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Datasheet for the decision of 23 May 2018

Case Number: T 2488/11 - 3.5.05

Application Number: 06011417.0

Publication Number: 1862928

IPC: G06F19/00

Language of the proceedings: EN

Title of invention:
A system and a method for managing sample test results and respective sample result context information

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

Headword:
Quality Control/ROCHE

Relevant legal provisions:
EPC Art. 56
RPBA Art. 13(1)

Keyword:
Inventive step - mixture of technical and non-technical features - (no)
Late-filed request - admitted (no)

Decisions cited:
T 0641/00

Catchword:

Europäisches Patentamt
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Beschwerdekammern

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Case Number: T 2488/11 - 3.5.05

D E C I S I O N
of Technical Board of Appeal 3.5.05
of 23 May 2018

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:	Raible Deissler Lehmann Patentanwälte PartG mbB Senefelderstrasse 26 70176 Stuttgart (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 7 July 2011 refusing European patent application No. 06011417.0 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chair	A. Ritzka
Members:	E. Konak
	F. Blumer

Summary of Facts and Submissions

I. The appeal is against the decision of the examining division to refuse the application for amendments containing subject-matter extending beyond the content of the application as originally filed (Article 123(2) EPC) and lack of inventive step (Article 56 EPC) over the following document:

D3: WO 98/26365.

II. With its statement setting out the grounds of appeal, the appellant filed claims 1 to 15 of a main request. It requested that the decision be set aside and a patent granted on the basis of this request. Oral proceedings were requested as an auxiliary measure.

III. In an annex to the summons to oral proceedings the board gave its preliminary opinion that claim 1 did not involve an inventive step (Article 56 EPC).

IV. At the oral proceedings the appellant filed claims 1 to 15 of a first auxiliary request.

V. Claim 1 of the main request reads as follows:

"A system for quality control of sample test results and respective sample result context information within a laboratory environment, the system comprising:
- at least one analytical unit (20) configured to run at least one test on a sample and to upload a received sample test result of the at least one sample test together with respective sample result context information to a management unit (10), the sample result context information including a reagent lot

number of a reagent package which has been used for the at least one sample test, and a quality control lot number of a quality control material used for a quality control measurement made in connection with the sample test;
- a barcode scanner (30) being configured to scan barcode information from a two dimensional barcode which is available on each reagent package and each quality control package and which provides reagent lot information and quality control information as a further part of the sample result context information, and further configured to transfer the scanned barcode information to the management unit (10),
- the management unit (10) connected with the at least one analytical unit (20) for data interchange, wherein said management unit (10) is configured to save and display on demand sample test results and respective sample result context information, to control dynamically at least one actual stock of the respective one of a reagent material and a quality control material as at least one item of the respective sample result context information with respect to a predefined minimum value and to initiate at least one of an output of a signal and a re-ordering of the respective one of the reagent material and the quality control material as soon as the actual stock of the respective material corresponds to the predefined minimum value according to a predefined execution plan schedule."

VI. Claim 1 of the first auxiliary request differs from claim 1 of the main request in that its last paragraph reads (with additions underlined and deletions ~~struck-through~~) as follows:

"- the management unit (10) connected with the at least one analytical unit (20) for data interchange, wherein

said management unit (10) is configured to save and display on demand sample test results and respective sample result context information, to control dynamically at least one actual stock of the respective one of a reagent material and a quality control material as at least one item of the respective sample result context information with respect to a predefined ~~minimum~~ value given by a scheduled stock and to initiate ~~at least one of~~ an output of a signal and an automatic re-ordering of the respective one of the reagent material and the quality control material as soon as the actual stock of the respective material corresponds to the predefined ~~minimum~~ value according to a predefined execution plan schedule."

Reasons for the Decision

1. Main request - Inventive step (Article 56 EPC)

1.1 It is common ground between the examining division and the appellant that D3 forms the closest prior art. In the contested decision the examining division considers the distinguishing features of claim 1 over D3 to constitute "the implementation of an administrative scheme, namely how to manage information that allows a reliable quality control and inventory reordering for stock management in a laboratory environment". The objective technical problem is then formulated, with reference to T 641/00, as how to "implement this non-technical constraint" and the solution is found to be a straightforward "alternative use of a commonly known bar [sic] scanner".

1.2 The appellant disputes the assessment of the examining division and argues that the invention provides for "enhanced quality control" and that the provision of

test results with higher quality "unquestionably solves a technical task". It also formulated, at the oral proceedings, the objective technical problem solved by the invention along these lines as the provision of a more efficient and reliable system for "quality control" of tests in a laboratory.

1.3 Both the examining division and the appellant refer to "quality control" in their argumentation. In the board's view, however, assessing the inventive step involved in the invention under this umbrella term is not appropriate.

1.3.1 A correct assessment of the inventive step requires a closer look at what the invention indeed achieves. The invention addresses two problems of clinical laboratories in the prior art:

(i) a regulatory or legal obligation to record, besides patient sample test results, additional information regarding the context in which a certain test was performed (see the description, page 1, penultimate paragraph to page 2, first paragraph);

(ii) managing the stock of different materials (reagents, quality control materials and calibrator materials) needed in the laboratories to perform tests (see the description, page 2, third and fourth paragraphs).

