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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* ABHISHEK S. SONI, PAUL J. GALLEY, ALAN GREENBURG,  
STEVEN BOUSAMRA, STEFAN WEINERT, and  
ERIC DIEBOLD

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Appeal 2017-011193  
Application 12/818,894<sup>1</sup>  
Technology Center 3600

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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 1–10, 14–28, 30, 32, 33, and 36–38, 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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<sup>1</sup> Appellants identify Roche Diabetes Care, Inc. as the real party in interest. App. Br. 2.

## STATEMENT OF THE CASE

### *Introduction*

The present invention “relate generally to devices collecting physiological information, and particularly to a system and method managing the implementation, execution, data collection, and data analysis of a structured collection procedure running on a portable, hand-held collection device as well as status reporting of the structured collection procedure.” Spec. ¶ 2. Claim 1 is exemplary:

1. A portable, hand-held collection device which addresses a medical question and improves compliancy with a structured collection procedure, said device comprising:

a glucose meter configured to perform a blood glucose measurement on a test strip read by a measurement engine comprising:

the measurement engine for reading the test strip;

a display;

a memory;

a processor connected to the memory and the display;

wherein the glucose meter comprises a housing containing therein the measurement engine, the display is exhibited on one face of the housing, and the housing has at one end a port for receiving the test strip; and

program instructions which when executed by the processor cause the processor to:

initiate a schedule of events of the structured collection procedure upon one or more entry criteria being met,

collect patient data for the structured collection procedure by monitoring blood glucose levels and when entered in response to a request in accordance with an event provided in the schedule of events after initiation,

store automatically in the memory the collected patient data,

assess automatically whether the collected patient data in response to the request meets one or more adherence and/or acceptance criteria,

wherein the one or more adherence and/or acceptance criteria is a different criteria from the entry criteria, wherein the one or more adherence and/or acceptance criteria comprises a defined range of values, and if the patient data does not fall within the range, the processor is configured to prompt for additional patient data and automatically extend the events in the schedule of events if an assessment provided by the processor is that steps leading up to taking of the patient data were not accomplished;

associate automatically with the stored collected patient data a unique identifier in the memory if satisfying the one or more adherence and/or acceptance criteria,

provide automatically a status report when the one or more adherence and/or acceptance criteria are not met during the structured collection procedure, and

end automatically the structured collection procedure upon one or more exit criteria being met, wherein the exit criteria establishes requirements which need to be met for exiting or completing the structured collection procedure such that adequate contextual data is collected to answer the medical question addressed by the structured collection procedure and wherein the schedule of events of the structured collection procedure continues onto a next event by which to collect further patient data until the requirements for the exit criteria are met;

wherein when executed by the processor, the program instructions further cause the processor to: check whether the patient data collected in response to the request which do not meet the one or more adherence criteria causes an adherence violation, to count the number of adherence violations, and end automatically the structured collection procedure when the number

of adherence violations exceeds an acceptable number of adherence violations for a particular type of violation, wherein the type of violation is indicated by the processor, which is configured to provide type codes for what caused the violation, and the processor is configured to provide the type codes of: a measurement taken before a window, the measurement taken after the window, the measurement skipped, incorrect amount of a medication taken, the medication is not taken, and the medication is taken at an incorrect time; and wherein the processor sets, for each type code, the number of adherence violations for the automatic ending of the procedure to address the medical question and improve the compliancy with the structured collection procedure; and

wherein the glucose meter comprises a microprocessor, a power source, and an indicator,

the indicator connected to the processor and which operates under the control of the processor to emit audible, tactile, and/or visual alerts to the individual of daily times for the blood glucose measurement; and the glucose meter sends a message to a physician when the individual fails to complete one of the one or more adherence criteria, wherein a communication link between a computer of the physician and the blood glucose meter is established upon connection via a web server.

### *Rejection<sup>2</sup>*

Claims 1–10, 14–28, 30, 32, 33, and 36–38 stand rejected under 35 U.S.C. § 101 because the claims are directed to patent-ineligible subject matter. Final Act. 2–6.

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<sup>2</sup> Throughout this Opinion, we refer to the (1) Final Rejection dated Sept. 9, 2016 (“Final Act.”); (2) Appeal Brief dated Feb. 14, 2017 (“App. Br.”); (3) Examiner’s Answer dated Apr. 28, 2017 (“Ans.”); and (4) Reply Brief dated June 28, 2017 (“Reply Br.”).

ANALYSIS<sup>3</sup>

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. 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, 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.”).

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<sup>3</sup> Appellants raise additional arguments. Because the identified issue is dispositive of the appeal, we do not need to reach the additional arguments.

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’s 2019 REVISED PATENT SUBJECT MATTER ELIGIBILITY GUIDANCE, 84 Fed. Reg. 50 (Jan. 7, 2019) (“Memorandum”). Under the guidance set forth in the Memorandum, 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* Memorandum at 54–56.

Turning to Memorandum 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. 12–15. 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 the claims is directed to a blood glucose meter configured to measure and monitor

glucose levels according to adherence criteria and notify a physician when the adherence criteria are not met (“invented blood glucose meter”). *See* claims 1–10, 14–28, 30, 32, 33, and 36–38. Our determination is supported by the Specification, which describes the shortcomings of prior art and the resulting need for the invented device. *See* Spec. ¶¶ 5–8.

In light of the Memorandum, because the invented blood glucose meter 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* Memorandum 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.); *see also* *Thales Visionix Inc. v. United States*, 850 F.3d 1343, 1349 (2017) (holding the claims are not directed to an abstract idea under *Alice* step one because the “claims specify a particular configuration of inertial sensors and a particular method of using the raw data from the sensors in order to more accurately calculate the position and orientation of an object on a moving platform”).

In particular, the invented blood glucose meter is not a mathematical concept, because it is not a mathematical relationship, mathematical formula or equation, or mathematical calculation. *See* Memorandum 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

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activities, teaching, and following rules or instructions). *See* Memorandum at 52. In addition, the invented blood glucose meter is not a mental process, as it is not a concept performed in the human mind (including an observation, evaluation, judgment, opinion). *See* Memorandum at 52.

Because the claims are not directed to an abstract idea, we do not sustain the Examiner's rejection of claims 1–10, 14–28, 30, 32, 33, and 36–38 under 35 U.S.C. § 101.

#### DECISION

We reverse the Examiner's decision rejecting claims 1–10, 14–28, 30, 32, 33, and 36–38.

REVERSED