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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte HEINRICH VON BUSCH, JENS-CHRISTOPH GEORGI, and
BERND SCHWEIZER¹

Appeal 2019-000725
Application 14/153,373
Technology Center 1600

Before RYAN H. FLAX, RACHEL H. TOWNSEND, and
CYNTHIA M. HARDMAN, *Administrative Patent Judges*.

HARDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to generating a treatment protocol, which have been rejected as being directed to patent-ineligible subject matter. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.²

¹ Appellants identify Koninklijke Philips N.V. as the real party in interest. Appeal Br. 2.

² Our Decision refers to the Final Office Action, mailed Jan. 11, 2018 (“Final Act.”); Appeal Brief, filed June 1, 2018 (“Appeal Br.”); Examiner’s Answer, mailed Sept. 13, 2018 (“Ans.”); Reply Brief, filed Nov. 8, 2018 (“Reply Br.”); and Specification, filed Jan. 13, 2014 (“Spec.”).

STATEMENT OF THE CASE

According to the Specification, the invention “relates to treatment planning in medical and other applications that benefit from the optimization or other evaluation of treatments using multiple treatment modalities.” Spec 1:11–13. The Specification states that “[i]n a combination treatment situation, [] a second or additional treatment modality does not find the object in its original (*i.e.*, in its untreated) state. In some cases, for example, an initial damage or sensitization to a second treatment modality is induced by the first treatment modality.” *Id.* at 2:15–18. The claims therefore relate to computer-based methods of modeling the combined treatment and side effects of two treatment modalities, and using a result of the modeling of the combined effects to generate a treatment protocol for application to an object. Appeal Br. 7–11 (Claims Appendix).

Claims 1, 3–8, 10–16, and 18–23 are on appeal. Claims 1 and 15 are independent claims. Claim 1 is illustrative and reads as follows:

1. A non-transitory computer readable storage medium containing instructions which, when executed by a computer, cause the computer to carry out a method comprising:

modeling a treatment effect of a first treatment modality, wherein the treatment effect of the first treatment modality includes a dose of the first treatment modality applied to a first target portion of an object;

modeling a side effect of the first treatment modality, wherein the side effect of the first treatment modality includes a dose of the first treatment modality applied to a first non-target portion of the object;

modeling a treatment effect of a second treatment modality, wherein the treatment effect of the second treatment modality includes a dose of the second treatment modality applied to a second target portion of the object;

modeling a side effect of the second treatment modality, wherein the side effect of the second treatment modality includes a dose of the second treatment modality applied to a second non-target portion of the object;

modeling a combined treatment effect (TE) of the first and second treatment modalities, including an interaction between the first and second treatment modalities;

modeling a combined side effect (SE) of the first and second treatment modality, including an effect of an interaction between the first and second treatment modality; and

using a result of the modeling of the combined treatment effect of the first and second treatment modalities and of the combined side effect of the first and second treatment modalities to generate a treatment protocol for application to the object.

Appeal Br. 7 (Claims Appendix). Independent claim 15 recites similar steps, however, it specifies “using a mathematical model” to model the treatment effects and side effects.

Claims 1, 3–8, 10–16, and 18–23 stand rejected under 35 U.S.C. § 101. Final Act. 2.

DISCUSSION

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. *See, 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 to what concept the claim is “directed.” *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 by the courts 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, 192 (1981)); “tanning, dyeing, making water-proof cloth, vulcanizing India rubber, smelting ores” (*id.* at 184 n.7 (quoting *Corning v. Burden*, 56 U.S. 252, 267–68 (1853))); 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, 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 also 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.*

The United States Patent and Trademark Office recently published revised guidance on the application of section 101. USPTO’s *2019 Revised Patent Subject Matter Eligibility Guidance* (“Guidance”).³ Under the Guidance, in determining what concept a claim is “directed to,” we first look to whether the claim recites:

(Step 1, Prong 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

³ *2019 Revised Patent Subject Matter Eligibility Guidance*, 84 Fed. Reg. 50–57 (January 7, 2019).

(Step 1, Prong 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)).

Only if a claim (1) recites a judicial exception and (2) does not integrate that exception into a practical application (Step 1, Prong 1), do we then look to whether the claim contains an “‘inventive concept’ sufficient to ‘transform’” the claimed judicial exception into a patent-eligible application of the judicial exception. *Alice*, 573 U.S. at 221 (quoting *Mayo*, 566 U.S. at 82). In so doing, we thus consider whether the claim:

(3) adds a specific limitation beyond the judicial exception that are not “well-understood, routine and 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.

See Guidance, 84 Fed. Reg. at 54–56.

Regarding *Mayo/Alice*’s step one, the Examiner determined that the claims are drawn to mathematically modeling certain treatment effects and side effects of treatment modalities, and using the result of the modeling to generate a treatment protocol. Final Act. 2. The Examiner found that “[t]he steps of mathematically modelling the treatment and side effects and generating a treatment protocol are drawn to mathematical algorithms,” and that “[m]athematical models are an abstract idea.” *Id.*; *see also* Ans. 3. The Examiner further determined that the dependent claims include “additional parameters, calculations, and data for implementing the claimed abstract idea of claims 1 or 15,” and that these “additional parameters, calculations, and data are themselves an abstract idea.” Final Act. 2–3.

Regarding *Mayo/Alice*'s step two, the Examiner found that “[t]he claims do not include additional elements that are sufficient to amount to significantly more than the judicial exception,” because the claims recite routine, conventional, and well-known devices (computer readable storage medium) and functions (presenting data and receiving a response). *Id.*; *see also* Ans. 3.

We discern no error in the Examiner’s determination and rationale. We analyze the record pursuant to the Guidance and address Appellants’ arguments below.

*STEP 1, PRONG 1*⁴

The Guidance identifies three key concepts identified as abstract ideas:

- (a) mathematical concepts including “mathematical relationships, mathematical formulas or equations, mathematical calculations”;
- (b) certain methods of organizing human activity, such as “fundamental economic principles or practices,” “commercial or legal interactions,” and “managing personal behavior or relationships or interactions between people”; and
- (c) mental processes including “observation, evaluation, judgment, [and] opinion.”

Guidance, 84 Fed. Reg. at 52.

Here, independent claim 1 recites the steps of “modeling a treatment effect;” “modeling a side effect;” “modeling a combined treatment effect;” and “modeling a combined side effect.” Independent claim 15 recites the steps of “using a mathematical model to model a treatment effect;” “using a

⁴ The Guidance refers to this step, along with Prong 2, as “Step 2A.”

mathematical model to model a side effect;” “using a mathematical model to model a combined treatment effect;” and “using a mathematical model to model a combined side effect.” Under the broadest reasonable interpretation of the claims, the claimed modeling is directed to use of mathematical formulas and relationships to carry out the specified modeling. The Specification supports this conclusion, by providing mathematical models and equations to carry out the modeling. *See, e.g.*, Spec. 8:23–13:3.

Several dependent claims additionally recite mathematical concepts. For example, claim 4 recites “determining a figure of merit that weights first and second effects of a treatment.” Claim 5 recites “calculating” “Delta(p_n)” using a specific mathematical equation. Claim 10 recites consideration of a “tumor control probability,” and claim 16 recites consideration of “a normal tissue complication probability.” Each of these claim limitations recites a mathematical concept, either expressly by reciting “determining” a figure using a mathematical relationship or “calculating” a figure using a specific equation, or implicitly by reciting use of mathematical concepts such as probabilities.

The Federal Circuit has “recognize[d] that defining the precise abstract idea of patent claims in many cases is far from a ‘straightforward’ exercise.” *Synopsys, Inc. v. Mentor Graphics Corp.*, 839 F.3d 1138, 1150 (Fed. Cir. 2016) (quoting *DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245, 1257 (Fed. Cir. 2014)). However, “if a claim is directed essentially to a method of calculating, using a mathematical formula, even if the solution is for a specific purpose, the claimed method is nonstatutory.” *Flook*, 437 U.S. at 595 (citation omitted); *SAP Am., Inc. v. Investpic, LLC*, 898 F.3d 1161, 1163 (Fed. Cir. 2018) (finding that an invention that is nothing more

than “a series of mathematical calculations based on selected information and the presentation of the results of those calculations” is patent-ineligible). Accordingly, we conclude the claims recite mathematical relationships, formulas, and calculations, and thus, abstract ideas.

STEP 1, PRONG 2

We next consider whether the claimed methods include additional elements that integrate the abstract idea into a practical application. Determining that the claimed abstract idea is integrated into a practical application requires identifying an additional element or combination of additional elements in the claim that apply, rely on, or use the judicial exception in a manner that imposes a meaningful limit on the judicial exception, such that the claim is more than a mere drafting effort designed to monopolize the judicial exception. *See, e.g., Mayo*, 566 U.S. at 77; Guidance, 84 Fed. Reg. at 54.

Once we strip away the limitations directed to the abstract idea in claims 1 and 13, we are left with a step of using the results of the modeling to “generate a treatment protocol for application to the object.” Appeal Br. 7, 10 (Claims Appendix). Thus, the end result of the claimed method amounts to generation of data (a treatment protocol). There are no steps in the claim that require any actual use or application of the treatment protocol in any way. For example, nothing in the claim requires that the treatment protocol be implemented to apply a specific treatment to a patient. *Cf. Vanda Pharm. Inc. v. West-Ward Pharm. Int’l Ltd.*, 887 F.3d 1117, 1136 (Fed. Cir. 2018) (finding claims that recite a specific method of treating patients based on a natural relationship to be patent-eligible). Thus, there is no implementation of the abstract idea into a practical application.

Appellants argue that the claims are not drawn to an abstract idea, because, like the claims in *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 837 F.3d 1299 (Fed. Cir. 2016), the claims “provide an improvement to an existing technological process.” Appeal Br. 4. Appellants assert that prior art methods of generating a treatment protocol using multiple treatment modalities “may be suboptimal,” because they “do not account for a later applied treatment modality not finding the object in its original, untreated state.” *Id.* (citing Spec. 2:3–20). Appellants assert that the claimed algorithm “accounts for the effect a first treatment modality has on a target when optimizing a second treatment modality.” *Id.* Appellants further assert that “[t]hese limitations are not merely an automation of an existing uncomputerized process carried [out] in the same manner,” but rather describe “a specific way to solve a problem with the current ways for generating treatment protocols.” *Id.* at 4, 5.

We are not persuaded by Appellants’ arguments. In *McRO*, the Federal Circuit found that claims which “set out meaningful requirements for [a] first set of rules” by which a computer could synchronize animated lip movements to spoken sounds were patent-eligible because they were directed to “a process specifically designed to achieve an improved technological result.” *McRO*, 837 F.3d at 1313, 1316. That result was computer-generated animation having automatically synchronized mouth movements. *Id.* Contrary to *McRO*, where the ultimate product produced was a synchronized computer animation, here the result of the claimed method is merely generation of a treatment protocol (data), with no requirement that the treatment protocol actually be implemented or applied in any way. The claimed invention does not improve the functioning of a

computer; it is not effecting a treatment for a medical condition; and it is not transforming a machine or matter in any way. *See, e.g.*, MPEP § 2106.05(a)–(c). Thus, Appellants’ argument that the claims provide an improvement to an existing technological process is not persuasive.

*STEP 2*⁵

Regarding *Mayo/Alice*’s step two, as noted above, the Examiner determined that “[t]he claims do not include additional elements that are sufficient to amount to significantly more than the judicial exception,” because the claims recite routine, conventional, and well-known devices (computer readable storage medium) and functions (presenting data and receiving a response). Final Act. 2–3; *see also* Ans. 3.

Again, we are not persuaded that the Examiner erred in determining that the claims, considering all elements both individually and as an ordered combination, do not amount to significantly more than the abstract idea of mathematical concepts. Appellants point to nothing in the claims that adds an inventive concept or some additional subject matter so as to confer patent eligibility to an abstract idea. Once we strip away the elements directed to the abstract idea, we are left with generation of a treatment plan (claims 1 and 15), and a generic non-transitory computer readable storage medium (claim 1). Neither outputting data (generating a treatment protocol) as a result of considering data, nor recitation of a generic computer readable storage medium, add any inventive concept to the claimed invention, when considered individually and with the other steps as an ordered combination.

⁵ The Guidance refers to this step as “Step 2B.”

Appeal 2019-000725
Application 14/153,373

See, e.g., SAP Am., Inc., 898 F.3d at 1169 (noting that invocation of already-available computers is not enough to establish an inventive concept).

For the above reasons, we are not persuaded that the Examiner erred in determining that the claims are patent-ineligible.

SUMMARY

We affirm the rejection of claims 1, 3–8, 10–16, and 18–23 under 35 U.S.C. § 101.

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)(1)(iv).

AFFIRMED