1.3.2 When the problems addressed by the invention are put in this perspective, the board cannot follow the argument that the invention provides "test results with higher quality". Recording additional information about a test does not increase the precision of the test itself. Likewise, guaranteed availability of sufficient amounts

of materials for tests in a laboratory through proper stock management may enable a laboratory to perform a certain test at any time, but does not effect the precision of the specific test results.

1.3.3 The appellant drew the board's attention at the oral proceedings to the fact that the quality of biological samples such as blood deteriorates after they are drawn, and argued that the availability of materials to perform a laboratory test as early as possible therefore had an impact on the quality of the test results and was technical. The board asked the appellant whether a night shift enabling laboratory clerks to perform tests as early on as possible would also increase the quality of the tests and if it should therefore be seen as technical, to which the appellant replied in the affirmative. In the board's view, however, this plainly demonstrates the unsuitability of umbrella terms such as "quality control" or "quality" for the assessment of inventive step, for they merely lead to confusion between diverse and unrelated problems, such as quality of service, effective management, process quality and precision of a clinical test, most of which are not technical.

1.4 The board judges the two problems identified supra under 1.3.1 to be distinct and unrelated. It further finds both problems not to be technical:

(i) Logging or documenting the execution details of tests carried out in a laboratory, irrespective of the technicality of the tests themselves, is not technical. The extent of such documentation, as suggested by the description, is usually imposed by national regulations, international standards or internal quality SOPs. The board concurs with the contested

decision that these constitute non-technical constraints to be met in the sense of T 641/00, Headnote 2.

(ii) Stock management is, as such, primarily a business problem and not a technical one. The fact that stock management is carried out in a laboratory does not change this finding. A clerk regularly checking empty vials of materials used in a laboratory and re-ordering low-stock items does not carry out a technical task.

1.5 The board does not even deem it necessary to start from D3 to assess the inventive step involved in claim 1. In the board's view, any prior-art distributed laboratory environment, as described in the section "Background of the Invention" of the description (pages 1 to 3), would suffice as a suitable starting point to demonstrate the lack of an inventive step in claim 1.

1.6 Starting from such a prior-art laboratory environment:

(i) If the documentation requirements of the laboratory require saving the reagent lot number of the reagent used and the quality control lot number of the quality control material used together with test results, it would be obvious to save and display the same on demand.

(ii) The only technical means used for the solution of the stock management problem are computers and barcode scanners. However, at the filing date of the application, barcodes were ubiquitous on packages of all kinds of products and the use of computers and barcode scanners for stock management was notoriously known.

1.7 Therefore the distinguishing features of claim 1 of the main request do not involve an inventive step (Article 56 EPC) and the appellant's arguments to the contrary do not convince the board:

1.7.1 The appellant argues that the usage of a barcode scanner in the context of the invention "does not correspond to the usage of a 'usual' barcode scanner and includes technical aspects", without specifying what it considers to be "the usual usage of barcodes". In the board's view, however, product identification and tracking belong to notorious uses of barcode technology. Furthermore, the board is not and was not made aware of any technical difficulty that the appellant had to overcome for the employment of well-known barcode technology in the context of the invention.

1.7.2 The appellant emphasises that the invention performs stock management automatically and in real time, namely that a modern laboratory is a complex and error-prone environment in which a clerk cannot possibly be aware of, let alone keep records of, all materials used in real time. These are, however, obvious advantages of any automation and the mere automation of a non-technical task by means of notorious technical means cannot involve an inventive step.

1.7.3 The appellant also points out that the invention consolidates all information about clinical tests, test results and information on stock levels in one entity, which is not the case in prior-art distributed laboratory environments. However, the decision to store information together or separately, in particular in a clinical laboratory environment, is not necessarily based on technical considerations, but may well be

dictated by non-technical constraints such as data protection laws and regulations. The board cannot see any technical considerations underlying the manner in which information is stored in the present case.

2. First auxiliary request - Admissibility (Article 13(1) RPBA)

2.1 The first auxiliary request was filed after the appellant filed its grounds of appeal and may thus be admitted at the board's discretion (Article 13(1) RPBA).

2.2 Among the criteria used by the boards of appeal to decide on the admissibility of such requests is whether the request addresses still outstanding objections (see Case Law of the Boards of Appeal, 8th edition, IV.E. 4.4.1).

2.3 The appellant submitted at the oral proceedings that this request clarifies its point of view with respect to the differences of the invention from the prior art, in particular by making explicit that the invention reorders materials automatically, unlike a laboratory clerk.

2.4 The board's assessment of the inventive step involved in claim 1 of the main request, however, had already taken into account that the invention is the automation of a task potentially performed either mentally or manually in the prior art (see 1.7.2 supra). Adding a feature, which the board already found not to be inventive, explicitly to the claim language cannot overcome the board's inventive-step objections.

2.5 Nor can the board's inventive-step objections be overcome by the newly added feature "given by a

scheduled stock". The amendment is based on page 19, lines 22 to 29, which merely mentions "a scheduled stock" but does not even explain what it is. Irrespective of its precise meaning, the term relates to an administrative rule that cannot contribute to the technical character of the invention.

2.6 As claim 1 of the first auxiliary request does not overcome still outstanding inventive-step objections, this request is not clearly allowable. Therefore the board exercises its discretion under Article 13(1) RPBA not to admit it into the appeal proceedings.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

K. Götz-Wein A. Ritzka

Decision electronically authenticated