Paper No. 1

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ROBERT BOSCH HEALTHCARE SYSTEMS INC,
Petitioner
v.
MY HEALTH, INC.,
Patent Owner

Patent No. 6,612,985
Issued: September 2, 2003
Filed: February 26, 2001
Inventors: Michael E. Eiffert and Lisa C. Schwartz

Title: METHOD AND SYSTEM FOR MONITORING AND TREATING A PATIENT

Inter Partes Review No.: _____

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I. REQUEST FOR *INTER PARTES* REVIEW

Pursuant to 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42, Petitioner, Robert Bosch Healthcare Systems, Inc. respectfully request *inter partes* review of all claims (1-9) of US Patent No. 6,612,985 ("the '985 patent") (Ex. 1001).

The challenged claims were the subject of three prior petitions: IPR2015-00102, IPR2013-00320 and IPR2014-00435. *Inter partes* review of all claims was instituted in IPR2013-00320 by decision dated November 19, 2013 instituted again in IPR2015-00102. *See* Ex. 1005, Ex. 1012. ***The present petition seeks review on precisely the same grounds on which review was instituted in IPR2013-00320 and IPR2015-00102***. A Joint Motion to Terminate was filed by the parties in both IPR2013-00320 and IPR2014-00435. IPR2013-00320 was terminated following settlement prior to a final written decision, and IPR2014-00435 was terminated prior to a decision on whether to institute review.

II. MANDATORY NOTICES

A. Certification that the Patent May Be Contested via *Inter Partes* Review by the Petitioner. Pursuant to 37 C.F.R. § 104(a), Petitioner certifies that the patent sought for review is available for *inter partes* review and that the petitioner is not barred or estopped from requesting an *inter partes* review of the patent.

B. Real parties-in-interest. Pursuant to 37 C.F.R. § 42.8(b)(1),

Petitioner identifies the real party-in-interest as Robert Bosch Healthcare Systems, Inc. ("Bosch")[1]. Petitioner is a Defendant in pending actions in U.S. District Court for the Eastern District of Texas.

C. Related Matters. Pursuant to 37 C.F.R. § 42.8(b)(2), in addition to IPR2015-00102, IPR2013-00320 and IPR 2014-00435 mentioned above, Petitioner identifies the following pending civil actions as related matters:

Petitioner is a Defendant in *My Health, Inc. v. Robert Bosch Healthcare Systems, Inc*., No. 14-cv-662. Other filed civil actions are included in the following list:

[1] Bosch is a wholly owned subsidiary of Robert Bosch North America Corp. Robert Bosch North America Corp, has a number of wholly-owned subsidiaries, including Robert Bosch LLC. Attorneys at Robert Bosch LLC are responsible for overall legal issues for all of Robert Bosch North America Corp.'s subsidiaries in North America. This includes decisions regarding hiring and retention of outside counsel, legal strategy, and final decisions about whether to bring, continue or settle disputes for these entities. However, Robert Bosch LLC does not control this IPR, has not provided any funding for this proceeding, and has had no input into the contents of this petition (which is substantially a copy of the IPR petitions discussed above).

E.D. Texas: No. 14-cv-652; No. 14-cv-654; No. 14-cv-655; No. 14-cv-657; No. 14-cv-658; No. 14-cv-659; No. 14-cv-660; No. 14-cv-661; No. 14-cv-663; No. 14-cv-664; No. 14-cv-680; No. 14-cv-681; No. 14-cv-682; No. 14-cv-683; No. 14-cv-684; No. 14-cv-685; **D. Del.:** No. 14-cv-0910; No. 14-cv-1085; No. 14-cv-1436; No. 15-cv-0248; No. 15-cv-1616; **N.D. Cal.:** No. 15-cv-0671; No. 15-cv-1351. **S.D. Cal.:** 15-cv-0932; **N.D. Tex.:** No. 15-cv-0726.

Lead and Back-up Counsel and Service Information. Pursuant to 37 C.F.R. §§ 42.8(b)(3)-(4) and 42.10(a), Petitioner identifies lead and back-up counsel as follows. Petitioner can be served as follows:

Lead Counsel	Back-up Counsel
Don Daybell	James Maune
Reg. No. 50,877	Reg. No. 67,187
Orrick, Herrington, & Sutcliffe LLP	Orrick, Herrington, & Sutcliffe LLP
2050 Main Street, Suite 1100	2050 Main Street, Suite 1100
Irvine, CA 92614-8255	Irvine, CA 92614-8255
d2dptabdocket@orrick.com	5jmptabdocket@orrick.com
(949) 567-6700 (tel)	(949) 567-6700 (tel)
(949) 567-6710 (fax)	(949) 567-6710 (fax)

D. Payment of Fees. The director is authorized to charge the fee specified by 37 C.F.R. § 42.15(a) to Deposit Account No. 15-0665.

E. Relief Requested. Pursuant to 37 C.F.R. § 42.22(a)(1), Petitioner respectfully requests the cancellation of claims 1-9 of the '985 patent as unpatentable under 35 U.S.C. §§ 102 and 103.

F. Threshold for Instituting *Inter Partes* Review. Pursuant to 35 U.S.C. § 314(a), Petitioner meets the threshold for institution of an *inter partes* review because there is a reasonable likelihood that they will prevail with respect to at least one of the challenged claims.

III. SUMMARY OF THE '985 PATENT

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

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); and generating compliance data comparing the reviewed and updated treatment plans (Fig. 4).

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"). In response to an initial rejection, the claims were amended to add language directed to reviewing an updated treatment plan and generating compliance data based on the updated and reviewed treatment plans. Ex. 1003, Response dated 2/10/2003, Appendix A.

The Applicant relied on the 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" to distinguish the cited art. See, e.g., Ex. 1003, p. 5-6.

Following this Amendment, the Examiner allowed all the pending claims, stating that "the claims distinguish over the prior art in that tracking physician compliance with treatment guidelines is not taught." Ex. 1004, Notice of Allowance dated 3/31/2003 p. 2.

IV. IDENTIFICATION OF CLAIMS BEING CHALLENGED

A. Grounds for Invalidity

As set forth in this Petition, claims 1-9 of the '985 patent are unpatentable as being anticipated under 35 U.S.C. § 102, and rendered obvious under 35 U.S.C. § 103, over the following references, taken alone or in combination: (1) U.S. Patent No. 6,126,596 to Freedman ("Freedman" – Ex. 1006); (2) PCT Publication No. WO 99/04043 to Caple, et al. ("Caple" – Ex. 1007) (3) U.S. Patent No. 6,024,699 to Surwit, et al. ("Surwit '699" – Ex. 1009); (4) PCT Publication No. WO 98/58,338 to Graham, et al. ("Graham" – Ex. 1008); (5) U.S. Patent No. 6,980,958 to Surwit et al. ("Surwit '958" – Ex. 1010); and (6) U.S. Patent No. 5,827,180 to Goodman ("Goodman" – Ex. 1011). The following chart summarizes the grounds for invalidity of claims 1-9 of the '985 patent:

Grounds for Invalidity		Claims
1	Claims 1-9 are anticipated under 35 U.S.C. § 102(a) and (e) by Freedman	**1-9**
2	Claims 1-9 are obvious under 35 U.S.C. § 103(a) over Freedman in view of Caple.	**1-9**
3	Claims 1-9 are obvious under 35 U.S.C. § 103(a) over Freedman in view of Caple and further in view of Graham.	**1-9**
4	Claims 1-9 are obvious under 35 U.S.C. § 103(a) over Freedman in view of Surwit '699.	**1-9**
5	Claims 1-9 are obvious under 35 U.S.C. § 103(a) over Freedman in view of Surwit '699 and further in view of Graham.	**1-9**
6	Claims 1-9 are anticipated under 35 U.S.C. § 102(e) by Surwit '958.	**1-9**
7	Claims 2, 5 & 8 are obvious under 35 U.S.C. § 103(a) over Surwit '958 in view of Freedman and Graham.	**2, 5 & 8**
8	Claims 1, 3, 4, 6, 7 & 9 are anticipated under 35 U.S.C. §102(b) by Goodman.	**1, 3, 4, 6, 7 & 9**
9	Claims 2, 5 & 8 are obvious under 35 U.S.C. § 103(a) over Goodman in view of Freedman and Graham	**2, 5 & 8**

B. Previously Instituted *Inter Partes* Review of Claims 1-9

Claims 1-9 of the '985 patent were the subject of *inter partes* review case No. IPR2013-000320, instituted on November 19, 2013, to review claims 1-9 under 35 U.S.C. § 102 as anticipated by Freedman; under 35 U.S.C. § 103 as obvious over Freedman, Caple, and Graham; and under 35 U.S.C. § 103 as obvious over Freedman, Surwit '699, and Graham. Ex. 1005 p.25, ll. 13-16. We agree with and reiterate the Board's grounds for instituting *inter partes* review of the '985 patent, (Ex. 1005, pp. 12-22) and set forth below additional grounds upon which *inter partes* review should be instituted.

C. Background

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 1990s 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, as outlined below, the patent claims are anticipated and obvious over the prior art.

D. Construction of Terms Used in the Claims

Certain terms were construed by the PTAB in IPR2013-000320. Because those claim constructions are believed to be reasonable and consistent with the specification of the '985 Patent, such claim constructions will be relied upon by petitioner in this petition.

1. "treatment plan"

The term "treatment plan" was construed by the PTAB to mean "a proposed scheme or procedure (i.e., a 'plan') for providing some form of therapy for a patient (or 'treatment')." *See* Ex. 1002, ¶ 25 (citing '985 patent col. 2:29-32; 4:35-

59); *see also* Ex. 1005 (Decision to institute IPR 2013-00320) at 6.

2. "current assessment"

The term "current assessment" was construed by the PTAB to mean "any present determination or evaluation of a previously diagnosed condition or illness in the patient." *See* Ex. 1002, ¶ 26 (citing '985 patent col. 2:17-23); *see also* Ex. 1005 (Decision to institute IPR 2013-00320) at 7.

3. "assessment guidelines"

The term "assessment guidelines" was construed by the PTAB to mean "a standard or principle by which to make a judgment (i.e., 'guidelines') that is used to determine a condition of (or 'assess') a patient." *See* Ex. 1002, ¶ 27; *see also* Ex. 1005 (Decision to institute IPR 2013-00320) at 7-8.

4. "treatment guidelines"

The term "treatment guidelines" was construed by the PTAB to mean "standards or principles by which to make a judgment or...course of action (i.e., 'guidelines') that are used to provide a course of therapy for a patient ('treatment')." *See* Ex. 1002, ¶ 28 (citing '985 patent col. 4:55-61, 4:25-30); *see also* Ex. 1005 (Decision to institute IPR 2013-00320) at 8.

5. "compliance data"

The term "compliance data" was construed by the PTAB to mean "data that is generated based on the updated treatment plan and the reviewed treatment

plan for each of the diagnosed conditions." *See* Ex. 1002, ¶ 29 (citing '985 patent col. 16:9-11, claims 2-3); *see also* Ex. 1005 (Decision to institute IPR 2013-00320) at 9.

E. Detailed Explanation Under 37 C.F.R. §§ 42.104(b)

1. Ground 1 – Claims 1-9 are anticipated under 35 U.S.C. § 102(a) and (e) by Freedman

Under the claim constructions above, Freedman explicitly or inherently describes all elements of claims 1-9 of the '985 patent.

a. Independent Claims 1, 4 and 7

Freedman describes a method, system, and computer readable medium useable for tracking compliance with treatment guidelines when treating diagnosed patients. Freedman describes a "computer based system" that "can monitor how congruent a medical provider's treatment decisions are with treatment guidelines." Ex. 1006, col. 1:10-13; col. 2:12-15.; Ex. 1002 ¶ 32.

As to the "current assessment" limitations, Freedman describes 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. Col. 4:5-12. The patient receiving a current assessment may have a "previously assigned diagnosis" which

is the subject of that current assessment. Col. 4:5-12; Fig. 3b elements 116, 118). The patient from whom data is received is located at a remote location. Col. 3:24-35. The current assessment (step 152 in Fig. 4a) is also based on assessment guidelines (e.g., "suggested DSM-IV criteria"). Col. 4:30-38; Fig. 4a. *See also* Ex. 1002, ¶ 33.

As to the "updating" limitation of claims 1 and 7 (and the corresponding "updates" limitation of claim 4), Freedman also describes, with reference to Figs. 3b and 4a-c, an updated treatment plan being generated and selected (Fig. 4c, element 172) based on information that includes answers to follow up questions from previously assigned diagnosis(es) (Fig. 3b, elements 116, 118), the clinician selected diagnosis(es) (Fig. 4a, elements 152, 154), and treatment guidelines (Fig. 4a, element 152; Fig. 4c, element 170). *See* col. 4:1, 30-38; col. 5:6-8; Figs. 4a-c. The previously assigned diagnosis(es) may have been associated with, *e.g.*, "medication history" (col. 6:48-62), in other words, an "existing treatment plan" as previously construed by the Board. *See also* Ex. 1002 ¶ 34.

As to the "reviewing" and "determining" limitations of claims 1 and 7 (and the corresponding "review system" limitation of claim 4), Freedman describes a "graphical display" for the clinician to review suggested diagnostic and treatment data. Col. 4:38-40. The clinician can "override treatment guidelines" and select a treatment plan on screen which deviates from the suggested treatment guidelines.

Col. 2:63-3:2; col. 5:7-17; Fig. 4c (block 172). Furthermore, it is inherent in Freedman that the clinician must necessarily "review" what is displayed in order to "select a treatment plan on screen." *Id*. col. 5:8-9. *See also* Ex. 1002 ¶ 35.

As to the "providing" limitation of claims 1 and 7 (and the corresponding "presentation system" limitation of claim 4), Freedman describes providing information associated with the reviewed treatment plan for each of the diagnosed conditions to the patient for review. Col. 7:17-22 ("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 also describes reviewing past treatments to determine whether a patient successfully used certain medications and providing new treatments accordingly. 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. Freedman further indicates that the patient is intimately involved in his/her 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. Col. 6:1-66; Fig. 8b, blocks 196, 200, 218. This inherently discloses that the patient is provided information about his/her treatment, in order to be an active participant in their treatment. Freedman further describes presenting a treatment plan to a clinician for review. Col. 5:7-17

and Fig. 4c ("in block 172, the clinician selects a treatment plan on screen"). *See also* Ex. 1002, ¶¶ 36-38.

As to the "generating and providing compliance data" limitation of claims 1 and 7 (and the corresponding "compliance system" limitation of claim 4), Freedman describes a compliance system that may "alert [a] clinician of deviations from guidelines with explanations" and provide "monitoring data on consistency of clinician treatment with treatment guidelines." Col. 2:63-3:5. The compliance data is based on the reviewed treatment plan (the "highlighted treatment guidelines") and updated treatment plan ("clinician treatment plan"). Col. 5:9-32. Specifically, Freedman discloses that the "system determines suggested treatments" (i.e., "the updated treatment plan") that are based on "recommendations from treatment guidelines" and "highlights them for the clinician." Fig. 4C, element 170. The clinician then reviews and "selects" a treatment plan (i.e., the "reviewed treatment plan.") Fig. 4C, element 172. The system then determines whether the selected treatment plan is "consistent with the treatment guidelines," and if not the system "stores the sequence for quality review" (i.e., generates and provides compliance data). Col. 5:14-15, 30; Fig. 4C, element 174, 184. *See also* Ex. 1002, ¶ 39.

Below is a claim chart comparing claims 1, 4 and 7 to Freedman:

Independent Claims 1 and 7	**Independent Claim 4**	**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:	"The present invention relates to a computer based system that diagnoses, establishes severity, and monitors a client's condition and also monitors medical decisions made by the clinician treating the client." (Freedman, Ex. 1006, col. 1:10-13; *see also* col. 2:12-15 ("The present invention is a system which can monitor how congruent a medical provider's treatment decisions are with treatment guidelines...") (Ex. 1002 ¶ 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	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;	Col. 4:5-12 and Fig. 3b elements 116, 118) ("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."); 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."); Col. 4:30-38 ("Figs. 4a-c show a process in which the system suggests

Independent Claims 1 and 7	Independent Claim 4	Freedman
conditions;		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."); Fig. 4a (step 152 - "suggested DSM-IV criteria"). *See also* Ex. 1002, ¶ 33.
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 updated treatment plan for each of the diagnosed conditions;	Col. 4:1, 30-38; col. 5:6-8; col. 6:48- 62; Figs. 3b and 4a-c. Specifically, Fig. 4c (updated treatment plan is generated and selected); Fig. 3b, elements 116, 118 and col. 6:48-62 (based on answers to follow up questions from previously assigned diagnosis(es), which may have been associated with, e.g., "medication history"); (Fig. 4a, elements 152, 154) (clinician selected diagnosis(es)); Fig. 4a, element 152 and Fig. 4c, element 170 (treatment guidelines). *See also* Ex. 1002 ¶ 34.
reviewing the updated treatment plan for each of the diagnosed conditions;	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;	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."); Col. 2:63-3:2) ("The clinician interface 18 may provide the following functions: ... alert clinician of deviations from guidelines with explanations, <u>allow</u>
determining if one or more changes are needed to the reviewed treatment plan for each of the		

Independent Claims 1 and 7	Independent Claim 4	Freedman
diagnosed conditions; changing the reviewed treatment plan if the one or more changes are determined to be needed;		a clinician to override treatment guidelines either with or without supervisor signoff."); 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."; Freedman Fig. 4c) (block 172). *See also* Ex. 1002 ¶ 35.
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	Claim 4: 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."); 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."); Fig. 4c (block 172). Claims 1, 7: Col. 7:17-22 (same as above); Col. 6:1-7:10; Fig. 8b, blocks 196, 200, 218. *See also* Ex. 1002, ¶¶ 36-38
generating and providing compliance data based on the updated treatment	a compliance system that generates and provides compliance data based on the reviewed treatment	Col. 2:63-3:5 ("The clinician interface 18 may provide the following functions: ... alert clinician of deviations from guidelines with explanations, allow

Independent Claims 1 and 7	Independent Claim 4	Freedman
plan and the reviewed treatment plan for each of the diagnosed conditions.	plan and the updated treatment plans.	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.") 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 specify diagnosis' Treatment Guidelines Module."); *see also* Fig. 4c. *See also* Ex. 1002, ¶39.

b. Dependent Claims 2, 5 and 8

Freedman discloses a system where 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," as recited in claims 2, 5 and 8. Freedman explains that "[t]he present invention is a system which can monitor how congruent a medical provider's

treatment decisions are with treatment guidelines" and provides "monitoring data on consistency of clinician treatment with treatment guidelines." Ex. 1006, col. 2:11-14, 3:4-5. Freedman discloses that the compliance data is individual to a particular assessment and particular provider. Col. 5:28-34. And as explained in the final paragraph addressing claims 1, 4 and 7 above, the "compliance data" stored by Freedman results from a comparison between the "reviewed treatment plan" and the "treatment guidelines," which form the basis for the "updated treatment plans." *See also*, Ex. 1002 at ¶ 40.

Below is a claim chart comparing claims 2, 5 and 8 to Freedman:

Claims 2, 5 and 8 of '985 Patent	**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, Ex. 1006, col. 2:11-14, 3:4-5 ("[t]he present invention is a system which can monitor how congruent a medical provider's treatment ***decisions*** are with treatment guidelines" and provides "monitoring data on consistency of clinician treatment with treatment guidelines."); *See also citations for the final element of claims 1, 4 and 7*; *See also*, Ex. 1002 at ¶ 40.

c. Dependent Claims 3, 6 and 9

Freedman discloses that the compliance data further includes "data on patient compliance with at least one of the existing treatment plan for each diagnosed condition," as in claims 3, 6 and 9. Freedman discloses that the system "determines whether" the patient had "previous positive response to [] medications," "had significant side effects from the medication," and "had an adequate trial." Ex. 1006, col. 6:46-67. All of these are related to an "existing treatment plan." It is inherent in Freedman that whether the patient had a positive response, side effects, or an adequate trial would necessarily depend on the patient's compliance with the existing treatment plan. The data gathered related to this history (Freedman col. 6:49-58, 6:67-7:1) would thus include data relating to patient compliance with an existing treatment plan. *See also*, Ex. 1002 at ¶ 41.

Below is a claim chart comparing claims 3, 6 and 9 to Freedman:

Claims 3, 6 and 9 of '985 Patent	**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 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.	Ex. 1006, col. 6:46-67 (the system "determines whether" the patient had "previous positive response to [] medications," "had significant side effects from the medication," and "had an adequate trial."); Col. 6:49-58, 6:67-7:1 (describing data gathered re: patient history); *See also*, Ex. 1002 at ¶ 41.

2. Grounds 2 and 3 - Claims 1- 9 are obvious under 35 U.S.C. § 103(a) over Freedman in view of Caple alone or further in view of Graham

Every element of claims 1-9 of the '985 patent is taught or suggested by Freedman in view of Caple. (Caple qualifies as prior art under 35 U.S.C. § 102(b).) As shown above, Freedman describes 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 combine Freedman and Caple because, among other reasons, both references deal directly with remote healthcare and patient treatment. *See* Ex. 1006 (Freedman), col. 3:24-35; Ex. 1007 (Caple), p. 5:23-28. Additionally, Freedman describes 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 patient diagnoses. Additional reasons to combine Freedman and Caple exist beyond the explicit teachings of the references. For example, it would have been 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. 1002, Decl. at ¶¶45-47. 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. Caple, p. 8:22-30; p. 11:1-5. Caple discloses a system that receives data from a patient (such as "remote sample collection") and performs testing. Caple, p. 13:14-17. The system "then transmits the patient test results with the patient history and recommends changes to the health care provider." *Id*. at 13:23-24. It would have been obvious to one of skill in the art that the recommendations would be based both on the test results and assessment guidelines. Ex. 1002, ¶44. The whole point of recommending changes after receiving the test results would be to suggest changes informed by the test results. *Id*. And the recommendations made by the system would necessarily be based on some standards or principles by which to make a judgment (i.e., "assessment guidelines"). *Id*.

Caple ***explicitly*** describes 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." Ex. 1007, 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." Caple,

p. 12:28-29, *see also* Abstract. In view of the explicit teachings of Freedman and Caple, as well as the motivation 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. Such modifications would have been a simple combination of known elements according to known methods to obtain predictable results, and would have been simply the use of known techniques to improve similar devices and methods in the same way. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 415-421 (2007); MPEP § 2143.

With respect to Ground 3, 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. (Graham qualifies as prior art under 35 U.S.C. § 102(b).) One of ordinary skill in the art would have been motivated 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 both recognizes in the art and addresses the need to generate reports and analysis for individuals and institutions and to indicate deviations from a recommended course of treatment for a physician. Graham, p. 3:9-26; p. 5:1-17. Accordingly, Graham teaches the

desirability of incorporating such physician compliance reporting into diagnostic and treatment systems such as those of Freedman and Caple. Thus, 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. 1002, Decl. at ¶¶53-56. Such a combination would have been a simple combination of known elements according to known methods to obtain predictable results, and would have been simply the use of known techniques to improve similar devices and methods in the same way. *See KSR*, 550 U.S. at 415-421; MPEP § 2143.

Below are claim charts comparing claims 1-9 to Freedman, Cable and Graham:

a. Independent Claims 1, 4 and 7

Independent Claims 1 and 7 of the '985 Patent	**Independent Claim 4 of the '985 Patent**	**Ground 2: Freedman in view of Caple** **Ground 3: Freedman in view of Caple, and further in view of Graham**
1. A method for tracking compliance with treatment guidelines, the method comprising: 7. A computer readable medium having stored	4. A system for tracking compliance in treating patients, each of the patients having one or more diagnosed conditions, the system comprising:	Freedman – see chart above. Caple – Abstract ("Automatic test tracking analysis and reporting... by an automated process and computer system, which can produce a global communications network, for the convenience of patients, health care providers and public health agencies to lower

Independent Claims 1 and 7 of the '985 Patent	**Independent Claim 4 of the '985 Patent**	**Ground 2: Freedman in view of Caple** **Ground 3: Freedman in view of Caple, and further in view of Graham**
thereon instructions for tracking compliance with treatment guidelines which when executed by a processor, cause the processor to perform the steps of:		health care costs... The test result 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." Graham – Abstract ("directed to a system for supporting the decision making of a physician. ... Based 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"); 5:1-2 ("It is an object of the invention to inform a physician when the physician deviates from a recommended course of action."); 12:27-32

Independent Claims 1 and 7 of the '985 Patent	**Independent Claim 4 of the '985 Patent**	**Ground 2: Freedman in view of Caple** **Ground 3: Freedman in view of Caple, and further in view of Graham**
		(system implemented in a computer network including a server and a number of remote computers)
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 – see chart above. Caple – p. 8:22-30, 11:1-5, 13:3-7 (determining a current assessment of a patient's diagnosed condition is based on a test sample FDE sent from a patient at a remote location site.); p. 9:36-10:3 (determining test results is based on testing the patient sample.); p. 13:30-31 (test results based on a patient test sample and "appropriate professional laboratory tests").
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	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 – see chart above. Caple – p. 13:3-7 (updating an existing treatment plan for a diagnosed condition); p. 13-30-14:2 ("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(updated treatment plan is based on the

Independent Claims 1 and 7 of the '985 Patent	**Independent Claim 4 of the '985 Patent**	**Ground 2: Freedman in view of Caple** **Ground 3: Freedman in view of Caple, and further in view of Graham**
generate an updated treatment plan for each of the diagnosed conditions;	of the diagnosed conditions to generate an updated treatment plan for each of the diagnosed conditions;	"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..."); p. 10:1-20 (uses a data base having treatment guidelines in order to generate the updated treatment plan)
reviewing the updated treatment plan for each of the diagnosed conditions;	a review system that modifies the updated treatment plan if one or more change are determined to be needed and provides a reviewed treatment plan;	Freedman – see chart above. Caple – p. 10:21-25 (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. 15:32-34 ("In cases where the
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		

Independent Claims 1 and 7 of the '985 Patent	**Independent Claim 4 of the '985 Patent**	**Ground 2: Freedman in view of Caple** **Ground 3: Freedman in view of Caple, and further in view of Graham**
needed;		CPU provides a treatment recommendation to a physician or other health care provider, the physician or heath care provider may have the opportunity to access the CPU and approve or modify the CPU's recommendation."); see also p. 13:30-14:2.
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	Freedman – see chart above Caple – p.13:30-14:2 ("The process and system will then automatically call the patient back with the patient's result report and recommended medication or treatment regimen changes."); p. 12:28-29 (the CPU can also "transmit the approved or changed diagnosis and recommendation, via a carrier or transmitter 86... to the patient."); *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.	Freedman – see chart above Graham – 50:8-18 ("The pretest assessments per physician report may list the actions selected by physicians following the pretest risk assessment, including any guideline deviations.").

b. Dependent Claims 2, 5 and 8

Claims 2, 5, and 8 of '985 Patent	Ground 2: Freedman in view of Caple Ground 3: Freedman in view of Caple, in further view of 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 the updated treatment plans for each provider.	Freedman – see chart above. Graham – 50:8-18 ("The pretest assessments per physician report may list the actions selected by physicians following the pretest risk assessment, including any guideline deviations."); 52:2-10 ("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).).

c. Dependent Claims 3, 6 and 9

Claims 3, 6, and 9 of '985 Patent	Ground 2: Freedman in view of Caple Ground 3: Freedman in view of Caple, in further view of Graham
3. The method as set forth in claim 1 wherein the	Freedman – see chart

Claims 3, 6, and 9 of '985 Patent	Ground 2: Freedman in view of Caple Ground 3: Freedman in view of Caple, in further view of Graham
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.	above

3. Grounds 4 and 5 – Claims 1- 9 are obvious under 35 U.S.C. § 103(a) over Freedman in view of Surwit '699 alone, or further in view of Graham

Freedman, in view of Surwit '699 describes all elements of the claims of the '985 patent. (Surwit '699 qualifies as prior art under 35 U.S.C. § 102(b).) As shown above, Freedman alone describes all elements of the claims of the '985 patent. Surwit '699, however, provides additional explicit discussion related to providing the treatment plan to a patient. One of ordinary skill in the art would recognize that, like Freedman, Surwit '699 makes a current assessment based on both the data collected from the patient and on one or more standards or principles by which to make a judgment ("assessment guidelines") contained in its software.

(Ex. 1002, ¶ 49). Surwit '699 discloses a "glucose meter 26 that uses patient-entered data and internal software to continuously alter insulin doses as needed." Ex. 1009 (Surwit '699), col. 8:27-28. The "software analyzes the entered data" and "calculates adjustments for a patient's insulin dosage according to a physician's prescription as applied to the data entered [] by the patient." *Id*. col. 8:41-46.

One of ordinary skill in the art would have been motivated to combine Freedman and Surwit '699 because both references describe the benefits of remote patient healthcare. *See* Ex. 1006 (Freedman), col. 3:24-35; Ex. 1009 (Surwit '699), col. 2:26-55; 3:40-55. Specifically, Freedman describes the desirability of integrating assessment and treatment guidelines into diagnoses of patients (col. 1:64- col. 2:7), and Surwit '699 specifically relates to accuracy and efficiency of such patient diagnoses so as to remotely modify the insulin doses needed to treat diabetes (Surwit '699, col. 4:23-25). Furthermore, Surwit '699 allows for the patient's progress to be "continuously monitored," for "changes [to] be made to the patient's insulin dosage," and for identification of patients with "emergency medical conditions requiring immediate medical attention or to calculate a new medication dosage according to a physician-prescribed algorithm." Surwit '699, col. 4:5-9, 23-25. 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. 1002, Decl. at ¶¶ 48-52. In view of the explicit teachings of Freedman and Surwit '699, 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 to provide the patient with his/her treatment plan as in Surwit '699. Ex. 1002, Decl. at ¶¶48-52. Such modifications would have been a simple combination of known elements according to known methods to obtain predictable results, and would have been simply the use of known techniques to improve similar devices and methods in the same way. *See KSR*, 550 U.S. at 415-421; MPEP § 2143.

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" as recited in claims 2, 5, and 8. One of ordinary skill in the art would have been motivated to combine Freedman and Surwit '699 with Graham because, among other reasons, each deals directly with efficient remote healthcare and patient treatment. *See* Freedman, col. 3:24-35; Surwit '699, col. 2:26-55; col. 3:40-55; Graham, p. 2:6-7. Additionally, Graham suggests the

desirability of incorporating such physician compliance reporting into diagnostic and treatment systems (Graham, p. 3:4-25), and therefore suggests combining its teachings with those of such systems as are described in Freedman and Surwit '699. Ex. 1002, Decl. at ¶¶51-54. Such a combination would have been a simple combination of known elements (in Freedman, Caple, and Graham) according to known methods to obtain predictable results in advancing medical care, and therefore would have been obvious to one of ordinary skill in the art. *See KSR*, 550 U.S. at 415-421; MPEP § 2143.

Below are claim charts comparing claims 1-9 with Freedman, Surwit '699, and Graham:

a. Independent Claims 1, 4 and 7

Independent Claims 1 and 7 of the '985 Patent	**Independent Claim 4 of the '985 Patent**	**Ground 4: Freedman in view of Surwit '699** **Ground 5: Freedman in view of Surwit '699, and further in view of Graham**
1. A method for tracking compliance with treatment guidelines, the method comprising: 7. A computer readable medium having stores thereon instructions for	4. A system for tracking compliance in treating patients, each of the patients having one or more diagnosed conditions, the system comprising:	Freedman – see chart for Ground 1 Surwit '699 – col. 2:40-42 (relates to "methods, systems and computer program products for monitoring, diagnosing, prioritizing and treating medical conditions of a plurality of remotely located patients."); col. 3:22-24 ("tracks whether a patient has performed actions associated with treatment recommended by a user.").

