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**D E C I S I O N**  
**of 12 July 2004**

**Case Number:** T 0847/03 - 3.2.2

**Application Number:** 95920602.0

**Publication Number:** 0844894

**IPC:** A61M 29/00

**Language of the proceedings:** EN

**Title of invention:**

Apparatus for performing diagnostic and therapeutic modalities  
in the biliary tree

**Applicant:**

BOSTON SCIENTIFIC CORPORATION

**Opponent:**

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**Headword:**

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**Relevant legal provisions:**

EPC Art. 52, 56

**Keyword:**

"Inventive step (yes, after amendments)"

**Decisions cited:**

-

**Catchword:**

-



Case Number: T 0847/03 - 3.2.2

**D E C I S I O N**  
of the Technical Board of Appeal 3.2.2  
of 12 July 2004

**Appellant:** BOSTON SCIENTIFIC CORPORATION  
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MA 01760-1537 (US)

**Representative:** Warren, Anthony Robert  
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**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted 17 February 2003  
refusing European application No. 95920602.0  
pursuant to Article 97(1) EPC.

**Composition of the Board:**

**Chairman:** T. Kriner  
**Members:** D. Valle  
U. J. Tronser

## Summary of Facts and Submissions

I. The appellant (applicant) lodged an appeal, on 4 April 2003, against the decision of the examining division posted on 17 February 2003, on the refusal of the European patent application No. 95 920 602.0. The fee for the appeal was paid simultaneously and the statement setting out the grounds for appeal was received on 12 June 2003.

II. The examining division held that the application did not meet the requirements of Article 53 and 56 EPC, having regard to the following documents:

D6 = JP-A-5-68 685 (including an English translation),  
and:

D7 = US-A-4 682 596.

III. In addition to these documents, the following documents, used in the examining procedure, have been considered for the present decision:

D1 = US-A-5 152 772

D2 = EP-A-0 385 588

D3 = US-A-4 295 464

D4 = JP-A-4 200 245.

IV. Following a communication of the board, the appellant submitted with letter of 19 Mai 2004 a new version of the application consisting of:

- claims 1 to 6;
- description, pages 1 to 7 and 9 to 14; and:
- drawings, sheets 1/5 to 5/5,

and requested the grant of a patent on the basis of these documents.

V. Claim 1 as filed with letter of 19 Mai 2004 reads as follows:

"Apparatus for use in a treatment modality including an enlargement procedure and a contrast agent-injecting procedure to be performed within a patient, of the type comprising:

catheter means (11) for being directed through internal passageways in the patient guided by a guidewire (57) previously positioned in the passageways, said catheter means having proximal (12) and distal (14) ends and proximal (13) and distal (15) portions adjacent to said proximal and distal ends respectively, and including

a first lumen (16) extending between said proximal (13) and distal (15) portions, said first lumen (16) having an axially facing distal port at said distal portion (15) and a proximal port (21) at said proximal portion (13) for enabling access to said first lumen, whereby said first lumen is adapted to receive the pre-positioned guidewire (57) therethrough so that said catheter means is slidable along the guidewire, and

second (20) and third (17B) lumens disposed generally parallel to said first lumen (16), said second lumen (20) and said third lumen (17B) extending between said proximal (13) and distal (15) portions, and said first lumen (16) being larger than said second (20) and third (17B) lumens,

said apparatus further including enlargement means comprising a cutting wire (31) for performing an enlargement procedure comprising a cutting procedure, said cutting wire (31) extending through said second lumen (20) for operating at said distal portion (15) in response to manipulations at said proximal end (12), and operator means (26) at said proximal end (12) attached to said catheter means (11) and a proximal portion of said cutting wire for operating said cutting wire from a point proximal of said catheter means (11),

characterized in that said third lumen (17B) has a proximal port (23) at said proximal portion (13) for providing access to said third lumen to enable a user to control the contrast agent-injecting procedure at said distal end (14) through said third lumen, and has an axially facing distal port (65) at said distal end (14) whereby fluid contrast agent introduced at said third lumen proximal port (23) discharges from said third lumen distal port (65)."

VI. The appellant argued that D6 - relied upon in combination with D7 by the examining division - did not address the problem underlying the invention. Moreover, D7 described an electrosurgical plaque-resolving and tissue-eroding device so dissimilar from the device disclosed in D6 that there was no reason to combine the teaching of these documents in any way. D6 furthermore explicitly taught away from a combination with D7 (see

column 1, line 6, to column 2, line 3). D7 did not address the problem of the invention either. The invention eliminated the interferences present in D6 between guidewire and contrast agent, due to the use of the same lumen for the guidewire and the contrast agent. These interferences arose - from one part, when the guidewire was kept in place - because the presence of the guidewire in the lumen disturbed the regular flow of the contrast agent, and - from the other part, when the guidewire was extracted during introduction of the contrast agent in the lumen - because residues of the contrast agent in the lumen could prevent a smooth reinsertion of the guidewire.

### **Reasons for the Decision**

1. The appeal is admissible.
2. *Amendments*

Claim 1 is derived from the originally filed claim 1 and the originally filed figures. Claims 2 to 6 are derived from the original claims 6 to 8, 15 and 16, respectively. The description has merely been adapted to the new claims.

Consequently, the amendments of the application meet the requirements of Article 123(2) EPC.

3. *Novelty*

3.1 D6 discloses an apparatus suitable for use in a treatment modality including an enlargement procedure and a contrast agent-injecting procedure (page 1, claim and point 0019 of the description) to be performed within a patient, of the type comprising:

catheter means (10) for being directed through internal passageways in the patient guided by a guidewire previously positioned in the passageways, said catheter means having proximal and distal ends and proximal and distal portions adjacent to said proximal and distal ends respectively, and including

a first lumen (19) extending between said proximal and distal portions, said first lumen having an axially facing distal port (16) at said distal portion and a proximal port at said proximal portion for enabling access to said first lumen, whereby said first lumen is adapted to receive the pre-positioned guidewire (see section 0019 of the description) therethrough so that said catheter means is slidable along the guidewire, and

second (17) and third (20 or 43) lumens disposed generally parallel to said first lumen (19), said second lumen (17) and third lumen (20 or 43) extending between said proximal and distal portions, and said first lumen (19) being larger than said second and third lumens,

said apparatus further including means comprising a cutting wire (12, see section 0032) for performing an enlargement procedure comprising a cutting procedure, said cutting wire extending through said second lumen (17) for operating at said distal portion in response to manipulations at said proximal end, and operator

means at said proximal end attached to said catheter means and a proximal portion of said cutting wire for operating said cutting wire from a point proximal of said catheter means.

However, D6 does not disclose the characterizing features of claim 1 of the present application according to which:

said third lumen has a proximal port at said proximal portion for providing access to said third lumen to enable a user to control the contrast agent-injecting procedure at said distal end through said third lumen, and has an axially facing distal port at said distal end whereby fluid contrast agent introduced at said third lumen proximal port discharges from said third lumen distal port.

In contrast to the claimed invention, the third lumen in D6 (20) is designed for softening the wall of the flexible sheath, and the contrasting means is inserted in the first lumen (19) without or after removal of the guidewire.

- 3.2 D7 discloses an apparatus for resolving or removing atherosclerotic plaque buildup or tissue in a blood vessel, but it can also be used in connection with clearing hepatic and bile ducts (column 12, from line 25). The plaque or tissue is removed through an electrode to which high frequency electrical current is supplied. The apparatus consists of a catheter with a first lumen (134, Figure 5) for the guidewire, a second lumen (136) for power supply and a third lumen (135) for flushing and suction of the debris coming from the



ablation. The third lumen can have an axially facing distant port (191, Figure 12). A radio-opaque dye can be injected into the vessel for confirmation of the complete plaque or tissue removal (column 12, from line 17); D7 does not specify from which lumen the dye is injected.

However, D7 does not disclose a lumen designed to deliver the contrast agent as claimed in claim 1.

3.3 The further documents cited during the examining procedure are less relevant than D6.

D1 is directed to a sphincterotomy catheter having three lumens, two of them for delivering gas to a balloon, the third (smaller) one for lodging the bias means to operate the blade. D1 does neither disclose a cutting wire nor a lumen for a contrast means.

D2 discloses a sphincterotomy catheter with two lumens, one lodging the conductor and the second a reinforcement wire to resist movements of the cutting edge. D2 does not disclose a third lumen.

D3 is directed to a ureteric stone extractor comprising two balloon catheters. D3 does not disclose a lumen adapted to receive a guidewire as claimed in claim 1.

D4 does also not disclose a lumen adapted to receive a guidewire as claimed in claim 1.

3.4 Therefore, the subject-matter of claim 1 is novel.

4. *Inventive step*

4.1 The most relevant state of the art is disclosed in D6.

As pointed out above, in the catheter according to D6 the contrast agent is delivered through the guidewire lumen. The procedure can be performed either by first extracting the guidewire to free the whole lumen, or with the guidewire in place, if the lumen is sufficiently broad. Both procedures are not ideal. With the first procedure, the extraction of the guidewire, extending throughout the endoscope, which has a typical length of 200 cm, is cumbersome and time-consuming. Residuals of the contrast agent can further impede the later reinsertion of the guidewire. The second procedure, with the guidewire in place, is not reliable due to the interference of the contrast agent with the guidewire.

4.2 Therefore, starting from D6, the object underlying the present application may be regarded (see page 4, lines 23 to 25) as to provide an apparatus as described in the preamble of claim 1 which is capable to perform both diagnosis and additional therapeutic treatment without requiring a catheter exchange.

This object is achieved by the provision of a third lumen as defined in the characterizing portion of claim 1, or in other words, by the provision of a third lumen, having proximal and distal ports, reserved for delivering the contrast agent.

4.3 The provision of a third lumen according to claim 1 of the present application is not suggested by the available state of the art.

D6 does not contain any hint toward the claimed invention, and none of the other present documents refers to the use of a third lumen as defined in claim 1.

In particular, D7 fails to suggest a lumen specifically designed for delivering a contrast agent in the form of claim 1. The combination of D6 and D7 can therefore not lead to the invention in an obvious way.

The combination of the teaching of D6 with any of D1 to D4 is also not suitable to make the subject-matter of claim 1 obvious, since none of these documents discloses all the features of the characterizing part of claim 1.

4.4 Therefore, the subject-matter of claim 1 involves an inventive step.

## **Order**

### **For these reasons it is decided that:**

1. The decision under appeal is set aside.
2. The case is remitted to the first instance with the order to grant a patent on the basis of the following version of the application submitted with letter of 19 Mai 2004:

- claims 1 to 6,
- description, pages 1 to 7 and 9 to 14, and:
- drawings, sheets 1/5 to 5/5.

The Registrar:

The Chairman:

V. Commare

T. Kriner