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D E C I S I O N
of 28 September 2004

Case Number: T 0474/01 - 3.4.2

Application Number: 89113614.5

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Language of the proceedings: EN

Title of invention:
Apparatus and method for providing assay calibration data

Patentee:
ABBOTT LABORATORIES

Opponent:
Roche Diagnostics GmbH

Headword:
-

Relevant legal provisions:
EPC Art. 54, 56

Keyword:
"Interpretation of claim, closest prior art"

Decisions cited:
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Catchword:
-

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Case Number: T 0474/01 - 3.4.2

D E C I S I O N
of the Technical Board of Appeal 3.4.2
of 28 September 2004

Appellant: (Proprietor of the patent)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 16 February 2001 revoking European patent No. 0353589 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairman: A. G. Klein
Members: G. M. Maaswinkel
C. Rennie-Smith

Summary of Facts and Submissions

I. European patent No. 0 353 589 (based on application No. 89 113 614.5) was revoked by the decision of the opposition division dated 16 February 2001.

II. On 24 April 2001 the patent proprietor filed an appeal against that decision and paid the appeal fee. The statement setting out the grounds of appeal was received on 26 June 2001.

III. The opposition had been filed against the patent as a whole on the basis of Article 100(a) EPC in combination with Articles 52(1), 54 and 56 EPC. To support its objections the opponent referred *inter alia* to the following documents:

(D1) US-A-3 907 503
(D2) GB-A-2 096 314
(D3) US-A-4 476 149
(D4) EP-A-0 225 474
(D6) US-A-4 568 184
(D8) US-A-4 558 013

IV. In its decision the opposition division found that the subject-matter of the independent claims 1, 5 and 6 was novel over the disclosure in document D1, which in its view was the closest prior art, by virtue of the feature of the use of binding components for the test samples, but that it did not involve an inventive step.

V. Oral proceedings requested by both parties were held on 28 September 2004.

VI. At the oral proceedings the appellant requested that the decision under appeal be set aside and that the patent be maintained as granted (*main request*) or on the basis of the first or second auxiliary requests filed with its letter of 27 August 2004 or of the third auxiliary request filed during the oral proceedings.

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

VII. Claim 1 of the main request (granted patent) reads as follows (*including the letters (a) to (j) to designate features as referred to by the parties*):

"(a) An automated apparatus (10) for analyzing biological samples, characterized by
(b) means (300, 302, 304, 306, 308, 310) for calibrating or normalizing the data obtained from a panel of assays for a plurality of test sample binding components
(c) performed simultaneously on a single biological sample wherein said calibrating or normalizing means comprises:
(d) predetermined machine readable assay calibration data (300) for said panel containing at least one standard value for each said binding component;
(e) data providing means (306) for providing said predetermined assay calibration data in association with a first code means;
(f) electronic storage means (310) for storing said calibration data (300) and its associated first code means;
(g) entering means (308) for entering said calibration data and its associated first code means to a location

(312, 314) in said storage means (310) without performing an assay;
(h) assay means (32, 80) for simultaneously carrying out said panel of assays on a single aliquot of a biological sample, wherein said assay means includes a panel of test sample binding components, each bound to its own discrete test site (84) in an array of isolated test sites in a disposable reaction cartridge means (80) and
(i) a second code means (94) associated with said panel in said cartridge means (80), said second code means (94) being used to access said electronically stored calibration data set ((300) for that panel of test sample binding components; and
(j) electronic correlation means (315) for correlating the stored calibration data for said panel with the assay results for said panel using said first and said second code means".

Claim 5 of the main request reads as follows:

"An automated apparatus (10) for analyzing a plurality of biological samples, characterized by a means (32,80) for assaying each sample simultaneously for a plurality of test sample binding components and a means (300, 302, 304, 306, 308, 310) for calibrating or normalizing the results obtained from each assay;
said assay means comprising a plurality of disposable reaction cartridge means (80) each designed for facilitating simultaneous contact between a panel of test sample binding components, each bound to its own discrete test site (84) in an array of isolated test sites contained in said reaction cartridge means (80), and a single aliquot of a biological sample, each

cartridge being [*sic*] means (80) associated with a second code means (94); and said assay means further comprising means (32) for measuring binding between each test site and components of the biological sample being assayed; and
said calibrating or normalizing means comprising: an electronically stored calibration data set (300) for each panel of test sample binding components containing at least one standard value for each binding component in the panel, each set being associated with a first code means; and electronic associating means (315) for associating each panel with its set of calibration data using said first and second code means, said second code means (94) being used to access said electronically stored calibration data set (300) for that panel of test sample binding components".

Claim 6 of the main request reads as follows:

"A method of calibrating or normalizing assay results, characterized in that
a single aliquot of a biological sample is simultaneously assayed with a panel of test sample binding components, each bound to its own discrete test site (84) in an array of isolated test sites in a reaction cartridge means (80); and in that a second code means (94) is associated with said panel in said cartridge means (80); and in that the results for the panel are calibrated or normalized using a previously electronically stored data set (300) which contains at least one standard value for each test sample binding component and which is associated with a first code means, said results and said data set being correlated using said first and second code means, said second

code means (94) being used to access said electronically stored calibration data set (200) for that panel of test sample binding components".

Claim 2 to 4 are dependent claims.

The wording of the claims in accordance with the appellant's auxiliary requests is not relevant for the purpose of this Decision.

VIII. The arguments of the appellant may be summarised as follows:

(a) As regards novelty, the appellant argued thus. The invention relates to an apparatus and method for analyzing biological samples in the field of immunobiology. In Claim 1 (*and the corresponding Claims 5 and 6*) this clearly follows from the features (a) and (h), furthermore from the introductory part of the patent specification which, together with the drawings, may be used to interpret the claims. Document D1, which had been considered in the decision under appeal as the closest prior art and which, according to the opponent, would even anticipate the subject-matter of Claim 1, belongs to the *different* technical field of analytical chemistry instruments. In column 2, lines 32 to 38 of this document it is disclosed that the test devices and test reagents comprise one or more *chemical* constituents which specifically react with the substance in the test fluid to give a detectable *chemical* response which relates to the amount of the constituent in the fluid. In D1 there is no explicit mentioning of *binding components* or *capture reagents*

and it is clear that the reactions involved in the test strips are purely chemical ones. Therefore, if only by virtue of features (a) and (h), the subject-matter of Claim 1 is new over the disclosure in D1.

In the decision under appeal it was furthermore argued that D1 refers to an automatic analytical apparatus having a ROM (read only memory) preloaded with different thresholds for each of the different reagents **for the purpose of calibration** (corresponding to the first code means of the claimed invention). As can be readily seen from Figure 4 in D1 this assessment is erroneous, since the ROM does not belong to the "calibrate and amplify unit" 23 but to the "function generator" 29. It comprises different reaction ranges which are independent of the specific features of the test strip under examination. The ROM is informed about the kind of reagent by access register 116 and it outputs to a decoder 112 a number of threshold values for this reagent. The ROM functions as a sort of translator which categorises and translates the unknown data into a printable form. Therefore no calibration is performed by means of the ROM in the sense of the claimed invention, i.e. raw data output by the reading means is not normalised by means of the ROM. It should be noted that, since a ROM is a read only memory, its contents cannot be changed and accordingly data cannot be entered. The threshold values stored in ROM 110 for each of the seven reagent-type categories (pH, glucose, etc.) cannot change with the particular test strip under consideration, nor do they depend on the batch or lot of origin of the single reagent used in such a test strip. Therefore these threshold values cannot be considered as calibration data in the sense of the

claimed invention and no entering means can be presented in the apparatus of D1 for entering such calibration data and an associated code means in the ROM. It follows that the subject-matter of Claim 1 not only differs from the apparatus disclosed in D1 in that binding components are used as is expressed by features (a) and (h), but also in that the apparatus of D1 does not comprise calibration data (*feature (d)*), data providing means for providing predetermined assay calibration data in association with first code means (*feature (e)*) and entering means for entering the calibration data and its associated first code means to a location of storage means (*feature (f)*) without performing an assay (*feature (g)*). Therefore the invention as defined in Claim 1 is novel over the disclosure in document D1. The same applies *mutatis mutandis* to the subject-matter defined in independent Claims 5 and 6.

(b) Concerning inventive step, the appellant argued that in the decision under appeal document D1 was considered to be the closest prior art. As already mentioned, that document does not belong to the same technical field of the invention as defined by features (a) and (h) of Claim 1 and the necessity of assay calibration is not an issue in the field of D1 (analytical chemistry) to the same extent as in the field of immunology assaying, where allergens or other assay binding components are produced in lots or badges of limited volume and where each lot has a different reaction behaviour. Further, in the field of immunology, the preparation of test sites before optical reading follows specific procedures as described in the patent specification. Such procedures involve, for instance, multiple washing

steps alternated with long incubation periods. Document D1 completely ignores such procedures because it does not deal with immunological reactions. The gist of the invention and the solution defined in the claims is to construct a library including predetermined calibration data specific for each individual lot and to which first code means are associated. This library is stored in the analyzer apparatus without performing an assay. With the test panel containing the assay binding components a second code means is associated which is a pointer to the library. When carrying out an assay the second code means points to the library to select the first code means which provide the calibration data relevant for the test sample binding components in use, whereupon the raw data are calibrated. Irrespective of the fact that the apparatus disclosed in D1 does not include the features (a) and (d) to (h) and that this disclosure does not deal with the problem underlying the invention, the "calibration" carried out in that apparatus is completely different from the procedure defined in the independent claims. As described in column 8, starting at line 55, the calibration in the apparatus of D1 is a calibration to obtain for each of the reagents a "zero value" and a "high positive value". In column 11, line 49 it is disclosed that these values are stored in the memory 84. This calibration in D1 is done *manually* by dipping the test stripes in respective zero and high positive test solutions. This is in contrast to the invention; see the patent specification on page 18, lines 46 and 47, where the calibration data are determined at the time the reaction cartridges are manufactured and which is reflected in the wording of feature (g) of Claim 1. Furthermore the only "code means" recognisable in document D1 is the code 17,

which (see column 8, line 42) has a first function of identifying the type of test stripes, and a further function of calibrating the instrument by sampling light reflecting from the surface of the code block. This is, however, an instrument calibration and does not relate to the feature "standard value for each binding component" as defined in Claim 1. Therefore D1 cannot suggest the combination of features of the claimed invention, since D1 was not conceived for the same purpose as the invention and the technology disclosed by it would not even hint to the person skilled in the art that he should build an apparatus comprising means for calibrating or normalizing the data obtained from a panel of assays for a plurality of test sample binding components as defined in Claim 1.

The appellant further argued that, with respect to the other available documents, only documents D6 and D8 lie in the same technical field of the invention as defined by features (a) and (h) of Claim 1 and by the introductory part of the description. If, starting from document D6 as the closest prior art, it is noted that, while its subject-matter lies in the field of immunology tests and more particularly radioimmunoassays, the document does not disclose or suggest calibration in the sense of the claimed invention. This document discloses a reader card including a photographic film comprising an exposure pattern. The pattern derives from an exposure of the film to a radioactive incubation bath where radioactively-tagged antibodies bind to antibodies previously bound to an *existing* antigen-coated carrier already incubated with a biological sample (column 1, lines 29 to 40). Therefore the starting point of D6 is

a test device for which no information is available or derivable regarding standard values of the binding components. The only "calibration" provided for in the apparatus disclosed here is a "black level" calibration which is an optical calibration of the densitometer instrument and which is not related at all to the calibration defined in the claims of the patent.

Document D8 discloses an apparatus for measuring the magnitude of reactions occurring between a predetermined class of components and their corresponding conjugates coated on an insoluble carrier. The carrier includes a plurality of separate test regions coated with a different component from the class and a negative reference region that is uncoated. The negative reference region serves as a reference optical density for the subsequent measurements of the coated test regions, thus correcting the effects of non-specific binding and background noise on these measurements, see column 4, lines 24 to 38. Also this document does not disclose the normalization of the data obtained from a panel of assays for a plurality of test sample binding components which takes into account predetermined calibration data containing *at least one standard value for each binding component*. This feature is also not known or suggested in any of the other available documents. Therefore the subject-matter of Claim 1 involves an inventive step, and similarly the further independent Claims 5 and 6.

IX. The arguments of the respondent may be summarised as follows:

(a) As regards novelty, the patent in suit relates to an automated apparatus for assaying a plurality of biological samples which is characterised by means for calibration or normalisation of the assay data. In the independent claims the expression "test sample binding components" is used. This is, however, a very broad concept which does not necessarily imply that the claimed apparatus, and similarly the corresponding method, are confined to immunology assays, or respectively to assays for screening allergens and antibodies. Furthermore the term "binding" with a test sample merely implies that there is an interaction between the components which allows a qualitative or quantitative detection. Also the concept of "calibration" or "normalisation" is not further defined in the claims. Therefore the claimed subject-matter does not allow to distinguish between "immunologic" and "(bio)chemical" assays. In consequence document D1 discloses all the features of Claim 1. In particular this document discloses an automated apparatus for analyzing biological samples (*for instance, urine or proteins; this corresponds to the claimed feature (a)*); with means for calibrating or normalising the data obtained from a panel of assays for a plurality of test sample binding components (*see module 23 in Figure 2; see also the Table in column 12 which distinguishes five ranges for calibration or normalisation; the plurality of detectable compounds are shown in Figure 1, which also include biological samples, e.g. proteins*), thereby disclosing features (b) and (c). With respect to feature (d), the apparatus of document D1 comprises a ROM 110 which, according to column 11, lines 57 to 59, is "preloaded for use with different thresholds for each of the reagents". The Table in column 12 includes

five calibration ranges for the pH test block which are predetermined and machine readable, as defined in feature (d). This ROM also provides the predetermined assay calibration data in association with a "first code means" as defined in feature (e), which in the apparatus of D1 corresponds to a specific area of the memory which is selectively addressable via a memory address thereby corresponding to a "first code means". The ROM is also the electronic storage means as defined in feature (f). Furthermore, as disclosed in the cited passage in column 11 of D1, the ROM is preloaded with the data via a computer, which are the "entering means" and the data are entered without performing an assay, corresponding to feature (g). The assay means as defined in feature (h) of Claim 1 are shown in Figure 1 and are described in column 5, lines 24 to 40 of D1. The "second code means" defined in feature (i) corresponds to the coding 17 on the test devices with which the pointer on the test device can be allocated, as is described in column 8, lines 42 to 51. Finally, via access register 116 which receives the code from code block 17 and the ROM, the calibration data for the panel stored in the ROM and the panel assay results are correlated using the first and second code means, as is disclosed in column 11, lines 54 to column 12, line 59. From the comparison with document D1, it follows that Claim 1 lacks novelty.

(b) As regards inventive step, the closest prior art for the issue of inventive step should be a document "disclosing subject-matter conceived for the same purpose or aiming at the same objective as the claimed invention and having the most relevant technical features in common, i.e. requiring the minimum of

structural modifications" (see Section I.D.3.1 of the "Case Law of the Boards of Appeal"). As already mentioned, the apparatus disclosed in D1 has most -if not all- of the features of the claimed subject-matter. Furthermore the patent in suit (see page 3, lines 47 and 48 and document D1, see column 1, lines 44 to 47) shares the *same* general technical problem and aims at the *same* solution, i.e. to provide test system for assaying a *plurality of constituents in a patient sample*. The invention relates to a diagnostic system for automatic testing of a plurality of samples and the question is how to process the measured data. The subject of the claimed invention is *not* an immunological test and the patent does not teach any steps which are only used for immunological tests and not in (bio)chemical tests. Rather its background lies in the improvement of an analysis apparatus. Therefore document D1 meets all the criteria to be considered as the closest prior art. Starting from this document the objective problem could be seen in the application of the known apparatus for immunological tests. This problem would be obvious to the skilled person, because document D1 already tested biological samples (proteins, urine) and lot-to-lot variations are equally known to be present in chemical tests. Therefore the skilled person would consider employing the apparatus disclosed in D1 for other biological, including immunological test samples as disclosed in document D6.

Should document D6 be considered as the closest prior art it is noted that column 1, line 22 of that document discloses a test card for determining allergic reactions. This document furthermore discloses in column 5, lines 37 to 40 and lines 56 to 62 that it was

known in the field of immunological tests before the priority date of the patent in suit to carry out, in automated analysis processes, calibration and normalisation on the basis of stored calibration data. The objective problem should then be seen as providing a further automatic process for detecting allergic reactions. The obvious solution is disclosed in document D1, see the cited passage in column 1, line 45. A further possible starting document for inventive step is document D8, which discloses an already automated apparatus for measuring immunological reactions and whose teaching is readily combinable with document D1. Finally it should be noted that the issue of charge specific calibration in this technical field is known from documents D2, D3 and D4, whence any features relating to such calibration may not contribute to inventive step.

Reasons for the Decision

1. The appeal is admissible.

2. *Main request*

2.1 Interpretation of Claim 1

2.1.1 Throughout the opposition and appeal proceedings the parties disagreed about the meaning of the expression "test sample binding components". The patent proprietor/ appellant argued that, because of the features (a) and (h) in Claim 1 and the introductory part of the patent specification, this expression clearly confined the claimed subject-matter to an

apparatus used for immunological assays. This also followed when using the description and the drawings to interpret the claims. Hence for the question of patentability the technical field of the invention was the field of immunology for testing allergens. The opponent/ respondent was of the opinion that because of the broad terminology of the claims an apparatus for analysing any kind of biological samples should be considered as the closest prior art, because "binding" with a test sample component merely implied that there was an interaction between the components; furthermore the terms "calibration" or "normalisation" were not further defined in the claims.

2.1.2 In the decision under appeal (*point 4*) the opposition division expressed the opinion "*...the only difference between the devices of claim 1 and document (1) lies in the use of binding components for the test samples. In document (1) biochemical reagents (enzymes, dyes etc.) are used. Usually, in the art the term "binding components" is used for substances like antibodies which only bind to the reaction partner without a resulting chemical change in one (or both) reaction partners*".

2.1.3 It appears that this interpretation of the term "binding component" from the field of immunology tests is supported throughout the description, see e.g. the patent specification, page 2 "Background of the Invention" and the Section "Exemplary Mode of Operation" (pages 20, line 55 to page 23, line 49). Furthermore, of the documents D1 to D8 filed in the opposition proceedings, the term "binding" together with "components" or "reaction" is only found in

documents D6 and D8, as to which the parties concurred that these documents belong to the field of immunology assays.

2.1.4 Hence, in the present case the expression "test sample binding components" in the context of assaying biological samples in the claims must be construed as relating to immuno-assays, because this is the technically sensible interpretation of this concept (see Section II.B.4.1 "Interpretation of claims - general" of the "Case Law of the Boards of Appeal", 2nd edition 2001).

2.2 Novelty

2.2.1 Document D1 which, in the opinion of the respondent, anticipates the subject-matter of Claim 1, discloses a test system for the semi-automatic analysis of chemical constituents (*see Abstract*). The sample to be analyzed may be of biological origin, for instance urine (*see the Example in column 14*). Therefore feature (a) of Claim 1 is known from D1.

2.2.2 With respect to feature (b) of Claim 1 the apparatus shown in Figure 2 of D1 comprises a calibrate and amplify module 23 in which the data obtained from a panel of assays (*test device 10*) are processed. However, as is disclosed in column 2, lines 33 to 38, the test reagents associated with the test devices comprise *chemical* constituents which specifically *react* with the substance in the test fluid to give a detectable *chemical* response. Therefore the test reagents in the test devices assayed in the apparatus of this document do not represent "test sample binding components"

relating to immuno-assays as reasoned in Section 2.1 *supra*. Therefore feature (b) is not known from document D1.

2.2.3 For the same reasons features (d), (h) and (i) are not disclosed in D1 because these similarly define conditions involving the binding components. In particular, feature (d) defines that for each of the binding components in each panel the calibrating or normalising means comprises predetermined machine readable assay calibration data, namely at least one standard value for each binding component. Furthermore, according to feature (e), these assay calibration data are associated with a first code means. Considering the calibrate and amplify module 23 in document D1, this carries out several calibration steps. According to column 6, line 57 and more in detail in column 7, lines 46 to 57; and column 8, lines 45 to 51, the module processes the initial calibrate signal by measuring the reflected light from (*highly reflective and preferably white*) code block 17. The purpose of this calibration step is to standardize the electronic circuitry pre-programmed for each of the test devices. The system is furthermore initially calibrated for use by inserting a first test device which has been dipped in a zero calibration solution; and a second test device, which has been dipped in a high positive solution (*see column 8, line 55 to column 9, line 2*). These tests provide eight different words to represent the zero values for each of the eight different reagents and eight different words which represent the high positive value of each reagent, which values are stored in memory 84 (*see column 10, lines 16 to 34*). Since these values are stored in memory 84 for each

reagent, it is implicit that the memory has corresponding addresses which represent "first code means". However, in contrast to feature (g) in Claim 1, in the apparatus disclosed in D1 the calibration values are obtained by manually performing two assays ("*zero*" *assay and* "*high positive*" *assay*) ***prior*** to the assay of the test device containing the unknown sample. Therefore the apparatus of D1 not only differs from the apparatus defined in Claim 1 by the type of components to be assayed (*chemical versus immunological*) but also differs in its concept of providing calibration data *by manually performing two calibration assays* whereas in the claimed apparatus *predetermined* calibration data are provided and stored in association with a first code means; and wherein second code means are associated with the test panel to be assayed, whereupon the combination of the first code means and the second code means enable the correlation of the assay results with predetermined calibration data corresponding to the particular test panel.

2.2.4 In its submissions the respondent argued that in document D1 the threshold values stored in ROM 110 corresponded to the assay calibration data defined in Claim 1 since the Table in column 12 showed that the vales are not just threshold values but that raw measured values are converted in analysis data, which represented a calibration.

The Board does not agree. As defined in Claim 1, the assay calibration data are *predetermined* and contain at least one standard value for each binding component of the panel to be assayed (*feature (d)*). These data are then input in the apparatus via entering means

(feature (g)). This implies that the apparatus must be equipped to allow the inputting and storing of the calibration data. In the apparatus disclosed in D1 the threshold data have *fixed* values and are entered *once* into memory 110, whereupon they cannot be modified anymore, because the memory is a read-only-memory. Rather it is noted that the only "calibration" steps disclosed in document D1 are the calibration using the reflection of the calibration block 17 to standardize the electronic circuitry of the device and the "zero" and "high positive" calibration of the test samples, which, however, is carried out manually by performing respective calibration assays before assaying a test device.

2.2.5 As to the further documents on file, only documents D6 and D8 relate to the field of immunology (*see for both documents the respective Sections* "*Background of the Invention*"). Document D6 discloses a reader card used in analyzing in a densitometer a photographic film which has been previously exposed in a radioimmunoassay. The data record on the film is presented in such manner that the instrument is calibrated for low light level and for non-specific binding produced during the incubation procedure (*column 2, lines 10 to 20*). The document does not disclose any further calibration or normalisation including standard values for the binding components as defined in feature (d) of Claim 1, nor does it disclose the further features of the claim relating to the handling of these data and correlation of the calibration data with the assay results as defined in features (e), (f), (g), (i) and (j) of this claim. Similarly document D8 discloses a method and an apparatus for measuring the binding reactions in a

radioimmunology assay. On an elongated carrier shown in Figure 3 a plurality of transverse threads 13 are coated with binding components and a further so-called designated "negative reference thread" which is not coated and which is used for measuring non-specific binding and background noise (*column 4, lines 25 to 37; and column 6, lines 31 to 37*). The system also performs a "maximum" test for which one thread is directly coated with the radioactively coated component (*column 6, lines 47 to 46*). The document does not disclose calibration of the binding components by collecting predetermined calibration data containing at least one standard value for each of the binding components as defined in feature (d) of Claim 1, nor the further features (e), (f), (g), (i) and (j) of the claim.

2.2.6 It is concluded that the subject-matter of Claim 1 is novel. Since Claims 5 and 6 define an apparatus and method relating to corresponding features as defined in Claim 1, their subject-matter is similarly novel.

2.3 Inventive step

2.3.1 According to the respondent the technical field of interest is not restricted to the field of immunology or that of assaying allergens or antibodies but rather to the more general field of automated analysis apparatuses of biological samples. The respondent also referred to Section I.D.3.1 of "Case Law of the Boards of Appeal" for the criteria for a document to be considered as the closest prior art, which criteria were fulfilled by document D1 which should therefore be

seen as the starting point for the problem and solution approach.

2.3.2 The Board does not concur with this assessment. In the above mentioned Section it is explained "*After the relevant prior art has been identified, careful consideration must be given to the question whether, in the case concerned, the skilled person taking into account all the available information on the technical context of the claimed invention, would have had good reason to take this prior art as the starting point for further development.*" In the opinion of the Board, the skilled person, taking into account all available information as to the technical context of the field as, for instance, summarized in the Section "Background" of the patent specification (*pages 2 and 3*), would not be lead to consider the disclosure in document D1 as a suitable starting point for a further development of an apparatus or method for assaying immunological samples, because it does not disclose the assaying of such samples and because the handling of the samples in document D1 (*manually, see column 1, lines 4 to 8; dipping the test device into the sample and shaking off excess fluid, see column 14, lines 62 to 65*) would not be suitable for immunological assaying which requires multiple washings. Furthermore, since document D1 does not have "*the same purpose or effect as the invention*", it would not be considered by the skilled person, at least not without the benefit of hindsight.

2.3.3 As discussed in Section 2.2.5 *supra*, document D8 discloses a method and an apparatus for measuring the magnitudes of binding reactions in a radioimmunology assay and therefore relates to the same technical field

as the patent in suit. According to column 7, lines 25 to 46, the scanning densitometer may be used in an automatic mode. The apparatus disclosed in document D8 comprises features (a), (b), (c) and (h) as defined in Claim 1.

2.3.4 The question of calibration of the binding conjugates on the carrier 11 is not addressed in document D8 and the subject-matter of Claim 1 differs from this disclosure by virtue of the features (e), (f), (g), (i) and (j) (*see Section 2.2.5*). The objective problem underlying these differences could be seen in improving the reproducibility and accuracy of the output of the immunologic assays. The solution to this problem as underlying the subject-matter of Claim 1 is to provide for each binding component on the test panel the corresponding predetermined calibration data specific for the lot; to assign to these calibration data a first code means; to store in the apparatus, without performing an assay the calibration data and the corresponding first code means; to assign to the test panel to be assayed a second code means; and to correlate the stored calibration data with the assay test results using said first and second code means.

2.3.5 This solution as defined in Claim 1 is not disclosed or suggested in document D8, nor is it suggested in any of the other documents. In particular, as set out in Section 2.2.3 *supra*, document D1 cannot suggest the invention because it does not relate to immunological assays and the "zero" and "high positive" calibration is carried out manually prior to the assay of the test device.

Moreover, the other documents referred to by the respondent do not disclose the type of calibration as defined in Claim 1. In this respect the Board notes that documents D2 and D3 both teach providing test strips for the chemical analysis of body fluids with bar codes bearing encoded batch-specific calibration data (*see D2, page 1, lines 90 to 96 and the last sentence of the abstract; D3, the last sentence of the abstract*). If applied to the closest prior art of document D8, this solution would require **for each batch of panels** the manufacturing of bar codes bearing all the relevant calibration data for the different assays and their applying to the panels, due care being taken to associate the correctly encoded bar codes to the very panels for which the encoded data are relevant. The technique disclosed in documents D2 and D3 thus in effect leads away from the claimed solution, according to which batch specific calibration data are stored directly into the automated analysis apparatus and retrieved automatically using second code means associated with each panel of assays: this second code means merely identifies the panel on which it is applied so as to allow retrieving of the corresponding previously stored calibration data.

2.3.6 It is concluded that the subject-matter of this claim involves an inventive step. This follows in a similar way for the subject-matter of independent Claims 5 and 6, which define substantially the same invention by way of a different wording and in terms of a method, respectively.

2.4 Therefore the claims of the main request meet the provisions of Article 52(1) EPC.

Claims 2 to 4 are dependent claims and equally fulfil these provisions.

2.5 For these reasons, the patent can be maintained unamended in accordance with the appellants' main request.

Since the appellants' main request is allowable, there is no need to address the auxiliary requests.

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 as granted.

The Registrar: The Chairman:

P. Martorana A. Klein