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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte PAUL J. GALLEY, ALAN M. GREENBURG, MARSHALL M. PARKER, JOHN F. PRICE, ROBIN S. WAGNER, and RICHARD W. WILSON

Appeal 2017-006310[1]
Application 13/593,557[2]
Technology Center 1600

Before ERIC B. GRIMES, JEFFREY N. FREDMAN, and JAMES A. WORTH, *Administrative Patent Judges*.

WORTH, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellants appeal under 35 U.S.C. § 134(a) from the Examiner's Final Rejection of claims 1–9 and 13–22. Claims 10–12 have been withdrawn. We have jurisdiction under 35 U.S.C. §§ 134 and 6(b).

We affirm.

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[1] Our Decision refers to Appellants' Appeal Brief ("Appeal Br.," filed Aug. 29, 2016) and Reply Brief ("Reply Br.," filed Mar. 9, 2017), and the Examiner's Final Office Action ("Final Act.," mailed May 4, 2016) and Answer ("Ans.," mailed Jan. 10, 2017).

[2] According to Appellants, the real party in interest is Roche Diabetes Care, Inc. (Appeal Br. 3).

Statement of the Case

Background

Appellants' application relates to "diabetes care medical devices used for diagnostics and therapy, and more particularly to a diabetes management device incorporating a bolus calculator that determines a maximum allowed blood glucose level of a patient to compare to a current blood glucose measurement." Spec. ¶ 1.

According to the Specification, "when the current bG [blood glucose] measurement is less than the target bG value, the allowable amount of bG value is set equal to the sum of the target bG value and the correction delta bG value." *Id.* ¶ 11, Fig. 8. "If the bolus calculator 22a determines that the current bG measurement value is greater than the target bG value, the bolus calculator sets the currently allowed bG value equal to the maximum allowed bG value." *Id.* ¶ 86, Fig. 8. The Specification then refers to various ways of calculating the correction delta bG value depending, *inter alia*, on the time elapsed. *See, e.g.*, *id.* ¶¶ 15, 27, 78, 92, Fig. 9.

The Claims

Claims 1 and 13 are the independent claims on appeal. Claim 1, reproduced below, is illustrative of the subject matter on appeal:

> 1. A computer-implemented method for determining an allowable amount of blood glucose (bG) of a patient, the allowable amount of blood glucose being used to calculate a bolus recommendation for a patient, the method comprising:
>
> maintaining a plurality of active advice history records, each of the plurality of active advice history records having been generated during a predetermined time period relative to a current time, and each of the plurality of active advice history records identifying data relating to one or more bG influencing

events and including a time corresponding to the one or more bG influencing events;

receiving, at the one or more processors, a current bG measurement corresponding to the patient, the current bG measurement indicating a current bG level of the patient;

determining, at the one or more processors, a target bG value for the patient, the target bG value corresponding to a desired bG level for the patient;

determining, at the one or more processors, a correction delta bG value based on one or more records of the plurality of active advice history records, the correction delta bG value being indicative of an aggregated bG lowering effect of the events defined in the one or more active advice history records on a bG value of the patient;

determining, at the one or more processors, a correction meal rise value based on a specific active advice history record of the plurality of active advice history records, the correction meal rise value being indicative of an amount the bG level of the patient can increase with respect to the target bG value without requiring a correction bolus;

determining, at the one or more processors, a maximum allowed bG value based on the target bG value, the correction delta bG value, and the correction meal rise value;

comparing, at the one or more processors, the current bG measurement to the target bG value;

setting, at the one or more processors, the allowable amount of bG value equal to the maximum allowed bG value when the current bG measurement is greater than the target bG value; and

setting, at the one or more processors, the allowable amount of bG value using the target bG value and the correction delta bG value and excluding the correction meal rise value when the current bG measurement is less than the target bG value.

(Appeal Br. 17–18, Claims App.)

The Issue

The Examiner rejected claims 1–9 and 13–22 under 35 U.S.C. § 101 as lacking patentable subject matter.

The Examiner determines that the claims are directed to an abstract idea of mathematical relationships, where the mathematical relationships are determining a target blood glucose value, determining a correction delta blood glucose value, determining a correction meal rise value, determining a maximum allowed blood glucose value, and comparing the current blood glucose measurement to the target blood glucose value. Final Act. 2–4. The Examiner further determines that the method steps themselves do not purport to improve the functioning of the computer itself nor do they effect an improvement in any other technology or technical field. *Id.* at 4. The Examiner determines that the claims here maintain history records (information), receive a measurement (information), determine values based on the information, and set allowable values. Ans. 3 (citing *Electric Power Group, LLC v. Alstom S.A.*, 830 F.3d 1350 (Fed. Cir. 2016); *FairWarning IP, LLC v. Iatric Systems, Inc.*, 839 F.3d 1089 (Fed. Cir. 2016)).

Appellants assert that claim 1 addresses the problem of accurately recommending an amount of insulin or an amount of carbohydrates to be ingested by a person with diabetes. Appeal Br. 12. Appellants argue that the Examiner characterized the invention too broadly and that the claimed steps are not abstract because they involve more than the mathematical relationships indicated by the Examiner. *See* Appeal Br. 12–13; Reply Br. 3–4 (citing *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327 (Fed. Cir. 2016)); Reply Br. 4 (citing *McRO, Inc. v. Bandai Namco Games America Inc.*, 837

F.3d 1299 (Fed. Cir. 2016)). Appellants argue that the Examiner inappropriately required Appellants to submit evidence to support the assertion that the claims provide a technological solution. *See* Appeal Br. 14.

To determine whether a claim is invalid under § 101, we employ the two-step *Alice* framework. In step one, we ask whether the claims are directed to a patent ineligible concept, such as an abstract idea or law of nature. *Alice Corp. Pty. Ltd. v CLS Bank Intl*, 134 S. Ct. 2347, 2355 (2014); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1375 (Fed. Cir. 2015). While method claims are generally eligible subject matter, method claims that are directed only to abstract ideas and/or natural phenomena are directed to a patent ineligible concept. *Ariosa*, 788 F.3d at 1376.

Alice Step One

We have reviewed the Examiner's determinations, and we agree that claim 1 is directed to the abstract idea of data processing according to mathematical relationships. The Examiner's determinations are adequately supported by the intrinsic evidence. Neither the claims nor the Specification provide any technological improvements to the mechanics of insulin delivery or blood glucose monitoring. Rather, the claims are directed to the information-processing steps of "maintaining . . . records," "receiving . . . [a] measurement," "determining . . . value[s]," and "setting . . . [a] value." *See* claim 1. We agree with the Examiner that this type of data processing is abstract, both as a matter of mathematical relationships and data processing. *SmartGene, Inc. v. Advanced Biological Laboratories, SA*, 555 Fed. Appx. 950, 955 (Fed. Cir. 2014)(claim directed "the mental steps of comparing

new and stored information and using rules to identify medical options" was held to be unpatentable subject matter); *Electric Power Group,* 830 F.3d at 1353–54 (presenting the results of the collection and analysis without more are patent ineligible abstract concepts). Comparing blood glucose values and calculating correction values are the types of comparisons that were held abstract in *SmartGene*, and the receiving and processing of data is the type of routine data processing held abstract in *Electric Power Group*. *See also Parker v. Flook*, 437 U.S. 584, 594 (1978) (method of updating alarm based on algorithmic calculation held patent ineligible subject matter). Further, the recited calculations are used to determine a dosage of insulin or carbohydrates, based in part on natural phenomena, in a similar fashion to the claims at issue in *Mayo*, which were directed to optimizing the dosage of 6-thioguanine. *See* 566 U.S. at 71.

Appellants state that the claims do not recite a basic concept that is similar to any abstract idea previously identified by the courts and that the Examiner failed to point to any controlling case law with analogous claims which were held to be ineligible. Appeal Br. 12. However, the Examiner's Answer provided citations to case law. *See* Ans. 3.

Appellants argue that claimed method improves the accuracy of the bolus recommendation. *See* Appeal Br. 13; Reply Br. 4. However, this is an argument that goes to utility rather than abstractness and does not make the claimed invention less abstract as in *Mayo*, where, as referred to above, information for optimizing therapeutic efficiency of 6-thioguanine was also designed to improve patient care, but was found unpatentable. *Mayo*, 566 U.S. at 71.

Alice Step Two

In *Alice* step two, we examine the elements of the claims to determine whether they contain an inventive concept sufficient to transform the claimed naturally occurring phenomena into a patent-eligible application of the phenomena. *Mayo*, 566 U.S. at 71–72 (quoting *Alice*, 134 S. Ct. at 2355). We must consider the elements of the claims both individually and as an ordered combination to determine whether additional elements transform the nature of the claims into a patent-eligible concept. *Ariosa*, 788 F.3d at 1375.

Appellants argue that, as in *Diamond v. Diehr*, 450 U.S. 175 (1981), the claims improve a technological area. Appeal Br. 13–14. Appellants assert by effecting an improvement in the area of diabetes treatment in the particular way according to the steps recited in the pending claims, the claims provide a solution to an identified problem and as such are transformed into patent eligible subject matter. Appeal Br. 13. We are unpersuaded. In *Diehr*, the claim at issue was directed to significantly more than a mathematical formula because it was "drawn to an industrial process for the molding of rubber products." 450 U.S. at 192. The Examiner correctly finds that using an analyzer to receive a test strip and determining a measurement from blood are well-known, routine and conventional in the diabetes management technology (*see, e.g.*, Spec. ¶ 6), and that the claims do not purport to improve computer technology or other technology areas, beyond referring to the patent-ineligible subject matter of maintaining records, receiving measurements, and setting an allowable amount or displaying a recommended amount, which are extra-solution activities. *See* Final Act. 4. We agree that this is patent-ineligible subject matter. *Electric*

Power Group, LLC v. Alstom S.A., 830 F.3d at 1353–54 (Fed. Cir. 2016); *see also Mayo*, 566 U.S. at 79 ("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. *Flook*, 437 U.S. at 590, 98 S. Ct. 2522; *see also Bilski*, 561 U.S. at ——, 130 S. Ct. at 3230 '[T]he prohibition against patenting abstract ideas "'cannot be circumvented by" ... adding "insignificant post-solution activity"' (quoting *Diehr*, supra. at 191–192, 101 S. Ct. 1048)."). Indeed, the Specification provides only generic and routine computer structures, such as a display (¶ 51); a database (¶ 52); a processing subsystem (*id.*); memory such as RAM (*id.* at 52–53); and a calculator software module (*see id.* at ¶ 54). Nor is there an improvement in the composition or the handling of insulin itself.

Appellants argue that the Examiner's rejection appears to only consider the steps individually rather than as an ordered combination. Appeal Br. 14. To the extent that Appellants contend that the claimed invention is patentable based on an ordered combination of limitations, this type of ordered combination has been found to be patent ineligible by *SmartGene*, where the comparison of received data according to a rule was held to be abstract.

As such, we sustain the Examiner's rejection under § 101 of claim 1. Claims 2–9 fall with claim 1 because they were not argued separately. 37 C.F.R. § 41.37(c)(1)(iv).

Although Appellants argue the patentability of claims 13 and 21 under separate headings, Appellants present similar arguments as for the patentability of independent claim 1. Claims 13 and 21 are directed to a device with similar requirements as claim 1. We determine that the claimed

invention is similarly directed to rules-based data processing and does not purport to provide an improvement in the mechanics of insulin delivery nor in computer technology.

With respect to claim 21, Appellants argue that "the claims" are analogous to that for transformation of cardiac signals in *Arrhythmia Research Technology v. Corazonix Corp.*, 958 F.2d 1053 (Fed. Cir. 1992). Appeal Br. 15. Claim 21 recites "The device of claim 13 further comprises a bG analyzer configured to receive a test strip and operates to determine the current bG measurement from a sample of blood on the the [sic] test strip." Appeal Br. 26, Claims App. However, a review of the intrinsic evidence, including the Specification, indicates that claim 21 is not directed to an improvement in the sensing of blood glucose, but rather is directed to data processing, as is claim 13, from which it depends. *See Electric Power Group, LLC v. Alstom S.A.*, 830 F.3d 1350, 1353–54 (Fed. Cir. 2016) (no particular assertedly inventive technology for performing functions). Claim 21 is directed to a device, based on its dependency from independent claim 13, which performs analysis of allowable blood glucose values based on data gathered from a source. This is analogous to the claims at issue in *Electric Power*, which performed an analysis on power grid events based on data gathered from a source. *Id.* at 1352. As such, we sustain the Examiner's rejection under § 101 of claims 13–22 for similar reasons as independent claim 1.

DECISION

The Examiner's decision to reject claims 1–9 and 13–22 under 35 U.S.C. § 101 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). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED