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# Datasheet for the decision of 15 September 2015

Case Number: T 1599/12 - 3.3.08

Application Number: 03756100.8

1509624 Publication Number:

IPC: C12Q1/68

Language of the proceedings: EN

#### Title of invention:

MET/FRET BASED METHOD OF TARGET NUCLEIC ACID DETECTION WHEREBY THE DONOR/ACCEPTOR MOIETIES ARE ON COMPLEMENTARY STRANDS

### Applicant:

SECRETARY, DEPARTMENT OF ATOMIC ENERGY

#### Headword:

FRET based detection of nucleic acids/SECRETARY, DEPARTMENT OF ATOMIC ENERGY

# Relevant legal provisions:

EPC Art. 84

#### Keyword:

Main request - Article 84 EPC - (no)

## Decisions cited:

## Catchword:



# Beschwerdekammern Boards of Appeal Chambres de recours

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Case Number: T 1599/12 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 15 September 2015

Appellant: SECRETARY, DEPARTMENT OF ATOMIC ENERGY

(Applicant) Government of India, Anushakthi Bhavan,

Chatrapati Shivaji Maharaj Marg

Mumbai 400 001 (IN)

Representative: Taylor, Kate Laura

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Decision under appeal: Decision of the Examining Division of the

European Patent Office posted on 30 November 2011 refusing European patent application No. 03756100.8 pursuant to Article 97(2) EPC.

## Composition of the Board:

Chairman M. Wieser Members: B. Stolz

J. Geschwind

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## Summary of Facts and Submissions

- I. The appellant filed an appeal against the decision of the examining division, dated 30 November 2011, whereby European patent application No. 03756100.8 was refused.
- II. The Examining Division decided that the main request (MR-1) before it did not meet the requirements of Articles 123(2) and 84 EPC. It did not admit a further request (MR-2) into the proceedings, because said request did not meet the requirements of Articles 123(2) and 84 EPC either (cf. point 2 of the decision under appeal).
- III. With its grounds of appeal, the applicant (appellant) filed an amended new main request.
- IV. The appellant was summoned to oral proceedings. A communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA) annexed to the summons, informed it of the preliminary non-binding opinion of the board regarding the non-compliance of the new main request with the requirements of Articles 123(2) and 84 EPC.
- V. The appellant made no further submissions.
- VI. In a letter dated 1 September 2015, the appellant informed the board that it will not attend the oral proceedings.
- VII. Oral proceedings were held on 15 September 2015 in the absence of the appellant.
- VIII. Claims 1, 2, 19 and 20 of the main request read as follows:

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- "1. A method of detection and/or quantification of a target nucleic acid sequence comprising:
- i) FRET between a donor FRET moiety and an acceptor FRET moiety provided separately on at least two separate oligonucleotides that are part of the opposite complementary strands of a nucleic acid segment with the donor and acceptor moieties separated from each other by 3 20 nucleotide pairs in the final amplification product, wherein said at least two oligonucleotides serve as a pair of primers for amplification of said target sequence;
- (ii) subjecting the target sequence to amplification such that the 3'ends of said pair of primers are on two opposite strands, and
- (iii) carrying out denaturation step and at least a selective annealing step in each cycle.
- 2. A method of claim 1 wherein one of the donor FRET moiety or acceptor FRET moiety of the two oligonucleotides of the nucleic acid amplification reaction is a fluorescent signaling moiety kept quenched when the labeled oligonucleotide is not incorporated into the amplification product, and wherein the same labeled oligonucleotide, when incorporated into the amplification product, is adapted to generate signal through removal of quenching by separating quencher from the signaling moiety.
- 19. A kit for use in the method according to any one of claims 1 to 12 comprising
- a polymerase or polymerases
- a first oligonucleotide of sequence complementary to the nucleotide sequence flanking a target nucleotide

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sequence suitably labeled with a donor FRET moiety 2-10 nucleotides away from the  $3^\prime$  end

- a second oligonucleotide of sequence at 5'end of the first nucleotide sequence complementary to the nucleotide sequence flanking the target nucleotide sequence or the segment of the target nucleotide sequence suitably labeled with an acceptor FRET moiety 2-10 nucleotides away from the 3' end
- deoxy nucleotides in a solution of water or buffer or lyophilized
- a reaction buffer for the nucleic acid amplification reaction

wherein the first and the second oligonucleotide sequences serve as the two primers of the nucleic acid amplification reactions and are adapted to generate a detectable signal whereby if the two oligonucleotides get incorporated into two opposite strands of the amplified product and come thereby in right proximity, and wherein the donor and acceptor moieties are adapted to be separated from one another by 3-20 nucleotide pairs in the final amplification product.

- 20. A kit according to claim 19 wherein the acceptor labeled second oligonucleotide is provided quenched by i) using one additional oligonucleotide suitably labeled with quencher, or ii) providing the oligonucleotide in a hair-pin configuration."
- Claims 3 to 12 define specific embodiments of the method of claim 1, claim 13 defines the use of any of the preceding methods in real time expression profiling, claims 14 to 18, 23 and 24 define specific embodiments of the claimed methods and uses, and claims

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21 and 22 define specific embodiments of the kits of claims 19 and 20.

IX. The arguments of the appellant, as far as relevant for the present decision, are summarized as follows:

Basis for amended claim 20 could be found in claim 43 as originally filed. The amendment rendered the claim clear and the requirements of Article 84 EPC were satisfied.

X. The appellant requests that the decision under appeal be set aside and a patent be granted on the basis of the claims of the main request filed with the grounds of appeal.

### Reasons for the Decision

Article 113(1) EPC and Rule 15(3) Rules of Procedure of the Boards of Appeal (RPBA)

- 1. The appellant decided not be represented at the oral proceedings.
- 2. The appellant can reasonably expect that during the oral proceedings the board will consider the objections and issues raised in its communication. By not attending the oral proceedings, the appellant effectively chooses not to avail itself of the opportunity to present its observations and counterarguments orally but instead to rely on its written case (cf. Article 15(3) RPBA; Case law of the Boards of Appeal, 7th edition, III.B.2.3.3, page 495).

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## File history

- 3. In a first communication, the examining division raised some objections under Articles 123(2) and 84 EPC (cf. points 1 and 4 of the communication dated 16 July 2009). In response, the applicant filed a new set of claims. In a second communication, annexed to summons to attend oral proceedings, the examining division raised further, different objections under Articles 123(2) and 84 EPC. In response, the applicant submitted a new main request and an auxiliary request. In a telephone consultation held on 12 September 2012, the first examiner gave a detailed preliminary opinion on the allowability of the requests on file. At the oral proceedings before the examining division, the applicant replaced the previously filed requests by a new main request (MR-1). After hearing the applicant, the examining division decided that this request was not allowable. A further main request (MR-2) was not admitted (cf. point 2 of the decision under appeal).
- 4. With its grounds of appeal, the appellant filed a new main request.

## Article 84 EPC

- 5. Independent claim 19 defines a kit comprising a second oligonucleotide complementary to the nucleotide sequence flanking the target nucleotide sequence or the segment of the target nucleotide sequence suitably labeled with an acceptor FRET moiety 2-10 nucleotides away from the 3' end (cf. item VIII, above).
- 6. Amended claim 20, depending on independent claim 19, (cf. item VIII above) specifies two different ways of providing the acceptor labeled second oligonucleotide

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quenched. Alternative (ii), "providing the oligonucleotide in a hair-pin configuration" has been newly added in the appeal procedure.

- 7. The signal of an acceptor molecule located near the 3' end of the second oligonucleotide will only be quenched upon formation of a hair-pin structure (as required by claim 20 ii)), if a quencher is attached near its 5' end (cf. description, page 19, lines 20 to 26, and page 22, lines 23 to 29).
- 8. In its communication annexed to the summons to oral proceedings, the board indicated its preliminary opinion that new claim 20 ii) lacked essential technical features. It informed the appellant that the hairpin conformation alone was not sufficient to provide quenching and that a quencher had to be attached to the 5' end of the oligonucleotide.
- 9. The appellant neither responded to this communication in writing nor did it attend the oral proceedings.
- 10. Since neither the presence of a quencher nor the technical information concerning the location of the quencher molecule with regard to the structure of the acceptor labeled oligonucleotide is stated in claim 20 ii), the claim defines its subject matter insufficiently and does not meet the requirements of Article 84 EPC.
- 11. Since claim 20, and as a consequence the main request, does not meet the requirements of Article 84 EPC, the board sees no necessity to examine compliance of the claims of appellant's sole request with the other requirements of the EPC.

# Order

# For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



A. Wolinski

M. Wieser

Decision electronically authenticated