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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JIANPING WU, DWIGHT E. NELSON,
XIN SU, and GREGORY F. MOLNAR

Appeal 2015-001048
Application 12/616,513
Technology Center 3700

Before JAMES P. CALVE, LEE L. STEPINA, and
FREDERICK C. LANEY, *Administrative Patent Judges*.

CALVE, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellants appeal under 35 U.S.C. § 134 from the final rejection of claims 1–28. Appeal Br. 6. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

CLAIMED SUBJECT MATTER

Claims 1, 13, 24, and 26 are independent. Claim 1 is reproduced below.

1. A method comprising, with one or more processors:
determining a sleep stage of a patient;
controlling an electrical stimulation device to deliver electrical stimulation to a substantia nigra of a brain of the patient based on the determined sleep stage; and
controlling the electrical stimulation device to deliver electrical stimulation to a subthalamic nucleus of the brain of the patient based on the determined sleep stage of the patient, wherein delivery of electrical stimulation to the substantia nigra and delivery of electrical stimulation to the subthalamic nucleus are independently controlled by the one or more processors.

REJECTION

Claims 1–28 are rejected under 35 U.S.C. § 102(a, e) as anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as unpatentable over, Wu (US 2009/0192556 A1, pub. July 30, 2009).

ANALYSIS

The Examiner found that Wu discloses a system and method of claims 1, 13, 24, and 26, that determines a patient's sleep stage using brain signals and controls electrical stimulation device 16 to deliver electrical stimulation independently to one or more target tissues that include the substantia nigra and subthalamic nucleus based on a sleep stage of the patent. Final Act. 5. Alternatively, the Examiner determined that it would have been obvious to deliver stimulation to the substantia nigra and subthalamic nucleus because Wu discloses a finite number of target locations including these regions and discloses that leads can be implanted at multiple target tissue sites. *Id.*

Appellants argue that Wu discloses therapy is delivered to a patient based on the determined sleep state of the patient, but Wu does not disclose that delivery of electrical stimulation to two different locations in the brain is *independently controlled* based on the determined sleep stage. Appeal Br. 8. Appellants also argue that Wu does not disclose independently controlling the delivery of electrical stimulation to the particular combination of target tissue sites of the substantia nigra and the subthalamic nucleus. *Id.* at 8, 17, 20–21. Appellants further argue that delivering separate stimulation pulses with different leads does not necessarily require independent control of the delivery of electrical stimulation to the different tissue sites based on a determined sleep stage. *Id.* at 9. Appellants assert that their Specification discloses the independent control of stimulation as stimulation delivered to the subthalamic nucleus at different times based on different parameters, such as different sleep stages or brain signals, than the stimulation to the substantia nigra. *Id.* at 9–10. We agree.

The Examiner has not established by a preponderance of evidence that Wu teaches or suggests independently controlling the delivery of electrical stimulation to the substantia nigra and subthalamic nucleus by one or more processors based on a determined sleep stage as recited in the independent claims 1, 13, 24, and 26. Appellants disclose independent control of therapy as allowing electrical stimulation to be delivered to the subthalamic nucleus at a different time based on different parameters (different sleep stages or brain signals) than to the substantia nigra. Spec. ¶ 23. Stimulation may be delivered to the substantia nigra and the subthalamic nucleus via different electrodes of a single lead or via different electrodes of two or more leads so the electrodes independently stimulate those regions. *Id.* ¶ 25, Figs. 5A, 5B.

The Examiner's determination that Wu's delivery of stimulations to separate leads inherently or obviously requires different control parameters to be used to generate a pulse and direct it to the proper lead is not supported by a preponderance of evidence. *See* Ans. 4–5. Wu's disclosure of delivery of electrical stimulation to multiple regions of the brain via two leads does not necessarily indicate that Wu's system independently controls delivery of that electrical stimulation to the substantia nigra independent of control of an electrical stimulation to the subthalamic nucleus. Wu discloses that multiple leads 20 may be positioned in different locations of the brain that include the substantia nigra and subthalamic nucleus (Wu ¶ 66), but the Examiner has not explained how this disclosure necessarily requires electrical stimulation via lead 20A to be *controlled* independently of electrical stimulation via lead 20B at two different sites based on determined sleep stages. Nor has the Examiner offered persuasive reasoning with rational underpinning to explain why it would have been obvious to modify Wu's system to independently control of electrical stimulation to the substantia nigra and the subthalamic nucleus as claimed.¹

¹ Wu discloses that stimulation therapy may be delivered to the subthalamic nucleus to treat movement disorders such as Parkinson's disease but other aspects of a patient's sleep may remain unimproved and require delivery of dynamic therapy configured to address particular sleep disorder symptoms based on the patient's sleep stage. Wu ¶ 55. Wu also discloses that therapy programs may be delivered by DBS system 10, which includes a processor, during detected sleep stages and may be decreased or deactivated upon the detection of particular sleep stages. ¶¶ 46, 49–51. Wu further discloses that therapy delivery sites for therapy delivery during one or more sleep stages of a patient may be the same as or different from the therapy delivery sites used to deliver therapy to a patient to manage the patient's other conditions such as a neurological disorder during a sleep stage. *Id.* ¶ 59. Thus, where a

Moreover, we are not persuaded that selection of the substantia nigra and subthalamic nucleus as sites for the claimed electrical stimulation would have been obvious to try from a finite number of locations as the Examiner found. Final Act. 5. Wu discloses “[e]xample locations” for leads that include the claimed regions of the brain and many other locations without any indication of the predictability or likelihood of success of one site versus another in treating any particular disorder. *See* Wu ¶ 66. Therefore, it is not clear that the claimed regions are part of a finite number of regions or that the selection of a particular region yields a predictable solution for stimulation therapy or any particular therapy.²

Thus, we do not sustain the rejection of claims 1–28.

DECISION

We REVERSE the rejection of claims 1–28.

REVERSED

therapy program group includes two or more therapy programs, stimulation therapy may be delivered simultaneously or on a time-interleaved basis, either in an overlapping or non-overlapping manner. *Id.* ¶ 64. Wu discloses that leads may be positioned to manage a patient’s symptoms associated with sleep impairment together with a neurological disorder of the patient such as a movement disorder. *Id.* ¶ 66.

² Wu does disclose that delivery of stimulation therapy to the subthalamic nucleus may be an effective treatment for movement disorders such as Parkinson’s disease, but other aspects of a patient’s sleep may require more treatment. Wu ¶ 55. This teaching might motivate a skilled artisan to try the other sites identified in paragraph 66 of Wu to treat a sleep disorder and thus to arrive at the claimed combination of substantia nigra and subthalamic nucleus as sites for treating a movement disorder and separate sleep disorder of a patient.