IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the *Inter Partes* Review of:

U.S. Patent No. 6,612,985

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Inventors: Michael E. Eiffert, et al.

Assignee: University of Rochester

Title: METHOD AND SYSTEM FOR MONITORING AND TREATING A PATIENT

Trial Number: To Be Assigned

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PETITION FOR *INTER PARTES* REVIEW UNDER 37 C.F.R. § 42.100

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On behalf of Cardiocom, LLC ("Cardiocom") and in accordance with 35 U.S.C. § 311 and 37 C.F.R. § 42.100, *inter partes* review is respectfully requested for claims 1-9 of U.S. Patent No. 6,612,985 ("the '985 Patent").

I. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8(a)(1)

As set forth below and pursuant to 37 C.F.R. § 42.8(a)(1), the following mandatory notices are provided as part of this Petition.

A. Real Party-In-Interest Under 37 C.F.R. § 42.8(b)(1)

Cardiocom, LLC is the real party-in-interest for petitioner.

B. Related Matters Under 37 C.F.R. § 42.8(b)(2)

The '985 patent is presently the subject of a patent infringement lawsuit brought by the assignee University of Rochester and purported licensee My Health, Inc. against Cardiocom, LLC captioned My Health, Inc. and University of Rochester v. Cardiocom, LLC, United States District Court for the Eastern District of Texas, Case No.: 2:13-cv-136.

C. Lead and Back-Up Counsel under 37 C.F.R. § 42.8(b)(3)

Pursuant to 27 C.F.R. §§ 42.8(b)(3) and 42.10(a), Petitioner provides the following designation of counsel.

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Pursuant to 37 C.F.R. § 42.10(b), a Power of Attorney accompanies this Petition.

D. Service Information Under 37 C.F.R. § 42.8(b)(4)

Service information for lead and back-up counsel is provided in the designation of lead and back-up counsel, above.

II. PAYMENT OF FEES UNDER 37 C.F.R. § 42.103

Payment of $23,000.00 for the fees set forth in 37 C.F.R. § 42.15(a)(1-2) for this Petition for *Inter Partes* Review accompanies this request by way of credit card payment. Nine claims are challenged, so no excess claim fees are required. The undersigned further authorizes payment for any additional fees that might be due in connection with this Petition to be charged to Deposit Account No. 13-2725.

III. REQUIREMENTS FOR *INTER PARTES* REVIEW UNDER 37 C.F.R. §§ 42.104

As set forth below and pursuant to 37 C.F.R. §§ 42.104, each requirement for *inter partes* review of the '985 Patent is satisfied.

A. Grounds for Standing Under 37 C.F.R. § 42.104(a)

Petitioner hereby certifies that the '985 Patent is available for *inter partes* review and that the Petitioner is not barred or estopped from requesting *inter partes*

review challenging the claims of the '985 Patent on the ground identified herein. More particularly, Petitioner certifies that: (1) Petitioner is not the owner of the '985 patent; (2) Petitioner has not filed a civil action challenging the validity of a claim of the '985 Patent; (3) this Petition is filed less than one year after the date on which the Petitioner, the Petitioner's real party-in-interest, or a privy of the Petitioner was served with a complaint alleging infringement of the '985 Patent; (4) the estoppel provisions of 35 U.S.C. § 315(e)(1) do not prohibit this *inter partes* review; and (5) the '985 patent is a patent that is not described in section 3(n)(1) of the Leahy-Smith America Invents Act and so is available for this *inter partes* review, per 37 C.F.R. § 42.102(a)(2).

B. Identification of Challenge Under 37 C.F.R. § 42.104(b) and Relief Requested

The precise relief requested by Petitioner is that the Patent Trial and Appeal Board find claims 1-9 of the '985 Patent unpatentable.

1. Claims for Which Inter Partes review is Requested Under 37 C.F.R. § 42.104(b)(1)

Petitioner requests *inter partes* review of claims 1-9 of U.S. Patent No. 6,612,985.

2. The Specific Art and Statutory Ground(s) on Which the Challenge is Based Under 37 C.F.R. § 42.104(b)(2)

Inter partes review of the '985 Patent is requested in view of the following references: (1) U.S. Patent No. 6,126,596 to Freedman ("Freedman"); (2) PCT

Publication No. WO 99/04043 to Caple, et al. ("Caple") (3) U.S. Patent No. 6,024,699 to Surwit, et al. ("Surwit"); (4) U.S. Patent No. 5,583,758 to McIlroy, et al. ("McIlroy"); and (5) PCT Publication No. WO 98/58,338 to Graham, et al. ("Graham").

Each of the patents listed above is prior art to the '985 Patent under pre-AIA 35 U.S.C. §§ 102(a), (b), or (e), as established in Section V(A), below.

Claim Nos.	Proposed Statutory Rejections for the '985 Patent
1-9	Claims 1-9 are anticipated under § 102(a) and (e) by Freedman
1-9	Claims 1-9 are obvious under § 103(a) over Freedman in view of Caple
1-9	Claims 1-9 are obvious under § 103(a) over Freedman in view of Caple in further view of Graham
1-9	Claims 1-9 are obvious under § 103(a) over Freedman in view of Surwit
1-9	Claims 1-9 are obvious under § 103(a) over Freedman in view of Surwit in further view of Graham
1, 2, 4, 5, 7, 8	Claims 1, 2, 4, 5, 7, and 8 are obvious under § 103(a) over McIlroy in view of Caple
1, 2, 4, 5, 7, 8	Claims 1, 2, 4, 5, 7, and 8 are obvious under § 103(a) over McIlroy in view of Caple in further view of Graham
1-9	Claims 1-9 are obvious under § 103(a) over McIlroy in view of Surwit
1-9	Claims 1-9 are obvious under § 103(a) over McIlroy in view of Surwit in further view of Graham

3. How the Challenged Claims Are To Be Construed Under 37 C.F.R. § 42.104(b)(3)

A claim subject to *inter partes* review receives the "broadest reasonable construction in light of the specification of the patent in which it appears." 42 C.F.R. § 42.100(b). Petitioner submits, for the purposes of the IPR only, the constructions given in section IV, below.

4. How the Construed Claims are Unpatentable Under 37 C.F.R. § 42.104(b)(4)

An explanation of how construed claims 1-9 of the '985 Patent are unpatentable under the statutory grounds identified above, including the identification of where each element of the claim is found in the prior art patents or printed publications, is provided in Section VI, below, in the form of claim charts.

5. Supporting Evidence Under 37 C.F.R. § 42.104(b)(5)

The exhibit numbers of the supporting evidence relied upon to support the challenge and the relevance of the evidence to the challenge raised, including identification of specific portions of the evidence that support the challenge, are provided in Section VI, below, in the form of claim charts. An Appendix of Exhibits identifying the exhibits is also attached. Pursuant to 37 C.F.R. § 42.63(a), Exhibit EX1009 is a Declaration by Bryan Bergeron, M.D. Regarding U.S. Patent No. 6,612,985 Under 37 C.F.R. § 42.63(a), attesting to, among other issues, the invalidity of claims 1-9 of the '985 patent, reasons for intercombination of the references cited in this Petition, and supporting bases for the proposed grounds of unpatentability.

IV. SUMMARY OF THE '985 PATENT

A. Description of the Alleged Invention of the '985 Patent

The '985 patent generally relates to systems for the health monitoring and treatment of remote patients for a diagnosed condition. (Ex. 1001, '985 patent, Abstract.) In particular, the '985 patent includes features directed towards two relevant features: assessing and updating existing treatment plans for patients, and tracking physician compliance in creating treatment plans that meet prescribed treatment guidelines. (Ex. 1001, col. 5:47-53.)

The '985 patent generally describes a system and method that involves collecting data from a patient (FIG. 2); generating a current "clinical assessment" for each diagnosed illness from the data (FIG. 3); algorithmically updating the patient's treatment plan based on the clinical assessment (FIG. 4); reviewing the updated treatment plan and making any changes (FIG. 4); generating compliance data comparing the reviewed and updated treatment plans (FIG. 4); and generating compliance data based on the patient's adherence to the treatment plan (FIG. 4). (*See also* Ex. 1001, claims 1, 4, and 7.)

In the context of the claims of the '985 patent, the "treatment plan" provided to a patient is generally a plan or series of specific medical treatments to be performed for treating a patient's medical condition. (*See* Ex. 1001, col. 4:31-49; Ex. 1009, Decl. at ¶25.) As such, the current "clinical assessment" relates to a

determination of a patient's condition in view of a diagnosis and an existing treatment plan, allowing a provider to update that treatment plan based on interaction with the patient (e.g., based on information from the patient).

In connection with assessing a patient and updating a treatment plan, the '985 patent also employs both "assessment guidelines" and "treatment guidelines." (*See* Ex. 1001, claims 1, 4, and 7.) The "assessment guidelines" represent guidelines in determining what questions to ask or tests to be performed to diagnose a patient. (*See* Ex. 1001, col. 9:39-47; Ex. 1009, Decl. at ¶27.) By way of contrast, the "treatment guidelines" represent guidelines for treatment of a relevant (diagnosed) disease or illness once that ailment has been diagnosed. (*See* Ex. 1001, col. 12:8-12; Ex. 1009, Decl. at ¶28.)

B. Summary of the Prosecution of the '985 Patent

The patent application that issued as the '985 patent was filed on Feb. 26, 2001 as U.S. Patent Application No. 09/793,191 (the "'191 application"). The claims of the '191 application were initially rejected over art not at issue in this Petition. In response, the Applicant amended the claims in the application by adding language directed to reviewing an updated treatment plan and generating compliance data based on the updated and reviewed treatment plans. (Ex. 1007, Response dated 2/10/2003, Appendix A.)

The Applicant argued that the amendments made the claims allowable over the cited references. In particular, the Applicant argued that the cited references did not disclose generating compliance data between a recommended treatment plan based on guidelines and a reviewed and modified treatment plan. (Ex. 1007, Response dated 2/10/2003, p. 5-6.) The Applicant relied on the newly added limitation of "generating and providing compliance data based on differences between the updated treatment plan and the reviewed treatment plan for each of the diagnosed conditions" as the basis of allowance. (see, e.g., Ex. 1007, p. 5-6) ("the compliance data discussed at col. 14, lines *45-55* in Szabo refers to compliance of a person to a proposed nutritional supplementation, not compliance between an earlier proposed nutritional supplementation based on a guideline and an updated nutritional supplementation which may have been reviewed and changed."),

Ultimately, the Examiner allowed the claims based on tracking physician compliance with published treatment guidelines. Following this Amendment, all of the pending claims were allowed. The Notice of Allowance, mailed March 31, 2003, included an Examiner's Amendment that, *inter alia*, removed the phrase "differences between" from the newly added limitation in the amended claims. A Statement of Reasons for Allowance stated "the claims distinguish over the prior art in that tracking physician compliance with treatment guidelines is not taught." (Ex. 1008, Notice of Allowance dated 3/31/2003 p. 2.) Because the patent was

granted based on the applicant's argument and examiner agreement as to the lack of physician compliance data in the prior art, the broadest reasonable construction of the term "compliance data" in claims 1, 4, 7 and their dependent claims appears to require that such compliance data includes *physician* compliance data, or data related to whether a physician-prescribed treatment plan complies with treatment guidelines.

