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Datasheet for the decision of 7 March 2013

Case Number: T 1354/09 - 3.5.05

Application Number: 02753539.2

Publication Number: 1428021

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Language of the proceedings: EN

Title of invention:
Biometric quality control process

Applicant:
BIO-RAD LABORATORIES, INC.

Headword:
Biometric quality control/BIO-RAD

Relevant legal provisions:
EPC 1973 Art. 84
EPC 1973 R. 71a
EPC R. 116, 137(3)

Keyword:
Clarity and support by the description - main request (no)
Correct exercise of first-instance discretionary power - auxiliary request (yes)

Decisions cited:
T 0755/96

Catchword:

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Case Number: T 1354/09 - 3.5.05

D E C I S I O N
of Technical Board of Appeal 3.5.05
of 7 March 2013

Appellant: (Applicant)	BIO-RAD LABORATORIES, INC. 1000 Alfred Nobel Drive Hercules California 94547 (US)
Representative:	Whitlock, Holly Elizabeth Ann R.G.C. Jenkins & Co 26 Caxton Street London SW1H 0RJ (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 5 February 2009 refusing European patent application No. 02753539.2 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 5 February 2009, refusing European patent application No. 02753539.2 on the grounds of lack of inventive step (Article 56 EPC 1973) with respect to a main request, having regard to

D1: WO-A-97/42588 or
D2: WO-A-00/12968,

and lack of clarity (Article 84 EPC 1973) with respect to a first auxiliary request.

Moreover, a second auxiliary request filed during the first-instance oral proceedings on 17 December 2008 was not admitted into the examination proceedings under Rules 116(1) and 137(3) EPC, since it was late-filed and not clearly allowable under Article 123(2) EPC.

II. Notice of appeal was received on 15 April 2009. The appeal fee was paid on the same day. With the statement setting out the grounds of appeal, received on 15 June 2009, claims 1 to 8 according to a main request (corresponding to the main request underlying the appealed decision) and to an auxiliary request (corresponding to the second auxiliary request underlying the appealed decision) together with amended description pages were submitted. The appellant requested that the decision of the examining division be set aside and that a patent be granted on the basis of the main request or, on a subsidiary basis, that the decision to not admit the former second auxiliary request be overturned and that a patent be granted on the basis of the claims of the auxiliary request or that the claims of this request be remitted to the

examining division for further examination. In addition, oral proceedings were requested as an auxiliary measure.

III. A summons to oral proceedings scheduled for 7 March 2013 was issued on 15 November 2012. In an annex to this summons, the board expressed its preliminary opinion on the appeal pursuant to Article 15(1) RPBA. In particular, objections were raised under Articles 123(2) EPC and 84 EPC 1973. The appellant was also informed that no preliminary view as to the matter of novelty and inventive step could be taken by the board, since the reasoning for assessing inventive step in the decision under appeal was found to be incomplete, and that the board did not see any reason to overrule the way in which the examining division had exercised its discretion not to admit the former second auxiliary request into the examination proceedings.

IV. With a letter of reply dated 5 March 2013, the appellant advised the board that it would not be represented at the scheduled oral proceedings and did not submit any comments on the substance of the board's communication under Article 15(1) RPBA.

V. Oral proceedings were held as scheduled on 7 March 2013 in the absence of the appellant. After due deliberation on the basis of the written submissions, the decision of the board was announced at the end of the oral proceedings.

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

"A computer-implemented method of processing

patient data for use in a patient based biometric quality control process, comprising:

acquiring patient data from one or more laboratory instruments for a specific analyte, said patient data including a plurality of weeks worth of data;

determining a percentage of the patient data to truncate for the analyte;

determining high and low truncation limits based on the patient data and the percentage of the patient data to truncate; and

determining the mean and standard deviation of the patient data between the high and low truncation limits for each hour of the week represented by the patient data,

wherein determining truncation limits includes: determining a first set of truncation limits which includes:

initially setting a high truncation limit (thi) to the highest value of the patient data, and low truncation limit (tlo) to the lowest value of the patient data; and

determining the optimal pair of tlo and thi that minimizes the difference between the percentage of the patient data to truncate and the percentage of patient data outside the thi-tlo pair by repeatedly:

calculating the percentage of patient data outside the high and low truncation limits;

re-setting the thi to the next highest value of the patient data,

re-setting the tlo to the next lowest value of the patient data."

Independent claim 1 of the auxiliary request reads as follows:

"A computer-implemented method of processing patient data for use in a patient based biometric quality control process, comprising:

acquiring training patient data from one or more laboratory instruments for a specific analyte, said training patient data including a plurality of weeks worth of data;

determining a set of truncation limits associated with a percentage of the training patient data to truncate for the analyte, by;

i) determining a plurality of candidate sets of truncation limits by calculating high and low truncation limits that truncate a candidate percentage of the training patient data, for each of a plurality of candidate percentage values; and

ii) calculating a number of bad results that are produced for each candidate set of truncation limits, by:

applying a quality control rule to said training patient data within that candidate set of truncation limits to output a plurality of error conditions, each associated with a result value indicating the difference between the true concentration and the measured concentration of the respective training patient data; and

calculating an average number of bad results produced, wherein a bad result is a result value which exceeds a total allowable error specification; and

iii) selecting the candidate set of truncation limits that produces the smallest number of bad results; and

processing a patient test result received from said one or more laboratory instruments

by:

determining if the patient test result is within the determined set of truncation limits;

if it is determined that the patient test result is within the determined set of truncation limits:

applying a quality control rule to the patient test result; and

generating an error signal if the patient test result exceeds the quality control rule limits."

Reasons for the Decision

1. Admissibility of the appeal

The appeal complies with the provisions of Articles 106 to 108 EPC (cf. point II above) and is therefore admissible.

2. Non-attendance at oral proceedings

The appellant decided not to attend the scheduled oral proceedings. Pursuant to Article 15(3) RPBA, the board is not obliged to delay any step in the appeal proceedings, including its decision, by reason only of the absence at the oral proceedings of any party duly summoned who may then be treated as relying only on its written case.

In the present case, the appellant did not submit any comments on the objections raised in the board's communication under Article 15(1) RPBA. The board reconsidered and maintained those objections, and was in a position to take a decision at the end of the oral proceedings in exercise of its discretion according to Article 15(3) RPBA.

3. MAIN REQUEST

This request corresponds to the main request underlying the appealed decision.

3.1 Article 84 EPC 1973

The board judges that claim 1 of this request does not meet the requirements of Article 84 EPC 1973, the reasons being as follows:

3.1.1 It is established case law that an independent claim must indicate all the essential features which appear to be necessary for solving the technical problem posed according to the application (cf. Case Law of the Boards of Appeal of the European Patent Office, 6th edition 2010, section II.B.1.1.4).

3.1.2 The technical problem dealt with in the application is to guide and manage laboratory analytical process control operations, and in particular to provide alerts to an operator when an actionable error is present and guide the operator in troubleshooting (cf. page 3, lines 20-27 of the application as filed). Claim 1 is obviously based on the embodiment related to "methodology 2" representing the second step of determining truncation limits for collected patient data by a truncation limits module (cf. page 15, lines 17-31 in combination with page 18, line 30 to page 20, line 7 of the application as filed). According to this embodiment, truncation limits are determined such that a decrease in the standard deviation of the truncated patient data is maximised relative to the number of samples that are truncated (cf. page 18, lines 31-33 of the application as filed). The underlying algorithm is supposed to determine how much

data should be truncated on either end of the patient data distribution to minimise the standard deviation of the truncated population relative to the truncated sample size according to the original application (cf. page 7, lines 19-23).

Claim 1, in principle, only specifies that optimal truncation limits are determined by calculating the percentage of patient data outside the predetermined truncation limits and resetting the truncation limits to the next highest and lowest values of the patient data. However, claim 1 fails to specify that the resetting of the truncation limits inevitably depends on the counted numbers of results and the respective standard deviations calculated as taught in the original application (cf. page 19, lines 10-36; claim 3 as filed) for actually determining truncation limits that maximise a decrease in the standard deviation of the truncated patient data relative to the number of samples that are truncated, as required by the application as filed (cf. page 18, lines 31-33). Claim 1 also fails to specify the provision of any alert signal, if errors are detected, to guide the operator in troubleshooting (cf. page 3, lines 20-27; claims 6 and 7 as originally filed).

3.1.3 The appellant submitted that the present invention, referring to page 2, line 10 to page 3, line 10 of the original application, was related to the technical problem of reducing false error detection in laboratory equipment and providing quality control systems that identify an actionable error for achieving a guided troubleshooting by a user (cf. statement setting out the grounds of appeal, items 10 and 24). Moreover, the alleged technical effect resulting from the independent claims was related to technical accuracy and efficiency

or reliability of the quality control system by generating less irrelevant error signals (cf. statement setting out the grounds of appeal, items 22 and 31).

In this regard, the board shares the view of the examining division, put forward in the context of assessing inventive step, that the alleged technical problem or purpose of reducing false error detection in laboratory equipment and providing quality control systems that identify an actionable error for a user is substantially speculative, because the features of claim 1 were neither necessary nor sufficient for such a reduction of false errors, and since the claimed truncation of patient data encompassed many possibilities of how to perform such a truncation and would not enable the purported identification of actionable errors due to a lack of a clear causal relationship between the features of claim 1 and the alleged problem to be solved (cf. appealed decision, sections 1.7 and 1.8).

3.1.4 For the above reasons, claim 1 lacks clarity and support by the description since it does not indicate all the essential features which appear to be necessary for solving the technical problem posed according to the application.

3.2 In conclusion, this request is not allowable under Article 84 EPC 1973.

4. AUXILIARY REQUEST

This request corresponds to the second auxiliary request underlying the appealed decision, which was not admitted into the first-instance proceedings by the examining division under Rules 116(1) and 137(3) EPC.

Claim 1 of this request differs from claim 1 according to the main request *inter alia* in that the claimed method further comprises the steps of

(a) determining if a processed patient test result is within the determined set of truncation limits;

(b) if it is determined that the patient test result is within the determined set of truncation limits

- applying a quality control rule to the patient test result;
- generating an error signal if the patient test result exceeds the quality control rule limits.

4.1 Review of the first-instance discretionary decision

The board holds that the examining division correctly exercised its discretionary power in not admitting the second auxiliary request filed during the first-instance oral proceedings, for the following reasons:

4.1.1 The second auxiliary request was not admitted into the proceedings by the examining division under Rule 116(1) EPC (corresponding to Rule 71a(1) EPC 1973 which is to be applied here) and Rule 137(3) EPC. In particular, the examining division held that the second auxiliary request was belatedly filed for the very first time and included extensive amendments which had not been investigated and searched before in the examination proceedings. Furthermore, claim 1 was not clearly allowable under Article 123(2) EPC, since the basis for the underlying amendments cited by the appellant during the oral proceedings was related merely to a multitude of possible embodiments with various aspects rather than to a single consistent embodiment (cf. appealed

decision, section 3).

4.1.2 Although Rule 116(2) EPC (Rule 71a(2) EPC 1973), related to the submission of new *documents*, rather than Rule 116(1) EPC (Rule 71a(1) EPC 1973), related to the submission of new *facts and evidence*, should have been cited as the legal basis for not admitting the second auxiliary request, the board takes the view that the examining division exercised its discretion on the basis of the relevant facts (i.e. late-filed request involving extensive amendments and features which had not been searched before), according to the right principle (i.e. criterion of "clear allowability"), and in a reasonable way (i.e. by providing a complete reasoning of its discretionary decision), in compliance with decision T 755/96 (cf. Reasons, point 4) cited by the appellant.

4.2 Since the appellant's request that the decision not to admit the former second auxiliary request as filed during the first-instance oral proceedings be overturned is to be rejected, there is no need to further consider the patentability of the auxiliary request or a remittal of the case to the department of first instance for further examination, as the latter is requested only as an auxiliary measure according to section 7 of the statement setting out the grounds of appeal.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

K. Götz A. Ritzka

Decision electronically authenticated