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COLLARD & ROE, P.C.
1077 NORTHERN BOULEVARD
ROSLYN, NY 11576

EXAMINER	
FITZSIMMONS, ALLISON G	

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte WEI ZHANG and ELKE SCHULTE

Appeal 2017-000283
Application 13/397,959
Technology Center 1700

Before LINDA M. GAUDETTE, CHRISTOPHER C. KENNEDY, and JENNIFER R. GUPTA, *Administrative Patent Judges*.

GUPTA, *Administrative Patent Judge*.

DECISION ON APPEAL[1]

Appellants[2] appeal under 35 U.S.C. § 134(a) from the Examiner's final decision rejecting claims 1–10. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM and enter a new ground of rejection.

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[1] In this Decision, we refer to the Specification filed February 16, 2012 ("Spec."), the Final Office Action dated October 26, 2015 ("Final Act."), the Appeal Brief filed May 20, 2016 ("Appeal Br."), the Examiner's Answer dated August 9, 2016 ("Ans."), and the Reply Brief filed October 4, 2016 ("Reply Br.").

[2] Appellants identify the real party in interest as Fresenius Medical Care Deutschland GmbH. Appeal Br. 1.

The subject matter of the claims on appeal relates to a dialyzer with a measuring unit assigned thereto, where the measuring unit transmits data to the dialyzer wirelessly. Spec. 1, ¶ 2.

Claim 1, reproduced below from the Claims Appendix of the Appeal Brief, is illustrative of the claims on appeal.

> 1. A method for signalling a possible connection of a measuring unit to a wrong patient, whereby the measuring unit is assigned to a dialyzer, whereby data transmission from the measuring unit to the dialyzer ensues wirelessly, wherein the method comprises steps of:
>
> commencement of a dialysis procedure performed via the dialyzer on a patient,
>
> determining during the dialysis procedure a first value of at least one measurable variable measured by the measuring unit at a point in time t or in a time window ti,
>
> transmitting to the dialyzer via a wireless link between the measuring unit and the dialyzer the determined first value of the at least one measurable variable,
>
> determining a second value of the at least one measurable variable measured at the same point in time t or in the same time window ti from the patient and by a measuring device that is connected physically to the dialyzer, and
>
> evaluating the first value in comparison to the second value so that a difference between the first value and the second value is determined,
>
> wherein if the difference is greater than a predetermined threshold value a warning is given indicating that the possible connection of the measuring unit to the wrong patient has occurred.

Appeal Br. 37 (Claims App.).

REJECTIONS

The Examiner maintains the following rejections on appeal:

Rejection 1: Claims 1–10 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement (Final Act. 2; Ans. 3);

Rejection 2: Claims 1–10 under 35 U.S.C. § 112, second paragraph, as indefinite (Final Act. 7–8; Ans. 8);

Rejection 3: Claims 1–10 under 35 U.S.C. § 101 as directed to judicially-excepted subject matter (i.e., an abstract idea) (Final Act. 11; Ans. 11); and

Rejection 4: Claims 1–10 under 35 U.S.C. § 103(a) as unpatenable over Spickermann (US 6,736,789 B1, issued May 18, 2004) in view of Vosburgh et al. (US 2005/0096557 A1, published May 5, 2005) ("Vosburgh) (Final Act. 16; Ans. 16).

DISCUSSION

Appellants argue the claims as a group with regard to each rejection above. *See* Appeal Br. 7–36. We select claim 1 as the representative claim for this group, and remaining claims 2–10 stand or fall with claim 1. 37 C.F.R. § 41.37(c)(1)(iv).

Rejection 1

When rejecting a claim for lack of enablement, "the [United States Patent and Trademark Office] bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application." *In re Wright*, 999 F.2d 1557, 1561–62 (Fed. Cir. 1993) (citing *In re Marzocchi*, 439 F.2d 220,

223–24 (CCPA 1971)). "[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *Id.*at 1561. The "undue experimentation" analysis involves the consideration of such factors as: (1) the quantity of experimentation; (2) the amount of direction or guidance presented; (3) the presence or absence of working examples; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims (the "Wands factors"). *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

After considering the *Wands* factors, we find that on this record, the preponderance of evidence supports Appellants' position that the claims are enabled. We highlight *Wands* factors (5)–(8) in our discussion below.

Appellants and the Examiner agree that the relative skill of those in the art is high. *Compare* Appeal Br. 10, *with* Final Act. 3. And, as Appellants point out, and the Examiner acknowledges, the prior art teaches a method of measuring two values and then comparing the measured values to a predetermined threshold value to indicate if an alarm should be sounded so that corrective action can be taken. *Compare* Appeal Br. 9–10, *with* Final Act. 3.

In addition, as Appellants point out, the Examiner's conclusion that the nature of the art is "unpredictable" (Final Act. 4) is unfounded given that using a dialyzer to perform a dialysis procedure on a patient is well known in the art. Appeal Br. 11; Spec. 1, ¶ 3. Thus, any experimentation needed to practice the scope of the claimed invention would seemingly be routine in the art. Likewise, we agree with Appellants that the Examiner's finding that

"[t]here is no indication when the measurements are being taken, how they are being taken, how they are compared to make such a determination (i.e. calculated)" (Final Act. 4) is also unfounded. Appeal Br. 13. As Appellants explain, claim 1 and Appellants' Specification set forth that the measurements are taken at the same point in time or within the same time window (Spec. 3–4), and one of ordinary skill in the art would know how to obtain such measurements (e.g., pulse rate). Appeal Br. 13. Further, claim 1 and Appellants' Specification set forth that the two measured values are compared to determine if the measurements are in agreement (i.e., whether there is a difference between the two measured values) (Spec. 3–4). Therefore, the Specification provides a scope of enablement commensurate with the scope of claim 1.

Because the evidence of record regarding the *Wands* factors supports Appellants' position that the claims are enabled, we do not sustain the rejection of claims 1–10 under § 112, first paragraph, for lack of enablement.

Rejection 2

The Examiner finds that claims 1–10 are indefinite under 35 U.S.C. § 112, second paragraph, because the claim language "wrong patient" and "threshold value" are unclear. Final Act. 8–9.

The legal standard for definiteness in prosecution is whether a claim reasonably apprises those of skill in the art of its scope. *In re Warmerdam*, 33 F.3d 1354, 1361 (Fed. Cir. 1994).

With regard to claim 1's "wrong patient" language, the Examiner finds that "[i]t is unclear what a 'wrong patient' is and what makes the patient 'wrong.'" Final Act. 8. The Examiner finds that "the disclosure

never defines what comprises 'wrong patient' or how the 'possible connection' is determined and how the signal is made." *Id.*

Appellants argue, and we are persuaded that, "[t]hose of ordinary skill in the art are familiar with the terminology of 'patient' and are familiar with the terminology 'wrong.'" Appeal Br. 21. Thus, one of ordinary skill in the art would read claim 1's language, in view of Appellants' Specification, and understand that "the '*possible connection*' of the measuring unit to the wrong patient refers to the possibility that the measuring unit[, which transmits data to the dialyzer wirelessly,] is connected to a patient who is not the intended patient that is matched with or assigned[, i.e., connected physically,] to a particular dialyzer." *Id.*; Spec. 2, ¶ 3 (full), 3, ¶ 1 (full). Accordingly, the terminology "wrong patient" in claim 1 is clear and definite.

With regard to claim 1's "threshold value" language, the Examiner finds that "[i]t is unclear what the 'threshold value' is that would be necessary to indicate that the 'measuring unit is [possibly] connected to a wrong patient.'" Final Act. 9.

Appellants argue that "[a] person of ordinary skill in the art knows to predetermine the threshold value to be above the measuring accuracy of the measuring unit." Appeal Br. 23.

Appellants' argument is not persuasive of reversible error because we are not convinced that one of ordinary skill in the art would readily understand that "a predetermined threshold value," is a value above the measuring accuracy of the measuring unit rather than some other value. Nor do Appellants direct us to any evidence in their Specification that defines or explains how to determine the scope of "a predetermined threshold value" as

recited in the claims. Accordingly, the terminology "predetermined threshold value" is not clear and definite. We therefore sustain the rejection of claims 1–10 as indefinite under 35 U.S.C. § 112, second paragraph.

Although we sustain the rejection of claims 1–10 as indefinite, we need not speculate about the meaning of the indefinite language in order to consider the merits of the rejection under 35 U.S.C. § 103(a).

Rejection 3

According to the Examiner, in determining "101 eligibility a process claim must pass the machine-or-transformation test in order to be determined as patent eligible subject matter under 35 U.S.C. § 101." Final Act. 11. Based on that test, the Examiner concludes that "the claim[s fail] the machine-or-transformation test and the claims are not 101 compliant." *Id.* at 15.

The Supreme Court has held that the machine-or-transformation test is a useful and important clue or investigative tool, it "is not the sole test for deciding whether an invention is a patent-eligible 'process'" under § 101. *Bilski v. Kappos*, 561 U.S. 593, 604 (2010). Thus, although we agree with the Examiner that ultimately the claims are directed to judicially-excepted subject matter (i.e., an abstract idea), the Examiner has presented an insufficient rationale to establish a prima facie case of patent ineligible subject matter by basing the rejection of claims 1–10 only on application of the machine-or-transformation test.

To determine whether a claim is directed to patent ineligible subject matter, we apply the analytical framework set out in *Mayo Collaborative Services. v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012), and further explained in *Alice Corp. v. CLS Bank International*, 573 U.S. 208 (2014).

This framework was applicable at the time of the Final Office Action dated October 26, 2015, and the Appeal Brief filed May 20, 2016, but was not employed by either the Examiner or Appellants. *Compare* Final Act. 11–15, *and* Ans. 11–15, 26–30, *with* Appeal Br. 26–30. We apply the *Mayo/Alice* analytical framework below. Our analysis focuses solely on independent claim 1.

According to the *Mayo/Alice* framework, the first step requires determining whether the claims at issue are directed to a patent-ineligible concept, such as an abstract idea. *See Alice*, 573 U.S. at 217 (citing *Mayo*, 566 U.S. at 76–77).

Claim 1 is directed to a method "for signaling a possible connection of a measuring unit to a wrong patient." The steps to accomplish the claimed method involve commencement of a dialysis procedure followed by: (1) "determining during the dialysis procedure a first value of at least one measurable variable measured by the measuring unit," (2) "transmitting to the dialyzer via a wireless link between the measuring unit and the dialyzer the determined first value of the at least one measureable variable," (3) "determining a second value of the at least one measureable variable . . . by a measuring device that is connected physically to the dialyzer," (4) "evaluating the first value in comparison to the second value so that a difference . . . is determined," and (5) "if the difference is greater than a predetermined threshold value a warning is given indicating that the possible connection of the measuring unit to the wrong patient has occurred."

Similar to the claims found patent ineligible in *Electric Power Group, LLC v. Alstom S.A.*, 830 F.3d 1350, 1353–54 (Fed. Cir. 2016), the recited steps in claim 1 do not appear to do anything more than collect and analyze

data, followed by displaying the results of the collection and analysis to the user by giving a warning. Although claim 1 recites a "dialyzer," the claim focuses on the "determining," transmitting," and "evaluating" steps. The steps themselves are not rooted in computer technology as evidenced by the fact that all that is needed to perform them is a generic "dialyzer." *See* Appeal Br. 28 (admitting that the plain language of claim 1 implies that a computer or device that is part of the dialyzer performs the evaluation and comparison step and would also give the warning or cause another device to give the warning is greater than the threshold value).

The second step of the *Mayo/Alice* framework requires examining "the elements of the claim to determine whether it contains an 'inventive concept' sufficient to 'transform' the claimed abstract idea into a patent-eligible application." *Alice*, 573 U.S. at 221 (quoting *Mayo*, 566 U.S. at 72, 79).

Appellants admit that "those of ordinary skill in the art understand the language of . . . claim 1 to imply that a computer or device that is part of the dialyzer performs the evaluation and comparison step and would also give the warning or cause another device to give the warning is greater than the threshold value." Appeal Br. 28; *Alice*, 573 U.S. at 221 ("[C]laims, which merely require generic computer implementation, fail to transform [an] abstract idea into a patent-eligible invention."). Moreover, as discussed above, the claims merely require a generic "dialyzer" to perform claim 1's method, which as evidenced by Appellants' Specification is well-understood, routine, and conventional. Spec. 1, ¶ 3 (Dialyzers as used in Appellants' invention, "in which the blood pressure is measured

automatically by the dialyser during the dialysis treatment, are already known.").

In view of the foregoing, we sustain the Examiner's conclusion that claim 1 is directed to patent-ineligible subject matter for being judicially-excepted from 35 U.S.C. § 101. Because we have relied on facts and reasoning not raised by the Examiner, we designate our affirmance as including a new ground of rejection. *In re Leithem*, 661 F.3d 1316, 1319 (Fed. Cir. 2011) ("Mere reliance on the same statutory basis . . . alone, is insufficient to avoid making a new ground of rejection when the Board relies on new facts and rationales not previously raised to the applicant by the examiner.").

We enter the new ground only for independent claim 1 and leave the evaluation of the patent ineligibility of dependent claims 2–10 to the Examiner.

Rejection 4

The Examiner finds that Spickermann teaches a method for continuous, noninvasive monitoring of an extracorporeal blood treatment that comprises all the steps of claim 1's method including comparing the relative change in blood pressure to a predetermined limit value (Final Act. 16 (citing Spickermann, 5:15–17, 40–53, 55–60, 6:4–8, 22–28, 7:8–22, Abstract)), but does not teach that "if the difference is greater than a predetermined threshold value a warning is given indicating that the possible connection of the measuring unit to the wrong patient has occurred" (*id.* at 17), and transmitting data wirelessly (*id.* at 18).

According to Appellants, Spickermann watches for a critical situation (i.e., when the blood pressure or relative change in blood pressure drops

below a predetermined limit (Abstract)) by (1) calculating a patient's blood pressure by utilizing multiple measurements of one or more of the multiple sensors, namely electrocardiograph 45, and photoplethysmograph 29 or pressure sensor 46 (5:15–60), and (2) comparing the calculated blood pressure with a predefined threshold (6:9–27). Appeal Br. 34. Electrocardiograph 45 and photoplethysmograph 29 or pressure sensor 46 measure different variables—electrocardiograph 45 measures the pulse wave transit time and photoplethysmograph 29 or pressure sensor 46 measures the pulse waves (Spickermann 5:54–60, 6:12–14, 28–29). The measurement of the other sensor, namely sphygmomanometer 43, in Spickermann is used to continuously measure blood pressure when the blood pressure or relative change in blood pressure drops below a predetermined limit. Appeal Br. 34; Spickermann 7:7–22. Thus, Appellants argue that Spickermann teaches a method for determining a patient's blood pressure by using data from multiple devices measuring different variables at different points in time. Appeal Br. 34.

Appellants' arguments are persuasive of reversible error. On this record, the Examiner has not established with sufficient evidence that Spickermann teaches or suggests measuring the same variable (e.g., pulse rate) using two different measuring devices at the same point in time t or in the same time window ti from the patient. The Examiner does not rely on Vosburgh to cure the deficiencies of Spickermann discussed above. Final Act. 18. Thus, the Examiner has not met the initial burden of setting forth a prima facie case of obviousness for claims 1–10 under 35 U.S.C. § 103(a) over Spickermann and Vosburgh. Accordingly, we do not sustain the rejection of claims 1–10 under 35 U.S.C. § 103(a).

DECISION

The rejection of claims 1–10 under 35 U.S.C. § 112, first paragraph, and the rejection of claims 1–10 under 35 U.S.C. § 103(a) as unpatenable over Spickermann in view of Vosburgh are reversed.

The rejection of claims 1–10 under 35 U.S.C. § 112, second paragraph is affirmed.

The rejection of claims 1–10 under 35 U.S.C. § 101 is affirmed, and designated as a new ground of rejection under 37 C.F.R. § 41.50(b).

This decision contains a new ground of rejection pursuant to 37 C.F.R. § 41.50(b). 37 C.F.R. § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review." 37 C.F.R. § 41.50(b) also provides that Appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new grounds of rejection to avoid termination of the appeal as to the rejected claims:

> (1) Reopen prosecution. Submit an appropriate amendment of the claims so rejected or new Evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the prosecution will be remanded to the examiner. The new ground of rejection is binding upon the examiner unless an amendment or new Evidence not previously of Record is made which, in the opinion of the examiner, overcomes the new ground of rejection designated in the decision. Should the examiner reject the claims, appellant may again appeal to the Board pursuant to this subpart.
>
> (2) Request rehearing. Request that the proceeding be reheard under § 41.52 by the Board upon the same Record. The request for rehearing must address any new ground of rejection and state with particularity the points believed to have been misapprehended or

overlooked in entering the new ground of rejection and also state all other grounds upon which rehearing is sought.

Further guidance on responding to a new ground of rejection can be found in the Manual of Patent Examining Procedure § 1214.01.

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; 37 C.F.R. § 41.50(b)