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Datasheet for the decision of 29 March 2012

Case Number: T 0813/09 - 3.4.02

Application Number: 00943418.4

Publication Number: 1200839

IPC: G01N35/00, G05B19/418

Language of the proceedings: EN

Title of invention:
AUTOMATED LABORATORY SOFTWARE ARCHITECTURE

Applicant:
Beckman Coulter, Inc.

Relevant legal provisions:
EPC Art. 54(1), 123(2)
EPC 1973 Art. 56, 84

Keyword:
Added subject-matter (no - amended claims)
Clarity (yes - amended claims)
Novelty and inventive step (yes - amended claims)

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T0813/09 - 3.4.02

D E C I S I O N
of the Technical Board of Appeal 3.4.02
of 29 March 2012

Appellant: (Applicant)
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Decision under appeal:
Decision of the Examining Division of the European Patent Office posted 27 November 2008 refusing European patent application No. 00943418.4 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman: A. G. Klein
Members: F. J. Narganes-Quijano
B. Müller

Summary of Facts and Submissions

I. The appellant (applicant) lodged an appeal against the decision of the examining division refusing European patent application No. 00943418.4 based on International application No. PCT/US/00/18753 (published with the International publication No. WO 01/09618).

In its decision the examining division held that the set of claims amended according to the main and the first and second auxiliary requests then on file were not allowable. In particular, the examining division raised objections of added subject-matter (Article 123(2) EPC), lack of clarity (Article 84 EPC) and lack of novelty and of inventive step (Article 52(1) EPC) over the disclosure of document

D2: "Abbott AxSYM^{TM} random and continuous access immunoassay system for improved workflow in the clinical laboratory" J. Smith *et al.*, Clinical Chemistry (US) Vol. 39 (1993), pages 2063 to 2069.

II. With the statement setting out the grounds of appeal the appellant submitted sets of claims amended according to a main and a first and second auxiliary requests and requested that the decision under appeal be set aside and a patent be granted. The appellant also requested oral proceedings on an auxiliary basis.

III. In response to the preliminary opinion expressed by the Board in a communication annexed to the summons to oral proceedings, the appellant, with its letter dated 19 March 2012, filed an amended set of claims 1 to 18 labelled "third auxiliary request" and amended pages of

the description and the drawings. In its letter of reply the appellant declared that, on condition that the Board found the application documents amended according to the third auxiliary request allowable without the need to hold oral proceedings on the matter, the main and first and second auxiliary requests and the request for oral proceedings were withdrawn.

In view of the declaration and the requests formulated by the appellant, the Board cancelled the oral proceedings.

IV. Independent claim 1 and dependent claims 8 and 14 amended according to the claim request labelled "third auxiliary request" read as follows:

"1. An integrated clinical laboratory system for testing a specimen, comprising:
a physical element layer (48), including a plurality of specimen processing modules (50), each specimen processing module for performing at least one test on the specimen; and
an integrated work flow automation layer (56) for communicating with said plurality of specimen processing modules, said work flow automation layer including,

a) order entry and test planning objects (80) for controlling workflow management and for controlling multiple and simultaneous test orders from independent entry points, wherein each of said test orders from a said independent entry point are combined as a single work order and accepted for processing,

b) instrument complex objects (90) for control of said plurality of specimen processing modules for performing said tests,

c) results processing and validation objects (120, 140, 142) for processing test data of said tests and for verifying test results by applying user-configurable test criteria, result verification rules and laboratory specific procedures,

d) system user objects (70) that communicate with remote external entities objects (72) to control transmitting of the multiple and simultaneous test orders from the said independent entry points, received by the external entities objects (72), to said order entry and test planning objects (80), and,

e) a system configuration manager object (130) for permitting a user to control and monitor said integrated clinical laboratory system to automate pre-analytical, analytical, and post-analytical laboratory processing of said specimens and said test data;

wherein the post-analytical laboratory processing comprises grouping related results objects (214), into result set objects (216) each of the result objects (214) including all data associated with a test activity object (204) of respective ones of the plurality of specimen processing modules (50), and combining and processing data from different ones of the result set objects (216)."

"8. The system according to claim 1 wherein said plurality of said system user objects further comprises a bar code reader user object responsive to user inputs deliver via bar code reading devices."

"14. The system according to claim 1 wherein said at least one specimen processing module comprises instrument hardware and embedded process control software."

The claim request also includes dependent claims 2 to 7, 9 to 13 and 15 to 18 all directed to particular embodiments of the system defined in claim 1.

V. The arguments submitted by the appellant in support of the third auxiliary request are essentially the following:

The objections of added subject-matter and of lack of clarity raised by the examining division are either not justified or overcome by way of amendment.

Document D2 fails to disclose the following features defined in claim 1 of the third auxiliary request:

- a plurality of the specimen processing modules,
- the means for controlling multiple and simultaneous test orders from independent entry points and for combining the test orders from an entry point as a single work order,
- the means for communicating with remote external entities,
- the means for verifying the test results by applying result verification rules and laboratory specific procedures,
- the means for grouping related results and combining and processing the corresponding data as claimed, and
- the means for performing an automated post-analytical processing of the specimens and the test data as claimed.

These novel features work in synergistic combination with one another to achieve a fully scalable system which is able to receive, manage, process and output multiple tests of different types and from different users.

The claimed combination of features is not rendered obvious by the prior art considered by the examining division or by the common general knowledge of the skilled person at the priority date of the application.

Reasons for the Decision

1. The appeal is admissible.

2. *Procedural matters*

According to the statements of the appellant in the letter dated 19 March 2012 (*cf*. point III above), the main and the first and second auxiliary requests and the request for oral proceedings were withdrawn on condition that the Board considered the application documents amended according to the third auxiliary request to be allowable without the need to hold oral proceedings; in the event that the Board did not consider the third auxiliary request to be allowable without holding oral proceedings, the request for oral proceedings was maintained for consideration of the main and the first, second and third auxiliary requests in this order.

As will become apparent below, the Board considers the third auxiliary request to be allowable without the need to hold oral proceedings. Thus the condition set

by the appellant is fulfilled and the so-called third auxiliary request has become the appellant's sole and main request. For ease of reference it will still be referred to below as "third auxiliary request". Under these circumstances it is not necessary to address the issues of admissibility and allowability of the main and the first and second auxiliary requests in the present decision, for which the Board had expressed a preliminary negative assessment in its communication annexed to the summons to oral proceedings.

3. *The "third auxiliary request"*

The application documents have been extensively amended according to the request labelled "third auxiliary request" and in the Board's view the amendments overcome the reasons for the refusal of the application (point I above).

3.1 *Amendments*

3.1.1 The Board is satisfied that the application documents as amended according to the appellant's request comply with the requirements of Article 123(2) EPC. In particular,

- claim 1 is based on claims 1 and 10 of the application as published together with Figures 3, 3a and 11 and the passages on page 10, line 20 to page 11, line 4, page 11, lines 15 to 28, page 12, second paragraph, page 13, second paragraph to page 14, first paragraph, page 15, lines 20 to 24, page 20, lines 16 to 24, and page 26, second paragraph of the description of the application as published, and
- dependent claims 2 to 15 are based on dependent claims 2 to 6 and 8 to 17 as published,

respectively, and dependent claims 17 and 18 are based on the paragraph bridging pages 11 and 12 of the description of the application as published.

3.1.2 The objections raised under Article 123(2) EPC by the examining division in the decision under appeal with respect to the sets of claims then on file have been overcome by way of amendment. In particular, claim 1 has been amended so as to specify the verification of test results "by applying user-configurable test criteria, result verification rules and laboratory specific procedures" as supported by the passages on page 15, lines 20 to 24 and page 26, lines 14 to 23 of the description of the application as published, and the dependent claims objected to by the examining division have been replaced by present dependent claims 17 and 18 which, as already noted above, comply with Article 123(2) EPC.

3.1.3 The text of the description has been revised and brought into conformity with the invention as defined in the claims as presently amended, and the pertinent prior art has been acknowledged in the introductory part of the description (Article 84 EPC 1973, second sentence together with Rules 27(1) (b) and (c) EPC 1973). The description and the drawings have also been amended to conform to the requirements of Rule 32(2)(j) EPC 1973.

3.2 *Article 84 EPC 1973*

In its decision the examining division raised a series of objections of lack of clarity with respect to the sets of claims then on file. Some of the objections are not found persuasive. In particular, the use of the term "object" in expressions such as "system user

objects" in present claim 1 or "bar code reader user object" in present dependent claim 8 does not give rise to a lack of clarity as the term "object" in the context of the claimed subject-matter is synonymous with the term "means" commonly used in the formulation of claims directed to a physical entity to designate a structural component arranged to perform a predetermined technical function. Moreover, the definition of a module comprising "instrument hardware and embedded process control software" (present dependent claim 14) is not objectionable under Article 84 EPC 1973 or under Article 52 EPC because, contrary to the opinion expressed by the examining division in its decision, a physical entity may include software and, in addition, the EPC only excludes the patentability of software "as such" (Article 52 EPC, paragraph (2)(c) together with paragraph (3)). The remaining objections of lack of clarity raised by the examining division do not apply any longer to the claimed subject-matter in view of the extensive amendments made to the present claims.

The Board is therefore satisfied that the subject-matter of the amended claims is sufficiently clear within the meaning of Article 84 EPC 1973.

3.3 *Novelty and inventive step*

In the decision under appeal the examining division held with regard to claim 1 amended according to the requests then on file that the claimed subject-matter was anticipated by document D2 or rendered obvious by the disclosure of the document and the customary practice followed by the person skilled in the art.

The claimed subject-matter, however, has been amended by incorporation of several features and in the Board's view the integrated clinical laboratory system defined in the amended claim 1 defines patentable subject-matter within the meaning of Article 52(1) EPC.

In particular, document D2 discloses the automated clinical laboratory instrument Abbott AxSYM^{TM} (page 2063, first paragraph together with Figure 2 and the corresponding description) comprising a module for performing different tests on specimens (paragraph bridging the two columns on page 2063) under the control of an integrated work flow automation system (page 2064, first column, second paragraph to page 2065, first column, third paragraph), this system including, among other components, means for specifying and processing the tests to be performed (Table 1 together with page 2066, first column, last paragraph to second column, second paragraph), means for processing the test data and for verifying or validating the test results (page 2065, first column, lines 40 to 43, and page 2067, first column, second paragraph), and means for automatically controlling and monitoring the system (page 2064, first column, third paragraph and second column, last paragraph to page 2065, first column, third paragraph). However, in document D2 the test orders are input locally and all the tests and the corresponding test results appear to be handled individually and independently of each other, and the document is silent as to the provision, first, of means for processing multiple and simultaneous test orders from different entry points communicating with remote external locations and combining test orders as a single work order as required by features a) and d) of claim 1 and, second, of means for grouping related test results from the

plurality of specimen processing modules and combining and processing data from the different groups as specified in the last of the features listed in claim 1. For this reason already, the claimed subject-matter is novel over the disclosure of document D2.

In addition, there is no hint in document D2 or in the remaining documents on file towards the distinguishing features identified above or the improvements achieved therewith, namely an integrated clinical laboratory system which can simultaneously handle multiple tests ordered by different users in remote locations while managing workflow and results processing in an integrated and efficient manner (*cf*. point V above, penultimate paragraph, together with page 2, lines 10 to 13, paragraph bridging pages 3 and 4, and the second paragraph of page 9 of the application as published).

Therefore, the subject-matter of claim 1 is novel and involves an inventive step over the available prior art (Articles 52(1) EPC). The same conclusion applies to dependent claims 2 to 18 by virtue of their dependence on claim 1.

3.4 The Board is also satisfied that the application documents as presently amended and the invention to which they relate meet the remaining requirements of the EPC within the meaning of Article 97(1) EPC.

4. In view of the above considerations and conclusions, the Board rules that the decision under appeal is to be set aside and a patent be granted on the basis of the application documents amended according to the request labelled "third auxiliary 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 on the basis of the following application documents:
   - claims: claims 1 to 18 amended according to the third auxiliary request filed with the letter dated 19 March 2012,
   - description: pages 1 to 3, 5 to 9, 11 to 13 and 16 to 22 of the application as published, page 10 filed with the letter dated 3 September 2008, and pages 4, 4a, 14, 15 and 23 to 36 filed with the letter dated 19 March 2012, and
   - drawings: sheets 1/28, 2/28, 4/28, 5/28, 18/28 to 23/28 and 28/28 of the application as published, sheet 3/28 filed with the letter dated 3 September 2008, and sheets 6/28 to 17/28 and 24/28 to 27/28 filed with the letter dated 19 March 2012.

The Registrar: The Chairman:

M. Kiehl A. G. Klein

Decision electronically authenticated