BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

Internal distribution code:
(A) [ ] Publication in OJ
(B) [ ] To Chairmen and Members
(C) [X] To Chairmen
(D) [ ] No distribution

D E C I S I O N
of 9 July 2003

Case Number: T 0922/01 - 3.4.2

Application Number: 89904212.1

Publication Number: 0359831

IPC: G01N 27/28, G01N 27/30, C12M 1/40, G01N 27/327

Language of the proceedings: EN

Title of invention:
Biosensor and process for its production

Patentee:
MATSUSHITA ELECTRIC INDUSTRIAL CO., LTD.

Opponent:
Inverness Medical Technology, Inc.
Roche Diagnostics Corporation (opposition withdrawn)

Headword:
-

Relevant legal provisions:
EPC Art. 52(1), 54, 56, 100(a), 100(c), 102(3), 111(1), 111(2), 113(1), 114(1), 114(2), 123(2), 123(3), 150(3), 158(3)
RPBA Art. 11(3)
EPC R. 27(1), 65(1), 71(2), 88

Keyword:
"Added subject-matter (no) - on the basis of the international application filed in Japanese"
"Withdrawal of one of the oppositions"
"Fresh ground of opposition - no comment of the patent proprietors"
"Novelty and inventive step (yes)"
"Remittal for adaption of the description"

Decisions cited:
G 0009/91, G 0010/91, G 0011/91, G 0008/93, T 0789/89

Catchword:
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0922/01 - 3.4.2

D E C I S I O N
of the Technical Board of Appeal 3.4.2
of 9 July 2003

Appellant: (Opponent)
Inverness Medical Technology, Inc.
200 Prospect Street
Waltham, Massachusetts 02154 (US)

Representative:
Mercer, Christopher Paul
Carpmaels & Ransford
43, Bloomsbury Square
London WC1A 2RA (GB)

Appellant: (Proprietor of the patent)
MATSUSHITA ELECTRIC INDUSTRIAL CO., LTD.
1006, Oaza-Kadoma
Kadoma-shi
Osaka 571-8501 (JP)

Representative:
VOSSIUS & PARTNER
Postfach 86 07 67
D-81634 München (DE)

Decision under appeal:
Interlocutory decision of the Opposition Division of the European Patent Office posted 2 July 2001 concerning maintenance of European patent No. 0359831 in amended form.

Composition of the Board:

Chairman: E. Turrini
Members: M. P. Stock
B. J. Schachenmann

Summary of Facts and Submissions

I. All three parties to the first-instance appeal proceedings, i.e. the patent proprietor, opponent I and opponent II, have appealed against the interlocutory decision of the opposition division finding European patent No. 0 359 831 (European application No. 89 904 212.1 filed as International application No. PCT/JP89/00337 and published under the PCT as WO-A-8 909 397) as amended according to the auxiliary request No. 7 submitted by the patent proprietor during the first-instance oral proceedings to meet the requirements of the EPC.

The oppositions filed by opponent I and opponent II against the patent as a whole were based on the grounds of lack of novelty and lack of inventive step (Article 100(a) EPC).

In the decision under appeal the opposition division held that the subject matter of the amended claims according to the auxiliary request No. 7 then on file was neither anticipated nor rendered obvious by the prior art and moreover allowed the replacement of the expression "embodiment of the prior art" at line 10 of column 5 of the description of the patent as granted by "embodiment of the invention".

II. Among the numerous documents, declarations and pieces of documentary and experimental evidence relied upon by the parties in the course of the appeal proceedings, the following are cited in the present decision:

D1: EP-A-0 170 375

D2: EP-A-0 255 291

D3: JP-A-63 058149 and English translation

D4: JP-A-63 003249 and English translation

D5: EP-A-0 225 061

D6: GB-A-2 090 659

E7: EP-A-0 136 362

III. The patent proprietor requested setting aside of the decision under appeal and the maintenance of the patent in amended form on the basis of a main request or one of a set of auxiliary requests filed with its statement of grounds of appeal.

With their respective statements setting out the grounds of appeal, opponent I and opponent II each requested setting aside of the decision and the revocation of the patent in its entirety.

All the parties requested oral proceedings on an auxiliary basis.

IV. Oral proceedings were appointed consequent to the auxiliary requests of the parties. In a communication accompanying the summons to oral proceedings the Board noted, *inter alia*, that the contested European patent was granted on the basis of the English translation (published pursuant to Article 158(3) EPC as EP-A-

0 359 831) of the International application as originally filed in Japanese (published under the PCT as WO-A-89 09397), the latter constituting, by virtue of Article 150(3) EPC, the European patent application as originally filed, and that, in the absence of any request from the parties to the contrary, it would be assumed for the purpose of the assessment of whether the amendments to the patent as granted fulfil the requirements of Article 123(2) EPC, that the English translation EP-A-0 359 831 of the original application is identical in content with the International application as originally filed in Japanese. The Board also noted that the allowability of the replacement of the expression "embodiment of the prior art" by "embodiment of the invention" at line 10 of column 5 of the patent specification, either as an amendment as such (Article 123(2) EPC) or as a correction of an error (Rule 88 EPC), would have to be assessed on the basis of the original application.

V. In reply to the summons, opponent I stated by letter of 22 April 2003 that it maintained its requests and that it would not attend the scheduled oral proceedings, the patent proprietor filed with the letter dated 26 May 2003 sets of amended claims according to a main request and auxiliary requests No. 1 to 17 together with a declaration of Teruo Naganuma dated 26 May 2003, and opponent II notified the Board by letter dated 10 June 2003 that it "dismisses (withdraws) its opposition".

Opponent II, having withdrawn its opposition, took no further part in the appeal proceedings.

In view of the envisaged non-attendance of opponent I at the oral proceedings, the board drew the attention of the parties to Article 11(3) of the amended Rules of Procedure of the Boards of Appeal that entered into force on 1 May 2003 (see Telefax dated 24 June 2003).

VI. Oral proceedings before the Board took place on 9 July 2003 in the presence of the representative of the patent proprietor and in the absence of opponent I. During the oral proceedings, the representative of the patent proprietor amended the set of claims according to the auxiliary request No. 13, requested to proceed with the resulting set of amended claims as the new single request, thus withdrawing all the sets of claims according to previous requests, and requested setting aside of the decision under appeal and the maintenance of the patent in amended form according to the new single request, with the description to be adapted subject to replacement of the expression "embodiment of the prior art" in column 5, line 10 of the patent specification by "embodiment of the invention". In reply to a question of the Board, the representative of the patent proprietor did not agree to the introduction of the ground of opposition under Article 100(c) EPC with regard to the features of dependent claim 8 as granted, which claim had been renumbered as dependent claim 6 in the new single request. At the end of the oral proceedings the Board gave its decision.

VII. Independent claims 1 and 11 according to the present request of the patent proprietor read as follows:

" 1. A biosensor for determining a substrate concentration in a sample solution comprising a base plate (1) comprising an electrode system (4, 5; 5', 41, 42, 43) being covered by a reaction layer (14), said electrode system (4, 5; 5', 41, 42, 43) and said reaction layer (14) having formed thereon a space (8; 81, 82) being defined by a spacer (7, 7') and a cover (9), said space (8, 81, 82) being provided with an introducing port (10) for introducing said sample solution into said space by capillary phenomenon and a discharge port (11, 12, 13) for discharging the gas in said space (8, 81, 82) by inflow of said sample solution, said electrode system (4, 5; 5', 41, 42, 43) being equipped with at least an electrode for measurement (4, 41, 42, 43) and a counter electrode (5, 5'), at least an enzyme being carried on said reaction layer (14), a change in concentration of a substance in the reaction between said enzyme and said sample solution being detected with said electrode system (4, 5; 5', 41, 42, 43) to determine a substrate concentration in said sample solution, wherein said electrode system (4, 5, 5'; 41, 42, 43) comprising at least said electrode for measurement (4; 41, 42, 43) and said counter electrode (5, 5') is formed on said base plate (1), being an insulating base plate, said reaction layer (14) is formed on the surface of said electrode system (4, 5, 5'; 41, 42, 43) and said reaction layer (14) comprising an enzyme layer composed of an oxidoreductase and a hydrophilic high molecular substance has formed thereon an electron acceptor layer containing a surface active agent. "

" 11.A process for preparing a biosensor which comprises forming an electrode system comprising at least an electrode for measurement and a counter electrode on an insulating base plate, coating a hydrophilic high molecular substance aqueous solution and an oxidoreductase aqueous solution on said electrode system and then drying to form an enzyme layer, spreading a mixture of an electron acceptor and an organic solvent onto said enzyme layer, removing said organic solvent to form an electron acceptor layer and then integrating this assembly with a cover for forming a space for receiving a sample by capillary phenomenon and having an introducing port and a discharge port, wherein said electrode system (4, 5, 5'; 41, 42, 43) comprising at least said electrode for measurement (4; 41, 42, 43) and said counter electrode (5, 5') is formed on said base plate (1), being an insulating base plate, said reaction layer (14) is formed on the surface of said electrode system (4, 5, 5'; 41, 42, 43) and said reaction layer (14) comprising an enzyme layer composed of an oxidoreductase and a hydrophilic high molecular substance has formed thereon an electron acceptor layer containing a surface active agent. "

Claims 2 to 10 and claims 12 to 14 are appended to claims 1 and 11, respectively.

VIII. During the written proceedings the patent proprietor advanced the following arguments in support of its requests:

The replacement of the expression "embodiment of the prior art" by "embodiment of the invention" in column 5, line 10 of the patent specification is based on the passages in column 4, lines 55 to 58 and column 9, lines 29 to 37 of the patent specification, it being immediately clear to the skilled reader of the passages that the expression "embodiment of the prior art" was a translation error and that the embodiment shown in Figure 11 is also described as an embodiment of the invention. This conclusion is further supported by the statements in point 2 of the declaration of T. Naganuma.

Document D1 discloses biosensors and mentions the use of enzymes and sucrose. However, sucrose is not a surface active agent within the meaning of the patent and in any case the document does not disclose any specific embodiment involving the use of an enzyme and sucrose. In particular, the single exemplified embodiment including an enzyme coating is disclosed with reference to Figure 8; the coating contains an immobilized urease enzyme but no sucrose is mentioned in the example.

The disclosure of document D2 only incorporates by way of reference the electrodes described in document D1 (column 4, line 52 ff.) and does not include any other feature of the biosensors disclosed in document D1.

The sensors disclosed in documents D3, D4 and E7 are constituted by a porous body and a filtration layer without a capillary fill space and the sensor disclosed in document D5 comprises two compartments separated by an electroactive membrane. Therefore, these documents

pertain to a completely different construction and working principle than the biosensor according to the patent.

In addition, none of the documents discloses the specific layered structure of the reaction layer according to claims 1 and 11.

In view of document D1, which appears to constitute the closest prior art, the problem solved by the invention is the provision of a biosensor suitable for accurately measuring a substance concentration in a trace amount and in which the sample is smoothly and uniformly sucked into the biosensor. When the oxidoreductase and the electron acceptor are mixed in a single layer, the two components can react during storage due to humidity in the atmosphere; upon reaction of these two components, the resulting blank signal is higher, and thus it would not be possible to measure low substance concentrations accurately. Experiments have shown that the specific layered structure of the claimed biosensor causes the blank response of a solution containing no glucose to be much lower; in particular, after 6 months of storage the blank signal of the claimed biosensor is only 10 to 20% of the blank signal of a biosensor having the same components mixed in one layer. In addition, apart from the manufacturing advantages mentioned in example 2 of the patent specification, the provision of the surface active agent in the electron acceptor layer assists in ensuring that the sample is smoothly and uniformly sucked into the biosensor, i.e. without the generation of bubbles that would have an adverse influence on the measurement accuracy.

Neither D1 nor the other documents suggest that these advantages can be achieved with the claimed biosensor. In particular, documents D3, D4, D5 and E7 pertain to a completely different construction and working principle and for this reason the skilled person would not have turned to these documents to solve the problem. In addition, in documents D2, D3 and D4 glucose oxidase and potassium ferricyanide are mixed together and document E7 teaches increasing the filtration rate by means of a surface active agent but does not suggest improving the smooth and uniform distribution of a sample in a capillary cell containing a reaction layer.

During the oral proceedings the patent proprietor essentially repeated the arguments submitted during the written proceedings, stressed that the blank signal of the biosensor is significantly lower when the layer containing the electron acceptor is formed on the enzyme layer and submitted that document E7 mentions the separation of the enzyme and the electron acceptor only in connection with the size of the crystals of the electron acceptor (page 14, line 4 ff.) without suggesting any effect on the measurement accuracy of a biosensor of the capillary fill cell type.

IX. During the appeal proceedings opponent I only commented on the patent as amended according to the request allowed by the opposition division and in a letter dated 11 July 2002 expressly declined "to file any further submissions" with regard to claims amended according to subsequent requests of the patent proprietor. Among the arguments submitted by opponent I in support of its requests, only the following are

pertinent to the present request of the patent proprietor:

The passage in column 5, lines 8 to 10 of the patent specification describes Figure 11 as an "embodiment of the prior art". The effect of the replacement of the expression "embodiment of the prior art" by "embodiment of the invention" is that Figure 11 is then disclosed as an embodiment of the invention. This amendment, however, cannot be derived directly and unambiguously from the original application within the meaning of decision G 11/91, OJ EPO 1993, 125 and therefore the amendment does not constitute an allowable correction. In addition, the amended expression introduces subject matter diametrically opposite to the information content of the corresponding passage of the original application and for this reason cannot be considered either as an allowable amendment under Article 123(2) EPC.

Reasons for the Decision

1. *Admissibility of the appeals filed by the patent proprietor and by opponent I*

The appeal filed by the patent proprietor and the appeal filed by opponent I each comply with the provisions mentioned in Rule 65(1) EPC and both are therefore admissible.

2. *Appeal filed by, and procedural status of opponent II*

The declaration made by opponent II during the appeal proceedings to withdraw its opposition (see point V above) is to be treated as a withdrawal of all its pending requests and therefore also as a withdrawal of its own appeal (see G 8/93, OJ EPO 1994, 887, point 2 of the reasons). In these circumstances, the Board considers it neither necessary nor appropriate to rule on the admissibility of the appeal filed by opponent II.

In addition, since during the appeal proceedings the parties have only raised substantive issues with regard to the opposed patent and there was no liability issue involving opponent II - see T 789/89, OJ EPO 1994, 482, points 2.3 to 2.6 of the reasons - opponent II ceased to be a party to the present appeal proceedings upon notification of the withdrawal of its opposition on 10 June 2003. Consequently, the submissions of opponent II are - unless otherwise expressly deemed appropriate by the Board pursuant to Article 114(1) EPC - disregarded in the following.

3. *Procedural matters*

3.1 Article 100(c) EPC as ground of opposition

During the written appeal proceedings, the assessment of features incorporated by way of amendment into the claims of previous requests and relating to the hydrophilic characteristics of the surface of the space of the biosensor as mentioned, *inter alia*, in dependent claim 8 of the patent as granted raised questions as to

the compliance of the amendments with the requirements of Article 123(2) EPC.

The amendments to the claims according to the present request of the patent proprietor, however, do not affect nor involve features pertaining to the hydrophilic characteristics of the space. In particular, the features of dependent claim 8 as granted were not amended, the single effect on this claim of the amendments according to the present request being the renumbering of the claim as dependent claim number 6 as a consequence of the deletion of previous dependent claims as granted.

In addition, the ground of opposition under Article 100(c) EPC was not originally invoked by the opponents in their respective grounds of opposition and during the oral proceedings held before the Board (see point VI above) the patentee did not agree to the introduction into the proceedings of the ground of opposition under Article 100(c) EPC with regard to the features of dependent claim 8 as granted.

In these circumstances, following the principles laid down by the Enlarged Board of Appeal in its decision G 9/91, OJ EPO 1993, 408 and in its opinion G 10/91, OJ EPO 1993, 420 (see points 18 and 19 of the Reasons of both cases and point 3 of the Opinion of case G 10/91), the Board is barred from considering the potential incidence of points raised during the written appeal proceedings on the issue of the compliance of the features of present dependent claim 6 with the requirements of Article 123(2) EPC.

3.2 Admissibility of evidence

During the appeal proceedings the parties have relied upon numerous documents, declarations and pieces of documentary and experimental evidence submitted after the nine-month opposition period in support of the corresponding submissions and have disputed the admissibility of some of these pieces of evidence, in particular that of document D6 which was not admitted by the opposition division into the proceedings on the procedural ground that the document was both late-filed and *prima facie* not relevant and the admission of which into the proceedings has been requested by opponent I during the appeal proceedings. Among these pieces of evidence, those that were considered only in support of submissions pertaining to features - such as the shape of the tip portion of the biosensor and the hydrophilic treatment of the space by means of a surface active agent - which were introduced by way of amendment into the claims of previous requests but that do not appear any longer in the amended claims according to the present request are disregarded by the Board as the corresponding pieces of evidence are not pertinent to the assessment of the parties' submissions with regard to the present request (Article 114(2) EPC). This is in particular the case of document D6 which was relied upon by the parties only in connection with the shape of the tip portion of the biosensor.

4. *Compliance of the amendments according to the patent proprietor's request with Articles 123(2) and (3) EPC*

4.1 As already noted by the Board in the communication accompanying the summons to oral proceedings (see

point IV above), compliance with the requirements of Article 123(2) EPC of the amendments brought to the patent is to be assessed with regard to the content of the International application as originally filed in Japanese and published as WO-A-89 09397 and, unless otherwise expressly contested by the parties (see point 4.3 below), the content of the publication EP-A-0 359 831 of the English translation of the International application is considered to be identical to the content of the International application as filed.

4.2 The subject matter of independent claims 1 and 11 according to the request of the patent proprietor results from the combination of the subject matter of claim 1 and claim 16 as granted, respectively, with the features of dependent claim 5 as granted, claims 1, 5 and 16 as granted corresponding to claims 1, 5 and 15, respectively, as originally filed. The resulting combination further specifies that the sample solution is introduced into the space by capillary phenomenon as supported by the passage at lines 17 to 24 of column 15 of the patent as granted and the corresponding passage of the English translation EP-A-0 359 831 of the International application.

Dependent claims 2 to 10 and 12 to 14 result from dependent claims 2, 3, 6 to 8, 12 to 15 and 17 to 19 as granted, respectively, after renumbering of the claims and adaptation of the wording of the claims to the subject matter of the corresponding amended independent claim, the amended feature of the resulting dependent claim 8 relative to the surface active agent being based on dependent claim 18 as granted and examples 8

(column 13, lines 16 to 23) and 9 (column 14, lines 4 to 9) of the patent specification and on the corresponding parts of EP-A-0 359 831.

Accordingly, the amendments brought to the claims of the patent as granted according to the present request of the patent proprietor satisfy the requirements of Article 123(2) EPC.

In addition, the amendments made to the claims result in a limitation of the scope of protection of the claims as granted. The Board is therefore satisfied that no extension of the protection conferred has occurred (Article 123(3) EPC).

4.3 The patent specification referred in column 5, lines 8 to 10 to the biosensor represented in Figure 11 as constituting "another embodiment of the prior art". The patent proprietor has requested the replacement of this expression by "another embodiment of the invention" as allowed by the opposition division with regard to the request then on file. Opponent I has submitted that this amendment is neither supported by the original application (Article 123(2) EPC) nor allowable as a correction within the meaning of G 11/91 (*supra*), i.e. as the correction of an error under Rule 88 EPC.

The corresponding passage of the English translation of the International application also refers to Figure 11 as "another embodiment of the prior art" (EP-A-0 359 831, page 9, line 10). However, according to point 2 of the declaration signed by T. Naganuma - the Japanese patent attorney who was in charge of the preparation of the English translation of the

International application originally filed in Japanese for the entry into the regional phase before the EPO - the Japanese expression used in the corresponding passage of the International application filed in Japanese does not mean "the prior art", but "the earlier" or "the prior" and in the context of the corresponding passage the expression refers to an embodiment of the invention described in the preceding part of the description of the application. The Board has no reason to doubt the correctness of these submissions which in addition have not been contested by opponent I. Accordingly, the application as originally filed identifies Figure 11 as an embodiment related to previous embodiments of the invention and therefore constitutes itself an embodiment of the invention. This conclusion is further supported by the passage in column 9, lines 29 to 37 of the patent specification and the corresponding passage of EP-A-0 359 831 according to which the shape of the tip portion of the biosensor shown in Figure 5 "was rounded as shown in the external view shown in Fig. 11"; since according to this passage Figure 5 constitutes an embodiment of the invention optionally incorporating the rounded tip portion shown in Figure 11 and the biosensor represented in Figure 11 only differs from that represented in Figure 5 by the rounded shape of the tip portion of the biosensor, it has to be concluded that Figure 11 was clearly described in the application as originally filed as another embodiment of the invention.

In view of the above, the replacement of the expression "embodiment of the prior art" by "embodiment of the invention" in column 5, line 10 of the patent

specification according to the present request of the patent proprietor satisfies the requirements of Article 123(2) EPC. The amendment being allowable as such under Article 123(2) EPC on the basis of the application as originally filed, the objection raised by opponent I with regard to the allowability of the amendment as the correction of an error under Rule 88 EPC is not pertinent anymore.

5. *Novelty of the subject matter of the claims according to the patent proprietor's request*

5.1 Claims 1 to 10

5.1.1 It has been undisputed by the parties that document D1 discloses a biosensor for determining the concentration of an analyte in a sample solution (abstract and the embodiment disclosed on page 14, line 14 to page 15, line 26 with reference to Figures 2 and 3), the biosensor comprising a base plate of an insulating material (lower plate 2, page 14, lines 18 to 20) comprising an electrode system formed on the base plate (the electrode system shown in Figure 1 and disclosed in page 13, lines 7 to 31, see page 15, lines 14 to 23) and covered by a reaction layer formed thereon (layer 7, see page 15, lines 1 to 14 together with page 3, lines 20 to 25), the electrode system and the reaction layer having formed thereon a space (the capillary cell cavity 4, see page 14, lines 18 to 26) being defined by a spacer (bonding tracks 3) and a cover (upper plate 1), the space being provided with an introduction port (the aperture at side 5) for introducing the sample solution into the space (page 14, lines 24 to 26) by capillary phenomenon (page 14, lines 30 to 36) and a discharge

port for discharging the gas in the space by inflow of the sample solution (page 14, lines 26 to 29), the electrode system being equipped with an electrode for measurement and a counter electrode (page 15, lines 14 to 18 together with page 12, lines 4 to 9), at least an enzyme being carried out on said reaction layer (page 15, lines 6 to 14), a change in concentration of the analyte in the reaction between the enzyme and the sample solution being detected with the electrode system to determine the analyte concentration in the sample solution (page 24, lines 16 to 35).

In addition, the reaction layer of the biosensor according to the embodiment disclosed with reference to Figures 2 and 3 includes urease enzyme as reactive component (page 15, lines 6 to 10) and optionally additional layers arranged side-by-side or superimposed on each other (page 15, lines 11 to 14) and the document mentions the alternative use of an oxidoreductase and an electron acceptor (glucose oxidase and ferrocene, respectively, see page 11, lines 9 to 13 together with page 12, lines 4 to 9) as reactive components of the reaction layer. Other variants disclosed in the document involve the use of sucrose (page 11, lines 13 to 20, the paragraph bridging pages 11 and 12, and page 16, lines 31 to 35).

In view of the foregoing, and independently of whether sucrose constitutes a surface active agent within the meaning of the invention as disputed by the parties during the appeal proceedings, there is no disclosure in document D1 that would anticipate a biosensor as claimed having the specific structure and composition of the reaction layer defined in claim 1, in particular

that an enzyme layer has formed thereon an electron acceptor layer containing a surface active agent.

5.1.2 Document D2 discloses a biosensor "with a configuration as described" in document D1 (column 3, lines 52 to 54) and more particularly constituted by "an adapted form of the capillary cells provided with electrodes as described" in document D1, the drawings and description of which "are incorporated [...] by reference, to be modified by the indications" given in the document (column 4, line 52 to column 5, line 4). The reaction layer comprises a hydrophilic carrier, an oxidoreductase and an electron acceptor (a low-molecular weight polyvinylpyrrolidone, glucose oxidase and potassium ferricyanide, respectively, see column 4, lines 7 to 19, and column 7, lines 1 to 19 and 33 to 37).

The patent proprietor has submitted that, apart from the electrodes, no other feature of the biosensor disclosed in document D1 is incorporated by way of reference in the disclosure of document D2. However, irrespectively of the extent to which the specific features of the disclosure of document D1 are incorporated by way of reference in the biosensor disclosed in document D2, the disclosure of document D2 does not anticipate the specific structure and composition of the reaction layer defined in claim 1, in particular that an enzyme layer has formed thereon an electron acceptor layer.

5.1.3 Document D5 discloses a sensor formed by a cell having two compartments separated by an electroactive barrier and an electrode in each compartment (abstract,

Figure 1 and paragraphs bridging columns 4 and 5). The document specifies the provision of an enzyme reactant such as urease in one of the compartments to generate a concentration difference of the electroanalysable material between the two compartments (column 3, lines 10 to 17 and column 4, lines 33 to 51) and discloses coating a surfactant on one or both of the two plates forming the cell to promote the capillary filling of the cell (column 5, lines 17 to 28).

Accordingly, document D5 discloses neither a sensor of the capillary fill cell type as claimed nor a reaction layer having the composition and the two-layer structure of the reaction layer defined in claim 1.

5.1.4 Documents D3, D4 and E7 pertain to sensors comprising a porous body overlying a substrate having an electrode system (Figure 1 of each of documents D3 and D4 and Figure 9 of document E7 together with the corresponding description), the porous body being made of a hydrophilic material such as cellulose paper or a non-woven nylon impregnated with a mixture of an oxidoreductase and an electron acceptor (glucose oxidase and potassium ferricyanide, respectively, see D3, page 5, lines 1 to 4 of the English translation; D4, page 6, lines 1 to 5 and page 7, lines 16 to 18 of the English translation; and E7, page 10, lines 10 to 21). According to document E7, the sensor includes a filter layer on the porous body (page 10, lines 21 to 23), the filter layer, the oxidoreductase and the electron acceptor are treated with a surface active agent to improve the rate of filtration and penetration of the sample (page 12, line 22 to 26), and the porous body is alternatively provided in the form of two

laminated pieces of nylon non-woven fabric carrying the enzyme and the electron acceptor, respectively (page 14, lines 4 to 8).

The sensors disclosed in documents D3, D4 and E7 operate by directly dripping or dropping the sample containing the analyte onto the porous body (D3, page 5, lines 8 and 9; D4, page 6, lines 7 to 9; and E7, abstract) and the sensors are not of the capillary fill cell type as claimed. In addition, none of documents D3, D4 and E7 disclose a reaction layer having the specific features of the reaction layer of the biosensor defined in claim 1.

5.1.5 Therefore, in view of the differences mentioned in points 5.1.1 to 5.1.4 above, the subject matter of claim 1 and that of dependent claims 2 to 10 appended to it is novel within the meaning of Articles 52(1) and 54 EPC.

5.2 Claims 11 to 14

Document D1 also discloses a process for preparing the biosensor having the features recited in point 5.1.1 above (page 15, line 32 ff.), the process including the formation of the electrode system on the base plate and the subsequent formation of the reaction layer on the electrode system (page 15, lines 1 to 23 together with page 3, lines 20 to 25). Documents D2, D3, D4, D5 and E7 also disclose a process for preparing the respective sensors, the process of D2 including in particular the formation of the reaction layer by drying techniques (column 6, lines 46 to 56).

However, as already discussed in points 5.1.1 to 5.1.4 above with regard to the subject matter of claim 1, none of these documents anticipates the specific structure and composition of the reaction layer according to claim 11, still less the formation of the two-layer structure of a reaction layer according to the coating steps defined in claim 11.

Having regard to the above, the subject matter of independent claim 11 and that of dependent claims 12 to 14 appended to it is considered to be novel within the meaning of Articles 52(1) and 54 EPC.

6. *Inventive step of the subject matter of the claims according to the patent proprietor's request*

6.1 Closest prior art

It has been undisputed by the parties that the biosensor disclosed in document D1 represents the closest prior art with regard to the invention defined in each of independent claims 1 and 11.

6.2 Claims 1 to 10

6.2.1 Objective problem

The subject matter of claim 1 differs from the biosensor disclosed in document D1 and comprising a reaction layer including an oxidoreductase and an electron acceptor and optionally additional superimposed layers (see point 5.1.1 above) in that the reaction layer comprises an enzyme layer composed of an oxidoreductase and a hydrophilic high molecular

substance having formed thereon an electron acceptor layer containing a surface active agent.

According to the submissions of the patent proprietor, the effect of the distinguishing features identified above is the improvement in the determination accuracy of the analyte concentration in a trace amount of the sample (column 3, lines 16 to 22 and column 4, lines 41 to 48 of the patent specification). This effect appears to result from the use of the surface active agent, which would ensure a smooth and uniform distribution of the sample within the capillary fill space without generation of bubbles on the reaction layer (column 3, lines 3 to 8 and column 6, lines 16 to 39), and from the provision of the electron acceptor component separated from and overlying the enzyme, this arrangement leading according to the patent proprietor's submissions (see points VIII.1 and VIII.2 above) to a reduction of the blank response of the biosensor induced by reaction of the oxidoreductase and the electron acceptor during storage of the biosensor.

Accordingly, the objective problem solved by the subject matter of claim 1 with regard to the disclosure of document D1 can be seen as the improvement of the accuracy of the biosensor in the determination of the analyte concentration in the sample.

6.2.2 Inventive step

The alternative embodiments and variants disclosed in document D1 would at the most suggest the provision of a reaction multilayer containing an oxidoreductase and an electron acceptor and possibly sucrose (see

point 5.1.1 above), but would not suggest the specific composition of the two-layer structure of the reaction layer of the biosensor according to claim 1.

In document D2 the reactive components of the reaction layer are mixed (see point 5.1.2 above) and the document fails to suggest any improvement of the measurement accuracy of the biosensor in terms of the composition and/or the structure of the reaction layer.

Document D5 (see point 5.1.3 above) would at the most suggest applying a surfactant coating on the major surfaces of the capillary fill space (document D5, column 5, lines 17 to 28) without however giving any hint towards the structure and the composition of the reaction layer of the claimed biosensor.

The constructional and operational principle of the sensors disclosed in documents D3, D4 and E7 is different from that of the biosensors disclosed in document D1 (see point 5.1.4 above). In particular, while in document D1 the sample fills the capillary fill cell and dissolves the components of the reaction layer so as to react with the reactive components present in the layer (page 3, line 27 to page 4, line 26) as it is the case with the present invention (column 4, lines 4 to 17), in documents D3, D4 and E7 the sample is dropped onto the porous body so as to flow and penetrate into the porous body where it reacts with the reactive components present in the body. Already for this reason, the skilled person would not have considered the teaching of these documents as providing a possible solution to the problem formulated above. In addition, in documents D3 and D4 the

oxidoreductase and the electron acceptor are mixed in a single porous body (D3, page 5, lines 1 to 4, and D4, page 6, lines 1 to 5), and document E7 teaches treating the filter layer overlying the porous body and the reactive components of the porous body with a surface active agent (page 12, lines 8 to 26 and page 13, lines 8 to 11) as well as the provision of the oxidoreductase and the electron acceptor in a respective one of two laminated pieces of nylon non-woven fabric (page 14, lines 4 to 8) without however specifying in which order the two pieces of fabric are laminated and disposed on the substrate. For these reasons, even if it were assumed for the sake of argument that the skilled person seeking to improve the determination accuracy of the analyte concentration would have contemplated the incorporation of features disclosed in any of these documents in the biosensor disclosed in document D1, she or he would not have arrived at the claimed subject matter.

Therefore, none of the documents suggests solving the problem identified above by means of a reaction layer as defined in claim 1. In particular, none of the documents suggests the provision of the electron acceptor containing layer on the enzyme layer nor the enhanced measurement accuracy achieved by means of the resulting reaction layer.

6.2.3 In view of the foregoing and in the absence of any submission from opponent I to the contrary, the Board concludes that the subject matter of claim 1 and that of dependent claims 2 to 10 appended to it involves an inventive step within the meaning of Article 56 EPC.

6.3 Claims 11 to 14

The process defined in claim 11 differs from the process of preparing the biosensor disclosed in document D1 in the coating steps defined in the claim and in the composition and the structure of the reaction layer of the resulting biosensor (see point 5.2 above). The effect of these distinguishing features is the improvement in the measurement accuracy of the biosensor, this effect resulting from the considerations already discussed in point 6.2.1 above and in addition from the improved uniformity and peeling-off strength characteristics of the resulting electron acceptor layer ascribable according to the patent specification to the use of the surface active agent during the manufacture of the reaction layer (see column 8, lines 2 to 15 of the patent specification).

Accordingly, the objective problem solved by the subject matter of claim 11 can be seen in the preparation of a biosensor having an improved measurement accuracy.

For reasons analogous to those given in point 6.2.2 above with regard to the subject matter of claim 1, none of documents D2, D3, D4, D5 or E7 suggests solving the problem formulated above by means of the distinguishing features identified above.

Having regard to the above, the Board is satisfied that the subject matter of claim 11 and that of dependent claims 12 to 14 appended to it involves an inventive step within the meaning of Article 56 EPC.

7. *Further procedure - Adaptation of the description*

In view of the positive conclusion reached by the Board with regard to the claims according to the request of the patent proprietor, the Board considers it expedient in the circumstances of the present case to exercise its discretion under Article 111(1) EPC and to remit the case to the department of first instance for adaptation of the description. In adapting the description, document D1 should be evaluated (Rule 27(1)(b) EPC) and care should be taken to amend statements and embodiments, in particular those defined in the examples, that are no longer fully consistent with the more restricted subject matter now claimed (Article 84 and Rule 27(1)(c) EPC).

It is however noted that according to Article 111(2) EPC the department of first instance is bound by the *ratio decidendi* of the present decision, and in particular by the issue settled in point 4.3 above, and that for this reason the adaptation of the description should be carried out without conflicting with the amendment in column 5, line 10 of the patent specification as allowed by the Board in the present decision (see point 2 of the Order below).

8. *Absence of opponent I at the oral proceedings*

The oral proceedings took place in the absence of opponent I pursuant to Rule 71(2) EPC and the decision was taken at the end of the oral proceedings pursuant to Article 11(3) of the amended Rules of Procedure of the Boards of Appeal that entered into force on 1 May 2003 (OJ EPO 2003, 89). In the present case, the

decision relies on a request which differs from the auxiliary request No. 13 submitted by the patent proprietor and previously notified to opponent I only in amendments of a purely redactional nature and is based on grounds, facts and evidence that were already known to opponent I before the oral proceedings (see points VIII.1 and VIII.2 above). Accordingly, opponent I has had due opportunity to comment on the grounds and evidence on which the present decision is based (Article 113(1) EPC). Moreover, opponent I had been informed by the Board of the fact that a decision could be announced at the end of the oral proceedings in the absence of a party (see point V above).

9. In view of the foregoing, the patent can be maintained as amended according to the patent proprietor's request (Article 102(3) EPC), subject to the adaptation of the description as indicated in point 7 above, and the appeal filed by opponent I is dismissed in view of the fact that its request for revocation of the patent cannot be followed.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent in amended form as follows:

   – claims 1 to 14 of the only request presented at the oral proceedings;

   – description to be adapted, subject to replacement of the expression "embodiment of the prior art" in column 5, line 10 of the patent specification by "embodiment of the invention"; and

   – drawings as granted.

The Registrar: The Chairman:

P. Martorana E. Turrini