Independent Claims 1 and 7 of the '985 Patent	**Independent Claim 4 of the '985 Patent**	**Ground 4: Freedman in view of Surwit '699** **Ground 5: Freedman in view of Surwit '699, and further in view of Graham**
tracking compliance with treatment guidelines which when executed by a processor, cause the processor to perform the steps of:		Graham – see Ground 3 above, referencing 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 assessment guidelines for each of the diagnosed conditions;	Freedman – see chart for Ground 1 Surwit '699 – col. 8:18-20, 27-31 (describing 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."); col. 8:23-24 (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"); *see also* '985 Patent, col. 1:67-col. 2:4 (admitting that Surwit '699 describes that "medical conditions of a plurality of remotely located patients are monitored, diagnosed,

Independent Claims 1 and 7 of the '985 Patent	**Independent Claim 4 of the '985 Patent**	**Ground 4: Freedman in view of Surwit '699** **Ground 5: Freedman in view of Surwit '699, and further in view of Graham**
		prioritized, and treated using a central data processing system configured to communicate with and receive data from a plurality of respective patient monitoring systems.").
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 updated treatment plan for each of the diagnosed conditions;	Freedman – see chart for Ground 1 Surwit '699 – col. 7:50-53 ("a PPM for a diabetes patient may contain physician-prescribed insulin dosage algorithms ... [and] store blood glucose readings along with other relevant self-monitoring patient data."); col. 7:55-58 ("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."); col. 8:56-58 (describing physician-prescribed insulin dosage algorithms 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."); *see also* col. 7:58-60 ("PPM may be configured to make automatic adjustments to a patient's self-monitoring and treatment regimen based on patient-entered data."); col. 6:55-7:4 (" An exemplary physician-prescribed

Independent Claims 1 and 7 of the '985 Patent	**Independent Claim 4 of the '985 Patent**	**Ground 4: Freedman in view of Surwit '699** **Ground 5: Freedman in view of Surwit '699, and further in view of Graham**
		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."
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	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 – see chart for Ground 1 Surwit '699 – col. 11:16-21 ("Case 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."); col. 10:18-21 ("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."); col. 11:30-33 ("an insulin dosage algorithm contained within the internal

Independent Claims 1 and 7 of the '985 Patent	**Independent Claim 4 of the '985 Patent**	**Ground 4: Freedman in view of Surwit '699** **Ground 5: Freedman in view of Surwit '699, and further in view of Graham**
needed;		software of a particular patient's PPM can be modified remotely by a case manager via a CMC 16."); col. 13:48-52 and Fig. 5 (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)."); col. 13:48-52 ("If a case manager decides to adjust a medicine dosage algorithm within a patient's PPM," Surwit '699 "facilitates this modification though a PAC server the next time communications are established between the PAC server and the patient's PPM (Block 274)").
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	Freedman – see chart for Ground 1 Surwit '699 – col. 13:57-59 (a "patient may be prompted to establish communications between his/her PPM and a PAC server to receive modifications made by a case manager."); col. 13:59-62 ("if a medicine dosage algorithm resides within a PAC server," Surwit '699 provides that "a case manager can instruct the PAC server to adjust medicine dosage and transmit this information to the patient.").
generating and	a compliance system	Freedman – see chart for Ground 1

Independent Claims 1 and 7 of the '985 Patent	**Independent Claim 4 of the '985 Patent**	**Ground 4: Freedman in view of Surwit '699** **Ground 5: Freedman in view of Surwit '699, and further in view of Graham**
providing compliance data based on the updated treatment plan and the reviewed treatment plan for each of the diagnosed conditions.	that generates and provides compliance data based on the reviewed treatment plan and the updated treatment plans.	Surwit '699 – col. 7:28-30 (PPM "[c]ollects patient supplied data on ...compliance to medical regime."); col. 3:14-24 ("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."); col. 19:8-12 (describing "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."). Graham – see Ground 3 above, referencing p. 50:8-18.

b. Dependent Claims 2, 5 and 8

Claims 2, 5, and 8 of '985 Patent	Ground 4: Freedman in view of Surwit '699 Ground 5: Freedman in view of Surwit '699, and further in view of 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 the updated treatment plans for each provider	Freedman – see chart for Ground 1 Graham – see Ground 3 above, referencing p. 50:8-18; p. 52:2-10.

c. Dependent Claims 3, 6 and 9

Claims 3, 6, and 9 of '985 Patent	Ground 4: Freedman in view of Surwit '699 Ground 5: Freedman in view of Surwit '699, and further in view of 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.	Freedman – see chart for Ground 1 Surwit '699 – col. 7:28-30 (a PPM "[c]ollects patient supplied data on... compliance

Claims 3, 6, and 9 of '985 Patent	Ground 4: Freedman in view of Surwit '699 Ground 5: Freedman in view of Surwit '699, and further in view of Graham
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.	to medical regime."); col. 20:64-66 ("the present invention also tracks appointment compliance (e.g., whether a patient kept his/her appointments).").

4. Ground 6 – Claims 1-9 are anticipated under 35 U.S.C. § 102(e) by Surwit '958.

Surwit '958, either explicitly or inherently, describes every element of Claims 1-9 of the '985 patent.

a. Independent Claims 1, 4 and 7

Surwit '958 describes a method, system, and computer readable medium for remote disease management, *i.e.*, tracking compliance with treatment guidelines when treating diagnosed patients. Ex. 1010, col. 7:57-65 ("a system 10 for monitoring, diagnosing, and treating medical conditions of remotely located patients with various chronic illnesses"); col. 6:63-7:7 ("[T]he present method may be embodied as a method, data processing system, or computer program product."). Surwit '958 describes a patient apparatus that "is configured to receive

and analyze information regarding patient compliance with medication and test regimens." Col. 4:47-50. *See also* Ex. 1002 ¶ 58.

As to the "current assessment" limitations, Surwit '958 shows remote patient monitors (*see* Fig. 1, item **12**), and the patient being monitored. *See* Fig. 5 (steps **200** and **202**, identifying a medical condition based on analysis of patients data); Fig. 6 (guidelines for determining a current assessment of a condition); *see also* col. 14: 41-48 ("[O]perations for analyzing patient data transmitted from a PPM to a PAC server to identify medical conditions requiring medical attention or treatment are schematically illustrated."). *See also* Ex. 1002 ¶ 59.

As to the "updating" limitation of claims 1 and 7 (and the corresponding "updates" limitation of claim 4), Surwit '958 describes updating an existing treatment plan based on the existing plan, the assessment, and treatment guidelines. Col. 15:27-35 ("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). If a case manager decides to adjust a medicine dosage algorithm within a patient's PPM, the present invention facilitates this modification though a PAC server the next time communications are established between the PAC server and the patient's PPM"). *See also* col. 8:32-49 ("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; ... April 1997 ... Another ... medication algorithm is described in *Long-term Patient Self-management of Oral/Anticoagulation* ... Arch Intern Med. 1995."). *See also* Ex. 1002 ¶ 60.

As to the "reviewing," "determining" and "changing" limitations of claims 1 and 7 (and the corresponding "review system" limitation of claim 4), Surwit '958 describes a method and system whereby an updated treatment plan is reviewed to determine if changes are needed, and changed if needed. Col. 10:34-39 ("A case manager can make adjustments to a patient's medication dose calculations, to a patient's dosage algorithm, and to a patient's fixed or contingent self-monitoring schedules. These adjustments can be made automatically within a PPM during routine data transfer to a PAC server."); col. 14:10-22 ("If emergency medical conditions are identified (Block 104) . . . . changes may also be made to medicine dosage algorithms stored within a PPM or within the PAC server, such that a patient's next dose of medicine is changed in response to the identified emergency medical condition."). *See also* col. 21:11-14 ("Expert input may be obtained at any step in the review and alteration process, and may involve referencing current patient data and unresolved medical conditions (if any) with a request for help."); col. 21:33-38 ("These latter personnel may be expected to provide either advise [*sic*] in written or other form, or may act directly upon (and publish) the overall

treatment regimen (medication dosages, dosage adjustment algorithm, or the fixed or contingent self-monitoring schedule) which may be conveyed to the Patient's PPM."). *See also* Ex. 1002 ¶ 61.

As to the "providing the patient with the reviewed treatment plan" limitations of claims 1 and 7 (and the corresponding "system that provides the reviewed treatment plan" limitation of claim 4), Surwit '958 describes a method and system for "publishing" (i.e., providing the patient) with the reviewed treatment plan. Col. 20:57-64 ("To make a newly saved prescription (e.g., modified medication doses, modified dosage algorithm(s), and modified fixed and contingent self-monitoring schedules and parameters) available to a patient, a case manager 'publishes' the prescription. Publishing a prescription means that an altered prescription, which may be conveyed to a patient via a PPM, is finalized to a point where it is officially ready to be given to the patient."). *See also* Ex. 1002 ¶ 62.

As to the "generating and providing compliance data" limitation of claims 1 and 7 (and the corresponding "compliance system" limitation of claim 4), Surwit '958 discloses a method and system for generating and providing compliance data based on the treatment plans. Col. 4:47-50 ("A patient apparatus (i.e., an apparatus utilized by a patient according to the present invention) is configured to receive and analyze information regarding patient compliance with

medication and test regimens."). *See also* col. 22:7-9 ("Preferably, the present invention also tracks appointment compliance (e.g., whether a patient kept his/her appointments)."); col. 23:37-41 ("Typically, a patient will interact with a CPM, such as that illustrated in Fig. 2, on a daily basis to assess data, signs, conditions, symptoms, behaviors and compliance with one or more prescribed medication regimens."). *See also* Ex. 1002 ¶ 63.

Below is a claim chart comparing claims 1, 4 and 7 to Surwit '958:

Independent Claims 1 and 7 of the '985 Patent	**Independent Claim 4 of the '985 Patent**	**Surwit '958**
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 diagnosed conditions, the system comprising:	Col. 7:57-65 (referencing Fig. 1, "a system 10 for monitoring, diagnosing, and treating medical conditions of remotely located patients with various chronic illnesses"); col. 6:63-7:7 ("[T]he present method may be embodied as a method, data processing system, or computer program product."); Abstract ("A patient apparatus is configured to receive and analyze information regarding patient compliance...").
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:		
determining a	an assessment	Fig. 5 (steps **200** and **202**, identifying

Independent Claims 1 and 7 of the '985 Patent	Independent Claim 4 of the '985 Patent	Surwit '958
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;	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;	a medical condition based on analysis of patients data); Fig. 6 (guidelines for determining a current assessment of a condition); Col. 14: 41-48("[O]perations for analyzing patient data transmitted from a PPM to a PAC server to identify medical conditions requiring medical attention or treatment are schematically illustrated."); Abstract ("a patient apparatus is configured to receive data from a patient, including physiological data, pathophysiological data, biological data, psychological data, neuropsychological data, and/or behavioral data.").
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	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	Col. 15:27-35 ("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**). If a case manager decides to adjust a medicine dosage algorithm within a patient's PPM, the present invention facilitates this modification though a PAC server the next time communications are established between the PAC server and the patient's PPM"); col. 8:32-49 ("An exemplary physician-prescribed

Independent Claims 1 and 7 of the '985 Patent	**Independent Claim 4 of the '985 Patent**	**Surwit '958**
updated treatment plan for each of the diagnosed conditions;	conditions to generate an updated treatment plan for each of the diagnosed conditions;	medication algorithm is described in *Guidelines for the Diagnosis and Management of Asthma*; Expert Panel Report Two; National Institutes of Health; ... April 1997 ... Another ... medication algorithm is described in *Long-term Patient Self-management of Oral/Anticoagulation* ... Arch Intern Med. 1995.").
reviewing the updated treatment plan for each of the diagnosed conditions;	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;	Col. 10:34-39 ("A case manager can make adjustments to a patient's medication dose calculations, to a patient's dosage algorithm, and to a patient's fixed or contingent self-monitoring schedules. These adjustments can be made automatically within a PPM during routine data transfer to a PAC server."); col. 14:10-22 ("If emergency medical conditions are identified (Block 104) . . . . changes may also be made to medicine dosage algorithms stored within a PPM or within the PAC server, such that a patient's next dose of medicine is changed in response to the identified emergency medical condition."); col. 21:11-14 ("Expert input may be obtained at any step in the **review and alteration process**, and may involve referencing current patient data and unresolved medical conditions (if any) with a request for help."); col. 21:33-38 ("These latter personnel may be expected to provide either advise [*sic*] in written or other
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;		

Independent Claims 1 and 7 of the '985 Patent	Independent Claim 4 of the '985 Patent	Surwit '958
		form, or may act directly upon (and publish) the overall treatment regimen (medication dosages, dosage adjustment algorithm, or the fixed or contingent self-monitoring schedule) which may be conveyed to the Patient's PPM.").
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	Col. 20:57-64 ("To make a newly saved prescription (e.g., modified medication doses, modified dosage algorithm(s), and modified fixed and contingent self-monitoring schedules and parameters) available to a patient, a case manager 'publishes' the prescription. Publishing a prescription means that an altered prescription, which may be conveyed to a patient via a PPM, is finalized to a point where it is officially ready to be given to the patient.")
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.	Col. 4:47-50 ("A patient apparatus (i.e., an apparatus utilized by a patient according to the present invention) is configured to receive and analyze information regarding patient compliance with medication and test regimens."); col. 22:7-9 ("Preferably, the present invention also tracks appointment compliance (e.g., whether a patient kept his/her appointments)."); col. 23:37-41 ("Typically, a patient will interact with a CPM, such as that illustrated in Fig. 2, on a daily basis to assess data, signs, conditions, symptoms, behaviors and compliance with one or

Independent Claims 1 and 7 of the '985 Patent	Independent Claim 4 of the '985 Patent	Surwit '958
		more prescribed medication regimens.").

b. Dependent Claims 2, 3, 5, 6, 8 and 9

Surwit '958 discloses both patient compliance data and provider compliance data. As to patient compliance, the patient compliance data relates to the patient's "compliance with medication and test regimens" (*i.e.*, the existing treatment plan). *See* Ex. 1010, col. 4:47-50 ("A patient apparatus (i.e., an apparatus utilized by a patient according to the present invention) is configured to receive and analyze information regarding patient compliance with medication and test regimens."); col. 22:7-9 ("Preferably, the present invention also tracks appointment compliance (e.g., whether a patient kept his/her appointments)."); col. 23:37-41 ("Typically, a patient will interact with a CPM, such as that illustrated in Fig. 2, on a daily basis to assess data, signs, conditions, symptoms, behaviors and compliance with one or more prescribed medication regimens."). *See also* Ex. 1002 ¶¶ 63-64.

As to physician compliance, Surwit '958 teaches that "screening mechanisms are provided for ensuring that treatment or information provided by a case manager is medically qualified for a particular patient before the treatment or information is communicated to a patient or to a patient's PPM." Col. 20:25-29. *See also* Ex. 1002 ¶ 64.

Below is a claim chart comparing Claims 2, 3, 5, 6, 8 and 9 to Surwit '958:

Claims 2, 3, 5, 6, 8 and 9 of the '985 Patent	**Surwit '958**
2. The method as set forth in claim 1 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.	Surwit '958 discloses both patient compliance data and provider compliance data. Col. 4:47-50 ("A patient apparatus (i.e., an apparatus utilized by a patient according to the present invention) is configured to receive and analyze information regarding patient compliance with medication and test regimens."); col. 22:7-9 ("Preferably, the present invention also tracks appointment compliance (e.g., whether a patient kept his/her appointments)."); col. 23:37-41 ("Typically, a patient will interact with a CPM, such as that illustrated in Fig. 2, on a daily basis to assess data, signs, conditions, symptoms, behaviors and compliance with one or more prescribed medication regimens."). Col. 20:25-29 ("Preferably, screening mechanisms are provided for ensuring that treatment or information provided by a case manager is medically qualified for a particular patient before the treatment or information is communicated to a patient or to a patient's PPM.")
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.	
5. The system as set forth in claim 4 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.	
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.	
8. The medium as set forth in claim 7 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.	
9. The medium as set forth in claim 7 wherein the compliance data further	

Claims 2, 3, 5, 6, 8 and 9 of the '985 Patent	Surwit '958
comprises data on patient compliance with at least one of the existing treatment plan for each diagnosed condition.	

5. Ground 7 – Claims 2, 5 and 8 are obvious under 35 U.S.C. § 103(a) over Surwit '958 in view of Freedman alone, or further in view of Graham

As explained above with regard to Ground 6, every element of claims 2, 5 and 8 of the '985 patent is taught by Surwit '958. However, Freedman and Graham provide additional explicit discussion related to providing compliance data that 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, as recited in dependent claims 2, 5 and 8. Ex. 1002 ¶ 65.

A person of ordinary skill in the art would be motivated to combine Freedman and Graham with Surwit '958 because each is concerned with tracking compliance with medical treatment guidelines. Both Freedman and Surwit '958 deal with remote healthcare and patient treatment. Ex. 1010 (Surwit '958) col. 7:57-65, col. 4:47-50; Ex. 1006 (Freedman), col. 3:24-35; col. 4:5-12, 26-28. *See also* Ex. 1002 ¶ 66-69.

Surwit '958 teaches tracking provider compliance, as explained above. *See also* Ex. 1010, col. 20:25-29 ("screening mechanisms are provided for ensuring

that treatment or information provided by a case manager is medically qualified for a particular patient before the treatment or information is communicated to a patient or to a patient's PPM."). Freedman and Graham amplify this compliance step. Freedman describes systems and methods that generate and provide compliance data ("monitoring data on consistency of clinician treatment with treatment guidelines"). (Freedman, col. 2:63-3:5). Specifically, Freedman discloses that the "system determines suggested treatments" (i.e., "the updated treatment plan") that are based on "recommendations from treatment guidelines" and "highlights them for the clinician." Fig. 4c, element 170. The clinician then reviews and "selects" a treatment plan (i.e., the "reviewed treatment plan.") Fig. 4c, element 172. The system then determines whether the selected treatment plan is "consistent with the treatment guidelines," and if not the system "stores the sequence for quality review" (i.e., generates and provides compliance data). Col. 5:14-15, 30; Fig. 4c, element 174, 184. *See also* Ex. 1002, ¶ 66.

Graham further 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. Graham recognizes a need to generate reports and analysis for individuals and institutions, and indicating deviations from a recommended course of treatment for a physician. Graham, at 3:9-26; 5:1-17;

50:8-18; 52:2-10; *see also* Ex. 1002, ¶ 67.

One of ordinary skill in the art would have been motivated to combine this element of Freedman and Graham with the method of Surwit '958 because Freedman and Graham teach the desirability and advantages of a quality review compliance method based on assessments of treatment plans (Freedman, col. 1:10-13; *see also* col. 2:12-15; Graham, p.50, ll. 8-18), and the person of ordinary skill, from Freedman and Graham, would want to add a detailed quality review assessment to the overall method of Surwit '958 – which already discloses assessing provider compliance – for providing an improved healthcare outcome. Apart from the explicit teachings of the references, one of ordinary skill in the art would have been motivated to combine the references for the provision of a more efficient and cost-contained healthcare system. *See* MPEP §2143; *See also* Ex. 1002 ¶¶ 66-69.

6. Ground 8 - Claims 1, 3, 4, 6, 7 and 9 are anticipated under 35 U.S.C. § 102(b) by Goodman

a. Independent Claims 1, 4, and 7

Goodman describes a method, system, and computer readable medium useable for remote disease management and personal health monitoring, *i.e.*, tracking compliance with treatment guidelines when treating diagnosed patients. *See* Ex. 1011, Fig. 1; col. 2:51-53 ("The host computer, which is operated by a party other than the patient or health care provider, functions as a central station for

collecting, analyzing and routing data."). Goodman discloses tracking patient compliance data. Col. 4:39-65 ("the message unit 20 stores a record of the so-called compliance data, including the date and time the switch was activated and the medication and dosage that the patient was scheduled to take... [T]he compliance data can be uploaded to the host computer 30."). *See also* Ex. 1002 ¶ 71.

As to the "current assessment" limitations, Goodman describes an assessment method and system that determines an assessment of a remote patient's previously diagnosed condition based on data from the patient and an algorithm based on guidelines. Col. 8:37-62 ("In one embodiment...logic sequences or algorithms 115 are developed based on a treatment plan or guidelines for a specific patient, which plan is provided by the primary provider 4. Such algorithms 115 can be converted to code suitable for implementation in a processor... The algorithm 115 accepts as input at least one indicia of the patient's then current health status. Such indicia can include a measurement of a physiological parameter such as pulse rate, peak flow, blood pressure and the like... The input is processed according to the algorithm... Since the treatment plan is developed specifically for the patient, and since the algorithm 115 based on the treatment plan accepts an indicia of the patient's then current health status, message content is thus customized for the patient and responsive to changes in the patient's health

status."). *See also* Ex. 1002 ¶ 72.

As to the "updating" limitation of claims 1 and 7 (and the corresponding "updates" limitation of claim 4), Goodman describes a system and method for updating an existing treatment plan based on the existing plan, the assessment, and treatment guidelines. Col. 2:67-3:4 ("The algorithm can be modified by the health care provider, as appropriate, to reflect changes in the treatment plan. As a result, the message device incorporates a customized treatment plan that is updatable based on data provided by the patient and the health care provider."); Col. 10:54-60 ("If the message device 20 is remotely programmable, the primary provider 4 or the third party facility 3 can conveniently modify the treatment algorithm as appropriate."). *See also* Ex. 1002 ¶ 73.

As to the "reviewing" and "determining" limitations of claims 1 and 7 (and the corresponding "review system" limitation of claim 4), Goodman describes a system and method whereby an updated treatment plan is reviewed to determine if changes are needed, and changed if needed. Col. 8:25-32 ("In some of the above-described embodiments, patient information including physiological data obtained from medical devices 70 is collected over a period of time, e.g., days, and then analyzed and reported to the primary provider 4. The primary provider 4 reviews such data and then may adjust the patient's treatment regimen as appropriate."); Fig. 10B (step 162); *see also* Fig. 10A (steps 130, 132, 134, and 138). *See also*

Ex. 1002 ¶ 74.

As to the "providing" limitation of claims 1 and 7 (and the corresponding "presentation system" limitation of claim 4), Goodman describes a method and system for providing the patient with the reviewed treatment plan. Col. 8:49-51 ("The input is processed according to the algorithm, and the results of the processing are delivered to the patient 2 as a message."); Fig. 10A (steps 134, 138, and 140); Fig. 10B (steps 162, 168, 170, and 172). *See also* Ex. 1002 ¶ 75.

As to the "generating and providing compliance data" limitation of claims 1 and 7 (and the corresponding "compliance system" limitation of claim 4), Goodman discloses a method and system for generating and providing compliance data based on the treatment plans. Col. 4:39-65 ("In one embodiment, the message device 20 provides a medication alarm. ... The patient turns off the alert by activating a switch 22 which also causes a programmable memory 23 to store the date and time the switch was activated. Hence, the message unit 20 stores a record of the so-called compliance data, including the date and time the switch was activated and the medication and dosage that the patient was scheduled to take ... [T]he compliance data can be uploaded to the host computer 30."). *See also* Ex. 1002 ¶ 76.

Below is a claim chart comparing claims 1, 4 and 7 to Goodman:

Independent Claims 1 and 7 of the '985 Patent	**Independent Claim 4 of the '985 Patent**	**Goodman**
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 diagnosed conditions, the system comprising:	Fig. 1; col. 2:51-53 ("The host computer, which is operated by a party other than the patient or health care provider, functions as a central station for collecting, analyzing and routing data.").
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:		
determining a current assessment of one or more diagnosed conditions in a patient based on data	an assessment processing system that determines a current assessment of each of the	Col. 8:37-62 ("In one embodiment . . . logic sequences or algorithms **115** are developed based on a treatment plan or guidelines for a specific patient, which plan is provided by
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;	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	the primary provider 4. Such algorithms **115** can be converted to code suitable for implementation in a processor . . . . The algorithm **115** accepts as input at least one indicia of the patient's then current health status. Such indicia can include a measurement of a physiological parameter such as pulse rate, peak flow, blood pressure and the like ...

Independent Claims 1 and 7 of the '985 Patent	Independent Claim 4 of the '985 Patent	Goodman
	assessment guidelines for each of the diagnosed conditions;	The input is processed according to the algorithm. . . . Since the treatment plan is developed specifically for the patient, and since the algorithm **115** based on the treatment plan accepts an indicia of the patient's then current health status, message content is thus customized for the patient and responsive to changes in the patient's health status.")
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 updated treatment plan for each of the diagnosed conditions;	Col. 2:67-3:4 ("The algorithm can be modified by the health care provider, as appropriate, to reflect changes in the treatment plan. As a result, the message device incorporates a customized treatment plan that is updatable based on data provided by the patient and the health care provider."); Col. 10:54-60 ("If the message device 20 is remotely programmable, the primary provider 4 or the third party facility 3 can conveniently modify the treatment algorithm as appropriate.")
reviewing the updated treatment	a review system that modifies the	Col. 8:25-32 ("In some of the above-described embodiments, patient

Independent Claims 1 and 7 of the '985 Patent	**Independent Claim 4 of the '985 Patent**	**Goodman**
plan for each of the diagnosed conditions;	updated treatment plan if one or more changes are determined to be needed and provides a reviewed treatment plan;	information including physiological data obtained from medical devices 70 is collected over a period of time, e.g., days, and then analyzed and reported to the primary provider 4. The primary provider 4 reviews such data and then may adjust the patient's treatment regimen as appropriate."); Fig. 10B (step **162**); See also Fig. 10A (steps **130**, **132**, **134**, and **138**).
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;		
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	Col. 8:49-51 ("The input is processed according to the algorithm, and the results of the processing are delivered to the patient **2** as a message."); Fig. 10A (steps **134**, **138**, and **140**); Fig. 10B (steps **162**, **168**, **170**, and **172**).
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.	Col. 4:39-65 ("In one embodiment, the message device **20** provides a medication alarm. . . . The patient turns off the alert by activating a switch **22** which also causes a programmable memory **23** to store the date and time the switch was activated. Hence, the message unit **20** stores a record of the so-called compliance data, including the date and time the switch was activated and the medication and dosage that

Independent Claims 1 and 7 of the '985 Patent	Independent Claim 4 of the '985 Patent	Goodman
		the patient was scheduled to take. . . . [T]he compliance data can be uploaded to the host computer **30**.").

b. Dependent Claims 3, 6 and 9

Goodman discloses patient compliance data reflecting compliance with a treatment plan. Ex. 1011, col. 4:39-65 ("In one embodiment, the message device 20 provides a medication alarm. . . . The patient turns off the alert by activating a switch 22 which also causes a programmable memory 23 to store the date and time the switch was activated. Hence, the message unit 20 stores a record of the so-called compliance data, including the date and time the switch was activated and the medication and dosage that the patient was scheduled to take. . . . [T]he compliance data can be uploaded to the host computer 30."). *See also* Ex. 1002 ¶ 76.

Below is a claim chart comparing claims 3, 6 and 9 to Goodman:

Claims 3, 6 and 9 of the '985 Patent	Goodman
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.	Col. 4:39-65 ("In one embodiment, the message device **20** provides a medication alarm. . . . The patient turns off the alert by activating a switch **22** which also causes a programmable memory **23** to store the date and time the switch was activated. Hence, the message unit **20** stores a record of the so-called
6. The system as set forth in claim 4 wherein the compliance data further comprises data on patient compliance	

Claims 3, 6 and 9 of the '985 Patent	Goodman
with at least one of the existing treatment plan for each diagnosed condition.	compliance data, including the date and time the switch was activated and the medication and dosage that the patient was scheduled to take. . . . [T]he compliance data can be uploaded to the host computer **30**.").
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.	

7. Ground 9 – Claims 2, 5 and 8 are obvious under 35 U.S.C. § 103(a) over Goodman in view of Freedman alone, or further in view of Graham

As explained above with regard to Ground 8, every element of claims 1, 3, 4, 6, 7, and 9 of the '985 patent is taught by Goodman. Freedman and Graham provide additional explicit discussion related to providing compliance data that 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, as recited in dependent claims 2, 5 and 8. Ex. 1002 ¶ 77.

A person of ordinary skill in the art would be motivated to combine Freedman and Graham with Goodman because each is concerned with remote healthcare and efficient patient diagnosis and treatment. Ex. 1011 (Goodman) col. 2:36-41; Ex. 1006 (Freedman), col. 3:24-35; col. 4:5-12, 26-28; Ex. 1008 (Graham) p. 2:6-7.; p. 3:9-26. *See also* Ex. 1002 ¶ 77-81.

Freedman and Graham both teach the advantages of tracking provider compliance, from both a public health and an economic perspective. Freedman

describes systems and methods that generate and provide compliance data ("monitoring data on consistency of clinician treatment with treatment guidelines"). (Freedman, col. 2:63-3:5). Specifically, Freedman discloses that the "system determines suggested treatments" (i.e., "the updated treatment plan") that are based on "recommendations from treatment guidelines" and "highlights them for the clinician." Fig. 4c, element 170. The clinician then reviews and "selects" a treatment plan (i.e., the "reviewed treatment plan.") Fig. 4c, element 172. The system then determines whether the selected treatment plan is "consistent with the treatment guidelines," and if not the system "stores the sequence for quality review" (i.e., generates and provides compliance data). Col. 5:14-15, 30; Fig. 4c, element 174, 184. *See also* Ex. 1002, ¶ 78.

Graham further 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. Graham recognizes a need to generate reports and analysis for individuals and institutions, and indicates deviations from a recommended course of treatment for a physician. Graham, at 3:9-26; 5:1-17; 50:8-18; 52:2-10; *see also* Ex. 1002, ¶ 79.

One of ordinary skill in the art would have been motivated to combine this element of Freedman and Graham with the method of Goodman because Freedman

and Graham teach the desirability and advantages of a quality review compliance method based on assessments of treatment plans (Freedman, col. 1:10-13; *see also* col. 2:12-15; Graham, p. 50, ll. 8-18), and the person of ordinary skill, from Freedman and Graham, would want to add a detailed quality review assessment to the overall method of Goodman for providing an improved healthcare outcome. Apart from the explicit teachings of the references, one of ordinary skill in the art would have been motivated to combine the references for the provision of a more efficient and cost-contained healthcare system. *See* MPEP §2143; *See also* Ex. 1002 ¶¶ 80-81.

V. CONCLUSION

In view of the foregoing, Petitioner respectfully requests institution of *inter partes* review of claims 1-9 of the '985 patent on the basis of the nine (9) grounds set forth above. It is submitted that there is a likelihood that Petitioner will prevail in showing that at least one claim of the '985 patent is invalid.

Accordingly, *inter parties* review of the '985 patent should be granted.

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Respectfully Submitted,
/Don Daybell/
Don Daybell, Reg. No. 50,877
James Maune, Reg. No. 67,187
ORRICK, HERRINGTON, & SUTCLIFFE LLP
2050 Main St., Suite 1100
Irvine, CA 92614
Counsel for Robert Bosch Healthcare Systems, Inc.

CERTIFICATION OF SERVICE (37 C.F.R. §§ 42.6(e), 42.105(a))

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(b), the undersigned certifies that on May 18, 2015 a complete and entire copy of this Petition for *Inter Partes* Review was provided via Federal Express to the Patent Owner by serving the correspondence address of record for the '985 Patent and Patent Owner's litigation counsel:

Gunnar G. Leinberg
Edwin V. Merkel
LeClairRyan, A Professional Corporation
70 Linden Oaks
Suite 210
Rochester NY 14625

A courtesy copy was provided to Counsel for Petitioners in IPR2015-00102:

Jeffrey Olson, Reg. No. 30,790
Sidley Austin LLP
555 W. Fifth St., Ste. 4000
Los Angeles, CA 90013
jolson@sidley.com

A courtesy copy was provided to Patent Owner's litigation counsel:

Joseph G. Pia
Joseph Shapiro, Reg. No. 66,774
Pia Anderson Dorius & Reynard
222 South Main
Suite 1830
Salt Lake City, Utah 84101
joe.pia@padrm.com
jshapiro@padrm.com

By: */Karen Johnson*

Karen Johnson

PETITION FOR INTER PARTIES REVIEW

OF U.S. PATENT NO. 6,612,985

Attachment B:

List of Evidence and Exhibits Relied Upon in Petition

Exhibit 1001	U.S. Patent No. 6,612,985, to Eiffert et al.
Exhibit 1002	Declaration by Bryan Bergeron, M.D.
Exhibit 1003	Response dated 2/10/2003, U.S. Patent App. No. 09/793,191
Exhibit 1004	Notice of Allowance dated 3/31/2003, U.S. Patent App. No. 09/793,191
Exhibit 1005	Decision instituting *inter partes* review of claims 1-9 of U.S. Patent No. 6,612,985, dated November 19, 2013
Exhibit 1006	U.S. Patent No. 6,126,596 to Freedman
Exhibit 1007	PCT Publication No. WO 99/04043 to Caple et al.
Exhibit 1008	PCT Publication No. WO 98/58338 to Graham et al.
Exhibit 1009	U.S. Patent No. 6,024,699 to Surwit et al. (Surwit ’699)
Exhibit 1010	U.S. Patent No. 6,980,958 to Surwit et al. (Surwit ’958)
Exhibit 1011	U.S. Patent No. 5,827,180 to Goodman
Exhibit 1012	Decision instituting *inter partes* review of claims 1-9 of U.S. Patent No. 6,612,985, dated April 16, 2015