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Datasheet for the decision of 1 July 2014

Case Number: T 1203/11 - 3.5.05

Application Number: 06011422.0

Publication Number: 1870825

IPC: G06F19/00

Language of the proceedings: EN

Title of invention:
A system and a method for managing information relating to sample test requests within a laboratory environment

Applicant:
F.Hoffmann-La Roche AG
Roche Diagnostics GmbH

Headword:
Automated medical testing/HOFFMANN-LA ROCHE

Relevant legal provisions:
EPC 1973 Art. 56, 84

Keyword:
Clarity - (yes, after amendment)
Inventive step - (yes, after amendment)

Decisions cited:

Catchword:

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Case Number: T 1203/11 - 3.5.05

D E C I S I O N
of Technical Board of Appeal 3.5.05
of 1 July 2014

Appellant: (Applicant 1)	F.Hoffmann-La Roche AG Grenzacherstrasse 124 4070 Basel (CH)
Appellant: (Applicant 2)	Roche Diagnostics GmbH Sandhofer Strasse 116 68305 Mannheim (DE)
Representative:	Hössle Patentanwälte Partnerschaft Postfach 10 23 38 70019 Stuttgart (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 21 January 2011 refusing European patent application No. 06011422.0 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chair	A. Ritzka
Members:	K. Bengi-Akyuerek
	G. Weiss

Summary of Facts and Submissions

I. The appeal is against the decision of the examining division, posted on 21 January 2011, to refuse European patent application No. 06011422.0 on the grounds of lack of clarity (Article 84 EPC) and lack of inventive step (Article 56 EPC), having regard to the disclosure of

D2: WO-A-98/26365.

Moreover, in an *obiter dictum*, the decision under appeal further indicated that the arguments submitted by the applicant with respect to the inventive-step objection in view of D2 were not convincing.

The following document was also cited in the course of the examination proceedings:

D1: US-A-2004/0033501.

II. Notice of appeal was received on 18 March 2011. The appeal fee was paid on the same day. With the statement setting out the grounds of appeal, received on 15 April 2011, the appellant filed a new set of claims. It requested that the decision of the examining division be set aside and that a patent be granted on the basis of the new claims. In addition, oral proceedings were requested as an auxiliary measure.

III. A summons to oral proceedings scheduled for 1 July 2014 was issued on 15 April 2014. In an annex to this summons, the board expressed its preliminary opinion on the appeal pursuant to Article 15(1) RPBA. In particular, it stated that the objections under Article 84 EPC 1973 raised in the decision under appeal

were considered to be remedied and that the subject-matter of claim 1 was considered to be new but did not involve an inventive step in view of D2 (Article 56 EPC 1973).

IV. With a letter of reply dated 2 June 2014, the appellant submitted amended claims according to an auxiliary request and provided counter-arguments with regard to the objections raised in the board's communication under Article 15(1) RPBA. It requested that a patent be granted on the basis of the main request or the auxiliary request.

V. Oral proceedings were held as scheduled on 1 July 2014, during which the appellant filed a new set of claims according to a "Main Request" together with an amended description page and withdrew all the previous claim requests. All the pending requests were discussed.

The appellant's final request was that the decision under appeal be set aside and that a patent be granted on the basis of claims 1 to 11 filed as new main request at the oral proceedings before the board.

At the end of the oral proceedings, the decision of the board was announced.

VI. **Claim 1** of the main (and sole) request reads as follows (the expressions in square brackets and the emphasis have been deleted by the board):

"A system for realising a workflow for performing a number of tests to be made on at least one sample (50) within a laboratory environment, the system comprising:

at least one pre-analytical unit (20) being configured to receive and to scan the at least one

sample (50) and to sort, aliquot and/or archive the at least one sample (50) on request according to respective test requests included within a respective sample order comprising a sample-ID and sample test requests, wherein pre-analytical sorting/aliquoting information is uploaded from the pre-analytical unit to a decision unit (20)[sic] and to scan the at least one sample (50) again when the sample is transported back to the pre-analytical unit after the sample order has been updated by the decision unit,

a plurality of analytical units (30_1,...30_N), each being configured to run at least one test of the number of tests on the appropriately sorted and/or aliquoted sample (50) and to upload the test results to the decision unit, and

the decision unit (10) enabling at least one host (200) to access the system and to submit the sample order for the at least one sample, and acting as intermediary and coordinator in communication between the at least one pre-analytical unit (20) and the plurality of analytical units (30_1,...,30_N), wherein the decision unit (10) coordinates processing of the number of tests via a workflow until all tests have been done, the decision unit (10) being further configured to download the sample order comprising the sample-ID and sample test requests from the at least one host (200), to distribute the at least one sample to an appropriate analytical unit (30) according to distribution criteria which are configured by the decision unit itself and which are based on pre-analytical information from the at least one pre-analytical unit (20) and on test results from tests of the number of tests which have already been performed by at least one analytical unit (30) optionally combined with other sample related information, to update the sample order with respect to

the uploaded test results and to add new or confirmation tests and to comment, block, release, replace, modify or extend any requested test and to combine current analytical data with other sample related information to decide a next pre-analytical step, so that the updated sample order is to be processed again until all test requests have been done and to collate gained test results with the sample (50) and to give a respective report towards the at least one host (200)."

Claim 8 of the main request, directed to a corresponding method, reads as follows (the expressions in square brackets and the emphasis have been deleted by the board):

"A method for realising a workflow for performing a number of tests to be made on at least one sample within a laboratory environment, the laboratory environment comprising a system according to claims 1 and 7, the method comprising the following steps:

A. receiving the sample by the at least one sample reception unit,

B. transporting the sample to the at least one pre-analytical unit (20),

C. identifying the sample by the at least one pre-analytical unit and assigning the sample to a sample order by the decision unit,

D. performing a sample scan by the at least one pre-analytical unit (20) and sending the sample scan to the decision unit (10),

E. receiving by the decision unit the sample order comprising a sample-ID and the sample test requests with sample test request information and sample related information from at least one host (200),

F. processing the sample according to the sample order by a dynamically adaptable coordinated interaction of the at least one pre-analytical unit (20) and the plurality of analytical units (30_1,...,30_N), wherein the at least one sample is distributed to an appropriate analytical unit (30) according to distribution criteria which are configured by the decision unit itself and which are based on pre-analytical information from the at least one pre-analytical unit (20) and on test results from tests of the number of tests which have already been performed by at least one analytical unit (30) optionally combined with other sample related information, and wherein the sample order is updated with respect to uploaded test results,

F' if necessary, commenting, blocking, releasing, replacing, modifying or extending any requested test by the decision unit and

F'' combining, by the decision unit, current analytical data with other sample related information to decide a next pre-analytical step, so that the updated sample order is to be processed again until all test requests have been done

F''' scanning the at least one sample (50) again, by the at least one pre-analytical unit, when the sample is transported back to the pre-analytical unit after the sample order has been updated by the decision unit,

F'''' appropriately distributing, by the decision unit, the sample to a further target in case that there are still open test requests,

G. collating, by the decision unit, gained test results with the corresponding sample, and

H. giving, by the decision unit, a report about the

processing to the at least one host (200), wherein the coordination between the at least one pre-analytical unit (20) and the plurality of analytical units (30_1,...,30_N) is coordinated by the decision unit (10) acting as intermediary and coordinator in communication between the respective units and the report is given by the decision unit (10) to the at least one host (200)."

Reasons for the Decision

1. The appeal is admissible.

2. MAIN REQUEST

In spite of the fact that this request was submitted during the oral proceedings before the board, i.e. at a very late stage of the overall procedure, the board admitted it into the appeal proceedings under Article 13(1) and (3) RPBA, since it was regarded as a successful attempt to overcome the outstanding objections raised by the board under Article 56 EPC (cf. point 2.2 below), and since the board could deal with it without having to adjourn the oral proceedings.

Claim 1 of the present main request differs from claim 1 of the main request underlying the appealed decision essentially in that it further specifies that (emphasis added by the board)

A) pre-analytical sorting/aliquoting information is uploaded from the pre-analytical unit <u>to a decision unit</u>;
B) the pre-analytical unit is configured to scan the at least one sample <u>again</u> when the sample is

transported back to the pre-analytical unit after the sample has been updated by the decision unit;

C) the analytical units are further configured to upload the test results to the decision unit;

D) a host is used (rather than a "host component");

E) the decision unit coordinates processing of the number of tests via a workflow until all tests have been done;

F) the decision unit is further configured to distribute the at least one sample to an appropriate analytical unit according to distribution criteria which are configured by the decision unit itself and which are based on pre-analytical information from the at least one pre-analytical unit and on test results from tests of the number of tests which have already been performed by at least one analytical unit optionally combined with other sample related information;

G) the decision unit is further configured to update the sample order with respect to the uploaded test results and to add new or confirmation tests and to comment, block, release, replace, modify or extend any requested test;

H) the decision unit is further configured to combine current analytical data with other sample related information to decide a next pre-analytical step, so that the updated sample order is to be processed again until all test requests have been done.

The features of the present independent claim 8, related to a method for realising the respective workflow, correspond substantially to those of claim 1.

Feature A) is supported e.g. by page 16, lines 13-16 of

the application as filed, whilst feature B) is based on page 17, lines 19-28. Feature C) is supported by page 16, lines 24-27 and feature D) is based e.g. on Fig. 1 of the application as filed. Feature E) is based on page 17, lines 28-33, while feature F) is supported e.g. by claims 6 and 16 of the application as filed. Feature G) is supported e.g. by page 16, line 29 to page 17, line 17 and feature H) is based on page 4, lines 16-20 of the application as filed.

Hence, the board is satisfied that the above amendments comply with Article 123(2) EPC.

2.1 Article 84 EPC 1973

The examining division held that the former independent claims were not clear (cf. appealed decision, section II.1), essentially because

- the term "host component" was unclear;
- the phrase "a decision unit ... acting as intermediary and coordinator in communication between the at least one pre-analytical unit and the at least one analytical unit such that the number of test is performed ... particularly until the sample (50) is completely measured" constituted a result to be achieved;
- the clause "to upload ... from the pre-analytical unit ..." included a contradiction.

As a result of the amendments made to the independent claims, in particular according to features A), D), and E), the board is satisfied that those objections no longer apply. Hence, the board concludes that the present claims comply with Article 84 EPC 1973.

2.2 Article 52(1) EPC: Novelty and inventive step

The board holds that present claims 1 and 8 meet the requirements of Article 52(1) EPC in conjunction with Articles 54 and 56 EPC 1973, for the following reasons:

2.2.1 The present invention concerns an automated data management system for testing medical samples in a laboratory environment based on a recursive workflow. The medical data management system is made up of a "host", a "decision unit", at least one "pre-analytical unit", at least one "analytical unit", and optionally at least one "post-analytical unit" (see e.g. Fig. 1 of the present application). According to the application, the problem to be solved by the present invention is to provide a medical testing system for realising an advanced sample workflow with reduced system complexity and improved laboratory quality enabling a satisfying work environment (cf. page 1, line 31 to page 2, line 5 and page 18, lines 29-31 of the application as filed).

The recursive workflow underlying the present invention (cf. page 4, line 29 to page 6, line 8 and page 10, line 15 to page 12, line 6 of the application as filed), in particular claims 1 and 8, includes the following steps:

1) issuing, by a host, a sample order (including a sample identifier and a list of sample test requests) for a sample to be tested to a decision unit;
2) transporting the sample to a pre-analytical unit;
3) identifying, by the pre-analytical unit, the transported sample and providing the sample identifier to the decision unit;
4) providing, by the decision unit, sample information (i.e. pending sample test requests,

sample target information) based on the sample order associated with the obtained sample identifier to the pre-analytical unit;

5) sorting, aliquoting, and archiving, by the pre-analytical unit, the sample based on the obtained sample information and providing pre-analytical sorting/aliquoting information (i.e. rack identifier and rack position associated with the analytical unit where the pre-processed sample is to be tested) to the decision unit;
6) transporting the sorted/aliquoted sample to the respective analytical unit according to the pre-analytical sorting/aliquoting information;
7) providing, by the decision unit, an extended sample order (including sample testing information) to the respective analytical unit;
8) performing, by the analytical unit, the tests requested according to the sample order and providing the test results to the decision unit;
9) updating, by the decision unit, the sample order based on the test results and optionally adding new test requests;
10) performing steps 2) to 9) until all the test requests have been processed, wherein
    10a) the next pre-analytical step is decided by combining current analytical data with other sample-related information;
    10b) the sample is transported to the respective analytical unit based on pre-analytical information and on test results from test requests which have already been performed;
11) providing, by the decision unit, a report on the test results to the host.

2.2.2 The board concurs with the finding of the decision under appeal that D2 represents the closest prior art,

since it is related to the same purpose as the present invention, namely to automated remote testing of medical samples in a laboratory environment upon request of a host ("remote client 100").

2.2.3 The board considers that D2 discloses the following limiting features of claim 1:

A system for realising a workflow for performing a number of tests to be made on a sample ("specimen 102") within a laboratory environment ("automation lab"; see Figs. 4 and 5), the system comprising:

- a pre-analytical unit ("task sequence controller TSC 136") being configured to receive a sample and sort/aliquot the sample on request according to respective test requests included within a respective sample order comprising sample test requests (see e.g. page 12, lines 22-24: "... TSCs 136 are capable of dynamic retasking, which, for example allows adding and subtracting assays ..."; page 20, lines 6-13: "... automated test instrument suite commands ... are provided 314 to the ... task sequence controller 136 ..." in conjunction with Fig. 11, step 314);
- analytical units ("automated instruments 106"; "infectron 135A"; "detectron 135B"; "SLM 134"), each being configured to run tests on the appropriately sorted sample (see e.g. page 10, lines 31-33; Figs. 7 and 9);
- a decision unit ("process controller 128" including "process control tools PCT 124") being configured to
  - enable a host ("remote client 100") to access the system and to submit the sample order ("test command message") for the sample (see

e.g. page 10, lines 19-24 in conjunction with Fig. 11, step 308 and Fig. 12, step 330);

- act as coordinator in communication between the pre-analytical unit and the analytical units (see e.g. page 12, lines 26-33);
- download the sample order comprising the sample test requests from the host (see page 10, lines 26-27 in conjunction with Fig. 11, step 308);
- distribute the sample to an appropriate analytical unit (see in particular page 10, lines 24-31; Fig. 4, "package 104" and "storage 104");
- update the sample order by adding new tests or replacing/modifying/extending requested tests (see e.g. page 13, lines 18-25: "An operation PCT 124B ... offers selections of standardized tests. This PCT 124B also allows researchers to design new experiments, and offers the test designer specified degrees of freedom ..."; page 19, lines 5-8: "... process controller 128 also provides high-level tools to remote clients 100 that allow programming of SLM controllers on the fly, enabling one instrument to perform any number of unique experiments ...");
- collate gained test results with the sample and give a respective report ("output 112") to the host (see e.g. page 10, lines 31-33 in conjunction with Fig. 11, step 316).

The examining division found that the "task sequence controller 136" of D2 corresponded to the decision unit claimed (cf. appealed decision, page 4, penultimate paragraph). The board agrees however with the appellant that the task sequence controller of D2 fails to

provide the functionalities of a decision unit as claimed. Rather, the board takes the view that the task sequence controller 136 of D2 corresponds to the pre-analytical unit of claim 1.

2.2.4 Hence, the difference between the subject-matter of claim 1 and the disclosure of D2 is considered to be that (emphasis added by the board)

a) the sample order comprises a sample ID;
b) the pre-analytical unit is configured to scan the sample once upon reception and again when the sample is transported back to the pre-analytical unit after the sample order has been updated by the decision unit;
c) the pre-analytical unit uploads pre-analytical sorting/aliquoting information while the analytical units upload the respective test results to the decision unit;
d) distribution of the sample to the appropriate analytical unit is performed by the decision unit according to distribution criteria based on pre-analytical information from the pre-analytical unit and on test results from tests of the number of tests which have already been performed by the analytical unit;
e) the decision unit acts as an intermediary in communication between the pre-analytical unit and the analytical units and coordinates processing of the number of tests until all tests have been done;
f) updating the sample order is performed by the decision unit with respect to the uploaded test results and the updated sample order is to be processed again until all test requests have been done;

g) the distribution criteria are configured by the decision unit itself;
h) the decision unit is configured to combine current analytical data with other sample-related information to decide a next pre-analytical step.

Consequently, the subject-matter of present claim 1 is found to be novel over D2 (Article 54 EPC 1973).

2.2.5 Regarding the assessment of inventive step, the board first notes that, in accordance with the conclusion drawn in the impugned decision (cf. page 5, penultimate paragraph, first and second sentences), the recursive workflow as defined in point 2.2.1 represents a workflow which may typically be devised and specified by a medical expert who has arguably no technical knowledge and skills. In view of the generality of its definition, the board also considers that the respective system units mentioned in the workflow are not restricted only to technical devices but may well be represented by human beings (for example, the "host" could be a physician, the "decision unit" a laboratory administrator, and the "pre-analytic unit" and "analytic unit" a first and a second laboratory assistant respectively). Thus, the (allegedly improved) workflow itself cannot contribute to an inventive step. The question which therefore arises next is whether the *technical implementation* of this recursive workflow according to claim 1 may justify an inventive step or whether it constitutes merely an obvious automation of the underlying medical workflow on a common distributed computer system using standard data processing techniques. To answer that question, it has to be ascertained whether distinguishing features a) to h) give rise to a non-obvious synergistic technical effect. In this context, it is first apparent that the

implementation of the medical workflow in question according to claim 1 relates to a mixture of automated electronic processing (partly of cognitive data such as "pre-analytical information"; see features c) and d) of claim 1) and physical/human-based distribution (transportation) of samples (see features b) and d) of claim 1).

2.2.6 As to distinguishing features a) and b), the board finds that they relate to the implementation of steps 1) and 3) of the recursive workflow. More specifically, those features obviously have the technical effect of *electronically* identifying the samples to be tested in the system under consideration. In this regard, D2 teaches the generation of labels or identification codes to be affixed to the test specimens (see D2, page 14, lines 2-4). Although document D2 does not disclose explicitly that the identification codes are scanned by the task sequence controller, the board takes the view that using a scannable sample ID constitutes one of several equally likely implementation alternatives for electronic identification purposes from which the skilled person would choose, depending on practical constraints such as implementation complexity or technological preferences (see e.g. D1, Fig. 1, according to which a bar code scanner/reader for sample identification is used). Thus, the board holds that features a) and b) constitute obvious measures for implementing steps 1) and 3) of the recursive workflow.

As to distinguishing features c) and d), they apparently relate to the implementation of steps 5), 6), 8), and 10b) of the recursive workflow. Those features allegedly have the technical effect that the decision unit is capable of forwarding a pre-analysed

sample to the appropriate analytical unit for being subsequently tested according to the respective sample order (cf. page 16, lines 13-17 in conjunction with page 23, lines 11-14 and 27-36 of the application as filed). In this context, D2 teaches that the test specimen has to be packaged and physically transported to the corresponding analytical unit "SLM" via "storage 104" (see D2, page 10, lines 24-31) and that a certain SLM can be directed by the task sequence controller to perform a function (see D2, page 11, lines 28-29). From this the skilled person in the field of computer-based medical systems would readily deduce that, in order to deliver the sample to be tested to the appropriate SLM, the task sequence controller, which is obviously the only unit that knows which SLM is supposed to perform the requested tests (see D2, page 11, lines 18-19), has to provide the target location of the sample in question (i.e. the respective "storage 104") to the process controller. The board therefore concludes that the implementation measures according to features c) and d) are a direct and straightforward consequence of steps 5), 6), 8), and 10b) of the recursive workflow.

2.2.7 In view of the above, the board judges that features a) and b) on the one hand, and features c) and d) on the other hand, are associated with separate and independent technical effects and that they constitute a mere juxtaposition of obvious implementation measures which do not produce any surprising synergistic effect which goes beyond the sum of the individual effects of those features. Hence, features a) to d) cannot contribute to an inventive step.

2.2.8 As to distinguishing features e) to h), the board finds, however, that they cannot be considered as a

direct and straightforward technical consequence of any step of the recursive workflow, for the following reasons. Features e) to h) imply that the corresponding test requests are iteratively processed without any intervention by the host computer. The board therefore accepts that those features provide the overall technical effect that the respective sample tests according to a sample order are performed substantially in real-time and in a consistent manner (see also page 18, lines 14-17 of the application as filed), with the bonus effect that no bandwidth is wasted with regard to the connection used between the host and the decision unit for sending an initial sample order and receiving a test report by the host. In other words, after the host has triggered the execution of sample tests by sending a sample order, the remaining units of the system under consideration, i.e. the decision unit, the pre-analytical unit, and the analytical units, automatically and autonomously perform all the test requests required by the respective sample order. Accordingly, the objective problem associated with features e) to h) may be formulated as "how to ensure that the system of D2 operates substantially in real-time and saves network bandwidth at the same time".

However, the skilled person in the field of computer-based medical systems, starting out from D2, would immediately recognise that it is the remote user (i.e. "remote client 100") of the underlying system who is exclusively allowed to specify and update the respective test procedures, and in particular to define new tests (see e.g. D1, page 10, lines 17-19 and 26-27 and page 19, lines 5-8). Thus, the remote client is apparently the pivotal point of the entire medical testing system of D2. This is also embodied by the flow

diagram of Figs. 11 and 12 of D2, according to which the remote client 100 is supposed to send, for each test request, a separate "access request message" (replied to by an "access enabling message") and an individual "test command message" (responded to by "testing data results") to the process controller 128 via the "communication link 126" such as the Internet (see e.g. page 20, lines 16-26 in conjunction with Fig. 11, steps 300 and 308; Fig. 12, steps 322 and 330). The skilled reader would readily understand from this that it is an indispensable cornerstone of the system of D2 that the remote user triggers each and every test request. Confronted with the above objective problem, the skilled person would notice that, in the system of D2, at least the request/response scheme (i.e. the exchange of access request/enabling messages) related to the access of the remote client to the testing system via the process controller 128 causes some unnecessary overhead with regard to the overall transmission speed and bandwidth efficiency as to communication link 126 (see Fig. 5). As a consequence, the person skilled in the art would attempt to avoid any such overhead either by dispensing with any prior access procedure or by applying such an access scheme only in the initialisation phase of the overall test procedure. However, this kind of implementation would plainly lead away from the solution according to present claim 1.

2.2.9 Moreover, the board finds that the other cited document on file, i.e. document D1, would not render the subject-matter of claim 1 obvious, regardless of whether taken alone or in combination with the disclosure of D2. This is due to the fact that D1, though also addressing the issue of testing medical samples via bar-code identifiers and of performing

user-defined tests, is completely silent as to iteratively implementing a comprehensive medical workflow in both a substantially real-time and bandwidth-efficient manner.

Therefore, even if the teachings of D2 and D1 were combined, the skilled person would not arrive at the claimed solution.

2.3 In conclusion, having regard to the cited prior art, the subject-matter of present claim 1 is new and involves an inventive step within the meaning of Article 52(1) EPC in conjunction with Articles 54 and 56 EPC 1973. The above observations also apply to the corresponding independent method claim 8.

2.4 Since all the other requirements of the EPC are also found to be fulfilled, the board decides to grant a patent on the basis of claims 1 to 11 according to the main request.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance with the order to grant a patent in the following version:

Description (pages):
- 1, 3 to 28 as originally filed;
- 2 filed at the oral proceedings before the board;

Claims (Nos.):
- 1 to 11 filed as new main request at the oral proceedings before the board;

Drawings (sheets):
- 1 filed on 27 October 2010;
- 2 to 5 as originally filed.

The Registrar: The Chair:

K. Götz-Wein A. Ritzka

Decision electronically authenticated