Internal distribution code:

(A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 21 March 2024

Case Number: T 1685/21 - 3.2.08

Application Number: 13178309.4

Publication Number: 2659861

IPC: A61F2/95, A61F2/24

Language of the proceedings: EN

Title of invention:
Handle for manipulating a catheter tip, catheter system and medical insertion system for inserting a self-expandable heart valve stent

Patent Proprietor:
JenaValve Technology, Inc.

Opponent:
Edwards Lifesciences Corporation, Law Department

Relevant legal provisions:
EPC Art. 123(2)
RPBA 2020 Art. 13(2)

Keyword:
Amendments - allowable (no)
Amendment after notification of communication - exceptional circumstances (no)

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 1685/21 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 21 March 2024

Appellant: (Patent Proprietor)	JenaValve Technology, Inc. 4 Cromwell, Irvine, CA 92618 (US)
Representative:	Meissner Bolte Partnerschaft mbB Patentanwälte Rechtsanwälte Postfach 10 26 05 86016 Augsburg (DE)
Appellant: (Opponent)	Edwards Lifesciences Corporation, Law Department One Edwards Way Irvine, CA 92614 (US)
Representative:	Grünecker Patent- und Rechtsanwälte PartG mbB Leopoldstraße 4 80802 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 26 July 2021 concerning maintenance of the European Patent No. 2659861 in amended form.**

Composition of the Board:

Chairwoman	P. Acton
Members:	G. Buchmann
	F. Bostedt

Summary of Facts and Submissions

I. The opposition division decided that the European patent No. EP 2 659 861 in amended form fulfilled the requirements of the EPC.

II. Both parties filed an appeal against this decision.

III. Oral proceedings took place before the Board on 21 March 2024.

IV. Appellant 1 requested that the decision be set aside and that the patent be maintained as granted or, in the alternative, that a patent be maintained on the basis of the claims of one of the auxiliary requests, in the following order:

- auxiliary requests I, III or IV filed on 18 March 2021,
- auxiliary request I filed at 16:00 hours during the oral proceedings before the opposition division,
- auxiliary requests 5 or 6 filed on 14 February 2024.

During the oral proceedings, appellant 1 filed a new auxiliary request

- auxiliary request of 21 March 2024,

which was to be dealt with after the pending auxiliary requests.

V. Appellant 2 requested that the decision be set aside and the patent be revoked.

VI. Claim 1 of the **main request** reads as follows. The numbering has been added by the Board. Amendments compared to claim 1 as filed are underlined.

1.1
"A handle (70-2) for manipulating a catheter tip (10) of a medical insertion system (100),
1.2
wherein the handle (70-2) has at least a first and a second operating means (71, 81), with which first and second housing portions (11, 21) of the catheter tip (10) can be manipulated (10) so that a self-expandable stent (101) housed in the catheter tip (10) can be released in steps in a previously defined or definable sequence of events from the catheter tip (10),
1.3
wherein the handle (70-2) further has at least one stop (75, 76, 77, 85, 86) associated with the operating means (71, 81),
1.4
which is designed to limit a longitudinal displacement stroke of the first and/or second housing portion (11, 21) of the catheter tip (10) that can be effected by actuation of the at least one operating means (71, 81),
1.5
and wherein the first operating means (71) is supported rotatably in the handle (70-2) and connected to the first housing portion (11) of the catheter tip (10) so as to execute a definable longitudinal displacement stroke on the first housing portion (11) of the catheter tip upon rotation of the first operating means (71), characterized in that
1.6
the handle (70-2) further comprises a third operating means (96) configured to enable manipulation of a flexural link region of a catheter system (30-2) of the

medical insertion system (100) to have a directed effect on the curvature of the flexural link."

VII. In **auxiliary request I**, Feature 1.5 has been amended to Feature **1.5'**, according to which

"the first operating means is in the form of a wheel, wherein the first operating means (71) is supported rotatably in the handle (70-2) and can turn between a first stop and a second stop, wherein the first operating means (71) is connected to the first housing portion (11) of the catheter tip (10) so as to execute a definable longitudinal displacement stroke on the first housing portion (11) of the catheter tip upon rotation of the first operating means (71)."

VIII. **Auxiliary request III**

This request is based on auxiliary request I, wherein additionally Feature 1.6 has been amended to Feature **1.6'** according to which
"the handle (70-2) further comprises a third operating means (96) in the form of a wheel, with which a flexural link region (34) of a catheter system (30-2) of the medical insertion system (100) can be deflected, said third operating means (96) being configured to enable manipulation of ~~a~~ the flexural link region (34) of ~~a~~ the catheter system (30-2) of the medical insertion system (100) to have a directed effect on the curvature of the flexural link region (34) when the third operating means (96) is connected to the flexural link region (34) by means of a device for force transmission."

IX. **Auxiliary request IV**

Based on the main request, Features 1.5 and 1.6 have been amended to Features **1.5''** and **1.6''**, according to which

1.5''
"the first operating means is in the form of a wheel, wherein the first operating means (71) is supported rotatably in the handle (70-2) and can turn between a first stop and a second stop, wherein the first operating means (71) is connected to the first housing portion (11) of the catheter tip (10) so as to execute a definable longitudinal displacement stroke on the first housing portion (11) of the catheter tip upon rotation of the first operating means (71), wherein the first operating means (71) is provided with a third stop between the first stop and the second stop, said third stop cooperates, on one side with the first stop and on the other side with the second stop so that, on actuation of the first operating means (71), a longitudinal displacement of the first housing portion (11) of the catheter tip (10-2) consisting of two defined separate steps can be effected,"
characterised in that
1.6''
"the handle (70-2) further comprises a third operating means (96) in the form of a wheel, with which a flexural link region (34) of a catheter system (30-2) of the medical insertion system (100) can be deflected, said third operating means (96) being configured to enable manipulation of ~~a~~ the flexural link region (34) of ~~a~~ the catheter system (30-2) of the medical insertion system (100) to have a directed effect on the curvature of the flexural link region (34) by means of a control wire (35) implemented as a device for force

transmission."

X. **Auxiliary request I filed at 16:00 hours during the oral proceedings before the opposition division**

Claim 1 of this request reads as follows. The numbering of the features, as far as not already present in the main request, is as suggested by appellant 2.

1.1
"A handle (70-2) for manipulating a catheter tip (10) of a medical insertion system (100),
1.2
wherein the handle (70-2) has at least a first and a second operating means (71, 81), with which first and second housing portions (11, 21) of the catheter tip (10) can be manipulated (10) so that a self-expandable stent (101) housed in the catheter tip (10) can be released in steps in a previously defined or definable sequence of events from the catheter tip (10),
HF22'
wherein the first operating means (71) cooperates with the first housing portion (11) of the catheter tip (10) so that, on actuation of the first operating means (71), a previously definable longitudinal displacement of the first housing portion (11) may be effected relative to a stent holder of the catheter tip (10),
HF23'
wherein the second operating means (81) cooperates with the second housing portion (21) of the catheter tip (10) so that a previously definable longitudinal displacement of the second housing portion (21) may be affected relative to the stent holder,

HF31' (see 1.3 and 1.4)
wherein the handle (70-2) further has ~~at least one~~ a

first stop (75) associated with the first operating means (71), and a second stop (76) associated with the first operating means
~~which is~~ wherein the first and second stop (75, 76) are designed to limit an overall longitudinal displacement stroke of the first ~~and/or second~~ housing portion (11) of the catheter tip (10) that can be effected by actuation of the ~~at least one~~ first operating means (71, 81),
HF32' (see 1.3 and 1.4)
wherein the handle (70-2) has a first stop (85) associated with the second operating means (81) and a second stop (86) associated with the second operating means (81),
wherein the first and second stop (85, 86) are designed to limit an overall longitudinal displacement stroke of the second housing portion (21) of the catheter tip (10) that can be effected by actuation of the second operating means(81),

1.5 (HF4)
and wherein the first operating means (71) is supported rotatably in the handle (70-2) and connected to the first housing portion (11) of the catheter tip (10) so as to execute a definable longitudinal displacement stroke on the first housing portion (11) of the catheter tip upon rotation of the first operating means (71),

HF41'
wherein a locking element is associated with the first operating means (71), said locking element being designed to interrupt a transmission of force from the first operating means (71) to the first housing portion (11) of the catheter tip (10), wherein the locking element is located removably in the force flow between

the first operating means (71) and the first housing portion (11) of the catheter tip (10),
characterized in that

1.6 (HF5)
the handle (70-2) further comprises a third operating means (96) configured to enable manipulation of a flexural link region of a catheter system (30-2) of the medical insertion system (100) to have a directed effect on the curvature of the flexural link."

