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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JOHANNES WILHELMUS WEEKAMP, JOHANNES HERMAN SAVENIJE, AALDERT ELEVELT, and MARCUS JOZEF VAN BOMMEL[1]

Appeal 2014-009013
Application 12/518,278
Technology Center 3700

Before ERIC B. GRIMES, ULRIKE W. JENKS, and ROBERT A. POLLOCK, *Administrative Patent Judges*.

PER CURIAM

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the Examiner's rejection of claims 1–3, 6, 7, 10, 11, 13, 14, and 21. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm-in-part.

STATEMENT OF THE CASE

The Specification discloses "a feeding tube . . . for total parental nutrition and/or medicine dosing including at least one inner tubing, at least

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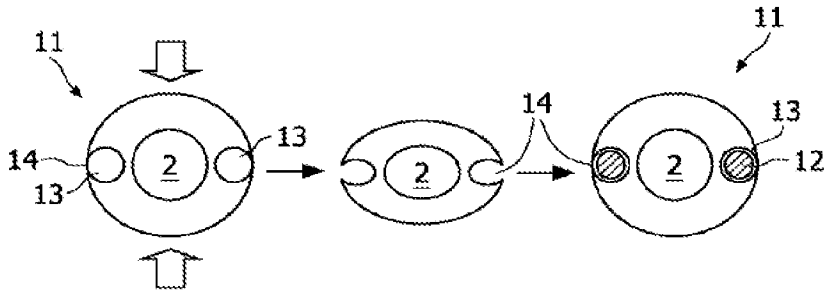
[1] Appellants identify the Real Party in Interest as Koninklijke Philips Electronics N.V. (App. Br. 1).

one lumen, [and] at least one sensor element, in particular an electrode." Spec. 1:6–8. The sensing element is "connected to at least one monitoring device by a wiring for internal monitoring of a patient's vital functions, the wiring being at least partially wound in tight contact with a surface of the inner tubing." *Id.* at 1:8–11.

Figure 3b is reproduced below.



The embodiment shown in figure 3b provides "a low cost manufactured feeding tube 11 . . . which may be a single or multi lumen feeding tube 11. The feeding tube 11 has outer lumens 13 for guiding and protecting a wiring 12." *Id.* at 9:27–30. "The outer lumens 13 each provide the continuous opening 14 in the circumference of the feeding tube 11." *Id.* at 10:3–5.

> The material of the feeding tube 11 is flexible. Therefore, the insertion of the wiring 12 into the outer lumens 13 may be easily conducted by using a method which is schematically shown in figure 3b. For insertion of the wiring 12, the feeding tube 11 is pressed at the outside on the top and the bottom of the feeding tube 11 as indicated in figure 3b by two arrows. By pressing the outside of the feeding tube 11, the feeding tube 11 is deformed. This leads to a widening of the openings 14 on the surface of the feeding tube 11 thus enabling an easy positioning of the wiring 12 in the outer lumens 13.

Id. at 10:12–19.

Claims 1, 7, and 13 are illustrative (emphases added):

1. A feeding tube configured for insertion in an esophageal opening including:

a flexible inner tubing including at least one lumen configured for parenteral nutrition and/or medicine dosing;

at least one sensing element disposed along one end of an outside surface of the inner tubing and configured for internally sensing a patient's vital functions;

electrically conductive wire connected to the at least one sensing element and to at least one monitoring device, and disposed on the outside surface of the inner tubing;

an outer tubing which covers the inner tubing and the electrically conductive wire, a surface of the outer tubing having a spiral shape; and

wherein *the inner tubing has recesses pre-formed on the inner tubing surface that match with the dimensions of and receive the at least one sensing element and the wire*.

7. A feeding tube configured for insertion in an esophageal opening including:

an inner tubing including at least one inner lumen configured for parenteral nutrition and/or medicine dosing and *at least one outer lumen disposed adjacent an outside surface of the inner tubing with an opening extending continuously along the at least one outer lumen* between the outer lumen and an outside surface of the inner tubing;

at least one sensing element disposed adjacent one end on the outside surface of the inner tubing and configured for internally sensing a patient's vital functions;

wire connected to the at least one sensing element and to at least one monitoring device, and disposed in the outer lumen of the inner tubing;

an outer tubing which covers the inner tubing and the wire; and

wherein the inner tubing is sufficiently flexible that radial pressure widens the opening to facilitate positioning the wire in the outer lumen.

13. A feeding tube, comprising:

an inner tubing including at least one lumen configured for parenteral nutrition and/or medicine dosing;

at least one sensing element disposed along one end of an outside surface of the inner tubing and configured for internally sensing a patient's vital functions;

electrically conductive wire connected to the at least one sensing element and to at least one monitoring device, and disposed on the outside surface of the inner tubing, the wire being wound around the inner tubing in a spiral; and

an outer tubing which covers the inner tubing and the electrically conductive wire, the outer tubing being shrunk fit to the inner tubing such that an outer surface of the outer tubing has a spiral shape.

The claims stand rejected as follows:

claims 3, 7, 10, and 11 under 35 U.S.C. § 102(b) in view of Levin[2];

claim 7 under 35 U.S.C. § 102(b) in view of Van Erp[3];

claims 1, 2, 6, 10, and 13 under 35 U.S.C. § 103(a) in view of Van Erp and Donlon[4];

claims 1, 2, 6, 7, 10, 11, 13, and 14 under 35 U.S.C. § 103(a) in view of Hadani[5] and Wessman[6];

claim 21 under 35 U.S.C. § 103(a) in view of Sinderby[7] and Hadani; and

claim 21 under 35 U.S.C. § 103(a) in view of Sinderby and Colson.[8]

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[2] Levin et al., US 6,078,830, issued June 20, 2000.
[3] Van Erp, US 5,591,142, issued Jan.7, 1997.
[4] Donlon, US 5,755,687, issued May 26, 1998.
[5] Hadani, WO 2006/060458 A1, published June 8, 2006.
[6] Wessman et al., US 2002/0143377 A1, published Oct. 3, 2002.
[7] Sinderby et al., US 2008/0125638 A1, published May 29, 2008.
[8] Colson et al., GB 2254253 A, published Oct. 7, 1992 ("Colson").

I.

Issue

The Examiner rejects claims 3, 7, 10, and 11 under 35 U.S.C. § 102(b) as anticipated by Levin. Final Rej. 3–4; Ans. 2.

Findings of Fact

FF1 Levin discloses "a catheter having a molded distal end assembly . . . [that] includes a plurality of electrodes and lead wires that are all molded into the walls of the assembly." Levin, Abstract. "[L]ead wires . . . are preferably spiral wound within the molded walls of the assembly to reduce the possibility that lead wires may become disconnected during manufacturing and use of the catheter." Levin, Abstract.

FF2 Figure 3 of Levin is shown below:

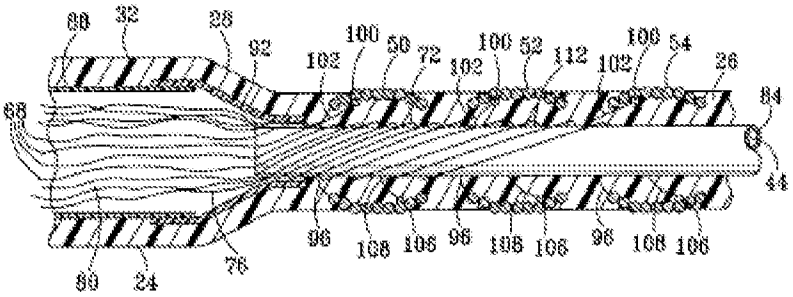

Figure 3 shows a "side cross-sectional view of a . . . multi-electrode assembly **12**" with electrodes 50, 52 and 54. Levin, col. 5, ll. 29–31. "[W]all **24** generally defines a central lumen **44**." Levin, col. 5, l. 8. "[C]entral lumen **44** includes a distal lumen section **72** defined by the distal wall section **26** . . . . The inner sidewall of the distal lumen section **72** is formed by a thin wall tubular section **84**." Levin, col. 5, ll. 34–41.

Analysis

The Examiner finds that Levin discloses "a hollow tube (capable of being used for feeding) with a polymer inner tubing (84), wire (112 . . .) connected to a distal sensor . . . a polymer outer tubing (26)," and a spirally would lead wire. Final Rej. 3–4, citing Levin, col. 5, ll. 23–29, col. 5, l. 49–col. 6, l. 11, and Fig. 3. The Examiner finds that Levin's "outer tubing has an opening to access the sensor (the wires cross the tubing wall through an opening . . .)." Final Rej. 4, citing Levin, Fig. 4. The Examiner finds that Levin's "device is made of polymers that are sufficiently elastic to bend and stretch during insertion, and the outer tubing is fit tightly over the inner tubing." Final Rej. 4.

Appellants argue that claim 7 requires an "inner tubing including at least one inner lumen . . . and at least one outer lumen disposed adjacent an outside surface of the inner tubing with an opening extending continuously along the . . . outer lumen." App. Br. 15. Appellants argue that Levin does not disclose or suggest an "outer lumen disposed adjacent an outside surface of the inner tubing." App. Br. 15. Appellants argue that Levin discloses "a molded distal portion of a catheter with the components molded within." App. Br. 15, citing Levin, Abstract.

The Examiner responds that "Levin teaches an inner tubing (84 between the center lumen and the wire) and an outer tubing (26 between the wire and the outer catheter surface . . .)." Ans. 8, citing Levin, Figs. 4 and 6.

We agree with Appellants that the Examiner has not adequately explained how Levin discloses the feeding tube of claim 7 that comprises an "*outer lumen disposed adjacent an outside surface of the inner tubing* with

an opening extending continuously along the at least one outer lumen between the outer lumen and an outside surface of the inner tubing," wherein wire is disposed in the outer lumen. Although Levin discloses an inner tubing 84, the wire is spirally wound around the outside of the inner tubing rather than being located within an outer lumen of the inner tubing. FF2.

Thus, we reverse the rejection of independent claim 7 and dependent claims 3, 10, and 11 under 35 U.S.C. § 102(b) as being anticipated by Levin.

II.

Issue

The Examiner rejects claim 7 under 35 U.S.C. § 102(b) as anticipated by Van Erp. Final Rej. 3; Ans. 2.

Analysis

FF3 Van Erp discloses a catheter that comprises a

> tubular, thin walled body having a metal wire reinforcing layer defined by metal wires which are woven or wound into a generally cylindrical weave of metal wire reinforcement incorporated into the tubular body[;] . . . . at least one lumen within the tubular body[;] . . . . [and a]t least one electrical operating element, such as an electrically conductive sensor, [] mounted on the distal end portion and [] electrically connected to at least one of the wires.

Van Erp, Abstract.

FF4 Figure 3 of Van Erp is shown below:

FIG. 3

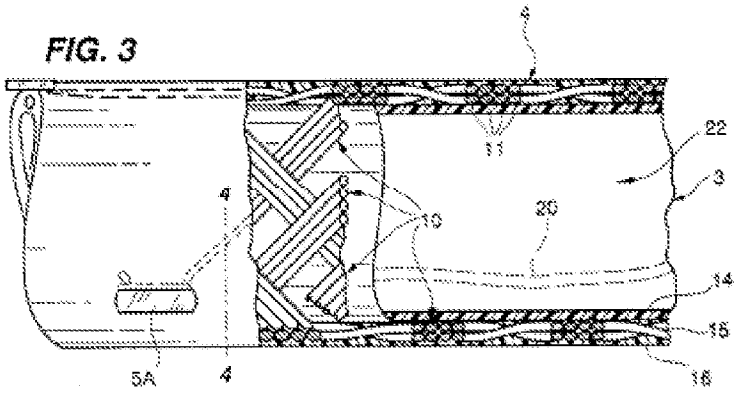

Figure 3 shows "a partly broken away view" of the catheter. Van Erp, col. 2, ll. 61–62. "The construction of the basic body of the catheter **3** . . . comprises a base tubular layer **14**, a woven metal wire reinforcing layer **15** forming a generally cylindrical weave of reinforcing wires **11** and a coating layer **16** arranged thereover." Van Erp, col. 3, ll. 37–41.

FF5 Figures 4 and 4A of Van Erp are shown below:

FIG. 4

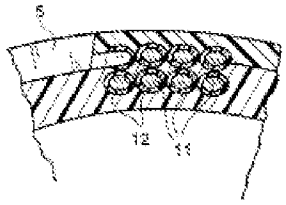

FIG. 4A

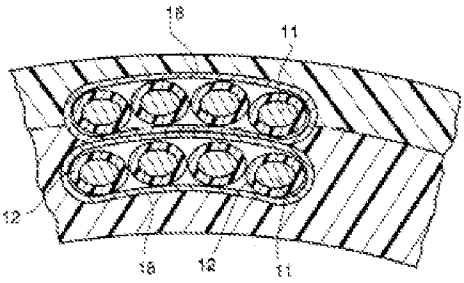

Figure 4 shows "a partial section" along lines 4–4 in Figure 3. Van Erp, col. 2, l. 64. Figure 4A shows a sectional view similar to Figure 4 "but shows a metal layer around the insulated wires of the metal wire reinforcement." Van Erp, col. 2, ll. 65–67.

Analysis

The Examiner find that Van Erp discloses "a hollow tube (capable of being used for feeding) with an inner tubing (14), helically wound wire (11 . . .) connected to a distal sensor (5 . . .) and a connector (5A), and an outer tubing (16)." Final Rej. 3, citing Van Erp, Figs. 2A, 2B, 4, and 5. The Examiner finds that Van Erp's "inner tubing has recesses for the wires and sensor . . . and the outer tubing has an opening to access the sensor." Final Rej. 3, citing Van Erp, Figs. 4 and 4A. The Examiner finds that Van Erp's "device is made of polymers that are sufficiently elastic to bend and stretch during insertion, and the outer tubing is fit tightly over the inner tubing." Final Rej. 3.

Appellants argue that that Van Erp does not disclose or suggest "at least one outer lumen disposed adjacent an outside surface of the inner tubing with an opening extending continuously along the at least one outer lumen between the outer lumen and an outside surface of the inner tubing," as required by claim 7. App. Br. 4, 15. Rather, Appellants argue, that Van Erp "only discloses an inner lumen 22 of the catheter." App. Br. 15, citing Van Erp, col. 4, ll. 26–30.

We agree with Appellants that the Examiner has not adequately explained how Van Erp discloses the feeding tube of claim 7 with "at least one outer lumen disposed adjacent an outside surface of the inner tubing." Van Erp discloses that the basic body of the catheter comprises a base tubular layer 14 and woven metal wire reinforcing layer 15. FF4. Thus, Van Erp discloses that the wires form a separate layer from the tubular layer. The Examiner points to Figures 4 and 4A of Van Erp as showing that the

inner tubing has recesses for wires, but such recesses are not described in Van Erp, and Van Erp's Figures 4 and 4A appear to show the wires embedded in the outer tubing 16. *See* FF5.

Accordingly, we reverse the rejection of independent claim 7 under 35 U.S.C. § 102(b) as being anticipated by Van Erp.

III.

Issue

The Examiner rejects claims 1, 2, 6, 10, and 13 under 35 U.S.C. § 103(a) as obvious in view of Van Erp and Donlon. Final Rej. 4–5; Ans. 2.

Findings of Fact

FF6 Donlon discloses an "aortic occlusion catheter [having] a blood return lumen for returning oxygenated blood to a patient and an occluding member for occluding the patient's ascending aorta." Donlon, Abstract.

