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**Datasheet for the decision
of 1 February 2016**

Case Number: T 2256/13 - 3.2.08

Application Number: 09704185.9

Publication Number: 2247263

IPC: A61F2/24, A61F2/84, A61F2/00,
A61F2/90, A61F2/86

Language of the proceedings: EN

Title of invention:
INFUNDIBULAR REDUCER DEVICE DELIVERY SYSTEM AND RELATED
METHODS

Patent Proprietor:
Medtronic Vascular Inc.

Opponent:
Stolmár, Matthias

Headword:

Relevant legal provisions:
EPC Art. 54, 56, 111(1)
EPC R. 103(1)(a), 111(2), 124

Keyword:

Reimbursement of appeal fee - (no)
Reimbursement of appeal fee -
violation of the right to be heard (no)
Reimbursement of appeal fee -
appealed decision sufficiently reasoned (yes)
Reimbursement of appeal fee -
substantial procedural violation (no)
Minutes of oral proceedings - request to correct
minutes of first instance proceedings (refused)
Appealed decision -
request to amend the appealed decision (refused)
Novelty - (yes)
Inventive step - (yes)

Decisions cited:

T 0068/02, T 1198/97, T 0231/99

Catchword:



**Beschwerdekammern
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Chambres de recours**

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Case Number: T 2256/13 - 3.2.08

**D E C I S I O N
of Technical Board of Appeal 3.2.08
of 1 February 2016**

Appellant: Stilmár, Matthias
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 17 July 2013
rejecting the opposition filed against European
patent No. 2247263 pursuant to Article 101(2)
EPC.**

Composition of the Board:

Chairman M. Alvazzi Delfrate
Members: C. Herberhold
D. T. Keeling

Summary of Facts and Submissions

- I. By its decision posted on 17 July 2013 the Opposition Division rejected the opposition against European patent EP-B-2247263.
- II. The appellant (opponent) lodged an appeal against that decision with notice of appeal dated 26 September 2013.
- III. On the same day the opponent filed another letter, requesting the EPO to correct the minutes of the oral proceedings and the decision of the Opposition Division. With a communication dated 19 November 2013 the Opposition Division decided to refuse these requests.
- IV. In the statement of grounds of appeal, dated 27 November 2013, the appellant requested
 - to amend the minutes and the written decision of the Opposition Division by inclusion of the explicit statement that "the attachment members known from document D10 do not have the same function and structure as the coil of the opposed patent" (see statement of grounds, point 2.1) and to reimburse the appeal fee in accordance with Rule 103(1)(a) EPC;
 - alternatively, to set aside the decision of the Opposition Division and to revoke the patent in its entirety;
 - as a second alternative, to summon for oral proceedings.

In its reply to the statement of grounds, the respondent (proprietor) requested

- to reject the request to amend the written decision of the Opposition Division;

- to dismiss the appeal and maintain the patent as granted, or, in the alternative, to maintain the patent on the basis of one of auxiliary requests 1 through 5 filed during the opposition proceedings with submission dated 22 April 2013;
- to hold oral proceedings before any decision adverse to the proprietor is taken.

V. With letter dated 20 November 2015 the appellant informed the Board that it would not attend the oral proceedings scheduled for 22 January 2016. On 14 January 2016, the Board cancelled the oral proceedings.

VI. Independent claims 1 and 10 of the main request (patent as granted) read as follows:

Claim 1:

"A delivery system (100) for delivery of a device to a body lumen, the device (500) comprising a proximal end (512) and a distal end, a central lumen there through, and a plurality of attachment members located at or near the proximal end (512), the system being

characterized by:

an elongated inner catheter (114) having a proximal end and a tapered, distal end (118) for insertion into a body lumen;

an elongated holding catheter (120) having a proximal end, a distal end, a center lumen passing there through to slidably maintain the inner catheter (114) and a coil (122) on the distal end for attachment to the plurality of attachment members on the device; and

an elongated outer sheath (126) having a proximal and a distal end and a center lumen passing there through to slidably and rotatably maintain the holding catheter (120), to collapse the device (500) as the holding

catheter (120) is slid proximally there through, and to hold the device (500) in a collapsed configuration for delivery to a body lumen."

Claim 10:

"A method of loading a device onto a delivery system, the method comprising the steps of:
receiving a self-expanding device having a proximal end and a distal end, a central lumen there through, and a plurality of attachment members located at or near the proximal end;
receiving a delivery system comprising a loading rail having two free ends, an elongated inner catheter having a proximal end and a tapered distal end, an elongated holding catheter having a proximal end and a distal end comprising a coil for attachment to the device and a center lumen passing there through to slidably maintain the inner catheter and the coil, and an elongated outer sheath having a proximal and a distal end and a center lumen passing there through;
extending the inner catheter through the lumen of the holding catheter and extending both the inner catheter and holding catheter through the lumen of the outer sheath;
threading the plurality of attachment members onto the loading rail;
connecting one free end of the loading rail to the coil on the holding catheter;
advancing the plurality of attachment members along the loading rail and onto the coil, wherein the advancing procedure partially collapses the device;
removing the loading rail from the coil after all of the attachment members are transferred to the coil;
collapsing the device in the outer sheath by sliding outer sheath over the device; and

enclosing the collapsed device by retracting the inner catheter proximally and pulling the distal tapered end into the distal end of the outer sheath."

The auxiliary requests do not play a part in this decision.

VII. The following documents were of relevance for the present decision:

D8: US-A-5234437;

D10: WO-A-2006/076890.

VIII. The essential arguments of the appellant can be summarised as follows:

Request to amend the minutes of the Opposition Division and the written decision

During the oral proceedings the Opposition Division had explicitly stated that the attachment system disclosed in document D10 did not have the same function as the coil mentioned in claim 1 of the opposed patent (statement of grounds, point 2.1, second paragraph). This statement, though of high relevance in the present case, was missing in the minutes and in the grounds of the decision. A request to correct the minutes accordingly was refused by the Opposition Division. The Board was thus requested to amend the minutes and written decision of the Opposition Division by inclusion of the explicit statement that the attachment members known from document D10 did not have the same function and structure as the coil of the opposed patent (statement of grounds, point 2.4).

Request for reimbursement of the appeal fee

Contrary to the Opposition Division's finding during the oral proceedings, the appealed decision repeatedly stated that - from a functional point of view - the attachment system disclosed in document D10 and the coil mentioned in claim 1 of the opposed patent were identical (statement of grounds, point 1.4).

This was firstly a completely new point of view, only provided in the grounds of the impugned decision, but not already in the oral proceedings, on which the opponent thus had not had an opportunity to present its comments, contrary to the requirements of Article 113 EPC (statement of grounds, point 2.3).

It secondly was clearly contradictory with the Opposition Division's assessment of novelty and inventive step (statement of grounds, point 1.5): if the function of the conventional D10 attachment means was indeed the same as the function of the coil, the technical problem could only be regarded as to provide an alternative attachment system and not as to control the speed of delivery of the medical device and avoid its jumping, the latter functionality being likewise fulfilled by the D10 mechanism. The technical problem was thus not appropriately worded.

Hence, the decision was not appropriately reasoned and the appellant's right to be heard had been violated, justifying the setting-aside of the decision and the reimbursement of the appeal fee in accordance with Rule 103(1) (a) EPC.

Main request - Novelty (see in particular point 4.7 of the statement of grounds)

As also acknowledged by the Opposition Division in its decision, the attachment means known from document D10 fulfilled exactly the function of the claimed coil for attachment to the plurality of attachment members on a device. Without any structural definition of the term "coil" to be found within the patent in dispute, the conventional attachment means of document D10 thus had to be interpreted as "a coil on the distal end for attachment to the plurality of attachment members on the device", claim 1 of the main request thus being not novel over prior art D10.

Main request - Inventive step

While it was agreed that document D10 was to be considered the closest prior art, the objective technical problem had been incorrectly formulated. In fact, control of the speed of delivery and avoidance of device jumping was also provided by the D10 attachment system, as the operator could choose the speed of delivery by either retracting the sheath quickly or slowly, resulting in a stepwise expansion of the device which would only detach once the sheath was retracted proximally far enough to completely uncover the attachment system. With all the technical effects of the device of the invention equally provided in the prior art document, the problem needed to be reformulated as modifying or adapting the conventional delivery device so as to provide an alternative attachment system.

In order to solve this technical problem the person skilled in the art would have considered document D8 which was likewise concerned with the provision of a mechanical means for detaching a device from a delivery system at a desired vessel site. As claim 1 was completely silent with respect to the kind of

prosthesis to be delivered by the claimed delivery system, it did not matter that the D8 delivery system was for very small devices compared to the heart valve of document D10. In fact, the heart valve known from document D10 most certainly had a compressed configuration similar to the vaso-occlusive device of D8. Using the D8 coil attachment mechanism furthermore did not require any changes in the D10 heart valve because in the unflared compressed state its attachment members could be easily attached to the coil. Indeed, even if the attachment means were to be changed, the solution still fell within the scope of claim 1 as maintained.

To conclude, the person skilled in the art would replace the attachment system known from document D10 with the coil shaped mechanical attachment means known from document D8, thus arriving at subject-matter falling under claim 1 as maintained.

Hence, claim 1 as maintained did not involve an inventive step.

IX. The essential arguments of the respondent can be summarised as follows:

Request to amend the minutes of the Opposition Division and the written decision

The appellant's first request, to amend the written decision of the opposition division, as included in appellant's letter of 27 November 2014, should be rejected because it was not contained in the notice of appeal (Rule 99(1)(c) EPC, nor was the respective decision of 19 November 2013, with which opponent's request for correction of 17 July 2013 was rejected, indicated in the notice of appeal (Rule 99(1)(b) EPC). Accordingly, any request mentioned for the first time

in the grounds of appeal of the present proceedings regarding the correction of the decision/minutes of the first instance was to be rejected as inadmissible.

Request for reimbursement of the appeal fee

During opposition proceedings the appellant repeatedly put forward his view regarding function and structure of a coil and of the attachment system of document D10. Also the request for correction of the decision and minutes was heard by the Opposition Division and a respective decision was issued accordingly. Hence, all of the appellant's arguments regarding this particular issue had been heard in first instance, and, therefore, no violation of Article 113 EPC occurred.

There was, furthermore, no contradiction in the Opposition Division's reasoning: the sentence "the attachment system disclosed in D10 may have the same function (attachment) but cannot be defined, by its structure, as a coil" simply stated that the attachment system of document D10 may have the same function as long as one refers to the abstract level of "attachment" *per se*. Said statement therefore left it open whether the attachment system of D10 also had the same function when it came to the specific attachment function as conferred by the coil of the claimed subject-matter. There was consequently no inconsistency if the Opposition Division later deduced a specific objective technical problem based on the lack of disclosure of a coil in document D10.

To conclude, there was neither a violation of the right to be heard nor an inconsistency in the reasoning of the Opposition Division.

Main request - Novelty (see in particular the reply of the respondent, page 7, second paragraph)

As could be seen from Figure 4, the attachment mechanism disclosed in document D10 comprised anchoring elements 8 formed at a bushing member 6, the anchoring elements formed to engage with respective eyelets on the implantable device. The only argument provided by the appellant that these could be considered a "coil" in the sense of the patent, was by reference to an interpretation allegedly given by the Opposition Division. However, as could be seen from the decision dated 19 November 2013, the Opposition Division strongly refuted the claim that it had made the respective statement and instead considered that a coil had a structural definition and not only a functional definition and that the attachment system disclosed in D10 might have the same function (attachment) but could not be defined, by its structure, as a coil. No further substantiation was provided by the appellant based on the actual disclosure of document D10. Hence, document D10 did not clearly, directly, and unambiguously disclose an elongated holding catheter having a proximal end, a distal end, and a centre lumen passing there through to slidably maintain an inner catheter and a coil on the distal end for attachment to the plurality of attachment members on the device, as recited in granted claim 1.

Main request - Inventive step

It was agreed that document D10 could be considered the closest prior art.

However, the delivery system disclosed therein did not avoid "jumping" of the device, which took place at the

transition from the state shown in Figure 3 to the state shown in Figure 4 of D10. The prior art thus did not solve the problem posed.

Moreover, even if the more general technical problem to provide an alternative attachment system was taken into account, the combination of the teachings of documents D10 and D8 was not obvious.

Starting from prior art D10, the person skilled in the art would not have considered the teaching of document D8, which discloses delivering of a very small, vaso-occlusive, thrombus-forming, non-expanding implantable coil, contrary to the 100 times larger, self-expanding artificial heart valve of D10.

Even if the person skilled in the art would envisage applying the D8 delivery mechanism to the D10 artificial heart valve, said delivery mechanism required a further coil at the proximal end of the device to be implanted. The artificial heart valve of D10 did not comprise such a proximal coil and it was unclear how the coil of document D8 could be attached to such a valve.

Hence, the person skilled in the art would not combine the teachings of documents D10 and D8. Therefore, the subject-matter of claim 1 involved an inventive step.

Reasons for the Decision

1. The appeal is admissible.
2. Request to amend the written decision and the minutes of the Opposition Division

- 2.1 The notice of appeal indicates, in accordance with Rule 99(1) EPC, the impugned decision, namely the decision of the Opposition Division to reject the opposition. Accordingly, neither the content of the minutes of the oral proceedings before the Opposition Division nor the decision refusing to correct them form part of the subject of this appeal.

Therefore, it is not within the competence of the Board to correct the minutes of the oral proceedings before the Opposition Division and the request to perform such a correction must be rejected.

- 2.2 Although the appeal is directed against the decision to reject the opposition, it is not within the competence of the Board to amend the decision of the Opposition Division either.

A Board of Appeal may set aside the decision of the Opposition Division and subsequently take its own decision, either exercising any power within the competence of the department of first instance which was responsible for the decision or remitting the case (Article 111(1) EPC). It cannot, however, amend the wording of the written decision, the drafting of which is the responsibility solely of the Opposition Division.

Thus, the request to amend the written decision of the Opposition Division must be rejected.

3. Request for reimbursement of the appeal fee

The appellant submitted that the reasoning of the written decision was deficient and that its right to be heard had been violated, requesting on this basis that

the appealed decision be set aside and that the appeal fee be refunded (points 1 and 2 of the statement of grounds).

A failure to provide a reasoned decision in accordance with Rule 111(2) EPC or a violation of the right to be heard enshrined in Article 113(1) EPC would indeed both constitute substantial procedural violations justifying the setting-aside of the appealed decision and reimbursement of the appeal fee. However, in the present case, the Board cannot see that either of these alleged substantial procedural violations has been committed.

3.1 Right to be heard (Article 113(1) EPC)

The appellant complains that the following statement allegedly made by the Opposition Division was missing in the minutes:

"The definition of the coil in document D10 is neither in a structural nor in a functional sense relevant for the assessment of novelty and/or inventive step of the subject-matter of claim 1 of the patent-in-suit."

There is however no complaint that any of the further events recorded in the minutes was incorrect. With respect to the arguments presented by the parties, the minutes are thus understood to correctly represent the course of the proceedings.

According to page 1, paragraph 10 of the minutes, the patent proprietor (now the respondent) argued "that the term coil implies certain structural limitations and that D10 discloses no coil", i.e. they argued that there was a structural difference. The respondent

further argued that "with the device disclosed in D10, the jumping effect during release cannot be avoided and the release does not take place at a controlled rate", i.e. they also argued that there was a functional difference.

As can be seen from the paragraph before (paragraph 9 of page 1 of the minutes), the appellant did counter these arguments by stating that D10 "discloses a device which functions in the same way and brings the same results as the device of claim 1 of the patent", i.e. he argued that there was no functional difference. The appellant further argued that "there is no specific definition for the term coil" [in the patent] and that thus "D10 can be considered as novelty destroying document", i.e. he argued that there was no structural difference or - if there were - it did not matter.

Consequently, both points i.e. whether there was a functional or a structural difference between the coil attachment mechanism of the patent and the attachment mechanism of D10 were discussed in the oral proceedings and the appellant did present his comments.

Both parties have to expect that the division may follow any of the arguments of the respective other party or the party's own arguments. In fact, it was the appellant himself who argued that the D10 device "functions in the same way and brings the same results". Therefore, the Opposition Division's statement that the D10 attachment system has the same (attachment) function (impugned decision, page 6, first paragraph) could hardly have been surprising for the appellant. It rather shows that the appellant's argument was indeed heard.

Accordingly, no violation of Article 113(1) EPC can be established.

3.2 Inconsistency in the decision of the Opposition Division

In this context the appellant argued that although the Opposition Division stated in the decision (page 6, first paragraph) that the D10 attachment system did have the same function as the coil of the patent, when discussing inventive step, the problem was not formulated as "to provide an alternative attachment means" but with respect to an alleged functional difference, i.e. to control the speed of delivery of the medical device and avoid its jumping. This was seen as inconsistent.

In the opinion of the Board this is not an inconsistency but rather a question of the level of detail taken into consideration. Both mechanisms have a function which *grosso modo* results in an attachment of the device to the delivery catheter. This is what the Opposition Division appears to have meant with the statement on page 6, first paragraph, that "the attachment system disclosed in D10 may have the same function (attachment)".

This does not, however, exclude that on a more detailed level there are differences between the respective particular attachment mechanisms which result in functional differences beyond the mere provision of an attachment and which thus justify the formulation of a respectively tailored technical problem, such as the one explicitly mentioned in the patent (paragraph [0036]) and referred to in the impugned decision (item 3.1.1).

The Board thus cannot identify an inconsistency in the reasoning. Accordingly, the decision is reasoned in the sense of Rule 111(2) EPC.

3.3 In the absence of a substantial procedural violation, the request to refund the appeal fee must be rejected (Rule 103(1) (a) EPC).

4. Main request - Novelty

4.1 Claim 1:

Document D10 discloses:

A delivery system (Figures 1 - 5) for delivery of a device to a body lumen, the device (Figure 4, No. 10) comprising a proximal end and a distal end, a central lumen there through, and a plurality of attachment members located at or near the proximal end ("see Figure 4: "Ösen" at the proximal end of No. 10), the system comprising

an elongated inner catheter (No. 2, 12) having a proximal end and a tapered, distal end (distal end of No. 5) for insertion into a body lumen;

an elongated holding catheter (No. 3, No. 6) having a proximal end, a distal end, a center lumen passing there through to slidably maintain the inner catheter (No. 2) and attachment means (No. 8, 16) on the distal end for attachment to the plurality of attachment members on the device; and

an elongated outer sheath (No. 7) having a proximal and a distal end and a center lumen passing there through to slidably and rotatably (not explicitly mentioned, however concentrically arranged tubes such as shown in Figure 4 of D10 longitudinally slidable relative to

each other, will be rotatable relative to each other unless further non-disclosed mechanisms were present to prevent such rotation) maintain the holding catheter (No. 3), to collapse the device (No. 10) as the holding catheter is slid proximally there through, and to hold the device in a collapsed configuration for delivery to a body lumen.

D10 does not disclose that the attachment means is a coil on the distal end of the holding catheter.

While D10 comprises attachment means (Figure 4, No. 8, 16: "Verankerungselemente", "Führungselemente"), these do not qualify as a "coil".

The appellant argued that the patent did not give a structural definition of the term "coil", which thus had to be understood as implying nothing more than an attachment function. Because elements No. 8 and 16 of D10 performed an attachment function, they had to be considered a "coil" in the sense of the patent in suit.

The Board does not agree. Terms used in patent documents should be given their normal meaning in the relevant art, unless the description gives the terms a special meaning. As there is no special definition in the patent, the term "coil" is given its normal meaning, implying a certain structure, which - according to the Merriam-Webster Dictionary - is:

- "a series of loops" or "a spiral";
- a single loop of such a coil;
- a number of turns of wire wound around a core [...].

Similar definitions are given in the Oxford English Dictionary:

- a length of cable, rope, etc., when "coiled" or gathered up into a number of concentric rings, either fake over fake, or in a flat disk with the fakes within each other;
- a series of concentric circles or rings in which a pliant body has been disposed [...].

The attachment means of D10 do not fall under any of these definitions. D10 thus does not disclose a coil.

The subject-matter of claim 1 as granted is thus novel.

