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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/566,874	08/03/2012	Phil Mayou	DEXCOM.197C1	6241

68851 7590 04/02/2018

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RIGGS II, LARRY D

ART UNIT	PAPER NUMBER
1631	

NOTIFICATION DATE	DELIVERY MODE
04/02/2018	ELECTRONIC

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte PHIL MAYOU, HARI HAMPAPURAM, DAVID PRICE, KERI WEINDEL, KOSTYANTYN SNISARENKO, MICHAEL ROBERT MENSINGER, LEIF N. BOWMAN, ROBERT J. BOOCK, APURV ULLAS KAMATH, ELI REIHMAN, and PETER C. SIMPSON

Appeal 2017-006314[1]
Application 13/566,874[2]
Technology Center 1600

Before JEFFREY N. FREDMAN, JAMES A. WORTH, and KRISTI L. R. SAWERT, *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 1–12 and 31, which are all pending claims. 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. 18, 2016) and Reply Brief ("Reply Br.," filed Mar. 7, 2017), and the Examiner's Final Office Action ("Final Act.," mailed Feb. 11, 2016) and Answer ("Ans.," mailed Jan. 9, 2017).

[2] According to Appellants, the real party in interest is DexCom, Inc. Appeal Br. 3.

Statement of the Case

Background

Appellants' application relates to "systems and methods for analyzing and detecting patterns in data received from an analyte sensor, such as a glucose sensor." Spec. ¶ 2. One embodiment allows the identification of a hypoglycemic event, and the detection of patterns based on events. *Id.* ¶¶ 222, 224. "As a result, the user may alter their behavior based on the indicated pattern information." *Id.* ¶ 283. In one embodiment, the outputted information is processed further to form or modify a medication administration routine. *Id.* ¶ 38.

> In some implementations, a user can use the user interface to turn on or off a hypoglycemia reoccurrence risk alert that, when turned on, triggers an alert if it is determined that there is a risk of the host reoccurring into hypoglycemia within a predetermined time of having already detected a hypoglycemia event or episode.

Id. ¶ 297.

The Claims

Claim 1, reproduced below, is the sole independent claim on appeal and is representative of the subject matter on appeal:

> 1. An analyte monitoring system configured to measure an analyte concentration of a host, the system comprising:
>
> a sensor configured to generate sensor data indicative of a concentration of an analyte in a host over time;
>
> a memory configured to store the sensor data;
>
> one or more processors configured to (i) receive the sensor data from the memory, (ii) detect a pattern in the data, the detecting comprising identifying a plurality of events based on the sensor data, associating at least some of the plurality of events based on a criterion to from a set of events, and

> qualifying the set of events as the detected pattern, and (ii) form or modify a medicament administration routine based on the detected pattern; and
>
> a medicament administration device configured to administer a medicament to the host according to the medicament administration routine.

Appeal Br. 28 (Claims App.).

The Issues

A. The Examiner claims 1–12 and 31 under 35 U.S.C. § 103(a) as being unpatentable over Böcker[3], Bortz[4], and Cohen[5].

B. The Examiner rejected 1–12 and 31 under 35 U.S.C. § 101 as lacking patentable subject matter.

A. 35 U.S.C. § 103 over Böcker, Bortz, and Cohen

The Examiner finds that Böcker teaches a system for monitoring patient blood concentration of a substance, e.g., glucose. Final Act. 7 (citing Böcker, Abstract, 5:17–45, 6:45–49, Figs. 1, 2). The Examiner finds that Bortz teaches monitoring glucose patterns at the same time over a plurality of days. *Id.* (citing Bortz, Abstract, ¶¶ 18, 20–22, 25–27, Figs.). The Examiner finds that Bortz and Böcker do not teach, form, or modify a medicament administration routine based on a detected pattern, but that Cohen teaches determining a pattern and forming or modifying a medicament administration routine based on a detected pattern and an infusion pump configured to administer a medicament according to the