XI. The **auxiliary request filed on 21 March 2024** (during the oral proceedings) is based on auxiliary request IV, wherein to Feature **1.5''** it was added that

"the third stop associated with the first operating means (71) is in the form of a locking element (77') designed to interrupt a transmission of force from the first operating means (71) to the first housing portion (11) of the catheter tip (10), wherein the locking element is located removably in the force flow between the first operating means (71) and the first housing portion (11) of the catheter tip(10)."

XII. **The arguments of appellant 1 can be summarised as follows:**

Amendments - Article 123(2) EPC

Feature 1.5 of claim 1 fulfilled the requirements of Article 123 (2) EPC.

Admittance of the auxiliary request filed on 21 March 2024 - Article 13 (2) RPBA 2020

The request was prima facie allowable and should be

admitted into the proceedings.

XIII. **The arguments of appellant 2 can be summarised as follows:**

Amendments - Article 123(2) EPC

Feature 1.5 of claim 1 of all requests filed in the written proceedings contravened Article 123 (2) EPC.

Admittance of the auxiliary request filed on 21 March 2024 - Article 13 (2) RPBA 2020

No cogent reasons were presented to justify exceptional circumstances which would allow the Board to take this request into account.

Reasons for the Decision

1. Amendments - Article 123(2) EPC

1.1 Feature 1.5 was added to claim 1 before grant of the patent. It is based on the description as originally filed, page 57, line 21 to page 58, line 15.

This is the only passage in the description which mentions the first operating means to be rotatable as required by Feature 1.5. The passages further cited by appellant 1 do not mention a rotatable first operating means: Page 8, lines 1-6 is a general description of the cooperation of the first/second operation means with the first/second housing portion of the catheter tip. Page 10, lines 28-31 and page 28, line 34 - page 29, line 1 describe that the first operating means effects a definable longitudinal displacement of the

first housing portion.

The passage starting from page 57, line 21 refers to the embodiment 100-2 of the insertion system which is shown in Figures 14 and 15. In this embodiment, the first operating means is described exclusively as being a wheel. No embodiment is described in the application as originally filed which discloses a rotatable first operating means which is not a wheel. From page 57, line 30, it is described that the claimed function "to execute a definable longitudinal displacement stroke" is achieved by the fact that the wheel can turn between a first stop and a second stop. Additionally, this embodiment is provided with a non-optional third stop between the first and second stops, in order to achieve a longitudinal displacement of the first housing portion in two defined separate steps (page 57, line 34 - page 58, line 6).

According to page 58, lines 8-15, this third stop is in the form of a locking element 77', positioned removably in the flow of force between the wheel and the first housing portion of the catheter tip. Alternatively, the locking element restricts the free rotation of the wheel.

1.2 The Board notes that none of the above mentioned features (the first operating means being a wheel; the first and second stops; the third stop between the first and second stops; and the locking element) is mentioned as being optional. Additionally, they are all functionally linked to each other and to the longitudinal displacement of the first housing portion.

Since this longitudinal displacement of the first housing portion is a core function of the claimed

handle, none of these features may be omitted when taking subject-matter from the description page 57-58 in order to amend claim 1.

1.3 Regarding the first operating means being a wheel, appellant 1 argued that everything which was rotatable (as mentioned in Feature 1.5) could be regarded as a wheel in a broader sense. The Board does not share this opinion because, for example, a rotatable spindle or a lever arm, despite being rotatable elements, would not be regarded as a wheel by a skilled person.

It is correct that page 58, lines 17-21 mentions that the first operating means could be no wheel. But in this case, the first operating means is implemented as a pusher which is not rotatable as required by Feature 1.5.

Given that the rotatable first operating means is mentioned in the description only in the form of a wheel, the omission of this term constitutes a generalisation which is not allowable under Article 123(2) EPC.

The Board also does not agree with the opposition division, which reasoned that "the structural ... features related to the first operating means ... do not depend on the shape of said operating means" (Decision, point 3.1.4). Since the first operating means is manually actuated, its shape plays a role for its usability during operation.

1.4 Appellant 1 argued that a locking element was anything that stopped the movement of the first housing portion. The described "locking element" had no additional meaning apart from being a "stop". Therefore, the term

locking element could be omitted from Feature 1.5.

However, on page 58, lines 8-15, the third stop is disclosed exclusively as a locking element when the first operating means is in the form of a wheel. The locking element may be embodied in two alternative forms. Either it is positioned removably in the flow of force between the wheel and the first housing portion of the catheter tip or, alternatively, it restricts the free rotation of the wheel. Therefore, the application discloses the third stop only in the form of a locking element.

The locking element is also not an alternative to the third stop element, as conceived by the opposition division. In fact, the stop is formed by the locking element (page 58, lines 8-15).

Appellant 1 also referred to page 68, lines 17-19. This passage describes an embodiment in which the operating means are linear pushers. It is correct that for this embodiment the "stop element 77'" is said to be optional. This passage refers, however, to a different embodiment of the handle which has no first operating means supported rotatably in the handle as required by Feature 1.5. Therefore, no conclusion can be drawn from this passage for the handle as claimed.

1.5 For the above reasons, to fulfil the requirements of Article 123(2) EPC, each of the following features should have been included into claim 1:

- the first operating means being a wheel;
- the first and second stops;
- the third stop between the first and second stops; and

- the locking element.

The absence of any of these features contravenes Article 123(2) EPC.

1.6 The main request lacks all of the above listed features.

Auxiliary requests I and III lack the third stop and the locking element.

Auxiliary request IV lacks the locking element.

In auxiliary request I filed at 16:00 hours during the oral proceedings before the opposition division, the first operating means supported rotatably in the handle is not specified as being a wheel.

Auxiliary requests 5 and 6 lack the locking element.

1.7 Therefore, none of the main request and auxiliary requests I, III, IV, I (filed at 16:00 hours during the oral proceedings before the opposition division), 5 and 6
fulfils the requirements of Article 123 (2) EPC.

2. Admittance of the auxiliary request filed on 21 March 2024 - Article 13 (2) RPBA 2020

2.1 During the oral proceedings before the Board, appellant 1 filed a new auxiliary request.

This request is based on auxiliary request IV, wherein the following was added to Feature **1.5''**:

"the third stop associated with the first operating

means (71) is in the form of a locking element (77') designed to interrupt a transmission of force from the first operating means (71) to the first housing portion (11) of the catheter tip (10), wherein the locking element is located removably in the force flow between the first operating means (71) and the first housing portion (11) of the catheter tip (10)."

2.2 The admittance of this request is regulated by Article 13(2) RPBA 2020. Accordingly, a request filed after the notification of a communication under Article 15(1) RPBA 2020 shall, in principle, not be taken into account by the Board unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned.

2.3 Appellant 1 provided the basis for the amendment (page 58, lines 8-15) and argued that the auxiliary request filed on 21 March 2024 did not comprise any surprising amendment and did not give raise to new objections. On the contrary, all prior objections would be overcome by this request and it was prima facie allowable.

However, these reasons do not in themselves constitute an exceptional circumstance which could justify the filing of this request at such a late stage of the proceedings.

2.4 Additionally, compared to the passage on page 58, lines 8-15, the wording "interrupting direct force transmission" was modified to "interrupt a transmission of force". This gives rise to the (new) question whether these wordings have different meanings, and whether this would have any relevance in view of Article 123(2) EPC.

2.5 Therefore, the Board decided not to admit the auxiliary request filed on 21 March 2024 into the proceedings.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar: The Chairwoman:

C. Moser P. Acton

Decision electronically authenticated