BESCHWERDEKAMMERN DES EUROPÄISCHEN PATENTAMTS

BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE

CHAMBRES DE RECOURS DE L'OFFICE EUROPEEN DES BREVETS

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

Datasheet for the decision of 1 July 2013

Case Number: T 1925/08 - 3.3.08

Application Number: 00126414.2

Publication Number: 1111386

IPC: G01N 33/558

Language of the proceedings: EN

Title of invention:
Test strip for the assay of an analyte in a liquid sample

Patent Proprietor:
Siemens Healthcare Diagnostics Inc.

Opponent:
Roche Diagnostics GmbH

Headword:
Infrared dye/SIEMENS

Relevant legal provisions:
EPC Art. 54, 56, 100(c), 123(3)
RPBA Art. 13(1)

Keyword:
"Main request (claims as granted) - basis in the application as filed (no)"
"First and second auxiliary request - breach of Article 123(3) EPC (yes)"
"Third auxiliary request - requirements of the EPC fulfilled"

Decisions cited:
G 0002/88, G 0001/93, G 0001/03, G 0002/03

Catchword:
-

Europäisches Patentamt | European Patent Office | Office européen des brevets

Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 1925/08 - 3.3.08

D E C I S I O N
of the Technical Board of Appeal 3.3.08
of 1 July 2013

Appellant I: (Patent Proprietor)
Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, NY 10591 (US)

Representative:
Michalski Hüttermann & Partner
Patentanwälte
Hafenspitze
Speditionsstrasse 21
D-40221 Düsseldorf (DE)

Appellant II: (Opponent)
Roche Diagnostics GmbH
Sandhoferstr. 116
D-68305 Mannheim (DE)

Representative:
Weiss, Wolfgang
Weickmann & Weickmann
Patentanwälte
Postfach 86 08 20
D-81635 München (DE)

Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 28 May 2008 concerning maintenance of European patent No. 1111386 in amended form.**

Composition of the Board:

Chairman: M. Wieser
Members: M. R. Vega Laso
C. Heath

Summary of Facts and Submissions

I. European patent No. 1 111 386 with the title "Test strip for the assay of an analyte in a liquid sample" was granted on European patent application No. 00126414.2. The patent was granted with 15 claims.

II. Claims 1 and 11 of the **patent as granted** read as follows:

"1. A test strip for determining the presence or concentration of one or more predetermined analytes in a liquid test sample comprising:

a) a support handle;

b) one or more test pads positioned on the support handle, each test pad comprising (i) a carrier matrix incorporating (ii) a reagent composition capable of interacting with a predetermined analyte to provide a detectable response; and

c) an infrared dye positioned at a predetermined location on the test strip, said infrared dye not labelling a component of said reagent composition.

11. A method of monitoring alignment of a test strip in an optical pathway of a detection apparatus comprising:

(a) providing a test strip, said test strip comprising

(i) a support handle;

(ii) one or more test pads positioned on the support handle, each test pad comprising (i) a carrier matrix incorporating (ii) a reagent composition capable of interacting

with a predetermined analyte to provide a detectable response; and
(iii) an infrared dye positioned at a predetermined location on the test strip;

(b) inserting the test strip in the detection apparatus;
(c) illuminating the predetermined location of the infrared dye on the test strip with infrared radiation;
d) measuring a reflectance of infrared radiation from the predetermined location on the test strip; and
(e) correlating the reflectance measurement to the alignment of the test strip in the detection apparatus."

Dependent claims 2 to 10 related to different embodiments of the test strip of claim 1, and dependent claims 12 to 15 to particular variants of the method of claim 11.

III. An opposition to the grant of the patent was filed based on the grounds for opposition under Article 100(a) and (c) EPC, in particular that the claimed subject-matter lacked novelty (Article 54 EPC) and an inventive step (Article 56 EPC), and that the subject-matter of claim 1 extended beyond the content of the application as filed.

IV. In an interlocutory decision under Articles 101(3)(a) and 106(2) EPC posted on 28 May 2008, the opposition division found that Article 100(c) EPC prejudiced the maintenance of the patent as granted, and that the

amendments introduced into the claims according to the first to fourth auxiliary requests then on file contravened Article 123(2) EPC. However, the subject-matter of claims 1 to 5 according to the auxiliary request 5 filed during the oral proceedings, and the invention to which the claims related were found to meet all requirements of the EPC.

