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D E C I S I O N
of 4 July 2006

Case Number: T 0134/02 - 3.2.02

Application Number: 93111900.2

Publication Number: 0582162

IPC: A61B 5/07

Language of the proceedings: EN

Title of invention:
A method and a device for monitoring heart function

Patentee:
SORIN BIOMEDICA CRM S.r.l.

Opponent:
St. Jude Medical AB

Headword:
-

Relevant legal provisions:
EPC Art. 84, 102(3)

Keyword:
"Clarity of amended claims (no)"

Decisions cited:
-

Catchword:
-

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Case Number: T 0134/02 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 4 July 2006

Appellant: (Patent Proprietor)
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Representative:
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Respondents: (Opponent)
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Representative:
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 6 December 2001 revoking European patent No. 0582162 pursuant to Article 102(1) EPC.

Composition of the Board:

Chairman: T. Kriner
Members: S. Chowdhury
A. Pignatelli

Summary of Facts and Submissions

I. The appellant (patent proprietor) lodged an appeal against the decision of the opposition division to revoke European patent No. 0 582 162. The decision was dispatched on 6 December 2001.

The appeal was received on 4 February 2002 and the fee for the appeal was paid on the same day. The statement setting out the grounds of appeal was received on 2 April 2002.

The opposition was filed against the whole patent and based on Article 100 (a) EPC (lack of novelty and inventive step, and that patentability was excluded on the grounds of Article 52 (4) EPC), and Article 100 (b) EPC. The opposition division decided that the subject-matter of claims 1 and 5 of the main request and the first and second auxiliary requests related to diagnostic methods excluded from patentability, and the subject-matter of claims 1 and/or 6 of the main request (bis), the first and second auxiliary requests (bis), and the first auxiliary request (ter) were not patentable under Article 52 (1) EPC. The patent was revoked, accordingly.

II. Oral proceedings, requested by both parties, were scheduled for 4 July 2006. Following a communication from the Board setting out its preliminary opinion on the points at issue the appellant withdrew its request for oral proceedings and notified the Board that it would not attend the oral proceedings. The oral proceedings were held as scheduled, nevertheless, in accordance with Rule 71 (2) EPC.

The appellant requested, in the written proceedings, that the decision under appeal be set aside and that the patent be maintained on the basis of claims of the main request or the first or second auxiliary request filed with the grounds of appeal.

The respondent (opponent) requested that the appeal be dismissed.

III. Claims 1 and 6 of the main request reads as follows: -

"1. A method of monitoring heart function, characterized in that it comprises the steps of monitoring (1) the momentum or velocity of the heart masses (C), that is, the heart mass as a whole and generating signals indicative of the momentum or velocity monitored.

6. A device for monitoring heart function, characterized in that it comprises sensor means (1) for monitoring the momentum or velocity of the heart masses (C), that is, the heart mass as a whole."

The first auxiliary request differs from the above only in that "and generating signals indicative of the momentum or velocity monitored" is added at the end of claim 6.

The second auxiliary request has method claims only, wherein claim 1 thereof corresponds to claim 1 of the main request and the first auxiliary request.

IV. The parties argued as follows:

Appellant

The invention was based on the concept of monitoring movement of the heart as a whole. While the heart was surrounded by tissues and connected to blood vessels, these did not restrain movement of the heart as a whole around a centre position, which was fixed. One way of monitoring the momentum of a body as a whole was to monitor it in correspondence with the barycentre of the body, at a location which was as little exposed to disturbances as possible. In the heart the IV wall was located at a barycentric position and exposed to little pulsatile movement of the heart.

Respondent

The amplification of claim 1 as granted by the words "that is, the heart mass as a whole" did not change the scope or meaning of the claims. Moreover, it was not clear that the mass of the heart could be isolated from movement of the pulmonary arteries.

In the patent the monitoring was not targeted at the whole heart movement, a sensor monitored movement of a part of the heart, for example the right ventricle wall. The signal had to be filtered to extract heart movement from the signal containing contractile and other signals. Claim 1 covered the generation of the raw signal, and only claim 5 related to the generation of the signal without the contractile component.

Reasons for the decision

1. The appeal is admissible.

Clarity of claim 1

2. *Claim 1 as granted*

In addition to the expressions "the heart masses" and "the heart mass as a whole" the patent also employs the expressions "the centre of masses of the subsystem" (page 3, line 47, page 4, line 12), and "the centre of masses of the heart mass" (page 3, line 36 and page 4 line 53), "the variable mass of the subsystem" (page 3, line 46), and "centre of the masses" (page 3, line 47), and it is not altogether clear what these mean. However, the patent appears to make a distinction between "the heart masses" and "the heart mass as a whole", the former expression standing for elements of the heart and the latter for the whole heart. For example, page 4, lines 12 to 16 and 51 to 52 indicate that elements of the heart are monitored, and the sum of the elements (i.e. the individual heart masses) makes up the heart mass as a whole.

Moreover, according to the different embodiments described in the patent a sensor may be implanted (page 4, lines 56 to 59) on the interventricular septum or on the atrioventricular septum, on the wall of the right ventricle which is contractile (page 5, lines 3 to 6), or several sensors may be used (page 5, lines 16 and 17). In each case, however, the motion of a portion of the heart only is monitored (page 5, lines 14 and 15). Therefore, the described sensors monitor the

motion of a part of the heart tissue only, which is referred to in the patent and in claim 1 as "the heart masses".

For these reasons the Board considers claim 1 as granted to refer to the monitoring of the (individual) heart masses.

3. *Claim 1 as amended*

Claim 1 as amended in all requests, however, refers to monitoring the momentum or velocity of the heart masses, **that is, the heart mass as a whole** [emphasis added], and the appellant argues that this does indeed mean that the motion of the heart as a whole is monitored. This gives rise to a contradiction in claim 1 since, whereas the embodiments described monitor motion of the (elemental) heart masses, the appellant insists that it is the motion of the heart as a whole which is monitored.

There is another difficulty with the amendment to claim 1, as follows: The patent discusses the theoretical basis of the invention by reference to Figure 2, which shows an ideal situation in which an isolated mass M moves in a direction opposite to that of blood flow in order to conserve momentum. The heart, however, is far from an isolated mass and the dynamics of heart motion are very complex since it is subjected to several forces in different directions, not just that due to blood flow in one direction as in the idealised model.

For example, the heart contracts and expands non-symmetrically, and it has forces applied to it by surrounding tissue and the connected blood circulatory system. Therefore, it is not clear that the heart as a whole has a net motion in a particular direction, at least the patent is completely silent on this point.

Unless the direction of the movement of the heart mass as a whole is defined a sensor cannot be positioned so as to monitor this motion, which is a vector quantity having a particular direction. Moreover, given the fact that a motion sensor would also be affected by ambient noise and vibrations, and its signal would contain breathing and patient movement artefacts, unless the direction of the heart mass as a whole is specified, it is not clear that a meaningful signal would be obtained by a sensor placed somewhere on the heart in a random direction. For these reasons it would appear unlikely that a sensor can monitor movement of the heart mass as a whole, and this amplifies the ambiguity in claim 1.

4. In summary, claim 1 as amended (all requests) is unclear by virtue of the amendment to the granted claim, and the claims do not meet the clarity requirement of Article 84 EPC. The claims are not allowable under Article 102 (3) EPC, accordingly.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar The Chairman

A. Counillon T. K. H. Kriner