

Internal distribution code:

- (A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

**Datasheet for the decision
of 27 April 2016**

Case Number: T 0621/12 - 3.4.02
Application Number: 07874167.5
Publication Number: 2095094
IPC: G01N21/64, G01N33/58, G06F19/00
Language of the proceedings: EN

Title of invention:

QUANTITATIVE, MULTISPECTRAL IMAGE ANALYSIS OF TISSUE SPECIMENS
STAINED WITH QUANTUM DOTS

Applicant:

Ventana Medical Systems, Inc.

Relevant legal provisions:

EPC 1973 Art. 84, 111(1)
RPBA Art. 13(3)

Keyword:

Claims - clarity - main request (no)
Late-filed auxiliary requests - amendments after arrangement
of oral proceedings - need for additional search (yes) -
admitted (no)

Decisions cited:

G 0010/93, T 1129/97, T 0049/99, T 0056/04



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 0621/12 - 3.4.02

D E C I S I O N
of Technical Board of Appeal 3.4.02
of 27 April 2016

Appellant: Ventana Medical Systems, Inc.
(Applicant) 1910 E. Innovation Park Drive
Tucson, Arizona 85755 (US)

Representative: Müller-Boré & Partner
Patentanwälte PartG mbB
Friedenheimer Brücke 21
80639 München (DE)

Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 19 October 2011
refusing European patent application No.
07874167.5 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman F. J. Narganes-Quijano
Members: A. Hornung
T. Karamanli

Summary of Facts and Submissions

- I. The applicant (appellant) lodged an appeal against the decision of the examining division refusing European patent application No. 07874167.5, filed on 7 December 2007, on the basis of Article 97(2) EPC because the main request then on file did not fulfil the requirements of Article 56 EPC.

- II. With the statement setting out the grounds of appeal, the appellant requested that the decision of the examining division be set aside and that a patent be granted on the basis of the set of claims of a main request or of one of the first to fourth auxiliary requests, all filed with the statement setting out the grounds of appeal. The appellant further requested that the adaption of the description be postponed until agreement on an allowable set of claims has been reached.

- III. In a communication pursuant to Article 15(1) RPBA annexed to summons to oral proceedings, the board informed the appellant about its preliminary opinion on the case.

As regards the independent method claim 8 of the main request, the board raised a series of objections under Article 84 EPC 1973 and gave reasons why it tended to maintain the objection of lack of inventive step raised by the examining division in the decision under appeal. Since the independent device claim 1 comprised essentially the same corresponding features as independent method claim 8, claim 1 lacked clarity for the same reasons as claim 8. Furthermore, the subject-matter of claim 1 of the main request appeared to lack novelty.

The board further noted that claim 1 of the first auxiliary request appeared to be identical to claim 1 of the main request, and that independent method claim 8 of the first

auxiliary request and method claim 1 of the second to fourth auxiliary requests appeared to be identical to independent method claim 8 of the main request. Therefore, the corresponding objections raised under Articles 84, 54(1) and 56 EPC 1973 against claims 1 and 8 of the main request were also valid for the first to fourth auxiliary requests.

- IV. In response to the communication annexed to the summons to oral proceedings, the appellant, with a letter of 22 March 2016, filed arguments and new first to fourth auxiliary requests in replacement of the previous first to fourth auxiliary requests. The appellant maintained the main request unchanged.
- V. In a further communication pursuant to Article 15(1) RPBA of 20 April 2016, sent in advance by fax on 14 April 2016, the board informed the appellant that it maintained its objections concerning the main request as expressed in the communication annexed to the summons to oral proceedings. As to the subject-matter of the independent device and method claims of the new first and second auxiliary requests, the board informed the appellant that concrete technical steps for achieving the claimed result of determining the coefficients $C_1 \dots C_N$, related to the concentrations of the N fluorophores, were still missing in the claims. Furthermore, the board questioned the admissibility under Article 13(1) and (3) RPBA of at least the new third and fourth auxiliary requests.
- VI. The appellant informed the board with letter dated 25 April 2016 that it would not be attending the oral proceedings and that its request for oral proceedings was explicitly withdrawn. The appellant requested a decision according to the state of the file. No further comments were filed.

Oral proceedings were held on 27 April 2016 in the absence of the duly summoned appellant. At the end of the oral proceedings the board announced its decision.

VII. Independent method claim 8 according to the main request reads as follows:

"A method for analysis of a biological specimen in which between 1 ... N quantum dots are applied to the specimen, comprising the steps of:

- (a) collecting a data set representing two-dimensional pixel data at M wavelengths of the specimen with the aid of a microscope, spectral filters, and an associated digital camera, comprising M two-dimensional digital images containing image data for a multitude of pixels obtained at M different wavelengths with the aid of the spectral filters, where M is an integer greater than 2;
- (b) unmixing the plurality of M images and reference spectral data associated with the 1 ... N quantum dots and responsively determining from the set of M images coefficients $C_1 \dots C_N$ for each pixel, wherein the coefficients $C_1 \dots C_N$ are related to the concentrations of the 1 ... N quantum dots present in the specimen imaged by each pixel;
- (c) morphologically processing an image constructed from the coefficients $C_1 \dots C_N$ to identify cells or cellular components in the specimen;
- (d) conducting a quantitative analysis of the specimen including calculating fluorophore concentrations for the cells or cellular components identified in step (c) from the coefficients $C_1 \dots C_N$;
and
- (e) displaying the results of the quantitative analysis process (d) on a display of a workstation."

The wording of the remaining claims 1 to 7 and 9 to 12 of the main request is not relevant for the present decision.

VIII. Independent device claim 1 according to the first auxiliary request reads as follows:

"A system for analysis of a biological specimen having between 1 and N different fluorophore(s) applied to the specimen, the fluorophores including at least one quantum dot, comprising,, in combination:

a microscope, spectral filters, and an associated digital camera for imaging the specimen at a plurality (M) of discrete wavelengths with the aid of the spectral filters and responsively generating a plurality of M two-dimensional digital images, each of which is composed of a plurality of pixels having pixel locations, the plurality of discrete wavelengths including a plurality of discrete wavelengths at which the 1 ... N fluorophores produce a luminescent response to incident light; and

a workstation including a processing unit for performing processing steps, comprising:

- (a) a linear spectral unmixing process processing the plurality of M images with reference spectral data associated with the 1 ... N fluorophores and responsively determining from the M images coefficients $C_1 \dots C_N$ at each pixel location, wherein the coefficients $C_1 \dots C_N$ represent the relative or absolute concentrations of the 1 ... N fluorophores present in the sample at each pixel location in terms of illumination intensity;
- (b) at least one morphological processing process identifying at least one biological structure in the specimen, measuring the size of the biological structure in the specimen, and counting the number of biological structures identified in the specimen, wherein the

biological structure comprises a cell or a cellular component;

(c) a quantitative analysis process calculating fluorophore concentrations for the biological structures identified in step (b) from the coefficients $C_1 \dots C_N$; and

(d) a display process for displaying the results of the quantitative analysis process (c) on a display associated with the workstation,

said display process allowing a user to select a segment of an image of the specimen displayed on the display and displaying quantitative results for the selected segment of the image, and

allowing a user to select a portion of a scatter plot, histogram, or other visualization of the quantitative data and displaying an image of the specimen with the biological structures associated with the selected portion of the scatter plot, histogram, or other visualization."

IX. Claim 1 of the second to fourth auxiliary requests have the features of the display process of step (d) of claim 1 of the first auxiliary request in common.

Reasons for the Decision

1. Procedural matters

Although the appellant withdrew its request for oral proceedings two days prior to the scheduled date of the oral proceedings and requested a decision "according to the state of the file", the board refrained from cancelling the oral proceedings for the following reasons:

According to Article 116(1), first sentence, EPC 1973, oral

proceedings take place before the board either at the instance of the board if it considers this to be expedient or at the request of any party to the appeal proceedings. The objective of this provision is twofold: first, to safeguard the party's right to an oral hearing which forms a substantial part of the right to be heard under Article 113(1) EPC 1973, and, second, to enhance procedural efficiency since it makes it possible that the board's final decision may be given as quickly as possible as it may be announced orally before the oral proceedings are closed (Article 15(6), second sentence, RPBA).

In the present appeal the appellant gave no reasons to support its request for a decision "on the state of the file". Since the board considered that, despite the appellant's announced intention not to attend, procedural economy were still best served by holding the oral proceedings as scheduled, this request was refused.

According to Article 15(3) RPBA, the appellant duly summoned to oral proceedings, which chose not to be present or represented at the oral proceedings, was treated as relying only on its written case.

2. Main request - Clarity

As already pointed out in the board's communication annexed to the summons to oral proceedings, step (b) of claim 8 merely attempts to define a result to be achieved, i.e. unmixing the M images and reference spectral data associated with the 1 ... N quantum dots and responsively determining the coefficients $C_1 \dots C_N$ which are related to the concentrations of the 1 ... N quantum dots present in the specimen, without defining the concrete technical steps required for actually achieving this result.

The only argument the appellant advanced against this objection is that "a person skilled in the art, in particular in view of the disclosure on page 13, lines 4 to 28, of the description, will clearly understand not only how unmixing is effected, but also how the above coefficients $C_1 \dots C_N$ are determined" (point 3.4.1 of the letter dated 22 March 2016).

This argument is not convincing since the claims must in principle be clear in themselves when read by the person skilled in the art. In the present case, the method claim 8 does not define any technical steps which are necessary to achieve the result in step (b) and a person skilled in the art, using normal skills, will not clearly understand from the wording of claim 8 alone how to achieve the result defined in step (b). Therefore, claim 8 in itself is unclear. This clarity deficiency in the claim wording cannot be rectified by the fact that the description could possibly help the reader to understand the technical subject-matter which the claim was intended to define (see in this respect decision T 49/99, Reasons, point 12, referring to decision T 1129/97, OJ EPO 2001, 273, Reasons, points 2.1.2 and 2.1.3). The board is aware of the jurisprudence which acknowledges that an exception to this principle may exist in the particular circumstances of a case (see e.g. decision T 56/04). However, the board sees no exceptional circumstances in the present case that would justify the use of the description for the definition of the matter to be protected by claim 8 as required in Article 84 EPC 1973. The board also notes that the appellant has not provided any argument that the present case involved exceptional circumstances.

It follows from the above that claim 8 lacks clarity, contrary to Article 84 EPC 1973.

3. First to fourth auxiliary requests - Admissibility

3.1 Pursuant to Article 13(3) RPBA, amendments sought to be made after oral proceedings have been arranged shall not be admitted if they raise issues which the board cannot reasonably be expected to deal with without adjournment of the oral proceedings.

3.2 In the present case the first to fourth auxiliary requests were filed after the summons to oral proceedings had been issued.

Step (d) of claim 1 of the first to fourth auxiliary requests includes subject-matter which, according to the international search report, was found to belong to groups of inventions non-unitary with the first group of inventions and, hence, was not searched. This subject-matter relates, in particular, to the selection of "a portion of a scatter plot, histogram, or other visualization of the quantitative data" and the display of the associated image of the specimen (see, for instance, claim 17 or claim 40 as originally filed).

The introduction of these features in claim 1 represents a major shift of the subject-matter sought to be granted in a direction which was not only absent from the debate during the examination proceedings but whose corresponding subject-matter was even excluded from the search. Admitting such amendments into the appeal proceedings would mean that, according to Article 111(1), second sentence, EPC 1973, the board could search and examine this new subject-matter or remit the case to the examining division for further prosecution. However, proceedings before the boards of appeal in ex-parte cases are primarily concerned with examining the contested decision (see G 10/93, OJ EPO 1995, 172, Reasons 4). Therefore, it would have been more

appropriate to remit the present case to the department of first instance for further prosecution, in particular to decide whether an additional search has to be carried out and, possibly, to examine for the first time the patentability of the amended subject-matter. In the particular circumstances of the case, a remittal to the first-instance department would have equated to an adjournment of the oral proceedings scheduled for 27 April 2016. Hence, admitting the first to fourth auxiliary requests into the appeal proceedings would have been contrary to the provisions of Article 13(3) RPBA.

- 3.3 In response to the board's communication of 20 April 2016, the appellant did not provide any arguments in favour of admitting the first to fourth auxiliary requests into the appeal proceedings.

The board also sees no special reason why these requests including amendments relating to unsearched subject-matter should exceptionally be considered for the first time at such a late stage of the appeal proceedings.

- 3.4 For the above reasons, the board decided not to admit the first to fourth auxiliary requests into the appeal proceedings under Article 13(3) RPBA.

4. In view of the above, none of the appellant's requests is allowable and, therefore, the board sees no reason to set aside the contested decision.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



M. Kiehl

F. J. Narganes-
Quijano

Decision electronically authenticated