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Datasheet for the decision of 16 October 2013

Case Number: T 1826/09 - 3.4.02

Application Number: 97933176.6

Publication Number: 912885

IPC: G01N15/14

Language of the proceedings: EN

Title of invention:
METHOD AND APPARATUS FOR PERFORMING AUTOMATED ANALYSIS

Applicant:
ABBOTT LABORATORIES

Headword:

Relevant legal provisions:
EPC Art. 56

Keyword:
Oral proceedings - non-attendance of party
Inventive step - (no)

Decisions cited:

Catchword:

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Case Number: T 1826/09 - 3.4.02

D E C I S I O N
of Technical Board of Appeal 3.4.02
of 16 October 2013

Appellant: (Applicant)	ABBOTT LABORATORIES CHAD 0377/AP6D-2 100 Abbott Park Road Abbott Park IL 60064-3500 (US)
Representative:	Modiano, Micaela Nadia Modiano Josif Pisanty & Staub Ltd Thierschstrasse 11 80538 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 22 April 2009 refusing European patent application No. 97933176.6 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman: A. Klein
Members: A. Hornung
B. Müller

Summary of Facts and Submissions

I. The applicant (appellant) appealed against the decision of the examining division refusing European patent application number 97933176.6 according to the main and the auxiliary request on the basis of Article 56 EPC.

II. The appellant requested that a patent be granted on the basis of a main request or two auxiliary requests. Claim 1 of present main and first auxiliary requests is identical to claim 1 of the main and first auxiliary requests as refused by the examining division, respectively. Claim 1 of the present second auxiliary request is basically identical to claim 1 as originally filed, except for a further limitation of claim 1 by a fluorochrome-labelled anti-platelet antibody.

As a precaution, the appellant requested oral proceedings.

III. In a communication annexed to the summons to oral proceedings, the board informed the appellant about its provisional and non-binding view on the patentability of the claimed subject-matter. Reference was made to documents D1 (WO9604544), D2 (EP0552707) and D3 ("Flow cytometry: a clinical test of platelet function", A. D. Michelson, Blood, Vol 87, No 12, June 15, 1996).

The board's objections were worded as follows:

" *5. Main request*

5.1 The subject-matter of claim 1 seems to be obvious in view of the disclosure of D1 (Article 56 EPC).

D1 discloses an automated method for distinguishing and differentiating cells in a whole blood sample (see page 13, lines 13-21), the method comprising the steps of:

(a) providing a whole blood sample (see page 13,lines 20-21),

(b) selecting one or more tests to be performed on the whole blood sample (see page 20, lines 10-12),

(c) correlating *the tests to be performed on the whole blood sample (since step (b) allows for either a single test or plural tests to be carried out, it is unclear whether step (c) means that a first test is correlated with a second test or whether it means that a single test is correlated, for instance, with a patient's health, which is implicit in D1; anyway, D1 discloses correlation of plural tests (see page 20, lines 27-29; page 103, line 20 - page 104, line 2: "combined patient analysis"; page 139, lines 25-29)),*

(d) aspirating a volume of the whole blood sample into an automated instrument system (see page 13, lines 26-28: "an automated instrument system comprising a sample handler for (...) aspirating (...) the sample"; page 109, lines 33-35),

the automated instrument system being capable of automatically performing conventional hematology analysis and fluorescent cytometry analysis on the whole blood sample (the exact technical meaning of the expression "conventional hematology analysis" is vague; anyway, D1 discloses this feature on page 13, lines 20-24),

(e) the instrument dispensing a first aliquot of the whole blood sample into at least one sample receiving vessel (see page 13, lines 26-28: "a sample handler for (...) dispensing the sample"; page 109, lines 33-35; page 113, lines 6-10),

(f) the instrument mixing the first aliquot of the whole sample with a fluorescent reagent (see page 110, line 30: "incubated Mab (monoclonal antibody)/blood pair" and page 111, line 33-35: antibody (Mab) marked with FITC (fluorescein isothyocyanate)"; page 113, lines 13-15: "reagent (...) contains a fluorescent dye"),

(g) the instrument diluting and transporting the first aliquot of the whole blood sample mixed with fluorescent reagent through a flow transducer system (see page 110, lines 28-32: "contents of cup 138 are piped directly to optical flowcell 170"; page 113, lines 23-24: "mixture of diluted blood and retic reagent is transported to optical flowcell 170"),

(h) the flow transducer system detecting multi-angle light scatter and fluorescence from the first aliquot of the whole blood sample mixed with fluorescent reagent (see page 113, lines 29-34: "scatter and fluorescence properties of the sample are measured"),

(i) the instrument storing detecting and differentiation data for the one or more tests performed on the whole blood sample (see page 22, lines 1-14: "the data station module 68 (...) stores measured data and test results"),

