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**Datasheet for the decision
of 30 April 2024**

Case Number: T 2216/22 - 3.2.01

Application Number: 11704362.0

Publication Number: 2536357

IPC: A61F2/24

Language of the proceedings: EN

Title of invention:

CATHETER ASSEMBLY WITH VALVE CRIMPING ACCESSORIES

Patent Proprietor:

Medtronic Vascular Inc.

Opponent:

Edwards Lifesciences Corporation

Headword:

Relevant legal provisions:

EPC Art. 123(2), 54

Keyword:

Amendments - extension beyond the content of the application
as filed (no)

Novelty - main request (yes)

Decisions cited:

Catchword:



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Case Number: T 2216/22 - 3.2.01

D E C I S I O N
of Technical Board of Appeal 3.2.01
of 30 April 2024

Appellant: Medtronic Vascular Inc.
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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
18 July 2022 concerning maintenance of the
European Patent No. 2536357 in amended form.**

Composition of the Board:

Chairman G. Pricolo
Members: A. Wagner
S. Fernández de Córdoba

Summary of Facts and Submissions

- I. The appeal of the patent proprietor lies against the decision of the Opposition Division concerning the maintenance of Patent No. 2536357 in amended form according to auxiliary request 3.
- II. In its decision, the Opposition Division held among others that the patent as granted contravenes the requirement of Article 100(c) EPC and that auxiliary request 1, filed during oral proceedings, does not meet the requirements of Article 54 EPC. Auxiliary request 2 was not admitted into opposition proceedings.

In order to come to these conclusions the opposition division considered, among others, the following documents:

D0": WO 2011/102968 A1 (publication of the original application of the patent in suit)

D14: WO 2004/071352 A1

- III. Oral proceedings by videoconference were held before the Board on 30 April 2024.
- IV. The appellant (patent proprietor) requested that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of auxiliary requests 1 (now main request) filed with the statement of grounds of appeal.

The opponent withdrew with letter dated 25 May 2023 their opposition and is no longer a party to the

proceedings.

V. Claim 1 of the main request on file reads as follows (feature numbering as used by the appellant).

F1 A catheter (100) for delivering an expandable prosthesis, the catheter (100) comprising:

F2 a handle assembly (102)

F2.1 including a rotatable distal control knob (112) and

F2.2 a rotatable proximal control knob (110),

F2.3 wherein the control knobs (112, 110) are secured to the handle assembly (102) to prevent axial movement thereof while permitting rotation of the control knobs (112, 110) around a longitudinal axis of the handle assembly (102);

F3 a distal tip assembly including (104) a first sleeve (126) and a second sleeve (204);

F4 a first elongate member (206) extending from the handle assembly (102), wherein the first elongate member (206) has a proximal end and a distal end and the first sleeve (126) is connected to the distal end of the first elongate member (206); and

F5 a second elongate member (106) extending from the handle assembly (102), wherein the second elongate member (106) has a proximal end and a distal end and the second sleeve (204) is connected to the distal end of the second elongate member (106),

F6 wherein the rotatable distal control knob (112) is connected to the first elongate member (206), and wherein the catheter (100) is configured so that

rotation of the rotatable distal control knob (112) moves the first sleeve (126) in an axial direction, and

F7 wherein the rotatable proximal control knob (110) is connected to the second elongate member (106), and wherein the catheter (100) is configured so that rotation of the rotatable proximal control knob (110) moves the second sleeve (204) in an axial direction.

VI. The appellant's (patent proprietor's) arguments relevant to the present decision may be summarized as follows:

Added subject-matter

The wording of feature 2.3 that "*the control knobs (112, 110) are secured to the handle assembly (102) to prevent axial movement thereof*" which was added during examination found basis in D0", paragraph [0032], page 9, line 10. The opposition division erred in its decision, point 2.1.4 with regard to the patent as granted, in concluding that the first elongate members needed to be defined as a guide wire shaft and the second elongate members needed to be defined as an outer delivery shaft. The specific shafts were not functionally related to the control knobs being prevented from axial movement. This became clear from the last sentence of paragraph [0032] referring to alternative mechanisms that could be used in the claimed delivery catheter.

Novelty over D14

The conclusion of the opposition division with regard to auxiliary request 1 underlying the impugned decision (point 3.3.4) that D14 disclosed a distal knob that

upon rotation moved a first sleeve was wrong. The claim wording required a relative movement of the first sleeve over at least one feature of the delivery catheter. However, in D14, upon rotation of knob 120 (figure 28), the whole delivery catheter including the alleged first sleeve (nose cone in figure 11) moved. In D14, the movement took place in relation to additional elements not being part of the delivery catheter, i. e. the guide catheter 30 (D14, page 20, lines 14 to 16).

Reasons for the Decision

1. Article 123(2) EPC

1.1 The main request (filed as auxiliary request 1 with the statement of grounds of appeal) meets the requirements of Article 123(2) EPC.

1.2 The patent in suit was originally filed as an international application published as WO 2011/102968 A1 (D0"). During examination, the wording in feature F2.3 "*wherein the control knobs (112, 110) are secured to the handle assembly (102) to prevent axial movement thereof*" was added to original claim 1.

1.3 The opposition division held (decision, points 2.1.3, 2.1.4) that based on the disclosure of D0", paragraph [0032], the following features were omitted in an unallowable manner in claim 1 as granted:

b) rotation of the control knobs around the longitudinal axis of the handle assembly is permitted,

c) the first elongate member is a guide wire shaft and the second elongate member is an outer delivery shaft.

1.4 Claim 1 of the main request is limited over claim 1 as granted by reciting the feature "while permitting rotation of the control knobs (112, 110) around a longitudinal axis of the handle assembly (102)" and thus solves issue b. With regard to issue c, the Board does not follow the findings of the opposition division.

1.4.1 Feature F2.3 finds basis in paragraph [0032]. It is true that paragraph [0032] refers to a specific embodiment describing a first elongated member being a guide wire shaft 504 and a second elongated member being an outer delivery shaft 106 (see e.g. figure 6). However, the feature that the control knobs are axially fixed with regard to the handle assembly is not inextricably linked to the specific kind of elongate member.

1.4.2 Instead, claim 1 as originally filed already included the functionality of the two control knobs to enable upon rotation the axial movement of the two elongate members and the respective sleeves (features F6, F7) - irrespective of whether the first and second elongate members are a guide wire shaft and an outer delivery shaft.

1.4.3 Feature F2.3 rather specifies features F2.1 and F2.2, namely how the control knobs are rotatably provided at the handle assembly. No specific means to achieve feature F2.3 need to be introduced into claim 1. Paragraph [0032] provides a generic disclosure for mechanisms for securing a knob rotatably but axially fixed to the handle assembly (page 9, lines 19, 20:

"Other structures can be used to secure control knobs 110 and 112 to handle assembly 102 to prevent axial movement thereof.").

2. Novelty over D14

2.1 The subject-matter of claim 1 of the main request is new over D14. D14 does not disclose a first sleeve that axially moves upon rotation of a distal control knob relative to components of the delivery catheter.

2.2 Claim 1 of the main request defines a delivering catheter with two elongate members, each being connected at one side with a control knob and at the other side with a sleeve. When the control knobs are rotated, the respective sleeve is moved in an axial direction.

2.3 An unbiased reading of the claim implies that each of the sleeves needs to be moved relative to at least one of the components of the claimed delivery catheter. Essentially, the claim wording requires that a first knob is dedicated to the movement of a first sleeve whilst a second knob is dedicated to the movement of a second sleeve. This reading is in accordance with the description of the patent in suit, disclosing that the first and the second sleeves at least move together with the respective elongate member relative to the handle assembly (see figure 6). Only with a mind willing to misunderstand can the claim be read as implying that rotation of the distal or proximal knob might move not only the first and second sleeves, respectively, relative to the delivery catheter, but also the whole delivery catheter.

- 2.4 D14 discloses a system comprising a delivery catheter, a guide catheter and a Touhy Borst (see e.g. claims 32 and 35). The delivery catheter is e.g. shown in figure 4 or figure 7(a). In use, before applying the delivery catheter, the guide catheter 30 is introduced and the Touhy Borst 20 is attached to the end of the guide catheter 30. Only then the delivery catheter is introduced until the required position is reached. Finally the Touhy Borst 20 that acts as a fitting between the guide catheter 30 and the delivery catheter, is locked to the stabilizer tube 25 of the delivery catheter (page 15, line 30, to page 16, to line 7, figure 7(c)).
- 2.5 It is undisputed that the deliver catheter comprises a second elongate member (catheter shaft 9) connected at the handle side to a proximal control knob (thumbscrew 11) and at the other side to a second sleeve (sheath 6). When rotating the control knob 11, rotation is converted into linear movement of the sheath 6 (D14, page 14, lines 7 to 11) relative to the control knob 11.
- 2.6 The opposition division was of the opinion (impugned decision, point 3.3.4) that the embodiment shown in figures 27, 28 of D14 also disclosed a distal control knob 120 that moves a first sleeve in an axial direction (tip 3 in figure 28, together with figure 11, nose cone at the end of inner core 5).
- 2.7 The Board does not agree.
D14 discloses on page 20, lines 6 to 25, referring to figures 27 and 28, a distal control knob 120 that *"may be used to move the handle (and hence the inner core assembly and stent position) proximally or distally relative to the guide catheter)"*. This means that

rotating the distal knob 120 results in an axial movement of the whole delivery catheter relative to the Touhy Borst and the guide catheter 30, both being separate entities additional to the delivery catheter. In figure 28, the axial movement occurs between the stabilizer 25 and the Touhy Borst which also becomes apparent from page 15, lines 5 to 7 (*"The external surface of the stabiliser tubing 25 may have sufficiently low friction so that the stent 1 may be repositioned without opening the Touhy Borst 20."*). Consequently, at the tip of the delivery catheter, shown in figure 11, the axial movement occurs between the guide catheter 30 and the whole assembly comprising the stent 1, the sheath 6 and the inner and outer core 5/10 including the nose cone.

Hence, in the delivery catheter of D14, rotation of the distal control knob 120 does not result in any axial movement of the nose cone (figure 11) relative to any other component of the delivery catheter but only relative to other parts of the system. The control knob 120 rather is a part of the system described in D14 and not of the delivery catheter. The control knob 120 alone with the delivery catheter of D14 does not have any function as its rotation would not result in any movement of the nose cone.

2.8 The subject-matter of claim 1 is thus new over the delivery catheter known from D14.

3. Further issues

3.1 The opposition was withdrawn during the appeal proceedings and the Board sees - apart from the issues that led to the impugned decision - no reasons for questioning the validity of the claims according to the

appellant's main request. Accordingly, the claims of the main request, together with the description and the figures of the patent as granted (no amendments being necessary here to bring them into conformity with the amended claims) form a suitable basis for the maintenance of the patent in amended form.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the opposition division with the order to maintain the patent in amended form with the following documents:
 - Claims 1 to 9 according to the auxiliary request 1 filed with the statement of grounds of appeal;
 - Description of the patent specification;
 - Figures of the patent specification.

The Registrar:

The Chairman:



M. Schalow

G. Pricolo

Decision electronically authenticated