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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* MARTIN T. GERBER and JOHN C. RONDONI<sup>1</sup>

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Appeal 2014-005466  
Application 12/989,754  
Technology Center 3700

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Before JENNIFER D. BAHR, JAMES P. CALVE, and  
AMANDA F. WIEKER, *Administrative Patent Judges*.

WIEKER, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Martin T. Gerber and John C. Rondoni (“Appellants”) appeal under 35 U.S.C. § 134(a) from the Examiner’s final rejection of claims 16–45. We have jurisdiction over the appeal under 35 U.S.C. § 6(b).

We REVERSE.

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<sup>1</sup> According to Appellants, the Real Party in Interest is Medtronic Inc. Appeal Br. 3.

### CLAIMED SUBJECT MATTER

The invention concerns “determin[ing] therapy parameter values for therapy delivered by medical devices.” Spec. ¶ 1. Claim 16 is illustrative of the subject matter on appeal, and recites:

16. A method comprising:
  - determining a first therapy program that comprises a set of therapy parameters values;
  - generating an algorithmic model of a therapy field based on the first therapy program, the algorithmic model representing where therapy will propagate from a therapy system delivering therapy according to the first therapy program; and
  - automatically determining a second therapy program that increases an operating efficiency of the therapy system while substantially maintaining the therapy field.*

Appeal Br. 16 (Claims App.) (emphasis added). Independent claims 30 and 44 contain similar language to that emphasized above in claim 16. *Id.* at 19, 21 (Claims App.).

### REJECTION

Claims 16–45 stand rejected under 35 U.S.C. § 102(b) as anticipated by McIntyre.

### ANALYSIS

Regarding claim 16, the Examiner finds that McIntyre discloses a FEM model that estimates a volume of activation.<sup>2</sup> Final Act. 4. The Examiner finds this “model is used in a system for optimizing stimulation parameters (operating efficiency).” *Id.*; *see also id.* at 3. Also, in the

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<sup>2</sup> McIntyre describes “volume of activation” as the “volume of tissue likely to be affected by typical stimulation parameters.” McIntyre ¶ 25.

Examiner's Answer to the Appeal Brief, the Examiner finds that the "score" created by McIntyre's algorithm, which evaluates how a modeled volume of activation "map[s] against desired and undesired [brain] regions," is the claimed "operating efficiency." Ans. 6.

Appellants contend that the Examiner makes inconsistent findings, between the Final Office Action and the Answer, as to what corresponds to the claimed step of "increases an operating efficiency." Reply Br. 5–7. Regarding the Examiner's findings in the Final Office Action, Appellants contend, *inter alia*, that neither McIntyre's disclosure of "optimizing stimulation parameters" nor McIntyre's ability to "optimize efficacy of treatment" *increases an operating efficiency* of the therapy system, as claimed. Appeal Br. 9–10 (citing Final Act. 3–4); Reply Br. 5–6. Regarding the Examiner's findings in the Answer, Appellants contend, *inter alia*, that McIntyre's "score" is unrelated to operating efficiency of a therapy system, under a broadest reasonable interpretation of that phrase. Reply Br. 8.

We agree with Appellants that the Examiner made inconsistent findings. Reply Br. 6–7. In the Final Office Action, the Examiner finds that McIntyre's stimulation parameters correspond to "operating efficiency." *See* Final Act. 4. In the Answer, the Examiner finds that McIntyre's score corresponds to "operating efficiency." Ans. 6. Appellants did not, however, file a Petition requesting the Examiner's Answer be designated a new ground of rejection, in light of this inconsistency. *See* MPEP § 1207.03(b); 37 C.F.R. §§ 1.181, 41.40. Instead, Appellants filed a Reply Brief disputing the Examiner's findings. *See* Reply Br. 5–8. Accordingly, we consider the

Examiner's findings as made in both the Final Office Action and the Examiner's Answer, and Appellants' arguments in response.

As a threshold matter, we must ascertain the meaning of the claim language "increases an operating efficiency." During patent examination proceedings, "claims are given their broadest reasonable interpretation consistent with the specification." *In re Hyatt*, 211 F.3d 1367, 1372 (Fed. Cir. 2000). Here, Appellants' Specification does not define this phrase expressly. The Specification does, however, provide examples of what is encompassed by this language. For example, the Specification explains that operating efficiency may be increased by "decreasing power consumption or operating at efficient amplitudes based on voltage multiplier levels." Spec. ¶¶ 9, 127, 132; *see also* Appeal Br. 17 (Claims App.) (claim 22). The Specification also explains that "operating efficiency data" may be utilized to "improve the energy efficiency of the [implantable medical device]." Spec. ¶¶ 121, 128, 131. Indeed, "small change[s] in therapy parameter values," such as, for example, "identify[ing] the position on the amplitude-duration curve that is most efficient," "may result in significant changes in battery recharge frequency and/or longevity." *Id.* ¶ 132. Therefore, a person of ordinary skill in the art, reading claim 16 in light of the Specification, would understand "increases an operating efficiency" to relate to increases in the functional efficiency of the therapy system in terms of, for example, energy usage or battery life, rather than efficacy of the therapy delivered.

In the Final Office Action, the Examiner finds that McIntyre's FEM model "is used in a system for optimizing stimulation parameters (operating efficiency)." Final Act. 4. However, the Examiner does not explain

persuasively how “optimizing stimulation parameters” relates to improving the functional efficiency of the system. McIntyre describes that stimulation parameters include, e.g., pulse amplitude, pulse bandwidth, frequency, the particular electrode contacts stimulated (when plural contacts are disposed on the same lead), and polarity. McIntyre ¶¶ 25, 72. The portions of McIntyre cited by the Examiner describe that McIntyre’s modeling system can be used to “optimize or otherwise adjust neural stimulation treatment by varying electrode position, stimulation protocol, or electrode design.” *Id.* ¶ 76. In other words, the cited portions explain that *stimulation treatment is optimized* by modifying stimulation parameters. *Id.*; *see also* Final Act. 3 (finding that McIntyre’s system “adjusts stimulation parameters to optimize efficacy of treatment”). The cited portions do not describe, however, whether these modifications in stimulation parameters also “increas[e] an operating efficiency,” i.e., increase the functional efficiency of the therapy system. *See, e.g.*, McIntyre ¶¶ 25, 76–77 (cited by Final Act. 4).

With respect to dependent claim 22, the Examiner cites paragraph 102 of McIntyre, which explains that “engineering optimization is used to assist the [stimulation parameter] selection process” and “limits on the stimulation parameters are determined by the output of the current clinical stimulator.” McIntyre ¶ 102; Final Act. 5. This disclosure, however, appears to relate to the technical operating limitations of the stimulator, e.g., the range of amplitude it is capable of generating, not the “operating efficiency” of the system. McIntyre ¶ 102. Neither McIntyre nor the Examiner explains whether those technical operating limitations impact how efficiently the system operates, e.g., in terms of its energy usage or battery life. Further,

even if “engineering optimization” were understood to correspond to the claimed “operating efficiency,” the Final Office Action fails to explain how a therapy field generated by McIntyre’s FEM model is “maintain[ed]” while the “engineering optimization” is increased, as claimed. *See* Final Act. 4–5.

Accordingly, the Examiner’s findings as made in the Final Office Action are not supported by a preponderance of evidence.

In the Examiner’s Answer, the Examiner finds that McIntyre’s “score is understood to be the ‘operating efficiency of the therapy system’ as claimed.” Ans. 6. The Examiner does not explain persuasively how McIntyre’s score, which maps a modelled volume of activation against regions of the brain in which activation is desired or undesired to predict the treatment efficacy of different electrode locations and parameter settings (*see* McIntyre ¶¶ 67–69), relates in any manner to “increasing an operating efficiency” of the therapy system, as that phrase has been construed. Accordingly, the Examiner’s findings as made in the Examiner’s Answer are not supported by a preponderance of evidence.

Therefore, we reverse the Examiner’s rejection of independent claim 16, and claims 17–29, which depend from claim 16.

Independent claims 30 and 44 recite systems that “automatically determin[e] a second therapy program that increases an operating efficiency of the therapy system.” Appeal Br. 19, 21 (Claims App.). For the reasons discussed above with respect to similar language in independent claim 16, we do not sustain the Examiner’s rejection of claims 30 or 44, or dependent claims 31–43 and 45, as anticipated by McIntyre.

Appeal 2014-005466  
Application 12/989,754

DECISION

The rejection of claims 16–45 is REVERSED.

REVERSED