UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/879,139	01/24/2018	Imad Libbus	279.A44US7	7234

45458 7590 07/01/2020

SCHWEGMAN LUNDBERG & WOESSNER/BSC
PO BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER	
STICE, PAULA J	

ART UNIT	PAPER NUMBER
3792	

NOTIFICATION DATE	DELIVERY MODE
07/01/2020	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

SLW@blackhillsip.com
uspto@slwip.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte IMAD LIBBUS, KRZYSZTOF Z. SIEJKO,
MARINA V. BROCKWAY, and ROBERT J. SWEENEY

Appeal 2019-006321
Application 15/879,139
Technology Center 3700

Before DANIEL S. SONG, STEFAN STAICOVICI, and
MICHAEL J. FITZPATRICK, *Administrative Patent Judges*.

FITZPATRICK, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellant, Cardiac Pacemakers, Inc.,[1] appeals under 35 U.S.C. § 134(a) from the Examiner's final decision rejecting claims 2–21. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

[1] "Appellant" refers to the applicant as defined in 37 C.F.R. § 1.42. Appellant identifies itself as the sole real party in interest. Appeal Br. 2.

STATEMENT OF THE CASE

The Specification

The Specification "relates generally to medical devices and, more particularly, to systems, devices and methods for managing heart failure using neural stimulation." Spec. 1:21–23

The Claims

Claims 2–21 are rejected. Final Act. 1. No other claims are pending. *Id.* Claims 2, 18, and 20 are independent. Appeal Br. 27–30. Claim 2 is illustrative and reproduced below.

> 2. A method, comprising:
>
> delivering a heart failure (HF) therapy including electrical stimulation;
>
> receiving parameter values from at least one HF-related parameter source, wherein the received parameter values include parameter values for at least two of a respiration parameter, a heart sound parameter or an activity parameter; and
>
> changing the electrical stimulation based on the received parameter values.

Id. at 27.

The Examiner's Rejections

The rejections before us are:

1. claims 2–21 under 35 U.S.C. § 112(a)/¶1 because the Specification does not enable the claimed invention (Final Act. 6);

2. claims 2–17 under 35 U.S.C. § 112(b)/¶2 as being indefinite (*id.* at 7);

3. claims 2–9, 11–14, 16, and 17 under 35 U.S.C. § 102(e) as anticipated by Pastore[2] (*id.* at 8); and

4. claim 10 under 35 U.S.C. § 103 as unpatentable over Pastore and Burnes[3] (*id.* at 9);

5. claim 15 under 35 U.S.C. § 103 as unpatentable over Pastore and Kroll[4] (*id.* at 10); and

6. claims 18–21 for nonstatutory (obviousness-type) double patenting over claims 14–21 of US 9,924,877 B2, issued March 27, 2018 (*id.* at 11).

DISCUSSION

Rejection 1—Enablement

Aside from claims 7 and 8, Appellant argues the enablement rejection of claims 2–21 together. Appeal Br. 12–20. We choose claim 2 as representative of claims 2–6 and 9–21 in deciding the enablement rejection. *See* 37 C.F.R. § 41.37(c)(1)(iv).

Claims 2–6 and 9–21

The Examiner determined that the Specification, although "enabling for neural stimulation, does not reasonably provide enablement for all possible permutations of electrical stimulation," encompassed by the claims. Final Act. 6. The Examiner explained the problem as follows:

> Claim 2 recites *delivering a heart failure therapy including electrical stimulation*. The breadth of the claim would include all types of electrical stimulation such as external stimulation, internal stimulation, stimulation of various tissues etc. The specification is specific to neural stimulation specifically to the

[2] US 2007/0260284 Al, published Nov. 8, 2007 ("Pastore").
[3] US 2004/0186525 A1, published Sept. 23, 2004 ("Burnes").
[4] US 2003/0149453 Al, published Aug. 7, 2003 ("Kroll").

> heart failure targets including peroneal nerve, sympathetic column in the spinal cord and cardiac post-ganglionic neurons. The specification does not provide support for the breadth of the claims as presented.

Id.; *see also* Ans. 4–6 (explaining that certain claim scope—for example, stimulation of one of the 12 cranial nerves or transcutaneous electrical neural stimulation ("TENS")—would require undue experimentation).

Appellant argues that "[t]he Examiner is improperly equating 'enablement' with a stringent requirement that every possible species is included in the disclosure. This is improper because the enablement requirement is separate and distinct from the written description requirement." Appeal Br. 13. Appellant's implicit characterization of the law of enablement is erroneous, as the Federal Circuit has held that the enablement requirement applies to the "full scope" of the claims.

> Section 112 requires that the patent specification enable those skilled in the art to make and use the full scope of the claimed invention without undue experimentation in order to extract meaningful disclosure of the invention and, by this disclosure, advance the technical arts. Because such a disclosure simultaneously puts those skilled in the art on notice of the enforceable boundary of the commercial patent right, the law further makes the enabling disclosure operational as a limitation on claim validity.

Invitrogen Corp. v. Clontech Labs., Inc., 429 F.3d 1052, 1070–71 (Fed. Cir. 2005) (citation, quotation marks, and footnote omitted); *see also In re Goodman*, 11 F.3d 1046, 1050 (Fed. Cir. 1993) ("[T]he specification must teach those of skill in the art how to make and how to use the invention as broadly as it is claimed." (quotation marks omitted)).

Appellant also argues that the Examiner has not set forth a *prima facie* enablement rejection because the Final Action does not explicitly address all

of the *Wands* factors. Appeal Br. 13 ("[T]he Examiner fails to properly interpret the claim language, fails to address who is the person of ordinary skill in the art, and fails to address what is considered undue experimentation."). Appellant, however, has not cited any legal authority to support its implication that an enablement rejection must explicitly discuss all eight *Wands* factors.

The *Wands* factors, consideration of which elucidates "whether a disclosure would require undue experimentation" are: "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

With respect to the breadth of the claims and level of skill in the art factors, Appellant argues:

> The claims are not reciting that all electrical stimulation provide heart failure therapy, but are reciting delivering a heart failure therapy including electrical stimulation. Additionally, *if* TENS prior art indicates that TENS provide heart failure therapy, *then* those ordinary skill in the art would know how to deliver TENS as a heart failure therapy. There is absolutely no requirement that the specification includes all that is known in the art.

Appeal Br. 16–17 (emphasis added). We agree that the Specification need not repeat what was already known in the art. But Appellant does not even assert, let alone substantiate, that "TENS prior art indicates that TENS provide heart failure therapy." *Id.* at 17. Nor does Appellant assert, let alone substantiate, that "those ordinary skill in the art would know how to deliver TENS as a heart failure therapy." *Id.*

Ultimately, Appellant's argument is that the full scope of claim 2 is enabled because the phrase "heart failure therapy" limits that scope to whatever happens to be enabled. *See, e.g.*, Reply Br. 3 ("The claim recites 'delivering a heart failure therapy . . .', which would not include TENS if it does not function as a heart failure therapy."). We disagree. If anything, Appellant's argument suggests the full scope of claim 2, in addition to being not enabled, is indefinite, as it may or may not include TENS, for example.

Appellant does not apprise us of error in the enablement rejection of claim 2. Accordingly, we affirm the enablement rejection of claim 2, as well as that of claims 3–6 and 9–21, which fall therewith. *See* 37 C.F.R. § 41.37(c)(1)(iv).

Claim 7

Claim 7 depends from claim 2 and recites "wherein delivering the HF therapy includes delivering electrical stimulation to heart muscle." Appeal Br. 27. Appellant argues that the Examiner effectively concedes enablement in her statement that "one of ordinary skill in the art could make and use the invention to deliver hea[r]t failure therapy including . . . cardiac muscle stimulation." Appeal Br. 19 (quoting Final Act. 3). We are not persuaded that the Examiner has erred in rejecting claim 7 as not enabled. The "cardiac muscle stimulation" to which the Examiner was referring was via an *internal* electrode or the like. The Examiner explained:

> The claim recites that the stimulation is delivered to the heart muscle. Again, this is broad and certain embodiments are not disclosed or discussed. For example this would include TENS stimulation, external to the patient, to be delivered to the heart muscle. It is unclear if this could or would work, no examples are given as to what the stimulation parameters would be or how this could be done.

Ans. 7–8. Appellant acknowledges the Examiner's explanation but does not dispute it. *See* Reply Br. 3. Instead, Appellant merely reiterates that TENS is not within the scope of the claim "*if* it does not function as a heart failure therapy." *Id.* (emphasis added).

Accordingly, we affirm the enablement rejection of claim 7.

Claim 8

Claim 8 depends from claim 2 and recites "wherein delivering the HF therapy includes delivering electrical stimulation to a neural target." Appeal Br. 27. Appellant argues that the Examiner effectively concedes enablement in her statement that "one of ordinary skill in the art could make and use the invention to deliver hea[r]t failure therapy including . . . vagus nerve . . . stimulation." Appeal Br. 19 (quoting Final Act. 3). We are not persuaded that the Examiner has erred in rejecting claim 8 as not enabled. As with claim 7, the argument is not persuasive of error because the stimulation to which the Examiner was referring was via an *internal* electrode or the like. Further, as pointed out by the Examiner, "neural target" is much broader than merely the vagus nerve. *See* Ans. 8 ("The claim recites that the stimulation is delivered to neural targets. This would necessary include any and all neural targets including cranial nerves, brain tissue etc.").

Accordingly, we affirm the enablement rejection of claim 8.

Rejection 2—Indefiniteness

The Examiner determined that claims 2–17 are indefinite "as being incomplete for omitting essential steps, such omission amounting to a gap between the steps." Final Act. 7. The purportedly essential step is creating a heart failure index. *Id.* The Specification repeatedly describes using at least two sensed parameters to create a heart failure index and changing the

electrical stimulation based on the index. Spec. 2:26–28, 2:31–3:3, 5:16–19. In contrast, claim 2 for example, recites "changing the electrical stimulation based on the received parameter values" without an intervening heart failure index.

Appellant argues that "[t]here is no basis for the Examiner to assert that determining 'indices' is critical. It is not described that way in the specification." Appeal Br. 22. To which the Examiner responds: "On page 5 within the Detailed Description the heart failure index is *explicitly taught as critical and essential* to the practice of the invention, see the first 3 paragraphs of the Detailed Description." Ans. 9 (emphasis added). The Examiner is mistaken. The cited portion of the Specification describes the heart failure index as neither "critical" nor "essential."

Accordingly, we reverse the indefiniteness rejection of claims 2–17.

Rejection 3—Anticipation by Pastore

Appellant argues the anticipation rejection of claims 2–9, 11–14, 16, and 17 together. Appeal Br. 23–24. We choose claim 2 as representative in deciding the anticipation rejection of all such claims. *See* 37 C.F.R. § 41.37(c)(1)(iv).

Appellant argues that Pastore does not teach "changing the electrical stimulation based on the received parameter values," as recited in claim 2. Appeal Br. 23–24. Appellant directs our attention to paragraph 49 of Pastore which states that "[v]arious embodiments use sensor input (e.g. activity or respiration sensor) to determine a desired time to initiate the sequence." Pastore ¶49. Appellant argues that Pastore might describe *initiating* an electrical stimulation sequence based on sensor input but it does not teach "changing" it. Appeal Br. 23. For the limitation at issue, however,

Examiner cited to paragraph 54, not paragraph 49. *See* Final Act. 8 ("Pastore discloses . . . changing the electrical stimulation based on the received parameter values (paragraph 0054)."). *See also* Ans. 11–12 (additionally citing Pastore ¶56 and explaining in detail where and how the limitation is taught by Pastore).

Of particular significance to an additional argument by Appellant, Pastore describes "sens[ing] parameters associated with nerve activity or surrogates of nerve activity such as blood pressure and respiration" and that "[s]ense circuits 733 are used to detect and process signals from a sensor, such as a sensor of nerve activity, blood pressure, respiration, and the like." Pastore ¶54. The Examiner construes claim 2's "activity parameter" as encompassing Pastore's sensing of "nerve activity." *See* Ans. 11 ("Paragraph 0054 indicates that the sensors 733 are for nerve activity (broadly interpreted to be activity)."). Appellant disputes this construction, arguing:

> Activity is distinguishable from nerve activity and cardiac activity as "activity" refers to the activity of the patient (page 18 line 1). Appellant respectfully submits that an activity sensor is a term of art (known by those of ordinary skill in the art) that refers to patient activity.

Reply Br. 6; *see also* Spec. 18:1 ("Activity sensors can be used to assess the activity of the patient.").

Appellant's argument about the scope of "activity" is not persuasive. The very next sentence of the Specification demonstrates that neural activity is within the scope of "activity." Referring to the sympathetic nervous system, it states: "Sympathetic activity naturally increases in an active patient, and decreases in an inactive patient." Spec. 18:2–3.

Appellant does not apprise us of error in the anticipation rejection of claim 2. Accordingly, we affirm the anticipation rejection of claim 2, as well as that of claims 3–9, 11–14, 16, and 17, which fall therewith. *See* 37 C.F.R. § 41.37(c)(1)(iv).

Rejections 4 and 5—Obviousness in view of Pastore and Burnes or Kroll

The Examiner has applied Pastore as prior art under (pre-AIA) 35 U.S.C. § 102(e) and rejected the claims as obvious under (pre-AIA) 35 U.S.C. § 103. Final Act. 8–10. Appellant argues that these rejections should be reversed pursuant to § 103(c)(1),[5] because Pastore has been identified as prior art only under § 102(e) and it was "owned by the same person or subject to an obligation of assignment to the same person (Cardiac Pacemakers, Inc.)." Appeal Br. 24–25.

The Examiner does not dispute Appellant's ownership assertion or assert that Pastore is also prior art under any subsections 102(a)–(d). Instead, the Examiner states that the rejected claims are not enabled by the earliest filed application in Appellant's claim of priority. Ans. 12. Such a determination is not relevant to the legal issue raised by Appellant.

On the record before us, Pastore is not available as prior art under 35 U.S.C. § 103. Accordingly, the obviousness rejections of claims 10 and 15 are reversed.

---

[5] Section 103(c)(1) states:

> Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Rejection 6—Nonstatutory (Obviousness-Type) Double Patenting

Appellant does not argue against, or otherwise establish error in, this rejection. Appeal Br. 25. Accordingly, we summarily affirm it.

SUMMARY

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
2–21	112(a)/¶1	Enablement	2–21	
2–17	112(b)/¶2	Indefiniteness		2–17
2–9, 11–14, 16, 17	102(e)	Pastore	2–9, 11–14, 16, 17	
10	103	Pastore, Burns		10
15	103	Pastore, Kroll		15
18–21		Nonstatutory Double Patenting	18–21	
Overall Outcome			2–21	

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