

Internal distribution code:

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

**Datasheet for the decision
of 5 April 2017**

Case Number: T 0159/11 - 3.3.08

Application Number: 98301581.9

Publication Number: 0861906

IPC: C12Q1/68

Language of the proceedings: EN

Title of invention:

Fluorescence energy transfer by competitive hybridization

Patent Proprietor:

Quest Diagnostics Investments Incorporated

Opponent:

Abbott Laboratories

Headword:

Competitive hybridization/QUEST DIAGNOSTICS

Relevant legal provisions:

EPC Art. 123(2)

Keyword:

Main request and auxiliary requests 1 and 2 - admitted into
the proceedings

All requests - added matter - (yes)

Decisions cited:

T 0028/92, T 1186/06, T 1587/07, T 0361/08, T 1067/08,
T 0023/10

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 0159/11 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 5 April 2017

Appellant: Quest Diagnostics Investments Incorporated
(Patent Proprietor) 300 Delaware Avenue
Wilmington, DE 19899 (US)

Representative: Schiweck, Wolfram
Schiweck, Weinzierl & Koch
Patentanwälte Partnerschaft mbB
Landsberger Straße 98
80339 München (DE)

Respondent: Abbott Laboratories
(Opponent) 100 Abbott Park Road
Abbott Park IL 60064 (US)

Representative: Miller, David J.
Mathys & Squire LLP
The Shard
32 London Bridge Street
London SE1 9SG (GB)

Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted on 16 November
2010 revoking European patent No. 0861906
pursuant to Article 101(3) (b) EPC.

Composition of the Board:

Chairman B. Stolz
Members: M. R. Vega Laso
J. Geschwind

Summary of Facts and Submissions

- I. European patent No. 0 861 906 with the title "Fluorescence energy transfer by competitive hybridization" was granted on the European patent application No. 98301581.9. In the present decision, references to the application as filed are those to the original application documents.
- II. The patent was opposed on the grounds for opposition under Article 100(a) in conjunction with Articles 54 and 56, 100(b) and 100(c) EPC.
- III. By a decision of an opposition division of the European Patent Office under Article 101(3)(b) EPC posted on 16 November 2010, the patent was revoked. In the decision, the opposition division found that the patent could not be maintained on the basis of any of the sets of claims then on file, because the subject-matter of claim 1 of the main request lacked novelty (Article 54 EPC), and the amended claims according to the 1st and 2nd auxiliary request did not comply with Articles 123(2) and 84 EPC.
- IV. The patent proprietor (appellant) lodged an appeal against the decision of the opposition division. Together with its statement setting out the grounds of appeal, the appellant submitted three sets of amended claims as main request and auxiliary requests 1 and 2 which replaced the sets of claims underlying the decision under appeal.
- V. Claim 1 according to the main request reads as follows:

"1. A method for monitoring nucleic acid amplification comprising:

performing nucleic acid amplification on a target polynucleotide using any method, wherein said amplification is carried out in the presence of a first oligonucleotide probe and a second shorter oligonucleotide probe varying in length by at least 2 base pairs, which allow monitoring of nucleic amplification;

the first probe having a fluorophore;

the second being complementary with the first probe and having a quencher molecule capable of quenching the fluorescence of said fluorophore, the fluorophore and quencher being attached on their respective probes at positions which results in the quencher molecule quenching the fluorescence of the fluorophore when the probes are hybridized to each other, wherein the longer probe binds preferentially to the target polynucleotide and when preferentially bound to the target polynucleotide the fluorescence intensity of the fluorophore is greater than the fluorescence intensity of the fluorophore when hybridized to the second probe, wherein the first oligonucleotide probe is in the range of 15-60 nucleotides in length,

and

monitoring the fluorescence of the fluorophore, the generation of fluorescence corresponding to the occurrence of nucleic acid amplification."

Dependent claims 2 to 10 are directed to particular variants of the method of claim 1.

VI. Auxiliary request 1 differs from the main request in that the wording "... wherein the first oligonucleotide probe is in the range of 15-60 nucleotides in length" in claim 1 has been replaced by "... wherein **both the first oligonucleotide probe and the second oligonucleotide probe** is in the range of 15-60

nucleotides in length". Auxiliary request 2 differs from auxiliary request 1 in that the range is "**15-30 nucleotides in length**" (emphasis in the quotations has been added by the board).

- VII. The opponent (respondent) replied to the grounds of appeal. Additional arguments were submitted by the appellant. Both the appellant and the respondent requested oral proceedings as a subsidiary request.
- VIII. The board summoned the parties to oral proceedings. In a communication under Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA) attached to the summons, the board made observations concerning the admission of the new requests into the proceedings and various issues under Articles 123(2), 84, 83 and 54 EPC.
- IX. Both parties replied to the board's communication.
- X. Oral proceedings were held on 5 April 2017.
- XI. The submissions made by the appellant concerning issues relevant to this decision, were essentially as follows:

Admission of the new sets of claims into the proceedings

The new sets of claims should be admitted into the proceedings because the amendments introduced into the claims addressed the issues on which the opposition division had decided adversely. Contrary to the respondent's allegation, claim 1 according to auxiliary request 1 was a fresh claim which differed from a tentative claim submitted in opposition proceedings. In any case, the circumstances of the present case

differed substantially from those underlying the decisions to which the respondent referred.

Main request - Article 123(2) EPC

The amendment introduced into claim 1 did not offend against Article 123(2) EPC because it had a basis on page 4, lines 7 to 9 of the application as filed, as well as in the example section where a first oligonucleotide probe with a length of 20 nucleotides was used (see page 8, Table III, probe C1). It was clear to a skilled person reading the whole paragraph starting on page 3, line 34 that the disclosed length applied to any oligonucleotide probe used in the context of the invention, and that some oligonucleotides might have a length falling within the range of 15-60 nucleotides, while others might not.

It was disclosed in the application as filed that the probes used in the invention could be of any length (see page 6, lines 9 to 11), and that the precise sequence and length of an oligonucleotide probe of the invention depended in part on the nature of the target oligonucleotide to which it binds (see page 4, lines 9 to 11). Reading these passages together with the passage on page 4, lines 7 to 9, a person skilled in the art would understand that the length of the first oligonucleotide probe might be in the range of 15-60 nucleotides, and that also the second oligonucleotide probe might have a length in the range of 15-60 nucleotides. Thus, both alternatives were disclosed. There was neither a contradiction with the disclosure that the first and second oligonucleotide probes varied in length by at least 2 base pairs, nor with the fact that the length of the second oligonucleotide probe was not defined in claim 1.

Auxiliary request 1 - Article 123(2) EPC

Basis for the amendment introduced into claim 1 was the passage on page 4, lines 7 to 9 of the application as filed as well as the example section, where a first oligonucleotide probe with a length of 20 nucleotides and a second oligonucleotide probe with a length of 17 nucleotides were used (see page 8, Table III, probes C1 and C2). The passage starting on page 3, line 34 of the application provided a general description of the oligonucleotide probes used in the context of the invention. As this passage taught the person skilled in the art that some oligonucleotides used might have a length falling within the range of 15-60 nucleotides, it was clear that more than one oligonucleotide used might fall within that range. Hence, the amendment introduced into claim 1 complied with Article 123(2) EPC.

Auxiliary request 2 - Article 123(2) EPC

The amendment to claim 1 had a basis in the passage on page 4, lines 7 to 9 of the application as filed which disclosed a length range of 15-60 and 18-30 nucleotides, and thus also a range of 15 to 30 nucleotides in accordance with the established case law. From the context of the passage in question, it was implicit that both the first and the second oligonucleotide used could have a length within the range of 15-30 nucleotides. Further support was provided by the example section of the application.

- XII. The respondent's submissions, insofar as they are relevant to the present decision, may be summarised as follows:

Admission of the new sets of claims into the proceedings

The new sets of claims submitted together with the statement of grounds of appeal could have been presented during the opposition proceedings. The claims according to auxiliary request 1 corresponded to claims that had been filed but withdrawn during the opposition proceedings. Their admission would be unfair to the respondent and/or contrary to procedural efficiency; it would either deprive the respondent of one legal instance, or necessitate the remittal of the case to the opposition division, thus resulting in an unnecessary prolongation of the proceedings and an associated loss of legal certainty for the public. Hence, in line with, *inter alia*, decisions T 361/08 of 3 December 2009, T 1587/07 of 10 October 2010, T 23/10 of 18 January 2011, T 1067/08 of 10 February 2011, T 1186/06 of 23 October 2009 and T 28/92 of 9 June 1994, the board should exercise the discretion conferred by Article 12(4) of the Rules of Procedure of the Boards of Appeal (RPBA) and disregard the new claims.

Main request - Article 123(2) EPC

The subject-matter of claim 1 extended beyond the content of the application as filed. There was no basis for the additional limitation that "... the **first** oligonucleotide probe is in the range of 15-60 nucleotides in length". It could not be established, clearly and unambiguously, whether "the oligonucleotide probe" mentioned on page 4, lines 7-9 was the first or the second oligonucleotide probe.

Auxiliary request 1 - Article 123(2) EPC

The range recited in the passage on page 4, lines 7-9 had only been disclosed as a feature of one (unspecified) oligonucleotide probe. There was no disclosure of that range in the context of **both** of the recited oligonucleotide probes. In the light of the later disclosure in the application that the second oligonucleotide probe should be at least 2 nucleotides shorter than the first oligonucleotide probe, it could not be concluded, let alone with any certainty, that the range of 15-60 nucleotides in length was applicable to both of the oligonucleotide probes. Thus, Article 123(2) EPC was clearly contravened.

Auxiliary request 2 - Article 123(2) EPC

The arguments presented with respect to auxiliary request 1 (which specified a range of 15-60 nucleotides) applied *mutatis mutandis* to auxiliary request 2 (which specified a range of 15-30 nucleotides).

- XIII. The appellant (patent proprietor) requested that the decision under appeal be set aside and that the patent be maintained on the basis of the set of claims according to the main request or either one of auxiliary requests 1 or 2, all filed with the statement setting out the grounds of appeal. Further, the appellant requested that the case be remitted to the opposition division for the assessment of inventive step.
- XIV. The respondent (opponent) requested that the main request and auxiliary requests 1 and 2 not be admitted into the procedure and that the appeal be dismissed. As

a subsidiary request, the respondent requested remittal of the case to the opposition division for assessment of sufficiency of disclosure and inventive step.

Reasons for the Decision

Admission of the new sets of claims into the proceedings

1. Pursuant to Article 12(4) of the Rules of Procedure of the Boards of Appeal (RPBA) in conjunction with Article 114(2) EPC, it is a matter of discretion of the board whether or not requests and evidence filed for the first time in appeal proceedings, but which could have been presented in the previous proceedings, are admitted and considered.

2. The sets of claims according to the main request and auxiliary request 2 filed by the appellant together with the statement of grounds of appeal are, undisputedly, fresh sets of claims as they were not on file in opposition proceedings. Moreover, contrary to the respondent's view, also the claims according to auxiliary request 1 have to be considered as fresh claims. Even though in opposition proceedings the appellant proposed a draft claim which included the feature introduced into claim 1 of the present auxiliary request 1, the wording of that claim differed slightly from the wording of claim 1 as now on file. Thus, it cannot be excluded that the difference in wording reflects a difference in subject-matter claimed. In any case, the circumstances of the present case do not seem to support the respondent's assumption that, by not pursuing the draft claim further, the patent proprietor (the present appellant) deliberately

attempted to prevent a decision of the opposition division on that particular claim.

3. The amendments introduced into the claims filed together with the statement of grounds of appeal are clearly intended to address the opposition division's adverse findings on novelty (Article 54 EPC) with respect to the main request then on file. The question whether or not these sets of claims could - and should - have been filed in opposition proceedings has to be answered having regard to the particular circumstances of the present case. It should be noted that the circumstances underlying previous decisions of the Boards of Appeal on the admission of fresh sets of claims into the appeal proceedings on which the respondent relied (see section XII above), including those by the present board differ from the circumstances in the present case. In fact, identical circumstances are unlikely.
4. In the present case, in a communication issued in preparation for oral proceedings the opposition division expressed the provisional opinion that the subject-matter of both the claims on file and the proposed claim lacked novelty over two documents, one of which had been filed by the opponent after expiry of the period for opposition. In reply to the opposition division's communication, the patent proprietor submitted seven auxiliary requests in order to overcome the novelty objections.
5. After the discussion of the main request at the oral proceedings, the opposition division expressed the view that only one of the documents relied upon by the opponent was prejudicial to the novelty. As a reaction, the patent proprietor withdrew several auxiliary

requests, renumbered a previous request as 1st auxiliary request and filed a fresh set of claims as 2nd auxiliary request. The amendments introduced into the claims according to the 1st and 2nd auxiliary request were however found to contravene Article 123(2) EPC and the claims to lack clarity and conciseness within the meaning of Article 84 EPC (see sections 4.3 and 5.2 of the minutes of the oral proceedings before the opposition division).

6. The sets of claims submitted together with the statement of grounds of appeal are an attempt to remedy deficiencies of the claims underlying the decision under appeal which became apparent at a late stage of the oral proceedings before the opposition division. Since there is no clear proof of any abuse of procedure, the board, exercising its discretion, decided to admit the three sets of claims into the proceedings.

Main request - Article 123(2) EPC

7. In the decision under appeal, the opposition division found that the objections under Article 123(2) EPC raised by the opponent with respect to claim 1 of the main request then on file were not justified (see points 14.2.3 and 14.3.3 of the decision). This finding has not been contested in appeal proceedings.
8. Thus, the sole question to be decided is whether the amendment introduced into present claim 1 complies with Article 123(2) EPC. Present claim 1 differs from the corresponding claim of the main request underlying the decision under appeal in that it includes the further feature "*... wherein the first oligonucleotide probe is in the range of 15-60 nucleotides in length ...*". As

basis for this feature, the appellant relied on the statements on page 4, lines 7 to 9, and on probe C1 in Table III on page 8 of the application as filed. The passage on page 4, lines 7 to 9 reads:

"Preferably, the oligonucleotide [sic] probe is in the range of 15-60 nucleotides in length"

9. Contrary to the appellant's view, this passage does not disclose that the length of the **first** probe is in the range of 15-60 nucleotides, as specified in claim 1. As a matter of fact, the passage in question is ambiguous because it mentions an oligonucleotide probe (in singular), but leaves open to which of the two probes used in the method for monitoring nucleic acid amplification, the first probe having a fluorophore and the second having a quencher, the disclosed length range applies.

10. Example 1 does not shed light on the question which of the two probes is meant in the passage quoted above. While it is true that the first probe shown in Table III of Example 1 (probe C1) has a length of 20 nucleotides and is, thus, within the range disclosed in the passage on page 4, the same is true for the second probe (probe C2) which has a length of 17 nucleotides. Hence, from the passage on which the appellant relies read in connection with Example 1 a person skilled in the art cannot derive, clearly and unambiguously, a method as claimed in claim 1 in which only the **first** oligonucleotide probe is in the range of 15-60 nucleotides in length, whereas the length of the second probe is not subject to any limitation other than that it is at least 2 nucleotides ("*base pairs*") shorter than the first probe.

11. The appellant relied further on the passages on page 3, lines 34 to 38 and page 4, lines 9 to 16 of the application as filed. On page 3, it is stated that the oligonucleotide probes of the invention can be synthesized by a number of approaches, conveniently on an automated DNA synthesizer using standard chemistries. There is no link apparent between this general disclosure, which applies to all probes, and the disclosure of a particular embodiment ("*Preferably*") concerning the length of a single probe ("*the oligonucleotide probe*"). More importantly, the passage on page 3 does not concern specifically the first probe, but any probe used in the method of the invention.

12. Nor does the passage on page 4 indicated by the appellant, which reads:

"The precise sequence and length of an oligonucleotide probe of the invention depends in part on the nature of the target polynucleotide to which it binds. The binding location and length may be varied to achieve appropriate annealing and melting properties for a particular embodiment. Preferably, the 3' terminal nucleotide of the oligonucleotide probe is blocked or rendered incapable of extension by a nucleic acid polymerase. Such blocking is conveniently carried out by the attachment of a reporter or quencher molecule to the terminal 3' carbon of the oligonucleotide probe by a linking moiety."

(see page 4, lines 9 to 16)

Neither the statements in the first two sentences of this passage, which deal generally with the sequence, binding location and length of **an** oligonucleotide probe

of the invention, nor the last two sentences, which relate to a specific embodiment, provide any information which would help the person skilled in the art to resolve the ambiguity in the previous sentence.

13. It follows from the above that the method of amended claim 1 cannot be derived directly and unambiguously from the application as filed. Since the amendment introduced into claim 1 contravenes Article 123(2) EPC, the patent cannot be maintained on the basis of the claims according to the main request.

Auxiliary request 1 - Article 123(2) EPC

14. As basis for the amendment introduced into claim 1 (see section VI above), the appellant relied on the same passage of the application as filed as for the amendment in claim 1 of the main request (see paragraph 8 above). It is stated in the passage in question that **the** oligonucleotide probe (in singular) **is** in the range of 15-60 nucleotides in length. Hence, this passage explicitly discloses the length of only one (unspecified) oligonucleotide probe, rather than of both the first and second probe, as in amended claim 1.
15. Neither the context in which the passage is found in the application, nor Example 1 can be acknowledged as an implicit disclosure of the feature introduced into claim 1. As stated above in connection with the main request, the passage starting on page 3, line 34 discloses a number of approaches for the synthesis of the oligonucleotide probes of the invention. The following passage, however, explicitly relates to a preferred embodiment characterized by the length of the (unspecified) nucleotide probe. There is no inconsistency between both disclosures which may induce

the skilled person to read the wording "the nucleotide probe is ..." as meaning "both nucleotide probes are ...". The fact that both the first probe (C1) and the second probe (C2) in Example 1 have a length within the range of 15-60 nucleotides (20 and 17 nucleotides, respectively) is consistent with the requirement that the second (shorter) oligonucleotide probe varies in length from the first probe by at least 2 base pairs (see page 2, lines 5 and 6 of the application) and is not in contradiction with the statement on page 4. Thus, in view of Example 1 a person skilled in the art would not consider that the actual length of the oligonucleotide probes in the example necessarily implied that both probes need to be 15-60 nucleotides in length.

16. Summarizing the above, it is concluded that there is neither explicit nor implicit disclosure in the application as filed of a method as defined in claim 1. Consequently, the subject-matter of this claim extends beyond the content of the application as filed and thus offends against Article 123(2) EPC.

Auxiliary request 2 - Article 123(2) EPC

17. Amended claim 1 according to auxiliary request 2 differs from the corresponding claim of the previous request in that the range has been limited to 15-30 nucleotides. The appellant relies on the passage on page 4, lines 7 to 9 of the application as filed as basis for this amendment. This passage reads:

"Preferably, the oligonucleotide [sic] probe is in the range of 15-60 nucleotides in length. More preferably, the oligonucleotide probe is in the range of 18-30 nucleotides in length."

18. The length range specified in claim 1 results from a combination of the lower and upper limit of the two ranges disclosed in this passage. However, in the context of Article 123(2) EPC the decisive issue is whether a person skilled in the art can derive from the passage in question the feature that both the first and second oligonucleotide probe are in the specified length range. For the same reasons as given in connection with the first auxiliary request (see paragraph 15 above), it is considered that this passage, read either alone or in combination with further technical information in the application, in particular Example 1, does not disclose, clearly and unambiguously, a method as claimed. Hence, the amendment introduced into claim 1 contravenes Article 123(2) EPC.

Conclusion

19. None of the sets of claims on file complies with Article 123(2) EPC. Thus, the appellant's request to set aside the decision under appeal and maintain the patent on the basis of any of these sets of claims cannot be granted.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



A. Wolinski

B. Stolz

Decision electronically authenticated