UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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CARDIOCOM, LLC
Petitioner

v.

UNIVERSITY OF ROCHESTER
Patent Owner

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Case IPR2013-00320
Patent 6,612,985 B2

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Before STEPHEN C. SIU, BRIAN J. MCNAMARA, and RAMA G. ELLURU,
Administrative Patent Judges.

SIU, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

I.   BACKGROUND

A.   Background

Cardiocom, LLC ("Petitioner") requests *inter partes* review of claims 1-9 of U.S. Patent No. 6,612,985 B2 (Ex. 1001, "the '985 patent") pursuant to 35 U.S.C. §§ 311 *et seq.*[1] University of Rochester ("Patent Owner") filed a preliminary response (Paper 11, "Prelim. Resp."). We have jurisdiction under 35 U.S.C. § 314. The standard for instituting *inter partes* review is set forth in 35 U.S.C. § 314 (a) which provides:

> THRESHOLD.—The Director may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.

We determine based on the record and Petitioner's detailed argument that Petitioner has demonstrated, under 35 U.S.C. § 314(a), that there is a reasonable likelihood that it would prevail with respect to at least one of the challenged claims.

Petitioner relies on the following prior art:

US 6,126,596 (Freedman)	Oct. 3, 2000	Ex. 1002
WO 99/04043 (Caple)	Jan. 28, 1999	Ex. 1003
WO 98/58338 (Graham)	Dec. 23, 1998	Ex. 1004
US 6,024,699 (Surwit)	Feb. 15, 2000	Ex. 1005
US 5,583,758 (McIlroy)	Dec. 10, 1996	Ex. 1006

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[1] We cite to the Corrected Petition for *Inter Partes* Review filed on June 5, 2013. Paper No. 6.

Petitioner contends that the challenged claims are unpatentable under 35 U.S.C. § 102 and/or § 103 based on the following specific grounds (Pet. 4):

Reference(s)	Basis	Claims challenged
Freedman	§ 102	1-9
Freedman and Caple	§ 103	1-9
Freedman, Caple, and Graham	§ 103	1-9
Freedman and Surwit	§ 103	1-9
Freedman, Surwit, and Graham	§ 103	1-9
McIlroy and Caple	§ 103	1, 2, 4, 5, 7, and 8
McIlroy, Caple, and Graham	§ 103	1, 2, 4, 5, 7, and 8
McIlroy and Surwit	§ 103	1-9
McIlroy, Surwit, and Graham	§ 103	1-9

B.   The '985 Patent

The '985 patent describes a system and method for monitoring and treating a patient with one or more diagnosed conditions or illnesses who is at a location remote from a treatment processing system. Ex. 1001, 5:43-46. The patient provides subjective data including a subjective self-evaluation of each of the diagnosed conditions. Ex. 1001, 8:25-26. The patient also may provide information on the patient's actual implementation of the treatment plan, such as the patient's usage of pharmaceuticals and other medical devices. Ex. 1001, 8:37-40. The patient enters and confirms the information via a user input device. Ex. 1001, 8:43-46; 9:10-13. The information is transmitted to a treatment processing system 12 where an algorithm for each diagnosed condition is used to

generate and store a clinical assessment of the patient's diagnosed conditions. Ex.
1001, 9:32-34, 39-43.

The treatment processing system 12 retrieves an existing treatment plan
from memory and updates the existing treatment plan for each of the diagnosed
conditions based on the clinical assessment. Ex. 1001, 12:1-6. The treatment
processing system 12 transmits the modifications of the existing treatment plan to a
provider at a provider processing system 18. Ex. 1001, 13:27-29. The provider
may accept the modifications to the existing treatment plan or may make alternate
modifications to the updated treatment plan. Ex. 1001, 13:35-39. The processing
system 12 determines whether the alternate modifications ordered by the provider
to the updated treatment plan "are in compliance with the recommended . . .
modifications to the existing treatment plan." Ex. 1001, 13:47-51. If the
modifications made by the provider are not in compliance with the modifications
to the existing treatment plan as generated by the treatment processing system 12,
information pertaining to the non-compliance is stored and analyzed to determine
"a provider's performance over time with respect to complying with established
guidelines for assessing conditions in patients and for treating conditions."
Ex. 1001, 14:15-18.

Claim 1 of the '985 patent is reproduced below:

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.

We note that the '985 patent is asserted currently in litigation captioned as *My Health, Inc. and University of Rochester v. Cardiocom, LLC*, United States District Court for the Eastern District of Texas, Case No.: 2:13-cv-136. *See* Pet. 1.

C.   Claim Interpretation

Consistent with the statute and the legislative history of the Leahy-Smith America Invents Act, Pub. L. 112-29, 125 Stat. 284, 329 (Sept. 16, 2011) ("AIA"), the Board interprets claim terms by applying the broadest reasonable construction in the context of the specification in which the claims reside. 37 C.F.R. § 42.100(b); *see Office Patent Trial Practice Guide*, 77 Fed. Reg. 48756, 48766 (Aug. 14, 2012).

Under the broadest reasonable interpretation standard, claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definition for a claim term must be set forth in the specification with reasonable clarity, deliberateness, and

precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994). In this regard, however, we are careful not to read a particular embodiment appearing in the written description into the claim, if the claim language is broader than the embodiment. *In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993).

In assessing the merit of Petitioner's arguments, we have construed the following claim terms in light of the Specification of the '985 patent for the purposes of this decision.

1.   "treatment plan"

Claim 1 recites a treatment plan for diagnosed conditions in a patient. The treatment plan, as recited in claim 1, is updated and reviewed. The treatment plan may be changed if changes are determined to be needed. Petitioner argues that the term "treatment plan" should be construed as "a plan or series of specific medical treatments to be performed for treating a patient's medical condition." Pet. 6. Patent Owner does not propose a construction for this term.

Based on the plain and customary meaning, as would have been understood by one of ordinary skill in the art, of the term "treatment" as being a course of therapy for a patient and the term "plan" as a "scheme for making, doing, or arranging something",[2] one of skill in the art would have understood a "treatment plan" to mean any procedure or scheme for making, doing, or arranging something for providing therapy to a patient. Hence, we construe the term "treatment plan" broadly, but reasonably, to include a proposed scheme or procedure (i.e., a "plan") for providing some form of therapy for a patient (or "treatment").

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[2] Webster's New Universal Unabridged Dictionary, Deluxe Second Edition, 1972.

2.   "current assessment"

Claim 1 recites determining a "current assessment of one or more diagnosed conditions in a patient." Petitioner argues that a "current assessment" should be construed as "a determination of a patient's condition in view of a diagnosis and an existing treatment plan."[3] Pet. 6-7. Patent Owner argues that the term "current assessment" should be construed "to apply to a patient that was diagnosed previously with the one or more conditions based on a prior assessment." Prelim. Resp. 4. Given the recitation in claim 1 that the current assessment is of one or more "diagnosed" conditions in a patient, we agree with the Patent Owner that the "current assessment" is determined at some point in time after the diagnosis of the patient's condition is determined.

Patent Owner also argues that the current assessment must be 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. Prelim. Resp. 4-5. Claim 1 explicitly recites that the current assessment is based on data about each of the diagnosed conditions from the patient and on one or more assessment guidelines. Therefore, we construe the term "current assessment," as recited in claim 1, broadly, but reasonably, to include any present determination or evaluation of a previously diagnosed condition or illness in the patient.

3.   "assessment guidelines"

Claim 1 recites one or more assessment guidelines for each of the diagnosed conditions. Petitioner argues that the term "assessment guidelines" should be

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[3] Although Petitioner proposes a construction of the term "clinical assessment," claim 1 recites "current assessment," as opposed to "clinical assessment." We assume Petitioner intends to refer to the term "current assessment" as recited in claim 1.

construed as "guidelines in determining what questions to ask or tests to be performed to diagnose a patient." Pet. 7. Patent Owner does not propose a construction of this term. Based on Patent Owner's construction of the term "assessment" to include "a determination of a patient's condition" (Pet. 6-7) and the plain and customary meaning of the term "guidelines" as being "a standard or principle by which to make a judgment or . . . course of action,"[4] we broadly, but reasonably, construe the term "assessment guidelines" to include a standard or principle by which to make a judgment (i.e., "guidelines") that is used to determine a condition of (or "assess") a patient.

      4.   "treatment guidelines"

Claim 4 recites one or more treatment guidelines for each of the diagnosed conditions. Petitioner argues that "treatment guidelines" should be construed as "guidelines for treatment of a relevant (diagnosed) disease or illness once that ailment has been diagnosed." Pet. 7. Patent Owner does not propose a construction of this term. Based on the plain and customary meaning, as would have been understood by one of ordinary skill in the art, of the term "treatment" as being a course of therapy for a patient and, as described above, the term "guidelines" as being "a standard or principle by which to make a judgment or . . . course of action", we broadly, but reasonably, construe the term "treatment guidelines" to include a "a standard or principle by which to make a judgment or . . . course of action" (i.e., "guidelines") that are used to provide a course of therapy for a patient (or "treatment").

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[4] Webster's New Universal Unabridged Dictionary, Deluxe Second Edition, 1972.

5.   "compliance data"

Petitioner argues that "compliance data" should be construed as including "*physician* compliance data, or data related to whether a physician-prescribed treatment plan complies with treatment guidelines." Pet. 9. Patent Owner argues that "compliance data" should be construed to include data that is "'*based on* the updated treatment plan *and* the reviewed treatment plan for each of the diagnosed conditions.'" Prelim. Resp. 6-7, quoting Ex. 1001, 16:9-11. Claim 1 explicitly recites compliance data that is generated "based on the updated treatment plan and the reviewed treatment plan for each of the diagnosed conditions." Therefore, we agree with Patent Owner that the term "compliance data," as recited in claim 1, should be construed to include data that is generated "based on the updated treatment plan and the reviewed treatment plan for each of the diagnosed conditions."

Claim 2 recites that compliance data comprises provider information. We agree with Petitioner that "compliance data," as recited in claim 2, also includes data pertaining to provider information.

Claim 3 recites that compliance data further comprises data on patient compliance. We broadly, but reasonably, construe the term "compliance data," as recited in claim 3, also to include data on patient compliance, as explicitly recited in claim 3.

II.   ANALYSIS

    A.   *Cited References*

        1. Overview of Freedman

Freedman discloses a computer-based system that collects data from a patient to evaluate the patient's medical condition and to monitor a clinician's decisions pertaining to treating the patient's condition. Ex. 1002, 3:9-12. The patient is located remotely from the health care facility and enters answers to health-related questions into the computer system, where the patient's answers are stored. Ex. 1002, 3:14-16, 31-34; 4:11, 20. The system checks the patient's past medical record and associated, previously assigned diagnosis to suggest diagnostic options based on treatment guidelines retrieved from memory. Ex. 1002, 4:5-7, 30-32. The clinician receives the suggested diagnostic option information, including the patient's record and suggested treatment guidelines, and selects a diagnosis based on the received information. Ex. 1002, 4:36-43. The clinician is informed by the system if the diagnosis selected by the clinician deviates from the diagnosis provided by the treatment guidelines. Ex. 1002, 4:43-46, 49-53. In such a case, the clinician may enter additional information and may confirm the diagnosis. Ex. 1002, 4:58-60. The system stores the sequence in memory for quality review. Ex. 1002, 4:67–5:2.

The system also suggests treatment options corresponding to the determined diagnoses from the treatment guidelines for selection by the clinician. Ex. 1002, 5:6-9. If the treatment option selected by the clinician is not consistent with treatment guidelines, the clinician may enter additional supporting information. Ex. 1002, 5:13-15, 25-26. The system stores the sequence in memory for quality review. Ex. 1002, 5:29-30.

2. Overview of Caple

Caple discloses an automatic medical test reporting process and system. Ex. 1003, 7:22-23. The patient uses a "test kit" to obtain a sample and submits the

sample to a computer or a laboratory for testing and analysis. Ex. 1003, 7:30; 8:22; 11:18-20. The collection and testing of the patient's sample may be used to monitor the status of the patient's disease progression or the patient's compliance with medication and treatment regimens. Ex. 1003, 13:8-10. The patient's test results and history, along with recommended changes to the patient's medication or treatment regimen, are sent to a health care provider. Ex. 1003, 13:23-24. The system also automatically calls the patient with the doctor's recommendations. Ex. 1003, 13:23-26, 35-36; 14:1-2.

3. Overview of Graham

Graham discloses a system that enables a physician to follow a guided diagnostic evaluation and treatment recommendation for a patient. Ex. 1004, 7:17-18. The physician enters a patient's symptoms into the computer system. Ex. 1004, 18:27-28. Based on the patient's symptoms, the system provides recommended actions to physicians that are used by the physician as a decision support tool during the physician's decision process. The recommended actions may be presented in a lookup table. Ex. 1004, 14:4-7; 22:19-21. The system also generates reports and statistical analyses that may include statistics concerning the physician. Ex. 1004, 44:16-17; 50:8. The statistics may concern actions selected by physicians including any guideline deviations. Ex. 1004, 50:13-15.

4. Overview of Surwit

Surwit discloses a medical data processing system that receives and stores patient data and generates treatment options for the patient. Ex. 1005, 1:10-11; 2:40-42, 45-47. The patient transmits patient data to a central processing system.

Ex. 1005, 7:64-66; 9:25-26. The processing system analyzes and stores the patient data and identifies medical conditions of the patient that require treatment. Ex. 1005, 9:50-51; 11:60-63. A list of identified prioritized medical conditions is provided and the selection of a medical condition results in an expanded list of corresponding available actions that may be taken for the selected medical condition. Ex. 1005, 17:42-43; 18:35-38. These available actions, or treatment information, may be communicated to the patient. Ex. 1005, 18:45. In addition, the system tracks a patient's appointment compliance and the patient's "compliance to medical regime," and "tracks whether a patient has performed actions associated with treatment recommended by a [physician]." Ex. 1005, 3:22-24; 7:28-30; 20:64-66.

B.   Anticipation by *Freedman*

Petitioner asserts that claims 1-9 are anticipated under 35 U.S.C. § 102(a) and 35 U.S.C. § 102(e) by Freedman. Pet. 4. In support of this asserted ground of unpatentability, Petitioner provides explanations as to how each claim limitation is disclosed by Freedman. Upon consideration of Petitioner's analysis and supporting evidence, and taking into account Patent Owner's preliminary response, we are persuaded that Petitioner has demonstrated there is a reasonable likelihood that it would prevail with respect to anticipation of claims 1-9 over Freedman.

With respect to claims 1, 4, and 7, Patent Owner argues that Freedman fails to disclose a current assessment that is "based on two distinct factors: (1) data about each of the diagnosed conditions from the patient who is at a remote location, *and* (2) one or more assessment guidelines for each of the diagnosed conditions." Prelim. Resp. 10. Claim 1, for example, recites a current assessment based on data about each of the diagnosed conditions from the patient and one or

more assessment guidelines for each of the diagnosed conditions. According to

Patent Owner, Freedman "merely discloses a system that provides suggested

diagnoses based on 'treatment guidelines.'" Prelim Resp. 10.

Patent Owner does not demonstrate persuasively that Freedman fails to

disclose a current assessment based on data about each of the diagnosed conditions

from the patient. Freedman discloses a "client" or patient entering data "in

response to questions" that relate to the patient's medical condition or

"psychological state" and the patient's "current symptoms for all possible

diagnoses." Ex. 1002, 4:15, 18-19, 26-28. The data entered by the patient also

may relate to a "previously assigned diagnosis" of the patient. Ex. 1002, 4:7-10;

Fig. 3b, elements 116, 118. Based on the "entered data" from the patient, data is

presented to the clinician from which the clinician "selects a diagnosis(es)." Ex.

1002, 4:37, 41. In other words, Freedman discloses a "current assessment" (i.e., a

determination or evaluation of the present condition of a patient[5] that was

diagnosed in the patient at some time prior to the time that the determination or

evaluation is made[6]) that is based on data about diagnosed conditions from the

patient (i.e., based on data entered by the patient pertaining to (or based on) the

patient's current condition of a "previously assigned diagnosis" of the patient).

Freedman also discloses that the "current assessment" is based on one or

more "assessment guidelines" (or a standard or principle by which to make a

judgment that is used to determine a condition of a patient). As described above,

Freedman discloses a system that displays diagnoses for a patient's condition (from

which a clinician "selects a diagnosis(es)"–Ex. 1002, 4:41) that are determined

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[5] Data presented to the clinician from which the clinician "selects a diagnosis."
Ex. 1002, 4:37, 41.
[6] A "previously assigned diagnosis" of the patient. Ex. 1002, 4:7-10, Fig. 3b,
elements 116, 118.

from medical related data entered by the patient that pertains to a current condition of the patient and/or a "previously assigned diagnosis." Freedman also discloses that the system, for example, utilizes "client's [(patient's)] answers" and "highlights suggested DSM-IV criteria diagnosis(es)." Ex. 1002, Fig. 4a, element 152. In other words, Freedman discloses that the diagnoses provided by the system are based on the patient's answers in view of "DSM-IV criteria diagnosis(es)." Patent Owner does not demonstrate persuasively a difference between the "assessment guidelines" as recited in claim 1, for example, and the criteria used in Freedman (e.g., "DSM-IV criteria") in determining diagnoses for a patient's condition. In both cases, standards or principles (i.e., "guidelines") are used to determine, or "assess," a condition of a patient.

Patent Owner also argues that Freedman "merely discloses providing a 'suggested treatment' based on treatment guidelines stored in the memory for clinician review," and fails to disclose "that an existing treatment plan is updated in any manner" or "updated based on three distinct factors [i.e., the existing treatment plan, current assessment, and treatment guidelines]." Prelim. Resp. 12-13.

As previously discussed, Freedman discloses a system that provides diagnoses for a patient based on information received from a patient, the patient's history, and a patient's previously assigned diagnosis. Ex. 1002, Fig. 4a, element 152; Fig. 3b, elements 116, 118; 4:7-10. Freedman also discloses that, based on the diagnoses provided by the system, the system determines suggested treatments for the diagnoses "by using data to look up the recommendations from treatment guidelines." Ex. 1002, Fig. 4c, element 170. In addition, the patient in the Freedman disclosure has an existing treatment plan associated with the previously assigned diagnosis (*e.g.*, "past . . . medication history"–Ex. 1002, 6:49.)

Hence, Freedman discloses an existing treatment plan (e.g., based on the patient's previously assigned diagnosis, including, for example, a past medication history), a current assessment (e.g., diagnoses provided for a patient by the system based on information currently received from the patient), and "suggested treatments" corresponding to the claimed "updated" treatment plan because both the suggested treatments of Freedman and the "updated" treatment plan recited in claim 1 have been modified and are based on a "current assessment."

Freedman also discloses that the updated treatment plan (i.e., suggested treatments based on the "data") is based on treatment guidelines. Ex. 1002, Fig. 4c, element 170. Patent Owner does not demonstrate persuasively a difference between the "updated" treatment plan of Freedman and updating an existing treatment plan as recited in claim 1.

Patent Owner also argues that Freedman "discloses a system that provides information associated with the reviewed treatment plan," but fails to disclose providing "the reviewed treatment plan itself." Prelim. Resp. 15. Claim 1 recites reviewing the updated treatment plan.

As discussed above, Freedman discloses an updated treatment plan (*e.g.*, "suggested treatments"–Ex. 1002, Fig. 4c, element 170). Freedman also discloses that the suggested treatments are reviewed by a clinician. For example, Freedman describes that the clinician "selects a treatment plan" from a list of suggested treatments provided by the system. Ex. 1002, Fig. 4c, element 172; 5:8-9. One of ordinary skill in the art would have understood that a clinician that selects a treatment plan from a selection of treatment plans would have "reviewed" the treatment plans (including the selected treatment plan) prior to selection. If the clinician does not review the suggested treatment plans, the clinician would be unable to select a treatment plan from the group of suggested treatment plans

because the clinician would not be aware of what treatment plans were available for selection.

Patent Owner also argues that Freedman fails to disclose a "previously reviewed" treatment plan, but Patent Owner fails to demonstrate that claim 1, for example, requires a "previously reviewed treatment plan." Prelim. Resp. 15.

Patent Owner also argues that "Freedman . . . teaches determining consistency between a selected treatment plan and the treatment guidelines stored in the memory," but Freedman fails to disclose "generating compliance data based on a reviewed treatment plan and an updated treatment plan." Prelim. Resp. 18.

Freedman discloses a system that displays treatments and "highlights suggested treatments for diagnosis(es) . . . according to treatment guidelines." Ex. 1002, 5:6-7. Therefore, Freedman discloses displaying treatment plans corresponding to diagnoses for a patient and highlighting those treatments (e.g., "updated" treatment plans) that are in accordance with stored "treatment guidelines." Conversely, one of ordinary skill in the art would have understood that in Freedman, those displayed treatment plans that are not in accordance with stored "treatment guidelines" would not be highlighted.

Freedman also discloses that "the clinician selects a treatment plan on screen." Ex. 1002, 5:8-9. The system determines if the treatment selected by the clinician is a "treatment plan [that] is consistent with highlighted treatment guidelines." Ex. 1002, 5:10-11. Freedman also discloses that "[i]f the treatment selected by the clinician in block **172** is not consistent with treatment guidelines," the system "stores the sequence for quality review." Ex. 1002, 5:14-15, 30. One of ordinary skill in the art would have understood that if a selected treatment is not consistent with treatment guidelines, then the selected treatment would not be one of the treatment plans highlighted by the system (i.e., not one of the "updated"

treatment plans that is highlighted by the system) because the system highlights only those displayed treatment plans that are in accordance with treatment guidelines. The "sequence" that is stored in Freedman therefore is based on both the treatment plans highlighted by the system (i.e., the "updated" treatment plans) and the treatment plan that is selected (or "reviewed") by the clinician (including any non-highlighted treatment plans). Patent Owner does not demonstrate persuasively a difference between Freedman and the claim limitation of data (i.e., "compliance data") that is based on the "updated" and "reviewed" treatment plans.

Regarding claims 2, 5, and 8, Patent Owner argues that Freedman "relates to a system that provides comparisons between a selected treatment plan and treatment guidelines stored in memory," but that Freedman fails to disclose "that the compliance data comprises information regarding differences between reviewed treatment plans and updated treatment plans." Prelim. Resp. 19-20.

As discussed above, Freedman discloses updated treatment plans (e.g., treatment plans highlighted by the system as being in accordance with treatment guidelines) and reviewed treatment plans (e.g., treatment plans that are "reviewed" and subsequently selected by a clinician) and generates data (e.g., a "sequence") that is stored in memory. The "sequence" is generated (and stored) if the treatment plan selected and reviewed by the clinician (i.e., the "reviewed treatment plan") is not consistent with a treatment plan that is in accordance with treatment guidelines (i.e., an "updated treatment plan"). One of ordinary skill in the art would have understood that a treatment plan that is in accordance with treatment guidelines would be different from a treatment plan that is not in accordance with treatment guidelines. Patent Owner has not demonstrated sufficiently that the stored "sequence" of Freedman is not associated with "differences" between the treatment plans.

Regarding claims 3, 6, and 9, Patent Owner argues that Freedman fails to disclose "that the compliance data comprises data on patient compliance with an existing treatment plan." Prelim. Resp. 21.

Freedman discloses that the system "determines whether [the patient] had [a] previous positive response with . . . medications," "whether [the patient] had significant side effects from the medication," and "whether [the patient] had an adequate trial . . . [that] is established from [the patient's] history information." Ex. 1002, 6:46-47, 54-55, 65-67. One of ordinary skill in the art would have understood that determining whether a patient had a previous positive response to medication (i.e., a response to an "existing treatment plan") would have included data on patient compliance with the treatment plan. Whether the patient had a previous positive response from treatment would depend on whether the patient was compliant with the treatment plan (e.g., whether the patient took the medication as prescribed in Freedman). If the patient had not been compliant with taking the medication in Freedman, one of ordinary skill in the art would have understood that the patient would not have a "positive response" to the medication, the patient not having taken the medication as prescribed in the first place.

Similarly, Freedman discloses determining whether the patient had an adequate trial with the medication based on the patient's history. One of ordinary skill in the art would have understood that data pertaining to whether the patient had an adequate trial of a medication would have included data on patient compliance with the medication. For example, the patient could not have had an adequate trial of the medication had the patient not been compliant to taking the medication as prescribed.

Thus, Petitioner has demonstrated there is a reasonable likelihood that it would prevail with respect to anticipation of claims 1-9 over Freedman.

C.   *Obviousness over Freedman, Caple, and Graham*

Petitioner asserts that claims 1-9 would have been obvious under 35 U.S.C.

§ 103(a) over Freedman, Caple, and Graham. Pet. 4. In support of this asserted

ground of unpatentability, Petitioner provides explanations as to how each claim

limitation is disclosed or suggested by Freedman, Caple, and Graham, and

articulates reasoning with rational underpinning to justify support for the

conclusion of obviousness over the combination of Freedman, Caple, and Graham.

Pet. 20-28. Upon consideration of Petitioner's analysis and supporting evidence,

and taking into account Patent Owner's preliminary response, we are persuaded

that Petitioner has demonstrated a reasonable likelihood that it would prevail with

respect to obviousness of claims 1-9 over Freedman, Caple, and Graham.

Patent Owner argues that Caple discloses "test results," but fails to disclose

or suggest "the determination of a current assessment based on the factors recited

in claims 1, 4, and 7." Prelim. Resp. 23-24. For example, claim 1 recites a current

assessment based on data about each of the diagnosed conditions from the patient

and one or more assessment guidelines for each of the diagnosed conditions. In

particular, Patent Owner argues that Caple fails to disclose or suggest a current

assessment that "is based on *both* the received patient data *and* one or more

assessment guidelines." Prelim. Resp. 25.

Caple discloses a system that monitors the status of a patient's disease

progression. Ex. 1003, 13:9. The system receives data from a patient (e.g., remote

sample collection) and performs laboratory testing. Ex. 1003, 13:14-15, 17. The

system transmits the patient's test results to a health care provider and

"recommends changes [to the patient's treatment plan] to the health care provider."

Ex. 1003, 13:23-24. It would have been obvious to one of ordinary skill in the art,

given the disclosure of Caple that a system obtains test results of a patient's sample and subsequently suggests changes to a pre-existing treatment plan, that that system generates the suggested changes to the pre-existing treatment plan based on the test results of the patient as a matter of common sense. Otherwise, the suggested changes to the pre-existing treatment plan in Caple would not be based on any specific criteria and there would be no reason in Caple to receive the patient sample from the patient in the first place. "[T]he common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not." *Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1161 (Fed. Cir. 2007) (citing *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007)). Hence, we agree with Petitioner that Caple discloses or suggests that the "current assessment" of the patient's condition is based on data from the patient (i.e., the patient sample received from the patient) and that the data is about a diagnosed condition.

The current assessment of Caple also is based on one or more "assessment guidelines" (or a standard or principle by which to make a judgment that is used to determine a condition of, or "assess," a patient) for a diagnosed condition, as recited in claim 1. It would have been obvious to one of ordinary skill in the art that the suggested recommendations in the patient's treatment plan generated by the Caple system would be informed by recommendations that are based on the patient's current condition (and test results) rather than random recommendations that are unrelated to the patient's condition or test results. This would have been obvious to one of ordinary skill in the art because random recommendations that are unrelated to the patient's condition would not be useful in treating the patient's condition and, as one of ordinary skill in the art would have understood, would have been potentially detrimental to the patient's health.

Also, it would have been obvious to one of ordinary skill in the art, given that the system generates suggested recommendations to a patient's treatment plan based on test results obtained from testing of the patient's sample, that the suggested recommendations generated by the system would have been derived by comparison of the patient's test results to standards or principles by which to make a judgment used to determine a condition of a patient (or "assessment guidelines"). One of ordinary skill in the art would have understood that without evaluating or assessing the patient's test results in comparison to known standards, the system would be unable to assess the patient's current health status with regard to the patient's disease progression. Thus, the Caple system would have been unable to recommend changes. However, Caple explicitly discloses that the system recommends changes. Ex. 1003, 13:25. Thus, it would have been obvious to one of ordinary skill in the art given the system of Caple to determine a current assessment based on one or more assessment guidelines.

Also, as noted above, Patent Owner does not demonstrate persuasively that Freedman fails to disclose or suggest this disputed claim feature.

Petitioner explains that Graham discloses or suggests compliance data based on the reviewed treatment plan and the updated treatment plan as recited in claim 1. Pet. 26. Patent Owner argues that Graham fails to disclose or suggest "generating or providing compliance data based on *both* an updated treatment plan *and* a reviewed treatment plan." Prelim. Resp. 28. Patent Owner reiterates this argument with respect to claims 2, 5, and 8. Prelim. Resp. 29.

Graham discloses that "information is used as the basis for providing recommendations to physicians," and a system that "provides recommendations/ suggestions to the physicians based on input data." Ex. 1004, 7:31-32; 8:4-5. Therefore, Graham discloses a system that provides a suggested treatment plan for

a patient based on input data. Graham also discloses that "physicians consider the recommendations using their professional judgment, and decide whether to follow the recommendations." Ex. 1004, 8:5-7. Therefore, Graham discloses a treatment plan that is "reviewed" by a physician (in order for the physician to determine whether to follow the recommendation). Graham also discloses that the physician may select a recommended option or may select a "non-recommended option." Ex. 1004, 43:5-6. Therefore, Graham discloses that a physician may review treatment plans and may also select a non-recommended treatment option (i.e., a "reviewed" treatment plan–the "reviewed" treatment plan in this embodiment being a "non-recommended treatment option"). Graham also discloses that when the physician's selection deviates from the recommended options, the data pertaining to the deviation is stored in "statistical reports." That is, the data includes "any guideline deviations." Ex. 1004, 50:8, 12-15.

Patent Owner argues that the data stored in the statistical reports of Graham merely pertain to "any guideline deviations" but are not based on "both an updated treatment plan and a reviewed treatment plan." Prelim. Resp. 28. However, as explained above and by Petitioner, the "guideline deviations" of Graham relate to both an updated treatment plan (i.e., recommended treatment plans generated by the system) and a reviewed treatment plan (i.e., a non-recommended treatment option selected by the physician). The "guideline deviations" of Graham is data pertaining to "deviations" between the treatment plans as described.

Also, as noted above, Patent Owner does not demonstrate persuasively that Freedman fails to disclose or suggest this disputed claim feature. Thus, Petitioner has demonstrated a reasonable likelihood that it would prevail with respect to obviousness of claims 1-9 over Freedman, Caple, and Graham.

D.   *Obviousness over Freedman, Graham, and Surwit*

Petitioner asserts that claims 1-9 are obvious under 35 U.S.C. § 103(a) over Freedman, Graham, and Surwit. Pet. 4. In support of this asserted ground of unpatentability, Petitioner provides explanations as to how each claim limitation is disclosed or suggested by Freedman, Graham, and Surwit, and articulates reasoning with rational underpinning to justify support for the conclusion of obviousness over the combination of Freedman, Graham, and Surwit. Pet. 29-37. Upon consideration of Petitioner's analysis and supporting evidence, and taking into account Patent Owner's preliminary response, we are persuaded that Petitioner has demonstrated a reasonable likelihood that it would prevail with respect to obviousness of claims 1-9 over Freedman, Graham, and Surwit.

Patent Owner argues that Surwit discloses "internally stored insulin monitoring software," but fails to disclose or suggest "determining a current assessment based on *both* the collected data *and* one or more assessment guidelines." Prelim. Resp. 34. Claim 1, for example, recites a current assessment based on data from the patient and one or more assessment guidelines.

Surwit discloses a "glucose meter . . . [that] uses patient-entered data and internal software to . . . alter insulin doses as needed." Ex. 1005, 8:27-28. The "software analyzes the entered data" and "calculates adjustments for a [patient] . . . as applied to the data entered . . . by the patient." Ex. 1005, 8: 27-28, 41-46. In other words, Surwit discloses a system that receives patient data and evaluates the present condition of the patient based on the received patient data. One of ordinary skill in the art would have understood that in order to evaluate the condition of the patient to calculate adjustments for the patient, the system would have evaluated the received data in view of a standard or principle by which to make a judgment

(i.e., "guidelines") that are used to determine a condition, or "assess," a condition. If the system of Surwit did not utilize corresponding standards or principles by which to make a judgment (or "guidelines") in the evaluation of the data received from the patient, the system of Surwit would have been unable to calculate adjustments for the patient because the system would not have criteria on which to base the recommended adjustments. This would be contrary to Surwit's explicit disclosure of calculating adjustments for the patient. Hence, Surwit discloses a determination or evaluation of the present condition of a patient (i.e., a "current assessment") that is based on data from the patient (i.e., patient-entered data) and one or more assessment guidelines (i.e., a standard or principle by which to make a judgment and to calculate adjustments for the patient).

Also, as noted above, Patent Owner does not demonstrate persuasively that Freedman fails to disclose or suggest this disputed claim feature.

Patent Owner argues that Surwit discloses "patient compliance with a treatment plan" and "user (medical personnel) compliance with communicating treatment information to a patient," but fails to disclose or suggest compliance data that is "based on *updated and reviewed treatment plans*." Prelim Resp. 35-37.

Surwit discloses a system that analyzes obtained patient data to "identify medical conditions" and "treatment options for treating . . . selected medical condition[s]." Ex. 1005, 3:49, 54-55. Hence, Surwit discloses data that is based on "updated" treatment plans (i.e., treatment options provided by the system based on received patient data). Surwit also discloses that the system "allow[s] case managers to change the treatment program for patients." Ex. 1005, 10:2-3. Hence, Surwit discloses data that is based on "reviewed" treatment plans (i.e., treatment plans provided by the system that were changed by the case managers). Therefore, Patent Owner has not adequately demonstrated that Surwit fails to disclose or

suggest data that are based on an updated treatment plan and a reviewed treatment plan, as recited in claim 1.

Thus, Petitioner has demonstrated a reasonable likelihood that it would prevail with respect to obviousness of claims 1-9 over Freedman, Graham, and Surwit.

E. *McIlroy and other asserted grounds of unpatentability*

Petitioner alleges additional grounds of unpatentability of claims 1-9 based on McIlroy in combination with Caple, Graham, and/or Surwit. These grounds are redundant to the grounds of unpatentability based on prior art (Freedman) on which we have instituted trial above, with respect to these claims. We do not authorize *inter partes* review on those redundant grounds.

III. CONCLUSION

We institute an *inter partes* review of claims 1-9 under 35 U.S.C. § 102 as anticipated by Freedman; under 35 U.S.C. § 103 as obvious over Freedman, Caple, and Graham; and under 35 U.S.C. § 103 as obvious over Freedman, Surwit, and Graham.

IV. ORDER

For the reasons given, it is

ORDERED that the petition is granted as to claims 1-9.

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(a), *inter partes* review of the '985 patent is hereby instituted commencing on the entry date of this

Order, and pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of a trial.

FURTHER ORDERED that the trial is limited to the grounds and claims identified above in the Conclusion. No other grounds are authorized as to these claims.

FURTHER ORDERED that an initial conference call with the Board is scheduled for December 5, 2013 at 1PM. The parties are directed to the *Office Patent Trial Practice Guide*, 77 *Fed. Reg.* 48756, 48765-66 (Aug. 14, 2012), for guidance in preparing for the initial conference call, and should come prepared to discuss any proposed changes to the Scheduling Order entered herewith and any motions the parties anticipate filing during the trial.

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