IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent of:	Michael E. Eiffert, et al.
U.S. Patent No.:	6,612,985
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Appl. Serial No.:	09/793,191
Filing Date:	February 26, 2001
Title:	METHOD AND SYSTEM FOR MONITORING AND TREATING A PATIENT
IPR Control No.:	IPR2017-00312

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PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,612,985
PURSUANT TO 35 U.S.C. §§ 311–319, 37 C.F.R. § 42

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EXHIBIT LIST

EXHIBIT 1001	U.S. Patent No. 6,612,985 to Eiffert, et al. ("the '985 Patent")
EXHIBIT 1002	'985 Patent File History: February 10, 2003 Response to Office Action
EXHIBIT 1003	'985 Patent File History: March 31, 2003 Notice of Allowance
EXHIBIT 1004	Declaration of Bryan P. Bergeron, M.D. ("Decl.")
EXHIBIT 1005	Curriculum Vitae of Bryan P. Bergeron, M.D.
EXHIBIT 1006	DECISION instituting *inter partes* review of claims 1-9 of U.S. Patent No. 6,612,985, dated November 19, 2013 (Case IPR2013-00320)
EXHIBIT 1007	DECISION instituting *inter partes* review of claims 1-9 of U.S. Patent No. 6,612,985, dated April 16, 2015 (Case IPR2015-00102)
EXHIBIT 1008	U.S. Patent No. 6,126,596 to Freedman ("Freedman")
EXHIBIT 1009	PCT Publication No. WO 99/04043 to Caple, et al. ("Caple")
EXHIBIT 1010	PCT Publication No. WO 98/58338 to Graham, et al. ("Graham")
EXHIBIT 1011	U.S. Patent No. 6,024,699 to Surwit, et al. ("Surwit '699")
EXHIBIT 1012	U.S. Patent No. 9,980,958 to Surwit, et al. ("Surwit '958")
EXHIBIT 1013	U.S. Patent No. 5,827,180 to Goodman ("Goodman")

I. INTRODUCTION

McKesson Corporation, McKesson Technologies Inc., InTouch Technologies, Inc., and Medical Depot, Inc. ("Petitioners") petition for *Inter Partes* Review ("IPR") under 35 U.S.C. §§ 311–319 and 37 C.F.R. § 42 of claims 1-9 ("the Challenged Claims") of U.S. Patent No. 6,612,985. As explained in this Petition, there exists a reasonable likelihood that Petitioners will prevail with respect to at least one of the Challenged Claims.

The Challenged Claims have been the subject of four prior IPR petitions, all terminated prior to a final written decision:

Case	**Filed**	**Institution Decision / Disposition**
IPR2013-00320	May 31, 2013	November 19, 2013 – petition granted (Ex. 1006) February 20, 2014 – terminated pursuant to settlement
IPR2014-00435	February 14, 2014	June 6, 2014 – terminated pursuant to settlement prior to institution decision
IPR2015-00102	October 21, 2014	April 16, 2015 – petition granted (Ex. 1007) July 28, 2015 – terminated pursuant to settlement
IPR2015-01218	May 18, 2015	July 28, 2015 – terminated pursuant to settlement prior to institution

Petitioners' present petition seeks review on the same grounds, among others, on which review was instituted in IPR2013-00320 and IPR2015-00102. The Challenged Claims are unpatentable based on teachings set forth in at least the refer-

ences presented in this Petition. Petitioners respectfully submit that an IPR should be instituted, and that the Challenged Claims should be canceled as unpatentable.

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

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

Petitioners McKesson Corporation, McKesson Technologies Inc., InTouch Technologies, Inc., and Medical Depot, Inc. are the real parties-in-interest.

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

Petitioners are not aware of any disclaimers, reexamination certificates, or pending petitions for *inter partes* review for the '985 Patent. The '985 Patent is the subject of the following civil actions:

- *My Health, Inc. v. McKesson Technologies Inc.*, Case No. 2:16-cv-00881, Eastern District of Texas (Marshall Division)
- *My Health, Inc. v. InTouch Technologies, Inc.*, Case No. 2:16-cv-00536, Eastern District of Texas (Marshall Division)
- *My Health, Inc. v. DeVilbiss Healthcare, LLC*, Case No. 2:16-cv-00544, Eastern District of Texas (Marshall Division)
- *My Health, Inc. v. MyNetDiary, Inc.*, Case No. 2:16-cv-00866, Eastern District of Texas (Marshall Division)
- *My Health, Inc. v. ALR Technologies, Inc.*, Case No. 2:16-cv-00535,

Eastern District of Texas (Marshall Division)[1]

- *Human Design Medical, LLC v. My Health, Inc.*, Case No. 1:16-cv-00767, District of Delaware
- *Fit4D, Inc. v. My Health, Inc.*, Case No. 1:16-cv-01076, District of Delaware

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

Petitioners provide the following designation of counsel:

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[1] The pending Eastern District of Texas civil actions are consolidated for pre-trial purposes in lead Case No. 2:16-cv-00535.

