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Datasheet for the decision of 26 April 2017

Case Number: T 2360/12 - 3.2.02

Application Number: 04776454.3

Publication Number: 1635900

IPC: A61M25/00

Language of the proceedings: EN

Title of invention:
CATHETER SYSTEMS AND METHODS FOR CROSSING VASCULAR OCCLUSIONS

Patent Proprietor:
Cordis Corporation

Opponent:
Terumo Kabushiki Kaisha

Headword:

Relevant legal provisions:
EPC Art. 123(2), 84, 56
EPC R. 42(1)(c)
RPBA Art. 13(1)

Keyword:

Amendments - extension beyond the content of the application as filed - main and first auxiliary request (yes), auxiliary request A (no)
Claims - clarity - auxiliary request A (yes)
Inventive step - auxiliary request A (yes)
Late-filed argument - admitted (no)
Description - conformity with auxiliary request A (yes)

Decisions cited:

Catchword:

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Case Number: T 2360/12 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 26 April 2017

Appellant: (Opponent)	Terumo Kabushiki Kaisha 44-1, Hatagaya 2-Chome Shibuya-ku Tokyo 151-0072 (JP)
Representative:	Prüfer & Partner mbB Patentanwälte · Rechtsanwälte Sohnckestraße 12 81479 München (DE)
Respondent: (Patent Proprietor)	Cordis Corporation 6500 Paseo Padre Parkway Fremont, CA 94555 (US)
Representative:	Prock, Thomas Marks & Clerk LLP 90 Long Acre London WC2E 9RA (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 13 September 2012 concerning the maintenance of European Patent No. 1635900 in amended form.**

Composition of the Board:

Chairman E. Dufrasne
Members: D. Ceccarelli
P. L. P. Weber

Summary of Facts and Submissions

I. The opponent has appealed the Opposition Division's decision, dispatched on 13 September 2012, that European patent No. 1 635 900 as amended according to the main request could be maintained.

II. The notice of appeal was received on 7 November 2012. The appeal fee was paid on the same day. The statement setting out the grounds of appeal was received on 11 January 2013.

III. Oral proceedings took place on 26 April 2017.

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

The respondent requested that the appeal be dismissed or, in the alternative, that the decision under appeal be set aside and that the patent be maintained on the basis of one of:

- the first auxiliary request, filed with letter dated 29 July 2013;
- Auxiliary Request A, filed during the oral proceedings;
- the second to eleventh auxiliary requests, filed with letter dated 29 July 2013;
- the twelfth and thirteenth auxiliary requests, filed with letter dated 1 August 2013;
- the fourteenth and fifteenth auxiliary requests, filed with letter dated 29 July 2013; and
- the sixteenth to twenty-third auxiliary requests, filed with letter dated 27 March 2017, in that order.

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

D1: JP-A-2001-178814;
D1A: English translation of D1;
D7: US-B-6,508,825;
D8: EP-A-0 439 932.

V. Claim 1 of the main request, on the basis of which the Opposition Division held that the patent could be maintained, reads as follows:

"A catheter system, for treating occlusions within blood vessels, comprising:

(a) a sheath catheter (300) having a shaft (320) including a braided tubular member (302), wherein at least one inner polymer liner (303) couples to an inside surface of the braided tubular member (302), wherein at least one outer polymer laminate (304 - 309) couples to an outside surface of the braided tubular member (302), wherein polymer materials of the outer polymer laminate (304 - 309) are interspersed through the braided tubular member (302) and connect into interstices of an outside surface of the inner polymer liner (303), the catheter shaft having a lumen with an annular opening at its distal end (330) at which there is provided an atraumatic tip (310) comprised of an inner polymer (304) and an outer polymer (309);

(b) a blunt dissection catheter (100) that is deliverable to and beyond the distal end (330) of the catheter shaft (320) of said sheath catheter (300) via said lumen thereof when loaded therein; and

(c) a sheath introducer (350) including a member (370) having a proximal end and a distal end (380) and having a single lumen (365) configured to track over a guide wire, wherein the member (370) is configured to

be inserted into the catheter shaft (320) of said sheath catheter (300), wherein a distal region of the member extends beyond a distal end (330) of the catheter shaft (320) when the sheath catheter (300) and sheath introducer (350) are assembled with the member (370) being fully inserted into the lumen of said sheath catheter (300), the assembly of the sheath catheter (300) and sheath introducer (350) affording a greater degree of flexibility at the distal end of the assembly thereof, than the assembly of the blunt dissection catheter (100) and the sheath catheter (300) wherein the blunt dissection catheter (100) is loaded within the sheath catheter (300) for delivery."

Compared with claim 1 of the main request, claim 1 of the first auxiliary request contains the following additional wording after the word "therein" in point (b):

", said blunt dissection catheter (100) having a catheter shaft (160, 170) that is distally terminated with an actuation assembly (120; 500) including one or more longitudinally arranged, atraumatic, blunt spreading members (122; 506, 508) each having a free distal end configured to rotate about a proximal end that is hinged to a base (502) of the actuation assembly".

Claim 1 of Auxiliary Request A reads as follows (additions to claim 1 of the main request are underlined by the Board):

"A catheter system, for treating <u>total</u> occlusions within blood vessels, comprising:

(a) a sheath catheter (300) having a shaft (320) including a braided tubular member (302), wherein at

least one inner polymer liner (303) couples to an inside surface of the braided tubular member (302), wherein at least one outer polymer laminate (304 - 309) couples to an outside surface of the braided tubular member (302), wherein polymer materials of the outer polymer laminate (304 - 309) are interspersed through the braided tubular member (302) and connect into interstices of an outside surface of the inner polymer liner (303), the catheter shaft having a lumen with an annular opening at its distal end (330) at which there is provided an atraumatic tip (310) comprised of an inner polymer (304) and an outer polymer (309);

(b) a blunt dissection catheter (100) that comprises a proximal handle and that is deliverable to and beyond the distal end (330) of the catheter shaft (320) of said sheath catheter (300) via said lumen thereof when loaded therein, said blunt dissection catheter (100) having a catheter shaft (160, 170) that is distally terminated with an actuation assembly including one or more longitudinally arranged, atraumatic, blunt spreading members (122; 506, 508) each having a free distal end configured to rotate about a proximal end that is hinged to a base (502) of the actuation assembly, the base being non-moveable and attached to the distal end of the catheter shaft, wherein the spreading members (122; 506, 508) are actuated via the proximal handle and move between a normally closed position wherein the catheter may be advanced, retracted and positioned with vessel, and an open, actuated position for disrupting material of the occlusion and generating a path through disrupted material; and

(c) a sheath introducer (350) including a member (370) having a proximal end and a distal end (380) and having a single lumen (365) configured to track over a guide wire, wherein the member (370) is configured to

be inserted into the catheter shaft (320) of said sheath catheter (300), wherein a distal region of the member extends beyond a distal end (330) of the catheter shaft (320) when the sheath catheter (300) and sheath introducer (350) are assembled with the member (370) being fully inserted into the lumen of said sheath catheter (300), the assembly of the sheath catheter (300) and sheath introducer (350) affording a greater degree of flexibility at the distal end of the assembly thereof, than the assembly of the blunt dissection catheter (100) and the sheath catheter (300) wherein the blunt dissection catheter (100) is loaded within the sheath catheter (300) for delivery."

Claims 2 to 12 of Auxiliary Request A are dependent claims.

VI. The appellant's arguments, as far as relevant for the present decision, may be summarised as follows:

Main request: extension of subject-matter - Article 123(2) EPC

In the subject-matter of claim 1 of the main request, a new catheter element - a so-called "blunt dissection catheter" - and some associated features provided by the functional definition in the last five lines of the claim had been introduced.

The introduction of the new catheter element constituted a significant shift in the claimed subject-matter compared to the subject-matter of the claims as granted. The application as originally filed made reference to catheter systems comprising the three claimed elements - a sheath catheter, a blunt dissection catheter and a sheath introducer - only in

relation to specific embodiments and situations, notably on page 14, line 24 to page 15, line 14 of the description and in claims 25, 40 and 49.

That passage of the description related to a special method for introducing a blunt dissection catheter, according to which the sheath catheter was delivered first by an assembly comprising the sheath catheter and the sheath introducer, and only then was the blunt dissection catheter delivered within the sheath catheter to a site of a vascular occlusion. Moreover, the presence of a guide wire was necessary. Claim 1 of the main request did not specify any step of that method and did not define any guide wire. It allowed for the presence of all three elements and their insertion together, or even any two at a time. Moreover, the above-mentioned passage of the description required that the sheath introducer included very flexible polymers. They were what ensured that the combination of the sheath catheter and the sheath introducer was more flexible at the distal end. Claim 1 of the main request did not define very flexible polymers either. For all of these reasons, it represented an inadmissible generalisation of the above-mentioned passage of the description, adding technical information not disclosed in that passage. Furthermore, the meaning of the paragraph spanning pages 14 and 15 of the application as originally filed was that the distal end portion of the assembly of the sheath catheter and the sheath introducer was more flexible than the more proximal portion of the same assembly. That provided no basis for the flexibility relationship set forth in the last five lines of claim 1 of the main request.

Claim 49 as originally filed was directed to a method for crossing an occlusion requiring a certain order of steps and involving the application of a special blunt dissection catheter with at least one spreading member and a guide wire. It defined steps closely associated to the spreading member and the guide wire. Claim 1 of the main request did not define either a spreading member or a guide wire. Moreover, it did not reflect the order of steps of original claim 49.

In particular, a "blunt dissection catheter" as generally defined in claim 1 of the main request had no basis in the application as originally filed. Page 6, lines 6 to 30 gave a specific meaning to the blunt dissection catheter and set the context of the embodiments described further on. The disclosure of original claims 25 and 40 related to a particular embodiment comprising an intravascular tissue-expanding catheter with special deflecting members. Original claims 43 and 49 were more specific too. Moreover, Figures 5a to 5c related to a particular embodiment of a special working element defined by specific constitutions and functions of spreading members. They provided no link between original claims 25 and 49. The passages on page 14, line 24 to page 15, line 4 and on page 28, lines 33 and 34 referred to by the respondent did not provide any more general disclosure either, since they had to be read in the context of the specific embodiments to which they related. In particular, it was clear that, according to the application as originally filed, the blunt dissection catheter had to serve the purpose of making a pathway through a total vascular occlusion, as also supported by page 1, lines 24 to 33 in combination with page 5, lines 19 and 20. In contrast, the general definition of the blunt dissection catheter in claim 1 of the main

request even included a classic angioplasty balloon.

For all of these reasons, claim 1 of the main request contravened Article 123(2) EPC.

First auxiliary *request: extension of subject-matter - Article 123(2) EPC*

The objections under Article 123(2) EPC against claim 1 of the main request applied to claim 1 of the first auxiliary request too.

In particular, claim 1 of the first auxiliary request still did not require that the blunt dissection catheter was suitable for making a pathway through a total vascular occlusion. The definition of the blunt spreading members did not imply that suitability. At least for this reason the first auxiliary request was not allowable under Article 123(2) either.

Auxiliary *Request A: extension of subject-matter - Article 123(2) EPC*

The objections under Article 123(2) EPC against claim 1 of the main request applied to claim 1 of Auxiliary Request A too.

In particular, there was no basis for the definition of a blunt dissection catheter possibly comprising only one blunt spreading member. A single spreading member was not capable of performing a dissection, since it could not provide any fracturing force. The definition of such a fracturing force was required in view of original claim 43, lines 11 and 12.

Auxiliary *Request A: extension of protection - Article 123(3) EPC and amendments not occasioned by a ground for opposition - Rule 80 EPC*

Compared with claim 1 of the patent as granted, in claim 1 of Auxiliary Request A the definition of "the catheter shaft having a lumen with an annular opening at its distal end" comprised amendments which extended the scope of protection of the patent and were not occasioned by a ground for opposition. More particularly, in claim 1 of the patent as granted "a distal termination of the catheter shaft lumen form[ing] an annular opening" was defined instead. These definitions were clearly different.

It had not been possible to raise this objection until the oral proceedings because the amendment was difficult to identify. In view of its relevance, the objection should be admitted into the proceedings.

Auxiliary *Request A: clarity - Article 84 EPC*

Claim 1 of Auxiliary Request A was directed to a product. However, it referred to a sequential order of steps, for example in relation to the definition of the functioning of the blunt spreading members. Such a mixture of product-related and method-related features resulted in a lack of clarity.

The definition of the relative flexibility of the distal ends of two different assemblies was unclear. It was not apparent how the flexibilities were to be compared, since the distal ends of those assemblies differed from one another. Moreover, the term "distal end" of one assembly consisting of an inner catheter inserted within the lumen of an outer catheter was

unclear as such, since the length of the region to be considered distal and its configuration could differ depending, in particular, on whether the inner catheter was completely or only partly inserted.

The expression "positioned with vessel" did not make any sense.

Auxiliary *Request A: inventive step – Article 56 EPC*

D8 was the closest prior art. It disclosed a catheter system for bringing a working catheter through a vascular occlusion. The catheter system comprised a sheath catheter (12, figure 1), a sheath introducer (26, figure 1) and a blunt dissection catheter (working catheter described in column 4, lines 20 to 26).

D8 did not disclose the claimed flexibility relationship between the assemblies of the sheath catheter and sheath introducer and of the blunt dissection catheter and sheath catheter. This feature was, however, obvious in view of the very purpose of D8: bringing a stiff working catheter to the occlusion site.

D8 did also not disclose the claimed blunt spreading members of the blunt dissection catheter. This feature was, however, known from D7, which showed dissection catheters for treating total occlusions with such spreading members (figures 26A to 27B, for example). The skilled person would implement this feature in the working catheter of D8 when desiring to effectively treat total occlusions.

The only further distinguishing feature of the

subject-matter of claim 1 of Auxiliary Request A compared with the disclosure of D8 was the claimed structure of the shaft of the sheath catheter, including, in particular, an inner polymer liner and an outer polymer laminate coupled to respective surfaces of a braided tubular member. Implementing such a structure in the sheath catheter of D8 was obvious in the light of the teaching of D1/D1A, which disclosed a catheter tube with such a structure in order to prevent delamination.

It followed that the subject-matter of claim 1 of Auxiliary Request A did not involve an inventive step.

Auxiliary *Request A: conformity of the description with the amended claims - Rule 42(1)(c) EPC*

Several paragraphs of the description were not in conformity with the amended claims. For example, in paragraph [0015] it was stated that the catheter system included two elements, whereas the claimed system included three elements. According to paragraph [0097] the blunt dissection catheter could be different from the specific one defined in claim 1. The embodiments referred to in several paragraphs, for example [0060], [0061], [0072] and from [0100] onwards, contained features not defined in claim 1. Paragraph [0133] was vague and gave the impression that the invention could be different from the subject-matter of the claims.

VII. The respondent's arguments, as far as relevant for the present decision, may be summarised as follows:

Main request: extension of subject-matter - Article 123(2) EPC

The subject-matter of claim 1 of the main request was based on claims 25, 40 and 49 of the application as originally filed, as far as the disclosure of a three-component catheter system including a sheath catheter, a blunt dissection catheter and a sheath introducer was concerned, and on page 14, line 24 to page 15, line 4 as far as the relative flexibility of the distal ends of the assemblies of the sheath catheter and sheath introducer, and of the blunt dissection catheter and the sheath catheter was concerned.

The claim contained all the essential features needed in order for the catheter system to be brought to a particular, otherwise unreachable site of the vasculature. For that purpose, which was the aim of the invention, neither very flexible polymers included in the sheath catheter, nor particular spreading members of the blunt dissection catheter, nor a guide wire were necessary. What was essential was the flexibility relationship as claimed.

Likewise, the nature of the blunt dissection catheter was not essential either. That was made clear, for example, by the passage on page 28, lines 33 and 34. Moreover, for the skilled person, it was implicit that a blunt dissection catheter as claimed was suitable for creating a separation of material in a total occlusion without injuring nearby tissue.

It followed that claim 1 of the main request complied with Article 123(2) EPC.

First auxiliary *request: extension of subject-matter - Article 123(2) EPC*

The added features of the blunt dissection catheter, for example the blunt spreading members, made it implicit for the skilled person that the claimed catheter system was suitable for treating any occlusion, in particular total occlusions, by generating a path through the material of the occlusion. These added features were derived from page 6, lines 15 to 20, of the application as originally filed.

Auxiliary *Request A: extension of subject-matter - Article 123(2) EPC*

Claim 1 of Auxiliary Request A explicitly defined that the claimed catheter system was suitable for treating total occlusions, by generating a path through disrupted material of the occlusion. This feature was derived from original claim 43, lines 11 and 12.

A blunt dissection catheter possibly comprising only one blunt spreading member was expressly disclosed on page 6, lines 15 to 20. There was no need to include an explicit reference to a fracturing force in the claim, since the claim was directed to a system and the fracturing force would only be applied when the system was being used, by moving the blunt spreading members from the open to the closed position. To that end, a single spreading member was sufficient, as also shown in the prior art (D7, figures 27A and 27B).

Auxiliary *Request A: extension of protection - Article 123(3) EPC and amendments not occasioned by a ground for opposition - Rule 80 EPC*

Prima facie, no technical difference was apparent between the expressions in claim 1 of Auxiliary Request A of "the catheter shaft having a lumen with an annular opening at its distal end" and in claim 1 of the patent as granted of "a distal termination of the catheter shaft lumen form[ing] an annular opening". The editorial nature of the amendment was justified in view of the other amendments made to the claim. In view of their lack of prima-facie relevance, the late-filed objections to that expression in claim 1 of Auxiliary Request A should not be admitted into the proceedings.

Auxiliary *Request A: clarity - Article 84 EPC*

In general the skilled person approached the claims with a mind willing to understand.

Claim 1 of Auxiliary Request A was clearly directed to a product defined by both structural and functional features. No ambiguity arose from the mere fact that both kinds of features were employed.

The definition of the relative flexibility of the distal ends of two different assemblies was clear, since the claim specified under which respective conditions the distal ends of both assemblies were compared. In particular the assembly of the blunt dissection catheter and sheath catheter was in a condition for delivery within a blood vessel.

Auxiliary *Request A: inventive step.- Article 56 EPC*

D8 was the closest prior art. The disclosed catheter system for bringing a working catheter through a vascular occlusion did not comprise, in particular, any sheath introducer within the meaning of claim 1 of Auxiliary Request A. Catheter 26 (figure 1), within sheath catheter 12, was used for bringing the working catheter to the occlusion site. In contrast to the claimed invention, it was not to be replaced by a blunt dissection catheter within the sheath catheter for creating a path through the occlusion.

In the available prior art, there was no teaching to provide the catheter system of D8 with a sheath introducer as claimed.

Hence, the subject-matter of claim 1 of Auxiliary Request A was inventive.

Auxiliary *Request A: conformity of the description with the amended claims - Rule 42(1)(c) EPC*

Paragraph [0010] made it clear that the invention was as defined in claim 1. Paragraph [0015], mentioning a catheter system generally including two elements, did not exclude the possibility that the system could include a further element, in accordance with the invention. Paragraphs [0097] and [133] had to be read in context, in particular in view of paragraph [0010]. The description did not state that the embodiments referred to in the several paragraphs identified by the appellant were embodiments of the invention.

It followed that the description was in conformity with

the claims of Auxiliary Request A.

Reasons for the Decision

1. The appeal is admissible.

2. The invention

The invention relates to a catheter system for treating (total) vascular occlusions.

Vascular occlusions block significantly or completely the flow of blood through the affected vessel and are generally caused by the gradual accumulation of fatty, fibrous and/or calcific deposits along the interior wall of the vessel. The treatment of vascular occlusions aims at restoring blood circulation and typically involves catheter-based or surgical methods. The surgical methods involve the placement of external conduits to bypass the occlusion. With the catheter-based methods, a pathway is typically generated through the occlusion by introducing a guide wire through it. Then, the pathway is expanded, typically by means of a catheter inserted over the guide wire, with which balloon angioplasty is performed. Possibly, a stent placement follows.

According to the patent (paragraph [0006]), conventional guide wires, which possess very flexible distal terminations, are not designed for generating a pathway through a total occlusion, whereas the system according to the invention is designed for precisely this purpose.

More particularly, the system defined in claim 1 of all requests comprises a sheath catheter, a sheath introducer and a blunt dissection catheter. The system is intended to be used in the following way. First, the sheath catheter is coupled to the sheath introducer by insertion of an elongate member of the introducer within a lumen of the catheter. The sheath introducer, by virtue of its flexibility, facilitates the operation of bringing the tip of the catheter into the region of the occlusion. Once the sheath catheter is in place, the sheath introducer is removed and replaced by the blunt dissection catheter, which is used to create a pathway through the occlusion.

3. Main request

3.1 Extension of subject-matter - Article 123(2) EPC

The individual features defined in claim 1 of the main request are generally derived from originally filed claims 25 and 40, which disclose a three-component catheter system and several features of the sheath introducer; claims 1, 8, 9 and 12, which disclose the features of the shaft of the sheath catheter; page 12, lines 29 to 33, which disclose the features of the blunt dissection catheter; and page 14, line 30 to page 15, lines 4, which disclose the relative flexibility of the assemblies of the sheath catheter and sheath introducer on the one hand, and of the blunt dissection catheter and sheath catheter on the other.

The appellant argued that the claimed features were not disclosed in combination in the application as originally filed and that the claim now contained several impermissible generalisations.

3.1.1 As far as the argument that the description and claim 49 as originally filed disclosed only specific methods for using the claimed three elements of the catheter system, which were not reflected in claim 1 of the main request, the Board notes that the latter claim is directed to a system and not to a method. A basis for generally claiming a catheter system comprising three elements can be found in the combination of originally filed independent claim 25, defining a catheter system with a first element in the form of a "sheath catheter" and a second element in the form of an "intravascular tissue expanding catheter", together with its dependent claim 40, further defining a "sheath introducer". Hence, the mere fact that claim 1 of the main request is directed to a system comprising three catheter elements is not, as such, in contravention of Article 123(2) EPC. For similar reasons the definition of a further catheter element in the form of a guide wire is not necessary in order for the claim to comply with Article 123(2) EPC. In the combination of claims 25 and 40 as originally filed, a guide wire is only mentioned in relation to a functional feature of the sheath introducer. The same functional feature is recited in claim 1 of the main request.

3.1.2 The appellant argued that, according to the application as originally filed, the claimed greater degree of flexibility at the distal end of the assembly of the sheath catheter and the sheath introducer compared to the assembly of the blunt dissection catheter and the sheath catheter could only be achieved if the sheath introducer included "very flexible polymers". According to page 14, line 27 to page 15, line 4 of the application as filed:

"*However, for applications in which the vasculature has a high degree of tortuosity, as is more often seen in certain coronary anatomies, an alternate method of gaining access to the site of the vascular occlusion may be desirable. If the tortuosity of the vasculature is too extreme for the Blunt Dissection Catheter and the Sheath Catheter to navigate as a system, it may be desirable to deliver the Sheath Catheter first via a more flexible delivery scheme, and to subsequently deliver the Blunt Dissection Catheter within the Sheath Catheter to the site of the vascular occlusion. The Sheath introducer includes very flexible polymers and thus the Sheath Catheter/Sheath Introducer combination can afford a greater degree of flexibility at the distal end of the assembly to allow tracking through higher degree of vascular tortuosity while delivering the distal end of the Sheath Catheter to the desired vascular location.*"

In the Board's view, this passage does not present "very flexible polymers" as essential. It is rather the claimed flexibility relationship which is presented as important in applications in which the vasculature has a high degree of tortuosity. "Very flexible polymers" included in the sheath introducer are merely presented as one possible way of obtaining that relationship. Hence, leaving them out of the subject-matter claimed does not provide the skilled person with any technical information that is not directly and unambiguously derivable from the application as originally filed.

The technical disclosure of the same passage, read as a whole, is that the distal end of the assembly of the sheath catheter and sheath introducer should be more

flexible than the distal end of the assembly of the sheath catheter and blunt dissection catheter. It is clearly the first assembly, compared to the second, which is supposed to "allow tracking through higher degrees of vascular tortuosity". This is consistent with the definition of the flexibility relationship in claim 1 of the main request.

3.1.3 The Board, however, shares the appellant's view that there is no basis in the application as originally filed for a "blunt dissection catheter" as generally defined in claim 1 of the main request.

More particularly, in the application as originally filed, a blunt dissection catheter is introduced on page 6, lines 6 to 14. According to this passage, the blunt dissection catheter can be used to perform "blunt dissection in the vascular occlusion **to produce a dissection track, or small pathway through the occlusion**" and, together with a sheath catheter, to "**cross total vascular occlusions** in both the coronary and peripheral vasculature" (emphasis added by the Board). This is consistent with the main aim of the invention as presented in the application as originally filed, which is the non-surgical treatment of chronic total occlusions (for example page 3, lines 22 to 29 and page 5, lines 19 to 20). Turning to claims 25, 43 and 49 as originally filed, each of them defines several structural features making it possible to generate a pathway through a total occlusion in a specific way. For example, claim 25 defines an "intravascular tissue expanding catheter" with "at least one deflecting member" having "a free distal tip that moves through an arc [...] to expand vascular tissue" and claims 43 and 49 define methods of crossing an occlusion by, in particular, "disrupting material of

the occlusion and generating a path through the disrupted material". Page 28, lines 33 and 34 read:

> "*The Blunt Dissection Catheter described above can be any of a number of catheters and/or working elements*".

This passage is to be read in context of the embodiments "described above", which, consistently, are all suitable for generating a pathway through a total vascular occlusion.

It follows that, according to the application as originally filed, the blunt dissection catheter must be suitable for generating a path through a total occlusion. In contrast, according to the general definition in claim 1 of the main request, such suitability is not required. The claim does simply not define any structural or functional features for it. By conveying the technical information that such suitability is merely optional, the subject-matter of claim 1 extends beyond the content of the application as originally filed, infringing Article 123(2) EPC.

3.1.4 For this reason alone the patent cannot be maintained on the basis of the main request.

4. First auxiliary request

4.1 Extension of subject-matter - Article 123(2) EPC

The features added to the subject-matter of claim 1 of the first auxiliary request compared with claim 1 of the main request still do not require that the blunt dissection catheter be suitable for generating a path through a vascular total occlusion. In particular, the

Board does not see how the general definition of "one or more longitudinally arranged, atraumatic, blunt spreading members (122; 506, 508) each having a free distal end configured to rotate about a proximal end that is hinged to a base (502) of the actuation assembly" can provide either structural or functional features explicitly or implicitly requiring such suitability.

It follows that the first auxiliary request cannot be allowed for lack of compliance with Article 123(2) EPC.

5. Auxiliary Request A

Auxiliary Request A was filed during the oral proceedings, after the Board had reached the conclusion that the main and the first auxiliary requests did not comply with Article 123(2) EPC for the reasons given above. The amendments made in this request compared with the higher-ranking requests are considered as a justified and straightforward attempt to remove the reasons of non-compliance. Moreover, the appellant did not object to the admissibility of Auxiliary Request A. Under Article 13(1) and (3) RPBA the Board admits Auxiliary Request A into the proceedings.

5.1 Extension of subject-matter - Article 123(2) EPC

5.1.1 Claim 1 of Auxiliary Request A has been amended to recite in particular that the catheter system is "for treating total occlusions within blood vessels" and for "disrupting material of the occlusion and generating a path through disrupted material" of the occlusion. This latter expression is derived from original claim 43, lines 11 and 12 and original claim 49, lines 16 and 17. The amendment, however, is in line with the general

teaching of the application as originally filed, as explained in point 3.1.3 above. In the Board's view, such an amendment removes the only cause of non-compliance of the higher-ranking requests with Article 123(2) EPC.

