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Datasheet for the decision of 14 October 2009

Case Number: T 1670/06 - 3.2.02

Application Number: 02707731.2

Publication Number: 1370182

IPC: A61B 17/22

Language of the proceedings: EN

Title of invention:
Ultrasound system and method for revascularization and drug delivery

Applicant:
Boston Scientific Limited

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 56, 52

Relevant legal provisions (EPC 1973):
-

Keyword:
"Inventive step (no)"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1670/06 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 14 October 2009

Appellant: Boston Scientific Limited
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Representative: Pfenning, Meinig & Partner GbR
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 21 April 2006 refusing European application No. 02707731.2 pursuant to Article 97(1) EPC.**

Composition of the Board:

Chairman: M. Noël
Members: P. L. P. Weber
M. J. Vogel

Summary of Facts and Submissions

I. The appeal is filed against the decision of the examining division dated 21 April 2006 to refuse European patent application number 02707731.2. The application was refused because of lack of inventive step of the subject-matter of claim 1 over a combination of documents D4 and D1.

The appeal was filed on 21 June 2006 and the appeal fee paid on the same day. The statement setting out the grounds of appeal was filed on 18 August 2006.

II. The following documents played a role in the appeal proceedings:

D1: WO-A-0016704
D2: WO-A-0018305
D4: US-A-5827203

III. Oral proceedings took place on 14 October 2009.

The appellant requested the decision be set aside and a patent be granted on the basis of claims 1 to 4 which correspond to claims 1 to 4 filed as first auxiliary request on 8 June 2009.

IV. Claim 1 reads as follows:

"A guidable elongated flexible ultrasound device for increasing the blood circulation to an area of interest in a heart muscle of a patient comprising:

an elongated tubular body (10,110) having a lumen (12,112), a longitudinal axis (14), a distal end and a proximal end;

a distal head (16,116) mounted on said distal end for introducing ultrasonic waves to said area of interest; and

a needle (20,120) for injecting a material (24,124) into said area of interest, said needle mounted to said elongated tubular body substantially parallel to said longitudinal axis of said tubular body,
said needle being attached adjacent to said elongated tubular body or being attached to said elongated tubular body within said lumen of said elongated tubular body and passing through the distal head
wherein the needle extends beyond the distal head."

V. The arguments of the appellant can be summarized as follows:

Starting from D4 as the closest prior art the skilled person would not arrive at the subject-matter of claim 1 even when considering the teachings of documents D1 and D2.

The differentiating feature when starting from the first embodiment of figure 6A of the D4, only concerning the use of the device in massaging mode (as in the case of the device of the present invention), was that a needle for injecting material into the area of interest was mounted to the elongated body and extended beyond the distal head.

Accordingly, the objective problem when starting from the above prior art was seen in the addition of a treatment of the area of interest in combination with the massaging already provided for.

The person skilled in the art would not be prompted by D4 to add any needle to the distal head of the device as a substance could already be delivered through the apertures 44 or 50.

D1 and D2 did not hint at the invention either.

Document D1 taught, in all embodiments, to go beyond the endocardial layer with the distal head in order to treat the myocardium, the cardial wall was thus pierced before any substance was delivered. In addition there was no disclosure in this document that the puncturing element was used as a needle and protruded beyond the distal head as required by claim 1. In the embodiment according to Figure 6 of this document the puncturing element protruded laterally of the distal head and not axially.

A person skilled in the art wanting to apply a further treatment to the area of interest when the device was in the massaging mode would not consider document D2 which only disclosed the use of a vibrating needle to create channels in the heart wall, in other words to make big holes in the myocardium before injecting medicament. Should the person skilled in the art try to apply the teaching of document D2 to the device disclosed in D4, this would simply mean using a needle instead of the ultrasound head, so that the person

skilled in the art would not arrive at the subject-matter of claim 1.

Reasons for the Decision

1. The appeal is admissible.

2. Present claim 1 fulfils the requirements of Article 123(2) EPC as it substantially is a combination of originally filed claims 15, 18 and 19.

3. Novelty was not questioned by the examining division and the Board is satisfied that the subject-matter of claim 1 is novel over the cited prior art.

4. Inventive step

4.1 The Board considers the following documents to be relevant:

D1: this document discloses a device for revascularization of heart muscle (TMR Transmyocardial Revascularization) which uses ultrasonic energy to create revascularization channels in the patient's heart wall. The distal head can be piercing or non-piercing (see page 11, lines 7 to 9) but in all cases the ultrasound transducer should create channels in the heart tissue. In addition to the ultrasonic head (see Figure 6) "a puncturing element 103" is contained within the introducer portion 18 of catheter 10 and is extendable into the heart. Through this puncturing element a medicament can be injected into the heart wall. Although not shown in the figures it is explained

on page 10, lines 14 to 19 that this puncturing element is positioned in one of axial lumen 30 or lumens 38,48,54, lumen 30 being the central lumen extending to the end of the distal head whereas the other lumens are laterally placed lumens. This puncturing element is said to be coupled to an advancement and retraction slide 59. A specific construction with the puncturing element placed in the central lumen is however not shown in the drawings.

D2: this document discloses a device for revascularization of heart muscle (TMR) also using ultrasonic energy instead of laser energy. The head consists mainly of a needle which punctures the heart muscle (minimal invasive embodiment see figure 3) while ultrasonic energy is applied to the needle. The needle can in addition be used to deliver beneficial agents to the heart tissue (see page 11, lines 11 to 17). There is no mention of a head to be used for massaging purposes.

D4: this document discloses a device for improving the circulation of blood to the heart muscle of a patient. Ultrasonic energy is applied to the area of interest of the heart via a head 34. This head is normally blunt, but it can have sharp tips, see figures 10A to 10E, column 13, line 58 to column 14, line 3.
The ultrasound device can be operated to effect myocardial revascularization in one of four ways, the first being to massage the endocardium area of interest without cutting or removing any tissue, see column 10, lines 8 to 28, lines 45 to 65.
An injection pump 38 is used to infuse coolant fluid to prevent overheating of the ultrasound transmission

member, see column 7, lines 9 to 30. This coolant fluid also cools the head from the outside, an aperture 44 allowing the fluid to flow from inside the catheter to the outside of the head.
The pump may be used to infuse an irrigation fluid or a radiographic contrast medium instead of coolant fluid, see column 7, lines 40 to 47.

4.2 The document D4 is considered to disclose the closest prior art as it is the only document disclosing an ultrasound head specifically allowing massaging without the removal of tissue, which is also the intended use of the head according to the invention.

As already mentioned above in the terms of claim 1 this document discloses a guidable elongated flexible ultrasound device for increasing the blood circulation to an area of interest in a heart muscle of a patient comprising:
an elongated tubular body 10 having a lumen 18, a longitudinal axis, a distal end and a proximal end;
and a distal head 34 mounted on said distal end for introducing ultrasonic waves to said area of interest.

The ultrasound device according to the embodiment shown in figures 1 to 4 of D4 further comprises two lumens 44 and 50 going through the head 34 so as to connect the inside of the catheter with the outside thereof. While the aperture 50 is said to be mainly used in combination with a guidewire the aperture 44 is used to infuse coolant fluid, irrigation fluid or radiographic contrast medium.

4.3 The difference between the ultrasound device known from D4 and that of claim 1 is that the latter is provided with a needle for injecting a material into said area of interest, said needle being mounted to said elongated tubular body substantially parallel to said longitudinal axis of said tubular body,
said needle being attached adjacent to said elongated tubular body or being attached to said elongated tubular body within said lumen of said elongated tubular body and passing through the distal head wherein the needle extends beyond the distal head.

4.4 The presence of a needle allows for injection of a material or substance into the area of interest of the heart wall. Such substances could be medicinal substances for enhancing revascularisation and healing of the area of interest or other substances such as a radiographic contrast medium for better visualisation of the treated area of interest.

4.5 The objective problem solved by the invention according to claim 1 can thus be seen in the provision of an alternative construction of the distal head allowing further treatment of the area of interest.

4.6 It is known from D4 to provide a lumen or aperture in the distal head through which a contrasting agent or other substance can be delivered.
In the Board’s view in order to solve the above mentioned objective problem it is obvious for a person skilled in the art to enhance the lumen or aperture 44 in the head of the ultrasound device according to D4 with a needle for injecting a substance into the area of interest, if needed.

The Board cannot see anything inventive in such a combination as this is nothing other than the use a known device (the needle) for a known purpose (to inject a liquid into a tissue). Moreover, it is already known in the same field (see D1 or D2) to use, in combination with an ultrasound device, a needle to inject a liquid into the heart tissue to be treated.

In particular document D1 teaches on page 10, lines 14 to 19 that the puncturing element can be positioned in one of the axial lumen 30 or lumens 38,48,54, lumen 30 being the central lumen extending to the end of the distal head. When the needle is placed in the central lumen as suggested it will necessarily extend beyond the distal head in order to be able to puncture the heart tissue. Thus the person skilled in the art is directly brought to the subject-matter of claim 1 by D1 which clearly teaches to provide the lumen with a needle or to insert a needle in the lumen in order to be able to inject a substance into the area of interest.

While D2 does not disclose the use of a specific distal head separate from the needle to apply ultrasound energy it is clear that this document also teaches the person skilled in the art that the application of ultrasound energy together with the injection of an additional treatment substance by means of a needle is beneficial for the revascularisation of the heart muscle.

4.7 The appellant argued that the skilled person would not be prompted to look at D1 or D2 because both documents deal with ultrasound devices meant to pierce the heart wall before injecting any substance and do not address

the case of a head only being used for massaging without removal of some portion of the heart tissue.

The Board cannot agree with this line of argument. The wording of claim 1 does not require the ultrasound device to be suitable for applying energy at a low level only sufficient for massaging the area of interest without removal of heart tissue. On the contrary all options are covered by the present wording including the application of higher levels of energy suitable for piercing the heart tissue before delivering the treatment substance as in the prior art documents D1 and D2. There is thus no reason for the person skilled in the art to disregard the teachings of these documents.

4.8 The appellant further argued that if the skilled person wanted to provide additional treatment on top of the massaging then the most common way to do it would be to use an intravenous injection.

The Board cannot agree with this argument either as it is clearly known in the art as shown for example in D1 or D2 to inject a treatment substance directly into the heart wall with a needle belonging to the ultrasound catheter device.

4.9 Claim 1 thus does not fulfil the requirement of Article 56 EPC, its subject-matter being obvious for the person skilled in the art.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar The Chairman

D. Sauter M. Noël