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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/737,268	01/09/2013	Alain Bock	26932 US1/dc	2020

67491 7590 05/03/2019

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EXAMINER	
RIGGS II, LARRY D	

ART UNIT	PAPER NUMBER
1631	

NOTIFICATION DATE	DELIVERY MODE
05/03/2019	ELECTRONIC

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ALAIN BOCK, DAVID L. DUKE, and ABHISHEK S. SONI

Appeal 2018-004561
Application 13/737,268[1]
Technology Center 1600

Before ELENI MANTIS MERCADER, CATHERINE SHIANG, and LINZY T. McCARTNEY, *Administrative Patent Judges*.

SHIANG, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellants appeal under 35 U.S.C. § 134(a) from the Examiner's rejection of claims 1, 3–16, and 19–25, which are all the claims pending and rejected in the application. We have jurisdiction under 35 U.S.C. § 6(b).

We reverse.

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[1] Appellants identify Roche Diabetes Care, Inc. as the real party in interest. App. Br. 2.

STATEMENT OF THE CASE

Introduction

The present invention relates to regulating blood glucose in diabetic patients, and in particular relates to delivering insulin to reduce a risk of a hypoglycemic episode in diabetic patients. *See* Spec. 1–2. Claim 5 is exemplary:

> 5. A method of considering the effect of aerobic exercise on blood glucose levels for an individual to deliver insulin based on an optimized insulin injection profile to reduce a risk of a hypoglycemic episode at least partially due to aerobic exercise, comprising:
>
> generating with a computing device a prediction of future blood glucose levels for the individual at least partly based on an exercise model, wherein the exercise model is based on parameters that are independent of intensity of the aerobic exercise to reduce a complexity of parameters processed by the computing device to generate the prediction while including at least one exercise parameter to reduce the risk of the hypoglycemic episode; and
>
> taking an action with the computing device at least based on the prediction from the exercise model, wherein said taking the action with the computing device includes utilizing an automated pancreas for collecting one or more blood glucose readings of the individual as a parameter of the exercise model and optimizing an insulin injection profile to prevent the hypoglycemic episode, performing a corresponding bolus calculation, and adjusting a bolus delivery to the individual that is based on the optimized insulin injection profile, wherein the optimized insulin injection profile is varying over a period of time and is based on the prediction.

Rejection[2]

Claims 1, 3–16, and 19–25 stand rejected under 35 U.S.C. § 101 because they are directed to patent-ineligible subject matter. Final Act. 2–6.

ANALYSIS[3]

35 U.S.C. § 101

We have reviewed the Examiner's rejection in light of Appellants' contentions and the evidence of record. We concur with Appellants' contention that the Examiner erred in this case.

Section 101 of the Patent Act provides "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101. However, the 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. *E.g.*, *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 216 (2014) (internal quotation marks and citation omitted).

In determining whether a claim falls within an excluded category, we are guided by the Supreme Court's two-step framework, described in *Mayo* and *Alice*. *Id.* at 217–18 (citing *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 75–77 (2012)). In accordance with that framework,

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[2] Throughout this opinion, we refer to the (1) Final Office Action dated March 10, 2017 ("Final Act."); (2) Appeal Brief dated September 21, 2017 ("App. Br."); (3) Examiner's Answer dated February 23, 2018 ("Ans."); and (4) Reply Brief dated March 26, 2018 ("Reply Br.").

[3] Appellants raise additional arguments. Because the identified issue is dispositive of the appeal, we do not need to reach the additional arguments.

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 Supreme 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 Supreme 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.* (citing *Benson* and *Flook*); *see, 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 (citation 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.* (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.*

The PTO recently published revised guidance on the application of § 101. USPTO, 2019 REVISED PATENT SUBJECT MATTER ELIGIBILITY GUIDANCE, 84 Fed. Reg. 50 (Jan. 7, 2019) ("Guidance"). Under the guidance set forth in the Guidance, we first look to whether the claim recites:

> (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) (Step 2A, Prong 1); and
>
> (2) additional elements that integrate the judicial exception into a practical application (*see* MANUAL OF PATENT EXAMINING PROCEDURE ("MPEP") § 2106.05(a)–(c), (e)–(h)) (9th Ed., Rev. 08.2017, 2018) (Step 2A, Prong 2).

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, conventional" in the field (*see* MPEP § 2106.05(d)); 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. (Step 2B.)

See Guidance, 84 Fed. Reg. at 54–56.

Turning to Guidance Step 2A, Prong 1 (*Alice* step one), we agree with Appellants that the Examiner has failed to identify a patent-ineligible abstract idea. *See* App. Br. 10–13. The Federal Circuit explains the "directed to" inquiry looks at the claims' "character as a whole," and is not simply asking whether the claims involve a patent-ineligible concept:

> The "directed to" inquiry [ ] cannot simply ask whether the claims *involve* a patent-ineligible concept, because essentially every routinely patent-eligible claim involving physical products and actions *involves* a law of nature and/or natural phenomenon—after all, they take place in the physical world. *See Mayo*, 132 S.Ct. at 1293 ("For all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas."). Rather, the "directed to" inquiry applies a stage-one filter to claims, considered in light of the specification, based on whether "their character as a whole is directed to excluded subject matter."

Enfish, LLC v. Microsoft Corp., 822 F.3d 1327, 1335 (Fed. Cir. 2016); *see also Diehr*, 450 U.S. at 188 ("In determining the eligibility of respondents' claimed process for patent protection under § 101, their claims must be considered as a whole."); *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 837 F.3d 1299, 1314 (Fed. Cir. 2016) (the question is whether the claims as a whole "focus on a specific means or method that improves the relevant technology or are instead directed to a result or effect that itself is the abstract idea and merely invoke generic processes and machinery").

Considering the claims as a whole, we determine each of claims 5–16 and 19–25 is directed to a method of predicting glucose levels and based on the prediction, using insulin injection to reduce the risk of a hypoglycemic episode ("invented treatment method"); and each of claims 1, 3, 4 is directed to a system of predicting glucose levels and based on the prediction, using insulin injection to reduce the risk of a hypoglycemic episode ("invented treatment system"). Our determination is supported by the Specification, which describes the shortcomings of prior art treatment models and the resulting need for the invented treatment model. *See* Spec. 1–4.

In light of the Guidance, because the invented treatment method (or system) is not a mathematical concept, an identified method of organizing human activity, or a mental process, we conclude the claims are not directed to an abstract idea. *See* Guidance, 84 Fed. Reg. at 52; *id.* at 53 ("Claims that do not recite matter that falls within these enumerated groupings of abstract ideas should not be treated as reciting abstract ideas, except" in rare circumstances.); *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals*, 887 F.3d 1117, 1135 (Fed. Cir. 2018) (holding "claims . . . directed to a method of using iloperidone to treat schizophrenia" are patent eligible).

In particular, the invented treatment method (or system) is not a mathematical concept, because it is not a mathematical relationship, mathematical formula or equation, or mathematical calculation. *See* Guidance, 84 Fed. Reg. at 52. Further, it is not an identified method of organizing human activity, as it is not (i) a fundamental economic principle or practice (including hedging, insurance, mitigating risk), (ii) a commercial or legal interaction (including agreements in the form of contracts; legal obligations; advertising, marketing or sales activities or behaviors; business

relations), or (iii) managing personal behavior or relationships or interactions between people (including social activities, teaching, and following rules or instructions). *See* Guidance, 84 Fed. Reg. at 52. In addition, the invented treatment method (or system) is not a mental process, as it is not a concept performed in the human mind (including an observation, evaluation, judgment, opinion). *See* Guidance, 84 Fed. Reg. at 52.

Because claims 1, 3–16 and 19–25 are not directed to an abstract idea, we do not sustain the Examiner's rejection of claims 1, 3–16 and 19–25 under 35 U.S.C. § 101.

DECISION

We reverse the Examiner's decision rejecting claims 1, 3–16, and 19–25.

REVERSED