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**Datasheet for the decision
of 17 April 2018**

Case Number: T 2077/16 - 3.3.08

Application Number: 10189426.9

Publication Number: 2336358

IPC: C12Q1/68

Language of the proceedings: EN

Title of invention:

Simultaneous detection of multiple nucleic acid sequences in a reaction

Applicant:

QIAGEN GmbH
Qiagen Hamburg GmbH

Headword:

Simultaneous detection multiple nucleic acid sequences/QIAGEN

Relevant legal provisions:

EPC Art. 76(1), 113(1), 123(2)
RPBA Art. 12(4)

Keyword:

Main request - added subject-matter (yes);
Auxiliary request I - admitted into appeal proceedings (no);
Auxiliary request II - added subject-matter (yes);
Right to be heard - opportunity to comment (yes)

Decisions cited:

G 0010/93

Catchword:



Beschwerdekammern
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Case Number: T 2077/16 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 17 April 2018

Appellant: QIAGEN GmbH
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40724 Hilden (DE)

Appellant: Qiagen Hamburg GmbH
(Applicant 2) Max-Volmer-Str. 3
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Representative: CH Kilger Anwaltspartnerschaft mbB
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Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 5 February 2016
refusing European patent application No.
10189426.9 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman B. Stolz
Members: P. Julià
R. Winkelhofer

Summary of Facts and Submissions

- I. European patent application No. 10 189 426.9 (with publication number 2 336 358; hereinafter "the patent application") is a divisional application of the earlier European patent application No. 08 155 687.0 (with publication number 2 116 614; hereinafter "the earlier patent application"). An examining division of the European Patent Office considered that the main request did not fulfil the requirements of Articles 54 and 56 EPC and the auxiliary request contravened Article 56 EPC. Accordingly, the patent application was refused (Article 97(2) EPC).
- II. In reply to the summons to oral proceedings, the applicants/appellants informed the examining division with submission dated 3 November 2015 that they would not attend the scheduled oral proceedings and that a decision "based on the state of the file" was requested. They filed an auxiliary request and maintained the set of claims filed with submission dated 25 February 2014 as main request.
- III. Claims 1 to 8 of the main request before the examining division were method-claims and claims 9 and 10 were product-claims directed to a kit. Independent claims 1 and 9 read as follows:
- "1. Method for simultaneously amplifying and detecting nucleic acid sequences in a reaction comprising the following steps:
- (i) providing a sample comprising at least one nucleic acid molecule;
 - (ii) providing reagents for performing an amplification reaction, wherein the reagents comprise at least two probe sets, wherein

- a. each probe set consists of at least three single probes;
 - b. each of the probes is specific for a nucleic acid sequence;
 - c. each of the probes in a given probe set carries a different fluorescent reporter label;
 - d. all of the probes in a given probe set have an identical melting temperature (T_m) when they are dissociated from their target nucleic acid sequence by heating,
- (iii) amplifying the nucleic acid sequences in the reaction;
 - (iv) detecting the amplified nucleic acids by determining whether the labeled probe has bound its nucleic acid sequence;
 - (v) detecting the temperature at which each given labeled probe dissociates from the nucleic acid sequence to which it has bound, wherein the probes carrying the same label differ in melting temperature (T_m) in a way that they are distinguishable by melting point, and
- wherein the probes are dual-labeled probes comprising said reporter label and a quencher molecule such that a difference in fluorescence emission is detectable between hybridized and melted configurations of said probes."

"9. Kit comprising at least 6 dual-labeled probes which are able to hybridize, under stringent conditions, to one or more nucleic acid molecules, wherein

- a) a first group of at least three single probes carries a first label and all the probes in this group differ with respect to their melting temperature and
- b) a second group of at least three single probes

carries a second label and all the probes in this group differ with respect to their melting temperature, wherein the dual-labeled probes comprise said reporter label and a quencher molecule such that a difference in fluorescence emission is detectable between hybridized and melted configurations of said probes, wherein the kit additionally comprises one or more PCR primers."

- IV. The auxiliary request before the examining division was identical to the main request except for deletion of the product-claims 9 and 10.
- V. An appeal was lodged by the applicants (appellants). With the statement setting out the grounds of appeal, the appellants filed a main request and auxiliary requests I and II. The main request and auxiliary request II are identical to the main request and the auxiliary request underlying the decision under appeal. Auxiliary request I is a new request in the proceedings. The appellants request that the decision under appeal be set aside and that a patent be granted on the basis of the main request or, alternatively, any of auxiliary requests I or II. Oral proceedings were requested as an auxiliary measure.
- VI. The auxiliary request I is identical to the main request underlying the decision under appeal, except for claim 9 which instead of reading "Kit comprising ..." reads "Kit consisting of ...".
- VII. In a communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA), the appellants were informed of the board's provisional, non-binding opinion on some issues of the case. In

particular, the board was of the opinion that the main request contravened Articles 76(1) and 123(2) EPC and did not fulfil the requirements of Articles 84, 83, 54 and 56 EPC (cf. points 8 to 23 of the board's communication). Except for the objections raised under Article 54 EPC, all the objections raised under Articles 76(1), 123(2), 84, 83 and 56 EPC applied also to auxiliary request II (cf. points 28 and 29 of the board's communication). The board also informed the appellants that it was, in the exercise of its discretion, minded not to admit auxiliary request I into the appeal proceedings (Article 12(4) RPBA) (cf. points 24 and 27 of the board's communication).

- VIII. In reply thereto, the appellants, without filing substantive arguments, withdrew their request for oral proceedings.
- IX. Oral proceedings took place on 17 April 2018 in the absence of the appellants. At the end of these proceedings, the board announced its decision.
- X. The appellants request that the decision under appeal be set aside and that a patent be granted on the basis of the main request or, in the alternative, any of auxiliary requests I or II, all filed with the statement setting out the grounds of appeal.

Reasons for the Decision

Article 113(1) EPC

1. In reply to the communication of the board, the appellants withdrew their request for oral proceedings

but did not respond in substance. The board did not cancel the scheduled oral proceedings.

2. By their decision not to attend the oral proceedings and not to file substantive arguments in reply to the board's communication, the appellants have chosen not to make use of the opportunity to comment on the board's provisional opinion, either in written form or at oral proceedings, although the board's provisional opinion was clearly in appellants' disfavour, i.e. the board was *"of the provisional, non-binding opinion that the appeal will likely have to be dismissed"* (cf. point 30 of the board's communication).

3. In view of the appellants' course of action in appeal proceedings and the fact that the examining division did not raise any objection under Articles 76(1) and 123(2) EPC, there are no submissions on file on any of these articles. Nor are any submissions of the appellants on file concerning the admission of auxiliary request I into the appeal proceedings. The present decision is thus based on the same grounds, arguments and evidence on which the provisional, non-binding opinion of the board was based.

Extent of the appeal

4. In an appeal from a decision of an examining division in which a European patent application was refused, the board of appeal has the power to examine whether the application or the invention to which it relates meets the requirements of the EPC. The same is true for requirements that the examining division did not take into consideration in the examination proceedings or which it regarded as having been met. If there is reason to believe that such a requirement has not been

met, the board shall include this ground in the proceedings (Headnote, decision G 10/93, OJ EPO 1995, 172).

5. In its communication, the board informed the appellants that, although the examining division in the decision under appeal had stated that the requests under consideration did not contravene Article 123(2) EPC, and no decision had been taken on Articles 84 and 83 EPC, the board had serious doubts that the requests complied with these articles. Therefore, issues related to these articles were also addressed in the board's communication (cf. points 6 and 7 of the board's communication).

Main request

6. The main request filed with the statement of grounds of appeal is identical to the main request underlying the decision under appeal, i.e. the set of claims filed with submission dated 25 February 2014 (cf. points II and III *supra*). The main request is thus part of the appeal proceedings.

Articles 76(1) and 123(2) EPC

7. The description and Figures of the patent application (EP 2 336 358) are identical to those of the earlier patent application (EP 2 116 614). The sole difference between both documents is the subject-matter of the claims, namely claims 1 to 15 in the earlier patent application and claims 1 to 10 in the patent application.
8. As regards Article 123(2) EPC, basis for claims 1 to 10 of the main request is found in claims 1 to 10 of the

patent application. Page 14, lines 13 to 15 (corresponding to first sentence of paragraph [0052]) of the patent application was given by the applicants/appellants as a basis for the introduction of the term "single" into claim 1(ii)(a) and claim 9 of the main request (cf. point 1 of applicants/appellants' submission dated 29 June 2011). No basis was given for the introduction of the feature "wherein the kit additionally comprises one or more PCR primers" into claim 9 (cf. point 1 of applicants/appellants' submission dated 25 February 2014).

Although generic disclosures are found in the patent application (cf. paragraphs [0062] to [0065]), there is no explicit disclosure of the specific feature introduced into claim 9 of the main request, let alone of the combination of features of the claim. Nor does the board see an implicit disclosure of this feature when in combination with all other features of claim 9 in the patent application.

9. As regards Article 76(1) EPC, basis for claims 1 to 10 of the main request is found in claims 1 to 9 and claim 15 of the earlier patent application. The basis for the term "single" in the earlier patent application is the same as that found in the patent application (cf. first sentence paragraph [0043] of the earlier application). Claim 1 of the main request and claim 1 of the earlier patent application differ by the presence of the feature "fluorescent reporter" in part (ii)(c) of claim 1 of the main request and the feature "wherein the probes are dual-labeled probes comprising said reporter label and a quencher molecule such that a difference in fluorescence emission is detectable between hybridized and melted configurations of said probes" at the end of claim 1 of the main

request. This feature is also present in part (b) of claim 9 of the main request but not in claim 15 of the earlier patent application. Moreover, claim 9 of the main request differs from claim 15 of the earlier patent application by the addition of further features, such as the characterisation of the probes as "dual-labeled" and "single", and the feature present at the end of claim 1 of the main request referred to above.

There is no basis in the earlier application for all the features and differences outlined above, in particular in combination with some of the subject-matter of the dependent claims. Claim 2 of the main request, for instance, requires the fluorescent reporter labels of the probes of the first and second probe sets to have a similar emission wavelength but not the fluorescent reporter labels of the further possible probe sets (see, however, paragraph [0030] of the earlier patent application). Claim 8 of the main request defines the dual-labeled probes as Molecular Beacon probes or TaqMan probes, although statements in the description of the earlier patent application do not seem to support the use of the TaqMan probes in the method of claim 1 of the main request (cf. *inter alia*, paragraph [0043] of the earlier patent application). Similar considerations apply to the subject-matter of claims 9 and 10 of the main request.

10. Thus, in view of the above considerations, the main request contravenes Articles 76(1) and 123(2) EPC.

Admission of auxiliary request I

11. According to the case law (cf. "Case Law of the Boards of Appeal of the EPO", 8th edition 2016, IV.E.1, 1065 ff; cf. also IV.E.4, 1127 ff), the function of an

appeal is to give a judicial decision upon the correctness of a separate earlier decision taken by a department of first instance. Appeal proceedings are not an opportunity to re-run the proceedings before the first instance. Article 12(4) RPBA furthermore leaves it at the discretion of the board not to consider facts, evidence or requests which could have been presented in the first instance proceedings.

12. The auxiliary request I filed with the statement of grounds of appeal is identical to the main request except for independent claim 9 which, instead of reading "*Kit comprising ..*" as in the main request, reads now in auxiliary request I "*Kit consisting of ...*" (underline by the board) (cf. point VI *supra*).

13. Objections for lack of novelty of claims directed to a kit were already raised in the first communication of the examining division issued on 8 March 2011 (cf. page 3, second paragraph), in the communications pursuant to Article 94(3) EPC issued by the examining division on 24 August 2011 (cf. page 2, point 3.2) and 16 October 2013 (cf. page 3, point 3.2), as well as in the communication attached to the summons to oral proceedings issued on 13 May 2015 (cf. page 2, point 3.2). Indeed, during the examination proceedings, objections against this subject-matter were also raised for lack of inventive step (cf. page 3, point 4.3 of the communication dated 24 August 2011) and lack of clarity (cf. page 2, point 2.2. of the communication dated 16 October 2013). At no point of these proceedings did the applicants/appellants file a request with an amendment as presented now in auxiliary request I, i.e. the change of the term "comprising" to "consisting" (*supra*). No reasons have been provided by the appellants to justify and/or to explain the

introduction of such amendment at this late stage of the proceedings and why this amendment could not have been made during the proceedings before the examining division. This course of action is not in line with the case law referred to above.

14. Therefore, the board, exercising its discretion pursuant to Article 12(4) RPBA, does not admit auxiliary request I into the appeal proceedings.

Auxiliary request II

15. The auxiliary request II filed with the statement of grounds of appeal is identical to the auxiliary request underlying the decision under appeal, i.e. the auxiliary request filed with submission of 3 November 2015 in reply to the "Summons to attend oral proceedings" issued on 13 May 2015 (cf. points II and IV *supra*). The auxiliary request II is thus part of the appeal proceedings.

16. The auxiliary request II is also identical to the main request except for the deletion of claims 9 and 10 of the main request directed to a kit. Therefore, the objections raised in point 9 above against claims 1 to 8 of the main request, that the subject-matter of some claims is not directly and unambiguously disclosed in the earlier patent application, apply also to the claims of this auxiliary request. Therefore, the auxiliary request II contravenes Article 76(1) EPC.

Conclusion

17. In the absence of an allowable request, the appeal has to be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



L. Malécot-Grob

B. Stolz

Decision electronically authenticated