V. THERE IS A REASONABLE LIKELIHOOD THAT AT LEAST ONE CLAIM OF THE '985 PATENT IS UNPATENTABLE UNDER 37 C.F.R. § 42.104(b)(4)

A. Identification of the References as Prior Art

U.S. Patent No. 6,126,596 to Freedman (Ex. 1002) was filed on June 2, 1997. Freedman predates by over three years the earliest claimed effective filing date of February 26, 2001 for the '985 patent. Freedman therefore qualifies as prior art under pre-AIA 35 U.S.C. §§102(a) and 102(e).

PCT Publication No. WO 99/04043 to Caple, et al. (Ex. 1003) was published January 28, 1999. Caple's publication predates the earliest claimed effective filing date for the '985 patent by more than a year. Therefore, Caple is prior art to the '985 Patent under 35 U.S.C. § 102(b).

U.S. Patent No. 6,024,699 to Surwit, et al. (Ex. 1005) was filed March 13, 1998, and issued February 15, 2000. Surwit's publication predates the earliest

claimed effective filing date for the '985 patent by more than a year. Therefore, Surwit is prior art to the '985 Patent under 35 U.S.C. § 102(b).

U.S. Patent No. 5,583,758 to McIlroy, et al. (Ex. 1006) was filed June 7, 1995, and issued December 10, 1996. McIlroy's publication predates the earliest claimed effective filing date for the '985 patent by more than a year. Therefore, McIlroy is prior art to the '985 Patent under 35 U.S.C. § 102(b).

PCT Publication No. WO 98/58,338 to Graham, et al. (Ex. 1004) was published December 23, 1998. Graham's publication predates the earliest claimed effective filing date for the '985 patent by more than a year. Therefore, Graham is prior art to the '985 Patent under 35 U.S.C. § 102(b).

Freedman, Caple, McIlroy, and Graham were not of record during prosecution of the '985 Patent. Surwit was incorporated by reference into the description of the '985 patent, and discussed as background to the purported invention of the '985 patent. None of the references was relied upon in any rejection of the claims.

B. Summary of Invalidity Arguments

Doctors have been relying for decades on the recommendations of professional organizations such as the National Institutes of Health for best practices as to how to diagnose and treat patients. Hospital administrators and

insurance administrators have been tracking doctors' compliance with those recommendations for nearly as long.

Concurrently, telehealth systems were developed in the 1990's that allowed for remote patient interaction, information gathering, and treatment. The '985 patent represents one of many attempts to merge remote patient interaction and compliance tracking. It was not the first such attempt, and in fact contrary to Reasons for Allowance, it was not the first to provide physician compliance.

As outlined in the claim charts below, both Freedman and McIlroy disclose patient assessment systems that allow providers to assess previously-diagnosed patients, update treatment plans, and manage and track compliance with treatment guidelines. Freedman specifically discloses two types of compliance: (1) provider compliance with treatment guidelines, and (2) patient compliance with a treatment plan ultimately prescribed. McIlroy discusses provider compliance, and discloses details of reports relating to deviations between a provider's treatment plan and the treatment suggested under a set of treatment guidelines. Graham also tracks provider compliance with treatment guidelines, and discloses specific statistical measures for doing so relative to an individual provider.

Surwit and Caple disclose patient assessment systems as well, and are within the same field of art as Freedman, McIlroy, and Graham. Surwit and Caple include specific teachings relating to interaction with remotely-located patients, and

providing patients with their treatment plans; in fact, applicants for the '985 patent admit that Surwit teaches such features. Surwit also discloses patient compliance with a particular treatment plan (e.g., attending appointments, etc.), which is relevant to features of dependent claims.

VI. DETAILED EXPLANATION UNDER 37 C.F.R. §§ 42.104(b)

A. Ground 1 – The '985 Patent is Anticipated by Freedman

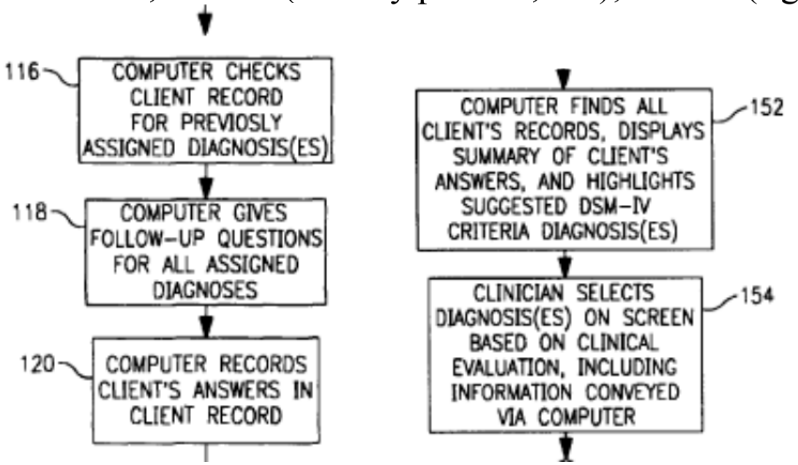
Under the broadest reasonable constructions, above, Freedman explicitly or inherently discloses all elements of the claims of the '985.

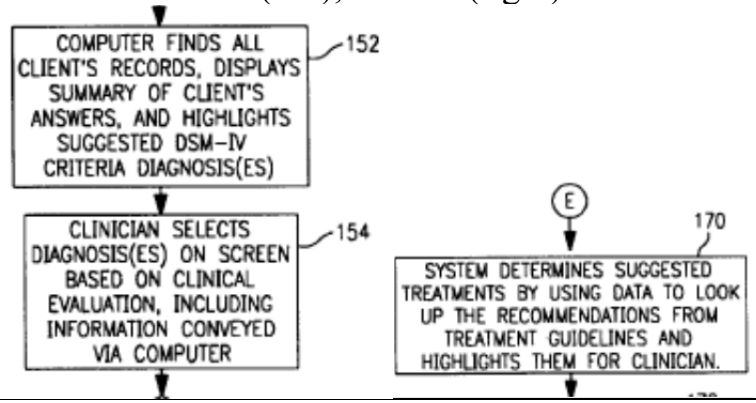
1. Independent Claims 1, 4, and 7

Independent Claims 1 and 7	**Independent Claim 4**	**U.S. Patent No. 6,126,596 ("Freedman")**
1. A method for tracking compliance with treatment guidelines, the method comprising: 7. A computer readable medium having stored thereon instructions for tracking compliance with treatment guidelines which when executed by a processor, cause the processor to perform the steps of:	4. A system for tracking compliance in treating patients, each of the patients having one or more diagnosed conditions, the system comprising:	Freedman discloses a method, system, and computer readable medium useable for tracking compliance with treatment guidelines when treating diagnosed patients. "The present invention relates to a <u>computer based system</u> that diagnoses, establishes severity, and monitors a client's condition and also monitors medical decisions made by the clinician treating the client." (Freedman, col. 1:10-13; *see also* col. 2:12-15.)[1]

[1] Emphasis added by underline throughout all claim charts.

determining a current assessment of one or more diagnosed conditions in a patient based on data about each of the diagnosed conditions from the patient who is at a remote location and on one or more assessment guidelines for each of the diagnosed conditions;	an assessment processing system that determines a current assessment of each of the diagnosed conditions based on data about each of the diagnosed conditions from the patient who is at a remote location and on one or more assessment guidelines for each of the diagnosed conditions;	Freedman discloses an assessment processing system that determines a current assessment of each of the diagnosed conditions based on data about each of the diagnosed conditions from the patient, and based on one or more assessment guidelines for each of the diagnosed conditions. In Freedman, a patient (client) provides data about his/her condition in response to questions asked by a computer. (Freedman, col. 4:5-12.) The patient receiving a current assessment may have a prior diagnosis which is the subject of that current assessment. (Freedman, col. 4:5-12.) ("If the medical staff member selects the follow-up option in block 110, the computer checks the records for a previously assigned diagnosis in block 116.") (*see also* FIG 3b, element 116.) The patient from whom data is received is located at a remote location. (Freedman, col. 3:24-35.) ("The system 20 of the present invention allows a client to enter data without having to be physically present at the facility of the clinician. By way of example, the terminals 22 and 24, and computer 26 may be linked by a LAN or WAN system.") In Freedman, the current assessment (step 152) is also based on assessment guidelines (e.g., "suggested DSM-IV criteria"). Freedman, col. 4:30-38 ("FIGS. 4a-c show a process in which the system suggests diagnostic options based on treatment guidelines retrieved from memory 20…The computer 26 then displays the client's records, including entered data and suggested treatment

		guidelines in block 152.") Freedman, FIG 3b (at entry point A, left); FIG 4a (right): 
updating an existing treatment plan for each of the diagnosed conditions based on the existing treatment plan, the current assessment, and on one or more treatment guidelines for each of the diagnosed conditions to generate an updated treatment plan for each of the diagnosed conditions;	a treatment processing system that updates an existing treatment plan for each of the diagnosed conditions based on the existing treatment plan, the current assessment, and on one or more treatment guidelines for each	Freedman discloses a treatment processing system that generates an updated treatment plan ("suggested treatments") for each diagnosed condition based on an existing treatment plan ("client's records" in FIG. 4a), a current assessment ("entered data"), and treatment guidelines for the diagnosed condition. (Freedman, col. 4:30-38.) ("FIGS. 4a-c show a process in which the system suggests diagnostic options based on treatment guidelines retrieved from memory 20…The computer 26 then displays the client's records, including entered data and suggested treatment guidelines in block 152."); (Freedman, col. 5:6-8) ("In block 170, the system highlights suggested treatments for diagnosis(es) entered in block 154 according to treatment guidelines in memory 20.")

	of the diagnosed conditions to generate an updated treatment plan for each of the diagnosed conditions;	Freedman FIG 4a (left); FIG 4c (right): 
reviewing the updated treatment plan for each of the diagnosed conditions; determining if one or more changes are needed to the reviewed treatment plan for each of the diagnosed conditions; changing the reviewed treatment plan if the one or more changes are determined to be needed;	a review system that modifies the updated treatment plan if one or more changes are determined to be needed and provides a reviewed treatment plan;	Freedman discloses a system that allows an updated treatment plan to be reviewed by a clinician to determine if one or more changes are necessary to the updated treatment plan. (Freedman, col. 4:38-40) ("The [suggested diagnostic and treatment] data can be provided to the clinician in a graphical display or other form of organized data compilation.") Changes may be made to the suggested treatment (the "reviewed treatment plan") that deviate from treatment guidelines, if such changes are determined to be necessary. (Freedman, col. 2:63-3:2) ("The clinician interface 18 may provide the following functions: …alert clinician of deviations from guidelines with explanations, allow a clinician to override treatment guidelines either with or without supervisor signoff."); (*see also* Freedman, col. 5:7-17) ("In block 172, the clinician selects a treatment plan on screen. In decision block 174, the process determines whether the clinician treatment plan is consistent with highlighted

		treatment guidelines."); (*see also* Freedman FIG 4c) (block 172).
providing the patient with the reviewed treatment plan for each of the diagnosed conditions; and	a presentation system that provides the reviewed treatment plan for each of the diagnosed conditions; and	With respect to claim 4, Freedman teaches a system that provides information associated with the reviewed treatment plan for each of the diagnosed conditions. (Freedman, col. 7:17-22) ("The system determines whether a treatment plan has been selected in decision block 244 and, if a treatment plan has been selected, the process provides educational material for the client in block 246 which can be downloaded and printed out at the printer 26.") Freedman further discloses presenting a treatment plan to a clinician for review. (Freedman, col. 5:7-17) ("In block 172, the clinician selects a treatment plan on screen. In decision block 174, the process determines whether the clinician treatment plan is consistent with highlighted treatment guidelines."); (*see also* Freedman, FIG 4c) (block 172). With respect to claims 1 and 7, it is inherent to the systems taught by Freedman to provide the reviewed treatment plan to the patient. As noted above, Freedman teaches display of a treatment plan to a clinician, as well as providing education about a treatment to the patient. Further, Freedman teaches reviewing past treatments to determine whether a patient successfully used certain medications and providing new treatments accordingly. (Freedman, col. 6:1-7:10.) Without having previously provided the reviewed treatment plan to the patient, the system would be unable, in later iterations, to review the outcome of that treatment. Additionally, Freedman, in the above-cited section, indicates that the patient or "client" is intimately involved in their treatment process, including determining whether he/she wants treatment,

		whether he/she wants to try an automated cognitive therapy module, and whether he/she wants to try anti-depressant medications. (Freedman, col. 6:1-66; FIG. 8b, blocks 196, 200, 218.) Freedman therefore teaches, inherently, that the patient is provided information about his/her treatment, in order to be an active participant in their treatment.
generating and providing compliance data based on the updated treatment plan and the reviewed treatment plan for each of the diagnosed conditions.	a compliance system that generates and provides compliance data based on the reviewed treatment plan and the updated treatment plans.	Freedman teaches a compliance system that generates and provides compliance data ("monitoring data on consistency of clinician treatment with treatment guidelines"). (Freedman, col. 2:63-3:5) ("The clinician interface 18 may provide the following functions: … alert clinician of deviations from guidelines with explanations, allow a clinician to override treatment guidelines either with or without supervisor signoff. The supervisor interface 14 displays alerts for treatment decisions that require sign-off, and provides monitoring data on consistency of clinician treatment with treatment guidelines.") Freedman discloses that the compliance data is based on the reviewed treatment plan (the "highlighted treatment guidelines") and updated treatment plan ("clinician treatment plan"). (Freedman, col. 5:9-32) ("In decision block 174, the process determines whether the clinician treatment plan is consistent with highlighted treatment guidelines.…In decision block 182, the process determines whether the discrepancy requires supervisory approval. If the process determines that supervisory approval is not required, it stores the sequence for quality review in memory 20 in block 184 and proceeds to specific diagnosis' Treatment Guidelines Module."); (*see also* Freedman, FIG. 4c.)

2. Dependent Claims 2, 5, and 8

Claims 2, 5, and 8 of '985 Patent	**U.S. Patent No. 6,126,596 ("Freedman")**
2. The method as set forth in claim 1 wherein the compliance data comprises provider information on the number of the reviewed treatment plans which are different from a corresponding one of the updated treatment plans for each provider. 5. The system as set forth in claim 4 wherein the compliance data comprises provider information on the number of the reviewed treatment plans which are different from a corresponding one of the updated treatment plans for each provider. 8. The medium as set forth in claim 7 wherein the compliance data comprises provider information on the number of the reviewed treatment plans which are different from a corresponding one of the updated treatment plans for each provider.	Freedman discloses a system wherein the compliance data comprises provider information on the number of reviewed treatment plans which are different from a corresponding one of the updated treatment plans for each provider. (Freedman, col. 2:12-24) ("The present invention is a system which can monitor how congruent a medical provider's treatment decisions are with treatment guidelines, including providing real-time alerts and mandatory review in the case of divergent decisions. The system includes a first terminal that allows a client to enter data in response to questions, and a second terminal at which a clinician can review the data, enter additional data, and enter a medical decision into the system. The system uses the data to look up recommended treatment from treatment guidelines stored in its memory, and reports those treatments that are consistent with the guidelines. The system also compares the medical decision entered by the clinician to the recommendation the system retrieved from the treatment guidelines."); (*see also* Freedman, col. 3:3-5) ("The supervisor interface 14 displays alerts for treatment decisions that require sign-off, and provides monitoring data on consistency of clinician treatment with treatment guidelines.)

	Freedman discloses that the compliance data is individual to a particular assessment and therefore by a particular provider. Individual cases of divergence from treatment guidelines are stored in memory, such that the memory stores a number of reviewed and divergent treatment plans. (Freedman, col. 5:28-34) ("In decision block 182, the process determines whether the discrepancy requires supervisory approval. If the process determines that supervisory approval is not required, it stores the sequence for quality review in memory 20 in block 184 and proceeds to specific diagnosis' Treatment Guidelines Module. If supervisory approval is required, clinician's supervisor enters a password and sequence is stored in memory 20 for quality review.")

3. Dependent Claims 3, 6, and 9

Claims 3, 6, and 9 of '985 Patent	**U.S. Patent No. 6,126,596 ("Freedman")**
3. The method as set forth in claim 1 wherein the compliance data further comprises data on patient compliance with at least one of the existing treatment plan for each diagnosed condition. 6. The system as set forth in claim 4 wherein the compliance data further comprises data on patient compliance with at least one of the existing treatment plan for each diagnosed	Freedman teaches a system that includes self-reported patient compliance information relative to a particular treatment. (Freedman, col. 2:56-63) ("The system is used to obtain non-provider information, compare the information with treatment and monitoring guidelines, guide clinician medical decisions, and require supervisor approval for decisions that deviate from standard guidelines. The non-provider information 12 may be client-entered self-report, laboratory data, or diagnostic tests and other reports. The non-provider information 12 is compared with treatment guidelines 16.") Accordingly,

condition. 9. The medium as set forth in claim 7 wherein the compliance data further comprises data on patient compliance with at least one of the existing treatment plan for each diagnosed condition.	Freedman discloses that compliance data further comprises data on patient compliance with at least one of the existing treatment plans for each diagnosed condition.

B. Grounds 2 and 3 – Each of claims 1-9 is Obvious over Freedman in Light of Caple in further light of Graham

The combination of Freedman in view of Caple teaches all elements of the claims of the '985 Patent. As shown above, Freedman teaches all elements of the claims of the '985 patent. Caple, however, provides additional explicit discussion related to providing the treatment plan to a patient, a feature that is inherent in Freedman. One of ordinary skill in the art would understand to combine Freedman and Caple because both references deal directly with remote healthcare and patient treatment. (See Freedman, col. 3:24-35; Caple, p. 5:23-28.) Additionally, Freedman teaches the desirability of integrating assessment and treatment guidelines into diagnosis of patients (col. 1:64-col. 2:7), and Caple specifically relates to accuracy and efficiency of such patient diagnoses. Furthermore, Caple provides additional explicit discussion related to a provider working with a remote patient and the system

providing the treatment plan to a patient. In particular, Caple provides for determining a current assessment of a patient's diagnosed condition (p. 13:3-7) based on a test sample sent from a patient at a remote location. (p. 8:22-30; p. 11:1-5.) In particular, Caple explicitly teaches presenting the reviewed treatment plan to the patient. Upon approving or changing the updated treatment plan, "[t]he process and system will then automatically call the patient back with the patient's result report and recommended medication or treatment regimen changes." (p. 13:30 – p. 14:2.) The CPU can also "transmit the approved or changed diagnosis and recommendation, via a carrier or transmitter 86…to the patient." (p. 12:28-29, *see also* Abstract.). Additional reasons to combine Freedman and Caple exist beyond the explicit teachings of the references. For example, it would be obvious to combine the art in order to improve patient care because the patient is more likely to abide by the desired treatment plan if the patient knows the plan. Yet additional reasons to combine the art include following healthcare guidelines and containing healthcare costs. (Ex. 1009, Decl. at ¶¶44-46.) In view of the explicit teachings of Freedman and Caple, as well as the motivations in the art generally at the time of invention of the '985 patent, it would have been obvious to modify the Freedman system to incorporate remote patient input and providing a patient with his/her treatment plan, such as in Caple.

With respect to ground 3, specifically, Graham provides additional explicit discussion related to generating and providing compliance data, and in particular compliance data with respect to the number of reviewed treatment plans that are different from the corresponding updated treatment plans. One of ordinary skill in the art would understand to combine Freedman, Caple, and Graham because each reference deals directly with remote healthcare and efficient patient treatment. (*See* Freedman, col. 3:24-35; Caple, p. 5:23-28; 35-37; Graham, p. 2:6-7.) Furthermore, Graham recognizes in the art and addresses a need to generate reports and analysis for individuals and institutions, and indicating deviations from a recommended course of treatment for a physician. (Graham, p. 3:9-26; p. 5:1-17.) Accordingly, Graham provides a teaching of the desirability of incorporating such physician compliance reporting into diagnostic and treatment systems. Accordingly, it would have been obvious to incorporate the specific reports of Graham with the teachings of Freedman and Caple, to provide additional enhancements to the physician compliance systems already present in those systems. (Ex. 1009, Decl. at ¶¶51-54.)

1. Independent Claims 1, 4, and 7

Independent Claims 1 and 7	**Independent Claim 4**	**Ground 2: U.S. Patent No. 6,126,596 ("Freedman") in view of WO 99/04043A1 ("Caple")** **Ground 3: U.S. Patent No. 6,126,596 ("Freedman") in view of**

		WO 99/04043A1 ("Caple"), in further view of PCT Pub. No. WO 98/058338 ("Graham")
1. A method for tracking compliance with treatment guidelines, the method comprising: 7. A computer readable medium having stored thereon instructions for tracking compliance with treatment guidelines which when executed by a processor, cause the processor to perform the steps of:	4. A system for tracking compliance in treating patients, each of the patients having one or more diagnosed conditions, the system comprising:	As explained in Ground 1, above, Freedman discloses a method, system, and computer readable medium useable for tracking compliance with treatment guidelines when treating diagnosed patients. (Freedman, col. 1:9-13; *see also* col. 2:12-15.) Caple relates to processes and systems for "[a]utomatic test tracking analysis and reporting…by an automated process and computer system, which can provide a global communications network, for the convenience of patients, health care providers and public health agencies to lower health care costs... The test results and patient profile medical history can be inputted into the system or network and compared with data bases of diseases, disorders, treatments, care plans, nutritional supplements, and medicine. The process and system can transmit an analysis and proposed treatment to the patient's physician or health care provider for approval or change before the test report and recommended medicine and treatment are sent to the patient. The process and system are also useful for automatic test tracking and reporting to public health organizations." (Caple, Abstract.) --- ***For Ground 3**:* Graham is "directed to a system for supporting the decision making of a physician." (Abstract.) More specifically, Graham provides that "[b]ased on input data concerning a patient and a 'best practice' knowledge base, the system provides recommendations to the physician, which the

		physician considers when deciding what action to take." (*Id.*) Graham provides that "[i]t is an object of the invention to inform a physician when the physician deviates from a recommended course of action." (*Id.* at 5:1-2.) The system is implemented in a computer network including a server and a number of remote computers. (*See id.* at 12:27-32.)
determining a current assessment of one or more diagnosed conditions in a patient based on data about each of the diagnosed conditions from the patient who is at a remote location and on one or more assessment guidelines for each of the diagnosed conditions;	an assessment processing system that determines a current assessment of each of the diagnosed conditions based on data about each of the diagnosed conditions from the patient who is at a remote location and on one or more assessment guidelines for each of the diagnosed conditions;	As explained in Ground 1, above, Freedman discloses an assessment processing system that determines a current assessment of each of the diagnosed conditions based on data about each of the diagnosed conditions from the patient, and based on one or more assessment guidelines for each of the diagnosed conditions. (Freedman, col. 4:5-12; *see also* FIG 3b, element 116; FIG. 4a, Freedman, col. 3:24-35; Freedman, col. 4:30-38.) In addition, Caple provides for determining a current assessment of a patient's diagnosed condition (p. 13:3-7) based on a test sample sent from a patient at a remote location site. (p. 8:22-30; p. 11:1-5.) For example, Caple discloses determining test results based on testing the patient sample. (Caple, p. 9:36-p. 10:3.) In this case, the test results are based on the received patient data (e.g., a patient test sample) and "appropriate professional laboratory tests" i.e., assessment guidelines. (Caple, p. 13:30-31.)
updating an existing treatment plan for each of the diagnosed conditions based on the	a treatment processing system that updates an existing treatment	As explained in Ground 1, above, Freedman discloses a treatment processing system that generates an updated treatment plan ("suggested treatments") for each diagnosed condition based on an existing treatment plan ("client's records" in FIG. 4a), a

existing treatment plan, the current assessment, and on one or more treatment guidelines for each of the diagnosed conditions to generate an updated treatment plan for each of the diagnosed conditions;	plan for each of the diagnosed conditions based on the existing treatment plan, the current assessment, and on one or more treatment guidelines for each of the diagnosed conditions to generate an updated treatment plan for each of the diagnosed conditions;	current assessment ("entered data"), and treatment guidelines for the diagnosed condition. (Freedman, col. 4:30-38; FIG. 4a, 4c; col. 5:6-8.) In addition, Caple provides for updating an existing treatment plan for a diagnosed condition (p. 13:3-7) based on a current assessment and treatment guidelines. For example, "the CPU can deliver treatment recommendations based upon a statistical analysis of the patients history and previous treatments" and "patient's medication or treatment regimen." (p. 15:22-31; p. 13:30-p. 14:2.) The updated treatment plan is based on the "test results and/or any interpretation thereof and desirably medical profile 15 (Figure 1) of the patient," which are "electronically inputted or scanned and fed into a central processing unit (CPU) with an electronic inputting device 16 (Figure 1)…The medical profile can comprise electronic patient data and files about, for example, the patient's age, sex, height, weight, current and/or past medical history…" (Caple, p. 15:22-31.) Caple utilizes a data base having treatment guidelines in order to generate the updated treatment plan, i.e., treatment recommendations. (Caple, p. 10:1-20.)
reviewing the updated treatment plan for each of the diagnosed conditions; determining if one or more changes are needed	a review system that modifies the updated treatment plan if one or more changes are determined to be needed and	As explained in Ground 1, above, Freedman discloses a system that allows an updated treatment plan to be reviewed to determine if one or more changes are necessary to the updated treatment plan. (Freedman, col. 4:38-40; col. 2:63-3:2; col. 5:7-17; FIG 4c, block 172). In addition, Caple describes changing the reviewed treatment plan

to the reviewed treatment plan for each of the diagnosed conditions; changing the reviewed treatment plan if the one or more changes are determined to be needed;	provides a reviewed treatment plan;	if the one or more changes are determined to be needed by medical personnel. For example, the "CPU's electronic diagnosis and recommendation can be transmitted by a transmitter 21 (Figure 1) to a medical personnel 22 (Figure 1), such as a physician or health care provider who can personally or through the assistance of others input their approval or changes via an electronic inputting updating device 24 (Figure 1) into the CPU at step 26 (Figure 1) to provide feedback to the patient. (p. 10:21-25.) "In cases where the CPU provides a treatment recommendation to a physician or other health care provider, the physician or health care provider may have the opportunity to access the CPU and approve or modify the CPU's recommendation." (Caple, p. 15:32-34; *see also* p. 13:30-p. 14:2.)
providing the patient with the reviewed treatment plan for each of the diagnosed conditions; and	a presentation system that provides the reviewed treatment plan for each of the diagnosed conditions; and	As explained in Ground 1, above, with respect to claim 4, Freedman teaches a system that provides information associated with the reviewed treatment plan for each of the diagnosed conditions. (Freedman col. 7:17-22; col. 5:7-17; FIG 4c, block 172.) Additionally, with respect to claims 1 and 7, it is inherent to the systems taught by Freedman to provide the reviewed treatment plan to the patient. (*see* Freedman col. 6:1-7:10.) In addition, Caple explicitly teaches presenting the reviewed treatment plan to the patient. For example, upon approving or changing the updated treatment plan, "[t]he process and system will then automatically call the patient back with the patient's result report and recommended medication or treatment regimen changes." (Caple, p. 13:30 – p. 14:2.) The CPU can also "transmit the approved or changed diagnosis and recommendation, via a

		carrier or transmitter 86…to the patient." (p. 12:28-29, *see also* Abstract.)
generating and providing compliance data based on the updated treatment plan and the reviewed treatment plan for each of the diagnosed conditions.	a compliance system that generates and provides compliance data based on the reviewed treatment plan and the updated treatment plans.	As explained in Ground 1, above, Freedman teaches a compliance system that generates and provides compliance data based on the updated and reviewed treatment plans. (Freedman, col. 2:63-3:5 col. 5:9-32; Fig. 4c.) ***For Ground 3,*** Graham provides statistics reports per physician. For example, "[t]he pretest assessments per physician report may list the actions selected by physicians following the pretest risk assessment, including any guideline deviations." (Graham, at 50:8-18.)

1. Dependent Claims 2, 5, and 8

Claims 2, 5, and 8 of '985 Patent	**Ground 2: U.S. Patent No. 6,126,596 ("Freedman") in view of WO 99/04043A1 ("Caple")** **Ground 3: U.S. Patent No. 6,126,596 ("Freedman") in view of WO 99/04043A1 ("Caple"), in further view of PCT Pub. No. WO 98/058338 ("Graham")**
2. The method as set forth in claim 1 wherein the compliance data comprises provider information on the number of the reviewed treatment plans which are different from a corresponding one of the updated treatment	As explained in Ground 1, above, Freedman discloses a system wherein the compliance data comprises provider information on the number of reviewed treatment plans which are different from a corresponding one of the updated treatment plans for each provider. (Freedman col. 2:12-24; *see also* Freedman, col. 3:3-5;

plans for each provider. 5. The system as set forth in claim 4 wherein the compliance data comprises provider information on the number of the reviewed treatment plans which are different from a corresponding one of the updated treatment plans for each provider. 8. The medium as set forth in claim 7 wherein the compliance data comprises provider information on the number of the reviewed treatment plans which are different from a corresponding one of the updated treatment plans for each provider.	col. 5:28-34.) ***For Ground 3:*** Graham provides statistics reports per physician. For example, "[t]he pretest assessments per physician report may list the *actions selected* by physicians following the pretest risk assessment, including any guideline deviations." (Graham, at 50:8-18.) Graham further provides for plotting compliance data for a physician based on the number of reviewed treatment plans (selected actions) which are different from corresponding updated treatment plans (recommendations) as follows: "As shown in Figure 19, the Statistics Routine generates statistics for the physicians, either separately or in a selected combination. The number of workups, pretest evaluations, stress tests, angiograms, pretest evaluation deviations, and stress test deviations per physician may be plotted. Additionally, the types of deviations (such as for deviations from pretest or stress test recommendations) may be plotted per physician. The graphs may be formatted for overall total numbers or broken down by physician (either by ID number or by name)." (Graham, at 52:2-10.)

2. Dependent Claims 3, 6, and 9

Claims 3, 6, and 9 of '985 Patent	**Ground 2: U.S. Patent No. 6,126,596 ("Freedman") in view of WO 99/04043A1 ("Caple")**

	Ground 3: U.S. Patent No. 6,126,596 ("Freedman") in view of WO 99/04043A1 ("Caple"), in further view of PCT Pub. No. WO 98/058338 ("Graham")
3. The method as set forth in claim 1 wherein the compliance data further comprises data on patient compliance with at least one of the existing treatment plan for each diagnosed condition. 6. The system as set forth in claim 4 wherein the compliance data further comprises data on patient compliance with at least one of the existing treatment plan for each diagnosed condition. 9. The medium as set forth in claim 7 wherein the compliance data further comprises data on patient compliance with at least one of the existing treatment plan for each diagnosed condition.	As explained in Ground 1, above, Freedman teaches a system that includes client-entered self-reporting information relative to a particular treatment. (Freedman, col. 2:56-63.) Accordingly, Freedman discloses that compliance data further comprises data on patient compliance with at least one of the existing treatment plans for each diagnosed condition.

C. Grounds 4 and 5 – Each of claims 1-9 is Obvious over Freedman in Light of Surwit in further light of Graham

Freedman, in light of Surwit teaches all elements of the claims of the '985 patent. As shown above, Freedman alone teaches all elements of the claims of the '985 patent. Surwit, however, provides additional explicit

discussion related to providing the treatment plan to a patient. One of ordinary skill in the art would understand to combine Freedman and Surwit because both references deal directly with remote healthcare and patient treatment. (*See* Freedman, col. 3:24-35; Surwit, p. 2:26-55; 3:40-55.) Additionally, Freedman teaches the desirability of integrating assessment and treatment guidelines into diagnosis of patients (col. 1:64-col. 2:7), and Surwit specifically relates to accuracy and efficiency of such patient diagnoses. Furthermore, Surwit is directed to improvements in efficiency by using at-home medical monitoring and diagnosis, and as such necessarily would teach features for providing that diagnosis to a patient. (Surwit, col. 2:26-55; col. 3:40-55.) Additional reasons exist even beyond the explicit teachings of the references. For example, it would be obvious to combine the art in order to improve patient care because the patient is more likely to abide by the desired treatment plan if the patient knows the plan. Yet additional reasons to combine the art include following healthcare guidelines and containing healthcare costs. (Ex. 1009, Decl. at ¶¶47-50.) In view of the explicit teachings of Freedman and Surwit, as well as the motivations in the art generally at the time of invention of the '985 patent, it would have been obvious to modify the Freedman system to incorporate remote patient input, and providing the patient with his/her treatment plan, such as in Surwit. (Ex. 1009, Decl. at ¶¶47-50.)

With respect to ground 5, specifically, Graham provides additional explicit discussion related to generating and providing compliance data with respect to the number of reviewed treatment plans that are different from the corresponding updated treatment plans. One of ordinary skill in the art would understand to combine Freedman, Surwit, and Graham because each reference deals directly with efficient remote healthcare and patient treatment. (*See* Freedman, col. 3:24-35; Surwit, col. 2:26-55; col. 3:40-55; Graham, p. 2:6-7.) Additionally, as noted above, Graham provides a teaching of the desirability of incorporating such physician compliance reporting into diagnostic and treatment systems, and therefore suggests to combine its teachings with those of such systems as are disclosed in Freedman and Surwit. (Ex. 1009, Decl. at ¶¶51-54.)

1. Independent Claims 1, 4, and 7

Independent Claims 1 and 7	**Independent Claim 4**	**Ground 4: U.S. Patent No. 6,126,596 ("Freedman") in view of U.S. Patent No. 6,024,699 ("Surwit")** **Ground 5: U.S. Patent No. 6,126,596 ("Freedman") in view of U.S. Patent No. 6,024,699 ("Surwit") in further view of PCT Pub. No. WO 98/058338 ("Graham")**
1. A method for tracking compliance with treatment guidelines, the	4. A system for tracking compliance in treating patients,	As explained in Ground 1, above, Freedman discloses a method, system, and computer readable medium useable for tracking compliance with treatment guidelines when treating diagnosed patients. (Freedman, col. 1:9-13; *see also* col. 2:12-15.)

method comprising: 7. A computer readable medium having stored thereon instructions for tracking compliance with treatment guidelines which when executed by a processor, cause the processor to perform the steps of:	each of the patients having one or more diagnosed conditions, the system comprising:	In addition to the disclosure in Freedman, U.S Patent No. 6,024,699 "(Surwit") relates to "methods, systems and computer program products for monitoring, diagnosing, prioritizing and treating medical conditions of a plurality of remotely located patients." (Surwit, col. 2:40-42.) Moreover, Surwit "tracks whether a patient has performed actions associated with treatment recommended by a user." (Surwit, col. 3:22-24.) ***For Ground 5**:* As outlined in Ground 3, above, Graham is directed to a method, system, and computer readable medium useable for tracking compliance with treatment guidelines when treating diagnosed patients. (Graham, Abstract; p. 5:1-2; p. 12:27-32.)
determining a current assessment of one or more diagnosed conditions in a patient based on data about each of the diagnosed conditions from the patient who is at a remote location and on one or more assessment guidelines for each of the diagnosed conditions;	an assessment processing system that determines a current assessment of each of the diagnosed conditions based on data about each of the diagnosed conditions from the patient who is at a remote location and on one or more	As explained in Ground 1, above, Freedman discloses an assessment processing system that determines a current assessment of each of the diagnosed conditions based on data about each of the diagnosed conditions from the patient, and based on one or more assessment guidelines for each of the diagnosed conditions. (Freedman, col. 4:5-12; *see also* FIG 3b, element 116; FIG. 4a, Freedman, col. 3:24-35; Freedman, col. 4:30-38.) In addition, Surwit discloses a portable patient monitor ("PPM") for collecting data from a patient diagnosed with diabetes that includes a glucose monitor and a display such that "[e]ach time the glucose meter is used to record blood glucose values, the internal software may query the patient for various information including, but not limited to, health status, diet, exercise, and insulin taken." (Surwit,

	assessment guidelines for each of the diagnosed conditions;	col. 8:18-20, 27-31.) In this case, the patient's medical condition is assessed based on the received patient data (both objective and subjective) using the PPM's "internally stored insulin monitoring software," i.e., assessment guidelines. (Surwit, col. 8:23-24.) As admitted in the '985 patent, Surwit discloses that "medical conditions of a plurality of remotely located patients are monitored, diagnosed, prioritized, and treated using a central data processing system configured to communicate with and receive data from a plurality of respective patient monitoring systems." ('985 Patent, col. 1:67-col. 2:4.)
updating an existing treatment plan for each of the diagnosed conditions based on the existing treatment plan, the current assessment, and on one or more treatment guidelines for each of the diagnosed conditions to generate an updated treatment plan for each of the diagnosed conditions;	a treatment processing system that updates an existing treatment plan for each of the diagnosed conditions based on the existing treatment plan, the current assessment, and on one or more treatment guidelines for each of the diagnosed conditions to generate an	As explained in Ground 1, above, Freedman discloses a treatment processing system that generates an updated treatment plan ("suggested treatments") for each diagnosed condition based on an existing treatment plan ("client's records" in FIG. 4a), a current assessment ("entered data"), and treatment guidelines for the diagnosed condition. (Freedman, col. 4:30-38; FIGs. 4a, 4c; col. 5:6-8.) In addition to the disclosure in Freedman, Surwit further provides for updating an existing treatment plan for a diagnosed condition based on a current assessment and treatment guidelines. For example, a "PPM may be configured to make automatic adjustments to a patient's self-monitoring and treatment regimen based on patient-entered data." (Col. 7:58-60.) Moreover, "[a] PPM, depending on the chronic illness of the patient, may contain software specifically designed for a particular patient's illness." (Surwit, col. 7:47-49.) For example, "a PPM for a diabetes patient may contain physician-prescribed insulin dosage algorithms . . .

	updated treatment plan for each of the diagnosed conditions;	[and] store blood glucose readings along with other relevant self-monitoring patient data." (Surwit, col. 7:50-53.) Specifically, the "PPM internal software calculates adjustments for a patient's insulin dosage according to a physician's prescription as applied to the data entered into the PPM by the patient." (Surwit, col. 7:55-58.) Surwit describes physician-prescribed insulin dosage algorithms, i.e., treatment guidelines, stored on the PPM as follows: "An exemplary medicine dosage algorithm for use within a PPM is the Diacare® insulin adjustment algorithm by Healthware Corporation, Chapel Hill, N.C." (Surwit, col. 8:56-58.) Other physician-prescribed medication algorithms are described by Surwit as follows: "An exemplary physician-prescribed medication algorithm is described in Guidelines for the Diagnosis and Management of Asthma; Expert Panel Report Two; National Institutes of Health; Heart and Lung Institute; Publication No.: 97-4051, April 1997 . . . [and] [a]nother exemplary physician-prescribed medication algorithm is described in Long-term Patient Self-management of Oral Anticoagulation; Jack E. Ansell et al.; Arch Intern Med. 1995; Vol. 155; pp. 2185-2189." (Surwit, col. 6:55, to col. 7:4.)
reviewing the updated treatment plan for each of the diagnosed conditions; determining if one or more changes are needed to the	a review system that modifies the updated treatment plan if one or more changes are determined to be needed and provides a	As explained in Ground 1, above, Freedman discloses a system that allows an updated treatment plan to be reviewed to determine if one or more changes are necessary to the updated treatment plan. (Freedman, col. 4:38-40; col. 2:63-3:2; col. 5:7-17; FIG 4c, block 172.) In addition to the disclosure in Freedman, Surwit also describes review of an updated treatment plan by a case worker, who may

reviewed treatment plan for each of the diagnosed conditions;	reviewed treatment plan;	change the updated treatment plan if necessary. For example, Surwit provides that "[c]ase managers preferably are able to review, via information downloaded from a PAC server 14, all patient activity and data for their assigned patients including data transmission history, prescription review, analysis and adjustment." (Surwit, col. 11:16-21.) In some cases, a "separate warehouse database may be added to a PAC server 14 to support complex analysis of patient data, and may also be used to review prescriptive changes made to a patient's medical regimens and medication dosages." (Surwit, col. 10:18-21.) For example, upon review of all patient activity and data described above, "an insulin dosage algorithm contained within the internal software of a particular patient's PPM can be modified remotely by a case manager via a CMC 16." (Surwit, col. 11:30-33.) In one example, with reference to Figure 5, Surwit provides that a "case manager may be presented with an option to adjust a medicine dosage algorithm, a patient's dosage, or a patient's fixed or contingent self-monitoring schedule, either within a patient's PPM or the PAC server (Block 264)." (Surwit, col. 13:48-52.) "If a case manager decides to adjust a medicine dosage algorithm within a patient's PPM," Surwit "facilitates this modification though a PAC server the next time communications are established between the PAC server and the patient's PPM (Block 274)." (Surwit, col. 13:48-52.)
changing the reviewed treatment plan if the one or more changes are determined to be needed;		
providing the patient with the reviewed	a presentation system that	As explained in Ground 1, above, with respect to claim 4, Freedman teaches a system that provides information associated with the

treatment plan for each of the diagnosed conditions; and	provides the reviewed treatment plan for each of the diagnosed conditions; and	reviewed treatment plan for each of the diagnosed conditions. (Freedman col. 7:17-22; col. 5:7-17; FIG 4c, block 172). Additionally, with respect to claims 1 and 7, it is inherent to the systems taught by Freedman to provide the reviewed treatment plan to the patient. (*see* Freedman col. 6:1-7:10.) In addition, Surwit provides that a "patient may be prompted to establish communications between his/her PPM and a PAC server to receive modifications made by a case manager." (Surwit, col. 13:57-59.) In other cases, "if a medicine dosage algorithm resides within a PAC server," Surwit provides that "a case manager can instruct the PAC server to adjust medicine dosage and transmit this information to the patient." (Surwit, col. 13:59-62.)
generating and providing compliance data based on the updated treatment plan and the reviewed treatment plan for each of the diagnosed conditions.	a compliance system that generates and provides compliance data based on the reviewed treatment plan and the updated treatment plans.	As explained in Ground 1, above, Freedman teaches a compliance system that generates and provides compliance data based on the updated and reviewed treatment plans. (Freedman, col. 2:63-3:5 col. 5:9-32; Fig. 4c.) In addition to the disclosure in Freedman, Surwit's PPM "[c]ollects patient supplied data on ...compliance to medical regime." (Surwit, col. 7:28-30.) More specifically, Surwit describes tracking patient compliance with reviewed and updated treatment plans as follows: "In addition to modifying dosage algorithms, a user may modify medicine doses and fixed or contingent self-monitoring schedules for a patient. . . . The present invention tracks whether a user has communicated treatment information to a patient regarding an identified medical condition. In addition, the present invention tracks

		whether a patient has performed actions associated with treatment recommended by a user." (Surwit, col. 3:14-24.) In another embodiment, Surwit describes "screening mechanisms . . . for ensuring that treatment or information provided by a case manager is medically sound for a particular patient before the treatment or information is communicated to a patient or to a patient's PPM." (Surwit, col. 19:8-12.) ***For Ground 5,*** As outlined in Ground 3, above, Graham provides statistical reports per physician regarding physician compliance. (Graham, p. 50:8-18.)

2. Dependent Claims 2, 5, and 8

Claims 2, 5, and 8 of '985 Patent	**Ground 4: U.S. Patent No. 6,126,596 ("Freedman") in view of U.S. Patent No. 6,024,699 ("Surwit")** **Ground 5: U.S. Patent No. 6,126,596 ("Freedman") in view of U.S. Patent No. 6,024,699 ("Surwit") in further view of PCT Pub. No. WO 98/058338 ("Graham")**
2. The method as set forth in claim 1 wherein the compliance data comprises provider information on the number of the reviewed treatment plans which are different from a corresponding one of the updated treatment plans for each provider. 5. The system as set forth in claim 4 wherein the	As explained in Ground 1, above, Freedman discloses a system wherein the compliance data comprises provider information on the number of reviewed treatment plans which are different from a corresponding one of the updated treatment plans for each provider. (Freedman col. 2:12-24; *see also* Freedman, col. 3:3-5; col. 5:28-34.)

compliance data comprises provider information on the number of the reviewed treatment plans which are different from a corresponding one of the updated treatment plans for each provider. 8. The medium as set forth in claim 7 wherein the compliance data comprises provider information on the number of the reviewed treatment plans which are different from a corresponding one of the updated treatment plans for each provider.	***For Ground 5:*** As outlined in Ground 3, above, Graham provides statistical reports regarding per physician compliance. Graham, p. 50:8-18; p. 52:2-10.)

3. Dependent Claims 3, 6, and 9

Claims 3, 6, and 9 of '985 Patent	**Ground 4: U.S. Patent No. 6,126,596 ("Freedman") in view of U.S. Patent No. 6,024,699 ("Surwit")** **Ground 5: U.S. Patent No. 6,126,596 ("Freedman") in view of U.S. Patent No. 6,024,699 ("Surwit") in further view of PCT Pub. No. WO 98/058338 ("Graham")**
3. The method as set forth in claim 1 wherein the compliance data further comprises data on patient compliance with at least one of the existing treatment plan for each diagnosed condition. 6. The system as set forth in claim 4 wherein the	As explained in Ground 1, above, Freedman teaches a system that includes client-entered self-reporting information relative to a particular treatment. (Freedman, col. 2:56-63.) Accordingly, Freedman discloses that compliance data further comprises data on patient compliance with at least one of the existing treatment plans for each diagnosed condition.

compliance data further comprises data on patient compliance with at least one of the existing treatment plan for each diagnosed condition. 9. The medium as set forth in claim 7 wherein the compliance data further comprises data on patient compliance with at least one of the existing treatment plan for each diagnosed condition.	In addition, Surwit provides for tracking patient compliance with an existing treatment plan. That is, a PPM "[c]ollects patient supplied data on . . . compliance to medical regime." (Surwit, col. 7:28-30.) More specifically, Surwit notes that "the present invention also tracks appointment compliance (e.g., whether a patient kept his/her appointments)." (Surwit, col. 20:64-66.)

D. Grounds 6 and 7 – Each of claims 1, 2, 4, 5, 7, and 8 is Obvious over McIlroy in Light of Caple in further light of Graham

The combination of McIlroy and Caple teaches all of the elements of claims 1, 2, 4, 5, 7, and 8 of the '985 patent. McIlroy teaches a health care management system wherein a healthcare provider may input patient information into the system, receive a recommended treatment plan from the system, review the recommended treatment plan, and make changes to said treatment plan. The system then generates comparison data regarding deviation of the final treatment plan from the recommended treatment plan. Although McIlroy does not explicitly describe receiving or reporting information about patient compliance with a treatment plan, such a modification of McIlroy would have been obvious at the time of invention of the '985 patent, in view of the closely-related diagnostic systems available at the time of invention. (Ex. 1009, Decl. at ¶¶64-65, 70.) In

particular, McIlroy describes a system in which realtime interaction with a patient record is provided, and which is directed to cost-effective health care use. (McIlroy, col. 2:32-36; Ex. 1009, Decl. at ¶69.) As explained in connection with grounds #2 and 3, Caple provides additional explicit discussion related to a provider working with a remote patient and the system providing the treatment plan to a patient. (Ex. 1009, Decl. at ¶67.) Furthermore, as also previously explained it would be obvious to combine the art in order to improve patient care, ensure that healthcare guidelines are followed, and contain healthcare costs. (Ex. 1009, Decl. at ¶68.) In view of the explicit teachings of McIlroy and Caple, as well as the motivations in the art generally at the time of invention of the '985 patent, it would have been obvious to modify the McIlroy system to incorporate remote patient input and providing a patient with his/her treatment plan, such as in Caple. (Ex. 1009, Decl. at ¶¶69-70.)

With respect to ground 7 specifically, Graham provides additional explicit discussion related to generating and providing compliance data with respect to the number of reviewed treatment plans that are different from the corresponding updated treatment plans. Graham also provides explicit teaching of capturing and providing compliance data comparing the patient's actions with a treatment plan. One of ordinary skill in the art would understand to combine McIlroy, Caple, and Graham because each reference deals directly with efficient healthcare

and patient treatment. (Ex. 1009, Decl. at ¶78; *See* McIlroy, col. 2:32-36; Caple, p. 5:23-28; 35-37; Graham, p. 2:6-7.) Additionally, as noted above, both Caple and Graham relate to issues of remote healthcare, and both McIlroy and Graham provide a teaching of the desirability of incorporating such physician compliance reporting into diagnostic and treatment systems. (Ex. 1009, Decl. at ¶¶78, 80.) The references therefore suggest intercombination of the teachings of Graham with those of such systems as are disclosed in McIlroy and Caple. (Ex. 1009, Decl. at ¶¶78, 80.)

1. Independent Claims 1, 4, and 7

Independent Claims 1 and 7	**Independent Claim 4**	**Ground 6: U.S. Patent No. 5,583,758 ("McIlroy") in view of in view of WO 99/04043A1 ("Caple")** **Ground 7: U.S. Patent No. 5,583,758 ("McIlroy") in view of WO 99/04043A1 ("Caple") in further view of PCT Pub. No. WO 98/058338 ("Graham")**
1. A method for tracking compliance with treatment guidelines, the method comprising:	4. A system for tracking compliance in treating patients, each of the patients having one or more	U.S. Patent No. 5,583,758 ("McIlroy") discloses a system, method, and computer-readable medium for tracking compliance with treatment guidelines. For example, McIlroy states: "According to the present invention, there is provided a processing unit and software-implemented health condition diagnosis-based guidelines… Through the interactive guideline query-response process, a guideline treatment option (or options) is obtained. The user may adopt or accept the guideline treatment option(s) or input an actual or proposed treatment that is different. Discrepancies between actual/proposed and guideline

7. A computer readable medium having stored thereon instructions for tracking compliance with treatment guidelines which when executed by a processor, cause the processor to perform the steps of:	diagnosed conditions, the system comprising:	treatment option(s) are identified and the user's choice is documented through interactive queries…" (McIlroy, col. 3:10-25; *see also* McIlroy, col. 1:26-34 (system, computer-readable medium); col. 3:4-8 (tracking compliance with diagnosed conditions); FIGS. 9a-9b (method steps).) In addition to the disclosure in McIlroy, and as explained above with respect to Grounds 2-3, Caple relates to processes and systems for automatic test tracking analysis and reporting by an automated process and computer system, The process and system can transmit an analysis and proposed treatment to the patient's physician or health care provider for approval or change before the test report and recommended medicine and treatment are sent to the patient. The process and system are also useful for automatic test tracking and reporting to public health organizations. (Caple, Abstract.) ***For Ground 7:*** As outlined in Ground 3, above, Graham is directed to a method, system, and computer readable medium useable for tracking compliance with treatment guidelines when treating diagnosed patients. (Graham, Abstract; p. 5:1-2; p. 12:27-32.)
determining a current assessment of one or more diagnosed conditions in a patient based on data about each of the	an assessment processing system that determines a current assessment of each of the diagnosed conditions	McIlroy discloses determining a current assessment of one or more conditions of a patient, including previously diagnosed conditions. This current assessment is based on data received from a patient, as well as assessment guidelines ("diagnosis-based guidelines"). (*See e.g.*, McIlroy, col. 2:66.) In McIlroy, a diagnosis is made in response to a patient presenting health concerns. For example, "[i]nitially, an individual presents a health condition to a provider. Next, the diagnosis process is initiated. The health care provider or other user collects information from the individual and performs

diagnosed conditions from the patient who is at a remote location and on one or more assessment guidelines for each of the diagnosed conditions;	based on data about each of the diagnosed conditions from the patient who is at a remote location and on one or more assessment guidelines for each of the diagnosed conditions;	tests or other procedures." (McIlroy, col. 10:28-32; *see also* FIG. 9b.) The system initiates the guideline process (McIlroy, col. 10:32-35), which includes requesting from the user information about previous treatments (i.e., based on a previously-diagnosed condition). (McIlroy, col. 10:35-37; McIlroy, col. 5:47-51.) McIlroy therefore contemplates that the diagnosis process of FIG. 9b corresponds to a current assessment (i.e., a re-diagnosis) of a patient's previously-treated or diagnosed condition. (*See e.g.*, McIlroy, col. 3:10-25 ("A user inputs an individual's health data into a new or existing case file in response to inquiries implemented in a health-condition specific guideline...").) The current assessment of the patient is based on assessment guidelines ("diagnosis-based guidelines"). (*See e.g.*, McIlroy, col. 2:66.) McIlroy teaches that diagnosis-based guidelines assist in assessment of a condition. For example, McIlroy states, "At the foundation of the system 300 is a set of diagnosis-based guidelines that are derived from medical professional and health care management expertise. Each guideline is associated with a particular health care condition for which treatment exists. Each guideline is intended to lead a system user through a sequence of interactive data-collection queries based on the specified health care condition observed in an individual patient." (McIlroy, col. 5:7-20.) The health condition information, both for the diagnosis and current assessment, is provided by a patient to a health care provider. (McIlroy, col. 10:14-23.) Although McIlroy does not explicitly disclose that the patient is "at a remote location," that reference suggests that the system is distributed across a number of locations: "It would be a decided improvement over the prior art to have a health care management data processing system that could be used by various health care participants, including doctors, nurses, health

		care administrators, payor administrators, employers, and evaluators at multiple stages of the health care process." (McIlroy, col. 2:9-14.) As explained above with respect to Grounds 2-3, Caple provides for determining a current assessment of a patient's diagnosed condition (Caple, p. 13:3-7) based on a test sample sent from a patient at a remote location site. (Caple, p. 8:22-30; p. 11:1-5.) In addition, Caple discloses determining test results based on testing the patient sample. (Caple, p. 9:36-p. 10:3.) In this case, the test results are based on the received patient data (e.g., a patient test sample) and "appropriate professional laboratory tests" i.e., assessment guidelines. (Caple, p. 13:30-31.)
updating an existing treatment plan for each of the diagnosed conditions based on the existing treatment plan, the current assessment, and on one or more treatment guidelines for each of the diagnosed	a treatment processing system that updates an existing treatment plan for each of the diagnosed conditions based on the existing treatment plan, the current assessment, and on one or more	McIlroy discloses a system that processes treatments by updating an existing treatment plan to arrive at a "guideline treatment option." (*See e.g.*, McIlroy, col. 3:15-16.) The guideline treatment option is based on the existing treatment plan and current assessment (e.g., an updated diagnosis), and on one or more treatment guidelines ("diagnosis-based guidelines"). (*See e.g.*, McIlroy, col. 7:45-48.) For example, McIlroy provides for "a processing unit and software-implemented health condition diagnosis-based guidelines. A user inputs an individual's health data into a new or existing case file in response to inquiries implemented in a health-condition specific guideline. Through the interactive guideline query-response process, a guideline treatment option (or options) is obtained. The user may adopt or accept the guideline treatment option(s) or input an actual or proposed treatment that is different. Discrepancies between actual/proposed and guideline treatment option(s) are identified and the user's choice is documented through interactive queries. Once a treatment is selected, the case information is added to the data base and a reviewer can analyze the file. The case may be re-

conditions to generate an updated treatment plan for each of the diagnosed conditions;	treatment guidelines for each of the diagnosed conditions to generate an updated treatment plan for each of the diagnosed conditions;	opened, and changes may be made at any stage in the process to reflect new conditions, or new or modified treatments." (McIlroy, col. 3:10-25.) In addition, and as explained above with respect to Grounds 2-3, Caple provides for updating an existing treatment plan for a diagnosed condition (Caple, p. 13:3-7) based on a current assessment and treatment guidelines. (Caple, p. 15:22-31); Caple, p. 13:30-p. 14:2.) The updated treatment plan is based on the test results and/or any interpretation thereof and desirably medical profile 15 (Figure 1) of the patient" which are "electronically inputted or scanned and fed into a central processing unit (CPU) with an electronic inputting device 16 (Caple, Figure 1)…The medical profile can comprise electronic patient data and files about, for example, the patient's age, sex, height, weight, current and/or past medical history…" (Caple, p. 15:22-31.) Caple utilizes a data base having treatment guidelines in order to generate the updated treatment plan, i.e., treatment recommendations. (Caple, p. 10:1-20.)
reviewing the updated treatment plan for each of the diagnosed conditions; determining if one or more changes are needed to the reviewed	a review system that modifies the updated treatment plan if one or more changes are determined to be needed and provides a reviewed treatment	McIlroy discloses a system that allows a user to review and change an existing treatment plan relative to a proposed updated treatment (the "guideline treatment option") to arrive at a reviewed treatment plan (the "final recommendation treatment"). (*See e.g.*, McIlroy, Abstract.) For example, McIlroy states, "Once the user reaches one or more guideline treatment options, the system 300 elicits from the user information identifying the actual treatment already given or, preferably, the treatment proposed for the individual that presented the health care condition. The system 300 compares the actual or proposed treatment against the guideline treatment option(s). …The system 300 develops a treatment evaluation based on the comparison to identify discrepancies between the guideline treatment option and the actual or proposed treatment. Following this evaluation, the

treatment plan for each of the diagnosed conditions; changing the reviewed treatment plan if the one or more changes are determined to be needed;	plan;	user enters a final recommendation treatment. If this final recommendation treatment differs from the guideline treatment option previously displayed, the system 300 elicits information on the reasons for the difference(s) found in the system's comparison of the two." (McIlroy, col. 5:46-65; *see also* McIlroy, col. 13:45-50 (specialist review); McIlroy, col. 15:32 - col. 16:21 (example guideline).) In addition, Caple describes changing the reviewed treatment plan if the one or more changes are determined to be needed by medical personnel. (Caple, Figure 1; p. 10:21-25; p. 15:32-34; p. 13:30-p. 14:2.)
providing the patient with the reviewed treatment plan for each of the diagnosed conditions; and	a presentation system that provides the reviewed treatment plan for each of the diagnosed conditions; and	McIlroy includes a presentation system that displays the recommended treatment and final recommendation. For example, McIlroy recites means for displaying the resources for the recommended treatment and final recommendation in side-by-side columns, respectively, and for displaying in a third column aligned with the side-by-side columns the reason codes accepted by a user." (McIlroy, Claim 3.) With respect to claims 1 and 7, although the display of McIlroy is intended to be used by a physician, specialist, or clinician. As stated above, it would be obvious to include a report of the final recommendation treatment to a patient. In addition, Caple explicitly teaches presenting the reviewed treatment plan to the patient. (Caple, p. 13:30 – p. 14:2; p. 12:28-29, Abstract.)
generating and providing	a compliance system that	McIlroy discloses generating and providing compliance data that analyzes differences between an updated treatment plan (i.e., a plan based on the current

compliance data based on the updated treatment plan and the reviewed treatment plan for each of the diagnosed conditions.	generates and provides compliance data based on the reviewed treatment plan and the updated treatment plans.	assessment) and a reviewed treatment plan (i.e., a treatment plan that is reviewed and optionally modified by a healthcare provider) for diagnosed conditions. For example, McIlroy states that "[a] primary purpose of the guidelines is to initiate and facilitate comparison and evaluation, if there is a difference between the final recommendation treatment and guideline treatment option or between the final recommendation treatment and proposed/actual treatment…" (McIlroy, col. 8:44-60; *see also* claim 3 (above).) McIlroy also discusses auditing records of such variances for quality assurance. "The information retained by the system allows for a consistent, efficient review process. Variances between actual or proposed and guideline treatment option(s) can be used for quality assurance and audit purposes." (McIlroy, col. 3:4-8; *see also* McIlroy, col. 3:15-24.) "An example of a quality management and planning (for each component) report is shown in FIG. 29. This report is sorted by guideline 266, proposed treatment 267, and final recommendation 268... For each guideline in each category, the following are listed: proposed 273 and final recommendation treatment 274, number of cases under each category 275, percent of the cases that carry the proposed/final combination 276, percent to specialist review 277, percent of cases with extensions (stay beyond the initial plan) 278, the number with a guideline variance 279, the type of guideline variance 280, the number of times each variance code was used 280a, and the percent of care changed by the treating physician 281." (McIlroy, col. 18:59 - col. 19:8; *see also* col. 16:53-57 (aggregative reporting); col. 14:65 to col. 15:11 ("Care Changed" field tracking deviance from recommended treatment).) --- ***For Ground 7***, As outlined in Ground 3, above, Graham provides statistical reports per physician regarding physician compliance. (Graham, p. 50:8-18.)

2. Dependent Claims 2, 5, and 8

Claims 2, 5, and 8 of '985 Patent	**Ground 6: U.S. Patent No. 5,583,758 ("McIlroy") in view of in view of WO 99/04043A1 ("Caple")** **Ground 7: U.S. Patent No. 5,583,758 ("McIlroy") in view of WO 99/04043A1 ("Caple") in further view of PCT Pub. No. WO 98/058338 ("Graham")**
2. The method as set forth in claim 1 wherein the compliance data comprises provider information on the number of the reviewed treatment plans which are different from a corresponding one of the updated treatment plans for each provider. 5. The system as set forth in claim 4 wherein the compliance data comprises provider information on the number of the reviewed treatment plans which are different from a corresponding one of the updated treatment plans for each provider.	McIlroy discloses compliance data about whether a provider, for each patient, deviates from an updated treatment plan based on treatment guidelines. A "quality management and planning report" can be generated that aggregates numbers and types of variances from treatment guidelines by a treating physician. "A primary purpose of the guidelines is to initiate and facilitate comparison and evaluation, if there is a difference between the final recommendation treatment and guideline treatment option or between the final recommendation treatment and proposed/actual treatment…" (McIlroy, col. 8:44-60.) McIlroy discusses auditing records of such variances for quality assurance. "The information retained by the system allows for a consistent, efficient review process. Variances between actual or proposed and guideline treatment option(s) can be used for quality assurance and audit purposes." (McIlroy, col. 3:4-8; *see also* col. 3:15-24.) "An example of a quality management and planning (for each component) report is shown in FIG. 29. This report is sorted by guideline 266, proposed treatment 267, and final recommendation 268... For each guideline in each category, the following are listed: proposed 273 and final recommendation

8. The medium as set forth in claim 7 wherein the compliance data comprises provider information on the number of the reviewed treatment plans which are different from a corresponding one of the updated treatment plans for each provider.	treatment 274, number of cases under each category 275, percent of the cases that carry the proposed/final combination 276, percent to specialist review 277, percent of cases with extensions (stay beyond the initial plan) 278, the number with a guideline variance 279, the type of guideline variance 280, the number of times each variance code was used 280a, and the percent of care changed by the treating physician 281." (McIlroy, col. 18:59 - col. 19:8; *see also* col. 16:53-57 (aggregative reporting); col. 14:65 - col. 15:11 ("Care Changed" field tracking deviance from recommended treatment).) ***For Ground 7:*** As outlined in Ground 3, above, Graham provides statistical reports regarding per physician compliance. (Graham, p. 50:8-18; p. 52:2-10.)

E. Grounds 8 and 9 – Each of claims 1-9 is Obvious over McIlroy in Light of Surwit in further light of Graham

The combination of McIlroy and Surwit teaches all elements of the claims of the '985 patent. Based on the above-described teachings of McIlroy (in Grounds #6-7) and Surwit (in Grounds #4-5), and as were present in the art generally, modification of the system of McIlroy to incorporate remote patient input would have been obvious at the time of invention of the '985 patent, in view of the efficiency and accuracy advantages of such systems. (Ex. 1009, Decl. at ¶¶74-75.) In particular, the disclosure in Surwit of additional patient compliance

tracking would be obvious to incorporate into the system of McIlroy, since both systems ultimately require a patient to comply with such a treatment plan. (Ex. 1009, Decl. at ¶76.)

With respect to ground 9, specifically, Graham provides additional explicit discussion related to generating and providing compliance data with respect to the number of reviewed treatment plans that are different from the corresponding updated treatment plans. One of ordinary skill in the art would understand to combine McIlroy, Surwit, and Graham because each reference deals directly with remote healthcare and patient treatment. Additionally, as noted above, both Surwit and Graham relate to issues of remote healthcare, and both McIlroy and Graham provide a teaching of the desirability of incorporating such physician compliance reporting into diagnostic and treatment systems. (Ex. 1009, Decl. at ¶¶79-80.) The references therefore suggest intercombination of the teachings of Graham with those of such systems as are disclosed in McIlroy and Caple. (Ex. 1009, Decl. at ¶¶79-80.)