4.2 Claim 10

The independent method claim comprises the step of

"receiving a delivery system comprising a loading rail having two free ends, an elongated inner catheter having a proximal end and a tapered distal end, an elongated holding catheter having a proximal end and a distal end comprising a coil for attachment to the device and a center lumen passing there through to slidably maintain the inner catheter and the coil, and an elongated outer sheath having a proximal and a distal end and a center lumen passing there through".

The subject-matter of claim 10 is thus also novel for the reasons discussed in point 4.1.

5. Main request - Inventive step

D10 uncontestedly forms the closest prior art.

As discussed under point 4.1. above, the subject-matter of claim 1 of the patent differs from this prior art in

that the attachment mechanism is a coil on the rotatable holding catheter.

According to the patent, paragraph [0036], line 31 ff, "the purpose of the coil 122 is to provide a means for loading a device 500 onto the system 100, holding the device 500 on the system 100 during delivery, and releasing the device 500 from the system 100" wherein "the speed that the device 500 is released from the system 100 is controlled by the rate of rotation of the coil 122, therefore preventing uncontrolled release of the device 500 in a manner known in the art as "jumping"."

The technical problem the inventors set out to solve may thus indeed be formulated such as to provide an attachment system which can control the speed of delivery of the device and avoid its jumping.

It is true that an original problem mentioned in the application may require reformulation if the problem is already solved in the closest prior art document. However, even if one accepted the appellant's argument that the D10 delivery system allowed for control of the speed of delivery and for avoidance of device jumping, an appropriately worded problem would be to provide an alternative attachment system which can control the speed of delivery of the device and avoid its jumping and not to provide an alternative attachment system per se.

D8, on the other hand, provides a delivery system for a non-expanding coil. There is thus no indication that its attachment mechanism would provide a solution for the problem posed, i.e. that it would provide for control of the speed of delivery of the device and

avoidance of its jumping out, simply because the D8 coil does not jump out but keeps its diameter constant upon delivery. Hence, the person skilled in the art could combine the teaching of the two documents, but would have no reason to do so.

Moreover, D8 does not disclose an attachment mechanism having a single coil on its pusher, but an attachment mechanism comprising two inter-engaging coils, one on the pusher member and one on the implant to be delivered. Isolating out of this functionally linked double coil attachment mechanism only one coil, i.e. the coil of the delivery device, and providing it on the D10 delivery catheter ("hohles Betätigungselement", No. 3) in order to inter-engage with other non-coil-like anchoring elements on the device carrying catheter (elements which do not exist in D8 and which are isolated out of the D10 attachment mechanism where they only hold the device in cooperation with holding catheter No. 7), while leaving the implant to be delivered without any inter-engaging coil, does not correspond to the teaching of document D8 and requires use of hindsight knowledge.

If at all, D8 would teach the person skilled in the art to provide also the heart valve, which is to be implanted with the D10 delivery tool, with a proximal attachment coil. This would require further modification of the D10 heart valve in a non-obvious manner as there is no indication whatsoever where such a proximal coil could be provided on the self-expanding valve, which, when implanted and expanded, needs to remain free of any additional thrombogenic object.

To conclude, firstly the person skilled in the art would not combine the teaching of documents D8 and D10,

and secondly, even if he did, would not arrive in an obvious way at subject-matter falling under the definition of claim 1.

The subject-matter of claim 1 thus involves an inventive step.

The argument applies *mutatis mutandis* to independent method claim 10.

6. With letter of 20 November 2015, the appellant informed the Board that he was not going to attend the oral proceedings. Accordingly, he did not wish to avail himself of the possibility of presenting his case orally. Therefore, the appellant's letter is equivalent to a withdrawal of the request for oral proceedings, i.e. of the possibility of presenting his case orally (see also Case Law of the Boards of Appeal, 7th edition 2013, III.C.2.3.1).

As explained above none of the opposition grounds invoked by the appellant prejudices the maintenance of the patent as granted and the appeal is to be dismissed. For such a situation - which is not adverse to the respondent - the respondent did not request oral proceedings. The case is thus decided in the written proceedings.

Order

For these reasons it is decided that:

1. The appeal is dismissed.
2. The request to reimburse the appeal fee is rejected.

The Registrar:

The Chairman:



S. Sánchez Chiquero

M. Alvazzi Delfrate

Decision electronically authenticated