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Datasheet for the decision of 22 June 2009

Case Number: T 0738/07 - 3.2.02

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

Patentee:
Boston Scientific Limited

Opponent:
Schmiedl, Roland, Prof. Dr.

Headword:
-

Relevant legal provisions:
EPC Art. 54, 56

Relevant legal provisions (EPC 1973):
-

Keyword:
"Novelty (yes)"
"Inventive step (no)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0738/07 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 22 June 2009

Appellant: (Opponent)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 16 March 2007 rejecting the opposition filed against European patent No. 0844894 pursuant to Article 102(2) EPC.

Composition of the Board:

Chairman: M. Noel
Members: D. Valle
A. Pignatelli

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal on 2 May 2007 against the decision of the opposition division posted on 16 March 2007 to reject the opposition. The fee for the appeal was paid simultaneously and the statement setting out the grounds for appeal was received on 16 July 2007.

II. The patent was opposed on the basis of Article 100 (a) EPC (lack of novelty and inventive step).

III. The following documents are relevant for the present decision:

E1 = JP 5-68685 and English translation
E2 = WO 93/23106.

IV. Oral proceedings have been held on 22 June 2009.

At the end of the oral proceedings the appellant requested that the decision under appeal be set aside and that the patent be revoked. The respondent (patentee) requested that the appeal be dismissed (main request) or that the patent be maintained in amended form according to the auxiliary request filed on 16 June 2009.

V. Claim 1 of the main request 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)."

Claim 1 of the auxiliary request differs from the main request in that the following features highlighted in italics are added:

"Apparatus for use in a treatment modality including an enlargement procedure and a contrast agent-injecting procedure to be performed within *the biliary tree of* a patient, of the type comprising:
catheter means (11) for being directed through *a working channel of a duodenoscope (50) and through* internal passageways in the patient guided by a guidewire (57) ...".

VI. The appellant argued essentially as follows.

The subject-matter of claim 1 of the main request was anticipated by E1. Lumens 20 of figure 6 were suitable for receiving the contrast agent. These lumens were through lumens since the normal manufacturing method for the catheter was extrusion which implied a through lumen. The lumens 20 did extend beyond the cutting blade and fork area 11 as shown in Figure 5 which made clear that the section of Figure 6 was taken at the bifurcation (VI-VI) close to the proximal end operator side of the apparatus. The alternative embodiments of Figures 1 and 7 showed lumens not having the cut-out upper part as the embodiment of Figure 6 and that

therefore could not be closed by the adhesive block 31 shown in Figure 5.

In any case the subject-matter of claim 1 did not involve an inventive step against a combination of the teachings of E1 and E2.

VII. The respondent contested the statements of the appellant and argued essentially as follows.

The subject-matter of claim 1 of the main request was novel against E1. Nowhere in E1 was disclosed a lumen specifically dedicated to the injection of a contrast agent, which implied having proximal and distal ports specifically designed for this purpose.

The subject-matter of claim 1 also involved an inventive step since a combination of the teachings of E1 and E2 was neither suggested nor sufficient to arrive at the claimed subject-matter.

The auxiliary request introduced an additional limitation to claim 1 since the specific use and capability of the apparatus was now clearly defined, despite the fact that the added features where already known from E1.

Reasons for the Decision

1. The appeal is admissible.

2. Main request

2.1 Novelty

E1 (see Figures 1 to 6 and paragraph [10] and [19] of the English translation) discloses an 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 for being directed through internal passageways in the patient guided by a guidewire (not shown) 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 at said distal portion (see Figure 3) and a proximal port 16 at said proximal portion (see Figure 2) for enabling access to said first lumen, whereby said first lumen is adapted to receive the pre-positioned guidewire therethrough (see paragraph [19]) so that said catheter means is slidable along the guidewire, and second 17 and third 20 lumens disposed generally parallel to said first lumen, said second lumen 17 extending between said proximal and distal portions, and said first lumen being larger than said second lumen, said apparatus further including enlargement means comprising a cutting wire 12, 18 for performing an enlargement procedure comprising a cutting procedure, said cutting wire 18 extending through said second lumen 17 for operating at said distal portion in response to manipulations at said proximal end, and operator means 11 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, E1 does not disclose that the third lumen 20 has a proximal port at said proximal portion for providing access to said third lumen to enable a user to control a contrast agent-injecting procedure at said distal end through said third lumen, nor that it has an axially facing distal port at said distal end for permitting a fluid contrast agent (possibly) introduced at said third lumen proximal port to be discharged from said third lumen distal port. The third lumen of E1 is only designed for softening the wall of the tube (see paragraphs [19] and [34]).

The arguments of the appellant are not convincing since nowhere in E1 is disclosed a lumen specifically designed for injecting a contrast medium. As a consequence, proximal and distal ports specifically designed for this purpose are also not provided in E1.

Accordingly the subject-matter of claim 1 is novel against E1.

2.2 Inventive step

Starting from E1, which is indisputably considered as the closest state of the art, the object of the invention is to be seen in providing an apparatus for performing several medical procedures with more flexibility than the known apparatus, i.e without requiring a catheter exchange (see patent in suit, paragraph 011). In particular it has been realized that

using the same and single lumen both for inserting the guidewire and injecting the contrast medium is time-consuming and reduces efficiency.

The solution to this problem is laid down in the characterising part of claim 1 and consists essentially in providing a third lumen exclusively dedicated to the injection of the contrast medium.

E2 belongs to the same field of biliary catheters as that of the invention and is directed to an endoscopic catheter which can more easily accomodate spring wire guide insertion and treading as well as contrast media infusion (see page 1, lines 9 to 11). To this purpose the document suggests providing two separate lumina, one dedicated to accommodate the spring guidewire and the other used for contrast media infusion (see page 4, lines 6 to 10 and Figure 3A). The suggestion applies also to catheters having more than two lumens of any geometric shape (see page 13, lines 16 - 24).

Accordingly, the skilled person in the field would be induced to combine the teachings of E1 and E2 and so doing would arrive to the invention as claimed without exercising any inventive skill, the more so since E1 already suggests providing the catheter with a plurality of lumens dedicated to different functions: 17 or 41 for a cutting wire, 19 or 42 for a guidewire and/or a contrast medium, and 20 or 43 for increasing the catheter flexibility (see paragraph [42]). The subject-matter of claim 1 of the main request, therefore, does not involve an inventive step having regard to the combination of E1 and E2.

3. Auxiliary request

Claim 1 of the auxiliary request differs from claim 1 of the main request in that the procedure is performed within the biliary tree of a patient and in that the catheter means is directed through a working channel of a duodenoscope.

However, these additional features are also known from E1 (see page 9, last paragraph to page 10, line 8) as was admitted by the respondent. Accordingly the conclusion drawn for the main request equally applies to the auxiliary request.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

A. Vottner M. Noël