

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ROBERT C. STEVENS

Appeal 2008-4426
Application 10/075,053
Technology Center 3700

Decided: January 15, 2009

Before ERIC GRIMES, LORA M. GREEN, and
RICHARD M. LEOVITZ, *Administrative Patent Judges*.

LEOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal from the Examiner's final rejection of claims 1, 3-11, 24, 26-28, 41, 43-61, and 63-65. Jurisdiction is under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

The claims are drawn to a reinforced catheter having a continuous coil reinforcement member carried on an elongate flexible tube. A first flexible

outer coating covers the coil reinforcement member. A second flexible coating covers the first coating at the proximal end, but not the distal end, of the catheter. The first coating is softer than the second coating, providing a soft distal tip to the catheter.

Claims 1, 3-11, 24, 26-28, 41, 43-61, and 63-65 stand rejected by the Examiner as follows:

1. Claims 1, 3, 6-11, 24, 26-28, 41, 43, 46-53, 56-61, and 63-65 under 35 U.S.C. § 103(a) as obvious in view of Nita (US 5,951,539, Sep. 14, 1999) (Ans. 3).

2. Claims 1, 3, 6-11, 24, 26-28, 41, 43, 46-53, 56-61, and 63-65 under 35 U.S.C. § 103(a) as obvious in view of Nita and Landuyt (US 2003/0109851, Jun. 12, 2003) (Ans. 7).

3. Claims 4, 5, 44, 45, 54, and 55 under 35 U.S.C. § 103(a) as obvious in view of Nita and Follmer (US 5,728,065, Mar. 17, 1998) (Ans. 11).

4. Claims 4, 5, 44, 45, 54, and 55 under 35 U.S.C. § 103(a) as obvious in view of Nita, Landuyt, and Follmer (Ans. 12).

Claim 1 is representative of the appealed subject matter and reads as follows:

1. A reinforced catheter comprising:
 - an elongate flexible tubular member defining a lumen of the catheter, the tubular member having a first end defining a proximal end of the catheter and a second end defining a distal end of the catheter;
 - a continuous coil reinforcement member carried on the elongate flexible tubular member and extending from the proximal end of the catheter and terminating at the second end of the tubular member;

a first flexible outer coating covering the coil reinforcement member and the tubular member substantially entirely between the proximal end of the catheter and the distal end of the catheter; and,

a second flexible outer coating covering a first portion of the first outer coating between a first transition area of the catheter and said proximal end of the catheter, a second portion of the first outer coating between said first transition area and said distal end of the catheter being uncovered by said second outer coating and defining a flexible distal tip of said catheter, the first coating being softer than said second coating.

1. OBVIOUSNESS OVER NITA

Claims 1, 3, 6-11, 24, 26-28, 41, 43, 46-53, 56-61, and 63-65 stand rejected under 35 U.S.C. § 103(a) as obvious in view of Nita (Ans. 3).

Issue

The principal issues in this rejection are as follows:

Does Nita describe a catheter comprising a continuous coil reinforcement member carried on a tubular member in which the reinforcement member is “extending” from the first proximal “end” to the second distal “end” of the tubular member as in claim 1?

Does Nita describe a catheter comprising a first and second outer coating in which the first coating covers the catheter’s distal end and is “softer than said second coating” as recited in claim 1?

Findings of Fact (FF)

The Nita patent

1. Nita describes a catheter having two or more spirally wound reinforcement ribbons or wires (Nita, at col. 7, ll. 42-43).

2. Appellant does not dispute the Examiner's findings that Nita's reinforced catheter comprises an elongate flexible tubular member around which are wound reinforcement ribbons, a first flexible outer coating, and a second flexible outer coating as in claim 1.

3. Fig. 5 of Nita, as reproduced below, shows a catheter with wound coils **307** and **309** (depicted in cross-section as broken lines) (Nita, at col. 15, ll. 1-5).

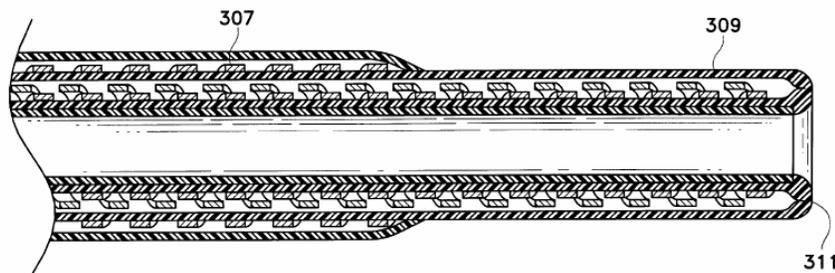


Fig. 5

Fig. 5 is said to show “a variation of the inventive catheter with an additional helically wound coil located proximally” (Nita, at col. 8, ll. 23-24).

4. Nita states that a “small ‘nose’ or distal tip (**311**) of polymer remains distal of the distal-most extension of the coil windings” (Nita, at col. 15, ll. 5-7).

5. Nita also states that “[u]se of layers of coil in excess of the preferred dual layer distal-to-proximal layers is a feature independent of the presence or absence of other features, e.g., the distal nose tip section (**311**), shown in this Figure [5] or in others” (Nita, at col. 15, ll. 7-11).

6. Fig. 9 of Nita, as reproduced below, “shows a distal portion (**520**) of the inventive catheter in which both helically wound coils (**522, 524**) extend distally to a tip or bumper (**526**)” (Nita, at col. 15, ll. 53-55).

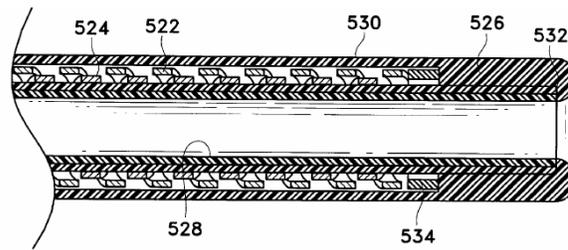


Fig. 9

Fig. 9 is said to show “in cross-section, a highly preferred variation of the distal tip of the inventive catheter” (Nita, at col. 8, ll. 30-31).

7. Nita states that “[f]or the purposes of describing this invention, a short bumper tip (526) is considered to have a negligible effect on the operation of the catheter assembly (other than to protect the intima of the arteries from damage by the coil members)” (Nita, at col. 15, ll. 61-65).

8. Nita also states:

When we note that a coil extends to the distal end of the catheter, we intend such a statement nevertheless to include the presence of such a bumper tip (526). It is specifically noted that, however, the short distal tip (526) shown in FIG. 9 is not the same structural feature as is the comparatively lengthy most-distal section (502) in FIG. 5 [sic, FIG. 8] which, in practice, may be 2.5 cm. or longer. Indeed, the bumper tip (526) may be used in conjunction with most-distal section (502).

(Nita, at col. 15, l. 65 to col. 16, l. 6).

9. In Example 1, Nita describes construction of “an intravascular catheter using the concepts of [its] invention” (Nita, at col. 19, ll. 3-4). The catheter is described as having a coiled reinforcing member attached to both ends of the catheter tubular member:

10. Nita states that the “reinforcing member . . . was secured to the distal end [of the tubing member] using a platinum band” (Nita, at col. 19, ll. 13-15) (emphasis added).

11. “The assembly was rotated in the coil-winder *to wind the ribbon from the distal end to the proximal end*. At the proximal end, the direction of the ribbon wind was changed so that the ribbon was being wound towards the distal end. *The ribbon was wound to the end of the catheter so that a double layer of ribbon was found from distal end to proximal end*” (Nita, at col. 19, ll. 16-23) (emphases added).

12. Nita does not describe a nose or bumper tip at the end of the intravascular catheter of Example 1.

13. In Example 2, Nita describes construction of intravascular catheters with two coils (Nita, at col. 19, ll. 35-39).

14. Nita states that “two ribbons on the inventive catheter (one wound clockwise and one wound counterclockwise) extended from the proximal end to the distal end” (Nita, at col. 19, ll. 48-51).

15. Nita expressly states that “[a] short bumper tip without coil was left on each distal end” (Nita, at col. 19, ll. 54-55).

16. Nita teaches that the distal catheter end must be flexible to allow the tip’s passage through blood vessels (Nita, at col. 2, ll. 10-14) and describes a prior art tip which is “flexible, soft, and floppy” (*id.* at col. 5, ll. 43-45). Nita’s own catheter is said to have a distal section which “is flexible and soft to allow deep penetration . . . without trauma (*id.* at col. 9, ll. 59-61). Nita also states that the “distal-most section” of the covering “is typically the softest and most flexible” (*id.* at col. 12, ll. 48-49; *see* Fig. 2F, 212).

17. Figure 3D of Nita shows a catheter with “four regions of polymer outer covering (**240**, **242**, **244**, and **246**)” (Nita, at col. 14, ll. 37-38). The most proximal portion **240** is comprised of a material which is “most preferably

. . . having a durometer value between 65D and 80D, most preferably 72D” (*id.* at col. 14, ll. 43-44). “Finally, segment (**246**) is located at the most distal end of the catheter and . . . is most flexible, preferably of a material having a durometer value between 20D and 40D, most preferably 25D” (*id.* at col. 14, ll. 51-55).

Analysis

Independent claims 1, 24, 41, 52, 61, and 65 are directed to catheters that carry a coil reinforcement member extending from the proximal end to the distal end of a tubular member. Although the wording in the independent claims varies, Appellant appears to interpret each of the claims to require that the coil member extends and terminates at the ends of the tubular member (Reply Br. 4). Appellant contends that Nita does not meet this limitation. Appellant states:

Rather, the coil reinforcement member as disclosed in Nita is carried in the catheter along the length thereof. It extends to a point near the distal end of the catheter but not to a point fully at the distal end. Essentially, in each of the embodiments of the catheter taught in Nita, some amount of catheter body not containing the coil reinforcement member is present at the tip area.

(Reply Br. 4).

Appellant argues that Nita specifically states that “[w]hen we note that a coil extends to the distal end of the catheter, we intend such a statement nevertheless to include the presence of such a bumper tip” (FF8). Thus, Appellant asserts that “the presence of a bumper tip is specifically included in each of the embodiments of the catheters described in Nita” (App. Br. 16; *see also* FF3-9; Nita, **311** of Fig. 5 and **526** of Fig. 9).

The Examiner contends that Nita teaches embodiments in which the coil extends from the proximal to the distal end (Ans. 3-5; 15). In reaching this conclusion, the Examiner relies on the statement by Nita that the use of coils “in excess of the preferred dual layer distal-to-proximal layers is a feature independent of the presence or absence of other features, e.g., the distal nose tip section (**311**), shown in this Figure [5] or in others” (Nita, at col. 15, ll. 7-11; FF5). The Examiner asserts that this sentence establishes that the distal nose tip section is an optional feature that may be present or absent from Nita’s catheter. When absent, the Examiner contends that Nita’s catheter would meet the claimed limitation of a reinforcement member “extending” from the first proximal “end” to the second distal “end” of the tubular member.

The Examiner has the better argument. Consistent with the Examiner’s interpretation of Nita to refer to the distal nose section as optional (Ans. 15), Example 1 describes a catheter in which “a double layer of ribbon was found from distal end to proximal end” (Nita, at col. 19, ll. 21-23; FF11). Nita does not describe a nose or bumper tip at the end of the intravascular catheter of Example 1 (FF12). In contrast, Nita’s Example 2 expressly describes a catheter having a distal bumper tip without coil (FF15). Thus, the preponderance of the evidence supports the Examiner’s position that Nita describes a catheter that carries an end-to-end coil reinforcement member as required by claim 1.

Appellant argues that the portion of Nita at column 15, lines 7-11, referred to by the Examiner

when properly read in context, means that the use of additional coil layers is a feature independent of the presence or absence of other features, e.g., the *particular/specific* distal nose tip

section (311), shown in this Figure or *the particular/specific distal nose tip sections shown in* other Figures. (emphasis added). The applicants in Nita wanted to be sure to not restrict the use of the additional coil layers on catheters of the type having the distal nose section as shown in Figure 5, but to extend its use to all of the disclosed catheters, regardless of the particular distal nose tip section (or any other feature) present.

(Reply Br. 6.) As Example 1 of Nita expressly describes construction of a catheter which lacks the distal nose section (FF12), we find Appellant's interpretation of what Nita intended to say at column 15, lines 7-11, inconsistent with what the patent as a whole would have taught persons of ordinary skill in the art.

Appellant also contends that the Nita patent does not teach, suggest, or fairly disclose a first coating which is softer than a second coating as recited in claim 1 (App. Br. 20). To the contrary, Nita expressly discloses that the distal section of its catheter, which would correspond to the first coating, is typically the softest section covering the catheter (FF16; *see also* FF17).

For the foregoing reasons, we affirm the rejection of claim 1.

Appellant makes the same arguments for independent claims 24, 41, 52, 61, and 65 as he did for claim 1. We thus, affirm the rejection of these claims for same reasons as for claim 1.

Appellant argues that the specific limitations recited in claims 6-11, 27, 28, 46-51, 54-60, 63, and 64 are not described by Nita (App. Br. 21-24, 26, 30-31, and 34-38). However, the Examiner explicitly identified on pages 5-6 of the Answer where such limitations could be found in Nita. We find no defect in the Examiner's findings and Appellant does not point to any. Thus, we affirm these rejections, as well.

Claims 3, 26, 43, and 53

Claims 3, 26, 43, and 53 specify that the catheter's first outer coating has a Shore hardness of about 40D and the second of about 70D. Appellant argues that

there is no teaching or suggestion in Nita that the layered structure would benefit in any way by providing layers of materials, each having a different Shore hardness as suggested by the Examiner. To the contrary, the problem of providing a stiff proximal end while having a flexible distal end is solved in the banded-type construction by providing "a third layer of ribbon (311)" (col. 15, ln. 2).

(App. Br. 21, 25-26).

This argument is not persuasive. Nita clearly teaches providing distal and proximal sections of its catheter with coatings that meet the claimed limitations of about 40D (distal segment 246) and 70D (proximal portion of "most preferably 72D") (FF17). Appellant does not challenge the Examiner's finding that Nita's distal and proximal sections correspond to the first and second covering, respectively (*see* Ans. 5). Nita provides a clear reason as to why the distal section should be more flexible and thus have a lower Shore hardness: to allow deep penetration without trauma to the tissue (FF16). Thus, contrary to Appellant's position, Nita does provide a reason as to why there would be a benefit of using layers with differing hardnesses.

2. NITA AND LANDUYT

Claims 1, 3, 6-11, 24, 26-28, 41, 43, 46-53, 56-61, and 63-65 stand rejected under 35 U.S.C. § 103(a) as obvious in view of Nita and Landuyt (Ans. 7).

The Examiner relies further on Landuyt for its teaching of “a catheter having a first coating (11) and a second coating (12) covering a first portion of the first coating between a first transition area of the catheter and the proximal end of the catheter” (emphasis removed) (Ans. 11). The Examiner concludes that it

would have been obvious . . . to choose the first coating of Nita et al to be softer than the second coating as taught by Landuyt **as both Nita et al and Landuyt disclose that it is desirable to have the proximal portion of the catheter be more stiffer than the distal portion and Landuyt teach the use of a harder material for the second coating to achieve the desired stiffness while still maintaining a softer distal portion.**

(Id.)

Appellant contends that the rejection is improper for the same reason as for Nita alone (App. Br. 18-19). As we did not find these arguments persuasive for Nita, and Appellant does not identify any deficiency in the Examiner’s rejection of the claims over the combination of Nita and Landuyt, we affirm the rejection for the reasons stated by the Examiner.

3, 4. NITA, FOLLMER, AND LANDUYT

Claims 4, 5, 44, 45, 54, and 55 stand rejected under 35 U.S.C. § 103(a) as obvious in view of Nita and Follmer (Ans. 11).

Claims 4, 5, 44, 45, 54, and 55 stand rejected under 35 U.S.C. § 103(a) as obvious in view of Nita, Landuyt, and Follmer (Ans. 12).

Claim 4 is directed to the reinforced catheter of claim 1 further comprising “a marker band disposed adjacent the distal end of the catheter on the first flexible outer coating.” Claim 5 is drawn to the “reinforced

catheter according to claim 4, wherein the marker band is formed of a one of gold material and platinum material.”

The Examiner states that, in view of the teachings of Nita and Follmer, it “would have been obvious to . . . place the marker band of Nita et al on the outer coating as taught by Follmer et al as both Nita et al and Follmer et al teach that it is desirable to provide catheters with marker bands and Follmer et al teach that the marker bands can be placed on the outer coating of the catheter” (Ans. 12-13). We agree with the Examiner’s reasoning, and as Appellant does not identify any defect in it, we affirm the rejection of claims 4 and 5 for the reasons stated by the Examiner.

Appellant argues that the specific limitations recited in claims 44, 45, 54, and 55 are not described by Nita or Nita in combination with the cited references (App. Br. 29-34). However, the Examiner explicitly identified on pages 5-6 of the Answer where such limitations could be found in Nita. We find no defect in the Examiner’s findings and Appellant does not point to any.

CONCLUSION OF LAW

Nita describes a catheter comprising a continuous coil reinforcement member carried on a tubular member in which the reinforcement member is “extending” from the first proximal “end” to the second distal “end” of the tubular member as in claim 1, and independent claims 24, 41, 52, 61, and 65. Nita also describes a catheter comprising a first and second outer coating in which the first coating covers the catheter’s distal end and is “softer than” the second coating as in claim 1, and independent claims 24, 41, 52, 61, and 65. We affirm the rejection of claims 1, 24, 41, 52, 61, and 65 in view of Nita, alone, and Nita in combination with Landuyt.

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Appellant did not distinguish the specific limitations recited in claims 3, 6-11, 26-28, 43, 46-51, 53-60, 63, and 64 from Nita, alone, or Nita in combination with Landuyt. We affirm the rejection of these claims.

Appellant also did not distinguish the specific limitations recited in claims 4, 5, 44, 45, 54, and 55 from Nita and Follmer or Nita, Landuyt, and Follmer. We affirm the rejection of these claims.

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).

AFFIRMED

LP

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