The appellant's arguments that the blunt dissection catheter had to comprise more than one blunt spreading member and that a definition of a fracturing force should be present in claim 1 are not convincing. As the respondent argued, page 6, lines 15 to 20 of the application as originally filed expressly define a blunt dissection catheter possibly having only one blunt spreading member. Moreover, an explicit definition of a fracturing force as mentioned in original method claims 43 and 49 is not necessary either. The suitability of the claimed system for the application of such a force in a condition of use is inherent, because there is at least one blunt spreading member that is capable of "generating a path through disrupted material" of a total occlusion. There is no technical obstacle to applying such a force with only one spreading member, as also shown, for example, in figures 27A and 27B of D7.

5.1.2 The appellant had no further objections and the Board does not see any either. It is therefore concluded that Auxiliary Request A complies with Article 123(2) EPC.

5.2 Extension of protection - Article 123(3) EPC and amendments not occasioned by a ground for opposition - Rule 80 EPC

During the oral proceedings - hence well after the filing of the ground of appeal - the appellant raised objections against claim 1 of Auxiliary Request A under

Article 123(3) and Rule 80 EPC for the first time. These objections do not arise from the specific amendments made in Auxiliary Request A, since they are directed to wording also present in claim 1 of the main request on which the impugned decision was based. These objections clearly constitute an amendment to the appellant's case.

Under Article 13(1) RPBA, "any amendment of a party's case after it has filed its grounds of appeal or reply may be admitted and considered at the Board's discretion. The discretion shall be exercised in view inter alia of the complexity of the new subject matter submitted, the current state of the proceedings and the need for procedural economy". It is the established jurisprudence of the boards that another important criterion to be considered is the prima-facie relevance of the amendment.

The Board notes that the appellant amended its case at the latest possible time, namely during the oral proceedings. No convincing reason was given for this. The argument that the alleged non-compliance with Article 123(3) and Rule 80 EPC was difficult to identify cannot be accepted, in particular in view of its subjective nature.

Moreover, on a prima-facie basis, the objections are of little relevance, since they concern amendments of the claim compared with the patent as granted which appear to be of a purely editorial nature, but justified to ensure clarity and consistency of the claim in view of other amendments. In particular, the Board cannot see any apparent technical difference - and the appellant has not explained any - between a shaft having a lumen with an annular opening at its distal end and a shaft

with a lumen, a distal termination of which forms an annular opening.

For these reasons the objections under Article 123(3) and Rule 80 EPC raised by the appellant against claim 1 of Auxiliary Request A are not admitted into the proceedings pursuant to Article 13(1) RPBA.

5.3 Clarity - Article 84 EPC

The appellant argued that the subject-matter of claim 1 of Auxiliary Request A was unclear.

In particular, the definition of a system by reference to method steps was considered ambiguous. However, the Board notes that defining a system by functional features referring to how the system is used does not necessarily result in a lack of clarity. According to the established jurisprudence such functional features simply define the suitability of the system for performing the claimed function. Whether this may result, in certain cases, in little limitation of the claimed subject-matter is not relevant for the assessment of the clarity of the claim. In this particular case the functional features of the blunt spreading members define the way those members can be operated during use, setting clear limitations on the mechanical arrangement of the actuation assembly.

As regards the definition of the relative flexibility of the distal ends of the assemblies of the sheath catheter and sheath introducer, and of the blunt dissection catheter and sheath catheter, the Board notes that the claim specifies the respective assembly states. The flexibilities concerned are "when the sheath catheter (300) and sheath introducer (350) are

assembled with the member (370) [of the sheath introducer] being fully inserted into the lumen of said sheath catheter (300)" and when "the blunt dissection catheter (100) is loaded within the sheath catheter (300) for delivery". In context, the delivery intended is clearly within the blood vessel, to the site of the vascular occlusion to be treated. The length of the region to be considered "distal" is clearly derivable for the skilled person in the light of its intended effect as explained in the description, namely gaining access to the site of a vascular occlusion when the vasculature has a high degree of tortuosity (page 12, lines 24 to 35 of the patent).

As far as the expression "positioned with vessel" is concerned, the Board acknowledges that, literally, it makes no sense.

However, the skilled person approaches a claim wording with a mind willing to make technical sense of it. In context, the Board has no doubt that the skilled person would understand this expression to refer to the possibility of placing the blunt dissection catheter in a certain position within a blood vessel.

In conclusion, the Board is satisfied that claim 1 of Auxiliary Request A complies with Article 84 EPC.

5.4 Inventive step - Article 56 EPC

5.4.1 Both parties considered D8 to be the closest prior art for the subject-matter of claim 1 of Auxiliary Request A.

D8 concerns a guide catheter system for treating coronary artery disease. The system comprises an outer

catheter (12, figure 1) with a lumen for receiving, in particular, an inner, slimmer and softer catheter (26, figure 1) having a lumen which, in turn, can receive a working catheter (column 5, lines 14 to 18). In use (described in column 4, line 49 to column 5, line 38 with reference to figures 1 and 2), the outer catheter is advanced until its distal end reaches the coronary ostium. A conventional guide wire is then introduced into the lumen of the outer catheter and manoeuvred until it reaches the site of the coronary artery to be treated. Immediately afterwards the inner catheter is slid over the guide wire, within the outer catheter, so that it reaches the treatment site. Subsequently, the guide wire is removed and a working catheter, which can be in the form of a balloon catheter, is advanced within the inner catheter. The use of such an inner catheter enables the working catheter to be deployed at sites which would be difficult to reach with a single guide catheter (column 2, lines 36 to 40). According to D8, it is important that the interior wall of the inner catheter be coated with a lubricious plastic, such as Teflon, so that the deployment of the working catheter is facilitated (column 2, lines 48 to 51 and column 5, lines 18 to 24).

5.4.2 The appellant argued that D8 disclosed a catheter system with a sheath catheter (the outer catheter), a blunt dissection catheter (the working catheter) and a sheath introducer (the inner catheter).

Even accepting this interpretation, D8 does not disclose, in particular, that the assembly of the sheath catheter and sheath introducer affords a greater degree of flexibility at the distal end of the assembly thereof than the assembly of the blunt dissection catheter and the sheath catheter, in the respective

assembly states specified. This has not been disputed by the appellant.

5.4.3 As stated in the patent itself, this flexibility relationship has the technical effect, in the system according to the invention as defined in claim 1 of Auxiliary Request A, of allowing tracking through higher degrees of vascular tortuosity by the assembly of the sheath catheter and sheath introducer in order to deliver the sheath catheter to a desired vascular location (column 12, lines 35 to 41).

As a consequence, the objective technical problem solved is how to improve the treatment of vascular occlusions at locations which are difficult to reach.

5.4.4 D8 teaches a completely different procedure to reach a desired vascular location. As explained above, the assembly of the sheath catheter with a guide wire is used. The sheath introducer as identified by the appellant is not involved in that procedure, but serves the purpose of enhancing the tracking of a working catheter received within it in order for the working catheter to be more easily manipulated during a treatment (column 5, lines 18 to 24).

There is therefore no obvious reason why the skilled person, starting from D8, should provide the flexibility relationship between the respective assemblies as claimed. Moreover, in the system of D8 those assemblies are of only theoretical nature, since it is not intended to work with an assembly of the working catheter (the blunt dissection catheter) and the outer catheter (the sheath catheter) without the inner catheter (the sheath introducer). It is therefore even problematic to define the distal ends of those

theoretical assemblies of D8 in the respective states as defined in claim 1 of Auxiliary Request A.

The other cited documents, referred to by the appellant in relation to other claimed features, do not address the objective technical problem either.

5.4.5 At least for this reason the subject-matter of claim 1 and, a fortiori, of its dependent claims 2 to 12, involves an inventive step within the meaning of Article 56 EPC. As a consequence it is not necessary for the Board to consider other potential distinguishing features over the disclosure of D8.

5.5 Conformity of the description with the amended claims - Rule 42(1)(c) EPC

The appellant argued that several passages in the description were not in conformity with the claims as amended according to Auxiliary Request A.

The Board notes that amended paragraph [0010] clearly states that the invention is defined in claim 1. No other passages of the description contradict this statement. More particularly, paragraph [0015] describing a catheter system including two elements does not preclude the catheter system according to the invention from including a further, third element. Similarly, nowhere is it stated that the blunt dissection catheter mentioned in paragraph [0097] and the embodiments referred to in the paragraphs cited by the appellant are in accordance with the claimed invention. Paragraph [0133], be it vague or not, does not contain any express statement indicating that the invention should be different from the subject-matter

of claim 1 of Auxiliary Request A.

For these reasons the Board is satisfied that the requirements of Rule 42(1)(c) EPC are fulfilled.

5.6 In conclusion, Auxiliary Request A is allowable. Hence, there is no reason for the Board to consider the respondent's lower-ranking auxiliary requests.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance with the order to maintain the patent on the basis of:

   - claims 1 to 12 of Auxiliary Request A filed during oral proceedings;
   - description columns 1 and 2, and 5 to 31 of the patent as granted and columns 3 and 4 as filed during oral proceedings; and
   - figures pages 20 to 39 of the patent as granted.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated