

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 IPR2024-00616
Patent 11,144,554 B2

DECLARATION OF DR. BRYAN BERGERON
IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF U.S.
PATENT NO. 11,144,554 B2

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LIST OF DOCUMENTS CONSIDERED

Exhibit	Shorthand	Description
1001	'554 Patent	U.S. Patent No. 11,144,554 B2
1002	Douglas	Pub. No. WO 1999/003045 A1
1003	Wager	Pub. No. US 2006/0149589 A1
1004	Chitiveli	Pub. No. US 2013/0179450 A1
1005	Klotsche	J. Klotsche et al., <u>The DETECT adherence score—structure and psychometric exploration of a novel approach to measure adherence to drug and non-drug interventions in primary care</u> , 20 Int. J. Methods Psychiatr. Res. 82 (2011)
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)
1015	ADAA	Printout of https://web.archive.org/web/20100116093130/https://adaa.org/supportgroups
1016	MayoBP	<u>Blood pressure test</u> , Mayo Clinic, https://www.mayoclinic.org/tests-procedures/blood-pressure-test/about/pac-20393098 (last accessed Oct. 28, 2023)
1017	MayoC	<u>Cholesterol test</u> , Mayo Clinic, https://www.mayoclinic.org/tests-procedures/cholesterol-test/about/pac-20384601 (last accessed Oct. 28, 2023)
1018	NetSuite	Printout of https://web.archive.org/web/20111102042326/https://www.netsuite.co.uk/portal/uk/resource/articles/cloud-computing.shtml

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. 11,144,554 B2 (the “’554 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 ’554 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 ’554 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 these same students, 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 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 McIntosh.

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 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 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 co-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 also includes 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 e.MD (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 two dozen 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. 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.

28. For the past decade, I have 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). Most recently, 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.

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 '554 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 1233, 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, 2, 4, 5, 7, 9, 10, 13, 15, and 17 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.

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 is performed by an administrator “based on information contained in the patient prescription form” (*id.* 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” (*id.* 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. As 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." *Id.* at 8:1-13, FIG. 6. Those goals also include interim steps—"one month goals 61"—toward the "final goals 62." *Id.* at 8:10-13; FIG. 6.

42. Douglas's system then periodically receives updated patient data, including data entered by the physician (Douglas at 11:1-5, FIG. 60), to determine the "patient's progress and compliance with the program" (*id.* at 11:26-28). 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." *Id.* 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." *Id.* at 24:3-26, FIG. 59.

2. *Claim 1*

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

44. Douglas discloses a method for tracking goal progression, as Douglas's system "recommends modifications and updates to both physician and patient by correlating the patient's progress with previously established goals." Douglas at 2:36-3:2; *see also* Douglas at Abstract, 8:1-8, 11:7-10, 11:18-12:2, 20:14-19, 20:29-30, FIG. 7.

(b) *Limitation 1[a]: receiving input, by an administrator, for 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 one or more networks;*

45. Douglas discloses receiving input by an administrator. In Douglas's method, "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 is input by the administrator. 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's 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

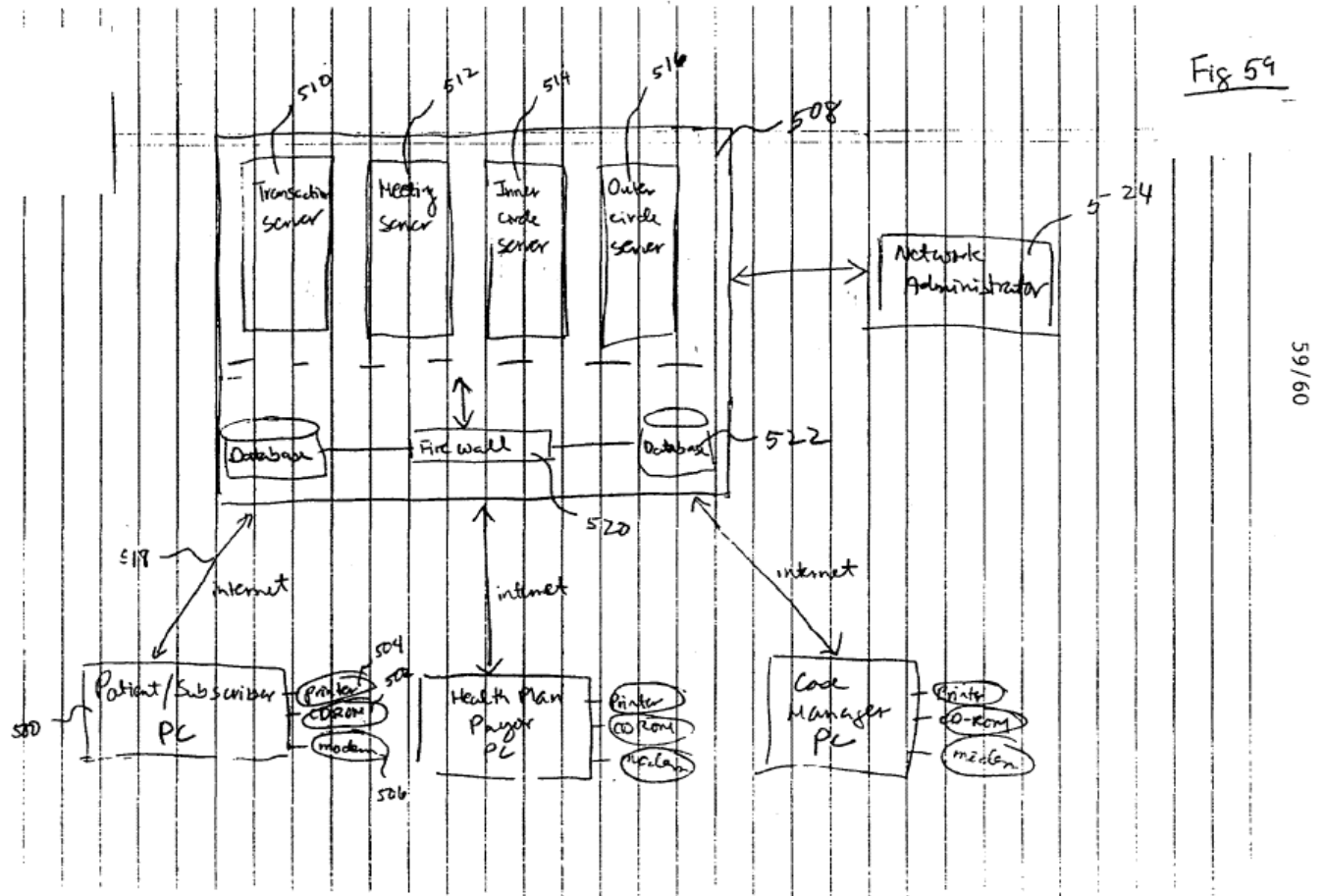
You will receive Fax confirmation within 24 Hours. For Assistance please call: (805) 969-2234

Douglas's FIG. 2

46. Douglas discloses that the administrator's input is for establishing an account for a client, as Douglas explains that "[o]nce the patient is set up on the

system” by the case administrator (as explained above), “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. ’554 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 on Douglas’s network server 508, shown in Douglas’s FIG. 59 (reproduced below).



Douglas FIG. 59

48. 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” (*id.* at 24:28-37), and those databases are also part of server 508 (*id.* at FIG. 59). Server 508 thus stores the patient’s account, as it contains “[a]ll the information needed by a user of the system,” including the patient. *Id.* at 24:28-37.

49. 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,” which is a network. Douglas at 24:12-13, FIG. 59, 8:28-31.

50. Finally, 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 the client to one or more of providers in response to selections from the administrator, wherein the one or more providers include at least individuals available to treat or assist the client;***

51. Douglas also discloses assigning the client to a provider. In Douglas’s system, the patient is assigned to their physician, who provides treatment or assistance to the patient (Limitation 1[a]). Indeed, Douglas teaches a “Responsible Physician” for a patient (Douglas at FIG. 47), Douglas explains that patients “keep in constant contact with their physician” (Douglas at 15:8-9), Douglas’s system sends alerts to a patient’s physician (*id.* at claims 11, 25), Douglas’s prescription form associates the patient, “Patient Name[/]ID,” with a physician, “Physician

Name[/]ID” (*id.* at FIG. 2), and Douglas’s system sends status reports to a patient’s physician (*id.* at FIG. 7 (“Dear Doctor **Cavello**: This is a status report on your patient”)).

52. This patient-to-physician assignment is required for Douglas’s system to “provide[] the physician with reports of patient progress,” “send an alarm to the physician,” or otherwise “notify the physician” regarding the patient’s progress. *Id.* at 11:6-12:2. Douglas’s physician is the claimed provider. ’554 Patent at 4:64-5:7 (“a provider is ... [a] caregiver” who “care[s] for ... patients.”).

53. Douglas further discloses that the 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 (explained above in Limitation 1[a]), where such information includes information associating the patient with a physician. Douglas at FIG. 2 (“Physician” name, ID, and signature). In view of the required nature of a patient-to-physician assignment, 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 the administrator’s assignment of the patient to the physician within Douglas’s system.

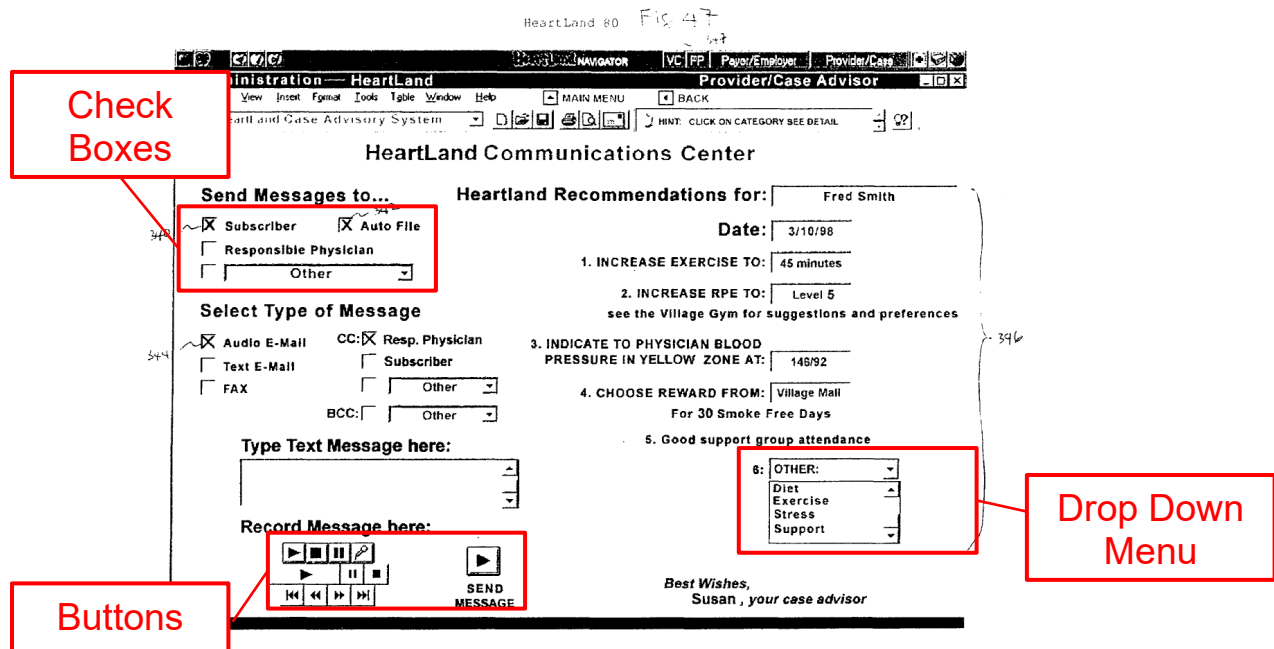
54. In my opinion, it also would have been logical and efficient for the case administrator to assign the patient to the physician. As explained above, such

assignment had to be created to achieve the functionality of Douglas's system, and the administrator was a logical and efficient option for creating it because it is the administrator who "sets up a new patient based on information contained in the prescription form" (Douglas at 6:33-7:20), and the prescription form identifies the patient's physician. In other words, it makes sense and is efficient for the one who sets up a patient on Douglas's system—the case administrator—to establish the required patient-physician link, particularly when that person has the information necessary to establish it.

55. Additionally, by entering the patient prescription form, the case administrator's assignment of the patient to the physician includes the administrator's selections of the patient and of the physician to be assigned to the patient. To be clear, to assign the patient to their physician requires the selection of that patient and the selection of that physician.

56. If it is found that something more is required to meet the claimed selections, it would have been logical and consistent with Douglas for the administrator to use graphical user interface ("GUI") components to assign the patient to the physician, which would have also been selections.

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



Annotated Version of Douglas's FIG. 47

More GUI components are shown in Douglas's FIGs. 5, 6, 38, 39, 46, 49-52, and 58.

58. It would have been logical to use Douglas's GUI components to assign the patient to the physician in each of the following ways:

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

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

60. In both options (1) and (2), the check boxes and drop-down menu 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 to create the patient-to-physician assignment. Thus, in options (1) and (2), the functions of the GUI components remain unchanged.

61. Each of the options would also lead to the predictable result of the chosen physician being assigned to the patient by the administrator.

62. Second, any of these options would have accomplished the necessary patient-to-physician assignment in Douglas's system (as explained above), and in a way that furthered Douglas's desire for that system to be GUI-based and using the GUI components it already uses. Douglas at 2:16-24 ("The present invention []

provides for [a] ... system ... through an integrated system of interactive graphical interfaces.”); *id.* at 3:24-5:20 (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 a GUI. Microsoft at 97 (a check box is “a[n] interactive control often found in graphical user interfaces”), 178, 239 (a graphical user interface is “[a] visual computer environment that represents programs, files, and options with graphical images, such as icons, menus”—such as drop-down menus—and dialog boxes on the screen”), and 79 (a button is “a graphic element in a dialog box that, when activated, performs a specified function”).

63. Although the claim states “assigning the client to one or more of providers,” should the claim be found to require multiple providers to be assigned to a patient, such would have been advantageous in Douglas’s system. Douglas’s system is used to treat patients with a variety of diagnoses, including those with multiple, or co-morbid, diagnoses. Douglas at FIGs. 2, 7. These patients would have benefited from having assigned physicians specialized in addressing those conditions, such as a cardiologist for a patient’s heart conditions (*id.* at FIG. 2 (Diagnostic Categories I-VII)), a psychiatrist for the patient’s mental conditions (*id.* at FIGs. 4 and 6, which show a baseline and goals for a patient’s “Depression”), and a general practitioner to address the patient’s general needs, such as diet and exercise

(*id.* at FIG. 6, which show baselines and goals, for example, a patient’s “Physical Activity” and “Eating Habits”).

(d) *Limitation 1[c]: determining, by the one or more providers, treatment and assistance for the client, which is used for establishing goals, a plan of action, and thresholds for the client, wherein the thresholds represent certain points of progress towards the goals;*

64. Douglas discloses determining, by the one or more providers, treatment and assistance for the client. “[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” (*id.* at 7:33-37), as shown in FIG. 5 (reproduced below).

HeartLand 69 Fig 5

SCREEN 2 OF 3

Design a new program for: **Fred Smith** Date: **3/10/98**
Heartland I.D. #: **23-642** Social Security #: **213-48-3947**

INITIAL SCALE

	LOW	INTENSITY	HIGH
DIET	☐ 1	☐ 2	☒ 3
EXERCISE	☐ 1	☐ 2	☒ 3
STRESS MANAGEMENT	☐ 1	☒ 2	☐ 3
GROUP SUPPORT	☐ 1	☐ 2	☒ 3
DRUGS	☐ 1	☐ 2	☒ 3
COMPLIANCE	☐ 1	☐ 2	☒ 3

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

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 hydrochlorothzid, Lovastatin	325 12.5 20 mg/da

Program Detail

Douglas's FIG. 5

“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” (*id.* at 8:8-11), as shown in FIG. 6 (reproduced below).

HeartLand 70 Fig 6

Administration — HeartLand

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HeartLand Health Assessment Review

HINT: CLICK ON CATEGORY SEE DETAIL

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 2/10/98	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	6'9" Male			
Weight	193	182	175	170
BMI	28.28	28.28	26.64	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	88 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	6	0
Blood Pressure	140/100 systolic/diastolic	140/100	130/90	130/90
Seatbelt Use	30 percent of time	50	75	100
Back Pain	Incidents per month	3	2	0
Pharmaceuticals				
- aspirin	325 mg	325 mg/da	325 mg/da	325 mg/da
- hydrochlorothz.d.	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

EDIT

OPTIONS...

Douglas FIG. 6

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

65. Mapping 1: Douglas’s disclosure of “[t]he physician ... confirm[ing] 63 or edit[ing] 64 the suggested program to modify the goals” is disclosure of determining, by the one or more providers, treatment and assistance for the patient, whether the provider confirms the goals as consistent with that determination or edits them to be so. Douglas at 8:12-13. Indeed, Douglas’s program provides “goals 52,” “one month goals 61,” and “final goals 62” for, e.g., weight loss, smoking cessation,

reduction of alcohol consumption, and dietary improvements. *Id.* at 8:1-13, FIGs.

5, 6. The presence of these goals in the program show they are aspects for which the provider determined the patient needs treatment and assistance.

66. Should it be found that determining by the provider of treatment and assistance for the patient requires more specific treatment or assistance, Douglas's goals for pharmaceutical use reflect specific, provider-determined treatments for addressing the patient's medical conditions. In particular, Douglas's goal for aspirin intake addresses a patient's pain, Douglas's goal for hydrochlorothiazide ("hydrochlorathzd.") intake addresses a patient's blood pressure, and Douglas's goal for Lovastatin intake addresses a patient's cholesterol. Douglas at 8:1-9, FIGs. 5, 6.

67. These treatments, by addressing these medical conditions, also assist the patient. Alternatively, to the extent assistance for the patient is required to be distinct from treatment for the patient, Douglas's "goal[] relating to ... group support" (Douglas at 8:1-9)—"1/2 hr 5 days per week" (*id.* at FIG. 5)—reflects a specific, provider-determined, and non-treatment assistance needed by the patient. Support groups were and are not considered treatment. ADAA at 5 ("ADAA does not endorse the use of a support group as a proper substitute for proper diagnosis and treatment.").

68. Mapping 2: Douglas's disclosure of the physician "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 disclosure of determining by the provider of treatment and assistance for the patient, with—if required—treatment being specifically reflected by the provider’s assigning an intensity level for the patient’s pharmaceutical requirements, and assistance being specifically reflected by provider’s assigning an intensity level for the patient’s need for group support (as explained in Mapping 1, above).

69. Mappings 1 and 2: Douglas discloses the determined treatment and assistance being used for establishing goals and thresholds for the client, wherein the thresholds represent certain points of progress towards the goals. Douglas explains that “[b]ased on the input information,” which can include the intensity levels (Mapping 2), “the system ... generates a set of goals 52 ... for the patient,” along with more-detailed “one month goals and final goals 62,” which “[t]he physician ... may confirm 64 or edit 64” (Mapping 1). Douglas at 8:1-13, FIGs. 5 and 6.

70. Douglas’s “goals 52” and “final goals 62” correspond to the claimed goals, and Douglas’s “one month goals 61” correspond to the claimed thresholds representing certain points of progress—e.g., one-month progress—toward the goals. Douglas at 8:1-13, FIGs. 5 and 6. The claimed plan of action is disclosed by

Douglas's overall "therapeutic program" that includes the above goals. *Id.* at 7:5-8:13; 6:24-27.

(e) ***Limitation 1[d]: periodically receiving updated data, from the one or more providers, about the status and/or well-being of the client;***

71. Douglas discloses receiving updated data, from the one or more providers, as "the system accepts updated patient data ... through data entered by the physician during office visits." Douglas at 11:1-5, FIG. 60; *see also* Douglas at claim 14, FIG. 41 ("Physician reported" blood pressure). This provider-entered, updated patient data is periodically received. *Id.* at FIG. 60 (blocks 1030 and 1034), claims 11 and 14.

72. Douglas also discloses that the updated data is about the status and/or well-being of the patient, given that "the system periodically correlates the updated patient health information with program goals to determine the patient's progress and compliance with the program," including its goals 52, 61, and 62, each of which are related to the status and/or well-being of the patient. Douglas at 11:6-12: 2, FIGs. 60, 5, 6. As specific examples of updated patient data, Douglas provides the patient's blood pressure and weight (*id.* at 11:11-22), and both relate to the patient's status and/or well-being.

- (f) *Limitation 1[e]: compiling data associated with the client received from the one or more providers utilizing computing or communications devices in communication with the server, wherein the computing or communications devices represent devices communicating with the server from any of one or more networks, in order to determine progress of the client towards achieving the goals; and*

73. Douglas discloses compiling data associated with the client received from the one or more providers to determine progress of the client towards achieving the goals. The updated patient data, as discussed for Limitation 1[d], is collected over time, or compiled, to determine progress of the patient toward achieving the goals. Such patient data compilation is shown by “[t]he system generating 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.”).

74. Douglas discloses that the compiled data is received from the provider utilizing computing or communications devices in communication with the server from a network, as the patient data is entered by the provider using a “PC 500 with

a Pentium microprocessor,” which is a computing and communications device, that “is electronically linked to network server 508 via the Internet 518,” which is a network, using “a high-speed modem 506,” which is a communications device, “connected to the PC 500.” Douglas at 24:3-26, FIG. 59; *see also* Douglas at 2:33-36, 11:3-5, 24:27-28, FIG. 60 (block 1034). Indeed, the physician “ENTER[S] UPDATED PAT. HEALTH INFO ONLINE” (Douglas at FIG. 60), and Douglas explains that the entry of such patient health info is achieved “via [the physician’s] personal computer.” *Id.* at 6:31-33 (“The doctor may input these vital factors into the system directly via his or her personal computer.”); *Id.* at 24:28-36, 11:3-5.

75. With the patient data that is compiled being received from the provider via Douglas’s computing or communications devices as explained above, the compilation or receiving “utilize[s]” those computing or communications devices.

(g) *Limitation 1[f]: determining whether the thresholds associated with the goals are being met based on the compiled data; and*

76. Douglas discloses determining whether the thresholds associated with the goals are being met, as Douglas’s “system compares actual data about the patient with the goals and parameters residing in the system’s database” and will “notify the physician or case advisor [if] these goals are not being met.” Douglas at 11:18-12:2. These goals include Douglas’s one-month goals 61, which are thresholds for Douglas’s final goals 62. Limitation 1[c]. Douglas further discloses that this

determination is based on the compiled data, given that “the system periodically correlates the updated patient health information [(compiled data)] with program goals to determine the patient’s progress and compliance with the program,” including its goals 52, 61, and 62. *Id.* at 11:6-12:2, FIGs. 60, 5, 6.

(h) *Limitation 1[g]: modifying the plan of action, by the one or more providers, in response to one or more of the thresholds not being met.*

77. Douglas discloses modifying the plan of action, by the one or more providers, in response to one or more of the thresholds not being met, as Douglas explains that if “these goals are not being met,” including Douglas’s one-month goals 61 or thresholds (Limitation 1[c]), “the physician or case advisor may recommend that the program”—the plan of action (Limitation 1[c])—“be modified to suit the patient’s condition.” Douglas at 11:18-25. As an example, the “physician can [] determine whether to modify the program by altering the goals or moving the patient into a different diagnostic category.” *Id.* at 11:26-34.

3. *Claim 2: The method according to claim 1, further comprising: automatically communicating alerts in response to the compiled data varying from one or more of the thresholds to become significant for the client.*

78. Douglas’s system includes an “‘alarm’ option” in which “[t]he system compares actual data about the patient with the goals and parameters residing in the system’s database and automatically notifies the physician or case advisor ... if a health risk is present.” Douglas at 11:11-15, FIG. 60. More specifically, Douglas

discloses the identification of such a health risk—“a threatening situation”—based on “the difference between current data and goals.” *Id.* at 11:18-19. Those goals include Douglas’s one-month goals, which are thresholds for Douglas’s final goals 62. Limitation 1[c]. Thus, Douglas discloses automatically communicating alerts in response to the compiled data varying from one or more of the thresholds (“difference between current data and goals,” including one month goals 61 or thresholds) to become significant for the client (“present[s] a threatening situation”).

4. Claim 4: The method according to claim 1, further comprising: establishing a baseline for the goals of the client.

79. Douglas discloses establishing a baseline for the goals of the client/patient. Such a baseline is shown in Douglas’s FIG. 4 patient record (reproduced below) that includes, in “second column 46 of the record,” “baseline values corresponding to the ... beginning of his or her participation in the program” (Douglas at 7:20-32, FIG. 1).

HeartLand 68 Fig 4

Administration — HeartLand Provider/Case Advisor

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HeartLand Health Assessment Review HINT: CLICK ON CATEGORY SEE DETAIL

SCREEN 1 OF 3

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.	23-842			
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	80		
	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 m/dl	225		
Resting Pulse Rate	88 Beats Per Minute	68		
Stress	8.5 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	325 mg/da		
- hydrochlorothz.	12.5 mg	12.6 mg/da		
- Lovastatin	20 mg	20 mg/da		

EDIT DESIGN 50

Douglas's FIG. 4

These baseline values are for the goals of the patient, as evidenced by Douglas setting "a final goal[]" 62" for each (Douglas at 8:10-13), shown in Douglas's FIG. 6 (reproduced below).

HeartLand 70 *Fig 6*

Administration — HeartLand **Provider/Case Advisor**

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

HeartLand Health Assessment Review HINT: CLICK ON CATEGORY SEE DETAIL

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 2/10/98	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	6'9" Male			
Weight	193	182	175	170
BMI	28.28	26.28	25.64	25.00
Smoke	5 Packs/Day	5	0	0
Physical Activity	0 / 0 / 0 minutes / x-week / RPE	20 / 3 / 3	25 / 6 / 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	88 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	6	0
Blood Pressure	140/100 systolic/diastolic	140/100	130/90	130/90
Seatbelt Use	30 percent of time	50	75	100
Back Pain	Incidents per month	3	2	0
Pharmaceuticals				
- aspirin	325 mg	325 mg/ds	325 mg/ds	325 mg/ds
- hydrochlorothz.	12.5 mg	12.5 mg/ds	12.5 mg/ds	0 mg/ds
- Lovastatin	20 mg	20 mg/ds	20 mg/ds	0 mg/ds

CONFIRM *63*
EDIT *64*
OPTIONS...

Douglas FIG. 6

5. **Claim 5:** The method according to claim 4, wherein the baseline is set based on tests, recorded activities, and general notes.

80. Douglas discloses that the baseline is set based on tests, as Douglas's baseline values (Claim 4) include "blood pressure readings ... and cholesterol levels." Douglas at 6:28-35, FIG. 4. As a POSITA would have understood, these were values set based on tests (since the TOI), and these tests were and are standardized across clinics/laboratories, i.e., test results for a patient's blood pressure and cholesterol would be the same, regardless of which clinic/laboratory was used. MayoBP at 1-3 (characterizing both "manual blood pressure measurement" and

“automated [blood pressure] measurement” as “blood pressure test[s]”); MayoC at 3 (“A cholesterol test is a blood test”).

81. Douglas also discloses that the baseline is set based on recorded activities, as the baseline in Douglas also includes values for the “patient’s smoking habit, physical activity, alcohol and eating habits ...[,] and seatbelt use,” which are each recorded activities. Douglas at 7:22-28. Specifically, the patient’s smoking habit baseline is set based on the number of packs of cigarettes the patient smokes per day, the patient’s physical activity baseline is set based on the duration, frequency, and intensity of the patient’s exercise, the patient’s eating habit baseline is set based on the percentages of food consumed by the patient, and the patient’s seatbelt use baseline is set based on the percentage of time the patient wears their seatbelt. *Id.* at FIG. 4.

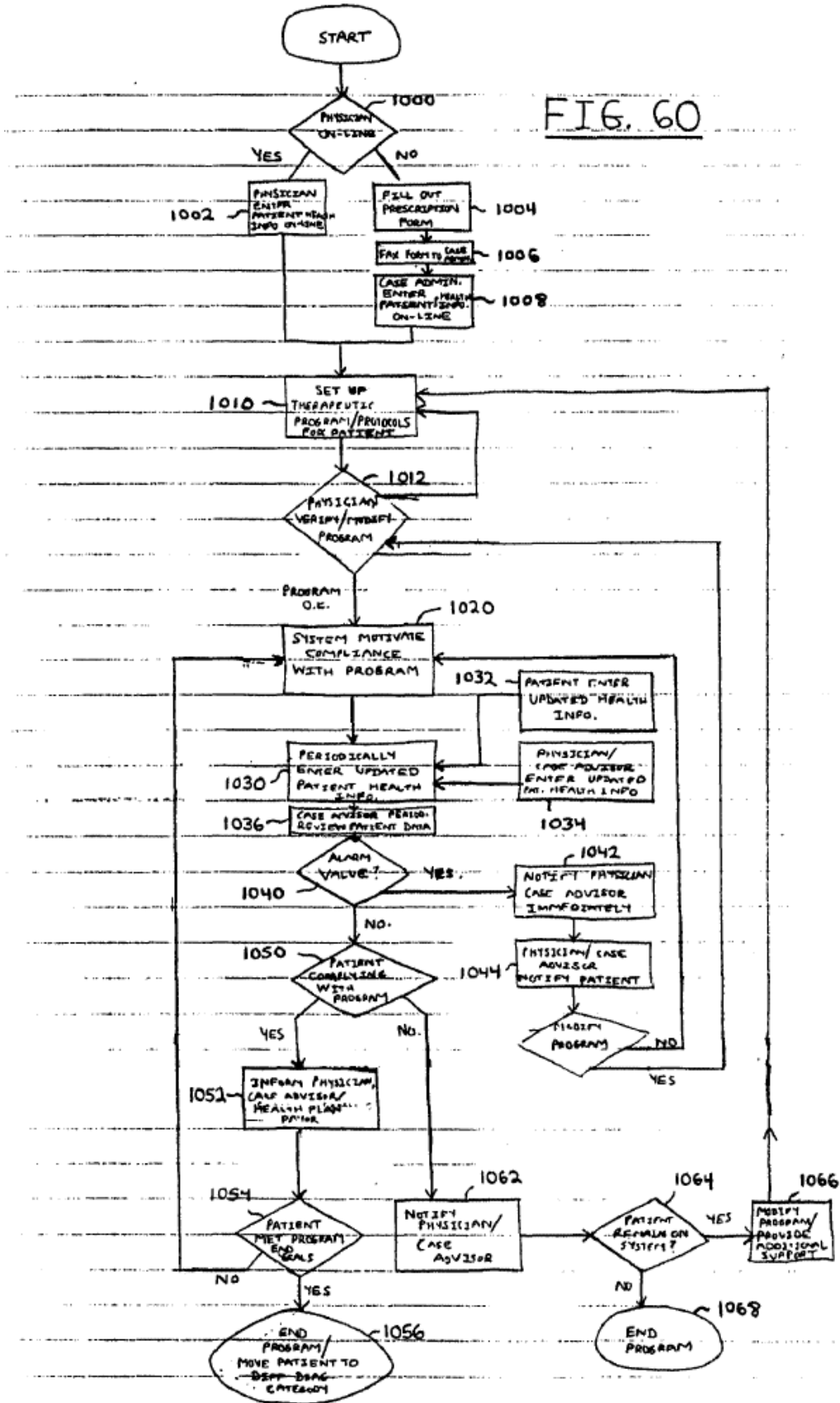
82. Finally, Douglas further discloses that the baseline is set based on general notes. Douglas’s prescription form allows the physician to note the patient’s “current and prescribed medications,” including “Comments/Changes” (Douglas at FIG. 2), which are general notes. As a POSITA would have understood, these notes would have been used to set Douglas’s baseline values for the patient’s medication intake. Douglas at FIG. 4. Indeed, Douglas’s FIG. 4 includes baseline values for aspirin, hydrochlorothiazide, and Lovastatin intake, but not other drugs such as Atenolol or Lisinopril, each of which is notable by the physician on FIG. 2’s

prescription form (Compare FIG. 4 with FIG. 2), indicating that these general notes were entered to set the patient's baseline.

6. ***Claim 7: The method according to claim 1, further comprising: establishing the goals and the plan of action for the client utilizing goal creating and tracking software, wherein the data, goals, plan of action, compiled data, and thresholds are associated with the account of the client.***

83. Douglas discloses establishing the goals and the plan of action for the client utilizing goal creating and tracking software, as Douglas's goals ("goals 52" and "final goals 62") and plan of action ("therapeutic program," including "goals 52" and "final goals 62" as well as "one month goals 62" or thresholds) (Limitation 1[c]) are created by Douglas's "compliance monitoring and feedback system." Douglas at 5:24-25. "FIG. 60 shows certain aspects of" that system, which is reproduced below:

FIG. 60



Douglas's FIG. 60

84. Douglas discloses that “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 7:17-20, FIG. 60. These goals include “goals 52,” shown in FIG. 5’s “Design” interface, and “recommended one month goals 61 and final goals 62,” shown in FIG. 6’s “Program Detail” interface. *Id.* at 7:29-8, 13, FIGs. 5, 6, 60. Douglas’s system therefore establishes Douglas’s therapeutic program, including creating its goals.

85. That system is also used to track the patient’s progress toward meeting the goals. Specifically, at block 1050, “the system periodically correlates updated patient health information with the program goals to determine the patient’s progress and compliance with the program.” Douglas at 11:26-28, FIG. 60.

86. Combined with the fact that Douglas’s compliance monitoring and feedback system is software, that system discloses the claimed goal creating and tracking software. Douglas at 1:7-10, 2:16-27, 8:28-31, 25:5-13, 25:22-26, FIGs. 5, 6, 41-44.

87. Finally, Douglas discloses that its data, goals, plan of action, compiled data, and thresholds are associated with the account of the client, as “[t]he system also enables direct feedback to the individual user,” allowing them to “view their levels of compliance and achievement of goals”—including Douglas’s disclosure of

thresholds, goals, and thus plan of action—as well as “[s]ystem generated charts and summaries” that “provide patients with an overview of how far they have come,” encompassing Douglas’s disclosure of data and compiled data. Douglas at 12:3-7.

7. *Claim 9: The method according to claim 1, further comprising: recommending a next goal in response to the client completing the goal.*

88. Douglas discloses recommending a next goal in response to the client completing the goal, as, if the “PATIENT MET PROGRAM END GOALS,” the patient can be “MOVE[D] TO DIFF. DIAG. CATEGORY.” Douglas at FIG. 60 (blocks 1054 and 1056), 12:28-34. And as Douglas explains, the “goals [of Douglas’s therapeutic program] vary depending on the patient’s diagnostic category.” *Id.* at 8:14-19. This discloses, or at a minimum renders logical and beneficial, recommending a new goal for this patient consistent with his or her new diagnostic category, particularly because this patient met his or her current goals but is continuing to use Douglas’s goal-based system as a member of that new diagnostic category, for which the “goals vary.”

8. *Claim 10: The method according to claim 1, further comprising: determining whether the data required is received from each of the one or more providers; and sending an alert to the one or more providers in response to determining there is missing data for the client associated with the one or more providers.*

89. Douglas discloses sending an “alert” to a client’s provider should the client’s data indicate a “threatening” situation. Claim 2 (discussed above). Given

that patient data may indicate a “threatening” or “potentially dangerous” situation (Douglas at 11:11-19), it would have been beneficial for Douglas’s system to determine whether patient data was missing and, if so, send an alert to the provider associated with the patient. Doing so would have encouraged the provider to enter the missing data (Limitation 1[d] (providers enter patient data)), thereby allowing Douglas’s system to identify (and potentially uncover) a threatening or potentially dangerous situation indicated by the data.

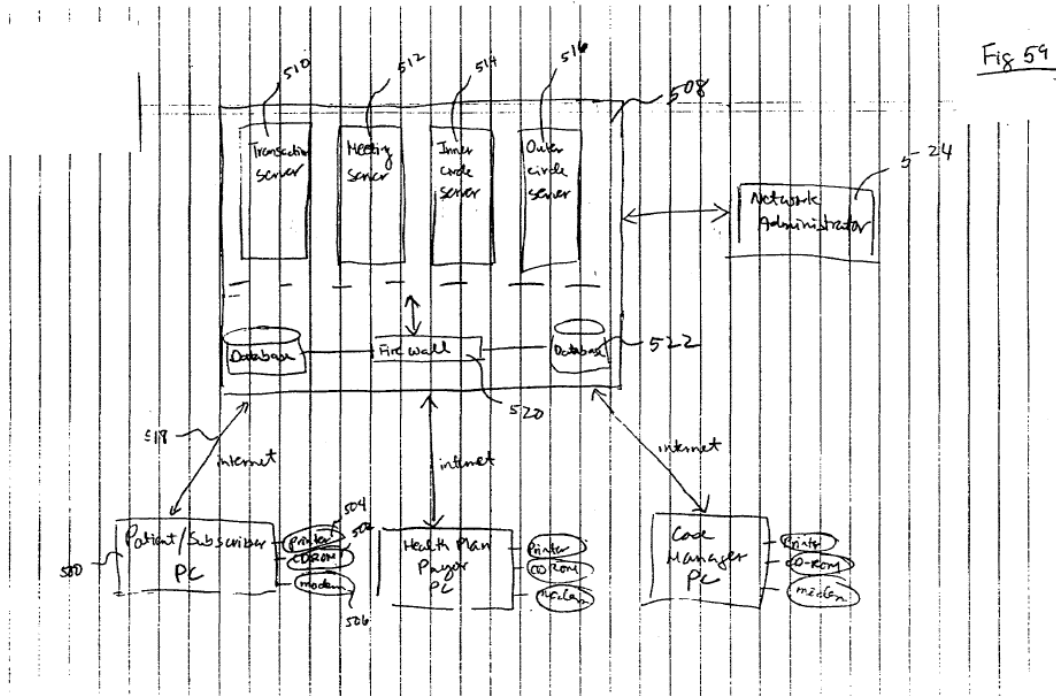
9. Claim 13

(a) Limitation 13[p]: A system for tracking goal progression, the system comprising:

90. Limitation 1[p] (above).

(b) Limitation 13[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:

91. Douglas discloses that its system includes a server that communicates with communications devices utilizing one or more networks, as Douglas describes “PC[s] 500 electronically linked to network server 508 via the Internet 518” (Douglas at 24:12-34), shown in Douglas’s FIG. 59.



Douglas's FIG. 59

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

92. 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 24:27-34. Specific transceivers that

Douglas discloses—any one or more of which disclose the claimed transceiver—include “high-speed modem 506 connected to the PC 500” (*id.* at 24:22-24) and transceivers for establishing a “cellular connection [or] satellite link ... [with the] network server” (*id.* at 8:28-31).

93. 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 (*id.* 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 (blocks 1052, 1062)).

Douglas’s system is software and therefore a processor executes the system. *Id.* at 25:22-26, 3:10-13, 2:25-27.

94. 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.

95. 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, as explained below. In particular, in my below Limitations 13[b] and 13[c], I describe how Douglas’s system sets up an account for and assigns a patient to a physician based on the patient prescription form that includes medical data of the patient, and in my below Limitations 13[d]-13[g], I explain how Douglas’s system determines the patient’s progress toward goals based on the patient’s medical data and updates to the same, and how the system responds 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.

96. 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.

97. Nevertheless, it also would have been advantageous for the processor executing 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 "all the information needed by a user of the system." Douglas at 24:28-25:4; 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 (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. *Id.* 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. *Id.* at 11:26-28, FIG. 60.

98. Therefore, a POSITA would have understood that locating the processor executing 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” (*id.* at 25:14-16, FIG. 59 (showing databases 522 behind firewall 520)), while it was “correlate[d] ... with the program goals” (*id.* at 11:26-28) as opposed to being transmitted outside of that firewall for such correlation where it would not have had the firewall's protection.

(c) ***Limitation 13[b]: receive input, by an administrator, for establishing an account for one or more providers serving a client, wherein the client is an individual receiving treatment or assistance, and wherein the accounts are stored in a server available through one or more networks***

99. Mapping 1: Douglas's disclosure of account set-up based on input from the case administrator (Limitation 1[a] (above)) also discloses setting up an account for one or more providers serving the client, in that the physician makes use of the account to treat the patient. Indeed, “[t]he system provides specific feedback to the physician so that he or she can modify or update the [patient's] program as the patient progresses” (Douglas at 3:13-14), “the patient's record may be updated on an ongoing basis by taking data from the patient ... from subsequent office visits” (*id.*

at 7:28-32), “[t]he physician ... can use the information provided in the [patient’s] journal to update the program on an on-going basis” (*id.* at 10:31-36), and “the system accepts updated patient data ... through data entered by the physician during office visits” (*id.* at 11:1-5). This understanding of an account for one or more providers [i.e., physician] serving a client [i.e., patient] is also consistent with Claim 13 itself, which in Limitation 13[h] (below) refers to that same account as being an account associated with the client and the one or more providers.

100. Mapping 2: Douglas discloses that “[a] network administrator 524, who may be the case administrator ... subscribes all users to the system except for clinical or wellness group participants.” Douglas at 25:17-19. Given that a physician is a user of Douglas’s system (*id.* at 19:27-30, 25:5-9) and is not a clinical or wellness group participant, which is instead a patient (*id.* at 6:6-14), the network administrator, per Douglas, subscribes the physician to the system. This is disclosure of receiving input by an administrator.

101. And that input is for establishing an account for one or more providers, i.e., a physician. Indeed, once so-subscribed, the physician “log[s]-on” using “their name 222 and corresponding password 224 ... to gain access to the system” (Douglas at 19:27-30, FIG. 38; *see also* Douglas at 25:5-11, FIG. 36); in other words, using their account.

102. For the same reasons described in Limitation 1[a] (above) for the patient account, the provider account is stored on Douglas's network server 508, and thus stored in a server available through one or more networks. Further, the patient is an individual receiving treatment or assistance. Limitation 1[a] (above).

(d) *Limitation 13[c]: assign the client to one or more of the providers in response to selections from the administrator, wherein the one or more providers include at least individuals available to treat or assist the client*

103. Mapping 1 from Limitation 13[b]: Limitation 1[b] (above).

104. Mapping 2 from Limitation 13[b]: The network administrator that sets up the provider account "may be the case administrator" (Douglas at 25:17-18) that therefore also "sets up a new patient based on information contained in the patient prescription form" (*id.* at 7:11-20). And as explained in Limitation 1[b] (above), Douglas discloses or renders logical the case administrator's assignment of the patient to their physician.

(e) *Limitation 13[d]: determine, by the one or more providers, treatment and assistance for the client, which is used to establish goals, a plan of action, and thresholds for the client, wherein the thresholds represent certain points of progress towards the goals*

105. Limitation 1[c] (above).

- (f) *Limitation 13[e]: compile data associated with the client received from the providers utilizing computing or communications devices in communication with the server*

106. Limitation 1[e]) (above).

- (g) *Limitation 13[f]: determine whether the thresholds associated with the goals are being met based on the compiled data*

107. Limitation 1[f] (above).

- (h) *Limitation 13[g]: modify the plan of action, by the one or more providers, in response to one or more of the thresholds not being met*

108. Limitation 1[g] (above).

- (i) *Limitation 13[h]: a database in communication with the server configured to store the data, goals, plan of action, compiled data, and thresholds with the account associated with the client and the one or more providers.*

109. 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 includes data and compiled data. Limitation 13[a] (above). It also includes Douglas’s disclosure of goals, plan of action, and thresholds, 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....”), Limitation 1[c], above (explaining mappings to goals, plan of action, and

thresholds), 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” (*id.* at 25:14-16, FIG. 59).

110. Douglas’s database(s) 522 also include an account associated with the client and the one or more providers. Limitation 13[b], including Mapping 1 or Mapping 2.

10. Claim 15: The system according to claim 13, wherein the client management program further establishes a baseline for the goals of the client, wherein the baseline is set based on tests, recorded activities, and general notes.

111. Douglas discloses establishing a baseline for the goals of the patient (Claim 4 (above)), which is performed using Douglas’s system, which discloses a client management program. Limitation 13[a] (above); Douglas at 6:28-35, 7:17-32. That baseline is set based on tests, recorded activities, and general notes. Claim 5 (above).

11. Claim 17

(a) Limitation 17[p]: A server comprising

112. Limitation 13[a], above (network server 508).

(b) Limitation 17[a]: a processor for executing a set of instructions

113. Douglas discloses or renders logical a processor within network server 508 for executing a set of instructions, specifically those for implementing Douglas’s system. Limitation 13[a], above.

(c) ***Limitation 17[b]: a memory for storing the set of instructions, wherein the set of instructions are executed by the processor to***

114. As a POSITA would have understood, 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. Limitation 13[a], above. A POSITA would have known that a processor required a memory—at a minimum, RAM—to store the instructions that the processor executed.

115. Should that well-understood proposition be disagreed with, the use of a memory to store software was within a POSITA's general knowledge. 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]). See my below Section VII.C.1. 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. Chitiveli at ¶¶ [0044]-[0046], FIG. 2.

(d) ***Limitation 17[c]: receive input, by an administrator, for establishing an account for one or more providers serving a client, wherein the client is an individual receiving treatment or assistance, and wherein the accounts are stored in a server available through one or more networks***

116. Limitations 13[b] and 13[a], above.

- (e) *Limitation 17[d]: assign the client to one or more of the providers in response to selections from the administrator, wherein the one or more providers include at least individuals available to treat or assist the client*

117. Limitations 13[c] and 13[a], above.

- (f) *Limitation 17[e]: determine, by the one or more providers, treatment and assistance for the client, which is used to establish goals, a plan of action, and thresholds for the client, wherein the thresholds represent certain points of progress towards the goals*

118. Limitations 13[d] and 13[a], above.

- (g) *Limitation 17[f]: periodically receive updated data about the status and/or well-being of the client from the providers, about the status and/or well-being of the client*

119. Limitations 1[d] and 13[a], above.

- (h) *Limitation 17[g]: compile data associated with the client received from the providers utilizing computing or communications devices in communication with the server, in order to determine progress of the client towards achieving the goals*

120. Limitations 13[e] and 13[a], above.

- (i) *Limitation 17[h]: determine whether the thresholds associated with the goals are being met based on the compiled data; and*

121. Limitations 13[f] and 13[a], above.

- (j) *Limitation 17[i]: modify the plan of action, by the provider, in response to determining whether the one or more thresholds are not being met.*

122. Limitations 13[g] and 13[a], above.

B. Ground 2 – Claims 1, 2, 4, 5, 7, 9, 10, 12, 13, 15, and 17 in View of Douglas and Wager

1. Wager Overview

123. Wager is directed to “a system and method for a management interface which presents a manager with an intuitive, visual interface for generating patient-to-care provider assignments, including capacity computation, skill set matching, [and] ratio management.” Wager at ¶ [0003], Title, and Abstract. An exemplary such “workforce management interface 106” (*id.* at ¶ [0011]) is shown in Wager’s FIG. 2, reproduced below.

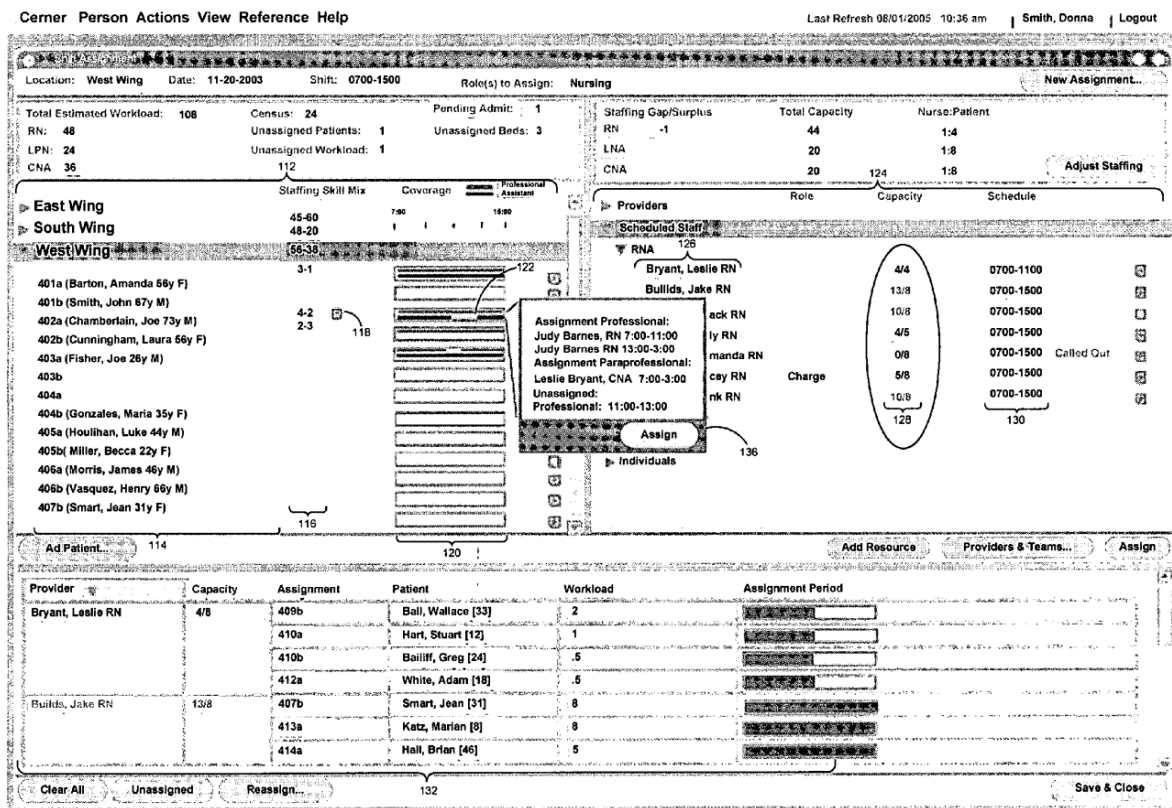


FIG. 2

124. As Wager explains, a “staff manager” associated with “a hospital or other clinical care facility” can “operate the workforce management interface 106 to ... generate care provider-to-patient assignments,” where those providers include “nurses, therapists, technicians, physicians, interns, or other clinical or other personnel whose responsibilities or activities are directed to or associated with patients.” Wager at ¶ [0011]. Specifically, workforce management interface 106 includes a “patient population profile 112,” which includes “a patient list 114” associating individual patients with “a patient needs rating 116 indicating the rated amount of workload or work effort represented by a patient’s care” and “a set of skill criteria 118 ... indicating that the care of a particular patient requires specialized training, certification or skills.” *Id.* at ¶ [0012]. “[T]he workforce management interface 106 may likewise include ... a provider population profile 124 which may contain a provider list 126” associating individual providers with “provider capacity ratings 128 which may indicate a given ... [provider’s] capacity to undertake patient care” that “may include or incorporate a scaling or adjustment factor to take a given provider’s experience level, specialized training, patient continuity and other factors into account.” *Id.* at ¶ [0014]. “Provider population profile 124 ... may further include a provider schedule” for each provider “indicating a provider’s availability ... for [certain] times or periods.” *Id.* at ¶ [0015].

125. Using Wager’s workforce management interface 106, “the ... staff manager may assess or determine the clinical care needs of patients,” including “specialized skills criteria 118,” and “assess and determine available care providers and their projected or estimated capacities, skill sets and other information or qualifications to service the patient population.” Wager at ¶¶ [0018]-[0021]. Proper assignments of the care providers to the patients are facilitated by matching the patients’ time- and skill-needs to the care providers’ capacities and skill sets. *Id.* at ¶¶ [0018]-[0022]. Per Wager, those assignments can be accomplished by “the staff manager ... selecting or highlighting a nurse, therapist, technician or other from provider list 126 and dragging that name or other object on top of a patient name in the patient list 114.” *Id.* at ¶ [0021].

2. *Modification of Douglas*

126. Douglas’s system is used to treat patients with a variety of needs, ranging from patients “who have suffered from a heart attack within the current year” to patients “who suffer from no particular ailment but are on the plan simply to promote wellness.” Douglas at 6:36-7:4, 6:6-14. Consistently, Douglas’s physicians treating those patients have varied skill sets. *Id.* at FIG. 57 (showing “Specialty[s]” of “Cardio” and “Primary”).

127. In my opinion, should it be found that Douglas does not disclose or render logical the case administrator’s assignment of the patient to a physician based

on the administrator's selections (Limitation 1[b], above), it would have been beneficial to modify Douglas's system to include an interface like Wager's that provided the administrator with "an intuitive, visual interface for generating patient-to-care provider assignments, including capacity computation, skill set matching, [and] ratio management" (Wager at ¶ [0003]) through which the administrator assigned the patient to a physician. The resulting system is referred to as the Douglas-Wager System.

3. *Motivation to Combine*

128. Doing so would have helped ensure that the assigned physician was equipped, in terms of skill set, to treat the patient, particularly in view of Douglas's patients having varied needs and Douglas's physicians having varied skill sets (see my Section VII.B.2, above). Such is explicitly taught by Wager, whose "invention overcome[s] ... problems," including "the unit or other managers ...[needs to] rely on manual notes, memory and institution to ... make appropriate provider-to-patient assignments," by the "staff manager [being] presented with a suite of provider assignment options and alternatives, to automatically organize and drive assignment ratios and other assignment parameters and options with compliance, capacity, best practice and other criteria taken into account." Wager at ¶¶ [0006]-[0007].

129. The Douglas-Wager System would have also helped ensure that the assigned physician had the capacity to effectively treat the patient. Shown by

Douglas's FIG. 51, there are many patients on Douglas's system. Douglas at FIG. 51 ("12,984" patients on the program). And those patients were not evenly distributed amongst physicians. *Id.* at FIG. 57. As a POSITA would have understood, a physician's capacity to tend to a patient decreases as the number of patients that the physician treats increases. Through use of Wager's interface, such capacity issues "may be more effectively managed against fluctuating clinical demands" (Wager at ¶¶ [0006], [0008], and [0020]), ultimately increasing quality of care for the patient.

4. *Claims 1, 2, 4, 5, 7, 9, 10, 13, 15, and 17*

130. My opinions regarding Claims 1, 2, 4, 5, 7, 9, 10, 13, 15, and 17 for Ground 2 are the same as for Ground 1 (see my Section VII.A), excepting Limitations 1[b], 13[c], 17[d], changes to which are addressed below.

(a) *Limitation 1[b]: assigning the client to one or more of providers in response to selections from the administrator, wherein the one or more providers include at least individuals available to treat or assist the client;*

131. In the Douglas-Wager System (see my Sections VII.B.2-3), the case administrator would assign to the patient a physician having a capacity and skill set that matched the patient's time- and skill-needs. Or multiple physicians, should such be required (see my Section VII.A.2(c) (Limitation 1[b])), at least to address a

patient's various needs. Wager at ¶¶ [0118], [0020] (emphasizing that providers' skill sets need to be matched to a patient's needs).

132. The Douglas-Wager System also discloses the assignments being in response to selections from the administrator—i.e., of the patient and of the physician to be assigned to the patient. These assignments would have each been performed by “selecting or highlighting a nurse, therapist, technician or other from provider list 126 and dragging that name or other object on top of a patient name in the patient list 114” (Wager at ¶ [0021]), which discloses selections from the administrator, i.e., selections to indicate the provider and the patient (*id.* (“dragging” the provider's name “on top of a patient name” constitutes “a patient [being] selected”)).

(b) ***Limitation 13[c]: assign the client to one or more of the providers in response to selections from the administrator, wherein the one or more providers include at least individuals available to treat or assist the client,***

133. See my Section VII.B.4(a) (Limitation 1[c]).

(c) ***Limitation 17[d]: assign the client to one or more of the providers in response to selections from the administrator, wherein the one or more providers include at least individuals available to treat or assist the client;***

134. See my Section VII.B.4(a) (Limitation 1[c]).

5. ***Claim 12: The method according to claim 9, further comprising: matching the client with a provider from the one or more providers for the next goal.***

135. See my Section VII.A.7 (Claim 9).

136. Further, in my opinion, it would have been advantageous to use the Douglas-Wager System interface to match the client with a provider from the one or more providers for the next goal. For example, when a patient was moved from a diagnostic category requiring a cardiologist (Douglas at FIG. 2 (diagnostic categories I-VI relate to heart ailments best addressed by a cardiologist)) to one not requiring that specialty (Douglas at FIG. 2 (diagnostic category VIII relates to “Health and Wellness,” Douglas at 6:10-23)), it would have freed up the patient’s former cardiologist to treat other patients while meeting that patient’s changed goals. Wager at ¶¶ [0118], [0020] (emphasizing that providers’ skill sets need to be matched to a patient’s needs).

C. Grounds 3 and 4 – Claim 6 in View of Douglas and Chitiveli (Ground 3), and Douglas, Wager, and Chitiveli (Ground 4)

1. Chitiveli Overview

137. 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:

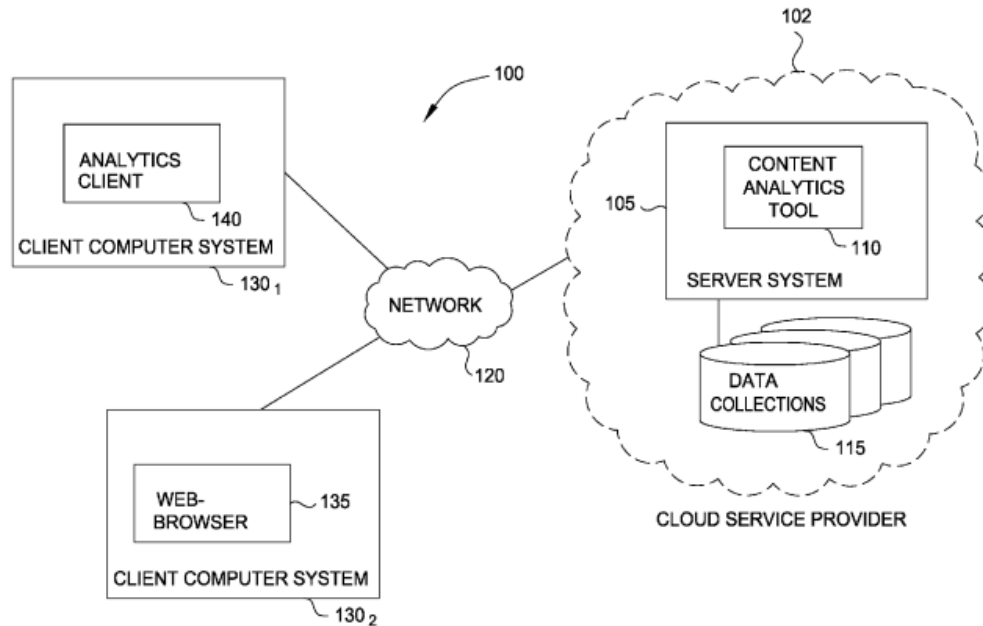


FIG. 1

Id. at ¶ [0035] and FIG. 1. 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.” *Id.* 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.” *Id.* 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.” *Id.* 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.” *Id.* at ¶ [0037].

138. 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*

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

- resides on a server (Chitiveli at FIG. 1; see my Section VII.A.9(b) (Limitation 13[a]));
- receives data from client devices such as a “desktop or laptop computer systems” (Chitiveli at ¶ [0036]; see my Section VII.A.2(f) (Limitation 1[e])); and
- analyzes that data to “generate periodic reports on the analyzed data to monitor progress on identified issues” (Chitiveli at ¶ [0037]; see my Section VII.A.2(f) (Limitation 1[e])).

140. In my opinion, it would have been beneficial to implement Douglas’s system 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 (Chitiveli at ¶¶ [0036]-[0037]). The resulting system is referred to as the Douglas-Chitiveli System.

3. *Motivation to Combine*

141. As a POSITA would have recognized, such modification would have provided several benefits. First, it would have reduced overhead by eliminating the need to procure, maintain, and find physical 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").

142. 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."). 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")). 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.

143. Should it be urged that an independent rationale is required to use a client application like Chitiveli’s analytics client 140 in the Douglas-Chitiveli System, such 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 6: The method according to claim 1, wherein the server is accessed through a cloud network, and wherein a client management program is executed by the computing or communications devices is utilized to receive the data and track progress of the goals.***

144. Ground 3: See my Section VII.A.2 (Claim 1).

145. Ground 4: See my Section VII.B.4 (Claim 1).

146. Grounds 3 and 4: See my Sections VII.C.2-VII.C.3. The Douglas-Chitiveli System 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 Douglas-Chitiveli System also

discloses that a client management program is executed by the computing or communications devices and is utilized to receive 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 my Section VII.A.2(f) (Limitation 1[e])) would have done so using a client application like Chitveli'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 receive the data and track progress of the goals.

D. Grounds 5 and 6 – Claims 11, 16, and 19 in View of Douglas and Klotsche (Ground 5), and Douglas, Wager, and Klotsche (Ground 6)

1. Klotsche Overview

147. Klotsche teaches an “approach to measure adherence to drug and non-drug interventions in primary care.” Klotsche at Title. As Klotsche explains, “patient compliance or rather adherence to medical measures and recommendations for lifestyle changes can pivotally influence the prognosis of the patients or disease progression.” Klotsche at Abstract. Indeed, “on average 26% of all patients across various disease groups experience a good outcome by adhering than by not adhering to medical recommendations.” *Id.* at 83. But measuring patient adherence to achieve these prognostic benefits was “extremely difficult to the fact that the

construct of ‘adherence’ is complex and comprised of many layers, and varies greatly in different disease groups.” *Id.* at Abstract.

148. To address these issues, Klotsche provides “a simple scoring scheme” that “cover[s] within one score both, pharmacologic and non-pharmacologic interventions in primary care,” namely, “drug adherence [and] behavioral adherence.” Klotsche at Abstract. Specifically, Klotsche’s score is based on a patient’s achievement of goals in areas targeted by the patient’s physician for improvement. *Id.* at 84-87. These target areas and associated goals are reproduced in TABLE 1, below (*id.* at 85-87).

TABLE 1: Klotsche’s Target Areas and Goals

Target Area	Goals
Increase physical activity	≥ 2 hours of physical activity per week
Reduce weight	Decrease waist circumference by 5%
Quit or reduce smoking	Cessation or reduction in daily cigarette smoking by $\geq 30\%$
Improve diabetes	Reduction of HbA1c to a specific physician target level or a level $< 7\%$ Hb
Improve cholesterol levels	Reduction of LDL/HDL-cholesterol by $\geq 10\%$, an LDL-cholesterol level ≤ 160 mg/dl, or total cholesterol level ≤ 200 mg/dl
Improve blood pressure	Reduction of mean arterial pressure (MAP) by $\geq 10\%$
Establish patient awareness	Awareness of diagnosis, including with respect to each of high blood pressure, diabetes, and high cholesterol
Increase patient motivation	Never or seldom having difficulties in following physician advice to change health behaviors with respect to each of

	physical activity, diet, waist circumference, and smoking habits
Attend counselling/classes	Patient participation in prescribed interventions and programs, including nutrition counselling, physical education classes, stress management classes, and smoking cessation programs
Improve/ensure medication adherence	Never or rarely have problems with intake of prescribed medication
Ensure drug and behavioural adherence	Physician's perception that the patient's total adherence is high

2. *Modification of Douglas*

149. Douglas, like Klotsche, is concerned with a patient's adherence to a health program's goals. Specifically, Douglas's system "generate[s] compliance data indicative of the individual's progress toward achievement of the program milestones" or goals (Douglas at Abstract, claims 4, 8, 11, and 25), which include pharmacologic goals (*id.* at FIG. 6 ("Pharmaceuticals")) as well as non-pharmacologic goals (*id.* (remainder)). Similarly, Klotsche proposes an "adherence score" to assess a patient's adherence to "both[] pharmacologic and non-pharmacologic interventions in primary care." Klotsche at 82, 88. Indeed, both Douglas and Klotsche are concerned with a patient's meeting of goals related to, e.g., increased physical activity, reduced weight, reduced smoking, reduced cholesterol levels, improved blood pressure, compliance with prescribed medications, patient attendance at counselling/classes, and patient motivation. Compare Douglas at FIGs. 5, 6, 45 with Klotsche at 85-87.

150. In my opinion, it would have been advantageous to modify Douglas's system such that that system generated a compliance score like Klotsche's. The resulting system is referred to as the Douglas-Klotsche System.

3. *Motivation to Combine*

151. First, Douglas's system generates "compliance data indicative of the individual's progress toward achievement of the program milestones." Douglas at Abstract, *see also* Douglas at 11:26-28, claims 4, 8, 11, 25. That compliance data is not black-or-white, given that Douglas discloses that there are "levels of compliance." *Id.* at 12:3-4. Douglas's system provides this compliance data so that the patient's physician, as well as the patient, can monitor the patient's compliance with Douglas's program. *Id.* at 11:26-12:7. This compliance data is also used to make decisions with respect to the patient, such as modifying a non-compliant patient's program, placing that patient on probation, or terminating the patient from the system. *Id.* at 11:35-12:2, 22:21-25, FIG. 50.

152. Douglas does not, however, disclose how his compliance data is generated or what form it takes. Douglas at 11:26-28. Klotsche would have filled that gap by providing a compliance score based on the patient's meeting (or not) of a variety of goals like Douglas's (see my Section VII.A.2(a)-(e) (Limitations 1[p]-[d]) and would have advantageously enabled Douglas's system to carry out its

compliance monitoring purpose as well as facilitated the compliance-based decisions with respect to the patient that Douglas contemplates (as explained above).

153. Second, as Klotsche shows, complete compliance is an unrealistic goal. Indeed, Klotsche's risk-corrected mean adherence score was 73.2%, with the percentages of patients reaching targeted intervention goals ranging from 5.5% (smoking cessation) to 91% (medication adherence). Klotsche at 89-90. Douglas, however, includes probation and termination (FIG. 50) as outcomes for a patient, with no explicitly disclosed way of deciding either. Implementing a score like Klotsche's would have provided a refined measure of the patient's level of compliance that facilitated those determinations and avoided placing on probation or terminating patients, who, though not in complete compliance, were still benefitting from Douglas's system.

154. Third, as a POSITA would have recognized, a compliance score like Klotsche's would have advantageously collapsed a patient's compliance with Douglas's multi-faceted goals (Douglas at FIG. 6) into "one score" (Klotsche at Abstract), allowing the patient's physician and the patient to readily ascertain (e.g., at a glance) the patient's level of compliance with the program. Douglas at 11:6-10, 12:3-7. Indeed, Douglas itself recognizes the "clear benefits" of having "information readily available to the physician regarding the patient's compliance

with the program” (*id.* at 2:1-4), which would have been furthered using a score like Klotsche’s.

4. ***Claim 11: The method according to claim 2, further comprising: generating a score based on the compiled data to determine if the compiled data varies from the thresholds to become significant for the client.***

155. Ground 5: See my Section VII.A.3 (Claim 2).

156. Ground 6: See my Section VII.B.4 (Claim 2).

157. Grounds 5 and 6: See my Sections VII.D.2-D.3. The Douglas-Klotsche system would have generated a compliance score like Klotsche’s to determine if the patient’s data falls short of the thresholds (see Section VII.A.2(d) (Limitation 1[c])) such that they should be put on probation or if already so, terminated, which are significant outcomes. Bergeron at ¶ 157.

5. ***Claim 16: The system according to claim 13, wherein the client management program further generates a score based on the compiled data to determine if the compiled data varies from the thresholds to become significant for the client.***

158. Ground 5: See my Section VII.A.9 (Claim 13).

159. Ground 6: See my Section VII.B.4 (Claim 13).

160. Grounds 5 and 6: See my Section VII.D.4 (Claim 11).

6. ***Claim 19: The server according to claim 17, wherein the set of instructions are further executed to generate a score based on the compiled data to determine if the compiled data varies from the thresholds to become significant for the client.***

161. Ground 5: See my Section VII.A.11 (Claim 17).

162. Ground 6: See my Section VII.B.4 (Claim 17).

163. Grounds 5 and 6: See my Section VII.D.4 (Claim 11).

E. Grounds 7 and 8 – Claims 8, 14, and 20 in View of Douglas and Koh (Ground 7), and Douglas, Wager, and Koh (Ground 8)

1. Koh Overview

164. Koh “explores data mining applications in healthcare,” including “in major areas such as the evaluation of treatment effectiveness.” Koh at 64, 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.” *Id.* 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.” *Id.* For this reason, and because data mining can, e.g., “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. *Id.*

165. 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*

166. 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, weight information relating to the health, life situation and diagnostic category of the patient,” and “the patient’s medication and other health conditions” to “established medical protocols for that type of patient.” *Id.* 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. *Id.* at 21:9-12.

167. Douglas does not explicitly disclose—apart from “established medial 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 across numerous diagnostic categories on Douglas’s system. Douglas at FIG. 50. Indeed, Douglas’s patients include “those with chronic ailments,” those “who are recovering from medical procedures,” and those “who simply want to maintain their health and prevent or reduce the risk of such ailments.” *Id.* at 6:6-14. And being on Douglas’s system, each of these patients would have been associated with a therapeutic plan including goals (*id.* at 8:2-9) and compiled data (see my Section VII.A.2(f) (Limitation 1[e])). Douglas at FIG. 50.

168. 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." *Id.* 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" (*id.* at 23:16-22) as well as those who were re-hospitalized for angina, suffered a heart attack (myocardial infraction ("MI")), underwent a coronary artery bypass graft ("CABG") or percutaneous transluminal coronary angioplasty ("PCTA"), or passed away (*id.* at FIG. 55).

169. In my opinion, it would have been advantageous to modify Douglas with Koh (hereinafter the "Douglas-Koh System") 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). In 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*

170. 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, "which treatments work best and are most cost-effective" would have been identified. *Id.* 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, and "design appropriate interventions" like modifications to Douglas's therapeutic plan to "reduce the number of hospital admissions and claims," which is a negative outcome that Douglas specifically seeks to avoid (Douglas at FIG. 55). *Id.*

4. **Claim 8**

- (a) ***Limitation 8a: The method according to claim 1, further comprising: data mining the compiled data to determine best practices***

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

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

173. Grounds 7 and 8: The Douglas-Koh System (see my Sections VII.E.2-3) would have included data mining the compiled data to determine best practices, as, in the system, 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 8b: recommending the best practices to the one or more providers in response to the best practices being associated with a client assigned to the one or more providers.***

174. Grounds 7 and 8: Douglas’s system recommends the therapeutic program to the patient’s physician as well as modifications thereto. Douglas at 2:36-3-2 (“the system can recommend a plan (also referred to as a therapeutic program) and goals” that “[t]he physician can modify,” and “the system recommends modifications [of the program] ... to [the] physician”), 7:17-20, 21:7-13.

175. In the Douglas-Koh System, that therapeutic program and modifications to the same reflected best practices as determined through data mining. See my Section VIII.E.4(a) (Limitation 8[a]).

5. ***Claim 14: The system according to claim 13, wherein the database is a relational database management system performing data mining to analyze the data from the providers to determine best practices, wherein the best practices are recommended for the client if relevant.***

176. Ground 7: See my Section VII.A.9 (Claim 13).

177. Ground 8: See my Section VII.B.4 (Claim 13).

178. Grounds 7 and 8: See my Section VII.E.4 (Claim 8). The Douglas-Koh System discloses that the database is a relational database management system, as Douglas's databases are "relational databases 522" (Douglas at 24:28-30, 22:6-7) being configured in the Douglas-Koh System to perform data mining to analyze the data to determine best practices, wherein the best practices are recommended for the patient if relevant. See my Section VII.E.2. Douglas's compiled data is from the providers. Section VII.A.2(f) (Limitation 1[e]).

6. ***Claim 20: The server according to claim 17, wherein the set of instructions are further executed to data mine the compiled data to determine best practices; and recommend the best practices to the providers in response to the best practices being associated with a client assigned to the providers.***

179. Ground 7: See my Section VII.A.11 (Claim 17).

180. Ground 8: See my Section VII.B.4 (Claim 17).

181. Grounds 7 and 8: See my Section VII.E.4 (Claim 8). In the Douglas-Koh System, it would have been beneficial for the processor executing Douglas's compliance monitoring and feedback system, which is in network server 508 alongside Douglas's databases 522, to also execute data mining of that compiled data to protect the confidentiality of the compiled data as described in my Section VII.A.9(b) (Limitation 13[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: *27 February, 2024*

Respectfully submitted,


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