



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/127,136	04/30/2014	Harold Wodlinger	CIN-020336 US PCT	2718
134888	7590	06/03/2019	EXAMINER	
TAROLLI, SUNDHEIM, COVELL & TUMMINO L.L.P. 1300 EAST NINTH STREET, SUITE 1700 CLEVELAND, OH 44114			MEHL, PATRICK M	
			ART UNIT	PAPER NUMBER
			3793	
			NOTIFICATION DATE	DELIVERY MODE
			06/03/2019	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rcline@tarolli.com
docketing@tarolli.com
rs.patents.five@medtronic.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte HAROLD WODLINGER, CHARULATHA RAMANATHAN,
and PING JIA¹

Appeal 2017-008105
Application 14/127,136
Technology Center 3700

Before DONALD E. ADAMS, ERIC B. GRIMES, and
FRANCISCO C. PRATS, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a system for localizing an object in a patient's body, which have been rejected as obvious and as being directed to patent-ineligible subject matter. We have jurisdiction under 35 U.S.C. § 6(b).

We reverse.

¹ Appellants identify the Real Party in Interest as CardioInsight Technologies, Inc. Appeal Br. 3.

STATEMENT OF THE CASE

“Various procedures exist in which an object is inserted into a patient’s body as part of a low invasive procedure in which a view of the object is obstructed from a direct line of sight.” Spec. ¶ 3. “In such operations, it is desirable to determine a position of the catheter or other object, which is referred to as localization.” *Id.*

The Specification discloses “systems and methods . . . [that] can be employed to localize an object, such as a catheter or pacing lead, by applying a localization signal (e.g., a pulse) to a patient’s tissue to produce an electric field.” *Id.* ¶ 14. “Electrical signals corresponding to the electrical field can be sensed via a plurality of sensors.” *Id.* “The sensed electrical signals can be mapped to tissue (e.g., corresponding to patient anatomy or a generic heart model) or other geometry based on geometry data for the patient.” *Id.* “A location where the localization signal was applied to the heart can be determined from the mapped electrical signals.” *Id.*

Claims 18, 20, and 22–31 are on appeal. Claim 18 is the only independent claim and reads as follows:

18. A system to localize an object in a patient’s body, the system comprising:
 - at least one electrode fixed to the object in the patient’s body;
 - a pulse generator configured to generate a localization signal comprising a subthreshold electrical signal and provide the localization signal to the at least one electrode, the subthreshold electrical signal having energy insufficient to stimulate electrical conduction in tissue of the patient’s body;

a sensor array configured to detect an electrical field produced in response to the localization signal and provide respective sensor signals; and

a processor configured to:

retrieve geometry data stored in memory, the geometry data representing a geometric relationship between patient anatomy and the sensor array;

reconstruct electrical signals based on the respective sensor signals and the geometry data; and

determine an absolute location where the localization signal was applied based on comparing amplitude and frequency characteristics of each of the reconstructed electrical signals with respect to the localization signal.

The claims stand rejected as follows:

Claims 18, 20, and 22–31 under 35 U.S.C. § 101 as being directed to patent-ineligible subject matter (Final Action² 3);

Claims 18, 20, 22, and 24–31 under 35 U.S.C. § 103 as obvious based on Armoundas³ and Rudy⁴ (Final Action 8); and

Claim 23 under 35 U.S.C. § 103 as obvious based on Armoundas, Rudy, and Yang⁵ (Final Action 14–15).

I

The Examiner has rejected claims 18, 20, and 22–31 under 35 U.S.C. § 101 as being directed to patent-ineligible subject matter. The Examiner concludes that claim 18 “sets forth or describes [an] abstract idea” because it

² Office Action mailed May 20, 2016.

³ Armoundas et al., US 6,370,412 B1, issued Apr. 9, 2002.

⁴ Rudy, US 6,772,004 B2, issued Aug. 3, 2004.

⁵ Yang et al., US 2009/0157136 A1, published June 18, 2009.

recites “‘reconstruct[ing] electrical signals based on the respective sensor signals and the geometry data’ and ‘determin[ing] an absolute location where the localization signal was applied’ and ‘comparing amplitude and frequency characteristics of each of the reconstructed electrical signals with respect to the localization signal’.” Final Action 3–4.

The Examiner reasons that these “limitations are similar to mathematical concepts or operations for manipulating and/or relating data, organizing information through correlations; calculating parameters; and/or collecting and comparing known data, i.e. ‘an idea of itself.’” *Id.* at 4. The Examiner finds that “[t]he generically recited ‘electrode’, ‘pulse generator’ ‘sensor array’ (elements) are all well-understood elements performing functions that are routine and conventional in the art,” and therefore, “[v]iewing all the additional claim limitations individually, or as an ordered combination, the claim(s) as a whole do (does) not add significantly more to the abstract idea.” *Id.* at 5.

Appellants argue that

[c]laim 18 sets out meaningful features that when considered as a whole (a combination) improve an existing approach of localizing an object in a patient’s body as well as an effectiveness (accuracy) of a subsequent therapy or other medical procedure (e.g., cardiac ablation, cardiac resynchronization therapy (CRT), etc.) that is based on localization of the object in the patient’s body).

Appeal Br. 7.

Appellants also argue that “claim 18 requires a fundamental change to data and thus is a change that cannot be performed in the human mind.” *Id.* at 8. Appellants argue that

the system of claim 18 includes a combination of interrelated structural features including at least one electrode, a pulse generator and a sensor array. It is by the claimed arrangement, configuration and interaction of such structure in conjunction with the operations of the processor that the system can localize an object in a patient's body.

Id.

We agree with Appellant that the Examiner has not established that the claimed system is patent-ineligible. 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 concluded that “[l]aws of nature, natural phenomena, and abstract ideas” are not patentable under 35 U.S.C. § 101. *See, e.g., Alice Corp. v. CLS Bank Int’l*, 573 U.S. 208, 216 (2014).

To determine if a claim falls into an excluded category, we apply a 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)). We first determine what 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.”).

Patent-ineligible abstract ideas 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)). In contrast, patent-eligible inventions 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 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 claimed method employed 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 192 (“We view respondents’ claims as nothing more than a process for molding rubber products and not as an attempt to patent a mathematical formula.”). The Supreme Court noted, however, 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, and “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 (alterations in original)). “[M]erely requir[ing] generic computer implementation[] fail[s] to transform that abstract idea into a patent-eligible invention.” *Id.*

We agree with Appellants that the Examiner erred in concluding that the claims are directed to an abstract idea without significantly more. The PTO recently published revised guidance on the application of § 101. *2019 Revised Patent Subject Matter Eligibility Guidance*, issued January 7, 2019 (“Memorandum”). Under that guidance, we first determine 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); and
- (2) additional elements that integrate the judicial exception into a practical application (*see* 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, do we then determine whether the claim:

- (3) adds a specific limitation beyond the judicial exception that is not a “well-understood, routine, conventional activity” 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 Memorandum.

Guidance Step 2(a), Prong 1

Claim 18 recites “at least one electrode,” “a pulse generator,” “a sensor array,” and

a processor configured to:

retrieve geometry data stored in memory, the geometry data representing a geometric relationship between patient anatomy and the sensor array;

reconstruct electrical signals based on the respective sensor signals and the geometry data; and

determine an absolute location where the localization signal was applied based on comparing amplitude and frequency characteristics of each of the reconstructed electrical signals with respect to the localization signal.

Claim 18.

Claim 18 is not directed to a method of organizing human activity, nor has the Examiner established that the functions carried out by the processor of claim 18 could practicably be performed in the human mind, and therefore amount to a mental process. The final category of abstract ideas that has been identified by the courts is mathematical concepts. *See* Memorandum.

Claim 18, however, does not recite any mathematical concept, such as a specific mathematical algorithm or formula (*see Flook*, 437 U.S. at 586; *Diehr*, 450 U.S. at 187). Claim 18 instead recites “retriev[ing] geometry data stored in memory,” “reconstruct[ing] electrical signals based on the respective sensor signals and the geometry data,” and “determin[ing] an absolute location where the localization signal was applied based on comparing amplitude and frequency characteristics of each of the

reconstructed electrical signals with respect to the localization signal.”

Claim 18.

While these steps involve mathematics, claim 18 does not recite a specific mathematical concept such as an algorithm or formula. Claim 18, therefore, does not recite an abstract idea that would make it patent-ineligible under 35 U.S.C. § 101.

Guidance Step 2(a), Prong 2

In addition, even if claim 18 were interpreted to recite a mathematical concept, and therefore an abstract idea, it would still be patent eligible if “the claim as a whole integrates the recited judicial exception into a practical application of the exception;” i.e., whether the claim “appl[ies], rel[ies] on, or use[s] the judicial exception in a manner that imposes a meaningful limit on the judicial exception.” 84 Fed. Reg. at 54. This analysis includes “[i]dentifying whether there are any additional elements recited in the claim beyond the judicial exception(s)” and “evaluating those additional elements individually and in combination to determine whether they integrate the exception into a practical application.” *Id.* at 54–55.

Here, claim 18 as a whole integrates any recited mathematical concept into a practical application. Specifically, Appellants’ Specification discloses that the claimed system is useful to “localize an object, such as a catheter or pacing lead, by applying a localization signal (e.g., a pulse) to a patient’s tissue to produce an electric field.” Spec. ¶ 14. We therefore conclude that, even if the functions carried out by the processor of claim 18 were interpreted to be a mathematical concept, claim 18 as a whole integrates that concept into a practical application; specifically, localizing an object such as

a catheter in a patient's body. Therefore, the claimed system, as a whole, is not "directed to . . . [a] patent-ineligible concept." *Alice*, 573 U.S. at 217.

We reverse the rejection of claim 18 under 35 U.S.C. § 101. Claims 20 and 22–31 depend from claim 18 and are therefore also patent-eligible for the reasons discussed above.

II

The Examiner has rejected claims 18, 20, 22, and 24–31 as obvious based on Armoundas and Rudy. The Examiner has also rejected claim 23 as obvious based on Armoundas, Rudy, and Yang. The same issue is dispositive for both rejections.

The Examiner finds that Armoundas discloses most of the limitations of claim 18 (Final Action 9–10), but "does not teach the processor configured to determine an absolute location of the object" (*id.* at 10). The Examiner finds that

Rudy teaches the determination of the absolute locations of a passive electrode array placed on a patient (col.5 1st and 2nd ¶, Figs. 5(a) and 5(b)), using a geometry determining device (Col.4 last ¶) with storing these locations (Fig.5(a) #24 and col.5 2nd ¶) for later analysis and generation of data (Fig. 5(a) #24).

Id. at 10.

The Examiner concludes that it would have been obvious to have modified the apparatus of Armoundas with the processor configured to determine the absolute location of the object, since acquiring geometric data mapping the absolute locations of passive sensing electrodes to the position of the patient was well known in the art using routine and conventional imaging devices, as taught by Rudy.

Id. at 10–11. “The motivation would have been to provide improved visual analysis in space, as suggested by Rudy (Col. 4).” *Id.* at 11.

Appellants argue that “[n]othing [in] Armoundas teaches or suggest[s] to one of ordinary skill in the art how to implement an approach consistent with claim 18 for determining *an absolute location* where a localization signal was applied. Armoundas is limited to determining *a relative position* of an active electrode on a catheter tip.” Appeal Br. 16 (emphasis added). Appellants also argue that “Rudy fails to remedy the shortcomings of Armoundas, as . . . Rudy describes an approach for *determining non-invasively* electrical activity on a heart (see Rudy, Abstract).” *Id.* at 17 (emphasis added).

We will reverse the rejections under 35 U.S.C. § 103(a). The Examiner acknowledges that Armoundas does not disclose a “processor configured to determine an absolute location of [an] object, as in claim 18” (Final Action 10), and relies on Rudy to disclose the missing claim limitation. Claim 18, however, is directed to a “system to localize an object *in a patient’s body*” (emphasis added), while Rudy is directed to “a system and method for *noninvasively* determining electrical activity on the surface of the heart of a human being.” Rudy 2:15–17 (emphasis added). Thus, Rudy’s method does not involve localizing an object, having an electrode fixed to it, in a patient’s body, much less “determin[ing] an absolute location” where a “localization signal was applied” to an electrode in a patient’s body “based on comparing amplitude and frequency characteristics of each of the reconstructed electrical signals with respect to the localization signal,” as recited in claim 18.

We therefore conclude that the Examiner has not provided evidence sufficient to support a prima facie case of obviousness under 35 U.S.C. § 103(a). The rejection of claims 18, 20, 22, and 24–31 as obvious based on Armoundas and Rudy is reversed. The rejection of claim 23 under 35 U.S.C. § 103(a) based on Armoundas, Rudy, and Yang relies on the same reasoning (Final Action 14–15) and is reversed for the same reason.

SUMMARY

We reverse all of the rejections on appeal.

REVERSED