(j) the instrument reporting results of the one or more tests performed on the whole blood sample in a quantitative manner if so requested (due to the expression "if so requested", doubt arises whether step (j) is merely an optional step; anyway, D1 discloses step (j), for instance, on page 13, lines 17-20: "to report test results in absolute or quantitative terms"; see also page 22, lines 1-14: "the data station module 68 (...) prints reports (...) to manipulate measured data, calculate parameters and display results"),

wherein the instrument system automatically performs all method steps without physically separating cells from the whole blood sample or an aliquot thereof and results of a conventional hematology analysis may be utilized in at least reporting of results of the fluorescent cytometry testing (see page 13, lines 21-24: "steps of automatedly performing both conventional hematology and fluorescence cytometry"; page 13, lines 26-33: "an automated instrument system comprising a sample handler (...), a sample analyzer (...) and a controller"; page 14, lines 3-4: "without separating cells from the sample during any phase of the analyses").

It follows that D1 (sample processing examples E and F), discloses all features of claim 1, except for the counting and differentiating of platelets by detecting multi-angle light scatter and fluorescence. Using both techniques has the technical effect of characterizing platelets via angular scattering and spectral fluorescence measurements. It solves the problem of the overlap of light scattering from different types of blood cells and, hence, the reduced precision and differentiation of platelet analysis.

In D1, platelets are counted using light scattering only (page 106, lines 21-24). However, in view of the use in D1 of fluorescence markers for lymphocyte and reticulocyte sample processing (examples E and F, pages 109-115), it would appear obvious for the skilled person to solve the above problem by marking platelets with adequate fluorescent antibodies. Such fluorescent antibodies, as well as their use and advantages, are well known in the art (see D1, page 44, lines 6-14; D2, column 3, lines 2-8, column 3, lines 44-55 and claims 5-6; D3, tables 2 and 3 and corresponding description)

Therefore, it seems that the claimed method lacks an inventive step within the meaning of Article 56 EPC in view of the disclosure of D1.

5.2 It is doubtful whether the claimed method comprises an inventive step when starting from D2 as closest prior art and the skilled person being confronted with the problem of automating the multidimensional cell differential analysis of D2. As mentioned in D3, page 4928, left column, first full paragraph, the need for such an automation was well known in the art.

6. First auxiliary request

Claim 1 differs from claim 1 of the main request in that step (f) stipulates that said fluorescent reagent is a fluorochrome-labelled anti-platelet antibody. The claimed subject-matter seems to lack an inventive step for the reasons given in point 5.

7. Second auxiliary request

Claim 1 of the second auxiliary request comprises all method steps of claim 1 of the first auxiliary request. In addition, it comprises method steps for counting and differentiating (i) red blood cells and platelets in a further aliquot of diluted whole blood sample, (ii) white blood cells in a still further aliquot of lysed whole blood sample and (iii) nucleated red blood cells or reticulocytes in any of these two aliquots.

These method steps appear to be disclosed in D1, see the sample processing examples C, D and F (see pages 105-109 and pages 113-115). Therefore, it would appear that the method of claim 1 of the second auxiliary request lacks an inventive step with respect to D1 for reasons corresponding to those given in point 5.

8. In view of the submissions already presented by the applicant, it does not appear necessary to file further submissions in writing. If, however, further submissions are filed, this should be done no later than one month before the date set for oral proceedings. The applicant's attention is drawn to Articles 12 and 13 RPBA."

IV. In response to the summons to oral proceedings, the appellant informed the board with a letter dated 30 September 2013 that he would not attend the oral proceedings. The letter contained no comments concerning the board's preliminary view as annexed to the summons.

V. Independent claim 1 of the main request reads as follows:

1. An automated method for distinguishing and differentiating cells in a whole blood sample, the method comprising the steps of:
(a) providing a whole blood sample;
(b) selecting one or more tests to be performed on the whole blood sample;
(c) correlating the tests to be performed on the whole blood sample;
(d) aspirating a volume of the whole blood sample into an automated instrument system, the automated instrument system being capable of automatically performing conventional hematology analysis and fluorescent cytometry analysis on the whole blood sample;
(e) the instrument dispensing a first aliquot of the whole blood sample into at least one sample receiving vessel;
(f) the instrument mixing the first aliquot of the whole blood sample with a fluorescent reagent;
(g) the instrument diluting and transporting the first aliquot of the whole blood sample mixed with fluorescent reagent through a flow transducer system;

(h) the flow transducer system detecting multi-angle light scatter and fluorescence from the first aliquot of the whole blood sample mixed with fluorescent reagent and counting and differentiating platelets or platelet clumps or both therein;
(i) the instrument storing detecting and differentiation data for the one or more tests performed on the whole blood sample;
(j) the instrument reporting results of the one or more tests performed on the whole blood sample in a quantitative manner if so requested,

wherein the instrument system automatically performs all method steps without physically separating cells from the whole blood sample or an aliquot thereof and results of a conventional hematology analysis may be utilized in at least reporting of results of the fluorescent cytometry testing.

VI. Independent claim 1 of the first auxiliary request reads as follows:

1. An automated method for distinguishing and differentiating cells in a whole blood sample, the method comprising the steps of:
(a) providing a whole blood sample;
(b) selecting one or more tests to be performed on the whole blood sample;
(c) correlating the tests to be performed on the whole blood sample;
(d) aspirating a volume of the whole blood sample into an automated instrument system, the automated instrument system being capable of automatically performing conventional hematology analysis and fluorescent cytometry analysis on the whole blood sample;
(e) the instrument dispensing a first aliquot of the whole blood sample into at least one sample receiving vessel;

(f) the instrument mixing the first aliquot of the whole blood sample with a fluorescent reagent, wherein said fluorescent reagent is a fluorochrome-labelled antiplatelet antibody;
(g) the instrument diluting and transporting the first aliquot of the whole blood sample mixed with fluorescent reagent through a flow transducer system;
(h) the flow transducer system detecting multi-angle light scatter and fluorescence from the first aliquot of the whole blood sample mixed with fluorescent reagent and counting and differentiating platelets or platelet clumps or both therein;
(i) the instrument storing detecting and differentiation data for the one or more tests performed on the whole blood sample;
(j) the instrument reporting results of the one or more tests performed on the whole blood sample in a quantitative manner if so requested,

wherein the instrument system automatically performs all method steps without physically separating cells from the whole blood sample or an aliquot thereof and results of a conventional hematology analysis may be utilized in at least reporting of results of the fluorescent cytometry testing.

VII. Independent claim 1 of the second auxiliary request reads as follows:

1. An automated method for distinguishing and differentiating cells in a whole blood sample, the automated method comprising the steps of:
(a) providing a whole blood sample;
(b) selecting three tests to be performed on the whole blood sample including a test for counting red blood cells and platelets, a test for counting and differentiating white blood cells, and a test counting and differentiating platelets or platelet clumps or both therein;

(c) aspirating a first volume of the whole blood sample into an automated instrument system, the automated instrument system being capable of performing conventional hematology analysis and fluorescent cytometry analysis on the whole blood sample;
(d) the instrument dispensing aliquots of the whole blood sample into at least three sample receiving vessels;
(e) the instrument diluting a first aliquot of the whole blood sample with a diluent reagent;
(f) the instrument lysing a second aliquot of the whole blood sample with a lysing reagent;
(g) the instrument mixing a third aliquot of the whole blood sample with a fluorescent reagent, wherein said fluorescent reagent is a fluorochrome-labelled antiplatelet antibody;
(h) the instrument transporting the first aliquot of diluted whole blood sample through a flow transducer system;
(i) the instrument flow transducer system detecting and counting red blood cells and platelets in the first aliquot of diluted whole blood sample;
(j) the instrument transporting the second aliquot of lysed whole blood sample through the flow transducer system;
(k) the flow transducer system detecting multi-angle light scatter from the second aliquot of lysed whole blood sample and counting and differentiating white blood cells in the second aliquot of whole blood sample;
(1) the flow transducer system detecting multi-angle light scatter and fluorescence from the second aliquot of lysed whole blood sample or the first aliquot of diluted whole blood sample and counting and differentiating nucleated red blood cells or reticulocytes or both therein;
(m) the instrument transporting the third aliquot of the whole blood sample through a flow transducer system;
(n) the flow transducer system detecting multi-angle light scatter and fluorescence from the third aliquot of whole blood sample and counting and differentiating platelets or platelet clumps or both therein;

(o) the instrument storing detecting and differentiating data for multiple tests performed on the whole blood sample; and
(p) the instrument reporting results of each of the multiple tests performed on the whole blood sample in a quantitative manner if so requested,

wherein the instrument system automatically performs all method steps without physically separating cells from the whole blood sample or an aliquot thereof and results of the conventional hematology analysis may be utilized in at least reporting of results of fluorescent cytometry testing.

VIII. Oral proceedings were held on 16 October 2013 in the absence of the appellant.

Reasons for the Decision

In the annex to the summons, the board expressed its view that the subject-matter of claim 1 of all current requests seemed to lack an inventive step (Article 56 EPC) (see above, point III).

The appellant neither attempted to rebut the board's provisional opinion, nor submitted any new requests aiming at overcoming the objections. The board sees no reason to deviate from its preliminary opinion.

It follows that the present patent application does not meet the requirements of the EPC within the meaning of Article 97(2) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

M. Kiehl A. Klein

Decision electronically authenticated