FF7 Figures 7 through 10 of Donlon are shown below:

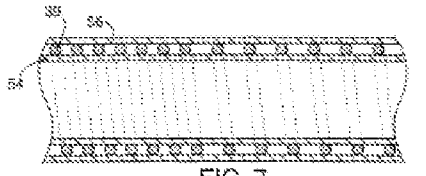

FIG. 7

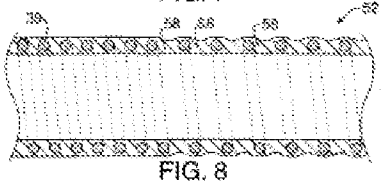

FIG. 8

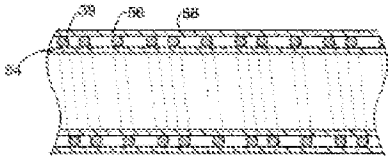

FIG. 9

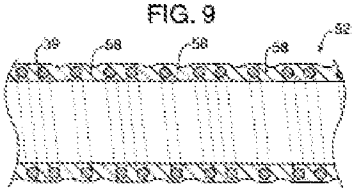

FIG. 10

Figures 7 and 9 show longitudinal cross-sectional views that illustrate methods of forming a wire-reinforced blood flow lumen. *Id.* at 2:64–3:3. Figures 8 and 10 show longitudinal cross-sectional views of the structure of Figure 7 and 9, respectively, after heating. *Id.* at 2:66–67, 3:4–5. In constructing the catheter, "[a] first tube **54** is mounted on a mandrel . . . and the wire **39** is wrapped in a helical fashion around the first tube **54**" as shown in Figures 7 and 9. *Id.* at 6:9–16. "A second tube **56** is then positioned over the wire **39** and the first and second tubes **54**, **56** are encased in a heat shrink tube (not shown) and heated so that the first and second tubes **54**, **56** and wire **39** form the reinforced tube **52**" shown in Figures 8 and 10. *Id.* at 6:17–21.

FF8 Donlon Figures 8 and 10 "illustrate slight depressions between adjacent portions of the wire **39** which are eventually filled when the

pressure lumens **34**, **36** and inflation lumen **38** are added." *Id.* at 6:41–45; *see id.* at 3:6–17, Figs 11–13.

Analysis

The Examiner relies on Van Erp as disclosing "the features of the claimed invention . . . including recesses in the inner tubing." Final Rej. 4. The Examiner finds that Van Erp "states that similar catheter construction is per se known." Final Rej. 4, citing Van Erp, 5:37–41. The Examiner finds that Donlon discloses a catheter device having "a hollow catheter body having an inner tubing (54), spiral windings (39), and an outer tubing of shrink fit (56)." Final Rej. 4. The Examiner finds that Donlon also discloses that "a sufficiently thin outer tubing of the design produces a spiral outer layer." Final Rej. 4, citing Donlon, Figs. 7–10. The Examiner concludes that, in view of Van Erp's suggestion to reference devices known in the art "for the tubing construction, it would have been obvious to one having ordinary skill in the art . . . [to consult] Donlon for the layer materials and manufacturing techniques for how to include a wound wire layer between two polymeric layers while leaving an open lumen." Final Rej. 4–5. The Examiner reasons that the "[u]se of the Donlon process would result in the device[]" recited in the claims. Final Rej. 5.

Claims 1, 6, and 10

Appellants argue that claim 1 requires "recesses pre-formed on the inner tubing surface that match with the dimensions of and receive the at least one sensing element and the wire." App. Br. 10. Appellants argue that although the Examiner points to Van Erp's Figures 4 and 4A as disclosing "recesses in the inner tubing," the reference does not disclose this feature.

Id. at 10–11. Appellants argue that Donlon also does not disclose or suggest such recesses and, therefore, "none of the references show the 'structural' feature of recesses on an inner tubing surface that match with the dimensions of and receive the at least one sensing element and the wire." App. Br. 11.

We agree with Appellants that the Examiner has not adequately explained how the combination of Van Erp and Donlon would have made obvious the feeding tube of claim 1, which requires that "*the inner tubing has recesses pre-formed on the inner tubing surface* that match with the dimensions of and receive the at least one sensing element and the wire" (emphasis added). As discussed above, the Examiner has not adequately shown that Van Erp discloses recesses on the inner tubing surface that contain the wires, nor has the Examiner explained how this limitation is satisfied by Donlon.

Thus, we reverse the rejection of independent claim 1 and dependent claim 6 under 35 U.S.C. § 103(a) as being obvious in view of Van Erp and Donlon.

Claim 10 depends from claim 7. As discussed above, claim 7 requires an inner tubing that includes "at least one inner lumen . . . and *at least one outer lumen disposed adjacent an outside surface of the inner tubing*" (emphasis added). The Examiner relies on Van Erp as disclosing recesses or an outer lumen adjacent an outside surface of the inner tubing. Because the Examiner has not adequately shown that either Van Erp or Donlon discloses an outer lumen, as recited in claim 7, and we also reverse the rejection of claim 10 as it depends from claim 7.

Claims 2 and 13

Claim 13 requires "an outer tubing which covers the inner tubing and the electrically conductive wire, the outer tubing being shrunk fit to the inner tubing such that an outer surface of the outer tubing has a spiral shape." Appellants argue that Van Erp "discloses a coating layer 16 arranged over a base tubular layer and a woven metal wire reinforcing layer 15 . . . [but] does not disclose properties of the outer surface of the coating layer or surface properties of the catheter." App. Br. 17. Appellants argue that the combination of Van Erp and Donlon do not teach or suggest a spiral shape. App. Br. 17–18 (arguing that "Donlon does not disclose, suggest, or imply a spiral shape of the outer surface").

We do not find Appellants' argument persuasive in light of the Examiner's reasoned findings that the combination of Donlon and Van Erp results in an "inherent spiral outer structure" because:

> Van Erp discloses winding the wire in a spiral and covering it with a thin layer (16). Donlon teaches that winding a wire (39) in a spiral over an inner tubing (54) and covering the wire with another thin layer of tubing (56; see Figs. 7 and 9). This covering layer is then shrink fit (Figs. 8 and 10), and results in a spiral outer shape (these figures illustrate that with a thin layer of shrink fit tubing over the spiral wound wire, the helical shape of the windings is preserved rather than "smoothed out" by a thicker tubing layer). Donlon explains that this layering technique results in depressions between the raised wire that is wound in a helix (i.e., a spiral outer surface; see col. 6, lines 41-43).

Ans. 10–11; *see* FF 7, 8. The Examiner further explains that "Donlon is used to replace the Van Erp outer layer of insulation with a thinner layer of shrink-fit insulation . . . not the entire Donlon structure of multiple pressure lumens." *Id.* at 10–11.

In light of the above, we affirm the rejection of independent claim 13 under 35 U.S.C. § 103(a) as being obvious in view of Van Erp and Donlon. Claim 2 falls with claim 13. *See* 37 C.F.R. § 41.37(c)(1)(iv).

IV.

Issue

The Examiner rejects claims 1, 2, 6, 7, 10, 11, 13, and 14 under 35 U.S.C. § 103(a) as obvious in view of Hadani and Wessman. Final Rej. 5–6; Ans. 2.

Findings of Fact

FF9 Hadani discloses a "feeding tube, such as a gastric tube or nasogastric tube . . . with at least one electrode suitable for electrical stimulation of a body organ (e.g., heart) and/or suitable for signal sensing from the body organ." Hadani 3:7–10.

FF10 Hadani discloses that "[e]lectrodes 108 are optionally positioned along the length of tube 100 . . . . In some embodiments of the invention, wires 110 connect electrodes 108 to a proximal electrical port." Hadani 7:26–29.

FF11 Figure 3 of Hadani is shown below:

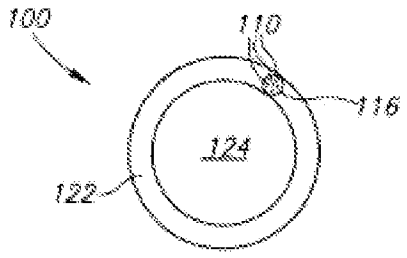

Figure 3 shows a cross-sectional view of a nasogastric tube. Hadani 7:5. "[T]ube 100 includes an internal channel 124 defined by a wall 122 . . . [and] a bundle 116 of wires 110, which connect electrodes 108 to electrical port 120, run along wall 122." Hadani 8:31–33. "Wires 110 of the electrodes 108 optionally pass along tube 100 in a single bundle 116 embedded in one side of the perimeter of a wall 122 of tube 100. Alternatively, wires 110 are distributed around wall 122, allowing wall 122 to be thinner than if the wires are concentrated." Hadani 9:30–32. "[A]lternatively . . . wires 110 pass within channel 124" or can "extend outside of tube 100." Hadani 10:6–10.

FF12 Wessman discloses a "lead body and method for lead body manufacture . . . [wherein] at least one conductor [is] positioned between an inner insulator and an outer insulator . . . [and] the outer insulator is fused to the inner insulator by heating." Wessman, Abstract.

FF13 Wessman discloses that a "variety of medical electrode catheters are available today . . . [which] can be used to sense electrical activity within the body." Wessman ¶ 4. "[A] reduced diameter lead is desired to limit the negative steric effects of lead implantation." Wessman ¶ 4.

FF14 Figure 1B of Wessman is shown below:

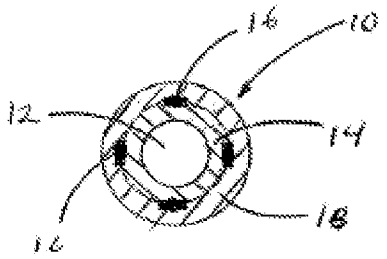

Figure 1B shows "a transverse cross-section of . . . a lead body." Wessman ¶ 13. "Lead body **10** includes a lumen **12**, an inner insulator **14**, at least one conductor **16** and an outer insulator **18**." Wessman ¶ 21. Conductors **16** can be wires. Wessman ¶ 21. "Conductors **16** are typically wound about the lumen and are insulated from the external environment by outer insulator **18** and from the lumen by inner insulator **14**." Wessman ¶ 21. "Inner insulator **14** and outer insulator **18** are fused together during manufacture." Wessman ¶ 21.

FF15 Figure 4C of Wessman is shown below:

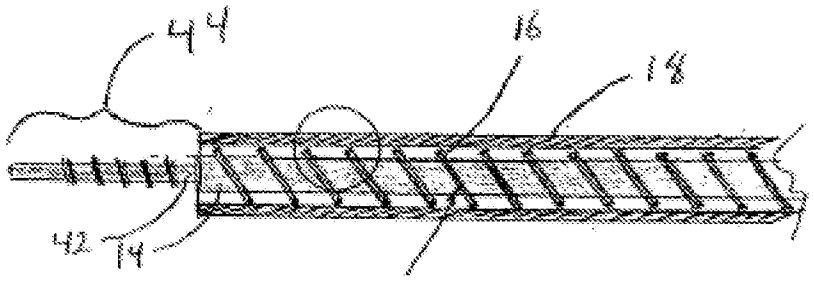

Figure 4C shows a partial cross-section of a lead embodiment "prior to fusing the outer insulator to the inner insulator." Wessman ¶ 18. "[A] desired number of conductors **16** are wound over inner insulator **14**." Wessman ¶ 24. "In addition to conductors **16**, an insulating spacer . . . [may be] wound between conductors. Insulating spacer **21** can function to maintain the spacing of the wires during manufacture and to further insulate the individual conductors." Wessman ¶ 24. "Outer insulator **18** is then applied over conductors **16**" and "fused to inner insulator **14** by heating the lead body." Wessman ¶ 24. "To

fuse the materials, a shrink-wrap, a vacuum or other method may be utilized." Wessman ¶ 24.

Analysis

The Examiner finds that Hadani discloses "a feeding tube connected to a monitoring device" Final Rej. 5, citing Hadani, Abstract. "A tubing (100) with a lumen (124) has electrodes (108) with wires (110) in the wall (the wires are in wall 122, forming an inner tube and a tight outer tube with the wires between)." Final Rej. 5. "Openings in the outer tubing (between the wire and outside surface) allow access to the electrode (the wires connect to the electrode outside the outer tubing . . .)." Final Rej. 5. "The construction also results in the wiring [being] located in an outer lumen near the surface." Final Rej. 5.

The Examiner finds that Wessman discloses "a large hollow sensing device . . . [and] catheters capable of being used for a feeding tube." Final Rej. 5, citing Wessman ¶ 4. The Examiner finds that Wessman discloses an "inner tube (14) ha[ving] a lumen (12), a sensing element . . . wiring (16) wound in tight contact with the inner tubing . . . and an outer tubing (18) over the wiring." Final Rej. 5, citing Wessman, Figs. 1–4. The Examiner finds that the "outer tubing can be made by shrink-wrapping the inner tube . . . which would give the surface of the outer tubing a spiral shape (the leads are spiral wound . . . [and] that shape would be maintained by a thin shrink wrap layer 18)." Final Rej. 5, citing Wessman
¶ 24 and Figs. 1A, 4B, and 4C.

The Examiner concludes that, in view of Hadani's suggestion "to locate the wires in the tube wall, it would have been obvious to one having

ordinary skill in the art . . . to look to devices such as that of Wessman for the necessary details of construction, and predictable results would ensue." Final Rej. 6. The Examiner finds that Wessman discloses "recesses in the outer tube for the wires . . . but does not disclose recesses on the surface of the inner tubing for the wires." Final Rej. 6, citing Wessman, Figs. 1A–B. The Examiner finds that it is known in the art that, "when a wire is between two tubes . . . equivalent recesses at the interface include (a) in the inner surface of the outer tube; (b) in the outer surface of the inner tube; and (c) matched partial recesses in the mating surfaces of both tubes." Final Rej. 6. The Examiner concludes that it would have been obvious to one of ordinary skill in the art to modify Wessman's device "by moving the recess from the inner surface of the outer tubing at least partially to the outer surface of the inner tubing for the predictable result of a tight hold for the wire." *Id.*

Claim 1

Claim 1 requires that "the inner tubing has recesses pre-formed on the inner tubing surface that match with the dimensions of and receive the at least one sensing element and the wire." Appellants argue that Wessman "does not disclose, teach, suggest, or imply recesses." App. Br. 12. With respect to Wessman's Figs. 1A and 1B, cited by the Examiner as showing recesses, Appellants argue that Wessman teaches that "an insulating spacer may be provided between the conductors" and the use of "a spacer between conductors is contrary to any suggestion of pre-formed recesses." App. Br. 12.

We agree with Appellants that the Examiner has not adequately explained how the combination of Hadani and Wessman would have made

obvious the feeding tube of claim 1 that comprises an inner tubing having "*recesses pre-formed on the inner tubing surface* that match with the dimensions of and receive the at least one sensing element and the wire" (emphasis added). Hadani discloses a tubing with wires that run along the inside or outside of the tubing, or that are embedded within the tubing wall. FF11. Wessman discloses that the wires are wrapped around an inner tubing, wherein an outer tubing is then fused to the inner tubing. FF14 and FF15. We do not discern, nor does the Examiner explain, where Wessman discloses that either the inner or outer insulators that form the tubing wall has recesses that hold the wires. The Examiner also fails to persuasively explain why, or how, one of skill in the art would have modified Wessman's procedure of wrapping the wire around the outer tubing to arrive at a procedure that generates recesses in the inner tubing. Accordingly, we reverse the rejection of independent claim 1 and dependent claim 6 under 35 U.S.C. § 103(a) in view of Hadani and Wessman.

Claim 7

Claim 7 requires an inner tubing that includes both an inner lumen and "at least one outer lumen disposed adjacent an outside surface of the inner tubing with an opening extending continuously along the at least one outer lumen between the outer lumen and an outside surface of the inner tubing." Appellants argue that Hadani does not teach or suggest the claimed "outer lumen disposed adjacent an outside surface of the inner tubing," because [t]he channels of Hadani are all internal to the tubing and not adjacent an outside surface." App. Br. 16. Appellants further argue that Wessman does not cure the defect in Hadani because Wessman discloses "an outer and an

inner insulator and fusing the outer and inner insulators to one another" to form a single lumen, such that Wessman fails to disclose an outer lumen as required by claim 7. App. Br. 16, citing Wessman ¶ 11.

We agree with Appellants that that the Examiner has not adequately explained how the combination of Hadani and Wessman would have made obvious the feeding tube of claim 7 comprising an outer lumen. As discussed above for claim 1, the Examiner has not explained why one of skill in the art would have modified Wessman's process of wrapping the wires around the inner tubing to arrive at an inner tubing that has a recess or an outer lumen adjacent the outer surface of the inner tubing. As this limitation is not found in Hadani, we reverse the rejection of independent 7 and dependent claims 10, 11, and 14 under 35 U.S.C. § 103(a) in view of Hadani and Wessman.

Claim 13

Appellants argue that claim 13 requires that the outer tubing is "shrunk fit to the inner tubing such that an outer surface of the outer tubing has a spiral shape." App. Br. 18. Appellants argue that Hadani "does not disclose an inner and . . . outer tube," or disclose a surface property of the tube. App. Br. 18. Appellants argue that Wessman does not disclose or suggest "a property of the outer surface or the lead." App. Br. 18. Appellants argue that, therefore, "claim 13 is distinguished from Hadani and Wessman." App. Br. 18.

Appellants' arguments are not persuasive. Wessman discloses heat fusing an outer tubing or outer insulator to an inner tubing or inner insulator, wherein the inner insulator is wrapped with wire in a spiral configuration.

FF14 and FF15. Wessman also discloses that the heat fusion takes place under pressure, e.g., shrink-wrapping. FF13 and FF15. In view of Wessman's disclosure, we agree with the Examiner that it would have been obvious to one of skill in the art to use a layer of outer tubing that is sufficiently thin such that heat fusion of the inner and outer layers would result in the spiral pattern of the wire being visible in the outer layer. *See* Ans. 9 (referencing discussion of Donlon). Thus, we affirm the rejection of claim 13 under 35 U.S.C. § 103(a) in view of Hadani and Wessman.

Claim 2

Claim 2 depends from claim 13 and further requires that "at least one opening is provided in the outer tubing at the location of the at least one sensing element to allow an access to the at least one sensing element." Appellants argue that Hadani "does not disclose an outer tubing." App. Br. 13. Appellants argue that Wessman discloses "an outer insulator layer but does not disclose an outer tubing . . . [or] disclose, suggest, or imply any opening." App. Br. 13.

Appellants' arguments are not persuasive. Although Wessman does not disclose the location of electrode placement in the lead, Hadani discloses a tubing with electrodes disposed on the outer surface of the tubing that are connected to wires that run within the tubing. FF10, FF11. Thus, it would have been obvious to one of ordinary skill in the art to connect wires that run between the inner and outer insulating layers, as disclosed in Wessman, to electrodes on the surface of the lead through openings in the outer insulating layer. *See* Ans. 9–10. Thus, we affirm the rejection of claim 2 under 35 U.S.C. § 103(a) in view of Hadani and Wessman.

V.

Issue

The Examiner rejects claim 21 under 35 U.S.C. 103(a) as obvious in view of Sinderby, and further in view of either Hadani or Colson. Final Rej. 6–7; Ans. 2. Claim 21 recites:

> 21. A feeding tube for total parenteral nutrition and/or medicine dosing including at least one inner tubing, at least one lumen, at least one sensing element which includes an electrode, the sensing element being connected to at least one monitoring device by a wiring for internal monitoring of a patient's vital functions, the wiring being at least partially wound in tight contact with a surface of the inner tubing, the inner tubing being at least partially surrounded by an outer tubing in order to cover the inner tubing and the wiring,
>
> wherein the outer tubing and the inner tubing are made from one-piece wherein at least one inner lumen is formed in the center of the feeding tube and at least one outer lumen is formed near the surface of the tubing for guiding and protecting the wiring to be inserted into the at least one outer lumen,
>
> wherein at least one groove is located in the at least one outer lumen which provides a continuous opening in the least one outer lumen to enable a positioning of the wiring in the outer lumen from outside,
>
> wherein the material of the feeding tube is flexible to enable a widening of the groove and an easy positioning of the wiring in the outer lumen by pressing at the outside of the feeding tube.

Findings of Fact

FF16 Sinderby discloses an "electrode catheter using thin metallic threads or wires." Sinderby, Abstract. "[E]mbodiments allow for the efficient mounting of at least one electrode on a catheter, resulting in the creation of a flexible ring-microelectrode." Sinderby, Abstract.

FF17 Figure 9 of Sinderby is shown below:

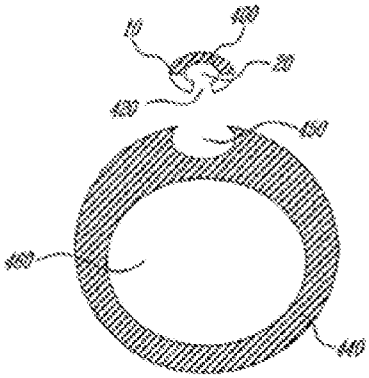

Figure 9 shows "a cross-sectional view of a wire carrier and a host tube." Sinderby ¶ 37. "Wire carrier **400** is formed with a series of transversal indents . . . through which the loop portions **10** can be mounted onto the wire carrier **400**." Sinderby ¶ 81. "The wire carrier **400** also has a longitudinal, inner groove **420** in which the wire portions **20** can be placed." Sinderby ¶ 81. "After the bared wire loop portions **10** have been mounted on the wire carrier **400** and after the insulated wire portions **20** have been placed inside the wire carrier **400**, the wire carrier **400** can be mounted onto a host tube **440**." Sinderby ¶ 82. Sinderby discloses that the tube may be, "for example a nasogastric tube[] with a lumen **460** and a groove **450** adapted to receive the wire carrier **400**." Sinderby ¶ 82. "The wire carrier **400** is secured in the groove **450** using mechanical means such as clipping, glue or any other method known to those of ordinary skill in the art." Sinderby ¶ 82.

Analysis

The Examiner finds that Hadani discloses "including wires (110) in the tube wall (the wires are in wall 122, forming an inner tube and a tight outer tube with the wires between)." Final Rej. 7. The Examiner finds that Sinderby discloses "a similar device including a feeding tube (440 . . .) with a central lumen (460) and a peripheral outer lumen (450) having a groove (the lumen 450 is open to the outside of the tube at a groove . . .)." Final Rej. 7, citing Sinderby ¶ 82 and Fig. 9. The Examiner finds that Sinderby's "wires (20) are placed through the groove into the outer lumen . . . [wherein the] grooved outer lumen would also expand or open if the tube were compressed." Final Rej. 7, citing Sinderby ¶¶ 81–82. The Examiner concludes that it would have been obvious to one of ordinary skill in the art to use Sinderby's "design of a grooved lumen to place the electrodes in the . . . Hadani device, as predictable results would ensue." Final Rej. 7.

Appellants argue that claim 21 requires that "the material of the feeding tube is flexible to enable a widening of the groove and an easy positioning of the wiring in the outer lumen by pressing at the outside of the feeding tube," but Sinderby does not disclose "widening of the groove and positioning of the wiring by pressing at the outside of the feeding tube." App. Br. 19.

Appellants' argument is not persuasive. With respect to "widening of the groove and an easy positioning of the wiring in the outer lumen by pressing at the outside of the feeding tube," we agree with the Examiner that this phrase comprises a product by process limitation. *See* Ans. 11–12. "The patentability of a product does not depend on its method of production.

If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985) (citation omitted).

Sinderby discloses the desirability of generally flexible micro-electrode catheters and that the "wire carrier **400** is secured in the groove **450** using mechanical means such as clipping, glue or any other method known to those of ordinary skill in the art." Sinderby, Abstract and ¶ 82; *see* FF17. Accordingly, we agree with the Examiner that the material of Sinderby's catheter "is sufficiently flexible to be assembled as recited," and that it would have been obvious to one of ordinary skill in the art to provide a groove in an outer lumen of a tubing that is sufficiently flexible to enable positioning of the wiring in the outer lumen by widening of the groove of the outer lumen. *See* Ans. 11–12.

Appellants further argue that Sinderby "positions the wiring in a wire carrier, not the groove as called for by the claim . . . [and] secures the *wire carrier*" in the groove. App. Br. 19. Thus, Appellants argue, "Sinderby teaches away from the claim by positioning wire in a wire carrier and not directly in the groove." App. Br. 19. Appellants' argument is not persuasive.

We do not read claim 21 as requiring "positioning wire . . . directly in the groove," as Appellants contend. *See SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004) ("Though understanding the claim language may be aided by the explanations contained in the written description, it is important not to import into a claim limitations that

are not a part of the claim."). Sinderby discloses positioning both the wire carrier and the associated wire in a groove in tubing. FF17. Hadani discloses securing wire within the wall of tubing. FF11. In view of the combination of the cited references, it would have been obvious to one of ordinary skill in the art to place the wire of Hadani inside a groove in the tubing to facilitate manufacturing of the feeding tube. Thus, we affirm the rejection of claim 21 under 35 U.S.C. § 103(a) in view of Hadani and Sinderby.

The rejection of claim 21 under 35 U.S.C. § 103(a) in view of Colson and Sinderby is cumulative, and affirmed for the same reasons.

SUMMARY

We *reverse* the rejection of claims 3, 7, 10, and 11 under 35 U.S.C. § 102(b) in view of Levin.

We *reverse* the rejection of claim 7 under 35 U.S.C. § 102(b) in view of Van Erp.

We *reverse* the rejection of claims 1, 6, and 10 under 35 U.S.C. § 103(a) in view of Van Erp and Donlon.

We *affirm* the rejection of claims 2 and 13 under 35 U.S.C. § 103(a) in view of Van Erp and Donlon.

We *reverse* the rejection of claims 1, 6, 7, 10, 11, and 14 under 35 U.S.C. § 103(a) in view of Hadani and Wessman.

We *affirm* the rejection of claims 2 and 13 under 35 U.S.C. § 103(a) in view of Hadani and Wessman.

We *affirm* the rejection of claim 21 under 35 U.S.C. § 103(a) in view of Sinderby and Hadani.

We *affirm* the rejection of claim 21 under 35 U.S.C. § 103(a) in view of Sinderby and Colson.

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-IN-PART