Datasheet for the decision
of 8 April 2014

Case Number: T 0872/09 - 3.4.02
Application Number: 01924446.6
Publication Number: 1269173
IPC: G01N27/327, C12Q1/00
Language of the proceedings: EN
Title of invention: RAPID RESPONSE GLUCOSE SENSOR
Patent Proprietor: Diabetes Diagnostics, Inc.
Opponent: Roche Diagnostics GmbH

Relevant legal provisions:
EPC 1973 Art. 54
EPC R. 106
RPBA Art. 12(4)

Keyword:
Novelty - (no) - ambiguous feature
Late-filed request - admitted (no) -
request not defended before opposition division
Decisions cited:
R 0011/11, R 0013/11, R 0001/13, T 1049/99, T 0144/09,
T 0652/09, T 0023/10

Catchword:
1. Novelty

The claimed sensor is defined by reference to characteristics of its response when used in a measurement set-up. Since none of the determining aspects of the measurement set-up is defined in claim 1, the technical features of the claimed sensor which are responsible for providing the measurement referred to in the claim remain obscure.

Legal certainty requires that a claimed subject-matter cannot be regarded as novel over the prior art on the basis of an ambiguous feature. Hence, defining a functional feature of the claimed sensor under undefined operating conditions is not appropriate to provide any distinction of the claimed sensor over the prior art sensors (see points 1.2 and 1.3 of the Reasons)

2. Admittance of auxiliary requests

None of the patentee's auxiliary requests were admitted into the proceedings because the patentee, during the first-instance opposition proceedings, deliberately chose not to defend any single auxiliary request, even though it was aware of the fact that its main request had not been found allowable by the opposition division (see points 2 and 3 of the Reasons).
Case Number: T 0872/09 - 3.4.02

DECISION
of Technical Board of Appeal 3.4.02
of 8 April 2014

Appellant: Diabetes Diagnostics, Inc.
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Decision under appeal: Decision of the Opposition Division of the European Patent Office posted on 6 February 2009 revoking European patent No. 1269173 pursuant to Article 101(2) EPC.

Composition of the Board:
Chairman: A.G. Klein
Members: A. Hornung
B. Müller
Summary of Facts and Submissions

I. The patentee appealed against the decision of the opposition division of 6 February 2009 revoking European patent No. 1269173.

Opposition was filed against the patent as a whole and based on the grounds of Article 100(a), together with Articles 54(1) and 56 EPC, and of Article 100(b) EPC.

In response to a summons to oral proceedings to be held before the opposition division, the patentee filed an auxiliary request.

At the end of the oral proceedings, the opposition division held that the ground for opposition mentioned in Article 100(a) EPC, together with Article 54(1) EPC, prejudiced the maintenance of the patent as granted.

II. Oral proceedings before the board were held on 8 April 2014.

III. The patentee requested that the decision under appeal be set aside and the case be remitted to the opposition division for further examination with the finding that the subject-matter of the claims of the main request or auxiliary requests 1, 2 or 3 is novel and that the decision under appeal on sufficiency is to be maintained, furthermore that Mr. Gerber (who accompanied the opponent at the oral proceedings) not be permitted to speak.

IV. The opponent requested that the appeal be dismissed and the patentee's auxiliary requests 1 to 3 not be admitted into the proceedings.
V. Independent claim 1 according to the patentee's main request is identical to claim 1 as granted and reads as follows:

"A disposable electrochemical sensor for the detection of an analyte in a liquid sample comprising a working electrode and a reference electrode disposed within a sample-receiving cavity, a reagent layer disposed within the sample-receiving cavity and over the working electrode, said reagent layer comprising an enzyme for producing an electrochemical signal in the presence of the analyte, wherein the sample-receiving cavity has a volume of less than 1.5 μl and wherein the sensor provides a measurement that correlates with the amount of analyte in a period of 10 seconds or less."

Independent claim 1 of the first auxiliary request is identical to claim 1 of the main request but for the additional feature "wherein the reagent layer further comprises an electron transfer mediator". It consists in the combination of claims 1 and 2 of the patent as granted.

Independent claim 1 of the second auxiliary request is identical to claim 1 of the first auxiliary request but for the additional features "wherein the analyte is glucose and the mediator is selected from ferricyanide, metallocene compounds, quinones, phenazinium salts, redox indicator DCPIP and imidazole-substituted osmium compounds". The additional features have been taken from the description.

Independent claim 1 of the third auxiliary request is identical to claim 1 of the main request but for the additional feature "wherein the reagent layer further comprises silica". It consists in the combination of claims 1 and 4 of the patent as granted.

VI. The following document relied on in the opposition proceedings will be referred to in the present decision:
D1: JP 05-312761.

An English translation of D1 was provided by the opponent, first as an annex to its letter dated 16 May 2006. Thereafter, a version that was corrected in part was filed with a letter dated 11 September 2008 and again, together with the reply to the statement of grounds of appeal, on 30 October 2009.

Reasons for the Decision

1. Main request

1.1 According to the appealed decision, the sensor of D1 anticipates all the features of claim 1. The patentee did not contest this finding except for the following feature F of claim 1: "wherein the sensor provides a measurement that correlates with the amount of analyte in a period of 10 seconds or less".

1.2 Construction of claim 1

Claim 1 is directed to a sensor as such, characterized amongst other features, by feature F.

Firstly, feature F is not worded as a structural feature but as a functional feature of the claimed sensor: "... the sensor provides a measurement ...". However, a sensor in itself provides a signal as such but cannot provide a measurement. It is the whole measurement set-up, using inter alia the sensor's output signal, which provides the measurement that correlates with the amount of analyte in a period of 10 seconds or less.
Furthermore, the functional feature F refers to a numerical parameter: "... a period of 10 seconds or less". However, whether a measurement correlates with the amount of analyte within the claimed range or not, depends not only on the sensor but on the whole measurement set-up involved in the measurement.

Still further, the functional feature F does not simply include language to the effect that a measurement of the amount of analyte is *provided* within a certain period of time but that the measurement *correlates* with the amount of analyte. The term "correlate" generally means that the relationship between the measurement provided and the amount of analyte to be measured is not as expected on the basis of randomness alone. However, the degree of correlation largely depends not only on the sensor but on the whole measurement set-up involved in the measurement.

The measurement set-up providing a measurement that correlates with the amount of an analyte within a predetermined period of time includes the following aspects:

- the type and the concentration of the analyte to be measured by the claimed sensor,
- the constitution of the liquid sample containing the analyte, e.g. the nature and the concentration of the perturbating interferants contained in the liquid sample,
- the constitution of the reagent layer for producing an electrochemical reaction with the analyte to be measured, e.g. the type of enzyme, the mediator,
- the material, size and geometry of the working electrode and the reference electrode,
- the voltage profile applied to the sensor as described, for instance, in paragraph [0032],
- the exact starting time of the measurement.
Each of the above aspects of the measurement set-up influences the final measurement result to a large extent.

Since none of these aspects of the measurement set-up is defined in claim 1, the relevant technical circumstances, under which the measurement referred to in the claim is provided within 10 seconds or less, remain undefined. It follows that the technical features of the claimed sensor which are responsible for providing that measurement remain obscure, too.

1.3 Legal certainty requires that a claimed subject-matter cannot be regarded as novel over the prior art on the basis of an ambiguous feature (see T 1049/99, reasons 4.4). Hence, defining a functional feature of the claimed electrochemical sensor under undefined operating conditions is not appropriate to provide any distinction of the claimed subject-matter over the prior-art electrochemical sensors, all the more so if these conditions influence the obtained result to a large extent, as in the case at hand.

In view of the fact that feature F does not delimit the claimed sensor from the sensor of D1, it follows that the sensor of D1 anticipates the subject-matter of claim 1 (Article 54(1) and (2) EPC 1973).

1.4 The patentee presented the following counter-arguments:

1.4.1 For the patentee, there is no direct and unambiguous disclosure in D1, and in particular not in figure 5 of D1, of a sensor which provides a measurement that correlates with the amount of analyte within 10 seconds. Indeed, even though curve C in figure 5 of D1, which represents the current measured by the sensor, seems to disclose a point in time t1 at which the measured current stops decreasing and starts
converging towards a final value, there is no evidence in D1 that any measurement at all is made at t1 or at any other point in time preceding t1. On the contrary, in paragraph [0030] of D1, it is clearly disclosed that "the duration of measurement was totally 15 seconds".

The board notes that it is not relevant whether or not D1 explicitly discloses a sensor providing, in one very specific set of conditions, a measurement of the amount of analyte which is outside the claimed range. The relevant point is that feature F is a functional feature of the claimed sensor, not a structural feature, with the technical circumstances under which the sensor is supposed to exhibit the claimed function being undefined. Therefore, no technical property of the claimed sensor, which would make a difference to the sensor of D1, can be deduced from feature F of claim 1.

1.4.2 The patentee submitted that the meaning of the term "correlates" was very clear from the patent as a whole. Exemplary correlation coefficients $R^2 = 0.95$ and $R^2 = 0.999$, falling under the scope of claim 1, were disclosed in [0006] and [0038] of the patent, whereas an exemplary correlation coefficient not falling under the claimed scope equalled $R^2 = 0.863$ and was obtained when using the conventional "QID sensor" instead (see [0038] of the patent).

The board is not convinced by this argument since the issue at stake is the attempt made in claim 1 to define a functional feature of the claimed sensor by using inter alia the term "correlates" in combination with a complete lack of definition of the technical circumstances under which the claimed correlated measurement is supposed to be provided. Leaving undefined, for instance, even the type and the concentration of analyte itself, deprives the term "correlates" in claim 1 of the possibility of distinguishing the claimed sensor from the sensor of D10 - this being all
the more so because claim 1 does not specify any concrete level of correlation and thereby covers any measurement provided by a sensor that is linked to the amount of analyte differently than by randomness only.

1.4.3 The patentee explained that claim 1 related to a well-known technical field, i.e. the detection of an analyte by an electrochemical sensor. In particular, the skilled person would know how to measure the current as claimed, including how to determine whether the measurement correlated or not with the amount of analyte in a period of 10 seconds or less. Therefore, feature F had a limiting effect on the scope of claim 1 and, notably, distinguished the claimed sensor from the sensor of D1.

This argument is not found convincing for reasons corresponding to those given in point 1.4.2 above. The question is not whether the skilled person is able to make a measurement of an amount of analyte but whether the claimed sensor is limited by its claimed function of providing a measurement under undefined circumstances. The board is convinced that this is not the case for the reasons given in point 1.3 above.

2. First auxiliary request

The board holds that the first auxiliary request is not admissible under Article 12(4) of the Rules of Procedure of the Boards of Appeal ("RPBA", OJ EPO 2007,537).

First-instance opposition proceedings

2.1 At the end of the first-instance oral proceedings, the patent was revoked for lack of novelty of the claimed subject-matter with respect to D1. In advance of those oral proceedings the patentee had filed a first auxiliary request whose claim 1
defined subject-matter which undisputedly overcame the novelty objection at stake. This first auxiliary request then on file was identical to the first auxiliary request being the subject of the present decision. However, after the patent according to its main request had been revoked during the oral proceedings, the patentee deliberately decided to either withdraw that auxiliary request, or at least not to pursue it any further during the first-instance proceedings. As a consequence, the decision of the opposition division dealt only with the issue of novelty of a single independent claim, i.e. claim 1 of the patent as granted, with respect to a single prior art document D1. In particular, the opposition division was not in a position to decide on any of the other numerous novelty and inventive step objections raised by the opponent in its notice of opposition. These objections had a wide scope since the subject-matter of claim 1, as well as that of various dependent claims, according to the opponent's submissions, was anticipated or at least rendered obvious by various prior art documents other than D1.

2.2 Due to the patentee's course of action, the opposition division was effectively prevented from taking a reasoned and sufficiently comprehensive decision on the patentability of the claimed subject-matter over the cited prior art. This issue was largely left unresolved given that the examination of the grounds for opposition was limited to the mere novelty assessment of claim 1 as granted with respect to D1. This is contrary to the purpose of Article 12(4) RPBA, namely of encouraging parties to complete their relevant submissions during the first instance opposition proceedings (see T 23/10, reasons 2.4 and 2.7).

Moreover, the board is convinced that the patentee could easily have defended the first auxiliary request in the first instance proceedings. Indeed, this auxiliary request was not only filed in preparation of those oral proceedings, but also
did its claim 1 incorporate a straightforward amendment, which would have undisputedly overcome the objection of lack of novelty at stake, as it merely combined claim 2 as granted with claim 1 as granted.

2.3 If the board decided to admit the first auxiliary request into the proceedings, it would either have to assess the compliance of a set of claims with the requirements of the EPC for the first time during opposition proceedings or to remit the case to the opposition division. None of these two options is satisfactory, be it due to the parties' general interest in having their case heard by two instances or their general interest in the proceedings being conducted in an efficient and foreseeable manner.

2.4 The patentee, in deliberately choosing during the first-instance opposition proceedings not to defend the patentability of the first auxiliary request then on file, deprived itself of the possibility of having the request admitted into the appeal proceedings (see T 144/09, reasons 1.9 and 1.14; T23/10, reasons 2.8).

2.5 Therefore, the board decides to exercise its discretion under Article 12(4) RPBA in not admitting the first auxiliary request into the proceedings.

2.6 The patentee presented the following arguments in favour of admissibility:

2.6.1 The patentee did not withdraw the auxiliary request 1 at the first instance oral proceedings. As explained in the patentee's letter dated 3 March 2014, the patentee's representative, at the first instance oral proceedings, "stated that he would not argue for the novelty of auxiliary request 1, but instead reserve the right to reintroduce this auxiliary request in appeal proceedings" and, as a response
to a question by the chairman of the opposition division, the patentee's representative "explicitly stated that it was not to be withdrawn".

The board notes that both the decision under appeal and the minutes of the first-instance oral proceedings mention the explicit withdrawal of the auxiliary request 1. The patentee raised no objections to these statements in its notice of appeal or upon receipt of the minutes of the oral proceedings. Furthermore, the explicit withdrawal of auxiliary request 1 was corroborated twice by the opponent: firstly, by the statement in the opponent's letter of 4 April 2014, point 1, and, secondly, when questioned by the board during appeal oral proceedings. Therefore, the patentee's assertion that auxiliary 1 request was not explicitly withdrawn is doubtful.

Whether or not the patentee explicitly withdrew auxiliary request 1, however, is of no fundamental importance to the present situation. The undisputed statement by the patentee's representative in the oral proceedings before the opposition division that "he would not argue for the novelty of auxiliary request 1, but instead reserve the right to reintroduce this auxiliary request in appeal proceedings" means in any case that it did not defend that request in those oral proceedings. This approach amounted to the acceptance that the patent be revoked by the opposition division without trying to defend it at that stage.

It appears that the patentee did not argue in favour of the novelty of auxiliary request 1 before the opposition division in the firm belief that the novelty debate would automatically be taken up in the appeal proceedings in case the main request would not be allowed. However, no legal basis for such an assumption exists. On the contrary, admissibility of new requests depends on the board's
discretion aiming at fair proceedings for both parties, especially in the present case where the facts and submissions had not changed from the beginning of the opposition proceedings. Neither were new objections raised nor were new prior art documents introduced into the proceedings by the opponent.

2.6.2 The representative submitted that he was surprised by the course of the debate at the oral proceedings before the opposition division. Indeed, in the annex to the summons to oral proceedings, the opposition division raised objections under Article 83 EPC against the claimed subject-matter of the main request but acknowledged novelty of the subject-matter of claim 1 with respect to the disclosure of any of the available cited documents including D1. Therefore, the patentee dealt with the sole objection under Article 83 EPC by filing auxiliary request 1 in preparation of the oral proceedings, with claim 1 comprising the allegedly missing electron transfer mediator of claim 2 as granted. There was no reason for the patentee to file in advance an amended set of claims to overcome a potential lack of novelty. The fact that the representative was then confronted during oral proceedings with the surprising change of mind of the opposition division and its finding of lack of novelty with respect to the sensor of D1, put the representative in a situation where it was not possible for him to properly deal with this novelty objection, especially in view of the nine further prior art documents which were cited by the opponent in its notice of opposition under Article 54 EPC. In the patentee's view, it filed a proper response to the surprising lack of novelty decision at the earliest possible point in time, i.e. with the statement of grounds of appeal.

This argument is not acceptable to the board, firstly, because the opposition division's explanations in the annex to the summons were, as usually, explicitly titled
"Preliminary and non-binding opinion of the opposition division". This confirms that the patentee evidently had to be prepared to deal with a change of mind of the opposition division during oral proceedings, especially in the present case where lack of novelty was a major objection raised by the opponent in its notice of opposition, founded on no less than ten prior art documents.

Secondly, being unwilling to file or defend an auxiliary request with an amended claim 1 overcoming the lack of novelty objection for the reason that claim 1 might not be properly amended, is not acceptable. Indeed, any party is required to conduct its proceedings with due diligence. This means, in the present case, that the patentee had the procedural obligation to make a reasonable attempt at overcoming the possible revocation of the patent as granted by filing adequate claim requests during first instance proceedings, instead of waiting for the appeal proceedings to start with such an undertaking. Moreover, it is to be noted that amendments which were filed as auxiliary requests during first-instance proceedings and which subsequently would reveal to be unsuitable to the patentee could be dropped in appeal proceedings.

Thirdly, the board notes that there is no evidence that the patentee at any time requested an interruption or adjournment of the oral proceedings before the opposition division to allow for preparation of a suitable claim request.

2.6.3 Referring to Article 13(1) RPBA, the patentee argued that auxiliary request 1 was admissible because (i) it was filed at the earliest possible stage of the appeal proceedings, (ii) the subject-matter of claim 1 was not complex and (iii) admittance did not impact on the procedural economy in view of the opponent having already provided comments in its notice of opposition.
These arguments are not relevant to the issue at stake which concerns the deliberate choice of the patentee not to have filed or defended amendments during first-instance proceedings to avoid the revocation of the patent as granted.

3. Second and third auxiliary request

The board holds that both the second and third auxiliary requests cannot be admitted into the proceedings pursuant to Article 12(4) RPBA.

The board exercised its discretion under Article 12(4) RPBA in not admitting both requests into the proceedings because the patentee, during the first-instance opposition proceedings, deliberately chose not to defend any single auxiliary request, even though it was aware of the fact that its main request had not been found allowable by the opposition division. As a consequence, the patentee restricted the debate to the main and sole request, which amounted to take over the control of when which request should be evaluated. The more detailed reasons given for not admitting the first auxiliary request, which are set out at points 2.1 to 2.4 above, apply by analogy.

4. Objection pursuant to Rule 106 EPC

4.1 As a reaction to the non-admittance of any of auxiliary requests 1 to 3, the patentee raised an objection under Rule 106 EPC and, at the board's request, put it into writing. The appellant complained that the board not admitting any of auxiliary requests 1 to 3 was contrary to established practice of the boards and therefore constituted a substantial procedural violation. In the patentee's view, it could be deduced from Article 12(2) and (4) RPBA that "the
default situation in appeal is that everything which is filed with the statement of grounds of appeal is admitted unless there are valid reasons why they should not be admitted”. Orally, the appellant explained that the board thus violated the appellant's right to be heard because it was denied the opportunity to file an auxiliary request.

4.2 The board dismissed the objection under Rule 106 EPC for the following reasons.

4.2.1 Pursuant to Rule 106 EPC, "A petition under Article 112a, paragraph 2(a) to (d), is only admissible where an objection in respect of the procedural defect was raised during the appeal proceedings and dismissed by the Board of Appeal ...". According to Article 112a(2)(c), "The petition [for review] may ... be filed on the grounds that ... a fundamental violation of Article 113 occurred".

4.2.2 In the context of the exercise of a board's discretion whether or not to admit a claim request in a particular case, the Enlarged Board of Appeal has repeatedly and consistently held that this was a substantive issue (with which the Enlarged Board could not interfere in petition proceedings); see R 1/13 of 17 June 2013, at point 16.3, and the case cited there; R 13/11 of 20 April 2012, at point 4 et seq. and the cases cited there. The Enlarged Board, in those cases, examined whether or not the petitioner had an opportunity to present its comments on the admissibility of the requests that were not admitted into the proceedings (see idem, at point 9 et seq.; R 13/11, idem, at point 5 et seq.). Furthermore, as stated in T 144/09 of 4 May 2011, at point 1.15, "the fact that the board finds [the patentee's] arguments unconvincing does not mean that the [patentee] has not had an opportunity to present its argument on the matter or that the board had ignored the [patentee's] submissions in this respect". Such is the case here.
4.2.3 In the present case, the patentee was given ample opportunity to argue why, in its view, auxiliary requests 1 to 3 had to be admitted into the proceedings, both in writing (see the patentee's letters dated 21 March 2011 and 3 March 2014) and subsequently at length orally during the oral proceedings conducted before the board. The patentee has not disputed this fact. For these reasons, the patentee's objection is manifestly unfounded.

The points below are therefore added for the sake of completeness only.

4.2.4 In its letter of 3 March 2014, the patentee referred to T 144/09, at point 1.14. It deduced from this decision that "the mere fact that auxiliary requests 2 and 3 were not filed in the first instance proceedings does not mean that they should not be admitted into the present proceedings". The board can only agree with this general statement: the provisions of Article 12(4) RPBA are not to be construed such that no amendments which were not already filed in the first instance proceedings can be advanced in the appeal proceedings. However, in the present case, the critical issue is that the patentee deliberately did not file or defend amendments to its main request, thereby preventing the opposition division from taking a sufficiently complete decision. This would compel the board to remit the case in the same status as it stood at the end of the opposition oral proceedings. This is a special situation which explains why the board, taking account of the particular circumstances of the case, exercised its discretion in not admitting auxiliary requests 1 to 3 into the proceedings. It should be noted that the patentee, in the case underlying the decision in case T 144/09, filed a petition for review. In its corresponding decision R 11/11, the Enlarged Board of Appeal held that non-admission of requests timely filed with the statement of
grounds of appeal did not constitute a violation of the right to be heard (see, for instance, the keywords of R 11/11).

4.2.5 In support of its written submission filed during oral proceedings on 8 April 2014, stating that not admitting the auxiliary requests was contrary to established practice of the boards, the patentee referred to case T 652/09. The board in this respect notes that whether its treatment of the patentee's auxiliary requests is correct and/or in conformity with established case law is a substantive issue and not one of Article 113 EPC, open to an objection under Rule 106 EPC (see point 4.2 above). Independent thereof, the patentee did not establish that the circumstances in the latter case were comparable to those in the case at hand. In particular, it is true that in case T 652/09 the patent was also revoked by the opposition division for lack of novelty of the independent claims of a single request. However, in contrast to the present situation, the opponent in case T 652/09 no longer raised any objection against the novelty of the claims as amended in the appeal procedure, neither did it object to the remittal of the case to the department of first instance (see point VI of the Summary of Facts and Submissions, last sentence).

5. The request that Mr. Gerber not be permitted to speak

With a letter of 11 March 2014 the respondent's professional representative informed the board about the participants in the oral proceedings, among them Mr. Gerber, an employee of the respondent and "representative[.]in accordance with Art. 133(3) EPC". At the beginning of the oral proceedings before the board an authorization, inter alia, for Mr. Gerber was submitted.

At no point in time during the oral proceedings, however, did the board become aware that Mr. Gerber wished to speak. The
appellant's request that Mr. Gerber not be permitted to speak is therefore moot.

Order

For these reasons it is decided that:

The Registrar: The Chairman:

M. Kiehl A.G. Klein

Decision electronically authenticated
Case Number: T 0872/09 - 3.4.02

DECISION
of Technical Board of Appeal 3.4.02
of 21 July 2014 correcting an error in the decision
of 8 April 2014

Appellant: Diabetes Diagnostics, Inc.
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Decision under appeal: Decision of the Opposition Division of the European Patent Office posted on 6 February 2009 revoking European patent No. 1269173 pursuant to Article 101(2) EPC.

Composition of the Board:
Chairman A. Klein
Members: A. Hornung
B. Müller
It is ordered that the following obvious omission in the decision dated 8 April 2014 be corrected under Rule 140 EPC:

The section at the end of the decision:

"Order

For these reasons it is decided that:

shall be followed by:

" 1. The objection under Rule 106 EPC is dismissed.

  2. The appeal is dismissed."

The Registrar: The Chairman

M. Kiehl A.G. Klein

Decision electronically authenticated