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Datasheet for the decision of 1 September 2020

Case Number: T 3142/19 - 3.5.06

Application Number: 14722003.2

Publication Number: 2973217

IPC: G06K9/00

Language of the proceedings: EN

Title of invention:
SYSTEM AND METHOD FOR REVIEWING AND ANALYZING CYTOLOGICAL SPECIMENS

Applicant:
Hologic, Inc.

Headword:
Analyzing Cytological Specimens/HOLOGIC

Relevant legal provisions:
EPC Art. 123(2)

Keyword:
Amendments - combination of optional features - added subject-matter (no)

Decisions cited:

Catchword:

Europäisches Patentamt
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Beschwerdekammern

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Case Number: T 3142/19 - 3.5.06

D E C I S I O N
of Technical Board of Appeal 3.5.06
of 1 September 2020

Appellant: (Applicant)	Hologic, Inc. 250 Campus Drive Marlborough, MA 01752 (US)
Representative:	CMS Cameron McKenna Nabarro Olswang LLP Cannon Place 78 Cannon Street London EC4N 6AF (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 16 July 2019 refusing European patent application No. 14722003.2 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	M. Müller
Members:	T. Alecu
	B. Müller

Summary of Facts and Submissions

I. This appeal is against the decision of the Examining Division to refuse European patent application number 14722003. The written decision was posted on 16 July 2019.

II. The notice of appeal was filed on 11 September 2019, the appeal fee was timely paid.

III. There were three requests, one main and two auxiliary requests, on file before the Examining Division, which held in the decision to refuse that the subject-matter of the independent claims of the main request and the first auxiliary request did not comply with Article 123(2) EPC. The second auxiliary request was not admitted under Rule 137(3) EPC.

IV. During prosecution, the Examining Division had also raised an objection under Article 52(1) and 54 EPC (see summons to oral proceedings, point 4), but this was not part of the reasons for the decision.

V. With the grounds of appeal filed on 16 November 2019, the appellant requested (point 1.1) that the decision be set aside and that a patent be granted on the basis of the claim set of the main request filed on 15 April 2019 and rejected by the Examining Division. The appellant also filed two auxiliary requests (points 1.2 and 1.3). Oral proceedings were requested should the Board not allow the main request (point 1.4).

VI. Should the Board find the main request compliant with Article 123(2) EPC, the appellant further requested the Board to address any outstanding issues or,

alternatively, to remit the application to the Examining Division for "continued prosecution" (point 10.12).

VII. With the letter of 23 July 2020 the appellant withdrew the request for oral proceedings if the board set the decision aside and granted the main request or remitted the case to the department of first instance for further prosecution on the basis of the main request.

VIII. Claim 1 of the main request reads:

A system for classifying or navigating within an image (110, 310) of a cytological specimen (412), the system comprising:
at least one processor operatively connected to a memory;
a user interface display (100, 300, 500);
an identification component, executed by the at least one processor, configured to identify objects of interest (112, 312) within the image (110, 310); and
a user interface component, executed by the at least one processor, configured to display the objects of interest (112, 312) within the user interface display (100, 300, 500), wherein the user interface component is configured to display a plurality of objects of interest (112,312) having a characteristic of interest established by a user so as to provide for comparison of the plurality of objects of interest (112,312) by a reviewer,
wherein the system is further configured to:
accept a user selection of an object of interest (112, 312) from the plurality of objects of interest (112, 312);

display a menu (322) of one or more calculated metrics within the user interface display (100, 500);
receive a user selection of at least one calculated metric of the one or more calculated metrics; and
display a plurality of images (310) of objects of interest (112, 312) having the at least one calculated metric.

Independent method claim 13 of the main request reads:

A method employing a processor-controlled device (522) for navigating and reviewing cytological image data, the cytological image data comprising images of a cytological specimen (412) including individual images (110, 310) of objects of interest (112, 312) therein, the method comprising:
identifying a plurality of objects of interest (112, 312) within the cytological image data;
displaying, on a display (100, 300, 500) integrated with or otherwise operatively associated with the device (522), a first plurality of images (110, 310) from the cytological image data, each image (110, 310) of the first plurality of images (110, 310) depicting a respective object of interest (112, 312) in the cytological specimen (412) having a characteristic of interest established by a user;
opening, on the display (100, 300, 500) responsive to user selection of a respective object of interest (112, 312), a menu (322) of calculated metrics computed for the respective object of interest (112, 312) in the selected image (110, 310), and
selecting via the user interface a calculated metric from the menu (322), thereby causing the device (522) to display on the display (100, 300, 500) a second plurality of images (110, 310), each image (110, 310)

of the second plurality of images (110, 310) depicting a cytological object (320) having the calculated metric.

IX. The claims of the auxiliary requests are not pertinent to the current decision.

Reasons for the Decision

The invention

1. The invention relates to a system and method for navigating and classifying cytological images (description paragraphs 2 and 5). Images of objects of interest (e.g. cells) are presented to the user, who can select one object and classify it (e.g. into normal and abnormal). The classification is aided by the possibility of displaying further similar objects of interest from the database (paragraphs 13 and 23).

2. The user interface provides for four interaction modes upon selection of an object of interest (paragraphs 40 to 50). Of interest for the present decision are the modes "more like this" (paragraphs 45 and 46), wherein the system displays similar images based on a measure of their similarity in terms of *cellular characteristics*, and "same calculated metrics" (paragraph 47), wherein the system displays the object of interest having the same values for specific *calculated metrics*.

Main Request - Article 123(2)

3. The Examining Division rejected the main request on the basis of the argument that the claimed *combination* of

features was not originally disclosed (point 2 in the grounds for the decision). Although the features were disclosed, there was no specific pointer to the particular combination claimed.

3.1 All the features were described as optional, and there was no indication by way of the technical problem solved to lead the skilled person to the conclusion that some of the features were actually not optional or that they were meant to be combined.

4. As basis for claim 1, the appellant provides (point 10 of the grounds of appeal) original claims 27, 30 and 31 in combination with paragraphs 23, 45 to 47 and 49. Referring to the "whole disclosure", the appellant also refers to the structure of the original claims.

4.1 The appellant further disagrees with the analysis of the Examining Division, submitting that the application should be read as a whole, and that when doing so, the claimed subject matter can be seen to comply with the "gold standard" for Article 123(2) EPC. In this context, the appellant also points out that no technical information is added (points 6.13 and 6.14 of the grounds of appeal).

5. The "gold standard" test can be seen as corresponding to two positive tests, one for each side of the argument. If one wants to show that the subject matter is not compliant with Article 123(2) EPC, it is necessary to indicate which information is added, i.e. goes beyond the content of the application as filed, from the perspective of the skilled person. The party claiming compliance with Article 123(2) EPC, in turn, needs to show that the skilled person would derive the identified information in a clear and unambiguous

manner from the entirety of the documents as filed, using their common general knowledge.

6. The Examining Division identified the added information as being the specific claimed *combination* of features.

6.1 The argument of the Examining Division remains at a fairly abstract level and seems to state that if no positive hint to a combination of features, otherwise presented as optional, is provided, e.g. if the technical problem does not point to a certain combination of technical features as a solution, then any such combination is new technical information.

6.2 This argument is valid in its reversed, positive form: if the description indicates that some combination is desirable, or necessary to solve a technical problem, then a clear pointer to - and thus disclosure of - the combination is provided. If not, however, it does not automatically mean that the combination is not derivable by the skilled person.

6.3 According to Article 123(2) EPC, the content of the application as filed delimits at the outset the broadest protection that the applicant may obtain. For example, if the application, when filed, declares that one may do A and one may do B, a third party should expect that the applicant may try to cover any of the respective four logical combinations.

6.4 It is, however, true that an accumulation of *optional features* may make it difficult to determine what the invention actually is (cf. the impugned decision, page 10, top paragraph, taking issue with the amount of options), and what combination of features may eventually be claimed. This is detrimental for third parties and may negatively impact on the completeness of the search.

6.5 An excessive number of optional features may also have an impact on the assessment of compliance with Article 123(2) EPC, in that, in a forest of optional features, a singled-out individual combination may not be clearly and unambiguously derivable by the skilled person. Whether this is indeed the case depends, however, on the specifics of the case, e.g. on the level of complexity caused by the optional features.

7. In this particular case, the appellant argues that the disclosure is based on the original claims 27 and 30, 31.

8. The Board sees three differences between present claim 1 and the wording of those three claims taken together (which is covered by original claim 31).

9. First, the system is also designated as being *for classifying*, and not only for navigating, within an image of a cytological specimen.

9.1 This was a not a point of dispute and the Board has no doubts that this information is derivable from the application as filed (see paragraph 2).

10. The second and third differences are at the core of the dispute and relate to the user interaction with the system. It is now recited (second difference) that: *wherein the user interface component is configured to display a plurality of objects of interest (112,312) having a characteristic of interest established by a user so as to provide for comparison of the plurality of objects of interest (112,312) by a reviewer,*

10.1 The underlined characterization of the objects was not present in the original claims provided as basis.

11. It is also recited (third difference) that the system is configured to
accept a user selection of an object of interest (112, 312) from the plurality of objects of interest (112, 312);
display a menu (322) of one or more calculated metrics within the user interface display (100, 500);
receive a user selection of at least one calculated metric of the one or more calculated metrics; and
display a plurality of images (310) of objects of interest (112, 312) having the at least one calculated metric.

11.1 The amendment consists in the replacement of the expression *cellular characteristics* used in original claims 27 to 31 by *calculated metrics*.

12. In order to be able to understand whether this amendment is derivable from the original application, one needs to read the entirety of the application through the eyes of the skilled person.

13. In paragraph 23, which is part of the summary of the invention, the skilled person is informed that the invention is (also) about a system with features which reproduce those of original claims 27 to 31, including a list of *cellular characteristics* as in claim 32, depending on the said claims.

14. In the detailed description, the skilled person expects to find specifics of the invention as already summarized.

15. The user interface for navigating and reviewing/ classifying cell images (objects of interest) presented in the detailed description displays first an initial set of objects of interest, which are obtained from new

images, or from previously processed images. Paragraph 41 states:

The thumbnail images 110 of OOIs (e.g., 112) may be displayed according to a predetermined ranking of the likelihoods that each OOI (e.g., 112) has a certain predetermined characteristic or other user/ cytotechnologist selected order. In some examples, the display shown on the display monitor is organized into an upper and lower portion. Within the upper portion a ranked list of thumbnails of OOIs can be shown (e.g., at 108). Users may select images from within a display bar 109. The ranking within the displayed images can be based on system generated probabilities that the displayed image contains a feature or characteristic. In some examples, a reviewer (e.g., cytotechnologist) can establish a characteristic of interest, and the system can display ranked images of OOIs in an upper portion of the display accordingly.

16. It is clear from this paragraph that a user can establish a predetermined characteristic, or one of interest, and that the system will display corresponding images. These images may be ranked based on the characteristic of interest, but the ranking may also be done in another user selected order. Likewise, the display can be organized in a particular way, but this is not necessary.

17. In the Board's view, the skilled person will understand these options as being exactly how they are described: options in a user interface. They may, or may not be provided. The Board is of the opinion that this passage provides a basis for a user interface having (only) the option of displaying images having a certain

characteristic of interest, without further specification of how they are displayed.

18. Given that this display of images is a precondition for any further user interaction (paragraph 41 describes the initial display for all figures 1-3b), the skilled person also understands that the features herein described are to be combined with any of the interaction modes described or claimed, thus also with claim 27. Hence the second amendment does not add subject matter.

19. The system is then described as providing for four interaction modes. As already noted above, of interest for the present decision are the modes "more like this", wherein the system displays similar images based on a measure of their similarity in terms of *cellular characteristics* and "same calculated metrics", wherein the system displays objects of interest having the same values for specific *calculated metrics*.

20. The skilled person will understand that these two modes are the specification of the system summarized in paragraph 23. Notably, the mode of interaction of paragraph 23 is replicated in the mode "same calculated metrics", and this is the only mode providing for this type of interaction. Hence a clear link is provided between those two paragraphs, which, however, do not apparently use the same type of characteristics in the selection menu.

21. The skilled person will then try to understand the relationship between the "cellular characteristics" and the "calculated metrics".

22. A calculated metric can only be based on measurements on the objects.

22.1 The description discloses feature measurements and that OOIs are evaluated on this basis at paragraph 66. It is stated therein:
In some embodiments, the processing module can evaluate OOIs based on any one or more of: morphological characteristics, stains (e.g., chromogenic, fluorescent, dual, etc.), cell size, nucleus/cytoplasm ratio, optical density, regularity of contour, color based criteria, and nucleic density. For each digital image, the input/output module 532 stores thumbnail images (e.g., 110) of the OOis (e.g., 112), along with their relative ranking, coordinates, and extracted features.

22.2 The skilled person will see that this list of criteria are calculated metrics in the sense of paragraph 47. Since no other passages in the description provide for measurements, the skilled person has no reason to believe that the calculated metrics can be based on anything else than what is described in this paragraph.

23. The list in paragraph 66 is the exact same list as in paragraph 23 (and original claim 32), where the term cellular characteristics is used. It is thus clear to the skilled person that the criteria of paragraph 66 and the cellular characteristics of paragraph 23 designate the same notion.

24. Further noting that the calculated metrics in the menu of the pertinent mode need not be all of the ones disclosed in paragraph 66, it follows that the *calculated metrics* cannot be anything else than (a subset of) *cellular characteristics*. Hence the third amendment does not add subject matter either.

25. Based on the above, the Board concludes that the amendments to claim 1 are compliant with Article 123(2) EPC. The same holds for the analogous amendments to corresponding independent method claim 13, which are also compliant with Article 123(2) EPC.

26. As a side remark, the Board is not convinced by the appellant's argument based on an iterative user selection (point 10.6.2 of the grounds of appeal) as a basis for the second amendment. An iterative use would necessitate an initial display and user selection of an image prior to establishing the characteristic of interest. If this were the only way described, the removal of the initial display and selection step would contain the new technical information that the user can establish the characteristic of interest in a different manner, e.g. by text input, and would thus constitute a non-allowable intermediate generalisation contrary to Article 123(2) EPC.

Remittal

27. As noted above, there are outstanding issues before a grant can be ordered. In fact, one can see that no other issues than those relating to Article 123(2) EPC have been discussed during examination. If the Board were to carry out a complete examination by itself, this would be contrary to the primary object of the appeal proceedings, which is a judicial review of the impugned decision (Article 12(2) RPBA 2020).

28. The Board takes the view that this is a special reason justifying remittal (Article 11 RPBA 2020).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the Examining Division for further prosecution.

The Registrar: The Chairman:

L. Stridde M. Müller

Decision electronically authenticated