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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte GUST H. BARDY

Appeal 2013-003214
Application 12/689,706[1]
Technology Center 3700

Before RICHARD M. LEBOVITZ, CHRISTOPHER G. PAULRAJ and ELIZABETH A. LAVIER, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal involves claims directed to methods for determining patient status and providing automated feedback to an individual patient. Appellant[2] appeals from the Examiner's rejections of claims 2–21. We have jurisdiction under 35 U.S.C. § 134. The rejections are affirmed.

STATEMENT OF CASE

Appellant appeals from the Examiner's final rejection of claims 2–21. The claims stand rejected by the Examiner as follows:

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[1] "The '706 Application."
[2] Appellant states the real party in interest is Cardiac Pacemakers, Inc. Appeal Br. 1.

1. Claims 2, 7 and 19 under 35 U.S.C. § 102(b) (pre-AIA) as anticipated by Nikolic (US 5,743,267, issued Apr. 28, 1998). Final Rej. 3.

2. Claims 2–4, 13, 14, 19, and 21 under 35 U.S.C. § 103(a) (pre-AIA) as obvious in view of Tacklind (US 5,704,366, issued Jan. 6, 1998) and Nikolic. *Id.* at 4.

3. Claims 5, 6, and 15–17 under 35 U.S.C. § 103(a) (pre-AIA) as obvious in view of Tacklind, Nikolic, and Bui (US 6,398,727 B1, issued Jun. 4, 2002). *Id.* at 5.

4. Claim 7 and 18 under 35 U.S.C. § 103(a) (pre-AIA) as obvious in view of Tacklind, Nikolic, Bui, and Lavin (US 5,772,585, issued Jun. 30, 1998). *Id.* at 6.

5. Claims 8–10 and 20 under 35 U.S.C. § 103(a) (pre-AIA) as obvious in view of Tacklind, Nikolic, and Levine (US 4,852,570, issued Aug. 1, 1989). *Id.* at 7.

6. Claim 11 under 35 U.S.C. § 103(a) (pre-AIA) as obvious in view of Tacklind, Nikolic, Levine, and Bui. *Id.* at 8.

7. Claim 12 under 35 U.S.C. § 103(a) (pre-AIA) as obvious in view of Tacklind, Nikolic, Levine, and Lavin. *Id.* at 9.

8. Claims 2–7 under 35 U.S.C. § 101 as directed to non-statutory subject matter. *Id.* at 2.

Claims 2, 8 and 13 are independent claims. The remaining claims depend from them. Independent claim 2 is representative and reproduced below. The claim has been annotated by the addition of bracketed numerals to indicate the steps of the claimed method.

> 2. A method for determining patient status and providing feedback to an individual patient for automated remote patient care, comprising:

> [1] organizing patient care records in a database, where each patient care record comprises information identifying an individual patient;
>
> [2] for a particular patient, receiving collected device measures to provide raw physiological measures for the patient, wherein the collected device measures are regularly generated and recorded by an implanted medical device comprising a plurality of physiological sensors;
>
> [3] determining derived device measures based on the collected device measures;
>
> [4] determining a patient status indicator based on analysis of the collected device measures; and
>
> [5] sending automated feedback to the patient based at least in part on the patient status indicator, wherein the automated feedback includes an interpretation of the patient status indicator and related health care information.

GROUND 1. ANTICIPATION BY NIKOLIC

The method of claim 2 comprises the step of [5] "sending automated feedback to the patient based at least in part on the patient status." The Examiner found this step met by the teaching in Nikolic at column 7, lines 5–10. The cited disclosure is as follows:

> For example, a plot illustrating a steady drop in a patient[']s maximum systolic pressure over a defined period of time may indicate a weakening of the patient's heart. A doctor can then prescribe a medical treatment to correct the problem before the patient progresses into a more severe condition requiring admission into a hospital.

Id. at col. 7, ll. 5–10.

Appellant contends that "teaching that a doctor can prescribe a medical treatment to correct a patient health problem, as in Nikolic is not analogous to, 'sending automated feedback to the patient' of independent claim 2 because the broadest reasonable interpretation of the word

'automated' does not encompass a doctor prescribing medical treatment." Appeal Br. 11.

To address this argument, we must begin with claim interpretation. During patent prosecution, claim terms are given their broadest reasonable interpretation, consistent with the specification, as they would be understood by one of ordinary skill in the art. *In re Buszard*, 504 F.3d 1364, 1367 (Fed. Cir. 2007); *In re Am. Acad. of Sci. Tech Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004). Neither "automated" nor "automated feedback" is defined in the '706 Application. We thus adopt the ordinary dictionary definition of "automated" to mean "to run or operate (something, such as a factory or system) by using machines, computers, etc., instead of people to do the work."[3] This interpretation is consistent with the Application, which describes automatic feedback generated by a server. '706 Appl. 13: 6–11; 14: 11–16.

Because Nikolic's system utilizes a person to send feedback ("doctor can then prescribe a medical treatment" at col. 7, ll. 7–8), it is not "automated feedback" as one of ordinary skill in the art would have understood the term at the time of the invention. Accordingly, we reverse the anticipation rejection of claim 2, and dependent claims 7 and 19.

GROUND 2. OBVIOUSNESS IN VIEW OF TACKLIND AND NIKOLIC

The Examiner found that Tacklind describes steps [1] through [5] of the method of claim 2, but does not teach collecting the measurements from "an implanted medical device" as required by the claim. Final Rej. 4.

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[3] http://www.merriam-webster.com/dictionary/automate. Accessed June 14, 2016.

However, the Examiner cited Nikolic for teaching that it was known to use an implantable medical device for remote monitoring of patients with chronic cardiac disease. *Id.* at 4–5. The Examiner concluded that it would have been obvious to use an implantable medical device in Tacklind's process "since such a modification would provide the predictable results of accurately monitoring patients that suffer chronic cardiac disease, where the chronic nature warrants an implanted/long term monitoring means." *Id.* at 5.

Appellant contends that the cited publications do not make claims 2 and 13 obvious because they do not teach or suggest "a plurality of physiological sensors" as recited in the claims. Appeal Br. 12. Appellant "concedes that Tacklind does reference multiple sensors, however, a mere reference to multiple sensors does not render obvious a method where a patient status indicator is determined based on collected device" because "Tacklind does not provide any information suggesting how one would combine data from multiple sensors to determine a patient status indicator, or any reason why one would do it in the first place." *Id.* at 13. Appellant argues that Nikolic does not "cure" the deficiency in Tacklind. *Id.* at 13–14.

Analysis

Again we start with claim interpretation because, before a claim is properly interpreted, it cannot be compared to the prior art. For this ground of rejection, the dispute between the Examiner and Appellant involves step [4] of claim 2, which recites "determining a patient status indicator based on analysis of the collected device measures."

Claims are interpreted in view of the specification of which they are part. *Am. Acad.*, 367 F.3d at 1364. We have not been directed to a

definition of "patient status indictor" in the '706 Application nor can we find an explicit definition in the application. An example is given in the '706 Application of measuring cardiac output as a "health trend" "as to the particular patient," and comparing the output to a group of patients to establish whether patient "is trending out of the norm." '706 Appl. 21:23–22:1. The '706 Application states that "[f]rom this type of analysis, the analysis module 53 generates a patient status indicator 54 and other metrics of patient wellness, as is known in the art." *Id.* at 22:1–3. The '706 Application also teaches that a "new and improved indicator of impending heart failure could be derived based on the exemplary cardiac collected measures set described with reference to FIGURE 5," where Fig. 5 lists various measurements, such as atrial electrical activity, cardiac output, oxygen level, etc. *Id.* at 18:2–7. Based on this description in the '706 Application, we interpret the patient status indicator to mean a module which provides "health trends" and "metrics of patient wellness." Claim 13 is similarly construed because it recites similar language, i.e., "code for determining a patient status indicator based on an analysis of the collected device measure."

While the '706 Application describes embodiments where the metrics of the patient status indicator is "derived" from measurements obtained from cardiac sensors (*e.g.*, *id.* at 18:2–7; 21:23–22:3), the claims do not require this step. Specifically, step [3] of the claim recites "determining derived device measures based on the collected device measures." However, in step [4], the patient status indicator is determined "based on the collected device measures" and therefore the patient status indicator is not necessarily determined from the "derived device measures" of step [3].

Next, we turn to Tacklind. Tacklind, as conceded by Appellant, explicitly discloses "a plurality of physiological sensors" as recited in claim 2. Tacklind teaches:

> A sensor device **10** is used to measure the value of a selected physiological characteristic of a patient such as respiratory functions, e.g., peak expiratory flow (PEF) and forced expiratory volume (FEV_1), blood glucose levels, blood pressure, heart rate, body weight, fluid intake and discharge rates, and caloric intake. Sensors for measuring these values and providing a digital sensor output encoding the measured values of the physiological characteristics are commercially available. A particular sensor for measuring respiratory functions will be described more fully below.

Tacklind, col. 5, ll. 20–30.

Thus, while Tacklind exemplifies a specific type of sensor, Tacklind has broader disclosure of utilizing a plurality of sensors to collect physiological characteristics of a patient.

Tacklind also describes a module that collects "the digital sensor outputs," displays "interpreted measurements" to the patient (e.g., [4] "the patient status indicator" of claim 1), and transferring them to a remote location:

> The intelligence and communications functions are provided in a monitor module **12** which is used by the patient. The sensor may be integrated into the monitor module **12** or be separate with a cable or other means. e.g., an IR beam, used to transfer the digital sensor output to the monitor module **12**. The monitor module **12** performs the intelligence functions of *collection and interpretation of measured values encoded in the digital sensor outputs*, the memory function of storing multiple measured values along with time stamps indicating when measurements were taken, the *display function of visually communicating the interpreted measurements to the patient*,

> and the communication function for *transferring measured values and time stamps via the telephone system*.

Id. at col. 5, ll. 31–44 (emphases added).

Appellant's argument that Tacklind does not teach "how one would combine data from multiple sensors to determine a patient status indicator" reads a limitation into the claim which does not appear in it. Appeal Br. 13. Appellant appears to be distinguishing Tacklind based on step [4] of claim 2 of "determining a patient status indicator based on analysis of the collected device measures." The properly interpreted step requires only that the patient status indicator provides "health trends" and "metrics of patient wellness." *See* discussion above. Appellant has not explained what language in the claim or definition in the Application would require data from multiple sensors to be combined. Consequently, we find that Appellant's argument is not supported by a preponderance of the evidence.

Because Appellant did not demonstrate error in the Examiner's rejection, we affirm the obviousness rejection of claims 2 and 13 based on Tacklind and Nikolic. Claims 3, 4, 14, 19, and 21 fall with claims 2 and 13 because separate reasons for their patentability were not provided. *See* 37 C.F.R. § 41.37(c)(1)(iv).

GROUND 5. OBVIOUSNESS IN VIEW OF TACKLIND, NIKOLIC, AND LEVINE

The Examiner further rejected claims 8–10 and 20 based on Levine. Independent claim 8 is directed to a "system for providing feedback to an individual patient for automated remote patient care" which, *inter alia*, recites "a server periodically receiving the collected measures set from the medical device" and "analyzing the collected measures set and one or more

of the plurality of collected measures sets relative to one or more other collected measures sets stored in the database to determine a patient status indicator." Claims 9, 10, and 20 depend from claim 8.

The Examiner cited Levine for its teaching of comparing collected device measurements to previous sets of measurements to determine patient status. Final Rej. 7. The Examiner reasoned it would have been obvious to one of ordinary skill in the art to implement Levin in Tacklind's process because "such a modification would provide the predictable results of facilitating detection of adverse trends that are indicative of problems and future problems such that preventative action may be taken." *Id.*

Appellant contends that Levine focuses on "identifying trends" rather than teaching or suggesting "determining a patient status indicator." Appeal Br. 16. Appellant also states there is no indication in Levine "that a *server* in Levine analyzes collected measures sets '. . . to determine a patient status indicator.' Levine does not teach or suggest that data sets are analyzed. The analysis of the measurements is by a person based on the data presented." *Id. See also* Reply Br. 6.

Appellant has not demonstrated error in the Examiner's rejection. The "trends" described by Levine are obtained from periodically taking medical tests and storing them on a card. Levine, col. 2, ll. 17–26. The physician reviews

> . . . results of the periodically made groups of tests. By comparing like measurements taken of that individual over many spaced periods of time, the doctor can more readily detect changes and "trends" that have progressively taken place over the long term. If such comparisons reveal unexplained, undesirable changes, the doctor is alerted to more intensively

> investigate the conditions indicated, and take such corrective measures as appear to be necessary.

Id. at col. 2, ll. 35–45.

The test measurements in Levine constitute patient health metrics and thus meet the limitation of a "patient status indicator" as we have construed the term. Indeed, the '706 Application uses the term "health trends" (at 21:23–22:1), as does Levine. Appellant has not provided adequate argument or evidence that the Examiner erred in finding that Levine meets the "patient status indicator."

Alternatively, the Examiner found that Tacklind meets the limitation of determining a patient status indicator and relied on Levine for its teaching of comparing the collected measures to one or more stored collected measure sets, and found it obvious to perform such comparative analysis in Tacklind. Answer 4. Appellant did not identify an error in this determination.

As to the argument that Levine's analysis is performed by a person and not a server as recited in the claim, the Examiner responded that the rejection is based on utilizing Levine's analysis in Tacklind's system which uses a "server/database for analysis of collected measures." Answer 4–5. The Examiner's reasoning is fact-based and sound. *See* Final Rej. 7. Appellant has not identified an error in it.

For the foregoing reasons, we affirm the rejection of claim 8. Claims 9, 10, and 20 were not argued separately and thus fall with claim 8. *See* 37 C.F.R. § 41.37(c)(1)(iv).

GROUNDS OF REJECTION 3, 4, 6, AND 7

Appellant's arguments as to Ground 3 (Appeal Br. 14), Ground 4 (*id.* at 14–15), Ground 6 (*id.* at 17), and Ground 7 (*id.*) are the same as the unpersuasive arguments set forth for the rejections based on Tacklind, Nikolic, and Levine. Consequently, we affirm these rejections for the reasons already discussed.

GROUND 8. SECTION 101 REJECTION

The Examiner rejected claims 2–7 under 35 U.S.C. § 101 based on the determination that the claimed invention is directed to non-statutory subject matter. Final Rej. 2; *see also* Answer 3.

A patent may be obtained for "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." 35 U.S.C. § 101. But, § 101 has long been understood as "contain[ing] an important implicit exception: Laws of nature, natural phenomena, and abstract ideas are not patentable." *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2354 (2014) (internal citation and quotation omitted).[4] In *Alice*, the Supreme Court reaffirmed the framework set forth previously in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012), "for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of these concepts." *Alice*, 134 S. Ct. at 2355. The first step in the analysis is to "determine whether the claims at issue are directed to one of those patent-ineligible concepts." *Id.* If so, the second step is to

[4] Although *Alice* issued after this appeal was docketed, we find that the Examiner's analysis is consistent with *Alice*.

consider the elements of the claims "individually and 'as an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patent-eligible application." *Id.* (quoting *Mayo*, 132 S. Ct. at 1298, 1297). Put differently, the second step is to "search for an 'inventive concept' — i.e., an element or combination of elements that is 'sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.'" *Id.* (brackets in original) (quoting *Mayo*, 132 S. Ct. at 1294).

Beginning with the first step of the *Alice* framework, we agree with the Examiner that claims 2–7 are drawn to an abstract idea, *see* Answer 3, namely to a method of data gathering and analysis, and the provision of feedback based on that analysis. Thus, claims 2–7 fall outside the ambit of § 101 unless, pursuant to the second step from *Alice*, the claims include an "inventive concept" that amounts to "significantly more" than the abstract idea itself. We conclude that they do not. The Examiner explained that claims 2–7 are not tied to a particular apparatus and do not transform a particular article, thus failing the machine-or-transformation test. *See* Final Action 2; Answer 3. The machine-or-transformation test is not dispositive, but it is a "useful clue" in assessing patent eligibility. *Bilski v. Kappos*, 561 U.S. 593, 604 (2010). Importantly, a claim drawn to an abstract idea cannot be rescued merely by "limiting the use of [that] abstract idea 'to a particular technological environment.'" *Alice*, 134 S. Ct. at 2358 (quoting *Bilski*, 561 U.S. at 610–11); *see also id.* at 2359 (applying substantially the same analysis to method claims). In this case, the steps in the claimed method are principally directed to data gathering (steps [1] and [2]) and the machine is only tangentially related to performing the steps [3]–[5] because such steps

can be performed by a person as evidenced by the discussion of step [5] in the anticipation rejection based on Nikolic and in the discussion of Levine where the data analysis and patient indicator of [3] and [4] is performed by a person. Thus, claim 2 does no more "than simply instruct the practitioner to implement the abstract idea," *Alice*, 134 S. Ct. at 2359. Claims 3–7, which are not argued separately, are similarly deficient, and fall with claim 2. Accordingly, we affirm the Examiner's rejection of claims 2–7 under § 101.

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