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D. Service Information

Please address all correspondence and service to the address listed above. Petitioners consent to electronic service by email to wqureshi@jw.com, crourk@jw.com, and dnguyen@lockelord.com.

III. PAYMENT OF FEES – 37 C.F.R. § 42.103

Petitioners have paid the fee specified by 37 C.F.R. § 42.15(a) in connection with the filing of this Petition.

IV. REQUIREMENTS FOR IPR UNDER 37 C.F.R. § 42.104

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

Petitioners certify that the '985 Patent is available for IPR. The present petition is not being filed more than one year from service of any complaints against Petitioners alleging infringement of the '985 Patent. Petitioners are not barred or estopped from requesting this review challenging the Challenged Claims on the below-identified grounds.

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

Petitioners request an IPR of the Challenged Claims on the grounds set forth in the table shown below and request that each of the Challenged Claims be found unpatentable and canceled. An explanation of how these claims are unpatentable is

provided in the form of detailed description and claim charts. Additional support for each ground of rejection is set forth in Exhibit 1004, the Declaration of Bryan P. Bergeron, M.D. ("Decl."), referenced throughout this Petition.

Pursuant to 35 U.S.C. § 314(a), Petitioners meet 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.

Ground	'985 Patent Claims	Basis for Rejection
Ground 1	1-9	§ 102: Freedman
Ground 2	1-9	§ 103: Freedman in view of Caple
Ground 3	1-9	§ 103: Freedman in view of Caple and Graham
Ground 4	1-9	§ 103: Freedman in view of Surwit '699
Ground 5	1-9	§ 103: Freedman in view of Surwit '699 and Graham
Ground 6	1-9	§ 102: Surwit '958
Ground 7	2, 5, and 8	§ 103: Surwit '958 in view of Freedman and Graham
Ground 8	1, 3, 4, 6, 7, and 9	§ 102: Goodman
Ground 9	2, 5, and 8	§ 103: Goodman in view of Freedman and Graham

The '985 Patent issued on September 2, 2003, maturing from U.S. Patent

Application No. 09/793,191 filed on February 26, 2001. Each reference relied on herein pre-dates the '985 Patent and qualifies as prior art as follows:

Reference	Date	Prior art
Freedman	June 2, 1997 (filed) October 3, 2000 (issued)	§ 102(e) § 102(a)
Caple	January 28, 1999 (published)	§ 102(b)
Graham	December 23, 1998 (published)	§ 102(b)
Surwit '699	February 15, 2000 (issued)	§ 102(b)
Surwit '958	January 11, 2000 (filed)	§ 102(e)
Goodman	October 27, 1998	§ 102(b)

Freedman, Caple, Graham, Surwit '958, and Goodman were not made of record during prosecution of the '985 Patent. Surwit '699 was made of record during prosecution of the '985 Patent but was not relied on by the Examiner for a ground of rejection or otherwise.

V. SUMMARY OF THE '985 PATENT

A. Described Subject Matter

Petitioners reference the Board's previous discussion on background of the '985 Patent. *See* Ex. 1006, pp. 3-4; Ex. 1007, pp. 2-4.

B. The '985 Patent Claims

The '985 Patent has 9 claims: independent claim 1, with claims 2 and 3 dependent therefrom; independent claim 4, with claims 5 and 6 dependent therefrom;

and independent claim 7, with claims 8 and 9 dependent therefrom.

The claims recite the purported invention broadly and at a high level of abstraction, and generally speaking, do not delve into computational, algorithmic, or implementation details. This is especially true of independent claim 1:

> 1. A method for tracking compliance with treatment guidelines, the method comprising:
>
> 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;
>
> 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;
>
> reviewing the updated treatment plan for each of the diagnosed conditions;
>
> determining if one or more changes are needed to the reviewed treatment plan for each of the diagnosed conditions;
>
> changing the reviewed treatment plan if the one or more changes are determined to be needed;
>
> providing the patient with the reviewed treatment plan for each of the

diagnosed conditions; and

generating and providing compliance data based on the updated treatment plan and the reviewed treatment plan for each of the diagnosed conditions.

Independent claims 4 and 7 are substantially similar to independent claim 1, directed respectively to "a system" and "a computer readable medium."

C. Level of Ordinary Skill in the Art

A person of ordinary skill in the art ("POSITA") as of the critical date would have at least three years of computer network experience and at least one year of experience in a clinical environment. Decl., ¶ 23. Alternatively, a POSITA with less than the amount of experience noted above could have had a correspondingly greater amount of education or training in the relevant field. *Id.*

D. Claim Construction under 37 C.F.R. §§ 42.104(b)(3)

The Board applied the BRI standard in construing certain claim terms of the '985 Patent in IPR2013-00320 and IPR2015-00102. *See* Ex. 1006, pp. 5-6; Ex. 1007, p. 7. Those constructions were adopted in consideration of Patent Owner's arguments. For purposes of this petition, Petitioners rely on the Board's constructions set forth in IPR2015-00102. Ex. 1007, pp. 7-10.

VI. MANNER OF APPLYING CITED PRIOR ART TO EVERY CLAIM FOR WHICH AN IPR IS REQUESTED

This request shows how the cited references disclose the limitations of the Challenged Claims, thereby invalidating claims 1-9 of the '985 Patent. As detailed

below, this request shows a reasonable likelihood that the Petitioners will prevail with respect to at least one of claims 1-9 of the '985 Patent. Petitioners submit that the grounds detailed below are set forth under the Board's claim constructions discussed in Section V.D *supra*.

A. Previously Instituted *Inter Partes* Review of Claims 1-9 of the '985 Patent

Claims 1-9 of the '985 Patent were the subject of *inter partes* reviews in IPR2013-00320 and IPR2015-00102. *See* Exhs. 1006 and 1007. In both, review was instituted on Grounds 1, 3, and 5 listed above. *See* Ex. 1006, p. 25; Ex. 1007, p. 20. Petitioners agree with and reiterate the Board's prior reasoning for instituting *inter partes* review of claims 1-9 of the '985 Patent. *See* Ex. 1006, pp. 12-25; Ex. 1007, pp. 10-19.

B. GROUND 1: Freedman anticipates claims 1-9 of the '985 Patent

1. Overview of Freedman

Petitioners reference the Board's previous overview discussion of Freedman. *See* Ex. 1006, p. 10; Ex. 1007, p. 10.

2. Independent claims 1, 4, and 7

Freedman discloses a method, system, and computer readable medium useable for tracking compliance with treatment guidelines when treating diagnosed patients. Freedman discloses a "computer based system" that "can monitor how congruent a medical provider's treatment decisions are with treatment guidelines."

Freedman: col. 1:10-13, 2:12-15. *See also* Decl., ¶¶ 31, 32.

As to the "current assessment" limitations, Freedman discloses an assessment processing system that determines a current assessment of each of the diagnosed conditions based on data about each of the diagnosed conditions from the patient, and based on one or more assessment guidelines for each of the diagnosed conditions. In Freedman, a patient (client) provides data about his/her condition in response to questions asked by a computer. *See* Freedman: col. 4:5-12. The patient receiving a current assessment may have a "previously assigned diagnosis" which is the subject of that current assessment. *Id*. at col. 4:5-12, Fig. 3b (elements 116, 118)). The patient from whom data is received is located at a remote location. *Id*. at col. 3:24-35. The current assessment (step 152 in Fig. 4a) is also based on assessment guidelines (e.g., "suggested DSM-IV criteria"). *Id*. at col. 4:30-38, Fig. 4a. *See also* Decl., ¶ 32.

As to the "updating" limitation of claims 1 and 7 (and the corresponding "updates" limitation of claim 4), Freedman also discloses, 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, 120), the clinician selected diagnosis(es) (Fig. 4a, elements 152, 154), and treatment guidelines (Fig. 4a, element 152; Fig. 4c, element 170). Freedman: col. 4:30-38, 5:6-8, Figs. 4a-c.

The previously assigned diagnosis(es) may have been associated with, *e.g.*, "medication history" (col. 6:48-62) – *i.e.*, an "existing treatment plan" as previously addressed by the Board. Ex. 1007, p. 12 ("we are not persuaded . . . that information about prior medication history, as disclosed in Freedman, fails to constitute an existing treatment plan, as claimed"). *See also* Decl., ¶ 33.

As to the "reviewing" and "determining" limitations of claims 1 and 7 (and the corresponding "review system" limitation of claim 4), Freedman discloses a "graphical display" for the clinician to review suggested diagnostic and treatment data. Freedman: col. 4:38-40. The clinician can "override treatment guidelines" and select a treatment plan on screen which deviates from the suggested treatment guidelines. *Id*. at col. 2:63–3:2, 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.* at col. 5:8-9. *See also* Decl., ¶¶ 34, 35.

As to the "providing" limitation of claims 1 and 7 (and the corresponding "presentation system" limitation of claim 4), Freedman discloses providing information associated with the reviewed treatment plan for each of the diagnosed conditions to the patient for review. Freedman: 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 dis-

closes reviewing past treatments to determine whether a patient successfully used certain medications and providing new treatments accordingly. *Id.* at 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. *Id*. at 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 discloses presenting a treatment plan to a clinician for review. *Id*. at col. 5:7-17, Fig. 4c ("in block 172, the clinician selects a treatment plan on screen") . *See also* Decl., ¶¶ 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 discloses 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." Freedman: 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"). *Id.* at 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." *Id.* at Fig. 4C (element 170). The clinician then reviews and "selects" a treatment plan (i.e., the "reviewed treatment plan."). *Id*. at 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). *Id*. at col. 5:14-30, Fig. 4C (elements 174, 184). *See also* Decl., ¶¶ 39-41.

Below is a claim chart illustrating Freedman's disclosure of each of the limitations in claims 1, 4, and 7 of the '985 Patent[2]:

Claims 1 and 7	**Claim 4**	**Freedman (Ex. 1008)**
1. A method for tracking compliance with treatment guidelines, the method comprising: 7. A computer readable medium having stored thereon instructions for tracking	4. A system for tracking compliance in treating patients, each of the patients having one or more diagnosed conditions, the system comprising:	Col. 1:10-13 ("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."); 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*** . . . .").

[2] All emphasis has been added unless otherwise noted.

Claims 1 and 7	Claim 4	Freedman (Ex. 1008)
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 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;	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 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").
updating an existing treatment plan for each of the diagnosed conditions based on the existing treatment	a treatment processing system that updates an existing treatment plan for each of the diagnosed conditions based on the existing treat-	Col. 4:30-38; 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, 120) and col. 6:48-62 (based on answers to follow up

Claims 1 and 7	Claim 4	Freedman (Ex. 1008)
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;	ment 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;	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; Fig. 4c (element 170) (treatment guidelines).
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, ***allow 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."); Fig. 4c (block 172).
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	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.");

Claims 1 and 7	Claim 4	Freedman (Ex. 1008)
		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; col. 7:10; Fig. 8b (blocks 196, 200, 218).
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. 2:63–3:5 ("The clinician interface 18 may provide the following functions: … ***alert clinician of deviations from guidelines with explanations***, allow a clinician to override treatment guidelines either with or without supervisor signoff. The supervisor interface 14 displays alerts for treatment decisions that require signoff, 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

Claims 1 and 7	Claim 4	Freedman (Ex. 1008)
		stores the sequence for quality review in memory 20 in block 184 and proceeds to specify diagnosis' Treatment Guidelines Module."); Fig. 4c.

3. 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 of the '985 Patent. 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." Freedman: col. 2:11-14, 3:4-5. Freedman discloses that the compliance data can be individual to a particular assessment and particular provider. *Id*. at 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." Decl., ¶ 40.

Below is a claim chart illustrating Freedman's disclosure of each of the limitations in claims 2, 5, and 8 of the '985 Patent:

Claims 2, 5 and 8	Freedman (Ex. 1008)
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.	Col. 2:11-14; col. 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.

4. 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 of the '985 Patent. 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." Freedman: 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 (col. 6:49-58, 6:67–7:1) would thus include data relating to patient compliance with an existing treatment plan. Decl., ¶ 41.

Below is a claim chart illustrating Freedman's disclosure of each of the limitations in claims 3, 6, and 9 of the '985 Patent:

Claims 3, 6 and 9	Freedman (Ex. 1008)
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.	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; col. 6:67–7:1 (disclosing data gathered re: patient history).

C. GROUNDS 2 AND 3: Claims 1-9 of the '985 Patent are obvious over Freedman in view of Caple alone, or further in view of Graham

1. Overview of Caple

Petitioners reference the Board's previous overview discussion of Caple. *See* Ex. 1006, pp. 10-11; Ex. 1007, p. 14.

2. Overview of Graham

Petitioners reference the Board's previous overview discussion of Graham.

See Ex. 1006, p. 11; Ex. 1007, pp. 14-15.

3. Independent claims 1, 4, and 7

As shown above, Freedman discloses all elements of the claims of the '985 Patent. Caple, however, provides additional explicit disclosure related to providing the treatment plan to a patient (Decl., ¶¶ 43, 44), a feature that may be deemed inherent in Freedman.

A POSITA would combine Freedman and Caple because, among other reasons, both references deal directly with remote healthcare and patient treatment. *See* Freedman: col. 3:24-35; Caple: p. 5:23-28; Decl., ¶¶ 44-47. Additionally, Freedman discloses the desirability of integrating assessment and treatment guidelines into diagnosis of patients (Freedman: col. 1:64–2:7), 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. Decl., ¶¶ 44-47. Furthermore, Caple explicitly discusses 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 (Caple: p.

13:3-7) based on a test sample sent from a patient at a remote location. Caple: p. 8:22-30, 11:1-5. Caple discloses a system that receives data from a patient (such as "remote sample collection") and performs testing. *Id*. at 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 p. 13:23-24. It would have been obvious to a POSITA that the recommendations would be based both on the test results and assessment guidelines. Decl., ¶ 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*** discloses 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." Caple: pp. 13:30–14:2. The CPU can also "transmit the approved or changed diagnosis and recommendation, via a carrier or transmitter 86 . . . to the patient." *Id*. at p. 12:28- 29, 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 combine the Freedman system with remote patient input and

providing a patient with his/her treatment plan, such as in Caple. Decl., ¶ 47. Such 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. A POSITA 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; Decl., ¶¶ 53, 54. 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, 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. Decl., ¶¶ 53-56. Such

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 is a claim chart illustrating Freedman's, Caple's, and Graham's disclosure of the limitations in claims 1, 4, and 7 of the '985 Patent:

Claims 1 and 7	**Claim 4**	**Ground 2: Freedman in view of Caple** **Ground 3: Freedman in view of Caple and Graham**
1. A method for tracking compliance with treatment guidelines, the method comprising: 7. A computer readable medium having stored thereon instructions for tracking compliance with treatment guidelines which when executed by a processor, cause the processor to perform the steps of:	4. A system for tracking compliance in treating patients, each of the patients having one or more diagnosed conditions, the system comprising:	**Freedman:** *see* chart above for Ground 1. **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 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

Claims 1 and 7	Claim 4	Ground 2: Freedman in view of Caple Ground 3: Freedman in view of Caple and Graham
		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"); p. 5:1-2 ("It is an object of the invention to inform a physician when the physician deviates from a recommended course of action."); p. 12:27-32 (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 condi-	**Freedman:** *see* chart above for Ground 1. **Caple:** p. 8:22-30, p. 11:1-5, p. 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.); pp. 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").

Claims 1 and 7	Claim 4	Ground 2: Freedman in view of Caple Ground 3: Freedman in view of Caple and Graham
	tions;	
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 above for Ground 1. **Caple:** p. 13:3-7 (updating an existing treatment plan for a diagnosed condition); pp. 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 "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

Claims 1 and 7	Claim 4	Ground 2: Freedman in view of Caple Ground 3: Freedman in view of Caple and Graham
		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; determining if one or more changes are needed to the reviewed treatment plan for each of the diagnosed conditions; changing the reviewed treatment plan if the one or more changes are determined to be needed;	a review system that modifies the updated treatment plan if one or more change are determined to be needed and provides a reviewed treatment plan;	**Freedman:** *see* chart above for Ground 1. **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 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***."); pp. 13:30–14:2.
providing the patient with the reviewed treatment plan for each of the diagnosed	a presentation system that provides the reviewed treatment plan for each of the diagnosed condi-	**Freedman:** *see* chart above for Ground 1. **Caple:** pp. 13:30–14:2 ("The process and system will then automat-

Claims 1 and 7	Claim 4	Ground 2: Freedman in view of Caple Ground 3: Freedman in view of Caple and Graham
conditions; and	tions; and	ically 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."); 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 for Ground 1. **Graham:** p. 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.").

4. Dependent claims 2, 5, and 8

Below is a claim chart illustrating Freedman's, Caple's, and Graham's disclosure of the limitations in claims 2, 5, and 8 of the '985 Patent:

Claims 2, 5, and 8	Ground 2: Freedman in view of Caple Ground 3: Freedman in view of Caple and 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	**Freedman:** *see* chart above for Ground 1. **Graham:** p. 50:8-18 ("The pretest assessments per physician report may list the actions selected by physicians

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.	following the pretest risk assessment, ***including any guideline deviations***."); p. 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).").

5. Dependent claims 3, 6, and 9

Below is a claim chart illustrating Freedman's, Caple's, and Graham's disclosure of the limitations in claims 3, 6, and 9 of the '985 Patent:

Claims 3, 6, and 9	**Ground 2: Freedman in view of Caple** **Ground 3: Freedman in view of Caple and Graham**
3. The method as set forth in claim 1 wherein the compliance data further comprises data on patient compliance with at least one of the existing treatment plan for each diagnosed condition. 6. The system as set forth in claim 4 wherein the compliance data further comprises data on patient compliance with at least one of the existing treatment plan for each diag-	**Freedman:** *see* chart above for Ground 1.

Claims 3, 6, and 9	Ground 2: Freedman in view of Caple Ground 3: Freedman in view of Caple and Graham
nosed 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.	

D. GROUNDS 4 AND 5: Claims 1-9 of the '985 Patent are obvious over Freedman in view of Surwit '699 alone, or further in view of Graham

1. Overview of Surwit '699

Petitioners reference the Board's previous overview discussion of Surwit '699. *See* Ex. 1006, pp. 11-12; Ex. 1007, pp. 17-18.

2. Independent claims 1, 4, and 7

As shown above, Freedman alone discloses all elements of the claims of the '985 patent. Surwit '699, however, provides additional explicit disclosure related to providing the treatment plan to a patient. A POSITA 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. Decl., ¶¶ 48, 49. Surwit '699 discloses a "glucose meter 26 that uses patient-entered data and internal software to continuously alter insulin doses as needed." Surwit '699: col. 8:27-28; Decl., ¶ 49. The "software analyzes the entered data" and "calculates adjust-

ments for a patient's insulin dosage according to a physician's prescription as applied to the data entered [] by the patient." Surwit '699: col. 8:41-46; Decl., ¶ 49.

A POSITA would have been motivated to combine Freedman and Surwit '699 because both references describe the benefits of remote patient healthcare. *See* Freedman: col. 3:24-35; Surwit '699: col. 2:26-55, 3:40-55; Decl., ¶¶ 48, 49. Specifically, Freedman describes the desirability of integrating assessment and treatment guidelines into diagnoses of patients (Freedman: col. 1:64–2:7), 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. Decl., ¶¶ 48-52. Yet additional reasons to combine the art include following healthcare guidelines and containing healthcare costs. *Id.* In view of the explicit teachings of Freedman and Surwit '699, as well as the motivations in the art gener-

ally at the time of invention of the '985 Patent, it would have been obvious to combine the Freedman system with remote patient input and to provide the patient with his/her treatment plan as described in Surwit '699. *Id*. Such 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 disclosure 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. A POSITA 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, 3:40-55; Graham:, p. 2:6-7; Decl., ¶¶ 53-56. Additionally, Graham teaches 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 described in Freedman and Surwit '699. Decl., ¶¶ 53-56. Such 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 a POSITA. *See* *KSR*, 550 U.S. at 415-421; MPEP § 2143.

Below is a claim chart illustrating Freedman's, Surwit '699's, and Graham's disclosure of the limitations in claims 1, 4, and 7 of the '985 Patent:

Claims 1 and 7	**Claim 4**	**Ground 4: Freedman in view of Surwit '699** **Ground 5: Freedman in view of Surwit '699 and Graham**
1. A method for tracking compliance with treatment guidelines, the method comprising: 7. A computer readable medium having stores thereon instructions for tracking compliance with treatment guidelines which when executed by a processor, cause the processor to perform the steps of:	4. A system for tracking compliance in treating patients, each of the patients having one or more diagnosed conditions, the system comprising:	**Freedman:** *see* claim chart above 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."). **Graham:** *see* Ground 3 above, referencing Abstract; pp. 5:1-2, 12:27-32.

Claims 1 and 7	Claim 4	Ground 4: Freedman in view of Surwit '699 Ground 5: Freedman in view of Surwit '699 and Graham
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* claim chart above for Ground 1. **Surwit '699:** col. 8:18-20, 27-31 (disclosing 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. 1:67–2:4 (admitting that Surwit '699 describes that "medical conditions of a plurality of remotely located patients are monitored, diagnosed, prioritized, and treated using a central data processing system configured to communicate with and receive data from a plurality of respective patient monitoring systems.").

Claims 1 and 7	Claim 4	Ground 4: Freedman in view of Surwit '699 Ground 5: Freedman in view of Surwit '699 and Graham
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* claim chart above 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 (disclosing 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."); 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 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 . . . .").

Claims 1 and 7	Claim 4	Ground 4: Freedman in view of Surwit '699 Ground 5: Freedman in view of Surwit '699 and Graham
reviewing the updated treatment plan for each of the diagnosed conditions; determining if one or more changes are needed to the reviewed treatment plan for each of the diagnosed conditions. changing the reviewed treatment plan if the one or more changes are determined to be needed;	a review system that modifies the updated treatment plan if one or more changes are determined to be needed and provides a reviewed treatment plan;	**Freedman:** *see* claim chart above 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 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 re-	a presentation system that pro-	**Freedman:** *see* claim chart above for Ground 1.

Claims 1 and 7	Claim 4	Ground 4: Freedman in view of Surwit '699 Ground 5: Freedman in view of Surwit '699 and Graham
viewed treatment plan for each of the diagnosed conditions; and	vides the reviewed treatment plan for each of the diagnosed conditions; and	**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 discloses that "a case manager can instruct the PAC server to adjust medicine dosage and transmit this information 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.	**Freedman:** *see* claim chart above for Ground 1. **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 (disclosing "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

Claims 1 and 7	Claim 4	Ground 4: Freedman in view of Surwit '699 Ground 5: Freedman in view of Surwit '699 and Graham
		patient or to a patient's PPM."). **Graham:** *see* Ground 3 above, referencing p. 50:8-18.

3. Dependent claims 2, 5, and 8

Below is a claim chart illustrating Freedman's, Surwit '699's, and Graham's disclosure of the limitations in claims 2, 5, and 8 of the '985 Patent:

Claims 2, 5, and 8	Ground 4: Freedman in view of Surwit '699 Ground 5: Freedman in view of Surwit '699 and 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 pro-	**Freedman:** *see* claim chart above for Ground 1. **Graham:** *see* Ground 3 above, referencing pp. 50:8-18, 52:2-10.

vider	

4. Dependent claims 3, 6, and 9

Below is a claim chart illustrating Freedman's, Surwit '699's, and Graham's disclosure of the limitations in claims 3, 6, and 9 of the '985 Patent:

Claims 3, 6, and 9	Ground 4: Freedman in view of Surwit '699 Ground 5: Freedman in view of Surwit '699 and Graham
3. The method as set forth in claim 1 wherein the compliance data further comprises data on patient compliance with at least one of the existing treatment plan for each diagnosed condition. 6. The system as set forth in claim 4 wherein the compliance data further comprises data on patient compliance with at least one of the existing treatment plan for each diagnosed condition. 9. The medium as set forth in claim 7 wherein the compliance data further comprises data on patient compliance with at least one of the existing treatment plan for each diagnosed condition.	**Freedman:** *see* claim chart above for Ground 1. **Surwit '699:** col. 7:28-30 (a PPM "[c]ollects patient supplied data on . . . compliance to medical regime."); col. 20:64-66 ("the present invention also tracks appointment compliance (e.g., whether a patient kept his/her appointments").

E. GROUND 6: Surwit '958 anticipates claims 1-9 of the '985 Patent

1. Overview of Surwit '958

Surwit '958 discloses a method, system, and computer readable medium for remote disease management, *i.e.*, tracking compliance with treatment guidelines when treating diagnosed patients. Surwit '958: 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 discloses a patient apparatus that "is configured to receive and analyze information regarding patient compliance with medication and test regimens." *Id*. at col. 4:47-50. *See also* Decl., ¶ 58.

2. Independent claims 1, 4, and 7

Surwit '958, either explicitly or inherently, discloses every element of Claims 1-9 of the '985 Patent. As to the "current assessment" limitations, Surwit '958 shows remote patient monitors (*see* Surwit '958: Fig. 1 (item 12)), and the patient being monitored. *See id.* at 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), 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* Decl., ¶ 59.

As to the "updating" limitation of claims 1 and 7 (and the corresponding "updates" limitation of claim 4), Surwit '958 discloses updating an existing treatment plan based on the existing plan, the assessment, and treatment guidelines. Surwit '958: 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 con-

tingent 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 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* Decl., ¶ 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 discloses a method and system whereby an updated treatment plan is reviewed to determine if changes are needed, and changed if needed. Surwit '958: 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 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. Decl., ¶ 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 discloses a method and system for "publishing" (i.e., providing the patient) with the reviewed treatment plan. Surwit '958: 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* Decl., ¶ 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. Surwit '958: 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. Decl., ¶ 63.

Below is a claim chart illustrating Surwit '958's disclosure of the limitations in claims 1, 4, and 7 of the '985 Patent:

Claims 1 and 7	**Claim 4**	**Surwit '958 (Ex. 1012)**
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 di-	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

Claims 1 and 7	Claim 4	Surwit '958 (Ex. 1012)
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:	agnosed conditions, the system comprising:	computer program product."); Abstract ("A patient apparatus is configured to receive and analyze information regarding ***patient compliance*** . . . .").
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;	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); 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 exist-	a treatment pro-	Col. 15:27-35 ("A case manager may be

Claims 1 and 7	Claim 4	Surwit '958 (Ex. 1012)
ing 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;	cessing 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;	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 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
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		

Claims 1 and 7	Claim 4	Surwit '958 (Ex. 1012)
changes are determined to be needed;		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.").
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

Claims 1 and 7	Claim 4	Surwit '958 (Ex. 1012)
		to assess data, signs, conditions, symptoms, behaviors and compliance with one or more prescribed medication regimens.").

3. 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* Surwit '958: 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* Decl., ¶¶ 63-64.

As to physician compliance, Surwit '958 discloses 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." Surwit '958: col. 20:25-29. *See also* Decl., ¶ 64.

Below is a claim chart illustrating Surwit '958's disclosure of the limitations in claims 2, 3, 5, 6, 8, and 9 of the '985 Patent:

Claims 2, 3, 5, 6, 8 and 9	**Surwit '958 (Ex. 1012)**
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	

Claims 2, 3, 5, 6, 8 and 9	Surwit '958 (Ex. 1012)
wherein the compliance data further comprises data on patient compliance with at least one of the existing treatment plan for each diagnosed condition.	

F. GROUND 7: Claims 2, 5, and 8 of the '985 Patent are obvious over Surwit '958 in view of Freedman alone, or further in view of Graham

As explained above in regard to Ground 6, every element of claims 2, 5 and 8 of the '985 Patent is disclosed by Surwit '958. However, Freedman and Graham provide additional explicit disclosure 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. Decl., ¶ 65.

A POSITA 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. Surwit '958: col. 7:57-65, 4:47-50; Freedman: col. 3:24-35, 4:5-12, 26-28. *See also* Decl., ¶¶ 66-69.

Surwit '958 discloses tracking provider compliance, as explained above. Surwit '958: 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 build on this compliance step. Freedman discloses 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." *Id*. at Fig. 4c (element 170). The clinician then reviews and "selects" a treatment plan (i.e., the "reviewed treatment plan."). *Id*. at 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). *Id*. at col. 5:14-30, Fig. 4c (elements 174, 184). *See also* Decl., ¶¶ 66-69.

Graham further provides additional explicit disclosure 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: pp. 3:9-26, 5:1-17, 50:8-18, 52:2-10. *See also* Decl., ¶¶ 66-69.

A POSITA would have been motivated to combine this element of Freed-

man 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, 2:12-15; Graham: p. 50:8-18), and the person of ordinary skill, from Freedman and Graham, would be motivated 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, a POSITA 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* Decl., ¶¶ 66-69.

G. GROUND 8: Goodman anticipates claims 1, 3, 4, 6, 7, and 9 of the '985 Patent

1. Overview of Goodman

Goodman discloses 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* Goodman: 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. *Id*. at 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 med-

ication and dosage that the patient was scheduled to take . . . [T]he compliance data can be uploaded to the host computer 30."). *See also* Decl., ¶ 71.

2. Independent claims 1, 4, and 7

As to the "current assessment" limitations, Goodman discloses 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. Goodman: 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* Decl., ¶ 72.

As to the "updating" limitation of claims 1 and 7 (and the corresponding "updates" limitation of claim 4), Goodman discloses a system and method for up-

dating an existing treatment plan based on the existing plan, the assessment, and treatment guidelines. Goodman: 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* Decl., ¶ 73.

As to the "reviewing" and "determining" limitations of claims 1 and 7 (and the corresponding "review system" limitation of claim 4), Goodman discloses a system and method whereby an updated treatment plan is reviewed to determine if changes are needed, and changed if needed. Goodman: 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), Fig. 10A (steps 130, 132, 134, and 138). *See also* Decl., ¶ 74.

As to the "providing" limitation of claims 1 and 7 (and the corresponding "presentation system" limitation of claim 4), Goodman discloses a method and sys-

tem for providing the patient with the reviewed treatment plan. Goodman: 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* Decl., ¶ 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. Goodman: 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* Decl., ¶ 76.

Below is a claim chart illustrating Goodman's disclosure of the limitations in claims 1, 4, and 7 of the '985 Patent:

Claims 1 and 7	Claim 4	Goodman (Ex. 1013)
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:	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.").
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;	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

Claims 1 and 7	Claim 4	Goodman (Ex. 1013)
		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 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. 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); 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 re-		

Claims 1 and 7	Claim 4	Goodman (Ex. 1013)
viewed 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 the patient was scheduled to take. . . . [T]he compliance data can be uploaded to the host computer 30.").

3. Dependent claims 3, 6, and 9

Goodman discloses patient compliance data reflecting compliance with a treatment plan. Goodman: 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* Decl., ¶ 76.

Below is a claim chart illustrating Goodman's disclosure of the limitations in claims 3, 6, and 9 of the '985 Patent:

Claims 3, 6 and 9	**Goodman (Ex. 1013)**
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 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.").
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.	

H. GROUND 9: Claims 2, 5, and 8 of the '985 Patent are obvi-

ous over Goodman in view of Freedman alone, or further in view of Graham

As explained above in regard to Ground 8, every element of claims 1, 3, 4, 6, 7, and 9 of the '985 Patent is disclosed by Goodman. Freedman and Graham provide additional explicit disclosure 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. Decl., ¶ 77.

A POSITA would be motivated to combine Freedman and Graham with Goodman because each is concerned with remote healthcare and efficient patient diagnosis and treatment. Goodman: col. 2:36-41; Freedman: col. 3:24-35, 4:5-28; Graham: pp. 2:6-7, 3:9-26. *See also* Decl., ¶¶ 77-81.

Freedman and Graham both teach the advantages of tracking provider compliance, from both a public health and an economic perspective. Freedman discloses 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." *Id*. at Fig. 4c (element 170). The clinician then reviews and "selects" a treatment plan (i.e., the "reviewed treatment plan."). *Id.* at 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). *Id.* at col. 5:14-30, Fig. 4c (elements 174, 184). *See also* Decl., ¶ 78.

Graham further provides additional explicit disclosure 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: pp. 3:9-26, 5:1-17, 50:8-18, 52:2-10. *See also* Decl., ¶ 79.

A POSITA 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, 2:12-15; Graham: p. 50:8-18), 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, a POSITA 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* Decl., ¶¶ 80-81.

VII. CONCLUSION

In view of the above, Petitioners respectfully request institution of IPR, and subsequently cancellation, of the Challenged Claims on the grounds presented herein.

Dated: November 29, 2016

Respectfully submitted,

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CERTIFICATION UNDER 37 CFR § 42.24(d)

Under the provisions of 37 CFR § 42.24(d), the undersigned hereby certifies that the word count for the foregoing Petition for *Inter Partes* Review totals 13,993, which is less than the 14,000 allowed under 37 CFR § 42.24(a)(i).

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CERTIFICATE OF SERVICE

Pursuant to 37 CFR §§ 42.6(e)(4)(i) *et seq.* and 42.105(b), the undersigned certifies that on November 29, 2016, a complete and entire copy of this Petition for *Inter Partes* Review and all supporting exhibits were mailed via UPS Next Day Air to the Patent Owner power of attorney address of record and lead litigation counsel for My Health, Inc.:

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