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# Datasheet for the decision of 25 January 2007

**Case Number:** T 0906/05 - 3.3.08

**Application Number:** 99927176.0

**Publication Number:** 1102991

**IPC:** G01N 33/543

**Language of the proceedings:** EN

**Title of invention:**
Diagnostic assay requiring a small sample of biological fluid

**Patentee:**
ABBOTT LABORATORIES

**Opponent:**
Roche Diagnostics

**Headword:**
Test-strip/ABBOTT

**Relevant legal provisions:**
EPC Art. 54, 104(1)
EPC R. 57a

**Keyword:**
"Main and first auxiliary requests - Amendment occasioned by ground for opposition (no)"
"Second and third auxiliary requests - novelty (no)"

**Decisions cited:**
-

**Catchword:**
-

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**Case Number:** T 0906/05 - 3.3.08

# D E C I S I O N
**of the Technical Board of Appeal 3.3.08**
**of 25 January 2007**

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**Decision under appeal:**
**Interlocutory decision of the Opposition Division of the European Patent Office posted 27 May 2005 concerning maintenance of European patent No. 1102991 in amended form.**

**Composition of the Board:**

**Chairman:** L. Galligani
**Members:** P. Julià
C. Heath

## Summary of Facts and Submissions

I. European patent No. 1 102 991 was granted on the basis of European patent application No. 99 927 176.0 (published as WO 99/64620, to be referred to in the present decision as "the application as filed") and was opposed on the grounds of Article 100(a) EPC for lack of novelty and of inventive step (Articles 54 and 56 EPC).

II. The opposition division maintained the patent in amended form and further decided an apportionment of costs due to a belated filing of documents by the opponent which led to a second oral proceedings.

III. The opponent (appellant) lodged an appeal and filed the statement setting out the grounds of appeal in a letter dated 22 September 2005.

IV. In a letter dated 20 February 2006, the patentee (respondent) replied thereto.

V. With the summons to oral proceedings, the parties were sent a communication under Article 11(1) of the Rules of Procedure of the Boards of Appeal (RPBA), wherein they were informed of the board's preliminary opinion on the relevant issues.

VI. In letters dated 22 December 2006 and 12 January 2007, the appellant and the respondent replied, respectively, to the communication of the board. The respondent further introduced a new document (D15, *infra*) into the proceedings and filed a new main request and first, second and third auxiliary requests.

VII. In a letter dated 19 January 2007, the appellant filed further submissions.

VIII. Oral proceedings took place on 25 January 2007. During the oral proceedings, the respondent filed a new third auxiliary request in replacement of the previous third auxiliary request.

IX. Claims 1 and 12 of the **main request** read as follows:

"1. An article suitable for use in determining the presence or amount of analyte in a biological sample by means of optical reading, said article comprising a multiple-layer element comprising:

(a) a base layer having two major surfaces, said base layer further having an opening as sample application site, a flow channel, and an optical reading chamber, one end of which flow channel communicates with said opening in said base layer and the other end of which flow channel communicates with said optical reading chamber, wherein said opening communicates with the external environment of the multiple-layer element at a lateral edge surface of said base layer, and

(b) a cover layer in face-to-face contact with the major surface of said base layer containing said opening, said cover layer having an opening therein to vent said element, a vent channel being provided in said base layer having a first end that communicates with the optical reading chamber and a second end that communicates with said opening in the cover layer to vent said element."

"12. An article suitable for use in determining the presence or amount of analyte in a biological sample by means of optical reading, said article comprising a multiple-layer element comprising:

(a) a core layer having two major surfaces, said core layer further having an opening as sample application site, a flow channel, and an optical reading chamber, one end of which flow channel communicates with said opening in said core layer and the other end of which flow channel communicates with said optical reading chamber, wherein said opening communicates with the external environment of the multiple-layer element at a lateral edge surface of said core layer, and

(b) a base layer in face-to-face contact with one major surface of said core layer; and

(c) a cover layer in face-to-face contact with the other major surface of said core layer, said cover layer having an opening therein to vent said element, a vent channel being provided in said core layer having a first end that communicates with the optical reading chamber and a second end that communicates with said opening in the cover layer to vent said element."

Independent claim 13 of this request was essentially as claim 12 except for the part (c), which read as follows:

"(c) a cover layer in face-to-face contact with the other major surface of said core layer, said cover layer having an opening therein to vent said element,

wherein said vent opening is directly over said optical reading chamber."

The main request differed from the request on the basis of which the patent was maintained by the opposition division by the presence of claim 13 and by the additional reference to a vent channel at the end of claims 1(b) and 12(c) ("*a vent channel being provided ... to vent said element*").

X. Claims 1, 12 and 13 of the **first auxiliary request** read as claims 1, 12 and 13 of the main request with the added feature at the end of part (b) of claim 1 and part (c) of claims 12 and 13:

"..., *whereby the biological sample is introduced to the element and flows through the flow channel by means of capillary flow into the optical reading chamber.*"

XI. The **second auxiliary request** read as the main request except for the deletion of independent claim 13.

XII. Claims 1 and 11 of the **third auxiliary request**, filed at the oral proceedings before the board, read essentially as claims 1 and 12 of the first auxiliary request with the feature "*wherein said vent opening in the cover layer is not directly over said optical reading chamber*" (which was present in the other requests as a dependent claim) added in part (b) of claim 1 and part (c) of claim 11 just before the reference to "*whereby the biological sample...*" mentioned in Section X above for the first auxiliary request. The other claims of the third auxiliary

request read as the first auxiliary request except for the deletion of independent claim 13.

Claims 2 to 10 and claims 12 to 20 were, respectively, directed to specific embodiments of claims 1 and 11. Claims 21 to 25 and claims 26 to 30 were related to methods for measuring the concentration of analyte in a sample which used, respectively, the articles of claims 1 and 11.

XIII. The following documents are cited in the present decision:

D9: US-4 323 536 (publication date 6 April 1982);

D15: EP-B-0 803 288 (publication date of the application 29 October 1997).

XIV. The appellant's arguments insofar as relevant to the present proceedings may be summarized as follows:

*Main request and first auxiliary request*
*Rule 57a EPC*

No formal objection under Rule 57a EPC was raised. However, the subject-matter of claim 13 was considered not to be originally disclosed as such and was seen as unclear (Articles 123(2) and 84 EPC).

*Second auxiliary request*
*Articles 123(2) and 84 EPC*

Whereas embodiments of the invention were defined in Figures 3 to 9 by very specific structural features,

the claims failed to recite all of them. Although the dimensions of the flow and the vent channels were not defined in these figures, they were structurally distinguishable from the (cylindrical) optical reagent chamber. This structural limitation was not present in the claims and therefore, references to a "first" and a "second end" communicating with something that was structurally not defined were ambiguous and resulted in subject-matter originally not disclosed.

The figures of the application as filed showed only rectangular test-strips with sample application sites on a very specific position of the lateral edge surface, namely on the short side. The layers of these test-strips were all of identical size, i.e. none was shorter or longer than the other ones. However, the feature "lateral edge surface" had been introduced into the claims without any of these structural limitations and thus, resulted in embodiments that were not disclosed in the application as filed, such as rectangular test-strips with sample opening sites on the long side or on lateral edge surfaces of step-like (with layers of different size) test-strips, and thereby unclarity was also introduced as to the actual scope of the claims. Moreover, this feature did not exclude lateral edge surfaces from punched holes formed on the test-strip. The specific embodiments shown in the figures of the application as filed were not a valid basis for broad generalizations.

This was even more so since there was no indication of the function and advantages achieved by this feature in the description as filed. Nor were they directly derivable from the figures. However, according to the

established case law, references to a feature disclosed solely in the drawings were only allowable if the structure of this feature was shown sufficiently clear in the drawing and if the function achieved was derivable therefrom.

*Article 54 EPC*

The devices of document D15, in particular the ones shown in Figures 9 to 11 and 17, comprised all the features and structural elements recited in the claims, i.e. a multiple-layer element comprising an opening as sample application site (located at a lateral edge surface), an air vent opening (located in the cover layer), a flow and a vent channel and an optical reading chamber. In these devices the sample was drawn to the reading chamber first by capillarity (into a pooling portion) and then by suction pressure. However, no particular drawing force was required by the claimed subject-matter. Nor did the claims define the specific features that differentiated the devices shown in the figures of the patent in suit from the ones of document D15, in particular, the feature that the vent channel did not branch from the flow channel but directly (separate and distinct) communicated with the reading chamber. In the absence of these features, the claimed subject-matter comprised the devices disclosed in document D15.

*Third auxiliary request*
*Admissibility of the request into the proceedings*

The facts and objections raised under Articles 54 and 56 EPC, in particular with regard to document D9, were

not new to the respondent. Auxiliary requests intended to overcome these objections had to be filed earlier so as to allow discussion of added features. The feature introduced in the request at issue was never discussed before. Thus, the filing of this request at the oral proceedings was a late filing.

*Article 54 EPC*

Document D9 disclosed multi-analyte test devices with the same features as the claimed articles. The support and cover members corresponded to the base and cover layers of the patent in suit. The intermediate member, characterized as defining a plurality of inner cavities and a liquid transport zone, was an intermediate layer. This was derivable in particular from Figures 1 to 3 that showed this member to comprise corners (40) occupied by plastic spacers. Moreover, since the distance "s" shown in Figure 2 was of about 25 to 500 microns, the major surface of the intermediate member was the same as for the core layer of the patent in suit. Thus, the cover member of these devices were also in face-to-face contact with the major surface of the intermediate member. Standard methods for manufacturing these devices were known to use moulded layers having the desired form (cavities, holes, etc.).

There was no restriction to the size and dimensions of the different elements cited in the claims (flow and vent channel, optical reading chamber). Thus, they could occupy a large area of the base or core layer and thereby be in contact with the cover layer only at its very periphery. Figure 2 of the patent in suit showed the core layer to be, at certain positions, a very

narrow band (17). There was no technical difference between this core layer and the intermediate member of document D9.

Figures 1 to 6 and 8 of document D9 showed a vent opening and an access aperture (sample application site) in the cover layer. The document referred to two other possible arrangements. Although not shown, reference was made, in the context of Figure 7, to an arrangement having a vent opening in the cover layer and an access aperture in the intermediate member, i.e. "top-vent" and "end-fill" as the patent in suit. No selection was required to achieve this arrangement, which was explicitly disclosed as such as a possible alternative.

It made no technical sense to locate the vent opening in the light path used for analyzing the sample in the optical reading chamber. A vent opening between the light source and the optical reading chamber were known to interfere with an appropriate reading. Thus, the reference to a vent opening located almost at the edge of the liquid transport zone (Figure 7) was understood by the skilled person as requiring the vent opening not to be directly over the reading chamber. When light was applied to the test element of Figure 7 for analyzing the sample, the light path created a boundary that defined a reading chamber and a vent channel. If the light source was concentrated in a specific region of this test element so as to avoid any interference by the air vent opening, the reading was then performed in this region, which was thus the actual optical reading chamber, away from (not directly over) the vent opening. Light tolerance or propagation, if any, was known to the skilled person and, accordingly, measures were

easily to be provided. Besides, a similar propagation was also present in the claimed articles. In this respect, there was no structural definition in the claims characterizing the elements cited therein and therefore, no clear boundaries could be drawn among them, in particular between the optical reading chamber and the vent channel.

*Apportionment of costs*

According to the Guidelines for Examination, Part D, Chapter IX, point 1.4, an apportionment of costs was justified when costs were culpably incurred as a result of irresponsible or even malicious actions. Presently, this was not the case. It was only after receiving the summons to the oral proceedings and the preliminary opinion of the opposition division, that the patentee reacted by introducing an unexpected feature into the claims. This feature was exclusively found in the figures of the patent in suit and its introduction into the claims was thus not to be expected. The opponent was prompted thereby to carry out a search in the prior art. Relevant documents resulting from this search were produced without delay (shorter than the one granted normally for setting out the grounds of opposition) and introduced into the opposition proceedings before the oral proceedings. The fact that the claims had been amended at an earlier stage of these proceedings, namely after reply of the statement setting out the grounds of opposition, was irrelevant, since the features then introduced into the claims were clearly not allowable under Article 123(2) EPC. No irresponsible or, even less, malicious actions could be derived therefrom.

XV. The respondent's arguments insofar as relevant to the present proceedings may be summarized as follows:

*Main request and first auxiliary request*
*Rule 57a EPC*

Claim 12 of these requests had been amended by introducing a reference to a vent channel in order to overcome lack of novelty (a ground of opposition) over document D15. This claim covered the embodiments of Figures 3 to 9 characterized by the presence of a vent channel. This feature, however, was absent in the embodiments shown in Figures 1 and 2. Therefore, the amendment of claim 12 made necessary to introduce a new independent claim, namely claim 13, covering the embodiments shown in Figures 1 and 2. Thus, claim 13 was the result of an amendment introduced for overcoming a ground of opposition.

*Second auxiliary request*
*Articles 123(2) and 84 EPC*

Article 84 EPC was not a ground of opposition and objections of lack of clarity could be raised only against the amendments. References to a vent channel were found in the granted (dependent) claims. The features introduced into the claims "a first end" and "a second end" reflected only the embodiments shown in Figures 3 to 9. There was no need to restrict the claims by reciting all the structural features derivable from those figures, since in the light of the description as a whole, the structural elements cited in the claims (flow and vent channel, optical reading

chamber, etc) were functionally defined in a clear manner.

Moreover, the disclosure of the application as filed was not limited to the embodiments illustrated in the figures. Neither the figures nor the description excluded a sample application site on the long (lateral edge) side of a rectangular test-strip. The feature "lateral edge surface" had a clear meaning for the skilled person, which was also based on the figures, namely the edge surface at the perimeter of the test-strip layer. This "edge" could not be arbitrarily interpreted as including the edges of a punched hole formed on the test-strip, since it was qualified as being "lateral" and as being on a surface of a specific (base or core) layer. This latter requirement excluded lateral edge surfaces of step-like (i.e. with layers of different size) test-strips and avoided any unclarity as regards the scope of protection of the claims.

The function of an opening as a sample application site was clearly disclosed in the application as filed and indicated in the figures, which showed a specific arrangement of this site and the vent opening. The claimed structure with this specific arrangement had several advantages for which evidence had been provided after the filing date of the application. This was in line with the established case law that allowed the submission of tests supporting advantages of a claimed subject-matter even after the filing date.

*Article 54 EPC*

Figure 1 of document D15 showed a device comprising a sample application site, a flow channel and a reading chamber. The device had a suction pressure generating means that, by first applying pressure on the cover layer and then releasing it, generated suction pressure and forced the sample to enter the channel and to be drawn into the reading chamber. Figures 9 to 11 and Figure 17 showed the same device with a vent channel, which branched from the flow channel upstream of the reading chamber, and a vent end opened to the outside of the device through the cover layer. The vent channel was used to draw the sample into a pooling portion of this device by capillarity. Even if the drawing of the sample occurred by capillarity, the sample required a pressure to be simultaneously applied by the suction pressure generating means, which also subsequently carried out forcefully the feeding and filling in of the reading chamber.

Neither the structure nor the subsequent functionality of these devices anticipated the claimed subject-matter. In the patent in suit, the vent opening communicated with the optical reading chamber, either directly (Figures 1 and 2) or through a vent channel (Figures 3 to 9) that had an end communicating with the reading chamber, and wherein the vent opening and vent channel constituted the actual driving force (capillarity) for filling the reading chamber with the sample. In document D15, the vent channel did not communicate with the reading chamber but branched from the flow channel. The driving force was not capillarity developed by the vent opening and vent channel but, instead, suction

pressure. The devices of document D15 could not achieve analysis of small volumes of samples as those achievable with the ones claimed in the patent in suit, since the latter could have a smaller (shorter, narrower) flow channel.

*Third auxiliary request*
*Admissibility of the request into the proceedings*

This request was essentially the same as the third auxiliary request filed within the time limit set out by the board in its communication under Article 11(1) RPBA. It only differed therefrom by the introduction of the subject-matter of a dependent claim into the independent claims so as to overcome an objection under Article 54 EPC that was raised for the first time at the oral proceedings. This amendment could not surprise the appellant and its introduction was in line with the case law of the Boards of Appeal.

*Article 54 EPC*

The claimed subject-matter and the devices of document D9 had a different purpose, which for these latter devices (analysis of a plurality of analytes in a liquid sample avoiding contamination between the various test elements) required a more complex structure. Several features rendered these devices different from the claimed ones. In particular, there was no face-to-face contact between the major surfaces of the core layer and the cover layer, since they were sealed only at their peripheries by an intermediate member that create a unique open chamber. The core layer was in fact a broad void chamber delimited only

laterally by peripheric walls (intermediate member) acting as spacers between the base and the cover layer. The major surface of this intermediate member was the vertical surface. Thus, contrary to the patent in suit, this intermediate member was not a layer. The broad void chamber did not allow for the presence of a flow and a vent channel communicating with a reading chamber. In fact, there was no reference to a vent channel in document D9, nor was this channel depicted in any of the figures of the document. None of the advantages mentioned in the patent in suit and obtained by the presence of a vent channel was suggested in document D9.

Figure 7 of document D9 showed a preferred arrangement having an air vent opening (50b) and an access aperture (46b) in the cover member (14b). This arrangement was the only one shown in all other figures. Nevertheless, there was a hint to other arrangements, which were however not shown, such as an air vent opening (100) in the intermediate member (20b). One alternative had an access aperture in the intermediate member (20b). However, there was no suggestion as to the position of the vent opening for this alternative. The claimed arrangement was at most the result of a selection among several alternatives mentioned in document D9. Thus, it was not directly and unambiguously derivable from this document.

The claims further required the vent opening not to be directly over the optical reading chamber, i.e. having an off-set position from the reading chamber. This feature was not arbitrarily chosen since it provided several advantages. However, it was not even suggested in document D9. There was nothing in this document to

support the interpretation that the reference to the vent opening as being at the edge of the cover layer was to be understood as requiring the vent opening not to be directly over the optical reading chamber. On the contrary, the figures of document D9 always showed the vent opening directly over the reading chamber. In particular in the device of Figure 7, light was to be applied through the test element (30b), which was located just below the vent opening (50b). Even if the light source was concentrated in a small area of this test element (away from the vent opening), there were no means to avoid its propagation through the whole inner cavity or broad chamber, which was thus the actual optical reading chamber. Therefore, the vent opening was always directly over the reading chamber.

*Apportionment of costs*

As a reply to the statement setting out the grounds of opposition and thus, at the beginning of the opposition proceedings, claims were filed that intended to cover a feature from the figures. Although the opposition division disagreed with the way the feature was drafted, the nature of this feature was evident from the beginning of the opposition proceedings. Therefore, a search in the prior art, if necessary, could have been carried out at that early stage. Relevant documents, if any, resulting from this search would have been available at a much earlier stage of the opposition proceedings without incurring unnecessary costs originated from their delayed introduction.

XVI. The appellant (opponent) requested that the decision under appeal be set aside and the patent revoked. The

appellant further requested to cancel the decision of the opposition division on the apportionment of costs.

XVII. The respondent (patentee) requested that the decision under appeal be set aside and the patent be maintained on the basis of the main request or the first, or second, all filed on 12 January 2007 or third auxiliary request filed during the oral proceedings. The respondent further requested to maintain the decision of the opposition division on the apportionment of costs.

## Reasons for the Decision

*Main request and first auxiliary request*
*Rule 57a EPC*

1. The figures of the patent in suit illustrate two different embodiments: a first one shown in Figures 1 and 2 and a second one shown in Figures 3 to 9. These embodiments have structural differences, notably in the absence (Figures 1 and 2) or the presence (Figures 3 to 9) of a vent channel and in the position of the vent opening with respect to the open reading chamber.

2. The granted claims comprise two independent claims directed to two articles, namely an article comprising a bi-layer (base and cover) element (claim 1) and an article comprising a three-layer (core, base and cover) element (claim 13). There is no reference in these claims to a vent channel or to the position of the vent opening. It is only in the dependent claims that reference is made to the presence of a vent channel

(claims 7 and 19, "*wherein said second opening communicates with a vent channel*") and to the position of the vent opening (claims 12 and 24, *"wherein said second opening is* ***not directly over*** *said optical reading chamber*") (in bold by the board), these claims being directly dependent on claims 1 (claims 7 and 12) and 13 (claims 19 and 24). The granted independent claims are thus generically drafted comprising several possible arrangements, which might - or might not - comprise the two specific embodiments shown in the figures of the patent in suit. However, there is no independent claim directly related to these two embodiments.

3. According to the respondent, independent claims 12 and 13 of the requests at issue cover only those two specific embodiments and they have been introduced so as to overcome a ground of opposition. In the respondent's view, claim 13, which comprises the feature "*wherein said vent opening is* ***directly over*** *said optical reading chamber*" (in bold by the board), covers the embodiment of Figures 1 and 2, whereas claim 12, which refers to "*a vent channel*" that communicates the optical reading chamber with the vent opening, covers the one of Figures 3 to 9 (cf. Section XV *supra*).

4. On the one hand, however, independent claim 12 of these requests is completely silent on the position of the vent opening and it is only dependent claim 23 that requires it to be "***not directly over*** *said optical reading chamber*" (in bold by the board). Thus, claim 12 is still a generically drafted claim that comprises different arrangements and it is not clearly limited to

the embodiments of Figures 3 to 9. On the other hand, the specific subject-matter of claim 13 is not found in any of the claims as granted nor in the claims as originally filed and thus, it was neither the subject of substantive examination in the examination procedure nor open to opposition owing to its non-existence in the granted patent. Contrary to the respondent's view, it is arguable whether claim 13 is clearly and exclusively restricted to the embodiment of Figures 1 and 2 (Article 84 EPC) or else whether it comprises further subject-matter that might even include embodiments not disclosed in the application as filed (Article 123(2) EPC) (cf. point 24 *infra*).

5. The introduction of these two independent claims, in particular of claim 13, is seen as an attempt to improve the original disclosure, which is not specifically necessitated by the grounds advanced for the opposition. Therefore, both the main request and the first auxiliary request contravene Rule 57a EPC.

*Second auxiliary request*
*Articles 123(2),(3) and 84 EPC*

6. The indication of the position of the sample application site (at a lateral edge surface) represents a limitation when compared to the granted claims. The introduction of subject-matter of a dependent claim (a vent channel) in the independent claims represents a further limitation as well. Thus, the requirements of Article 123(3) EPC are fulfilled.

7. In the absence of a structural characterization of all the elements comprised in the multiple-layer element

(optical reading chamber, vent and flow channel), the references to a "first end" and a "second end" of a vent channel have been objected for lack of clarity (cf. Section XIV *supra*). Although granted claims 7 and 19 refer to a vent channel that communicates with a vent opening, there is no reference to the "ends" of this channel in these claims. The same wording is found however in the context of the flow channel in granted claims 1 and 13, namely "*one **end** of which flow channel communicates with ... and the other **end** of which flow channel communicates with*" (in bold by the board). This flow channel communicates with two elements, namely the sample application site and the optical reading chamber, for which there is no further structural definition in the claims. Nor is there any further characterization for said flow channel or for the cited "ends". Since the wording used in the amendments is identical to the one already present in the granted claims (although for a different channel), an objection under Article 84 EPC is considered not to be pertinent. It is noted, however, that the absence of structural definitions for all these elements might well have - and in fact has - consequences for the assessment of novelty (cf. *infra*).

8. There is no formal support in the description of the application as filed for the wording "lateral edge surface". This support is provided only by the figures of the application as filed. In the appellant's view, this support does not meet the conditions set out in the established case law of the Boards of Appeal and the introduction of this feature results both in added subject-matter and a lack of clarity (Articles 123(2) and 84 EPC) (cf. Section XIV *supra*).

9. It is established case law that a skilled person, when considering a claim, should try to arrive at an interpretation of the claim which is technically sensible and takes into account the whole disclosure of the patent (cf. "Case Law of the Boards of Appeal of the EPO", 5th edition 2006, II.B.5.1, page 205). Appellant's interpretation of the feature "lateral edge surface" as including the edge surface of punched holes formed on the multiple-layer element does not take into account the whole disclosure of the patent. The presence of the term "lateral" in this feature cannot be ignored and, in the light of the whole disclosure, is clearly understood as indicating that the edge surface must be on the side of this multiple-layer element, i.e. in its perimeter, and excluding edge surfaces in the middle of said multiple-layer element. This is even more so since the feature "lateral edge surface" is directly related to a specific function, namely the application of a sample, and structurally constrained to a specific (base, core) layer. Thus, this feature reflects only the structural arrangement shown in the figures of the patent.

10. Although Figures 1 and 2 only show rectangular multiple-layer elements and Figures 3 to 9 partial illustrations thereof, neither the application nor the claims as filed contain any limitation as regards the specific shape of these elements. Nor is there any limitation on the position of the sample application site, even though this opening is always shown on the shorter side of the lateral edge surface of these rectangular elements. There is no indication in the figures nor in the application as filed that these two features are directly linked in such a manner that the

presence of one (rectangular shape) necessarily requires the presence of the other one (application site on the shorter side). In the absence of such indication, the introduction into a generic claim of only one of these features (sample application site at a lateral edge surface) cannot be seen as introducing added subject-matter (Article 123(2) EPC).

11. In this sense too, the independent claims of the request at issue and the corresponding granted claims are both generically drafted claims and thus, they both might well cover the step-like test-strips referred to by the appellant (cf. Section XIV *supra*). In fact, appellant's objection raised under Article 84 EPC concerning the scope of the claims is not directly related to the amendments introduced into the claims, since it could also be raised for the generic claims as granted. In line with the established case law of the Boards of Appeal (cf. "Case Law", *supra*, VII.C.6.2, page 575), this objection is thus not to be considered.

12. It is also arguable whether or not, in the absence of an explicit disclosure in the application as filed, the advantages achieved by the introduced feature (sample application site at the lateral edge surface) would be immediately evident to the skilled person. However, although this question might be relevant for assessing the requirements of Article 56 EPC, it has no bearing for the assessment of Article 123(2) EPC since, in the present case, there is a formal support for this feature clearly derivable from the figures of the application as filed.

13. Thus, the requirements of Articles 123(2) and 84 EPC are considered to be fulfilled.

*Article 54 EPC*

14. Figures 9 to 11 of document D15 (N.B. The B specification has been referred to in these proceedings. However, these figures and the corresponding description are found identically in the A specification) disclose a multi-layer element that comprises the same elements as the claimed subject-matter, in particular a core layer having an opening as sample application site (4), a flow channel (2) and an optical reading chamber (3), wherein one end of this flow channel communicates with the opening and the other end with the optical reading chamber and, wherein the sample application site communicates with the external environment at a lateral edge surface of the core layer. A cover layer, which is in face-to-face contact with the core layer, has a vent opening (26) that communicates with a vent channel (25) provided in the core layer. Figures 9 to 11 show this vent channel to branch out directly from the flow channel and not, as in the figures of the patent in suit, directly from the optical reading chamber. However, this technical difference is not reflected in the claims at issue which only refer to "*a vent channel ... having a first end that communicates with the optical reading chamber*" (cf. Sections IX and XI *supra*). Although the vent channel is thus required to communicate with the reading chamber, there is no additional limitation as regards the type and nature of this communication.

15. In accordance with the established case law, when novelty is assessed, there is no reason for using the description to interpret an excessively broad claim more narrowly if it is a question not of understanding concepts that require explanation but rather of examining an excessively broad request in relation to the state of the art (cf. "Case Law", *supra*, I.C.2.9, page 78). In the present case, there is no doubt that the vent channel shown in Figures 9 to 11 of document D15 communicates with the reading chamber, albeit through a flow channel and not directly therewith. However, no requirement for a direct communication is found in the claims at issue, which thus comprise the devices of document D15 as well.

16. Likewise, there is no limitation in the claimed subject-matter as regards the type and nature of driving force required for drawing the sample into the reading chamber nor on the size of the different elements defined in the claims (flow and vent channel, reading chamber). Therefore, in line with the established case law, the presence of suction pressure means or the size of the sample to be applied are not relevant features for the assessment of novelty.

17. Thus, the claimed subject-matter does not fulfil the requirements of Article 54 EPC.

*Third auxiliary request*
*Admissibility of the request into the proceedings*

18. In reply to the board's communication under Article 11(1) RPBA, the respondent filed a new main request and first, second and third auxiliary requests

(cf. Section VI *supra*). This third auxiliary request was withdrawn during the oral proceedings and a new third auxiliary request was filed. This new third auxiliary request is identical to the previous one except for the introduction into the independent claims of a feature that, in the previous third auxiliary request, was present only in the dependent claims (cf. Section XII *supra*). This feature intends to overcome a novelty objection raised at the oral proceedings. In the board's judgement, the amendment does not give rise to fresh subject-matter (Article 10b(3) RPBA) and, in line with the established case law (cf. "Case Law", *supra*, VII.D.14.2, page 641), the board, in exercising its discretion under Article 114(2) EPC, decided to admit it into the proceedings (Article 10b(1) RPBA).

*Articles 123(2),(3) and 84 EPC*

19. The appellant raised under these articles the same objections as against the second auxiliary request. The same reasons given in points 6 to 13 *supra* apply here and thus this request, as the second auxiliary request, is considered to fulfil the requirements of these articles.

*Article 54 EPC*

20. The claimed subject-matter comprises a multiple-layer element with several layers containing different elements, in particular a flow and a vent channel and an optical reading chamber. Although the properties of these layers as well as the ones of these elements are disclosed in detail in the patent in suit, they are described as being "*not critical*" and representing only

"*preferred embodiments*" (cf. paragraphs [0024] to [0031]). None of these properties is required by the claims and therefore, in line with the case law (cf. point 15 *supra*), they cannot be read into the claims. Thus, in a broad interpretation, the optical reading chamber might extend over a large area of the core or base layer or else it might well have the very same dimensions as the flow and the vent channel. In this latter case, the core or base layer contains only a simple capillary channel, the optical reading chamber being defined by the region into which the light source is applied and the actual reading of the sample takes place.

21. Document D9 discloses multi-analyte test devices based on a capillary flow which comprise different members, in particular a support (12), a cover (14) and a spacer or intermediate member (20) (cf. *inter alia* Figures 1 to 3, column 2, lines 22 to 33 and column 3, lines 13 to 23). In the respondent's view, three features distinguish these devices from the claimed ones, namely: (i) the intermediate member is not a layer and therefore, there is no face-to-face contact of its main surface with the cover layer; (ii) there is no disclosure of a sample application site at the lateral edge surface of these devices (end-fill) and a vent opening in the cover layer (top-vent), and (iii) there is in fact no disclosure of a vent channel and the vent opening is located directly over the optical reading chamber (cf. Section XV *supra*).

22. The members of document D9 are non-fibrous plastics (cf. column 5, lines 46 to 49) and, accordingly to the figures of this document, they all have a similar

thickness, which is within the range indicated for the capillary flow path ("s"), i.e. "*between about 25 microns and about 500 microns*" (cf. column 3, lines 35 to 42). This range embraces the preferred thickness of the base (0.1 mm), cover (0.1 mm) and core (0.3 mm) layers as referred to in the patent in suit (cf. paragraph [0024]). The intermediate member, as the core layer of the patent in suit, might comprise narrow bands limiting the reaction chamber (cf. Figure 2 of the patent in suit for comparison) as well as large surfaces (cf. the corners (40) of Figure 1, column 3, lines 32 to 34 of document D9), all of them in face-to-face contact with the cover and the support member. Document D9 further identifies prior art concerned with test strips as constituting relevant state of the art (cf. column 1, lines 49 to 52) and methods for manufacturing those test strips using moulded (non-fibrous) plastic layers are standard in the prior art as evidenced by documents on file.

23. Except for Figure 7, all figures of document D9 show the sample application site (46, 46a, 46b) and the vent opening (50, 50a, 50b) in the cover member. Figure 7 shows however other possible alternative arrangements, in particular one with the vent opening (100) in the intermediate member (cf. column 7, lines 41 to 44). Reference is also made to still another alternative with the sample application site in the intermediate member (cf. column 7, lines 47 to 49). Even though for this latter arrangement, there is no indication as regards the position of the vent opening, only two positions come into consideration, either in the cover member or else in the intermediate member. No selection is required for any of these two possible arrangements,

since both are implicitly disclosed in this document. In particular, the former arrangement, which has the vent opening in the preferred position, i.e. in the cover member as exemplified in all figures, corresponds to an "end-fill" and "top-vent" arrangement.

24. Document D9 emphasizes that "*vent apertures 50 are formed in cover member 14* ***almost at the edge*** *of zone 38 as defined by intermediate member 20*" and "*a vent aperture 50b is located* ***at an end*** *of each of test element*" (in bold by the board) in the context, respectively, of Figure 2 and Figures 6 to 8 (cf. column 4, lines 1 to 3 and column 6, lines 49 to 52). The requirement to have the vent opening in the cover member at the very edge or at the end of the capillary flow path immediately conveys to the skilled person the additional information that it is advantageous, if not necessary, to have this opening away from the test element or reading zone so as not to have any interference or disturbance in the reading of the sample. Indeed, this only reflects what is already known by the skilled person as shown by the fact that there is no prior art on file having the vent opening directly over the reading chamber. In this regard, it is arguable whether or not the vent opening shown in Figures 1 and 2 of the patent in suit is actually directly over the reading chamber, since it is only slightly shifted or skewed towards this chamber, i.e. partially off-set over the chamber (cf. point 4 *supra*).

25. The devices of document D9 comprise test elements (30, 32, 34, 36 in Figures 1 to 3) with one or more reagent layers (54, 56 in Figure 2) (cf. column 4, lines 31 to 45). The instruments used to separately read each of

these elements are adapted through the use of filters and means so as to index the scanning beam to each test element (cf. column 5, lines 31 to 45). In line with the reasoning of point 24 above, the scanning beam is thus indexed or directed away from the vent opening. In doing so, the scanning beam not only defines an optical reading chamber in the sense of the patent in suit, i.e. the region into which the light source is applied and the actual reading takes place, but it further defines a region next to this reading chamber and directly underneath the vent opening, which corresponds to a vent channel as also defined in the patent in suit. Thus, there are no technical differences between the elements (optical reading chamber, flow and vent channels) of the devices of document D9 and the ones of the claimed subject-matter in its broadest interpretation (cf. point 20 *supra*). In this respect, the problems put forward by the respondent as regards the possible propagation of the light (scanning beam) through the vent channel are shared by both devices and no particular feature (length of the vent channel, shape of the reading chamber, etc.) is present in the claims for its avoidance or prevention.

26. From all the foregoing, it is concluded that none of the three features mentioned by the respondent distinguish the claimed subject-matter from the devices of document D9 and therefore, the request at issue is considered not to be novel (Article 54 EPC).

*Apportionment of costs*

27. The introduction of features taken from the dependent claims or from the description into the independent

claims so as to overcome objections raised during opposition proceedings is a normal amendment in those proceedings. Accordingly, the opponent is expected to react to these amendments, just as the patentee is expected to react to the submission of new relevant prior art or new lines of argumentation within the time limits set out in the EPC. In both cases, and, under certain circumstances, it might well be reasonable to request an extension of a given time limit or even, if summoned, postponement of oral proceedings. It is then within the discretion of the corresponding instance to decide whether or not it is appropriate to grant such a request. In any case, it is always recommended to a party to prepare its case as completely as possible and not to disregard other objections for a claim which is believed not to be formally allowable under Article 123(2) EPC.

28. In the present case, at the beginning of the opposition proceedings, the patentee on 28 January 2004 reacted to the opponent's grounds of opposition by filing an amended set of claims which intended to cover an "end-fill" and "top-vent" arrangement. Although the claims were further amended on 26 July 2004, after the summons to oral proceedings had been issued on 3 May 2004 by the opposition division and its preliminary opinion communicated to the parties, these later amendments were intended only to find an appropriate drafting for the same arrangement. No request for extension of time limits, let alone for a postponement of the oral proceedings, were ever made by the opponent, neither before nor after knowing the preliminary opinion of the opposition division. It was only on 23 September 2004, i.e. six days before the scheduled

date for the oral proceedings on 29 September 2004, that four new documents were filed by the opponent. These documents were considered to be *prima facie* relevant by the opposition division, and, upon request of the patentee, the opposition division decided to adjourn these oral proceedings.

29. As the opponent failed to request an extension of time, the argument for the lateness in filing the four documents, i.e. the short time available for preparing the case and for carrying out a complete search in the prior art, is not convincing to the board. All the more so, since the relevant feature, although different in wording, was already introduced at the beginning of the opposition proceedings. The fact that the opponent considered this feature to contravene Article 123(2) EPC could not, even if acknowledged in a preliminary opinion, guarantee that the opposition division would share the opponent's view. On the contrary, as it happened in the present case, this feature was allowable under Article 123(2) EPC, and it was thus necessary to assess patentability under Articles 54 and 56 EPC. It was the opponent's responsibility to properly prepare its case for an argument of novelty and inventive step. Only the failure to do so in due time made a postponement of the proceedings necessary.

30. The board thus does not see any reason to differ from the decision under appeal on this issue and thus to set aside the corresponding order.

## Order

**For these reasons it is decided that:**

1. The decision under appeal is set aside but for the order on the apportionment of costs.

2. The patent is revoked.

The Registrar: The Chairman:

A. Wolinski L. Galligani