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**D E C I S I O N**  
**of 15 September 2005**

**Case Number:** T 0754/02 - 3.4.2

**Application Number:** 96114575.2

**Publication Number:** 0764469

**IPC:** B01L 11/00

**Language of the proceedings:** EN

**Title of invention:**

Method and apparatus for marking predetermined events with a biosensor

**Applicant:**

Bayer Corporation

**Opponent:**

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**Headword:**

-

**Relevant legal provisions:**

EPC Art. 84, 56

**Keyword:**

"Clarity: yes"

"Inventive step: yes"

**Decisions cited:**

-

**Catchword:**

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Case Number: T 0754/02 - 3.4.2

**D E C I S I O N**  
of the Technical Board of Appeal 3.4.2  
of 15 September 2005

**Appellant:** Bayer Corporation  
Pittsburgh, PA 15205-9741 (US)

**Representative:** Linhart, Angela  
c/o Bayer Healthcare AG  
D-51368 Leverkusen (DE)

**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted 11 December 2001  
refusing European application No. 96114575.2  
pursuant to Article 97(1) EPC.

**Composition of the Board:**

**Chairman:** A. G. Klein  
**Members:** A. G. M. Maaswinkel  
C. Rennie-Smith

## Summary of Facts and Submissions

- I. The appellant lodged an appeal, received on 8 February 2002, against the decision of the examining division, dispatched on 11 December 2001, refusing the European patent application 96114575.2. The fee for the appeal was paid on 8 February 2002 and the statement setting out the grounds of appeal was received on 16 April 2002.
- II. The examining division objected that the features relating to "marker member" and "meter function" in the claims then on file were not clear whence the claims were objectionable under Article 84 EPC; and furthermore that, since these features did not impose a restriction over the prior art, the application did not meet the requirements of Article 52(1), 54 and 56 EPC because the subject matter of the claims was neither novel over documents D1 or D2, nor inventive over D1 and common general knowledge. The said documents were:  
D1: EP-A-0 651 250  
D2: WO-A-96 07908.
- III. In a telephone consultation with the appellant the rapporteur made reference to document WO-A-95 24233 (D3) from the same technical field as the patent application (*blood sensors*) and from which disclosure the concepts "marker" and "meter" were known, whence its use in a claim would not appear objectionable under Article 84 EPC.
- IV. In reply the appellant filed with a letter dated 16 August 2005 amended documents. The appellant requested that the decision under appeal be set aside

and a patent be granted on the basis of the following documents:

Claims: 1 to 8 as filed with the letter of  
16 August 2005;

Description: pages 3 to 10 as originally filed;  
pages 1 and 1a filed with the letter of  
8 May 2001;  
pages 2 and 2a filed with the letter of  
16 August 2005;

Drawings: sheets 1/9 to 9/9 as originally filed.

V. The wording of independent claim 1 reads as follows:

"A biosensor (10) comprising:

means for receiving a user sample (32);

processor means (52) with a meter function (56)  
responsive to said user sample receiving means for  
performing a test sequence at said user sample for  
measuring a parameter value corresponding to said test  
sequence;

memory means (54) coupled to said processor means  
(52) for storing said parameter data values;

during said test sequence, said processor means  
(52) checking for a user input with a marker member  
(36) and said processor means (52) responsive to an  
identified selected user input of said marker member  
(36) for storing said corresponding one of a plurality  
of predetermined events adjoined with said user input  
with a parameter data value corresponding to said test  
sequence,

characterized in that,

said marker member (36) is manually insertable by the user to said processor means (52),

and said marker member (36) includes a plurality of different electrically measurable values (36A, 36B, 36C and 36D) each corresponding to one of a plurality of predetermined events".

The wording of independent claim 8 reads as follows:

"A method for marking predetermined events with a biosensor (10) comprising the steps of:

providing the biosensor (10) with a sensor (30) for receiving a user sample and a processor (52) for performing a test sequence for measuring a parameter value;

providing a marker member (36) and selectively manually coupling said marker member by the user to said processor (52);

said marker member (36) including a plurality of different electrically measurable values (36A, 36B, 36C and 36D) corresponding to a plurality of predetermined events;

during said test sequence, said processor (52) checking for a user input with said marker member (36) and said processor (52) responsive to the user selectively manually coupling one of said plurality of different electrically measurable values (36A, 36B, 36C and 36D) of said marker member (36) to said processor (52) for storing said corresponding one of a plurality of predetermined events adjoined with the marker member (36) with a parameter data value corresponding to said test sequence".

Claims 2 to 7 are dependent claims.

VI. The appellant's arguments may be summarised as follows:

Amended claim 1 is based on original claim 1 with further features in its characterising portion taken from originally filed claim 10 and supported by original page 8, lines 7 to 21 and Figure 7. Claims 2 and 8 have been amended in accordance with the amendment of claim 1. The specification has been amended to include an acknowledgement of document D3.

The subject matter of claim 1 is new over document D3. This document, which can be regarded as the closest prior art does not disclose the features of the characterising portion of claim 1 of a marker member including a plurality of different electrically measurable values which is a separate device and which is manually insertable in the processor means of the biosensor. Instead, in D3 the member with a function comparable to that of the marker member of the present invention is a marker key on the function key pad 310, which has to be pressed to insert the marks (page 28, lines 20 to 25). For the same reasons independent claim 8 and the dependent claims are also new. Document D1 discloses a data managing method carried out in a portable blood sugar value measuring apparatus having no operation button by selectively mounting one of the removable electrodes on the apparatus to execute a function in correspondence with a resistance value of the selected electrode. This function is either a calibration or a test of the apparatus or includes carrying out a measurement. Document D2 discloses a biosensor apparatus for reading a test strip comprising an analyte in a liquid, such as blood. The test strip

comprises a reaction zone that varies in reflectance as a function of the quantity of analyte present in the liquid. The apparatus can be programmed to identify a calibration coefficient using an apparatus readable code carried by the test strip. These documents provide neither suggestion of a biosensor nor the use of a marker member as taught by the present invention. Therefore the subject matter of claims 1 and 8 is novel over documents D1 to D3.

For the issue of inventive step D3 can be regarded as closest state of the art. The provision of a marker key on the function key pad for the marking of predetermined events as disclosed in D3 increases the number of keys on the key pad. Even for those users who are not interested in the marking function this additional key is always present. Other users, who want to use the marking function, have to follow a certain marking procedure when pressing this key, which is not described exactly in D3, but from the result (see D3, Figure 24(d)) it is clear that such a procedure includes at least the selection of the type of event such as Meal, Exercise etc. and the marking action itself. It would be desirable to increase the user compliance of such a biosensor device in reducing the number of keys and simplifying the selection of the predetermined event. The solution of such problem can be found in claims 1 and 8. With the new features concerning the marker member the user compliance of the biosensor is increased compared to the device of D3. Those users, who are not interested in the marking feature, can just disregard it and do not have to deal with an additional key on the biosensor, which is still able to perform the test sequence. The person skilled

in the art does not find the solution of the above mentioned problem in D1. In the device of D1 all operation buttons have been eliminated from the biosensor (D1, page 3, lines 29 to 33). The functions to be performed are initiated by mounting removably a selected type of electrode to the device (i.e. testing, calibrating, measuring electrode; see D1, page 8, lines 20 to 27). The purpose of these electrodes is not to perform just an add-on feature like marking certain data with predetermined events like in the amended claim 1, to the contrary the basic functions like the measuring function of the biosensor would not work without the electrode being mounted. The device of D1 is inoperable if the user does not mount one of the separate electrodes, because the device itself has no operation buttons. The person skilled in the art learns from D1 with respect to D3, that all function keys should be replaced by removably mountable electrodes. There is no hint in D1 to selectively replace certain keys of D3, especially the key with the marking function (marker key), by the removably mountable electrodes of D1. And even the simple replacement of the marker key of D3 by a removably mountable electrode, which initiates the marking function, would leave open the question how to distinguish between different predetermined events. Therefore the subject matter of the amended claim 1 is based on an inventive step over D3 alone or in combination with D1. For the same reasons independent claim 8 and the dependent claims are also based on an inventive step.



## Reasons for the Decision

1. The appeal is admissible.
2. *Amendments (Article 123(2) EPC)*

The board is satisfied that the amendments in the claims are fairly supported by the original application documents referred to by the appellant. The adaptation of the description is equally admissible.

3. *Article 84 EPC*

Since the current set of claims differs in its wording from the one on which the decision had been based some of the objections pertaining to lack of clarity in the prior claims are no longer valid. The further objections are not shared by the board. The concept of "marker" in a biosensor (blood characteristic monitor) is known, for instance as disclosed in D3, page 27, line 29 to page 28, line 26, where markers are set and recorded by the user to indicate certain events or changes from the regular medical regime. In this document also the term "meter" for indicating a blood glucose meter is used, which is similar to the "meter function" on page 5, lines 16 to 18 of the patent application, which is understood to embody the interface between the microprocessor 52 and the sensor 32. Indeed in the present case this definition is in the form of a functional feature, but such a way of defining apparatus features is not prohibitive, as explained in the Guidelines, CIII, 2.1 *"It is not necessary that every feature should be expressed in terms of a structural limitation. Functional features*

*may be included provided that a skilled person would have no difficulty in providing some means of performing this function without exercising inventive skill*". In particular in the field of measurement apparatus embodying microprocessors this is common and accepted terminology, thus the board cannot find anything objectionable in this respect.

#### 4. *Patentability*

##### 4.1 *Novelty*

4.1.1 Document D3 discloses a medication delivery device and a blood characteristic monitor or biosensor (300, Figure 22) which includes means (test strip interface 316) for receiving a user sample (test strip 318), processor means (Figure 23) with a meter function (glucose meter 302, see page 26, lines 24 to 27 in the context of page 21, lines 3 to 6) and memory means (Figure 23, RAM and ROM). This sensor device also includes a marker member (located on the function keypad 310) for inputting information on one of a plurality of predetermined events (meal times such as breakfast, lunch, dinner, snacks, exercise times, injection events etc, see page 28 line 1 and lines 17 to 25). Document D3 does not disclose a *manually insertable* marker member because the marker key is integrated in the keypad. The biosensor defined in claim 1 differs therefore from the disclosure in D3 by the feature that the marker member is manually insertable and that it includes a plurality of different electrically measurable values, each corresponding to one of a plurality of predetermined

events. This similarly applies to the method defined in claim 8.

4.1.2 Document D1 discloses a portable blood sugar value measuring apparatus which does not have an operation switch (Figure 7, page 5, lines 5 to 10). The sensor includes means for receiving a user sample (electrode 4, which may be a measuring electrode) and a processor means (Figure 8) with a (blood sugar) meter function and with memory means (RAM). This apparatus does not include a marker member within the definition of claims 1 and 8, i.e. enabling the processor means, after having been input manually by the user, to store a corresponding one of a plurality of predetermined events adjoined by the user with a parameter data value corresponding to the test sequence, which marker member should furthermore include a plurality of different electrically measurable values each corresponding to one of said events.

4.1.3 In its decision the examining division was of the opinion that the apparatus disclosed in D1 did comprise a "marker means", in this respect referring to the paragraph bridging pages 3 and 4, disclosing that this biosensor had means "for outputting a function selection signal based on a resistance value of the electrode". It also noted that in general the operating mode of the apparatus was determined by the electrode resistance value of the marker and that, for instance, a testing electrode having a certain resistance would generate a certain predetermined read-out (referring to page 8, lines 22 to 27 of D1).

4.1.4 The board does not agree with this interpretation of document D1. According to this document (see the Section "Field of the invention" on page 3), D1 discloses a data managing method in a portable blood sugar value measuring apparatus having no operation buttons (disclosed in more detail in a prior document referred to in Section 2 of D1). In order to dispense with input keys or buttons all device input is via electrodes 4, which may be of the following types (page 6, lines 39 to 56): either a measurement electrode (for carrying out the actual blood sample measurement) or an adjusting electrode which in turn may be one of the following types: calibrating (determining the working curve from a plurality of working curves associated with the lot or badge of the particular analyte); testing (containing a fixed resistance value and displays the corresponding voltage to a density on the LCD, for checking that the device behaves correctly); or unit-switching type (for converting display units). The adjusting electrode is therefore used exclusively for inputting the apparatus parameters which are necessary for obtaining a reliable measurement and its display. There is no disclosure in document D1 that electrode 4 could be provided with a plurality of different electrically measurable values, each corresponding to one of a plurality of predetermined events adjoined with the user input, which features imply that it is the user who may associate or "tag" one of a number of predetermined data or events to a measurement cycle in the sensor, whereby these data can be correlated in the processor.

4.1.5 Document D2 discloses a biosensor comprising means (strip holder 16 with opening 14, Figure 1) for

receiving a user sample and a processing means (microprocessor 33, Figure 6) with a meter function (measuring and evaluating glucose). The user sample is contained in a test pad 48 on the test strip 46 (Figure 4) which strip in addition includes a "standard zone" 60. This strip may be used for calibration purposes (for instance, calibration of the lots of reactants; or tests of malfunction of the device). This strip is, however, not a marker member within the definition of claims 1 and 8, since the user does and cannot add one of a plurality of predetermined events to the measurement, the standard zone being an integral part of the test strip.

4.1.6 It is concluded that the subject matter of claims 1 and 8 is novel.

4.2 *Inventive step*

4.2.1 The board agrees with the appellant that document D3 discloses the closest prior art. The biosensor in claim 1 differs from the prior art sensor in that the marker member is manually insertable and that it includes a plurality of different electrically measurable values, each corresponding to one of a plurality of predetermined events.

4.2.2 The technical problem addressed by these differences could be seen as the provision of an alternative solution to the known biosensor.

4.2.3 In the opinion of the board the skilled person, starting from the teaching in document D3 and looking for an alternative blood sensor by modifying the known

apparatus, would not be lead by the available prior art to the solution in claim 1. The biosensor disclosed in D3, Figure 22, has been designed as a wrist watch comprising a watch setting key pad 306 and a power/data key pad 310. According to D3, this key pad 310 comprises a marker key (page 28, line 20) with a function similar to the marker means defined in claim 1, but in addition it comprises a power/data key pad to upload program instructions and download information stored in the RAM (page 25, lines 5 and 6) and also provides the capability to produce detailed reports and to interface with an external computer (page 26, lines 14 and 15). It does not appear obvious why the skilled person would consider modifying this wrist watch shaped apparatus by replacing one of the keys (the "marker" key) by a marker member as in the apparatus of claim 1, because he would still wish to maintain the other functions mentioned above, for which the further keys would be needed.

4.2.4 In the opinion of the board, the documents on file do not suggest such a replacement. In particular document D1 offers a diametrically opposed solution, because it is this document's philosophy to avoid all buttons or keys. It would hence appear that the teachings of these documents may not be combined without inventive skill, because the technical solutions of data entry means are mutually exclusive. In any case it is noted that D1 does not disclose the introduction of user information relating to predetermined events to be adjoined with a test sequence. Therefore a combination of the teachings of these documents does not appear obvious and, furthermore, would not result in the claimed solution without the benefit of hindsight. The board in this

respect notes that none of the pieces of prior art brought to light so far discloses nor even suggests a separate marker member including a plurality of different electrically measurable components which a user can selectively manually insert into an apparatus as a means for inputting corresponding information, in any technical application whatsoever.

4.2.5 Document D2 is a document only relevant under Article 54(3) EPC and is therefore not prior art for the discussion of inventive step.

4.2.6 It is concluded that the subject matter of claim 1 involves an inventive step.

This applies equally to the method defined in claim 8.

4.2.7 Claims 2 to 7 are dependent of independent claim 1 and therefore they also define patentable subject-matter.

5. For the above reasons, the board finds that the appellant's request meets the requirements of the EPC and that a patent can be granted on the basis thereof.

## Order

### For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance with the order to grant a patent on the basis of the following documents:

Claims: 1 to 8 as filed with the letter of  
16 August 2005;

Description: pages 3 to 10 as originally filed;  
pages 1 and 1a filed with the letter of  
8 May 2001;  
pages 2 and 2a filed with the letter of  
16 August 2005;

Drawings: sheets 1/9 to 9/9 as originally filed.

The Registrar:

The Chairman:

P. Martorana

A. Klein