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**Datasheet for the decision  
of 11 December 2006**

**Case Number:** T 0880/05 - 3.2.02

**Application Number:** 00307282.4

**Publication Number:** 1078644

**IPC:** A61M 5/32

**Language of the proceedings:** EN

**Title of invention:**

Apparatus for intracardiac cell delivery and cell  
transplantation

**Applicant:**

Biosense Webster, Inc.

**Opponent:**

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**Headword:**

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**Relevant legal provisions:**

EPC Art. 56

**Keyword:**

"Inventive step (no)"

**Decisions cited:**

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**Catchword:**

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Case Number: T 0880/05 - 3.2.02

**D E C I S I O N**  
of the Technical Board of Appeal 3.2.02  
of 11 December 2006

**Appellant:** Biosense Webster, Inc.  
3333 Diamond Canyon Road  
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California 91765 (US)

**Representative:** Mercer, Christopher Paul  
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**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted 23 December 2004  
refusing European application No. 00307282.4  
pursuant to Article 97(1) EPC.

**Composition of the Board:**

**Chairman:** T. Kriner  
**Members:** D. Valle  
E. Dufrasne

## Summary of Facts and Submissions

- I. The appellant (applicant) lodged an appeal on 1 March 2005 against the decision of the examining division posted on 23 December 2004 to reject the European patent application 00 307 282.4. The fee for the appeal was paid on the same day and the statement setting out the grounds for appeal was received on 29 April 2005.
- II. The examining division held that the requests submitted by the applicant did not meet the requirements of the Article 54 EPC (main request, first and second auxiliary requests then on file) and Article 84 EPC (third auxiliary request then on file).

The examining division held in particular that the subject-matter of claim 1 of the main request and of the first and second auxiliary requests was not novel having regard to:

D1 = EP - A - 900 549.

The following further document cited in the search report is also relevant for the present decision:

D2 = EP - A - 908 194.

- III. Oral proceedings took place on 11 December 2006.

The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request or, in the alternative, of the auxiliary request both filed with the letter dated 29 April 2005.

IV. Claim 1 of the main request reads as follows.

"A combination, comprising: a cell delivery apparatus for delivering a cell (88) to a heart (70) of a patient for inducing angiogenesis or myogenesis, said apparatus comprising:

a catheter (20, 64, 78), said catheter (20, 64, 78) having at least one position sensor (32) for determining the position and orientation of said catheter (20, 64, 78), the sensor (32) being adapted to generate signals responsive to an applied field, said signals being for generating position and orientation coordinates;

a cell delivery device (24, 47, 54, 92) for delivering said cell (88);

control circuitry (52) for determining the position and orientation coordinates of a distal end (22) of said catheter (20, 64, 78) and for generating a viability map of a site in the heart (70) that is suitable for targeted therapy by the catheter (20, 64, 78); and

one or more electrodes (38) for identifying said site;

wherein said apparatus is adapted to deliver said cell (88) to said site in response to said signals from said position sensor (32) for inducing angiogenesis or myogenesis at said site; and

a cell utilised for angiogenesis or capable of being transplanted for myogenesis."

Claim 1 of the auxiliary request differs from claim 1 of the main request in that the last feature:

"a cell utilised for angiogenesis or capable of being transplanted for myogenesis"

is replaced by the feature:

"a cell as an expression vector capable of resulting in angiogenesis or a cell fusion mechanism capable of resulting in myogenesis".

V. In support of his requests the appellant brought forward essentially the following arguments.

D1 did not disclose a combination according to the present application, since it referred to a delivery apparatus for delivering drugs. However, such an apparatus was inherently different from an apparatus for delivering cells according to the present invention. Drugs were smaller than cells by 2 - 3 orders of magnitude. Consequently the apparatus disclosed in D1 was not suitable for delivering cells and the claimed subject-matter was novel over the disclosure of D1. It also involved an inventive step, since none of the prior art documents suggested to modify the device according to D1 in order to make it suitable for delivering cells. D2 taught using a catheter for delivering several types of drugs, but it gave no motivation to modify a catheter so that it was suitable for delivering cells.

The auxiliary request had been submitted for further clarification. However, the differences between claim 1 of the main request and that of the auxiliary request had no bearing for the assessment of inventive step.

## Reasons for the Decision

1. The appeal is admissible.
2. *Main request*

D1 discloses a combination, comprising: a delivery apparatus for delivering a drug to a heart of a patient for inducing angiogenesis or myogenesis (see column 13, lines 33 to 40), said apparatus comprising: a catheter (10), said catheter having at least one position sensor (72) for determining the position and orientation of said catheter, the sensor being adapted to generate signals responsive to an applied field, said signals being for generating position and orientation coordinates; a delivery device suitable for delivering said drug; control circuitry for determining the position and orientation coordinates of a distal end of said catheter and for generating a viability map of a site in the heart that is suitable for targeted therapy by the catheter; and one or more electrodes (36, 38) for identifying said site; wherein said apparatus is adapted to deliver said drug to said site in response to said signals from said position sensor (see column 11, lines 26 to 50) for inducing angiogenesis or myogenesis at said site (see paragraph bridging columns 10 and 11 and column 13, lines 33 to 40); and a drug utilised for angiogenesis or capable of being transplanted for myogenesis.

However, D1 does not disclose that the drug is a cell.

Starting from D1 the problem to be solved by the claimed invention can therefore be seen in finding new

ways of enhancing angiogenesis using the device according to D1.

Since it is well known to deliver cells directly to a cardiac tissue to enhance angiogenesis (see description of the patent application, page 37, lines 6 to 14), and since a cell can be regarded as a particular form of a drug, the skilled person confronted with this problem will be led in an obvious way to the claimed invention.

Accordingly the subject-matter of claim 1 of the main request does not imply an inventive step.

The appellant's argument that a drug delivering apparatus as disclosed in D1 was not suitable for delivering a cell because the dimension of the cell was sensibly higher than the dimension of the elementary particles of a drug, and that it was not obvious to modify the known apparatus so that it was suitable for delivering cells is not convincing. The term "drug" is a general term which can comprise also substances provided in the form of elementary particles of a size comparable to that of a cell. This is especially true in the field of drugs to be delivered by a heart catheter (see for example D2, column 16, point 0080, in particular last two lines of this column). Furthermore, according to the wording of the original application, a cell can be regarded as a particular type of drug (see page 37, lines 4, 5). Hence there is no reason which could prevent the skilled person to select a cell as a drug and to adapt the delivery apparatus to the size of this cell.

3. *Auxiliary request*

Claim 1 of the auxiliary request differs from claim 1 of the main request merely in the fact that the cell to be delivered is "an expression vector capable of resulting in angiogenesis or a cell fusion mechanism capable of resulting in myogenesis" instead of being "a cell utilised for angiogenesis or capable of being transplanted for myogenesis".

As agreed by the appellant, this amendment does not affect the conclusions above regarding the question of inventive step.

Accordingly also the subject-matter of claim 1 of the auxiliary request does not imply an inventive step.

**Order**

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

The appeal is dismissed.

The Registrar:

The Chairman:

V. Commare

T. Kriner