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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte MICHAEL D. BAUDINO

Appeal 2019-006792
Application 13/749,489
Technology Center 3600

Before DONALD E. ADAMS, RICHARD M. LEBOVITZ, and JOHN E. SCHNEIDER, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

The Examiner rejected the claims under 35 U.S.C. § 112 as lacking a written description and under 35 U.S.C. § 103 as obvious. Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from the Examiner's decision to reject the claims. 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. Appellant identifies the real party in interest as Medtronic, Inc. Appeal Br. 2.

STATEMENT OF THE CASE

This is the second time an appeal in this application has been before the Board. A decision in the first appeal was entered June 19, 2018 ("Dec. App."). The appealed rejections were affirmed in the decision and a new ground of rejection under 37 C.F.R. § 41.50(b) was entered. Prosecution was reopened and the claims were again finally rejected over the same prior art in the first appeal. Final Act. (Oct. 16, 2018).

The claims stand finally rejected by the Examiner as follows:

1. Claims 1–17 and 21 under 35 U.S.C. § 112(a) or 35 U.S.C. § 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. Final Act. 2.

2. Claims 1, 2, 10, and 15 under pre-AIA 35 U.S.C. § 103(a) as obvious in view of Boling (U.S. Pat. No. 7,146,222 B2, issued Dec. 5, 2006) ("Boling") and Desai et al. (U.S. Pat. Appl. Publ. No. 2011/0054581 Al, published Mar. 3, 2011) ("Desai"). Final Act. 4.

3. Claims 1, 2, 6, 9–17, and 21 under pre-AIA 35 U.S.C. § 103(a) as obvious in view of Erickson et al. (U.S. Pat. Appl. Publ. No. 2005/0209667 A1, published Sep. 22, 2005) ("Erickson") and Desai. Final Act. 6.

4. Claims 3–5, 7, and 8 under pre-AIA 35 U.S.C. § 103(a) as obvious in view of Erickson, Desai, and Colvin (U.S. Pat. Appl. Publ. No. 2006/0247749 Al, published Nov. 2, 2006) ("Colvin"). Final Act. 9.

Claim 1, the only independent claim on appeal, is reproduced below:

> 1. An implantable medical lead comprising:
>
> a proximal end portion including a plurality of contacts and having a proximal end; and
>
> a distal end portion including an array of electrodes and having a distal end for tunneling and a generally flat body extending proximally from the distal end, each of the electrodes

> of the array being discretely electrically coupled to one of the plurality of contacts and the array of electrodes being exposed through a surface of the generally flat body along an array length,
>
> wherein the body of the distal end portion is sufficiently stiff to be pushed through subcutaneous tissue without use of an introducer and without use of a stylet.

WRITTEN DESCRIPTION REJECTION

Claim 1 is directed to an implantable medical lead "wherein the body of the distal end portion is sufficiently stiff to be pushed through subcutaneous tissue without use of an introducer and without use of a stylet." The phrase "without use of a stylet" was added by amendment on Aug. 16, 2018. In response to the amendment, the Examiner rejected the claims as lacking written description. Final Act. 2. The Examiner stated that there is "no mention of exclusion or prohibition of using a stylet" in the Specification. *Id.* at 3. The Examiner also found that a stylet is used in an embodiment described in the Specification to facilitate implantation into subcutaneous tissue. *Id.*

We reverse this rejection.

To satisfy the written description requirement of 35 U.S.C. § 112, the inventor must "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563–64 (Fed. Cir. 1991) (emphasis omitted). "One shows that one is 'in possession' of the invention by describing the invention, with all its claimed limitations . . . ." *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997) (emphasis omitted).

As recognized by the Examiner, the Specification describes embodiments which describe a lead containing a stylet. Spec. 10:10–15. However, the Specification also describes an embodiment where the lead is made of a material which imparts the requisite stiffness and facilitates its ability to be pushed through subcutaneous tissue as required by claim 1. Spec. 7:3–21 ("If the lead body is too thin and is made of a material or materials having relatively low modulus of elasticity, the ability of the lead to be pushed through subcutaneous tissue may be compromised, while lead having thicker lead bodies made of the same material may be readily pushed through subcutaneous tissue."). This embodiment is not described as containing a stylet. Accordingly, the rejection describes an embodiment where the lead "is sufficiently stiff to be pushed through subcutaneous tissue . . . without use of a stylet" and therefore demonstrates that the inventor had possession of the claimed embodiment with all its limitations. The written description rejection of claims 1, and dependent claims 2–17 and 21, is reversed.

REJECTION BASED ON BOLING AND DESAI

The Examiner found that Boling describes an implantable lead with the features of claim 1. Ans. 4–5. The Examiner found that Figure 7 of Boling shows a core member 180 at its proximal end which "would provide the lead with rigidity to be pushed through brain tissues." *Id.* at 5. The Examiner further found that Desai describes a lead with a tip portion that is "sufficiently stiff to be pushed through subcutaneous tissue without use of an introducer and without use of a stylet" as required by the rejected claim. *Id.* The Examiner found that it would be within the skill of the ordinary skilled

worker to use Desai's material to make Boling's lead because "both inventions are concerned with the same field of endeavor." *Id.*

Appellant argues that the embodiments disclosed in Boling do not describe the implantable lead as sufficiently stiff to be pushed through subcutaneous tissue without use of an introducer and without use of a stylet as recited in claim 1. Appeal Br. 8. Appellant states that Boling uses a stylet to impart rigidity. *Id.* (quoting also from the previous Decision (Dec. App. 4) which made this finding). Appellant also argues that Boling does not teach that core member 180 provides sufficient stiffness for the lead to be pushed through brain tissue. Appeal Br. 8. Appellant states that the Examiner did not give sufficient reason to combine Boling with Desai. *Id.* at 11.

Appellant's argument is persuasive.

Boling describes a core member 180 at the distal portion of the lead 100. Boling, col. 8, ll. 4–8. While Boling describes core member 180 as being a solid structure, and made of a metal, Boling does not disclose that its purpose is to impart rigidity to the lead so that the lead may be pushed through brain tissue. *Id.* at col. 8, ll. 9–29.

Boling describes the lead as "flexible." *Id.* at col. 6, ll. 49–53. Boling characterizes the lead 100 as having "sufficient flexibility where it exits the cortex 330 to avoid adverse pressure effects on the brain or any portion of the lead 100." *Id.* at col. 18, ll. 39–41. To insert the lead into the brain, Boling describes using a *stylet* which "provides rigidity and serves to 'push' the lead 100 through the soft brain tissue." *Id.* at col. 19, ll. 3–8. Thus, the stylet, not the core member, is described by Boling as providing the stiffness to the lead enabling it to be pushed through tissue. Because Boling teaches that the lead is flexible, e.g., to avoid adverse pressure effects on the brain,

and uses a stylet to push the flexible lead through brain tissue, we fail to see the Examiner's logic that one of ordinary skill in the art would have had reason to use Desai's material to make the distal end portion of the lead stiff. Ans. 5.

"An examiner bears the initial burden of presenting a prima facie case of obviousness." *In re Huai-Hung Kao*, 639 F.3d 1057, 1066 (Fed. Cir. 2011). As that burden was not met here, we are compelled to reverse the obviousness rejection of claim 1, and dependent claims 2, 10, and 15 that depend from claim 1 and incorporate all its limitations.

REJECTION BASED ON ERICKSON AND DESAI

The Examiner found Erickson describes an implantable lead with the features of the lead of claim 1. Final Act. 6. The Examiner acknowledged that Erickson does not disclose the limitation "wherein the body of the distal end is sufficiently stiff to be pushed through subcutaneous tissue without use of an introducer and stylet." *Id.* However, the Examiner found that Desai describes a lead made with a material that would possess the same stiffness. *Id.* The Examiner determined it would have been obvious to one of ordinary skill in the art to have modified Erickson with the material in Desai "since both invention are concerned with the same field of endeavor, namely electrical stimulation leads configured to be implanted within the patient with known biocompatible materials." *Id.* at 7.

Appellant argues that Erickson teaches that "lead body does not have a great deal of stiffness, stating that a stylet may be used as a stiffening member for handling and placing the lead." Appeal Br. 15. Appellant also argues that Desai, on the other hand, describes a harder lead to enable it to

be pushed to the fixation site. *Id.* at 15–16. Appellant contends that the Examiner did not provide an adequate reason as "why one of skill in the medical device arts or medicine would make the lead of Erickson et al. stiffer." *Id.* at 15.

We agree with Appellant. Erickson describes a flexible electrode and specifically teaches it is "formed so as to not otherwise significantly impair the inherent flexibility of the paddle structure." Erickson ¶ 48. Erickson discloses that, in certain embodiments, the invention includes "providing the body of the lead with at least one waisted region that effectively increases the flexibility of the body." *Id.* ¶ 15. Another object of Erickson is described as including "certain features [in the lead] to increase the flexibility of such lead, thus enhancing the steerability of such lead." *Id.* ¶ 18. To drive the lead forward, Erickson describes using a stylet. *Id.* ¶ 65. Based on Erickson's repeated requirement of a flexible lead (*see also id.* ¶¶ 40, 68, 69), we are not persuaded by the Examiner's argument that one of ordinary skill in the art would have had a reason to make it stiffer using the materials in Desai. Because the Examiner did not meet the burden of establishing prima facie obviousness of the claims, we reverse the rejection of claim 1, and dependent claims 2, 6, 9–17, and 21 that depend from claim 1 and incorporate all its limitations.

REJECTION FURTHER BASED ON COLVIN

The Examiner further cited Colvin to meet limitations in the dependent claims 3–5, 7, and 8. Final Act. 10. Because Colvin does not make up for the deficiencies in Erickson and Desai, the rejection of these claims is reversed.

CONCLUSION

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1–17, 21	112	Written Description		1–17, 21
1, 2, 10, 15	103	Boling, Desai		1, 2, 10, 15
1, 2, 6, 9–17, 21	103	Erickson, Desai		1, 2, 6, 9–17, 21
3–5, 7, 8	103	Erickson, Desai, Colvin		3–5, 7, 8
Overall Outcome				1–17, 21

REVERSED