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Malcolm E. Whittaker
Whittaker Law Firm
2341 Glen Haven Boulevard
Houston, TX 77030

EXAMINER	
FAIRCHILD, MALLIKA DIPAYAN	

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ARNOLD B. VARDIMAN

Appeal 2018-002108
Application 14/616,893
Technology Center 3700

Before JENNIDER D. BAHR, MICHAEL J. FITZPATRICK, and ARTHUR M. PESLAK, *Administrative Patent Judges*.

FITZPATRICK, *Administrative Patent Judge*.

DECISION ON APPEAL

Arnold B. Vardiman ("Appellant")[1] appeals under 35 U.S.C. § 134(a) from the Examiner's final decision rejecting claims 1–9. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

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[1] Appellant identifies himself as the real party in interest. Appeal Br. 3.

STATEMENT OF THE CASE

The Specification

The claimed invention "relates to deep brain stimulating probes, such as electrodes." Spec. 1. The specification discloses various features of such probes, including "depth graduated" control of their insertion and positioning. *Id.* at 4. According to Appellant, prior to his invention, "deep brain stimulating probes [did] not allow a surgeon to determine the depth . . . inserted into the patient's brain." *Id.* at 23.

Figure 11 is reproduced below.

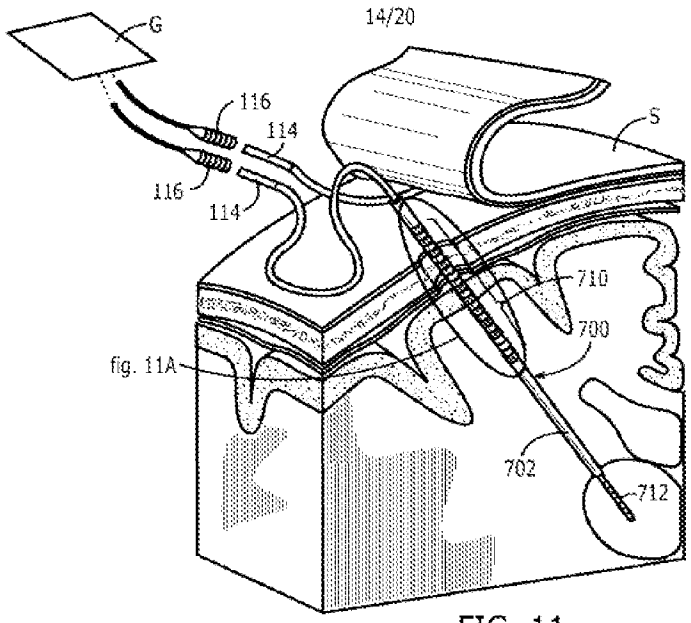

FIG. 11

Figure 11, reproduced above, "shows a depth graduated deep brain stimulation probe 700." *Id.* The probe includes color bands 710 indicative of different depths of the probe. *Id.* "If a surgeon knows the depth that he needs to insert probe [700], . . . the surgeon could determine which color band 710 corresponded to the appropriate depth and insert probe 700 into the

patient's brain only until the color band for this depth is just visible above the insertion point into the patient's brain." *Id.*

The Rejected Claims

All pending claims, namely claims 1–9, stand rejected. Final Act. 1. Claim 1, the sole independent claim, is representative and reproduced below.

> 1. A bilateral deep brain stimulator for insertion into
>
> a brain of a patient, the brain having two hemispheres, comprising:
>
> a first shaft having a first plurality of electrodes arranged thereon, the first shaft adapted to be inserted to a pre-selected depth into one hemisphere of the patient's brain therethrough a first burr hole in the skull of the patient and adapted to produce a modulatable electrical field, the modulatable electrical field providing electrical stimulation to a pre-selected target located in one hemisphere of the patient's brain;
>
> a first plurality of depth graduated bands disposed on the first shaft above the first plurality of electrodes, the first plurality of depth graduated bands adapted to position the first shaft proximate the pre-selected target located in one hemisphere of the patient's brain;
>
> a second shaft having a second plurality of electrodes arranged thereon, the second shaft adapted to be inserted to a pre-selected depth into the other hemisphere of the patient's brain therethrough a second burr hole therethrough the skull of the patient and adapted to produce a modulatable electrical field capable of providing electrical stimulation to the pre-selected target located in the other hemisphere of the patient's brain;
>
> a second plurality of depth graduated bands disposed on the second shaft above the second plurality of electrodes, the second plurality of depth graduated bands adapted to position the second shaft proximate the pre-selected target in the other hemisphere of the patient's brain;

> a pulse generator, the pulse generator generating an electrical fields in at least one electrode in each of the first and the second plurality of electrodes;
>
> a first line electrically connecting the pulse generator to a first connector, the first connector detachably electrically connecting the pulse generator to the first shaft, the first line comprising an upper and a lower segment, the lower segment electrically connected to the pulse generator and the first connector and the upper segment electrically connected to the first connector and the first shaft;
>
> a second line electrically connecting the pulse generator to a second connector, the second connector detachably electrically connecting the pulse generator to the second shaft, the second line comprising an upper and a lower segment, the lower segment electrically connected to the pulse generator and the second connector and the upper segment electrically connected to the second connector and the second shaft;
>
> wherein the electrical stimulation provided to the pre-selected target located in one hemisphere of the patient's brain provides therapeutic value to the patient and,
>
> wherein the electrical stimulation provided to the pre-selected target located in the other hemisphere of the patient's brain provides therapeutic value to the patient.

Appeal Br. 21–22.

The Appealed Rejections

The following rejections under 35 U.S.C. § 103 are before us for review:

1. claims 1 and 6–9 over Gielen,[2] Pianca[3] or Wahlstrand,[4] and Norris[5] (Final Act. 5–6); and

2. claim 2 over Gielen, Pianca or Wahlstrand, Norris, and Errico[6] or Avery[7] (Final Act. 9–10); and

3. claims 3–5 over Gielen, Pianca or Wahlstrand, Norris, Errico or Avery, and Zarembo[8] (Final Act. 11).

DISCUSSION

Rejection 1

The Examiner rejected claims 1 and 6–9 over Gielen, Pianca or Wahlstrand, and Norris. Final Act. 5–6.

Gielen teaches a bilateral deep brain stimulator for insertion into a brain of a patient. *See, e.g.*, Gielen, at [57], ¶33. The Examiner relied on Gielen as teaching all subject matter of claim 1 except for the limitations directed to detachable electrical connectors[9] and depth graduated bands.[10] *Id.* at 6–8.

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[2] US 2003/0204219 A1, published Oct. 30, 2003 ("Gielen").
[3] US 2003/0032997 A1, published Feb. 13, 2003 ("Pianca").
[4] US 2005/0070972 A1, published Mar. 31, 2005 ("Wahlstrand").
[5] US 4,909,263, issued Mar. 20, 1990 ("Norris").
[6] US 6,175,769 B1, issued Jan. 16, 2001 ("Errico").
[7] US 3,738,368, issued June 12, 1973 ("Avery").
[8] US 2005/0258242 A1, published Nov. 24, 2005 ("Zarembo").
[9] Claim 1 recites "the first connector detachably electrically connecting the pulse generator to the first shaft" and "the second connector detachably electrically connecting the pulse generator to the second shaft."
[10] Claim 1 recites "a first plurality of depth graduated bands disposed on the first shaft above the first plurality of electrodes, the first plurality of depth graduated bands adapted to position the first shaft proximate the pre-selected target located in one hemisphere of the patient's brain" and "a second

As for detachable electrical connectors, the Examiner found that each of Pianca and Wahlstrand teach such a feature and determined that it would have been obvious to incorporate it into Gielen for reasons Appellant does not contest and which we find sufficient. *See* Final Act. 8; *see generally* Appeal Br.

As for depth graduated bands, the Examiner found that Norris teaches such a feature and determined that it would have been obvious to incorporate it into Gielen (as modified by Pianca or Wahlstrand) for reasons Appellant does contest. *See* Final Act. 9; *see generally* Appeal Br. 11–16. As discussed below, we find the Examiner's reasoning sufficient, and we are not persuaded by Appellant's arguments to the contrary.

Norris teaches "an intravaginal vehicle and associated external recording and stimulation means to provide precise determination of pressures and EMG (electromyography) data" used, for example, "in the treatment of urinary incontinence." Norris, at [57], 2:22–25. "The proximal end of the vehicle is provided with a series of annular fitting indicia or markers 15 printed or engraved thereon." *Id.* at 3:37–39. "When the vehicle body is inserted into the vagina, the appropriate marker 15 adjacent the vaginal orifice can be read. The indicia may be in metric or inch scale in order to provide an accurate measurement of insertion depth to determine the position of greatest contractile force of muscle." *Id.* at 3:39–45. The Examiner found these indicia/markers to be depth graduated bands within

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plurality of depth graduated bands disposed on the second shaft above the second plurality of electrodes, the second plurality of depth graduated bands adapted to position the second shaft proximate the pre-selected target in the other hemisphere of the patient's brain."

the meaning of the claims and determined that a person of ordinary skill in the art would have incorporated them into Gielen "in order to provide the predictable results of providing the clinician with an accurate measurement of the insertion depth of the shafts and avoiding brain damage during surgery." Final Act. 9.

Appellant points out that the Norris vehicle also includes two pressure sensors and that data from the pressure sensors is what allows a physician to determine the optimal depth of insertion. Appeal Br. 12–13; *see also* Norris 4:39–48. In other words, the Norris indicia/markers are not used by the physician to insert the Norris vehicle to a predetermined depth; rather, they are used to measure the depth of insertion when the pressure sensors indicate the vehicle has been optimally inserted. *See* Norris 3:39–45. After explaining these additional teachings by Norris, Appellant argues that incorporating the Norris indicia/markers into Gielen "is incorrect because the modification of Norris renders Norris 'inoperative' and 'unsatisfactory for its intended purpose.'" Appeal Br. 12. Appellant elaborates that "if pressure sensors 30 and 31 are removed, Norris' apparatus 10 is inoperative because it cannot determine if the 'optimum positioning [the proper depth of insertion of apparatus 10 in the patient's body cavity] has been achieved.'" *Id.* at 13 (quoting Norris 4:46–47) (emphasis omitted, bracketed material added by Appellant).

Appellant's argument is not persuasive. The rejection is not premised on any modification of Norris, let alone specifically the removal of its pressure sensors. The rejection, rather, is based on a modification of Gielen, specifically adding Norris' indicia/markers to Gielen. *See* Final Act. 8–9.

Appellant also argues a person of ordinary skill in the art would not have been motivated to add Norris' indicia/markers to Gielen because, in Gielen, "the leads are always fully inserted into the brain." Appeal Br. 14; *see also id.* at 7. Appellant does not cite any description from Gielen to support its interpretation of how Gielen is allegedly always used. *See id.* at 7, 14. Instead, Appellant bases its interpretation on a drawing of Gielen, stating: "As illustrated [in Figure 3] the proximal ends of Gielen's leads 204, 208 are flush with patient 202's skull. Phrased differently, leads 204 and 208 are always fully inserted into patient 202's brain." *Id.* at 7.

Figure 3 of Gielen is reproduced below.

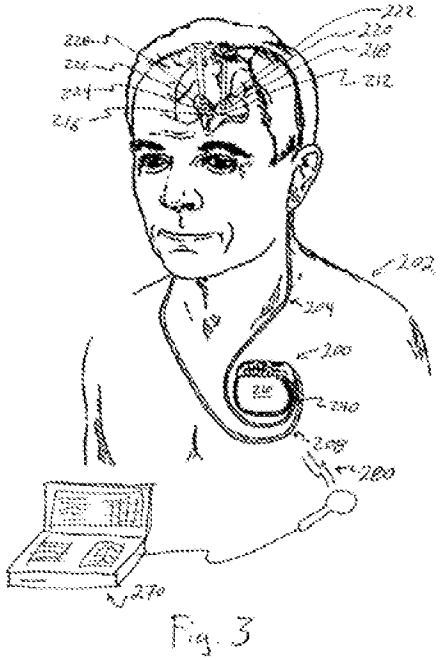

Figure 3, reproduced above, "is a schematic diagram illustrating an implantable medical device system according to one embodiment of the [Gielen] invention." Gielen ¶22. Figure 3, which appears to be at least partially hand drawn and quite imprecise, does not support Appellant's interpretation that it teaches that "the leads are always fully inserted into the

brain." *See* Appeal Br. 14. It is far from evident to us that Gielen intended to convey, through Figure 3 alone or otherwise, that its leads are always fully inserted into the brain. *See Hockerson-Halberstadt, Inc. v. Avia Grp. Int'l, Inc.*, 222 F.3d 951, 956 (Fed. Cir. 2000) ("[P]atent drawings do not define the precise proportions of the elements and may not be relied on to show particular sizes if the specification is completely silent on the issue.").

In fact, Figure 3 undermines Appellant's position. Gielen refers to "first brain stimulation lead 204" and "second brain stimulation lead 208." Gielen ¶67. In Figure 3, those reference numerals point specifically to portions of wires/leads that are in the chest area of the patient. *See id.* at Fig. 3, ref. 204, 208.

For the foregoing reasons, we affirm the Examiner's rejection of claims 1 and 6–9 under 35 U.S.C. § 103 over Gielen, Pianca or Wahlstrand, and Norris.

Rejection 2

The Examiner rejected claim 2 over Gielen, Pianca or Wahlstrand, Norris, and Errico or Avery. Final Act. 9–10.

Claim 2 depends from claim 1 and additionally recites "a first laterality indicator associated with the first line; and, a second laterality indicator associated with the second line." Apart from the originally-filed claims, the application as filed does not mention "laterality indicators." Appellant argues their meaning as follows:

> To the extent that claim 2 needs construction, for purposes of this appeal, it is appropriate to construe claim 2 as found in the applicant's specification at pp. 24–25 in which first and second lines are color coded or marked as "left" and "right" to

> distinguish the left and right electrical lines connected to their respective deep brain stimulating lead.

Appeal Br. 19.

The Examiner found that each of Errico and Avery teaches color coding of lead lines to medical device electrodes and determined that a person of ordinary skill in the art would have incorporated the feature into Gielen to obtain the predictable result of providing a physician with easily identifiable markers associated with the lead lines. Final Act. 10–11. Appellant argues that "both the Errico and Avery reference[s disclose] a single device (i.e. non-bilateral) fastened to the patient's spine. Therefore, there is no need to distinguish between the left and right elements of a non-bilateral device." Appeal Br 17. Appellant concludes that "neither Avery nor Errico teach or suggest, or even mention, using colored portions to distinguish a 'left line' from a 'right line.'" *Id.* at 19. We are not persuaded by Appellant's arguments.

It does not matter whether Avery and Errico use differently colored wires to indicate left and right wires (or to indicate wires associated respectively with shafts inserted into left and right hemispheres of a brain). The rejection is based on a combination of teachings. Gielen provides two leads (shafts) inserted into a brain, one in the left hemisphere and one in the right hemisphere. Gielen, Fig. 3. Avery and Errico are relied on for their teaching of color coding lead lines to medical device electrodes. Incorporating that feature into Gielen (as modified by Pianca or Wahlstrand and by Norris) yields the subject matter claimed in claim 2.

For the foregoing reasons, we affirm the rejection of claim 2 over Gielen, Pianca or Wahlstrand, Norris, and Errico or Avery.

Rejection 3

The Examiner rejected dependent claims 3–5 over Gielen, Pianca or Wahlstrand, Norris, Errico or Avery, and Zarembo. Final Act. 11. For this rejection, Appellants rely on the same arguments they present for Rejection 1 (*see* Appeal Br. 19–20), which rejection we affirm above. Thus, we also affirm this rejection.

CONCLUSION

For the reasons discussed, we affirm all of the Examiner's rejections.

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED