

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte TRACY HARMON BLUMENFELD

Appeal 2008-3771
Application 10/118,369
Technology Center 3600

Decided: September 8, 2008

Before WILLIAM F. PATE, III, HUBERT C. LORIN, and
JOSEPH A. FISCHETTI, *Administrative Patent Judges*.

LORIN, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Tracy Harmon Blumenfeld (Appellant) seeks our review under 35
U.S.C. § 134 of the final rejection of claims 1, 3-12, 14-21, and 28-31.

Claims 2 and 13 have been cancelled and claims 22-27 have been withdrawn. We have jurisdiction under 35 U.S.C. § 6(b) (2002).

SUMMARY OF DECISION

We AFFIRM.¹

THE INVENTION

The invention is directed to a system and method for evaluating the performance and progress of research trials and more specifically to providing benchmark metrics in real time. (Specification 1:3-5.)

Currently no electronic mechanism exists that systematically and automatically provides clinicians and/or pharmaceutical sponsors with the ability to obtain interactive, real-time benchmarks and with those benchmarks better assess physician capabilities for matching physicians and research sites and with those data better assess physician capabilities for matching physicians and research sites for future clinical trials.

(Specification 1:15-2:2.)

Claim 1, reproduced below, is illustrative of the subject matter on appeal.

1. A method for permitting a sponsor of an activity to contact a plurality of potential participants in the activity and for monitoring progress of the activity,

¹ Our decision will make reference to the Appellant's Appeal Brief ("App. Br.," filed Jun. 15, 2007) and Reply Brief ("Reply Br.," filed Dec. 10, 2007), and the Examiner's Answer ("Answer," mailed Oct. 9, 2007).

the method comprising:

- (a) storing, on a database server, information concerning the plurality of potential participants to allow the sponsor to access the information concerning the plurality of potential participants;
- (b) storing, on the database server, information submitted by the sponsor concerning the activity to allow the plurality of potential participants to access the information concerning the activity;
- (c) providing contact between the sponsor and at least one of the plurality of potential participants concerning the activity to allow selection of at least one participant from the plurality of potential participants;
- (d) selecting said at least one participant;
- (e) storing, on the database server, information concerning the progress of the activity and displaying some or all of the information at least to the at least one participant selected in step (d);
- (f) automatically calculating, from the information stored in step (e), benchmarks concerning the progress of the activity once said at least one participant is selected; and
- (g) displaying some or all of the benchmarks at least to the at least one participant.

THE REJECTION

The Examiner relies upon the following as evidence of unpatentability:

Benigno	US 2002/0087361 A1	Jul. 4, 2002
Knight	US 2002/0099570 A1	Jul. 25, 2002

The following rejection is before us for review:

1. Claims 1, 3-12, 14-21, and 28-31 are rejected under 35 U.S.C. §103(a) as being unpatentable over Benigno and Knight.

ISSUE

The issue before us is whether the Appellant has shown that the Examiner erred in rejecting claims 1, 3-12, 14-21, and 28-31 under 35 U.S.C. §103(a) as being unpatentable over Benigno and Knight. The issue turns on whether the prior art would have led one of ordinary skill in the art to conduct claim steps (d) and (g) using the same participant.

FINDINGS OF FACT

We find that the following enumerated findings of fact (FF) are supported by at least a preponderance of the evidence. *Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1427 (Fed. Cir. 1988) (explaining the general evidentiary standard for proceedings before the Office).

The scope and content of the prior art

1. Benigno relates to “systems useful for analyzing medical data related to clinical pathways and performing actions based upon the analyses.” [0003].
2. Benigno [0025] describes its system as one which allows a caregiver, such as a doctor or nurse, to review a proposed clinical pathway.
3. Benigno [0113] describes its system as one which can determine optimal clinical pathways based on various criteria developed from a patient’s history.

4. Knight describes techniques for recruiting patients into a clinical trial.

Any differences between the claimed subject matter and the prior art

5. The claimed method combines Benigno's benchmarking system with Knight's patient selection process but instead of displaying the benchmarks to the caregiver, as Benigno suggests, displaying them to the selected patient.

The level of skill in the art

6. Neither the Examiner nor the Appellant has addressed the level of ordinary skill in the pertinent arts of benchmarking and medical care. We will therefore consider the cited prior art as representative of the level of ordinary skill in the art. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001)("[T]he absence of specific findings on the level of skill in the art does not give rise to reversible error 'where the prior art itself reflects an appropriate level and a need for testimony is not shown'") (Quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163 (Fed. Cir. 1985)).
7. One of ordinary skill in the art of medical care would have known that most, if not all, caregivers share health-related information they have gathered on a patient with that patient herself.

Secondary considerations

8. There is no evidence on record of secondary considerations of non-obviousness for our consideration.

PRINCIPLES OF LAW

Obviousness

“Section 103 forbids issuance of a patent when ‘the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.’” *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1734 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art, (2) any differences between the claimed subject matter and the prior art, and (3) the level of skill in the art. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). *See also KSR*, 127 S.Ct. at 1734 (“While the sequence of these questions might be reordered in any particular case, the [*Graham*] factors continue to define the inquiry that controls.”) The Court in *Graham* further noted that evidence of secondary considerations “might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.” 383 U.S. at 17-18.

