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Datasheet for the decision of 29 June 2011

Case Number: T 1431/07 - 3.5.06

Application Number: 01954957.5

Publication Number: 1311950

IPC: G06F 11/30

Language of the proceedings: EN

Title of invention:
Method of evaluating performance of a hematology analyzer

Applicant:
BIO-RAD LABORATORIES, INC.

Headword:
Hematology analysis/BIO-RAD

Relevant legal provisions (EPC 1973):
EPC Art. 56

Keyword:
"Inventive step - no (all requests)"

Decisions cited:
-

Catchword:
-

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Case Number: T 1431/07 - 3.5.06

D E C I S I O N
of the Technical Board of Appeal 3.5.06
of 29 June 2011

Appellant: BIO-RAD LABORATORIES, INC.
1000 Alfred Nobel Drive
Hercules
California 94547 (US)

Representative: Lerwill, John
A.A. Thornton & Co.
235 High Holborn
London, WC1V 7LE (GB)

Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 14 February 2007 refusing European patent application No. 01954957.5 pursuant to Article 97(1) EPC 1973.**

Composition of the Board:

Chairman: D. H. Rees
Members: M. Müller
M.-B. Tardo-Dino

Summary of Facts and Submissions

I. The appeal lies against the decision of the examining division to refuse the European patent application no. 01954957.5 for lack of an inventive step. The decision was delivered during oral proceedings on 12 May 2006 and dispatched with letter dated 14 February 2007.

II. A notice of appeal was received on 16 April 2007 and the appeal fee was paid on 17 April 2007. On 22 June 2007, a statement of grounds of appeal including amended requests was received.

III. By letter dated 11 March 2011, the board summoned the appellant to oral proceedings. In an annex to the summons the board referred *inter alia* to the following documents,

D2: US 5,532,941 A
D4: Gulati G L *et al.*, "Quality control in hematology", Clinics in Laboratory Medicine, vol. 6, no. 4, 1986, pp. 675-688

and gave its preliminary opinion that the independent claims according to all requests went beyond the application as originally filed, were unclear and lacked an inventive step over D2 in view of D4.

IV. In response to the summons, on 27 May 2011, the appellant filed amended claims 1-25 according to a main request and amended claims 1-25, 1-17 and 1-15 according to first to third auxiliary requests, respectively.

V. The appellant requested that the decision under appeal be set aside and that a patent be granted based on the claims of any of these four requests.

VI. All requests contain an independent method claim 1 and independent claims relating to a computer readable medium and computing system, respectively, which correspond in wording closely to the method claim.

Claim 1 according to the main request reads as follows.

"A method for evaluating an instrument (10) by comparing data generated by an operation on the instrument with data generated by a group of like instruments, characterised by the steps of:

identifying a group of like instruments as determined by a non-static criterion;

collecting group data (16) generated by performing substantially the same operation on said group of instruments;

storing said group data (14);

conducting said operation on an individual instrument and generating individual data from said operation; and

comparing said individual data with said group data,

wherein the criterion is definable by a user selecting desired attributes of the group."

Claim 1 according to the 1st auxiliary request is identical with that of the main request except for the storing and comparing steps which read as follows:

"... storing said group data in categorised groupings (14); ...

comparing said individual data with group data selected from the stored group data and concerning the identified group of like instruments, ..."

Claim 1 according to the 2nd auxiliary request is identical with that of the main request except for the following passage which is added to its end:

"... wherein said storing said group data comprises storing said group data in a global database on a server computer, said method further comprising:

accessing said global database and retrieving said group data corresponding to said individual data; and

transferring said retrieved group data to a client database."

Claim 1 according to the 3rd auxiliary request is identical with that of the 2nd auxiliary request except for the following passage which is added to its end:

"... wherein said client database is provided in a second computing system, said method further comprising:

exchanging said group data and said individual data between said first computing system and said second computing system by a synchronization process, said synchronization being initiated at will at said second computing system; and

analysing said individual data and said group data on said second computing system, said analysing including manipulating said group data generating multiple plots of individual data versus group data

including a time-frame plot, a geographic region plot, an instrument type plot and a composition utilized plot."

VII. The decision of the board was announced at the end of the oral proceedings.

Reasons for the Decision

1. The appeal meets the requirements of Article 108 and Rule 99 EPC and is thus admissible (see points I and II).

The Invention

2. The invention relates to evaluating an individual instrument by comparing data generated by that instrument ("individual data") with data generated by a peer-group of "like instruments" ("group data"). The preferred application of the invention is for quality control of hematology analyzers in clinical laboratories. The peer group can be defined according to a specific geographic area, a specific test procedure, or a specific reagent, and the group data can further be selected from a specified time period (cf. *e.g.* claims 5-7 of the main request, and the description, p. 6, line 23 - p. 7, line 10).

Clarity

3. All independent claims specify that the group of like instruments is selected according to a "non-static

criterion, ... definable by a user by selecting desired attributes of the group".

3.1 The board considers that the notion of a "non-static criterion" is ambiguous between a criterion which changes over time (defining, say, the best instruments during the last month) and one which can be changed on need.

3.2 The board notes that the description does not use the term "non-static" once; what it does use is the term "dynamic" (cf. *e.g.* p. 6, lines 3-4 and 7-8, and p. 8, lines 5-6). While these terms appear to be intended to mean the same thing, as confirmed by the appellant during oral proceedings, the board has doubts whether this can be established in view of the description. Assuming they are indeed intended to be synonymous, the references on page 6 do not help to resolve the intended meaning in the claim. The reference on page 8 would appear to support the second interpretation (*i.e.* "changed on need").

3.3 It is left open whether, as a consequence, the independent claims conform with Article 84 EPC 1973 and whether a possible deficiency could remedied. Instead, in the following the inventive merit of the independent claims is assessed on the basis of the intended interpretation that the criterion is non-static by virtue of being user-definable. This interpretation was the one adopted by the appellant in its arguments in appeal (see *e.g.* grounds of appeal, sec. 2), including in the oral proceedings. Also during oral proceedings the appellant agreed to leave open the clarity problem while proceeding to the discussion of inventive step.

Main Request

4. It is common ground that document D2 is the closest piece of prior art to hand and discloses a similar method of comparative instrument evaluation.

4.1 More specifically, D2 discloses a method for evaluating instruments against a peer group of like instruments located in geographically dispersed laboratories. The evaluation is performed at a central station to which each of the instruments periodically transmits control data. Based on this data the central station determines a so-called golden peer group of instruments which have recently proven to operate at high quality standards. The actual performance of the golden peer group expressed in statistical terms is set as the target - the so-called "golden peer group standard" - against which all individual instruments are evaluated. A CCC-Report containing the results of this evaluation is then returned to the participating laboratories (cf. fig. 2; col. 2, lines 42-58; col. 7, lines 57-67; col. 8, lines 1-58; col. 9, lines 12-34; col. 13, lines 41-59).

4.2 D2 further discloses that the analysis should be performed for "a large plurality of laboratory instruments" and "numerous kinds of samples" and that, therefore, many peer databases containing control data from different peer groups are provided (col. 25, lines 20-32). The board interprets this as implying that the central station holds a separate peer database for each combination of instrument and "kind of sample" that may have to be evaluated. D2 does not disclose how,

in any given case, the relevant peer database is identified and selected.

4.3 Claim 1 specifies to collect, once a peer group is identified, group data generated by performing substantially the same operation on said group of instruments. Beyond that, claim 1 characterizes the group data only by the requirement that it be compared with the given individual data. The description of the application discloses further that the group data consists of "statistical summaries" produced from the raw test data (cf. p. 6, lines 6-16). The precise form of these summaries is not disclosed.

4.4 In the board's judgment, the statistical summaries correspond in D2 to the golden peer group standard which is derived from the pertinent peer data and used for comparison with the individual data (cf. D2, col. 9, lines 12-34).

4.5 Accordingly, D2 discloses all features of claim 1 except of the fact that the group data of like instruments is identified as determined by a non-static criterion definable by a user selecting desired attributes.

4.6 This feature enables the user of the system of D2 to customize the quality control if necessary and therefore contributes to increased accuracy of the system of D2.

5. Claim 1 leaves undefined the claimed "user" which thus subsumes, in the board's view, the administrator of the central station of D2. The description however makes it

clear that the end-user at the individual local laboratories is rather intended. To the benefit of the appellant, the board adopts this interpretation of claim 1.

6. Document D4 is a paper discussing various aspects of quality control in hematology, either within an individual laboratory ("internal quality control", p. 675) or across laboratories in different geographical locations ("external quality control, p. 684). D4 discloses that participants in a regional and/or national quality control program transmit test results to a central "distributor" and receive, in response, statistical analysis data, and that "method, instrument, and reagent-based peer group data can help select the system that provides the best result (p. 684, last par - p. 685, line 4). Elsewhere D4 refers to "comparison with instrument, method and/or reagent-based peer group data" (p. 686, 3rd par., lines 1-3).

6.1 The board interprets in particular the latter statement as a clear indication that individual data may have to be compared with data obtained for several peer groups according to a choice of parameters or "attributes" such as instrument type, method or reagent. Likewise, the optional participation in national or regional programs suggests the relevance of further attributes relating to geographical locations (p. 686, 3rd par., lines 3-6).

6.2 The appellant qualifies D4 as an "elementary text on clinical diagnostic quality control" which, while mentioning various peer group comparisons, "gives no hint on how to achieve this" (submission of 27 May 2011,

point 2.8.2). The board, accepting both statements, considers that D4 surveys common knowledge in the art and, as a survey article, mentions many issues without going into them in detail.

7. Even without such implementation details D4 teaches that the skilled person is aware of the possibility of improving the accuracy of quality control by comparing individual test data against different peer groups defined by "desired attributes of the group". Accordingly, the skilled person would be incited to modify the system of D2 so as to enable the user to select amongst such peer groups.

7.1 In doing that, the skilled person would first determine which peer groups should be available for selection. Keeping with the architecture of D2, the corresponding peer databases would also be precomputed.

7.2 Given peer groups which are characterized by "attributes" it would, in the board's judgment, be obvious for the skilled person to enable selection amongst the peer groups by indication of such attributes. It is noted in passing that the provision of attributes such as reagent number is anticipated in D2 at least for individual data (col. 7, line 28-31). It would also be obvious for the skilled person to make the selection available to the user.

7.3 Again, the skilled person would want to modify the system of D2 so that it can continue to run, as far as possible, without user intervention (cf. *e.g.* col. 25, lines 34-36). To achieve this, it would be obvious, for example, to enable user selection at fixed points in

time and for subsequent periods such as a week or a month. The board notes that claim 1 is silent about when, how and how often the user is allowed to choose a peer group.

7.4 Thus, the skilled person would arrive at the claimed invention in an obvious manner and without the need for any major changes to the system architecture of D2, let alone its "complete reconfiguration" as the appellant suggested in its submission of 27 May 2011 (point 2.10) and maintained during oral proceedings.

8. In summary, the board concludes that claim 1 lacks an inventive step over D2 in view of generally desirable aims as known from D4, and therefore does not conform with Article 56 EPC 1973.

1st Auxiliary Request

9. Over the main request, claim 1 of the 1st auxiliary request specifies that group data is stored in "categorized groupings" from which the pertinent group data is selected.

9.1 The description explains (p. 3, lines 13-17), that historical data is "grouped in categories for comparative analysis" from which a particular one is selected for comparison. The board was unable to find any more specific disclosure about the nature of categorized groupings as claimed, nor did the appellant provide any when asked during the oral proceedings.

9.2 The peer group data according to D2 represents historical data from which the appropriate one is

selected for comparison with individual data. Moreover, peer group data which is, as assumed above, precomputed for several combinations of attributes can, in the board's judgment, naturally be considered to be "grouped in categorized groupings" as claimed.

9.3 The board therefore concludes that the assessment of the main request carries over to claim 1 of the 1st auxiliary request to show the lack of an inventive step.

2nd Auxiliary Request

10. Claim 1 according to the 2nd auxiliary request specifies, over claim 1 of the main request, that the group data is stored in a global database on a server computer from which the relevant group data is retrieved and transferred to a client database.

10.1 D2 discloses that the golden peer group standard is computed over time and stored centrally (see fig. 6, esp. nos. 176 and 177, and col. 20, lines 59-63). When several peer databases are available, as D2 discloses, it is obvious to store the data representing the pertinent quality standards in a suitable global database as claimed.

11. The system of D2 will report the results of a quality analysis to the participating laboratory (*e.g.* col. 8, lines 39-41, and fig. 1, item 49). These reports contain, *inter alia*, the relevant quality standard (see col. 13, lines 42-60, and fig. 2, nos. 101-103).

11.1 The board considers it to be an obvious option to store the reports locally for documentation and later

reference in a suitable "client database" as claimed. The board therefore concludes that claim 1 of the second auxiliary request also lacks an inventive step over D2 and D4.

3rd Auxiliary Request

12. Claim 1 according to the 3rd auxiliary request specifies, over claim 1 of the 2nd auxiliary request, that

a) client and server as claimed are different (first and second) computing systems between which individual data and group data is exchanged by a synchronization process initiated "at will" by the client computer, and that
b) the client computer locally produces multiple plots of the individual data versus the group data, in particular all of a time-frame plot, a geographic region plot, an instrument-type plot, and a composition utilized plot.

13. Synchronization

13.1 In view of the description (p. 6, lines 10-17), the claimed synchronization is intended to comprise the transfer of new or modified (*i.e.* individual) data from the client to the server and the later transmittal of statistically summarized group data back to the client.

13.2 According to D2, the local laboratories transmit control data to the central station at their own initiative - *i.e.* "at will" - and later receive a report comprising statistical evaluation of the

laboratory against its peers (col. 7, lines 1-2, and col. 8, lines 34-41).

13.3 The board therefore concludes that D2 discloses client-server "synchronization" as claimed.

14. Plots

14.1 According to D2, the evaluation charts are generated at the central station and then transmitted to the client.

14.2 In the board's view is it obvious that laboratory staff may develop the need for different or additional graphical representations (*i.e.* plots) of the analysis results, and also that these needs may differ between individual laboratories. For reasons of flexibility and in order to reduce the load on the central server it is further obvious to enable the clients to produce such plots locally.

14.3 Specifically claimed are "a time-frame plot, a geographic region plot, an instrument type plot and a composition utilized plot" of individual data versus global data.

14.4 Instrument type and time-frame plots are known from D2 (cf. fig. 2, items 100, 102 and 103).

14.5 As argued above (see esp. point 13.1), D4 suggests the relevance of quality control in view of other criteria, in particular reagent and geographic location. This specifically suggests, in the board's view, the provision of a geographic region plot and a composition utilized plot.

14.6 The board therefore concludes that claim 1 according to the 3rd auxiliary requests also lacks an inventive step over D2 and D4, in violation of Article 56 EPC 1973.

Summary

15. There being no allowable request, the appeal must be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

B. Atienza D. H. Rees