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**Datasheet for the decision  
of 8 February 2017**

**Case Number:** T 0052/11 - 3.4.01

**Application Number:** 05733067.2

**Publication Number:** 1735631

**IPC:** G01R33/465

**Language of the proceedings:** EN

**Title of invention:**

NMR CLINICAL ANALYZERS AND RELATED METHODS, SYSTEMS, MODULES  
AND COMPUTER PROGRAM PRODUCTS FOR CLINICAL EVALUATION OF  
BIOSAMPLES

**Applicant:**

Liposcience, Inc.

**Headword:**

**Relevant legal provisions:**

EPC Art. 123(2)  
EPC 1973 Art. 84, 56  
RPBA Art. 13(1)

**Keyword:**

Claims - clarity (no) - clarity after amendment (yes)  
Amendments - added subject-matter (yes)  
Late-filed auxiliary requests - procedural economy - admitted  
(yes) - admitted (no)  
Inventive step - could-would approach

**Decisions cited:**

T 0775/90

**Catchword:**



**Beschwerdekammern**  
**Boards of Appeal**  
**Chambres de recours**

European Patent Office  
D-80298 MUNICH  
GERMANY  
Tel. +49 (0) 89 2399-0  
Fax +49 (0) 89 2399-4465

Case Number: T 0052/11 - 3.4.01

**D E C I S I O N**  
**of Technical Board of Appeal 3.4.01**  
**of 8 February 2017**

**Appellant:** Liposcience, Inc.  
(Applicant) 2500 Sumner Boulevard  
Raleigh, NC 27616 (US)

**Representative:** Williams, Lisa Estelle  
Haseltine Lake LLP  
Redcliff Quay  
120 Redcliff Street  
Bristol BS1 6HU (GB)

**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted on 18 August 2010  
refusing European patent application No.  
05733067.2 pursuant to Article 97(2) EPC.

**Composition of the Board:**

**Chairman** G. Assi  
**Members:** P. Fontenay  
J. Geschwind

## **Summary of Facts and Submissions**

- I. European patent application No. 05 733 067 was refused by decision dated 18 August 2010.

In the "Reasons" for the decision, the examining division held that the subject-matter of independent claims 1, 37 and 46 of a main request and auxiliary requests 1 to 3 lacked an inventive step contrary to the requirements of Article 56 EPC 1973. Particular reference was made, in this respect, to document D4 (WO-A-03/012416).

Moreover, independent claims 1, 36 and 47 of auxiliary request 1 were considered to define added subject-matter contrary to Article 123(2) EPC. Concretely, according to Figure 11 of the application as published, consecutive failures in adjusting operating parameters of selected components led to the process being aborted, an operator being alerted to verify the system and the calibration procedure being repeated. However, only the latter step of this whole sequence had been reproduced in the independent claims. The examining division thus held that the claimed subject-matter constituted an intermediate generalisation of the disclosure of Figure 11.

- II. On 6 October 2010, the appellant (applicant) filed a notice of appeal. The prescribed appeal fee was paid on the same date.

The statement setting out the grounds of appeal was filed on 17 December 2010.

With the statement of grounds, the appellant requested that the decision to refuse the application be set

aside and that a patent be granted on the basis of a main request filed with the statement of grounds of appeal and corresponding to the main request underlying the impugned decision, that is, the request filed during the oral proceedings before the examining division on 2 March 2010.

As an alternative, the appellant requested that a patent be granted on the basis of one of various sets of claims according to auxiliary requests 1 to 8, filed with the statement of grounds.

- III. A summons to attend oral proceedings before the Board was issued on 23 September 2016.
- IV. In a communication of the Board pursuant to Article 15(1) RPBA issued on 20 December 2016, the appellant was informed of the provisional opinion of the Board with regard to the requests then pending.
- V. In a letter of reply dated 30 January 2017, the appellant filed auxiliary request 9.
- VI. At the oral proceedings before the Board on 8 February 2017, the appellant filed amended auxiliary request 9 and new auxiliary request 10.
- VII. Claim 1 of the appellant's main request reads:

*"1 A method of operating a clinical NMR in vitro diagnostic analyzer, the clinical NMR analyzer comprising a flow probe held in a magnet bore of an NMR spectrometer, the method comprising the steps of:  
introducing patient biosamples to the flow probe in the NMR spectrometer;*

*obtaining NMR signal spectra of the introduced biosamples;*

*electronically generating at least one clinical quantitative measurement of the patient biosamples based on the obtained NMR spectra; characterised in that the method further comprises the steps of:*

*automatically executing a calibration procedure at start-up as part of a self-test diagnostic start-up procedure before authorizing or allowing evaluation of patient samples wherein the calibration procedure includes delivering a calibration standard to the flow probe in the NMR spectrometer;*

*electronically monitoring data associated with a plurality of selected parameters of the clinical NMR analyzer during normal operation;*

*electronically determining whether the selected parameters are within desired operational ranges based on the monitored data;*

*automatically adjusting operational parameters of selected components of the clinical NMR analyzer based on data obtained by the electronically determining step;*

*automatically executing the calibration procedure when one or more of the selected parameters are determined to be outside desired operational ranges based on the determining step, wherein the calibration procedure includes delivering a calibration standard to the flow probe in the NMR spectrometer; and/or*

*automatically executing the calibration procedure at desired time intervals during normal operation of the clinical NMR analyzer, wherein the calibration procedure includes delivering a calibration standard to the flow probe in the NMR spectrometer."*

Claims 2 to 36 of the main request depend on claim 1.

Independent claim 37 of the main request relates to a clinical NMR in vitro diagnostic analyzer. It reads:

*"37 A clinical NMR in vitro diagnostic analyzer, comprising:*

*a flow probe held in a magnet bore of an NMR spectrometer;*

*an automated sample handler configured to introduce patient biosamples to the flow probe in the NMR spectrometer;*

*means for obtaining NMR signal spectra of the introduced biosamples;*

*means for electronically generating at least one clinical quantitative measurement of the patient biosamples based on the obtained NMR spectra; characterised in that the analyzer further comprises*

*means for automatically executing a calibration procedure at start-up as part of a self-test diagnostic start-up procedure before authorizing or allowing evaluation of patient samples wherein the calibration procedure includes delivering a calibration standard to the flow probe in the NMR spectrometer;*

*means for electronically monitoring data associated with a plurality of selected parameters of the clinical NMR analyzer, during normal operation of the clinical NMR analyzer, to monitor that the selected parameters of the clinical NMR analyzer are within desired operational ranges based on the monitored data;*

*means for automatically adjusting operational parameters of selected components of the clinical NMR analyzer based on data obtained by the means for electronically monitoring data;*

*means for automatically executing the calibration procedure when one or more of the selected parameters are determined to be outside the desired operational ranges, wherein the calibration procedure includes*

*delivering a calibration standard to the flow probe in the NMR spectrometer; and/or*

*means for automatically executing the calibration procedure at desired time intervals during normal operation of the clinical NMR analyzer, wherein the calibration procedure includes delivering a calibration standard to the flow probe in the NMR spectrometer."*

Claims 38 to 45 of the main request depend on independent claim 37.

Independent claim 46 of the main request concerns a computer program product for automating clinical NMR in vitro diagnostic analyzer. Claim 46 reads:

*"46. A computer program product for automating clinical NMR in vitro diagnostic analyzer comprising a magnet with a magnet bore, the clinical NMR analyzer comprising a flow probe held in the magnet bore, the computer program product comprising computer readable program code embodied in a computer-readable storage medium, the computer readable program code comprising:*

*computer readable program code configured to control an automated sample handler to introduce patient biosamples to the flow probe in the magnet bore;*

*computer readable program code configured to obtain NMR signal spectra of the introduced patient biosamples; and*

*computer readable program code configured to electronically generate at least one clinical quantitative measurement of the patient biosamples based on the obtained NMR spectra; characterised in that the computer program product further comprises computer readable program code configured to execute an automated calibration procedure at start-up as part of*



*a self-test diagnostic start-up procedure before authorizing or allowing evaluation of patient samples, wherein the calibration procedure includes delivering a calibration standard to the flow probe in the magnet bore;*

*computer readable program code configured to electronically monitor data associated with a plurality of selected parameters of the clinical NMR analyzer during normal operation of the clinical NMR analyzer;*

*computer readable program code configured to electronically determine whether the monitored data associated with the selected parameters are within desired operational ranges based on the monitored data;*

*computer readable program code configured to automatically adjust operational parameters of selected components of the clinical NMR analyzer based on data obtained by the electronically determining step;*

*computer readable program code configured to execute the automated calibration procedure when one or more of the selected parameters are determined to be outside desired operational ranges based on the determining step, wherein the calibration procedure includes delivering a calibration standard to the flow probe in the magnet bore; and/or*

*computer readable program code configured to execute the automated calibration procedure at desired time intervals during normal operation of the clinical NMR analyzer, wherein the calibration procedure includes delivering a calibration standard to the flow probe in the magnet bore."*

Claims 47 to 58 depend on independent claim 46.

Claim 59 of the main request depends on claim 42. It concerns a clinical NMR analyzer in combination with a networked system of clinical NMR analyzers.

Claims 60 to 86 of the main request depend on independent claim 59.

Claims 87 to 90 of the main request depend on method claim 1.

- VIII. Claim 1 of appellant's auxiliary request 1 differs from claim 1 of the main request in that the claimed method further includes the additional steps of *"aborting, alerting the operator for verification and automatically executing the calibration procedure after a number of consecutive attempts to adjust operational parameters of selected components of the NMR analyzer have failed"*. The added method steps were introduced following the step of automatically adjusting operational parameters of selected components of the clinical NMR analyzer based on data obtained by the electronically determining step.
- IX. Claim 1 of appellant's auxiliary request 2 differs from claim 1 of the main request in that the step of adjusting operational parameters has been amended to read: *"automatically adjusting operational parameters of selected components of the clinical NMR analyzer **on the fly** based on data obtained by the electronically determining step"*, with emphasis in bold added by the Board on the amendment carried out.
- X. Claim 1 of appellant's auxiliary request 3 differs from claim 1 of the main request in that the method further includes at the end of the claim the step of *"automatically reviewing and generating approval of each biosample test results and/or a retest or reject decision"*.

- XI. Claim 1 of appellant's auxiliary request 4 differs from claim 1 of the main request in that the claimed method incorporates at the end of the claim the further limitation: *"wherein the step of introducing patient biosamples to the flow probe in the NMR spectrometer comprises introducing the patient biosamples to the NMR spectrometer in a high throughput rate of at least about 400 samples per 24 hours"*.
- XII. Claim 1 of appellant's auxiliary request 5 differs from claim 1 of the main request in that the claimed method includes at the end of the claim the further step of *"transmitting data regarding monitored operating parameters to a remote control system, said remote control system monitoring selected local operating parameters associated with each clinical NMR analyzer of a network of clinical analyzers"*.
- XIII. Claim 1 of appellant's auxiliary request 6 differs from claim 1 of the main request in that the claimed method incorporates at the end of the claim the further steps of *"automatically determining a diagnostic test to be carried out on the biosample; and adjusting testing parameters based on the properties of the biosample and/or the test to be carried out"*.
- XIV. Claim 1 of appellant's auxiliary request 7 differs from claim 1 of the main request in that the claimed method incorporates at the end of the claim the further step of *"automatically detecting temporally relevant data of selected operational parameters at desired intervals and generating an electronic maintenance file thereof, where local NMR analyzers are configured to electronically store their respective maintenance files for electronic interrogation by a remote system"*.

XV. Claim 1 of appellant's auxiliary request 8 differs from claim 1 of the main request in that the claimed method incorporates at the end of the claim the further step of *"running a validation control sample and validation control protocol at start-up and at desired time intervals, where the desired time intervals are increased based on signal degradation of the proton NMR spectrum lineshape, when an unknown sample is quantified outside normal bounds and/or upon other automatically detected and monitored parameters"*.

XVI. Claim 1 of appellant's auxiliary request 9 differs from claim 1 of the main request in that the feature of *"automatically executing the calibration procedure when one or more of the selected parameters are determined to be outside desired operational ranges based on the determining step, wherein the calibration procedure includes delivering a calibration standard to the flow probe in the NMR spectrometer"* has been deleted and replaced by the feature of *"aborting, alerting the operator for verification and automatically executing the calibration procedure after a number of consecutive attempts to adjust operational parameters of selected components of the NMR analyzer have failed"*.

With regard to auxiliary request 1, claim 1 of auxiliary request 9 differs in that the step of *"automatically executing the calibration procedure when one or more of the selected parameters are determined to be outside desired operational ranges based on the determining step, wherein the calibration procedure includes delivering a calibration standard to the flow probe in the NMR spectrometer"* has been deleted.

Claim 1 of appellant's auxiliary request 10 differs from claim 1 of auxiliary request 9 in that it includes

at the end of the claim the additional step of "*running a validation control sample and validation control protocol at start-up and at desired time intervals, where the desired time intervals are increased based on signal degradation of the proton NMR spectrum lineshape or when an unknown sample is quantified outside normal bounds*".

The independent claims relating to the clinical NMR analyzer and computer program product of all auxiliary requests 1 to 10 contain amendments corresponding to those made with regard to the corresponding independent method claim.

### **Reasons for the Decision**

1. *Applicable law*

It is noted that the revised version of the Convention (EPC 2000) does not apply to European patent applications pending at the time of its entry into force (13 December 2007), unless otherwise provided. In the present decision, where Articles or Rules of the former version of the EPC apply, their citation is followed by the indication "1973".

2. *Admissibility of the appeal*

The appeal meets the requirements of Articles 106 to 108 EPC and Rule 99 EPC. It is thus admissible.

3. *Admissibility of the main request and auxiliary requests 1 to 8*

The main request and auxiliary requests 1 to 8 were filed with the grounds of appeal. They are admissible (Article 12(1)(a) RPBA).

4. *Main request and auxiliary requests 2 to 8*  
*Article 123(2) EPC*

4.1 As put forward by the appellant in its reply of 30 January 2017, claim 1 of the main request stemmed from original claim 1. It contained additional features regarding the calibration procedure and the conditions under which said procedure was to be repeated. The calibration procedure was disclosed, as such, in Figure 9 and the corresponding passages of the description. Reference to a possible reiteration of the start-up or calibration procedure at desired time intervals was provided in various paragraphs of the original disclosure as published under the PCT under number WO-A-2005/098463 (cf. e.g. page 33, lines 24-31).

During the oral proceedings, the appellant stressed that the condition that *"one or more of the selected parameters are determined to be outside desired operational ranges based on the determining step, wherein the calibration procedure includes delivering a calibration standard to the flow probe in the NMR spectrometer"* for *"automatically executing the calibration procedure"* was directly and unambiguously derivable from the original disclosure. In this respect, reference was made, more specifically, to the flow charts of Figures 9 and 11 according to which various parameters were monitored and, if necessary, adjusted before reiteration of the calibration procedure.

In the Board's judgement, however, the passages and Figures referred to do not constitute a valid basis for the new introduced steps. It is stressed, in this respect, that the steps of monitoring data associated with selected parameters, determining whether the parameters are within desired operational ranges and adjusting said parameters are carried out "*during normal operation*", as explicitly recited with regard to the step of monitoring data associated with a plurality of selected parameters. It follows that Figure 9, which describes the calibration procedure as such, is not relevant insofar as the conditions for repeating said calibration procedure are concerned. The statement on page 33, lines 29-31, according to which the start-up procedure may be configured to run when the process appears to be out of absolute or relative process limits is too vague to imply that it refers precisely to the "*selected parameters*" being electronically monitored during normal operation, as required by the claim's wording.

As a possible basis for the proposed amendments, the flow chart of Figure 11 thus appears to be more relevant since it relates to normal operation. The step of reiterating the calibration procedure when one or more of the selected parameters are determined to be outside desired operational ranges is indeed disclosed as part of the whole procedure illustrated in said Figure 11. However, this action appears to constitute the final step of a more elaborated procedure including a succession of various operations. According to block 526 in Figure 11, the calibration (start-up) procedure is indeed repeated after consecutive failures in adjusting the operation parameters, but only after that the measurement process has first been aborted and an operator been alerted in order to verify the system.

The passage of the description relating to Figure 11 is limited to five lines on page 34. It does not expound the process. There is accordingly no basis to be found in the original disclosure indicating that the steps of aborting the normal measurement process and alerting the operator for verification of the system are not essential and could therefore be omitted.

The interruption of the measurement process and intervention of the operator, after consecutive failures in adjusting operational parameters, is technically meaningful. Consecutive failures in adjusting operational parameters may be indicative of damaged components which would require being exchanged or repaired. Reiteration of the calibration procedure without first interrupting the process and verifying the system would possibly generate further damages to the system.

For these reasons, the skilled person would have not been able to recognise from the original disclosure that the omitted steps of aborting the measurement process and alerting an operator could have been dissociated from the final step of repeating the calibration procedure. The omission of these two steps in claim 1 of the main request leads therefore to an intermediate generalisation of the originally disclosed method for which no basis can be found in the original disclosure, contrary to Article 123(2) EPC.

The same findings apply, *mutatis mutandis*, to the subject-matter of independent claim 37 as to a clinical NMR analyzer and 46 as to a computer program product.



- 4.2 The same objection raised with regard to the main request also applies to the independent claims of auxiliary requests 2 to 8 which therefore also contravene Article 123(2) EPC.
- 4.3 The main request and auxiliary requests 2 to 8 are, therefore, not allowable.
5. *Auxiliary request 1*  
*Article 84 EPC 1973 and Article 123(2) EPC*
- 5.1 Claim 1 of auxiliary request 1 comprises the feature of *"aborting, alerting the operator for verification and automatically executing the calibration procedure after a number of consecutive attempts to adjust operational parameters of selected components of the NMR analyzer have failed"*. It further comprises the feature of *"automatically executing the calibration procedure when one or more of the selected parameters are determined to be outside desired operational ranges based on the determining step, wherein the calibration procedure includes delivering a calibration standard to the flow probe in the NMR spectrometer"*.
- 5.2 The claimed wording is contradictory and therefore unclear, contrary to the requirements of Article 84 EPC 1973, since it defines sequences of actions which rely on one and the same condition, namely the fact that one or more selected parameters are determined to be outside desired operational ranges, but exclude each other. The present wording, in effect, suggests that in the case of repeated failures for adjusting operational parameters, the whole process would be aborted and an operator alerted while at the same time automatic execution of the calibration procedure would take place.

5.3 It may be argued, in favour of the appellant, that the skilled person, in an attempt to make sense of the claim's wording, would have considered a literal interpretation of the objected features. Under this assumption, the claim's wording would imply that the calibration would be repeated each time an attempt to adjust the operational parameters fails, while the process would be aborted and an operator alerted only after a predetermined number of consecutive failures.

This interpretation of the claimed method would, however, be at odds with the teaching of the original application documents. It would thus correspond to a process for which no basis can be found in the original disclosure, contrary to the requirements of Article 123(2) EPC. In particular, according to the embodiment of Figure 11, which describes normal operation, the sole condition for the calibration procedure eventually being repeated is the identification of consecutive failures.

5.4 The objections raised against claim 1 also apply to the subject-matter of independent claims 37 and 46 of auxiliary request 1.

5.5 Auxiliary request 1 is, therefore, not allowable.

6. *Auxiliary request 9*

6.1 *Admissibility*

The Board's discretion under Article 13(1) RPBA to decide on the admissibility of late filed requests shall be exercised in view of *inter alia* the complexity

of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy.

Auxiliary request 9 was filed during oral proceedings before the Board, that is, at a very late procedural stage of the appeal proceedings. Its admissibility would therefore be compatible with the need for procedural economy if the amended claims successfully addresses the issues raised with regard to the previous requests without giving rise to new objections (cf. Case Law of the Boards of Appeal, 8th edition 2016, IV.E.4.2.5).

Auxiliary request 9 solves the issue of added subject-matter (Article 123(2) EPC) raised with regard to the main request in that it incorporates the steps of aborting the process during normal operation and alerting the operator following consecutive failures to adjust operational parameters. The independent claims regarding the clinical analyzer and the computer program product have been amended accordingly.

Moreover, the amended independent claims are clear (Article 84 EPC 1973). In particular, an interpretation of claim 1 of the kind mentioned above with regard to auxiliary request 1, which would lead to added subject-matter (Article 123(2) EPC) is now excluded since the step of "*automatically executing the calibration procedure when one or more of the selected parameters were determined to be outside operational ranges...*" has been deleted. Similar considerations apply with regard to the other independent claims.

The amendments carried out in the independent claims of auxiliary request 9 are thus straightforward. They do

not generate new problems with regard to clarity and added subject-matter.

Consequently, the Board, exercising its discretion under Article 13(1) RPBA, admitted auxiliary request 9 into the appeal proceedings.

## 6.2 *Article 56 EPC 1973*

6.2.1 Document D4 discloses a clinical NMR *in vitro* diagnostic analyzer which comprises a flow probe in an NMR spectrometer and a sample handler for introducing biosamples to the flow probe. The NMR analyzer of D4 generates clinical quantitative measurements of patient biosamples based on the obtained NMR spectra.

Document D4 belongs to the same technical field as the present invention. Moreover, the method disclosed in D4 relies on the same principle as the process according to the present invention. In particular, D4 comprises the step of acquiring NMR spectra of e.g. blood samples in order to obtain information as to the presence and concentration of specific analytes. The method relies, concretely, on the analysis of lineshapes of the spectra obtained (cf. D4, page 3, lines 5-10).

For these reasons, the Board concurs with the examining division and the appellant that D4 discloses the closest prior art on file.

6.2.2 Specifically, the method disclosed in D4 comprises introducing patient biosamples to the flow probe in a NMR spectrometer and obtaining NMR signal spectra of the introduced biosamples (cf. page 13, lines 18-29; page 14, lines 13-18; page 15, lines 1-13; Figure 6).

Based on the obtained NMR spectra, a clinical quantitative measurement of the patient biosample is performed by dedicated computer means (cf. page 6, line 23 to page 7, line 8; page 8, lines 5-23; page 11, lines 3-6).

Thus, as acknowledged by the appellant, the features of the preamble of claim 1 according to auxiliary request 9 are known from D4.

6.2.3 In the appellant's view, having regard to the characterising features of claim 1, the objective technical problem solved by the invention would thus consist in providing a more efficient analyzer that can accurately analyze a high throughput of samples without the need for operation and/or intervention by a highly skilled person.

6.2.4 In the Board's judgement, however, the method of D4 also comprises a calibration procedure being performed at start-up before authorizing or allowing evaluation of patient samples, as recited in the characterising part of claim 1. It is stressed, in this respect, that the claim does not define which parameters are actually adjusted during the calibration procedure. It follows that the shimming procedure referred to on page 14, lines 19-27, of D4 may be equated with such a calibration procedure.

Moreover, as may be derived from the reference on page 17, lines 7-9, to the same conditions as those prevailing for the reference samples, the method disclosed in D4 *de facto* also includes a step of electronically monitoring data associated with a plurality of selected parameters of the NMR analyzer during normal operation.

- 6.2.5 Therefore, the claimed method differs from the method known from D4, in that,
- (i) the whole process is automated;
  - (ii) the method is aborted, an operator is alerted for verification and the calibration procedure is automatically executed after a number of consecutive attempts to adjust operational parameters of selected components of the clinical NMR analyzer have failed;
  - (iii) the calibration procedure is automatically executed at desired time intervals during normal operation of the NMR analyzer.
- 6.2.6 The problem solved by the claimed invention is thus reformulated in that it consists in providing a more efficient analyzer that can accurately analyze a high throughput of samples while requiring a limited need for operation and/or intervention by a highly skilled person.
- 6.2.7 The boards of appeal have on various occasions stressed that the *"mere automatisation of functions previously performed by persons corresponds to the general trend in technics and cannot as such be considered inventive"* (cf. e.g. T 0775/90, point 5.3). The Board cannot identify any reason, under the present circumstances, to depart from this approach. Consequently, no inventive contribution can be recognised in feature (i).

Moreover, in the Board's judgement, neither distinguishing feature (ii) nor distinguishing feature (iii) suffice to establish the existence of an inventive step. Contrary to the appellant's view, the skilled person would have not only opted for these features as a mere possibility among other envisageable

alternatives when attempting to increase the throughput of the analyzer while maintaining the reliability and accuracy of the analysing procedure (the "*could*" scenario), but "*would*" have effectively done as now recited in claim 1.

It is namely stressed that the claimed solution directly results from the recognition by the skilled persons of situations indicative of possible shortcomings in the whole measurement process. One of these situations would obviously correspond to consecutive failures in attempts to adjust parameters of selected components. This situation is manifestly indicative of a fundamental problem affecting the analyzer. This problem may result from the values for the operational parameters defined during the initial calibration procedure being no more adapted because, for example, of changing environmental conditions (temperature, humidity, ...), but may also be the result of components being damaged or broken. In this latter case, continuation of the process or reiteration of the calibration procedure could obviously lead to further far reaching damages to the analyzer. The interruption of the process and the intervention of an operator appear, under the circumstances, not only desirable but also necessary.

Moreover, as mentioned above, operational parameters identified during the initial calibration procedure may later on, in the course of normal operation, no more correspond to optimal measuring conditions. This may result from a drift of the original settings due to some changes in the environmental conditions or to ageing of certain components. The skilled person is well aware that complex systems whose behaviour depends on a multiplicity of various parameters interacting

with each other are particularly vulnerable to such changing conditions. In order to guarantee optimal and accurate results, the skilled person would ensure that the operational parameters of the analyzer are constantly updated to compensate for possible drifts of the initial settings. This is achieved by automatically repeating the calibration of the analyzer at desired time intervals.

Contrary to the opinion put forward by the appellant, the claimed process, as defined in claim 1, does not define one possibility among others which could have been envisaged by the skilled person but appears to be the direct consequence of the analysis to be made when facing repeated failures in adjusting parameters while considering basic aspects regarding maintenance of complex system.

For these reasons, the subject-matter of claim 1 of auxiliary request 9 results in an obvious manner from the prior art. It is thus not inventive in the sense of Article 56 EPC 1973. The same applies for the other independent claims.

6.3 In conclusion, auxiliary request 9 is not allowable.

7. *Auxiliary request 10*

7.1 *Admissibility*

Auxiliary request 10 was filed during oral proceedings before the Board, that is, at a very late procedural stage of the appeal proceedings. In applying the admissibility criteria recalled above with regard to auxiliary request 9, the Board has to consider whether the new request indeed successfully meets the



objections raised so far without giving rise to new ones.

As a matter of fact, the Board doubts that the amendments made indeed permit to remedy to the objection of lack of an inventive step which led to auxiliary request 9 being considered not allowable. It is noted, in particular, that the steps of running a validation control sample and validation control protocol at start-up appears to be known from D4 (cf. page 17, 1 line 31 to page 18, line 16). It is further observed, in this respect, that the samples used in D4 are not limited to a solution containing trimethylacetate, but consist of various reference standards including chylomicrons, VLDL, LDL and HDL (cf. page 17, line 31). It is also foreseen in D4 to repeat the validation control procedure on a daily basis (cf. page 18, lines 11-13). It thus appears that the additional features recited in claim 1 do not constitute distinguishing features with the closest prior art and that the analysis developed above with regard to auxiliary request 9 would also apply *mutatis mutandis* to claim 1 of auxiliary request 10.

Moreover, even if said additional features were considered to define distinguishing features, it is, for the same reasons as those developed above with regard to the reiteration of the calibration step, doubtful whether the conditions recited in claim 1 of auxiliary request 10 for running a validation sample and control protocol would suffice to establish the presence of an inventive step.

Auxiliary request 10, therefore, does not appear, at least on a *prima facie* basis, to be clearly allowable.

For these reasons, it is not admitted in the appeal procedure (Article 13(1) RPBA).

**Order**

**For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

The Chairman:



L. Malécot-Grob

G. Assi

Decision electronically authenticated