

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

TELADOC HEALTH, INC.,
Petitioner,

v.

DATA HEALTH PARTNERS, INC.,
Patent Owner.

Case IPR2026-00390
Patent 11,675,791 B2

DECLARATION OF DR. BRYAN BERGERON
IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF U.S.
PATENT NO. 11,675,791 B2

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LIST OF DOCUMENTS CONSIDERED

Exhibit	Shorthand	Description
1001	'791 Patent	U.S. Patent No. 11,675,791 B2
1002	Douglas	Pub. No. WO 1999/003045 A1
1004	Chitiveli	Pub. No. US 2013/0179450 A1
1009	Koh	Hian Chye Koh & Gerald Tan, <u>Data Mining Applications in Healthcare</u> , 19 J. Healthcare Information Management 64 (2005)
1014	Microsoft	<u>Microsoft Computer Dictionary</u> (5th ed. 2002)
1018	NetSuite	Printout of https://web.archive.org/web/20111102042326/https://www.netsuite.co.uk/portal/uk/resource/articles/cloud-computing.shtml
1022	Virginia	<u>Autism Spectrum Disorders and the Transition to Adulthood</u> , VA Dep't of Educ. (2010)
1024	Khanuja	Pub. No. US 2004/0102683 A1
1025	'616FWD	Final Written Decision in IPR2024-00616 for U.S. Patent No. 11,144,554 B2
1026	'617FWD	Final Written Decision in IPR2024-00617 for U.S. Patent No. 11,151,142 B2

I. INTRODUCTION AND SCOPE OF WORK

1. My name is Bryan Bergeron. I am over the age of twenty-one (21) years, of sound mind, and capable of making the statements set forth in this Declaration. I am competent to testify about the matters set forth herein. All the facts and statements contained herein are within my personal knowledge, and they are, in all things, true and correct.

2. I have been retained by Teladoc Health, Inc. (“Teladoc”) to provide my opinions and views on the materials I have reviewed related to U.S. Patent No. 11,675,791 B2 (the “’791 Patent”), and the scientific and technical knowledge regarding that subject matter. I have been asked to consider what a person of ordinary skill in the art (“POSITA”) at the time of the invention (“TOI”) of the ’791 Patent would have understood about the issues I address below. I have been asked to assume by counsel for Teladoc that the TOI was March 15, 2013.

3. My opinions, set forth below, are guided by my appreciation of how a POSITA would have understood the state of the relevant art, the teachings of the references I discuss below, and the claims of the ’791 Patent at the TOI.

II. EDUCATION AND EXPERIENCE

4. My curriculum vitae, attached as Exhibit 1013, includes my detailed employment background, professional experience, and list of technical publications and patents. A summary of relevant experience is provided below.

5. I taught in the Harvard-MIT Program in Health Sciences and Technology (HST) in Cambridge, Massachusetts for approximately 30 years. This program is a collaboration between the Massachusetts Institute of Technology (MIT), Harvard Medical School, Harvard University, and Boston area teaching hospitals that integrates science, medicine, and engineering to solve problems in human health. I taught clinical medicine, including cardiac pathophysiology and pulmonary pathophysiology, to medical students in the HST program, as well as medical informatics to students and faculty at MIT and Harvard Medical School, graduate students at the Harvard Law School, Harvard School of Public Health, and Harvard Business School.

6. Medical informatics is a discipline at the intersection of information science, computer science, and health care. It deals with the resources, devices, and methods for optimizing the acquisition, storage, retrieval, and use of information in various medical environments. In my course in medical informatics, I covered topics such as electronic medical record (EMR) systems, HIPAA privacy and security, large database design and implementation, physician performance, artificial intelligence, computer programming, microcontrollers and embedded systems, bedside monitoring and therapy systems, robotic surgery, mobile computing, modeling and simulation, graphical user interface design, and a variety of human

factors issues associated with clinician acceptance and use of information technology.

7. In 1980, I obtained my Bachelor of Science (B.S.) degree in Psychology, with honors, in the Tulane University Scholar's Program, with minors in physics and chemistry. Prior to receiving my B.S. degree, I studied electrical engineering at Louisiana State University in Baton Rouge, Louisiana, and I also performed research in neurological signal detection and analysis at the Marine Biology Laboratory in Woods Hole, Massachusetts. I obtained my Doctor of Medicine (M.D.) degree from Louisiana State University Medical Center in 1984, and was licensed to practice medicine and surgery in 1985. From 1985 through 1987, I was a post-doctoral research fellow in medical informatics at Brigham & Women's Hospital, a Harvard Medical School teaching hospital located in Boston, Massachusetts. As part of my post-doctoral fellowship, I studied computer science at Harvard University. In parallel with coursework, my postdoctoral research focused on the development of computer hardware and software programs that could be used to train medical students and other medical professionals by simulating various medical patients or medical problems. This involved first acquiring representative physiologic data from the patient's bedside and then comparing the simulated and real-life data from various physiologic systems. A major focus of my

research was the added value of a properly designed graphical user interface vs. the then-common textual user interface.

8. In 1984, when I was a fourth-year medical student, I founded my first company, Home Health Software, in New Orleans, Louisiana. I was the sole employee, and I worked as both the company president and programmer. Home Health Software focused on the development of software for various types of medical analyses and planning, including one of the first commercial nutritional analysis and planning applications that could be utilized by a lay-person on a home microcomputer. In each application, I developed novel graphical user interfaces using assembler code in the manner used to construct computer games.

9. Home Health Software produced several commercial patient simulation software titles, as detailed in my curriculum vitae, which were sold nation-wide. In late 1984, Apple Inc. made me one of a handful of Certified Developers for their new Macintosh Computer. I retired Home Health Software in 1985 when I moved to Boston to pursue my post-doctoral fellowship, but I continued and expanded my relationship with Apple. During my post-doctoral fellowship at Brigham & Women's Hospital and Harvard Medical School (from 1985-1987), I developed HeartLab, the first commercial multimedia patient simulator for a microcomputer. HeartLab was sold and marketed by Williams and Wilkins Publishers, Baltimore, MD, to virtually all medical schools in the United States, as well as major medical

schools in Canada and Europe. This was one of the first commercially successful medical applications developed specifically for the graphical Macintosh interface.

10. As a result of the success of the HeartLab system, as well as other work that I performed as a post-doctoral fellow, Apple provided more support for courseware development. I also competed for and won a First Independent Research Support and Transition (“FIRST”) Award by the National Library of Medicine (“NLM”) in 1988. This award provided six years of support and funding for me to develop and evaluate new technologies.

11. In 1987, after my post-doctoral fellowship, I began work as an Application Specialist at Children’s Hospital, Boston. In this position, I managed the first HL7 installation on the East Coast, defined (with others) the hospital’s data dictionary, and designed the clinical workstation. The clinical workstation aggregated all clinical data on a particular patient or group of patients – including current labs, radiology, and physiological data (e.g., pulse, respiration, and EKG) from the bedside – under one intuitive interface. The workstation used an XWindows client-server model with an Oracle back-end.

12. In 1989, I began work as an Instructor at Harvard Medical School, as well as an Assistant Director of the post-doctoral fellowship program in Medical Informatics at Brigham & Women’s Hospital and Harvard University. One of my major responsibilities as Assistant Director of the post-doctoral fellowship program

was to facilitate the development of innovative, graphical, computer-based teaching programs—such as patient simulation software—that could be used to train students in the Harvard Medical School and Harvard-MIT HST programs. Accordingly, I continued my work on the software and research development funded by the FIRST Award during this time, utilizing the Harvard Medical School and HST programs as the testing and development environments.

13. As noted earlier, this work in modeling and simulation required me to obtain physiologic data from patients and then work to simulate these data. For example, in developing HeartLab, I first had to acquire the patient data that would later be simulated in software. As such, I developed a bedside heart monitoring system that acquired and digitized heart sounds in patients with various disease states, e.g., aortic stenosis. Similarly, with EKGLab, a program that I developed to simulate the range of EKG tracings possible with a variety of disease states, I had to first design and develop a bedside data acquisition system. I also developed a pulmonary monitoring system to acquire auscultatory data for LungLab, a program that I co-developed with HST faculty to teach pulmonary pathophysiology.

14. In each of the above programs, I defined the possible use cases and designed the appropriate user interfaces and defined the appropriate supporting infrastructure.

15. As detailed in my curriculum vitae, starting in 1989, I managed a team of post-doctoral fellows in medical informatics, medical students, and visiting fellows, students, and faculty in developing over a dozen commercial-grade patient simulators as well as back-end infrastructures and databases for tracking and documenting learner progress in the various medical educational systems. In 1990, I was elected Fellow of the American College of Medical Informatics (FACMI).

16. In 1996, I founded Archetype Technologies, Inc. in order to offer consulting services to industry and compete for government funding. As the head of Archetype, I also served as Chief Scientist for various clients—generally startup companies or other small medical technology companies.

17. In my work with Kurzweil Applied Intelligence (from 1988-2000), which developed the first large-vocabulary medical dictation system, I helped define the medical vocabularies and edited the overall hierarchy of medical terms used in the speech recognition engine in Pathology, Radiology, and Emergency Medicine.

18. In 1999, I served as Principal Investigator on a Small Business Innovation Research (SBIR) grant I won on behalf of Kurzweil Applied Intelligence, for which I developed a rule-based medical record quality assurance system for automatically reviewing (e.g., parsing and evaluating) reports in EMR systems. This application of natural language understanding technology to EMR systems was immediately commercialized and sold by Lernout & Hauspie Speech Products.

19. My EMR and EHR experience ranges from stand-alone lab systems I used as a phlebotomist in the early 80's to much later work with KFSH&RC, Riyadh to develop and extend a large data warehouse. As documented in four books, this data warehouse provides a central repository of EMR data from a variety of clinical and administrative systems, including an EMR system. My EMR experience further includes reviewing systems and associated applications for publication in various journals.

20. I also have extensive experience with computer hardware and software programming, especially as used and implemented in the medical industry. I have experience in 6502 and 68000 Assembler, FORTH, LISP, PROLOG, PASCAL, NEON, SMALLTALK, C/C++, JAVA, PERL, SQL, and numerous embedded processor, desktop and server-based scripting languages, including DBMS languages.

21. As noted in my curriculum vitae, I obtained several endorsements from the Federal Communications Commission (FCC) starting in 1971, over a decade prior to obtaining my license to practice medicine and surgery.

22. At 16, as a freshman at LSU, I was a judge for physics and electronics at the state science fair and, at the request of the Dean, developed the curriculum for the Solid-State Laboratory course in electrical engineering at LSU. The course included analog, digital, and hybrid circuits. I have continued my involvement in

science fairs as a judge in physics and electronics at the annual state fair at MIT, and my involvement in electronics and robotics as editor in chief of both Nuts & Volts (for experimentalists in general electronics) and SERVO (for experimentalists in robotics) magazines, two major resources for STEM educators.

23. I have held a variety of posts in organizations that focus on the application of computing to the practice and teaching of medicine. For example, I have served as Chairman of the Mathematical Modeling & Simulation Committee for the Symposium on Computer Applications in Medical Care (SCAMC), Chairman of the SCAMC Human-Computer Interfacing Committee, and Chairman of the Healthcare Information and Management Systems Society (HIMSS) Conference on Innovative Informatics for Reducing Medical Errors.

24. I have also served on fourteen editorial boards for various publications related to medical informatics, including eMD (Founding Editor-in-Chief), Physicians Home Page, HealthStream, Medical Software Reviews, WebMD/Medscape Tech Med, Healthcare Informatics, Robotics Business Review, and Servo Magazine.

25. I am a frequent contributor to the field of medical informatics. I have written over 1,400 articles for various journals and publications, including Computer Methods and Programs in Biomedicine, the Journal of Medical Education Technology, the Journal of Educational Multimedia and Hypermedia, the Journal of

Instructional Delivery Systems, Perspectives in Biology and Medicine, the British Journal of Knowledge Management, and the International Journal of Mechanical Engineering and Robotics Research. Many of those articles are in the field of robotics (including telerobotics) and telemedicine. I am the author of over 30 books, several chapters, and have given hundreds of lectures and courses on topics regarding computer technology, computer-assisted training, medical informatics, data dictionary design issues, emerging technologies in healthcare, and robotics.

26. I am a named inventor on 11 U.S. patents. Four of the patents on which I am a co-inventor are related to virtual, web-based, and processor-enabled training for medical personnel. Another patent deals with intelligent tutoring systems, and two other patents deal with translational reality interfaces using embedded processors.

27. For over a decade, I served as the Principal Investigator on a series of research grants sought by Accella Learning Company related to the development of electronic simulator hardware and software for intelligent tutoring systems that train medical first responders for nuclear, chemical, and biological warfare events. These grants were funded through the United States Department of Defense (DoD). In my most recent grant, I served as the chief medical consultant on DoD-funded grants to design and develop the software infrastructure for a national physiology research platform, BioGears. This platform is designed to build lifelike mannequins, realistic

online military games, and a variety of medically-accurate scenarios for training and testing.

28. I presently serve as President of Archetype Technologies, Inc. in Brookline, Massachusetts, which designs and develops custom hardware and software solutions for medical device and medical information system companies, and is developing software and hardware systems for commercialization in the field of translational reality. I also continue to write and edit technology articles and books.

29. Having the above knowledge and experience, I am well qualified to offer the opinions I express in this Declaration.

III. COMPENSATION

30. My work on this matter is being billed to Teladoc at \$425 per hour, and I am also being reimbursed for reasonable expenses I incur in relation to my services. My compensation is not dependent on my testimony or the outcome of this or any other proceeding.

IV. LEGAL CONSIDERATIONS

31. I am not a lawyer and I offer no legal opinions. For the purposes of this Declaration, I have been informed by counsel for Teladoc about certain aspects of the law that are relevant to my analysis, as summarized below.

32. My opinions address what would have been logical to a POSITA at the TOI, given the state of the relevant art, the knowledge and skill that a POSITA would have had, the teachings of the references discussed below, how a POSITA would have understood those teachings, and the predictability of the systems discussed below, including in the modified forms I discuss below. My opinions also address whether a POSITA would have had a reasonable expectation of the modified systems below successfully yielding the results discussed below.

33. I understand that a POSITA is a hypothetical person. He is not a genius. He thinks along the lines of conventional wisdom. I understand that a POSITA is also a person of ordinary creativity, not an automaton. Section VI, below, includes qualifications of a POSITA. I also understand that, in determining who would qualify as a POSITA, it is appropriate to consider criteria such as: (a) the type of problems encountered in the art; (b) prior art solutions to those problems; (c) the rapidity with which innovations are made; (d) the sophistication of the technology; and (e) the education level of active workers in the field.

34. I understand that a claim term is given the meaning that the term would have to a POSITA at the TOI, which generally is the ordinary and customary meaning of the term. I further understand that the ordinary and customary meaning of a term may be evidenced by a variety of sources, including the words of the claims themselves, the specification, the prosecution history, and extrinsic evidence

concerning relevant scientific principles, the meaning of technical terms, and the state of the art.

V. BASIS FOR OPINIONS

35. My opinions are based on my education, training, and experience, as well as items that I reviewed to prepare my opinions, including the '791 Patent and at least the documents listed in the table at the beginning of this Declaration.

VI. LEVEL OF ORDINARY SKILL IN THE ART

36. Taking into consideration the factors discussed in my paragraph 33, it is my opinion that a POSITA as of the TOI would have had at least a bachelor's degree in a healthcare field as well as 1-2 years of experience with health information technology, including specific experience with computer-based systems for recording, tracking, and analyzing patient health information.

37. At the TOI, my level of skill in the art was beyond that of a POSITA. Furthermore, based on my education, research, and teaching experience in the healthcare field and with computer-based systems for recording, tracking, and analyzing patient health information, I worked with individuals who qualified as POSITAs. I am therefore well acquainted with the level of ordinary skill described above. Thus, I am capable of rendering an informed opinion on the level of ordinary skill in the art at the TOI. My opinions are provided from this perspective of a POSITA at the TOI, whether or not those opinions are explicitly identified as such.

VII. ISSUES CONSIDERED

38. I was asked to consider several issues raised in Petitioner’s Grounds, which I address below, grouped by the Grounds to which they pertain.

A. Ground 1 – Claims 1-7, 9, 11-14, and 16-19 in View of Douglas

1. *Douglas Overview*

39. Douglas discloses “[a] therapeutic behavior modification program, compliance monitoring and feedback system” that “enables development of a therapeutic behavior modification program having a series of milestones for an individual to achieve lifestyle changes necessary to maintain his or her health.” Douglas at Abstract, 1:8-10, 2:5-9.

40. In Douglas’s system, a patient—ranging from one having “coronary artery disease” to one “who simply want[s] to maintain their health”—is subscribed to the system. Douglas at 6:6-14. The patient’s subscription can be performed by an administrator, who “enter[s]” “baseline vital factors” “based on information contained in the patient prescription form” (Douglas at 6:33-7:20, FIG. 60), which is filled out and signed by the patient’s physician (*id.* at FIG. 2). An account is created as part of that process into which the patient can “log in” to “view their levels of compliance and achievement of goals” (Douglas at 8:29-31, 12:3-7), and the patient’s physician updates the account as the patient progresses through the system, both in terms of the goals and the patient data used to assess achievement of those goals (*id.* at 3:13-14, 11:1-5, 11:26-28).

41. At to those goals, “[o]nce the ... administrator enters the patient into the system, [] the system ... recommends a default set of goals based on the patient’s needs and existing medical protocols that may be modified by the physician.” Douglas at 7:17-8:13. Exemplary goals set by Douglas’s system include everything from “intake of calories from fat” to “Seatbelt Use.” Douglas at 8:1-13, FIG. 6. Those goals also include interim steps—“one month goals 61”—toward the “final goals 62.” Douglas at 8:10-13; FIG. 6.

42. Douglas’s system then periodically receives updated patient data, including from a biometric device (Douglas at 11:1-5, FIG. 60), to determine the “patient’s progress and compliance with the program” (*id.* at 11:26-28). For example, Douglas’s “system might also prompt the patient to input his or her vital signs 102, such as blood pressure and heart rate... .” *Id.* at 10:10-19, 2:32-36; FIG. 13. “This can be done manually or automatically. For example, devices can be hooked into the computer's serial port for automatic input of blood pressure and heart rate into the system.” *Id.* If the updated patient data shows that the patient is not meeting their goals, the system “notif[ies] the physician,” who “may contact the patient in order to support and to further motivate” the patient or “recommend that the program be modified to suit the patient’s condition.” Douglas at 11:18-25.

43. Douglas’s system is implemented on a “network server 508” including “relational databases 522 ... that contain all the health plan data” and, more

generally, “[a]ll the information needed by a user of the system.” Douglas at 24:12-34, FIG. 59. Being so-implemented, the system is accessible by “patients, physicians,” and other users, for example, “via the Internet 518” and using “a PC 500.” Douglas at 24:3-26, FIG. 59.

2. Claim 1

(a) Limitation 1[p]: A method for tracking progression toward a customized goal, comprising:

44. Douglas discloses a method for tracking progression toward a customized goal. For example, “a physician prescribes ... goals for a [sic] such a therapeutic behavior modification program to help a patient recover from an ailment or surgical procedure... The system ... helps monitor compliance with the program... .” Douglas at 2:25-32; *see also* Douglas at Abstract, 6:24-32, 8:1-9, 11:7-10, 11:18-12:2, 20:14-19, 20:29-30, FIG. 7.

(b) Limitation 1[a]: receiving input establishing accounts for clients, wherein the clients are individuals receiving treatment or assistance, and wherein the accounts are stored in a server available through one or more networks;

45. Douglas discloses receiving input establishing accounts for clients. In Douglas, “the case administrator sets up a new patient based on information contained in the patient prescription form” (Douglas at 6:36-7:20), which involves the administrator “enter[ing] the patient into the system” (*id.*) and entering patient information online (*id.* at FIG. 60), each of which constitutes input. This input

includes the “information contained in the patient prescription form” that formed the basis of the administrator’s set up of the new patient (*id.* at 7:11-13). The patient prescription form is illustrated in Douglas FIG. 2 (reproduced below):

Fig 2

22 ~ **HeartLand Prescription Form**

23

Patient Name	Patient ID	Date	Physician Name	Physician ID

1. Fill in diagnosis:

Patient Diagnosis	Co-morbid Diagnosis

2. Circle a diagnostic category:

24 ~

Category	Diagnosis	Level 1 (mos.)	Level 2 (mos.)	Level 3 (mos.)	Health and Wellness
I	Current year MI survivor	3	3	6	Contin.>12th month
II	Current year alt. to PTCA or CABG	3	3	6	Contin.>12th month
III	Current year diagnosed CAD	3	3	6	Contin.>12th month
IV	All diagnosed Angina	3	3	6	Contin.>12th month
V	Prior years' post MI/surgical--High Risk	3	3	6	Contin.>12th month
VI	Prior years' post MI/surgical--Low Risk	1	1	10	Contin.>12th month
VII	2 or more Risk factors	0	2	4	Contin.>6th month
VIII	Health and Wellness	0	0	0	Continuous

3. Please circle as appropriate:

30 ~

Does the patient need smoking cessation?	Yes	No
Have you prescribed nicotine patch or gum?	Yes	No
Does the patient need weight reduction?	Yes	No

If yes, target weight: _____

32 ~ 4. What are patient's current and prescribed medications?

Medication	Standard Dosage	Comments/Changes
HCTZ	25 mg	
Atenolol	50 mg	
Lisinopril	20 mg	
Atorvastatin	20 mg	
Lovastatin	20 mg	
Antioxidant: Vitamin E	400 IU	
Antioxidant: Vitamin C	500 mg	
Other:		
Other:		
Other:		
Other:		

34 ~ 5. Circle or fill in desired 3-month targets:

	1200	1500	2000	2500	3000
Daily calories					
Sat Fat Grams	<15	15	18	20	25
Pct Fat Cal	10%	15%	20%	25%	30%
Exercise (Freq/wk/RPE)	20/5x/3	30/5x/4	45/5x/5	50/5x/6	60/5x/7
Max Heart Rate					
Stress Reduction Needs	Low Need	Some	Definite	High	Very High
Lipid Level Target					
Total Cholesterol	140	150	175	200	<225
LDL	60	70	80	<100	<125
HDL	35	37	39	41	>42

Physician's Signature: _____ Telephone: _____

FAX THIS FORM TO SALUS MEDIA: (805) 969-3601

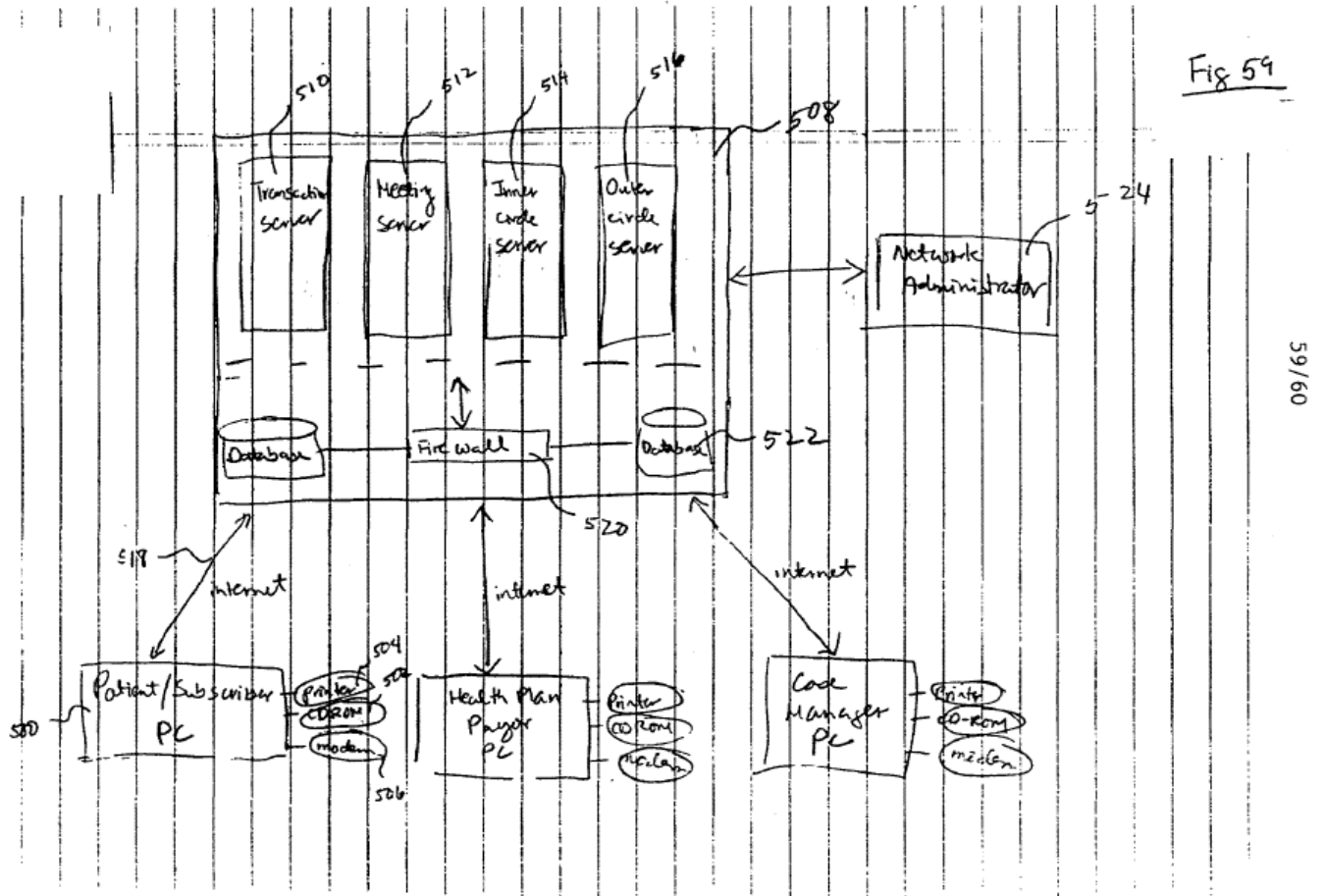
You will receive Fax confirmation within 24 Hours. For Assistance please call: (805) 969-2234

Douglas FIG. 2

46. Douglas discloses that such input is for establishing an account for a client, as Douglas explains that "[o]nce the patient is set up on the system, it assists

him or her in complying with his or her behavior modification program,” and “[t]o use the program, the patient logs into the system network” (Douglas at 8:28-31) using a “user id and password” (*id.* at 25:5-10, FIG. 36). In other words, the patient logs into an account established for the patient. Douglas’s patient is a client. ’791 Patent at 5:5-7 (“Individuals being cared for may be referred to as clients [or] patients”).

47. Douglas further discloses that the patient accounts are stored in a server, as this patient account—like other patient accounts in Douglas’s system—is stored in Douglas’s network server 508, shown in Douglas’s FIG. 59 (reproduced below):



Douglas FIG. 59

Specifically, Douglas’s server 508 includes “a transaction server 510, meeting server 512, ‘inner circle’ server 514, and ‘outer circle’ server 516.” Douglas at 24:12-16. “The servers 510-516 have access to one or more relational databases 522 (such as SQL) that contain all the health plan data” along with “[a]ll the information needed by a user of the system” (Douglas at 24:28-37), and those databases are also part of server 508 (*id.* at FIG. 59).

48. Server 508 thus stores the patient’s account, as it includes, and has access to, relational databases 522 that contain “[a]ll the information needed by a

user of the system,” including the patient. Douglas at 24:28-37. Douglas discloses that server 508 is available through one or more networks, as Douglas discloses that “each PC 500 is electronically linked to network server 508 via the Internet 518.” Douglas at 24:12-13, FIG. 29; *see also* Douglas at 8:28-31.

49. Douglas’s patient is an individual receiving treatment or assistance from their physician. Prior to being set up on the system, the physician “diagnoses [the patient] with an ailment ... [and] recommend[s] a health care maintenance or recovery program which requires the patient to” take certain medications and actions, meaning the patient is receiving treatment or assistance from their physician. Douglas at 6:24-35.

(c) ***Limitation 1[b]: assigning each of the clients to one or more of providers in response to selections from an administrator, wherein the one or more providers communicate with the client via at least a communications device;***

50. In the ’616FWD and the ’617FWD, the Board construed “‘selection’ as including inputs to a user interface, thereby ‘assigning’ a client to a provider within the system” and “that assigning and selection must be distinct elements, because they are separately listed, and assigning happens in response to selection(s).” ’616FWD at 11-12; ’617FWD at 8-10. Applying these constructions, Douglas discloses assigning each of the clients to one or more providers in response to selections from an administrator.

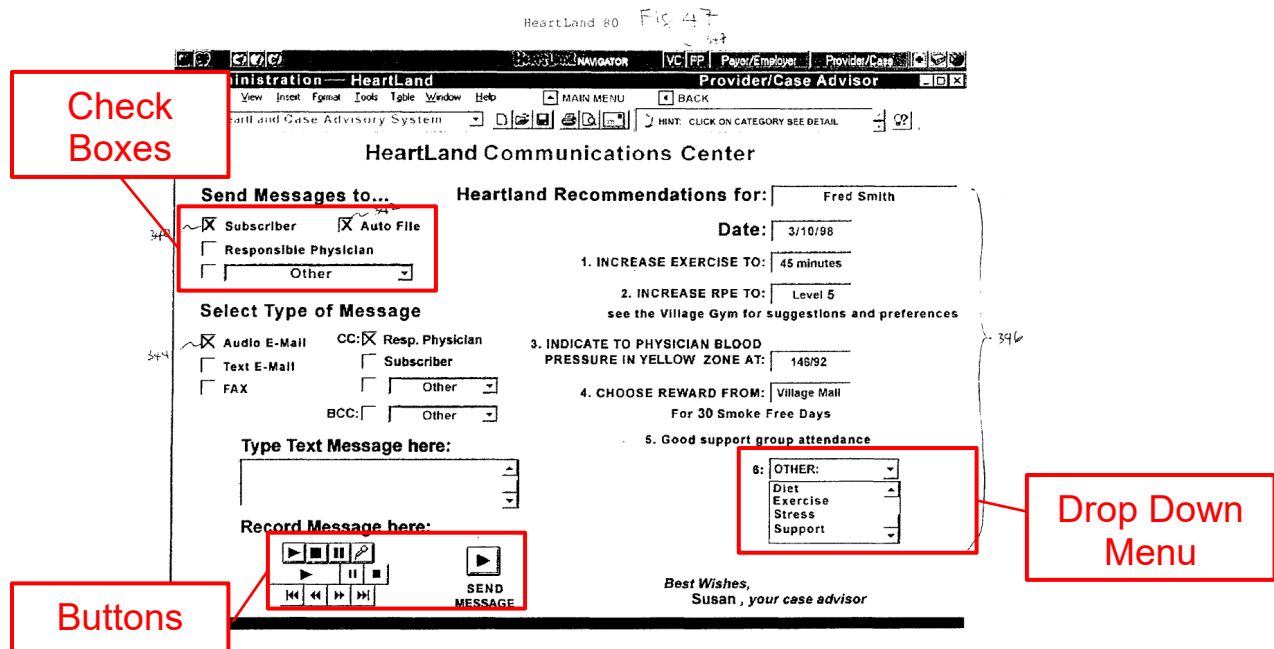
51. In Douglas's system, the patient is assigned to their physician, who provides treatment or assistance to the patient (*see* Section VII.A.2(b) (Limitation 1[a])). Douglas at 21:24-28, FIG. 47 (showing the "Responsible Physician" for patient "Fred Smith"), 15:8-9 (patients "keep in constant contact with their physician"), claims 11, 25 ("alerting the individual's physician"), FIG. 2 (associating the patient, "Patient Name[/]ID," with a physician, "Physician Name[/]ID"), FIG. 7 ("Dear Doctor **Cavello**: This is a status report on your patient"). Indeed, such patient-to-physician assignment is required for Douglas's system to, among other things, "provide[] the physician with reports of patient progress," "send an alarm to the physician," or otherwise "notify the physician" of the patient's progress. Douglas at 11:6-12:2. Douglas's physician is the claimed provider. *See* '791 Patent at 6:7-14 ("a provider is ... [a] caregiver" who "care[s] for ... patients.").

52. Douglas further discloses that such assigning of clients to providers is in response to selections from the administrator, as the case administrator sets up the patient on Douglas's system by entering the information contained in the patient prescription form, as discussed above for Limitation 1[a], where such information includes information associating the patient with a physician. Douglas at FIG. 2 ("Physician" name, ID, and signature). In my opinion, a POSITA would have understood Douglas's disclosure of the administrator entering this patient-physician information from the patient prescription form to be disclosure of selections by the

administrator. In the '616FWD and the '617FWD, the Board agreed that the claimed selections from an administrator can “include[e] inputs to a user interface,” which includes such entering of information. And these selections result in the Douglas system assuming a state in which the patient is associated with the physician in the system, as discussed above, which, in my opinion, a POSITA would have understood to be disclosure of the resulting assignment of the patient to the physician in response to the selections from the administrator.

53. In my opinion, a POSITA also would have found it to have been logical and advantageous in view of Douglas to assign clients to providers in response to selections by the administrator e.g., by using graphical user interface (“GUI”) components.

54. Douglas discloses several GUI components, including check boxes, drop-down menus, and buttons, which are shown in, for example, Douglas’s FIG. 47 (reproduced below):



Annotated Version of Douglas FIG. 47

See also e.g., Douglas at FIGS. 5, 6, 38, 39, 46, 49-52, 58.

55. In my opinion, a POSITA would have found it logical to use Douglas's GUI components to receive selections from an administrator to assign the patient to the physician in each of the following ways:

- (1) by receiving a selection of a check box associated with the physician in a list of physicians and receiving a selection of a button to assign the patient to the physician; and
- (2) by receiving a selection of the physician from a list of physicians in a drop-down menu and receiving a selection of a button to assign the patient to the physician.

56. Each of these options represents a combination of familiar elements according to known methods that does no more than yield predictable results. As Douglas's FIG. 47 reflects, Douglas discloses the use of selectable check boxes and drop-down menus from which to choose items. Douglas at FIG. 47 (check boxes for "Send Messages to..." and "Type of message" and drop-down menus for the same in addition to "Recommendations" for the patient). FIG. 47 also discloses Douglas's use of a selectable button to act upon those choices. Douglas at FIG. 47 ("SEND" the chosen message type to the chosen recipients with the chosen recommendations).

57. In both options (1) and (2) above, the check boxes and drop-down menu, respectively, would perform the same choosing-from-a-list function they do in Douglas's FIG. 47, but for a list of physicians. And the button would, like in FIG. 47, act upon the choices—here, to create the patient-to-physician assignment. Thus, in options (1) and (2), the functions of the GUI components remain unchanged. Each of the options would also lead to the predictable result of the administrator assigning the chosen physician to the patient.

58. Any of these options would have accomplished the necessary patient-to-physician assignment in Douglas's system (*supra*) in a way that furthered Douglas's desire for that system to be GUI-based and using the GUI components it already leverages. Douglas at 2:16-24 ("The present invention [] provides for [a] ...

system ... through an integrated system of interactive graphical interfaces.”); *see also* Douglas at 3:24-5:21 (describing FIGS. 3-6 and 8-58 as “graphical representation[s]”), FIGS. 3-6 and 8-58. Indeed, as a POSITA would have understood, option (1)’s check boxes, option (2)’s drop-down menu, and both options’ buttons were basic building blocks of such a GUI. Microsoft at 97, 239, and 79.

59. Finally, Douglas discloses the limitation “wherein the one or more providers communicate with the client via at least a communications device.” Douglas discloses that “[t]he communications feature of the system ... allows user to keep in constant contact with their physician,” including “via e-mail ... instant messaging, conference calls, and/or video conferencing as alternate means of communication.” Douglas at 15:8-13; FIGS. 47, 48. Such communications are accomplished via the “PC,” i.e., the “computer,” of the patient and the “PC”/“computer” of the physician. Douglas at 24:3-25:9, 15:28-29, 21:24-38, FIGS 59, 46-48, 20.

(d) *Limitation 1[c]: establishing customized goals for each of the clients based on treatment or assistance required;*

60. Douglas discloses establishing customized goals for each of the clients. “[T]he physician ... can design a new program ... for [a] patient by selecting the system’s Design option 50.” Douglas at 7:29-32, FIG. 4. “[T]he system [then] prompts the physician ... to assign intensity levels 51 corresponding to the patient’s

diet, exercise, stress management, need for group support, anticipated compliance, and pharmaceutical requirements,” as shown in FIG. 5 (reproduced below):

HeartLand 69 *Fig 5*

Administration — HeartLand Provider/Case Advisor

File Edit View Insert Format Tools Table Window Help MAIN MENU BACK PREVIEW WITH PATIENT PROGRAM

HeartLand Health Assessment Review HINT: CLICK BOX TO DESIGN PROGRAM

SCREEN 2 OF 3

Design a new program for: Date:

Heartland I.D. #: Social Security #:

INITIAL SCALE

51 ~

	LOW INTENSITY HIGH				
DIET	☐	☐	☒	☐	☐
EXERCISE	☐	☐	☒	☐	☐
STRESS MANAGEMENT	☐	☒	☐	☐	☐
GROUP SUPPORT	☐	☐	☒	☐	☐
DRUGS	☐	☐	☐	☐	☐
COMPLIANCE	☐	☐	☐	☒	☐

Based on your input, Heartland suggests the following program and goals for:

52 ~

Diet	15%	Calories From Fat
Exercise	3/4 4	hr days per week
Stress Management	1/2 7	hr days per week
Group Support	1/2 5	hr days per week
Compliance Mgt. Freq.	4	times per Month
Smoking		Cessation
Drug	-aspirin -hydrochlorothz. -Lovastatin	325 12.5 20 mg/da

Program Detail 54

Douglas at 7:33-37.

61. “Based on the input information,” which includes the intensity levels as well as patient characteristics “such as age, sex, weight and information,” “the system ... generates a set of goals 52” for the patient as part of “a therapeutic program” for the patient. Douglas at 8:1-9, FIG. 5. “The physician or case advisor may view details as to how the suggested goals may be implemented by selecting

the system's Program Detail option 54," which shows "recommended one month goals 61 and final goals 62," as shown in FIG. 6 (reproduced below):

HeartLand 70 *Fig 6*

SCREEN 3 OF 3

Based on your Input, here is HeartLand's recommended program for: Fred Smith
Use the buttons to confirm or edit this program.

PATIENT STATUS & GOALS: DETAILS		Now 2/16/98	1 month Goal	GOALS
Name / D.O.B.	Fred Smith 2-5-49			
Starting Date	2/1/98			
Heartland I.D.	23-642			
Height / Sex	6'9" Male			
Weight	193	182	175	170
BMI	28.28	26.20	25.64	25.00
Smoke	.5 Packs/Day	.5	0	0
Physical Activity	0 / 0 / 0 minutes / x-week / RPE	20 / 3 / 3	25 / 5 / 4	4 / 6 / 8
Alcohol	2 Average Drinks per Day	2	1	1
Eating Habits	40 %Fiber/Complex Carb Intake	60	70	80
	40 %Fatty Food Intake	20	20	15
	40 %Fatty Dairy Intake	20	10	5
Calories	3,600	3,300	3,100	2,800
Fat Calories & %	45%	45%	20%	15%
Cholesterol - LDL	142	140 mg/dl	125 mg/dl	100 mg/dl
Cholesterol - HDL	35	37 mg/dl	39 mg/dl	45 mg/dl
Cholesterol	246 mg/dl	225	210	190
Resting Pulse Rate	68 Beats Per Minute	68	65	79
Stress	8.5 Scale of 1 to 10 (10 being high stress)	7.0	6.0	3.5
Depression	Scale of 1 to 10 (10 being greatest)	10	5	0
Blood Pressure	140/100 systolic/diastolic	140/100	130/90	130/80
Seatbelt Use	30 percent of time	60	75	100
Back Pain	Incidents per month	3	2	0
Pharmaceuticals				
- aspirin	325 mg	325 mg/da	325 mg/da	325 mg/da
- hydrochlorothz.	12.5 mg	12.5 mg/da	12.5 mg/da	0 mg/da
- Lovastatin	20 mg	20 mg/da	20 mg/da	0 mg/da

CONFIRM 63
EDIT 64
OPTIONS...

Douglas at 8:8-11. "The physician ... may confirm 63 or edit 64 the suggested program to modify the goals by making appropriate selections." Douglas at 8:11-13.

62. Douglas's "goals 52" and "final goals 62" correspond to the claimed goals. Douglas at 8:1-13, FIGS. 5 and 6. These goals are "customized" to the patient as they result from data specific to the patient, such as the "intensity levels 51 corresponding to the patient's diet, exercise, stress management, need for group

support, anticipated compliance, and pharmaceutical requirements,” and the “patient characteristics “such as age, sex, weight and information.”

63. Douglas’s disclosure of “[t]he physician or case advisor confirm[ing] 63 or edit[ing] 64 the suggested program to modify the goals” is disclosure of establishing the customized goals based on treatment and assistance required, whether the physician or case advisor confirms the goals as consistent with such treatment and assistance or edits them to be so. Douglas at 8:12-13. Indeed, Douglas’s program provides “goals 52” and “final goals 62” for weight loss, smoking cessation, reduction of alcohol consumption, and dietary improvements. Douglas at 8:1-13, FIGs. 5, 6. Douglas’s disclosure of the physician or case advisor “assign[ing] intensity levels 51 corresponding to the patient’s diet, exercise, stress management, need for group support, anticipated compliance, and pharmaceutical requirements” (Douglas at 7:33-37, FIG. 5) is also disclosure of determining treatment and assistance for the client. Treatments needed are further indicated by the intensity levels and confirmed or edited goals relating to the patient’s use of pharmaceuticals (Douglas at FIG. 5 and 6), and assistance needed is further indicated by the provider-received intensity levels and confirmed or edited goals relating to the patient’s participation in group support (Douglas at FIGs. 5 and 6).

64. Beyond that, the therapeutic program’s pharmaceutical treatments, taking “aspirin,” “hydrochlorathzd.,” and “Lovastatin” (Douglas at FIG. 6), are also,

as a POSITA would have recognized, linked to other goals, reflecting a determination that such treatments are needed to meet those goals. Indeed, aspirin reduces “Back Pain,” hydrochlorothiazide reduces “Blood Pressure,” and Lovastatin reduces “Cholesterol,” each of which is a goal. Douglas at FIG. 6. Similarly, a POSITA would have recognized that the therapeutic program’s recommended assistance—attending “Group Support”—is linked to, e.g., goals of reducing “Alcohol” consumption, “Stress,” and “Depression,” reflecting a determination that such assistance is needed to meet those goals. Douglas at FIG. 6.

(e) *Limitation 1[d]: receiving data associated with each of the clients from a biometric device via the communication device;*

65. Douglas discloses receiving data associated with each of the clients from a biometric device via the communication device. Douglas states that “the system might also prompt the patient to input his or her vital signs 102, such as blood pressure and heart rate ... For example, devices can be hooked into the computer’s serial port for automatic input of blood pressure and heart rate into the system.” Douglas 10:12-19. “This information is stored in the system’s database.” Douglas 10:18-19. A POSITA would have understood that such devices for blood pressure or heart rate monitoring are biometric devices. The patient’s computer, which is a communication device to which the devices can be hooked, receives the biometric data associated with each of the clients.

66. Douglas also discloses receiving data from the one or more providers as “the system accepts ... data entered by the physician during office visits.” Douglas at 11:1-5, FIG. 60; *see also* claim 14, FIG. 41 (“Physician reported” blood pressure). A POSITA would have understood that the physician “enter[ing]” such data from a biometric device, such as a blood pressure monitor, is disclosure of the data being entered via the physician’s computer, i.e., a communication device.

(f) *Limitation 1[e]: compiling data associated with each of the clients;*

67. Douglas discloses compiling data associated with each of the clients. Data associated with each of the clients, such as the data received from the biometric device as discussed for Limitation 1[d], is collected over time—i.e., compiled—to determine progress of the patient toward achieving the goals. For example, Douglas discloses that “[t]he system generates reports on patient progress based on the data shown in FIGS. 40-45,” which depict various aspects of patient data collected over time, namely, blood pressure, smoking activity, physical activity, pulse, weight, stress level, medication intake, caloric intake, cholesterol level, and attitude toward change, charted against respective patient goals. Douglas at 20:3-37, FIGS. 40-45; *see also* Douglas at 20:14-19 (discussing FIGS. 41-44); “These graphs allow the physician ... to review and grasp the patient’s progress visually over a period of time, and ... determine how the patient is doing in relation to the ultimate goals.”).

- (g) *Limitation 1[f]: determining whether the customized goals are being met in response to consecutive data points of the compiled data passing one or more thresholds to become significant for one or more of the clients; and*

68. Douglas discloses determining whether the customized goals are being met in response to consecutive data points of the compiled data passing one or more thresholds to become significant for one or more of the clients. First, Douglas discloses customized goals and one or more thresholds. As noted above, Douglas discloses customized goals such as goals 52 and final goals 62. *See* VII.A.2(d). Further, Douglas's "one month goals 61" correspond to the claimed thresholds representing certain points of progress toward the customized goals. Douglas at 8:1-13, FIGS. 5 and 6. For example, in FIG. 6, Douglas discloses rows containing various medical parameters (e.g., blood pressure), one month goals in the second column from the right, and final goals 62 in the last column (with data from 2/98).

69. Douglas's system records the patient's data for these various medical parameters in consecutive data points, as shown, for example, in the patient health record of FIG. 40:

HeartLand 72 Fig 40

Administration — HeartLand Provider/Case Advisor

File Edit View Insert Format Tools Table Window Help MAIN MENU BACK BEHAVIOR RECOMMEND

Heartland Case Management Review HINT: CLICK ON CATEGORY SEE DETAIL 276

Chosen case for review: Fred Smith 240
Heartland I.D. #: 23-642 242
Subscriber since: 1/20/98 244
Date: 3/10/98 244
Social Security #: 213-48-3947 244
Total weeks on Heartland program: 3 246

Fred Smith 258 48 years, anterior M.I. 1/6/98 260 Risk Factors: Hypertension, smoker, lack of exercise, elevated LDL cholesterol 262, 264, 266, 268 270

	2/10/98	2/17/98	2/24/98	3/2/98	3/9/98	GOALS 272
250 B.P. (160/98 mmHG)	156/96	156/92	148/90	148/90	146/92	B.P. < 140/90 mmHG
252 Cigarettes/day (20)	15	10	0	0	0	Complete Smoking Cessation
254 Physical Activity minutes/x-week/RPE	0 / 0 / 0	20 / 3 / 3	30 / 4 / 3	35 / 4 / 3.5	35 / 4 / 4	45 mins walking / 7 days week / 6
Resting H.R.	88	79	68	69	67	
256 Weight baseline (180 lbs.)	179 lbs.	178 lbs.	176 lbs.	176 lbs.	172 lbs.	WEIGHT: 170 BMI: 25.00
Stress level (8) (weekly average)	7.0	7.2	6.9	6.1	6.9	3.5 (10=MAX)
Aspirin 325 mg/day (missed dose/wk)	1	2	1	1	1	Compliant use of Medications
Hydrochlorothiazide 12.5 mg. daily (missed dose/wk)	1	1	0	0	0	
Lovastatin 20 mg/day (missed dose/wk)	1	1	0	0	0	
Calories avg / day	3,600		3,300		3,100	2,800 cal / day
Fat Calories %	45%		45%		20%	15% fat calories
258 Cholesterol - LDL	142 mg/dl		140 mg/dl		125 mg/dl	100 mg/dl
Cholesterol - HDL	35 mg/dl		37 mg/dl		39 mg/dl	45 mg/dl
Cholesterol	246		225		210	190

In this health record, “[c]olumn 258 shows the patient’s vital signs and other health-related factors, such as blood pressure 250.” Douglas at 20:5-7. These factors “may be monitored and reported on a weekly basis, as shown in columns 260-268” or “on a bi-weekly basis, as shown in columns 260, 264, and 268. The ultimate goal to be achieved in each of the specified areas is given in column 272.” Douglas at 20:7-11. For example, for blood pressure 250, there are weekly consecutive measurements during the months of 2/98 and 3/98, including at dates of 2/10/98, 2/17/98, 2/24/98, 3/2/98 and 3/9/98. Douglas at FIG. 40.

70. Further, Douglas discloses determining whether the customized goals, such as goals 52 and final goals 62, are being met in response to the compiled data, including the consecutive data points described above, passing one or more thresholds, such as one month goals 61, to become significant for one or more of the clients. Douglas's "system periodically correlates the updated patient health information with program goals to determine the patient's progress and compliance with the program," including one-month goals 61 (i.e., the claimed threshold). Douglas at 11:26-12:2, FIGS. 60 (block 1050), 5, 6. A POSITA would have understood Douglas's periodic comparison of the consecutive points of patient data to the goals, including the one-month goals 61, as disclosure of determining whether the compiled data passes one or more thresholds. Douglas at 11:18-12:2, 11:12-13 ("The system compares actual data about the patient with the goals and parameters residing in the system's database"). Douglas also discloses determining that the difference between the patient data and the one-month goals is significant in a number of ways, including at least by Douglas's indication that the determined difference causes "the physician [to] then determine[] whether to modify the patient's therapeutic program, provide the patient with additional support, or remove the patient from the system." Douglas at 11:28-12:2, 11:18-24 (the difference between the data and goals "must ... be addressed by the physician or case advisor,").

71. Douglas also discloses reviewing program activity at various different review periods. For example, Douglas indicates exemplary “case advisory review” periods of “4x/mo.,” “2x/mo.,” and “1x/mo.” Douglas at FIG. 46. A POSITA thus would have understood that Douglas’s periodic correlation of the updated patient health information with program goals to determine the patient’s progress, discussed above, could occur at one or more of the exemplary review periods including, e.g., 4x/mo., 2x/mo., and 1x/mo. Douglas therefore discloses, at least for periodic review periods of 2x/mo and 1x/mo, and for data collected on a weekly basis, evaluating, in a given review period, two to four new consecutive data points since the start of data collection or a previous review. Thus, Douglas’s determination of whether customized goals are being met will be in response to consecutive data points passing the one month thresholds to become significant, such as when consecutive new data points pass the threshold during a review.

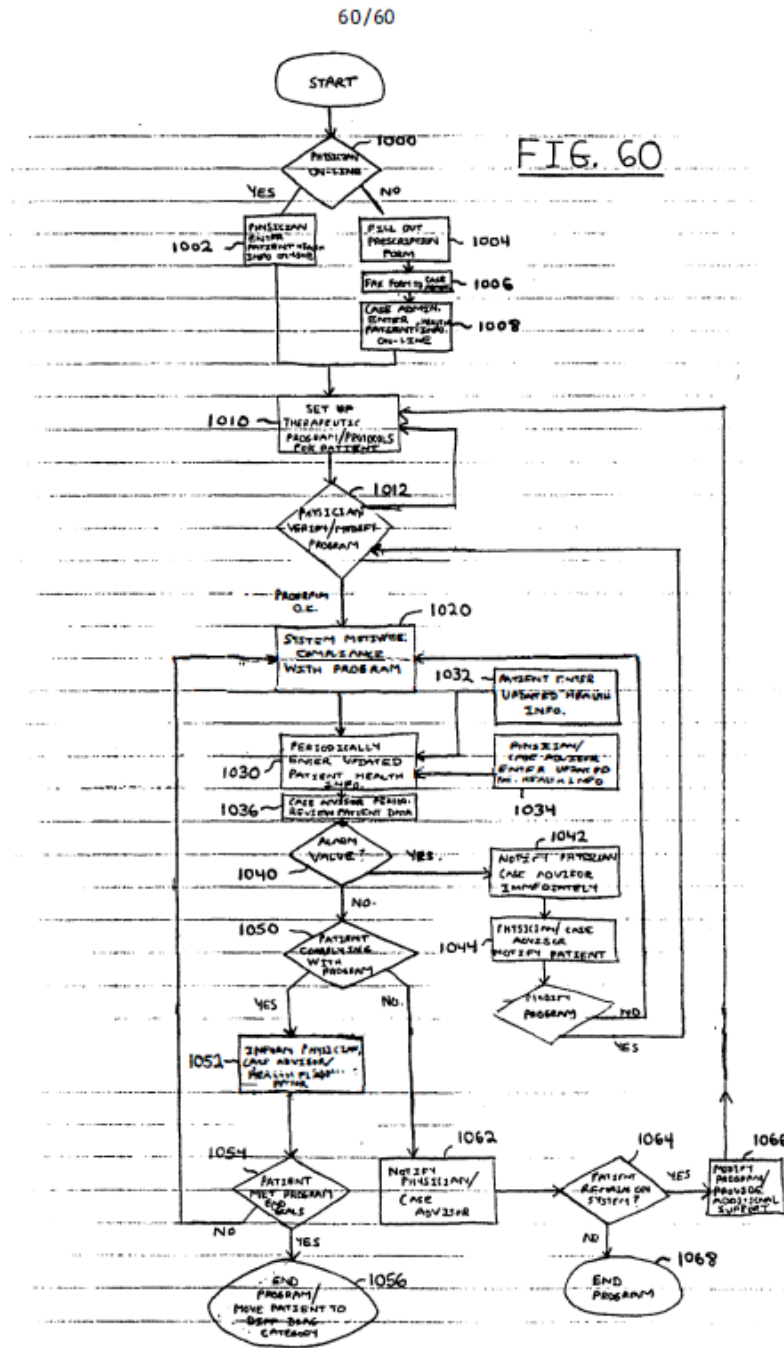
72. Similarly, Douglas also indicates that “[t]he system generates reports on patient progress based on the data shown in FIGS. 40-45, as frequently as the physician desires,” and “depend[ing] on the needs of the particular patient.” Douglas at 20:33-37. A POSITA thus also would have found it to be logical and advantageous for Douglas’s periodic correlation of the updated patient health data with program goals to determine the patient’s progress to have occurred at one more of the exemplary review periods including, e.g., 4x/mo., 2x/mo., and 1x/mo,

depending on a particular physician's desires, and in view of the patient's needs. A POSITA therefore also would have found it to be logical and advantageous that for periodic review periods of 2x/mo and 1x/mo, and data collected on a weekly basis, the periodic correlation of the updated patient health data with program goals to determine the patient's progress would have been in response to consecutive data points passing the one month thresholds to become significant, such as when consecutive new data points for a given review pass the threshold.

(h) *Limitation 1[g]: automatically communicating alerts to at least the one or more providers to at least perform a review of the goals for the one or more of the clients in response to consecutive data points of the compiled data varying from the one or more thresholds to become significant for the one or more of the clients.*

73. Douglas's system provides multiple mechanisms to automatically communicate alerts to the providers to perform a review of the goals of the clients in response to consecutive data points of the compiled data varying from the one or more thresholds to become significant. As noted above for Limitation 1[f], Douglas's system determines whether the customized goals 52, 62 are being met in response to consecutive data points of the complied data passing one or more of the one month goals 61—i.e., thresholds—to become significant for a client. The Douglas system then automatically communicates alerts to a provider to perform a review of the goals when this happens.

74. For example, FIG. 60 and the related description in Douglas disclose a compliance feedback look beginning at block 1020:



75. As part of Douglas's periodic review process at block 1050 discussed above for Limitation 1[f], Douglas discloses that "If the patient is progressing in accordance with his or her program, the system informs the physician and/or case advisor (block 1052, FIG. 60)." Douglas at 11:28-30. "The system also notifies the physician or case advisor if the patient is not progressing toward program goals or is not using the system (block 1060, FIG. 60)." Douglas at 11:35-36, *see also* Douglas at 11:12-15 ("automatically notifies the physician or case advisor, if a health risk is present (block 1042, FIG. 60)"), 11:18-21 ("[i]f the difference between current data and goals does not represent a threatening situation, the system will notify the physician ... that these goals are not being met."). A POSITA would have understood Douglas's "inform[ing]" and "notify[ing]" the physician to disclose generating an alert. A POSITA also would have understood Douglas' indication that "the system" informs and notifies the physician as disclosure of the system automatically doing so.

76. Further, Douglas's system providing notifications to the physician causes the physician to review the goals for the patient, as "[i]f the patient is progressing in accordance with his or her program," the "physician can [] determine whether to modify the program by altering the goals," and "if the patient is not progressing the physician can again "determine[] whether to modify the patient's therapeutic program," as indicated in blocks 1046, 1052, 1056, and 1066. Douglas

at 11:28-12:2, *see also* Douglas at 11:21-25 (“the physician or case advisor may recommend that the program be modified to suit the patient’s condition”). Such modification of the program discloses the claimed review of the goals of the client in response to consecutive data points of the compiled data varying from the thresholds to become significant for a client.

3. *Claim 2: The method of claim 1, wherein the one or more providers further include individuals available to treat or assist the clients.*

77. In Douglas’s system, one or more of the physicians includes individuals available to treat or assist the client. Douglas at 21:24-28, FIG. 47 (showing the “Responsible Physician” for patient “Fred Smith”), 15:8-9 (patients “keep in constant contact with their physician.”), claims 11, 25 (“alerting the individual’s physician”), FIG. 2 (associating the patient, “Patient Name[/]ID,” with a physician, “Physician Name[/]ID”), FIG. 7 (“Dear Doctor **Cavello**: This is a status report on your patient”).

4. *Claim 3: The method of claim 1, further comprising: intervening in response to communicating the alerts to at least the one or more providers or caregivers associated with the one or more of the clients.*

78. As discussed above in Section VII.A.2(h) (Limitation 1[g]), in response to the alerts, the physician can modify the patient’s program, including “by altering the goals.” Douglas at 11:24-25, 31-34, 36-12:2. Such modification discloses the claimed intervening in response to communicating the alerts to at least the one or more providers or caregivers associated with the one or more of the clients.

5. Claim 4: The method of claim 3, wherein the one or more providers physically intervene to treat or assist the one or more of the clients.

79. Douglas discloses that if the patient's data presents a health risk, the physician is required to take immediate action. Douglas at 11:18-21 ("For instance, if a patient's current blood pressure is potentially dangerous, the system will automatically send an alarm to the physician or case advisor and require his or her immediate action."). A POSITA would have understood that such immediate action includes physical intervention.

80. Additionally, as discussed above in Section VII.A.2(h) (Limitation 1[g]), Douglas discloses that a physician may contact the patient or provide the patient with additional support if the patient data shows the patient is not on track to meet the goals or even if the patient is on track. Douglas at 11:18-25. In my opinion, a POSITA would have understood that both of these actions can include a physical intervention.

6. Claim 5: The method of claim 1, wherein the customized goals, data, compiled data, thresholds, and alerts are saved in the server.

81. Douglas discloses that the customized goals, data, compiled data, thresholds, and alerts are saved in the server. As discussed above in Section VII.A.2(b) (Limitation 1[a]), Douglas discloses that network server 508 includes "one or more relational databases 522 (such as SQL) that contain all the health plan data" as well as "[a]ll the information needed by a user of the system." Douglas at

24:28-37. Such data and information includes Douglas's disclosure of the customized goals, data, compiled data, one month goals (thresholds), and alerts given that: (1) they are needed by users—patients and physicians—of Douglas's system (Douglas at 12:3-7 (“users may view their levels of compliance and achievement of goals”), 8:11-13 (“The physician ... may edit 64 the suggested program to modify the goals....”); and (2) they reflect confidential health plan data that a POSITA would have therefore understood resided behind firewall 520 that “protects confidentiality of health plan data” (Douglas at 25:14-16, Douglas at FIG. 59).

7. *Claim 6: The method of claim 1, wherein the one or more providers include biometric sensors worn by or proximate to the clients.*

82. As discussed above in Section VII.A.1 and VII.A.2(e) (Limitation 1[d]), Douglas discloses receiving data from a biometric device, including blood pressure and heart rate data provided by the patient or physician using a device connected to a computer. Douglas 10:12-19; 11:1-5, FIG. 60; see also claim 14, FIG. 41. A POSITA would have understood that such devices include biometric sensors worn by or proximate to the clients. For example, a POSITA would have understood that blood pressure devices typically include a cuff, including a sensor, that is worn by a patient, and that heart rate sensors typically include a strap or band, having a sensor, worn by a patient. In my opinion, a POSITA also would have found it to have been logical and advantageous in view of Douglas that the device used by

the patient be provided by, and thus included in, the one or more providers, as it was known for physicians to supply such devices as a part of the treatment and assistance. A POSITA also would have understood that a device used by the physician is also included in the one or more of the providers.

8. *Claim 7: The method of claim 1, wherein the compiled data indicates the behavior of the clients, and wherein the one or more thresholds include a range.*

83. As discussed above in Section VII.A.1, Douglas discloses a therapeutic behavior modification program based on a review of health data, including data that indicates the behavior of the clients. Douglas at Abstract, 1:8-10, 3:13-14, 11:1-5, 11:26-28; FIGS. 5-7, 40. In addition, as discussed above in Section VII.A.2(g) (Limitation 1[f]), Douglas discloses one month goals (thresholds) that include a range, e.g., blood pressure range. Douglas FIGS. 5-7, 7.

9. *Claim 9: The method of claim 1, further comprising: establishing the customized goals in response to input from each of the clients and the one or more providers associated with each of the clients.*

84. As discussed in Sections VII.A.2(a) (Limitation 1[p]) and VII.A.2(d) (Limitation 1[c]), the customized goals are created in response to input from a provider associated with a client. In addition, the customized goals result from data specific to the patient, which must come at least in part as a result of input from the patient. Douglas at 7:17-19. For example, “[o]nce the physician or case administrator enters the patient into the system, either the system or case advisor

recommends a default set of goals based on the patient's needs and existing medical protocols that may be modified by the physician.” Douglas at 7:17-19. FIG. 4 provides “an exemplary patient record” based on input from the patient that serves as a basis for establishing the customized goals:

HeartLand 68 *Fig 4*

44 SCREEN 1 OF 3 48

PATIENT STATUS & GOALS: DETAILS		Now 2/10/98	1 month Goal	GOALS
Name / D.O.B.	Fred Smith 2-5-49			
Starting Date	2/1/98			
Heartland I.D.	23-642			
Height / Sex	5'9" Male			
Weight	193	182		
BMI	28.28	28.28		
Smoke	5 Packs/Day	.5		
Physical Activity	0 / 0 / 0 minutes / x-week / RPE	20 / 3 / 3		
Alcohol	2 Average Drinks per Day	2		
Eating Habits	40 % Fiber/Complex Carb Intake	60		
	40 % Fatty Food Intake	20		
	40 % Fatty Dairy Intake	20		
Calories	3,600	3,300		
Fat Calories & %	45%	1,500		
Cholesterol - LDL	142	140 mg/dl		
Cholesterol - HDL	35	37 mg/dl		
Cholesterol	246 mVdl	225		
Resting Pulse Rate	88 Beats Per Minute	68		
Stress	8.8 Scale of 1 to 10 (10 being high stress)	7.0		
Depression	Scale of 1 to 10 (10 being greatest)	10		
Blood Pressure	140/100 systolic/diastolic	140/100		
Seatbelt Use	30 percent of time	60		
Back Pain	Incidents per month	3		
Pharmaceuticals	- aspirin 325 mg - hydrochlorothzid. 12.5 mg - Lovastatin 20 mg 325 mg/da 12.5 mg/da 20 mg/da			

EDIT DESIGN *50*

Douglas at 7:20-28. “The second column 46 of the record sets forth the baseline values corresponding to the vital signs and patient characteristics at the beginning of his or her participation in the program.” Douglas at 7:26-28. Thus, the customized goals disclosed in Douglas are, in part, in response to input from each of the clients.

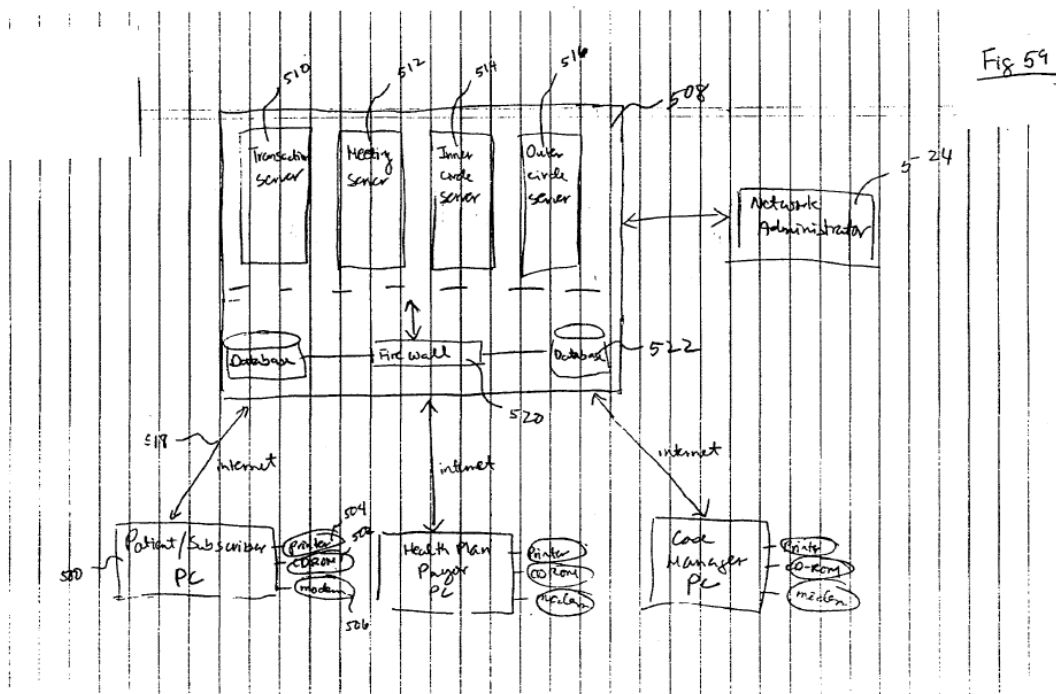
10. *Claim 11*

a) Limitation 11[p]: A system for tracking progression toward a customized goal, the system comprising:

85. See Section VII.A.2(a) (Limitation 1[p]).

b) Limitation 11[a]: a server communicates with communications devices through a transceiver utilizing one or more networks, the server includes a processor that executes a client management program to:

86. Douglas discloses that its system includes a server that communicates with communications devices utilizing one or more networks, as Douglas discusses “PC[s] 500 electronically linked to network server 508 via the Internet 518,” shown in Douglas’s FIG. 59 (reproduced below):



Douglas FIG. 59

Douglas at 24:12-34. Such PCs include those for “patients, physicians, case advisors, and health plan payors.” Douglas at 24:3-6. These PCs are communications devices, as they communicate with the server. Douglas at 24:22-27-34.

87. The communications between PCs 500 and network server 508 were also through a transceiver, which a POSITA would have understood to be “[a] device that can both transmit and receive signals.” Microsoft at 527. Indeed, Douglas discloses that PCs 500 transmit signals that are received by network server 508, and the network server transmits signals that are received by the PCs, indicating the presence of a transceiver at each of the PCs and the network server for transmitting and receiving the communications. Douglas at 24:22-34. Specific transceivers that Douglas discloses—any one or more of which meet the claimed transceiver—include “high-speed modem 506 connected to the PC 500” (Douglas at 24:22-24) and transceivers for establishing a “cellular connection [or] satellite link ... [with the] network server” (Douglas at 8:28-31).

88. Douglas further discloses a client management program, specifically, Douglas’s “therapeutic behavior modification program’s compliance monitoring and feedback system.” Douglas at 5:22-25, FIGS. 59 and 60. That system manages a patient in that it:

- provides for the creation of a patient account (Douglas at 6:33-35, FIG. 60 (block 1008));
- “recommends a default set of goals based on the patient’s needs and existing medical protocols that may be modified by the physician” (*id.* at 7:17-20, FIG. 60 (blocks 1010, 1012));
- “assists [the patient] in complying with his or her behavior modification program” (*id.* at 8:28-29, FIG. 60 (block 1020));
- “periodically correlates [] updated patient health information with the program goals to determine the patient’s progress and compliance with the program” (*id.* at 11:26-28, FIG. 60 (block 1050)); and
- “informs the physician” regarding the patient’s progress or lack thereof, who then “determines whether to modify the patient’s therapeutic program, provide the patient with additional support, or remove the patient from the system” (*id.* at 11:28-12:2, FIG. 60 (1052, 1062)).

89. Douglas’s system is software and therefore a processor executes the system. Douglas at 25:22-26, 3:10-13, 2:25-27. A POSITA would have understood that Douglas’s compliance monitoring and feedback system resided on Douglas’s network server 508 and so did the processor that executed it, and thus Douglas discloses the server including the processor.

90. First, as Douglas explains, network server 508 includes an “‘inner circle’ server 515” that “is dedicated to handle sensitive data, such as medical records.” Douglas at 24:13-19, FIG. 59. Such handling of sensitive medical records is what the relied-on portions of Douglas’s system do. *See, e.g., infra* Sections VII.A.10(c) and VII.A.10(d) (Limitations 11[b] and 11[c]) (setting up an account and assigning a patient to a physician based on the patient prescription form that includes medical data of the patient), VII.A.10(e)-VII.A.10(h) (Limitations 11[d]-11[g]) (based on that medical data and updates to the same, setting and determining the patient’s progress toward goals and responding accordingly). A POSITA would have thus understood, per Douglas, that these relied-on portions of Douglas’s system are implemented by “inner circle” server 515 of network server 508.

91. Second, as Douglas explains, patients, physicians, case advisors, and health plan payors must log into the system to use or access it, further indicating its implementation on network server 508. Douglas at 8:29-31 (“To use the program, the patient logs into the system network via ... connection into a network server.”), 19:27-30 (“log-on screen 220 ... for a physician/case advisor ... ensur[es] that only legitimate users are able to gain access to the system”), 25:5-11, FIG. 59.

92. Nevertheless, in my opinion a POSITA also would have found it to have been logical and advantageous for the processor implementing Douglas’s system to reside in network server 508. To begin, network server 508 includes “one or more

relational databases 522 (such as SQL) that contain all the health plan data” and “[a]ll the information needed by a user of the system.” Douglas at 24:28-25:4; *see also* Douglas at FIG. 59. Given that a patient on Douglas’s system and their physician—both users of that system—each need access to the patient’s health data over time (*see* Douglas at FIGS. 41-44 (charts of a patient’s data over time, which are provided to the patient and physician (*id.* at 20:14-19, 12:3-7))), a POSITA would have understood, per Douglas, that such health data was stored in databases 522. *See also* Douglas at 24:32-33 (“Information,” such as patient health data, “will also be uploaded to the [] server”). And Douglas’s system makes periodic use of that health data. *See, e.g.*, Douglas at 11:26-28, FIG. 60.

93. Therefore, a POSITA would have understood that locating the processor implementing Douglas’s system in the server containing the health data upon which that system operated—databases 522 of network server 508—would have achieved Douglas’s goal of “protect[ing the] confidentiality of health plan data.” Douglas at 25:14-16; *see also* Douglas at 10:7-9, 19:29-30, 22:12-14, 24:18-19, 25:5-9. In this arrangement, the health data could remain behind firewall 520 that “protects confidentiality of health plan data” (Douglas at 25:14-16, Douglas at 59 (showing databases 522 behind firewall 520)), while it was “correlate[d] ... with the program goals” (Douglas at 11:26-28) as opposed to being transmitted outside of that firewall for such correlation.

c) Limitation 11[b]: receive input establishing an account for a client, wherein the client is an individual receiving treatment or assistance, and wherein the accounts are stored in a server available through the one or more networks;

94. See Section VII.A.2(b) (Limitation 1[a]).

d) Limitation 11[c]: assign the client to one or more of providers in response to selections from an administrator, wherein the one or more providers communicate with the client via at least one of the communications devices;

95. See Section VII.A.2(c) (Limitation 1[b]).

e) Limitation 11[d]: establish customized goals for the client based on treatment or assistance required;

96. See Section VII.A.2(d) (Limitation 1[c]).

f) Limitation 11[e]: receive data associated with the client from a biometric device via the communications device;

97. See Section VII.A.2(e) (Limitation 1[d]).

g) Limitation 11[f]: compile the data associated with the client received from the communications devices in communication with the server;

98. See Section VII.A.2(f) (Limitation 1[e]).

h) Limitation 11[g]: determine whether the customized goals are being met in response to consecutive data points of the compiled data passing one or more thresholds to become significant for the client; and

99. See Section VII.A.2(g) (Limitation 1[f]).

- i) Limitation 11[h]: automatically communicate alerts to at least perform a review of the treatment and assistance in response to consecutive data points of the compiled data varying from the one or more thresholds to become significant for the client; and***

100. See Section VII.A.2(h) (Limitation 1[g]).

101. Douglas's notifications to the physician cause the physician to review the treatment and assistance for the patient, as "determine[ing] whether to modify the program," "moving the patient into a different diagnostic category," and "remov[ing] the patient from the system" each disclose at least reviewing the treatment received by the patient, and "provid[ing] the patient with additional support" discloses at least reviewing the assistance received by the patient. Douglas at 11:26-12:2, Fig. 60.

- j) Limitation 11[i]: a database in communication with the server configured to store the data, customized goals, compiled data, and thresholds associated with the client in the account.***

102. See Sections VII.A.2(b) (Limitation 1[a]) and VII.A.6 (Claim 5).

103. Douglas further discloses a database in communication with the server, as Douglas discloses that network server 508 includes "servers 510-516" that "have access to one or more relational databases 522," as discussed in Section VII.A.2(b). Douglas at 24:12-16, 28-30. A POSITA would have understood that the components of the network server 508 having access to the database 522 discloses that the network server 508 is in communication with the database 522. Further, as discussed

in Section VII.A.6, Douglas discloses that this database 522 includes Douglas's disclosure of the received data, customized goals, compiled data, and one month goals (thresholds).

11. Claim 12: The system of claim 11, wherein the one or more providers further include individuals available to treat or assist the client.

104. See Section VII.A.3 (Claim 2).

12. Claim 13: The system of claim 11, wherein the threshold is a customized range established for the client.

105. See Sections Section VII.A.2(g) (Limitation 1[f]) and VII.A.8 (Claim 7).

106. Douglas discloses one month goals (thresholds) that include a customized range, e.g., blood pressure range, established for the client. Douglas FIGS. 5-7.

13. Claim 14: The system of claim 11, wherein the one or more providers or caregivers associated with the client physically intervene in response to the alerts.

107. See Sections VII.A.4 (Claim 3) and VII.A.5 (Claim 4).

14. Claim 16

(a) Limitation 16[p]: A server comprising:

108. See Section VII.A.10(b) (Limitation 11[a]) (network server 508).

(b) *Limitation 16[a]: a processor for executing a set of instructions; and*

109. Douglas discloses or renders to a POSITA as logical and advantageous a processor within network server 508 for executing a set of instructions for implementing Douglas's system. For example, as discussed in Section VII.A.10(b) (Limitation 11[a]), Douglas discloses or renders logical and advantageous that its network server 508 includes a processor to execute its "therapeutic behavior modification program's compliance monitoring and feedback system," which is software. Douglas at 5:22-25, FIGS. 59 and 60. Further, Douglas also discloses that this software system includes a set of instructions, as it "is constructed using the C++ programming language in conjunction with SQL 6.5, Cold Fusion, ... Visual Basic, ... and HTML," as well as "Active X and Java components," which a POSITA would understand are all programming languages or tools used to produce program instructions. Douglas at 25:22-26.

(c) *Limitation 16[b]: a memory for storing the set of instructions, wherein the set of instructions are executed by the processor to:*

110. Douglas discloses a memory in network server 508 for storing the set of instructions that the server's processor executes to implement Douglas's system. See Section VII.A.10(b) (Limitation 11[a]). A POSITA would have known that a processor required a memory—at a minimum, RAM—to store the instructions that the processor executed.

111. Additionally, the use of a memory to store software was within a POSITA's general knowledge and would have been logical to do. Chitiveli, for instance, discloses that his server includes a "memory 230 including the content analytics tool" (Chitiveli at ¶¶ [0044]-[0046], FIG. 2), which—like Douglas's compliance monitoring and feedback system—analyzes patient data (*id.* at ¶ [0019]). This general knowledge, reflected by Chitiveli, is mappable to the claimed memory. And using such a memory to store Douglas's system amounts to nothing more than the use of the memory to perform its established, software-storing function. *See* Chitiveli at ¶¶ [0044]-[0046], FIG. 2.

(d) ***Limitation 16[c]: receive input establishing accounts for clients, wherein the clients are individuals receiving treatment or assistance, and wherein the accounts are stored in a server available through one or more networks;***

112. *See* Sections VII.A.2(b) and VII.A.10(c) (Limitations 1[a] and 11[b]).

(e) ***Limitation 16[d]: assign each of the clients to one or more of providers in response to selections from an administrator, wherein the one or more providers communicate with the client via at least a communications device;***

113. *See* Sections VII.A.2(c) and VII.A.10(d) (Limitations 1[b] and 11[c]).

(f) ***Limitation 16[e]: establish customized goals for each of the clients based on treatment or assistance required;***

114. *See* Sections VII.A.2(d) and VII.A.10(e) (Limitations 1[c] and 11[d]).

- (g) *Limitation 16[f]: compile data associated with each of the clients received from a biometric device via the communications device;*

115. See Sections VII.A.2(e)-VII.A.2(f) and VII.A.10(f)-VII.A.10(g) (Limitations 1[d]-1[e] and 11[e]-11[f]).

- (h) *Limitation 16[g]: determine whether the customized goals are being met in response to consecutive data points of the compiled data passing one or more thresholds to become significant for one or more of the clients; and*

116. See Sections VII.A.2(g) and VII.A.10(h) and (Limitations 1[f] and 11[g]).

- (i) *Limitation 16[h]: automatically communicate alerts to at least the one or more providers to at least perform a review of the goals, treatment, and assistance for the one or more of the clients in response to the compiled data varying from the one or more thresholds to become significant for the one or more of the clients.*

117. See Sections VII.A.2(h) and VII.A.10(i) (Limitations 1[g] and 11[h]).

15. *Claim 17: The server of claim 16, wherein the one or more providers include individuals available to treat or assist the clients and the one or more providers include biometric sensors worn by or proximate to the clients.*

118. See Sections VII.A.3 (Claim 2) and VII.A.7 (Claim 6).

16. *Claim 18: The server of claim 16, wherein the one or more providers physically intervene with the one or more clients in response to the alerts.*

119. See Sections VII.A.4 (Claim 3) and VII.A.5 (Claim 4).

17. Claim 19: The server of claim 16, wherein the compiled data indicates the behavior of the clients.

120. See Section VII.A.8 (Claim 7).

B. Ground 2 – Claims 1-7, 9, 11-14, and 16-19 in view of Douglas and Khanuja

1. Khanuja Overview

121. Khanuja discloses “a patient monitoring system for monitoring various physiological characteristic data of a patient, such as blood pressure, pulse rate, blood glucose, weight and others” Khanuja at [0004]. “The system includes a portable physiological transducer or patient monitoring device that can be worn by a patient,” “such as a blood pressure monitor, heart rate monitor, weight scale, thermometer, spirometer, single or multiple lead electrocardiograph (ECG), a pulse oxymeter, a body fat monitor, a cholesterol monitor or a signal from an exercise machine, such as a heart rate.” *Id.* at [0029], [0036]. “The data from the patient monitoring device is wirelessly transmitted to a local hub, which, in turn, is configured to automatically transfer the data to a remote server” *Id.* at [0010].

122. “[T]he remote server is configured as a web portal which selectively allows access to patient data by selected third party users, such as physicians, clinicians, patients, and/or relatives,” and “automatically generate[s] communications with the patient or other third parties . . . when predetermined thresholds for selected physiological characteristics are exceeded.” *Id.* at [0004].

123. A user, including a physician, “sets up an alert by choosing the condition that they would like to be alerted to and by providing the parameters (e.g. threshold value for the reading) for alert generation.” *Id.* at [0119]. “Each alert thus set up has an interval associated with it,” such as “the number of data points or a time duration ... depending on the type of reading for which this alert is being set up.” *Id.* at [0120]. “The values of readings lying within the interval specified by the user must all either positively or negatively exceed the Specified threshold for the alert to be generated” *Id.* at [0121]. For example, “[t]he user may choose certain parameters of the triggering events e.g. if their blood pressure is above X for Y days, then trigger an alert, where X and Y are chosen by the user.” *Id.* at [0250]. In another example, as show in FIG. 21, an alert may be set for blood pressure by indicating a threshold and a number of readings that the data needs to be above the threshold to generate an alert. Additionally, “[t]he user chooses the destination where the alert may be sent,” such as to “the user's portal, e-mail, pager, voice-mail,” and/or to “third parties, such as the physician and/or relatives.” *Id.* at [0122], [0033].

2. *Modification of Douglas*

124. In a first mapping, in my opinion a POSITA would have found it to have been logical and advantageous to modify the Douglas system to determine whether the customized goals are being met in Douglas in response to a selected

number of consecutive readings for a particular medical parameter being above or below a threshold as in Khanuja, resulting in the Douglas-Khanuja System.

125. In a second, alternative mapping, in my opinion a POSITA would have found it to have been logical and advantageous to modify the Douglas system in view of Khanuja as in the first mapping, and to also use the patient monitoring devices of Khanuja to measure and provide the patient's vital signs to the Douglas patient computer for transmission into the system. As discussed above, Douglas's system periodically receives updated patient data, including from a biometric device (Douglas at 11:1-5, FIG. 60), to determine the "patient's progress and compliance with the program" (id. at 11:26-28). Douglas provides examples of biometric devices to measure blood pressure and heart rate (Douglas at 10:10-19; FIG. 13) "hooked into the computer's serial port for automatic input of blood pressure and heart rate into the system." Id. The Douglas-Khanuja System of this second mapping would implement a biometric device using the patient monitoring device 32 of Khanuja to monitor physiological characteristic data of a patient. In such a Douglas-Khanuja system, instead of connecting to a hub, the patient monitoring device of Khanuja would connect to the patient computer of Douglas, which would then transmit the data to the network server. Such a connection between the patient monitoring device and the computer could have been either wired, as in the connection of the Douglas biometric device to the computer (with the Khanuja

patient monitoring device being modified to provide a wired connection), or wireless, as in the connection of the Khanuja patient monitoring device to the hub (with the Douglas patient computer being modified to accept a wireless connection). Douglas at 10:15-16; Khanuja at [0036]-[0037].

126. In a third, alternative mapping, in my opinion a POSITA would have found it to have been logical and advantageous to modify the Douglas system in view of Khanuja as in the first and second mappings, and to also implement notifications to physicians in Douglas, such as in response to periodic reporting, using the alerts as in Khanuja.

3. *Motivation to Combine*

127. For the first mapping, a POSITA would have been motivated to determine whether the customized goals are being met in Douglas in response to a selected number of consecutive readings for a particular medical parameter being above or below a threshold as in Khanuja because this would have provided an enhanced, more customizable evaluation framework for determining whether the goals were being met. Douglas discusses comparing the patient data with the one month goals 61—i.e., thresholds—such as at certain periodic intervals, but does not otherwise indicate how to further customize the comparison as between different types of medical parameters, such as between blood pressure versus weight. Khanuja teaches a need for “enhanced functionality and expanded access to the

healthcare data,” and correspondingly provides functionality for users, such as both the provider and patient, to set the conditions for alerts in more detail, including by setting both a custom interval, or number of consecutive data points, and a custom threshold, as the conditions for the alert. Khanuja at [0009], [0117]-[0123]. This would also allow the use of “[s]pecific preset alerts ... based on medically established conditions in the case of common reading types e.g. heart rate, weight, blood sugar etc.,” which could also be further modified. Khanuja at [0123].

128. Additionally for the first mapping, a POSITA would have understood that evaluating data against a threshold as done in Khanuja was known, and could be applied to evaluating whether the patient data indicated that goals were being met in a known behavioral modification program like that of the Douglas system, and that such an approach would work in Douglas’s system in essentially the same way that it works in Khanuja, with the results of the combination being predictable.

129. For the second mapping, in addition to the above motivations to combine for the first mapping, a POSITA would have been motivated to use the patient monitoring devices of Khanuja with the Douglas system in order to measure a wider variety of physiological characteristics for a patient. Douglas discloses the use of certain types of biometric devices, including for blood pressure and heart rate, but Khanuja discloses other types of biometric devices, including also for blood pressure and heart rate, as well as for weight, temperature, blood oxygen, body fat,

cholesterol, and exercise. Khanuja at [0036]. A POSITA would have recognized that modifying the Douglas system to additionally use other types of biometric devices, such as those disclosed in Khanuja, would have improved the scope of devices a patient could use to measure biometric data, such as blood pressure, heart rate and other data types.

130. Additionally for the second mapping, a POSITA would have understood that in the Douglas-Khanuja System, the patient monitoring devices of Khanuja were known, and could be used to monitor and transmit patient data in a known behavioral modification program like that of the Douglas system. Such an approach would work in Douglas's system in essentially the same way that it works in Khanuja, with the results of the combination being predictable.

131. For the third mapping, in addition to the above motivations to combine for the first and second mappings, a POSITA would have been motivated to use the alerts of Khanuja to implement the notifications in Douglas's system because this would have provided a more customizable framework for setting up and sending the notifications. Douglas discloses sending notifications "via e-mail or facsimile []or pager," but Khanuja discloses additional ways of sending alerts, including to via the "portal, e-mail, pager, voice-mail or any combination of the above." A POSITA would have recognized that modifying the Douglas system to additionally use other

types of alerts, such as those disclosed in Khanuja, would have improved the effectiveness and reach of the alerts.

