



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.
15/446,872	03/01/2017	Steven L. Waldhauser	CAR.003C1	4699
20995	7590	09/02/2020	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			GETZOW, SCOTT M	
			ART UNIT	PAPER NUMBER
			3792	
			NOTIFICATION DATE	DELIVERY MODE
			09/02/2020	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):

efiling@knobbe.com
jayna.cartee@knobbe.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte STEVEN L. WALDHAUSER, STEVEN D. GOEDEKE, and
DUANE G. FRION

Appeal 2019-005269
Application 15/446,872
Technology Center 3700

Before MICHAEL C. ASTORINO, ANNETTE R. REIMERS, and
PHILIP J. HOFFMANN *Administrative Patent Judges*.

ASTORINO, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), the Appellant¹ appeals from the Examiner's decision to reject claims 1–20. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

¹ We use the word “Appellant” to refer to “applicant” as defined in 37 C.F.R. § 1.42. The Appellant identifies the real party in interest as Cardionomic, Inc. Appeal Br. 3 (“Appeal Br.” refers to the Appeal Brief filed January 30, 2019).

STATEMENT OF THE CASE

Claimed Subject Matter

Claims 1, 6, and 13 are the independent claims on appeal. Claim 1, reproduced below, is illustrative of the claimed subject matter.

1. A catheter for use in electrical neuromodulation, the catheter comprising:
 - an elongate body having a proximal end and a distal end;
 - a first opening in the elongate body;
 - a second opening in the elongate body, the second opening between the proximal end of the elongate body and the distal end of the elongate body and on a first side of the elongate body;
 - a deflection lumen extending between the first opening and the second opening;
 - an elongate deflection member having a first end and a second end,
 - the deflection lumen having a size configured to allow the deflection member to pass through the deflection lumen,
 - the elongate deflection member configured to extend out of the second opening with the first end of the elongate deflection member proximal to the proximal end of the elongate body upon application of pressure to the first end of the elongate deflection member towards the first opening,
 - the elongate deflection member comprising a support wire comprising an austenitic metal alloy,
 - the support wire configured to provide column strength and a predefined shape to the elongate deflection member upon laterally extending out of the second opening; and
 - a plurality of electrodes on a second side of the elongate body, the second side opposite the first side, wherein extension of the elongate deflection member out of the second opening is laterally away from the plurality of electrodes and is configured

to bring the plurality of electrodes into contact with a luminal surface of a pulmonary artery.

Rejections

Claims 1, 3–9, 11–17, 19, and 20 are rejected under 35 U.S.C. § 103 as unpatentable over Demarais et al. (US 2007/0135875 A1, pub. June 14, 2007) (“Demarais”) and Webster, Jr. (US 5,782,239, iss. July 21, 1988) (“Webster”).

Claims 2, 10, and 18 are rejected under 35 U.S.C. § 103 as unpatentable over Demarais, Webster, and Foster (US 2009/0281608 A1, pub. Nov. 12, 2009).

ANALYSIS

Independent claims 1 and 6 recite “[a] catheter for use in electrical neuromodulation” including “a second opening in the elongate body . . . on a first side of the elongate body,” “the elongate deflection member configured to extend out of the second opening,” and “a plurality of electrodes on a second side of the elongate body, the second side opposite the first side.” Appeal Br. 19, 20, Claims App.

The Examiner finds that Demarais’ port 805 and elongated member 857 correspond to the claimed “second opening” and “elongate deflection member,” respectively. *See* Non-Final Act. 2; Final Act. 2; Ans. 3–4; Demarais ¶¶ 79–80, Fig. 8F.²

² “Non-Final Act.” refers to the Non-Final Office Action mailed March 5, 2018. “Final Act.” refers to the Final Office Action mailed August 31, 2018. “Ans.” refers to the Examiner’s Answer mailed April 30, 2019.

The Examiner finds that Demarais' wall contact electrode 856 corresponds to one of the claimed "plurality of electrodes." *See* Non-Final Act. 2; Final Act. 2; Ans. 3–4. The Examiner does not find that Demarais teaches "a plurality of electrodes on a second side of the elongate body, the second side opposite the first side," as recited in claims 1 and 6. In other words, the Examiner does not rely on Demarais to teach the claimed number and location of electrodes.

To remedy this deficiency, the Examiner determines "[t]o use more than one electrode is considered to be an obvious design choice since it would allow for more complete coverage, and merely yield predictable results." Non-Final Act. 2; *see also* Ans. 4–5. Our best understanding of the foregoing is that the Examiner modifies Demarais' electrode, as shown in Figure 8F, so that there would have been multiple of the same type of electrodes. This modification addresses the number of electrodes, but fails to address the location of the electrodes.

Accordingly, the Examiner's rejection needs to provide some articulated reasoning with some rational underpinning as why one of ordinary skill in the art would have positioned the electrodes opposite of port 805. To remedy this deficiency, the Examiner appears to provide numerous findings and modifications to Demarais' teachings.

First, the Examiner finds that, "port [805] can be considered to be at least opposite a portion of the electrode" (Final Act. 2) because "at least a side of a circumferential electrode is opposite the port 805 of Demarais" (Ans. 4 (emphasis omitted)). *Alternatively*, the Examiner determines "[e]ven if the port 805 of Demarais were not on an opposite side of the electrode 856, to make it on the opposite side would merely yield predictable

results, such as being able to more efficiently and effectively urge the electrode to the vessel wall.” *Id.* at 3–4.

The Appellant argues that electrode 856 is a single electrode, which appears to surround the perimeter of catheter 852 (i.e., a circumferential electrode), and therefore, one cannot establish that it is positioned opposite of port 805. *See* Appeal Br. 12–13; *see also* Reply Br. 4.³ Additionally, to the extent that one would attempt to find that electrode 856 is positioned opposite of port 805, the finding would be based on conjecture. *See* Appeal Br. 13. We agree with the Appellant’s argument.

Second, the Examiner determines:

since the electrode is a wall contact electrode [856] and is meant to stimulate the wall of the lumen, to use an electrode that only surrounds a portion of the catheter, such as a point or segment electrode, would merely yield the predictable result of stimulating the lumen wall, and is considered to be well known to the skilled artisan in the field.

Final Act. 2; *see id.* at 3 (citing Haverkost ¶ 71, Fig. 4a).⁴ The Examiner explains that “port 805 of Demarais can be considered to be on an opposite side of the segment electrode 856 since if it were not, the electrode would not be urged in contact with the vessel wall in an effective manner.” Ans. 4.

Initially, we cannot identify from the record a rationale for modifying the type of electrode from a circumferential electrode to a point or segment electrode. Here, the Examiner only explains that the result of modification is predictable, but does not provide a reason why one of ordinary skill in the art would have modified the electrode type. Even assuming a rationale for

³ “Reply Br.” refers to the Reply Brief filed June 27, 2019.

⁴ Haverkost (US 2012/0029510 A1, pub. Feb. 2, 2012) (“Haverkost”).

this proposed modification was presented on the record, we cannot reconcile the Examiner's earlier rationale of "more complete coverage" for the modification of having a plurality of electrodes with the rationale for changing the type of electrode, as the latter would seem to have less coverage. Further, the basis for the Examiner's determination that as a result of the modification of electrode type that the plurality of electrodes and port 805 would necessarily be on opposite sides appears to be based on conjecture.

Third, the Examiner either modifies the location of port 805 to be located at the bottom of catheter 852 or suggests doing so. *See* Final Act. 2. Once again, the Examiner only explains that the result of modification is predictable, and fails to provide a rationale why one of ordinary skill in the art would have modified the location of the port.

Lastly, the Examiner fails to rely on Webster's teachings in any manner that would remedy the deficiency in the Examiner's rejection as discussed above.

In view of the foregoing, we do not sustain the Examiner's rejection of independent claims 1 and 6, and dependent claims 3–5, 7–9, 11, and 12 as unpatentable over Demarais and Webster.

Independent claim 13 has different requirements than independent claims 1 and 6. *See* Appeal Br. 21, Claims App. The Examiner recognizes these differences in the Answer. *See* Ans. 3 ("independent claim 13 . . . merely states that the deflection member extends out of the second opening 'laterally away from the plurality of electrodes'"). However, the Examiner rejects claim 13 on the same exact basis as claims 1 and 6. Non-Final Act. 3. In the interest of fairness, for this case, we elect to not dissect

aspects of the Examiner's rejection of claims 1 and 6 on an *ad hoc* basis to conjure together a separate rejection of claim 13. Therefore, for the same reasons as discussed above, we do not sustain the Examiner's rejection of independent claim 13 and dependent claims 14–17, 19, and 20 as unpatentable over Demarais and Webster.

Further, we note that the Examiner fails to rely on Foster's teachings in any manner that would remedy the deficiency in the Examiner's rejection of independent claims 1, 6, and 13. Therefore, for the same reasons as discussed above for claims 1, 6, and 13, we do not sustain the Examiner's rejection of dependent claims 2, 10, and 18 as unpatentable over Demarais, Webster, and Foster.

CONCLUSION

In summary:

Claims Rejected	35 U.S.C. §	References/Basis	Affirmed	Reversed
1, 3–9, 11–17, 19, 20	103	Demarais, Webster		1, 3–9, 11–17, 19, 20
2, 10, 18	103	Demarais, Webster, Foster		2, 10, 18
Overall Outcome				1–20

REVERSED