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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/338,695	07/23/2014	Tamara C. Baynham	6279.013US1	1002

45458 7590 01/22/2019
SCHWEGMAN LUNDBERG & WOESSNER/BSC
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MINNEAPOLIS, MN 55402

EXAMINER	
WU, TONG E	

ART UNIT	PAPER NUMBER
3792	

NOTIFICATION DATE	DELIVERY MODE
01/22/2019	ELECTRONIC

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte TAMARA C BAYNHAM
and JORDI PARRAMON[1]

Appeal 2018-000675
Application 14/338,695
Technology Center 3700

Before DANIEL S. SONG, JAMES P. CALVE, and JILL D. HILL,
Administrative Patent Judges.

CALVE, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellant appeals under 35 U.S.C. § 134(a) from the Office Action finally rejecting claims 1–3, 6–8, 10–15, 17, 18, 21, and 22. Appeal Br. 1, 23. Claims 4, 5, 9, and 16 are withdrawn. Final Action 1 (Office Action Summary). We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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[1] Boston Scientific Neuromodulation Corporation is identified as the real party in interest (*see* Appeal Br. 2), and is also the Applicant pursuant to 37 C.F.R. § 1.46.

CLAIMED SUBJECT MATTER

Claims 1 and 21 are independent. Claim 1 is reproduced below.

1. A method, comprising:

providing a sub-perception therapy to a patient such that the patient does not perceive stimulation, including delivering electrical modulation energy to a target tissue site of the patient at a programmed intensity value;

automatically calibrating the sub-perception therapy to a perception threshold in response to an event, wherein the automatically calibrating the sub-perception therapy to the perception threshold includes:

automatically detecting the perception threshold, including:

delivering electrical modulation energy using a series of incrementally increasing intensity values relative to the programmed intensity value to increase an intensity of the delivered electrical modulation energy to at least the perception threshold; and

sensing at least one evoked compound action potential (eCAP) indicative of the perception threshold in a population of neurons at the target tissue site of the patient in response to the delivery of the electrical modulation energy at the series of incrementally increasing intensity values; and

selecting one intensity value from the series of incrementally increased intensity values corresponding to the at least one sensed eCAP indicative of the perception threshold; and

computing a decreased intensity value as a function of the selected intensity value; and

delivering electrical modulation energy to the target tissue site of the patient at the computed decreased intensity value to provide the sub-perception therapy.

Appeal Br. 24 (Claims App.).

REJECTIONS

Claims 1–3, 11–15, 17, 18, and 21 are rejected under 35 U.S.C. § 103 as unpatentable over Wacnik (US 2013/0282078 A1, pub. Oct. 24, 2013) and Parker (US 2014/0236257 A1, pub. Aug. 21, 2014).

Claims 6–8, 10, and 22 are rejected under 35 U.S.C. § 103 as unpatentable over Wacnik, Parker, and Barreras, Sr. (US 5,941,906, iss. Aug. 24, 1999) ("Barreras"). 2-8303

ANALYSIS

Claims 1–3, 11–15, 17, 18, and 21
Unpatentable over Wacnik and Parker

The Examiner finds that Wacnik provides sub-perception therapy as recited in independent claims 1 and 21, except for using evoked compound action potential (eCAP) for a perception response automatically for an event. Final Act. 4–5. The Examiner relies on Parker to teach sensing at least one eCAP indicative of a perception threshold in order to determine a paresthesia threshold more accurately and automatically in response to an event. *Id.* at 5. The Examiner determines that it would have been obvious to modify Wacnik to use eCAP for a perception response automatically in response to an event, as taught by Parker, to determine a paresthesia threshold more accurately and to adjust sub-threshold stimulation automatically in response to changes that affect the perception threshold. *Id.*

Appellant argues that Wacnik does not teach a process that finds a perception threshold, use a sensed eCAP to indicate a perception threshold, or identify an intensity value of electrical modulation energy corresponding to the sensed eCAP/perception threshold. Appeal Br. 15.

These arguments are not persuasive for several reasons.

First, the Examiner relies on Parker to teach the use of a sensed eCAP to indicate a perception threshold (Final Act. 5) as Appellant recognizes (*see* Appeal Br. 16).

Second, the Examiner provides detailed findings regarding Wacnik's automated process for providing sub-perception therapy by automatically calibrating stimulation therapy parameters to a perception threshold, albeit without reliance on a sensed eCAP as indicative of a perception threshold. Final Action 4–5. The Examiner relies on Parker to teach the use of eCAP as a proxy or indication of a perception threshold automatically in response to an event as claimed. *Id.* at 5. Appellant's arguments do not address the findings of the Examiner that Wacnik teaches the claimed process except for using a sensed eCAP (*see* Appeal Br. 14–16; Reply Br. 2–5), and therefore do not apprise us of Examiner error. *See* 37 C.F.R. § 41.37(c)(1)(iv) (the Appeal Brief must contain the arguments of appellant explaining why the examiner erred as to each ground of rejection contested by appellant); *see also In re Jung*, 637 F.3d 1356, 1365 (Fed. Cir. 2011) (approving of Board's long-standing practice of requiring an applicant to identify the alleged error in an examiner's rejections); *Ex parte Frye*, 94 USPQ2d 1072, 1075 (BPAI 2010) (precedential) ("The panel then reviews the obviousness rejection for error based upon the issues identified by appellant, and in light of the arguments and evidence produced thereon.") (cited with approval in *Jung*, 637 F.3d at 1365).

Wacnik expressly teaches a therapy mode that *automatically* changes stimulation intensity to be below the perception threshold of a patient and then automatically increases the intensity to above the perception threshold stimulation intensity of the patient. Wacnik ¶¶ 33, 34, 62, 135–143.

Wacnik discloses an implanted modulation device (IMD 14) that gradually and *automatically* increases the stimulation intensity until the patient or a sensor perceives the stimulation. *Id.* ¶¶ 33–36, 62, 138–140. The perception may include a perception of paresthesia. *Id.* ¶¶ 7, 35, 137.

Wacnik also teaches that the perception threshold is the minimum stimulation intensity at which the patient first perceives (e.g., feels) one or more substantial effects from the electrical stimulation therapy such as a motor response, a stimulation perception response, a detected physiological response, or "a nerve action potential." *Id.* ¶ 35.

The Examiner relies on Parker for further teachings on the use of a detected physiological response such as a nerve action potential or eCAP as claimed. Final Act. 5. In this regard, Parker teaches that it is well known to use the eCAP measurements to provide completely automated device fitting to a patient because the eCAP response provides measurement of the fibers being stimulated and "[t]he perception threshold corresponds to the appearance of an evoked response." Parker ¶¶ 73, 75, 76. Therefore, the Examiner correctly reasons that Parker's process uses eCAP (evoked CAP) to determine a perception threshold more accurately. Final Act. 5.

Parker records the eCAP measurements during implantation. Parker ¶¶ 78, 79. Parker records these measurements for different user postures. *Id.* ¶ 91, Fig. 19. As a result, these stored measurements also can be used to determine whether lateral movement of the electrode has occurred and then change stimulation therapy parameters/electrodes automatically, in real time in response to automated neural response measurements. *Id.* ¶¶ 153, 154. Stimulation intensity may be reduced to avoid undesired sensation, and stimulation location may be shifted to resume the desired response level. *Id.*

These adjustments to stimulus parameters based on evoked response measurements return the neural response to the first, stored neural response measurement. *Id.* ¶ 159. A table of program parameters can be updated with new posture and program data determined from neural responses. *Id.*

Wacnik and Parker automatically calibrate to provide sub-perception therapy to a patient. They do so by sensing evoked physiological responses to a series of incrementally increased stimulation intensities to identify the sensed value that corresponds to a stored value indicative of the perception threshold. Their automated methods select the intensity that provides this sensed value. Wacnik ¶¶ 5–7, 9–11, 29–36, 62, 135–143; Parker ¶¶ 7, 29, 35–37, 75–80, 90–93, 147. Wacnik automatically, incrementally increases the stimulation intensity from below the perception threshold to just above the perception threshold to detect the perception threshold. Then, Wacnik lowers the stimulation intensity to just below the perception threshold. *See* Wacnik ¶¶ 62. Parker induces paresthesia in response to postural changes to identify treatment locations and then reduces stimulation to sub-threshold levels. Parker ¶¶ 33, 35–37, 91, 147, 153, 154, 159.

Wacnik and Parker both detect a stimulation perception threshold by sensing an acute, physiologically significant response while increasing the stimulation intensity from a low intensity to a higher intensity. For Wacnik, the response includes a motor response, a stimulation perception response, or a detected physiological response such as *nerve action potential*. Wacnik ¶ 35. For Parker, the response includes *eCAP*, which is provided above a recruitment threshold for neural response and therapeutic effect but below a comfort threshold to minimize energy expenditure. Parker ¶¶ 7, 8, 29, 35.

Appellant's arguments that Parker does not automatically calibrate to a perception threshold and Wacnik does not use sensed eCAP to calibrate automatically to a perception threshold or event (Appeal Br. 15–16) are not persuasive because the Examiner relies on Wacnik to teach automatically calibrating to a perception threshold and Parker to teach the use of sensed eCAP to identify a perception threshold upon occurrence of an event (i.e., a posture change) (Final Act. 4–5). Moreover, as discussed above, Wacnik uses sensed physiological responses to identify a perception threshold, and Parker uses sensed eCAP to identify a perception threshold automatically and provide sub-threshold therapy upon occurrence of an event.

We agree with the Examiner that using eCAP, as taught by Parker, in the method of Wacnik would not alter the principle of operation of Wacnik. Ans. 7. The Examiner proposes a simple substitution of Parker's sensed eCAP values as a means to detect a patient's perception threshold and then to deliver sub-threshold stimulation therapy where Wacnik already teaches to sense a variety of different physiological responses of a patient in order to identify a perception threshold and deliver sub-threshold therapy.

Thus, we sustain the rejection of claim 1 and dependent claims 2, 3, 12–15, 17, and 18, which are not argued separately. Appeal Br. 13–19.

<u>Claim 11</u>

The Examiner correctly finds that Parker adjusts stimulation therapy in response to an event that includes an identified physical activity/posture of a user, a user-initiated signal, a signal indicating an electrode migration, or on a periodic basis, as recited in claim 11. Final Act. 6. Appellant argues that Parker does not automatically calibrate to a perception threshold in response to an event. Appeal Br. 17–18.

This argument is not persuasive as the Examiner relies on Wacnik, not Parker, to teach automatic calibration to a perception threshold and further relies on Parker to teach the calibration of stimulation therapy in response to an event that includes the events recited in claim 11. Final Act. 6 (citing Parker ¶¶ 33, 153, 154, 159). Paragraph 33 of Parker describes the adaptive control of stimuli in response to user's postural changes, which correspond to the claimed event. Parker compares measured neural fiber conduction to desired fiber class recruitment to provide desired pain suppression response. Parker ¶ 34. Parker also identifies a "perception" threshold below which no evoked response arises from the stimulus and a maximum, comfort threshold and uses this data to adaptively control the stimuli in response to postural changes of a user to maintain stimuli at a sub-threshold level. *Id.* ¶¶ 35–37.

Paragraph 153 describes how the system monitors and estimates the lateral movement of an electrode for a given stimulus intensity and uses the sensed responses to change the stimulus electrodes, location, and intensity as needed. These automated neural response measurements adjust the system in real time. *Id.* ¶ 154. Accelerometer posture measurements can be used simultaneously with the neural response measurements to adjust stimulus parameters and to return the neural response measure to the first, desired neural response measure automatically in a feedback loop. *Id.* ¶ 159.

As discussed above, Wacnik teaches a method that adaptively controls the stimulation intensity and parameters in a closed feedback loop based on sensed physiological responses to identify a patient's perception threshold and then set stimulation to a sub-perception threshold. Parker teaches to run adaptive, feedback loops in response to events that affect stimulation therapy such as posture changes and to provide sub-perception stimulation therapy.

A skilled artisan would understand that Parker's feedback loop is used to sense and identify a perception threshold upon occurrence of an event and then to set stimulation therapy at a sub-perception threshold. In addition, Wacnik's measures responses to identify a patient's perception threshold and then provides sub-perception therapy. The Examiner reasonably determines, and we agree that, it would have been obvious to run Wacnik's method upon the occurrence of an event, as Parker teaches to do, so the IMD continues to provide efficacious, sub-perception, stimulation therapy even if the location of the leads change due to user movement and the like. Final Act. 5, 6.

Thus, we sustain the rejection of claim 11.

Claim 21

Appellant argues the patentability of independent claim 21 based, in part, on arguments presented for claim 1. Appeal Br. 18. This argument is not persuasive for the reasons discussed for the rejection of claim 1.

Appellant also recites various limitations of claim 21 and argues that Wacnik and Parker do not teach or suggest these features. *Id.* at 18–19.

Merely reciting limitations of a claim and asserting that the prior art does not teach of suggest these features does not apprise us of Examiner error and does not constitute effective argument for the separate patentability of claim 21. *See* 37 C.F.R. § 41.37(c)(1)(iv); *In re Lovin*, 652 F.3d 1349, 1357 (Fed. Cir. 2011) (holding that the Board had reasonably interpreted 37 C.F.R. § 41.37(c)(1)(vii) (the predecessor to § 41.37(c)(1)(iv)) as requiring "more substantive arguments in an appeal brief than a mere recitation of the claim elements and a naked assertion that the corresponding elements were not found in the prior art").

Thus, we sustain the rejection of claim 21.

Claims 6–8, 10, and 22
Unpatentable over Wacnik, Parker, and Barreras

Claim 6

The Examiner relies on Barreras to teach comparing a characteristic of at least one sensed eCAP to a corresponding characteristic of a reference eCAP that is indicative of a perception threshold to select an intensity value indicative of a perception threshold as recited in claim 6. Final Act. 6–7.

Appellant argues that Barreras does not teach a reference paresthesia threshold and establishing stimulation parameters to provoke paresthesia in a pain patient. Appeal Br. 19–20.

We agree with the Examiner that Barreras teaches a biological sensor used to recognize an evoked response resulting from stimulating a remote nerve tissue for the purpose of automatically establishing the stimulation parameters required to provoke paresthesia. Barreras, 12:30–36. Barreras also teaches delivering a stimulus pulse and detecting the evoked response signals, which are compared against a prerecorded morphology for patient paresthesia. *Id.* at 12:36–39. Tissue stimulator 12 periodically resets to zero and then slowly increases the stimulus in very small steps until the desired evoked potential is detected (by comparison to the prerecorded paresthesia morphology) to indicate paresthesia is reestablished. *Id.* at 12:40–44.

In addition, as discussed above, Wacnik senses stimulus responses to identify a perception threshold (i.e., paresthesia), and Parker also compares sensed eCAP responses to recorded eCAP values indicative of paresthesia for this same purpose of identifying a perception threshold. Parker ¶¶ 75–78, 91–93, 153, 154, 159.

Thus, we sustain the rejection of claim 6.

Claim 8

The Examiner finds that Barreras teaches a method that senses two or more eCAPs in response to the delivery of electrical modulation energy and determines which sensed eCAPs has the characteristics that best match a reference eCAP that is indicative of the perception threshold as recited in claim 8. Final Act. 7 (citing Barreras, 12:31–44); Ans. 7–8. In this regard, Barreras uses a sensor to recognize a prerecorded morphology of an evoked response that resulted from stimulating a remote nerve tissue for the purpose of automatically establishing the stimulation parameters required to provoke paresthesia. Barreras, 12:31–36. Tissue stimulator 12 periodically goes into a "search" mode whereby the amplitude is reset to zero and then increased slowly in very small steps until the desired evoked potential is detected to indicate that paresthesia has been reestablished. *Id.* at 12:40–44.

The Examiner correctly finds that Barreras compares plural sensed eCAPs of incrementally increased intensity with a stored reference eCAP to identify which of the sensed eCAP best matches the reference eCAP that is indicative of paresthesia. Final Act. 7 (citing Barreras, 12:31–44); Ans. 7–8. Barreras thus teaches determining which of the two or more sensed eCAPs has characteristics that best match the characteristics of the reference eCAP. Barreras then selects the intensity value corresponding to the eCAP that best matches the reference eCAP to reestablish paresthesia. Barreras, 12:31–44.

In view of these teachings of Barreras, which the Examiner sets forth in the Answer (Ans. 7–8), Appellant's argument that the Office Action does not address these limitations is not persuasive. *See* Appeal Br. 20.

Thus, we sustain the rejection of claim 8.

Claim 10

The Examiner finds that Parker and Barreras store a list of reference eCAP characteristics indicating a perception threshold for multiple patient postures and select a reference eCAP from this list to compare to a sensed eCAP for an identified posture as recited in claim 10. Final Act. 7 (citing Parker ¶¶ 91, 159, Fig. 19 for storing reference eCAP data and sensing current posture); Ans. 8. Appellant's argument that the Office does not address the "specific claim language" of claim 10 (Appeal Br. 21) does not apprise us of error in the Examiner's findings, which notify Appellant of the basis of the rejection. Thus, we sustain the rejection of claim 10.

Claim 22

For similar reasons as claim 8, Barreras also compares a characteristic of a sensed eCAP to a corresponding characteristic of a reference eCAP that is indicative of the perception threshold to select an intensity value that corresponds to the sensed eCAP that is indicative of a perception threshold as recited in claim 22. Final Act. 7 (citing Barreras, 12:31–44). Barreras uses this process to provoke or reestablish paresthesia, which corresponds to the claimed perception threshold. *See* Spec. ¶¶ 57, 59.

Thus, we sustain the rejection of claim 22.

DECISION

We affirm the rejections of claims 1–3, 6–8, 10–15, 17, 18, 21, and 22.

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