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**D E C I S I O N**  
**of 1 March 2005**

**Case Number:** T 0039/04 - 3.3.8

**Application Number:** 95934497.9

**Publication Number:** 0779983

**IPC:** G01N 33/52

**Language of the proceedings:** EN

**Title of invention:**

Optically readable strip for analyte detection having on-strip orientation index

**Patentee:**

LIFESCAN, INC.

**Opponent:**

Roche Diagnostics GmbH

**Headword:**

Readable strip/LIFESCAN

**Relevant legal provisions:**

EPC Art. 54, 56, 84, 123(2)(3)

**Keyword:**

"Main request: clarity (no)"  
"Auxiliary request: added matter (no)"  
"Clarity (yes)"  
"Novelty (yes)"  
"Inventive step (yes)"

**Decisions cited:**

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**Catchword:**

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Case Number: T 0039/04 - 3.3.8

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.8  
of 1 March 2005

**Appellant:** LIFESCAN, INC.  
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**Decision under appeal:** Decision of the Opposition Division of the  
European Patent Office posted 30 May 2003  
revoking European patent No. 0779983 pursuant  
to Article 102(1) EPC.

**Composition of the Board:**

**Chairman:** L. Galligani  
**Members:** T. J. H. Mennessier  
S. C. Perryman

## Summary of Facts and Submissions

- I. The patent proprietor (appellant) lodged an appeal against the decision of the opposition division, given at oral proceedings on 30 April 2003, with written reasons posted on 30 May 2003, whereby European patent 0 779 983 granted on European application No. 95 934 497.9 (published as international application WO 96/07907) was revoked. Basis for the revocation were the main request of 17 April 2003 and the first auxiliary claim request of 30 April 2003.
- II. The patent had been opposed by one opponent (respondent) on the grounds as set forth in Article 100(a) EPC that the invention was not new and did not involve an inventive step.
- III. Reasons for the revocation were as follows: (i) as regards the main request (claim 5): presence of added matter (Article 123(2) EPC), extension of the scope of protection (Article 123(3) EPC) and lack of clarity (Article 84 EPC), and (ii) as regards the auxiliary request (claims 1, 5 and 10): lack of inventive step over document RD1 in combination with document RD8 (Article 56 EPC).
- IV. Together with its statement of grounds, the appellant filed a new main request and three new auxiliary requests.
- V. In reply to that statement the respondent filed observations and cited three new documents, namely documents RD9 (see Section X, *infra*), RD10 and RD11.

VI. Then, the Board issued a communication under Article 11(1) RPBA containing preliminary and non-binding opinions. In reply to that communication the opponent filed observations and the appellant filed a new main request with a letter dated 3 December 2004. The respondent objected to said claims with a letter of 20 December 2004 and the appellant filed an amended version of the main request with a letter of 31 January 2005.

VII. Oral proceedings took place on 1 March 2005 at which the appellant filed a new auxiliary request to replace the former auxiliary requests.

VIII. The **main request** consisted of five claims of which claim 5 read:

"5. A method for determining that a test strip (46/62) of claim 1 or claim 3 has been properly oriented in an apparatus (12) of claim 4 for determining the presence or quantity of an analyte in a liquid applied to said strip and inserted into said apparatus (12), said method comprising:

(a) applying a liquid sample to the overlying transport medium (50) of the test strip (46/62) according to claim 1 or claim 3;

(b) inserting said strip into said apparatus;

(c) determining the reflectance of the major surface (43/66) of the strip (46/62) by directing light at a fixed position in the pathway of the strip as it is inserted and detecting the reflected light;

(d) detecting the presence or absence of reflected light corresponding to the passage of said orientation

index zone (58/76) past said fixed position as the strip is inserted into said passageway (26); and (e) providing the presence of the orientation index zone (58/76) is detected in step (d), determining the presence or quantity of the analyte in the liquid sample, wherein the presence and/or quantity of the analyte is calculated as a function of the standard zone reflectance and the reaction zone reflectance."

IX. The **auxiliary request** also consisted of five claims and was different from the main request only in respect of page 4 which contained the last part of claim 5.

Claim 1 read:

"1. A test strip (46) for determining the presence or quantity of an analyte in a liquid by inserting said test strip (46) into an optical reading apparatus (12); said test strip (46) comprising:  
an elongate and generally rectangular support (47) onto which is attached a test pad (48) containing reactants and an overlying transport medium (50) for having liquid applied thereto, wherein a support aperture (52) is provided through the support (47), such that a portion of the bottom of the surface of the test pad (48) provides an optically visible area on a major surface (43) of the strip, the optically visible area defining a reaction zone (54), the reaction zone (54) being longitudinally placed between the leading edge (56) of the strip and the opposite edge, such reaction zone (54) varying in reflectance as a function of the quantity of analyte in the applied liquid;  
said test strip further comprising an optically visible area on said major surface (43) defining an orientation

index zone (58), said orientation index zone (58) being located at the extreme leading portion of the major surface (43), said orientation index zone (58) having a low reflectance relative to that of the area of the major surface contiguous (43) to the orientation index zone (58), characterized in that there is a single orientation index zone (58), said orientation index zone (58) being positioned to lead said reaction zone (54) as said strip (46) is inserted into said apparatus (12), said orientation index zone (58) having a length, in the direction of insertion, of from 0.125 to 1 cm (0.05 to 0.4 inches);

wherein the area of the major surface (43) leading the reaction zone (54), other than the orientation index zone (58), exhibits high relative reflectance and serves as a standard zone; and

wherein the reflectance of said contiguous area is at least 1.5 times the reflectance of said orientation index zone (58)."

Claim 2 was dependent on claim 1 and was directed to a specific embodiment of the test strip according to claim 1.

Claim 3 read:

"3. A test strip (62) for determining the presence or quantity of an analyte in a liquid by inserting said test strip (62) into an optical reading apparatus (12); said test strip (62) comprising:

a support (64) having a major surface (66) with an aperture (68) therethrough for viewing a reaction zone (70) of a test pad (72) provided with a transfer medium (74) for having liquid applied thereto, such that a

portion of the bottom of the surface of the test pad (72) provides an optically visible area on a major surface (66) of the strip, the optically visible area defining a reaction zone (70), such reaction zone (70) varying in reflectance as a function of the quantity of analyte in the applied liquid;

said test strip further comprising an area on said major surface (66) defining an orientation index zone (76), said orientation index zone (76) being located on the leading portion of the major surface (66) adjacent to the aperture (68), said orientation index zone (76) having a low reflectance relative to that of the area of the major surface (66) contiguous to the orientation index zone (76), characterized in that there is a single orientation index zone (76), said orientation index zone (76) being positioned to lead said reaction zone (70) as said strip (62) is inserted into said apparatus (12), and said orientation index zone (76) having a length, in the direction of insertion, of from 0.125 to 1 cm (0.05 to 0.4 inches);

wherein the area of the major surface (66) leading the reaction zone (70), other than the orientation index zone (76), exhibits high relative reflectance and serves as a standard zone; and

wherein the reflectance of said orientation index zone (76) is no more than two thirds of the reflectance of the contiguous portion of the major surface (66)."

Claim 4 read:

"4. An apparatus (12) for determining the presence or quantity of an analyte in a liquid applied to a test strip of claim 1 or claim 3 and inserted into said apparatus (12), said apparatus comprising:

a strip holder (16) comprised of an upper guide (22) and a lower guide (24) which together form a longitudinally extending strip passageway (26) having an open end (14) for receiving said strip (10) and an opposed end (31), wherein the passageway (26) is canted at an angle with respect to the plane of the bottom (28) of the apparatus (12) so as to facilitate the insertion of the test strip (10) into the apparatus (12) when the apparatus (12) is sitting on a flat surface; wherein the lower guide (24) is provided with an aperture (30) through which the bottom surface (11) of the test strip (10) can be seen by the optics located below the lower guide (24), the aperture (30) being positioned along the lower guide (24) such that the bottom surface of the reaction zone (54/70) of the test strip (10) is visible when the test strip (10) is fully inserted into the passageway (26); wherein a bias means (40) is incorporated into the upper guide (22) which is adapted to be biased toward the upper surface (42) of the lower guide (24) in the area of the aperture (30) so as to ensure that the portion of the strip (10) lying over the aperture (30) is flat and presents an optically consistent surface to the optics; optics located in an optic block (32) affixed to the apparatus (12) comprising a light source for directing light through aperture (30) into said passageway (26) at a position between said open end (14) and said opposed end (31); and a light detector (38) for detecting light reflected from said passageway (26), and for converting said detected reflected light into a signal; and



microprocessing means for receiving said signal to detect the presence or absence of the orientation index zone in the passageway (26); wherein the same optics are used sequentially to determine the reflectance value of the major leading surface of the test strip (10) as the test strip (10) is being inserted into the optical reading apparatus (12) such that the reflectance value of the standard zone is determined; the presence or absence of the orientation index zone (58/76) on the major surface (43/66) of the test strip (46/62) is detected; and the reflectance value of the reaction zone (54/70) is read once the strip is fully inserted into the strip passageway (26); and wherein the presence and/or quantity of the analyte is calculated as a function of the standard zone reflectance and the reaction zone reflectance."

Claim 5 differed from claim 5 of the main request only in that step (e) had been deleted therefrom.

X. The following documents are referred to in the present decision:

(RD1) EP-A-0 492 326 (published on 1 July 1992)

(RD2) EP-A-0 405 513 (published on 2 January 1991)

(RD3) EP-A-0 594 108 (published on 27 April 1994)

(RD4) US-A-4,876,204 (published on 24 October 1989)

(RD5) Urotron® RL9 Benutzer-Handbuch, a cover sheet bearing the phrase "Ausgabe 8/87" having been submitted at the oral proceedings on 1 March 2005

(RD6) US-A-4,279,514 (published on 21 July 1981)

(RD6b) B. K. Sojka, Med. Labor., Vol. 33(4), 1980, Pages 93 to 101

(RD8) US-A-3,907,503 (published on 23 September 1975)

(RD9) US-A-5,304,468 (published on 19 April 1994)

XI. The submissions made by the appellant (patentee), insofar as they are relevant to the present decision, may be summarised as follows:

Procedural matters

The main request was filed in reply to an invitation made in the Board's communication under Article 11(1) RPBA. As it contained only restrictive amendments it should be admitted into the appeal proceedings.

The respondent had not announced in advance that it would support its pleading at the oral proceedings with the demonstrative operating of a test device. The appellant was taken by surprise and was not in a position to prepare counter-arguments. Therefore, the respondent should not be authorised to do so.

Documents RD9, RD10 and RD11 were filed only with the respondent's letter of 1 February 2005 in reply to an

invitation made in the Board's communication under Article 11(1) RPBA. As being late filed documents, they should not be introduced into the appeal proceedings.

The date of publication of document RD5 was uncertain and, therefore, it could not be established whether the document was part of the state of the art.

Main request (claim 5 / objection to lack of clarity - requirements of Article 84 EPC)

Step (e) of the method claim 5 only had the function of specifying that the determination of the presence or quantity of the analyte in the liquid sample had to take place only if the presence of the orientation index zone had been detected in step (d). Therefore, the claimed subject-matter was unambiguously defined.

Auxiliary request

- Requirements of Article 123(2) EPC (added matter)

The term "single" as used in claims 1 and 3 had an implicit support in the application as filed from which it was clear that it was intended to use only one orientation index zone on a test strip.

- Requirements of Article 84 EPC (clarity)

The term "single" as used in claims 1 and 3 had a clear meaning. It was also not doubtful that in the strip represented in Figure 5 the orientation index zone lay near the support aperture. Therefore, in accordance with the definition given in "The Little Oxford

Dictionary" the orientation index zone was actually "adjacent" to the aperture.

The standard zone as referred to in claims 1, 3, 4 and 5 had been given an unambiguous definition in the patent in suit. It was a portion of the major surface leading the reaction zone and having a high relative reflectance compared to the reflectance of both the reaction zone and the orientation index zone.

The process features found at the end of claim 4 contributed to the characterisation of the apparatus.

Only one optic block comprising a set of optics with one or more light emitting diodes was used to measure the reflectance of the various zones on the test strips. The expression "same optics" as used in claim 4 designated the set of optics and, therefore, had a clear meaning.

The semi-colons used in the paragraph of claim 4 dealing with the use of the "same optics" only had the function clearly to identify the operations performed in sequence using the optics of the apparatus.

It was obvious from paragraphs 0045 and 0046 in columns 11 and 12, and in Figure 6 in the patent specification that the standard zone should have a reflectance higher than the reflectance of the orientation index zone. Therefore, the use of the relative terms "low" and "high" to characterise the respective reflectances of the orientation index zone and of the portion of the leading portion of the major surface of the test strip

serving as a standard zone in claims 1 and 3 could not be objected to.

It was common practice to use in a claim a back-reference to a previous claim. Referring back in claim 4 to the test strips claims 1 and 3 to specify the apparatus or in claim 5 to specify the use of the apparatus of claim 4 was justified and did not render the claimed subject-matter unclear.

In claim 5 the sequence of steps (a) to (d) was appropriate whether a test strip of claim 1 or of claim 3 was used.

- Requirements of Article 54 EPC (novelty)

Neither of documents RD1 and RD2 disclosed a test strip having a single orientation index zone. Indeed they each disclosed test strips having an identification bar code and a bar-shaped mark both of which were read and detected by a bar code reading device. Therefore, they differed from the test strips of claim 1 and 3, which had no such items and carried an orientation index zone, the presence of which was detected upon a reflectance measurement. Furthermore, each of documents RD1 and RD2 disclosed apparatus having two sets of optics located at different places, one being part of a reflection measuring device and the other being part of a bar code reading device, and, therefore, differed from the apparatus of claim 4, the optics of which were located in a single optic block. As the apparatus of claim 4 was new, the method of claim 5 was also new.

- Requirements of Article 56 EPC (inventive step)

Document RD1 was the closest state of the art for each independent claim.

No reasons were given in the decision under appeal why the skilled person would have combined documents RD1 and RD8. The teachings of these documents were not complementary. Document RD1 disclosed a small, portable test system for use by the unskilled operator at home while document DR8 was concerned with an apparatus for use in the laboratory. Document RD8 addressed the problem of how to simplify automatic laboratory systems, not that of providing an improved, simplified method for determining the presence or quantity of an analyte using a small, portable test system. Thus, document RD8 did not address the problem of the present invention. There was no motivation for the skilled person to consider document RD8 when considering possible improvements of the test system of RD1. Document RD1 was directed to the prevention of the inadvertent use of a test strip that did not belong to the batch whose evaluation curve had just been stored. To meet this objective, the presence of the identification bar code was essential. Equally the use of a code carrier prior to the insertion of the test strip was also essential. There was absolutely no incentive for the skilled person to depart from the very essence of the system of document RD1. There was no incentive for the skilled person to provide an analysis system having no code carrier and no identification bar code on the test strip. The disposal of the code carrier and the removal of the identification bar code went against the teaching of document RD1.

None of the other cited prior art documents concerned an apparatus intended for home use or provided any guidance to the skilled person facing the technical problem solved by the invention.

- XII. The submissions made by the respondent (opponent), insofar as they are relevant to the present decision, may be summarised as follows:

Procedural matters

The main request was filed with a letter of 31 January 2005. Therefore, it was late filed. Moreover, it contained so many amendments that a complementary search in the state of the art would have been necessary to enable an accurate assessment of the patentability of the claimed subject-matter. Thus, the main request should not be admitted into the proceedings.

In support of its pleading, authorisation was requested to show how a test device corresponding to the device of document RD1 was designed and operated. This would have shown that such a device attained exactly the same effect as the one claimed.

Documents RD9, RD10 and RD11 were cited and clearly identified in the respondent's letter of 2 June 2004 filed within the four month time limit fixed by the Board for making written submissions in reply to the statement setting the grounds of appeal. Therefore, they were not late filed and should be introduced into the proceedings.

Document RD5 was a notice of instructions concerning a semi-automatic analyser which was also described in documents RD6 and RD6b. Document RD5 was published before the priority date as established by the cover-sheet submitted at the oral proceedings. Thus, it should be considered when discussing inventive step.

Main request (claim 5 / objection to lack of clarity - requirements of Article 84 EPC)

Claim 5 lacked clarity. This was because step (e) therein was a step of determining the presence or quantity of the analyte in a liquid applied to the test strip, whereas the claim was directed to a method for determining that a test strip had been properly oriented in an apparatus.

Auxiliary request

- Requirements of Article 123(2) EPC (added matter)

The use in claim 1 and claim 3 of the term "single" to qualify the phrase "orientation index zone" had resulted in the introduction of added matter. In the description as filed the phrase was used together with the indefinite article "a". Even if the meaning of the word "a" was identical with the meaning of "one", the latter word could not be equated with the word "single" which meant "exactly one and not more than one".

There was no support for the feature indicated at the very end of claim 3 according to which the reflectance of the orientation zone index **was no more than two**



**thirds** of the reflectance of the contiguous portion of the major surface.

- Requirements of Article 84 EPC (clarity)

The term "single" used in claims 1 and 3 had no clear meaning. Nor was the term "adjacent" used to specify the orientation index zone as referred to in claim 3 clear. Indeed the orientation index zone shown in Figure 5 was not located directly next to the aperture and thus could not be considered to be adjacent thereto.

There was no definition in the patent in suit of a "standard zone" as referred to in claims 1, 3, 4, and 5.

The features at the end of claim 4 (see from line 19 to line 27 on page 3 of the claim request) were not appropriate to characterise the apparatus as they were process features.

The expression "same optics" as used in claim 4 was inappropriate in view of the last statement in the description (see column 14, lines 44 to 48 in the patent specification) indicating that the proper orientation of the strip was detected and then the reflectance of both the white zone and the reaction zone was read, a two-step process which implied the use of different optics.

The use of semi-colons in the portion of the characterising part of claim 4 stating that the same optics were used sequentially rendered uncertain whether the reflectance measurements on the different

zones of the major surface of the strip were actually made sequentially.

The use in claims 1 and 3 of the relative terms "low" and "high" to characterise the respective reflectances of the orientation index zone and of the portion of the leading portion of the major surface of the test strip serving as a standard zone rendered the claimed subject-matter indefinite.

The presence of back-references to the strip claims in claim 4 and to the apparatus claim in claim 5 rendered unclear the claimed subject-matter.

The sequence of steps in claim 5, with step (c) preceding step (d), was not appropriate in the case where a test strip of claim 3 was used.

- Requirements of Article 54 EPC (novelty)

The identification bar code of the test strip of document RD1 or of document RD2 was located in the leading portion thereof and provided, in addition to an information useful for the calibration of the system, an indication that the test strip had been correctly oriented when it was inserted into the apparatus. As furthermore these test strips had also a circular aperture and an intermediate zone located between said orientation index zone and aperture which could serve as a standard zone for the purpose of measuring reflectance values, the test strips of claim 1 and of claim 3 were not new. Like the apparatus of claim 4, the apparatus of document RD1 or of document RD2 was also equipped with optics appropriate for the detection

of the identification bar code serving as an orientation index zone and for the measurement of the reflectance of the reaction zone. As the apparatus of claim 4 was not new, its use as referred to in claim 5 was also not new.

- Requirements of Article 56 EPC (inventive step)

Document RD1 represented the closest state of the art.

The fact that the identification bar code present on the test strip of document RD1 had a calibration function could not influence the reasoning for the assessment of inventive step. The claimed test strip might not employ a separate code carrier and not use this for a calibration function. Such a simplification, however could not be inventive. If a system refrained from using a specific feature but also did not have the advantage of the technical function of this feature, then the system was simplified but not inventive.

Nevertheless, each of documents RD3, RD4, RD6, RD6b and RD8 described a test strip carrying a mark ("black mark" denoted "23" in document RD3, "black adhesive tape" denoted "2D" in document RD4, "black strip" denoted "99" in document RD6, black block denoted "schwarze Markierungslinie" on the test strip of Figure 1 in document RD6b and "code block" denoted "17" in document RD8) which had a reflectance different from that of other portions of the test strip (white/black contrast) and could have served the purpose of detecting a correct orientation of the test strips. Therefore, the tests strips of claims 1 and 3 were not inventive in view of any combination of document RD1

with any of documents RD3, RD4, RD6, RD6b and RD8. Also document RD9 was relevant if the calibration issue was considered.

In view of these documents it would have been also obvious to equip the apparatus of document RD1 with only one set of optics and thereby arrive at the apparatus of claim 4. As the apparatus of claim 4 was not inventive, its use according to claim 5 was also not inventive in view of the same combinations of the prior art documents.

XIII. The appellant (patentee) requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request filed on 31 January 2005, or of the auxiliary request filed at oral proceedings on 1 March 2005 which differs from the main request only in respect of page 4 of the 4-page claim request filed on 31 January 2005.

XIV. The respondent (opponent) requested that the appeal be dismissed.

## **Reasons for the Decision**

Procedural matters

*Admissibility of the main request into the appeal proceedings*

1. The main request was introduced for the first time into the proceedings with the appellant's letter of 3 December 2004 and then re-filed, in the form of a modified version to correct a clerical error, with the

appellant's letter of 31 January 2005. The respondent objected to its admission into the proceedings for the reasons that it was late filed and contained so many amendments that a complementary search in the state of the art would be necessary to enable an accurate assessment of the patentability of the presently claimed subject-matter.

2. The main request was filed in reply to the communication pursuant to Article 11(1) RPBA issued by the Board objecting to the claim requests then on file, which contained a whole series of complex amendments, and advising the appellant explicitly to put forward one or more new claim request(s) (see point 10 of the communication) which, departing from the claims as granted, showed the precise origin of each amendment, the reason(s) why it was made and the justification for making it. The amendments made in response to this communication were explained as being to overcome objections to lack of novelty and lack of inventive step, and the amendments essentially consisted in the addition of restricting technical features. In the Board's judgment, the appellant was entitled to file the main request. Said filing did not cause undue extra work for the respondent or the Board. Thus, in exercising its discretion, the Board decides to admit the main request into the proceedings.

*Authorisation to illustrate a pleading by demonstrating operation of a test device*

3. At the oral proceedings held before the Board the respondent requested to be authorised to support its pleading with a demonstration of how a commercial test

device corresponding to the device referred to in document RD1 was operated. The appellant objected to this because it had not been announced in advance.

4. Neither the Board nor the appellant had been informed before the oral proceedings of the respondent's intention to rely on such means of evidence and, therefore, both the Board and the appellant were taken by surprise. In the exercise of its discretion, the Board has decided not to authorise the respondent to rely on such means of evidence, as the appellant did not have an opportunity to prepare itself for such demonstration.

*Admissibility into the appeal proceedings of documents RD9, RD10 and RD11*

5. Three additional documents, namely documents RD9, RD10 and RD11, were cited, in support of its reasoning for the assessment of inventive step, by the respondent in its letter of 2 June 2004 filed within the four month time limit fixed by the Board for making written submissions in reply to the statement setting out the grounds of appeal. A copy of the documents was not enclosed with said letter but was sent together with the letter of 1 February 2005, ie one month before the oral proceedings, in reply to the invitation made by the Board in its communication pursuant to Article 11(1) RPBA. Considering that these documents have been late filed, the appellant objected to their admission into the proceedings.
6. Although, in principle, an appeal should be essentially based on facts and evidence which were already available to the department of the first instance,

parties in their efforts to make a full statement of the grounds why the revision of the contested decision is requested often rely on additional evidence. Such evidence is not necessarily defined as being "late-filed". Much depends on its *prima facie* relevance, the Board being empowered essentially either i) to disregard it under Article 114(2) EPC or ii), having admitted it, to remit the case to the department of first instance under Article 111(1) EPC for further prosecution, or iii), having admitted it, to decide on the case.

7. In the present case, the Board, exercising its discretion, decides to admit document D9, which is closely related to the US patents referred to in column 2, lines 47 and 48 in the patent specification, into the appeal proceedings, as well as documents D10 and D11 in spite of their marginal relevance. The two latter documents were not relied on by any of the parties during the oral proceedings.

*Admissibility of document RD5 as a document belonging to the state of the art*

8. As regards document RD5, the opposition division in Section II of the decision under appeal indicated that it was published "before 1990". However the copy on file bears no date. Invited by the Board to comment thereon, the respondent has provided at the oral proceedings a cover sheet with the typed phrase "Ausgabe 8/87". The submission of this only cover sheet may not amount to a proof that document RD5 had actually been published in 1987 or at another date before the effective date of the patent. Consequently,

the date of publication of document RD5 remains uncertain. Thus, the Board decides to disregard it for the assessment of inventive step.

#### Main request

9. In the Board's judgment claim 5 of the main request does not meet the clarity requirement of Article 84 EPC. Whereas, according to its preamble, the claim is directed to a method for determining that a test strip has been properly oriented in an apparatus, step (e), not appearing in any claim as granted (cf claim 16 as granted), of the characterising part of the claim is a step of determining the presence or quantity of the analyte in a liquid applied to the test strip.
10. This produces a discrepancy between the preamble and the characterising part of the claim which amounts to an ambiguity as to the precise definition of the subject-matter for which protection is sought: a method for determining the orientation of a test strip or a method for determining the analyte?
11. Therefore, claim 5 does not meet the requirements of Article 84 EPC. Consequently, the main request which contains it is not allowable.

#### Auxiliary request

##### *Article 123(3) EPC*

12. The respondent did not raise any objections under Article 123(3) EPC. Nor does the Board have any objections in this respect.



*Article 123(2) EPC*

13. The respondent argued that the use in claim 1 and claim 3 of the term "single" to qualify the phrase "orientation index zone" had resulted in the introduction of added matter.
14. When reading the application as filed in the published version (see WO 96/07907) one has to conclude that it suggests the use of a single orientation index zone. The application shows only one such zone and the skilled person is given no hint or reason suggesting possible use of two or more orientation index zones. The clear intention of the appellant was to use **only one** orientation index zone on the leading portion of the major surface of the test strip, in order that the detection of an upside down oriented strip can be made. This view is further confirmed by the constant use of the definite article "the" and the use of the determiner "this" throughout the description as filed before the phrase "orientation index zone" which furthermore is always in the singular form (see page 9, line 20; page 21, lines 10, 15 and 29; page 22, lines 4, 12, 17 and 26; page 23, lines 2, 3, 12 and 32; and page 25, lines 12, 20 and 21). A further illustration thereof is provided by Figures 4 and 5 which represent preferred strips having only one, ie a single, orientation index zone.
15. The respondent also argued (see its letter of 20 December 2004) that there was no support for the feature indicated at the very end of claim 3 according to which the reflectance of the orientation zone index

**was no more than two thirds** of the reflectance of the contiguous portion of the major surface.

16. This argument is contradicted by the sentence on page 22, lines 25 to 30 in the application as filed which reads "Similarly, for the embodiment shown in Figure 5, the reflectance of the orientation zone should be no more than two thirds of the reflectance of the contiguous portion of the major surface" and, thereby, provides an explicit support for the feature.
17. As the respondent did not raise any further objections, the Board, having no objections on its side, concludes that the requirements of Article 123(2) EPC are met by the auxiliary request.

*Article 84 EPC*

18. The respondent raised a series of objections to lack of clarity in respect of claims 1, 3, 4 and 5.

18.1 Term "single" (claims 1 and 3)

As discussed above (see point 14) there can be no doubt that the term "single" which stands for "only one" has a clear meaning.

18.2 Term "adjacent" (claim 3)

- 18.2.1 The respondent argued that the orientation index zone shown in Figure 5 was not located directly next to the aperture and thus could not be considered to be "adjacent" thereto as specified in claim 3.

18.2.2 It is explicitly indicated in the patent in suit (see column 12, lines 28 to 31) that in the embodiment represented in Figure 5 the orientation index zone is placed **adjacent** to the aperture. As stated in "The Little Oxford Dictionary" referred to by the appellant in its letter of 31 January 2005, "adjacent" means "lying near". It is not doubtful that in the test strip represented in Figure 5 the orientation index zone lies near the aperture. Therefore, the term "adjacent" as used in the context of the patent in suit has a clear meaning.

18.3 The concept of a "standard zone" (claims 1, 3, 4 and 5)

18.3.1 The respondent argued that there was no definition in the patent in suit for a "standard zone" as referred to in the claims.

18.3.2 This argument is contradicted by a statement in the description (see column 13, lines 36 to 42 in the patent specification) which indicates that in the embodiments illustrated in Figures 4 and 5, the portions of the major surface leading the reaction zone (other than the orientation index zone) have a high relative reflectance, and, hence may serve as the standard zone which provides a calibrated standard reflectance value against which the reflectance of the reaction zone may be measured. Thereby, an unambiguous definition is given.

18.4 Characterising part of the apparatus claim (claim 4)

18.4.1 The respondent argued that the features at the end of claim 4 (see from line 19 to line 27 on page 3 of the

claim request) were not appropriate to characterise the apparatus as they are process features.

18.4.2 These features, which relate to the way the optics are used and the way the presence and/or quantity of the analyte is determined, indicate how the apparatus is equipped to be useful, and indeed provide an implicit limitation of the structural features of the apparatus, in that they must be such as to be usable in the way stated. Thus, they are features which properly contribute to the characterisation of the apparatus.

18.5 Expression "same optics" (claim 4)

18.5.1 The respondent argued that the expression "same optics" was inappropriate in view of the last statement in the description (see column 14, lines 44 to 48 in the patent specification) indicating that the proper orientation of the strip was detected and then the reflectance of both the white zone and the reaction zone was read according to a two-step process which the respondent considered to imply the use of different optics.

18.5.2 **The optics for the apparatus** are referred to in paragraph 0029, columns 7 and 8 in the patent specification. **They are located in an optic block** affixed to the apparatus, which optic block contains one or more light emitting diode(s) depending on the analyte determination to be made (see further paragraph 0053, column 13 in the patent specification), a photodetector, as well as a device capable of intercepting light reflected from the surface upon which the one or more light emitting diode(s) focus(es),

and converting such light into a measurable voltage. As further indicated in paragraph 0022, column 5, lines 48 to 58, in the patent specification, "the apparatus, utilizing **the same optics** provided to read the reflectance of the reaction zone once the strip is fully inserted, may also employ such optics to **sequentially** determine the reflectance value of the portion of the major leading surface of the strip as the strip is being inserted into the apparatus" (emphasis added by the Board), the reflectance of the surface presented to the optics being measured in multiple readings as the strip is inserted into the apparatus (see paragraph 0054, column 14 in the patent specification). Therefore, a reading of the description leads to the observation that the expression "same optics" as used in the claims unambiguously designates the set of optics contained in the optic block.

- 18.6 The use of semi-colons in the portion of the characterising part of claim 4 stating that the same optics are used sequentially
  - 18.6.1 The respondent argued that the use of semi-colons in the claim rendered uncertain whether the reflectance measurements on the different zones of the major surface of the strip were made sequentially.
  - 18.6.2 The Board sees no difficulty associated with the use of semi-colons which only have the function of facilitating identification of the operations performed in sequence using the same optics.

18.7 Use of relative terms (claims 1 and 3)

18.7.1 The respondent objected to the use of the relative terms "low" and "high" to characterise the reflectance exhibited by the orientation index zone and the standard zone in claims 1 and 3.

18.7.2 In reality, the claims are formulated in such a way that the reflectance of the orientation index zone is stated to be low **relative to** that of the major surface contiguous thereto serving as a standard zone and *vice versa* the reflectance of the said major surface serving as standard zone is stated to be high **relative to** the orientation index zone.

18.7.3 Thus, the claims exactly reflect the content of the description, according to which the standard zone should have a reflectance **higher than** the reflectance of the orientation index zone in order that either a sharp rise in reflected light (case of a strip of claim 1 with the orientation index zone being first read) or a sharp decrease in reflected light (case of a test strip of claim 3 with the standard zone being first read) is detected (see column 12, lines 15 to 22 and 31 to 38 in the patent specification). Therefore, the relative terms "low" and "high" as used in claims 1 and 3 unambiguously contribute to the characterisation of the strips for which protection is sought.

18.8 Back-references to claim 1 or claim 3 (claims 4 and 5) and to claim 4 (claim 5)

18.8.1 The respondent argued that back-references to the strip claims in claim 4 and to the apparatus claim in claim 5 rendered the claimed subject-matter unclear.

18.8.2 It is common practice to introduce into a claim a back-reference to a previous claim in order to avoid uninformative repetition of wording. The presence in claim 4 of a back-reference to claims 1 and 3 has the effect of implying that the apparatus according to claim 4 is suited to read a test strip according to claim 1 or claim 3. The presence in claim 5 of back references to claims 1, 3 and 4 implies that the method makes use of said strips in such an apparatus. Thus, the use in claims 4 and 5 of back-references to the previous claims does not render the claimed subject-matter unclear.

18.9 Sequence of steps in claim 5

18.9.1 The respondent objected that the sequence of steps in claim 5, with step (c) preceding step (d), was not appropriate in the case where a test strip of claim 3 was used.

18.9.2 It is clear to the skilled person that claim 5 covers the use of an apparatus equipped with only one set of optics contained in a single optic block in association with a test strip which, as defined in claim 1 or in claim 3, has been designed to exactly fit with the functioning of the apparatus. Thus, reading the claim, the skilled person would readily understand that the

use of the apparatus, with whichever test strip, involves four steps, namely (a) a step of applying the sample, (b) a step of inserting the test strip into the apparatus, (c) a step of determining the reflectance of the major surface of the strip, and (d), based on the variation of the reflectance upon a reading of the orientation index zone and the standard zone (expressed as either a sharp rise or a sharp decrease), a step of detecting the presence or absence of reflected light corresponding to the passage of the orientation index zone. Therefore, the wording of claim 5 is clear.

- 18.10 In view of the above remarks, none of the respondent's objections to lack of clarity can be considered to show a lack of compliance of the claims with the requirements of Article 84 EPC. As the objection raised against claim 5 of the main request (see point 9, supra) does not apply to claim 5 of the auxiliary request as a result of the deletion of step (e), and the Board has no further objections on its side, it concludes that the requirements of Article 84 EPC are met by the auxiliary request.

#### Article 54 EPC

19. The respondent argued that the claimed subject-matter as a whole was not new over document RD1 or document RD2.
20. Document RD1 describes a system consisting of a meter intended for home use, test strips and code carriers. The meter comprises a test strip receiver covered by a top which is formed by a hinged lid that is pivotable (see column 5, lines 43 to 48). The meter is equipped



with two optic blocks, one set of optics being part of a reflection photometric measuring device (denoted 38 on Figure 4) for measuring the reflectance of the reaction pad on the test strip and the other set of optics being part of a bar code reading device for reading an **identification bar code** and detecting a **bar-shaped mark**, both bar code and mark being present on the test strip. A test strip of document RD1 (see Figure 2) has a recess near the extremity which is first inserted into the meter; this recess allows the exact positioning of the strip. On the face to be read by the optics (the sample to be tested being applied on the other side) the test strip bears, located after the recess and one after the other, (i) the afore-mentioned **identification bar code** (denoted "12" in Figure 2) which contains the type- and batch-specific identification information, (ii) a circular aperture through which the lowest layer of the test pad can be distinguished and read by the reflection photometric measuring device, and (iii) also the afore-mentioned **bar-shaped mark** (denoted "13" in Figure 2) which serves the purpose of ascertaining whether the strip is exactly positioned in the device. **The bar-shaped code** and **the identification bar code** are located in such a way that they are each read by the only bar code reading device of the apparatus. The strip is of the non-wipeable type (see column 5, lines 51 to 56), ie its test pad is capable of retaining an excess of the biological liquid to be tested. The code carriers are in the strip form and contain the information required for the evaluation of a pack of test strips.

21. Document RD2 describes a system similar to that of document RD1. The meter (see page 3, column 4, lines 6

to 20) has also a test strip receiver covered by a top, which is formed by a hinged lid that is pivotable, and is equipped with two optic blocks, one set of optics being part of a reflection photometric measuring device and the other set of optics being part of a bar code reading device (respectively denoted "24" and "26" on Figure 5). The test strip of document RD2 (see Figure 5) is typically the same as that of document RD1: its underside also comprises a recess, a bar code (denoted "72" in Figure 5), which in the same way as in document RD1 serves the purpose of identifying the test strip in order that the appropriate evaluation data known from a bar code on the surface of a reference code carrier ("Prüfstreifen") be applied for the testing, and a bar-shaped mark (denoted "74" in Figure 5).

Claims 1 and 3 (test strips)

22. The test strips according to claims 1 and 3 have in common the presence of **a single orientation zone index** located either at the extreme leading portion of the major surface of the strip (see the test strip according to claim 1) or located on the leading portion of the major surface of the strip adjacent to the aperture for viewing the reaction zone of the test pad (see the test strip according to claim 3). In contrast to the identification bar code of the test strips of documents RD1 and RD2, the orientation index zone of claims 1 and 3 is not required to contain coded information, but is required to exhibit a low reflectance relative to the reflectance of a portion of the major surface of the strip immediately adjacent to it. Therefore, upon insertion of a test strip, the difference in reflectance - a sharp rise (with a test

strip of claim 1) or a sharp decrease (with a test strip of claim 3) - is measured, **if the strip is properly orientated**. This is a function which the bar-shaped mark of documents RD1 and RD2 does not have. Thus, the orientation index zone of the test strips of claims 1 and 3 cannot be equated with either the identification bar code or the bar-shaped mark of the strips of documents RD1 and RD2. Therefore, the test strips according to claims 1 to 3 are new over document RD1 or document RD2. As claim 2 is dependent on claim 1, the same conclusion applies to it.

Claim 4 (apparatus)

23. The apparatus of claim 4 is also a meter intended for home use. It requires a passageway having an open end through which a test strip is inserted. In contrast to the apparatus of document RD1 or of document RD2, the passageway of the claim is not covered by a pivotable hinge lid but forms a sort of case into which the test strip is to be introduced. A further difference compared to the apparatus of document RD1 or of document RD2 lies in the fact that the apparatus of claim 4 has only one set of optics. Therefore, the apparatus of claim 4 is new over document RD1 or document RD2.

Claim 5 (method)

24. Claim 5 is to be construed as meaning the use of the apparatus of claim 4 in a method of determining that a test strip of claim 1 or claim 3 has been properly oriented therein.

25. As the test strips of claims 1 and 3 and the apparatus of claim 4 are considered to be new over document RD1 or document RD2, the same conclusion must apply to a method which uses them. Therefore, also the method of claim 5 is new over document RD1 or document RD2.
26. Therefore, as no other document on file discloses any of the aspects of the invention for which protection is sought, the auxiliary request as a whole meets the requirements of Article 54 EPC.

#### Inventive step

27. Both parties regard document RD1 as the closest state of the art for the assessment of inventive step in respect of the whole claimed subject-matter. The Board does not dispute this view.
28. The system of document RD1 has been already discussed in detail at point 20 (see supra). For the assessment of inventive step it is also important to take into consideration some further aspects associated with the functioning of the system. During the introduction of the test strip into the meter of document RD1, the hinged lid is in the closed position. As soon as the meter detects the bar-shaped mark, said detection being the indication that the test strip is exactly fixed, ie in such a way that the test strip is pressed against the stop denoted "27" in Figure 4 (see column 5, lines 28 to 31), the operator, who typically is a non-skilled person, opens the hinged lid and applies to the test pad a drop of the sample to be tested (see column 5, lines 50 and 51).

29. In view of this closest state of the art, the technical problem to be solved may be regarded as the provision of an alternative system consisting of a meter intended for home use and a test strip. The solution to that problem is a test strip according to claim 1 or claim 3 and a meter according to claim 4, the test strip being inserted after the sample to be analysed has been applied on its test pad and the system being equipped with means which (a) allow the **immediate detection** of an inadvertent upside down (with respect to the optics of the meter) orientation of the test strip in the meter and (b) in the absence of said detection, prompt the operator to **discard the test strip before its complete insertion**.
30. The question to be answered is whether the skilled person would have found any incentive in any of the cited prior art documents to design such a meter and test strip.
31. To answer the question, the documents considered by the respondent to be relevant in combination with document RD1 - ie documents RD3, RD4, RD6, RD6b, RD8 and RD9 - are assessed in the following sub-paragraphs. It is shown that none of them is concerned with the problem of the immediate detection of an inadvertent upside down orientation (with respect to the optics) of a test strip upon its insertion into a meter intended for home use and, therefore, could not have provided any suggestions to the skilled person in that respect.
- 31.1 **Document RD3** describes a complex apparatus which is automatically operated. The apparatus includes a test strip automatic supply device having a function of

supplying test strips, stored therein beforehand, one by one in synchronism with the analysing cycle, a sample shifting device allowing for the dipping of the test strips in the sample to be tested, a reflection photometric measuring device and a test strip handling device having a function of moving the test strip from one of the aforementioned devices to the other. A photometric detector is disposed **in the supply device** to detect a black mark (denoted "23" in the document) on the test strip and, thereby, to assess whether each successive test strip has been placed (not inserted) in a receiving groove in such a way that it faces up properly or not. If not properly placed, the test strip is reversed by a reversing mechanism. After having been dipped into the sample to be tested, the test strip is then mechanically placed on a roller paper contained within the measuring device, moved therewith and finally discarded. The correct "positioning" of the test strip with respect to the optics of the measuring device, ie the meter of the apparatus, is not a problem as it depends on an earlier detection which occurs in the supplying device.

31.2 Similar remarks apply *mutatis mutandis* to **document RD4** which describes another complex apparatus automatically operated and the performance of which includes a step of detecting in the supply device the incorrect positioning of a test strip and subsequently inverting the test strip.

31.3 **Document RD6** describes a semi-automatic apparatus for the analysis of test strips which have been previously dipped in a urine sample to be tested. The test strips are **not inserted** but **manually placed** one after the

other in receptacles arranged on the surface of a drum parallel to its axis of rotation. As soon as a test strip is placed, **whether correctly or not**, the drum rotates. Upon rotation each of the test strip comes to a position opposite to a measuring device comprising a reflex photometer. After the measurement and upon further rotation of the drum, the test strip falls out of its receptacle and is collected in a storage tray. There is no indication in document RD6 that an incorrect positioning of the test strips is intended to be detected. This is not the function of the **black bar** (denoted "99" in the document) which is located on the surface of the test strips. Indeed, this black bar serves the purpose of **generating a synchronizing signal** which provides an indication through the measuring device of the beginning of a row of test areas on the test strip (see column 10, lines 14 to 19).

- 31.4 **Document RD6b** describes an apparatus which is related to the apparatus of document RD6. On page 97, there is the indication that the **black bar** on the test strip serves the purpose of providing the indication to the apparatus that the test strip has been correctly placed on the drum and that the support is facing outwards with the test areas apparent. Nevertheless, as soon as a test strip has been placed, whether correctly or not, the drum rotates and a measurement is automatically made. The operator is only a *posteriori* informed of the defect in the form of a large peak on the report delivered by the apparatus and thereby is not given the opportunity to discard an incorrectly positioned test strip before the measuring is performed.

- 31.5 **Document RD8** describes a test system which comprises an automatic or semi-automatic instrument to be used in combination in particular with test carriers and code carriers both in the form of strips. The instrument is not described in detail. It appears that the test strip is not actually **inserted** but is rather **placed** on a carrier and advanced to bring successive ones of the reagent blocks beneath the readout position (see from line 28 of column 10 to line 28 on column 12). Furthermore, the test strips of document RD8, as typically represented by the test strip of Figure 1 and as detailed in Example 1, have not been designed with the idea of permitting the photometric detection of their correct orientation into the apparatus, the opaque white block (number 17 in Figure 1) located thereon serving the purpose of identifying the particular test strip on use and of calibrating the instrument (see column 8, lines 42 to 46).
- 31.6 **Document RD9** describes an apparatus (see Figure 1) in which a test strip is inserted in a fixed position. Nevertheless, the correct orientation (with respect to the optics of the apparatus) of the test strip is not regarded as a problem, a fact which is confirmed by the absence of any particular zone which, such as an orientation zone index, could have been used upon measurement of its reflectance to assess whether the correct orientation has occurred.
32. In view of the above remarks, the Board believes that none of the quoted documents, alone or in combination, would have provided an incentive for the skilled person to design a meter intended for home use and test strips adapted thereto, the test strips carrying an



orientation index zone located on their leader portion, the detection of which generates an immediate sharp variation in reflected light in comparison with a contiguous standard zone, and the meter being equipped with only one set of optics which is capable of reading the reflectance of the orientation index zone, the standard zone and the reaction zone of the test strips. Therefore, the subject-matter of claims 1 and 3 (test strips) as well as that of claim 4 (apparatus) involves an inventive step. The same conclusion applies *de facto* to dependent claim 2 and to independent claim 5, as this latter claim is directed to the use of an inventive apparatus in association with inventive test strips. Thus the auxiliary request meets the requirements of Article 56 EPC and can form a basis for the maintenance of the patent in amended form.

**Order**

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

1. The decision under appeal is set aside.
  
2. The case is remitted to the first instance with the order to maintain the patent on the basis of claims 1 to 5, submitted as pages 1-3 of the request filed on 31 January 2005 and page 4 as filed at oral proceedings on 1 March 2005 and a description to be adapted thereto.

The Registrar:

The Chairman:

A. Wolinski

L. Galligani