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

Case Number: T 2202/08 - 3.4.02

Application Number: 05010661.6

Publication Number: 1577669

IPC: G01N33/487, C12Q1/00, G01N27/30

Language of the proceedings: EN

Title of invention:
Improved electrochemical biosensor test strip

Applicant:
Roche Diagnostics Operations, Inc.

Headword:
-

Relevant legal provisions:
EPC Art. 123(2), 76(1)

Keyword:
Extension of an amended divisional application beyond the content of the divisional as originally filed or the earlier (parent) application as originally filed.

Decisions cited:
T 0331/87, T 0260/85, T 0384/91, G 0001/93

Catchword:
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Case Number: T2202/08 - 3.4.02

D E C I S I O N
of the Technical Board of Appeal 3.4.02
of 6 September 2011

Appellant: Roche Diagnostics Operations, Inc.
(Applicant) 9115 Hague Road
Indianapolis, Indiana 46250, U.S.A.

Representative: Dittrich, M
Weickmann & Weickmann
Patentanwälte
Postfach 86 08 20
81635 München (Germany)

Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted 2 July 2008
refusing European patent application No.
05010661.6 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman: A. Klein
Members: M. Stock
D. Rogers

Summary of Facts and Submissions

- I. The applicant has appealed against the decision of the examining division refusing European patent application number 05010661.6, published as EP 1 557 669 A2, which is a divisional application from the earlier application 98960645.4, published as international application WO99/30152, in the following: "the parent application".

The examining division found that the subject-matter of claim 1 according to any of the main and auxiliary requests 1 to 3 then on file infringed the requirements of Article 76(1) EPC. None of these requests could be admitted into the proceedings under Rule 137(3) EPC. Accordingly there was no agreed text on file as required by Article 113(2) EPC and the application had to be refused under Article 97(2) EPC.

- II. The appellant's arguments can be summarised as follows:

As understood by a skilled reader the present application referred to test strips for determination of an analyte in a fluid. A first problem to be solved by the present invention was the smallness of the strip such that vision impaired persons (such as diabetics) might have difficulties in properly adding a sample to the strip.

A second problem to be solved by the present invention was the difficulty of introducing the test sample to the capillary reaction chamber due to the smallness of the capillary space and the composition of the materials, ("dose hesitation "). Further, too little of the sample might be drawn into the capillary reaction

chamber. It was clear that this problem was independent of the first problem.

A third problem to be solved by the present invention was to provide a test reagent which could withstand processing steps, such as mechanical punching . It was clear that this problem was independent of the first and second problems.

The summary of the invention described an improved biochemical biosensor test strip with four new features:

- (1) an indentation along one edge for easy identification of the sample application port for vision impaired persons,
- (2) a transparent or translucent window operating as a "fill to here" line,
- (3) a notch or multiple notches located at the sample application port for reducing dose hesitation. A notch might be created in the first insulating substrate and the roof of the strip so that they overlaid one another.
- (4) a test reagent including polyethylene oxide from 100 to 900 kDal and concentrations from 0,2 % to 2 % by weight.

The application provided a generic disclosure of the four features (1) to (4) in a test strip. No specific structures of the test strip were disclosed in this context except for the features (1) to (4).

On page 1 of the application, reference was made to known test strips having the disadvantages as described above. From pages 1 to 3, the skilled reader was taught that features (1) and (2) solved the first problem, feature (3) solved the second problem, and feature (4) solved the third problem as indicated above. The skilled reader would therefore conclude that known test strips were to be modified by including features (1) to (4) only if all problems indicated above were to be solved. The skilled reader would also conclude that the four features independently solved one of the problems of the present application corresponding to claims 1 to 4 of the parent application recited as "Items 1 to 4" in the present divisional application.

In summary, there was:

- a generic disclosure of all four features (1) to (4) indicated herein in a test strip, such as in a known test strip (p. 1-3),
- a disclosure about preferred embodiments having all novel features except the test reagent (see figures), and
- a disclosure about four preferred embodiments having only one of the four features (Items 1 to 4).

From the preferred items 1 to 4 solving a single one of the problems of the present invention, and the disclosure of the four novel features of the test strip on p. 1 to 3 independently solving the problems of the present application, the person skilled in the art would recognise that a test strip having only one of the four features would be able to solve one of the problems of the present application irrespective of other features of the preferred embodiments of the figures or the items.