[3] Böcker, US 5,507,288, iss. Apr. 16, 1996.
[4] Bortz, US 2003/0216628 A1, pub. Nov. 20, 2003.
[5] Cohen, US 2010/0160740 A1, pub. June 24, 2010.

administration routine. *Id.* at 7–8 (citing Cohen ¶¶ 5–6, 63, 84, 88, 101, Figs.). The Examiner determines that a person of ordinary skill would have recognized the combination of teachings as predictable, i.e., following Cohen's teaching to utilize patterns in blood glucose to adapt therapy delivered to a patient. *See* Final Act. 8 (citing Cohen, Abstract, ¶¶ 5–6).

The issue with respect to this rejection is: Does the evidence of record support the Examiner's conclusion that Böcker, Bortz, and Cohen render claims 1–12 and 31 obvious?

Appellants argue that Böcker fails to disclose identifying events and detecting a pattern as recited in independent claim 1, i.e., "(ii) detect a pattern in the data, the detecting comprising identifying a plurality of events based on the sensor data, associating at least some of the plurality of events based on a criterion to from a set of events, and qualifying the set of events as the detected pattern." Appeal Br. 21. Appellants argue that even if the Examiner is correct that Böcker discloses providing warnings of hypoglycemia, that the providing of warnings does not constitute identifying a plurality of events and qualifying the set of events as a pattern. *Id.* at 21–22. Appellants also assert that Bortz discloses selecting a pattern based on calculations, but fails to disclose identifying events and qualifying the events as a pattern. *Id.* at 22.

However, as above, the Examiner instead relies on Cohen for the teaching of determining a pattern in the data based on identified events. Final Act. 8 (citing Cohen ¶¶ 84, 88, Figs.). Indeed, paragraphs 84 and 88 of Cohen disclose analyzing sensor reading data in a report and determining a pattern of an anomalous line based on a set of events. In this connection,

paragraph 87 of Cohen discloses that an event, such as lunch, can be identified by user input or by inferring user action.

Appellants argue that Cohen fails to suggest "forming or modifying medicament administration as recited in independent claim 1, i.e., (ii) form or modify a medicament administration routine based on the detected pattern." Appeal Br. 23. Appellants assert that Cohen "suggests that the user modifies the insulin delivery patterns." *Id.* The Examiner relies, *inter alia*, on paragraph 101 of Cohen. Final Act. 8. Although Cohen describes an embodiment in which the user may be instructed to increase the basal rate of insulin in response to a glucose pattern level showing a rise, Cohen immediately thereafter describes that, "if so configured, to automatically increase the insulin delivery rate (basal or temporary) or administer a bolus." Cohen ¶ 101.

As such, we sustain the Examiner's rejection under 35 U.S.C. § 103 of independent claim 1.

Although Appellants list the recitations of other claims in arguing their patentability, Appellants do not provide specific arguments with respect thereto aside from quoting the claim language of these claims. As such, the arguments with respect to these claims are waived. 37 C.F.R. § 41.37 ("A statement which merely points out what a claim recites will not be considered an argument for separate patentability of the claim.") We, therefore, sustain the Examiner's rejection under 35 U.S.C. § 103 of claims 2–12 and 31, for similar reasons as for independent claim 1.

B. 35 U.S.C. § 101

The Examiner determines that the claims are directed to an abstract idea of an idea of itself of associating events with a pattern. Final Act. 2–

3. The Examiner further determines that the claims are "directed to a process implemented on a computer system or embedded on a computer readable medium comprising instructions for carrying out the method." *See id.* at 3–4. The Examiner determines that "[t]he method steps themselves are considered to be an abstract idea because they do not purport to improve the functioning of the computer itself, there is no specific or limitation recitation of improved computer technology, nor do they effect an improvement in any other technology or technical field." *Id.* at 4. The Examiner states that the independent claims recite the elements of "sensor," "memory," "one or more processors" and a "medicament administration device." Ans. 5. The Examiner determines that "[t]he generic recitation of a medicament administration device configured to administer a medicament are general, well-known, routine and conventional in the art." Final Act. 4. The Examiner further determines that "[w]ithout additional limitations, a process that employs mathematical algorithms to manipulate existing information to generate additional information is not patent eligible." *Id.*

The Examiner additionally reasons that the claimed invention is abstract because it automates a function performed by a physician when it receives data from a sensor, looks at the data for patterns, and defines or modifies a therapy based on a pattern. *See* Ans. 3 (citing *SmartGene, Inc. v. Advanced Bio. Labs SA*, 555 Fed. App'x 950, 955–56 (Fed. Cir. 2014)). The Examiner also concludes that the claimed invention resembles the type of abstract idea found unpatentable in the following cases: the collection, analysis, and display of available information in a particular field, found unpatentable in *Electric Power Group*, and the broad concept of monitoring audit log data, found unpatentable in *FairWarning IP LLC*. Ans. 4 (citing

Elec. Power Grp., LLC v. Alstom S.A., 830 F.3d 1350 (Fed. Cir. 2016); *FairWarning IP LLC v. Iatric Sys., Inc.*, 839 F.3d 1089 (Fed Cir. 2016)).

The Appellants assert that claim 1 recites "a sensor configured to generate sensor data indicative of a concentration of an analyte in a host over time," "detect a pattern in the data, the detecting comprising identifying a plurality of events based on the sensor data, associating at least some of the plurality of events based on a criterion to from a set of events, and qualifying the set of events as the detected pattern," "form or modify a medicament administration routine based on the detected pattern," and "a medicament administration device configured to administer a medicament to the host according to the medicament administration routine." Appeal Br. 13. Appellants argue that the Examiner characterized the invention too broadly, that the claims are drawn to more than an idea of itself, that the aforementioned limitations are not well-known and routine, and that improvements need not be physical. *Id.* at 13–14.

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 Int'l*, 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 a rule based system. 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 glucose sensing. Rather, as the Examiner found, the claims are directed to a "sensor," detecting a pattern, and forming or modifying a routine for medicament administration. *See* claim 1. We agree with the Examiner that this type of data processing is abstract, both as a matter of mathematical relationships (pattern recognition and dosage modification based thereon) and data processing itself. *See SmartGene, Inc. v. Advanced Biological Labs., SA*, 555 Fed. App'x 950, 955 (Fed. Cir. 2014) (claim directed "the mental steps of comparing new and stored information and using rules to identify medical options" which was held to be unpatentable subject matter); *Elec. Power Grp.*, 830 F.3d at 1353–54 (presenting the results of the collection and analysis without more are patent ineligible abstract concepts). Comparing glucose readings and basing dosage modifications thereon is the type of rule-based comparison with generation of options that was held abstract in *SmartGene*. Appellants argue that the presence of a sensor distinguishes the claimed invention from the database system of *SmartGene*. Reply Br. 8. Nevertheless, the receiving and processing of data to detect events, including data gathered from sources being monitored, is the type of

routine data processing held abstract in *Electric Power Group*, 830 F.3d at 1355.

Appellants similarly argue that the claimed invention can improve diabetes management. Appeal Br. 15. However, this is an argument that goes to the issue of utility rather than whether the claimed invention is directed to unpatentable subject matter, e.g., as abstract or claiming a law of nature. Further, the claimed invention in *Mayo* sought to optimize the therapeutic efficacy of 6-thioguanine but was still held to be unpatentable subject matter. *Mayo*, 566 U.S. at 71.

Appellants assert that the rejection must rely on evidence, case law, or intrinsic evidence, and address the limitations individually and as a whole, and that the Examiner fails to do so. Appeal Br. 15–16. However, as above, the Examiner's Answer provided citations to case law and in comparing the combination of limitations to prior cases in which there was monitoring, comparing data to a rule, and generation of options. *See* Ans. 3–4. Further, the Examiner's finding that sensors and medicament administration devices are well-understood, routine and conventional in diabetes management technology (*see id.* at 5), is supported by the evidence of record, as discussed above with respect to the rejection under § 103. *See also* Spec. ¶¶ 4–5, 139, 153, 155, 163.

Appellants imply that the claimed invention is comparable to *Enfish*, in which there was an improvement in logical structures and processes rather than physical features because the claim here detects a pattern and modifies medicament administration based thereon, the claimed invention. *See* Appeal Br. 16; Reply Br. 10 (citing *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327 (Fed. Cir. 2016)). However, the claims in *Enfish* were directed to

an improvement in database structure (a self-referential table). *Enfish*, 822 F.3d at 1335. Here, the Examiner correctly finds that the claims do not provide an improvement in computer technology, nor do the claims provide any improvement in insulin delivery. Final Act. 4. Indeed, the Specification provides only generic and routine computer structures, such as a touchscreen display devices (¶¶ 148, 175); a personal computer (¶ 157); a sensor electronics module (¶ 160); a graphical user interface (¶ 299); and a date slider control (¶ 319). The Specification does not present any of these features as more than standard components.

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. *Alice*, 134 S. Ct. at 2355 (quoting *Mayo*, 566 U.S. at 71–72). 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 claimed invention is not a mathematical formula in isolation because it recites medicament administration based on a detected pattern similar to the rubber-molding press of *Diehr* responding to the Arrhenius equation calculations. Appeal Br. 14 (citing *Diamond v. Diehr*, 450 U.S. 175 (1981)). Although the claimed invention at issue in *Diehr* was based on mathematical principles, an invention directed to determining the proper dosage of a medicament appears to be more similar to *Mayo*, in which the Court held unpatentable an invention directed to optimizing therapeutic efficacy of 6-thioguanine. *Mayo*, 566 U.S. at 71.

Appellants argue that the Examiner's rejection appears to only consider the steps individually rather than as an ordered combination. Appeal Br. 15–16. 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 and the generation of options was held to be abstract.

Appellants argue that the claimed invention, when considered as a whole, amounts to significantly more than any potential exception because it constitutes an improvement to a particular technology, i.e., healthcare delivery using a device. Reply Br. 6. Appellants contend that the claimed invention resembles an example in a USPTO's guidance document on subject matter eligibility, July 2015 Update: Subject Matter Eligibility Appendix 1. *Id.* at 5–6. In particular, Appellants assert:

> Similar to Example 26, in which "the rate of change of the engine throttle position" is applied to the exhaust gas recirculation valve to "change the position of the exhaust gas recirculation valve," the present [c]laim 1 recites "the detected pattern" that is used to "form or modify [the] medicament administration routine," which is further used by "a medicament administration device configured to administer a medicament to the host according to the medicament administration routine."

Id. However, in the instant application, neither the claims nor the Specification are directed to an improvement in the mechanical delivery of insulin but are rather directed to an improvement in associated data processing. As such, Appellants' invention is essentially computational and is therefore unlike a valve in an engine that changes position, to which they compare their invention. Further, as above, the Supreme Court has held the

calculation of dosage to be unpatentable subject matter. *Mayo*, 566 U.S. at 71.

As such, we sustain the Examiner's rejection under § 101 of claim 1.

Appellants make similar arguments with respect to the remaining claims. We have reviewed the additional limitations of claims 2–12 and 31 and determine that they are directed to the same abstract idea of monitoring, receiving, and comparing data. We, thus, sustain the Examiner's rejection under § 101 of claims 2–12 and 31 for similar reasons as independent claim 1.

DECISION

The Examiner's decision to reject claims 1–12 and 31 under 35 U.S.C. § 103 is affirmed.

The Examiner's decision to reject claims 1–12 and 31 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