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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* SRIJOY MAHAPATRA and GEORGE T. GILLIES<sup>1</sup>

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Appeal 2017-002933  
Application 12/741,710  
Technology Center 3700

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Before JEFFREY N. FREDMAN, RICHARD J. SMITH, and  
JOHN E. SCHNEIDER, *Administrative Patent Judges*.

SMITH, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to an epicardial pacing system and method for use with an epicardial pacing catheter. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

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<sup>1</sup> According to Appellants, the real party in interest is University of Virginia Patent Foundation. (Appeal Br. 3.)

STATEMENT OF THE CASE

*Claims on Appeal*

Claims 1–70, 72–119, and 121–134 are on appeal. (Claims Appendix, Appeal Br. 16–30.) Claims 1 and 103 are illustrative and read as follows:

1. An epicardial pacing system, said system comprising:
  - an epicardial pacing catheter configured to be disposed in the middle mediastinum of the thorax of a subject and configured for use in electrical pacing of the heart at one or more locations on the epicardial surface, said epicardial pacing catheter comprising:
    - a proximal portion, a distal portion, and a longitudinal structure there between;
    - and
    - at least one electrode in communication with the distal portion, wherein the at least one electrode is insulated on at least one side to allow pacing of the heart without damage to adjacent anatomical structure, and
    - a steering mechanism configured for steering said epicardial pacing catheter by selectively changing a shape of said epicardial pacing catheter while disposed in the subject.

*(Id.* at 16.)

103. A method for use with an epicardial pacing catheter, said method comprising:
  - disposing said epicardial pacing catheter in the middle mediastinum of the thorax of a subject;
  - pacing the heart at one or more locations with electrical energy from an at least one electrode; and
  - at least partially insulating the electrical energy to allow pacing of the heart without damage to adjacent anatomical structures,
  - wherein disposing the epicardial pacing catheter includes steering at least a distal portion of the epicardial pacing catheter by selectively changing a shape of the epicardial pacing catheter while in the subject.

*(Id.* at 27.)

*Examiner's Rejections*

1. Claims 1–29, 44–70, 72–94, 103, 107–109, 114–119, and 121–125 stand rejected under pre-AIA 35 U.S.C. § 103(a) as obvious over Christlieb<sup>2</sup> and Qin.<sup>3</sup> (Ans. 2–7.)

2. Claims 104–106 stand rejected under pre-AIA 35 U.S.C. § 103(a) as obvious over Christlieb, Qin, and Reddy.<sup>4</sup> (*Id.* at 7–8.)

3. Claims 30–43, 98–102, 110–113, and 131–134 stand rejected under pre-AIA 35 U.S.C. § 103(a) as obvious over Christlieb, Qin, and Sigg.<sup>5</sup> (*Id.* at 8–9.)

4. Claims 93 and 126 stand rejected under pre-AIA 35 U.S.C. § 103(a) as obvious over Christlieb, Qin, and Camps.<sup>6</sup> (*Id.* at 9.)

5. Claim 127 stands rejected under pre-AIA 35 U.S.C. § 103(a) as obvious over Christlieb, Qin, Camps, and Meiry.<sup>7</sup> (*Id.* at 9–10.)

6. Claims 95–97 and 128–130 stand rejected under pre-AIA 35 U.S.C. § 103(a) as obvious over Christlieb, Qin, Camps, and Kassab.<sup>8</sup> (*Id.* at 10.)

FINDINGS OF FACT

The following findings are provided for emphasis and reference purposes. Additional findings may be found in this Decision and the Examiner's Answer.

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<sup>2</sup> Christlieb, US 5,158,097, issued Oct. 27, 1992.

<sup>3</sup> Qin et al., US 5,807,249, issued Sept. 15, 1998 (“Qin”).

<sup>4</sup> Reddy et al., US 2005/0096522 A1, pub. May 5, 2005.

<sup>5</sup> Sigg et al., US 2004/0068312 A1, pub. April 8, 2004.

<sup>6</sup> Camps et al., US 5,792,217, issued Aug. 11, 1998.

<sup>7</sup> Meiry, US 2009/0030469 A1, pub. Jan. 29, 2009.

<sup>8</sup> Kassab, US 2010/0069849 A1, pub. March 18, 2010.

FF 1. The Examiner finds that Christlieb discloses a pacing catheter/lead 28 that is disposed on the exterior surface of the heart (i.e., the epicardium) and “is configured to deliver electrical pacing to the heart at one or more epicardial locations.” The Examiner further finds that Christlieb discloses that “the device can be used to stimulate any desired muscle or tissue and is intended to be a replacement for standard epicardial pacing leads.” (Ans. 2, citing Christlieb Abstract, Figures 6–8, cols. 1 and 2, col. 5, ll. 1–8, and col. 12., ll. 1–21.)

FF 2. The Examiner finds that “the lead 28 of Christlieb is inherently ‘configured for’ use in electrical pacing of the heart. Furthermore, since the heart is located in the middle mediastinum and the lead is placed on the exterior of the heart, the lead is also necessarily disposed in the middle mediastinum of the patient.” (Ans. 2.)

FF 3. The Examiner finds that Christlieb’s lead includes a proximal portion, a distal portion, and a longitudinal structure therebetween, and that electrodes are in communication with the distal portion and insulated on one side to allow pacing of the heart without damage to adjacent anatomical structures. (Ans. 2–3, citing Christlieb Figures 6–8, col. 3, ll. 35–68, and col. 12, ll. 47–64.)

FF 4. The Examiner finds that Christlieb’s lead is “flexible along its entirety in all dimensions in order to help orient the lead as it is inserted in the body,” can be bent at any point along its length, and “can have multiple points of curvature as it is steered through the body.” (Ans. 3, citing Christlieb Figure 8; *see also* Christlieb col. 7, ll. 53–54 (“[t]he present invention . . . provides a . . . lead which permits a single flexible insulated lead”).)

FF 5. The Examiner finds that Qin discloses an epicardial electrode catheter that has a plurality of steering mechanisms “that can selectively change a shape of the catheter along a plurality of preconfigured points of curvature,” and that because “the lead curves in two directions, there are inherently two points of curvature around which the lead curves.” (Ans. 3, citing Qin cols. 3 and 4, and Figures 1A and 1B.)

## DISCUSSION

We adopt the Examiner’s findings and conclusions as our own, including with regard to the scope and content of, and motivation to combine, the prior art, as set forth in the Answer (Ans. 2–14). We discern no error in the rejections of the claims as obvious.

### *Rejection No. 1*

#### *Issue*

Whether a preponderance of evidence of record supports the Examiner’s rejection of claims 1–29, 44–70, 72–94, 103, 107–109, 114–119, and 121–125 under pre-AIA 35 U.S.C. § 103(a).

#### *Principles of Law*

A prior art reference “may be read for all that it teaches, including uses beyond its primary purpose,” *In re Mouttet*, 686 F.3d 1322, 1331 (Fed. Cir. 2012), and “is not limited to the disclosure of specific working examples.” *In re Mills*, 470 F.2d 649, 651 (CCPA 1972).

The test for obviousness is “what the combined teachings of the references would have suggested to those of ordinary skill in the art,” and to justify combining the teachings of references “it is not necessary that a

device shown in one reference can be physically inserted into the device shown in the other.” *In re Keller*, 642 F.2d 413, 425 (CCPA 1981) (citing cases).

An obviousness analysis “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

#### *Analysis*

The Examiner concludes that “it would have been obvious to one of ordinary skill in the art at the time of [Appellants’] invention to add the steering mechanisms of Qin to the catheter of Christlieb in order to effectively steer the catheter through the body, thus allowing for proper placement due to increased flexibility of the lead.” (Ans. 3–4.)

Appellants advance arguments regarding claim 1, claim 103, claim 21, claims 75/121, and the Official Notice taken by the Examiner. (Appeal Br. 6–15; Reply Br. 2–9.) We address those arguments below.

#### *Claim 1*

Appellants argue that the Examiner has not shown “that the cited references include all the features of the rejected claims,” and that the “combination of Christlieb in view of Qin would not have been obvious.” (Appeal Br. 6–11.) In particular, Appellants contest the Examiner’s position that it would have been obvious to modify Christlieb by adding the steering mechanisms of Qin to the catheter of Christlieb in order to effectively steer the catheter through the body. (*Id.*; *see also* Reply Br. 2–5.)

Appellants advance several arguments in support of those contentions.

Appellants argue that “Qin is directed to a catheter ablation device for use *inside of the heart*,” and thus the catheter tip in Qin “must be able to *fit in*, and *pass through*, the blood vessel of the patient in order to fulfill its intended purpose.” (*Id.* at 8.) On the contrary, according to Appellants, “Christlieb is directed to a paraneural stimulating lead that is configured to stimulate a muscle *outside of the heart*,” and one of skill in the art would recognize “that the Christlieb device is *incompatible with* the catheterization techniques described in Qin, *e.g.* based on the inability to navigate [Christlieb’s] electrodes 29 and 30 *with insulating shieldings 33 and 36* through the blood vessel and into the heart.” (*Id.* at 9.)

We are not persuaded. First, a conclusion of obviousness based on the teachings of Christlieb and Qin does not require that the respective devices shown in those references be physically combinable. *See Keller*, 642 F.2d at 425. Second, as the Examiner explains, the rejection is based on “merely combining the steering mechanisms of Qin with the lead of Christlieb, and not the entire implantation procedure,” and Qin states that its invention is intended to improve the flexibility of prior art catheters/leads. (Ans. 11, citing Qin col. 1, ll. 44–46.)

Appellants also argue that the Christlieb and Qin devices “do not share similar objectives [or] treatment procedures, nor do they both address a ‘particular problem.’” (Appeal Br. 11.) Thus, according to Appellants, “[i]n view of the completely different objectives and treatment procedures involved in the two references, it cannot be assumed, and is certainly not *obvious*, that one of skill in the art would have modified Christlieb in the manner suggested.” (*Id.*)

We are not persuaded. As an initial matter, we agree with the

Examiner that Appellants appear to be arguing that Christlieb and Qin are not analogous art. (Ans. 12.) Moreover, we agree with the Examiner that Qin and Christlieb are in the same field of endeavor (“[t]hey are both devices implanted in the body with associated electrodes that can stimulate the heart”), and both are reasonably pertinent to the particular problem with which Appellants were concerned (“implantation of electrodes near the heart”). (*Id.*) See *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004).

Finally, Appellants argue that it would not have been obvious to modify Christlieb (in view of Qin) to include the features of a steering mechanism because “Christlieb only mentions *once* that the lead is ‘flexible,’” there is no mention in Christlieb that the flexibility is “in order to help orient the lead as it is inserted in the body,” and that there is no reasonable suggestion that the flexibility of the lead in Christlieb “is even related to *navigation* of the lead” or “that Christlieb would have been obviously improved based on Qin’s unrelated disclosure.” (Appeal Br. 10–11.)

We are not persuaded. Figure 8 of Christlieb (shown below) illustrates the flexible lead 28 deployed within the body.

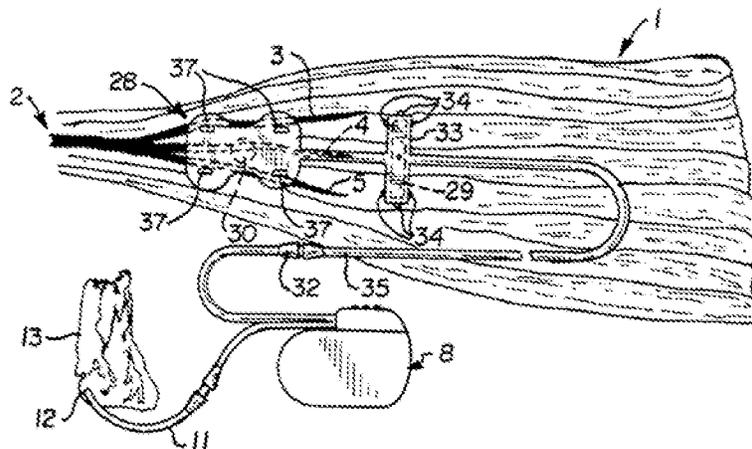


FIG. 8

Figure 8 above illustrates a stimulating lead implanted on a muscle flap 1. (Christlieb col. 10, ll. 3–5.)

Based on the disclosure of Christlieb, including Figure 8 above, we find that a person of ordinary skill in the art would appreciate that the flexibility of Christlieb’s lead helps orient the lead within the body, and that such flexibility is related to navigation of the lead, with Qin’s teaching providing steering through the body. *See KSR*, 550 U.S. at 418.

Accordingly, for the reasons of record and as set forth above, we affirm the rejection of claim 1.<sup>9</sup>

*Claim 103*

In contesting the rejection of method claim 103, Appellants rely on essentially the same arguments as advanced in connection with claim 1. (Appeal Br. 12–13; Reply Br. 6.) Those arguments are unpersuasive for the reasons set forth above.

Accordingly, for the reasons of record and as set forth above, we affirm the rejection of claim 103.

*Claim 21*

Appellants contest the rejection of a claims 21, 45, 50, 61, 62, 67, 109, and 115–117 as a group. (Appeal Br. 13–14; Reply Br. 6–7.) We select claim 21 for consideration. *See* 37 C.F.R. § 41.37(c)(1)(iv).

Claim 21 recites “[t]he system of claim 1, wherein said at least one

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<sup>9</sup> We acknowledge, but are unpersuaded by, Appellants’ argument regarding “hindsight reconstruction.” (Reply Br. 4–5.) Appellants point to no evidence that any of the Examiner’s findings were beyond the level of ordinary skill at the time of the invention or could have been taken only from Appellants’ Specification. *See In re McLaughlin*, 443 F.2d 1392, 1395 (CCPA 1971).

electrode is deployable.” (Appeal Br. 18.) Appellants contend that Christlieb does not teach a deployable electrode. (*Id.* at 13–14.) However, we agree with the Examiner’s analysis that “when the electrode is placed in the body, it is considered . . . to be ‘deployed.’”<sup>10</sup> (Final Action dated June 15, 2015 (“Final Act.”), at 4.)

Accordingly, for the reasons of record and as set forth above, we affirm the rejection of claim 21. Claims 45, 50, 61, 62, 67, 109, and 115–117 fall with claim 21.

*Claims 75/121*

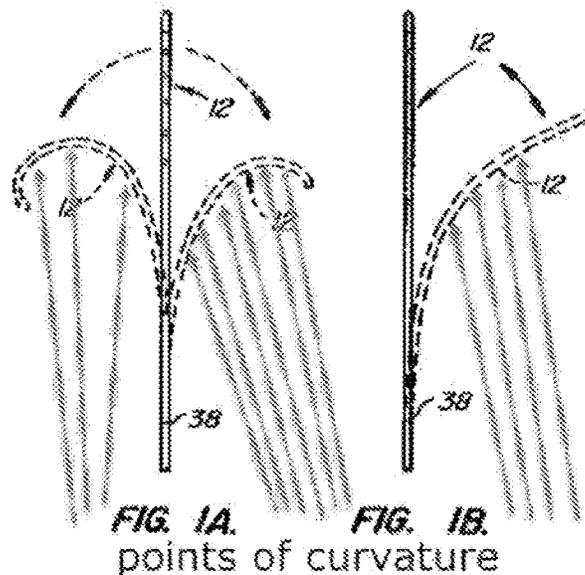
Dependent claim 75 recites “wherein said steering mechanism allows orientation of said epicardial pacing lead about two or more preconfigured points of curvature.” (Appeal Br. 24.) Dependent claim 121 recites “wherein said steering is about at least two preconfigured points of curvature.” (*Id.* at 29.) Appellants contest the Examiner’s reliance on Figure 8 of Christlieb (shown above) as having multiple points of curvature, arguing that such disclosure does not correspond to steering “about at least two *preconfigured* points of curvature,” and that “flexibility does not correspond to, or necessarily include, preconfigured points of curvature as those terms would be understood by those of skill in the art.” (Appeal Br. 14.)

The Examiner responds that claims 75 and 121 do not define what a “preconfigured point of curvature” actually entails, and refers to Qin Figures

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<sup>10</sup> We acknowledge, but are unpersuaded by, Appellants’ argument regarding “deployable” and “non-deployable” (Appeal Br. 13–14; Reply Br. 6–7), and we discern no error in the Examiner’s finding that Christlieb teaches a “deployable” electrode.

1A and 1B (annotated by the Examiner) as showing “countless points at which the device is preconfigured to curve.” (Ans. 14.) The Examiner’s annotated version of FIG. 1A and FIG. 1B of Qin is shown below:



The illustration above shows the tip section 12 of the Qin catheter annotated by the Examiner.

Appellants reply that “there is no evidence provided that the seemingly random points labeled by the Examiner are ‘preconfigured’ in any meaningful sense,” and that “the Examiner appears to be applying an overly broad and unreasonable construction.” (Reply Br. 9.)

We find that the Examiner has the better position. The term “preconfigured points of curvature” is not defined in the Specification. However, the Specification indicates that there may be more than two points of curvature, that the proximal and distal points of curvature may be located at various points and “may be implemented as may be desired or required according to medical procedures, device/system operations and anatomical

considerations,” and that the “points of curvature may be uni-directional, *bi-direction*, tri-direction, quadra-directional, or greater than quadra-directional.” (Spec. 16, ll. 1–16 (emphasis added).)

