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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte BORIS P. KOVATCHEV and DANIEL J. COX

Appeal 2011-003312
Application 10/524,094
Technology Center 1600

Before TONI R. SCHEINER, ERICA A. FRANKLIN, and JOHN G. NEW,
Administrative Patent Judges.

FRANKLIN, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to methods and systems for evaluating the glycosylated hemoglobin (HbA_{1c}) of a patient based on blood glucose data. The Patent Examiner rejected the claims as being directed to non-statutory subject matter, as being indefinite, and as anticipated. We have jurisdiction under 35 U.S.C. § 6(b)(1). We affirm-in-part.

STATEMENT OF THE CASE

“The invention includes a data analysis method and computer-based system for the simultaneous evaluation, from routinely collected SMBG [self-monitoring blood glucose] data, of the two most important components of glycemic control in diabetes: HbA_{1c} and the risk of hypoglycemia.”

(Spec. 7, ll. 3-5.)

Claims 1-39, 112-158, 160-178, 180-218, 220-224, and 226 are on appeal.¹ Claims 1 and 6 are representative and read as follows:

1. A method for evaluating the glycosylated hemoglobin (HbA_{1c}) of a patient based on blood glucose (BG) data collected over a first predetermined duration, said method comprising:

pre-processing the collected BG data to convert the collected BG data into derived BG data derived from said collected BG data,

estimating HbA_{1c} by applying at least one predetermined formula to said derived BG data,

validating the estimate via sample selection criteria;

electronically transforming the estimate into a visual depiction; and

outputting the visual depiction of the estimate to a user.

¹ Appellants state that claims 1-39 and 112-226 are on appeal. (App. Br. 2; Reply Br. 10.) However, in the Answer, the Examiner withdrew the rejection of claims 1, 5, 19, 23, 37, 38, 135, 139, 155, 159, 175, 179, 195, 199, 215, 219, 221 and 225 under 35 U.S.C. § 102(b). (Ans. 3.) None of the remaining rejections includes claims 159, 179, 219, and 225 that were included among the claims in the withdrawn rejection. Thus, claims 159, 179, 219, and 225 do not stand rejected and are not considered on appeal.

6. The method of claim 1, wherein the preprocessing of the data comprises:

conversion of plasma to whole blood BG mg/dl via $BG = PLASBG$
(mg/dl) /1.12;

conversion of BG measured in mg/dl to units of mmol/l via $BGMM = BG/18$;
and computing Low Blood Glucose Index (RL01) and High Blood Glucose
Index (RHI1) using a predetermined mathematical formula defined as:

$Scale = [\ln(BG)]^{1.0845} - 5.381$, wherein BG is measured in units of
mg/dl,
 $Risk1 = 22.765(Scale)^2$, wherein
 $RiskLO = Risk1$ if (BG is less than about 112.5) and therefore risk of
LBGI exists, otherwise $RiskLO = 0$, and
 $RiskHI = Risk1$ if (BG is greater than about 112.5) and therefore risk of
HBGI exists, otherwise $RiskHI = 0$,
BGMM1 = average of BGMM per patient,
RLO1 = average of RiskLO per patient,
RHI1 = average of RiskHI per patient,
L06 = average of RiskLO computed only for readings during the
night, otherwise missing if there are no readings at night,
N06, N12, N24 are percentage of SMBG readings in time intervals,
NC1 = total number of SMBG readings in the first predetermined
duration; and
NDAYS = number of days with SMBG readings in the first
predetermined duration.

The Examiner rejected the claims as follows:

- claims 1-18, 112, 113, 135-154, and 195-214 under 35 U.S.C. § 101
as being directed to non-statutory subject matter;

- claims 6, 8-10, 24, 26-28, 120, 122-124, 140, 142-144, 160, 162-
164, 180, 182-184, 200, 202-204, 220, and 226 under 35 U.S.C. § 112,
second paragraph, as being indefinite for failing to particularly point out and
distinctly claim the subject matter regarded as the invention;

• claims 1, 19, 37, 38, 135, 155, 175, 195, 215, and 221 under 35 U.S.C. § 102(e) as anticipated by Heinonen.²

NON-STATUTORY SUBJECT MATTER

The Examiner's position is that the rejected claims are directed to an abstract idea. (Ans. 5.) Specifically, the Examiner found that: (a) "the claims do not include an express or inherent recitation of a specific machine to perform the method of evaluating the HbA1c of a patient;" b) "the claims merely recite mathematical concepts of manipulating data by pre-processing data to convert it to a derived data, estimating the HbA1c from a predetermined formula, and validating the estimate without the recitation of a machine in which to perform such steps;" c)

the recitation of 'electronically transforming the estimate into a visual depiction' is not material to or central to the purpose of the claimed subject matter and does not constitute a transformation to a different state or thing. The recitation is tangentially related to the performance of the evaluation of HbA_{1c}, which is calculated by conversion of the collected BG data, and estimated by applying a predetermined formula.

(*Id.* at 5-6.)

Appellants contend that the claims are not directed to abstract intellectual concepts or mental processes, but are instead directed to a specific method of estimating the glycosylated hemoglobin of a patient and communicating the estimate to a user, involving analysis of quantitative physical characteristics of a physical patient, and having a practical application in the prevention or treatment of an adverse physical condition of

² Patent No. US 6,421,633 B1 issued to Pekka Heinonen et al., Jul. 16, 2002.

the patient. (App. Br. 14-15.) Appellants assert that the claimed method meets the “transformation” test discussed in *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) because (a) “it converts SMBG data representative of blood glucose, to an estimate of HbA_{1c} data representative of glycosylated hemoglobin” (*id.* at 15) and (b) “the claims all set forth electronic transformation of the estimate data into a visual depiction that is presented to a user” (*id.* at 16).

The test for patent eligible subject matter involves weighing factors to evaluate the claim as to whether the claim represents an abstract idea or is tailored narrowly enough to encompass only a particular application of a fundamental principle. While we understand that the Federal Circuit's “machine or transformation test” is not the sole test, as asserted by Appellants (*see* App. Br. 14-15; Reply Br. 2) the Supreme Court did acknowledge, based on the Court's precedent, that the test is a “useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under § 101.” *Bilski v. Kappos*, 130 S.Ct. 3218, 3227 (2010); *see also Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S.Ct. 1289, 1296 (2012). Thus, the Examiner appropriately assessed patent eligibility under the machine-or-transformation test.

We have considered the claimed methods taken as a whole and agree with the Examiner that the claims are directed to an abstract idea, and therefore recite patent ineligible subject matter under 35 U.S.C. § 101.

Appellants do not allege that the claims satisfy the machine arm of the *Bilski* “machine or transformation test.” Rather, Appellants assert that the claims satisfy the “transformation” arm of the test. (App. Br. 16-17.)

However, we agree with the Examiner that the method claims at issue are not transformative for the following reasons.

We do not find that the claimed method meets the “transformation” test by “convert[ing] SMBG data representative of blood glucose, to an estimate of HbA_{1c} data representative of glycosylated hemoglobin.” (*See* App. Br. 15.) The conversion of this data does not involve transforming an article into a different state or thing, but instead converting one number to another. *See Bilski*, 545 F.3d at 962-963. Indeed, as claim 1 recites, such conversion involves merely “applying at least one predetermined formula to said derived BG data.” (App. Br. 24, Claims App’x.)

We also do not find that the claims meet the “transformation” test by “set[ting] forth electronic transformation of the estimate data into a visual depiction that is presented to a user.” (*See id.* at 16.) In particular, the “estimate data” is not “raw” data “represent[ing] physical and tangible objects,” such as the structure of bones, organs, and other body tissues as discussed in *Bilski*. *See Bilski*, 545 F.3d at 962-963. Rather, the estimate data of the claimed method represents *processed* data, i.e., BG data converted into derived BG data, from which a numerical estimate was formulated by applying at least one predetermined formula. Thus, the claimed step of “electronically transforming the estimate into a visual depiction” did not comprise a visual depiction of a physical or tangible object. Rather, this visual depiction merely involved an electronic communication of the numerical estimate to a user.

Moreover, to the extent that Appellants assert that collecting blood glucose from a patient is an inherent step of the claimed method and that such step provides additional evidence that the claims are not directed to

abstract ideas (App. Br. 17) we disagree. The collection of a blood sample from a patient is a “well-understood, routine, conventional activity previously engaged in by researcher in the field” that is insufficient to transform an abstract idea into an eligible concept. *See Mayo Collaborative Servs. v. Prometheus Labs, Inc.*, 132 S.Ct. at 1294-1298 (“Purely ‘conventional or obvious’ ‘[pre]-solution activity’ is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law.”); *accord Perkinelmer, Inc. v. Intema Ltd.*, 2012 WL 5861658, *5 (Fed. Cir. 2012) (purely conventional “measuring” steps insufficient to make the claims reciting mental processes and natural laws patent-eligible).

Accordingly, we conclude that the method of independent claim 1 is patent ineligible subject matter under 35 U.S.C. § 101. Claims 2-18, 112, 113, 135-154, and 195-214 have not been argued separately and therefore fall with claim 1. 37 C.F.R. § 41.37(c)(1)(vii).

INDEFINITENESS

The Examiner’s position is that the claims recite “using a predetermined mathematical formula defined as,” but fail to recite any such mathematical formula. (Ans. 6.) According to the Examiner, the claims merely define certain criteria, such as “scale” and “risk” without any association to an actual formula. (*Id.*) Therefore, the Examiner found that it is unclear as to what is being computed. (*Id.*)

Appellants contend that “actual mathematical formulae are in fact set forth in the claims under rejection.” (App. Br. 18.) For example, Appellants assert that claim 6 requires computing Low Blood Glucose Index (RLO1)

and High Blood Glucose Index (RHI1) using a predetermined mathematical formula defined as $RLO1 = \text{average of Risk LO per patient}$, and $RHI1 = \text{average of Risk HI per patient}$, which are actual mathematical formulae. (*Id.*)

We agree with Appellants that the claims specifically recite predetermined mathematical formula for computing RLO1 and RHI1. Accordingly, we reverse the indefiniteness rejection.

ANTICIPATION

The Examiner found that Heinonen taught a method and system whereby levels of HbA_{1c} are predicted using a mathematical model which is derived to predict the behavior of HbA_{1c} relative to blood glucose, therefore meeting the limitations of converting BG data and estimating HbA_{1c} and providing an output of the data. (Ans. 7-8.)

Appellants contend that Heinonen does not disclose the claimed method, in particular Heinonen does not disclose a step of validating the estimate via sample selection criteria. (App. Br. 21; Hearing Transcript 9, ll. 4-10.)

The Examiner's position is that in Heinonen, "[t]he data are validated by recalculation of modeling coefficients based on levels attained previously." (Ans. 12.)

Appellants note that the Examiner has not provided any citation to Heinonen to support this finding. (Hearing Trans. 9, l. 22- 10, l. 3.) Further, Appellants assert that Heinonen's disclosure of "updating the model when a new glycosylated haemoglobin component level is measured using that new measurement and recent new blood glucose level measurements" (Heinonen

col. 2, ll. 30-33) is not validating the estimate, as it is not an estimate, but a model matrix that is being updated (Hearing Trans. 10, l. 5- 11. l. 3).

We agree with Appellants that the Examiner has not established that Heinonen disclosed validating the estimated HbA_{1c} via sample selection criteria. The Specification sets forth the parameters for achieving such validation, which requires that the first predetermined duration sample meets at least one of the listed criteria. (*See Spec. 13, ll. 10-25.*) Not only does Heinonen not address the sample selection criteria disclosed in the instant Specification, Heinonen also does not disclose validating its estimate by any means. Rather, as Appellants have correctly asserted, Heinonen merely updates the model that is applied to predict the HbA_{1c} level.

Accordingly, we reverse the anticipation rejection.

SUMMARY

We affirm the rejection of claims 1-18, 112, 113, 135-154, and 195-214 under 35 U.S.C. § 101 as being directed to non-statutory subject matter;

we reverse the rejection of claims 6, 8-10, 24, 26-28, 120, 122-124, 140, 142-144, 160, 162-164, 180, 182-184, 200, 202-204, 220, and 226 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention;

we reverse the rejection of claims 1, 19, 37, 38, 135, 155, 175, 195, 215, and 221 under 35 U.S.C. § 102(e) as anticipated by Heinonen.

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Application 10/524,094

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-IN-PART

cdc