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Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO. Includes details for application 10/234,070, inventor Kristoff Nelson, and attorney VIDAS, ARRETT & STEINKRAUS, P.A.

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte KRISTOFF NELSON

Appeal 2012-000239
Application 10/234,070
Technology Center 3700

Before TONI R. SCHEINER, ERIC GRIMES, and STEPHEN WALSH,
Administrative Patent Judges.

GRIMES, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a stent/graft delivery system. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

The Specification discloses “a stent/graft composite prosthesis and a deployment device” (Spec. 4). Figure 1 of the Specification is shown below:

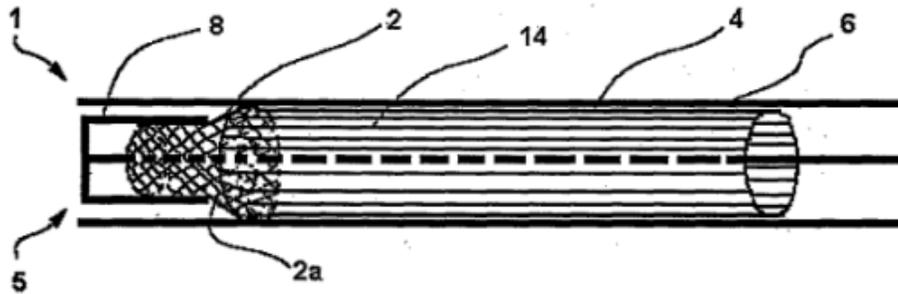


Figure 1 shows “a stent/graft composite prosthesis 14 and a stent retaining device 5” (Spec. 6). The prosthesis 14 includes graft 4 and stent 2 (*id.*). The Specification discloses that the “deployment device 5 ... includes an elongated outer sheath 6 which supports the prosthesis 14 in a compressed condition” (*id.* at 8), as well as “a stent retaining member in the form of a nose cap 8, which supports extending portion 2a of stent 2 in [a] compressed condition within outer sheath 6” (*id.*).

The Specification states that the stent/graft is deployed by retracting outer sheath 6 to allow stent 2 and graft 4 to expand, while “nose cap 8 holds the proximal [sic, distal?] end of the stent 2 so it can be repositioned” (*id.* at 9). The nose cap 8 can then be advanced away from the stent, allowing stent portion 2a to expand, after which the nose cap can be retrieved through the lumen of the expanded stent/graft (*see id.* at 10).

Claims 1-9, 11, 12, and 51-53 are on appeal. Claim 1 and 51 are representative and read as follows:

1. A prosthesis delivery system comprising:
 - a stent/graft composite prosthesis comprising a radially expandable stent having opposed proximal and distal stent ends and a stent body therebetween, and an elongated graft extending from said distal stent end; and
 - a deployment device comprising:
 - an elongated outer sheath, the outer sheath overlying the graft and said distal stent end of said prosthesis, the outer sheath maintaining said

overlayed portions of said prosthesis in a radially compressed state, said outer sheath being retractable with respect to said graft for allowing radial expansion of said graft and said distal stent end; and

a stent retaining member, the stent retaining member overlying and engaging said proximal stent end, the stent retaining member maintaining said proximal stent end in a radially compressed state independent of the outer sheath, said proximal stent end is positionable within said stent retaining member, said retaining member being independently removable from said proximal stent end for allowing radial expansion of said proximal stent end independent from the expansion of said distal stent end, wherein said stent retaining member is positionable within said elongated outer sheath and wherein said stent retaining member is retractable in the opposite direction of retraction of said outer sheath.

51. A delivery system comprising:

a retaining device, the retaining device comprising a first retaining member and a second retaining member;

a prosthesis, the prosthesis comprising a first end region and a second end region, the first end region being a stent and a second end region being a graft, the prosthesis having a first state and a second state;

in the first state the stent has a reduced diameter and the graft has a reduced diameter wherein the first retaining member surrounds a first portion of the stent and maintains at least the first portion of the stent in the reduced diameter and the second retaining member surrounds a second portion of the stent and the graft and maintains the second portion of the stent and the graft in a reduced diameter; and

in the second state the first portion of the stent has a reduced diameter and the second portion of the stent and the graft have an expanded diameter which is greater than the reduced diameter, wherein the first retaining member surrounds the first portion of the stent and maintains the first portion of the stent in a reduced diameter, the second retaining member does not overlay the prosthesis, and no portion of the second end region of the prosthesis is surrounded by any portion of the retaining device.

The claims stand rejected under 35 U.S.C. § 103(a) as follows:

- Claims 1-7, 11, and 12 in view of Ryan¹ and Brown;²
- Claim 8 in view of Ryan, Brown, and Ravenscroft;³
- Claim 9 in view of Ryan, Brown, and Roberts;⁴ and
- Claims 51-53 in view of Ravenscroft and Brown.

I.

The Examiner has rejected claims 1-7, 11, and 12 under 35 U.S.C. § 103(a) as obvious in view of Ryan and Brown. The Examiner has also rejected claims 8 and 9 as obvious in view of Ryan and Brown, combined with Ravenscroft or Roberts, respectively. Since the same issue is dispositive for all of these rejections, we will consider them together.

The Examiner finds that Ryan discloses “a prosthesis delivery system comprising a catheter 10, self or balloon expandable stent 24, slidable sheath retaining member 92 ... and [a] proximal stent end retaining member 40 that is [sic] moves independent from and in opposite direction of the sheath” (Answer 5). The Examiner finds that Ryan does not disclose “delivering an implant comprising a stent extending from a graft” (*id.* at 6), but that Brown discloses such an implant (*id.*). The Examiner concludes that it would have been obvious to use Ryan’s device “to deliver the device of Brown in order to reduce the implant[']s profile while ... permitting it to be placed within more areas of patient’s vascular” (*id.*).

¹ Ryan et al., US 5,108,416, issued Apr. 28, 1992.

² Brown et al., US 5,769,887, issued June 23, 1998.

³ Ravenscroft et al., US 5,480,423, issued Jan. 2, 1996.

⁴ Roberts et al., US 5,984,964, issued Nov. 16, 1999.

Appellant contends that the cited references would not have made obvious a prosthesis delivery system in which the “stent retaining member is retractable in the opposite direction of retraction of said outer sheath,” as required by claim 1, because Ryan’s “sheath 92 and end cap 26 are retracted in the same direction” (Appeal Br. 11-12).

We agree with Appellant that the Examiner has not adequately shown that the cited references would have made obvious the prosthesis delivery system of claim 1. Ryan discloses a “system for introducing a stent ... [which] comprises a balloon catheter having a stent surrounding the balloon portion of the catheter” (Ryan, abstract). Figure 4 of Ryan is shown below:

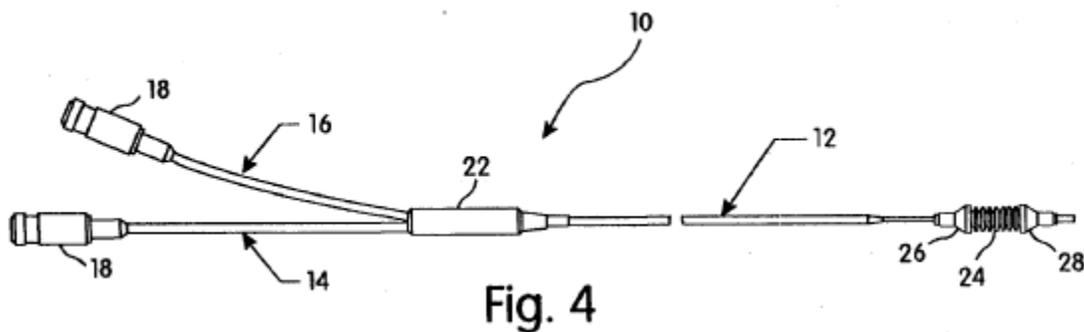


Figure 4 shows “a multi lumen catheter shaft **12**, having a balloon **20** (concealed), mounted at the distal end of the shaft.... A stent **24** ... surrounds the balloon and is retained in position by end caps **26**, **28** which receive and capture the proximal and distal ends of the stent” (*id.* at col. 5, ll. 24-26, 39-42). Ryan discloses that inflation of the balloon **20** causes radial expansion of the stent **24** and “also causes end caps **26**, **28** to be urged radially and axially away, in umbrella-like fashion from the center of the balloon, so that they retract and release the stent **24**” (*id.* at col. 5, ll. 55-60). Ryan discloses that “[o]nce the balloon **20** and end caps **26**, **28** have returned to their initial, non-retracted configuration, they have a cross-sectional

diameter which is less than that of the interior diameter of the expanded stent. The delivery catheter can then be withdrawn.” (*Id.* at col. 5, l. 67 to col. 6, l. 3.)

Figure 14 of Ryan is shown below:

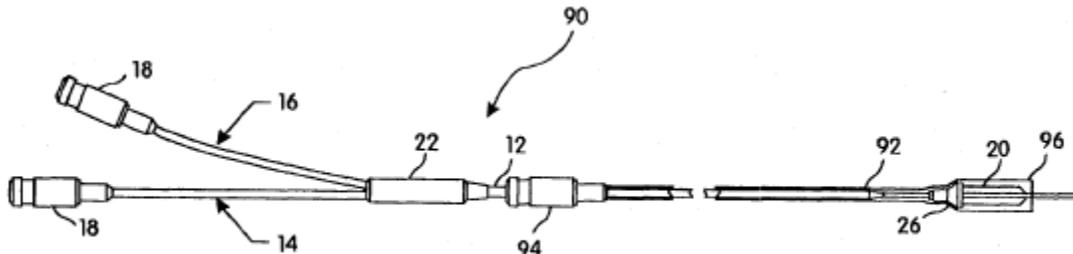


Fig. 14

Figure 14 shows an “embodiment of the stent delivery system employing a proximal end cap and a retractable sheath” (*id.* at col. 3, ll. 45-47). Ryan discloses that the “distal end **96** of the sheath has a diameter large enough to surround end cap **26** and the stent prior to stent expansion” (*id.* at col. 10, ll. 18-20). Ryan discloses that after the catheter distal end is positioned at the desired location, the physician “slides the hub **94** toward the Y-fitting [22]. In so doing, the distal end of the sheath is withdrawn from the distal end of the introducer, thereby exposing the stent.” (*Id.* at col. 10, ll. 24-29.)

Thus, the embodiment shown in Ryan’s Figure 4 lacks an outer sheath, as required by claim 1, and the embodiment shown in Ryan’s Figure 14 includes a proximal end cap (26) (or “stent retaining member,” in claim 1), which is retracted in the same direction as the sheath. Even if the two embodiments of Ryan’s were combined, and included a distal end cap that could be retracted in the opposite direction from the sheath, the Examiner has not explained how such a system could be modified to contain a graft extending from one end of the stent, as required by claim 1, if both ends of

the stent are covered by end caps. Thus, we reverse the rejection of independent claim 1 and dependent claims 2-7, 11, and 12.

We also reverse the rejections of claims 8 and 9 because these rejections rely on the findings with respect to Ryan and Brown, as discussed above, and the Examiner relies on Ravenscroft and Roberts only to show the obviousness of limitations in dependent claims.

II.

The Examiner has rejected claims 51-53 as obvious in view of Ravenscroft and Brown. The Examiner finds that Ravenscroft discloses “a prosthesis delivery system comprising [a] prosthesis and first and second retaining devices” (Answer 9). The Examiner finds that Ravenscroft’s system achieves the first and second states recited in claim 51 (*id.*) but Ravenscroft does not disclose “an implant comprising a stent extending from a graft” (*id.*).

The Examiner finds that “Brown discloses an implant comprising a stent extending from a graft member” (*id.*). The Examiner concludes that it would have been obvious to use Ravenscroft’s system “to deliver the device of Brown in order to reduce the implant[’]s profile while retaining its anchor” (*id.*).

Appellant contends that Ravenscroft does not disclose two retaining members that surround portions of the stent, as required by claim 51 (Appeal Br. 19). Appellant argues that the dictionary defines the word “surround” to mean “to enclose on all sides; encompass” or “to form an enclosure round; encircle” (*id.* at 18), while in Ravenscroft the relevant elements “do not **surround** the distal end of the stent because the end members do not

encircle, and are not positioned around the circumference of, the distal end of the stent” (*id.* at 20).

We agree with Appellant that the Examiner has not adequately shown that the cited references would have made obvious a delivery system with first and second retaining members that each surrounds a portion of the stent. Ravenscroft discloses “a system for positioning a prosthesis in contact with tissue within a patient” (Ravenscroft, col. 1, ll. 47-48). Figure 2A of Ravenscroft is shown below:

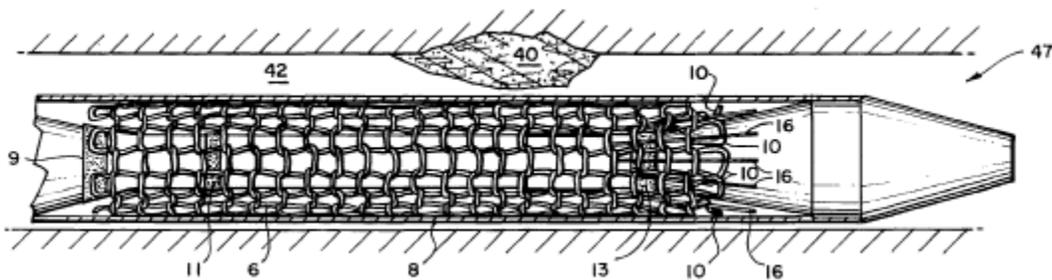


Figure 2a shows a catheter body “carrying a prosthesis **6**, which is held in a compact state for most of its length by a retractable restraining sheath **8**. The prosthesis **6** is a self-expanding knit-form stent having a series of end loops **10**” (*id.* at col. 4, ll. 17-20).

Ravenscroft discloses that the catheter body “includes a series of flexible elongate members **16**” (*id.* at col. 4, ll. 20-22) and that “[o]ne end of the members **16** is attached to the catheter body **4**. The other, free end ... extends through the end loops **10**, holding the end loops ... in compact form” (*id.* at col. 4, ll. 23-28). Ravenscroft discloses that the “end loops **10** of the prosthesis **6** can be released from the catheter body ... by axially withdrawing the catheter body **4** so the free ends **17** of the members **16** slip back through the end loops **10**” (*id.* at col. 4, ll. 29-35).

The Examiner finds that the struts 16 and sheath 8 of Ravenscroft correspond to the first and second retaining members of claim 51, respectively (Answer 10). However, we agree with Appellant that one of ordinary skill in the art would not interpret a first retaining member that “surrounds a first portion of the stent” as encompassing the stent-retaining struts 16 of Ravenscroft. The Specification does not provide an express definition of “surrounds,” which is therefore given its ordinary and customary meaning. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (“[T]he words of a claim ‘are generally given their ordinary and customary meaning.’”). The Examiner does not dispute that “surrounds” has the meaning of the dictionary definitions provided by Appellant, but argues that the “nose cone struts of Ravenscroft comprise a plurality of strut members that extend around the entire circumference of the catheter. The struts are separated by gaps, but all of the struts combined surround a portion of the stent.” (Answer 12.)

We disagree. As best shown in Ravenscroft’s Figures 2b-2e (*see also id.* at col. 4, ll. 15-35), the struts 16 of Ravenscroft’s device lie inside of the stent except for the free ends that extend through the stent’s end loops 10. Since the elongated struts of Ravenscroft do not circumscribe the exterior of the stent, they do not “enclose [it] on all sides; encompass” or “form an enclosure round; encircle” the stent (*cf.* Appeal Br. 18). Therefore, they do not “surround” a portion of the stent according to the ordinary meaning of the word. We reverse the rejection of independent claim 51 and dependent claims 52 and 53 as being obvious in view of Ravenscroft and Brown.

Appeal 2012-000239
Application 10/234,070

SUMMARY

We reverse the rejections of claims 1-9, 11, 12, and 51-53 under 35
U.S.C. § 103(a).

REVERSED

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