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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte MARK A. HOFFMAN and DAVID P. MCCALLIE, JR.[1]

Appeal 2014-005776
Application 10/826,595
Technology Center 1600

Before FRANCISCO C. PRATS, MELANIE L. MCCOLLUM, and JOHN E. SCHNEIDER, *Administrative Patent Judges*.

SCHNEIDER, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to a computer system for providing information about the risk of an atypical clinical event, which have been rejected as lacking statutory subject matter, as indefinite and as obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

STATEMENT OF THE CASE

The invention relates to a method for determining the risk of an atypical clinical event occurring by determining if a patient has a gene associated with an atypical event, specifically a drug interaction. Spec. ¶ 11.

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[1] Appellants identify the Real Party in Interest as Cerner Innovation, Inc. Br. 3.

The method involves receiving clinical agent information, and then determining if there is a gene associated with the clinical agent information. *Id.* Clinical agents include drugs, pharmaceuticals, nutraceuticals, foods, salves, dietary supplements and the like. Spec. ¶ 31. Next, a determination is made whether the patient has had a genetic test to determine the presence of a gene associated with the clinical agent. Spec. ¶ 37. If not, a determination is made as to the likelihood that the patient has a gene or a variant of the gene indicative of an atypical clinical event. Spec. ¶ 11. When it is determined that the gene or gene variant may be present a determination is made whether to order a test to confirm the presence of the gene or variant. Spec. ¶ 38.

Claims 1, 3, 5, 6, 11–14, 16, 18, 20–23, 27–31, 33, and 52–63 are on appeal. Claim 1 is illustrative and reads as follows:

> 1. A computer-implemented method for displaying a warning that a clinical agent received from a clinician should not be administered to a person, comprising the steps of:
>
> receiving from a clinician clinical agent information, the clinical agent information including an identifier of a specific clinical agent and a dosage of the specific clinical agent, wherein receiving comprises:
>
> (a) receiving a selection of an entry in a listing of clinical agents on a graphical user interface (GUI); and
>
> (b) receiving a selection of the dosage from a range of dosages recommended for the clinical agent associated with the selected entry on the GUI;
>
> identifying the genes associated with the clinical agent by comparing the identifier of the clinical agent received from the clinician to a first data set including agent-gene associations, wherein the associated genes are likely to interact with the clinical agent to result in an atypical clinical event;

when a gene is associated with the clinical agent, automatically obtaining a genetic test result value for the associated gene of a person, wherein automatically obtaining comprises:

(a) receiving identification of the person to whom the clinical agent is to be administered and receiving proper authorization to access an electronic medical record (EMR) of the person; and

(b) utilizing the identification and the proper authorization from the clinician to access patient information within the EMR of the person stored within a comprehensive healthcare system;

when the patient information comprises the genetic test result value for the associated gene of a person, comparing the genetic test result value to the second data set containing one or more polymorphism values associated with one or more atypical clinical events for the clinical agent;

otherwise, performing the following procedure:

(a) determining whether to seek a clinician's authorization to order a test of the person or whether to order the test without the clinician's input based on both a likelihood of one or more genetic variations of the associated gene occurring and a severity of interaction of the one or more occurring genetic variations with the clinical agent;

(b) when the severity and the likelihood of the associated gene's one or more genetic variations indicate ordering the test without the clinician's input, automatically ordering the test to determine the genetic test result value for the associated gene of the person when the test is available;

(c) when the severity and the likelihood of the associated gene's one or more genetic variations indicate seeking the clinician's authorization to order the test, seeking a clinician's authorization for the test by presenting a genetic test ordering window; and

(d) automatically ordering the test to determine the genetic test result value for the associated gene of the person when the test is available and the authorization is granted by a clinician at the genetic test ordering window;

> determining whether the genetic test result value correlates to one or more of the one or more polymorphism values contained in the second data set; and
>
> when the genetic test result value correlates to one or more of the one or more polymorphism values, displaying a warning to the clinician that the clinical agent received from the clinician should not be administered, and recording an indication of the warning in the EMR of the person.

Br. 25–27 (Claims Appendix).

The claims stand rejected as follows:

Claims 1, 3, 5, 6, 11–14, 16, 18, 20–23, 27–31, 33, and 52–63 have been rejected under 35 U.S.C § 101 as being drawn to non-statutory subject matter.

Claims 1, 3, 5, 6, 11–14, 16, 18, 20–23, 27–31, 33, and 52–63 have been rejected under 35 U.S.C. § 112 second paragraph as being indefinite for failing to particularly point out an distinctly claims the subject matter the inventor regards as his invention.

Claims 1, 3, 5, 6, 11–14, 16, 18, 20–23, 27–31, 33, and 54–58 have been rejected under 35 U.S.C. § 103(a) as unpatentable over Hogan US 2002/0110823 A1 (published Aug. 15, 2002) ("Hogan"), in view of Classen, U.S. 6,219,674 B1 (issued Apr. 17, 2001) ("Classen"), Portwood, et al. US 5,950,630 (issued Sep. 14,1999) ("Portwood") and Markin, US 5,985,670 (issued Nov. 16, 1999) ("Markin") and in further view of Fey, et al., US 2002/0052761 A1 (published May 2, 2002) ("Fey").

REJECTION UNDER 35 U.S.C. § 101

Appellants have presented no arguments with regard to the Examiner's rejection based on 35 U.S.C. § 101. We therefore summarily affirm the rejection. MPEP § 1205.02.

REJECTION UNDER 35 U.S.C. § 112

Issue

In rejecting the pending claims as indefinite the Examiner finds that the claims are directed to a computer implemented method or a computer system but the claims are not clear as to how a computer is used to perform the specific steps. Final Act. 3. The Examiner finds that there is no actual algorithm or description as to how the individual steps are performed. *Id.* The Examiner finds that while the claimed method calls for using a computer, the individual steps recite only mental steps without calling for the use of even a general purpose computer. Ans. 4.

Appellants contend that the claims are not indefinite in that they are clear as written. Br. 11. Appellants contend that no algorithm is needed. *Id.* Appellants further contend that the Specification provides a clear description as to how each step is to be performed. *Id.*

The issue with respect to this rejection is whether the Examiner has established by a preponderance of the evidence that the pending claims are indefinite as defined by 35 U.S.C. § 112, second paragraph.

Principles of Law

"[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to

inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S.Ct. 2120, 2124 (2014).

"[W]hen the USPTO has initially issued a well-grounded rejection that identifies ways in which language in a claim is ambiguous, vague, incoherent, opaque, or otherwise unclear in describing and defining the claimed invention, and thereafter the applicant fails to provide a satisfactory response, the USPTO can properly reject the claim as failing to meet the statutory requirements of § 112(b)." *In re Packard*, 751 F.3d 1307, 1311 (Fed. Cir. 2014).

Analysis

Claim 1 is representative of the pending claims and is directed to a system for determining the likelihood of an atypical clinical event based on a patient's genetic profile. We agree with the Examiner that the pending claims fail to particularly point out and distinctly claim the subject matter of the invention. Ans. 22–25. Claim 1 is directed to a computer implemented method and includes, in particular, an alternative series of steps that are "otherwise" performed, the alternative series of steps including a step of determining whether to seek a clinician's authorization to order a test or to order the test without the clinician's input based on both a likelihood of one or more occurring genetic variations and a severity of interaction of the one or more occurring genetic variations with the clinical agent. Br. 26 (Claim Appendix). We agree with the Examiner that the claim does not point out how this step is performed, does not define objective criteria for making the

determination, nor is the claim clear as to how a computer is used to perform the step, thus rendering the claim indefinite. Ans. 23.

Appellants argue that the steps are clear, especially when read in light of the Specification. Br. 10–12 (citing Spec. ¶¶ 38–41). We are not persuaded. Appellants do not explain with any particularity how the identified portions of the Specification disclose how the individual steps are implemented by a computer, particularly the determining step noted above. Appellants do not, therefore, persuade us that the Examiner erred in finding that the Specification fails to provide guidance as to how to use a computer to determine when the severity of likelihood associated with the associated gene's one or more genetic variations indicates ordering a test. Ans. 23–24.

Conclusion of Law

We find that the Examiner has established by a preponderance of the evidence that claim 1 is indefinite as defined by 35 U.S.C § 112, second paragraph.

Claims 3, 5, 6, 11–14, 16, 18, 20–23, 27–31, 33, and 52–63 have not been argued separately and therefore fall with claim 1. 37 C.F.R. § 41.37(c)(1)(iv).

REJECTION UNDER 35 U.S.C. § 103(a)

Issue

In rejecting claims 1, 3, 5, 6, 11–14, 16, 18, 20–23, 27–31, 33, and 52–58 as obvious under 35 U.S.C. § 103(a), the Examiner finds that Hogan describes a method for tailoring a patient's surgical treatment, including anesthesia, using genetic information. Final Act. 10. The Examiner finds

that Hogan teaches that the genetic information is used to determine if there is a possible adverse reaction with the anesthetic. Final Act. 11. The Examiner also finds that Hogan teaches that if the genetic marker is present, the dose of the anesthetic is adjusted or a different agent is used. *Id.* The Examiner finds that Hogan teaches that the method can be accomplished through the use of a computer. Final Act. 12.

The Examiner finds that Portwood teaches a computer system wherein data prescribed is compared to pharmaceutical data to verify that the dosage is within acceptable limits. Final Act. 14. The Examiner finds that Markin discloses a system for automated testing of lab specimens in a hospital setting. Final Act. 15. The Examiner finds that Markin teaches a system that enables a doctor to provide authorization for a test using a user interface and that the test is automatically ordered based on the authorization. Final Act. 15–16. Next, the Examiner finds that Fey teaches the use of a graphical user interface to order genetic tests. *Id.* at 16.

The Examiner concludes that

> [i]t would have been obvious to one of ordinary skill in the art at the time of the instant invention to have used the database and methods for assessing risk based on general population data and construct a message to communicate said information as taught by Classen with the method taught by Hogan, Portwood et al., Markin, and Fey et al. This is because Hogan teaches an invention directed to determining risk based on an obtained genomic profile. Hogan teaches calculating risk based on a genomic profile wherein the information is communicated to the clinician or other third party users. It would be implicit that if a genomic test result value is not available, the relevant risk assessment as taught by Classen would be grounds for prompting the performance of such a genomic test. Using this data as warrant to bypass clinician

> authority, is suggested by Hogan at paragraph [0035] which teaches the use of the disclosed invention in an emergency situation, where risk overwhelms the need for clinician approval, and the test is automatically ordered.

Final Act. 18.

With respect to claim 1, the Examiner finds that Hogan teaches that genomic testing only needs to be performed where there is sufficient information about the correlation between the gene and the agents. Final Act. 19. The Examiner also finds that Hogan teaches that genetic markers may be subtracted from the screening process where the markers do not affect the patient. *Id.* The Examiner finds that "it is implied from the teaching of Hogan, that if an agent is not associated with a gene from a known data set, that the administration of the agent would be approved." *Id.* The Examiner concludes that "it would have been obvious to one of ordinary skill in the art at the time of the instant invention to have approved the administration of a clinical agent if the agent is not associated with a gene from a data set known to be associated with the agent." *Id.*.

With respect to claim 58, the Examiner finds that Hogan teaches the use of a risk assessment method to account for post-treatment patient care. Final Act. 22. The Examiner finds that it would have been obvious to apply this methodology to after the fact exposure. *Id.*

Appellants contend that Hogan does not teach or suggest a likelihood of a genetic variation or severity of interaction of the genetic variations that are both used to determine whether to seek a clinicians' authorization. Br. 15. Appellants maintain that the secondary references do not cure this deficiency. Br. 15–17. With respect to claim 18, Appellants contend that

Hogan fails to teach determining whether the risk of damage from not administering the clinical agent is greater than the risk of damage by lowering the dosage of the clinical agent. Br. 18–19. Appellants contend that the secondary references do not make up for the deficiency of Hogan. Br. 19–20. Finally, with respect to claim 58, Appellants argue that Hogan does not teach determining whether to request authorization for a clinician based on three criteria, the cost of the genetic test, whether the test is available and the likelihood of a genetic variation based on the demographic information of the patient. Br. 21. Appellants again contend that the secondary references do not address the deficiencies of Hogan. *Id.*

The issue with respect to this rejection is whether the Examiner has established by a preponderance of the evidence that the rejected claims would have been obvious over Hogan in combination with Classen, Portwood, Markin and Fey as defined by 35 U.S.C. § 103(a).

Findings of Fact

We adopt as our own the Examiner's findings and analysis. The following findings are included for emphasis and reference convenience.

FF1. Hogan discloses a computer based method for tailoring a surgical treatment to reflect genetic information. Hogan, Abstract.

FF2. Hogan teaches that surgical treatment includes the administration of anesthesia and/or other drugs. Hogan ¶¶ 4–10.

FF3. The method of Hogan includes determining if the patient is a candidate for genomic profiling. Hogan ¶ 187.

FF4. Determination of whether a profile should be developed includes reference to the patient's medical history or medical exam. Hogan ¶ 123.

FF5. Hogan teaches that if the patient is a candidate for preparation of a genomic profile, a sample is taken and a profile is developed. *Id.*

FF6. Hogan discloses that the method used to generate the genomic profile is selected based on the method's ability to provide useful information, its practicality, including costs, and the validity of the assay for clinical utility. *Id.*

FF7. Hogan teaches that the data from the genomic assay can be generated, processed, and/or managed using electronic communication systems. *Id.*

FF8. Hogan teaches that the genetic markers can be selected using medical histories, physical exams and non-genomic testing. Hogan ¶ 123.

FF9. Hogan teaches a computer based analysis can be used to translate the raw data generated by the genomic profile into data of predictive value. Hogan ¶ 188.

FF10. Hogan teaches that the "[r]esults of the genomic profile are used to make appropriate decisions about patient care, including choice of analgesics and anesthetics, post-surgical monitoring, and additional medications or treatments." Hogan ¶ 203.

FF11. Hogan teaches that the genetic information is used to establish the patient's prognosis or odds of survival. Hogan ¶ 36.

FF12. Hogan goes on to teach that in some embodiments, the information is used to select the safest and most efficacious surgical procedure. *Id.*

FF13. Hogan teaches that the genetic markers can be selected for which the alternative treatment has little or no effect on the cost or inconvenience of the patient. Hogan ¶ 124.

FF14. Hogan also teaches the use of demographic information to select markers. Hogan ¶ 123.

FF15. Hogan teaches that the genetic markers are selected based on analytical validity, clinical validity and commercial value. Hogan ¶ 122.

FF16. Portwood teaches a computer system for improving medical regimes wherein data prescribed is compared to pharmaceutical data to verify acceptable limits, durations and to check for contraindications and/or abnormalities. Portwood, Abstract.

FF17. Markin teaches a computerized system which enables a doctor to enter a request for a specific test to be performed to include authorization and the test is then automatically ordered. Markin col. 3, ll. 1–9.

FF18. Classen teaches storing adverse event data for drugs in a database. Classen col. 3, ll. 13–21.

FF19. Classen teaches that the data can be used to analyze the risk for an individual wherein the data is compared to patients with similar characteristics before receiving the medication. Classen col. 6, ll. 9–30.

Principles of Law

"The factual predicates underlying an obviousness determination include the scope and content of the prior art, the differences between the

prior art and the claimed invention, and the level of ordinary skill in the art." *In re Rouffet*, 149 F.3d 1350, 1355, 47 USPQ2d 1453, 1455 (Fed. Cir. 1998).

"[W]hile an analysis of obviousness always depends on evidence that supports the required *Graham* factual findings, it also may include recourse to logic, judgment, and common sense available to the person of ordinary skill that do not necessarily require explication in any reference or expert opinion." *Perfect Web Techs., Inc. v. Info USA, Inc.*, 587 F.3d 1324, 1329 (Fed. Cir. 2009).

Analysis

Claim 1

We agree with the Examiner that claim 1 would have been obvious to one skilled in the art. Hogan discloses a computer based method for tailoring patient's surgical treatment using data from a genetic profile. FF1. The genetic profile can be ordered if indicated by the patient's medical history or medical exam. FF3. The genetic profile can be used to alter the surgical procedure to include changing the amount of type or anesthetic used or the amount or type of drugs administered. FF10. The genetic test is selected using a cost benefit analysis. FF12 and 13. Portwood teaches a computer system wherein data relating to prescribed medication is compared with pharmaceutical data to verify acceptable limits, duration and to check for contraindications or abnormalities. FF16. Markin teaches a computer based system to automatically order a lab test when authorized by a physician. FF17. Classen teaches the use of a database of adverse clinical information that comprises "subgroup analysis" to determine specific high

risk groups. FF 18. The groups of Classen can include patients with similar genetic characteristics. FF18. We agree with the Examiner that one skilled in the art at the time the invention was made would have combined the method of Hogan with the teachings of Portwood, Clausen, Markin and Fey to develop the claimed invention. Ans. 18. For example, the system and pharmaceutical data described by Portwood would enable a person using the method of Hogan to have more efficient access to the pharmaceutical data to tailor a patient's medical regime. Ans. 15. Markin's automated ordering system would improve the processing of tests needed to practice the method of Hogan. Ans. 16. Using the risk analysis of Clausen would serves as grounds for ordering the genomic test and bypassing a clinician's authority if the risk indicates. Ans. 17–18.

Appellants argue that the references do not teach the limitation of determining whether to seek a clinician's authorization to order the test or whether to order the test without the clinician's input. Br. 14. We are unpersuaded. First, as the Examiner pointed out, the limitation at issue is preceded by the words "otherwise, perform the following procedure:" Ans. 26. This makes the recited steps optional. *Id.* The prior art teaches all the steps up to the optional step. Moreover, we agree with the Examiner that

> it would have been obvious to one of ordinary skill in the art at the time of the instant invention to have used the database and methods for assessing risk based on general population data and construct a message to communicate said information as taught by Classen with the method taught by Hogan, Portwood et al., Markin, and Fey et al. This is because Hogan teaches an invention directed to determining risk based on an obtained genomic profile. Hogan teaches calculating risk based on a genomic

> profile wherein the information is communicated to the clinician or other third party users. It would be implicit that if a genomic test result value is not available, the relevant risk assessment as taught by Classen would be grounds for prompting the performance of such a genomic test. Using this data as warrant to bypass clinician authority, is suggested by Hogan at paragraph [0035] which teaches the use of the disclosed invention in an emergency situation, where risk overwhelms the need for clinician approval, and the test is automatically ordered.

Ans. 28

Claims 3, 5, 6, 11–14, and 16.

While these claims have been separately listed in Appellants' brief, the only argument presented is that the arguments for claim 1 are applicable to these dependent claims. Br. 17. Therefore these claims fall with claim 1.

Claim 18

With respect to claim 18, Appellants argue that none of the references teach using the genetic data to "determine whether a risk of damage from not administering the clinical agent is greater than the risk of damage by lowering the dosage of the clinical agent." Br. 19. We agree with the Examiner that

> [w]hile Hogan does not explicitly recite the steps of determining whether a risk of damage from not administering the clinical agent is greater than the risk of damage by lowering the dosage of the clinical agent, it is inherent in the description of Hogan that the operating physician would go through the same decision tree when determining the optimal agent corresponding to the surgical procedure at hand, specifically in view of knowing if a patient had a predisposition.

Ans. 30. Hogan teaches that the genetic information is used to establish the patient's prognosis or odds of survival. FF11. Hogan goes on to teach that in some embodiments, the information is used to select the safest and most efficacious surgical procedure. FF12. Common sense dictates that the physician would inherently need to determine whether the risk of not administering a clinical agent is greater than using a lower dosage of the agent.

Claims 20–23, 27–31, 33, and 54–57

Claims 20–23, 27–31, 33, and 54–57 depend, either directly or indirectly, from claim 18. Appellants have offered no separate arguments to support patentability for these claims other than the arguments relating to claim 18 discussed above. Br. 20. Therefore, these claims fall with claim 18.

Claim 58

Appellants contend that none of the references of record teach the limitation that the determination of whether to request authorization for a test is based on three criteria, whether the genomic profiles are cost and time effective, whether the test is available and the likelihood of a genetic variation based on demographic data of the patient. Br. 21–23. We are unpersuaded. Hogan teaches that the genetic markers can be selected for which the alternative treatment has little or no effect on the cost or inconvenience of the patient. FF13. Hogan also teaches that the genetic markers are selected based on several criteria including analytical validity, clinical validity, and commercial value. FF15. Hogan also teaches the use of demographic information to select markers. FF14. We therefore agree

with the Examiner that "Hogan contemplates the three categories of information when implementing the invention." Ans. 31–32.

Conclusion of Law

We conclude that the Examiner has established by a preponderance of the evidence that claims 1, 3, 5, 6, 11–14, 16, 18, 20–23, 27–31, 33, and 54–58 are obvious over Hogan in combination with Portwood, Classen, Markin and Fey as defined by 35 U.S.C. § 103(a).

SUMMARY

We affirm the rejection of claims 1, 3, 5, 6, 11–14, 16, 18, 20–23, 27–31, 33, and 52–63 under 35 U.S.C § 101 as being drawn to non-statutory subject matter.

We affirm the rejection of claims 1, 3, 5, 6, 11–14, 16, 18, 20–23, 27–31, 33, and 52–63 under 35 U.S.C. § 112 second paragraph as being indefinite for failing to particularly point out and distinctly claims the subject matter the inventor regards as his invention.

We affirm the rejection of claims 1, 3, 5, 6, 18, 20–23, 27–31, 33, and 54–58 under 35 U.S.C. § 103(a) as unpatentable over Hogan, in view of Classen, Portwood, and Markin, and in further view of Fey

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED