Under that framework, when evaluating discretionary denial arguments under § 325(d), the Board reviews “(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, at least the second prong of *Advanced Bionics* is not met. The primary reference Paterno, and the secondary reference Aspel, were not listed in an IDS or otherwise cited in the file history. A patent related to Gawlick was listed in an IDS, and Valdes was listed in another IDS with over 100 other references, but neither was substantively argued or otherwise meaningfully addressed during examination.⁸ Goodnow was argued substantively by the examiner in rejections, but not for the limitations in claims 5-7 and 17-19 as addressed in this petition.

The petition thus reflects the examiner’s errors in a manner material to the patentability of the challenged claims. Under *Becton, Dickinson* factor (c), the related Gawlick reference and Valdes were listed in IDS submissions but were not

⁸ The Office has proposed changing this aspect of the §325(d) analysis. *See USPTO Notice of Proposed Rulemaking* [including Rules for 325(d) Considerations], 89 Fed. Reg. 28,693, 28,705 (Apr. 19, 2024) (“An initialed Information Disclosure Statement, without more, does not satisfy [the proposed §325(d) discretionary denial] standard.”).

the basis for any of the many rejections during examination. Furthermore, under *Becton, Dickinson* factor (f), the examiner erred by overlooking at least the materiality of the related Gawlick reference and Valdes to the challenged claims during examination. As demonstrated herein, the combination of Gawlick and Valdes—whose relevant disclosures were ignored by the examiner—renders the challenged claims obvious. *See STMicroelectronics, Inc. v. Trustees of Purdue Univ.*, IPR2022-00309, Paper 14 at 12–13 (P.T.A.B. July 6, 2022) (petitioner demonstrated that examiner erred by not appreciating that IDS reference disclosed features recited in the challenged claims).

XI. CONCLUSION

Petitioner respectfully requests *inter partes* review and cancellation of claims 1-3, 5-7, 12-14, and 17-19 of the '204 patent.

Respectfully submitted,

Date: May 3, 2024

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Counsel for Petitioner

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 13,871 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 3, 2024

/Peter P. Chen/

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.105, I hereby certify that on May 3, 2024, I caused a true and correct copy of the foregoing Petition for *Inter Partes* Review of U.S. Patent No. 11,213,204 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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