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Datasheet for the decision of 6 July 2020

Case Number: T 0777/19 - 3.2.02

Application Number: 15158361.4

Publication Number: 2907458

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Language of the proceedings: EN

Title of invention:
MEDICAL DEVICE FOR CAUSING HEMOSTASIS

Patent Proprietor:
Boston Scientific Limited

Opponent:
M T W-Endoskopie W. Haag KG

Headword:

Relevant legal provisions:
EPC Art. 54(1), 54(2), 56, 76(1), 84, 100(a), 100(b), 100(c), 123(2), 123(3)

Keyword:

Subject-matter extends beyond content of original or earlier application - main request and auxiliary requests 1 to 4B (yes) - auxiliary request 5 (no)
Claims - clarity and support in the description - auxiliary request 5 (yes)
Amendments - extension of the scope of protection of the patent (no)
Insufficiency of disclosure (no)
Novelty - auxiliary request 5 (yes)
Inventive step - auxiliary request 5 (yes)

Decisions cited:

T 0639/13, T 2002/13

Catchword:

Europäisches Patentamt
European Patent Office
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Beschwerdekammern

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Case Number: T 0777/19 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 6 July 2020

Appellant: (Patent Proprietor)	Boston Scientific Limited Clarendon House 2 Church Street Hamilton HM11 (BM)
Representative:	Vossius & Partner Patentanwälte Rechtsanwälte mbB Siebertstrasse 3 81675 München (DE)
Appellant: (Opponent)	M T W-Endoskopie W. Haag KG Goldsbergstraße 18 46487 Wesel (DE)
Representative:	Brötz, Helmut Rieder & Partner mbB Patentanwälte - Rechtsanwalt Corneliusstrasse 45 42329 Wuppertal (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 18 January 2019 concerning the maintenance of European Patent No. 2907458 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 have appealed against the Opposition Division's decision, posted on 18 January 2019, that, account being taken of the amendments according to auxiliary request 14 then on file, European patent No. 2 907 458 and the invention to which it related met the requirements of the EPC.

The patent is derived from a divisional application of European patent application No. 02 775 909.1 ("the parent application"), which was the object of case T 639/13. It was opposed on the grounds of added subject-matter, insufficiency of disclosure, lack of novelty and lack of inventive step.

II. Oral proceedings took place on 6 July 2020.

The appellant/patent proprietor ("the proprietor") requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or on the basis of one of auxiliary requests 1A to 1D, 2 to 2B, 3 to 3B, 4 to 4B and 5 to 5D, filed with the statement setting out the grounds of appeal dated 27 May 2019 (auxiliary requests 1A, 1B, 2 to 2B, 3 to 3B, 4 to 4B, 5 to 5B) and with letter dated 13 December 2019 (auxiliary requests 1C, 1D, 5C and 5D).

The appellant/opponent ("the opponent") requested that the decision under appeal be set aside and that the patent be revoked.

III. The following documents are mentioned in the present decision:

E1: DE-A-199 25 304
E3: EP-A-0 738 501
E4: US-A-5,766,189

IV. **Claim 1 of the patent as granted** reads as follows:

"A medical device (100) for causing the hemostasis of a blood vessel for use through an endoscope, said medical device comprising:

a clip (101), the clip (101) having at least two clip legs (102, 103);
a control wire (108);
an axially rigid sheath (111) enclosing the control wire (108), the sheath (111) able to communicate a first force opposing a second force of the control wire (108);
a lock sleeve (113), wherein the control wire (108) is able to be pulled in a proximal direction to pull the clip (101) through the lock sleeve (113), thereby closing the clip legs (102, 103);
a retainer (110) releasably coupled to the lock sleeve (113);
a retainer release arrangement (109), the retainer release arrangement (109) able to engage the retainer (110) to uncouple the retainer (110) from the lock sleeve (113) in order to release or uncouple the lock sleeve (113) from the device (100);
a handle coupled to the axially rigid sheath (111); and
an actuator coupled to the control wire (108), the control wire (108) engageable by the actuator to

open the at least two clip legs (102, 103), to close the at least two clip legs (102, 103), and to uncouple the control wire (108) from the clip (101),
wherein the control wire (108) is coupled to the clip (101) by a j-hook (107), the j-hook (107) being able to be deformed by a first predetermined tensile force, and wherein, when the j-hook (107) is deformed, the control wire (108) uncouples from the clip (101); and
wherein the control wire (108) is reversibly operable both to open the at least two clip legs (102, 103) and to close the at least two clip legs (102, 103)."

Claim 1 of each of auxiliary requests 1A to 1C reads as claim 1 of the patent as granted.

Claim 1 of auxiliary request 1D reads as claim 1 of the patent as granted with the addition of the following wording at the end of the claim:

", wherein the control wire (108) is able to be pushed in a distal direction to push the clip (101) out of the lock sleeve (113), thereby opening the clip legs (102, 103)".

Claim 1 of each of auxiliary requests 2 to 2B reads as claim 1 of the patent as granted with the addition of the following wording after the second occurrence of the expression "wherein the control wire (108)":

"offers sufficient strength in both tension and compression, wherein the control wire (108)".

Claim 1 of each of auxiliary requests 3 to 3B reads as claim 1 of the patent as granted with the addition of the following wording after the second occurrence of the expression "wherein the control wire (108)":

"is a stainless steel wire, wherein the control wire (108)".

Claim 1 of each of auxiliary requests 4 to 4B reads as claim 1 of the patent as granted with the addition of the following wording after the second occurrence of the expression "wherein the control wire (108)":

"is a stainless steel wire that offers sufficient strength in both tension and compression, wherein the control wire (108)".

Claim 1 of auxiliary request 5 reads as claim 1 of the patent as granted except that the term "deformed" (two occurrences) is replaced by "straightened".

Dependent claims 4 to 7 of auxiliary request 5 read as follows:

"4. The medical device of claim 1, 2 or 3, wherein the retainer (110) is coupled to the control wire (108) and engages the lock sleeve (113)."

"5. The medical device of claim 2, 3, or 4, wherein the outer sleeve (112) has retainer cut-outs, wherein the retainer release arrangement (109) forces the retainer (110) to be disengaged from the outer sleeve (112) as the control wire (108) is actuated."

"6. The medical device according to claim 5, wherein the retainer cut-outs house retainer tabs (118, 119) of the retainer (110)."

"7. The medical device of claim 6, wherein the outer sleeve (112) has two retainer cut-outs situated 180° apart from each other."

Claims 2, 3 and 8 of auxiliary request 5 are further dependent claims.

V. The proprietor's arguments, where relevant to the present decision, may be summarised as follows:

Main request and auxiliary requests 1 to 4B - extension of subject-matter

The definition of the deformation of the j-hook in claim 1 of the patent as granted and each of auxiliary requests 1 to 4B was not so general that any kind of deformation would fall under the scope of the claim. Rather, claim 1 defined a specific deformation occurring under the application of a tensile force and causing the uncoupling of the control wire from the clip. For such a definition, there was a partial basis in claim 3 of the parent application as filed, which disclosed such a deformation as a straightening of the j-hook. Moreover, page 11, lines 5 to 9, disclosed that the j-hook was "able to deform to a straightened position (i.e. release) at a predetermined tensile load".

After the detailed description of a first embodiment, the parent application as filed provided a "wrap-up", starting on page 21, line 26, which applied to all embodiments of the invention. According to page 22,

lines 5 to 9, the property of the j-hook which was important for the functionality of the device was its general ability to be deformed under the application of a tensile load. The specific deformation by straightening, recited in claim 3 of the parent application, was therefore to be considered as a mere option in view of that more general disclosure.

Hence, the addition of the feature of the j-hook being able to be deformed in claim 1 of the patent as granted and each of auxiliary requests 1 to 4B would not have given the person skilled in the art any information that was not derivable from the parent application as filed. The specific deformation by straightening was not inextricably linked to the specific technical effect to be obtained by the deformation of the j-hook.

Auxiliary request 5 - extension of subject-matter of claim 1

The original application as filed comprised the description, the drawings and the claims, in the form of "aspects" described on pages 4a to 4k, of the parent application as filed. For the assessment of added subject-matter, if a certain claim feature found a basis in the parent application as filed, a corresponding basis would also be present in the original application as filed.

In claim 1 of auxiliary request 5, the j-hook was defined as being able to be straightened by a first predetermined tensile force so that the control wire would uncouple from the clip. This feature was fully based on claim 3 of the parent application as filed.

More generally, the subject-matter of claim 1 of

auxiliary request 5 was based on claims 1, 3, 16 and 20 of the parent application as filed. Although claim 16 was not drafted as dependent on claim 3, the features recited in those claims were not incompatible and were disclosed in combination in the detailed description of the preferred embodiment.

The feature of the uncoupling of the retainer from the lock sleeve being "in order to release or uncouple the lock sleeve from the device" was not expressly recited in the combination of claims 1, 3, 16 and 20 of the parent application as filed.

However, an additional basis for this feature was provided on page 8, lines 17 to 20, together with page 10, lines 1 to 4. The specific wording "release or uncouple" did not define a mere alternative from a technical point of view. While the lock sleeve could be in an uncoupled but still not released state with respect to the device, the release could only take place if the two elements were uncoupled. Moreover, the feature in question was not illogical. The claim simply meant that the lock sleeve was part of the device prior to release and would separate from the (rest of) the device upon release.

Compared with the combination of claims 1, 3, 16 and 20 of the parent application as filed, claim 1 of auxiliary request 5 defined the control wire as being coupled to the clip instead of being able to be coupled to the clip. The difference was purely linguistic: if the control wire were not coupled to the clip, the medical device could not work properly. Moreover, the coupling was already implied in the claims of the parent application as filed and was clearly disclosed in the description of the preferred embodiment of the

invention.

Auxiliary request 5 - extension of subject-matter of dependent claims

The features of the retainer defined in claim 4 of auxiliary request 5 were based on page 7, line 30, of the parent application as filed. No impermissible intermediate generalisation had taken place in view of claim 20 of the parent application as filed and the common general knowledge of the person skilled in the art.

As regards claims 5 and 6, the parent application as originally filed disclosed two retainer cut-outs situated 180° apart from each other. However, the person skilled in the art would clearly have realised that additional retainer cut-outs could be provided and that the angle between such cut-outs could be varied. The technical effect provided by the retainer cut-outs was not dependent on limiting their number to two or a particular angular spacing of 180°.

Auxiliary request 5 - clarity and support in the description

The amendment in claim 1 of auxiliary request 5 with respect to claim 1 of the patent as granted did not add any lack of compliance with Article 84 EPC. In particular, no other essential features had to be added in the claim because of the definition of the j-hook being able to be straightened. The description of the preferred embodiment supported this definition.

Auxiliary request 5 - extension of the scope of protection

Due to the amendment in claim 1 of auxiliary request 5, the scope of protection of the patent according to this request was narrower than that of the patent as granted. The term "straightened" was more specific than "deformed". Hence, no *aliud* had been added by the amendment. The opponent had failed to provide any explanation why the amendment would lead to embodiments being claimed that were not within the scope of the granted claims.

Auxiliary request 5 - sufficiency of disclosure

The invention as claimed in auxiliary request 5 was sufficiently disclosed in the patent. Paragraph [0011] described the object of the invention. Paragraph [0016] explained that this object was achieved by the ability of the device to repeatedly open and close the clip. The description of the preferred embodiment disclosed how such a device could be carried out in practice. Paragraph [0017] of the patent was not related to the claimed reversibility. More generally, the opponent had not provided any verifiable facts that could raise serious doubts whether the claimed invention could be put into practice.

Auxiliary request 5 - double patenting

European patent No. 2 907 459, derived from a further divisional application of the parent application of the patent in suit, had a different scope. Moreover, this other European patent was also the object of appeal proceedings (T 1648/19) which were not yet terminated. It followed that the maintenance of the patent in this

case could not give rise to a case of double patenting.

Auxiliary request 5 - novelty

The subject-matter of claim 1 of auxiliary request 5 was novel over E3. This document did not disclose a control wire which was reversibly operable both to open and to close two clip legs, as also explained in decision T 639/13, which had already considered the disclosure of E3. Column 5, lines 51 to 54, and column 14, lines 51 to 58 explained how the clip disclosed in E3 worked. Once the clip had been pulled within a clip fastening ring, it was not possible to reverse this movement.

E4 did not disclose a control wire which was reversibly operable both to open and to close two clip legs either. The clip disclosed in relation to different embodiments of E4 functioned in a manner similar to that of E3, as explained in column 5, lines 15 to 21 and 39 to 45, and column 6, lines 53 to 56.

It followed that the subject-matter of claim 1 of auxiliary request 5 was novel.

Auxiliary request 5 - inventive step

As derivable from paragraph [0016] of the patent, the problem solved by the distinguishing feature of claim 1 of auxiliary request 5 over each of E3 and E4 was to obtain a quicker endoscopic procedure, requiring less clips to be deployed, with a higher success rate.

This problem was not addressed in either E3 or E4. Since these documents did not disclose the distinguishing feature either, the subject-matter of

claim 1 of auxiliary request 5 was inventive over these two documents, alone or in combination with each other.

E1 concerned a very different kind of device, in particular for achieving hemostasis in intracranial surgical procedures. Accordingly, it disclosed a clip device which allowed not only to apply a clip but also to remove it from the point of application (column 4, lines 31 to 34). There was no reason why the person skilled in the art would have considered E1 for solving the objective technical problem. Moreover, the structure of E1 was completely different from that of E3 and E4. If the person skilled in the art had considered E1 at all for the solution of this problem, he or she would have not tried to modify E3 or E4 but would rather have adopted the complete structure of E1. This would not have led to the subject-matter of claim 1 of auxiliary request 5, which was therefore inventive when starting from either of E3 or E4 in combination with E1.

Other objections

The opponent had raised further objections which were completely unsubstantiated. They should be disregarded.

VI. The opponent's arguments, where relevant to the present decision, may be summarised as follows:

Main request and auxiliary requests 1 to 4B - extension of subject-matter

There was no basis in the parent application as filed for the feature of the j-hook being able to be deformed by a first predetermined tensile force, as defined in claim 1 of the patent as granted and each of auxiliary

requests 1 to 4B. The parent application as filed consistently taught (page 10, lines 1 to 4, and page 11, lines 4 to 9, for example) that the j-hook had to be straightened for the control wire to uncouple from the clip.

Page 22, lines 5 to 9, referred to by the proprietor, concerned the specific description of the first embodiment of the patent, which comprised a j-hook to be straightened. The deformation mentioned in that passage related to the properties of the material of the control wire necessary for the ability of the device to release the clip as described in the first embodiment.

The generalisation of the specific deformation by straightening would have presented the person skilled in the art with information not derivable from the parent application as filed.

Auxiliary request 5 - extension of subject-matter of claim 1

Although on pages 4a to 4k the application as filed formally comprised the claims of the parent application, recited as aspects being preferred embodiments of the invention, the person skilled in the art would have immediately recognised that these aspects were incompatible with the subject-matter claimed in the application as filed. Hence, these aspects constituted an independent disclosure, separate from the rest of the application as filed. The combination of features of this separate disclosure with features of the rest of the application was not permissible in view of Article 123(2) EPC. It was as if features belonging to two separate lists were

arbitrarily combined with each other.

Moreover, claims 3 and 16 of the parent application as filed had been drafted as individually dependent on claim 1 but not on each other. Hence, these claims did not disclose their respective features in combination. It followed that the subject-matter of claim 1 of auxiliary request 5 could not be based on the combination of claims 1, 3, 16 and 20 of the parent application as filed. Only the detailed description of the embodiment depicted in Figures 1 to 6 of the patent could serve as a basis for the claimed subject-matter when assessing compliance with Articles 76(1) and 123(2) EPC.

However, according to this detailed description, several other non-claimed features were inextricably linked with the claimed ones. In particular, the j-hook was part of the control wire and provided in its distal end; the clip was provided with cut-outs in which the j-hook would be inserted for coupling with the clip; the control wire comprised a retainer release formed in it; the clip legs comprised lock holes; and the lock sleeve comprised lock pawls such that a coupling between the lock holes and the lock pawls kept the clip closed after deployment.

There was no basis in the parent application or the application as filed for the wording "to release or uncouple" in claim 1 of auxiliary request 5. The term "uncouple" was only employed in relation to the clip; not to the lock sleeve. The problematic wording clearly defined two alternatives. However, there was no disclosure of any difference between these alternatives. Moreover, the parent application and the application as filed consistently taught that the lock

sleeve was part of the claimed medical device. This contradicted the claim wording, which expressly recited that the lock sleeve could be uncoupled from the device. It followed that the claim made no technical sense. Still, in accordance with decision T 2002/13, even nonsensical features needed a basis in the application as filed for compliance with Article 123(2) EPC.

Claim 1 also recited that the control wire was coupled to the clip. This had a different meaning from the originally disclosed feature, according to which the control wire was able to be coupled to the clip. Its two elements were already coupled, they could not be again coupled. Hence, the claim did not make any technical sense in this respect either. Whether Figures 1 to 7 showed a control wire coupled to the clip was of little relevance in the assessment of added subject-matter since it was not permissible to pick only some features of an originally disclosed combination.

Auxiliary request 5 - extension of subject-matter of dependent claims

The additional features defined in dependent claims 4, 5, 6 and 7 were disclosed in the parent application as filed only in inextricable combination with each other and other features disclosed together on page 7, lines 27 to 32.

As regards the retainer cut-outs and retainer tabs defined in claims 5 and 6, both the parent application and the application as filed only disclosed two retainer cut-outs disposed in front of each other. Moreover, page 11, lines 20 to 23, of the parent

application as filed disclosed that the retainer release engaged and deformed the retainer so that the retainer tabs disengaged from the outer sleeve. This necessary deformation would be hindered if more than two tabs were present.

Auxiliary request 5 - clarity and support in the description

The description of the patent only supported a combination of a j-hook which could be straightened, together with the other features of the embodiment of Figures 1 to 6, in particular the j-hook being formed in the distal end of the control wire. Hence, the subject-matter of claim 1, which did not comprise those other essential features, contravened Article 84 EPC. The replacement in the claim of the term "deformed" with "straightened" had given rise to this objection. For example, it was possible to conceive a j-hook made of sheet metal which could not be straightened. There was no support in the description for such a j-hook.

Auxiliary request 5 - extension of the scope of protection

The addition of the term "straightened" in claim 1 of auxiliary 5 extended the scope of protection of the patent. In this respect, it was not decisive whether "straightened" was more specific than "deformed". Since different embodiments had been combined, an *aliud* had been added into the claim. This was not permissible under Article 123(3) EPC.

Auxiliary request 5 - sufficiency of disclosure

The feature of the control wire being "reversibly

operable both to open the at least two clip legs (102, 103) and to close the at least two clip legs (102, 103)" in claim 1 of auxiliary request 5 was not sufficiently disclosed in the patent.

According to the patent (column 3, lines 56 to 59), "the 'single-use' (disposable) embodiments of the invention disclosed here would function the same with each clip, in each procedure." However, it was not explained how this could be possible in view of the effects of wear and fatigue.

Auxiliary request 5 - double patenting

European patent No. 2 907 459 had been maintained in amended form after first-instance opposition proceedings. The scope of the claims of auxiliary request 2, on the basis of which the patent had been maintained, impermissibly overlapped with the scope of the claims of auxiliary request 5 of the patent in suit. Whether European patent No. 2 907 459 was the object of still ongoing appeal proceedings (T 1648/19) was not decisive.

Auxiliary request 5 - novelty

The subject-matter of claim 1 of auxiliary request 5 was not novel over E3. In particular, the claim did not require that the clip could be completely closed or should grasp tissue during the reversible operation of the control wire to open and to close the two clip legs. The magnitude of the force applied to clip fastening ring 46 by coupling ring 29 in a device disclosed in E3 was dependent on the nature of the fit between these two elements. It would have been clear to the person skilled in the art that a suitable fit would

allow partially withdrawing the clip within, and then back out of, clip fastening ring 46 without any relative motion of the clip fastening ring with respect to the coupling ring. This partial withdrawal amounted to a reversible opening and closing of the clip legs as defined in claim 1.

The subject-matter of claim 1 of auxiliary request 5 was not novel over E4 either. E4 disclosed a control wire reversibly operable both to open two clip legs and to close the two clip legs based on considerations similar to those with respect to E3. According to a first embodiment described in relation to Figures 1A to 8 and a second embodiment described in relation to Figures 9A and 9B, the claimed reversible operation was performed by the presence of a coil pipe (7a) in cooperation with a holding tube (4), the latter permitting the closing and opening of the clip legs. Column 4, lines 32 to 36 and 52 to 57, disclosed that the diameters of the coil pipe and the holding tube were to be chosen to enable the insertion of the coil pipe in the holding tube. This inevitably meant a certain interference fit to avoid loosing the two elements concerned.

Auxiliary request 5 - inventive step

Even if it were considered that E3 and E4 did not directly and unambiguously disclose a control wire reversibly operable both to open two clip legs and to close the two clip legs, when starting from either of these documents as the closest prior art, this distinguishing feature would have been obvious. The feature was formulated in terms of a result to be achieved and, as such, would have prompted the person skilled in the art to implement it. More specifically,

the person skilled in the art would have implemented an interference fit between clip fastening ring 46 and coupling ring 29 of E3 and between holding tube 4 and coil pipe 7a of both embodiments of E4 to avoid the danger of the clip fastening ring or the holding tube falling off. E3 disclosed clips which permitted a reversible movement, albeit in relation to a different device (column 18, lines 49 to 57 and Figures 22 to 25). An interference fit was taught by E4 in column 4, lines 32 to 36 and 52 to 57. Moreover, when considering an interference fit, the person skilled in the art would have provided a fit that enabled the clip to be moved in and out of the clip fastening ring of E3 or the holding tube of E4 as a mere matter of design optimisation, as the advantages of such an arrangement would have been apparent.

The subject-matter of claim 1 of auxiliary request 5 did not involve an inventive step either in view of the teaching of E1. E1 disclosed a device for endoscopic procedures, which was not limited to brain surgery. This was derivable, in particular, from claim 1 of E1.

E1 disclosed a clip device which allowed applying and removing a clip when needed (column 1, lines 49 to 53). For this purpose it employed a bayonet coupling mechanism. The person skilled in the art, considering that such a mechanism permitted easily repositioning a clip in endoscopic procedures, would have applied the teaching of E1 to the closest prior art and adapted the mechanisms for deploying the clip such that the two clip legs could be reversibly opened and closed. In doing so, he or she would have arrived at the subject-matter of claim 1 of auxiliary request 5 in an obvious way.

Other objections

In the written procedure, reference was made to all the objections raised during the first-instance proceedings, in particular to those of lack of novelty and inventive step based on documents published after the priority date of the patent. These documents, which had not been considered by the Opposition Division in the impugned decision, belonged to the state of the art since the lack of compliance with Article 76(1) EPC rendered invalid the priority claim. There was no need in appeal proceedings to repeat the arguments on which these objections were based. On the contrary, reasons had to be given as to why the impugned decision should be set aside, instead of only repeating arguments already presented in the first-instance proceedings.

Reasons for the Decision

1. The invention

The invention relates to a medical device for causing the hemostasis of a blood vessel for use through an endoscope.

According to the patent, such a device can be employed to stop the bleeding of blood vessels located along the gastrointestinal tract. An endoscope permits reaching the target site.

Figures 1 to 7 of the patent depict an embodiment of the invention. Figure 1 is reproduced below.

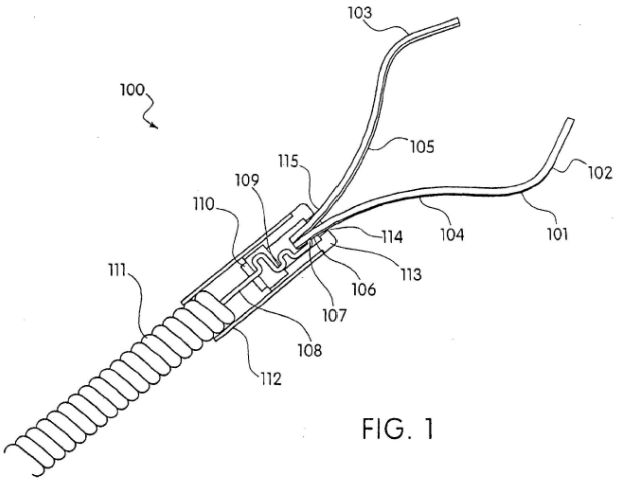

FIG. 1

The device comprises a clip (101) to be released at the target site. The clip has at least two legs (102, 103) intended, when deployed, to close around and compress the bleeding blood vessel.

The device further comprises a mechanism for deploying the clip, comprising a control wire (108); an axially rigid sheath (111) enclosing the control wire; a lock sleeve (113) through which the clip can be pulled by pulling the control wire, thus closing the clip legs; a retainer (110) releasably coupled to the lock sleeve; and an actuator coupled to the control wire to open and close the clip legs and uncouple the control wire from the clip.

The control wire is reversibly operable both to open and to close the at least two clip legs by being coupled to the clip by a j-hook (107). The j-hook can be deformed (according to claim 1 of the patent as granted) or straightened (according to claim 1 of auxiliary request 5) by a first predetermined tensile force. When the j-hook is deformed the control wire uncouples from the clip, which is left in situ in the closed state around the blood vessel to be treated.

According to the patent, the ability of the device to repeatedly open and close the clip until the desired tissue pinching is accomplished leads to a quicker procedure, requiring less clips to be deployed, with a higher success rate (paragraph [0016]).

2. Main request and auxiliary requests 1 to 4B - extension of subject-matter

In the impugned decision, the Opposition Division held that the subject-matter of claim 1 of the main request extended beyond the content of the parent application as filed. In particular, the claim feature "the j-hook (107) being able to be deformed by a first predetermined tensile force, and wherein, when the j-hook (107) is deformed, the control wire (108) uncouples from the clip (101)" was considered to add an impermissible intermediate generalisation.

The Board agrees with the proprietor that this feature does not imply that any kind of deformation of the j-hook falls within the scope of the claim. A more specific deformation under the application of a tensile force is defined. Still, the Board concurs with the Opposition Division's conclusions.

The feature in question finds a partial basis in claim 3 of the parent application as filed. However, this claim is more specific as it discloses that the uncoupling of the control wire from the clip takes place when the j-hook is straightened by a first predetermined tensile force.

Straightening of the j-hook under the application of a predetermined tensile force is consistently taught in claim 40 as well as in the detailed description of the

first embodiment of the invention in relation to Figures 1 to 7 (page 8, lines 15 and 16; page 10, lines 1 to 4; page 11, lines 4 to 9 and 18 to 24).

The only passage in the parent application as filed in which a more general deformation is mentioned alone is on page 22, lines 4 to 9:

> "*The control wire in the first embodiment may be a stainless steel wire. Because the wire must offer sufficient strength in both tension and compression, the material properties of the wire are important to the functionality of the device. Also, the end of the wire, where the j-hook is formed, must deform when a predetermined tensile load is applied. The device's ability to release the clip is dependent on this property.*"

However, contrary to the proprietor's assertion, this passage does not apply to all the embodiments but specifically concerns a material of the control wire of the first embodiment, as stated in the first sentence. Hence, the mentioned deformation of the j-hook is in relation to the material properties necessary for the control wire of that embodiment. In other words, the teaching of the passage is that certain material properties are needed to ensure that the specific deformation (by straightening) of the j-hook of the first embodiment reliably takes place. There is no teaching that only the ability of the j-hook to be deformed under the application of a predetermined tensile load would be of importance for the functionality of the device of the invention.

In view of the specific shape and arrangement of the j-hook in Figures 1, 2, 5 and 6, the person skilled in

the art, based on the common general knowledge, would not have figured out either that a deformation of the j-hook other than the disclosed straightening could also be implemented. It is the specific deformation by straightening that enables j-hook 107 to come out of engagement with the clip.

It is therefore the Board's view that the parent application as filed inextricably links, from a technical point of view, the straightening of the j-hook with the uncoupling of the control wire from the clip.

In conclusion, omitting the straightening from claim 1 amounts to a non-allowable intermediate generalisation as it conveys the information, not disclosed in the parent application as filed, that this straightening is not necessary for the uncoupling to take place.

It follows that the patent cannot be maintained as granted for lack of compliance with Article 76(1) EPC. The same applies to auxiliary requests 1 to 4B since their respective claim 1s also omit the straightening of the j-hook.

3. Auxiliary request 5 - extension of subject-matter of claim 1

3.1 The application as filed comprises the description and figures of the parent application as filed. It also comprises the claims of the parent application on pages 4a to 4k. These claims are named "aspects" and are stated to be preferred embodiments of the invention.

The opponent argued that these aspects were not compatible with claim 1 of the application as filed.

However, for the assessment of added subject-matter, the disclosure of the application as a whole has to be considered. This disclosure conveys the explicit information that the "aspects" are embodiments of the invention. It also conveys the information that the subject-matter of the claims defines the invention. The Board notes that these pieces of information overlap to a large degree since aspect 1 is merely broader than claim 1 of the application as filed, which additionally comprises the feature "wherein the control wire is coupled to the clip by a j-hook, the j-hook being able to be deformed by a first predetermined tensile force, and when the j-hook is deformed, the control wire uncouples from the clip". Such a difference between what is stated to be the invention in the description and what is defined by the claims does not affect the contribution of the information conveyed to the person skilled in the art by each individual disclosure in combination with the remaining part of the application. It could be, at most, a matter to be addressed during substantive examination of the application in view of the requirements of clarity and support in the description of the claims according to Article 84 EPC.

This leads the Board to the conclusion that the whole content of the parent application as filed is included in the application as filed and that the objections of added subject-matter with respect to both of these applications can be assessed with reference only to the parent application as filed.

3.2 In claim 1 of auxiliary request 5, the problematic feature of claim 1 of the higher-ranking requests has been amended to read "the j-hook (107) being able to be straightened by a first predetermined tensile force, and wherein, when the j-hook (107) is straightened, the

control wire (108) uncouples from the clip (101)".

This solves the issue of added subject-matter analysed under point 2 above.

The subject-matter of claim 1 of auxiliary request 5 is mainly based on the combination of claims 1, 3, 16 and 20 of the parent application as filed.

Claim 20 is dependent on claim 16, but claims 3 and 16 are individually dependent on claim 1 and not on each other.

However, claim 3 defines features of the j-hook, while claims 16 and 20 define features of the lock sleeve, the retainer and the retainer release arrangement.

In view of the original parent application as a whole, which has to be duly taken into account without any artificial separation between the claims, the description and the drawings, these features are not mutually exclusive. The first embodiment described in relation to Figures 1 to 7 clearly comprises them in combination. Their interaction permits the manipulation and the release of the clip.

It follows that the person skilled in the art directly and unambiguously would have received the technical information that the features recited in these claims of the parent application as filed, at their level of generality, could coexist in combination.

Whether the detailed description of the first embodiment contains further non-claimed features, such as the ones identified by the opponent, is of little relevance since the claims teach that those other

features are optional.

3.3 The opponent argued that there was no basis in the parent application as filed for the feature of "the retainer release arrangement (109) able to engage the retainer (110) to uncouple the retainer (110) from the lock sleeve (113) in order to release or uncouple the lock sleeve (113) from the device (100)". More specifically, it argued that the wording "to release or uncouple" was problematic.

Claims 1, 3, 16 and 20 of the parent application as filed, alone, do not provide a basis for this feature. However, a basis is provided on page 8, lines 16 to 20, and page 10, lines 1 to 4, of the parent application as filed. These passages expressly mention that once the j-hook has been pulled out of engagement with the clip, the retainer and the control wire are no longer attached to the lock sleeve which will consequently release from an outer sleeve (of the device) and be left in place.

Whether the term "uncouple" is employed in relation to the lock sleeve in the parent application as filed is irrelevant if the technical information conveyed by this term is directly and unambiguously derivable from the parent application as filed. That technical information is provided by the disclosure of the lock sleeve being no longer attached to the outer sleeve.

The opponent's argument that there was no disclosure of any difference between "release" and "uncouple" is not convincing. The passages mentioned just above differentiate between the situation of the lock sleeve being no longer attached (i.e. uncoupled) and the lock sleeve being released and left in place. Hence, the

alternative defined by the term "or" makes technical sense. It follows that the opponent's reference to decision T 2002/13, concerning nonsensical claim features, is irrelevant.

The opponent further argued that the parent application as filed disclosed that the lock sleeve was part of the claimed medical device and that, as a consequence, it could not be uncoupled from that device. However, in the Board's view the person skilled in the art, when reading the claim with the intention of making technical sense out of it and in the light of the disclosure of the patent as a whole, would have understood the claim to mean that the uncoupling of the retainer from the lock sleeve would cause the lock sleeve to be released or uncoupled from the rest of the device. There is a basis for this technically meaningful construction of the claim on page 8, lines 16 to 20, and page 10, lines 1 to 4, of the parent application as filed, as explained above.

3.4 Compared with the combination of claims 1, 3, 16 and 20 of the parent application as filed, claim 1 of auxiliary request 5 defines the control wire as being coupled to the clip instead of being able to be coupled to the clip.

The Board agrees with the proprietor that this difference is purely linguistic in view of the remaining claim features. Claim 3 of the parent application as filed recites that when the j-hook is straightened, the control wire uncouples from the clip. This implies a coupling. Accordingly, Figure 1 of the first embodiment of the invention clearly shows the condition of the control wire being coupled to the clip. This makes technical sense and is necessary for

the intended use of the device, i.e. the application of clips to bleeding blood vessels.

3.5 For these reasons, the subject-matter of claim 1 of auxiliary request 5 complies with Articles 76(1) and 123(2) EPC.

4. Auxiliary request 5 - extension of subject-matter of dependent claims

The opponent argued that the subject-matter of claims 4 to 7 extended beyond the content of the parent application and the application as filed because these claims constituted impermissible intermediate generalisations.

Claim 4 is literally based on page 7, line 30, of the original application, which specifies a feature of the retainer. This passage belongs to the detailed description of a specific embodiment. Clearly, such a detailed description links the combination of all the features of the embodiment concerned. However, this is not decisive for the assessment of added subject-matter. The question is whether the original disclosure conveyed the information that other non-claimed features had to be necessarily present in combination with the claimed features. In the Board's view, this is not the case. The description does not suggest this, and claim 20 of the parent application as filed, for example, is even more general with respect to the features of the retainer.

The same applies to the features of the retainer tabs and cut-outs defined in claims 5 to 7, which generalise the disclosure of page 9, lines 22 to 29, and Figure 6 of the application as filed. The person skilled in the

art would have recognised that the number of the cut-outs and tabs and their specific angular position are not decisive to ensure that the retainer is first held together with and then uncoupled from the outer sleeve. It is only a matter of choosing an adequate tab flexibility to obtain the necessary deformation.

For these reasons, the subject-matter of claims 4 to 7 of auxiliary request 5 complies with Articles 76(1) and 123(2) EPC.

5. Auxiliary request 5 - clarity and support in the description

The opponent argued that essential features were missing in claim 1 of auxiliary request 5 and that the description did not support the claim since a specific j-hook which could be straightened was only described, in the patent, in combination with other features.

The Board does not share this view. The description of the patent consistently explains that the deformation by straightening the j-hook causes the control wire to uncouple from the clip (column 5, lines 23 to 26; column 6, lines 38 to 43; column 7, lines 34 to 41; column 7, line 54, to column 8, line 4). It does not explain that other features, in particular the j-hook being formed in the distal end of the control wire, are necessary for this specific deformation to take place. The opponent's argument that it was possible to conceive a j-hook made of sheet metal which could not be straightened is not convincing. The patent certainly does not teach - and the person skilled in the art would certainly not have conceived - such a j-hook which would render the medical device useless. Such a hypothetical j-hook would not fall under the scope of

the claim either.

Furthermore, the description of the patent expressly states that the invention relates to a medical device as defined in the claims (paragraph [0013]). Hence, there is no contradiction with claim 1 of auxiliary request 5.

In conclusion, the requirements of clarity and support in the description under Article 84 EPC do not prejudice the maintenance of the patent on the basis of auxiliary request 5.

6. Auxiliary request 5 - extension of the scope of protection

Compared with claim 1 of the patent as granted, claim 1 of auxiliary request 5 has been amended by the replacement of the term "deformed" by "straightened".

Straightening is a specific type of deformation. Hence, the amendment does not extend but rather restricts the scope of the claim with respect to the granted version.

The Board cannot accept the opponent's argument that an *aliud* had been added by the amendment, since it cannot figure out any embodiment of the medical device that would fall under the scope of claim 1 of auxiliary request 5 without falling under the scope of claim 1 of the patent as granted. The opponent did not point to such an embodiment either.

It follows that claim 1 of auxiliary request 5 complies with Article 123(3) EPC.

7. Auxiliary request 5 - sufficiency of disclosure

The opponent argued that the feature of the control wire being "reversibly operable both to open the at least two clip legs (102, 103) and to close the at least two clip legs (102, 103)" in claim 1 of auxiliary request 5 was not sufficiently disclosed in the patent.

How this feature can be put into practice is disclosed in relation to the first embodiment of the invention, for example, in paragraph [0020] of the patent.

The sentence in column 3, lines 56 to 59, referred to by the opponent, cannot be read in isolation outside of the technical context of the patent. The information that would have been conveyed to the person skilled in the art by the expression "the 'single-use' (disposable) embodiments of the invention disclosed here would function the same with each clip, in each procedure" is simply that the clips disclosed in the patent can be repeatedly opened and closed and work adequately in known endoscopic procedures aimed at stopping the bleeding of blood vessels located along the gastrointestinal tract. Designing the clips and the claimed device in general, in particular with respect to their material properties which may ensure such a reliable use under the normal conditions of wear and fatigue in these procedures, would have been within the competence of the person skilled in the art. The opponent did not present verifiable facts which could raise serious doubts about the performance of such a mechanical design task.

Hence, the ground for opposition under Article 100(b) EPC on sufficiency of disclosure does not prejudice the maintenance of the patent on the basis of auxiliary

request 5.

8. Auxiliary request 5 - double patenting

As pointed out by the opponent, European patent No. 2 907 459, derived from a further divisional application of the parent application of the patent in suit, was maintained in amended form after first-instance opposition proceedings. However, the claims of auxiliary request 2, on the basis of which that patent was maintained, are different in scope from the claims of auxiliary request 5 of the patent in suit. For example, claim 1 of auxiliary request 2 of that patent recites that the j-hook is formed at an end of the control wire. This feature is not present in claim 1 of auxiliary request 5 of the patent in suit. A mere overlap in scope, even if to a large extent, does not result in double patenting.

It follows that the opponent's objection in this regard is without merit for this reason alone. Hence, there is no need for the Board to consider the effects of the fact that European patent No. 2 907 459 is still the object of ongoing appeal proceedings (T 1648/19).

9. Auxiliary request 5 - novelty

The opponent argued that the subject-matter of claim 1 of auxiliary request 5 was not novel over each of E3 and E4.

9.1 E3 discloses an endoscopic treatment tool comprising a clip to be positioned around and tightly hold vital tissue (Figures 1A, 1B, 14, 15A and 15B reproduced below, and column 15, lines 19 to 24).

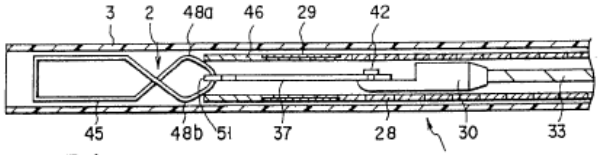

FIG. 1A

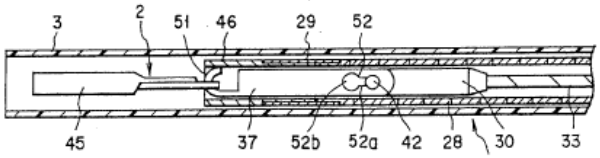

FIG. 1B

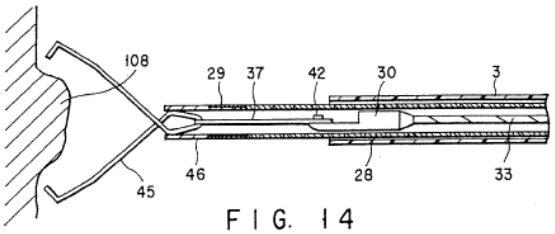

FIG. 14

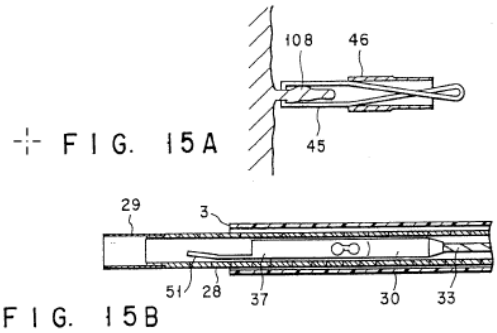

FIG. 15A

FIG. 15B

It is common ground that E3 discloses a medical device with a clip (45) having two clip legs, a control wire (33) with a j-hook (51) and an axially rigid sheath (28).

E3 does not disclose that the control wire is reversibly operable both to open the at least two clip legs and to close the at least two clip legs.

The Board concurs with the analysis of the functioning of the medical device of E3 made in case T 639/13, point 4.1 of the reasons, based on column 14, line 11,

to column 15, line 33, of E3:

"The clip is brought to the desired location inside the patient's body with the endoscope 3 shown in Figures 1A and 1B."

"After arrival at the desired location, the clip together with the ring 46 on the tube 28 is pushed out of the endoscope 3. The clip arms are then opened by pulling the clip portions 48a and 48b inside the ring 46 as shown in Figure 14."

"When the clip is to be closed, it is pulled further inside the ring 46 until it is held completely closed as shown in Figure 15A. In that position the hook is straightened as shown in Figure 15B."

"The ring 46 obviously has to be loosely fitted in the tube 28, otherwise it could not easily be freed from the tube 28 together with the clip. Moreover, as can be seen in Figures 1B and 3A, the clip is loosely attached to the hook 51, and the link 37 is attached to the hook 30 of the control wire 33 with a pin 42 in a longitudinal hole 52a including a larger opening 52b.

The mechanical consequence of the above is that, if the control wire is pushed distally, for instance, when the clip is in the position shown in Figure 14, before the clip can move distally, the length of the longitudinal hole 52a has to be compensated for and the longitudinal play at hook 51 has to be compensated for. Then, since the parts 48a and 48b are (frictionally) trapped within the ring 46, the latter would move distally

because it is loosely fitted in the tube 28. Hence, once the parts 48a and 48b of the clip are trapped within the ring 46 it is no longer possible to push them distally out of it."

The opponent argued that claim 1 did not require that the clip could be completely closed or should grasp tissue during the reversible operation of the control wire to open and to close the two clip legs.

The Board does not agree. The claim defines a closed position in contrast to an open position. Inherently, the closed position should cause the hemostasis of a blood vessel because this is the intended application of the claimed medical device. The ends of the clip legs do not necessarily have to touch each other in the closed position. Even so, a deviation from the open position by minimally pulling clip portions 48a and 48b inside clip fastening ring 46, which would not allow grasping tissue, cannot be interpreted as the closed position within the meaning of the claim.

It follows that it is irrelevant whether a minimal interference fit is present between clip fastening ring 46 and coupling ring 29 of tube 28. E3 certainly does not disclose, in a direct and unambiguous way, that such a hypothetical interference fit would allow withdrawing the clip inside fastening ring 46 so as to reach the closed position and then push it reversibly back out of the ring.

9.2 E4 also concerns an endoscopic treatment tool comprising a clip to be positioned around and tightly hold tissue.

The first embodiment of the tool, depicted in Figures

1A to 8 (Figures 5 and 6 are reproduced below), is closely similar to the device depicted in Figures 1A, 1B, 14, 15A and 15B of E3, and comprises a clip (2) having two clip legs (2A, 2B), a control wire (13) with a j-hook (at the distal end of coupling plate 3) and an axially rigid sheath (7a, 7b).

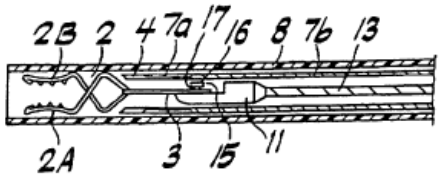

FIG. 5

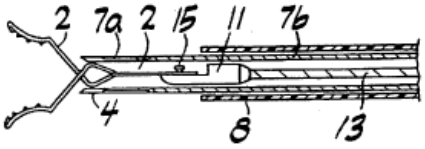

FIG. 6

Functionally, holding tube 4 shown in Figures 1 to 8 of E4 corresponds to clip fastening ring 46 of E3, and coil pipe 7a corresponds to coupling ring 29.

