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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte NICOLE BERNINI, PAUL J. GALLEY, STEFAN LINDEGGER,
JOHN F. PRICE, RETO SIGRIST, ROBIN S. WAGNER,
and RICHARD W. WILSON

Appeal 2017-006308¹
Application 13/593,575²
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 1–17, which constitute all the claims pending in this application. We have jurisdiction under 35 U.S.C. §§ 134 and 6(b).

We affirm.

¹ Our Decision refers to Appellants' Appeal Brief ("Appeal Br.," filed Aug. 19, 2016) and Reply Brief ("Reply Br.," filed Mar. 29, 2017), and the Examiner's Final Office Action ("Final Act.," mailed Apr. 5, 2016) and Answer ("Ans.," mailed Jan. 9, 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 an insulin pump and methods for operating the insulin pump, namely methods for generating insulin delivery records and methods for determining an amount of insulin to deliver in a multiwave bolus." Spec. ¶ 1. In one embodiment, the insulin pump includes a controller configured to instruct the insulin delivery mechanism to begin delivery of the insulin to the patient, monitor the delivery of the insulin to determine whether the insulin pump is able to deliver the entire amount of insulin, maintain a timer until the insulin pump recommences the delivery of the insulin when the insulin pump is unable to deliver the entire amount of insulin, and compare an amount of time indicated by the timer to a time threshold when the insulin pump recommences the delivery of the insulin. *Id.* ¶ 20.

The Claims

Claims 1 and 11 are the independent claims on appeal. Claim 1, reproduced below, is illustrative of the subject matter on appeal:

1. A method for delivering insulin to a patient using an insulin pump having one or more processors, the insulin pump being configured to operate in a pause mode, the method comprising:

receiving, at the insulin pump, an amount of insulin to deliver to a patient from a remote device;

beginning, at the insulin pump, delivery of the insulin to the patient;

monitoring, at the insulin pump, the delivery of the insulin to determine whether the insulin pump is able to deliver the entire amount of insulin;

maintaining, at the insulin pump, a timer until the insulin pump recommences the delivery of the insulin when the insulin pump is unable to deliver the entire amount of insulin,

when the insulin pump recommences the delivery of the insulin, comparing an amount of time indicated by the timer to a pause threshold;

when the amount of time indicated by the timer is less than the pause threshold, generating a first insulin delivery record indicating that a first amount of insulin was delivered to the patient, the first amount being the entire amount of insulin, and storing the first record on a computer readable medium of the insulin pump; and

when the amount of time indicated by the timer is greater than the pause threshold, generating a second insulin record indicating that a second amount of insulin was delivered to the patient and storing the second record on the computer readable medium, the second amount being less than the entire amount of insulin that was to be delivered to the patient.

(Appeal Br., Claims App.)

The Issue

The Examiner rejected claims 1–17 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, i.e., comparing an amount of time to a threshold. Final Act. 2–3. 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 receiving data is an insignificant extra-solution activity, that calculating is non-statutory subject matter, and that the computer and/or program/product amount to mere

instruction to implement an abstract idea. *Id.* at 4; Ans. 3 (citing *Electric Power Group, 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)).

Appellants assert that claim 1 recites delivering insulin to the patient by an insulin pump, monitoring the delivery of insulin by the insulin pump and accurately recording the amount of insulin delivered to a patient by the insulin pump. Appeal Br. 11. Appellants argue that the Examiner characterized the invention too broadly and that the claimed steps are not abstract because they involve more than merely comparing an amount of time to a threshold, and that delivery of insulin is not “insignificant extra-solution activity.” Appeal Br. 11; Reply Br. 3. Appellants argue that the Examiner inappropriately required Appellants to submit evidence to support the assertion that the claims provide a technological solution. Appeal Br. 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 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 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 monitoring. Rather, as the Examiner found, the claims are directed to “monitoring” and “receiving” data, running a timer, and “comparing” the elapsed time to a threshold. *See* claim 1. We agree with the Examiner that this type of data processing is abstract, both as a matter of mathematical relationships (comparing the time to a threshold) and data processing. *See SmartGene, Inc. v. Advanced Biological Laboratories, SA*, 555 Fed. Appx. 950, 955 (Fed. Cir. 2014) (claim directed to “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 time to a threshold is the type of rule-based comparison that was held abstract in *SmartGene*, and the receiving and processing of data is the type of routine data processing held abstract in *Electric Power Group*.

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. 11–12. However, the Examiner’s Answer provided citations to case law. *See* Ans. 3.

Appellants assert that by accurately recording the amount of insulin, the pending claims improves upon the computer-related aspect of an insulin pump. *Id.* at 12 (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)). The cited cases dealt respectively with inventions directed to an improvement in database structure (a self-referential table) and a specific asserted improvement in computer animation driven by subjective determinations. *Enfish*, 822 F.3d at 1335; *McRO*, 837 F.3d at 1315. However, the Examiner correctly finds that the claims do not provide an improvement in computer technology. Final Act. 4. Indeed, the Specification provides only generic and routine computer structures, such as a touchscreen display (§ 54); a database (§ 55); a processing subsystem (§ 56); memory such as RAM (*id.*); a calculator (*see* § 125); and a datastore (§ 129). Neither the claims nor the Specification attempt to provide an improvement in the mechanical handling of insulin. Rather the claims are directed to associated data processing.

Appellants argue that information recorded by the claimed invention can be used by a health care provider to determine whether the recommended amount of insulin was actually delivered, and whether there was a pause in the delivery, in order to improve patient care. *See* Reply Br. 3. 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 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. *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, by effecting an improvement in the area of insulin delivery 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; Reply Br. 2. Appellants maintain that the Examiner erred in stating that “patenting abstract ideas cannot be circumvented by attempting to limit the use [the idea] to a particular technological environment” in view of *Alice* and *Diamond v. Diehr*, 450 U.S. 175 (1981). 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 192–93. We agree with the Examiner that the claims do not provide significantly more than the mathematical relationship of comparing the time to a threshold, and the additional limitations make use of routine data processing, i.e., receiving data. 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.

Appellants state without detailed argument with respect to the claims at issue that “if claims are directed to a solution to a technical problem and do not impose a disproportionate preemption of the use of an underlying concept to solve other problems or solve the same problem in a different way, then the claims are indeed directed to a patent-eligible subject matter.” Appeal Br. 12–13. However, a showing of pre-emption is not required for a determination that an idea is directed to non-patentable subject matter. *Ariosa*, 788 F.3d at 1379 (“Where a patent’s claims are deemed only to disclose patent ineligible subject matter under the *Mayo* framework, as they are in this case, preemption concerns are fully addressed and made moot.”). This is a situation where the issue of pre-emption is adequately addressed by the underlying issues set forth above. As such, we sustain the Examiner’s rejection under § 101 of claim 1.

We have reviewed the additional limitations of claims 2–10 and determine that they are directed to the same abstract idea of monitoring, receiving, and comparing data, and sustain the Examiner’s rejection under § 101 of claims 2–10 for similar reasons as independent claim 1.

Although claims 11–17 recite an insulin pump, 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. As such, we sustain the Examiner’s rejection under § 101 of claims 11–17 for similar reasons as independent claim 1.

DECISION

The Examiner’s decision to reject claims 1–17 under 35 U.S.C. § 101 is affirmed.

Appeal 2017-006308
Application 13/593,575

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