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**Datasheet for the decision
of 27 May 2014**

Case Number: T 0737/13 - 3.4.02

Application Number: 08101755.0

Publication Number: 1935983

IPC: G01N15/14

Language of the proceedings: EN

Title of invention:

Method for determination of biological particles in blood

Patent Proprietor:

ChemoMetec A/S

Opponent:

HemoCue AB

Relevant legal provisions:

EPC Art. 56, 111(1), 125

RPBA Art. 13(1), 13(3), 23

Keyword:

Inventive step (main and first to eighth auxiliary requests -
no)

Ninth auxiliary request - Admissibility (yes) - Remittal

Decisions cited:

T 0671/08, T 0434/12



**Beschwerdekammern
Boards of Appeal
Chambres de recours**

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Case Number: T 0737/13 - 3.4.02

D E C I S I O N
of Technical Board of Appeal 3.4.02
of 27 May 2014

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
21 January 2013 concerning maintenance of the
European Patent No. 1935983 in amended form.**

Composition of the Board:

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

Summary of Facts and Submissions

- I. The appellant (opponent) lodged an appeal against the interlocutory decision of the opposition division finding European patent No. 1935983 (based on European patent application No. 08101755.0) as amended by the respondent (patent proprietor) according to the then second auxiliary request to meet the requirements of the EPC.

The opposition filed by the appellant against the patent as a whole was based on the grounds for opposition under Articles 100 (a), (b) and (c) EPC, in particular on the grounds of lack of novelty and lack of inventive step.

- II. In its statement setting out the grounds of appeal the appellant contested *inter alia* the opposition division's view that the subject-matter of claim 1 of the then second auxiliary request was novel and involved an inventive step over the disclosure of document

D1: WO-A-9109297.

- III. Oral proceedings before the Board were held on 27 May 2014.

The appellant requested that the decision under appeal be set aside and that the patent be revoked.

The respondent requested as a main request that the patent be maintained on the basis of the second auxiliary request underlying the decision under appeal, or on the basis of the first to fourth auxiliary

requests filed with a letter dated 3 October 2013, or the fifth to eighth auxiliary requests filed with a letter dated 25 April 2014, or the ninth to eleventh auxiliary requests filed during the oral proceedings, or that the proceedings be continued in writing.

At the end of the oral proceedings the Board gave its decision.

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

"A method for the assessment of at least one quantity parameter and/or at least one quality parameter of biological particles in blood or blood product, comprising

applying a volume of a liquid sample comprising the blood or blood product or being derived therefrom by dilution, concentration or extraction to a sample compartment having a wall part defining an exposing area, the wall part allowing electromagnetic signals from the sample in the compartment to pass through the wall and to be exposed to the exterior

exposing, onto an array of active detection elements arranged in two directions in such a way that the detection elements form a series of substantially parallel straight lines, the series forming a rectangle, a two dimensional spatial image of electromagnetic signals having passed from the sample compartment, the image being one which is detectable as an intensity by individual active detection elements, under conditions which will permit processing of the intensities detected by the array of detection elements during the exposure in such a manner that images of electromagnetic signals from the biological particles are identified as distinct from images of electromagnetic signals from background, and wherein

the spatial image exposed onto the array of active detection elements is subject to such a linear enlargement that the ratio of a linear dimension of the image on the array of detection elements to the original linear dimension in the sample compartment is smaller than 10:1,

wherein the volume of liquid sample is at stand still during the exposure,

processing the intensities detected by the detection elements in such a manner that signals from the biological particles are identified as distinct from background signals,

and correlating the results of the processing to the at least one quantity parameter and/or the at least one quality parameter of the blood or blood product."

Claim 1 of the first auxiliary request differs from claim 1 of the main request in that the expressions "processing of the intensities detected" and "processing the intensities detected" in the third and the fifth paragraphs of the claim have been replaced by the expressions "processing of the image detected" and "processing the image detected", respectively.

Claim 1 of the second auxiliary request differs from claim 1 of the first auxiliary request in that the sentence "processing the image detected by the detection elements in such a manner that [...]" in the fifth paragraph of the claim now reads "processing the image detected by the detection elements using image processing means and methods in such a manner that [...]".

Claim 1 of the third auxiliary request differs from claim 1 of the main request in that the sentence "wherein the volume of liquid sample is at stand still

during the exposure," of the fourth paragraph of the claim further reads "where stand-still is defined as the situation where at least a part of the image of a particle does not move any more than it is contained substantially within the boundary of the same detection elements during one measurement period,".

Claim 1 of the fourth auxiliary request differs from claim 1 of the third auxiliary request in that the expression "during one measurement period" at the end of the fourth paragraph has been replaced by the expression "during two measurement periods".

Claim 1 of the fifth auxiliary request differs from claim 1 of the main request in that the claim incorporates the amendments made to claim 1 of the first and the third auxiliary requests and specified above.

Claim 1 of the sixth auxiliary request differs from claim 1 of the main request in that the claim incorporates the amendments made to claim 1 of the first, the second and the third auxiliary requests as specified above.

Claim 1 of the seventh auxiliary request differs from claim 1 of the main request in that the claim incorporates the amendments made to claim 1 of the first and the fourth auxiliary requests as specified above.

Claim 1 of the eighth auxiliary request differs from claim 1 of the main request in that the claim incorporates the amendments made to claim 1 of the first, the second and the fourth auxiliary requests as specified above.

Claim 1 of the ninth auxiliary request differs from claim 1 of the main request in that

- the expression "to a sample compartment having" in the second paragraph has been replaced by the expression "to a removable sample compartment having",

- the second paragraph further reads ", wherein the sample is contained in said removable sample compartment before, during, and after assessment,", and

- the expression "during the exposure" at the end of the fourth paragraph has been omitted.

The set of claims of the ninth auxiliary request includes amended dependent claims 2 to 52 referring back to claim 1.

The wording of the claims of the tenth and the eleventh auxiliary requests is not relevant to the present decision.

Reasons for the Decision

1. The appeal is admissible.
2. *Main request - Novelty and inventive step*
 - 2.1 The second auxiliary request underlying the interlocutory decision under appeal constitutes the present main request. Claim 1 of this request is directed to a method of assessment of a quantity and/or quality parameter of biological particles in blood or in a blood product. The claimed method requires, among

other features, applying a volume of a liquid sample to a sample compartment having an exposing area, exposing a spatial image of electromagnetic signals from the sample compartment onto a two-dimensional array of detection elements under a linear enlargement smaller than 10:1, and processing the intensities detected by the detection elements so that signals from the biological particles are identified as distinct from background signals.

Document D1 discloses a process for counting particles, in particular blood particles, in a fluid sample passing through an optical cell comprising the steps mentioned in the former paragraph (abstract and Figure 1, together with the corresponding description, and page 6, lines 3 to 5). In its decision the opposition division found that document D1 required a sample flow and held that the claimed method was novel and involved an inventive step over the disclosure of document D1 by virtue of the claimed feature "the volume of liquid sample is at stand still during the exposure". During the appeal proceedings the appellant has contested the opposition division's view in this respect and the respondent has not disputed that, apart from this feature, the remaining features of the method of claim 1 are anticipated by document D1.

The issue of novelty and inventive step of the claimed method therefore boils down to the question of whether the claimed feature "the volume of liquid sample is at stand still during the exposure" is anticipated or at least rendered obvious by the disclosure of document D1.

- 2.2 In the method of document D1 the step of exposing the two-dimensional array of detection elements to an image

of the fluid sample is carried out as the fluid sample flows through the optical cell so that detection takes place as the exposure image is moving across the detector array (abstract together with the paragraph bridging pages 2 and 3). The further reference in the document to the information from the detector array being "sampled as 10 «frame freeze pictures»" and being "real time information from a moving fluid" (page 8, lines 15 to 21) further corroborates this finding. The Board therefore concurs with the respondent that the measurement method of document D1 relies on movement of the fluid sample during exposure, and that consequently the document excludes carrying out measurements on a fluid sample that is held stationary or at rest with respect to the detector array.

However, this finding does not necessarily imply that document D1 excludes that the volume of fluid sample is at "stand still during the exposure", at least not within the meaning of the patent in suit. Indeed, the technical concept of "stand still during the exposure" is not synonymous with stationary or at rest in absolute terms, but it rather describes a physical condition with reference to the exposure time and therefore constitutes a relative term. This view is in addition confirmed by the patent specification which, as agreed by both parties, provides a definition of what is to be understood by "stand still during the exposure" in the context of the claimed invention. Indeed, according to paragraph [0050] of the description of the patent specification (corresponding to the last paragraph on page 15 of the application as originally filed) the liquid in which the particles to be measured are suspended "is at stand-still, where stand-still is defined as the situation where at least apart [*sic*] of the image of a particle does not move

any more than it is contained substantially within the boundary of the same detection elements during one measurement period." The same paragraph further reads: "The stand-still situation is preferably such that at least a part of the image of a particle does not move any more than it is contained substantially within the boundary of the same detection element during at least two measurement periods".

Thus, the stand-still condition of the volume of liquid sample is defined in claim 1 with reference to the exposure and according to the patent specification this condition is determined with reference to the boundary of the detection elements "during one measurement period", and preferably "during at least two measurement periods"; consequently, the mentioned condition depends not only on the state of movement of the sample, but also on the actual value of the exposure time or the measurement period. It follows that, contrary to the respondent's submissions, the claimed method does not actually exclude movement of the volume of the liquid sample, it rather allows movement of the volume but only to the extent implied by the above definition. In addition, the claim is silent as to the value of the exposure time and the value of the measurement period, and consequently the claimed stand-still condition can even be satisfied for volumes of the liquid sample flowing at a significant speed when the exposure time or the measurement period is sufficiently small.

This conclusion is, as noted by the appellant, also in conformity with the disclosure of the application as originally filed which contemplated the possibility that the sample "is moved through the domain or sample compartment during the exposure, and the exposure is

performed over a sufficiently short period of time so [sic] substantially obtain stand still condition during the exposure" (page 20 of the application as originally filed, lines 28 to 31). This statement confirms that the "stand still condition during the exposure" can be achieved with a moving sample by selecting a sufficiently short exposure time or a sufficiently short measurement period and that, contrary to the respondent's submissions, the claim condition does not require stopping the sample.

As already mentioned above, in document D1 the exposure image, during exposure, moves across the detector array, and according to the disclosure of the document as the images of the particles traverse the detector array "the information concerning each particle can be checked several times. Sampling will generally be of the order of 50 times per second." (page 3, lines 22 to 28). In addition, the document proposes in this context that "If the particle stream is found to be moving too fast for accurate counting, the speed may be controlled, for example by feedback of information from the CCDs" (page 3, lines 28 to 31). In the Board's opinion the skilled person would see in this proposal a clear teaching that the accuracy in the counting of particles can be improved by reducing the value of the flow speed of the fluid volume relative to the exposure time or the measurement period of the detector array. The skilled person seeking to implement this teaching in order to improve the accuracy of the particle counting process would therefore slow down the fluid flow with respect to the exposure time or the measurement period, depending on the circumstances to an extent such that at least a part of the image of a particle imaged on the detector array would not move beyond the boundary of the same detector elements to

the degree referred to in the patent specification during one or, if appropriate, during two consecutive measurement periods.

Thus, a straightforward application of the technical teaching of document D1 would lead to a method in which the volume of the liquid sample would be "at stand still during exposure" within the meaning of this expression given in the patent specification.

The respondent has submitted that the skilled person would not consider slowing down the flow in document D1 to such an extent, let alone to stop the flow, because this would undermine the characteristics of the flow required in the document, such as the movement of a thin stream of sample liquid past the detector and the imaging of a thin slice of the fluid sample (page 5, lines 1 to 4 and 16 to 19), and would also go against the teaching of the document which requires taking several pictures of each particle as it moves (page 8, lines 15 to 18). However, none of the features of claim 1, and in particular the stand-still condition of the volume of liquid sample relative to the exposure and the use of a sample compartment, excludes a sample flow, and document D1 teaches to slow down the flow relative to the exposure time or the measurement period of the detectors, without however stopping the flow. In addition, the characteristics of the flow mentioned above depend on the absolute value of the speed of the flow, and what document D1 teaches is reducing the relative value of the speed of the flow with respect to the exposure time or the measurement period; the skilled person following this teaching would therefore select a sufficiently low flow speed relative to the exposure time or the measurement period in such a way

that the characteristics of the flow required in document D1 are still preserved.

The respondent has also submitted arguments concerning the technical improvements achieved over the disclosure of document D1 when the flow is stopped. However, as already concluded above, the claimed subject-matter does not require carrying out the measurements on a stationary sample, and consequently the claimed method includes embodiments in which a certain degree of flow or movement of the sample in relation to the exposure time or the measurement period is allowed; the technical improvements submitted by the appellant are therefore not supported by the subject-matter actually claimed.

Having regard to the above, the Board concludes that the method defined in claim 1 results in an obvious way from the disclosure of document D1 (Article 56 EPC).

3. *First and second auxiliary requests - Inventive step*

Claim 1 of the first auxiliary request differs from claim 1 of the main request in that the expressions "processing [of] the intensities" now read "processing [of] the image", and claim 1 of the second auxiliary request differs from claim 1 of the first auxiliary request in that the claim further specifies that the image processing involves "using image processing means and methods" (cf. point IV above). As noted by the respondent during the proceedings, these amendments emphasize that what is processed in the claimed method are images, and not just intensity signals, i.e. that the image is detected and processed as an image.

These amendments were made by the respondent in order to emphasize the differences between the method of the invention and prior art disclosures considered during the proceedings other than document D1, and there was no submission that these amendments would imply additional distinguishing features over the disclosure of document D1 beyond those considered in point 2 above, or that they would influence the assessment of inventive step over document D1.

It follows that the amendments to claim 1 according to the first and the second auxiliary requests have no impact on the assessment of inventive step made in point 2 above with regard to claim 1 of the main request. For this reason the method defined in claim 1 of these two auxiliary requests does not involve an inventive step for the same reasons as those given above with respect to claim 1 of the main request (Article 56 EPC).

4. *Third auxiliary request - Inventive step*

Claim 1 of the third auxiliary request differs from claim 1 of the main request in that the claim specifies explicitly what is meant by "stand still during exposure", i.e. "as the situation where at least a part of the image of a particle does not move any more than it is contained substantially within the boundary of the same detection elements during one measurement period" (cf. point IV above).

This definition of the claimed stand-still condition corresponds to the definition given in the description of the patent specification, and the assessment of inventive step of claim 1 of the main request in point 2 above was made on the basis of this definition.

Accordingly, the incorporation of the definition in the formulation of the claim has no impact on the assessment of inventive step in point 2 above, and therefore the method of claim 1 of the third auxiliary request does not involve an inventive step for the same reasons as those given above with respect to claim 1 of the main request.

5. *Fourth auxiliary request - Inventive step*

Claim 1 of the fourth auxiliary request differs from claim 1 of the third auxiliary request in that the stand-still condition is not defined with reference to "one measurement period", but with reference to "two measurement periods" (cf. point IV above).

This definition of the claimed stand-still condition corresponds to the preferred embodiment given in the description of the patent specification and already considered in point 2 above. The amended definition, however, does not change the assessment of inventive step in point 4 above because in document D1 the area of the image of each particle on the detector array is of the order of the area of the detector elements (page 3, lines 12 to 18 together with page 2, lines 14 to 22 and claim 1) and the amended claimed condition "at least a part of the image of a particle does not move any more than it is contained substantially within the boundary of the same detection elements during two measurement periods" still allows, as submitted by the appellant, a portion of the image of a particle to move from one detector element to the adjacent one between two consecutive measurement periods and therefore still allows for a relatively low flow consistent with the teaching of the document. In particular, document D1 requires, as pointed out by the respondent, the

detection of several images of the same particle at different positions as it moves, and this exposure regime can still be achieved with a flow satisfying the amended claimed condition.

Therefore, the amendment to claim 1 restricts the speed with which the liquid sample may flow, but does not exclude relatively low sample flows that the skilled person would consider in an obvious way when applying the teaching of document D1 (cf. point 2 above).

6. *Fifth to eighth auxiliary requests - Inventive step*

When compared with claim 1 of the main request (cf. point IV above),

- claim 1 of the fifth auxiliary request incorporates the amendments of claim 1 of the first and the third auxiliary requests,

- claim 1 of the sixth auxiliary request incorporates the amendments of claim 1 of the first, the second and the third auxiliary requests,

- claim 1 of the seventh auxiliary request incorporates the amendments of the first and the fourth auxiliary requests, and

- claim 1 of the eighth auxiliary request incorporates the amendments of claim 1 of the first, the second and the fourth auxiliary requests.

Since it was concluded in points 2 to 5 above that the subject-matter of claim 1 amended according to the first to fourth auxiliary requests does not involve an inventive step, the same conclusion applies to the various combinations of amendments defined in the subject-matter claim 1 of the fifth to eighth auxiliary requests (Articles 56 EPC).

7. *Ninth auxiliary request - Admissibility - Remittal*

7.1 The amended set of claims of the ninth auxiliary request was submitted during the oral proceedings in response to the discussion on the patentability of the previous claim requests as the Board showed reluctance to endorse the respondent's and opposition division's construction of the claimed feature "stand still during the exposure" as excluding a fluid sample flow. The appellant objected to the admission of the amended claim request into the proceedings at such a late stage of the proceedings. The appellant submitted in particular that the amendments addressed objections that had already been raised in the statement of grounds of appeal; in addition, the amendments gave rise to new issues under Articles 123(2), 123(3), 83 and 84 EPC and would also require a new analysis of the issues of novelty and inventive step, so that the proceedings might then have to be continued in writing, possibly after remittal of the case. According to the appellant, the admission of the amended claim request into the proceedings would, under these circumstances, be contrary to the provisions of Articles 13(1) and 13(3) RPBA (Rules of Procedure of the Boards of Appeal).

7.2 The Board notes that during the written proceedings, and in particular in the statement of grounds of appeal, the appellant had indeed already pointed out that according to the definition of the stand-still condition of the liquid sample given in the patent specification the particles might move. However, it was during the discussion at the oral proceedings that it became clear that the claimed feature "stand still during the exposure" did not only not exclude movement of the particles alone (as a consequence, for instance,

of the thermal Brownian motion inherent to particles suspended in a fluid), but also did not exclude a flow of the volume of liquid sample which was relatively slow when compared with the exposure time, and that this latter issue was critical to the outcome of the case since it was at variance with the finding on which the decision under appeal was based (cf. point 2.1 above).

The set of claims of this request has been amended, *inter alia*, so that claim 1 now requires that the sample "is contained in [a] removable sample compartment before, during, and after assessment", and this amendment, in the Board's view, constituted a reasonable attempt to exclude measurement of the particles in a flow regime as required by document D1, and also a direct and legitimate reaction to the developments during the oral proceedings mentioned in the former paragraph.

Notwithstanding the appellant's objections against the formal admission into the proceedings of the amended claim request at such a late stage of the proceedings, the Board considered it fair and appropriate in the specific circumstances of the case to admit, despite of its late filing, the amended set of claims of the ninth auxiliary request into the proceedings. When admitting this claim request into the proceedings the Board was of the opinion that the amendments would not "raise issues which the Board or the other party or parties cannot reasonably be expected to deal with without adjournment of the oral proceedings" within the meaning of the provisions of Articles 13(1) and 13(3) RPBA, because it will be for the department of first instance to deal with the issues surrounding the amended claim request after remittal. In addition, even considering

the present situation to be at variance with the aforementioned provisions, the Board notes that, as already acknowledged by other Boards (see for instance decision T 434/12, point 1.3 of the reasons, and decision T 671/08, point 7.5), the particular circumstances of a case may preclude a strict, purely literal application of the provisions of these two articles. As regards the present case, the right to fair procedure is one of the most important principles of procedural law generally recognized in the Contracting States and has therefore to be taken into account under Article 125 EPC, and this principle may prevail over the provisions of Article 13(3) RPBA because according to Article 23 RPBA the Rules of Procedure "shall be binding upon the Boards of Appeal, provided that they do not lead to a situation which would be incompatible with the spirit and purpose of the Convention".

- 7.3 During the oral proceedings the appellant, after closer consideration of the amendments made according to the ninth auxiliary request, indicated to be unprepared to discuss in detail the amended set of claims because new issues under Articles 84, 123(2) and 123(3) EPC emerged from the amendments and, more particularly, because the objections under Articles 100(b) and 83 EPC raised during the proceedings with regard to the previous claim requests would need to be reformulated and complemented in view of the amendments to claim 1. In addition, the amendments required a re-assessment of patentability as compared to the previous claim requests.

In view of the fact that the parties' case could not be adequately developed for the Board to satisfactorily decide on the different new issues as a sole instance,

of the fact that the whole proceedings had been conducted in a speedy way (notice of opposition filed on 22 March 2012, interlocutory decision of the opposition division posted on 21 January 2013, and oral proceedings before the Board held on 27.05.2014), and of the respondent's request to proceed further in writing, the Board considered remittal, in the specific circumstances of the case, to be the most appropriate step from the point of view of both procedural fairness and efficiency. Accordingly, the Board decided to exercise its discretion under Article 111(1) EPC in remitting the case to the opposition division for further prosecution on the basis of the set of claims of the ninth auxiliary request.

8. Pending the outcome of the ninth auxiliary request, there was no need to deal with the tenth and eleventh auxiliary requests of the appellant.

9. With a letter dated 23 June 2014 the opponent requested amendment of the minutes of the oral proceedings before the Board. The Board notes that the present decision reflects the points raised in that request. The Board therefore sees no need to amend the minutes.

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 for further prosecution.

The Registrar:

The Chairman:



M. Kiehl

A. G. Klein

Decision electronically authenticated