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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte BORIS P. KOVATCHEV, DAVID PRICE,
ERIK OTTO, and ALAN COULSON

Appeal 2017-006008
Application 11/943,226[1]
Technology Center 1600

Before DONALD E. ADAMS, RICHARD J. SMITH, and
RYAN H. FLAX, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This Appeal under 35 U.S.C. § 134(a) involves claims 1, 2, 4, 6, 7, 20, 29, 30, 32, 34, 35, 48, 57–59, 61, 63, 64, 77, 87, 88, 90, 92, 93, 106, 115, 116, 118, 120, 121, 134, 144, 145, 147, 149, 150, 157, 262, 264, 266, 268, 270, 272, 276, 278, 280, and 282 (*see* Ans. 4; *see generally* App. Br. 2).[2] Examiner entered rejections under 35 U.S.C. § 101 and 35 U.S.C. § 103(a). We have jurisdiction under 35 U.S.C. § 6(b). We AFFIRM.

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[1] Appellants identify the real party in interest as "the Assignees University of Virginia Patent Foundation of Charlottesville, Virginia" (App. Br. 1).

[2] Pending "[c]laims 3, 5, 8-19, 21-28, 31, 33, 36-47, 49-56, 60, 62, 65-76, 78-86, 89, 91, 94-105, 107-114, 117, 119, 122-133, 135-143, 146, 148, 151-156, 158-261, 263, 265, 267, 269, 271, 273-275, 277, 279, 281, 283, and 284 [] stand withdrawn from consideration subject to restriction" (App. Br. 2).

STATEMENT OF THE CASE

Appellants disclosure "relates generally to the art of glucose monitoring, and more particularly to hypo- and hyper-glycemic risk assessment" (Spec. 1). Appellants' claim 1 is representative and reproduced below:

> 1. A computer-implemented method for identifying and/or predicting patterns of hyperglycemia of a user, said method comprising:
>
> taking SMBG[3] measurements from blood of said user;
>
> acquiring, by a processor, a plurality of SMBG data points from said SMBG measurements taken over a plurality of predefined periods of time with predetermined durations, said SMBG data points representing blood glucose levels of said user during said predefined periods of time;
>
> classifying, by a processor, said SMBG data points into said predefined periods of time over 24 hour periods to develop a daily blood glucose profile for said user;
>
> in a period of time during which a SMBG measurement has been taken, evaluating, by a processor, blood glucose levels of said user for a subsequent period of time within 24 hours based on classified SMBG data points in said daily blood glucose profile; and
>
> in said period of time during which a SMBG measurement has been taken, outputting a message to said user indicating a risk of hyperglycemia for said subsequent period of time if said evaluation results in a determination of such risk.

(App. Br. 21.)

[3] Appellants define the acronym "SMBG" as "self-monitoring of blood glucose" (Spec. 2).

The claims stand rejected as follows:

Claims 1, 2, 4, 6, 7, 20, 29, 30, 32, 34, 35, 48, 57–59, 61, 63, 64, 77, 87, 88, 90, 92, 93, 106, 115, 116, 118, 120, 121, 134, 144, 145, 147, 149, 150, 157, 262, 264, 266, 268, 270, 272, 276, 278, 280, and 282 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Kovatchev '892[4] and Kovatchev.[5]

Claims 1, 2, 4, 6, 7, 20, 29, 30, 32, 34, 35, 48, 57–59, 61, 63, 64, 77, 87, 88, 90, 92, 93, 106, 115, 116, 118, 120, 121, 134, 144, 145, 147, 149, 150, 157, 262, 264, 266, 268, 270, 272, 276, 278, 280, and 282 stand rejected under 35 U.S.C. § 101.

The rejection under 35 U.S.C. §103(a):

ISSUE

Does the preponderance of evidence relied upon by Examiner support a conclusion of obviousness?

ANALYSIS

Appellants disclose that "[a] day, i.e. a twenty-four hour period, may be divided into time bins with predetermined durations. For simplicity of [Appellants'] description . . . [Appellants] assume time periods with a predetermined duration of 4-hour time periods, with an 8-hour time period during the night" (Spec. 12). In this regard, Appellants "assume that an

[4] Kovatchev et al., US 2005/0214892 A1, issued Sept. 29, 2005.
[5] Boris P. Kovatchev, Ph.D., *Methods for Quantifying Self-Monitoring Blood Glucose Profiles Exemplified by an Examination of Blood Glucose Patterns in Patients with Type 1 and Type 2 Diabetes*, 4 DIABETES TECHNOLOGY & THERAPEUTICS 295–303 (2002).

SMBG reading [] taken at 11 PM[] . . . initializes the next time period of a predetermined duration, e.g. 11 PM-7 AM" (*id.* at 13).

> An aspect of [Appellants'] . . . invention [] includes providing indications of the risk of hyperglycemia . . . of a user for a next period of time, i.e. a subsequent period of time, based on the evaluation of glucose values in each period of time. The indication of the risks . . . may occur after the completion of the following steps: the acquisition of [a] plurality of SMBG data points, the classification of SMBG data points within periods of time with predetermined durations, and the evaluation of glucose values in each period of time. The indications may be in the form of messages that are issued to the user indicating risk . . . prior to the next period of time. Indications may occur . . . within 24 hours of acquisition of a plurality of SMBG data points.

(*Id.*)

The method of Appellants' claim 1 requires, *inter alia*, the following steps: (a) the acquisition of a plurality of SMBG data points from SMBG measurements taken, from blood of a user, over a plurality of predefined periods of time with predetermined durations; (b) classifying the SMBG data points into predefined periods of time over 24 hour periods; (c) in a period of time during which a SMBG measurement has been taken, evaluating blood glucose levels for a subsequent period of time within 24 hours based on the classified SMBG data points; and (d) in a period of time during which a SMBG measurement has been taken, outputting a message to a user indicating a risk of hyperglycemia for a subsequent period of time if the evaluation results in a determination of such a risk (*see* App. Br. 21).

Thus, when read in light of Appellants' Specification, the method of Appellants' claim 1 encompasses the following steps: (a–b) the acquisition of a plurality of SMBG data points from SMBG measurements taken once

every four hours during the day with one data point collected in an eight hour time period during the night, thereby, classifying the data points into predefined periods of time over 24 hour periods; (c) evaluating the blood glucose levels acquired and classified in steps (a–b) to determine an indication of risk of hyperglycemia for a subsequent 24 hour time period; and (d) if the evaluation results in a determination of a risk of hyperglycemia, outputting a message to a user indicating a risk of hyperglycemia for the subsequent 24 hour time period (*see generally* App. Br. 17–18 ("per [Appellants'] claim language, . . . a predefined period of time is less than 24 hours since multiple predefined periods are defined as being over 24 hour periods. And, the blood glucose evaluation is made for a subsequent period of time within 24 hours"); *id.* at 18 ("According to [Appellants'] claimed invention, when a (i.e. a specific) SMBG measurement is taken for a current period of time, the 'subsequent period of time' . . . is evaluated and the patient is informed about that time period, within 24 hours as claimed"); *see also* Reply Br. 4–5).

Kovatchev '892 discloses:

> [A] method, system, and computer program product for identifying 24-hour periods (or other select periods) of increased risk of hypoglycemia. This is accomplished through the computation of the short-term risk of hypoglycemia using SMBG readings collected over the previous 24 hours. In one embodiment, [Kovatchev '892's] invention provides a computerized method and system for evaluating the short term risk for severe hypoglycemia (SH) of a patient based on [blood glucose (BG)] data collected over a predetermined duration. The method (or system or computer usable medium) includes evaluating the short term probability for severe hypoglycemia

> (SH) of a patient based on BG data collected over a predetermined duration.

(Kovatchev '892 ¶ 86; *see also id.* ¶ 26; *see generally* Ans. 9–11.) Kovatchev '892 discloses that a warning is provided in the event of an "upcoming short term SH" (Kovatchev '892 ¶ 90; *see also id.* ¶¶ 91 and 116; Ans. 9 and 18 ("Kovatchev '892 at paragraph [0090] describes providing a warning of upcoming short term severe hypoglycemia within the subsequent 24 hour time period")).

Examiner recognizes that Kovatchev '892 "do[es] not explicitly teach applying all the method steps to hyperglycemia" (Ans. 11), but finds that Kovatchev '892's "method/program/system for identifying and/or predicting patterns of hypoglycemia" are applicable to determining a risk of hyperglycemia (*see id.* at 17). In support of this finding, Examiner directs attention to Kovatchev for a disclosure of methodologies, similar to those of Kovatchev '892, which are applied to hyperglycemia (Ans. 11).

Based on the combination of Kovatchev '892 and Kovatchev, Examiner concludes that, at the time Appellants' invention was made, it would have been prima facie obvious to apply "the mathematical methods taught by [Kovatchev '892], in the method of evaluating the risk of hyperglycemia taught by Kovatchev" (Ans. 11).

As discussed above, Kovatchev '892 identifies "24-hour periods (or other select periods) of increased risk of hypoglycemia. This is accomplished through the computation of the short-term risk of hypoglycemia using SMBG readings collected over the previous 24 hours" (Kovatchev '892 ¶ 86). Thus, stated differently, and recognizing Examiner's findings, discussed above, regarding the applicability of Kovatchev '892's method to both hypo- and hyper-glycemia, Kovatchev

'892 discloses the following steps: (a–b) the acquisition and classification of a *plurality of* SMBG *data points* (i.e. "readings") from SMBG measurements taken over a 24-hour period (*id.*); (c) evaluating the data points of steps (a–b) to determine an indication of risk of hyperglycemia for a subsequent 24 hour time period (*id.*); and if the evaluation results in a determination of a risk of hyperglycemia, outputting a message to a user indicating a risk of hyperglycemia for the subsequent 24 hour time period (*id.* ¶ 90).

Appellants contend that Kovatchev '892 "relates to identifying 24-hour periods of increased risk of hypoglycemia using SMBG readings collected over the previous 24-hours" (*id.*; *cf.* Kovatchev '892 ¶ 86 ("identifying 24-hour periods (*or other select periods*) of increased risk of hypoglycemia . . . using SMBG reading*s* collected over the previous 24 hours) (emphasis added)). We find that by disclosing 24-hour periods *or other select periods*, Kovatchev '892 suggests periods of time less than 24 hours (*see id.* ¶ 86). In this regard, we note that Kovatchev '892 uses the data points collected over a prior 24-hour period to "estimate[] short-term risk of hypoglycemia (i.e. for the next 24 hours)" and discloses the use of "warnings, such as an alarm, that indicates imminent hypoglycemic episodes" (*id.* ¶ 116). Thus, a person of ordinary skill in this art would have reasonably understood Kavatchev '892's disclosure to mean that data from a prior 24-hour period is evaluated, within 24-hours of data collection, to provide an estimated risk assessment for the subsequent 24-hour period and, if this evaluation estimated an imminent risk of a hypoglycemic episode for that subsequent 24-hour period, a warning would be made within that 24-hour period (*see id.* ¶¶ 86 and 116; *see* Ans. 11 and 17 (Examiner finds that

Kovatchev '892's "method/program/system for identifying and/or predicting patterns of hypoglycemia" are applicable to determining a risk of hyperglycemia)).

For the foregoing reasons, we are not persuaded by Appellants' contention that Kavatchev '892

> does not correspond to [Appellants'] claimed method, wherein SMBG data points are classified into predefined periods of time over 24 hour periods to develop a daily BG profile, wherein in a period of time during which a SMBG measurement is taken, BG levels are evaluated for a subsequent period of time within 24 hours, and in said period of time, a message is outputted to the user indicating risk of hypo/hyperglycemia for the subsequent period of time. There is no disclosure in [Kavatchev] [']892 of classification of data points into predefined periods of time over 24 hour periods; there is only one 24-hour period. There is no disclosure that the evaluation is performed in [] such [a] period of time in which a measurement is taken. There is no evaluation for a subsequent period of time within 24 hours.

(App. Br. 18–19; *see* Reply Br. 5–6.)

The method of Appellants' claim 1 requires, *inter alia*, "classifying . . . SMBG data points into [] predefined periods of time over 24 hour periods to develop a daily blood glucose profile for [the] user" and using these "classified SMBG data points" to "evaluate . . . glucose levels of [a] user for a subsequent period of time within 24 hours" (*see* App. Br. 21). As discussed above, Kovatchev '892 identifies "24-hour periods (or other select periods) of increased risk of hypoglycemia . . . using SMBG readings [i.e., more than one reading,] collected over the previous 24 hours" (Kovatchev '892 ¶ 86). Thus, Kovatchev '892 discloses the classification of SMBG data points into predefined periods of time over 24 hour periods to evaluate increased risk of hypoglycemia within a subsequent 24-hour period.

Therefore, we are not persuaded by Appellants' contention that Kovatchev '892 "does not disclose classification of SMBG data points within different periods of time with predetermined durations or evaluation of glucose values in each such period of time" (App. Br. 19).

For the reasons set forth above, we are not persuaded by Appellants' contentions that Kovatchev '892 does not "evaluat[e], in a period of time during which a SMBG measurement has been taken, [] blood glucose levels of a user for a subsequent period of time based on classified SMBG data points" or "output[] [] a message to [a] user indicating a risk of hyperglycemia for that subsequent period of time if the evaluation results in a determination of such risk of hyperglycemia or hypoglycemia" (*id.*).

CONCLUSION OF LAW

The preponderance of evidence relied upon by Examiner supports a conclusion of obviousness. The rejection of claim 1 under 35 U.S.C. § 103(a) as unpatentable over the combination of Kovatchev '892 and Kovatchev is affirmed. Claims 2, 4, 6, 7, 20, 29, 30, 32, 34, 35, 48, 57–59, 61, 63, 64, 77, 87, 88, 90, 92, 93, 106, 115, 116, 118, 120, 121, 134, 144, 145, 147, 149, 150, 157, 262, 264, 266, 268, 270, 272, 276, 278, 280, and 282 are not separately argued and fall with claim 1.

The rejection under 35 U.S.C. § 101:

ISSUE

Does the evidence of record support Examiner's finding that Appellants' claimed invention is directed to non-statutory subject matter?

ANALYSIS

Examiner finds that Appellants' claimed invention is directed to patent ineligible subject matter (*see* Ans. 3–7).

The scope of 35 U.S.C. § 101 "is subject to an implicit exception for 'laws of nature, natural phenomena, and abstract ideas,' which are not patentable." *Intellectual Ventures I LLC v. Capital One Financial Corp.*, 850 F.3d 1332, 1338 (Fed. Cir. 2017), citing *Alice Corp. Pty. Ltd. v. CLS Bank Int'l.*, 134 S. Ct. 2347, 2355 (2014); *see also Mayo Collaborative Services v. Prometheus Labs., Inc.*, 566 U.S. 66, 70 (2012) ("'[L]aws of nature, natural phenomena, and abstract ideas' are not patentable" (citation omitted, alteration original)).

Alice, sets forth the following two-step analysis for determining patent eligibility under Section 101:

> First, we determine whether the claims at issue are directed to one of those patent-ineligible concepts [e.g., a law of nature, natural phenomenon, or abstract idea]. If so, we then ask, what else is there in the claims before us? . . . We have described step two of this analysis as a 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.

Alice, 134 S. Ct. at 2355 (alterations, citations, and quotation marks omitted).

With respect to *Alice*'s first step, Examiner finds that, when considered as a whole, Appellants' claimed invention is "involves the abstract and computational steps of acquiring self-monitoring blood glucose data, classifying the data, and evaluating the data. As such, . . . [Appellants'] claims are drawn [] to an abstract process that only manipulates data" (Ans. 4; *see also id.* at 5 (Examiner finds that the

"mathematical algorithms/formulas for acquiring self-monitoring blood glucose data, classifying the data, and evaluating the data[, as set forth in Appellants' claims,] are mathematical algorithms")). Thus, Appellants' claimed invention comprises the steps of collecting, manipulating, and displaying data. "[A]n invention directed to collection, manipulation, and display of data [is] an abstract process." *Intellectual Ventures*, 850 F.3d at 1340; *see generally id.* at 1340–41.

> Without additional limitations, a process that employs mathematical algorithms to manipulate existing information to generate additional information is not patent eligible. "If a claim is directed essentially to a method of calculating, using a mathematical formula, even if the solution is for a specific purpose, the claimed method is nonstatutory." *Parker v. Flook*, 437 U.S. 584, 595[] (1978) (internal quotations omitted).

Digitech Image Techs., LLC v. Elecs. For Imaging, Inc., 758 F.3d 1344, 1351 (Fed. Cir. 2014). *See also FairWarning IP, LLC v. Iatric Systems, Inc.*, 839 F.3d 1089, 1093 (Fed. Cir. 2016) ("analyzing information by steps people go through in their minds, or by mathematical algorithms, without more," are "essentially mental processes within the abstract-idea category"); *Synopsys, Inc. v. Mentor Graphics Corp.*, 839 F.3d 1138, 1146 (Fed. Cir. 2016) ("Methods which can be performed entirely in the human mind are unpatentable . . . because [they] embody the 'basic tools of scientific and technological work' that are free to all men and reserved exclusively to none").

We recognize the Appellants' claimed invention requires the display of a warning if certain conditions are met (*see e.g.*, App. Br. 21 ("outputting a message to said user indicating a risk of hyperglycemia for said subsequent period of time if said evaluation results in a determination of such risk.")).

There is, however, no requirement in Appellants' claims that requires such a condition, that would trigger a warning message, ever be met. Nevertheless, we note "that customizing information and presenting it to users based on particular characteristics is abstract as well." *Intellectual Ventures*, 850 F.3d at 1340.

To the extent that specific hardware, i.e. a glucose meter, is required to perform Appellants' claimed invention, Appellants concede a "glucose meter is common in the industry and includes essentially any device that can function as a [blood glucose] acquisition mechanism" (Spec. 26). In this regard, Examiner finds that the data collection, manipulation, and display steps set forth in Appellants' claimed invention "do not purport to improve the function of the computer[, i.e. glucose meter,] itself, there is no specific [] limitation [or] recitation of improved computer technology, nor to [Appellants' claims] effect an improvement in any other technology or technical field" (Ans. 5; *see generally id.* at 4–5). *See Mayo*, 566 U.S. at 84–86 ("simply implementing a mathematical principle on a physical machine, namely a computer, [is] not a patentable application of that principle"); *Alice*, 134 S. Ct. at 2360 ("none of the hardware recited by the [] claims 'offers a meaningful limitation beyond generally linking 'the use of the [method] to a particular technological environment,' that is, implementation via computers" (alteration original)); *see generally* Ans. 7.

With respect to *Alice*'s second step, the search for an inventive concept, Examiner finds that "[t]he step of taking SMBG measurements is considered an insignificant pre-solution activity or merely a data gathering step" and "the final step of outputting a message indicating a risk of hyperglycemia is interpreted as essentially an 'apply it' limitation" that

"does not actually require any action based upon said output and is not considered an applicable inventive step" (Ans. 6). In addition, as made clear in the foregoing discussion of the obviousness rejection on this record, taking SMBG measurements and providing warnings when certain conditions are met is well-known, conventional or routine in this art (*see generally* Ans. 6). *See Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369, 1376 (Fed. Cir. 2016) (Appellants "must provide something inventive, beyond mere well-understood, routine, conventional activity") (quotation omitted).

For the foregoing reasons, we find no error in Examiner's finding that Appellants' claimed invention is directed to patent ineligible subject matter.

For the foregoing reasons, we are not persuaded by Appellants' contention that Examiner's "rejection fails to articulate exactly what the alleged abstract idea is" (App. Br. 10; Reply Br. 2) or that Appellants' claimed invention encompasses more than data manipulation because it is linked to a particular machine, i.e. a glucose meter, wherein a particular glucose meter is assigned to a particular individual (App. Br. 11 (Appellants' "recited limitations are directed to acquisition, classification and evaluation of self-monitoring blood glucose data that is representative of specific levels of glucose in the blood of a specific user"); Reply Br. 3). (*See generally id.* at 9–11; Reply Br. 1–4.)

For the same reasons, we are not persuaded by Appellants' contention that the "subject matter of [Appellants'] claims . . . is non-analogous to the method of exchanging obligations between parties that was the subject of . . . [*Alice*]" and, therefore, "does not constitute an 'abstract idea' such as a legal

obligation, a financial risk, or a mathematical relationship, which have been held to be examples of 'abstract ideas'" (App. Br. 12; *see also id.* at 11–13).

We recognize Appellants' contention that "'acquiring self-monitoring blood glucose data' does not refer to the abstract concept of acquiring data, but instead relates to a specific acquisition of blood glucose data from blood measurement taken from a patient" (Reply Br. 4). We note, however, as discussed above with respect to the obviousness rejection, that even if Appellants' contention were true, the collection of blood glucose data is well-known, conventional, and routine in this art. Further, as discussed above and notwithstanding Appellants' contention to the contrary, the classification and evaluation steps of Appellants' claimed invention represent an abstract idea. *See Intellectual Ventures*, 850 F.3d at 1340 ("collection, manipulation, and display of data [is] an abstract process"). This is true even if, as Appellants contend, the data that is classified and evaluated "relates to . . . a specific patient, based on self-monitoring blood glucose readings taken from the patient" (*cf.* Reply Br. 4). *See Digitech Image Techs., LLC v. Elecs. For Imaging, Inc.*, 758 F.3d 1344, 1351 (Fed. Cir. 2014) (citing *Parker v. Flook*, 437 U.S. 584, 595[] (1978) (internal quotations omitted)) ("If a claim is directed essentially to a method of calculating, using a mathematical formula, even if the solution is for a specific purpose, the claimed method is nonstatutory").

CONCLUSION OF LAW

The evidence of record supports Examiner's finding that Appellants' claimed invention is directed to non-statutory subject matter. The rejection of claim 1 under 35 U.S.C. § 101 is affirmed. Claims 2, 4, 6, 7, 20, 29, 30, 32, 34, 35, 48, 57–59, 61, 63, 64, 77, 87, 88, 90, 92, 93, 106, 115, 116, 118,

120, 121, 134, 144, 145, 147, 149, 150, 157, 262, 264, 266, 268, 270, 272, 276, 278, 280, and 282 are not separately argued and fall with claim 1.

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