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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte MICHAEL J. ROSENBERG

Appeal 2017-004890[1]
Application 12/102,992
Technology Center 3600

Before HUBERT C. LORIN, MICHAEL W. KIM, and NINA L. MEDLOCK, *Administrative Patent Judges*.

KIM, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

This is an appeal from the final rejection of claims 1, 3–9, 12–19, 21–27, and 30–36. We have jurisdiction to review the case under 35 U.S.C. §§ 134(a) and 6(b).

The invention relates generally to "collection of various types of data, for being able to rapidly analyze and respond to such data (as well as corresponding meta-data), and to provide real-time reporting." Spec. 1:11–13.

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[1] The Appellant identifies "the estate of the inventor, Dr. Michael J. Rosenberg (deceased)," as the real party in interest. Appeal Br. 2.

Independent claim 1 is illustrative:

> 1. A computer-implemented method for centrally managing data in an adaptive clinical trial or other adaptive process that is conducted at a plurality of geographically remote sites according to a set of procedures or parameters, said method comprising the steps of:
>
> (a) collecting data in the course of conducting said clinical trial or other process at a remote site, wherein the data comprise performance metrics with respect to said clinical trial or other process;
>
> (b) electronically transmitting the data from said remote site to a processing location;
>
> (c) checking the transmitted data at said processing location, in automated fashion, to assess the consistency of the data with respect to other collected data, to evaluate changes in the data as compared with data collected previously, or to monitor the data for trends over time;
>
> (d) electronically reporting the data to a pre-programmed computer module;
>
> (e) determining, by use of said pre-programmed computer module, whether procedures or parameters utilized in conducting said clinical trial or other process require modification; and
>
> (f) providing instructions, based on said determining, to follow or modify the procedures or parameters utilized in conducting said clinical trial or other process.

The Examiner rejected claims 1, 3–9, 12–19, 21–27, and 30–36 under 35 U.S.C. § 101 as directed to patent-ineligible subject matter.

We AFFIRM.

PRINCIPLES OF LAW

An invention is patent eligible if it claims a "new and useful process, machine, manufacture, or composition of matter." 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).

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.").

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, 69 (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 176; *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 (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.* (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.*

ANALYSIS

The Examiner asserts the following:

> Claims 1, 3–9, 12–19, 21–27, 30–36 are directed to an abstract idea because an abstract idea is recited in the claims. The abstract idea is identified as *collecting clinical trial data to check the data to evaluate changes in the data and monitor the data for*

> *trends over time, determining if the data's parameters/procedures require modification and providing instruction to follow or modify trial procedures or parameters*. Evaluating patient data and other data for providing instructions to modify the procedures or parameters utilized in a clinical trial is an abstract idea because it uses categories to organize, store and transmit information (*such as organizing types of patient and rule data*), compares new and stored information and uses rules to identify options (*such as to identify how to modify the trial or not modify the trial*).
>
> The claims do not include additional elements that are sufficient to amount to significantly more than the judicial exception because the additional elements or combination of elements in the claims, other than the abstract idea per se, amount to no more than a recitation of
>
> A) generic computer structure that serves to perform generic computer functions that serve to merely link the abstract idea to a particular technological environment (*i.e. host computer, central processing site computer . . .*). Applicant's specification, [Page 9, lines 4–10 and lines 13–16] discloses these items to include typical and conventional computers; and
>
> B) functions that are well-understood, routine, and conventional activities previously known to the pertinent industry (*i.e. collecting, transmitting, checking, assessing, evaluating, comparing, monitoring, reporting, determining, providing and modifying*).

Ans. 2–3. We analyze independent claim 1 as representative. *See* 37 C.F.R. § 41.37(c)(1)(iv).

The Appellant asserts that the following limitations are not accounted for adequately in the Examiner's analysis: "determining . . . whether procedures or parameters utilized in conducting said clinical trial or other process require modification"; and "providing instructions, based on said determining, to follow or modify the procedures or parameters utilized in

conducting said clinical trial or other process." App. Br. 6–10. We address each in turn.

We are unpersuaded that the Examiner has not accounted adequately for "determining . . . whether procedures or parameters utilized in conducting said clinical trial or other process require modification." Indeed, the Examiner has identified that limitation expressly as being part of the abstract idea recited in the claims. Ans. 2–3; *see also* Ans. 6–7 (reciting limitations that are part of the abstract idea). The Appellant asserts that the Examiner has not accounted for the fact that the "determining" occurs while the clinical trial is "ongoing" and "being conducted." App. Br. 6–7. The assertion is misplaced, as the Appellant has not identified any claim limitation that limits the above "determining" to the specified time period.

The Appellant make similar assertions for "providing instructions, based on said determining, to follow or modify the procedures or parameters utilized in conducting said clinical trial or other process," but replaces "ongoing"/"being conducted" with "timely"/"adaptive"/"continuously." App. Br. 7. The assertions are unpersuasive for the same reasons.

The Appellant also takes issue with the Examiner's comparison of the above claim limitations with those found patent ineligible in *SmartGene, Inc. v. Advanced Biological Laboratories*, 555 F. App'x 950 (Fed. Cir. 2014), which the Examiner cites for showing that

> *comparing new and stored information and uses rules to identify options (such as checking the transmitted data consistent to the data with respect to other data to evaluate the changes in data and to monitor the data trends and using these data to modify procedures and parameters utilized in conducting the clinical trial*

is an abstract idea. Ans. 7. Specifically, the Appellant asserts that "[u]nlike SmartGene's simple organization and ranking of information from routine lists of previously known data, the instant claims are directed to measuring and analyzing performance metrics, and determining therefrom exactly how to make 'real time' modifications to a (clinical trial) process." App. Br. 11. Again, the distinction identified by the Appellant, "real time," is inapposite because it is not commensurate with the scope of the claim. Instead, we agree with the Examiner that, like the claims in *SmartGene*, independent claim 1 recites limitations that involve mental processes, specifically, evaluating data and rendering a judgment or opinion as to how the trial should or should not be modified based on the evaluation. *See* 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50, 52–53 (Jan. 7, 2019) (footnote 15).

The Appellant asserts additionally that the Examiner has not accounted adequately for the recited "performance metrics." App. Br. 6, 10–11; Reply Br. 2–4. We disagree, as we are unpersuaded that the "performance metrics" are entitled to any substantively significant weight. The method steps would be performed in the same manner whether the data being evaluated were "performance metrics" or otherwise. *See Praxair Distrib., Inc. v. Mallinckrodt Hosp. Prod. IP Ltd.*, 890 F.3d 1024, 1032 (Fed. Cir. 2018) ("Claim limitations directed to the content of information and lacking a requisite functional relationship are not entitled to patentable weight because such information is not patent eligible subject matter under 35 U.S.C. § 101.").

> The Appellant further asserts the following:
>
> Th[e determining and providing steps] are meaningful limitations that add more than generally linking the use of the abstract idea (the general concept of organizing and comparing data) to [conducting clinical trials], because they solve [a clinical trial-] centric problem with a claimed solution that is necessarily rooted in computer technology . . . . These limitations, when taken as an ordered combination, provide unconventional steps that confine the abstract idea to a particular useful application.

App. Br. 8; Reply Br. 6–7.

> The claim does not merely recite [the steps] in isolation, but integrates these ideas into the [clinical trial] process . . . . The totality of the steps act in concert to improve another technical field, specifically the field of [clinical trials, by enabling an "adaptive" process]. In addition, the claimed steps taken as a combination effect a transformation of the [standard clinical trial] into a different state or thing, *i.e.*, [an adaptive clinical trial].

App. Br. 9; Reply Br. 6–7. We are unpersuaded that limiting the claims to "clinical trials" is any more than a general field of use or technological environment, which alone cannot confer subject matter eligibility. *See* Manual of Patent Examining Procedure ("MPEP") § 2106.05(h). We are also unclear how an improvement to "clinical trials" is an improvement rooted to computer technology, when we are unable to identify any limitation that performs the above-identified mental processes (i.e., evaluating, and rendering a judgment or opinion) in a computer-specific manner. *See* MPEP § 2106.05(a), (f). Finally, the types of "transformations" shown to be sufficient to confer subject matter eligibility usually involve a "physical object or substance," of which a "clinical trial" is not. *See* MPEP § 2106.05(c).

The Appellant takes issue with the approach the Examiner has taken as to whether certain claim limitations are "well-understood, routine, and

conventional," in that the Examiner has primarily taken that approach only for claim limitations that fall outside of the abstract idea itself. App. Br. 9–10. Specifically, the Appellant asserts that such an approach has no basis in case law. We disagree. The Federal Circuit has held that, after formulating the concept the claims are "directed to," the inquiry under *Alice* step two is to determine whether claim limitations *other than the steps for executing the formulated concept* are "well-understood, routine, and conventional." *BSG Tech LLC v. BuySeasons, Inc.*, 899 F.3d 1281, 1290 (Fed. Cir. 2018). Accordingly, the Examiner's treatment of the aforementioned "determining" and "providing" steps as part of the abstract idea identified above is proper, and for the computer components the Examiner has identified as "well-understood, routine, and conventional," the Examiner has provided adequate support from the Specification (*see, e.g.*, Ans. 7 (citing Spec. 1:20–26; 5:16–24, 19:4–10, 13–16) or case law (Ans. 8–9). The Appellant does not challenge these citations with any specificity. Reply Br. 5–6.

We sustain the Examiner's rejection of claims 1, 3–9, 12–19, 21–27, and 30–36 under 35 U.S.C. § 101 as directed to patent-ineligible subject matter.

DECISION

We AFFIRM the rejection of claims 1, 3–9, 12–19, 21–27, and 30–36 under 35 U.S.C. § 101.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED