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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte RICHARD S. KUSLEIKA and BROOKE REN

Appeal 2012-000201
Application 11,972,778
Technology Center 3700

Before DEMETRA J. MILLS, ERIC GRIMES, and FRANCISCO C. PRATS, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to embolic protection devices. The Examiner has rejected the claims as anticipated and obvious. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

During treatments like balloon angioplasty, “particulate debris can be generated at the treatment site. Infarcts, strokes, and other major or minor adverse events are caused when debris embolizes into vasculature from the treatment site.” (Spec. 1, ¶ 3.) The Specification discloses “an embolic

protection device for removing emboli from a blood vessel in a patient's body comprising a mesh element being expandable from a collapsed configuration to an expanded configuration" (*id.* at 2, ¶ 8).

Claims 1, 3-47 and 49-70 are on appeal. Claims 24 and 63 are representative and read as follows:

24. An embolic protection device for removing emboli from a blood vessel in a patient's body, comprising:
a mesh element being expandable from a collapsed configuration to an expanded configuration;

an elongate tubular element having a proximal end having a proximal opening, a distal end having a distal opening, and a lumen between the proximal and distal openings, the lumen having a diameter large enough to slideably accommodate a standard guidewire; and

an elongate shaft having no lumen, the elongate shaft being attached to the proximal end of the elongate tubular element,

the mesh element being disposed on the elongate tubular element and the mesh element being attached to a proximal band and a distal band, the bands being coupled to the elongate tubular element, and one of the proximal and distal bands being fixed to the elongate tubular element and one of the proximal and distal bands being slidable on the elongate tubular element.

63. An embolic protection device for removing emboli from a blood vessel in a patient's body, comprising:

a mesh element being expandable from a collapsed configuration to an expanded configuration;

a first elongate tubular element having a proximal end having a proximal opening, a distal end having a distal opening, and a lumen between the proximal and distal openings, the lumen having a diameter large enough to slideably accommodate a standard guidewire; and

a second elongate tubular element having a proximal end having a proximal opening, a distal end having a distal opening, and a lumen between the proximal and distal openings, the lumen having a diameter large enough to slideably accommodate a standard guidewire,

a distal region including the distal end of the second elongate tubular element being disposed in a portion of the lumen of the first elongate tubular element,

a first portion of the mesh element being fixed to the first elongate tubular element and a second portion of the mesh element being fixed to the second elongate tubular element, the mesh element being expandable from a collapsed configuration to an expanded configuration by movement of the first and second elongate tubular elements relative to each other.

The claims stand rejected as follows:

- Claims 24-29 under 35 U.S.C. § 103(a) in view of Clubb,¹ Wasicek² and Linder;³
- Claims 1, 3-16, 18-23, 31, 32, 34, 44-47, 49, 50, and 52-55 under 35 U.S.C. § 103(a) in view of Clubb, Wasicek, Linder and Boyle;⁴
- Claim 17 under 35 U.S.C. § 103(a) in view of Clubb, Wasicek, Linder, Boyle and McGuckin;⁵
- Claims 30, 33, and 35-41 under 35 U.S.C. § 103(a) in view of Clubb, Wasicek, Linder, Boyle and Berrada;⁶
- Claims 42 and 43 under 35 U.S.C. § 103(a) in view of Clubb, Wasicek, Linder, Boyle and Maahs;⁷
- Claim 51 under 35 U.S.C. § 103(a) in view of Clubb, Wasicek, Linder, Boyle and Hanson;⁸

¹ Clubb et al., US 2004/0153118 A1, Aug. 5, 2004

² Wasicek et al., US 2006/0229657, Oct. 12, 2006

³ Linder et al., US 2006/001541 A1, Jan. 19, 2006

⁴ Boyle et al., US 2003/0144685 A1, July 31, 2003

⁵ McGuckin, Jr. et al. US 2005/0004597 A1, Jan. 6, 2005

⁶ Berrada et al., US 2003/0176884 A1, Sept. 18, 2003

⁷ Maahs, US 6,743,246 B1, June 1, 2004

⁸ Hanson et al., US 2002/0042626 A1, Apr. 11, 2002

- Claims 56-59 and 61 under 35 U.S.C. § 103(a) in view of Clubb, Wasicek and Boyle;
- Claims 60 and 62 under 35 U.S.C. § 103(a) in view of Clubb, Wasicek, Boyle and Berrada;
- Claims 63, 64, and 66-70 under 35 U.S.C. § 102(b) in view of Berrada; and
- Claim 65 under 35 U.S.C. § 103(a) in view of Berrada and Chin.⁹

I.

The Examiner has rejected claims 1, 3-47, and 49-62 as obvious based on Clubb and Wasicek, further combined with at least one of Linder, Boyle, Berrada, McGuckin, Maahs, and Hanson. Since the same issue is dispositive for all of these rejections, we will consider them together.

All of the rejected claims are directed to embolic protection devices that comprise, among other things, an elongate tubular element, with a mesh element disposed on it, and comprising a lumen with a “diameter large enough to slideably accommodate a standard guidewire.” (*See* claims 1, 24, 27, and 56.)

The Examiner finds that Clubb discloses an embolic protection device comprising “a mesh element (20) being expandable from a collapsed configuration to an expanded configuration; an elongate tubular (25) element; and the mesh element being disposed on the elongate tubular element” (Answer 7), but does not disclose that its tubular element has a lumen to slidably accommodate a standard guidewire (*id.*). The Examiner

⁹ Chin et al., US 2002/0042628 A1, Apr. 11, 2002

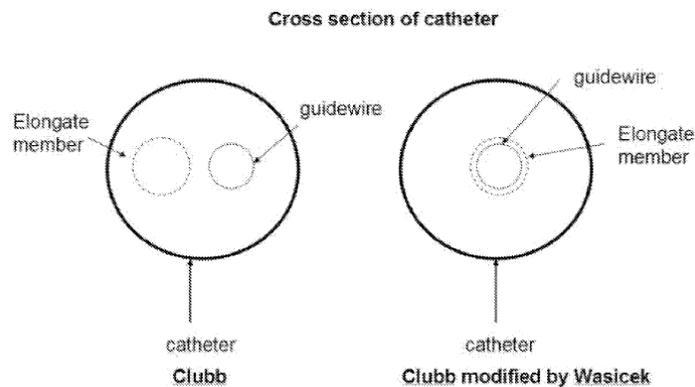
finds that Wasicek discloses a filter device in which “a guide wire (30) slidably passes through the lumen of an elongate tubular element (40)” (*id.*), and concludes that it would have been obvious to modify Clubb’s device “with a guide wire in the lumen of the elongate tubular member to reduce the space necessary for a guide wire thus reducing the overall profile of the device” (*id.* at 7-8).

Appellants argue that it would not have been obvious for one of skill in the art to combine Wasicek’s co-axial guidewire with Clubb’s device because “the methods of use taught by Clubb describe the use of the device of Clubb with a separate guidewire or not using a guidewire at all. Thus, there is no motivation to modify the elongate support member of the device of Clubb to include a guidewire lumen.” (Appeal Br. 13.)

We agree with Appellants that the Examiner has not provided adequate reason for concluding that Wasicek would have made it obvious to modify Clubb to include a lumen with a “diameter large enough to slideably accommodate a standard guidewire,” as claimed. The Examiner points to element 25 of Clubb’s device as corresponding to the claimed elongate tubular element (Answer 7). Clubb describes element 25 of its device as “elongate support member **25**” (Clubb 5, ¶ 0056). Clubb states that the “elongate support member is structurally similar to a traditional guidewire in some respects. However, it is not used as a means of navigating the patient’s vascular system and, therefore, does not need to be provided with all of the features of flexibility and steerability as does a traditional guidewire.” (*Id.* at 2, ¶ 0029.) The Examiner has not pointed to evidence in

Clubb that would indicate that elongate support member 25 has a lumen at all, even if it was too small to accommodate a standard guidewire.

The Examiner reasons, however, that Clubb teaches that “a catheter containing the filter may be advanced over the guidewire to the target.... Thus the guidewire would run side by side inside the catheter with the filter device.” (Answer 23.) The Examiner concludes that modifying Clubb’s device to have a coaxial arrangement a guidewire inside an elongate shaft, as taught by Wasicek, would reduce the profile of the device and prevent entanglement of the components (*id.* at 23-24). The Examiner provides the following diagram to illustrate:



(*Id.* at 24.) The diagram shows two cross-sections of a catheter, one (“Clubb”) in which a guidewire and elongate member are side-by-side and another (“Clubb modified by Wasicek”) in which the guidewire is inside an elongate member, which itself is inside a catheter.

The Examiner, however, has not provided an adequate basis for the finding that Clubb actually discloses a device in which an elongate member and a guidewire run side-by-side within a catheter. The Examiner points to Clubb’s paragraph 29 as support for this finding (Answer 23). That paragraph states that

[i]n a typical procedure ..., the elongate support member and filter are loaded into an introducing sheath or catheter and moved ... through the catheter to the treatment site. This is done typically by advancing a first, or introduction guidewire, through the vessel to the region of interest. A catheter is advanced over the guidewire to the region of interest, and the guidewire removed. Then the filter or other functional device carried by the elongate support member is advanced down a catheter sheath to the region of interest but within the catheter.

(Clubb 2, ¶ 0029.)

Clubb also states that “[a]lternatively, the filter is preloaded into a catheter and ... they are together advanced through the vessel to the region of interest without using an initial guidewire” (*id.*). Finally, Clubb states that,

[i]n a second alternative, an introduction guidewire is advanced to the region of interest, and the filter (contained in a catheter) is advanced over the guidewire to the region of interest ... In this embodiment the filter is not comprised of an elongate support member ..., and the guidewire and/or filter may be configured to preserve a spatial relationship between the guidewire and the filter.

(*Id.*)

None of these embodiments describes a system that includes a guidewire that is side-by-side with an elongate member within a catheter. The Examiner has not pointed to any other disclosure in Clubb that supports the finding that Clubb discloses this feature.

The Examiner’s reason for combining Clubb and Wasicek is based on the finding that Clubb discloses a guidewire running side-by-side an elongate member of a filter device inside a catheter. Because the Examiner’s basis for rejecting claims 1, 3-47, and 49-62 in view of Clubb, Wasicek and the other cited references is based on this erroneous finding, we

are compelled to reverse the rejections under 35 U.S.C. § 103(a) based on Clubb and Wasicek.

II.

The Examiner has rejected claims 63, 64, and 66-70 as anticipated by Berrada, and has rejected claim 65 as obvious in view of Berrada and Chin. The same issue is dispositive for both rejections.

The Examiner finds that Berrada discloses an embolic device that comprises all of the claimed elements, including “a distal region including the distal end of the second elongate tubular element (104) being disposed in a portion of the lumen of the first elongate tubular element (102)” (Answer 5).

Appellants argue that Berrada’s device does not comprise this limitation because, although Berrada’s “distal shaft 104 ... is disposed within a lumen of proximal shaft 102 ... the distal end of distal shaft 104 is not disposed within the lumen of proximal shaft 102” (Appeal Br. 9).

We agree with Appellants that the Examiner has not adequately shown that Berrada’s device has “a distal region including the distal end of the second elongate tubular element being disposed in a portion of the lumen of the first elongate tubular element.” Figure 4C of Berrada is shown below:

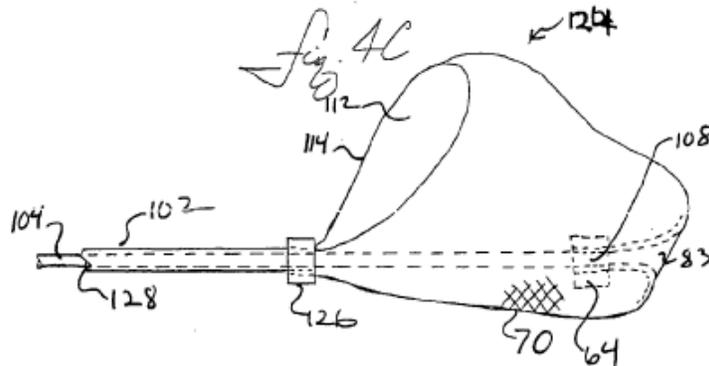


Figure 4C shows “an everting filter device **124** including filter body **70** secured to distal shaft **104** at distal region **108** with distal ring **64**” (*id.* at 7, ¶ 0092). Berrada discloses that “distal shaft **104** is disposed within a lumen **128** within proximal shaft **102**. Proximal shaft **102** may be seen to terminate distally at a proximal ring **126**.” (*Id.*) Berrada discloses that “the degree of eversion of filter body **70** may be controlled by slidably translating distal shaft **104** within proximal shaft **102**” (*id.*).

As shown in Figure 4C above, the distal end of distal shaft 104 is encircled by a distal ring 64 that secures the filter body to distal shaft 104. Distal ring 64 thus would prevent the distal end of distal shaft 104 from being disposed within the lumen of proximal shaft 102, even when distal shaft 104 was translated proximally. Thus, the Examiner has not pointed to an adequate basis to support the finding that Berrada’s device includes a second elongate tubular element having its distal end disposed in the lumen of a first elongate tubular element, as required by claim 63.

The Examiner’s reasoning that “a portion of the distal end of the distal shaft 104 is in fact inside the lumen of proximal shaft 102” and that the term “distal end” is not “limited to the very distal edge or plane of the shaft” (Answer 22), is not persuasive. “[D]uring examination proceedings, claims are given their broadest reasonable interpretation consistent with the specification.” *In re Hyatt*, 211 F.3d 1367, 1372 (Fed. Cir. 2000). Claim 63 states that the distal shaft has “distal end” as well as a “distal region including the distal end.” In view of the claim language distinguishing between the distal end itself and a distal region that includes the distal end, the Examiner’s interpretation of the claim term “distal end” as encompassing

Appeal 2012-000201
Application 11/972,778

a portion of the distal region other than the end itself is not reasonable. We reverse the rejection of claim 63 and dependent claims 64 and 66-70 as anticipated by Berrada. For the same reason, we also reverse the rejection of claim 65 as obvious in view of Berrada and Chin.

SUMMARY

We reverse all of the rejections on appeal.

REVERSED

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