ANALYSIS

The Appellant argued claims 1, 3-12, 14-21, and 28-31 as a group (App. Br. 4-6; Reply Br. 1-3). We select claim 1 as the representative claim for this group, and the remaining claims 3-12, 14-21, and 28-31 stand or fall with claim 1. 37 C.F.R. § 41.37(c)(1)(vii) (2007).

Benigno describes a system for analyzing medical data related to clinical pathways. (FF 1.) The Examiner argued that Benigno describes automatically calculating benchmarks concerning the progress of an activity

of a participant (citing [0025] and [0113]-[0115]) and displaying the benchmarks to the participant; the activity being care of a patient and the participant being a nurse. (Ans. 4-5.) The Examiner conceded that “Benigno fails to teach ... [claim step] (d) selecting said at least one participant.” (Ans. 5.) To meet this limitation, the Examiner relied on Knight. According to the Examiner, Knight

teaches recruitment of patients into clinical trials (Knight: [0005]) and includes acquiring patient data (Knight: [0050]) and providing sponsor contact information to the patient (Knight: Fig 13; [0083]) if a match exists between the patient and the requirements of a clinical trial (Knight: [0017]).

In an embodiment of Knight, a pharmaceutical company can access patient information to pre-enroll (Knight: [0130]); read on by select) patients in a trial. If a patient is selected for participation in the trial as a result of the system having matched the patient to the trial, patient data can be sent to the system’s server via the clinical trial.

(Answer 5.) The Examiner concluded:

[i]t would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Benigno and Knight with the motivation of providing highly current patient data collected by a clinician (Benigno: [0038]), thus further accelerating the patient recruitment process into a clinical trial (Knight: [0130]).

(Ans. 6.)

The Appellant disagreed arguing that “[t]here is no teaching or suggestion to display the benchmarks to the patient.” (App. Br. 6.)

According to the Appellant

The system for determining optimal pathways taught in [Benigno] is not taught as displaying benchmarks to a patient. With regard to the claim limitation directed to selecting said at least one participant (claim 1, step (d)), the Final Rejection reads that limitation on the selection of a patient in Knight. If that is the case, then with regard to the claim limitation directed to displaying some or all of the benchmarks at least to the at least one participant (claim 1, step (g)), the at least one participant ought to be the patient as well, since the meaning of the term cannot shift within a single claim. However, the Final Rejection reads the limitation of step (g) on paragraphs of [Benigno] that do not teach or even vaguely suggest displaying any benchmarks to the patient. Rather, the cited paragraphs of [Benigno] teach displaying such benchmarks to the caretaker or the nurse, or to unspecified parties.

(App. Br. 5.)(See also Reply Br. 2-3.)

If we understand the Appellant’s argument correctly, the Appellant is saying that Benigno, which describes displaying benchmarks to a nurse or doctor and Knight, which describes selecting a patient, would lead one of ordinary skill in the art to display the benchmarks to the nurse or doctor but not to the patient. We are not persuaded as to error in the rejection by this argument. In our view, the argument falls in the face of common sense.

Benigno describes a method for determining the clinical pathways that are optimal for a patient depending on that patient’s history. (FF 3.) Patient information is gathered and evaluated according to criteria for determining

an optimal clinical pathway for the patient and that optimal clinical pathway is then communicated. Benigno does not limit communication of the optimal clinical pathway to nurses and doctors, although Benigno mentions nurses and doctors as the caregivers who communicate with the system that determines the optimal clinical pathways. (FF 2 and 3.) Clearly, the optimal clinical pathway for a patient must be communicated to a caregiver so that the patient may be cared for consistent with the determined optimal clinical pathway. But there is nothing in Benigno that limits display of the determined optimal clinical pathway to a caregiver. Most if not all caregivers share health-related information they have gathered on a patient with that patient herself. That is notoriously well known in the field of medical care. (FF 7.) One of ordinary skill in the art reading Benigno alone would understand its scope and content to be such that it would cover displaying the optimal clinical pathways to the patient involved. That Benigno should be read to suggest that benchmarks be displayed only to nurses and doctors, and not to patients, even where a nurse or doctor may be the very patient being monitored, presumes one of ordinary skill in the art lacks the common sense to understand that caregivers share patient information with their patients. That is not a presumption we believe can be supported by objective evidence, especially given that “[a] person of ordinary skill is also a person of ordinary creativity, not an automaton.” *KSR*, 127 S.Ct. at 1742.

On the question of whether the cited prior art describes or discloses selecting a participant whose activity will be monitored, there is no dispute that Benigno is drawn to clinical trials. It is generally well known that patients are selected to be in clinical trials. This is evidenced by Knight.

Accordingly, given the cited prior art which describes determining optimal clinical pathways for a patient (Benigno) and selecting a patient for a clinical trial (Knight), and that caregivers normally share medical results with their patients, it would have been obvious to select a participant whose activity will be monitored and benchmarked and to display some or all of the benchmarks to the selected participant.

CONCLUSIONS OF LAW

We conclude that the Appellant has not shown that the Examiner erred in rejecting claims 1, 3-12, 14-21, and 28-31 under 35 U.S.C. §103(a) as being unpatentable over Benigno and Knight.

DECISION

The decision of the Examiner to reject claims 1, 3-12, 14-21, and 28-31 is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv) (2007).

AFFIRMED

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