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**D E C I S I O N**  
**of 23 September 2005**

**Case Number:** T 0568/03 - 3.4.01

**Application Number:** 93116654.0

**Publication Number:** 0600200

**IPC:** A61N 1/365

**Language of the proceedings:** EN

**Title of invention:**

Detector for sensing events in living tissue

**Patentee:**

St. Jude Medical AB

**Opponent:**

Biotronik GmbH & Co. KG

**Headword:**

-

**Relevant legal provisions:**

EPC Art. 100(a), 56, 114(2)

**Keyword:**

"Late filed evidence - yes"  
"Inventive step - yes"

**Decisions cited:**

-

**Catchword:**

-



Case Number: T 0568/03 - 3.4.01

**D E C I S I O N**  
of the Technical Board of Appeal 3.4.01  
of 23 September 2005

**Appellant:**  
(Opponent)

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**Representative:**

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**Respondent:**  
(Proprietor of the patent)

St. Jude Medical AB  
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**Representative:**

Harrison, Michael Charles  
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**Decision under appeal:**

Decision of the Opposition Division of the  
European Patent Office posted 3 March 2003  
concerning rejection of the opposition against  
the European patent No. 0600200.

**Composition of the Board:**

**Chairman:** B. Schachenmann  
**Members:** G. Assi  
M. Rognoni

## Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal, received on 2 May 2003, against the decision of the opposition division, dispatched on 3 March 2003, rejecting an opposition against the European patent No. 0 600 200 (application number 93116654.0). The appeal fee was paid on 2 May 2003. The statement setting out the grounds of appeal was received on 4 July 2003.

II. The opposition had been filed against the patent as a whole and was based on the grounds pursuant to Article 100(a) EPC that the subject-matter of the patent was not patentable within the terms of Articles 52(1), 54 and 56 EPC. Moreover, the opposition was based on the grounds pursuant to Articles 100(b) and 100(c) EPC.

During the opposition procedure the following documents were cited:

(D1) US-A-4 766 902,

(D2) US-A-5 050 599,

(D3) US-A-4 664 116,

(D4) US-A-4 880 004.

In the decision under appeal, the opposition division disregarded documents D3 and D4 submitted with a letter dated 19 December 2002 (Article 114(2) EPC). The opposition division also disregarded the grounds

pursuant to Articles 100(b) and 100(c) EPC for lack of substantiation (Article 99(1) and Rule 55(c) EPC).

With regard to the grounds for opposition pursuant to Article 100(a) EPC, the opposition division held that they did not prejudice the maintenance of the patent as granted.

III. With the grounds of appeal, the appellant filed the following further document:

(D5) US-A-4 386 610.

IV. Oral proceedings before the Board of Appeal were held on 23 September 2005. The appellant was not represented at the oral proceedings as announced by a letter of 22 June 2005.

V. The appellant requested in writing that the decision under appeal be set aside and the patent be revoked.

VI. At the oral proceedings, the respondent requested that the appeal be dismissed, as a main request.

Alternatively, the respondent requested that the patent be maintained in amended form according to a first, a second or a third auxiliary request, all submitted with a letter of 23 August 2005.

The respondent further requested that the case be remitted to the first instance for further prosecution unless the main or the first auxiliary requests were allowed.

VII. The wording of claim 1 of the patent as granted reads as follows:

*"A detector (10) for sensing events in living tissue (3), comprising a comparator (16) which compares an input signal corresponding to electrical signals from the living tissue with a defined signal detection level, a first integrator (14) which generates the input signal (21) by integrating the electrical signals (20) from the tissue (3) over a defined integration interval, characterized in that the comparator (16) compares the input signal (21) with a threshold level (26) higher than the level of detection (23), the comparator (16) determining an event to have occurred if the input signal (21) exceeds the defined level of detection (23) without exceeding the threshold level (26) during a defined first interval."*

Claims 2 to 11 of the patent as granted are dependent claims.

## **Reasons for the Decision**

1. The appeal is admissible.
2. *Admission of document D4 into the proceedings*
  - 2.1 Procedural considerations
    - 2.1.1 During the opposition procedure, in a communication accompanying the summons of 14 June 2002 to attend oral proceedings, the opposition division expressed the provisional opinion that documents D1 and D2 on file

did not disclose a detector comprising an integrator and a comparator with two thresholds permitting to determine whether an event occurred.

In reply, the appellant filed document D4 with the letter dated 19 December 2002. This document, in the appellant's view, was intended to overcome the concerns expressed by the opposition division in its communication.

At the oral proceedings before the opposition division the respondent objected to the admission of D4 into the procedure on the grounds of late filing and lack of technical relevance.

The opposition division then decided to disregard D4 pursuant to Article 114(2) EPC because "*its prima facie relevancy could not be seen*".

2.1.2 In the statement setting out the grounds of appeal, the appellant criticized this conclusion. From a substantive point of view, the appellant considered that D4 represented the closest state of the art and that the subject-matter of claim 1 did not involve an inventive step with regard to the combination of documents D4 and D1.

The respondent contested the appellant's view.

2.1.3 The dispute thus concerns whether the opposition division, when exercising the discretionary power conferred to it by Article 114(2) EPC, reached a correct conclusion.

2.1.4 In this respect, it has to be considered at first whether document D4 was late filed; in other words, whether the appellant adduced convincing reasons to explain the fact that this evidence was produced at a late time in the opposition procedure, well after the opposition period prescribed by Article 99(1) EPC.

The Board acknowledges that the letter of 19 December 2002, by which document D4 was filed, was received before the final date, set by the opposition division in the summons, for making written submissions and/or amendments. However, this fact *per se* is not sufficient for concluding that D4 was not late filed. As the respondent correctly submitted at the oral proceedings before the Board, the document cited in paragraph [0004] of the description of the patent in suit already disclosed a detector for sensing events comprising a comparator for comparing an input signal with a reference, the input signal being integrated over a predetermined time interval. Moreover, it should be noted that document D1 already disclosed an automatic sensitivity control for a cardiac pacemaker, in which a signal related to sensed ventricular activity is compared with the thresholds of two sensing amplifiers. In these circumstances, the reasons adduced by the appellant that the filing of D4 was occasioned by the concerns expressed by the opposition division are not convincing. The new document D4 indeed discloses features for which evidence was already on file.

Moreover, according to the established case law of the boards of appeal, the legal and factual reasons in support of the statement of the grounds of opposition must be set out in the notice of opposition

sufficiently completely so that the entire case of the opponent against the maintenance of the patent as granted can be properly understood on an objective basis, both by the patent proprietor and by the EPO. The filing of new evidence could then be justified by later amendments to the claims. However, in the present case, the patent in suit was unamended.

2.1.5 In conclusion, as the filing of document D4 was not occasioned by any action of the opposition division or the proprietor, the Board regards it as being late filed.

## 2.2 Substantive considerations

2.2.1 In order to decide whether to admit D4 into the proceedings, the opposition division relied on the criterion of technical relevance. On the basis of a *prima facie* assessment, the opposition division identified two "*fundamental*" differences between the disclosure of D4 and the subject-matter of claim 1 of the patent as granted. First, the integrator shown in Figure 4 of D4 was part of a bandpass filter. Second, the comparator known from D4 (see Figures 2 and 5) merely controlled the gain of the amplifier 60. Contrary to the teaching of claim 1, a signal above the threshold level was not disregarded in the device of D4. These differences represented a sufficient reason to deny the relevance of the document which was not admitted into the proceedings.

2.2.2 During the appeal procedure, in the grounds of appeal but also in the following letters of both parties, the disclosure of D4 was the subject of discussions going



far beyond the limits of the *prima facie* assessment on which the opposition division relied. Indeed, in the grounds of appeal, the appellant presented, in support of the opposition ground of lack of inventive step, a problem-and-solution approach based on the combination of document D4, to be considered as the closest state of the art, with document D1. The appellant's argumentation occasioned a detailed reply of the respondent followed by further letters of both parties. This situation *de facto* leads the Board to an assessment of the disclosure of D4 which, which independently of its relevance, goes beyond the limits of the *prima facie* examination carried out by the opposition division.

2.2.3 The appellant submitted that the detector according to claim 1 of the patent as granted only differed from the cardiac stimulator disclosed by D4 in that the comparator determined an event to have occurred if the input signal exceeded the defined level of detection without exceeding the threshold level during a defined interval.

2.2.4 Among the claimed features, which the appellant presented as being known from D4, the provision of the "*integrator*" requires particular consideration. According to D4 (see Figures 2 and 4), the output of AGC amplifier 60 is supplied to "*bandpass filter*" 141 (see column 10, line 8) and then to "*active bandpass filter amplifier*" 130 (see column 9, lines 30-42).

The appellant stated that the active bandpass filter amplifier 130 represented an integrator in view of the arrangement of a negative feedback capacitor.

Conversely, the respondent held that this interpretation was inconsistent with the disclosure of the patent in suit. In its view, although the known bandpass filter amplifier 130 might have some integration effect in some circumstances, it could not be regarded as an integrator which, as recited by claim 1, generated the input signal by "*integrating the electrical signals from the tissue over a defined integration interval*". This clearly resulted from the fact that, according to D4 (see column 10, lines 10-19), the QRS complexes passed "*faithfully*" through the section constituted by the bandpass filter 141 and the bandpass filter amplifier 130. In the context of the patent in suit (see column 2, lines 24-27), however, integration was required because the area of the tissue's electrical signals and not their amplitude was used as a decision parameter.

In the Board's view, the appellant's approach relies on a "*photographic*" comparison of a feature (the integrator) of the claimed detector with a feature (the amplifier 130) of the known cardiac stimulator, these features being compared *per se* out of their context. The conclusion drawn by the appellant on the basis of this approach is doubtful.

First, a skilled person knows that an analogue "*integrator*" consists in an operational amplifier with a resistance at the inverting input and a negative feedback either being purely capacitive or, alternatively, including a resistance in parallel to a capacitor. The amplifier 130 would then differ from an integrator in that an impedance represented by the

filter 141, rather than a resistance, is provided at its inverting input, as the respondent itself underlined.

Second and more importantly, when assessing inventive step, as in the present case, the claimed subject-matter should be dealt with as a whole so that the claimed features are analysed in combination to each other. Moreover, any technical function or effect which may be related to a claimed feature should be duly considered.

On this basis, an essential difference between the claimed integrator and the bandpass filter amplifier 130 known from D4 can be identified in their functions. According to the disclosure of D4, the input signal is merely bandpass filtered without any noticeable integration effect within the frequency range of interest. The disclosure does not give any hint to integrate the signal in order to yield the area of the input signal, instead of its amplitude, for further processing.

2.2.5 With regard to the last feature of claim 1, the appellant itself agreed that it is not disclosed by document D4.

2.3 Therefore, in the light of the foregoing, from a procedural point of view, document D4 is considered to be late filed. From a substantive point of view, the appellant's submission that it represented the closest state of the art is not convincing because it does not disclose two essential features of the claimed invention, i.e. the integrator and the comparator with

two thresholds defining the occurrence of an event. In these circumstances, the Board holds that the opposition division correctly decided to disregard D4 pursuant to Article 114(2) EPC. The fact that, for the reasons explained above, the Board's examination of the technical relevance of the document went beyond the limits of the *prima facie* assessment on which the opposition division relied does not alter this finding.

In conclusion, document D4 is not admitted into the proceedings.

3. *Admission of document D5 into the proceedings*

- 3.1 Document D5 was filed with the grounds of appeal (see page 4, No. 4, second paragraph) as evidence for the knowledge of the skilled person that the generation of stimulation pulses should not be inhibited by noise detection. In the appellant's view, however, D5 was not intended to be combined with document D4 (see letter of 18 June 2004, page 4, fifth paragraph).

The respondent stated that D5 concerned a pacemaker entirely unrelated to that disclosed by D4.

- 3.2 Document D5 discloses an atrial-synchronized cardiac pacer with independently implemented atrial refractory and ventricular inhibit functions. The atrial refractory function consists in that a refractory period is established following spontaneous P-waves, whereas a fixed atrial rate is imposed when noise is detected on the atrial lead. The ventricular inhibit function provides for spontaneous signals from the

ventricle inhibiting ventricular stimulation except when noise is detected.

- 3.3 Evidence for the above mentioned knowledge of the skilled person is not necessary. Nor is document D5 relevant for the present case.

In conclusion, document D5 is not admitted into the proceedings.

4. *Respondent's main request*

- 4.1 In the grounds of appeal, the appellant contested the conclusion drawn by the opposition division in the decision under appeal that the subject-matter of claim 1 of the patent as granted involved an inventive step.

The appellant's argumentation at the appeal stage was based on the combination of documents D4 and D1. Document D4 is, however, not admitted into the proceedings for the reasons set out above and the appellant has not produced any argument in support of the objection of lack of inventive step on the basis of document D1 alone.

- 4.2 The Board agrees with the respondent that D1 is not relevant. This document (see abstract; claim 1; Figure 3) relates to a cardiac pacemaker comprising a pulse generator for providing pacing pulses and a pair of separate amplifiers 34 and 36 for sensing activity of the heart. A first one 34 of the sensing amplifiers has a slightly lower sensitivity level than the other one 36. Means 42 and 47 are provided for automatically

adjusting the sensitivities so that the first sensing amplifier will sense the heart activity and the other one will not. The ideal situation requiring no sensitivity adjustment consists in that the first amplifier 34 detects spontaneous electrical activity while the other amplifier does not (see column 4, lines 11-14; column 5, lines 23-25; Figure 4). However, when the activity exceeds the sensitivity levels of both amplifiers, the pacemaker still acts as though an event had occurred and merely assumes that the sensitivity needs an adjustment (see column 4, lines 31-46; Figure 4, steps 2 and 4 to 8). A condition in which the output signal from the second amplifier 36 goes high may be caused by noise; the pacemaker then waits a number of cycles before changing sensitivities (see column 5, lines 8-13).

In conclusion, the pacemaker of D1 does not comprise an integrator and is not concerned with the analysis of an integrated signal. Moreover, it does not seek to determine that an event has occurred based on whether a first threshold is exceeded and a second higher threshold is not.

4.3 Since D1 does not disclose two essential features of the claimed invention concerning the integrator and the comparator with two thresholds, it does not permit to conclude that the subject-matter of claim 1 of the patent as granted lacks inventive step.

4.4 Therefore, the opposition ground of lack of inventive step does not prejudice the maintenance of the patent as granted.

5. *Respondent's further requests*

In view of the conclusion reached with regard to the respondent's main request, there is no need to deal with its auxiliary requests.

**Order**

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

The appeal is dismissed.

The Registrar:

The Chairman:

R. Schumacher

B. Schachenmann