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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ANDREA FACCHINETTI, SIMONE DEL FAVERO,
GIOVANNI SPARACINO, and CLAUDIO COBELLI

Appeal 2023-001547
Application 15/067,104
Technology Center 3700

Before JEFFREY T. SMITH, WILLIAM A. CAPP, and
CYNTHIA L. MURPHY, *Administrative Patent Judges*.

SMITH, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant¹ appeals from the Examiner’s decision to reject claims 1–11 and 19–22. *See* Final Act. 1. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

¹ “Appellant” refers to “applicant” as defined in 37 C.F.R. § 1.42. Appellant identifies the real party in interest as Dexcom, Inc. (Appeal Br. 2.).

CLAIMED SUBJECT MATTER

The claims are directed to a method to improve safety monitoring in type-1 diabetic patients by detecting in real-time failures of the glucose.

Claim 1, reproduced below, illustrates the claimed subject matter:

1. A device for determining a failure in the monitoring or insulin treatment of a patient, comprising:
 - (a) a continuous glucose monitoring system that is configured to generate glucose data indicative of the patient's glucose level;
 - (b) a continuous subcutaneous insulin infusion pump that is configured to inject insulin into the patient and that is configured to generate insulin data regarding insulin that has been injected into the patient;
 - (c) a processor, in communication with the continuous glucose monitoring system and the insulin pump, that is programmed to select a model from among a plurality of models that describe a relationship between glucose data measured by the continuous glucose monitoring system and insulin injected by the continuous insulin infusion pump, the processor further programmed to individualize the model based on patient data, the processor further programmed with a discrete-time reiterative filter that is at least partially derived based on the selected model, wherein the discrete-time reiterative filter is configured to calculate one or more predicted glucose levels at different prediction horizons based on the insulin data and the glucose data, wherein the discrete-time reiterative filter is further configured to calculate confidence intervals associated with each of the one or more predicted glucose levels so that the confidence intervals are based on model accuracy and the confidence intervals are able to increase as the prediction horizons increase, the processor being further programmed to generate an alert based on the glucose levels being different from the predicted glucose levels by at least an amount that

depends on a statistical comparison therebetween, taking into account the confidence intervals; and

(d) an alert generating device coupled to the processor and configured to generate an event corresponding to the generation of the alert, wherein the event is an audible alarm, a visual alarm, a vibrational alarm, or a combination thereof.

REJECTION

The Examiner maintains the rejection of claims 1–11 and 19–22 under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter without significantly more.

OPINION

35 U.S.C. § 101 REJECTION

Principles of Law

A. SECTION 101:

Inventions for a “new and useful process, machine, manufacture, or composition of matter” generally constitute patent-eligible subject matter. 35 U.S.C. § 101. However, the U.S. Supreme Court has long interpreted 35 U.S.C. § 101 to include implicit exceptions: “[l]aws of nature, natural phenomena, and abstract ideas” are not patentable. *Alice Corp. v. CLS Bank Int’l*, 573 U.S. 208, 216 (2014).

In determining whether a claim falls within an excluded category, we are guided by the Court’s two-step framework, described in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012), and *Alice*, 573 U.S. at 217–18 (citing *Mayo*, 566 U.S. at 75–77). In accordance with that framework, we first determine what concept the claim

is “directed to.” *See Alice*, 573 U.S. at 219 (“On their face, the claims before us are drawn to the concept of intermediated settlement, *i.e.*, the use of a third party to mitigate settlement risk.”); *see also Bilski v. Kappos*, 561 U.S. 593, 611 (2010) (“Claims 1 and 4 in petitioners’ application explain the basic concept of hedging, or protecting against risk.”).

Concepts determined to be abstract ideas, and thus patent ineligible, include certain methods of organizing human activity, such as fundamental economic practices (*Alice*, 573 U.S. at 219–20; *Bilski*, 561 U.S. at 611); mathematical formulas (*Parker v. Flook*, 437 U.S. 584, 594–95 (1978)); and mental processes (*Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)). Concepts determined to be patent eligible include physical and chemical processes, such as “molding rubber products” (*Diamond v. Diehr*, 450 U.S. 175, 191 (1981)); “tanning, dyeing, making water-proof cloth, vulcanizing India rubber, smelting ores” (*id.* at 182 n.7 (quoting *Corning v. Burden*, 56 U.S. 252, 267–68 (1854))); and manufacturing flour (*Benson*, 409 U.S. at 69 (citing *Cochrane v. Deener*, 94 U.S. 780, 785 (1876))).

In *Diehr*, the claim at issue recited a mathematical formula, but the Court held that “a claim drawn to subject matter otherwise statutory does not become nonstatutory simply because it uses a mathematical formula.” *Diehr*, 450 U.S. at 187; *see also id.* at 191 (“We view respondents’ claims as nothing more than a process for molding rubber products and not as an attempt to patent a mathematical formula.”). Having said that, the Court also indicated that a claim “seeking patent protection for that formula in the abstract . . . is not accorded the protection of our patent laws, . . . and this principle cannot be circumvented by attempting to limit the use of the formula to a particular technological environment.” *Id.* at 191 (citing *Benson*

and *Flook*); *see also, e.g., id.* at 187 (“It is now commonplace that an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.”).

If the claim is “directed to” an abstract idea, we turn to the second step of the *Alice* and *Mayo* framework, where “we must examine 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 (internal quotation marks omitted). “A claim that recites an abstract idea must include ‘additional features’ to ensure ‘that the [claim] is more than a drafting effort designed to monopolize the [abstract idea].’” *Id.* (alterations in original) (quoting *Mayo*, 566 U.S. at 77). “[M]erely requir[ing] generic computer implementation[] fail[s] to transform that abstract idea into a patent-eligible invention.” *Id.*

B. USPTO SECTION 101 GUIDANCE:

In January 2019, the U.S. Patent and Trademark Office (“USPTO”) published revised guidance on the application of 35 U.S.C. § 101. *See* 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50 (Jan. 7, 2019) (“2019 Guidance”), *updated by* USPTO, *October 2019 Update: Subject Matter Eligibility* (available at https://www.uspto.gov/sites/default/files/documents/peg_oct_2019_update.pdf) (“October 2019 Guidance Update”); *see also* October 2019 Patent Eligibility Guidance Update, 84 Fed. Reg. 55942 (Oct. 18, 2019) (notifying the public of the availability of the October 2019 Guidance Update). “All USPTO personnel are, as a matter of internal agency management, expected to follow the guidance.” 2019 Guidance, 84 Fed. Reg. at 51; *see also* October 2019 Guidance Update at 1. The Manual of Patent Examining Procedure

(“MPEP”) now incorporates this revised guidance and subsequent updates at Section 2106 (9th ed. Rev. 10.2019, rev. June 2020).²

Under MPEP § 2106, we first look to whether the claim recites the following:

- (1) any judicial exceptions, including certain groupings of abstract ideas (i.e., mathematical concepts, certain methods of organizing human activity such as a fundamental economic practice, or mental processes); and
- (2) additional elements that integrate the judicial exception into a practical application.³

MPEP §§ 2106.04(a), (d).

Only if a claim (1) recites a judicial exception and (2) does not integrate that exception into a practical application, do we then look to whether the claim:

- (3) adds a specific limitation beyond the judicial exception that is not “well-understood, routine, [and] conventional activity” in the field; or
- (4) simply appends well-understood, routine, conventional activities previously known to the industry, specified at a high level of generality, to the judicial exception.

MPEP § 2106.05(d).

² All references to the MPEP are to the Ninth Edition, Revision 10.2019 (Last Revised June 2020), unless otherwise indicated.

³ “Examiners evaluate integration into a practical application by (1) identifying whether there are any additional elements recited in the claim beyond the judicial exception(s), and (2) evaluating those additional elements individually and in combination to determine whether the claim as a whole integrates the exception into a practical application.” MPEP § 2106.04(d)II.

Claims 1–11, 19–22

Appellant does not present arguments under separate headings for any of the rejected claims. Appellant’s arguments are directed to the limitations of independent claim 1. (Appeal Br. 5–12.) We therefore select independent claim 1 as representative of the claimed subject matter for this rejection. Claims 2–11 and 19–22 stand or fall with claim 1.⁴ (Appeal Br. 12.)

THE EXAMINER’S DETERMINATIONS

Claim 1 recites a device for determining a failure in the monitoring or insulin treatment of a patient. The Examiner determines the claim is directed to a product, which is one of the statutory categories of invention. The Examiner determines the that limitations in (c) recite processes performed through the use of mathematical concepts and that can be performed in the human mind. (Final Act. 2–3.)

Specifically, the Examiner determines that the limitations of (c) “are highly generalized (a continuous glucose monitoring system ... a continuous subcutaneous insulin infusion pump ... a processor ... an alert generating device) and amount to well-known methods for obtaining glucose/insulin data, a highly generalized processor that performs the mathematical calculation, and providing an alert thereafter.” (Final Act. 4.) As such, the Examiner finds that the limitations of (c) recite abstract ideas. (Final Act. 4.)

⁴ Our analysis equally applies to independent claim 6.

The Examiner further states:

Independent claim 6 recites mirrored imitations in system claim form and is not patent eligible for substantially similar reasons.

Dependent claims 2-5, 8, and 19-22 also fail to add something more to the abstract independent claims as they merely further limit the abstract idea.

Dependent claims 7, 9, 10, and 11 amount to pre-solution and post-solution activity and thus do not integrate the judicial exception into a practical application. See MPEP 2106.05(g).

(Final Act. 4, emphasis omitted.)

ANALYSIS

STEP 1

The claimed subject matter of claims 1–11 and 19–22 falls within the four statutory categories of patentable subject matter identified by 35 U.S.C. § 101: process, machine, manufacture, or composition of matter.

Accordingly, we turn to step 2A of the 2019 Guidance.

STEP 2A, PRONG 1

Under step 2A, prong 1, of the 2019 Guidance, we first look to whether the claims recite any judicial exceptions, including certain groupings of abstract ideas (i.e., mathematical concepts, certain methods of organizing human activity such as a fundamental economic practice, or mental processes). MPEP § 2106.04(a). The “mental processes” judicial exception also includes concepts that can be performed by a human with a pen and paper as well as those that can be performed entirely in the mind. MPEP § 2106.04(a)(2)III; *see also* October 2019 Guidance Update at 9 (“A claim that encompasses a human performing the step(s) mentally with the aid of a pen and paper recites a mental process”) (emphasis omitted).

Additionally, the mathematical concepts judicial exception includes

mathematical formulas, equations, or calculations, as constituting a patent-ineligible abstract idea. MPEP § 2106.04(a).

Limitation (c) requires a processor that is programmed to select a model from among a plurality of models that describe a relationship between glucose data measured by the continuous glucose monitoring system and insulin injected by the continuous insulin infusion pump. The processor utilizing patient data, calculating one or more predicted glucose levels at different prediction horizons based on the insulin data and the glucose data, the processor further programmed to generate an alert based on the glucose data. (Appeal Br. 13, Claims Appx.). We, therefore, conclude that the emphasized portions of claim 1, reproduced above, recite mathematical concepts and concepts that can be practically performed in the human mind or with the assistance of pen and paper (including an observation, evaluation, judgment, opinion). Concepts performed in the human mind fall under the category of mental processes (i.e., an abstract idea). Accordingly, we agree with the Examiner's determination that limitations (c) recite abstract ideas. The 2019 Guidance expressly recognizes such mental processes as constituting a patent-ineligible abstract idea. MPEP § 2106.04(a).

We must still determine whether the abstract idea is integrated into a practical application, namely whether the claims apply, rely on, or use the abstract idea in a manner that imposes a meaningful limit on the abstract idea, such that the claims are more than a drafting effort designed to monopolize the abstract idea. *See* MPEP 2106.04(d). We, therefore, (1) identify whether there are any additional recited elements beyond the abstract idea, and (2) evaluate those elements both individually and

collectively to determine whether they integrate the exception into a practical application. *See id.*

Accordingly, we proceed to prong 2.

STEP 2A, PRONG 2

Under step 2A, prong 2, of the 2019 Guidance, we next analyze whether the claims recite additional elements that individually or in combination integrate the judicial exception into a practical application. MPEP § 2106.04(d). The 2019 Guidance identifies considerations indicative of whether an additional element or combination of elements integrate the judicial exception into a practical application, such as an additional element reflecting an improvement in the functioning of a computer or an improvement to other technology or technical field. *Id.*

Claim 1 limitations (a), (b), and (d) are the only portions of the claim that recite additional elements beyond the abstract idea. These additional elements, either individually or in combination, do not integrate the abstract idea into a practical application because they do not impose any meaningful limits on practicing the abstract idea for the following reasons.

Limitation (a) recites a “continuous glucose monitoring system.” [CGM]. (Appeal Br. 13, Claims App.). Appellant’s Specification discloses the CGM has a sensor that generates the glucose level data. (Spec. ¶¶ 13, 21, 22.) Limitation (b) recites a “insulin infusion pump that is configured to inject insulin into the patient and that is configured to generate insulin data regarding insulin that has been injected.” (Appeal Br. 13, Claims App.) The Specification discloses the insulin infusion pump that generates data regarding when and how much insulin has been injected into the patient. (Spec. ¶ 10.) Appellant’s Specification discloses the processor (limitation

(c) is in data communication with the CGM and the insulin pump wherein the processor is programmed to calculate a predicted glucose level corresponding to a predicted glucose level currently expected to be sensed by the CGM. (Spec. ¶ 10.) Limitation (d) recites a “alert generating device coupled to the processor.” (Appeal Br. 13, Claims App.) The Specification discloses the processor is configured to generate an alert when the actual glucose level is different from the predicted glucose level by a predetermined amount. (Spec. ¶ 10.) Accordingly, the Specification discloses that the processor operates for the sole purpose of manipulating data. The manipulation of data can be performed by generic computer components. The Specification does not disclose more than generic computer components are required. Merely adding generic data generating hardware and computer components, namely a generic processor, to perform an abstract idea does not integrate the abstract idea into a practical application. *See* 2019 Guidance, 84 Fed. Reg. at 55 (identifying “merely includ[ing] instructions to implement an abstract idea on a computer” as an example of when an abstract idea has not been integrated into a practical application).

The Specification states:

[T]he invention is an improvement to a glucose monitoring system for monitoring a diabetic patient that includes a continuous glucose monitoring system that is configured to generate glucose data indicative of the patient's actual glucose level and an insulin pump that is configured to inject insulin into the patient and that is configured to generate insulin data regarding when and how much insulin has been injected into the patient. The improvement includes a processor, in data communication with the continuous glucose monitoring system and the insulin pump, that is programmed with a failure detection module to calculate a predicted glucose level based on the insulin data and the glucose data over time and that is

programed to generate an alert when the actual glucose level is different from the predicted glucose level by a predetermined amount. (Spec. ¶ 11.) The claimed improvement in CGM resides in data calculations performed by the processor. Thus, the alleged improvements are improvements in processor operation, which fall within the category of an abstract idea, as discussed above, not an improvement to technology. “[A] claim for a *new* abstract idea is still an abstract idea.” *Synopsys, Inc. v. Mentor Graphics Corp.*, 839 F.3d 1138, 1151 (Fed. Cir. 2016) (emphasis added). Although Appellant relatedly contends that the claimed invention provides improvement in CGM, Appellant does not point to any evidence in the Specification to support this specific improvement. *See* Appeal Br. 5–7 (citing Spec. ¶¶ 6–8 45 (describing problems in CGM systems)).

The processor of claim 1 does not function differently than conventional processors. The Specification fails to disclose an improvement in processor operation compared to conventional processors. The present claims recite an abstract idea, as discussed above, or at best, improving an abstract idea—not a technological improvement.

For these reasons, claim 1 is not directed to an improvement in the glucose monitoring system or to any other technology or technical field. MPEP § 2106.05(a). Accordingly, claim 1 does not integrate the recited abstract idea into a practical application within the meaning of the 2019 Guidance. *See* 2019 Guidance, 84 Fed. Reg. at 52–55.

STEP 2B

Under step 2B of the 2019 Guidance, we next analyze whether the claims add any specific limitations beyond the judicial exception that, either

alone or as an ordered combination, amount to more than “well-understood, routine, conventional” activity in the field. MPEP § 2106.05(d).

As noted above, the only limitations of claim 1 that recite an additional element beyond the noted abstract ideas are the limitations (a) CGM system, (b) insulin pump, and (d) alert device. The Specification, discloses the improvement lies with the processor that is in data communication with the continuous glucose monitoring system and the insulin pump. (Spec. ¶ 11.) The Specification only describes the processor at high levels of generality, that compares data generated from the CGM system and insulin pump to generate an alert. (Spec. ¶ 12.) The identified additional elements, either individually or in combination, do not integrate the abstract idea into a practical application.

The Specification does not disclose that the invention requires more than a generic processor along with the above conventional components. (Spec. ¶¶ 11–12.) A general-purpose processor that merely executes the judicial exception is not a particular machine. *See Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 709, 716–17 (Fed. Cir. 2014), *cited in* MPEP § 2106(b)(I). As such, the Specification indicates that the CGM system, insulin pump, alert device and processor that may be used to carry out the present invention were well understood, routine, and conventional. Furthermore, Appellant’s Specification does not indicate that consideration of these conventional elements as an ordered combination adds any significance beyond the additional elements, as considered individually. Rather, Appellant’s Specification indicates that the invention is directed to an abstract idea performed on a processor that is in data communication with the continuous glucose monitoring system, an insulin pump or comparing

data models—i.e., mathematical concepts or mental processes that can be performed in the human mind or with the aid of pencil and paper— and generating an alert with an alert device.

Therefore, claim 1, at best, recites an abstract idea that includes additional elements that are the result of executing the abstract idea using a generic processor. However, merely improving the abstract idea by using conventional computer equipment, does not recite significantly more than the abstract idea. *See BSG Tech LLC v. Buyseasons*, 899 F.3d 1281, 1290 (Fed. Cir. 2018) (“It has been clear since *Alice* that a claimed invention’s use of the ineligible concept to which it is directed cannot supply the inventive concept that renders the invention ‘significantly more’ than that ineligible concept.”); *SAP Am., Inc. v. InvestPic, LLC*, 898 F.3d 1161, 1168 (Fed. Cir. 2018) (“What is needed is an inventive concept in the non-abstract application realm.”).

For these reasons, we determine that claim 1 does not recite additional elements that, either individually or as an ordered combination, amount to significantly more than the judicial exception within the meaning of the 2019 Guidance. MPEP § 2106.05(d).

Accordingly, we sustain the Examiner’s rejection of claims 1–11 and 19–22 under 35 U.S.C. § 101 as being directed to an exception to patent-eligible subject matter without reciting significantly more.

CONCLUSION

The Examiner’s rejection is AFFIRMED.

Appeal 2023-001547
Application 15/067,104

DECISION SUMMARY

The following table summarizes our decision:

Claim(s) Rejected	35 U.S.C. §	Reference(s)/ Basis	Affirmed	Reversed
1-11, 19-22	101	Eligibility	1-11, 19-22	

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). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED