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**Datasheet for the decision  
of 6 July 2011**

**Case Number:** T 0245/08 - 3.2.02

**Application Number:** 95935672.6

**Publication Number:** 0785746

**IPC:** A61B 5/00

**Language of the proceedings:** EN

**Title of invention:**

Automatically activated blood pressure measurement device

**Patentee:**

Masimo Corporation

**Opponent:**

Fresenius Medical Care Deutschland GmbH

**Headword:**

-

**Relevant legal provisions:**

EPC Art. 123(2), 84

EPC R. 80

**Relevant legal provisions (EPC 1973):**

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**Keyword:**

"Added subject-matter (yes)"

"Clarity and support by the description (no)"

**Decisions cited:**

-

**Catchword:**

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Case Number: T 0245/08 - 3.2.02

**D E C I S I O N**  
of the Technical Board of Appeal 3.2.02  
of 6 July 2011

**Appellant 1:** Fresenius Medical Care Deutschland GmbH  
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**Representative:** Herrmann, Uwe  
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**Appellant 2:** Masimo Corporation  
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**Representative:** Vossius & Partner  
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**Decision under appeal:** Interlocutory decision of the Opposition  
Division of the European Patent Office posted  
28 November 2007 concerning maintenance of  
European patent No. 0785746 in amended form.

**Composition of the Board:**

**Chairman:** M. Noël  
**Members:** M. Stern  
M. J. Vogel

## Summary of Facts and Submissions

- I. Both parties lodged an appeal against the interlocutory decision of the Opposition Division dispatched on 28 November 2007 to maintain the European patent No. 0785746 in amended form.
- II. The opposition had been filed on the ground of Article 100(a) EPC in conjunction with Articles 52(1) and 56 EPC, and on the ground of Article 100(c) EPC.
- III. The opponent (appellant 1) filed a notice of appeal on 28 January 2008, paying the appeal fee the same day. A statement setting out the grounds of appeal was filed on 8 April 2008.
- IV. The patent proprietor (appellant 2) filed a notice of appeal on 8 February 2008, paying the appeal fee the same day. A statement setting out the grounds of appeal was filed on 8 April 2008 together with amended sets of claims comprising a main request and three auxiliary requests.
- V. Oral proceedings took place on 6 July 2011.

The patent proprietor withdrew the first and second auxiliary requests filed with letter of 8 April 2008 and requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or, as an auxiliary measure, that the patent be maintained in amended form on the basis of a first auxiliary request filed as third auxiliary request during the oral proceedings before the Board, or on the basis of a second auxiliary request filed as

fourth auxiliary request with the letter dated 28 August 2008.

The opponent requested that the decision under appeal be set aside and that the European patent be revoked.

VI. The independent claims of the various requests read as follows:

Claim 1 of the main request (as granted):

"A monitor which determines when to activate a blood pressure measurement device, the monitor comprising: a noninvasive first sensor adapted to be applied to a patient (10) and configured to generate a first signal responsive to changes in the patient's blood pressure, wherein the first sensor comprises an optical sensor or an ECG sensor; a sphygmomanometer (20, 22) adapted to be applied to the patient (10) and configured to generate a blood pressure reference signal indicative of the blood pressure of the patient (10), characterized by a processor (30) coupled to said noninvasive first sensor and said sphygmomanometer (20, 22) to process input signals comprising said first signal and said reference signal, wherein said processor (30) also generates a trigger signal activating the sphygmomanometer (20, 22) when said first signal meets predetermined temporal criteria."

Claim 1 of the first auxiliary request:

"A monitor which measures blood pressure noninvasively and intermittently by determining when to activate a blood pressure measurement device, the monitor comprising:

a noninvasive first sensor adapted to be applied to a patient (10) and configured to generate a first signal responsive to changes in the patient's blood pressure, wherein the first sensor comprises a photoplethysmograph or an ECG sensor; a sphygmomanometer (20, 22) adapted to be applied to the patient (10) and configured to generate a blood pressure reference signal indicative of the blood pressure of the patient (10), characterized by a processor (30) coupled to said noninvasive first sensor and said sphygmomanometer (20, 22) to process input signals comprising said first signal and said reference signal, said monitor further comprising a noninvasive second sensor adapted to be applied to the patient (10) and configured to generate a second signal representative of a physiological parameter of the patient (10), wherein said processor (30) is coupled to said second sensor and wherein said input signals include said second signal, and wherein said processor (30) also generates a trigger signal activating the sphygmomanometer (20, 22) when said first signal meets predetermined temporal criteria, said predetermined temporal criteria being time difference of arrival."

Claim 5 of the first auxiliary request:

"A monitor which determines when to activate a blood pressure measurement device, the monitor comprising: a noninvasive first sensor adapted to be applied to a patient (10) and configured to generate a first signal responsive to changes in the patient's blood pressure, wherein the first sensor comprises a photoplethysmograph; a sphygmomanometer (20, 22) adapted to be applied to the patient (10) and configured to generate a blood pressure reference signal indicative of the blood pressure of the patient (10), characterized by a processor (30) coupled to said noninvasive first sensor and said sphygmomanometer (20, 22) to process input signals comprising said first signal and said reference signal, an exciter (72) adapted to be applied to the patient (10) and configured to induce a transmitted exciter waveform into the patient (10), wherein said processor (30) also generates a trigger signal activating the sphygmomanometer (20, 22) when said first signal meets predetermined temporal criteria, said predetermined temporal criteria being one of the group of phase change criteria and time of transit criteria."

The second auxiliary request also comprises two independent claims, of which claim 1 is identical to claim 1 of the first auxiliary request.

VII. The arguments of the appellant 1 (opponent) are summarised as follows:

- In claim 1 of the main request, the expressions of predetermined **temporal** criteria and of the first sensor comprising an **optical** sensor or an **ECG** sensor introduced subject-matter extending beyond the content of the application as originally filed, contrary to the requirements of Article 123(2) EPC.
- The first auxiliary request was not admissible under Rule 57a EPC 1973 (Rule 80 EPC 2000) since the formulation of two independent claims 1 and 5 in the same category was not occasioned by the grounds of opposition. Moreover, claim 1 did not specify the function of the second signal generated by the noninvasive second sensor. In particular, claim 1 failed to specify the essential aspect of the second signal of being used for calculating the time difference of arrival in connection with the first signal from the ECG sensor. Therefore, claim 1 was in breach of Articles 123(2) and 84 EPC.
- The second auxiliary request suffered from the same deficiencies.

VIII. The arguments of the appellant 2 (proprietor) are summarised as follows:

- Although the term "temporal" had not been explicitly mentioned in the original application, the term is supported by a variety of examples

given in the description, such as "periodicity, peak value, low value, wave shape" (page 6, lines 29 to 30), "wave shape" including "start time, peak time and ending time" (page 6, lines 31 to 32), time difference of arrival (TDOA; page 7, lines 34 et seq.), or time delay (page 9, lines 30 et seq.). Hence, the term "temporal" only summarised various disclosed embodiments, and since a whole range of examples was given in the description it did not represent an unallowable intermediate generalisation. Also the parameters "peak value" and "low value" were clearly temporal since they related to the wave shape and were based on measurements which were determined at specific points in time.

- A basis for reciting an ECG sensor in isolation from a second further noninvasive sensor was given on page 9, lines 9 to 10 disclosing that in Figure 6 the ECG unit (shown in Figure 4) was replaced by an oximeter unit, and on page 13, lines 4 to 13 disclosing the general exchangeability of noninvasive sensors. The term "optical sensor" was directly and unambiguously supported by the disclosure of, for example, a photoplethysmograph, in particular an oximeter control unit (on page 7, lines 7 et seq.; page 9, line 16; page 13, line 7, and in original claim 4).
  
- The original description clearly described that the time difference of arrival related to differences in the sensed time of arrival of a pulse wave signal sensed by two distanced sensors.



It was thus unambiguously clear that the definition in claim 1 of the first auxiliary request meant precisely this time difference. Moreover, since claim 1 was a combination of claims 1, 4 and 5 of the patent as granted, objections based upon Article 84 EPC were not allowed since they did not arise out of the amendments made; decision T 367/96.

- Since claim 1 of the first auxiliary request specified two sensors generating a first signal and a second signal which were both input into a processor, and since it was required that one of these signals met certain time difference of arrival criteria, this time difference had to be understood on the basis of the description as being clearly in relation to the second signal. These functionalities were clearly discussed in the patent specification, e.g. at paragraphs [0024] and [0025], particularly at column 5, lines 53 to 56.

## **Reasons for the Decision**

1. The appeals are admissible.
2. Main request
  - 2.1 Claim 1 of the main request defines a blood pressure monitor comprising, inter alia, a noninvasive first sensor configured to generate a first signal responsive to changes in the patient's blood pressure, wherein the first sensor comprises an **optical** sensor or an **ECG**

sensor, a sphygmomanometer configured to generate a blood pressure reference signal indicative of the blood pressure of the patient, and a processor coupled to said noninvasive first sensor and said sphygmomanometer which generates a trigger signal activating the sphygmomanometer when said first signal meets predetermined **temporal** criteria.

#### 2.1.1 Predetermined "temporal" criteria

The term "temporal" has not been explicitly mentioned in the application as originally filed, in particular not as a qualification of the "predetermined criteria" defined in original claim 1. The term "temporal" not only encompasses some of the disclosed embodiments which the reader of the application may infer as clearly having "temporal" characteristics, such as start time, peak time, ending time, time difference of arrival, or time delay of a signal (cf page 6, lines 29 to 30; page 7, lines 34 et seq.; page 9, lines 30 et seq.). The term also encompasses further specific examples of variables with "temporal" characteristics which were not explicitly disclosed, such as the slope of the signal, and which may not have been contemplated by the skilled reader of the original application. Moreover, the proprietor's unusual interpretation of the notion of "temporal" characteristics as encompassing also signal *amplitude* parameters such as the signal "peak value" or the signal "low value" (cf page 6, lines 29 to 30) only underlines the breadth which this originally undisclosed term is actually intended to carry.

Thus, the introduction of the term "temporal" leads to an unacceptable generalisation of the predetermined criteria provided in the original application, whereby the patent proprietor would improve its position by adding subject-matter not disclosed in the application as filed, contrary to Article 123(2) EPC; see G 1/93, point 9 of the Reasons.

#### 2.1.2 ECG sensor

According to one of the alternatives defined in claim 1, the noninvasive first sensor comprises an ECG sensor. However, in the original application, in particular in the embodiments of Figures 4, 7, and 8, the provision of such an ECG sensor is disclosed only in combination with at least another noninvasive sensor. None of the other disclosed embodiments comprises just a single ECG sensor. There is also no disclosure in the original application of the provision of predetermined "temporal" criteria from a signal generated (solely) by an ECG sensor. The original application discloses the time difference of arrival to be the time difference between a first signal generated by the ECG sensor and a second signal generated by a noninvasive second sensor at a different point in the body (see page 7, lines 34 to 36; page 8, lines 19 to 29; see also the flowchart of Figure 5).

The passages in the original application cited by the proprietor cannot be seen as providing a valid basis for reciting an ECG sensor in isolation from a second further noninvasive sensor. The cited passage on page 9, lines 9 to 10 refers to the replacement of an ECG unit referred to previously in the description,

rather than providing support for its consideration as the sole sensor. The cited passage on page 13, lines 4 to 13 is irrelevant in that it does not even mention ECG sensors and merely presents a general indication of noninvasive sensors which may be used for sensing physiological parameters.

### 2.1.3 Optical sensor

Contrary to the proprietor's view, the Board considers that the originally undisclosed term "optical sensor" also encompasses other specific examples of noninvasive blood pressure sensors which were not originally disclosed, such as an infrared camera for detecting infrared light emitted from the patient, for example from a pulsating blood vessel. Such a system would differ from a photoplethysmograph which is based on light absorption emitted from an external light source, as the proprietor pointed out when referring to the principles of pulse oximetry explained in the application on page 7, lines 16 to 27. Hence, the originally undisclosed term "optical sensor" constitutes an unallowable generalisation of the only specific example disclosed in this respect, viz. a photoplethysmograph.

2.2 For the aforementioned reasons, the subject-matter of claim 1 of the main request extends beyond the content of the application as filed, contrary to the requirement of Article 123(2) EPC.

3. First and second auxiliary requests

3.1 Admissibility

The claims of the first auxiliary request correspond to the claims of the amended patent as maintained by the Opposition Division. They include two independent claims, i.e. independent claims 1 and 5, each specifying a different "temporal" criteria, as a response to the aforementioned objection of unallowable generalisation of the term "temporal". Each of these two specific examples of "temporal" criteria is now defined in the context of the features of dependent claims 5 and 2 respectively of the patent as granted.

In its decision, the Opposition Division held these independent claims to be admissible since they were occasioned by the objections under Article 100(c) EPC raised by the opponent and justified in view of the proprietor's legitimate interest in obtaining adequate protection for the more specific subject-matter not affected by these objections. It also held that in view of the large difference between the embodiments involved, two independent claims appeared to be appropriate and justified.

On appeal, the opponent raised again the objection under Rule 57a EPC 1973 (Rule 80 EPC 2000), thereby challenging the way in which the Opposition Division had exercised its discretion on this procedural matter concerning the admissibility of the amended claims. However, it is not the function of a board of appeal to review all the facts and circumstances of the case as if it were in the place of the department of first

instance, and to decide whether or not it would have exercised such discretion in the same way (see Case Law of the Boards of Appeal of the European Patent Office, 6th Edition 2010, VII.E.6.6). In the present case, the Board cannot see any failure in the way the Opposition Division has exercised its discretion, and has therefore no reason to challenge the admissibility of the first auxiliary request.

### 3.2 Amendments

Claim 1 of the first auxiliary request differs from claim 1 of the main request essentially in that the predetermined "temporal" criteria to be used is the time difference of arrival, and in that a noninvasive second sensor is coupled to the processor for generating a second signal.

The claim defines that the criteria of time difference of arrival is to be met by the first signal generated, in particular by an ECG sensor. However, throughout the application as originally filed, the signal from the ECG sensor was disclosed only as providing just one of the two signals necessary for determining said criteria of time difference of arrival. In fact, said time difference of arrival is explained to be the time difference between a first signal generated by the ECG sensor *and* a second signal generated by a second noninvasive sensor at a different point in the body (see page 7, lines 34 to 36; page 8, lines 7 to 10 and 19 to 29; see flowchart of Figure 5). Also the somewhat broader formulation of original claims 6 and 7 makes it clear that the criteria of time difference of arrival is to be met by the first signal *and* the second signal.

The subject-matter of claim 1 of the first auxiliary request thus extends beyond the content of the application as filed, contrary to the requirement of Article 123(2) EPC.

### 3.3 Clarity and support by the description

Claim 1 of the first auxiliary request also includes the feature of a second signal generated by the noninvasive second sensor, without however specifying the function of this second signal. As explained under points 2.1.2 and 3.2 above, the feature of the second signal is consistently presented in the description as an essential aspect for calculating the time difference of arrival. As a consequence of the omission of this essential functional feature from the definition given in claim 1, the claimed subject-matter lacks both clarity and support by the description, contrary to the requirements of Article 84 EPC.

The patent proprietor's argument that claim 1 of the first auxiliary request is a combination of claims 1, 4 and 5 as granted is not accepted by the Board. Whilst it is true that claim 1 comprises a combination of individual features which are all recited in claims 1, 4 and 5 as granted, this specific combination was however not claimed as such in the patent as granted. In fact, granted claims 4 and 5 were each individually appended just to granted claim 1; granted claim 5 was however not appended to granted claim 4. Hence, a monitor comprising the combination of features of all three claims 1, 4 and 5 was not actually claimed in the patent as granted.

3.4 Since claim 1 of the second auxiliary request is identical to claim 1 of the first auxiliary request, the aforementioned objections under Articles 123(2) and 84 EPC raised against the first auxiliary request also apply to the second 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:

D. Sauter

M. Noël