The person skilled in the art would thus conclude that:

- a test strip having an indentation along an edge solves the problem related to the smallness of the strip;
- a test strip having a notch located at the sample application port solves the problem related to "dose hesitation";
- a test strip having a transparent or translucent window in the roof solves the problem of the smallness of the strip;
- a test strip comprising a test reagent solves the mechanical problems related to the test reagents.

A vent hole was not mentioned in the context of the problems of the present invention and the generic disclosure on p. 1 to 3. Therefore it had to be concluded that there was no technical relation of the vent hole to the four "new" features (1) to (4) as disclosed on p. 1 to 3. The vent hole was merely disclosed in the preferred embodiments. A function of the vent hole was not disclosed. There was no indication that the vent hole was required to provide a solution to one of the problems indicated above by one of the four novel features.

Claim 1 of the main request in its latest version (see section V below), which corresponds to the fourth auxiliary request underlying the impugned decision, differed from item 1 of the present divisional application (corresponding to claim 1 of the parent application) in that the vent hole had become independent of the first insulating substrate. It was clear that a test strip of this claim, wherein the vent hole was not necessarily located in the first

insulating substrate, would solve the problem to the same extent. Thus, there was no interaction of the vent hole and the indentation. The function of the vent hole would not be affected, if it were located in a structure in the test strip different from the first insulating substrate.

Regarding the test according to decision T 331/87 the appellant is of the opinion that skilled person would directly and unambiguously recognise that

- (i) the location of the vent hole was not essential, as the generic disclosure of the four novel features in a test strip did not refer to this feature;
- (ii) in the light of the technical problem to be solved (improved handling of a test strip by vision impaired persons), the location of the vent hole was not indispensable. The test strip having an indentation did not require the presence of a vent hole in the first insulating substrate, as indicated above;
- (iii) no real modification of other features was required to compensate for the change, as there was no technical interaction of the location of the vent hole with respect to the indentation, as indicated above.

In summary, the location of the vent hole was merely limiting the scope as required by G 1/93 and T 384/91, because there was no technical relationship between this feature and the indentation. The term "vent hole" implied that there was a functional relation to the capillary test chamber. As the function of the vent

hole, which might be required for proper filling, did not depend on its location in the test strip, the location of the vent hole could in no way influence the effects of the indentation. There was, in fact, no technical contribution of the vent hole per se to the invention, as this feature was not required to solve the technical problem by the indentation, and did not interact with the indentation.

From this and the test under T 331/87, the appellant is of the opinion that provision of a vent hole independent of the first insulating substrate does not violate Art. 76(1) EPC.

III. In preparation for the oral proceedings requested by the appellant, the Board made preliminary non-binding comments related to the application in the present case of a three-criteria test as set out in decision T 331/87 for an allowable generalisation by replacement or removal of a feature from a claim and relied upon by the appellant. The Board further stated that an allowable claim could be based on claim 1 according to the fourth auxiliary request underlying the impugned decision of the examining division, which should be further amended by defining that the vent hole (4) was formed in the first insulating substrate (1) (see points 7 to 9 of the Board's communication).

IV. One month before the oral proceedings the appellant submitted claim sets according to a main request and presented arguments supporting these claims. At the oral proceedings before the Board the submitted claim sets according to auxiliary requests 1 to 3. At the oral proceedings on 6 September 2011 the appellant maintained claim 1 according to the main request which reads as follows:

1. An electrochemical biosensor test strip comprising:
 - a first insulating substrate (1) having first (22) and second (23) surfaces and an indentation along an edge;
 - a vent hole (4);
 - at least two conductive tracks (5, 6) disposed on the first surface (22) of the first insulating substrate (1);
 - a second insulating substrate (7) having first (8) and second (9) surfaces, an indentation similar to the indentation of the first insulating substrate and first and second openings (10,11), the second surface (9) being affixed to the conductive tracks (5, 6) and the first surface (22) of the first insulating substrate (1) and oriented so that the indentation of the second insulating substrate overlays the indentation of the first insulating substrate, the first opening (10) exposing a portion of the conductive tracks for electrical connection to a meter capable of measuring an electrical property, the second opening (11) exposing a different portion of the conductive tracks (5, 6) and the vent hole (4);
 - a test reagent (12) overlaying at least a portion of the conductive tracks (5, 6) exposed by the second opening (11); and a roof (13) having first (16) and second (17) surfaces

and an indentation similar to the indentations of the first and second insulating substrates, the second surface (17) of the roof (13) being affixed to the first surface (8) of the second insulating substrate (7) and positioned so that the second surface (17) of the roof (13) and the first surface (22) of the first insulating substrate (1) form opposing walls of a capillary test chamber comprising a sample application port (20), and the indentation of the roof overlays the indentations of the first and second insulating substrates.

According to the first auxiliary request, filed at the oral proceedings, "a vent hole (4)" in the second feature of claim 1 according to the main request is cancelled and is substituted for "the vent hole (4)" in the fourth feature of claim 1 according to the main request.

The second and third auxiliary requests are directed to versions of claim 1 according to the main request and the first auxiliary request, respectively, including the further amendment at the end of the claim-wording "wherein the indentation along an edge of the test strip is for identification of the sample application port" as a supplement.

During the oral proceedings the appellant made reference to the following document (designated as D2 in the following):

D2: US-A-5 575 895

At the end of the oral proceedings the decision was given by the Board.

Reasons for the Decision

1. Content of the present divisional application and its parent application

For the purpose of original disclosure under Articles 123(2) and 76(1) EPC reference will be made to the publications of the present divisional application (EP 1 577 669 A2) and its parent application (WO99/30152). There is no doubt that these publications are identical with respect to their contents with the corresponding original application documents. Even though for the divisional application as filed the requirements of Article 76(1) EPC apply (no extension beyond the content of the parent application is permitted), it is Article 123(2) EPC which governs later amendments of the divisional application. In the present case the description in paragraphs 0001 to 0057 and Figures 1 to 6 of the divisional application are identically found in the parent application. Claims 1 to 32 of the parent application are repeated as items 1 to 32 in paragraph 0058 of the description of the divisional application. The claims of the divisional application (Nos. 1 to 18) partly differ from those of the parent application. However, the claims according to the latest requests in the present divisional application are based on the claims and corresponding items in the parent and divisional application, respectively, which have been further amended by features disclosed in the description. Therefore there is no substantial difference, whether the comparison of the the subject-matter claimed in the present divisional application

with that of the parent application or with that of the divisional application as originally filed is made.

2. Amendments according to the main request

The subject-matter of claim 1 according to the main request is essentially disclosed by original claim 1 of the parent application, which is repeated as item 1 in the description of the present divisional application, see paragraph 0058 in column 8. Only two further amendments were made. In accordance with one amendment the test chamber, which evidently is the original fill chamber, comprises a "sample application port (20)", see the penultimate line of claim 1. This feature is disclosed in the description of the divisional application, see paragraphs 0047 and 0051, and in the description of the parent application, see corresponding locations on pages 13 and 14. The other amendment is related to the generalisation of the location of the vent hole (4) due to the fact that the latter is now specified in the claim without reference to it being located in the first insulating substrate. The original definition of the first insulating substrate having inter alia a vent hole is changed by the new wording defining that the test strip among other features comprises a vent hole.

3. Novelty test for amended subject-matter

According to Article 123(2) EPC, the application may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as (originally) filed. For the purpose of examination whether an application contains such an extension, the question must be answered whether a

person skilled in the art derives the amended feature "directly and unambiguously" from the application as originally filed, see Case Law, 6th edition 2010, III.A.7. A number of tests are available from case law for deciding whether a feature is derivable directly and unambiguously from the originally filed application documents. When generalising a feature as in the present situation, the novelty test, i.e. the test whether the amended subject-matter would be new over the original disclosure, is only applicable, if it is interpreted in terms of change of content of the amended subject-matter over the original application. The amended subject-matter would extend beyond the application as originally filed if the amended content minus the original content left a remainder. Evidently such a remainder is information which is not present in the original application documents, thus leading to an infringement of Articles 123(2) EPC. This situation arises also between a divisional application and its parent application, see Article 76(1) EPC.

4. Novelty test applied to claim 1 of the main request

In the present case the vent hole was described in the original versions of the divisional and its parent application only in connection with the first insulating substrate, see published divisional application, paragraphs 0015, 0020, 0027 and 0058. Therefore generalised subject-matter of present claim 1, which leaves the location of the vent hole open, covers in addition to the first insulating substrate having the vent hole, that the the roof 13, see Figure 1, or the second insulating substrate 7 have the vent hole. However, since according to the claim-wording the second insulating substrate has first and second

openings, the second opening 11 exposing a different portion of the conductive tracks 5 and 6 (disposed on the first surface of the first insulating substrate, see claim 1, third feature), it is difficult to imagine how the vent hole can be formed in the second insulating substrate and exposed by its opening 11 at the same time. Therefore the only possible alternative for providing a vent hole would be the roof 13. However, this location could only be considered as being derivable "directly and unambiguously" from the original application documents, if the layered construction of the test strip were symmetric with respect to a median horizontal plane in such a way that the definition of the first insulating surface and the roof were interchangeable. The definition in claim 1 of a "roof" already shows that this symmetry is not present. It is also evident from Figures 4 and 5 that the arrangement of vent hole 4 in the substrate 1 has the consequence that the vent hole 4 is formed in the dried test reagent 12 (which also overlies a portion of the conductive tracks, see paragraph 0027 and definition in claim 1, lines 22-23), whereas a vent hole in the roof would not contact this dried reagent.

5. Function of the vent hole

The appellant has argued that although no particular function of the vent hole was explained in the present application, it could be assumed that its purpose was to let the air escape from the test chamber during filling. This would be achieved, even if the vent hole was not located in the first insulating substrate. Such an arrangement of a vent hole was described e.g. in document D2, Figures 1 and 2 with the associated description, disclosing a biosensor having the same sequence of layers as employed in the present

application, namely a first insulating substrate 6 with conductive tracks 2 and 3, a second insulating substrate 8 with an opening 11 and a cover layer 9. A vent hole 13 was formed in the cover layer 9 corresponding to the roof described in the present application.

This argument does not convince the Board which is of the opinion that a specific disclosure of a given feature does not necessarily allow to be re-formulated in terms of its function only. The Board considers that, where a feature is consistently described in relation only to particular constructional details, these are normally part of the disclosure of the feature.

6. Appellant's application of the test from T 331/87 (three criteria)

The appellant has made reference to decision T 331/87 according to which the replacement or removal of a feature from a claim may not violate Article 123(2) EPC provided the skilled person would directly and unambiguously recognise that (1) the feature was not explained as essential in the disclosure, (2) it is not, as such, indispensable for the function of the invention in the light of the technical problem it serves to solve, and (3) the replacement or removal requires no real modification of other features to compensate for the change. It was clear that this is applicable also to divisional applications and their disclosure in the corresponding parent application.

As to criterion (1), in the general part of the original description (see pages 2 and 3 of the parent

application: "Summary of the Invention") there is no mention of a vent hole, let alone its location in the first insulating substrate. Therefore criterion (1) was met.

For the discussion of criterion (2) the appellant has made reference to decisions T 260/85 and T 331/87, the latter, see point 6 of the Reasons, stating that "the feature in question may be inessential even if it was incidentally but consistently presented in combination with other features of the invention. Any replacement by another feature must, of course, be examined for support in the usual manner with regard to added matter". Whereas T 260/85 is related to a coaxial electrical connector assembly comprising "an air space dielectric (33)" which plays a role in the achievement of all but the first two of eight objects indicated in the description, in the application underlying T 331/87 claim 1 is directed to a machine tool punch process in which "...laser cutting head carried by the main frame..." was replaced by "... laser cutting head carried in fixed horizontal relationship to the frame. Therefore the "air space dielectric" could not be omitted, since it had a function, i.e. to achieve certain objects. In contrast to that "carried by the main frame" only represents an advantageous embodiment of the more general functional feature "horizontal fixing in relation to the main frame" which was essential to the solution of the problem, and its omission did not therefore contravene Article 123(2) EPC.

According to the appellant's interpretation, in the present case the particular location of the vent hole in the first insulating substrate had no function. It was the second opening in the second insulating

substrate, exposing the vent hole to ensure the functioning of the invention, which is related to improving the filling of the capillary chamber. Therefore the vent hole being in the first insulating substrate was not, as such, indispensable for the invention to work, i.e. to improve filling, in the light of the problem, i.e. to improve sensitivity and accuracy. Therefore condition (2) was satisfied.

Criterion (3) was also fulfilled since positioning the vent hole elsewhere, that is, other than in the first insulating substrate, would not require any real modification of other features to compensate for the change. No issue under EPC Article 84 or 83 would arise, if the vent hole was not to be provided in the first insulating substrate.

Therefore the feature related to the vent hole could be generalised without infringing Article 123(2) or 76(1) EPC in agreement with the mentioned decisions.

7. Discussion of T 331/87 (3 criteria) by the Board

The Board is of the opinion that it may not always be necessary, nor expedient, to apply the test employing the three criteria in a case which is as simple as the present one. When a concrete feature such as a vent hole is consistently and exclusively described as being provided in the first of two insulating substrates forming walls of a capillary chamber, the skilled person simply derives no other construction from that information, no matter if upon further reflection other constructive solutions were possible or even more advantageous. The Board notes in this context that, according to T 260/85 mentioned in T 331/87 and cited also by the appellant, "it is not permissible to delete

from an independent claim a feature which the application as originally filed consistently presents as being an essential feature, since this would constitute a violation of Article 123(2) EPC" (see the last sentence of the Reasons). But even if the cumbersome test employing the three criteria was employed, it does not show in the present case that the desired generalisation is justified.

8. Criterion (1)

According to the first criterion the feature which is intended to be generalised may not be explained as essential in the present application. Since there is no explanation at all in the original application documents of the function of the vent hole, it must be accepted this criterion is formally fulfilled, even if it cannot be denied that the feature "the first insulating substrate having a vent hole", being consistently defined as a common feature in all three independent claims 1 to 3 of the parent application directed to a biosensor test strip is thereby at least presented as important.

9. Criterion (2)

This criterion requires that the feature was not, as such, indispensable for the function of the invention in the light of the problem it serves to solve. The Board again notes that there is no discussion of the function of the vent hole and of its specific position in the description of the present divisional or parent application. The skilled person would nevertheless derive from the designation "vent hole" that in the context of the claimed biosensor a vent hole is related to a duct which ensures that gases such as air, or

vapour can escape from the test chamber, when the chamber is filled with the sample to be tested. Therefore the function of the vent hole must be seen in the context of the problem which is related to completely filling the chamber and thus ensuring a reliable measurement. In the Board's opinion, the fact that the function of the vent hole is not mentioned in the present application does not mean that it is completely irrelevant where it is placed. On the contrary its view is that the skilled reader would not envisage placing it somewhere else than indicated in the present application. In accordance with the embodiment shown in Figures 1 to 4 the vent hole 4 is created by a die punch in a manufacturing process, in which a plurality of vent holes are punched in a single step through a single sheet of insulating substrate material before separation of the individual test strips, see paragraph 0027, whereby the vent hole extends through the dried layer of test reagent 12 which is formed on the first insulating substrate. This arrangement would not be possible if the vent hole were formed in the roof 13. Incidentally, it is also noted that the originally filed description of both the present divisional and the parent applications explicitly disclose such mechanical punching as a potential source of cracking or breaking of the layer of dried reagent (see paragraph 0063), which is mitigated by the special reagent formulation defined in the fourth independent claim of the original parent application. In this sense, mechanical punching of the first insulating layer with its dried reagent as is required for formation of the vent hole in such layer is presented as inevitable. Hence, criterion (2) is not fulfilled.

10. Criterion (3)

As was set out in point 4 above, the only alternative which would be feasible was the arrangement of the vent hole in the roof. It is evident that it is more difficult to find a suitable location in view of the limited space available in the roof due to indentation 14, translucent window 18, hydrophilic coating 25 and reagent 12 and still have the vent hole exposed by the second opening 11 of the second insulating substrate 7. Therefore it seems very likely that appropriate modifications would have to be made in the roof-related features, thus infringing criterion (3).

11. Auxiliary requests

As claim 1 according to the main request, the versions of claim 1 according to any of the first to third auxiliary requests contain the feature that the test strip comprises a vent hole, the location of which is not limited to being in the first insulating substrate. Since it is evident that the other amendments in claim 1 according to these requests in addition to those of claim 1 according to the main request (see section V above) do not change the situation, similar objections under EPC Article 123(2) or 76(1) arise.

12. Conclusion

The Board considers that the subject-matter of claim 1 according to the main and auxiliary requests do not comply with the requirements of Articles 76(1) and 123(2) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

M. Kiehl

A. Klein

Decision electronically authenticated