For the same reasons as the ones given in relation to E3, the first embodiment of E4 does not anticipate a control wire reversibly operable both to open the at least two clip legs and to close the at least two clip legs. Whether E4 discloses that the diameters of the coil pipe and the holding tube are chosen to enable the insertion of the coil pipe in the holding tube is irrelevant in this respect if it is not disclosed, in a

direct and unambiguous way, that the coupling between the coil pipe and the holding tube would allow withdrawing the clip inside holding tube 4 to reach the closed position and then push it reversibly back out of the tube.

The second embodiment of E4, partly illustrated in Figures 9A and 9B, does not differ from the first embodiment in the details of the control wire concerning the opening and closing of the clip. Hence, it does not deprive the subject-matter of claim 1 of auxiliary request 5 of novelty for the same reasons.

9.3 In conclusion, the opponent's objections of lack of novelty in view of Article 54(1) and (2) EPC do not prejudice the maintenance of the patent on the basis of auxiliary request 5.

10. Auxiliary request 5 - inventive step

10.1 The opponent argued that the subject-matter of claim 1 of auxiliary request 5 lacked an inventive step when starting from E3 or E4 as the closest prior art.

As explained, the devices of E3 and E4 considered above do not comprise a control wire reversibly operable both to open the at least two clip legs and to close the at least two clip legs.

The technical effect of the distinguishing feature is to allow repositioning the clip after an attempt in which a blood vessel to be treated has not been successfully pinched.

The opponent's argument that the distinguishing feature was formulated in terms of a result to be achieved and,

as such, would have prompted the person skilled in the art to implement it is not convincing. The distinguishing feature is simply a functional feature which defines a property of the claimed medical device and the control wire, made possible by the structural features defined in the claim.

Whether implementing such a feature in the devices of E3 or E4 would have been obvious has to be assessed in light of the objective technical problem solved, within the framework of the problem and solution approach. According to established case law, the objective technical problem must not contain pointers to its solution and its definition should normally start from the problem described in the contested patent (Case Law of the Boards of Appeal, 9th edition 2019, I.D.4.3.2).

As derivable from paragraph [0016] of the patent, the objective technical problem solved by the technical effect of the distinguishing feature is to achieve a quicker endoscopic procedure, requiring less clips to be deployed, with a higher success rate.

10.2 This problem is not addressed in E3 or E4 in conjunction with the claimed solution. Whether a particular interference fit between clip fastening ring 46 and coupling ring 29 of E3 and between holding tube 4 and coil pipe 7a of both embodiments of E4 could be implemented to avoid the danger of the clip fastening ring or the holding tube falling off or to provide further advantages (as the opponent put it) is irrelevant since E3 and E4 simply do not teach that such an implementation may address the objective technical problem formulated above. In particular, the further device of E3 referred to by the opponent, described in relation to Figures 22 to 25, is not for

deploying clips to be left in the body. It is a biopsy device comprising a holding clamp actuated via an operating wire fixed to the holding clamp by brazing (column 17, lines 43 to 45).

10.3

It follows that the subject-matter of claim 1 of auxiliary request 5 is inventive in view of E3 and E4.

10.4 The opponent also argued that the further teaching of E1 would render obvious the subject-matter of claim 1 of auxiliary request 5.

E1 concerns an endoscopic surgical device for the positioning of clips. With this device, it should be possible to position the clips and then, if needed, to remove them (column 1, lines 49 to 53). For this purpose, E1 comprises a bayonet-like coupling (14, 15) of the clip (1, 4) with a proximal part of a working tube (13) (Figure 4 reproduced below).

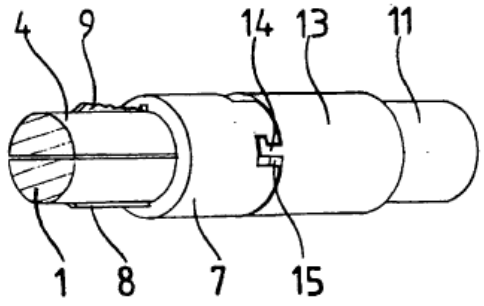

Fig.4

This is in contrast with the teaching of E3 and E4, which deal with clips to be left inside the body (column 15, lines 30 to 33 of E3 and column 1, lines 56 to 60 of E4). The present invention, like E3 and E4, is not meant for an endoscopic possibility of removing an already deployed clip.

This is a major difference of the device E1 over the devices of E3 and E4 that points to completely different fields of application.

If, nevertheless, the person skilled in the art had considered the combination of these documents, he or she would have implemented the whole coupling mechanism of E1, which does not comprise a j-hook able to be straightened by a predetermined tensile force, in the devices of E3 or E4. Implementing the whole mechanism would be much simpler, as a mechanical task, than only extracting some functionalities of the mechanism and implementing them in the devices of E3 and E4. These devices comprise completely different mechanisms for coupling the clip.

The device resulting from this combination of E1 with E3 or E4 would therefore not comprise any j-hook able to be straightened by a predetermined tensile force, contrary to the requirements of claim 1 of auxiliary request 5.

It follows that the subject-matter of claim 1 of auxiliary request 5 is inventive when starting from E3 or E4, in view of E1.

10.5 In conclusion, the opponent's objections of lack of inventive step in view of Article 56 EPC do not prejudice the maintenance of the patent on the basis of auxiliary request 5.

11. Other objections

The opponent made a general reference to all the objections raised during the first-instance proceedings. However, by their nature, these objections

neither take into account the findings and the reasons given in the impugned decision nor expressly specify the facts, arguments and evidence it relied on. Nor do they set out clear and concise reasons as to why it is requested that the decision under appeal be set aside. Thus, these objections remain disregarded. This is in accordance with Article 12(2) RPBA 2007 which, due to the fact that in this case the grounds of appeal were filed already in 2019, is applicable. The transitional provision of Article 25(2) RPBA 2020 stipulates that, under this condition, Article 12(4) RPBA 2007 remains applicable. Article 12(4) RPBA 2007 in turn refers to Article 12(2) RPBA 2007.

In addition, as regards objections of lack of novelty and inventive step based on documents published after the priority date of the patent, these are conditional on the claims infringing Article 76(1) EPC, which is not the case for auxiliary request 5, as explained above. Hence, there is no need for the Board to consider these objections.

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 claims 1 to 8 of auxiliary request 5 filed with the statement setting out the grounds of appeal dated 27 May 2019 and the description and the drawings of the patent specification.

The Registrar: The Chairman:

D. Hampe M. Alvazzi Delfrate

Decision electronically authenticated