132. Additionally for the third mapping, a POSITA would have understood that the alerts of Khanuja could have been used to implement notifications in the Douglas-Khanuja System in essentially the same way that they work in Khanuja, with the result of the combination being predictable. KSR Int'l Co., 550 U.S. at 401.

4. Claims 1-7, 9, 11-14, and 16-19

133. My opinions regarding Claims 1-7, 9, 11-14, and 16-19 of the '791 for Ground 2 are the same as for Ground 1 (see my Section VII.A), excepting Limitations 1[d], 11[e], 16[f], 1[f], 11[g], 16[g], 1[g], 11[h], and 16[h], changes to which are addressed below.

(a) Limitations 1[d], 11[e], and 16[f]: receiving data associated with each of the clients from a biometric device via the communication device (or similar);

134. For the first mapping, the Douglas-Khanuja System discloses these claim limitations for the same reasons discussed above in Sections VII.A.2(e) (Limitation 1[d]), VII.A.10(f) (Limitation 11[e]), and VII.A.14(g) (Limitation 16[f]) based on Douglas's disclosure alone. For the second and third mappings, the Douglas-Khanuja System also discloses these claim limitations for the same reasons discussed above in Sections VII.A.2(e), VII.A.10(f) and VII.A.14(g), but with the combined System using the portable monitoring device of Khanuja connected to the

patient computer in Douglas instead of the device of Douglas connected to the computer, as discussed in VII.B.2. Thus, the Douglas-Khanuja System receives data associated with each of the clients from Khanuja's portable monitoring device.

- (b) *Limitations 1[f], 11[g], and 16[g]: determining whether the customized goals are being met in response to consecutive data points of the compiled data passing one or more thresholds to become significant for one or more of the clients; and*

135. For all three mappings, the Douglas-Khanuja System discloses these claim limitations for the same reasons discussed above in Sections VII.A.2(g) (Limitation 1[f]), VII.A.10(h) (Limitation 11[g]), and VII.A.14(h) (Limitation 16[g]), but with the combined System performing the comparison of the patient data with the goals to determine whether the goals are being met by determining whether a selected number of consecutive readings of the data is above or below a selected threshold as in Khanuja as discussed in Section VII.B.2. Khanuja at [0250], FIG. 21.

- (c) *Limitations 1[g], 11[h], and 16[h]: automatically communicating alerts to at least the one or more providers to at least perform a review of the goals for the one or more of the clients in response to consecutive data points of the compiled data varying from the one or more thresholds to become significant for the one or more of the clients.*

136. For all three mappings, the Douglas-Khanuja System discloses automatically communicating alerts to at least the one or more providers to at least

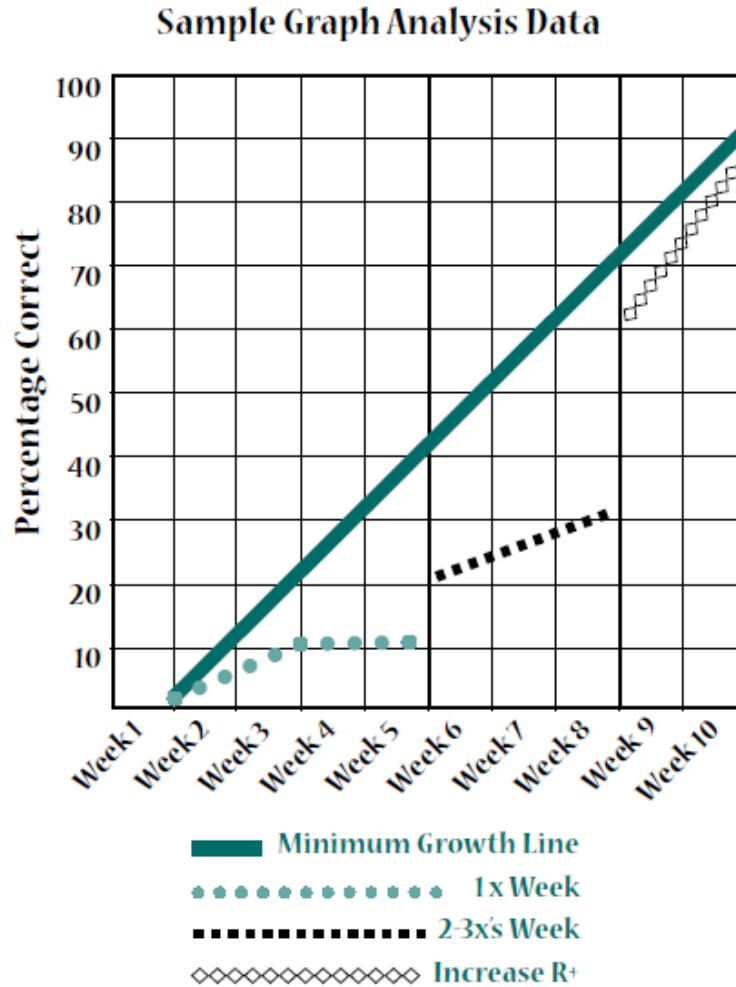
perform a review of the goals for the one or more of the clients in response to consecutive data points of the compiled data varying from the one or more thresholds to become significant for the one or more of the clients as discussed in Sections VII.A.2(h) (Limitation 1[g]), VII.A.10(i) (Limitation 11[h]), and VII.A.14(i) (Limitation 16[h]), except the alerts are automatically communicated in response to a selected number of data points, such as for blood pressure, being above or below a selected threshold in the Douglas-Khanuja System as discussed in Section VII.B.4(b). Additionally for the third mapping, although the notifications in Douglas already disclose alerts, the Douglas-Khanuja System's implementation of notifications using alerts as in Khanuja discloses the claimed alerts as well.

C. Ground 3 – Claims 1-7, 9, 11-14, and 16-19 in View of Douglas and Virginia

1. Virginia Overview

137. Virginia “describe[s] how to help persons with autism” in “acquiring skills ... that will increase their success in adulthood.” Virginia at 5, 12. Specifically, Virginia utilizes a minimum growth line (“MGL”)-based approach. Virginia at 27. In this approach, a teacher establishes a “baseline” performance of a student as well as a “goal [that] stipulates a mastery criterion ... [to be achieved] by the end of [a] teaching period.” Virginia at 27. A line is then drawn on a graph “between the baseline ... and the goal criterion,” which “is called the *minimum*

growth line.” Virginia at 27. Virginia’s FIG. 4, reproduced below, shows a sample MGL:



Virginia FIG. 4

Virginia at 27.

138. To evaluate progress, the teacher also plots the student’s performance data over time to “compare the student’s performance against [the] line.” Virginia at 27. As shown in FIG. 4, there are consecutive data points that are measured and compared. If “the student demonstrates performance that is on or above the line,

then the student is on track to master the goal.” Virginia at 27-28. But “[i]f the student demonstrates performance below that line for three data points, then the teacher should revise their teaching strategy.” Virginia at 28.

139. While Virginia applies its progress-monitoring method to an autistic student’s performance in learning skills and behavior to transition to adulthood (*see* Virginia at 5, 27-28), Virginia is in the same field of endeavor of the ’791 Patent, which is directed to tracking goal progression (*see, e.g.*, ’791 Patent at Abstract, 1:42-44, 6:4-6, 27-29), including of “individuals with ... autism” (*id.* at 1:22-29) and students generally (*id.* at 5:57-61) (“the subject may be a ... student”). It is also reasonably related to a problem faced by the inventors of the ’791 Patent: how to assess an individual’s progress toward a goal. *See, e.g.*, ’791 Patent at Abstract, 1:15-19, 30-38, 6:26-37.

2. *Modification of Douglas*

140. In my opinion, a POSITA would have found it to have been logical and advantageous to modify the Douglas system to perform the evaluation of compliance with the program in Douglas by analyzing the patient’s data using an MGL-based approach as discussed in Virginia, resulting in the Douglas-Virginia System. Virginia at 27-28. In such a modified System, data related to the patient (such as the duration, frequency, and intensity of physical activity; weight; etc.) for corresponding goals (such as related to physical activity, weight, etc.) is evaluated

“at the beginning” of the program to establish a “baseline,” a program “goal stipulates a mastery criterion” value for the data to be achieved “by the end” of the program, and an MGL is extended from the baseline data to the goal. Douglas at 7:20-29, 8:10-11, 11:3-5, 26-28, FIGS. 4, 6; Virginia at 27. As the patient progresses through the program, if the patient data “is on or above the line,” then the patient “is on track to master the goal,” and the physician is notified of such, but if the patient data is “below that line for three data points,” then the physician is again notified and the program is evaluated and may need to be “revise[d].” Virginia at 27-28.

3. *Motivation to Combine*

141. First, a POSITA would have been motivated to use a MGL-based approach like in Virginia to evaluate progress toward meeting goals in the Douglas system to provide an “evidence based” evaluation of the sufficiency of the progress to meet the goals in a specified time period, as taught by Virginia. Virginia at 27-28. That is, Douglas discusses program goals for completion in “certain period[s],” but does not specify in detail how to evaluate whether progress is sufficient to meet a goal by the specified time. Douglas at 7:5-7, 7:8-10, 8:10-11. But Virginia teaches that the MGL approach enables an evaluation of whether an individual attempting to meet a goal is “on track to master the goal” by the “end” of a corresponding “period.” Virginia at 27-28.

142. Second, a POSITA would have been motivated to use such a modified System to improve the chances of meeting goals of the program by a specified deadline, as taught by Virginia. Virginia at 27-28. That is, Douglas discusses “determin[ing] whether to modify the patient's therapeutic program” “if the patient is not progressing toward program goals,” but does not discuss in detail the timing of when to make changes. Douglas at 11:35-12:2. However, Virginia teaches iteratively evaluating whether the individual “demonstrates performance below [MGL] for three data points,” and, if so, revising the program to enable “mastering the skill at the targeted criterion,” where if an initial revision results in “performance [being] improved, but not enough to master the skill within the time left,” then further revisions are made to ensure compliance by the target date. Virginia at 28.

143. Third, a POSITA would have understood that an MGL approach like that in Virginia was known, and could be applied to evaluating the timeliness of progress in a known behavioral modification program like that of the Douglas system, and that such an approach would work in Douglas's system in essentially the same way that it works in Virginia, with the results of the combination being predictable. *KSR Int'l Co.*, 550 U.S. at 401; Douglas at 7:20-29, 8:10-11, 20:5-11, FIGS. 4, 6; Virginia at 27-28.

4. *Claims 1-7, 9, 11-14, and 16-19*

144. For claim elements or any part of claim elements not explicitly discussed below, the Douglas-Virginia system discloses or renders to a POSITA as logical and advantageous all of the limitations of claims 1-7, 9, 11-14, and 16-19 of the '791 Patent for the reasons discussed above for Ground 1 in Section VII.A.

(a) *Limitations 1[f], 11[g], and 16[g]: determining whether the customized goals are being met in response to consecutive data points of the compiled data passing one or more thresholds to become significant for one or more of the clients; and*

145. As discussed in Section VII.C.2, the Douglas-Virginia System discloses determining whether the customized goals are being met in response to consecutive data points of the compiled data passing one or more thresholds to become significant, as the combined System evaluates whether goals are being met in response to three consecutive data points passing the threshold of the minimum growth line. Douglas at 11:11-12:2; Virginia at 27-28 (“If the student demonstrates performance below that line for three data points, then the teacher should revise their teaching strategy”).

- (b) Limitations 1[g], 11[h], and 16[h]: automatically communicating alerts to at least the one or more providers to at least perform a review of the goals for the one or more of the clients in response to consecutive data points of the compiled data varying from the one or more thresholds to become significant for the one or more of the clients.**

146. The Douglas-Virginia System discloses automatically communicating alerts to at least the one or more providers to at least perform a review of the goals for the one or more of the clients in response to consecutive data points of the compiled data varying from the one or more thresholds to become significant for the one or more of the clients as discussed in Sections VII.A.2(h), VII.A.10(i) and VII.A.14(i), except the alerts are automatically communicated in response to three consecutive data points passing the threshold of the minimum growth line in the Douglas-Virginia system as discussed in Section VII.C.4(a).

D. Ground 4, 5, and 6 – Claim 8 in View of Douglas and Chitiveli (Ground 4), Douglas, Khanuja, and Chitiveli (Ground 5), and Douglas, Virginia, and Chitiveli (Ground 6)

1. Chitiveli Overview

147. Chitiveli discloses “techniques for a software as a service (SaaS) provider to host a content analytics tool to evaluate data collections for multiple customers.” Chitiveli at ¶ [0014]. Chitiveli FIG. 1 (reproduced below) “illustrates an example computing infrastructure 100” embodying those techniques:

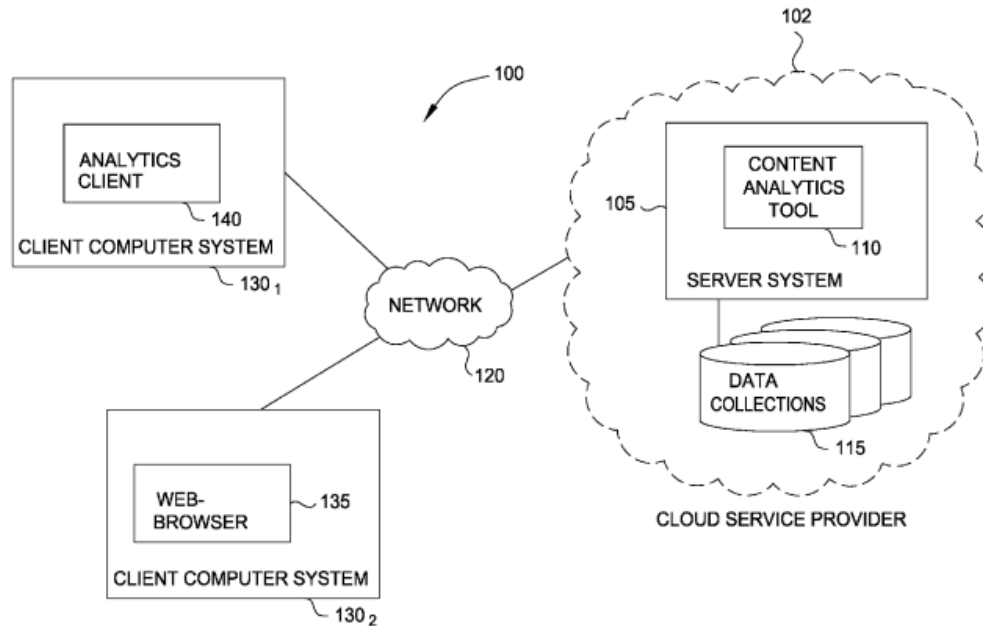


FIG. 1

Chitiveli at ¶ [0035].

148. That computing infrastructure includes “a cloud based service provider 102 hosting a server system 105 and also includes computing client systems 130₁₋₂, all of which are connected to a communications network 120.” Chitiveli at ¶ [0035]. Client computing system 130₁ “execute[s] an analytics client 140” and client computing system 130₂ “execute[s] a web browser 135” to “communicate with a content analytics tool 110 on the server system 105.” Chitiveli at ¶ [0036]. Using the analytics client or the web browser, a user can “upload enterprise data associated with a given tenant as well as access the resulting data collections 115 hosted by the service provider 102.” Chitiveli at ¶ [0036]. Content analytics tool 110 then performs “analytical processing” on the uploaded data to “generate periodic reports

... or dynamically generate insights as new data is provided to the content analytics tool 140.” Chitiveli at ¶ [0037].

149. While Chitiveli’s computing infrastructure 100 is usable in many fields, Chitiveli expressly discloses its use in the medical field to analyze patient data. Chitiveli at ¶¶ [0019], [0020], [0034], [0042], [0048], [0054], [0063], FIG. 7.

2. *Modification of Douglas*

150. Like Chitiveli’s content analytics tool 110, Douglas’s compliance monitoring and feedback system:

- resides on a server (Chitiveli at FIG. 1; *see* Section VII.A.10(b) (Limitation 11[a]));
- receives data from client devices such as a “desktop or laptop computer systems” (Chitiveli at ¶ [0036]; *see* Section VII.A.2(e) (Limitation 1[d])); and
- analyzes that data to “generate periodic reports on the analyzed data to monitor progress on identified issues” (Chitiveli at ¶ [0037]; *see* Sections VII.A.2(f) and VII.A.2(g) (Limitations 1[e] and 1[f])).

151. In my opinion, a POSITA would have found it to have been logical and advantageous to implement Douglas’s system (Ground 4), the Douglas-Khanuja System (Ground 5, all three mappings), and the Douglas-Virginia System (Ground 6) using a SaaS provider like Chitiveli discloses for his content analytics tool, with

Douglas's network server 508 implemented on a cloud network (Chitiveli at ¶ [0035], FIG. 1), and Douglas's PCs 500 executing client applications to upload patent data to that server for analysis using Douglas's system (*id.* at ¶¶ [0036]-[0037]). For Grounds 5 and 6, the modifications of Douglas by Khanuja and Virginia are not affected. The resulting systems are referred to as the Douglas-Chitiveli System (Ground 4), Douglas-Khanuja-Chitiveli System (Ground 5), and the Douglas-Virginia-Chitiveli System (Ground 6).

3. *Motivation to Combine*

152. As a POSITA would have recognized, such modification of Douglas by Chitiveli would have provided several benefits.

153. First, it would have reduced overhead by eliminating the need to procure, maintain, and find space for the network server or to maintain Douglas's system. Chitiveli at ¶ [0031] (cloud computing allows "computing resources ... [to] be rapidly provisioned and released with minimal management effort" and accessed "without regard for the underlying physical systems (or locations of those systems)"); NetSuite at 1 ("Upgrades, maintenance and system administration take place in the cloud and are managed by the vendor, so you don't have to spend nights or weekends").

154. Second, it would have provided increased availability of Douglas's system. NetSuite at 1 (“Cloud software architectures ... frequently deliver better application-level availability than conventional, on-premise solutions.”).

155. Third, using a cloud service provider would have resulted in increased security (NetSuite at 1 (“the level of security ... provided by a software-as-a-service provider far exceeds that which [a company] can provide themselves”)), which is a focus of Douglas (Douglas at 25:5-9 (discussing “three levels of security implementation”)).

156. Fourth, it would have saved costs—“eliminating the need for on-premise hardware, cloud computing reduces overall server room electric consumption as well.” NetSuite at 1.

157. Should it be argued that an independent rationale is required to use a client application like Chitiveli's analytics client 140 in the Douglas-Chitiveli System, this represents no more than the predictable use of a client application like Chitiveli's to do the same thing that it does in Chitiveli. In the combination, that client application would continue to perform its Chitiveli-disclosed functions of allowing a client to: (1) “upload enterprise data” in the form of Douglas's updated patient data; (2) “access the resulting data collections” in the form of Douglas's compiled patient data; (3) receive “periodic reports on the analyzed data from” a

“content analytics tool 110” in the form of periodic reports from Douglas’s system.

Chitiveli at ¶¶ [0036]-[0037].

4. ***Claim 8: The method of claim 1, wherein the server is accessed through a cloud network, and wherein a client management program is executed by communications devices utilized by the one or more providers to input the data.***

158. Ground 4: See Section VII.A.2 (Claim 1)

159. Ground 5: See Section VII.B.4 (Claim 1)

160. Ground 6: See Section VII.C.4 (Claim 1)

161. Grounds 4, 5, and 6: See Sections VII.D.2-VII.D.3. The Douglas-Chitiveli System (Ground 4), the Douglas-Khanuja-Chitiveli System (Ground 5), and the Douglas-Virginia-Chitiveli System (Ground 6) each discloses that the server is accessed through a cloud network, since Douglas’s network server 508 would have been implemented on, and thus accessed through, a cloud network, as in Chitiveli. The combined Systems also each discloses that a client management program is executed by the computing or communications devices and is utilized by the providers to input the data and track progress of the goals, since, in the system, PCs 500 used by physicians to transmit patient data to the network server for tracking patients’ progress toward their goals in Douglas (*see* Sections VII.A.2(e)-VII.A.2(g) (Limitations 1[d]-1[f])) would have done so using a client application like Chitiveli’s analytics client 140. Such client applications disclose the claimed client

management program, and they are utilized in the combination so that Douglas's system can input the data and track progress of the goals.

E. Grounds 7, 8, and 9 – Claims 10, 15, and 20 in View of Douglas and Koh (Ground 7), Douglas, Khanuja, and Koh (Ground 8), and Douglas, Virginia, and Koh (Ground 9)

1. Koh Overview

162. Koh “explores data mining applications in healthcare,” including “in major areas such as the evaluation of treatment effectiveness.” Koh at 64; *see also id.* at 66. Per Koh, data mining “aims to identify valid, novel, potentially useful, and understandable correlations and patterns in data by combing through copious data sets to sniff out patterns that are too subtle or complex.” Koh at 65. Such copious data sets are “generated by healthcare transactions,” and they are “too complex and voluminous to be processed and analyzed by traditional methods.” Koh at 65. For this reason, and because data mining can “identify[] effective treatments and best practices” from such a data set and thereby benefit “healthcare providers, such as hospitals, clinics and physicians, and patients,” data mining “is becoming increasingly popular if not essential” in the healthcare field. Koh at 65.

163. Data mining is performed on a data set through, e.g., “online analytical processing; traditional statistical methods, such as cluster analysis, discriminant analysis and regression analysis; and non-traditional statistical analysis, such as neural networks, decisions trees, link analysis and association analysis.” Koh at 65.

2. *Modification of Douglas*

164. Douglas's system "recommends a default set of goals based on the patient's needs and existing medical protocols that may be modified by the physician." Douglas at 7:17-20. "This is done by correlating patient information such as age, sex, [and] weight," and "the patient's medication and other health conditions" to "established medical protocols for that type of patient." Douglas at 8:1-13. Such recommendations are made by Douglas's system not just at the outset of the patient's treatment, but throughout the patient's treatment. Douglas at 21:9-12.

165. Douglas does not explicitly disclose—apart from "established medical protocols"—how those initial or subsequent recommendations are made. But Douglas's system contains a copious amount of patient health data; for instance, his FIG. 50 shows a total of 12,978 patients on Douglas's system. Douglas at FIG. 50. And Douglas's patients include "those with chronic ailments," those "who are recovering from medical procedures," and those "who simply want to maintain their health." Douglas at 6:6-14. Being on Douglas's system, each of these patients would have been associated with a therapeutic plan including goals (Douglas at 8:2-9) and compiled data (*see* Section VII.A.2(f) (Limitation 1[e])). Douglas at FIG. 50.

166. Douglas's system also tracks outcomes for these patients. For one, FIG. 50 breaks down its patients into "participating patients complying with the program

368, participating patients put on probation due to lack of compliance 372, and patients terminated 376.” Douglas at 22:21-25. Douglas’s system further includes a “review outcomes 354 option,” which Douglas broadly explains includes “information as to the various patient outcomes, based on various pre-determined categories.” Douglas at 23:16-22. Specific examples are shown in Douglas’s FIG. 55, which include “information as to the percent of compliant subscribers who had an emergency room (“ER”) visit 420” (Douglas at 23:16-22) as well as those who were re-hospitalized for angina, suffered a heart attack, underwent a coronary artery bypass graft or percutaneous transluminal coronary angioplasty, or passed away (*id.* at FIG. 55).

167. In my opinion, a POSITA would have found it to have been logical and advantageous to modify the Douglas system (Ground 7), the Douglas-Khanuja System (Ground 8), and the Douglas-Virginia System (Ground 9) with Koh (hereinafter the “Douglas-Koh System”, the “Douglas-Khanuja-Koh System,” and the “Douglas-Virginia-Koh System,” respectively) such that Douglas’s compiled data was data mined to identify best practices for patients; specifically, the “therapeutic program including goals” that Douglas’s system recommends for those patients (Douglas at 8:1-9). For Grounds 8 and 9, the modifications of Douglas by Khanuja and Virginia are not affected. In the Douglas-Koh System, Douglas-

Khanuja-Koh System, and the Douglas-Koh System, data mining would be used to identify:

- (1) a therapeutic plan for a patient based on therapeutic plans for similarly situated patients that were correlated with improvement in compiled data or other positive outcomes, such as compliance with the program or a lack of re-hospitalization, heart attack, or surgery; and/or
- (2) a trend in the patient's compiled data that, for similarly situated patients, was correlated with deterioration in compiled data or other negative outcomes, such as non-compliance with the program or re-hospitalization, heart attack, or surgery, to recommend changes to that therapeutic plan to avoid such negative outcomes.

3. Motivation to Combine

168. Modifying Douglas's system to data mine its compiled data, as taught by Koh, would have "benefitted [Douglas's] healthcare providers ... and patients, for example, by identifying effective treatments and best practices." Koh at 65. As to example (1), "[b]y comparing and contrasting ... courses of treatments" and "outcomes," like Douglas's therapeutic plans and outcomes (*see* Section VII.E.2), "which treatments work best and are most cost-effective" would have been identified. Koh at 66. And as to example (2), "data mining applications can be developed to better identify ... high-risk patients," like those whose compiled data

is trending toward a negative outcome (*see* Section VII.E.2), and “design appropriate interventions” like modifications to Douglas’s therapeutic plans to “reduce the number of hospital admissions and claims,” which is a negative outcome that Douglas seeks to avoid (*see* Douglas at FIG. 55). Koh at 66.

4. Claim 10

(a) Limitation 10a: The method according to claim 1, further comprising: data mining the compiled data to determine best practices; and

169. Ground 7: *See* my Section VII.A.2 (Claim 1).

170. Ground 8: *See* my Section VII.B.4 (Claim 1).

171. Grounds 7, 8, and 9: The Douglas-Koh System (Ground 7), the Douglas-Khanuja-Koh System (Ground 8), and the Douglas-Virginia-Koh System (Ground 9) (*see* Sections VII.E.1 - VII.E.3) would have included data mining the compiled data to determine best practices, as Douglas’s compiled data for his numerous patients would have been data mined to determine best practices for a specific patient, particularly, a therapeutic program or a modification to the therapeutic program for that specific patient.

(b) Limitation 10b: recommending the best practices in response to the best practices being associated with one of the clients.

172. Grounds 7, 8 and 9: The Douglas system, Douglas-Khanuja System, and Douglas-Virginia System each recommends the therapeutic program to the patient’s physician as well as modifications thereto. Douglas at 2:36-3-2, 7:17-20,

21:7-13. In the Douglas-Koh System, Douglas-Khanuja-Koh System and Douglas-Virginia-Koh System, that therapeutic program, and modifications to the same reflected best practices associated with one of the clients as determined through data mining. *See* Section VII.E.4(a) (Limitation 10[a]).

5. ***Claim 15: The system of claim 11, wherein the database is a relational database management system performing data mining to analyze the data to automatically associate best practices with the client.***

173. Ground 7: *See* my Section VII.A.10 (Claim 11).

174. Ground 8: *See* my Section VII.B.4 (Claim 11).

175. Ground 9: *See* my Section VII.C.4 (Claim 11).

176. Grounds 7, 8, and 9: *See* my Section VII.E.4 (Claim 10). The Douglas-Koh System, Douglas-Khanuja-Koh System, and Douglas-Virginia-Koh System each discloses that the database is a relational database management system, as Douglas's databases are "relational databases 522" (Douglas at 24:28-30 ("SQL" is a language used by a database management system), 22:6-7), and that the Systems are used to perform data mining to analyze the data to automatically associate best practices with the clients. *See* Section VII.E.2.

6. ***Claim 20: The server of claim 16, wherein the set of instructions are further executed to: recommend best practices in response to historic success with one or more of the clients.***

177. Ground 7: *See* my Section VII.A.14 (Claim 16).

178. Ground 8: *See* my Section VII.B.4 (Claim 16).

179. Ground 9: *See* my Section VII.C.4 (Claim 16).

180. Grounds 7, 8, and 9: *See* my Section VII.E.4 (Claim 16). In the Douglas-Koh System, Douglas-Khanuja-Koh System, and Douglas-Virginia-Koh System, the therapeutic program and modifications to the program reflected best practices determined to be historically successful through data mining. *See* Section VII.E.4(a) (Limitation 10[a]).

In signing this Declaration, I recognize that the Declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I also recognize that I may be subject to cross-examination in the case, and that cross-examination will take place within the United States. If cross-examination is required of me, I will appear for cross-examination within the United States during the time allotted for cross-examination.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: *June 4, 20*

Respectfully submitted,

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