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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JONATHON E. GIFTAKIS and NATHAN A. TORGERSON

Appeal 2014-008524
Application 12/432,268
Technology Center 3700

Before JENNIFER D. BAHR, GEORGE R. HOSKINS, and
LEE L. STEPINA, *Administrative Patent Judges*.

HOSKINS, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Jonathon E. Giftakis and Nathan A. Torgerson (“Appellants”)¹ appeal under 35 U.S.C. § 134 from the Examiner’s decision rejecting claims 12–14, 17–21, 32–34, 37–39, 42, 44–49, 52–58, 61–66, and 69–71 in this application. The Board has jurisdiction over the appeal under 35 U.S.C. § 6(b).

We REVERSE.

¹ The Appeal Brief identifies Medtronic, Inc. as the real party in interest. Appeal Br. 3.

CLAIMED SUBJECT MATTER

Claims 12, 32, and 42 are independent. Claim 12 illustrates the claimed subject matter on appeal, and it recites:

12. A method comprising:
 - receiving, with a processor, a first signal indicative of a physiological parameter of a patient;
 - receiving, with the processor, a second signal indicative of a patient parameter of the patient; and
 - adjusting, with the processor, a seizure detection algorithm of a medical device based on the first and second signals, wherein adjusting the seizure detection algorithm comprises:
 - identifying, with the processor, a target seizure based on the second signal;
 - determining, with the processor, whether the medical device, while implementing the seizure detection algorithm, identified the target seizure based on the first signal;
 - in response to determining that the medical device did not identify the target seizure based on the first signal, determining whether a portion of the first signal associated with the target seizure is indicative of a baseline non-seizure state of the patient; and
 - adjusting the seizure detection algorithm if the portion of the first signal associated with the target seizure is not indicative of the baseline non-seizure state of the patient.

REJECTIONS ON APPEAL

Claims 12–14, 17, 32–34, 42, 44–46, 52, 56, 57, 64, 65, and 69 stand rejected under 35 U.S.C. § 102(e) as anticipated by Leyde (US 2009/0171168 A1, pub. July 2, 2009).

Claims 18, 19, 37, 53, 61, and 71 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Leyde and Donoghue (US 2005/0203366 A1, pub. Sept. 15, 2005).

Claims 20, 38, and 47 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Leyde and Giftakis (US 2006/0135877 A1, pub. June 22, 2006).

Claims 21, 39, and 48 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Leyde, Giftakis, and Donoghue.

Claims 49, 58, and 66 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Leyde and Nathan (US 2012/0053491 A1, pub. Mar. 1, 2012).

Claims 54, 62, and 70 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Leyde and Greene (US 2008/0319335 A1, pub. Dec. 25, 2008).

Claims 55 and 63 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Leyde and Osorio (US 6,560,486 B1, iss. May 6, 2003).

ANALYSIS

A. Anticipation by Leyde

Claims 12–14, 17, 56, and 57

In rejecting claim 12, the Examiner finds Leyde discloses the claimed “first signal” as monitored neurological EEG data. Final Act. 3 (citing Leyde ¶¶ 28, 31). The Examiner finds Leyde discloses the claimed “second signal” as monitored clinical manifestation data, for example convulsions or ictal moans, which “identify[] . . . a target seizure” occurrence as claimed. *Id.* (citing Leyde ¶¶ 28, 33, 40, 97–98); *see also* Leyde ¶ 30 (“ictal state” is “a state in which a neurological event, such as a seizure, is occurring”). The Examiner finds Leyde discloses the claimed “determining . . . whether the medical device . . . identified the target seizure based on the first signal”

when Leyde compares the clinical manifestation data with the EEG data to determine if the device correctly predicted or determined a seizure state based on the EEG data. Final Act. 3 (citing Leyde ¶¶ 97–98).

The Examiner finds Leyde discloses the claimed “*in response to determining that the medical device did not identify the target seizure based on the first signal [i.e. EEG data], determining whether a portion of the first signal [i.e. EEG data] associated with the target seizure is indicative of a baseline non-seizure state of the patient*” (with emphasis added to claim language). *Id.* at 3–4 (citing Leyde ¶¶ 30, 97–98). In particular, the Examiner determines Leyde’s analysis of the EEG data to see if the EEG seizure detection algorithm should be corrected “is equivalent to determining if the [EEG] signal is indicative of a non-seizure state, i.e.[,] the EEG is normal,” and “[t]hen the algorithm is corrected, if necessary, for example if the device did not accurately predict or a detect a seizure state” based on the EEG data. *Id.* at 4 (citing Leyde ¶ 98). The Examiner further states the claimed “baseline” state “is arbitrary and does not differentiate . . . from a non-seizure state,” and “[a]ny non-seizure state or activity would generally be considered a baseline state as normal EEG activity is not ictal or epileptiform activity.” *Id.* at 16.

Appellants argue the Examiner errs in finding Leyde discloses *both* of the determining steps recited in claim 12. Appeal Br. 8–9; Reply Br. 7–8. Appellants also argue the Examiner errs in interpreting “the claimed ‘baseline non-seizure state’ as equivalent to any non-seizure state.” Appeal Br. 11. We agree with these arguments.

First, as a matter of claim construction, claim 12 recites “determining . . . whether the medical device, while implementing the

seizure detection algorithm, identified the target seizure based on the first signal” (hereafter “first determination”). Appeal Br. 27 (Claims App.). Claim 12 then recites, “in response to” the first determination indicating the device did not identify the target seizure based on the first signal, “determining whether a portion of the first signal associated with the target seizure is indicative of a baseline non-seizure state of the patient” (hereafter “second determination”). *Id.* (emphasis added). The separateness of these first and second determinations is established by the second determination being made “in response to” a specified result of the first determination.

Further, both of the first and second determinations are made with respect to the claimed “first signal,” which the Examiner finds to be Leyde’s neurological EEG data. Final Act. 3. Thus, to anticipate claim 12, Leyde must disclose *firstly* determining whether its seizure detection algorithm identified a target seizure based on the EEG neurological data, and then *secondly* (i.e., in response to determining that the algorithm did not identify the target seizure) determining whether a portion of the EEG neurological data is indicative of a baseline non-seizure state.

The Examiner’s rejection conflates these two steps in finding both steps are met by the one action of determining whether Leyde’s seizure detection algorithm reports a seizure state or a non-seizure (i.e. normal) state based on the neurological EEG data. *See* Final Act. 3–4, 16–17; Ans. 16–17.

Further, the Examiner’s construction of the claimed “baseline non-seizure state” as encompassing “[a]ny non-seizure state or activity” (Final Act. 16) is unreasonably broad, in light of the language of claim 12 and Appellants’ supporting Specification. As to the claim language, claim 12

recites the second determination—that is, the baseline non-seizure state determination—is made “*in response to* determining that the medical device *did not identify the target seizure.*” Appeal Br. 27 (emphases added). Thus, as recited in the claim, the baseline non-seizure state determination is made based on the EEG data only *after* it has *already* been determined that the EEG data algorithm did not identify a target seizure state. As claimed, the baseline non-seizure state must be different from another non-seizure state or activity. That is, the word “baseline” specifies a type of non-seizure state.

That understanding is consistent with Appellants’ Specification, which differentiates the “baseline state” from an “abnormal” state, where *both* of those states are non-seizure states. Spec. ¶¶ 108–111, 141. The Specification indicates differentiating between those two types of non-seizure states is useful to “confirm” that the identification of a target seizure based on the second signal (e.g., the convulsion / ictal moan activity signal) was not a false positive. *Id.* A baseline non-seizure state suggests the claimed “identifying . . . a target seizure state based on the second signal” may be a false positive, whereas an abnormal non-seizure state suggests the claimed “not identify[ing] the target seizure based on the first signal” may be a false negative.² *Id.*

For the foregoing reasons, we do not sustain the rejection of claim 12, and of claims 13, 14, 17, 56, and 57 depending from claim 12, as anticipated by Leyde.

² The Examiner states “[i]f the baseline non-seizure state is [considered to be] different than [a] normal brain state without a seizure, . . . this . . . would raise a 112 issue as the specifics of establishing this baseline state is not recited in the method claim language.” Final Act. 16. However, there is no rejection of claim 12 under 35 U.S.C. § 112 for us to review.

Claims 32–34, 42, 44–46, 52, 64, 65, and 69

Independent claim 32 recites a system comprising a processor that adjusts a seizure detection algorithm by, in part, performing the same steps recited in method claim 12 that are discussed above. Appeal Br. 30 (Claims App.). For the reasons provided in connection with claim 12, we do not sustain the rejection of claim 32, and of claims 33, 34, 64, 65, and 69 depending from claim 32, as anticipated by Leyde.

Independent claim 42 recites a system comprising means for adjusting a seizure detection algorithm by, in part, performing the same steps recited in method claim 12 that are discussed above. Appeal Br. 32 (Claims App.). For the reasons provided in connection with claim 12, we do not sustain the rejection of claim 42, and of claims 44–46 and 52 depending from claim 42, as anticipated by Leyde.

B. Obviousness based on Leyde and one or more of Donoghue, Giftakis, Nathan, Greene, and Osorio

The Examiner's additional consideration of dependent claims 18–21, 37–39, 47–49, 53–55, 58, 61–63, 66, 70, and 71 in light of Leyde in combination with one or more of Donoghue, Giftakis, Nathan, Greene, and Osorio, does not cure the deficiency of Leyde in connection with independent claims 12, 32, and 42 noted above. *See* Final Act. 10–16. Therefore, we do not sustain the various obviousness rejections of these dependent claims.

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DECISION

The Examiner's decision to reject claims 12–14, 17–21, 32–34, 37–39, 42, 44–49, 52–58, 61–66, and 69–71 is reversed.

REVERSED