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Datasheet for the decision of 3 March 2026

Case Number: T 0241/25 - 3.2.02

Application Number: 20194277.8

Publication Number: 3769722

IPC: A61F2/24, A61M25/00, A61M25/10

Language of the proceedings: EN

Title of invention:
LOW PROFILE DELIVERY SYSTEM FOR TRANSCATHETER HEART VALVE

Patent Proprietor:
Edwards Lifesciences Corporation

Opponent:
J A Kemp LLP

Headword:

Relevant legal provisions:
EPC Art. 100(c), 76(1), 83, 56
RPBA 2020 Art. 12(4)

This datasheet is not part of the Decision
It can be changed at any time and without notice

Keyword:

Grounds for opposition - subject-matter extends beyond content of earlier application - main request (yes)
Sufficiency of disclosure - (yes)
Inventive step - auxiliary request 1'' (yes)
Amendment to case - amendment within meaning of Art. 12(4) RPBA 2020

Decisions cited:

T 0367/20, T 0873/23, T 1762/21, T 0824/23, T 1888/22

Catchword:

Merely referring to an embodiment of the original disclosure and stating that an unallowable intermediate generalisation of this embodiment has been introduced is not a substantiated objection of added subject-matter. An objection to an intermediate generalisation in a claim requires (i) identifying the features which are impermissibly omitted from the claim and (ii) explaining why the omission introduces added subject-matter. According to established case law of the boards this explanation needs to show that the omitted features are inextricably linked with (some of) the claimed ones according to the original disclosure. Only in this way it is possible to (i) identify the objection and (ii) understand the reasoning supporting the objection.

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Case Number: T 0241/25 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 3 March 2026

Appellant: (Patent Proprietor)	Edwards Lifesciences Corporation One Edwards Way Irvine, CA 92614 (US)
Representative:	Thum, Bernhard Thum & Partner Thum Mötsch Weickert Patentanwälte PartG mbB Ismaninger Straße 57 81675 München (DE)
Appellant: (Opponent)	J A Kemp LLP 80 Turnmill Street London Greater London EC1M 5QU (GB)
Representative:	Marks & Clerk LLP 15 Fetter Lane London EC4A 1BW (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 3 February 2025 concerning the maintenance of European Patent No. 3769722 in amended form**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	D. Ceccarelli
	C. Schmidt

Summary of Facts and Submissions

I. The patent proprietor and the opponent appealed against the opposition division's decision that, account being taken of the amendments made by the patent proprietor during the opposition proceedings according to auxiliary request 1', European patent No. 3 769 722 and the invention to which it relates met the requirements of the EPC.

II. The patent in suit is derived from European application No. 20194277.8, which is a divisional application of European application No. 19189544.0, which is a divisional application of European application No. 18210923.1, which is a divisional of European application No. 09743346.0 (the earliest application).

III. The board summoned the parties to oral proceedings and sent its preliminary opinion in a communication pursuant to Article 15(1) RPBA.

IV. Oral proceedings took place on 3 March 2026.

The patent proprietor requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or that it be maintained on the basis of one of auxiliary requests 1 to 12, 1' to 10' and 1'' to 10'', to be considered in this order and filed with letter dated 17 December 2024.

The opponent requested that the decision under appeal be set aside and that the patent be revoked.

V. The following documents are mentioned in this decision:

D1: US 2008/0065011 A1
D5: WO 93/18817 A1
D7: US 6,027,460 A
D8: US 2008/0051707 A1
D9: EP 0 787 019 B1
D11: WO 92/21397 A1
D12: Communication of the opposition division for European application No. 20 194 267.9 dated 14 March 2025

VI. **Claims 1 and 3 of the main request** read as follows:

"1. An apparatus for indicating flex of a distal end of a catheter comprising:

an elongated shaft (152);
at least one pull wire (174) connected to a distal end portion (188) of the elongated shaft (152);
a handle portion (158) comprising a flex activating member (154), the flex activating member (154) being coupled to the at least one pull wire (174) such that adjustment of the flex activating member (154) causes the distal end portion (188) of the elongated shaft (152) to flex;
a slide member (192) connected to the at least one pull wire (174); and
a flex indicating member (156);
wherein adjustment of the flex activating member (154) causes the flex indicating member (156) to move relative to the handle portion (158), and
wherein the flex activating member (154) comprises a rotatable member (155, 157) which includes an internally threaded surface portion (160)
characterised in that the flex activating member

also has an externally threaded surface portion (162), wherein the internally threaded surface portion (160) is configured to receive the slide member (192) connected to the at least one pull wire (174), and the externally threaded surface portion (162) is configured to receive an extending portion (166) of the flex indicating member (156)."

"3. The apparatus of any one of claims 1 or 2, wherein the flex activating member (154) and the flex indicating member (156) are separate members."

Claim 3 of each of auxiliary requests 1 to 11 and 1' to 10' reads as claim 3 of the main request.

Claim 1 of auxiliary request 12 reads as claim 1 of the main request.

Claim 1 of auxiliary request 1'' reads as claim 1 of the main request with the addition of the following wording after the expression "characterised in that":

"the rotatable member (155, 157) of"

VII. The proprietor's arguments relevant to this decision can be summarised as follows.

Main request - added subject-matter

The opposed patent was derived from a divisional application of a series of divisional applications. All these divisional applications as filed comprised the content of the earliest application as filed.

The feature in claim 1 "the flex activating member also has an externally threaded surface portion" did not add

subject-matter. First, the claim specified a flex activating member comprising a rotatable member with an internally threaded surface portion. The use of the term "also has" in the definition of the externally threaded surface portion signalled that the externally threaded surface portion was an additional feature of the feature presented before, namely the rotatable member. Moreover, the technically sensible reading of the language of claim 1 was that both the internally threaded surface portion and the externally threaded surface portion were part of the rotatable member such that rotating the rotatable member actuated both the flex activating mechanism and the flex indicating mechanism. Paragraph [0031] of the earliest application as filed disclosed that the flex activating member could comprise a rotatable member "in specific implementations" and that the rotatable member could include an internally threaded surface portion and an eternally threaded surface portion "in other specific implementations". Since the flex activating member comprised the rotatable member, it followed that the flex activating member also had the externally threaded surface portion. Furthermore, paragraph [0165] of the earliest application as filed described the feature of the externally threaded surface portion with the same language as used in claim 1 of the main request.

The feature of claim 1 of the main request concerning the flex activating member being coupled to at least one pull wire such that adjustment of the flex activating member caused the distal end portion of the elongated shaft to flex did not involve any unallowable intermediate generalisation. Paragraph [030] of the earliest application as filed disclosed a flex activating member "coupled to the at least one wire such that adjustment of the flex activating member

causes the distal end portion of the shaft to flex". Claim 1 of the main request was more specific only in that the wire was a pull wire. However, no wire other than a pull wire had been disclosed in the earliest application as filed. Hence, the person skilled in the art, reading the earliest application as filed as a whole, would have understood that the wire mentioned in paragraph [030] was a pull wire. Moreover, the limitation of the general teaching of paragraph [030] was consistent with the embodiment described in paragraphs [0171] and [0172] with reference to Figures 31 to 38B, where a pull wire was used. Apart from that, the disclosure of this embodiment was in complete agreement with the general disclosure of paragraph [030], which was a mechanism to actively impart flex to a distal end portion of an elongated shaft. The wire being in the form of a pull wire was not inextricably linked with other features, such as an adjustment knob and a steerable resilient section as mentioned in connection with the embodiment. As regards the omission of the resiliency of the steerable section, the opponent's objection in this regard should not be admitted as it had been substantiated for the first time with the statement of grounds of appeal. The opponent's reference to D12, the preliminary opinion of the opposition division in proceedings regarding another patent, was irrelevant for added subject-matter as it related to a different claim and was not applicable to claim 1 of the main request.

The opponent's objection that the language "to indicate an amount of flex of the distal end portion of the shaft" had been inadmissibly omitted from claim 1 of the main request was not convincing either. From the claim as a whole, it was clear that the function of the flex indicating member was to indicate flex of the

distal end portion of the elongated shaft because this portion was what could be caused to flex by the flex activating mechanism as defined in claim 1 of the main request.

Although there was no explicit statement that the flex activating member and the flex indicating member were separate members in the earliest application as filed, the person skilled in the art understood from paragraphs [030] and [031] and the whole context of the earliest application as filed that the flex activating member and flex indicating member were necessarily separate members. Otherwise it would have been nonsensical to refer to the one member causing movement of the other member. Hence, claim 3 of the main request did not comprise added subject-matter.

Auxiliary requests 1 to 12 and 1' to 10'

These auxiliary requests addressed some of the objections of added subject-matter raised by the opponent. They did not comprise added matter.

Auxiliary request 1'' - sufficiency of disclosure

The opponent's argument that the invention was not sufficiently disclosed over the full breadth of claim 1 of auxiliary request 1'' because the claim did not recite a longitudinal slot was flawed. The patent clearly disclosed a working embodiment. Starting from this disclosure, the person skilled in the art could carry out the invention over the whole range claimed based on common general knowledge.

Auxiliary request 1'' - inventive step

The opponent had raised objections of lack of inventive step starting from D1 or D9. These documents had been taken into account by the Unified Patent Court (UPC) in parallel proceedings. The UPC had upheld the patent in decision UPC_CFI_380/2023.

Neither D1 nor D9 disclosed a flex indicating member received in an externally threaded surface portion of a flex activating member and moving relative to a handle portion when the flex activating member was actuated.

D5, D7, D8 and D11 referred to by the opponent did not disclose the identified distinguishing features of claim 1 of auxiliary request 1'' over D1 or D9. The person skilled in the art would not have combined and adapted pieces of prior art to resemble the claimed subject-matter.

The technical effect of the distinguishing features was a proper indication of the imparted flex. Although the flex indicating member might not measure and indicate actual flex, it reliably reflected the actuation input transmitted through the pull wire system. Reliability in this context meant that the indicator moved in a controlled and predictable manner in line with actuation. Whether, depending on the conditions of use, there could be temporal deviations between the indicated and actual flex did not undermine the technical effect of the claimed feature combination.

The problem solved by the distinguishing features was therefore providing feedback on the flexed configuration of the catheter for helping a surgeon steer the catheter. The technical problem formulated by

the opponent, i.e. a means for indicating to the user the amount of actuation input applied by the user to the flex activating member, was incorrect as it contained a pointer to the claimed solution.

In relation to the embodiments of a flexed catheter used as starting points in D1 and D9, these documents did not teach a flex indicating mechanism as defined in claim 1 of the main request, nor did they disclose any feedback on the configuration of the flexed catheter.

None of D5, D7, D8 and D11 related to flex indication. The opponent's reference to D12 was misleading and not decisive. Some of the opponent's arguments concerning D7 had been filed only in reply to the board's preliminary opinion. These should be disregarded. Although D7 addressed the problem of helping steer catheters through vasculature, this document was concerned with the provision of an indication of applied torque to catheters which had a predetermined shape and were twisted to facilitate navigation (column 10, lines 47 to 53). Hence, D7 did not provide any indication of flex. The person skilled in the art would not have considered D7 for providing feedback on the flexed configuration of a catheter according to D1 or D9. The indication of applied torque was not relevant for a flexing catheter.

VIII. The opponent's arguments relevant to this decision can be summarised as follows.

Main request - added subject-matter

In the impugned decision, the opposition division had been correct to find that the feature "the flex activating member also has an externally threaded

surface portion" added subject-matter due to the omission of the requirement that the externally threaded surface portion was part of a rotatable member, as specified in paragraph [031] of the earliest application as filed. Also, paragraph [0165] of the earliest application as filed disclosed that the flex activating member comprised an externally threaded surface portion within the context of the flex activating member being rotatable (i.e. being an adjustment knob). This requirement was not implicit in claim 1 of the main request.

The feature of claim 1 of the main request concerning the flex activating member being coupled to at least one pull wire such that adjustment of the flex activating member caused the distal end portion of the elongated shaft to flex was an unallowable intermediate generalisation. Paragraph [030] of the earliest application as filed disclosed a wire. A pull wire was a type of wire. Moreover, wires other than pull wires could be used in devices of the claimed type. Hence, paragraph [030] did not provide a basis for the feature in dispute. A pull wire was only disclosed in paragraphs [0171] and [0172] of the earliest application as filed, in combination with several other features, including an adjustment knob and a resilient steerable section of the elongated shaft. In this respect, a rotatable member and a flexible catheter as mentioned in claim 1 of the main request were less specific than the adjustment knob and the resilient steerable section as disclosed in paragraphs [0171] and [0172]. The objection to the omission of the resiliency of the steerable section was within the context of the objection concerning the intermediate generalisation as raised for the first time with the notice of opposition, which referred to

paragraphs [0171] and [0172] in their entirety. It had not been raised late. The features of the adjustment knob and the resilient steerable section were inextricably linked with the pull wire, the entire purpose and function of which was to connect the adjustment knob and the steerable section to actively flex the latter and let it slowly return to its initial configuration if no flex was imparted. This was important to effectively steer and then extract the catheter. In D12, the opposition division had concluded that there was an unallowable intermediate generalisation in a similar situation for a parallel case.

The omission in claim 1 of the main request that the movement of the flex indicating member relative to the handle portion was to indicate an amount of flex of the distal end portion of the elongated shaft was an impermissible intermediate generalisation. Paragraph [030] of the earliest application as filed made clear that the entire function and purpose of the flex indicating member moving relative to the handle portion was to indicate to the user the amount of flex applied to the distal end portion of the shaft. Claim 1 was, however, open to the possibility that this movement could be for another, unclaimed, purpose.

The definition in claim 3 of the main request that the flex activating member and the flex indicating member were separate members implied that claim 1 encompassed embodiments in which these two members were not separate. However, there was no disclosure in the earliest application as filed of such a definition or of its effect on the scope of claim 1.

Auxiliary requests 1 to 12 and 1' to 10'

These auxiliary requests did not overcome all the objections of added subject-matter.

Auxiliary request 1'' - sufficiency of disclosure

The invention was not sufficiently disclosed over the full breadth of claim 1 of auxiliary request 1''. The subject-matter claimed extended to cover embodiments that did not comprise a longitudinal slot into which the flex indicating member extended. However, the patent exemplified only a technical solution with such a slot (paragraph [0113]). The person skilled in the art would have been unable to carry out the invention in embodiments lacking this slot.

Auxiliary request 1'' - inventive step

Contrary to the findings of the opposition division in the impugned decision, the subject-matter of claim 1 of auxiliary request 1'' lacked inventive step over D1 or D9 in combination with D5, D7, D8 or D11. The assessment of inventive step made in D12 supported the opponent's conclusion. The UPC's assessment of inventive step in its decision UPC_CFI_380/2023 contained the same flaws as that of the opposition division and was irrelevant for the current case.

D1 and D9 did not disclose a rotatable member of the flex activating member having an externally threaded surface portion configured to receive an extending portion of the flex indicating member.

This distinguishing feature was a means for indicating to the user the amount of actuation input applied by

the user to the claimed flex activating member. The position of the flex indicating member was not directly indicative of the flex experienced by the catheter. The technical problem was a mechanical problem relevant to the hand-held portion of the device, not a problem specific to the functional movement that happened to be caused at the distal end of the catheter in D1 or D9. Including a reference to the indication of flex in the objective technical problem, as done by the opposition division, was therefore inappropriate.

Hence, the problem solved by the distinguishing feature was how to determine the extent to which the adjustment knob disclosed in D1 or D9 had been actuated to cause functional movement in the catheter. With this problem, the person skilled in the art was not directed towards any particular solution. Hence, the formulation of the problem contained no hindsight.

The problem formulated by the board in the preliminary opinion was incorrect. The claimed device was not restricted to catheters to be steered through vasculature. Moreover, there was a disconnect between the amount of flex requested by a user rotating the flex activating member and the actual amount of flex experienced at the distal end of catheter.

The problem of determining the extent to which an adjustment knob has been actuated to cause functional movement in a catheter was widely applicable to any catheter system comprising a rotatable actuator.

Therefore, the person skilled in the art would have considered prior-art documents irrespective of the type of functional movement produced in the catheter. It followed that D5, D7, D8 and D11 were all relevant. The

mechanisms disclosed in these documents to indicate the actuation of an adjustment knob were easy to implement in the devices of D1 and D9. The person skilled in the art would have done so and arrived at the subject-matter of claim 1 of auxiliary request 1'' in an obvious way.

D7 was particularly relevant as it expressly related to the problem of helping steer catheters through vasculature. The additional arguments concerning D7 which had been filed after the board's preliminary opinion were a simple refinement of the opponent's case and had been filed in response to factual errors of the board in the preliminary opinion. These arguments should be admitted.

D7 discloses a system for gaining control over the rotational orientation of the distal end of guiding catheters (column 2, lines 13 to 15 and 49 to 54) while navigating the catheters to areas of interest (column 10, lines 46 to 49). Hence, D7 would have been considered by the person skilled in the art, who would have implemented its teaching in the devices of D1 and D9 to provide feedback on the configuration of the catheters of these documents. The implementation involved no technical difficulties and was therefore obvious.

Reasons for the Decision

1. Subject-matter of the patent

The patent is concerned with an apparatus for indicating flex of a distal end of a catheter, for example, for implanting a prosthetic aortic valve in a

human heart. Figures 31 and 36 of the patent, reproduced below, depict the apparatus in a schematic way.

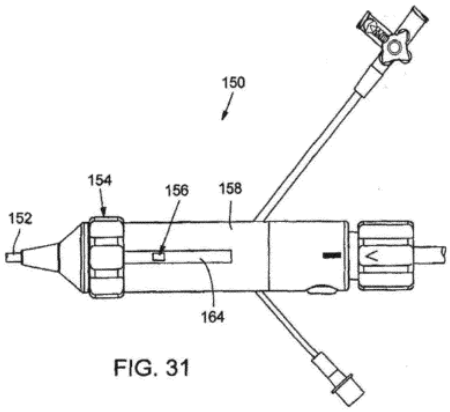


FIG. 31

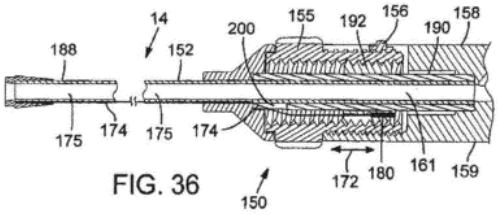


FIG. 36

The apparatus comprises an elongated shaft (152), a pull wire (174), a handle portion (158), a slide member (192) and a flex indicating member (156).

The pull wire is connected to a distal end portion of the elongated shaft.

The handle portion comprises a flex activating member (154) coupled to the pull wire such that adjustment of the flex activating member causes the distal end portion of the elongated shaft to flex and the flex indicating member to move relative to the handle portion.

The slide member is connected to the pull wire.

The flex activating member comprises a rotatable member (155) which includes an internally threaded surface portion and an externally threaded surface portion. The internally threaded surface portion is configured to receive the slide member, and the externally threaded surface portion is configured to receive an extending

portion of the flex indicating member.

The indication of flexing can help a physician to effectively steer the catheter to advance it through a patient's vessel.

2. Main request - added subject-matter

2.1 The patent in suit is derived from a divisional application of a series of divisional applications originating from the earliest application. It is common ground that all the divisional applications as filed comprise the description, the drawings and the claims (as embodiments of the invention at the end of their descriptions) of the earliest application as filed. For the assessment of added subject-matter in view of Articles 76(1) and 123(2) EPC, it is therefore sufficient to consider the content of the earliest application as filed.

2.2 The subject-matter of claim 1 of the main request relates to the disclosure of paragraphs [030] and [031] of the summary and paragraphs [0161] to [0175] of the detailed description, together with Figures 31 to 38B of the earliest application as filed.

2.2.1 The opposition division considered that the feature of the flex activating member comprising an externally threaded portion in claim 1 of the main request extended beyond the content of the earliest application as filed.

In its preliminary opinion, the board explained why it agreed with the opposition division's conclusion. The proprietor did not wish to add any comments on this issue after receiving the preliminary opinion.

As the proprietor argued, the earliest application as filed discloses an externally threaded portion of a flex activating member. However, paragraph [031] of this application is more precise and recites that the same rotatable member which includes the internally threaded surface portion has an externally threaded surface portion. Paragraph [0165] recites an "externally threaded surface portion 162 of flex activating member 154". However, in the illustrated embodiment, flex activating member 154 is the rotatable member which includes the internally threaded surface portion (paragraph [0164] and Figure 32).
Paragraph [0165] of the earliest application as filed discloses that the externally threaded portion of the rotatable member cooperates with a flex indicating member 156, such that, as the rotatable member is rotated to flex the distal end of the catheter (via the internally threaded surface portion interacting with the slide member, paragraph [0164]), the flex indicating member tracks the externally threaded portion and moves, thereby indicating the amount of flex.

For the person skilled in the art, it is therefore the externally threaded surface portion of the rotatable member including the internally threaded surface portion - not any externally threaded surface of the flex activating member - which must cooperate with the flex indicating member to indicate flex. In other words, the earliest application as filed inextricably links the externally threaded portion of the rotatable member with other claimed features. Not claiming this portion of the rotatable member amounts to a non-allowable intermediate generalisation.

The proprietor's argument that the person skilled in the art would implicitly understand, from the wording of claim 1, that the externally threaded surface portion was part of the rotatable member, is not convincing. Claim 1 states that the flex activating member comprises a rotatable member, this meaning that the flex activating member may comprise other members. It then states that the rotatable member includes an internally threaded surface portion, but it does not state that the rotatable member also includes an externally threaded surface portion. According to the claim, it is the flex activating member - not the rotatable member - which also has an externally threaded surface portion. This portion could therefore be on a member other than the rotatable member.

2.2.2 The opponent argued that claim 1 of the main request comprised added subject-matter also because claiming a pull wire was an unallowable intermediate generalisation of the disclosure of paragraphs [0171] and [0172] of the earliest application as filed. An adjustment knob and a resilient steerable section of the claimed elongated shaft had been impermissibly omitted.

While the omission of the adjustment knob was discussed in the opposition proceedings, the objection to the omission of the resiliency of the steerable section of the elongated shaft was raised and substantiated for the first time with the opponent's statement of grounds of appeal. Merely referring to an embodiment of the original disclosure and stating that an unallowable intermediate generalisation of this embodiment has been added, as was done in point 5.1.3 of the notice of opposition ("The term 'pull wire' is disclosed only in paragraphs [0171] and [0172] of the parent application

which discloses '[o]ne or more pull wires 174' in combination with several other features"), is not a substantiated objection of added subject-matter. An objection to an intermediate generalisation in a claim requires (i) identifying the features which are impermissibly omitted from the claim and (ii) explaining why the omission introduces added subject-matter. According to established case law of the boards this explanation needs to show that the omitted features are inextricably linked with (some of) the claimed ones according to the original disclosure. Only in this way is it possible to (i) identify the objection and (ii) understand the reasoning supporting the objection (see Case Law of the Boards of Appeal of the EPO, 11th edn., 2025, II.E.1.9.1; as well as, for instance decisions T 1762/21, catchword, T 824/23, point 1.7.1 and T 1888/22, third item of point 3.2.2).

Hence, the admittance into the appeal proceedings of the objection concerning the omission of the resiliency of the steerable section is at the board's discretion under Article 12(4) RPBA. Since this objection is not complex and was submitted at the earliest possible stage on appeal, the board decides to admit it into the appeal proceedings.

However, the board's view is that the objection is not convincing. Indeed, the board comes to the conclusion that the definition of a pull wire in claim 1 of the main request does not amount to an unallowable intermediate generalisation.

Paragraphs [030] and [031] of the earliest application as filed disclose an apparatus for indicating flex of a distal end of a catheter with a wire connected to a distal end portion of the elongated shaft and coupled

to the flex activating member such that adjustment of the flex activating member causes the distal end portion of the elongated shaft to flex. As the proprietor submitted, claim 1 of the main request is more specific than paragraphs [030] and [031] in this respect only in that the wire is defined as a pull wire. However, no wire other than a pull wire is disclosed in the earliest application as filed.

Moreover, the features defined in claim 1 of the main request are all present in the embodiment of Figures 31 to 38B, described in paragraphs [0161] to [0175] of the earliest application as filed. For the person skilled in the art, there is no reason to assume that because the wire mentioned in paragraph [030] is specified as a pull wire, the general teaching of paragraphs [030] and [031] should not remain valid for the described embodiment. According to this embodiment (paragraph [0163]), the flexing of the distal end portion of the elongated shaft takes place by pulling on a pull wire, which is achieved by rotating a rotatable member of a flex activating member. In the earliest application as filed, no other features, let alone the adjustment knob or the resilient steerable section of the elongated shaft, are disclosed as indispensable for achieving the flexing of the distal end portion of the elongated shaft, which is what the general teaching of paragraphs [030] and [031] is concerned with. Hence, the omitted features are not inextricably linked to the feature that the wire is a pull wire. Whether an adjustment knob and a resilient steerable section together with the pull wire may provide further advantages to effectively steer and then extract the catheter, as the opponent argued, is of no relevance.

As regards the opponent's reference to D12, the board notes that this document relates to an opinion of an opposition division in a related case but on a different claim, directed to a flex catheter for implantation of a prosthetic heart valve. For this reason alone, D12 is of no relevance for the assessment of added subject-matter in the current case.

2.2.3 The opponent argued that claim 1 of the main request comprised added subject-matter also because the omission in claim 1 of the main request that the movement of the flex indicating member relative to the handle portion was to indicate an amount of flex of the distal end portion of the elongated shaft was an impermissible intermediate generalisation.

In its preliminary opinion, the board explained why it considered this objection unconvincing. The opponent did not wish to add any comments on this issue after receiving the preliminary opinion.

Paragraph [030] of the earliest application as filed discloses that adjustment of the flex activating member causes the flex indicating member to move relative to the handle to indicate an amount of flex of the distal end portion of the shaft. Claim 1 of the main request recites that the flex activating member causes the flex indicating member to move relative to the handle. In the claim, the fact that this movement indicates flex is implied by the definition of the flex indicating member as part of an apparatus for indicating flex, and no other movement of the flex indicating member is defined. Hence, no intermediate generalisation is present.

2.3 The opponent raised a further objection of added subject-matter against claim 3 of the main request. In its preliminary opinion, the board explained why it found this objection convincing. The proprietor did not wish to add any comments on this issue after receiving the preliminary opinion.

Claim 3 of the main request specifies that "the flex activating member (154) and the flex indicating member (156) are separate members". It is common ground that the earliest application as filed does not provide a literal basis for this feature.

To assess whether the claim comprises added subject-matter, the feature has first to be interpreted. The interpretation has to be done in view of the patent as a whole (T 367/20, catchword and point 1.3.2 and T 873/23, point 1.6.1). The patent does not give an explicit definition of what is to be understood as "separate members". As the proprietor submitted and the opposition division concluded, the wording of claim 1 of the main request already implies that the flex activating member and the flex indicating member are distinct as they are listed as individual items, with the flex activating member having a portion configured to receive an extending portion of the flex indicating member.

The person skilled in the art would try to give a technically sensible meaning to the wording of claim 3 going beyond what is already defined in claim 1. As the opponent submitted, since claim 3 specifies that the two members are separate, claim 1 must be considered to include the option in which the members are not separate, otherwise claim 3 would be meaningless.

The term "separate" must therefore be considered to mean something different from simply distinct. In this context, the technically meaningful interpretation is that, according to claim 3, the two members in question are held at a distance from one another, for example, by means of an intermediate element. The board notes that the patent uses the term "separate" with this meaning in paragraph [0098] for the description of Figure 25.

Claim 1 does not exclude such an interpretation as it does not require a direct engagement of the two members but merely requires that a portion of the flex activating member be configured to receive an extending portion of the flex indicating member. With this construction, claim 3 finds no basis in the earliest application as filed. Hence, it includes added subject-matter.

2.4 In conclusion, the feature of the flex activating member comprising an externally threaded portion in claim 1 and the feature of the flex activating member and the flex indicating member being separate members in claim 3 of the main request extend beyond the content of the earliest application as filed. Hence, the ground for opposition in Article 100(c) EPC prejudices the maintenance of the patent on the basis of the main request.

The definition of a pull wire and the omission of the explicit definition that the movement of the flex indicating member relative to the handle portion is to indicate an amount of flex of the distal end portion of the elongated shaft in claim 1 of the main request do not result in added subject-matter.

3. Auxiliary requests 1 to 12 and 1' to 10'

Claim 3 of each of auxiliary requests 1 to 11 and 1' to 10' reads as claim 3 of the main request. It has not been disputed by the parties that the wording of claim 1 of these requests implies that the flex activating member and the flex indicating member are distinct. For the reasons given for claim 3 of the main request, these auxiliary requests are not allowable for added subject-matter (Article 76(1) EPC).

Claim 1 of auxiliary request 12 reads as claim 1 of the main request. For the reasons given for claim 1 of the main request, auxiliary request 12 is not allowable for added subject-matter (Article 76(1) EPC).

Hence, the patent cannot be maintained on the basis of any of auxiliary requests 1 to 12 and 1' to 10'.

4. Auxiliary request 1'' - extension of subject-matter and sufficiency of disclosure

4.1 Auxiliary request 1'' comprises a single claim (claim 1) which recites that it is the rotatable member of the flex activating member which also has an externally threaded surface portion. It is common ground that this overcomes the opponent's objection to the feature of the flex activating member comprising an externally threaded portion directed to claim 1 of the main request. It follows that none of the opponent's objections of added subject-matter prejudice the maintenance of the patent on the basis of auxiliary request 1''.

4.2 The opponent argued that the invention as defined in claim 1 of auxiliary request 1'' was not sufficiently

disclosed. In its preliminary opinion, the board explained why it did not find this objection convincing. The opponent did not wish to add any comments on this issue after receiving the preliminary opinion.

The opponent argued that the omission of the definition of a longitudinal slot for the flex indicating member resulted in the claimed invention being insufficiently disclosed, in essence because the person skilled in the art would not know how to make the flex indicating member indicate flex if no slot was present.

First and foremost, the claim does not require the absence of a slot. Moreover, sufficiency of disclosure must be assessed taking into consideration the description as a whole and the common general knowledge of the person skilled in the art. The claims can generalise a description as long as the person skilled in the art can figure out other arrangements according to the claims which are equivalent to the ones described. The description of the patent, in particular paragraph [0113], clearly discloses an embodiment in which the interaction between the flex activating member and the flex indicating member makes the latter move relative to the handle portion to indicate flex. In the third sentence of paragraph [0113], it is disclosed that the flex indicating member in the form of an indicator pin is trapped between the externally threaded surface portion of the rotatable member of the flex indicating member and the handle portion. This is achieved by a portion of the indicator pin extending into a longitudinal slot of the handle portion. However, the person skilled in the art knows other mechanical arrangements equivalent to the slot of the handle portion to trap the pin. For example, the flex

indicating member itself could have a slot for receiving an extending portion of the handle portion. To provide sufficiency of disclosure, there is therefore no need to claim the slot of the handle portion, as argued by the opponent.

Hence, the opponent's objection of insufficient disclosure (Article 83 EPC) does not prejudice the maintenance of the patent on the basis of auxiliary request 1''.

5. Auxiliary request 1'' - inventive step

The opponent argued that the subject-matter of claim 1 of auxiliary request 1'' was not inventive when starting from D1 or D9 in combination with D5, D7, D8 or D11.

5.1 It is common ground that D1 discloses (Figures 3A and 3B, reproduced below) an apparatus for flexing a distal end of a catheter comprising an elongated shaft (22), a pull wire (74), a handle portion (20), comprising a flex activating member with a rotatable member (70), and a slide member (68).

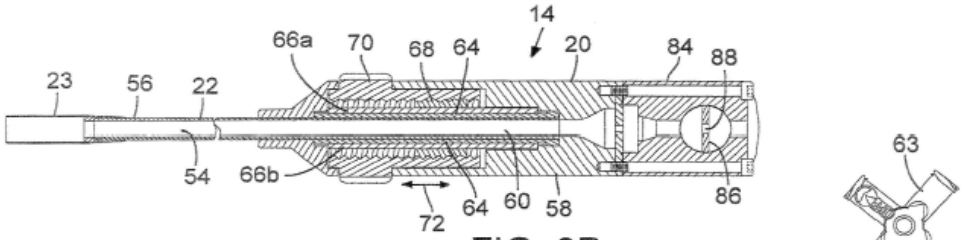


FIG. 3B

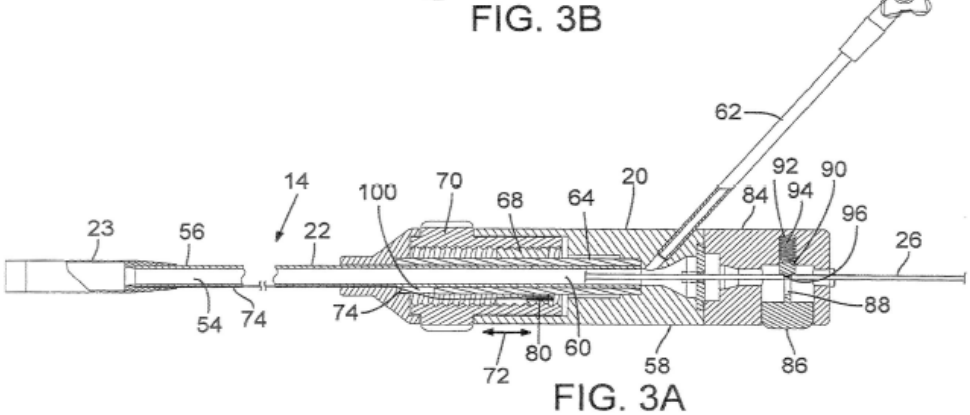


FIG. 3A

D1 does not disclose that the rotatable member of the flex activating member has an externally threaded surface portion configured to receive an extending portion of a flex indicating member.

5.2 D9 discloses an apparatus for flexing a distal end of a catheter (paragraph [0001]) and for indicating whether flex has been imparted to the catheter (paragraph [0047]).

The apparatus comprises (Figures 1, 2 and 7, reproduced below) an elongated shaft (40), a pull wire (70), a handle portion (23) comprising a flex activating member with a rotatable member (thumbwheel 25), a slide member (slideblock formed by 80 and 90) and a flex indicating member (the tab portion travelling in annular space 46 of indicator ring 45, as explained in paragraph [0047]).

FIG. 1

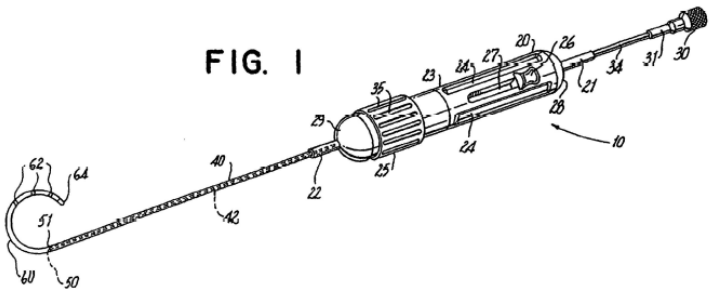


FIG. 2

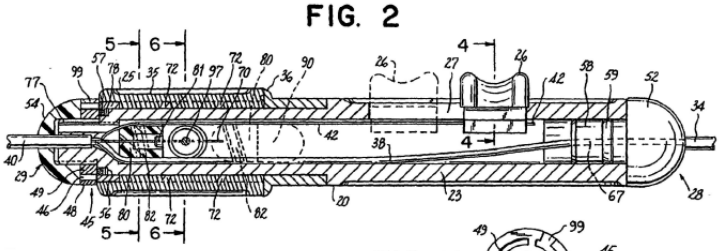
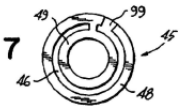


FIG. 7



Having identified the flex indicating member as explained above, D9 also discloses that adjustment of the flex activating member causes the flex indicating member to move relative to the handle portion.

D9 does not disclose that the rotatable member of the flex activating member has an externally threaded surface portion configured to receive an extending portion of the flex indicating member.

5.3 The board agrees with the opponent's view that the technical effect of the distinguishing feature over both D1 and D9 is that the degree of actuation of the rotatable member of the flex activating member can be indicated as the extending portion of the flex indicating member travels within the threads on the externally threaded surface portion of the rotatable member. The board is also convinced that the indication does not necessarily reflect the amount of flex experienced by the distal end portion of the elongated shaft. This is because that amount may also depend on the anatomy of a vessel in which the elongated shaft is

being navigated. The vessel anatomy may keep or force the elongated shaft into a flexed configuration even if the rotatable member is not actuated. The board is also convinced by the opponent's argument that the claimed apparatus is not restricted to catheters to be steered through vasculature.

However, the board does not share the opponent's view that the objective technical problem should be formulated as a pure mechanical problem without any reference to an indication of flex of the elongated shaft. As the proprietor submitted, the movement of the flex indicating member along the externally threaded surface portion of the rotatable member indicates the amount of flex actively imparted by a user to the distal end portion of the elongated shaft in a continuous way. When flex is actively imparted, the distal end portion of the elongated shaft experiences at least that imparted amount of flex. The objective technical problem must therefore relate to the provision of the indication of the degree of imparted flex. This is what the patent describes as the purpose of the flex indicating member and what is not disclosed in D1 and D9. The problem formulated by the opponent, i.e. how to determine the extent of actuation of the rotatable member, is not acceptable.

From paragraphs [0109] and [0110] of the patent, it is derivable that the continuous indication of the imparted flex may help a surgeon steer the catheter through a patient's vessel. This is because the imparted flex provides information on the possible configurations of the distal end of the elongated shaft. The objective technical problem solved by the distinguishing feature is therefore providing feedback on the flexed configuration of the catheter for helping

a surgeon steer the catheter through a patient's vessel.

Neither D1 nor D9 discloses a flex indicating member which can provide a continuous indication of the degree of flex imparted to the distal end of a catheter. D1 does not disclose any indication of the degree of imparted flex. D9 discloses a flex indicating member which only indicates when the rotatable member has not imparted any flex to the distal end of the catheter. Once the rotatable member is rotated from its initial position to flex the distal end of the catheter, the flex indicating member is no longer visible (through hole 99, Figure 7, as described in paragraph [0047]).

The opponent referred to D5, D7, D8 and D11 as secondary documents. However, none of these other documents disclose the distinguishing features for the solution of the objective technical problem.

D5, D7 and D8 are concerned with twistable tip catheters (page 1, lines 5 to 10 of D5; column 1, lines 4 to 6 of D7; paragraph [0058] of D8). According to D5, D7 and D8, it is desirable to twist the tip of the catheter once the catheter has reached its target (page 1, line 27 to page 2, line 7 of D5; column 1, lines 22 to 29 of D7; paragraph [0083] of D8).

After receiving the board's preliminary opinion, the opponent argued that D7 also related to the problem of helping steer catheters through vasculature as it disclosed a system for gaining control over the rotational orientation of the distal end of guiding catheters (column 2, lines 13 to 15 and 49 to 54) while navigating the catheters to areas of interest (column 10, lines 46 to 49). The board admits the

opponent's arguments and accepts that D7 is also concerned with navigating catheters through a patient's vessel.

Nevertheless D7, as well as D5 and D8, is not concerned with providing feedback on the flexed configuration of catheters. The distal end section of the twistable tip catheters according to these documents has a fixed amount of flex.

Hence, the person skilled in the art, faced with the objective technical problem, would have found no solution to it in D5, D7 or D8.

D11 is concerned with catheters having guidewire components (page 1, lines 8 to 12). It discloses means for visually indicating the amount of rotation of a guidewire component within a catheter. It does not suggest providing any feedback on the flexed configuration of the catheter itself. The person skilled in the art, faced with the objective technical problem, would have found no solution to it in D11 either.

It follows that the person skilled in the art would have had no obvious reason to implement components disclosed in D5, D7, D8 and D11 in the devices according to D1 or D9, irrespective of the technical feasibility of such implementations.

As a consequence, the board must conclude that the opposition division correctly decided that the subject-matter of claim 1 of auxiliary request 1'' involves an inventive step (Article 56 EPC) over the combination of D1 or D9 with D5, D7, D8 or D11. The board notes that this conclusion is in agreement with the findings of

the UPC in decision UPC_CFI_380/2023.

As regards the opponent's reference to D12, this document relates to an opinion of an opposition division in a related case but on a different claim. Moreover, the opposition division did not express an opinion on inventive step but only stated that inventive step might have to be discussed in light of some considerations. D12 does not change the board's assessment of inventive step in the current case.

6. Since none of the opponent's objections prejudices the maintenance of the patent on the basis of auxiliary request 1'', the patent must be maintained accordingly.

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 on the basis of:

   - claim 1 of auxiliary request 1'', filed with letter dated 17 December 2024

   - the description and the drawings of the patent specification

The Registrar: The Chairman:

A. Chavinier-Tomsic M. Alvazzi Delfrate

Decision electronically authenticated