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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte CAMERON C. MCINTYRE and JAY L. ALBERTS

Appeal 2014-006814
Application 13/288,684
Technology Center 3700

Before MICHAEL L. HOELTER, THOMAS F. SMEGAL, and LISA M. GUIJT, *Administrative Patent Judges*.

GUIJT, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellants¹ seek our review under 35 U.S.C. § 134 of the Examiner's decision² rejecting claims 1–17, 19, and 20.³ We have jurisdiction under 35 U.S.C. § 6(b).

¹ Appellants identify the real party in interest as The Cleveland Clinic Foundation. App. Br. 1.

² Appeal is taken from the Final Office Action dated October 9, 2013 (“Final Act.”).

³ Claim 18 is cancelled. *See* Amendment dated July 9, 2013.

We AFFIRM and enter NEW GROUNDS OF REJECTION pursuant to 37 C.F.R. § 41.50(b).

CLAIMED SUBJECT MATTER

Claims 1, 19, and 20, reproduced below, are the independent claims on appeal. *See* Appeal Br. (Claims App.).

1. A computer-implemented method, comprising:

obtaining postural stability results of at least one administered dual task test, the dual task test requiring simultaneous performance of a motor function task and a cognitive function task; and

selecting, by a computer processor, stimulation parameters for stimulating an anatomical region of a patient, the selection being based on the results.

19. A non-transitory computer-readable [medium] having stored thereon instructions executable by a processor, the instructions which, when executed by the processor, cause the processor to perform a method, the method comprising:

obtaining postural stability results of at least one administered dual task test, the dual task test requiring simultaneous performance of a motor function task and a cognitive function task; and

selecting stimulation parameters for stimulating an anatomical region of a patient, the selection being based on the results.

20. A system, comprising:

a computer processor configured to:

obtain postural stability results of at least one administered dual task test, the dual task test requiring simultaneous performance of a motor function task and a cognitive function task; and

select stimulation parameters for stimulating an anatomical region of a patient, the selection being based on the results.

REJECTIONS

I. Claims 1–3, 8, 13–17, 19, and 20 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Meadows (US 2009/0118786 A1; pub. May 7, 2009) and “Bilateral subthalamic stimulation impairs cognitive – motor performance in Parkinson’s disease patients,” Alberts et al, *Brain* (2008), vol. 131, p. 3348–3360 (hereinafter “Alberts”).

II. Claims 6, 7, and 12 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Meadows, Alberts, and “Effects of deep brain stimulation and levodopa on postural sway in Parkinson’s disease,” Rocchi et al., *J. Neurol Neurosurg Psychiatry* (2002), vol. 73, p. 267–274.

III. Claims 4, 5, and 9–11 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Meadows, Alberts, and Stone (US 2007/0203546 A1; Aug. 30, 2007).

ANALYSIS

Rejection 1

The Examiner found, *inter alia*, that Meadows teaches a computer-implemented method (claim 1), computer readable medium (claim 19), and system (claim 20) comprising obtaining postural stability results of *at least one* administered test, and selecting, by a computer processor, stimulation parameters based on the test results for stimulating an anatomical region of the patient. Final Act. 6–7 (citing Meadows ¶¶ 2, 9, 33, 53, 54). In particular, the Examiner found that Meadows discloses therapeutic application of deep brain stimulations (DBS⁴) for treating Parkinson’s Disease, which causes a motor dysfunction such as posture dysfunction, by

⁴ Spec., p. 2, l. 1.

measuring a physiological end-function (e.g., a kinematic function) and using such measurement to adjust the DBS stimulation parameters. *Id.*

Determining that Meadows “do[es] not specifically teach [obtaining] results of a test that is a *dual task test* requiring simultaneous performance of a motor function task and a cognitive function task,” the Examiner relied on Alberts for teaching that “it is well known to have patients perform dual task tests as claimed (i.e. tests comprising a cognitive function task and a motor function task) and [to] obtain the results of the dual task tests.” *Id.* at 6–7 (citing Alberts, Abstract, p. 3351, cols. 1, 2, p. 3352, col. 1, ll. 1–17) (emphasis added). The Examiner explained that “Alberts['] teachings show[] that patients with Parkinson’s [D]isease perform . . . dual task tests . . . simultaneously such as a force maintenance test for motor function . . . and an N-Back test to test cognitive dysfunction to evaluate therapy parameters in Parkinson’s disease patients.” *Id.* at 7–8 (citing Alberts, p. 3351, col. 1, l. 4–col. 2, l. 20).

The Examiner reasoned that it would have been obvious to “modify the teachings of Meadows with the teachings of Alberts in order to provide the predictable results of treating motor as well as cognitive dysfunction in Parkinson’s disease patients” (*id.* at 8) and also “to provide the predictable results [of] improving the DBS programming as these conditions better reflect the context in which daily activities are performed” (Ans. 9; *see* Alberts p. 3348, Abstract (“[there is a] need to assess cognitive and motor function simultaneously during DBS programming as these conditions may better reflect the context in which daily activities are performed.”)).

First, Appellants point out that Meadows does not disclose the use of a dual task test, and also argue that “the cited section of Alberts merely

discusses evaluations for comparing *previously performed* unilateral and bilateral [(DBS)] with respect to their effect to motor and non-motor task functions.” App. Br. 3–4 (citing Alberts, 3350 col. 2, p. 3355, col. 1); Reply Br. 2. Appellants submit that “Alberts does not suggest that the results of a dual task test are used for selecting stimulation parameters to be used for a later performed stimulation,” and that Alberts “does not enable one of ordinary skill in the art to use the dual task test to develop stimulation parameters for DBS.” App. Br. 4; Reply Br. 2–3. Appellants explain that “[b]y using stimulation parameters determined by a computer from results of dual task test(s) in which postural stability assessment is a necessary limitation, Appellants’ invention effectively makes use of the dual task results to limit diminished cognitive performance and increase[] motor scores.” App. Br. 4.

Appellants’ argument, however, does not address the Examiner’s findings stated *supra*. The Examiner relies on Alberts, not Meadows, for disclosing a dual task test, and indeed, Alberts teaches a dual task test involving an n-back task and a force-maintenance task. *See* Alberts, p. 3351, col. 2, paragraph titled, “Dual task: n-back and force maintenance simultaneously”; *cf.* Spec. ¶ 23 (“During the dual-task, participants performed the n-back and force-tracking tasks simultaneously.”). The Examiner also relies on Meadows, not Alberts, for disclosing use of the test results for selecting stimulation parameters for future (or later performed) DBS therapeutic application. *See* Meadows ¶ 33 (“the measured physiological end-function . . . can be used to adjust the stimulation parameters.”).

Thus, Appellants' argument that Albert fails to enable the use of a dual task test to develop stimulation parameters for DBS is misplaced. Notably, as an example of a measured physiological end-function (or test), Meadows discloses "a positioning chair in which the patient can be positioned to perform a variety of physical exercises involving movement of the patient's limbs, and a computer system for controlling and implementing the physical exercise, and quantitatively measuring the patient's neuromuscular ability." Meadows ¶ 55. Appellants do not argue that Meadows' measurement of a physiological end-function is not at least a single task test. Thus, Appellants' argument does not apprise us of error in the Examiner's findings with respect to Meadows and Alberts.

Second, Appellants conclude that "Meadows and Alberts did not suggest any system that could include these features." App. Br. 4. More particularly, Appellants argue that "the mere knowledge of existence of a dual task test in no way suggests its use to select stimulation parameters." Reply Br. 3. Appellants submit that "Alberts explicitly suggests that there was no reasonable expectation of success at that time, [of a using dual task test] but rather further investigation was still required." App. Br. 5; Reply Br. 3. Appellants also submit that the Examiner's proposed combination impermissibly relies on hindsight reasoning, "because only [Appellants' Specification] indicates how these features may be realized." App. Br. 5; Reply Br. 3.

Regarding Appellants' argument that neither Meadows nor Alberts suggests the Examiner's proposed combination, such an argument appears to be holding the Examiner to the old TSM (teaching, suggestion, or motivation) standard; such a standard is not required. *KSR Int'l Co. v.*

Teleflex Inc., 550 U.S. 398, 415 (2007). Moreover, as stated *supra*, the Examiner's rationale is expressly supported by Alberts. Ans. 9 (citing Alberts, p. 3348, Abstract). In addition, although Alberts discusses the use of a dual task test to determine the effects of DBS therapy rather than for selecting stimulation parameters (*see, e.g.*, Alberts, Abstract), we do not agree with Appellants that because Alberts discloses that there is an investigation into the effectiveness of using "an abridged version of dual-task paradigm in the selection of DBS parameters" (Alberts, p. 3358, col. 2, ll. 10–12; App. Br. 4), there was no reasonable expectation of success that a dual task test would work in the system disclosed by Meadows. To the contrary, Albert's disclosure provides motivation to modify Meadows to use a dual task test. Appellants also do not identify any knowledge that the Examiner relied upon that was gleaned only from Appellants' disclosure and that was not otherwise disclosed in either Meadows or Alberts, or within the level of ordinary skill at the time of the invention. *See In re McLaughlin*, 443 F.2d 1392 (CCPA 1971).

Accordingly, we sustain the Examiner's rejection of independent claims 1, and claims 2, 3, 8, and 13–17 depending therefrom, and independent claims 19 and 20.

Rejection II

Appellants submit that claims 6, 7, and 12 are allowable "for at least the same reasons as claim 1." App. Br. 5. Because we sustain the Examiner's rejection of independent claim 1, we also sustain the Examiner's rejection of claims 6, 7, and 12 depending therefrom.

Rejection III

Appellants submit that claims 4 and 5 are allowable “for at least the same reasons as claim 1.” App. Br. 6. Because we sustain the Examiner’s rejection of independent claim 1, we also sustain the Examiner’s rejection of claims 4 and 5 depending therefrom.

Regarding claims 9–11, in addition to the arguments presented *supra*, Appellants argue that the Examiner fails to show how Stone discloses the limitations of claims 9–11 and also that the Examiner relies on Appellants’ Specification, which is improper hindsight reasoning. App. Br. 6–7.

Claim 9 depends from claim 1 and recites “wherein the selecting is performed to maximize stimulation of a target motor anatomical region and minimize current creep to non-motor anatomical regions.” App. Br. (Claims App.). The Examiner found that Stone teaches that

it is well known to have software that provides a 3D view of the patient’s images, DBS electrodes and/or calculate volumes of activation for specified stimulation parameters based on which the clinician can modify the volume of tissue activation so that there is maximum stimulation of the target motor area and minimal spread to the non-motor areas of the brain.

Final Act. 11. The Examiner reasons that it would have been obvious to modify the teachings of Meadows in view of Alberts to include calculating a computational model of estimated activated tissue and providing a visualization as taught by Stone in order to provide the predictable results of giving the user/clinician a user-friendly visual image of the active regions of the brain to make more targeted and accurate determination of the stimulation therapy parameters.

Id.

Although Stone generally discloses that “[t]he ‘best’ program may be a program that best balances greater clinical efficacy and minimal side

effects experienced by the patient” (Stone ¶ 5), we agree with Appellants that Stone does not expressly disclose selecting parameters that maximize stimulation of a target motor anatomical region and minimize current creep to non-motor anatomical region, as required by claim 9. However, Meadows more specifically states that “[t]he best stimulus parameter set will typically be one that delivers stimulation energy to the volume of tissue that must be stimulated in order to provide the therapeutic benefit (e.g., treatment of movement disorders), while minimizing the volume of non-target tissue that is stimulated” (Meadows ¶ 4), and describes applying DBS therapy to a patient having motor dysfunction (*id.* ¶ 14). Thus, we determine that Meadows discloses the limitations recited in claim 9 and sustain the Examiner’s rejection. Because we rely on Meadows, rather than Stone, we designate our affirmance as a new ground of rejection under 37 C.F.R. § 41.50(b) to provide Appellants with a full and fair opportunity to respond to the rejection.

Claim 10 depends from claim 9 and recites “wherein the anatomical regions are part of the subthalamic nucleus (STN)” (App. Br. (Claims App.)), and the Examiner relies on Meadows, not Stone, for teaching this limitation. Final Act. 12 (citing Meadows ¶ 64 (“electrodes **26** are adjacent a target tissue region whose electrical activity is the source of the dysfunction (e.g., . . . [the] subthalamic nucleus).”) Thus, we are not apprised of error in the Examiner’s finding. Because claim 10 depends from claim 9, and because we sustain the rejection of claim 9 pursuant to a new ground of rejection, we also designate our affirmance of claim 10 as a new ground of rejection under 37 C.F.R. § 41.50(b).

Claim 11 depends from claim 1 and recites “wherein the stimulation parameters are selected to minimize stimulation-related cognitive declines” (App. Br. (Claims App.)) and similar to claim 9 *supra*, we agree with Appellants that Stone does not expressly disclose this limitation. However, as discussed *supra* with respect to claim 9, Meadows discloses that “[t]he best stimulus parameter set will typically be one that delivers stimulation energy to the volume of tissue that must be stimulated in order to provide the therapeutic benefit (e.g., treatment of movement disorders), while minimizing the volume of non-target tissue that is stimulated” (Meadows ¶ 4), and describes applying DBS therapy to a patient having motor dysfunction (*id.* ¶ 14). Further, Alberts discloses that “data support[s] . . . the hypothesis that non-motor pathways are likely activated during STN DBS and may contribute to the present observation,” namely, “cognitive and motor performance decline.” Alberts, p. 3356, col. 1, l. 1, col, 2, ll. 48–54.

Thus, in view of Albert’s suggestion of a decline in cognitive performance that results from stimulation of non-motor pathways, and Meadows’ disclosure to minimize stimulation of non-target tissue (e.g., non-motor pathways), we find that one skilled in the art would understand the combined disclosures of Alberts and Meadows to teach the limitation of claim 11, namely, the selection of parameters to minimize stimulation-related cognitive declines, and we sustain the Examiner’s rejection. Because we rely on Meadows and Alberts, rather than Stone, we designate our affirmance as a new ground of rejection under 37 C.F.R. § 41.50(b) to provide Appellant with a full and fair opportunity to respond to the rejection.

NEW GROUND OF REJECTION

Section 101 of the Patent Act defines the subject matter eligible for patent protection: “Whoever 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. The Supreme Court has explained that laws of nature, natural phenomena, and abstract ideas fall outside the scope of this provision and are not patentable subject matter. *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2354 (2014). For example, abstract ideas include, but are not limited to, fundamental economic practices, methods of organizing human activities, an idea of itself, and mathematical formulas or relationships. *Id.* at 2355–57.

The Court in *Alice* emphasized the use of the two-step framework for analysis of patentability set forth in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289, 1297 (2012):

First, we determine whether the claims at issue are directed to one of those patent-ineligible concepts. If so, we then ask, “[w]hat else is there in the claims before us?” To answer that question, we consider the elements of each claim both individually and ‘as an ordered combination’ to determine whether the additional elements ‘transform the nature of the claim’ into a patent-eligible application.

Alice, 134 S. Ct. at 2355 (quoting *Mayo*, 132 S. Ct. at 1298, 1297). In other words, the second step is to “search for an ‘inventive concept’-- *i.e.*, an element or combination of elements that is ‘sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.’” *Id.* The prohibition against patenting an abstract idea “cannot be circumvented by attempting to limit the use of the

formula to a particular technological environment or adding insignificant post-solution activity.” *Bilski v. Kappos*, 561 U.S. 593, 610-11 (2010) (citation and internal quotation marks omitted). The Court in *Alice* noted that “[s]imply appending conventional steps, specified at a high level of generality,’ was not ‘enough’ [in *Mayo*] to supply an ‘inventive concept.’” *Alice*, 134 S. Ct. at 2357 (quoting *Mayo*, 132 S. Ct. at 1300, 1297, 1294).

We begin our analysis by applying the first step of the *Mayo* test. As stated *supra*, the independent claims recite, in relevant part, (i) a computer implemented method comprising the steps of obtaining test results (from a known, conventional test⁵) and selecting (by a computer processor) stimulation parameters based on the results (claim 1); (ii) a non-transitory computer-readable medium with stored instructions executable by a processor to perform a method comprising the steps of obtaining such test results, and selecting stimulation parameters based on the test results (claim 19); and (iii) a system comprising a computer processor configured to obtain such test results and to select stimulation parameters based on the test results (claim 20).

We conclude that the claims are directed to an abstract idea under step one of the *Alice* analysis because obtaining test results from a known, conventional test is a data gathering step and selecting stimulation parameters based on the test results is a mental step that may be performed in the mind of a physician. Data gathering steps are not sufficient to render the subject matter statutory under § 101 (*see CyberSource Corp. v. Retail Decision Inc.*, 654 F.3d 1366, 1371-72 (Fed. Cr. 2016)) and “mental processes - or

⁵ See Alberts, p. 3351, col. 2, paragraph titled, “Dual task: n-back and force maintenance simultaneously.”

processes of human thinking - standing alone are not patentable even if they have practical application.” *In re Comiskey*, 499 F.3d 1365, 1377 (Fed. Cir. 2007).

Applying the second step of the *Mayo* test to independent claim 1, we determine that the claim limitations of requiring the method to be computer-implemented wherein a computer processors selects the stimulation parameters, when considered individually and as an ordered combination, do not add anything that would transform the nature of the claims from the abstract idea into a patent-eligible application. As the Court explained in *Alice*, implementation of an abstract idea by a computer does not transform the abstract idea into a patent-eligible application. *Alice*, 134 S.Ct. at 2358 (“stating an abstract idea ‘while adding the words “apply it” is not enough for patent eligibility.’”) (citations omitted).

We further determine that claims 2 and 4–17, which depend from claim 1, and which further qualify the test for generating results and/or the selection of the stimulation parameters, also fail to transform the nature of the claim into a patent-eligible application when considered individually and as an ordered combination.

Applying the second step of the *Mayo* test to independent claim 19, we determine that the claim limitations of requiring a non-transitory computer-readable medium having stored instructions executable by a processor to perform the method of obtaining the test results and selecting stimulation parameters based on the results, when considered individually and as an ordered combination, do not add anything that would transform the nature of the claims from the abstract idea into a patent-eligible application. Again, as the Court explained in *Alice*, implementation of an abstract idea by

a computer does not transform the abstract idea into a patent-eligible application. *Alice*, 134 S.Ct. at 2358.

Applying the second step of the *Mayo* test to independent claim 20, we determine that the claim limitation of requiring a computer processor configured to obtain the test results and select stimulation parameters, when considered individually and as an ordered combination, does not add anything that would transform the nature of the claims from the abstract idea into a patent-eligible application. As discussed *supra*, implementation of an abstract idea by a computer does not transform the abstract idea into a patent-eligible application. *Alice*, 134 S.Ct. at 2358.

Claim 3 depends from claim 2 and recites “wherein the stimulation is performed using implanted electrodes of a deep brain stimulation (DBS) device.” App. Br. (Claims App.). We determine that such stimulation is conventional post-solution activity that is not sufficient to transform the abstract idea into patent-eligible subject matter. *See Parker v. Flook*, 437 U.S. 584, 590–92, 98 S.Ct. 2522, 57 L.Ed.2d 451 (1978); *see, e.g., Meadows* ¶¶ 2, 3 (“[DBS] has been applied therapeutically for well over a decade for the treatment of neurological disorders, including Parkinson’s Disease” wherein “[e]ach of these implantable neurostimulation systems typically includes one or more electrode carrying stimulation leads, which are implanted at the desired stimulation site.”).

Accordingly, we enter a new ground of rejection of claims 1–17, 19, and 20 under 35 U.S.C. § 101 as being directed to non-statutory subject matter.

DECISION

The Examiner's decisions to reject claims 1–17, 19, and 20 under 35 U.S.C. § 103(a) are AFFIRMED, and we designate our affirmance of the Examiner's decision to reject claims 9–11 as a NEW GROUND OF REJECTION.

Pursuant to 37 C.F.R. § 41.50(b), we enter a NEW GROUND OF REJECTION of claims 1–17, 19, and 20 under 35 U.S.C. § 101 as being directed to non-statutory subject matter.

This decision contains a new ground of rejection pursuant to 37 C.F.R. § 41.50(b). Section 41.50(b) provides “[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review.” Section 41.50(b) also provides:

When the Board enters such a non-final decision, the appellant, within two months from the date of the decision, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

(1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new Evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the prosecution will be remanded to the examiner. The new ground of rejection is binding upon the examiner unless an amendment or new Evidence not previously of Record is made which, in the opinion of the examiner, overcomes the new ground of rejection designated in the decision. Should the examiner reject the claims, appellant may again appeal to the Board pursuant to this subpart.

(2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same Record. The request for rehearing must address any new ground of rejection and state with particularity the points believed to have been

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misapprehended or overlooked in entering the new ground of rejection and also state all other grounds upon which rehearing is sought.

Further guidance on responding to a new ground of rejection can be found in the Manual of Patent Examining Procedure § 1214.01.

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; 37 C.F.R. § 41.50(b)