

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

**DECLARATION OF LANE DESBOROUGH IN SUPPORT OF 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.***

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I. INTRODUCTION

1. I, Lane Desborough, have been retained by counsel to render certain opinions as an expert witness, for the above-referenced inter partes review (“IPR”) proceeding regarding U.S. Patent No. 11,213,204 B2 (the “’204 patent”). In connection with my analysis, I have reviewed the ’204 patent, the respective file history, and the documents listed in Section III, below. I have been asked to provide a declaration regarding my opinions on the patentability of claims 1-3, 5-7, 12-14, and 17-19 of the ’204 patent.

2. This report sets forth the opinions I have formed in this IPR and provides the bases and reasons for those opinions. I have summarized in this section my educational background, professional experience, and publications.

3. This report is based on information currently available to me. I have personal knowledge of the facts set forth in this declaration and, if called to testify as a witness, could and would do so competently.

4. I am being compensated at my usual litigation consulting rate for my work on this matter. My compensation is in no way dependent upon my opinions or testimony or the outcome of this proceeding. To the best of my knowledge, I have no financial interest in Abbott. To the extent any mutual funds or other investments that I own have a financial interest in Abbott, I am not aware of, nor

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do I have control over, any financial interest that would affect or bias my
judgment.

II. PROFESSIONAL BACKGROUND AND QUALIFICATIONS

5. I have included below a description of my professional background and qualifications. In addition, my education and professional experience are described in my curriculum vitae, Ex-1004.

Education

6. I graduated with a Bachelor of Science in Chemical Engineering from the University of Waterloo in 1990. I received a Master's degree in Chemical Engineering from Queen's University in 1992, for which my thesis was titled, "Performance Assessment Measures for Univariate Control."

7. Chemical Engineers often specialize in one of several domains: process control, heat transfer, thermodynamics, organic chemistry, physical chemistry, etc. I specialized in process control, which focuses on the application of computers to the control and monitoring of continuous process industry facilities such as oil refineries and chemical plants. The subject of my graduate work was developing methods for monitoring the performance of industrial control loops.

Relevant Employment History

8. After completing my graduate engineering studies in 1992, I started my career as a process control engineer at Nova Chemicals (then called

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NOVACOR) in Joffre, Alberta, at a large petrochemical production site. I worked on a project to upgrade the control system for one of the plants. This work involved connecting sensors (transmitters) to a network of computers, which in turn connected to consoles in the control room, allowing operators to receive alarms and display graphs, thereby enhancing their ability to monitor and control the plant. During this project, I became interested in alarm systems and automation human factors.

9. I joined Honeywell International, Inc. in 1995 to pursue this interest. Honeywell was and remains one of the world's largest providers of industrial automation systems. At Honeywell, I implemented and remotely monitored automation systems at oil refineries, chemical plants, pulp mills, power plants, and mines.

10. In 1998, I led the team which created Honeywell Loop Scout, a Software as a Service ("SaaS") offering to remotely monitor and diagnose control loops. Loop Scout securely collected data from hundreds of sites, transported the data to a central server, analyzed that data, and provided reports / notifications to control engineers.

11. In 2000, I led a team which developed Alarm Scout, a remote monitoring SaaS for alarm systems which was used to identify troublesome alarms and improve overall alarm system performance at customer facilities.

12. In 2008, I left Honeywell and joined a new system engineering team at General Electric Energy Services. One of my first activities was to help redesign GE Energy Service's Remote Monitoring and Diagnostics (RM&D) system, which led one year later to a new role as Product Manager for the RM&D center. The RM&D center collected data from over a thousand gas turbine combined cycle power plants, securely transported it to a central server, generated notifications, and sent those notifications to authorized personnel who then retrieved additional diagnostic data such as graphs and trends from the server. GE was and continues to be one of the largest providers of remote monitoring and diagnostic services for various industries it serves. As of 2010, when I was product manager for the RM&D center, GE was also remotely monitoring locomotives, aircraft, wind turbines, gas turbines, and CT / MRI machines from various RM&D centers around the world.

13. During my tenure at GE, in 2009, my then-10-year-old son was diagnosed with type 1 diabetes. I am not a physician, yet our family learned very quickly that type 1 diabetes is a chronic condition requiring frequent interactions (up to many dozens daily) to manage blood glucose variation with insulin. The activities of daily life—eating, exercise, social interactions, sleep—can have a large effect on blood glucose. As an engineer, I also consider Type 1 diabetes as a data condition: insulin delivery—automated or manual—is informed by the person

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with diabetes' physiological and behavioral data. Real time and historical data related to blood glucose, meals, and physical activity is used to determine the timing and magnitude of insulin injections (boluses, basal adjustments) and other therapeutic interventions (e.g., carbohydrate "rescues" or glucagon administration for hypoglycemia). For people with type 1 diabetes ("pwd"), mistakes, lapses, and errors in insulin dosing can result in severe adverse consequences.

14. The physical, cognitive, and emotional burdens of managing blood glucose which are borne by the person with diabetes can be shared remotely with care partners near and far, including parents, teachers, school nurses, and coaches of children with diabetes; partners and coworkers of adults with diabetes; and adult children of older adults with diabetes. Soon after my son's diagnosis, it became apparent to me that remote monitoring would be a helpful feature of glucose monitoring for parents of children with type 1 diabetes.

15. Shortly after my son's diagnosis, we enrolled him in a clinical trial testing the safety and efficacy of Automated Insulin Delivery ("AID"), at Stanford University under the care of Dr. Bruce Buckingham. I learned from Dr. Buckingham that Medtronic had developed but not yet commercialized a prototype remote monitoring system, mySentry. The mySentry included a "wall unit" (later called the mySentry Outpost) placed in the child's bedroom, and a remote monitor

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akin to a “baby monitor,” from which parents—in a remote location such as their bedroom—could receive alarms and review glucose trends.

16. In part motivated by my knowledge of mySentry, I joined Medtronic in April 2010 as a Product Strategist, reporting to the CTO of Medtronic’s diabetes division. Medtronic was, and is, one of the largest medical device companies in the world. Medtronic developed the first commercial continuous glucose monitor (“CGM”), insulin pump, and AID system. My responsibilities as Product Strategist included evaluating how new consumer technologies and connectivity could reduce the burden for families living with type 1 diabetes.

17. Shortly after I joined Medtronic, the company permitted my family to use a prototype mySentry to remotely monitor my son’s glucose values. The mySentry CGM system included four main components: a continuous glucose sensor, a Medtronic insulin pump acting as a receiver, an Outpost that relayed the signal, and a monitor. The monitor displayed real-time insulin pump status and glucose data and conveyed audible alerts and alarms. The monitor could be used to silence these notifications for the monitor and to view current and historical glucose data.

18. The mySentry prototype allowed us to monitor my son’s glucose remotely, e.g., from our bedroom overnight. My son’s schoolteacher remotely monitored his glucose using another mySentry unit. We used mySentry for most of

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the rest of 2010 and then returned it to Medtronic. Based on our experience, I

began to envision building my own remote monitoring system, using commercial, off-the-shelf technologies. Medtronic's protocols were public and unencrypted, which allowed anyone with knowledge of basic wireless protocols to create systems to wirelessly receive data from Medtronic insulin pumps.

19. In early 2011, I devised and built a remote monitoring project, which I called pcSentry because it used laptop PCs. We used the pcSentry system through April 2013, when my son stopped using the Medtronic CGM and started using the Dexcom G4 CGM.

20. After my son's switch to the Dexcom product, I researched how to remotely monitor the Dexcom CGM and collaborated with others on what eventually became known as Nightscout, an open-source diabetes remote monitoring system. Nightscout was never commercialized. Instead, it was offered as "educational source code" for anyone to download and install for their own family's use. I believe that approximately fifty thousand families around the world use Nightscout. I have not personally been involved in Nightscout software development since 2013.

21. In late 2014, I left Medtronic and co-founded Bigfoot Biomedical. As Chief Engineer, I was responsible for AID algorithm and simulator development. Although Bigfoot was not focused on remote monitoring per se, we recognized that

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it would be advantageous to provide remote monitoring during clinical trials, and remote monitoring was made available to the clinical staff to monitor the status of the Bigfoot system and the delivery of therapy. I have no remaining financial interest in Bigfoot Biomedical.

22. In the fall of 2019, I joined AITA Bio, which was focused on early-stage development of a novel insulin pumping mechanism for which I was providing data science support.

23. In January 2020, I co-founded Nudge BG. I am currently CEO of Nudge BG, an engineering consulting services and algorithm development company focused on the modeling, simulation, and control of physiological systems such as AID for people living with insulin-requiring diabetes. At Nudge BG, my activities related to remote monitoring have been limited to pro bono advocacy to encourage CGM companies and the FDA to allow people with diabetes to programmatically access their data in real time.

Publications and Patents

24. I am the lead or other named author on over a dozen published journal articles on topics ranging from process control to automated insulin delivery to remote monitoring and diagnostics.

25. I am a named inventor on over 30 issued U.S. patents and pending U.S. patent applications.

III. MATERIALS AND OTHER INFORMATION CONSIDERED

26. In connection with my study of this matter and reaching the opinions stated herein, I have reviewed the exhibits in the table below and any cited sources identified in this Declaration.

Exhibit	Description
1001	U.S. Patent No. 11,213,204 (the “’204 patent”)
1002	File History for U.S. Patent No. 11,213,204
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)

IV. UNDERSTANDING OF APPLICABLE LEGAL STANDARDS

27. Although I am not an attorney, I have a general understanding of the applicable legal standards pertaining to the patentability issues presented in this proceeding. I understand that, in this inter partes review, Petitioner has the burden of proving that each challenged claim is unpatentable by a preponderance of the evidence.

28. I understand that a patent claim is unpatentable if, at the time of the invention, it would have been obvious to one of ordinary skill in the art to combine the teachings of the prior art to yield the patent claim.

29. I also understand that it is not required (although it is acceptable) that each element of a patent claim be found in a single reference to find a patent claim obvious. For a patent claim to be found obvious, all the elements of the patent claim may also be found in a combination of references at which a person of ordinary skill in the art would have been reasonably expected to arrive.

30. I understand that a proper analysis of whether an invention is unpatentable for obviousness includes a review of the scope and content of the prior art, the differences between the patent claims at issue and the prior art, the level of ordinary skill in the field of the invention at the time of the invention, and other objective considerations identified below.

31. I understand that a showing of obviousness requires some articulated reasoning with a rational underpinning to support the combination of the references. I understand that one of ordinary skill in the art has ordinary creativity and is not an automaton.

32. I understand that in consideration of the issue of obviousness it is important to identify whether a reason existed at the time of the invention that would have led a person of ordinary skill in the pertinent art to combine elements

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of the references in a way that yields the claimed invention. Petitioner's counsel has informed me that in considering obviousness, it is important not to determine obviousness using the benefit of hindsight derived from the patent being considered.

33. I understand that a claim may be considered unpatentable for obviousness for various reasons. I have been informed that the following exemplary rationales may support a finding of obviousness:

(A) combining prior art elements according to known methods to yield predictable results;

(B) simply substituting one known element for another to obtain predictable results;

(C) use of a known technique to improve similar devices in the same way;

(D) applying a known technique to a known device ready for improvement to yield predictable results;

(E) choosing from a finite number of identified, predictable solutions with a reasonable expectation of success;

(F) known work in a field that prompts variations in the work in the same or a different field that leads to predictable results; and

(G) some teaching, suggestion, or motivation in the prior art that would have led a person of ordinary skill in the art to modify a prior art reference or combine multiple prior art references or teachings to arrive at the claimed invention.

34. I understand that various objective or “real world” factors may be indicative of non-obviousness. I understand that such factors include: the commercial success of the claimed invention; the existence of a long-felt, unresolved need for a solution to the problem solved by the claimed invention; failed attempts to solve the problem solved by the claimed invention; copying of the claimed invention; unexpected results of the claimed invention; praise for the claimed invention by others in the relevant field; and willingness of others to accept a license under the patent because of the merits of the claimed invention.

V. LEVEL OF ORDINARY SKILL

35. 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

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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

36. In making this Declaration, I have been asked to consider the terms found in the claims of the '204 patent according to their “ordinary and customary meaning” in light of the specification, a standard applied in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005), for how those terms would have been understood to a POSITA at the time of the claimed invention in December 2012.

37. I have been asked to apply specific claim constructions for certain claim elements. First, I have been asked to adopt DexCom’s explanation for the “rules”/“settings” claim terms in the challenged claims. I have reviewed DexCom’s explanation (Ex-1012, pp. 15-18) and adopted it for my analysis below.

38. Second, I have been asked to apply both DexCom’s and Abbott’s proposed construction in dependent claims 7 and 19 of “wherein accepting the invitation, programmatically establishes an account associated with the [remote monitor /apparatus] at the secure server.” Ex-1010, p.19. I understand Abbott’s construction of this term is: “wherein accepting the invitation automatically, without user log in or other user intervention, establishes an account associated

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with the [remote monitor / apparatus] at the secure server.” Ex-1010, p.19. I

understand from DexCom’s claim construction brief (Ex-1011, pp.18-20) that DexCom argues “‘programmatically’ does not require an automatic occurrence without user involvement.” I have analyzed the claims using both proposed constructions.

39. I am informed Petitioner reserves the right to dispute in a different forum whether the Challenged Claims are definite under 35 U.S.C. § 112.

VII. SUMMARY OF OPINIONS

40. As addressed in detail below, it is my opinion that claims 1-3 and 12-14 of the '204 patent would have been obvious based on Gawlick in view of Valdes under 35 U.S.C. § 103; 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; claims 7 and 19 would have been obvious based on Gawlick in view of Valdes, Goodnow, and Aspel under 35 U.S.C. § 103; claims 1-3 and 12-14 would have been obvious based on Paterno in view of Valdes under 35 U.S.C. § 103; 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; and claims 7 and 19 would have been obvious based on Paterno in view of Valdes, Goodnow, and Aspel under 35 U.S.C. § 103.

VIII. TECHNOLOGY BACKGROUND

41. The following section provides an overview of relevant technology before or in 2012.

A. General Overview of Monitoring and Diagnostics Workflows and Systems

42. Based on my three decades of remote monitoring and diagnostics experience across multiple domains, “monitoring” can be thought of as refocusing attention on the aspect of the system requiring attention, based on changes in data values, while “diagnostics” is the gathering of additional contextual data to determine an appropriate course of action once attention has been refocused. *See* Desborough L., Miller R., *Increasing customer value of industrial control performance monitoring: Honeywell’s experience*. In: AIChE symposium series. American Institute of Chemical Engineers, New York, pp 169-189 (2002).

43. Monitoring and diagnostics tasks—and the systems which support them—have existed for over 60 years. One of the first remote monitoring systems for physiologic data was developed in the late 1950s during the NASA Gemini Program where astronauts’ physiological data was monitored while in space by NASA officials on the ground: “Spacelabs Medical was co-founded by Ben Ettelson and James A. Reeves in 1958 for the express purpose of working with NASA and the U.S. Air Force on systems to monitor the vital signs of astronauts in

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space. As a prime contractor to NASA for the Gemini Program, Spacelabs Medical company manufactured and delivered prototypes of miniaturized signal conditioners to measure astronauts' temperature, respiration, and cardiac activity. This technology was first worn by astronauts James A. McDivitt and Edward H. White II during their historic Gemini IV flight—the first American spacewalk—to assure proper evaluation of their health and performance.” *See* Space-Proven Medical Monitors: The Total Patient Care Package, https://spinoff.nasa.gov/Spinoff2006/hm_2.html (2006). Spacelabs is now a leading provider of remote monitoring in healthcare. *See* Spacelabs Healthcare, <https://spacelabshealthcare.com/>; [Patents and Trademarks, https://spacelabshealthcare.com/about-us/patents-trademarks/](https://spacelabshealthcare.com/about-us/patents-trademarks/).

44. NASA / Spacelabs Medical illustrates that real time remote monitoring of health data has occurred for as long as there has been a capability to collect real time health data electronically, with radios to transport that data via wireless transmission, and computers to store, process, and present this data as notifications or visualizations.

45. Beginning in the 1960s, systems were developed to allow control room operators to monitor and control potentially hazardous industrial facilities located at a distance. For instance, at the NOVACOR site in Joffre, Alberta, Canada, there was a specialized system in the computer room, which was used to

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monitor remotely located pipelines for potential leaks. Even the on-site control rooms can be hundreds of meters (or more) from the process units themselves, to minimize exposure to dangerous or explosive chemicals. I was involved with a project to upgrade the control system for the Joffre plant. This involved connecting sensors (transmitters) to a network of computers, which in turn connected to consoles in the control room, allowing operators to receive alarms and display graphs, thereby facilitating their ability to monitor and control the plant. While these early monitoring efforts were not identical to the remote monitoring subject matter of the '204 patent, they illustrate the general concept of monitoring data being generated elsewhere.

B. Continuous Glucose Monitors

46. Practical, useful realtime CGMs first appeared commercially in 2007, a few years before my son was diagnosed with Type 1 diabetes. CGMs include a small sensor implanted just under the skin that transmits a wireless signal to a local receiver (or insulin pump serving as a receiver). CGMs provide data in the form of a time series of estimated glucose values (“egvs”). These measurements are referred to as *estimated* glucose values because the sensor does not directly measure glucose levels in veinous or capillary blood but measures the interstitial fluid.

47. CGMs also typically provide capabilities to turn their data into events that will prompt a user to take corrective action. For example, the CGM might detect when the egv crosses a threshold indicating the possibility of low blood glucose (“hypoglycemia”), which would trigger a notification. These notifications—also referred to as alarms and alerts—help the person with diabetes or their caregiver monitor if glucose values are unsafe. The CGM can provide additional context, such as a historical egv trend graph, to help determine a proper course of action. Corrective actions include consuming additional carbohydrates, e.g., glucose tablets, to raise blood glucose or administering a bolus of additional insulin to lower blood glucose.

C. Remote Monitoring of CGM Data

48. As mentioned above, I had access in 2010 to a prototype of the Medtronic mySentry remote monitoring product. Medtronic received FDA approval for mySentry in January 2012. As stated above, mySentry was a continuous glucose-monitoring system with four primary components: a continuous glucose sensor, an insulin pump, a signal transceiver, and the mySentry remote monitoring device. Other CGM remote monitoring activity had emerged by 2011, for several reasons.

49. **CGMS were widely available but considered Class III.** The primary impediment to development of remote monitoring systems was regulatory.

I am not a regulatory expert but understand that the Food and Drug Administration (“FDA”) classifies medical devices into different classes. Each class imposes a set of legal requirements on the device manufacturer to gain approval to manufacture and sell the device. The FDA pathway for Class III devices is expensive and time consuming. At the time, any device which interacted with a Class III device, including a remote monitoring system over a network connection, itself became a Class III device.

50. **CGMs used proprietary but open communications.** CGMs use radio signals to communicate glucose information from body-worn transmitters connected to a sensor to nearby receivers, including some insulin pumps. By 2012, it was possible to gain direct access to transmissions from CGMs and insulin pumps. This enabled the development of remote monitoring systems that were based on publicly available general-purpose tools and hosting services. At the same time, Bluetooth Low Energy (BLE) had emerged as a de facto standard for low bandwidth, low energy local wireless communications.

51. **CGM data, once collected, was easily monitored.** The use of CGM remote monitoring uses general practices of data collection, data transportation, data storage, data notification, and data presentation methods, tools, and processes, because the technical requirements are low as compared, for instance, to gas

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turbine or aircraft or locomotive remote monitoring. Full stack software developers can and have created CGM remote monitoring systems.

52. **Smartphones with push notifications were widely available.** By 2012, it was widely recognized that smartphones were replacing other devices, including medical devices, so that users would have fewer devices to carry. I was aware of this trend while working at Medtronic. People with diabetes preferred fewer devices to buy, carry around, pair, and (re)charge. By 2012, push notifications were an accepted and necessary feature of smartphone apps to exchange data with server systems.

53. As noted above, I and other technically inclined people affected by diabetes worked to develop and use remotely monitored CGM systems. For example, I and other volunteer engineers in the diabetes community designed and built Nightscout, a remote monitoring system using widely available software and database technologies.

54. The following table provides a summary of just some of the technological milestones related to remote monitoring.

Technology	Year	Example
Vital sign remote monitoring	1960s	NASA, Spacelabs Medical
Client-server architecture	1960s	IBM System/360

Digital SCADA systems	1970s	Honeywell
Cellular networks	1973	1G network by NTT (Japan)
Internet	1983	TCP/IP protocol adopted
Wi-Fi networks	1997	Wi-Fi Alliance founded
CGMs (real-time)	2007	Medtronic Guardian
iPhone	2007	iPhone 1
Push notifications	2009	Apple iOS 3.0
Prototype CGM remote monitoring	2009	Medtronic Diabetes
Bluetooth Low Energy (BLE)	2010	Bluetooth 4.0 specification
Smartphone with BLE	2011	iPhone 4S
Commercial CGM remote monitoring	2012	Medtronic Sentry
Wearable-smartphone BLE connection	2012	Fitbit One

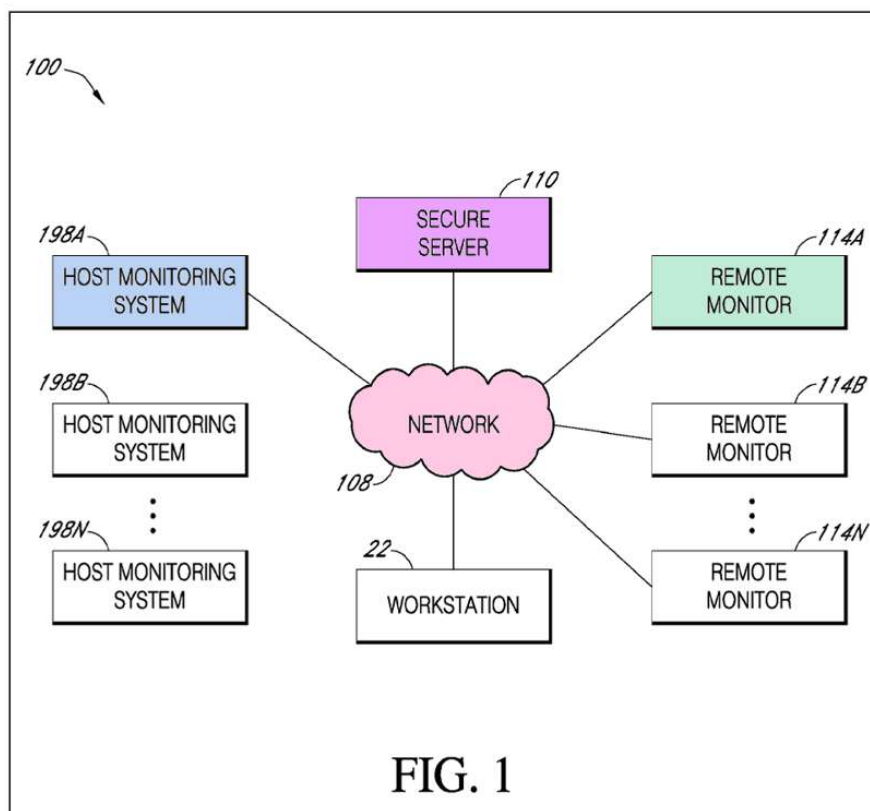
IX. ANALYSIS OF THE '204 PATENT

55. 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: CGM systems; devices for remote

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monitoring generally; and the ability to wirelessly transmit data from one person or device to another.

56. The '204 patent is directed to “remote monitoring of analyte data.” Ex-1001, 1:60-62. The patent generically 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. These were well-known ways of computer-automating the sending and provision of medical data to a remote device configured to modify certain settings of the host, as shown in the patent’s figures.

57. 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. 1.¹ Figure 1 includes a plurality of “host monitoring systems 198A-198N connected to a plurality of remote monitors 114A-114M via network 108.” Ex-1001, 5:50-53. Figure 1 also depicts “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, 5:65-6:5.

¹ All patent figures in this declaration that include color have been annotated, unless otherwise noted.

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communication device 105²,” Ex-1001, 13:38-41. In this embodiment, “the host communication device 105 is a mobile telephone having a host monitoring application” Ex-1001, 13:63-66.

59. The Challenged Claims involve methods and devices for remote monitoring, whereby the remote monitor may modify default rules (e.g., for monitoring the host’s glucose levels) that the host sets and sends to the remote monitor.

60. 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 alerts based on a host’s analyte data. The limitations are generic and well-known computer operations of remote monitoring systems. There is nothing novel or inventive in such claims—whether independent or dependent.

A. Prosecution History

61. A brief summary of the lengthy file history of the ’204 Patent reflects that it was filed as Application No. 15/617,977 (“the ’977 Application”) on June 8,

² The Challenged Claims recite a *host device*. The specification refers to the “gateway 104” including either a “host device 105,” e.g., Ex-1001, 22:60–66, or “host communication device 105,” Ex-1001, 13:41–46.

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2017, claiming priority to U.S. Provisional Application No. 61/747,717, filed
December 31, 2012. Ex-1001, 1.

62. There were seven examiner rejections over the next three-plus years, after the last of which DexCom amended the claims, on December 21, 2020, by removing certain elements from the then-pending claims and adding elements, including “wherein modifying the at least one rule of the set of one or more rules comprises modifying, by the remote monitor, the first setting by the host device.” Ex-1002, 685-695.

63. On March 22, 2021, the Examiner again rejected the claims, in part as being obvious. Ex-1002, 717-734. On May 20, 2021, the Examiner held an interview with DexCom in which DexCom “proposed to amend claim 1 with limitations that recite that the modifying of a setting by the remote monitor only modifies the setting for the remote monitor.” Ex-1002, 761. On June 9, 2021, DexCom amended the claims as follows:

AMENDMENTS TO THE CLAIMS

I. (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 (highlighted).

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

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. For example, the following excerpt includes the last paragraph of page 8, continuing onto page 9:

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.

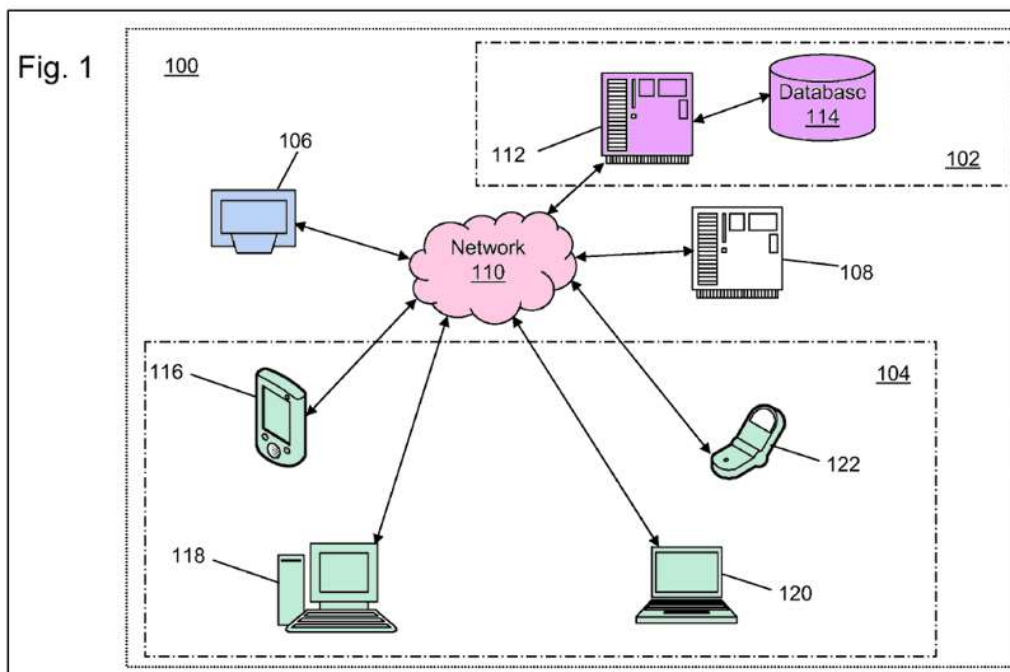
Ex-1002, 773-774.

X. OVERVIEW OF THE PRIOR ART

A. Gawlick (Ex-1005)

65. The Gawlick reference is U.S. Patent Application Publication No. 2011/0202495, titled “Adjustable Alert Rules for Medical Personnel,” to Gawlick (“Gawlick”). It was filed on February 18, 2010, and published on August 18, 2011. I understand and am informed that Gawlick qualifies as prior art to the ’204 patent.

66. Gawlick discloses a medical alert system 100 depicted in Figure 1.

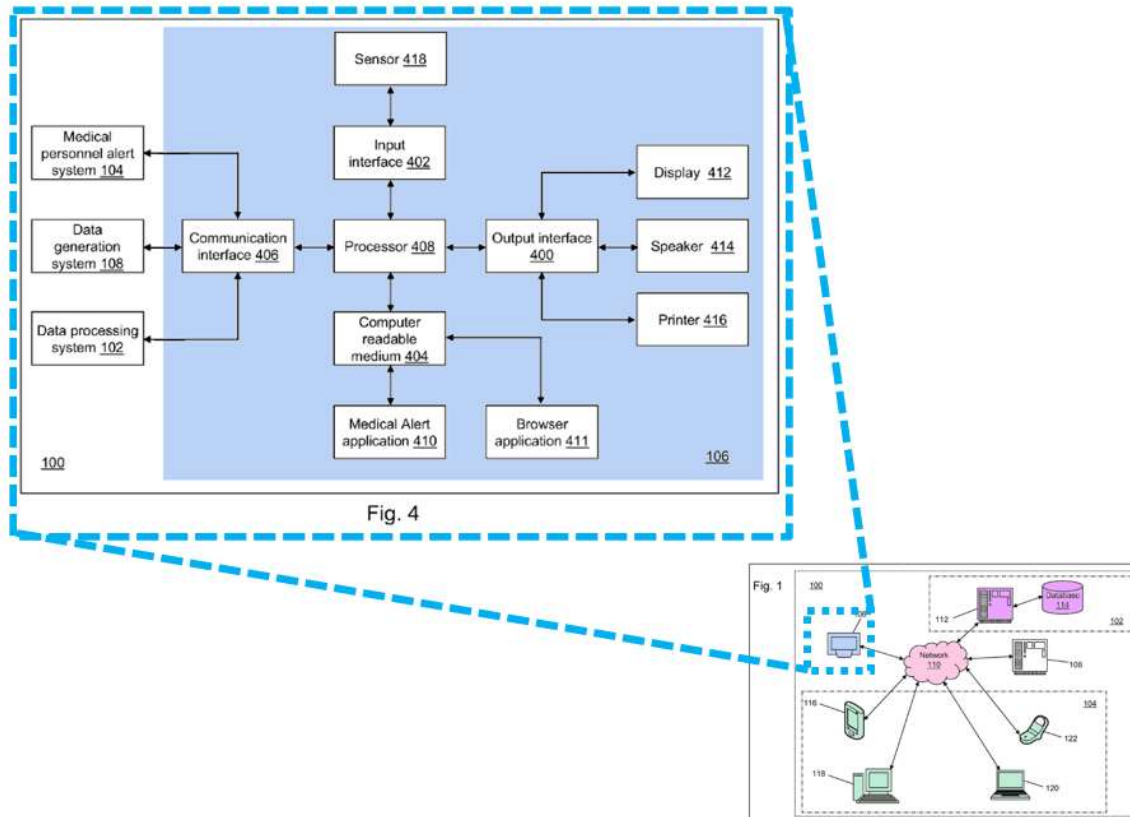


Ex-1005, Fig.1. Medical alert system 100 is comprised of several subsystems, including “a data processing system 102, a medical personnel alert system 104,” and “a patient monitor system 106.” Ex-1005, [0017]. These subsystems are interconnected through “a network 110.” Ex-1005, [0017].

67. The flow of information begins at the patient. A sensor “monitors, senses, measures, and/or detects, one or more physiological characteristics of a patient,” including “blood chemistry[.]” Ex-1005, [0039]. These physiological data are then received by “patient monitor system 106,” which has the functions displayed in Figure 4 below (shown as a call-out from Fig. 1). Ex-1005, [0037]. Among other things, “patient monitor system 106” includes “communication interface 406,” “processor 408,” “sensor 418,” “input interface 402,” “output interface 400,” “medical alert application 410,” and “browser application 411.” Ex-1005, [0037]. “Communication interface 406” operates to “to receive” information from “data generation system 108.” Ex-1005, [0030].³ Patient monitor system 106 has “one or more electronic devices that continuously, periodically, and/or upon request monitor the physiological characteristics of patients[.]” Ex-1005, [0021]. “Different and additional components may be incorporated into patient monitor system 106.” Ex-1005, [0037]. The “data generation system 108” “generates data related to a patient,” which may include “a sensor for measuring a physiological

³ 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]. Accordingly, when explaining the design and operation of Figure 4, I will sometimes cite to relevant explanations related to Figure 2.

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characteristic”and “computing device[s] of any form factor used by medical
personnel to capture patient physiological characteristics.” Ex-1005, [0022].



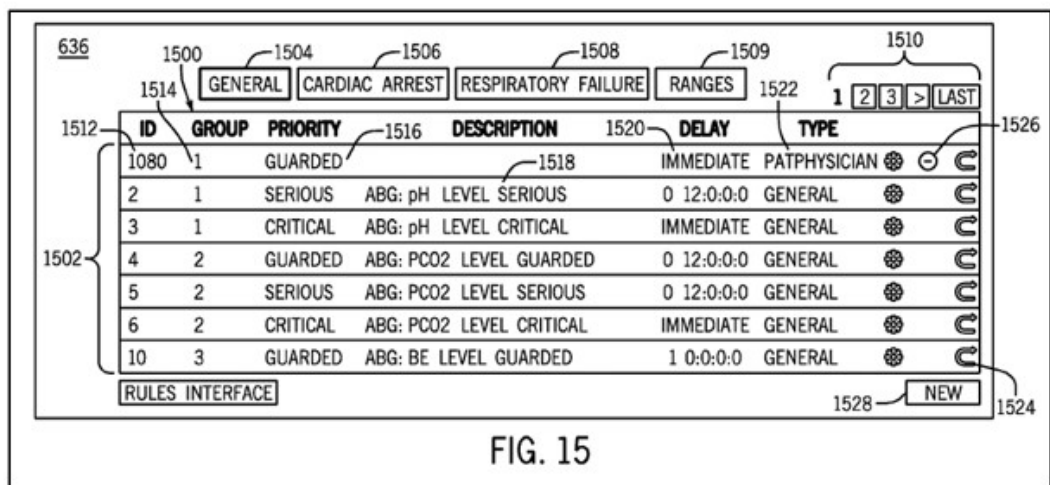
68. Next, patient monitoring system 106 can also “provide the data through communication interface 406 to one or more of a medical personnel alert system 104, a data generation system 108, and a data processing system 102.” Ex-1005, [0039]. Medical alert application 410 “performs operations associated with alerting” as well as “updat[ing] a status of the patient[.]” Ex-1005, [0031].

69. The data processing system 102—receiving data associated with a physiological characteristic from patient monitoring system 106—“may include a

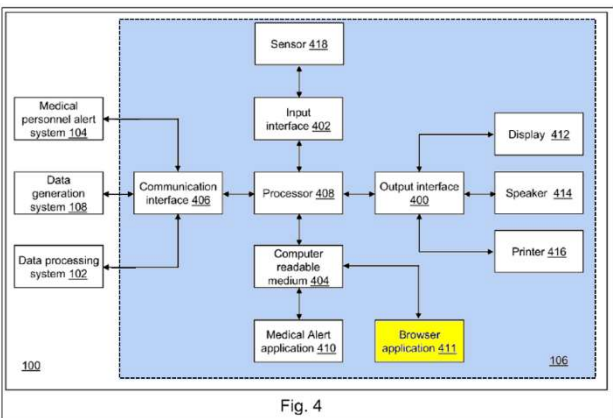
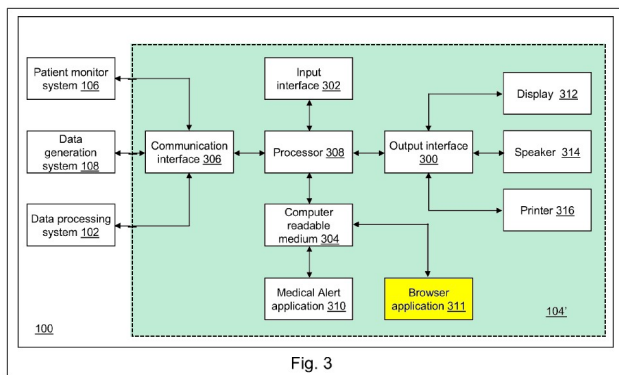
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server computing device 112 and a database 114.” Ex-1005, [0018], [0040]. Server computing device 112 “can access database 114,” and evaluate stored data using “a rules engine.” *Id.* This “rules engine works based on events” that “are matched to previously defined rules.” Ex-1005, [0018]. Since “one or more of the components of medical alert system 100 may be connected using network 110,” Ex-1005, [0024], data processing system 102 can communicate events or “alerts” both back to patient monitoring system 106 and to any other device or system connected to the network.

70. These alerts and patient data can be sent to “medical personnel alert system 104,” which includes “one or more computing devices.” Ex-1005, [0020]. These computing devices include, for example, “a desktop 118, a laptop 120,” and “a smartphone[.]” Ex-1005, [0020].

71. Gawlick depicts in Figure 15 a “dashboard space 636” that “may include an alert rule list 1500 presented under control of browser application 311 in combination with second medical alert application 310 and through interaction with medical alert application 210 at medical personnel alert device 104’.” Ex-1005, [0068].



Both the “medical personnel alert system 104” and “patient monitor system 106” provide access to the “dashboard” as indicated by the highlighted “Browser application” in the figures below.



72. Gawlick’s system discloses an “alert rule” based on blood glucose levels. Ex-1005, Fig. 17, [0086].

636

1700

1702 GROUP (TIP: LEAVE IN BLANK TO NEW GROUP) 8

1704 PRIORITY CRITICAL

1706 TYPE PATIENT UNDER PHYSICIAN

1708 DELAY (TIP: DELAY FORMAT IN DD HH:MM:SS)

1710 DESCRIPTION

1712 ACTION

1714 OVERRIDES THE FOLLOWING RULES:

ID	PRIORITY	DESCRIPTION
23	CRITICAL	ABG: GLUCOSE LEVEL CRITICAL

1716 SEARCH RULES TO OVERRIDE:

1718 EVALUATE RULE EVERY: 1720 MINUTE

1724 CONDITION (USE < AND > FOR < AND > RESPECTIVELY)

1725 <condition>
<object name='r0'> rtype='ABG_GLUCOSE' AND (value < 64 OR value > 160) </object>
</condition>

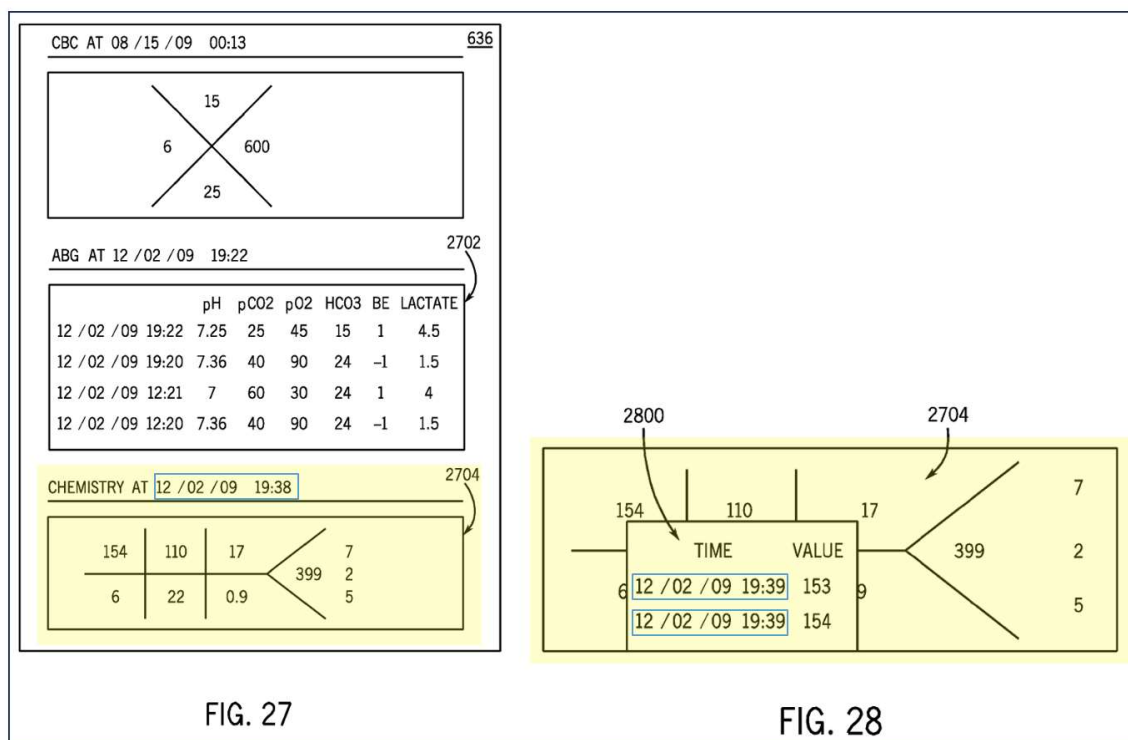
1726

1730 SAVE CANCEL 1732

1728

FIG. 17

73. The “medical alert application” includes a “dashboard 636,” depicted in Figures 27 and 28 below, showing the results of continuous monitoring of “blood chemistry” including “glucose level” (showing values at 19:38, 19:39, and 19:39). Gawlick explains that “[b]lood chemistry chart 2704 may include the results of a blood panel such as a . . . **glucose level** . . .” Ex-1005, [0112]. “Upon receipt of an indication of a user scrolling over a value of blood chemistry chart 2704, a summary window 2800 may be presented as shown with reference to FIG. 28. Summary window 2800 may show a history of previous measurements.” Ex-1005, [0112].

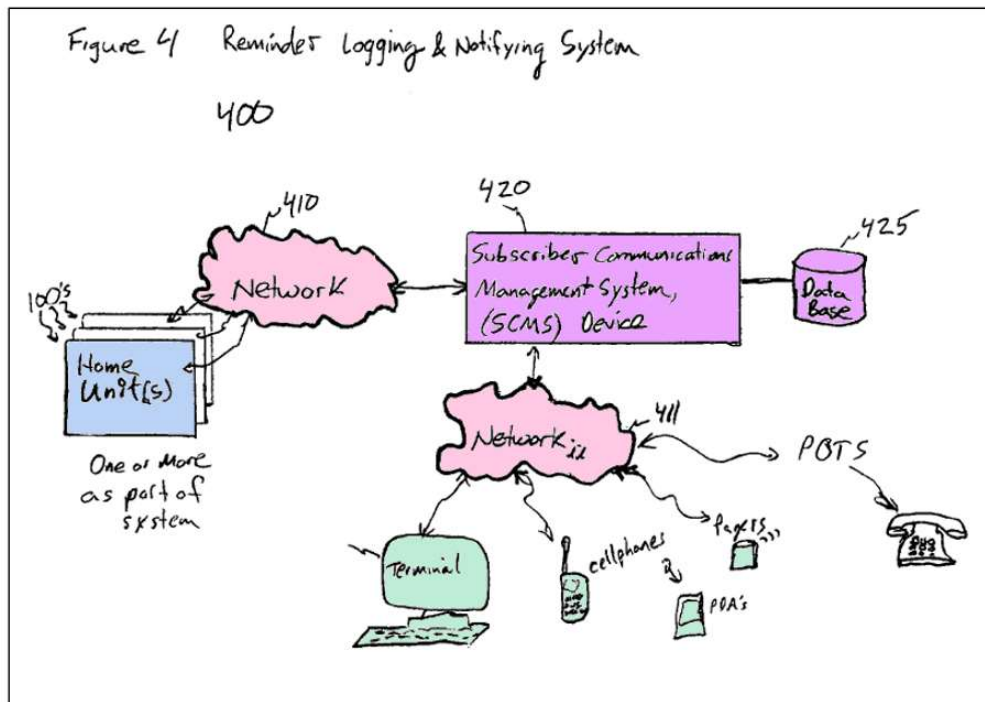


B. Paterno (Ex-1006)

74. The Paterno reference is U.S. Patent No. 7,301,463, titled “Assisting and Monitoring Method and System,” to Paterno (“Paterno”). It was filed on April 13, 2005, and issued on November 27, 2007. Ex-1006, 1. I understand and am informed that Paterno qualifies as prior art to the ’204 patent.

75. Paterno discloses an “[a]ssisting and [m]onitoring method and system” that “help[s] an individual and select caregivers of the individual track the individual’s performance of routine tasks.” Ex-1006, 1:66, 2:9-11. The disclosed system includes “network(s),” “two-way communication devices to exchange information between remotely located event logging devices,” and a central server.

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Ex-1006, 3:30-33. Paterno further discloses Home Units used by “the individual” being monitored, and (remote) “conventional messaging devices” used to monitor the individual (cellphones, PDAs, pagers, computer terminal). Ex-1006, 11:19-20; Fig. 4.



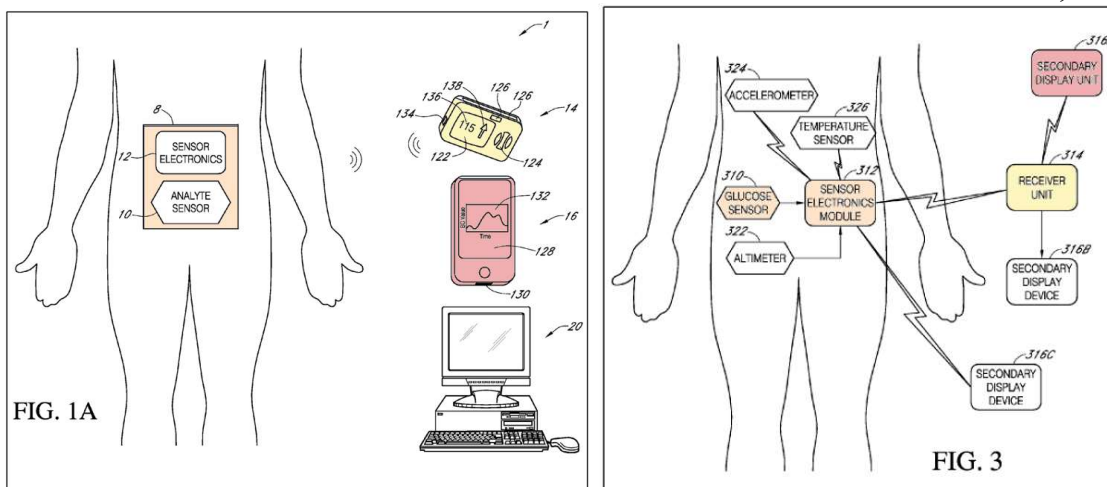
Ex-1006, Fig. 4. The individual can “provide account access to one or more people” (i.e., caregivers) with “customized access permissions” so that the caregivers can make changes relating to “the programming sending of messages, alerts, ... and for setting what notifications and messages they will receive from the system[.]” Ex-1006, 3:52-63. Thus, remote caregivers with the requisite access can change the caregiver monitoring parameters stored in the Subscriber Communication Management System’s database for remotely monitoring a patient,

Decl. of Lane Desborough in Support of Petition for *Inter Partes* Review of U.S. Pat. No. 11,213,204 such as “who, how, and when members of a subscribed account are notified of” different events. Ex-1006, 3:41-42. If granted permission, remote members may also set their own or others’ custom monitoring/alert settings. Ex-1006, 16:30-17:26. Paterno also discloses that “in home monitoring of critical health parameters such as blood sugar” was known in the art. Ex-1006, 1:46-48.

C. Valdes (Ex-1007)

76. The Valdes reference is U.S. Patent Publication No. 2011/0320130, titled “Systems and Methods for Communicating Sensor Data Between Communication Devices,” to Valdes *et al.* (“Valdes”). It was filed on June 23, 2011, and published on December 29, 2011. Ex-1007, 1. I understand and am informed that Valdes qualifies as prior art to the ’204 patent. Valdes is also admitted prior art in the specification for the ’204 patent. Ex-1001, 54:27-28.

77. Valdes discloses a “[s]ystem and method for communicating glucose concentration information between devices of a continuous glucose monitoring system.” Ex-1007, Abstract. These devices include (1) “a sensor electronics module 8” that “generates a glucose concentration measurement”; (2) “a receiver unit 14” that can be configured “to receive sensor data indicative of a glucose concentration in a host”; and (3) “one or more secondary display devices 16 and 20,” such as a mobile phone. Ex-1007, [0002], [0008], [0108]-[0109].



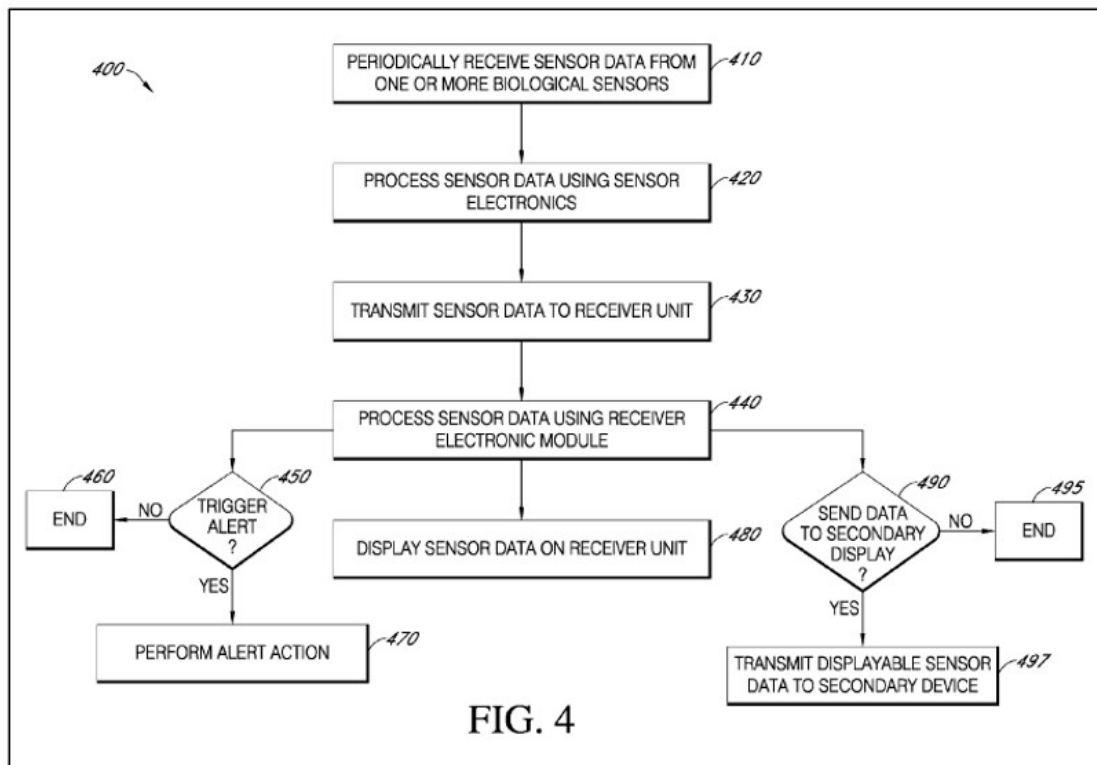
Ex-1007, Figs. 1A, 3.

78. Beginning with the host, a “continuous analyte sensor” provides “sensor data” to a receiver that is “directly related to the measured analyte from an analyte sensor. Ex-1007, [0062]. The “receiver unit” “can be configured to be a stand-alone device or physically connect to a secondary display device.” Ex-1007, [0002].

79. When the two devices are separated (annotated Figure 1A, above), 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]. Depending on the user, a “secondary display device” can function as a device for use by the host, (*e.g.*, the host receiving sensor data on a mobile phone through an application), Ex-1007, [0098], or by a third-party caregiver (*e.g.*, parents remotely monitoring “a child’s glucose levels” on a

Decl. of Lane Desborough in Support of Petition for *Inter Partes* Review of U.S. Pat. No. 11,213,204 personal computer with “user configurable alerts”), Ex-1007, [0157]. More than one “secondary display device” may be used within a disclosed continuous glucose monitoring system.

80. Valdes Fig. 4 “is a flowchart illustrating one embodiment of a method 400 of using a receiver unit, such as receiver unit 14 or 314, first as a stand-alone device and then used in combination with a secondary display device, such as secondary device 16, 20, 316A, 316B or 316C . . . to enhance processing and displaying functionality.” Ex-1007, [0168].



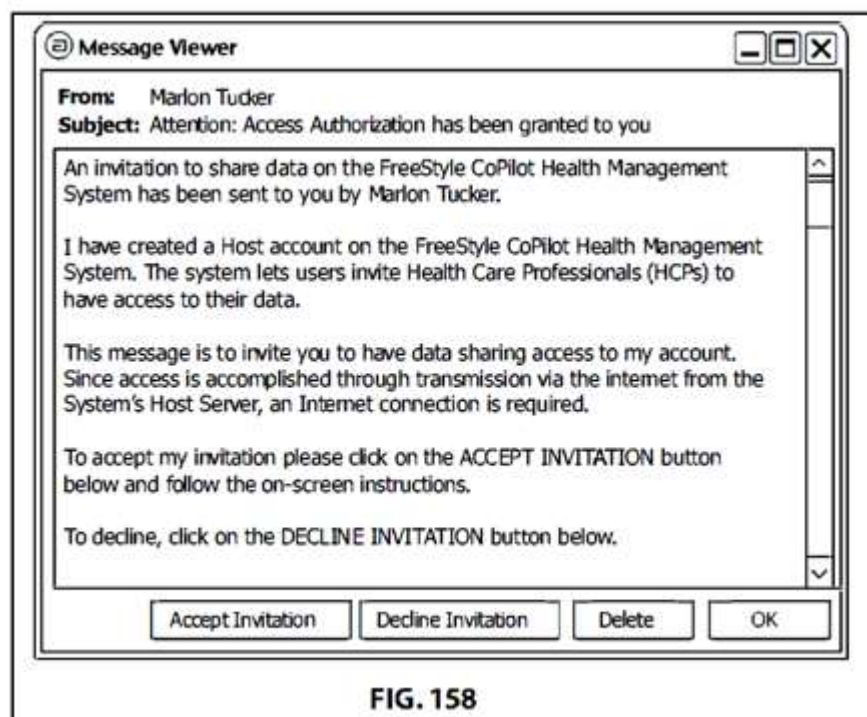
Ex-1007, Fig. 4.

D. Goodnow (Ex-1008)

81. The Goodnow reference is U.S. Patent Application Publication No. 2011/0178717, titled “Diabetes Care Host-Client Architecture and Data Management System” to Goodnow (“Goodnow”). It was filed on July 23, 2010, and published on July 21, 2011. Ex-1008, 1. I understand and am informed that Goodnow qualifies as prior art under to the ’204 patent.

82. Goodnow discloses a “personal computing appliance software application that enables users to upload, store, and/or analyze glucose readings and other important information for diabetes management.” Ex-1008, [0206]. Anticipated users for this system include both “home users (people with diabetes or their caregivers), and HCP users (healthcare professionals).” Ex-1008, [0205]. Goodnow further discloses “data sharing securely over the Internet with selected HCPs,” Ex-1008, [0209]. “For users who want to communicate and share data remotely, the system 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].

83. A user can securely synchronize their glucose data with an HCP by inviting them to do so through the disclosed platform or through email. Ex-1008, [0343]-[0349], [0351]-[0353].



Ex-1008, Fig. 15. Either way, the patient locates the HCP's account information or email, decides on whether to provide "Read-Only Access or Full Access," and then "send[s] an invitation to share data to the HCP." Ex-1008, [0345].

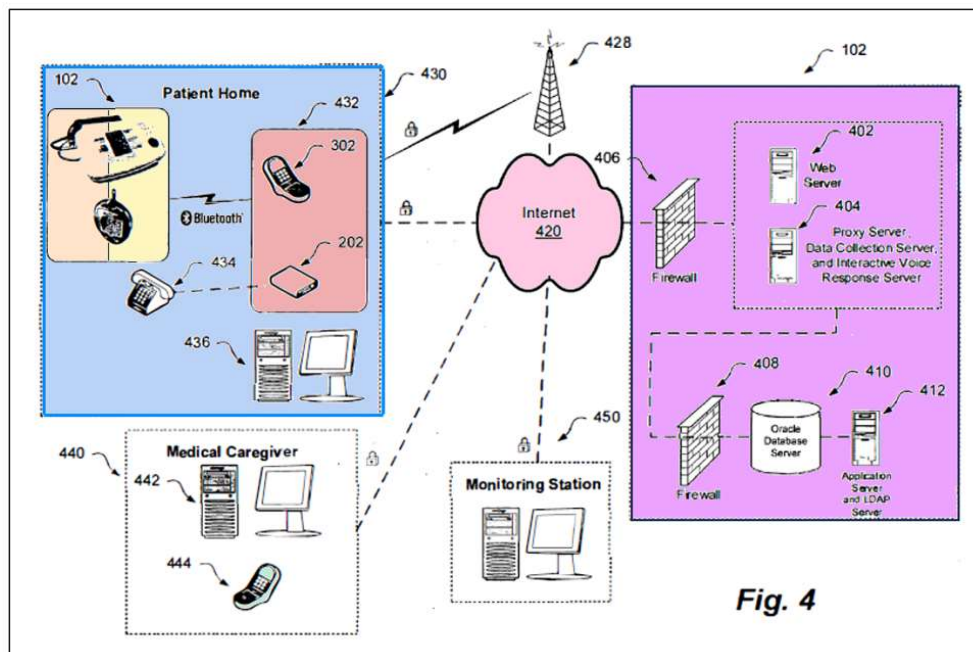
E. Aspel (Ex-1009)

84. The Aspel reference is U.S. Patent Application Publication No. 2008/0154099, titled "Health Monitoring System and Method," to Aspel ("Aspel"). It was filed on November 6, 2007, and published on June 26, 2008. Ex-1005, p.1. I understand and am informed that Aspel qualifies as prior art to the '204 patent. Aspel was not cited or considered during prosecution.

85. Aspel discloses a "system for ongoing collection, transmission, storage, analysis, and presentation of physiological and other personal data from

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individuals” to “authorized system users” like “medical doctors and other
Caregivers.” Ex-1009, Abstract.

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



87. As disclosed in the Figure, users (care partners) can access a data center through a stationary desktop computer or “[w]ireless access can be provided through a cellular network 428 ... to a wireless device such as cellphone 302,” Ex-1009, [0052].

88. The system is also “designed to alert users and Caregivers based on the reception of certain data or the absence of data within a set time.” Ex-1009, [0089]. These data include glucose readings. Ex-1009, Fig. 17B.

1702

Fax:

Hospitalization #:

Treaty #:

Family Doctor Information

Name:

Phone:

Fax:

Equipment Serial Number

Blood Glucose Meter Serial Number:

Blood Pressure Meter Serial Number:

Note: The serial numbers are case sensitive

Description of Insulins

Insulin A:

Insulin B:

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

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

Glucose Alerts: (Units are xxxxx/L)

An alert will be generated if there are readings above within days.

An alert will be generated if there are consecutive readings above .

An alert will be generated if there are readings within days.

FIG. 17B

89. As with the physiological sensor data, alerts can be “presented to patients, their Caregivers, designated medical professionals and monitoring centers in the web interface to the system.” Ex-1009, [0091]. This alert information “can then be viewed along with the patient information to determine a course of action[.]” Ex-1009, [0093]. While a patient may establish “user defined alerts,” or alerts that initiate when “readings are out of a configurable set of target ranges,” Ex-1009, [0090], a caregiver with the proper access—a “multi-Caregiver”—can

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also “set[] alert levels” that will trigger events based on that patient’s data, Ex-1009, [0128].

F. The Cited Prior Art is Analogous Art

90. The ’204 patent is titled “Remote Monitoring of Analyte Measurements,” Ex-1001, 1(54), and “generally relates to **remote monitoring**,” Ex-1001, 1:18-21.⁴ The ’204 patent explains that the “[i]mplementations described herein can include a system for one or more caretakers (e.g., a parent, spouse or healthcare practitioner) to **remotely monitor health characteristics** of one or more hosts.” Ex-1001, 4:28-31. “The health characteristics can include an analyte concentration of a host, such as glucose, or a bodily function, such as heart rate, blood pressure, temperature and the like.” Ex-1001, 4:31-34. I understand that each of the cited prior art references must be analogous art to the ’204 patent, i.e., either from the same field of endeavor as the ’204 patent, or reasonably pertinent to the particular problem addressed by the ’204 patent.

91. Gawlick is titled “Adjustable Alert Rules for Medical Personnel.” Ex-1005, p.1 (54). Gawlick explains that “[m]odern medical institutions have electronic devices that continuously **monitor** the vital signs of patients such as

⁴ Unless otherwise noted, I have added emphasis in quoted text, as indicated by a **bold** font.

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heart rate, respiratory rate, cardiac rhythm, blood pressure, oxygen saturation, and many other **patient physiological characteristics**.” Ex-1005, [0001]. Gawlick seeks to improve on these existing monitoring systems, i.e., the “alert rules” for a “medical alert system 100 [that] may be positioned in a single location, a single facility, and/or may be **remote** from one another.” Ex-1005, [0006], [0024]. Gawlick discloses glucose as an analyte for remote monitoring in the figures and specification. Gawlick relates to the field of remote monitoring and is at least reasonably pertinent to the remote monitoring problem addressed by the ’204 patent.

92. Paterno is titled “Assisting and Monitoring Method and System.” Ex-1006, p.1 (54). Paterno discloses an “**Assisting and Monitoring method and system** for compliance logging and monitoring system for routine activities” and “an automated communications/notification system.” Ex-1006, 3:15-20. Paterno seeks to improve upon existing “[m]onitoring devices and systems . . . that can provide in home monitoring of **critical health parameters** such as blood sugar, pressure, heart rate and weight.” Ex-1006, 1:45-47. Paterno relates to the field of remote monitoring and is at least reasonably pertinent to the remote monitoring problem addressed by the ’204 patent.

93. Valdes is titled “Systems and Methods for Communicating Sensor Data Between Communication Devices,” Ex-1007, p.1 (54). Valdes discloses a

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“[s]ystem and method for communicating glucose concentration information
between devices of a continuous glucose **monitoring system**[.]” Ex-1007, [0002].
Valdes also discloses a “continuous glucose monitoring system” that “when an alert triggers that indicates severe hypoglycemia, the receiver unit can perform multiple actions, such as activating an alarm on the receiver unit, **transmitting a data package to a remote display device indicating activation of an alarm on the display, and transmitting a data package as a text message to a care provider.**” Ex-1007, [0106]. In addition, the ’204 patent identifies Valdes as disclosing “methods and devices suitable for use in conjunction with aspects of the preferred embodiments.” Ex-1001, 54:27-28. Valdes is from the same field of endeavor as the ’204 patent.

94. Goodnow is titled “Diabetes Care Host-Client Architecture and Data Management System.” Ex-1008, p.1 (54). Goodnow relates generally to “**diabetes care data management**, and particularly to a host-client architecture for communicating, managing and analyzing the data and for generating versatile reports.” Ex-1008, [0002]. Goodnow discloses a “System [that] may be used to **monitor the health status of the patients** [HCP users] manage.” Ex-1008, [0205]. Goodnow is from the same field of endeavor as the ’204 patent.

95. Aspel is titled “Health Monitoring System and Method.” Ex-1009, 1 (54). Aspel “relates generally to healthcare and medical telephony, and more

Decl. of Lane Desborough in Support of Petition for *Inter Partes* Review of U.S. Pat. No. 11,213,204 specifically, to a system for and method of collecting and managing physiological and lifestyle information for use by individuals, familial and personal Caregivers, and medical professions in managing health and wellness decisions.” Ex-1009, [0002]. “It is an object of the invention to provide an **improved health monitoring and management system** and method.” Ex-1009, [0013]. The system includes a collection and display of “**glucose data**” including “a number of different blood glucose reports.” Ex-1009, [0164], [0165]. Aspel relates to the field of remote monitoring and is at least reasonably pertinent to the remote monitoring problem addressed by the ’204 patent.

XI. 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

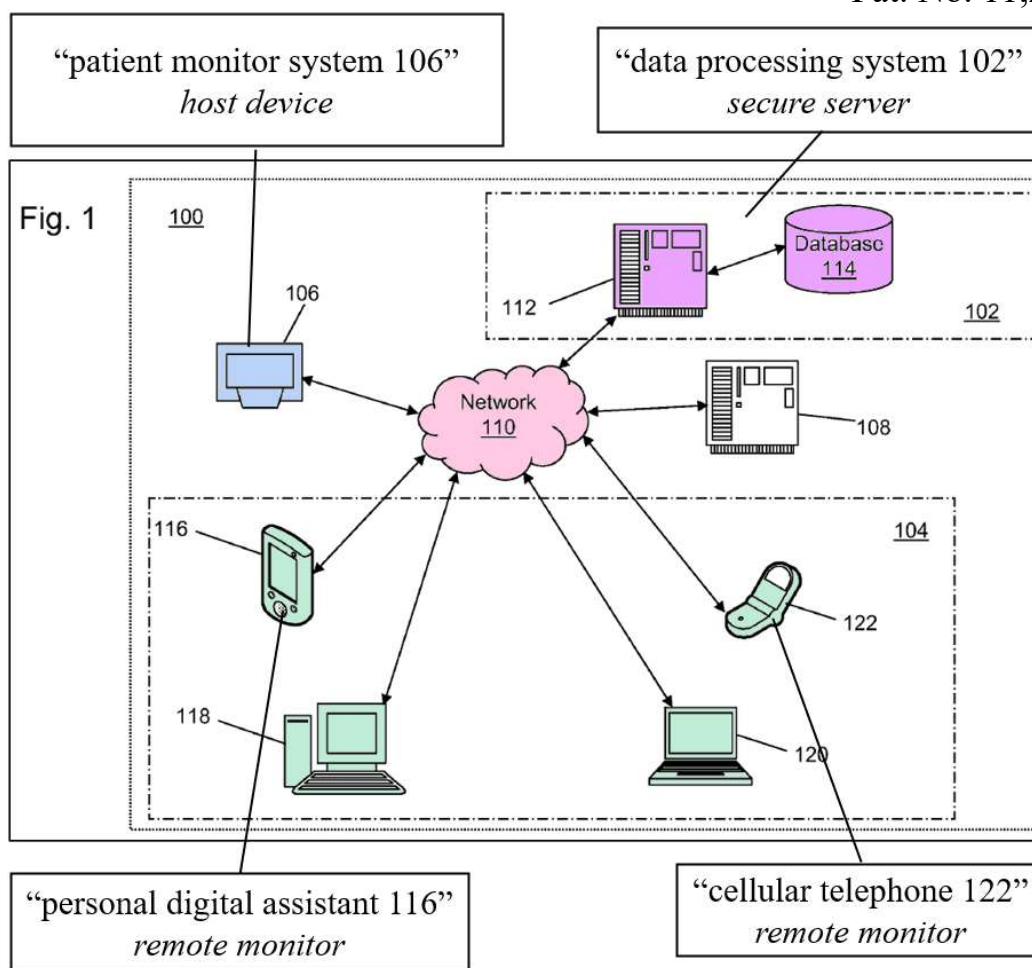
96. As shown below, claims 1-3 and 12-14 would have been obvious based on the combination of Gawlick and Valdes.

97. Gawlick discloses a “medical alert system 100” comprising several subcomponents. The “medical 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 smartphone, a pager, etc.” Ex-1005, [0020]. Each of these “one or more computing

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devices” teaches the recited *remote monitor*.⁵ Gawlick also depicts “data processing system 102” comprising a “server computing device 112,” which either singly or in combination with “database 114,” discloses a *secure server*. As discussed below in ¶ 178, a POSITA would have recognized the use of a *secure server* was needed to comply with HIPAA, and for other data security reasons.

98. The Gawlick system also includes a “patient monitor system 106.” including structure and function teaching the recited *host device*. “Patient monitor system 106 includes one or more electronic devices that continuously, periodically, and/or upon request monitor the physiological characteristics of patients such as heart rate, respiratory rate, cardiac rhythm, blood pressure, oxygen saturation, blood chemistry, etc. Some or all of the various electronic devices that makeup patient monitor system 106 may be connected to network 110 for the transmission of data, for example, for storage in database 114.” Ex-1005, [0021]-[0022], [0037].

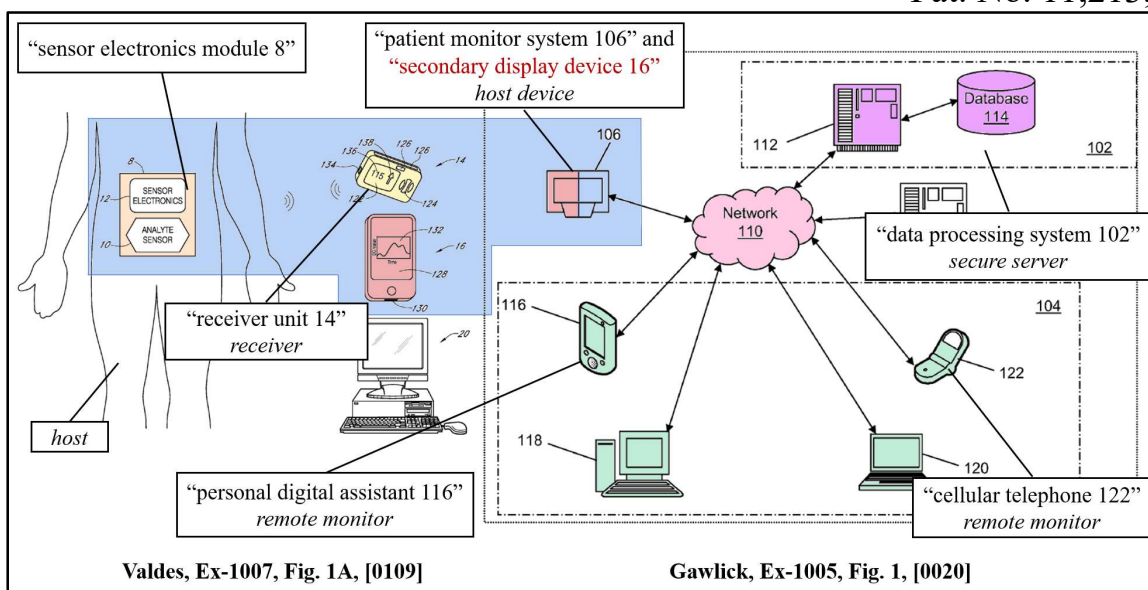
⁵ Throughout my declaration I use *italics* to indicate language from the Challenged Claims.



99. While Gawlick’s disclosure including Figures 26 and 27 suggests a continuous glucose monitoring, Valdes discloses a CGM system and method “for communicating glucose concentration information between devices of a continuous glucose monitoring system.” with a “receiver unit,” a *receiver*, that receives and processes the analyte sensor data.” Ex-1007, Abstract, [0097]. A host’s “glucose concentration” is a well-known *analyte state of a host*. Ex-1007, [0059]. Valdes further discloses a “secondary display device,” including a *host device*. Specifically, the “receiver unit 14, 314 determines whether to send data to a

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secondary display device, such as secondary display device 16, 20, 316A, 316B or 316C.” Ex-1007, [0177].

100. The annotated figure below further illustrates the combination of Gawlick in view of Valdes, depicting the CGM of Valdes Fig.1A adjacent to Gawlick’s Figure 1. Gawlick’s patient monitor system 106 (i.e., *host device*) has been shaded partially with red to indicate that in the combined system the “patient monitor system 106” would make explicit what is implicit in Gawlick and includes CGM capabilities that interact with a “secondary display device.” A POSITA would have understood that this would require the “patient monitor system 106” to have an interface to facilitate communication with the “receiver unit.” At the time, a POSITA would have understood that the development of said interface is facilitated by an interface control document (ICD), an interface design description (IDD), or similar technical documents that outline the characteristics of an interface between two or more systems, subsystems, hardware components, software components, or other elements, essentially serving as a blueprint for how these different parts will interact and exchange data. A POSITA would have been able to connect the “receiver unit” and “patient monitor system” using well-known and standard network communication techniques present at the time, including but not limited to Bluetooth Low Energy, USB, Wi-Fi, ethernet, and cellular.



1. Motivation to combine Gawlick and Valdes with reasonable expectation of success

101. A POSITA would have combined Gawlick with Valdes. Gawlick discloses that its system may be used to monitor various patient physiological characteristics, without being solely dedicated to any particular physiological characteristic, in order to manage myriad acute or chronic health conditions. Gawlick discloses glucose measurements as a physiological characteristic and at least suggests continuous glucose readings as shown in Figures 26 and 27. This flexible teaching in Gawlick combined with the disclosure of glucose readings would have motivated the POSITA to consider continuous glucose monitoring systems to use with Gawlick's teachings. A POSITA implementing Gawlick's system would have been motivated to use Valdes's "continuous analyte sensor," "receiver unit," and "secondary display unit" to explicitly implement what is

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already suggested in Gawlick's system with patient analyte data for use by the system. A POSITA would have understood that continuous monitoring of glucose levels provides important and distinct advantages over infrequent, invasive, periodic sampling of blood glucose using blood assay or finger stick. By 2012, there were many published studies to demonstrate the advantage of continuous glucose monitoring.

Teaching, Suggestion, Motivation

102. In addition, 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 heart rate, respiratory rate, cardiac rhythm, blood pressure, oxygen saturation, blood chemistry, etc.**” Ex-1005, [0021]. Gawlick also discloses glucose as one specific physiological characteristic. Ex-1005, Figs. 16, 17, 26, 27. “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 illness, which is consistent with Gawlick's criticism of preexisting monitoring systems for ignoring the differences between different types of patients. Ex-1005, [0001].

103. A POSITA would have readily understood that one such “sensor[.]” that used known “sensing/detection technology” was a continuous glucose monitor, such as the one disclosed by Valdes, which is useful for patients with diabetes mellitus. Gawlick includes exemplary rules for blood glucose, Ex-1005, Fig. 17, but these measurements are the result of a “blood panel.” Ex-1005, [0112]. A POSITA would have known that for people with diabetes mellitus, a continuous glucose monitor as disclosed by Valdes offers advantages. For example, Valdes explains that when “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]. “In fact, it is not only unlikely that a diabetic will take a timely SMBG [(self-monitoring blood glucose)] value, but additionally the diabetic will not know if his blood glucose value is going up (higher) or down (lower) based on conventional methods.” Ex-1007, [0004]. Thus, a POSITA would have appreciated that combining the monitoring system disclosed by Gawlick with the continuous glucose monitor disclosed by Valdes would be advantageous for patients with diabetes mellitus.

104. The advantages of a subcutaneous minimally invasive sensor which produces periodic estimated glucose readings versus sporadically lancing the fingertip to provide a capillary blood sample to be placed on the strip of a blood glucose meter (“BGM”) or glucometer were obvious to a POSITA by the time of

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the '204 patent: a CGM is nearly painless, continuous, and does not require the person with diabetes or their care partner to be awake for sampling. Instead of producing infrequent (3-10) “spot” samples per day like with a BGM, a CGM produces many periodic equispaced samples per day (for example, 288 samples per day, one every 5 minutes), affording a capability for trending, reporting, and exception-based notifications (e.g., only notify if glucose level and / or trend deviates from established thresholds set in rules).

105. A POSITA would have modified the Gawlick’s “patient monitor system 106” to accept data from the receiver, i.e., act as a Valdes secondary display device, because then the receiver unit can act as an “intermediary” between the “sensor electronics module 8” and the “display device,” which allows the “display device” to obtain data without including an “authentication mechanism” for the sensor. Ex-1007, [0110]. This approach would have been advantageous for Gawlick’s flexible system with multiple sensors because it leaves the sensor and receiver devices unchanged and avoids implementing a new authentication mechanism for each sensor type and manufacturer. This would be particularly helpful for a setting in which a hospital or healthcare provider wants to support devices from different CGM manufacturers who might have different methods of communicating between their sensor and receiver.

Other Factors and Reasonable Expectation of Success

106. Combining Gawlick and Valdes would have merely involved combining known prior art elements (i.e., Valdes's continuous glucose monitor sensor and "receiver unit" with Gawlick's "patient monitor system") according to known methods to yield predictable results (i.e., continuous measurement and monitoring of the glucose level of a host). As I explained above, this would have required merely implementing the interface needed for the "receiver unit" to provide its data, a task well within the knowledge of a POSITA.

107. 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., 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 already suggested, if not taught, by Gawlick. A POSITA would have understood that continuous, minimally invasive analyte sampling confers advantages over sporadic, manual analyte sampling/testing and would have been motivated to substitute the former for the latter. Indeed, Valdes discloses that the receiver can transmit data wirelessly to a "secondary display unit." Modifying Gawlick's "patient monitor system 106" with Valdes's "receiver unit" to receive

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the data by acting as a “secondary display unit” would have required a mere substitution of the data-receiving components of the “secondary display unit” in Valdes into Gawlick’s “patient monitor system 106.”

108. Receiving data using 2012 de facto standard wired (i.e., Universal Serial Bus or USB) and wireless (i.e., Bluetooth Low Energy or BLE) protocols to connect CGMs to the “patient monitor system” would have been obvious to a POSITA. Many blood glucose meters (“BGM”) in 2012 had capabilities to send data to secondary display units. For instance, the Bayer Contour Link blood glucose meter “[t]ransmits glucose values to compatible MiniMed Paradigm and Guardian REAL Time devices” using a wireless RF (radio) link. *See* CONTOUR LINK 510(k) Summary, https://www.accessdata.fda.gov/cdrh_docs/pdf11/K110587.pdf (March 28, 2012). Both the MiniMed Paradigm—an insulin pump—and the Guardian REALtime—a CGM—may be considered secondary CGM displays. The Bayer Contour Next USB BGM added a USB connection to secondary display units such as a Windows PC running appropriate software to display glucose information. *See* Contour NEXT USB Blood Glucose Monitoring 510(k) Summary, https://www.accessdata.fda.gov/cdrh_docs/pdf12/K121087.pdf (June 28, 2012).

109. Continuous glucose monitors, including the Valdes CGM, were well known in the art to yield predictable results. By 2010 the clinical benefits of

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continuous glucose monitoring were well-established in numerous publications, and the adoption of continuous glucose monitoring by people with diabetes was growing rapidly. In addition, Valdes discloses using well-known “direct wireless communication” protocols to send a “data package” using standard protocols “including radio frequency, Bluetooth, universal serial bus, any of the wireless local area network (WLAN) communication standards, including the IEEE 802.11, 802.15, 802.20, 802.22 and other 802 communication protocols, and/or a proprietary communication protocol.” 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 protocols 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 Valdes’s continuous glucose monitor to generate data and transmit it to Gawlick’s patient monitor 106 for use in Gawlick’s monitoring system using routine programming techniques. A POSITA would have been familiar with these protocols and communication methods. Provided with an interface control document (ICD), an interface design description (IDD), or similar technical documents describing the device’s interface characteristics, they would have been able to create a compatible interface.

2. Claim 1

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

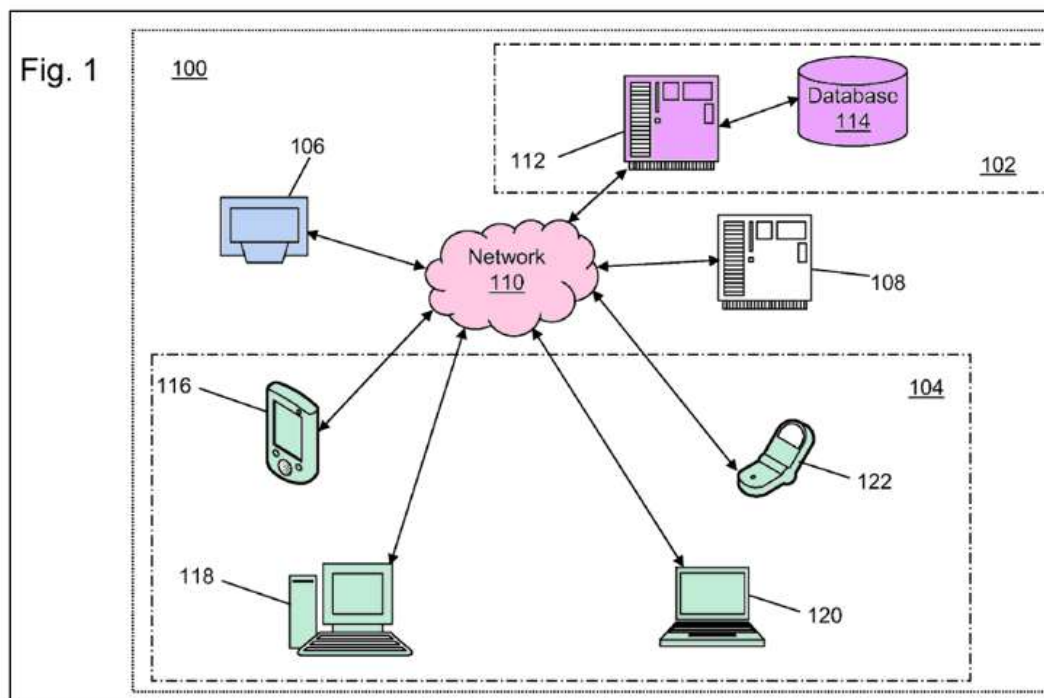
110. Gawlick discloses the preamble, to the extent it is limiting.

111. Gawlick discloses “a method for adjusting an alert rule used to indicate a status of a patient.” Ex-1005, [0006].

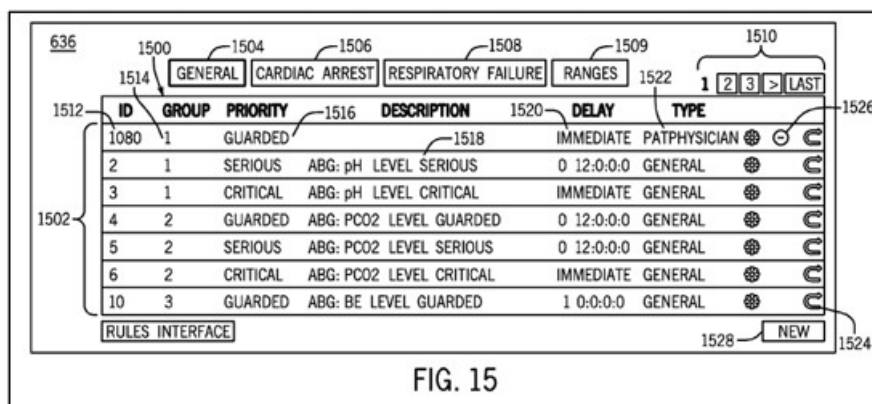
b) *1[a]: “identifying, by a remote monitor, a set of one or more rules that define conditions for communications between a secure server and the remote monitor,”*

112. Gawlick discloses this limitation.

113. Gawlick discloses a medical alert system 100 as depicted in Figure 1, below. Gawlick’s “medical personnel alert system 104” includes “one or more computing devices,” or *remote monitors*, 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]. Gawlick also discloses 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]. The use of login credentials is indicative of the server implementing security protocols. Thus, a POSITA would have understood “data processing system 102” to be a *secure server*.



114. 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." Gawlick depicts in Figure 15 a "dashboard space 636 may include an alert rule list 1500 presented under control of browser application 311 in combination with second medical alert application 310 and through interaction with medical alert application 210 at medical personnel alert device 104'." Ex-1005, [0068]. Using this list, the user of the remote monitor may configure rules that define when alerts are sent from the 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,”*

115. The combination of Gawlick and Valdes renders this limitation obvious.

116. Gawlick discloses a “data processing system 102,” or *secure server*, including “database 114” that uses a “rules engine.” Ex-1005, [0018]-[0019]. Gawlick’s “data processing system 102” 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*, when requested. Ex-1005, [0068] (explaining “with reference to FIG. 15, dashboard space 636 may include an alert rule list 1500 presented under control of **browser application 311 in combination with second medical alert application 310 and through interaction with medical alert application 210 at medical personnel alert device 104’.**”), [0087].

117. Figure 5 depicts “operations performed using a medical alert application” on a “medical personnel alert device,” or *remote monitor*. Ex-1005, [0014]-[0015]. Figure 17, below, also depicts *one or more* alert rule settings that the system will use to generate *one or more rules* that are provided to the *remote monitor* by the “data processing system 102,” or *secure server*.

FIG. 17

The rule shown in Figure 17 above is associated with blood glucose level (data associated with ... an analyte state of a host).

118. The Gawlick system includes a “patient monitor system 106,” inclusive of a host device. The “patient monitor system 106” may be connected to “network 110” to transmit data to the “database 114,” which is part of “data processing system 102,” or secure server. Ex-1005, [0021].

119. When combined with Valdes, one of the sources of data is a continuous glucose monitor, which includes a receiver configured to monitor the analyte state of a host. In particular, Valdes discloses a system and method “for communicating glucose concentration information between devices of a continuous glucose monitoring system.” Ex-1007, Abstract. The “glucose concentration” is a well-known analyte state of a host. Ex-1007, [0059]. Valdes discloses a “continuous analyte sensor” for providing “sensor data includ[ing] a raw data stream, or simply data stream, of analog or digital signal directly related to the measured analyte from an analyte sensor. Ex-1007, [0062].

120. Valdes discloses a “receiver unit,” or *receiver*, that receives and processes data from the analyte sensor, *i.e.*, is *configured to monitor the analyte state of a host*. Ex-1007, [0097] (“The receiver unit can include electronics configured to process sensor data received from the sensor electronics module and display or otherwise communicate (e.g., via audible communication) sensor-related information to a user.”). In the Gawlick-Valdes combination, the *rules* implemented by Gawlick’s “rules engine” that are *provided to the* “one or more computing devices,” *remote monitors*, are *associated with data associated with* Valdes’s *receiver*, which is *configured to monitor an analyte state of a host*.

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

- d) *I[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"*

122. Gawlick renders this limitation obvious, by itself or in view of Valdes. A POSITA would have understood that FDA reviews and approves / clears medical devices for commercial use on a risk-benefit basis, providing guidance and recognized standards to industry, and that some system architecture, device connectivity, and system form-function allocation choices would represent higher or lower risk than other alternatives. A POSITA would have understood that configuration of an initial set of rules on the receiver would be lower risk than configuration of an initial set of rules on a secondary display, web page served by a central server, or other location in the system.

123. Gawlick discloses a *host device*, within "patient monitor system 106," that can be used to configure "an alert rule table 1100," with *preferences or settings* that will be used to generate *the set of one or more rules* for the "medical personnel alert devices" (*remote monitors*). A block diagram of "patient monitor system 106" is depicted in Figure 4. Ex-1005, [0014]. The "patient monitor system

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106” 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, [0037]. These interfaces and applications provide “the same or similar functionality” as the first and second interfaces and applications and allow a user to adjust *preferences or settings* using the “patient monitor system 106,” i.e., *host device*. Ex-1005, [0038].

124. These *preferences or settings* are used to generate one or more rules. 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 106,” which includes the recited *host device*. Ex-1005, [0014]-[0015]. 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. Alert rules may be predefined for a general patient population based on the values indicated in alert rule table 1100. Alternatively, a different table of alert values may be defined based on the protocol for which the patient is admitted, based on a group of medical personnel such as a nurse or a physician, based on a specific medical person such as a specific physician, based on a specific type of physician such as a surgeon or a cardiothoracic specialist, etc.” Ex-1005, [0061]. Figure 17 provides an exemplary “plurality of user interface controls that allow the

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user to define a new alert rule.” Ex-1005, [0076]-[0087] (explaining how each of the user interface controls is used to configure a rule).

Ex-1005, Fig. 17 (depicting creation of a rule for blood glucose values).

125. Alternatively, Valdes provides additional disclosures of configuring preferences or settings for generating the set of one or more rules. Valdes discloses that the “receiver unit” can be used in combination with a “secondary display device.” Ex-1007, Fig. 4. As explained above, Gawlick’s “patient monitor system 106,” which includes the recited *host device*, would operate as a “secondary display device” when combined with Valdes. Valdes further explains that the “receiver unit” (*receiver*), when “used in combination with a secondary display device,” provides blood-glucose readings, the *analyte state of a host*, to the

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“secondary display device” (Gawlick’s “patient monitor system 106,” or *host device*). Ex-1007, [0168], [0177].

126. In addition, Valdes discloses that the user may set user parameters such as alert/alarm settings (such as thresholds) using the secondary device. 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 106,” which includes the recited *host device*. For example, Figure 17 of Gawlick (shown above), shows a “condition” that includes glucose thresholds of “64” and “160” mg/dL, which match the glucose thresholds used for alerts in Valdes. Ex-1005, Fig. 17. Once saved, these *preferences or settings* are stored in the “alert rules table of database 114” of “data processing unit 102,” or *secure server*, Ex-1005, [0087], and are used to “trigger actions to alert medical personnel” via the “medical alert application” in the “medical personnel alert device,” or *remote monitor*, Ex-1005, [0042].

127. It would have been obvious to a POSITA to use Gawlick’s “patient monitor 106” to include the functionality of Valdes’s “secondary display device” to set hypoglycemic- or hyperglycemic-alert thresholds for at least the reasons explained above and in Section XI.A.1. A POSITA would have recognized that these are simple rules, with no signal processing experience required to implement

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them. The rules lead directly and obviously to diagnostic, troubleshooting, or treatment activities. For these reasons it would have been obvious to a POSITA to set hypoglycemic or hyperglycemic alert thresholds. XI.A.1.

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

128. Gawlick discloses this limitation.

129. Gawlick discloses using a “medical alert application” on a “medical personnel remote device,” or *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. 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 explains that the user of the remote monitor can use the second medical alert application to modify and save alert rules. Ex-1005, [0049].

130. For example, “[t]hird user interface window 1000 further may include a save button 1044 . . . Upon 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** and third user interface window 1000 is closed. In an example embodiment, **the adjusted alert range values are also associated with the user adjusting the values** based on the account associated

with the username and password. Thus, **the adjusted alert range values may be customized for the patient and/or medical personnel adjusting the alert values.** Of course, not all medical personnel may have permission to adjust the alert values.” Ex-1005, [0059].

131. Gawlick explains in detail how to edit an alert rule. For example, “[u]pon receipt of an indication of a user selection of modifier selector 1524 associated with an alert rule of the one or more alert rules 1502, an alert rule window may be presented under control of browser application 311 in combination with second medical alert application 310 and through interaction with medical alert application 210 at medical personnel alert device 104’. **The alert rule window allows the user to adjust the parameters associated with the alert rule.** In an example embodiment, the user may only override the alert rule so that the modified alert rule is only associated with the user, and thus, does not affect the alert rules of other users. Override indicator 1526 may be used to indicate that the alert rule is a modified alert rule that is overriding another 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*

132. The combination of Gawlick and Valdes renders this limitation obvious.

133. 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 102,” or *secure server*, includes a database 114 that stores data, i.e., as received from Valdes’s “receiver unit,” or *receiver*, via the “patient monitor 106,” which includes the recited *host device*, corresponding to the blood-glucose level of the host, or *the analyte state of the host at a first time*. See Section XI.A.2.c. The “data processing system 102,” *secure server*, 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*.

FIG. 17

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

134. Gawlick discloses that the “alert rule[s] [are] triggered based on receipt of a measured value of a physiological characteristic.” Ex-1005, [0062].

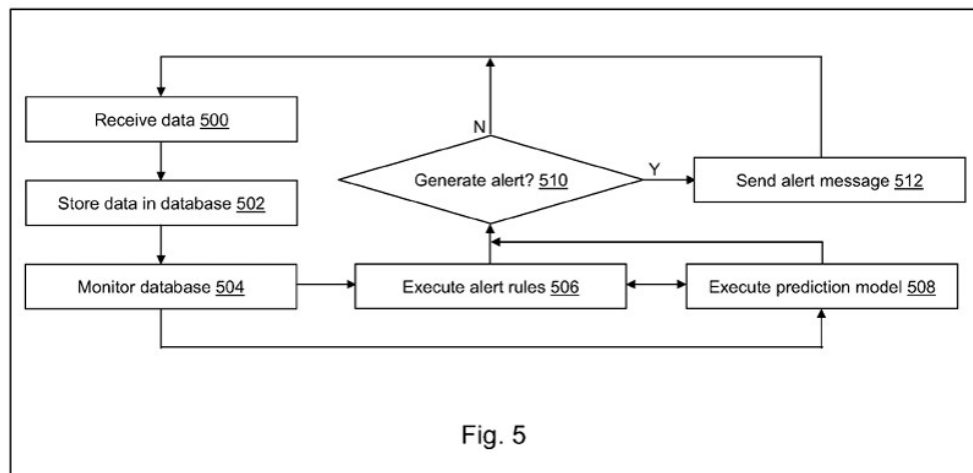
“For example, patient monitor system 106 may measure a blood pressure of a patient which is sent to data processing system 102 and stored in database 114 for comparison with an alert rule or rules associated with the blood pressure. **Thus, the measured value of the physiological characteristic is sent by patient monitor system 106 and received by data processing system 102 along with a characteristic indicator of the physiological characteristic which indicates to which physiological characteristic the measured value is associated. An** applicable alert rule may be identified by comparing the characteristic indicator of

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the measured value to the physiological characteristic indicator associated with the alert rule.” Ex-1005, [0062].

135. “FIG. 5 depicts a flow diagram illustrating example operations performed using medical alert application of the server computing device of FIG. 2, the medical personnel alert device of FIG. 3, and/or the patient monitor system of FIG. 4 in accordance with an example embodiment.” Ex-1005, [0015].

136. “With reference to FIG. 5, example operations associated with medical alert application 210 . . . are described.” Ex-1005, [0040].



Ex-1005, Fig. 5. “The data may be received from . . . patient monitor system 106.” Ex-1005, [0040]. “In an operation 506, an alert rule is executed. In an example embodiment, the alert rule is stored in a table of database 114. The alert rule may be a simple alert rule or a complex alert rule. In an example embodiment, Oracle(R) Rules Manager **evaluates the alert rule or rules and triggers actions to alert**

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medical personnel such as doctors and nurses about a condition of a patient.”

Ex-1005, [0042]. 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 XI.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,”*

137. Gawlick discloses this limitation.

138. As explained above in XI.A.2.f with reference to Figure 5, Gawlick discloses a process for evaluating data and generating alerts. Ex-1005, [0040]-[0043]. Gawlick explains that if an “alert is generated,” *when triggered at the first time*, it may be sent to a “medical personnel alert device,” *causes an alert message to be sent to the remote monitor from the secure server to notify the remote monitor of the event*. “If a determination is made that an alert should be generated, in an operation 512, an alert is generated and processing continues at operation 500. For example, an alert may be sent to one or more medical personnel alert device 104’ of medical personnel such as doctors and nurses.” 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”*

139. Gawlick discloses this limitation.

140. Gawlick discloses using a “medical alert application” on a “medical personnel alert device,” or *remote monitor*, for *modifying the first setting set by the host device*. Ex-1005, [0014]-[0015]. Figure 15 depicts an “alert rule list 1500.” Ex-1005, [0071]. Using the alert rule list 1500, the user may “adjust the parameters associated with the alert rule.” Ex-1005, [0075]. Alternatively, the user can use “New button 1528” to create a new alert rule. Ex-1005, [0076].

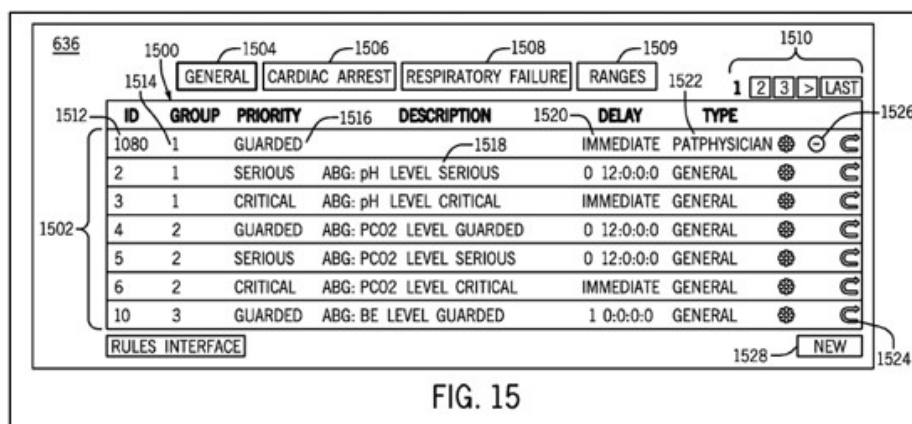


FIG. 15

141. For example, Gawlick explains that the “[t]hird user interface window 1000 further may include a save button 1044 . . . Upon 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** and third user interface window 1000 is closed. . . . 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 have understood that the “alert rules list” being accessed using the “medical personnel alert device,” or *remote monitor*, corresponds to the “patient indicated in patient demographic information 604” that Gawlick discloses, using the *remote monitor*, to modify the *first setting set by the host device*.

- 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.”*

142. Gawlick discloses this limitation.

143. Gawlick discloses that a “medical personnel alert device,” or *remote monitor*, allows a user to “override the alert rule,” or *modify the first setting by the remote monitor*, “so that the modified alert rule is only associated with the user” of the “medical personnel alert device” and thus the *remote monitor modifies the first setting for the remote monitor without changing the first setting at the host device*.

144. For example, Gawlick discloses that “[u]pon receipt of an indication of a user selection of modifier selector 1524 associated with an alert rule of the one or more alert rules 1502, an alert rule window may be presented under control of browser application 311 in combination with second medical alert application 310 and through interaction with medical alert application 210 at medical personnel alert device 104’. The alert rule window allows the user to adjust the parameters

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associated with the alert rule. **In an example embodiment, 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.** Override indicator 1526 may be used to indicate that the alert rule is a modified alert rule that is overriding another alert rule.” Ex-1005, [0075].

145. Gawlick discloses many fields available for user configuration—shown in detail by Figures 17 and 18. Ex-1005, [0079] (“Selection of the ‘Patient’ option in the drop down selector box may indicate that the alert rule is applied to a specific patient. The specific patient may default to the patient indicated in patient demographic information 604 or the user may be requested to select a patient from a list of patients.”). “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.** Rule override search control 1716 includes a drop down selector box user interface control into which the user may enter text and from which the user may select an alert rule to override. The alert rules from which the user may select are created based on matching the text entered by the user with an existing alert rule description.” Ex-1005, [0083]. “In the example embodiment of FIG. 17, test condition control 1724 includes a text box in which the user may define an alert rule test condition 1725. Alert rule test condition 1725 may include

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a physiological characteristic indicator 1726 and a test condition 1728.” Ex-1005,
[0086].

3. Claim 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.”*

146. Gawlick discloses this limitation or renders this limitation obvious in view of Valdes.

147. As discussed in Sections XI.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, Gawlick Fig. 17 includes an “ABG_GLUCOSE_CRITICAL” alert when “ABG_GLUCOSE” is less than a threshold of 64.

FIG. 17 is a screenshot of a medical alert application interface. The interface is enclosed in a rectangular frame. At the top, there is a header bar with the text "GROUP (TIP: LEAVE IN BLANK TO NEW GROUP)" and a label "636". Below the header, there are several input fields and dropdown menus, each with a label and a reference number: "1702" for "8", "1704" for "PRIORITY" (with a dropdown arrow), "1706" for "TYPE" (with a dropdown arrow), "1708" for "DELAY (TIP: DELAY FORMAT IN DD HH:MM:SS)", "1710" for "DESCRIPTION", "1712" for "ACTION", and "1714" for "OVERRIDES THE FOLLOWING RULES:". Below "1714", there is a table with columns "ID", "PRIORITY", and "DESCRIPTION". The table contains one row with the value "23" in the ID column, "CRITICAL" in the PRIORITY column, and "ABG: GLUCOSE LEVEL CRITICAL" in the DESCRIPTION column. Below the table, there is a label "1716" for "SEARCH RULES TO OVERRIDE:". Below "1716", there is a checkbox labeled "1718" for "EVALUATE RULE EVERY:". To the right of the checkbox, there is a text input field labeled "1720" and a dropdown menu labeled "1722" with the value "MINUTE". Below the checkbox, there is a label "1724" for "CONDITION (USE ⁢ AND > FOR < AND > RESPECTIVELY)". Below "1724", there is a text input field labeled "1725" containing the text "<condition>". Below "1725", there is a text input field labeled "1726" containing the text "<object name='r0'>rtype='ABG_GLUCOSE' AND 'value < 64 OR value > 160' </object>". Below "1726", there is a label "1728" for "</condition>". At the bottom of the interface, there are two buttons labeled "1730" for "SAVE" and "1732" for "CANCEL".

148. The “medical alert application” allows the “medical personnel alert device,” or *remote monitor*, to modify this threshold. As discussed in above Sections XI.A.2.f-g, Gawlick discloses that the “alert rule engine” in “data processing system 102,” or *secure sever*, determines that the data 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*.

149. Similarly, Valdes discloses a rule based on “exceeding a hypoglycemia threshold.” Ex-1007, [0017]; *see also* Ex-1007, [0101] (“For example, a **hypoglycemic alert** may include alert conditions indicating a minimum glucose level.”). In the Gawlick-Valdes combination, the *remote monitor* would be

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able to modify this threshold in the same way it can modify the low-glucose threshold value of 64 disclosed in Gawlick. 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" for at least the reasons explained above and in Section XI.A.1.

4. Claim 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."*

150. Gawlick discloses this limitation or renders this limitation obvious in view of Valdes.

151. As discussed above in Sections XI.A.2.f, h, & i, 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.

152. The “medical alert application” allows the “medical personnel alert device,” or remote monitor, to modify this threshold. As discussed above in Sections XI.A.2.f & g, Gawlick discloses that the “alert rule engine” in “data processing system 102,” or secure sever, determines that the data 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.

153. Similarly, Valdes discloses a rule based on “exceeding a hyperglycemia threshold.” Ex-1007, [0017]; see also Ex-1007, [0034] (“[T]he default settings comprise a setting indicative . . . of a **hyperglycemic event** threshold, . . .”). In the Gawlick-Valdes combination, the remote monitor would be

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able to modify this threshold in the same way it can modify the high-glucose threshold of 160 disclosed in Gawlick. 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" for at least the reasons explained above and in Section XI.A.1.

5. Claim 12

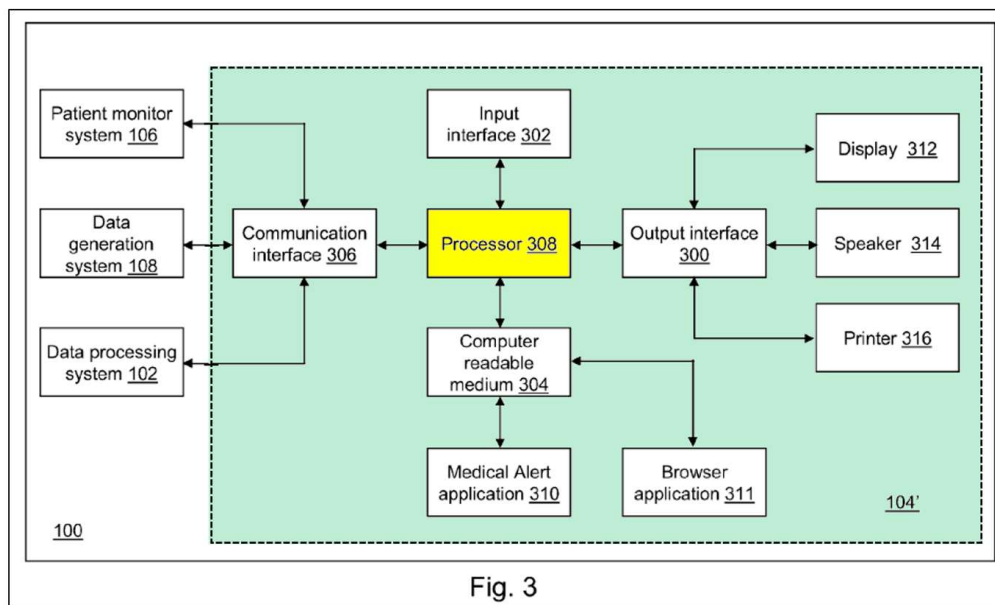
- a) 12[preamble]: "*An apparatus for remote monitoring of a host's analyte levels, the apparatus comprising:*"

154. To the extent the preamble is limiting, Gawlick discloses this limitation or renders this limitation obvious in view of Valdes. *See* Sections XI.A.2.a-b.

- b) 12[a]: "*at least one processor; and*"

155. Gawlick discloses this limitation.

156. Gawlick discloses a "medical personnel alert device 104'," or *remote monitor*, that is depicted in the block diagram of Figure 3 and includes a "second processor 308," or *at least one processor*. Ex-1005, [0034].



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

157. Gawlick discloses this limitation.

158. Gawlick discloses a medical personnel alert device 104', or *remote monitor*, that is depicted in the block diagram of Figure 3 and includes “computer readable medium 304,” or *at least one memory including code*, that is *executed by the at least one processor*. Ex-1005, [0034].

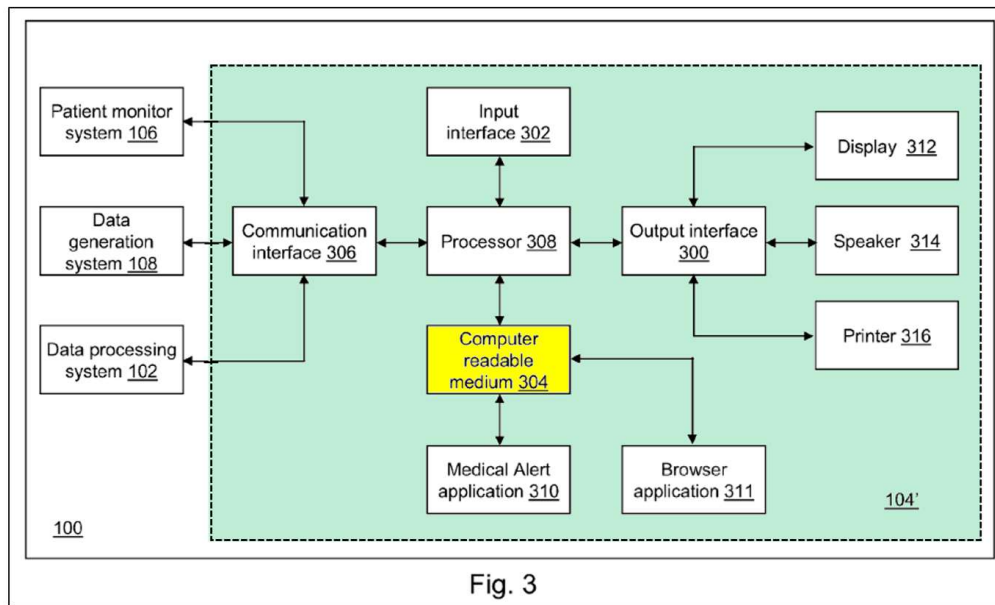


Fig. 3

159. For the block diagram in Figure 2, Gawlick explains that “computer-readable medium 204 is an electronic holding place or storage for information so that the information can be accessed by processor 208 as known to those skilled in the art. **Computer-readable medium 204 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 (e.g., hard disk, floppy disk, magnetic strips, . . .), optical disks (e.g., CD, DVD, . . .), smart cards, flash memory devices, etc.**” Ex-1005, [0028]. A POSITA would also understand that this same explanation applies to the “computer-readable medium 304.” A POSITA would have understood that the “medical alert application 310” would be implemented as *code* for performing the various

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operations described by Gawlick when executed by the included *processor*. See
Ex-1005, [0031].

- 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,”*

160. Gawlick discloses this limitation or renders this limitation obvious in view of Valdes. See Section XI.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,”*

161. Gawlick discloses this limitation or renders this limitation obvious in view of Valdes. See Section XI.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”*

162. Gawlick discloses this limitation or renders this limitation obvious in view of Valdes. See Section XI.A.1.d.

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

163. Gawlick discloses this limitation or renders this limitation obvious in view of Valdes. See Section XI.A.1.d.

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

164. Gawlick discloses this limitation or renders this limitation obvious in view of Valdes. *See* Section XI.A.1.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,*”

165. Gawlick discloses this limitation or renders this limitation obvious in view of Valdes. *See* Section XI.A.1.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,*”

166. Gawlick discloses this limitation or renders this limitation obvious in view of Valdes. *See* Section XI.A.1.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*”

167. Gawlick discloses this limitation or renders this limitation obvious in view of Valdes. *See* Section XI.A.1.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.”*

168. Gawlick discloses this limitation or renders this limitation obvious in view of Valdes. *See* Section XI.A.1.i.

6. Claim 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.”*

169. Gawlick discloses this limitation or renders this limitation obvious in view of Valdes. *See* Section XI.A.3.

7. Claim 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.”*

170. Gawlick discloses this limitation or renders this limitation obvious in view of Valdes. *See* Section XI.A.4.

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

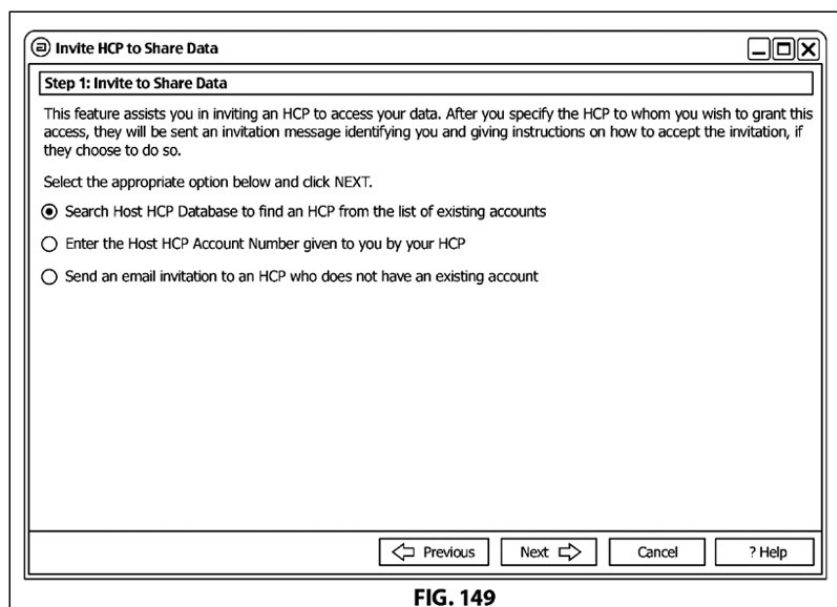
171. As shown below, claims 5-7 and 17-19 would have been obvious based on Gawlick in view of Valdes and Goodnow. Gawlick discloses a “medical alert application” that requires users to log into the system using a username and password. Ex-1005, [0049]. Gawlick also explains that different users of its system may have different permissions, e.g., “not all medical personnel may have permission to adjust the alert values.” Ex-1005, [0059]. A POSITA would have understood that these account features were well-known in the art prior to the alleged invention of the ’204 patent. For example, Goodnow discloses, among other things, inviting a new user to access data and how that new user’s account would be created. A POSITA would have used Goodnow’s disclosures, below, to implement the features discussed in Gawlick. Specifically, a POSITA would have modified the “medical alert application” in the “patient monitor 106” (including a *host device*), “data processing system 102” (*secure sever*), and “medical personnel alert system 104” (*remote monitors*) based on Goodnow’s disclosure, below, to implement the features discussed in Gawlick. Ex-1005, [0012]-[0016].

172. For example, Goodnow discloses an “Initial User Setup” page for creating a “User ID” and “Password.” Figure 8 depicts this user interface.

The figure shows a screenshot of a software window titled "Initial User Setup". The window has a standard Windows-style title bar with minimize, maximize, and close buttons. The main content area is divided into two sections. The first section, "Application Mode", contains the text "Select whether you want to run the program as a Home User or Health Care Professional:" followed by two radio buttons. The "Home User" radio button is selected and is pointed to by a dashed line labeled "20". The "Health Care Professional" radio button is pointed to by a dashed line labeled "22". The second section, "User Identification", contains the text "Before using the FreeStyle CoPilot Health Management System, you must provide your Name and a User ID and Password." followed by four text input fields: "First Name:", "Last Name:", "E-Mail Address:", and "User ID*:". The "User ID*" field is highlighted with a yellow background and is pointed to by a dashed line labeled "24". Below the "User ID*" field is a "Password*" field, and below that is a "Confirm Password*" field. At the bottom of the window are three buttons: "OK", "Cancel", and "? Help". A note at the bottom states: "*User ID and Password are case-sensitive and must be at least 5 characters long."

FIG. 8

Ex-1008, Fig. 8, [0222]. Similarly, Goodnow discloses inviting a health-care professional, or “HCP,” to share data.



Ex-1008, Fig. 149, [0341]. Additional features and modifications are detailed below.

1. Motivation to combine Gawlick, Valdes, and Goodnow with reasonable expectation of success

173. A POSITA implementing Gawlick's system would have been motivated to use Goodnow's systems and methods to implement those disclosed account features.

Teaching, Suggestion, Motivation

174. Gawlick discloses that “[a]s known to those skilled in the art, the user may have logged into third medical alert application 410, second medical alert application 310, and/or medical alert application 210 using a user name and password when initially requesting access to the URL entered in URL window 602. The username may be associated with an account that is associated with a medical personnel group such as nurse, medical technician, physician, etc. and/or a

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specific individual.” Ex-1005, [0050]. Gawlick further discloses that different users of the disclosed system may have different permissions to perform operations, e.g., to “adjust the alert values.” Ex-1005, [0059]. Thus, Gawlick contemplates a POSITA would understand how to implement these user-account features. *See* Ex-1005, [0030]-[0032], [0117]-[0118].

175. As of the priority date for the ’204 patent, such features were well-known. 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

176. Combining Gawlick and 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 health care professionals to share data). A POSITA would understand that these features could be implemented using well-known techniques. For example, Lightweight Directory Access Protocol (LDAP) was an existing standard for controlling access to distributed resources.

177. Combining Gawlick and Valdes with Goodnow would require a simple substitution of one known element for another to obtain predictable results. Gawlick discloses a system having usernames/passwords and account permissions. Ex-1005, [0039].

178. Software systems with user accounts including usernames, passwords, and permissions were pervasive in the art prior to the '204 patent. It was obvious to a POSITA that to comply with Health Insurance Portability and Accountability Act ("HIPAA"), authorization and security measures are necessary components of a CGM remote monitoring system. HIPAA aims to protect individually identifiable health information of patients. For systems which involved collecting patient health data remotely (e.g., estimated glucose values from a CGM) and transmitting it to care partners / HCP's, HIPAA compliance was mandatory. Generally, HIPAA requires a patient's written authorization before using or disclosing their Personal Health Information (PHI) for most purposes. HIPAA mandates that covered entities such as providers of remote monitoring systems implement appropriate security measures to safeguard PHI, such as access controls and encryption of data during transmission. Thus, a POSITA would have been very aware of different methods that could be used to provide these account features including the use of a *secure server*.

179. The technology disclosed by Goodnow was well known, and a POSITA would have had a reasonable expectation of success in applying Goodnow's account features and invitation protocol with Gawlick's remote monitoring system using routine programming techniques. A POSITA would know that by the time of Gawlick's filing in 2010, which is well before the filing of the '204 patent, account creation and invitation protocols for web-based app / services had converged to a streamlined process which minimized manual entry and maximized security by relying on already-established trust and authentication relationships.

2. Claim 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"*

180. Gawlick renders this limitation obvious in view of Valdes and Goodnow.

181. As explained above for claim 1, Gawlick discloses a "medical alert application" that is accessible at a "medical personnel alert system," or *remote monitor*, and a "data processing system," or *secure server*, that includes a database for storing data, including data from the "patient monitor," which includes the recited *host device*. The combination of Gawlick and Valdes would result in data from Valdes's "receiver unit," or *data associated with the receiver*, being sent to

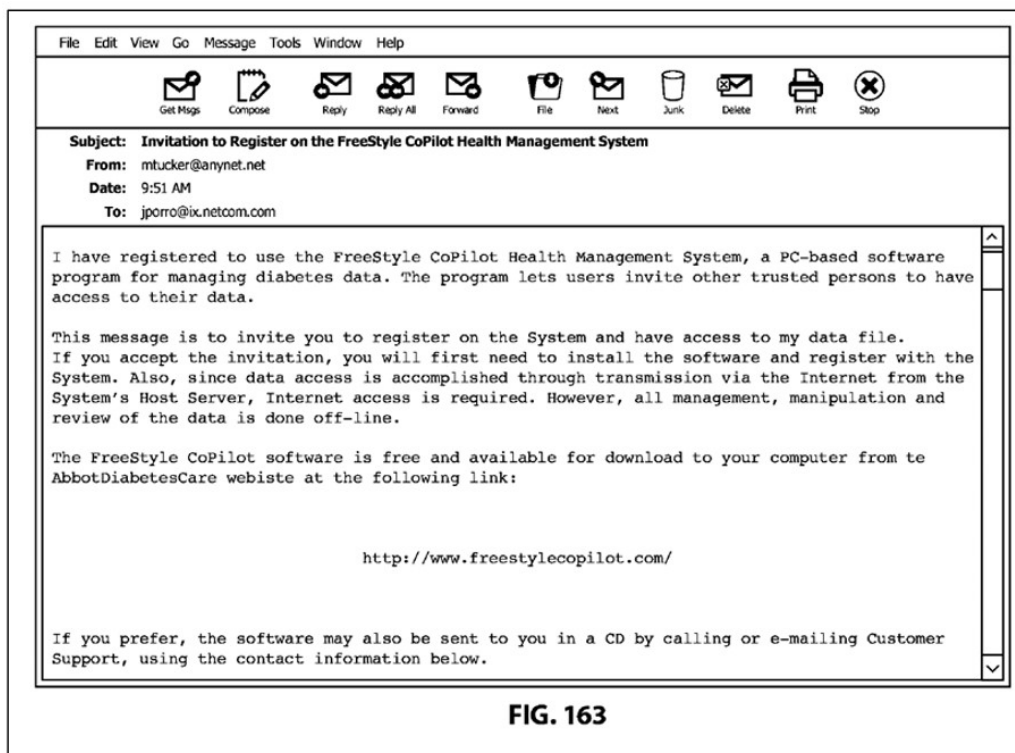
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the “data processing system,” or *secure server*. Gawlick does not, however, describe the process for inviting a new user to access this information. Goodnow discloses the process of sending an *invitation to access the secure server and the data associated with the receiver*. Goodnow further discloses that “a user receives an e-mail invitation to share data.” Ex-1008, [0354]. A POSITA would understand that the “medical personnel alert system” of Gawlick includes “one or more computing devices,” or *remote monitors*, 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.

182. Goodnow discloses a method of inviting a user to access the host’s data. 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.** This notifies the Host that the user will allow the selected HCP to view (and in some cases, edit) their data.” Ex-1008, [0341]. Goodnow explains that the invitation process changes depending on whether the HCP is known. Ex-1008, [0343]-[344]. 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

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(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].

183. 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 download the Health Management System from the Internet (e.g., by just clicking on the hyperlink in blue), install the software and 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].



184. A POSITA implementing Gawlick's system would have been motivated to use Goodnow's systems and methods to implement those disclosed account features. A POSITA would have combined Goodnow with Gawlick and Valdes for at least the reasons described above in Section XI.B.1 and XI.A.1.

b) *"providing, from the remote monitor to the secure server, an acceptance to the invitation."*

185. Gawlick renders this limitation obvious in view of Valdes and Goodnow.

186. 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

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also discloses that “[a]fter the user has downloaded and installed the software, he

or she 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].

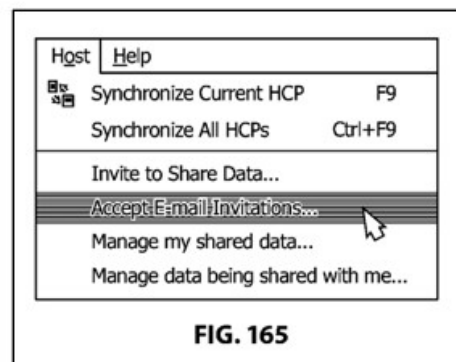
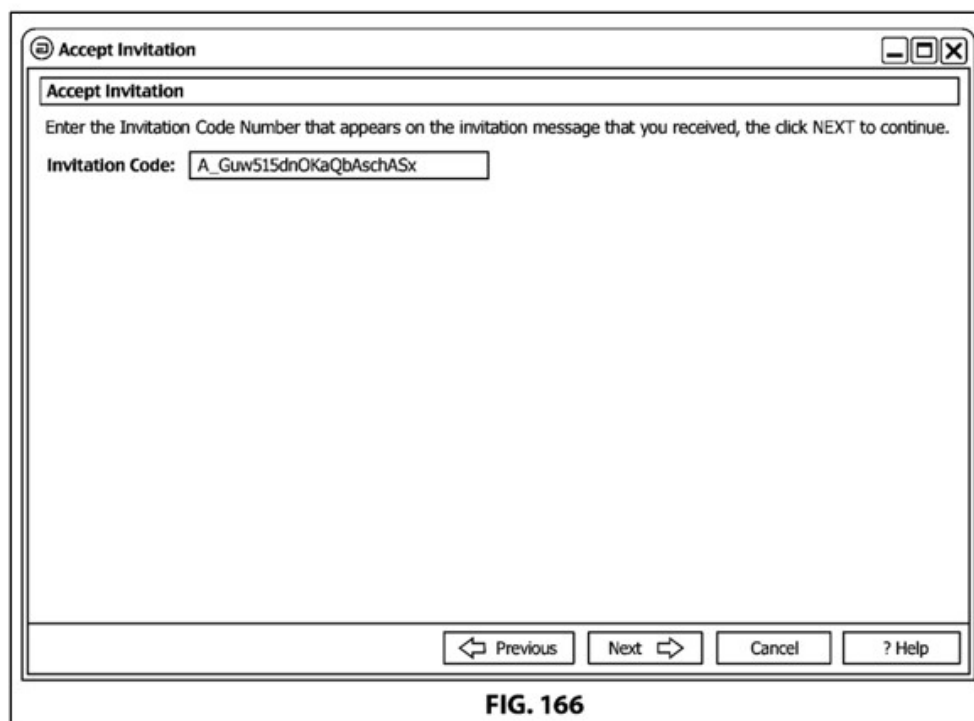


FIG. 165



187. A POSITA would have combined Goodnow with Gawlick and Valdes for at least the reasons described above in Section XI.B.1 and XI.A.1.

3. Claim 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.”*

188. Gawlick renders this limitation obvious in view of Valdes and Goodnow.

189. As explained above in Section XI.A.2.d, Gawlick discloses *a set of recommended rule settings* that are associated with a particular patient and have been configured using a “patient monitor system 106,” which includes the recited

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host device. In Gawlick's system, the user of the "medical personnel alert system 104," or *remote monitor*, sees these *recommended rule settings* in an "alert rule list," as explained above in Section XI.A.2.b. The user of the *remote monitor* can *accept* or *modify* these rule settings, as explained in Sections XI.A.2.e, XI.A.2.h, and XI.A.2.i. A POSITA would understand that Goodnow's invitation protocol, is thus *associated with a set of recommended rule settings configured by the host device*.

190. 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 automatically synchronizing this "data" once the invitation is accepted. Ex-1008, [0355] ("The Host then synchronizes with the user's system, and the patient's data is downloaded."). Thus, a POSITA would understand that Goodnow's invitation protocol, is associated with *a set of recommended rule settings configured by the host device*. A POSITA would have combined Goodnow with Gawlick and Valdes for at least the reasons described above in Section XI.B.1 and XI.A.1.

4. Claim 7

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

191. Gawlick renders this limitation obvious in view of Valdes and Goodnow and the knowledge of a POSITA under DexCom’s proposed construction, as explained above in Section VI.

192. Goodnow discloses a process for establishing an account, that “[a]fter the user has downloaded and installed the software, he or she 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]. A POSITA would have combined Goodnow with Gawlick and Valdes for at least the reasons described above in Section XI.B.1 and XI.A.1.

5. Claim 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.”*

193. Gawlick discloses this limitation or renders this limitation obvious in
view of Valdes and Goodnow. *See* Section XI.B.2.

6. Claim 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.”*

194. Gawlick discloses this limitation or renders this limitation obvious in
view of Valdes and Goodnow. *See* Section XI.B.3.

7. Claim 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.”*

195. Gawlick discloses this limitation or renders this limitation obvious in
view of Valdes and Goodnow. *See* Section XI.B.4.

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

196. Claims 7 and 19 would have been obvious based on Aspel’s teachings
modifying Gawlick in view of Valdes, and Goodnow under Abbott’s proposed
construction. Ex-1010, p.19. As explained above, Goodnow discloses inviting a
new user to access data and how that new user’s account would be created. Aspel

Decl. of Lane Desborough in Support of Petition for *Inter Partes* Review of U.S. Pat. No. 11,213,204 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]; A POSITA would understand and appreciate that automating account creation by maximizing programmatic rather than manual entry of account information lower barriers to adoption and reduces the possibility of entering incorrect or duplicative account information. In addition, by automatically generating the account information once the invitation is accepted, a POSITA could avoid polluting the system with numerous dead and unused accounts when invitations are declined.

1. Motivation to combine Gawlick, Valdes, Goodnow, and Aspel with reasonable expectation of success

197. As explained above, the Gawlick-Valdes-Goodnow system includes well-known account features. 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, Fig.17A-C, [0151]-[0159].

Other Factors and Reasonable Expectation of Success

198. 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). A POSITA would be familiar with contemporary web-based account creation workflows which minimized manual or redundant account information.

199. 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 in applying Aspel's username and password creation features with the Gawlick-Valdes-Goodnow remote monitoring system using routine programming techniques. A POSITA would be familiar with methods to establish and confirm identity during account creation in widespread use by the time of Gawlick's filing in 2010, which is well before the filing of the '204 patent, such as the programmatic sending of email confirmations which include links to confirm identity and complete account information.

2. **Claim 7**

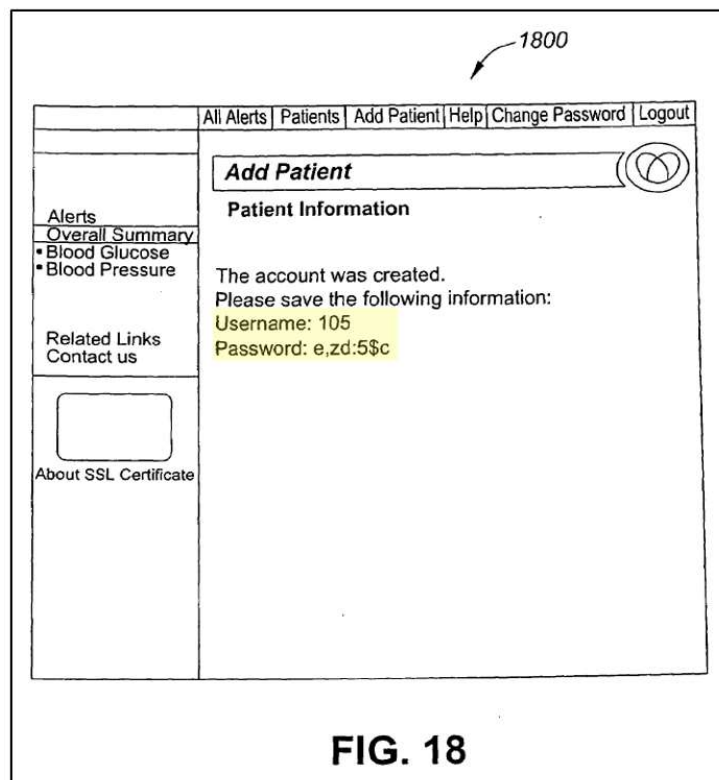
- a) *“The method of claim 5, wherein accepting the invitation, programmatically establishes an account associated with the remote monitor at the secure server.”*

200. Gawlick discloses this limitation and/or renders this limitation obvious in view of Valdes, Goodnow, and Aspel under Abbott’s proposed construction, as explained above in Section VI.

201. As explained above for claim 5, Section XI.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 and security of the user. Generating the username and password once the invitation is accepted also enhances security because only the person receiving the invitation would have the account credentials. 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 an

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invitation was accepted. A POSITA would understand from Figure 18, that the “Username” “105” is a simple ID number that was assigned by the system and the “Password” of “e,zd:5\$c” was an automatically generated temporary password that can be changed by the user after initially logging into the system. Thus, Goodnow’s new user form would be modified to omit the username and password fields.



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

3. **Claim 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.”*

203. Gawlick discloses this limitation and/or renders this limitation obvious in view of Valdes, Goodnow, and Aspel under Abbott’s proposed construction, as explained above in Section VI. *See* Section XI.C.2 above.

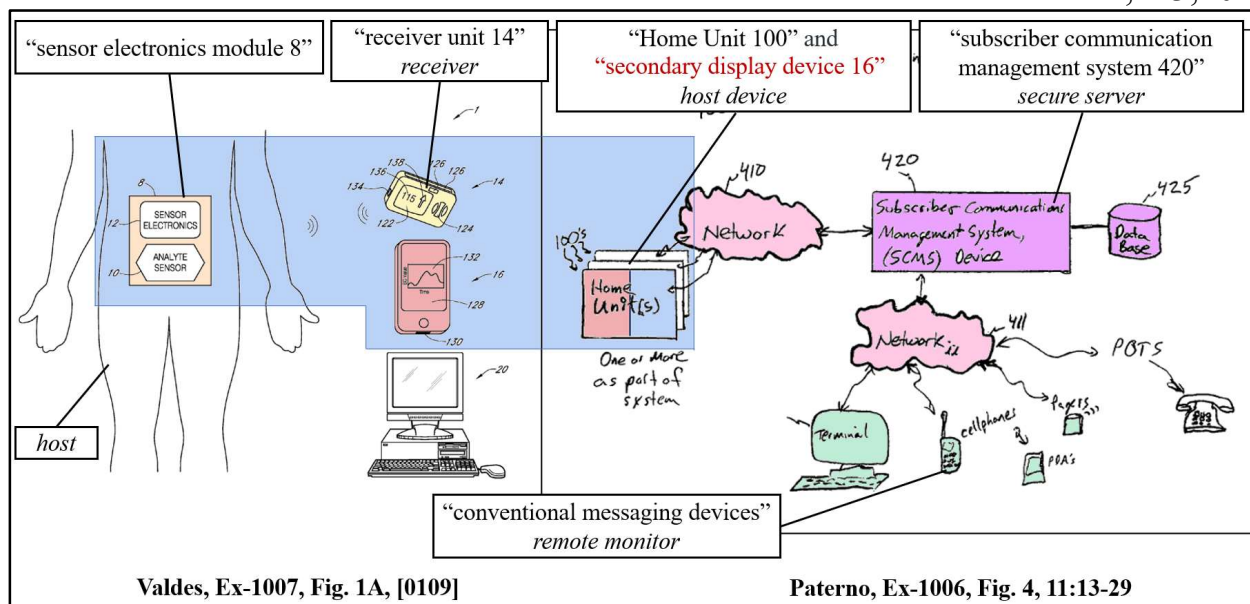
D. Ground IV: Claims 1-3 and 12-14 Would Have Been Obvious Based on Paterno in view of Valdes

204. As shown below, claims 1-3 and 12-14 would have been obvious based on Paterno in view of Valdes. Paterno discloses “[a]n Assisting and Monitoring method and system for compliance logging and monitoring system.” As described above in Section X.B, Paterno discloses that a “monitoring and notification service provider may offer to subscribers an ability to remotely deliver messages and scheduled event reminders,” a “Home Unit” at a user’s/patient’s location for providing reminders and logging and a server, its SCMS. Although Paterno acknowledges the prior art of monitoring systems and devices for “in-home monitoring . . . of blood sugar,” *id.* 1:45-47, it does not expressly disclose a glucose monitoring system used to gather patient analyte data. Paterno discloses that data could be obtained from “one or more input devices, which can be within the unit or external to it,” Ex-1007, 4:22-40, and explains benefits of “captur[ing]

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valuable data on the health of the individuals . . . [that] would lead to improved outcomes[,]” Ex-1007, 13:48-51.

205. As discussed in Ground I, Valdes discloses a system and method “for communicating glucose concentration information between devices of a continuous glucose monitoring system.” Ex-1007, Abstract. The Valdes system includes a “receiver unit,” a *receiver*, that receives and processes data from an analyte sensor and a “secondary display device.” Ex-1007, [0059], [0097], [0177]. The Valdes system includes “initiating an alert upon the occurrence of a predetermined event” such as “exceeding a hypoglycemia threshold [and] exceeding a hyperglycemia threshold.” Ex-1007, [0017].

206. In the annotated figure below, the sensor and receiver unit of Valdes Fig.1A is depicted adjacent to Paterno’s Figure 4. Paterno’s “Home Unit,” the *host device*, has been shaded partially with red to indicate that in the combined Paterno-Valdes system the “Home Unit” as modified by Valdes would include capabilities to interact with the Valdes “receiver unit” as a “secondary display device.” In addition, the Paterno-Valdes system would include alerts based on the occurrence of a predetermined event as disclosed by Valdes.



1. Motivation to combine Paterno and Valdes with reasonable expectation of success

207. A POSITA implementing Paterno's system would have been motivated to use Valdes's "continuous analyte sensor," "receiver unit," and "secondary display unit" to implement Paterno's system by providing patient data for use in the system and by incorporating predetermined events based on patient analyte data.

Teaching, Suggestion, Motivation

208. In addition, Paterno discloses that "Home Unit(s) 100 are part of a reminding, logging and notification system 400. . ." Ex-1006, 6:6-10. Paterno further discloses that "monitoring devices and systems exist that can provide in home monitoring of critical health parameters **such as blood sugar** . . ." Ex-1006, 1:46-48. Paterno discloses that "[t]he SCMS 7000 . . . can support numerous data

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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 but does not explicitly disclose incorporating a “blood sugar” sensor into the Home Unit.

209. A POSITA, however, would have understood that a sensor would be needed to provide in home monitoring of blood sugar as taught by Paterno. That POSITA would have also known that one way to monitor “blood sugar” is to use a continuous glucose monitor, such as the one disclosed by Valdes. A POSITA would understand that for patients with diabetes mellitus, a continuous glucose monitor offers several advantages over other types of blood sugar monitoring, such as finger pricks or other types of blood draws, sometimes referred to as SMBG. For example, Valdes explains that when “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]. “In fact, it is not only unlikely that a diabetic will take a timely SMBG value, but additionally the diabetic will not know if his blood glucose value is going up (higher) or down (lower) based on conventional methods.” Ex-1007, [0004]. Thus, a POSITA would understand that combining the continuous glucose monitor, and

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associated predetermined events, disclosed by Valdes with the monitoring system disclosed by Paterno would be advantageous for patients with diabetes mellitus.

Other Factors and Reasonable Expectation of Success

210. Combining Paterno and Valdes would have involved merely combining prior art elements (i.e., adding Valdes's continuous glucose monitor sensor and receiver to Paterno's system) according to known methods to yield predictable results (i.e., remote monitoring of continuous measurements of the blood glucose level of a host). As I explained above, combining these systems would merely require implementing the interfaces needed to receive the wireless or wired communication from the Valdes "receiver unit" in Paterno's "Home Unit."

211. Continuous glucose monitors, like the one disclosed by Valdes, were well known in the art to yield predictable results. 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, including the IEEE 802.11, 802.15, 802.20, 802.22 and other 802 communication protocols, and/or a proprietary communication protocol." Ex-1007, [0092]-[0093]. Paterno, in turn, describes communication by "wireless means" or "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

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cases industry standard, a POSITA would have had a reasonable expectation of success in using Valdes's continuous glucose monitor to generate data and transmit it to Paterno's Home Unit for use in Paterno's monitoring system by using routine programming techniques.

2. Claim 1

a) *1[preamble]: "1. A method comprising:"*

212. Paterno discloses the preamble, to the extent it is limiting.

213. Paterno discloses "[a]n Assisting and Monitoring method and system for compliance logging and monitoring system for routine activities is presented as well as an automated communications/notification system that can relay the activity and/or inactivity recorded by a Home Unit device to other systems and/or specifically designated people." Ex-1006, 1:66-2:4.

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,"*

214. Paterno discloses this limitation.

215. Paterno discloses "conventional messaging devices," or *remote monitors*, that communicate with a "Subscriber Communications Management System, SCMS," or *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**

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of the caregivers associated with the Home Unit (reminder & logging) system subscribers.” Ex-1006, 11:16-21. The SCMS includes “account record[s]” that contain “pertinent Subscriber profile information that 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.” Paterno discloses that the “**system can provide these configuration options through a convenient interface, for example an Internet Portal**, a telephone voice prompt, and/or live telephone operator.” 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*.

216. The SCMS provides “conventional messaging devices,” *remote monitors*, with interfaces to allow programming of the Home Unit, or *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 and CPTBs,” 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*.

217. The “conventional messaging devices of the caregivers,” or *remote monitors*, include computer terminals, cellphones, PDA’s, and pagers. Ex-1006, Fig.4. Paterno discloses that the “conventional messaging devices,” or *remote monitors*, 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 provide 8010-8050.” Ex-1006, 16:34-39.

- 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,”*

218. Paterno renders this limitation obvious in view of Valdes.

219. Paterno discloses that the “conventional messaging devices,” or *remote monitors*, access rules that are provided by the SCMS, or *secure server*, via an “Internet Portal,” thus, the *set of one or more rules are provided to the remote monitor by the secure server*. For example, “[t]he SCMS device 420 may access the database 425 via the database interface 7020 through the network 410.” Ex-1006, 15:38-40. “The database 425 may include a list 8000 of profiles 8010, 8020, 8030, and 8050 as shown in FIG. 13. Each profile 8010-8050 corresponds to a single Home Unit 100, and associated subscriber account.” Ex-1006, 15:41-44. “A

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generic example of the contents of a Profile record is provided in FIG. 14. The profile 8010 includes information such as unique identification 9010 of the associated Home Unit 100, event schedule of reminders 9020, reminder contents for scheduled events 9030, communications schedule 9040, Account Member Information 9050, Integrated Services parameters 9055, and Notification parameters 9060.” Ex-1006, 15:54-62.

220. Paterno discloses that the SCMS, or *secure server*, provides *rules* to the “conventional messaging devices,” or *remote monitor* of a *host*, whose medical condition is being monitored, but it does not expressly disclose rules *associated with data associated with a receiver configured to monitor an analyte state of a host*. As described above in Ground I, however, Valdes discloses a system and method “for communicating glucose concentration information between devices of a continuous glucose monitoring system.” Ex-1007, Abstract. The “glucose concentration” is a well-known *analyte state of a host*. Ex-1007, [0059]. Valdes discloses a “continuous analyte sensor” for providing “sensor data includ[ing] a raw data stream, or simply data stream, of analog or digital signal directly related to the measured analyte from an analyte sensor. Ex-1007, [0062].

221. Valdes also discloses a “receiver unit,” or *receiver*, that receives and processes data from the analyte sensor to *monitor an analyte state of a host*. Ex-1007, [0097] (“The receiver unit can include electronics configured to process

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sensor data received from the sensor electronics module and display or otherwise communicate (e.g., via audible communication) sensor-related information to a user.”). In the Paterno-Valdes combination, Paterno monitors a host’s “blood sugar” through Valdes’s sensor and receiver, with the host’s “profile” including “notification parameters,” *rules*, for alerting *remote monitors* based on the host’s blood sugar levels.

222. A POSITA would have combined Paterno and Valdes for at least the reasons explained above and in Section XI.D.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”*

223. Paterno renders this limitation obvious in view of Valdes.

224. 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, 3:57-63. Paterno does not include the specific glucose alert conditions described by Valdes.

225. A POSITA would understand that the Paterno-Valdes combination would implement Paterno's "Home Unit" as a "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 the 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 the 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 Home Unit, or *host device*, to set a first setting of the one or more preferences or settings.

226. It would have been obvious to a POSITA that Paterno's "Home Unit" (host device), 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 always retain the "receiver" for local monitoring of blood glucose levels while simultaneously allowing the "Home Unit" to serve as the gateway to Paterno's monitoring system for the *remote monitor*.

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

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

228. Paterno discloses this limitation.

229. Paterno discloses that a caregiver’s “conventional messaging devices,” or *remote monitor*, can be used to change, or *modify*, “profile records,” i.e., *at least one rule of the set of one or more rules*, in the SCMS, or *secure server* using a provided “Internet portal.”

230. 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, 3:57-63. “The system can provide these configuration options through a convenient interface, for example an Internet portal, a telephone voice prompt, and/or live telephone operator.” Ex-1006, 3:63-66.

231. A caregiver device, or *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

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email sent to her every time the SCMS device 420 receives an update from Betty's Home Unit 100, and a text message to her cell phone any time the SCMS receives an immediate action initiated communication from the Home Unit, and after 5 AM any time the SCMS does not receive the expected daily communication (between 2 AM and 4 AM)." Ex-1006, 16:50-58. "The subscriber can further request customized access permissions by person in the account group. For instance, 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, 3:52-63.

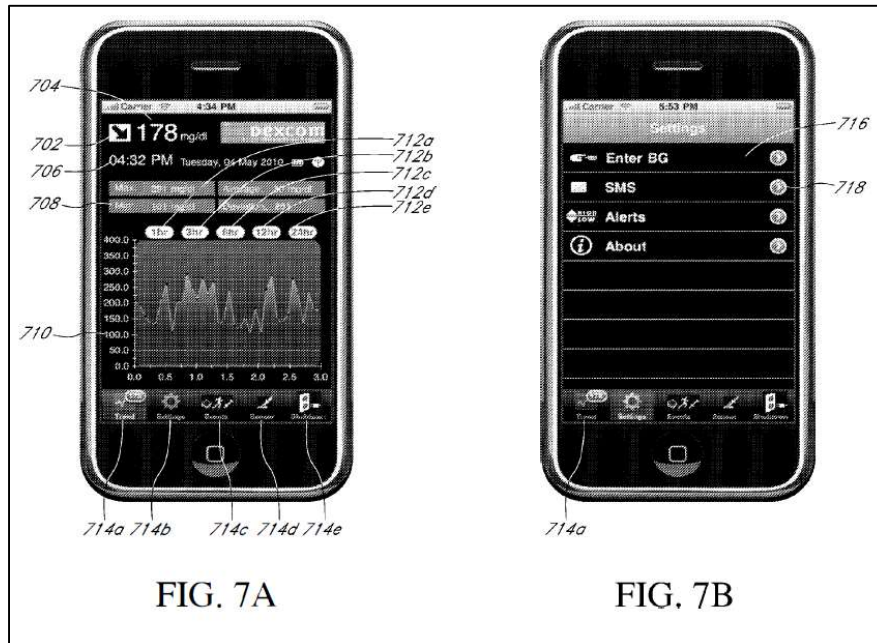
- f) *1[e]: "wherein the set of one or more rules include a first rule defining an alert representative of an event associated with the analyte state of the host, the event being determined by the secure server based on a first measurement of the data associated with the receiver regarding the analyte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

232. Paterno renders this limitation obvious in view of Valdes.

233. 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*. For example, Valdes discloses user interfaces for monitoring the analyte state of the

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host in Figures 7A-7E and defines specific rules for the data it generates. These rules would be incorporated into the “profile records” in Paterno’s system, to monitor “blood sugar” as taught by Paterno. In the combined system, the SCMS, or *secure server*, 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.*



234. 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. . . In the exemplary settings screen of FIG. 7B, the user interface 700 can include a menu of a plurality of selectable

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items. Functions associated with the plurality of selectable items include: inputting a blood glucose (BG) reference value for use with calibrating continuous glucose sensor data, for example; modifying settings relating to sending SMS alerts; modifying high and low blood glucose threshold alerts; and an ‘about’ setting that can initiate a ‘help’ process that allows a user to query for information related to the glucose monitoring system 1.” Ex-1007, [0198]. These rules can be defined using a “secondary display device,” such as Paterno’s “Home Unit” in the combined system. Ex-1007, [0017]. A POSITA would accordingly incorporate the different alert *rules* disclosed by Valdes into Paterno’s remote monitoring system.

235. Valdes discloses a rule defining an alert representative of hypoglycemia or hyperglycemia (each, *an event associated with the analyte state of the host*). Ex-1007, [0017] (“the software further comprises instructions for determining an occurrence of a predetermined event based on the processed received sensor data, and for initiating an alert upon the occurrence of the predetermined event, the alert comprising one or more of an audible alert, a vibratory alert or a visual alert, each of the alerts being performed using a communication unit user interface, **wherein the predetermined event comprises an event selected from the group consisting of exceeding a hypoglycemia threshold, exceeding a hyperglycemia threshold, exceeding an approaching hypoglycemia threshold, exceeding an approaching hyperglycemia threshold, and**

Decl. of Lane Desborough in Support of Petition for *Inter Partes* Review of U.S. Pat. No. 11,213,204 exceeding a glucose concentration rate-of-change threshold.”); *see also* Ex-1007, [0101] (“For example, **a hypoglycemic alert** may include alert conditions indicating a minimum glucose level.”).

236. Thus, Valdes discloses settings for “glucose threshold alerts” that are based on a measurement of the data from the sensor that is sent to and received by the receiver. It would have been obvious to a POSITA to modify Paterno’s SCMS to incorporate Valdes’s hypoglycemia threshold and hyperglycemia threshold and to determine whether the analyte data from Valdes’s receiver exceeded those thresholds. The use of these thresholds for patients with diabetes was well-known by the time of the ’204 patent. And if that data did exceed either threshold, the SCMS would then notify, *alert*, the *remote monitors*. Paterno discloses that “[t]he SCMS 7000 . . . can support numerous data analysis and reporting tools for the information collected by the Home Units, CPTBs, and connected communications tools of the account group members.” Ex-1006, 15:17-27.

237. A POSITA would have combined Paterno and Valdes for at least the reasons explained above and in Section XI.D.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,”

238. Paterno discloses this limitation.

239. Paterno discloses that the “SCMS device 420,” or *secure server*, is used to “generate and deliver” “notification messages,” or *alert messages*, “to the communications tools of the caregivers,” or *remote monitors*. These “notification messages” are each *an alert message to be sent to the remote monitor from the secure server to notify the remote monitor of the event*.

240. Paterno discloses that “[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** and integrated service systems associated with each of the Home Unit/subscriber account profiles 8010-8050.” Ex-1006, 16:30-39. “The SCMS controller 7010 scans the profile records 9000 of every profile, 8010-8050 and determines when, how and what notification messages should be delivered to each member or integrated service system of each subscriber account profile 8010-8050.” Ex-1006, 16:34-39. 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.

- h) *I[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”*

241. Paterno discloses this limitation.

242. Paterno discloses that the “Home Unit,” or *host device*, configures a *first setting*, as explained above in XI.D.2.d. Paterno further discloses that

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caregivers with “conventional messaging devices,” or *remote monitors*, use an “Internet Portal” provided by the SMCS, or *secure server*, 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,” or *host device*.

243. 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 that are 2 to 4 per day, depending on day of the week, and a communication schedule 9040 that is daily between 2 AM and 4 AM and after any reminder alert that is not answered after the maximum retries with the user logged ‘Home’. **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, and a text message to her cell phone any time the SCMS receives an immediate action initiated communication from the Home Unit, and after 5 AM any time the SCMS does not receive the expected daily communication (between 2 AM and 4 AM).” Ex-1006, 16:42-58.

- i) *I[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.”

244. Paterno discloses this limitation.

245. First, in the combined 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 “database 425.” Ex-1006, 15:27–32. For example, Paterno discloses that the primary caregiver may specify in the “notification parameters” a series of 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, among other things, “Notification parameters 9060,” Ex-1006, 15:54-61.

246. 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, at the host device. Paterno discloses “memory record contents for a Home Unit.” Ex-1006, 2:43-45, 5:3-5. The Home Unit memory record depicted in Figure 2 lacks the “notification parameters” of the SCMS database’s profile table record that are used to modify the settings for each *remote monitor*.

247. 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, or *secure server*. Paterno discloses an "Internet Portal" that can be used to modify the "profile records" at the *remote monitor without changing the first setting at the host device*. Thus, a caregiver can use the *remote monitor* to adjust the "notification parameters" in the "profile records." Doing so would not alter the *first setting* (Home Unit memory record depicted in Figure 2) at the Home Unit, which is *the host device*.

248. Before the '204 patent's effective filing date, it would have been obvious to a POSITA to personalize hypoglycemia and hyperglycemia notifications for each pwd-remote monitor pair. In addition to the aforementioned contextual differences between the pwd and their care partner (the former is local, the latter is remote), there are other important reasons why, for instance, a mother remotely monitoring her five year old child overnight may have different thresholds and delays for notifications than those of a husband remotely monitoring their wife while on a business trip. These reasons include but are not limited to safety, agency, embarrassment, privacy, and status of transition to selfcare. For instance, a teenager may have a "contract" with their parents: "I'll manage my highs, so you only get to monitor my lows during school." A school

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nurse may only be permitted to monitor children during school hours (this was the case when my wife was a school nurse monitoring a dozen children at five schools).

3. Claim 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.”*

249. Paterno renders this limitation obvious in view of Valdes.

250. As discussed above in Sections XI.D.2.h & i, Paterno discloses modifying a rule by overriding a setting specifically for a given *remote monitor*. As discussed above in Section XI.D.2.f, Valdes discloses a rule based on “exceeding a hypoglycemia threshold.” Ex-1007, [0017]; *see also* Ex-1007, [0101] (“For example, **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 XI.D.1 above.

4. Claim 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.”

251. Paterno renders this limitation obvious in view of Valdes.

252. As discussed above in Sections XI.D.2.h & i, Paterno discloses modifying a rule by overriding a setting specifically for a given *remote monitor*. As discussed above in Section XI.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 XI.D.1 above.

5. Claim 12

a) *12[preamble]: “An apparatus for remote monitoring of a host's analyte levels, the apparatus comprising:”*

253. To the extent the preamble is limiting, Paterno discloses this limitation or renders this limitation obvious in view of Valdes. *See* Section XI.D.2.a-c above.

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

254. Paterno discloses this limitation.

255. Paterno discloses caregiver devices such as a “Terminal,” “cellphones,” “PDA’s,” and “Pagers.” Ex-1006, Fig. 4. A POSITA would know that each of these *remote monitors* necessarily includes *at least one processor*, and possibly more than one.

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

256. Paterno discloses this limitation.

257. Paterno discloses caregiver devices such as a “Terminal,” “cellphones,” “PDA’s,” and “Pagers.” Ex-1006, Fig. 4. A POSITA would readily understand that each of these *remote monitors* necessarily includes *at least one memory* and that the methods disclosed by Paterno would have been implemented as software, or *code*.

- 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,”*

258. Paterno discloses this limitation or renders this limitation obvious in view of Valdes. *See* Section XI.D.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,”*

259. Paterno discloses this limitation or renders this limitation obvious in view of Valdes. *See* Section XI.D.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”*

260. Paterno discloses this limitation or renders this limitation obvious in view of Valdes. *See* Section XI.D.2.d.

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

261. Paterno discloses this limitation or renders this limitation obvious in view of Valdes. *See* Section XI.D.2.d.

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

262. Paterno discloses this limitation or renders this limitation obvious in view of Valdes. *See* Section XI.D.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,”

263. Paterno discloses this limitation or renders this limitation obvious in view of Valdes. *See* Section XI.D.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,”

264. Paterno discloses this limitation or renders this limitation obvious in view of Valdes. *See* Section XI.D.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”

265. Paterno discloses this limitation or renders this limitation obvious in view of Valdes. *See* Section XI.D.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.”

266. Paterno discloses this limitation or renders this limitation obvious in view of Valdes. *See* Section XI.D.2.i.

6. Claim 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.”

267. Paterno discloses this limitation or renders this limitation obvious in view of Valdes. *See* Section XI.D.3.

7. Claim 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

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*the first measurement indicating an analyte measurement
that is higher than the second threshold.”*

268. Paterno discloses this limitation or renders this limitation obvious in view of Valdes. *See* Section XI.D.4.

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

269. As shown below, claims 5-7 and 17-19 would have been obvious based on Paterno (Ex-1006) in view of Valdes (Ex-1007) and Goodnow (Ex-1008). As discussed above, Paterno discloses an “Internet portal” provided by the “SCMS,” or *secure server*, to access the system. Ex-1006, 3:63-66. Paterno discloses that “[e]ach Home Unit has associated with it an account record in the SCMS. Each account record associated with a Home Unit user account contains pertinent Subscriber profile information that 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.**” Ex-1006, 3:33-39. “The monitoring and notification service may also provide account access to one or more people **as requested by the subscriber.**” Ex-1006, 3:52-54.

270. A POSITA would understand that these account features were well-known in the art prior to the alleged invention of the ’204 patent. For example, Goodnow discloses, among other things, how a host may invite a new user to access their data and how the system creates that new user’s account. A POSITA

Decl. of Lane Desborough in Support of Petition for *Inter Partes* Review of U.S. Pat. No. 11,213,204 would have used Goodnow's disclosures to implement the features discussed in Paterno. Specifically, a POSITA would have modified the "Internet portal" based on Goodnow's disclosure to implement the features discussed in Paterno. Ex-1005, [0012]-[0016].

271. For example, Goodnow discloses an "Initial User Setup" page for creating a "User ID" and "Password." Figure 8 depicts this user interface.

Initial User Setup

Application Mode

Select whether you want to run the program as a Home User or Health Care Professional:

☒ Home User ☐ Health Care Professional

User Identification

Before using the FreeStyle CoPilot Health Management System, you must provide your Name and a User ID and Password.

First Name:

Last Name:

E-Mail Address:

User ID*:

Password*:

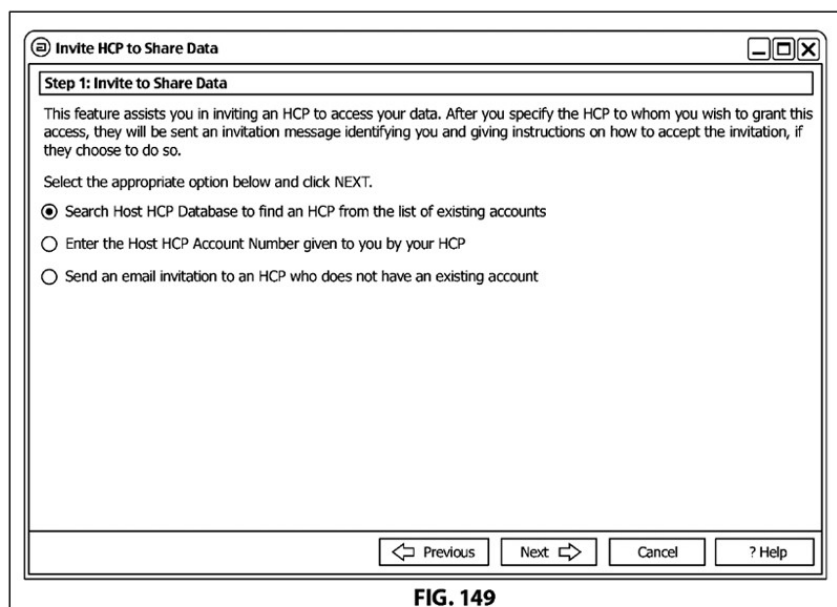
Confirm Password*:

*User ID and Password are case-sensitive and must be at least 5 characters long.

OK Cancel ? Help

FIG. 8

Ex-1008, Fig. 8, [0222]. Similarly, Goodnow discloses inviting a health care professional, or "HCP," to share data.



Ex-1008, Fig. 149, [0341]. Additional features and modifications are detailed below.

1. Motivation to combine Paterno, Valdes, and Goodnow with reasonable expectation of success

272. A POSITA implementing Paterno's system would have been motivated to use Goodnow's system and methods to implement the disclosed account features.

Teaching, Suggestion, Motivation

273. 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. 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 comparable patient-data access scheme:

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“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

274. 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 health care professionals and other care partners such as parents to receive data). Adding new users to use a system such as Paterno would be necessary functionality.

275. Combining Paterno and Valdes with Goodnow would require 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.

2. Claim 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”*

276. Paterno renders this limitation obvious in view of Valdes and Goodnow.

277. Paterno discloses “[a]n Assisting and Monitoring method and system for compliance logging and monitoring system for routine activities is presented as well as an automated communications/notification system that can relay the activity and/or inactivity recorded by a Home Unit device to other systems and/or specifically designated people.” Ex-1006, 3:15-20.

278. Goodnow discloses a method of inviting a user to access the host’s data. 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. This notifies the Host that the user will allow the selected HCP to view (and in some cases, edit) their data.” Ex-1008, [0341]. Goodnow explains the process to send the invitation. “From 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]. “FIG. 150 illustrates a Find HCP from Existing Accounts Screen. The user can then click Search. HCPs

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from the selected state with a Host Account will be displayed. The user can then highlight the HCP he or she wants and click Next. The screen for selecting Access Level displays.” Ex-1008, [0344]. “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].

279. Goodnow describes receiving an e-mail invitation. “When a user receives an e-mail invitation to share data, the message will instruct the user to download the Health Management System from the Internet (e.g., by just clicking on the hyperlink in blue), install the software and 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].

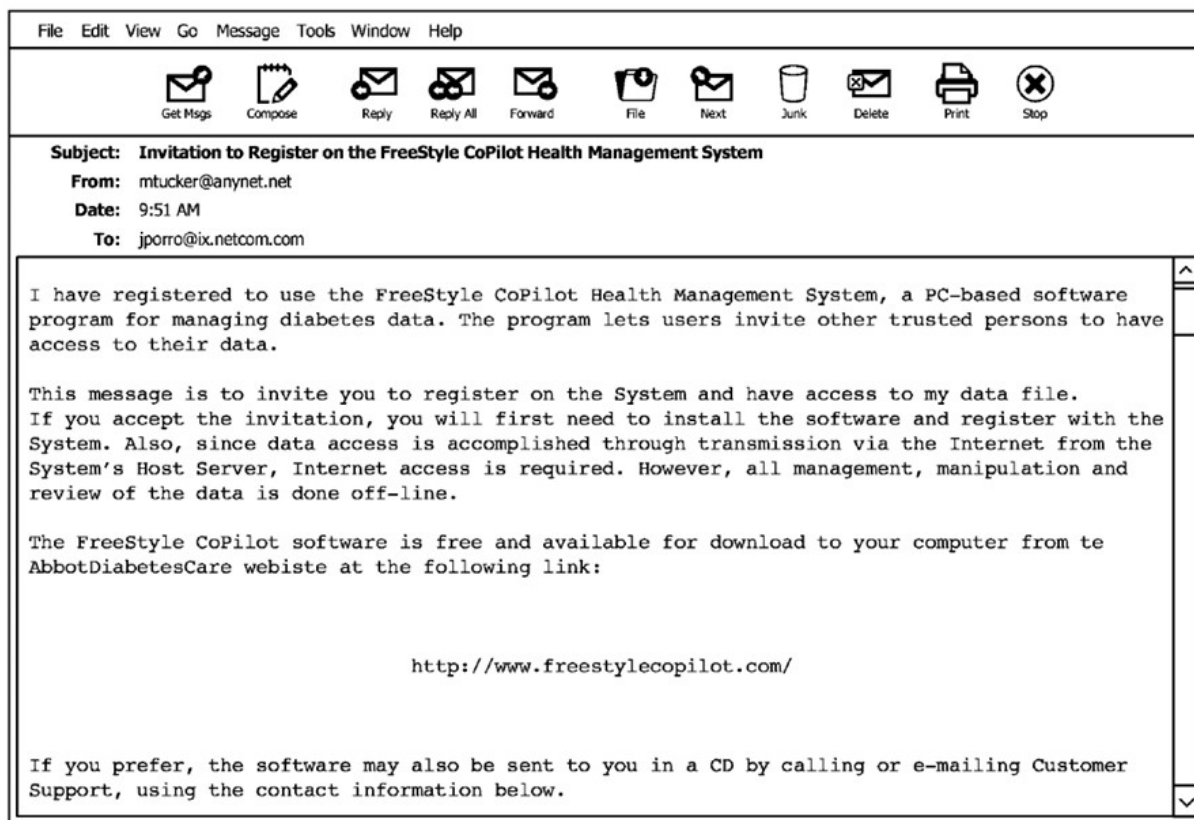


FIG. 163

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

b) *“providing, from the remote monitor to the secure server, an acceptance to the invitation.”*

281. Paterno renders this limitation obvious in view of Valdes and Goodnow.

282. Goodnow discloses that “[a]fter the user has downloaded and installed the software, he or she 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

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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].

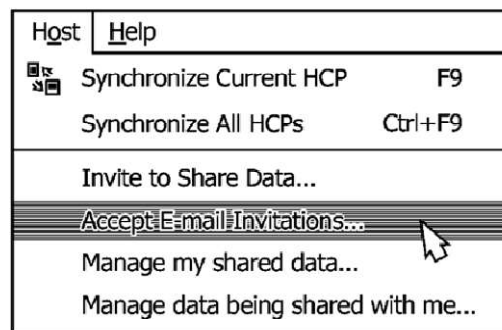


FIG. 165

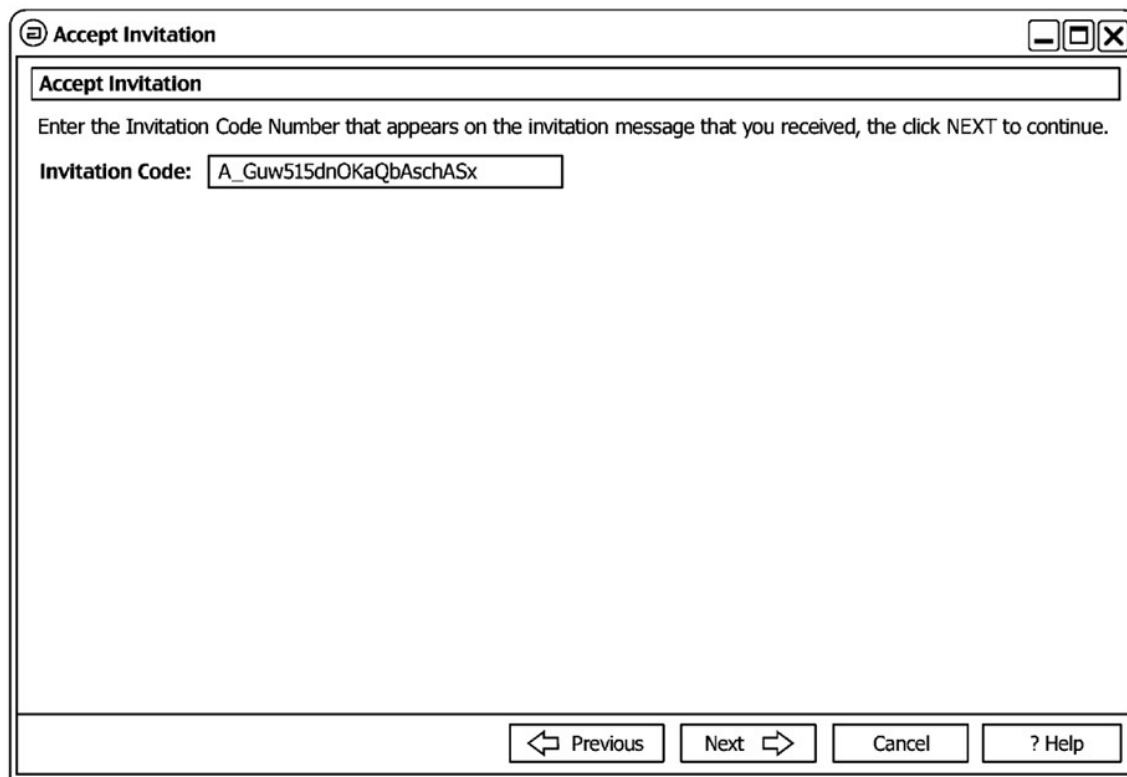


FIG. 166

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

3. Claim 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.”*

284. Paterno renders this limitation obvious in view of Valdes and Goodnow.

285. As discussed above in Section XI.A.1.f, it would have been obvious to a POSITA that Paterno’s “Home Unit” (*host device*) operating as Valdes’s

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“secondary device” would be used to set hypoglycemic- or hyperglycemic-alert thresholds, i.e., rules generated from the host device’s first setting of preferences. Ex-1007, [0017]; *see also* Ex-1007, [0101].

286. 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 automatically synchronizes this “data” with the new account. Ex-1008, [0355] (“The Host then synchronizes with the user’s System, and the patient’s data is downloaded.”). Thus, a POSITA would understand that Goodnow’s invitation is associated with a set of *recommended rule settings* configured by the *host device*.

287. As discussed above in Section [[XI.A.1.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 Paterno’s “Home Unit” as modified by Valdes, to import initial hypoglycemic- or hyperglycemic-alert threshold *settings* that could be modified later using the *remote monitor*.

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

4. Claim 7

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

289. Paterno renders this limitation obvious in view of Valdes and Goodnow, and the knowledge of a POSITA under DexCom’s proposed construction, as explained above in Section VI.

290. Goodnow discloses a process for establishing an account, that “[a]fter the user has downloaded and installed the software, he or she 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].

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

5. Claim 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.”

292. Paterno discloses this limitation or renders this limitation obvious in view of Valdes and Goodnow. *See* Section X.E.2.

6. Claim 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.”*

293. Paterno discloses this limitation or renders this limitation obvious in view of Valdes and Goodnow. *See* Section XI.E.3.

7. Claim 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.”*

294. Paterno discloses this limitation or renders this limitation obvious in view of Valdes and Goodnow. *See* Section XI.E.4.

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

295. Claims 7 and 19 would have been obvious based on Aspel’s teaching of automatic account creation modifying Paterno in view of Valdes and Goodnow, under Abbott’s proposed construction. Ex-1010, p.19. As explained above, the

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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.

1. Motivation to combine Paterno, Valdes, Goodnow, and Aspel with reasonable expectation of success

296. 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

297. 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). By the time of the ’204 patent, the use of username and passwords, including automatically generated default usernames and passwords, for Internet-accessible systems was pervasive.

298. Combining Paterno-Valdes-Goodnow with Aspel 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.

2. Claim 7

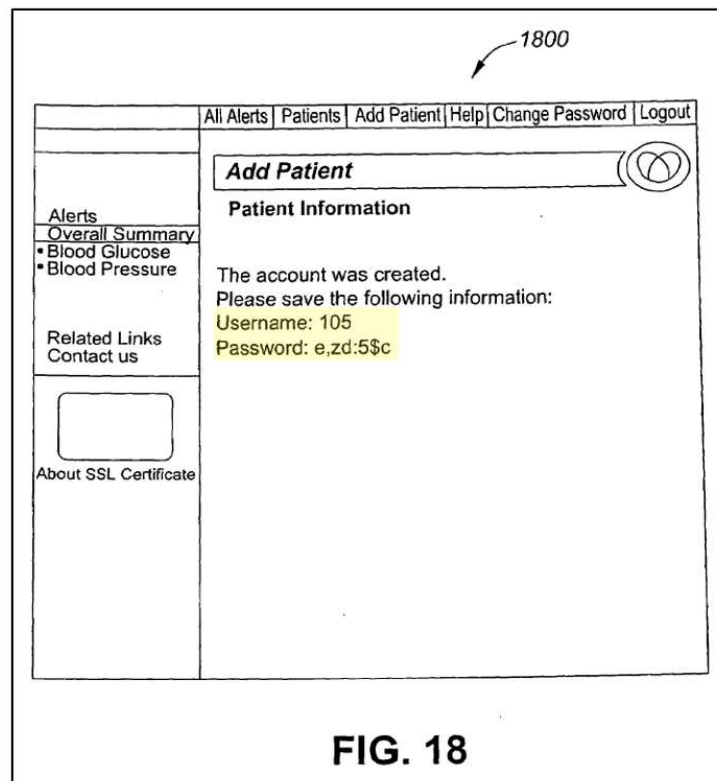
- a) *"The method of claim 5, wherein accepting the invitation, programmatically establishes an account associated with the remote monitor at the secure server."*

299. Paterno discloses this limitation and/or renders this limitation obvious in view of Valdes, Goodnow, and Aspel under Abbott's proposed construction, as explained above in Section VI.

300. As explained above for claim 5, Section XI.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. 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

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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. Delaying account creation until after an invitation is accepted would avoid introducing dead or stale accounts when invitations are not accepted. Thus, Goodnow’s new user form would be modified to omit the username and password fields.



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

3. **Claim 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.”*

302. Paterno discloses this limitation and/or renders this limitation obvious in view of Valdes, Goodnow, and Aspel under Abbott’s proposed construction, as explained above in Section VI. *See* Section XI.F.2 above.

XII. CONCLUSION

All of the statements made in this declaration of my own knowledge are true. All statements made on information and belief are believed to be true. These statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code.

Respectfully submitted,

Dated: May 3, 2024

By:

A handwritten signature in blue ink, appearing to be "Lane Desborough", written over a horizontal line.