Accordingly, the term “preconfigured points of curvature” is given its broadest reasonable interpretation consistent with the Specification. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1256–57 (Fed. Cir. 2007). Thus, in this case, the term is interpreted in accordance with its ordinary and customary meaning, as would be understood by a person of ordinary skill in the art. *See id.*

Rather than overbroad and unreasonable, we find that the Examiner’s implicit interpretation of “preconfigured points of curvature” is consistent with its ordinary and customary meaning, in view of the Specification. Here, as pertinent to a lead or catheter, the term is interpreted to mean points about which the lead or catheter is adapted in advance to curve.<sup>11</sup> Christlieb’s flexible lead makes it adapted in advance to curve about multiple points. (Christlieb Figure 8; FF 4.) In the case of Qin, there are multiple points about which the catheter is adapted in advance to curve, as illustrated by the Examiner in FIG. 1A and FIG. 1B. (Ans. 14.) Moreover, Qin illustrates “bi-direction” curvature (*see* Spec. 16, l. 15), which is “inherently two points of curvature around which the lead curves.” (Ans. 3; FF 5.) Qin thus discloses “two or more” or “at least two” preconfigured points of curvature, as recited in claims 75 and 121, respectively.

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<sup>11</sup> *See, e.g.*, definition of preconfigure: to configure or adapt in advance. <http://www.oed.com/view/Entry/149721?redirectedFrom=preconfigured#eid51141511>.

Accordingly, for the reasons of record and as set forth above, we affirm the rejections of claims 75 and 121.

*Official Notice*

Appellants assert that the Examiner's Official Notice is improper and unsupported. (Appeal Br. 11–12.) In particular, Appellants contest the Examiner's position that the use of the claimed conducting material, rods, wires, strings, etc. recited in dependent claims 49, 51–53, 55, 118, and 119 are “notoriously old and well known in the art.” (*Id.*; see also Final Act. 10–11.) Notably, Appellants argument is that the “Official Notice [is] unsupported by documentary evidence” and not that the limitations recited in the subject claims are not old and well known in the art. (Appeal Br. 12.)

The Examiner responds by pointing out that the Official Notice rejection has been in multiple prior rejections without traverse by Appellants,<sup>12</sup> and further presents O'Neill<sup>13</sup> as showing that the features recited in the subject claims are well known in the art. (Ans. 12–13.) In reply, Appellants argue that the “configuration in FIG. 6A of Christlieb . . . is specifically designed to *avoid* the use of helical electrodes as depicted in O'Neill,” and “there is no obvious manner by which *a helical electrode* would have been advantageously included in the relied-upon configuration of Christlieb.” (Reply Br. 5.)

We are not persuaded by Appellants' arguments, and discern no error in the Examiner's Official Notice. The Examiner presented O'Neill to show that the features recited in claims 49, 51–53, 55, 118, and 119 are old and well known in the art. (Ans. 13.) Although the Examiner refers to “a helical

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<sup>12</sup> See MPEP § 2144.03(C) regarding Official Notice and admitted prior art.

<sup>13</sup> O'Neill, US 4,280,510, issued July 28, 1981.

electrode 13” disclosed by O’Neill (Ans. 13), none of the claims subject to the Official Notice recite a *helical* electrode, and thus the Examiner’s position was clearly not that a *helical* electrode be included in the Christlieb device. Moreover, Appellants do not present persuasive arguments that any of the limitations of claims 49, 51–53, 55, 118, and 119 are not “notoriously old and well known in the art.”

*Rejection Nos. 2–6*

Appellants do not contest Rejection Nos. 2–6. Accordingly, the rejections of claims 30–43, 93, 95–102, 104–106, 110–113, and 126–134 are summarily affirmed. *See Hyatt v. Dudas*, 551 F.3d 1307, 1314 (Fed. Cir. 2008).

*Conclusion of Law*

A preponderance of evidence of record supports the Examiner’s rejection of claims 1, 21, 75, 103 and 121 under 35 U.S.C. § 103(a). Claims 2–20, 22–70, 72–74, 76–102, 104–119, and 122–134 were not argued separately and fall with claims 1, 21, 75, 103 and 121.

SUMMARY

We affirm the rejections of all claims on appeal.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED