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**Datasheet for the decision
of 15 July 2016**

Case Number: T 1821/11 - 3.3.08
Application Number: 03799976.0
Publication Number: 1583843
IPC: C12Q1/68, C12P19/34, C07H21/04
Language of the proceedings: EN

Title of invention:

SINGLE PRIMER WHOLE GENOME AMPLIFICATION

Applicant:

QIAGEN GmbH

Headword:

Single primer whole genome amplification/QIAGEN GmbH

Relevant legal provisions:

EPC Art. 123(2), 84, 109(1), 111(1)

Keyword:

Main request - Articles 123(2) and 84 EPC - (yes)
Interlocutory revision - Article 109(1) EPC
Remittal to the examining division - Article 111(1) EPC

Decisions cited:

Catchword:



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Case Number: T 1821/11 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 15 July 2016

Appellant: QIAGEN GmbH
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Representative: Qiagen GmbH
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted on 8 March 2011 refusing European patent application No. 03799976.0 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman M. Wieser
Members: B. Stolz
J. Geschwind

Summary of Facts and Submissions

- I. The appellant (applicant) filed an appeal against the decision of the examining division whereby European patent application No. 03799976.0 was refused. The Examining Division decided that neither the main request filed on 13 August 2009 nor any of auxiliary requests 1 to 4, all filed with letter of 23 August 2010, meets the requirements of Article 83 EPC. Auxiliary request 4, in addition, did not meet the requirements of Article 123(2) EPC.

- II. With the statement setting out the grounds of appeal, the appellant submitted a new main request comprising claims 1 to 20 and requested that the decision under appeal be set aside and a patent be granted on the basis of its new main request. As an auxiliary measure, oral proceedings were requested.

- III. The board issued a communication informing the appellant of its preliminary non-binding opinion that the main request seemed well founded and suitable to overcome the only objection for which a reasoned decision was given by the examining division. The board expressed its preliminary opinion that the examining division should have rectified its decision according to Article 109(1) EPC and that it therefore intended to set aside the decision under appeal and to remit the case to the examining division for further examination.

The appellant was asked to indicate, within a period of two months after receipt of this communication, whether it maintained its request for oral proceedings.

- IV. With letter dated 4 July 2016, the appellant withdrew its request for oral proceedings in case a decision in

line with the board's preliminary opinion would be issued.

- V. Claim 1 of the main request reads as follows (for comparison with the main request before the examining division, amendments by deletions are indicated and newly added insertions are underlined):

"1. A method of amplifying genomes, the method comprising, bringing into contact a single primer, DNA polymerase, and a genomic nucleic acid sample, and incubating the genomic nucleic acid sample under conditions that promote replication of nucleic acid molecules in the genomic nucleic acid sample, wherein the primer has a specific nucleotide sequence and wherein the primer contains at least one modified nucleotide such that the primer can be resistant to 3'-5' exonuclease, wherein the DNA polymerase is Phi 29 DNA polymerase, wherein the genomic nucleic acid sample comprises all or 90% or more of the sequences of a genome, wherein replication of the nucleic acid molecules in the genomic nucleic acid sample proceeds by strand displacement replication, ~~wherein replication of the nucleic acid molecules in the genomic nucleic acid sample results in replication of all or 90% or more of the nucleic acid molecules in the genomic nucleic acid sample~~ and wherein the conditions that promote replication of the nucleic acid molecules are substantially isothermic."

- VI. The arguments of the appellant as far as relevant for this decision can be summarized as follows:

Removal of the feature "*wherein replication of the nucleic acid molecules in the genomic nucleic acid sample results in replication of all or 90% or more of*

the nucleic acid molecules in the genomic nucleic acid sample" rendered moot the objections raised under Article 83 EPC in point 2.1. of the decision under appeal.

The new feature "*wherein the primer contains at least one modified nucleotide such that the primer can be resistant to 3'-5' exonuclease*" was disclosed on page 207 of the published application document WO 2004/058987 (the application as filed). The new feature "*wherein the DNA polymerase is Phi 29 DNA polymerase*" was for instance disclosed on page 54 of the application document.

Claims 1 to 20 of the main request met the requirements of the EPC.

- VII. The appellant requests that the decision under appeal be set aside and a patent be granted on the basis of claims 1 to 20 of the main request.

Reasons for the Decision

1. The appeal was filed within the time limit and in the form required by Article 108 EPC and Rule 99 EPC and is admissible.
2. Claim 1 of the main request and of auxiliary requests 1 to 4 of the decision under appeal comprised the functional feature that the claimed method of amplifying genomes resulted in "*replication of all or 90% or more of the nucleic acid molecules in the genomic nucleic acid sample*" (cf. item V, above). The examining division decided that none of these requests met the requirements of Article 83 EPC because the application failed to provide sufficient guidance to

produce suitable primers, apart from the AluR11 based primer, which were able to produce more than 90% loci representation according to claim 1 (cf. point 2 of the decision under appeal). In addition, claim 1 of auxiliary request 4 comprised a combination of features including a limitation of the length of the primers and the list of suitable primers which did not meet the requirements of Article 123(2) EPC. These were the only reasoned issues of the decision for refusing the patent application (further remarks made in point 3 of the decision, which are not substantiated reasons for refusal, also refer to the afore mentioned functional feature of claim 1 (cf. point 3.3)).

3. The statement setting out the grounds of appeal was filed on 18 July 2011. On 3 August 2011, i.e. within the period of three months from the date of receipt of the statement setting out the grounds of appeal according to Article 109(2) EPC, the examining division decided that interlocutory revision was not granted.
4. With the statement setting out the grounds of appeal, the appellant submitted a single new main request which no longer comprised the feature that the claimed method of amplifying genomes results in "*replication of all or 90% or more of the nucleic acid molecules in the genomic nucleic acid sample*". However, three additional features have been added to claim 1.
5. The three new features specify that a) the primer contains at least one modified nucleic acid such that the primer becomes resistant to 3'-5' exonuclease, b) the DNA polymerase is Phi 29 DNA polymerase, and c) the conditions of replication are substantially isothermic.

6. The subject matter of claim 1 is a strand displacement amplification procedure using a single primer. A general basis for such method can be found starting at page 200 of the patent application as filed, without the requirement that replication of all or 90% or more of the nucleic acid molecules in the genomic nucleic acid sample takes place.

7. That the primer contains at least one modified nucleotide such that it can be resistant to 3'-5'-exonuclease is disclosed on page 207, lines 13 and 14 of the application as filed.

According to page 91 of the description, Phi 29 DNA polymerase is the most preferred DNA polymerase for the multiple displacement reactions disclosed throughout the application as filed.

Use of a strand displacement amplification or strand displacement replication reaction was already part of claim 1 of the requests before the examining division. These reactions are generally performed under isothermal conditions. Moreover, there is explicit basis for this feature on page 207, lines 16 to 17 of the application as filed.

8. The deletion of the feature leading to the refusal of the patent application and the combination of the new features with the features already present in claim 1 of the main request before the examining division does therefore not lead to the creation of subject matter which extends beyond the application as filed. Amended claim 1 meets the requirements of Article 123(2) EPC.

9. Claim 1 is also clear within the meaning of Article 84 EPC.

10. As the objection under Article 123(2) EPC, raised by the Examining Division with regard to the fourth auxiliary request before it, is not relevant for the new main request (see item (2) above), the objection under Article 83 EPC, caused by the feature "*replication of all or 90% or more of the nucleic acid molecules in the genomic nucleic acid sample*" remains the only reasoned issue why the examining division has decided to refuse the application. This feature has been removed. The main request is well founded and the only objection for which a reasoned argumentation is given in the decision under appeal is overcome.

11. According to Article 109(1) EPC, the department whose decision is contested shall rectify its decision if it considers the appeal admissible and well founded. Since these requirements are both met, i.e. the present appeal is admissible and well founded, the Examining Division should have granted interlocutory revision (cf. Case Law of the Boards of Appeal, 7th edition, IV.E.2.9.1, page 969; see also point 6 of decision T 47/90 of 20 February 1990; point 2.1. of decision T 919/95 of 16 January 1997; point 3 of decision T 1362/13 of 27 November 2013; and point 4.1 of decision T 1060/13 of 16 December 2013).

12. In view of the above, the decision under appeal is set aside and the case is remitted to the Examining division for further examination (Article 111(1) EPC).

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 examination on the basis of claims 1 to 20 of the main request filed with the statement setting out the grounds of appeal.

The Registrar:

The Chairman:



A. Wolinski

M. Wieser

Decision electronically authenticated