1. Independent Claims 1, 4, and 7

Independent Claims 1 and 7	**Independent Claim 4**	**Ground 8: U.S. Patent No. 5,583,758 ("McIlroy") in view of U.S. Patent No. 6,024,699 ("Surwit")** **Ground 9: U.S. Patent No. 5,583,758 ("McIlroy") in view of**

		U.S. Patent No. 6,024,699 ("Surwit") in further view of PCT Pub. No. WO 98/058338 ("Graham")
1. A method for tracking compliance with treatment guidelines, the method comprising: 7. A computer readable medium having stored thereon instructions for tracking compliance with treatment guidelines which when executed by a processor, cause the processor to perform the steps of:	4. A system for tracking compliance in treating patients, each of the patients having one or more diagnosed conditions, the system comprising:	As explained above in Grounds 6-7, McIlroy discloses a system, method, and computer-readable medium for tracking compliance with treatment guidelines. (McIlroy, col. 3:10-25; *see also* McIlroy, col. 1:26-34 (system, computer-readable medium); col. 3:4-8 (tracking compliance with diagnosed conditions); FIGS. 9a-9b (method steps).) In addition to the disclosure in McIlroy, and as discussed above with respect to Grounds 4-5, Surwit relates to methods, systems and computer program products for monitoring, diagnosing, prioritizing and treating medical conditions of a plurality of remotely located patients. (Surwit, col. 2:40-42; col. 3:22-24.) ***For Ground 9****:* As outlined in Ground 3, above, Graham is also directed to a method, system, and computer readable medium useable for tracking compliance with treatment guidelines when treating diagnosed patients. (Graham, Abstract; p. 5:1-2; p. 12:27-32.)
determining a current assessment of one or more diagnosed conditions in a patient based on data about each of the diagnosed conditions from the	an assessment processing system that determines a current assessment of each of the diagnosed conditions based on data about each of the	As explained above in Grounds 6-7, McIlroy discloses determining a current assessment of one or more conditions of a patient, including previously diagnosed conditions. This current assessment is based on data received from a patient, as well as assessment guidelines ("diagnosis-based guidelines"). (*See e.g.*, McIlroy, col. 2:9-14, 66; col. 10:14-23, 28-37; *see also* FIG. 9b; col. 5:47-51; col. 3:10-25; col. 5:7-20.)

patient who is at a remote location and on one or more assessment guidelines for each of the diagnosed conditions;	diagnosed conditions from the patient who is at a remote location and on one or more assessment guidelines for each of the diagnosed conditions;	In addition, as explained above in Grounds 4-5, Surwit discloses a PPM for collecting data from a patient diagnosed with diabetes that includes a glucose monitor and a display such that "[e]ach time the glucose meter is used to record blood glucose values, the internal software may query the patient for various information including, but not limited to, health status, diet, exercise, and insulin taken." (Surwit, col. 8:18-20, 27-31; col. 8:23-24.) As admitted in the '985 patent, Surwit discloses that "medical conditions of a plurality of remotely located patients are monitored, diagnosed, prioritized, and treated using a central data processing system configured to communicate with and receive data from a plurality of respective patient monitoring systems." ('985 Patent, col. 1:67-col. 2:4.)
updating an existing treatment plan for each of the diagnosed conditions based on the existing treatment plan, the current assessment, and on one or more treatment guidelines for each of the diagnosed conditions to generate an updated treatment plan for each of the	a treatment processing system that updates an existing treatment plan for each of the diagnosed conditions based on the existing treatment plan, the current assessment, and on one or more treatment guidelines for each of the	As explained above in Grounds 6-7, McIlroy discloses a system that processes treatments by updating an existing treatment plan to arrive at a "guideline treatment option." (*See e.g.*, McIlroy, col. 3:15-16.) The guideline treatment option is based on the existing treatment plan and current assessment (e.g., an updated diagnosis), and on one or more treatment guidelines ("diagnosis-based guidelines"). (*See e.g.*, McIlroy, col. 7:45-48;*see generally*, col. 3:10-25; col. 7:47-60; col. 8:56-58; col. 6:55, to col. 7:4.)

diagnosed conditions;	diagnosed conditions to generate an updated treatment plan for each of the diagnosed conditions;	
reviewing the updated treatment plan for each of the diagnosed conditions; determining if one or more changes are needed to the reviewed treatment plan for each of the diagnosed conditions; changing the reviewed treatment plan if the one or more changes are determined to be needed;	a review system that modifies the updated treatment plan if one or more changes are determined to be needed and provides a reviewed treatment plan;	As explained above in Grounds 6-7, McIlroy discloses a system that allows a user to review and change an existing treatment plan relative to a proposed updated treatment (the "guideline treatment option") to arrive at a reviewed treatment plan (the "final recommendation treatment"). (*See e.g.*, McIlroy, Abstract;*see generally*, col. 5:46-65; *see also* col. 13:45-50 (specialist review); col. 15:32 - col. 16:21 (example guideline).) In addition to the disclosure in McIlroy, and as explained above in Grounds 4-5, Surwit also describes review of an updated treatment plan by a case worker, who may change the updated treatment plan if necessary. (Surwit, col. 11:16-21, 30-33; col. 10:18-21; col. 13:48-52.)
providing the patient with the reviewed treatment plan for each of the diagnosed	a presentation system that provides the reviewed treatment plan for each of the	As explained above in Grounds 6-7, with respect to claim 4, McIlroy includes a presentation system that displays the recommended treatment and final recommendation. (McIlroy, claim 3.) With respect to claims 1 and 7, although the display

conditions; and	diagnosed conditions; and	of McIlroy is intended to be used by a physician, specialist, or clinician, as stated above, it would be obvious to include a report of the final recommendation treatment to a patient. In addition, Surwit provides a patient with his/her treatment plan for diagnosed conditions. (Surwit, col. 13:57-59; col. 13:59-62.)
generating and providing compliance data based on the updated treatment plan and the reviewed treatment plan for each of the diagnosed conditions.	a compliance system that generates and provides compliance data based on the reviewed treatment plan and the updated treatment plans.	As explained above in Grounds 6-7, McIlroy discloses generating and providing compliance data that analyzes differences between an updated treatment plan (i.e., a plan based on the current assessment) and a reviewed treatment plan (i.e., a treatment plan that is reviewed and optionally modified by a healthcare provider) for diagnosed conditions. (McIlroy, col. 8:44-60; *see also* claim 3; McIlroy, col. 3:4-8; McIlroy, col. 3:15-24; col. 18:59 - col. 19:8; col. 16:53-57 (aggregative reporting); col. 14:65 to col. 15:11.) In addition to the disclosure in McIlroy, and as explained above in Grounds 4-5, Surwit's PPM "[c]ollects patient supplied data on ...compliance to medical regime." (Surwit, col. 7:28-30; *see also* col. 3:14-24.) In another embodiment, Surwit describes "screening mechanisms . . . for ensuring that treatment or information provided by a case manager is medically sound for a particular patient before the treatment or information is communicated to a patient or to a patient's PPM." (Surwit, col. 19:8-12.) ***For Ground 9***, As outlined in Ground 3, above, Graham

		provides statistical reports per physician regarding physician compliance. (Graham, p. 50:8-18.)

2. Dependent Claims 2, 5, and 8

Claims 2, 5, and 8 of '985 Patent	**Ground 8: U.S. Patent No. 5,583,758 ("McIlroy") in view of U.S. Patent No. 6,024,699 ("Surwit")** **Ground 9: U.S. Patent No. 5,583,758 ("McIlroy") in view of U.S. Patent No. 6,024,699 ("Surwit") in further view of PCT Pub. No. WO 98/058338 ("Graham")**
2. The method as set forth in claim 1 wherein the compliance data comprises provider information on the number of the reviewed treatment plans which are different from a corresponding one of the updated treatment plans for each provider. 5. The system as set forth in claim 4 wherein the compliance data comprises provider information on the number of the reviewed treatment plans which are different from a corresponding one of the updated treatment plans for each provider. 8. The medium as set forth in claim 7 wherein the compliance data comprises provider information on the number of the reviewed treatment plans which are different from a corresponding one of	As explained above in Grounds 6-7, McIlroy discloses compliance data about whether a provider, for each patient, deviates from an updated treatment plan based on treatment guidelines. A "quality management and planning report" can be generated that aggregates numbers and types of variances from treatment guidelines by a treating physician. (McIlroy, col. 8:44-60; col. 3:4-8; col. 3:15-24; col. 18:59 - col. 19:8; col. 16:53-57 (aggregative reporting); col. 14:65 - col. 15:11.) ***For Ground 9:*** As outlined in Ground 3, above, Graham provides statistical reports regarding per physician compliance. (Graham, p. 50:8-18; p. 52:2-10.)

the updated treatment plans for each provider.	

3. Dependent Claims 3, 6, and 9

Claims 3, 6, and 9 of '985 Patent	**Ground 8: U.S. Patent No. 5,583,758 ("McIlroy") in view of U.S. Patent No. 6,024,699 ("Surwit")** **Ground 9: U.S. Patent No. 5,583,758 ("McIlroy") in view of U.S. Patent No. 6,024,699 ("Surwit") in further view of PCT Pub. No. WO 98/058338 ("Graham")**
3. The method as set forth in claim 1 wherein the compliance data further comprises data on patient compliance with at least one of the existing treatment plan for each diagnosed condition. 6. The system as set forth in claim 4 wherein the compliance data further comprises data on patient compliance with at least one of the existing treatment plan for each diagnosed condition. 9. The medium as set forth in claim 7 wherein the compliance data further comprises data on patient compliance with at least one of the existing treatment plan for each diagnosed condition.	As explained above in Grounds 6-7, McIlroy discloses tracking patient outcomes and treatments. (McIlroy, col. 16:53-57 (aggregative reporting).) As stated above, it would have been obvious at the time of invention of the '985 patent, in view of the closely-related telehealth diagnostic systems available at the time of the invention, to modify McIlroy to include receiving or reporting information about patient compliance with a treatment plan. In addition, and as explained above in Grounds 4-5, Surwit provides for tracking patient compliance with an existing treatment plan. (Surwit, col. 7:28-30; col. 20:64-66.)

VII. CONCLUSION

For the foregoing reasons, *inter partes* review of claims 1-9 of U.S. Patent No. 6,612,985 is respectfully requested.

Respectfully submitted,

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(Trial No. _____) *ATTORNEYS FOR PETITIONER*

CERTIFICATE OF SERVICE ON PATENT OWNER

Pursuant to 37 C.F.R. § 42.6(e), the undersigned certifies that on the 31st day of May, 2013, a complete and entire copy of this Petition for *Inter Partes* Review Under 37 C.F.R. §42.100, alongside an accompanying Power of Attorney, Exhibit List, and Exhibits 1001-1009, were provided via Federal Express, postage prepaid, to the Patent Owner by serving the correspondence address of record for the '985 Patent, as well as litigation counsel for the copending lawsuit captioned in the foregoing Petition:

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