V. The patent proprietor (appellant I) and the opponent (appellant II) each lodged an appeal against the decision of the opposition division.

VI. Together with its statement of grounds of appeal, appellant I submitted four sets of claims as main request and first to third auxiliary requests, respectively.

The set of claims according to the **main request** is identical to the claims of the patent as granted.

The claims according to the **first auxiliary request** differ from the claims as granted in that claim 1 has been amended to replace the negative feature "*... said infrared dye not labelling a component of said reagent composition*" by "*... said infrared dye being positioned on the support handle of the test strip formed from hydrophobic material*". Moreover, claim 3 has been deleted, and claims 4 to 15 have been renumbered and their dependencies amended accordingly.

The claims of the **second auxiliary request** differ from the claims as granted in that the negative feature "*... said infrared dye not labelling a component of said reagent composition*" has been replaced by

"*...wherein the infrared dye is incorporated into one or more test pad, said infrared dye not adversely affecting the reagent incorporated into the test pad*".

The set of claims according to the **third auxiliary request**, which is identical to the auxiliary request 5 underlying the decision under appeal, consists of claims 11 to 15 as granted, which have been renumbered as claims 1 to 5.

VII. In its statement of grounds of appeal, appellant II contested the findings of the opposition division on novelty and inventive step in respect of the subject-matter of the claims of the auxiliary request 5 in opposition proceedings (present third auxiliary request). Appellant II also filed an additional document as support for a new objection of lack of novelty.

VIII. As a subsidiary request, both appellants requested oral proceedings.

IX. Each party replied to the statement of grounds of appeal of the other party.

X. On 29 May 2009 appellant II filed a further submission including additional evidence.

XI. On 2 July 2009 appellant I filed a reply and **amended** the claims according to the **first auxiliary request** by replacing the wording "*... said infrared dye being positioned on the support handle of the test strip formed from hydrophobic material*" in claim 1 of the previous set of claims by "*... said infrared dye being*

positioned on the support handle of the test strip, wherein the handle is formed from hydrophobic material".

XII. Further submissions were filed by appellant II on 1 October 2009 and 15 February 2010. In the latter, yet another objection of lack of novelty based on a new document was raised.

XIII. Appellant I replied by letter dated 13 November 2009, requesting that the new evidence filed by appellant II not be admitted into the proceedings. Further submissions by appellant I were received on 9 March 2010 and 29 June 2010.

XIV. On 30 June 2010 appellant II filed additional evidence in support of an objection of lack of novelty.

XV. In a reply dated 3 December 2010, appellant I argued that the new documents filed by appellant II had not been submitted in due time and were *prima facie* not relevant, and that, therefore, they should be disregarded.

XVI. The appellants were summoned to oral proceedings. In a communication under Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA) attached to the summons, the board drew attention to Article 12(4) of the Rules of Procedure of the Boards of Appeal (RPBA) and expressed a provisional opinion on some of the issues to be discussed during the oral proceedings, in particular issues in connection with Articles 100(c), 123(3) and 84 EPC.

XVII. The scheduled oral proceedings were postponed upon a reasoned request by appellant II.

XVIII. In reply to the board's communication, appellant II submitted additional observations.

XIX. Together with its reply, appellant I filed an additional set of claims which was identical to the auxiliary request 6 filed before the opposition division.

XX. Oral proceedings were held on 1 July 2013.

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

(1): US 4,772,561, published on 20 September 1988;

(2): EP 0 837 320 A2, published on 22 April 1998;

(4): EP 0 887 421 B1, application published on 30 December 1998;

(5): WO 00/29831, published on 25 May 2000;

(6): EP 0 405 513 B1, published on 10 May 1995;

(9): US 5,526,120.

XXII. The submissions made by appellant I were essentially as follows:

Main request - Article 100(c) EPC

The subject-matter of claim 1 as granted did not extend beyond the content of the application as filed. The application contained a direct and unambiguous disclosure for the negative feature "*said infrared dye not labelling a component of said reagent composition*" in claim 1. It was disclosed on page 12, lines 3 to 8 of the application as filed that the infrared dye (IR dye) did not adversely affect the reagent incorporated into the test pad. This implied that the infrared dye could not label a component of said reagent composition because this would adversely affect the component of said reagent.

It was clear from the disclosure of the patent that the function of the infrared dye was to ensure a proper alignment of the test strip in the detection apparatus, while the function of the reagent was to change colour when contacted by an analyte (see, e.g., page 9, lines 15 to 19, and page 1, lines 29 to 32 of the application as filed). Thus, there was no doubt that the infrared dye and the reagent composition were totally different elements having independent and different functions, which would not interfere with each other. Further, it was stated on page 9, lines 11 to 14 that the infrared dye was incorporated in conjunction with or separately from the assay reagent. This logically excluded the infrared dye from being a label of a component of the reagent composition.

First auxiliary request – Article 123(3) EPC

The feature "*... said infrared dye being positioned on the support handle of the test strip ...*" introduced into claim 1 replaced the objected negative feature and was based on claim 3 and the specification as originally filed. The new feature was equivalent in meaning to the omitted feature and limited the position of the dye to a location not interfering with the test pads comprising the reagent composition. Thus, the scope of the claims was not extended by the amendment.

Second auxiliary request – Article 123(3) EPC

The features replacing the objected negative feature were based on claim 4 and the specification as originally filed. Amended claim 1 specified that the infrared dye did not adversely affect the reagent incorporated into the test pad. Since labelling a component of the reagent composition would adversely affect the reagent and, consequently, the measuring of the analyte, the negative feature in claim 1 as granted and the feature in the present claim were equivalent. The amendment did not extend the scope of the claims.

Third auxiliary request

Article 54 EPC - Novelty - Documents (1) and (2)

The step of correlating the reflectance measurement to the alignment of the test strip in the detection apparatus (step (e) of the method of claim 1) was not described in either document(1) or document (2). Thus, the subject-matter of the claims was novel.

Article 56 EPC - Inventive step

Document (6) could not be considered to be the closest state of the art because no reference was made in this document to the use of an infrared dye or the measurement of reflectance of infrared radiation. Even if a person skilled in the art had started from this document, he/she would have had no incentive to exchange the black bar code on the test strip by an infrared dye, because there was no interference between the test field and the markings of the bar. Moreover, document (6) provided no hint towards any of the documents (1), (2) and (4). A combination of document (6) with document (1) would rather teach away from the method of the present patent. Hence, the subject-matter of the claims was not obvious.

XXIII. The submissions made by appellant II may be summarized as follows:

Main request - Article 100(c) EPC

Article 100(c) EPC prejudiced the maintenance of the patent in the granted form. The negative feature in claim 1 did not have a basis in the application as filed. The fact that the infrared dye would not adversely affect the reagent incorporated into a test pad - as it was stated in the application - was not a direct disclosure of the dye not labelling a component of the reagent composition. The term "component" could designate every component, irrespective of its function in the reagent composition. Thus, labelling a component of the reagent composition would not necessarily impair

the ability of the composition to react with the analyte, because situations were conceivable where the infrared dye labelled a component which was not required for the reaction.

First auxiliary request - Article 123(3) EPC

The omission of the negative feature in amended claim 1 extended the scope of the claim. The new feature specifying the position of the infrared dye was in no way limiting, because the position on the support handle included the test pads, as could be gathered from the wording of claims 3 and 4.

Second auxiliary request - Article 123(3) EPC

The wording of amended claim 1 merely excluded those infrared dyes which adversely affected a reagent incorporated into a test pad. However, labelling a component did not necessarily mean adversely affecting the reagent composition. Thus, the introduction of the new feature could not compensate for the omission of the objected negative feature included in claim 1 as granted. As a consequence, the scope of the claim was extended.

Third auxiliary request

Article 54 EPC - Novelty

Document (1)

It was not subject of dispute that document (1) described a test strip with the features specified in

step (a) of the method of claim 1. Steps (c) and (d) were described on, respectively, column 10, lines 19 to 20, and 42 to 47 of document (1). Since the wording "alignment" was vague, step (e) could be understood as any correction for variations in pad thickness, pad volume or position of the reagent pad, as described in column 12, lines 49 to 56 of document (1). Thus, the method of claim 1 lacked novelty with regard to the content of this document.

Document (2)

Document (2) described a system for the optical identification of an analyte using a diagnostic test strip. The test strip used could not be distinguished from a test strip according to the patent. Since reflectance in the infrared region was measured (see column 6, lines 28 and 29), the marker field on the test strip had to include an infrared dye. According to document (2), when a test strip was introduced into the reading device, the marker field on the test strip was illuminated and the reflectance was measured (see column 6, lines 20 to 29). The information obtained by the reflectance measurement could then serve different purposes. For example, it could allow the software of the apparatus to look up information on critical measurement parameters such as location of reacting areas (see column 8, lines 13 to 15). Subsequently, after identification of the marker field, the instrument would move the test strip to the proper location (column 8, lines 16 to 18). Thus, the information regarding localization of the reaction areas was correlated with the future positioning of the test strip within the apparatus. Hence, document (2)

described correlating the reflectance measurement to the desired alignment of the test strip, as required in step (e) of the method of claim 1. Since all the features of the method of claim 1 were derivable from document (2), the requirement of Article 54 EPC was not met.

Article 56 EPC - Inventive step

The subject-matter of the claims did not involve an inventive step. Document (6) was regarded as the closest state of the art. The wording "infrared dye" in claim 1 had to be interpreted broadly and did not exclude dyes having a visible colour. Therefore, the definition of an infrared dye encompassed any dyes which absorb at least to a certain extent in the infrared area. If the board should nevertheless conclude that the black bar code used in document (6) could not be regarded as an infrared dye, the sole difference in the method of present claim 1 would be the use of the reflectance of an infrared dye in the infrared area instead of the reflectance of a black bar code, in order to monitor the alignment of a test strip. Thus, the problem underlying the present invention was to provide an alternative marker on the test strip.

It had already been known from document (1) at the priority date that infrared dyes were suitable for the marking on test strips and could provide various types of information, e.g. information regarding the position variability of the reagent pad (see document (1), column 12, lines 54 to 56). If, starting from document (6), the skilled person would have looked for an alternative for the black bar code for position

control, he would have been guided by document (1) towards the use of an inert dye absorbing in the infrared region. The advantages of such a dye were already known. The use of an infrared dye was thus merely an obvious alternative which was not based on an inventive step.

XXIV. Appellant I (patent proprietor) requested that the decision under appeal be set aside and the patent be maintained as granted, in the auxiliary that the patent be maintained based on the first auxiliary request filed with letter of 2 July 2009, or on the basis of the second auxiliary request filed with the statement setting out grounds of appeal, further in the auxiliary that the appeal of appellant II be dismissed (third auxiliary request), further in the auxiliary that the decision under appeal be set aside and the patent be maintained based on the fourth auxiliary request, filed as auxiliary request 6 before the opposition division.

XXV. Appellant II (opponent) requested that the decision under appeal be set aside and the patent be revoked.

Reasons for the Decision

Main request (claims as granted) - Article 100(c) EPC

1. In the decision under appeal, the opposition division found that Article 100(c) EPC prejudiced the maintenance of the patent as granted. In particular, the opposition division held that the subject-matter of claim 1 extended beyond the content of the application as filed because the negative feature "*... said infrared dye not labelling a component of said reagent*

composition", which had been introduced into claim 1 in examination proceedings to establish novelty over intermediate document (5) (cited as D6 in examination proceedings), was neither disclosed in the application as filed nor met the requirements established by the Enlarged Board of Appeal in decisions G 1/03 and G 2/03 (OJ EPO 2004, 413 and 448) for a disclaimer to be considered allowable.

2. In appeal proceedings, appellant I maintained that the objected feature had a basis in the application as filed, in particular on the passages on page 12, lines 3 to 8 and page 9, lines 11 to 14. These passages read:

> "*In embodiments wherein the IR dye is incorporated into a test pad, the IR dye cannot adversely affect the reagent incorporated into the test pad or adversely affect an interaction between the analyte of interest and reagent present in the test pad*" (page 12, lines 3 to 8)
>
> "*In another aspect of the invention, the IR dye is incorporated into a test pad of the strip, either in conjunction with the assay reagent or separately from the assay reagent*" (page 9, lines 11 to 14)

3. Like the opposition division, the board is not convinced that a person skilled in the art could derive, directly and unambiguously, from the passages of the application as filed quoted above that the infrared dye on the claimed test strip does not label a component of the reagent composition. As regards the first passage,

the statement that neither the reagent incorporated into the test pad nor the interaction between the reagent and the analyte of interest should be adversely affected by the infrared dye would not be interpreted by a person skilled in the art as a requirement that the infrared dye does not label a component of the reagent composition. Labelling a component of the reagent composition with an infrared dye does not necessarily have to interfere or adversely affect the reagent incorporated into the test pad or its interaction with the analyte. Conversely, if there is an adverse effect in the presence of an infrared dye, it may be caused by different kinds of interaction between the dye and a component of the reagent, other than labelling.

4. As regards the second passage, the board does not share appellant I's view that the skilled person could derive the objected feature from the statement that the infrared dye can be incorporated into the test pad separately from the assay reagent. Two different embodiments are disclosed in this passage. While the possibility that the infrared dye labels a component of the reagent composition would in fact be logically excluded in the second embodiment, it cannot be excluded from the first (i.e. the infrared dye is incorporated in conjunction with the assay reagent). Thus, the feature that the infrared dye does not label a component of the reagent composition cannot be considered to be **unambiguously** derivable from this passage.

5. In appeal proceedings, appellant I did not contest the opposition division's finding that the negative feature

in claim 1 cannot be regarded as an allowable disclaimer (see G 1/03 and G 2/03, *supra*), and the board does not see any reasons which may allow a different finding.

6. In view of the above, the board confirms the opposition division's finding that Article 100(c) EPC prejudices the maintenance of the patent in the granted form.

Admission of the claims according to the first and second auxiliary request into the proceedings

7. Claims 1 to 14 of the first auxiliary request presently on file were filed on 2 July 2009 and are essentially identical to those of the first auxiliary request submitted together with the statement of grounds of appeal, except for an amendment of the wording introduced by appellant I to remedy a clarity deficiency. The set of claims according to the second auxiliary request was filed together with the statement of grounds of appeal.

8. Both requests have been filed in an attempt to overcome the ground for opposition raised under Article 100(c) EPC, which was considered by the opposition division to prejudice the maintenance of the patent in the granted form.

9. However, in the summons issued in preparation of the oral proceedings the opposition division had expressed the (provisional) view that there was a basis in the application as filed for the contested negative feature, and that the feature in question also fulfilled the requirements for an allowable disclaimer established in

decision G 1/03 (*supra*). Appellant I has credibly argued that it had been taken by surprise by the opposition division changing its mind during the oral proceedings, and that, under time pressure, it had not been able to amend the claims to obviate the objected negative feature and avoid the "inescapable trap" of Article 123(2) and (3) EPC.

10. In view of these particular circumstances, the sets of claims according to the first and second auxiliary request are admitted into the proceedings.

First auxiliary request (claims 1 to 14 filed on 2 July 2009) - Article 123(3) EPC

11. The board accepts that amended claim 1 was filed as an attempt to overcome the objection under Article 100(c) EPC by replacing the negative feature lacking a basis in the application as file by the feature that the infrared dye is positioned on the support handle of the test strip (see decision G 1/93; OJ EPO 1994, 541). The question arises whether or not the amendment breaches Article 123(3) EPC.

12. In appellant I's view, the feature introduced into claim 1 limited the claimed subject-matter to test strips in which the infrared dye was positioned outside of the test pad. Since according to the claim the reagent composition was located only in a test pad, this necessarily implied that the infrared dye would not label a component of the reagent composition, as required in claim 1 as granted.

13. The board disagrees with appellant I's interpretation of the introduced feature. Although the wording "support handle" appears to be somehow ambiguous, it is apparent from claim 1 itself and, especially, from claim 3, which is dependent on claim 1 and specifies that "*... the infrared dye is incorporated into one or more test pad*", that the feature "*said infrared dye being positioned on the support handle*" does not preclude the infrared dye being incorporated into a test pad where the reagent composition is also located. Thus, as appellant II argued, the new feature does not introduce any limitation to the scope of the claim. Since, on the other hand, the limiting negative feature included in claim 1 as granted has been omitted in the amended claim 1, the latter claim encompasses subject-matter which extends beyond the scope of the claims as granted, contrary to Article 123(3) EPC.

14. For the sake of completeness, the board observes that, even though the additional feature "*... wherein the handle is formed from hydrophobic material*" in amended claim 1 is, in fact, a limiting feature, the scope of the claim has, nevertheless, been extended compared to claim 1 as granted, as a result of the omission of the negative feature. Since the additional feature does not limit the scope of the claim to the same - or a larger - extent that it is extended by the omission of the negative feature, the amendments introduced into the claim do not conform to Article 123(3) EPC.

15. It follows from the above that, contrary to appellant I's request, maintenance of the patent in amended form cannot be based on the claims according to the first auxiliary request.

Second auxiliary request (claims 1 to 14 filed together with the statement of grounds of appeal) - Article 123(3) EPC

16. A similar conclusion is reached in respect of the amended claim 1 of the second auxiliary request. Claim 1 of this request specifies that the infrared dye is incorporated into one or more test pad, the dye not adversely affecting the reagent incorporated into the test pad. As stated above in connection with the main request (see point 3 above), an infrared dye that labels a component of the reagent composition could, but not necessarily has to adversely affect the reagent composition. Since the feature "*not adversely affecting the reagent*" excludes from the scope of the claim only those embodiments in which there is in fact an adverse effect, the amended claim seems to encompass those embodiments of the test strip in which a component of the reagent is labelled with an infrared dye, but the labelling has no deleterious effects on the reagent or the interaction with the analyte. Such an embodiment of the test strip did not fall under the scope of the claims as granted.

17. Since as a consequence of the amendment the scope of the claim has been extended, contrary to Article 123(3) EPC, the patent cannot be maintained on the basis of the claims of the second auxiliary request.

Third auxiliary request

Articles 123(2) (3), 84 and 83 EPC

18. No objections under these articles were raised by appellant II, and the board does not see any reason to do it of its own motion. Thus, the respective requirements are regarded as fulfilled.

Article 54 EPC - Novelty

19. In the decision under appeal, the opposition division decided on objections of lack of novelty raised by the opponent relying on documents (1) and (2). In its statement setting out the grounds of appeal, appellant II submitted arguments against the novelty of the subject-matter of present claim 1 with regard to documents (2) and (6), and in its further written submissions documents (6) and (9) were also cited . However, at the oral proceedings appellant II stated that its novelty objection was based solely on documents (1), (2) and (4).

Document (1)

20. In the decision under appeal, the opposition division found that the claimed methods of monitoring alignment of a test strip in an optical pathway of a detection apparatus were novel with regard to document (1). In the opposition division's view, the purpose of the method described in document (1) was to enable a quantitative correction of the measurement carried out on a "primary color forming or color changing indicator" in a reagent composition. This was achieved

by using a secondary inert chromogen marker, e.g. an infrared dye. The opposition division stated that "correction" in document (1) was meant to be a numerical calculation, rather than monitoring the position of the test strip in a detection apparatus, as in the claimed method. Consequently, the step of correlating the reflectance measurement of the infrared dye to the alignment of the test strip in the detection apparatus (step (e) of the method of claim 1) could not be derived from document (1) (see section 5.6 of the decision under appeal).

21. Appellant II contested this finding relying in particular on the passage in column 12, lines 46 to 56 of document (1). This passage reads:

> "*The secondary, inert chromogen marker is capable of correlating primary chromogen reflectance measurement to achieve approximately a two-fold increase in measurement accuracy. The secondary, inert chromogen marker corrects for variations in reagent pad scattering coefficient, pad thickness, pad volume, reflectance of reagent strip backing or support material, height variability of the reagent pad, position variability of the reagent pad and drift within the specrophotometer*[sic]"

22. The board observes that, rather than appellant's line of argument, this passage supports the opposition division's view that the purpose of a "correction" in the method of document (1) is not to monitor the alignment of the test strip in the detection apparatus, but to achieve an increase in measurement accuracy by introducing into the calculation a "correction factor"

which is derived from the measurement of a secondary, inert marker. The board also remarks that the whole second sentence in this passage, and specifically the wording "*position variability of the reagent pad*", on which appellant II particularly relied, relates to the correction of variations concerning the **reagent pad**. Thus, the wording "*position variability*" in the passage quoted above is understood by the board as referring to the variability in the position of the reagent pad within the test strip, rather than to a possible misalignment of the test strip within the detection apparatus.

23. This interpretation is supported by the passage on column 5, lines 33 to 37, to which the opposition division referred in its decision, and which reads:

> "*This correction factor allows the calculated concentration of the analyte to be corrected for* ***variations in reagent strip characteristics*** *such as thickness and scattering coefficient as well as instrumental variability*" (emphasis added by the board)

In the board's understanding, the wording "i*nstrumental variability*" in this passage stands for a variation between different detection apparatuses, rather than for a variation in the position of the test strip within the detection apparatus.

24. For these reasons, the board concludes that document (1) does not describe a method of monitoring alignment of a test strip in an optical pathway of a detection apparatus comprising the step of correlating the

reflectance measurement to the alignment of the test strip. Hence, document (1) is not prejudicial to the novelty of claim 1.

Document (2)

25. In the decision under appeal, the opposition division held that document (2) did not destroy the novelty of claim 1 because this document did not describe measuring the reflectance of infrared radiation from an infrared dye for monitoring the alignment of a test strip in a detection apparatus (see sections 5.2 to 5.4 of the decision under appeal).

26. It is undisputed that document (2) describes a method using a test strip with a marker field absorbing in the infrared region. Also steps b) to d) of the method of present claim 1 can be derived from this document (see, e.g., claim 1 in document (2)). Thus, for the assessment of novelty with regard to document (2), the decisive question is whether or not this document describes a method of monitoring the alignment of the test strip in a detection apparatus.

27. In this respect, appellant II pointed to the passage on column 8, lines 13 to 18 reading:

> "[The color coding sequence] *... can also allow the software to look up information on critical measurement parameters such as location of reacting areas, critical times, strip age, and reactivity. After the color sequence has been identified, the instrument will move the test*

> *strip to the proper location, i.e. test field 501 ...*"

The passage goes on as follows:

> "*... and collect data at the proper wavelengths and at the proper time or times such that the collected data can be analyzed by an appropriate algorithm to complete the assay*" (see column 8, lines 19 to 22)

28. As indicated by the opposition division in the decision under appeal, it is apparent from the quoted passage that, after the test strip is moved to the proper location based on the information provided by the "color coding sequence" (e.g. a bar code with marker fields absorbing in the infrared regions of the spectrum), the test results for the analyte are measured. Hence, the purpose of the "color coding sequence" described in document (2) is not to assess whether or not the strip has been correctly introduced into the apparatus, but to direct the test strip to a position in which the analyte can be measured.

29. For these reasons, the board shares the opposition division's view that, with regard to document (2), the method of claim 1 is novel.

Document (4)

30. During the oral proceedings, appellant II raised - for the first time in appeal proceedings - a novelty objection in respect of the claims of the third auxiliary request relying on document (4). According to

Article 13(1) RPBA, any amendment to a party's case after it has filed its grounds of appeal or reply may be admitted and considered at the board's discretion. This discretion is exercised taking into account, *inter alia*, the state of the proceedings.

31. There is no doubt that appellant II could have raised and substantiated a novelty objection against claims 1 to 5 of the third auxiliary request based on document (4) much earlier in appeal, for instance in the statement of grounds of appeal, the reply to appellant I's statement or any of the numerous submissions filed in appeal (see sections X, XII, XIV and XVIII above). Appellant II did not give any reason why the objection was submitted at such a late stage of the proceedings. Since the late submission deprived the other party of the time required for a careful preparation of counter-arguments, the board, exercising its discretion under Article 13 RPBA, decides to disregard the novelty objection based on document (4). The objection is, thus, not subject of this decision.

32. Summarising the above, the board concludes that the subject-matter of claim 1 - as well as that of dependent claims 2 to 5 - is novel with regard to documents (1) and (2).

Article 56 EPC - Inventive step

33. In the decision under appeal, document (1) was regarded as the closest state of the art, and the objective technical problem to be solved as the provision of an alternative method of avoiding errors due to position variability. The opposition division took the view that

the subject-matter of the claims was not obvious in view of the content of document (1) alone or in combination with either document (6) or document (4) (see sections 6.3 and 6.4 of the decision under appeal).

34. In its submissions in appeal proceedings, appellant II relied on document (6) as the closest state of the art, and argued that the subject-matter of the present claims lacked an inventive step in view of the combination of this document with any of documents (1), (2) and (4).

35. Document (6) describes a device for photometric analysis of liquid samples, in particular body fluids. The device has two reading units for reading test strips having a test field onto which the liquid sample has been applied. The test strip is provided with two coding systems: the first coding system is a bar code consisting of bars of varying width, and the second coding system has a bar code including a clock track and a data track. When the test strip is inserted into the device, the clock track is read by one reading unit, which triggers the reading of the data track by the other reading unit (see claim 1 in document (6)).

36. In order to ensure that the test strip has reached and also maintains a predetermined position within the device, the test strip can be provided with an additional mark. If the test strip has been correctly introduced, this mark is positioned in front of the reading units. By reading the mark, the device monitors whether or not the test strip has reached the final position for measurement ("Endlagenkontrolle"; see paragraph bridging columns 1 and 2).

37. Figure 5 of document (6) shows a test strip 34 having a data track 72 which includes information required for measuring the test results, and a track 74 for monitoring the correct position ("Endlagenanzeige"). The track can be provided as a bar code or a single bar on the test strip (see column 5, lines 11 to 14).

38. Contrary to the opposition division's assessment, the board takes the view that a person skilled in the art can derive from document (6) a method having the same purpose as the method of the present invention, namely to monitor whether or not a test strip is correctly aligned in the optical pathway of a detection apparatus. The difference between the two methods is that, instead of a bar code or a single bar in black colour as used in document (6), the method of the present invention uses an infrared dye. Accordingly, in the claimed method, the predetermined location where the infrared dye is located on the test strip has to be illuminated with infrared radiation (step (c) in claim 1), and a reflectance of infrared radiation from the predetermined location measured (step (d) in claim 1). Also these features of the claimed method cannot be derived unambiguously from document (6).

39. Appellant II argued that the term "infrared dye" as defined in the patent (see paragraph [0033] of the patent specification) included any dye that absorbs not only in the infrared region, but also at different wavelengths. Thus, in its view, a black ink which shows at least some absorbance in the infrared region has to be regarded as an "infrared dye".

40. The board disagrees with this view. Paragraph [0033] of the patent specification defines an infrared dye as a dye having a **strong** absorbance in the infrared region. Apart from the fact that there appears to be no evidence on file showing that the black ink used in document (6) has a strong absorbance in the infrared region, the board observes that, even if the black ink may possibly absorb infrared radiation to a certain extent, a person skilled in the art reading document (6) would not learn from the document that absorbance in the infrared region is an essential feature of the ink. When determining the content of document (6) for the assessment of inventive step, the question to be decided is what this document makes available to a skilled person, not what might be inherent in what is made available (see decision G 2/88, OJ EPO 1990, 93).

41. Both the method of document (6) and the method of the invention seem to achieve the same technical effect: an increased accuracy and the avoidance of false negative assay results. In the absence of any hint in document (6) to possible drawbacks or any suggestion for improvements, in particular in respect of the track for monitoring the correct position, the problem to be solved must be formulated as the provision of an alternative method of monitoring alignment of a test strip. As a solution, the patent proposes the method as defined in claim 1, which credibly solves the posed problem.

42. Appellant II's argument that it was obvious to a person skilled in the art to replace the black ink in the method of document (6) by an infrared dye as described in any of documents (1), (2) and (4) fails to convince

the board. While a person skilled in the art seeking for an alternative to the method of document (6) could, in principle, replace the black ink by any of the different dyes suggested in documents (1), (2) and (4), the board cannot see why the skilled person would consider in particular an infrared dye, as this would require to adapt the detection device described in document (6) by adding to the first and second reading units a third dedicated reading unit suitable for measuring reflectance of infrared radiation. This would only increase the complexity (and the price) of the detection apparatus, without bringing any apparent further advantages in accuracy in comparison to the method described in document (6).

43. The board is not persuaded that, in view of the above, a person skilled in the art had an incentive to replace the black bar code of document (6) by an infrared dye. He/she would be rather deterred from doing it because this would require additional technical means and increase the complexity of the measurement.

44. The board thus concludes that the method of claim 1 was not obvious to a person skilled in the art, within the meaning of Article 56 EPC. This confirms the opposition division's finding.

Conclusion

45. Having considered the arguments put forward by the parties in appeal proceedings, the board sees no reason to set aside the decision under appeal.

Order

For these reasons it is decided that:

The appeals are dismissed.

The Registrar: The Chairman:

A. Wolinski M. Wieser