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Datasheet for the decision of 26 October 2018

Case Number: T 2200/13 - 3.3.06

Application Number: 07855599.2

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Language of the proceedings: EN

Title of invention:
MICROFLUIDIC SYSTEM AND METHOD TO TEST FOR TARGET MOLECULES IN A BIOLOGICAL SAMPLE

Applicant:
Fio Corporation

Headword:
Microfluidic system/Fio Corporation

Relevant legal provisions:
EPC Art. 84, 123(2)

Keyword:
Amendments - allowable (no) - Main Request
Claims - Clarity and Support by the description (no) - Main Request

Decisions cited:

Catchword:

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Case Number: T 2200/13 - 3.3.06

D E C I S I O N
of Technical Board of Appeal 3.3.06
of 26 October 2018

Appellant: (Applicant)	Fio Corporation 111 Queen Street East, Suite 500 Toronto, ON M5C 1S2 (CA)
Representative:	Grünecker Patent- und Rechtsanwälte PartG mbB Leopoldstraße 4 80802 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 14 May 2013 refusing European patent application No. 07855599.2 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	J.-M. Schwaller
Members:	G. Santavicca
	R. Cramer

Summary of Facts and Submissions

I. The appeal lies from the decision of the Examining Division to reject the European patent application n° **07855599.2**.

II. The application was refused because the claims of the Main Request and of Auxiliary Requests 2 and 3 did not comply with Article 123(2) EPC, whilst Auxiliary Request 1 was not admitted because its claims concerned not searched subject-matter.

III. With its statement setting out the grounds of appeal the Applicant filed a new set of Claims 1 to 3 as its sole and Main Request, allegedly based on Auxiliary Request 3 then pending before the Examining Division and overcoming all of the grounds of refusal.

Claim 1 thereof reads as follows (amendments to Claim 1 as originally filed made apparent by the Board):

"*1. A test system for use with a buffer to test for the presence of target molecules of one or more target types in a biological test sample, the test system comprising:*

a) a first set of test molecules ~~*selected from the group consisting of i)*~~ ***wherein the test molecules are*** *biorecognition molecules (BRMs) of one or more BRM types,* ***comprising microbeads tagged with one or more BRM fluorophores coupled to the microbead,*** *wherein each of the BRM types is conjugable with a respective one of the target* ~~*types*~~ ***molecules, the BRM fluorophore being such as to emit at least a BRM part of the fluorescence spectrum after absorption of EMF radiation,*** *and* ~~*ii) conjugates of the BRMs and the target molecules, if*~~

~~present in the test sample,whereinthe conjugates are of one or more conjugate types~~ **target marker fluorophores conjugable with the target molecules, the target marker fluorophore being such as to emit at least a target part of the fluorescence spectrum after absorption of EMF radiation, wherein the BRMs and target marker fluorophores form one or more conjugate types with the target molecules if present in the biological test sample,** each **conjugate type** corresponding to a different one of the BRM types in conjugation with its said respective one of the target types;

b) a microfluidic chip comprising a chip substrate portion shaped to define:

i) one ~~or more~~ elongate sample channel therein sized to enable passage therethrough of the test molecules; and

ii) ~~one or more~~ **two** flow focusing channels **adjoining the one elongate sample channel upstream of the aforesaid elongate sample channel,** therein for operative passage therethrough of the buffer, with the ~~one or more~~ flow focusing channels adjoining the ~~one or more elongated~~ sample channel~~s~~ **from opposing sides,** with the buffer exiting from the flow focusing channels operatively directing a single-file stream of the test molecules through the sample channel~~s~~;

c) an irradiating device operatively delivering electromagnetic frequency (EMF) radiation, at an irradiation position along said ~~at least one of the~~ sample channel~~s~~, for absorption by the test molecules in the single-file stream, ~~the test molecules emit fluorescence after absorption of the EMF radiation, and~~ wherein the fluorescence of the test molecules

comprises a distinct fluorescent spectrum for each one of the conjugate types; and

d) a detection device ***wherein the detection device comprises at least two avalanche photodetectors (APD)*** *monitoring the single-file stream for the fluorescence emitted by the test molecules,* ~~*wherein the detection device identifies the presence of the conjugates in the first set of test molecules by monitoring for teh distinct fluorescent spectrum of each one of teh conjugate types*~~ ***a first one of the avalanche photodetectors adapted to receive and identify the presence of the BRM part of the fluorescence emitted by the test molecules and a second one of the avalanche photodetectors adapted to receive and identify the presence of the target part of the fluorescence emitted by the test molecules;***

whereby the test system identifies the presence of the target molecules in the test sample."

Dependent Claims 2 and 3 concern particular embodiments of the test system according to Claim 1.

IV. The **Appellant** (**Applicant**) requested in writing that the decision under appeal be set aside and that a European patent be granted on the basis of Claims 1 to 3 according to sole and Main Request filed with the statement setting out the grounds of appeal.

V. After the summons to oral proceedings, the Board issued a communication expressing its provisional opinion on the salient issues of the case. In particular, objections were raised against the formal allowability and the clarity of amended Claim 1.

VI. By phone call on 24 October 2018, the Appellant informed the Board that it would not attend the set oral proceedings. No response whatsoever to the Board's communication ever reached the Board.

VII. Oral proceedings were held on 26 October 2018 as scheduled, in the announced absence of the Appellant, pursuant to Rule 115(2) EPC.

Reasons for the Decision

Amendments - Article 123(2) EPC

1. Claim 1 at issue is based on originally filed claims 1, 2, 11 and 18, however with exceptions and consequences as follows:

1.1 Original Claim 1 generally defines the test system, in particular its features a) and a)i), b), i) and ii), c) and d), which constitutes the backbone of the original, general disclosure of the invention.

1.1.1 Feature a) of Claim 1 at issue still mentions original feature a), "*a first set of test molecules*", and includes original feature a)i), without however mentioning original feature a)ii), i.e. the "*conjugates of the BRMs*".

1.1.2 The Board accepts that the "*conjugates*" are not part of a test system which is not yet in use.

1.1.3 An objection under Article 123(2) EPC however arises from
- the insertion of the feature "*and target marker fluorophores* ...", not present in original Claim 1,

which is defined in original Claim 9 only in combination with the "*conjugates*",
- its combination with the feature "*first set of test molecules*", and
- the generalisation arising from the non definition that the target markers are as such not part of the BRMs.

1.2 A further objection arises from the amendment "*a respective one ... molecule*" (Claim 1, line 6), insofar according to original Claim 1 (feature a)ii)), each of the BRM types conjugates with its ... respective one of the target types (see Claim 1 at issue, lines 12-14).

1.3 Original Claim 2 refers back to original Claim 1 and defines the features "*each of the BRMs comprises a microbead tagged with*" and "*comprising microbeads tagged with one or more BRM fluophores coupled to the microbead*" and "*... the BRM fluorophores emit at least a BRM part of the fluorescence of the distinct fluorescent spectrum after absorption of the EMF radiation*", in the context of feature a) of Claim 1.

1.3.1 Claim 1 at issue however no longer defines that **each** of the BRMs comprises the microbead tagged with fluorophores, nor that "*the BRM fluorophore**s** emit at least a BRM part of the fluorescence of the **distinct** fluorescent spectrum after absorption of the EMF radiation*". Therefore, also this amendment contravenes the requirement of Article 123(2) EPC.

1.4 Original Claim 18 refers back to the test system of original Claim 1 and defines that in the test system according to original Claim 1 "*the flow focusing channels comprise at least two flow focusing channels, adjoining the one or more elongate sample channels*

upstream of said at least one of the sample channels, with the two flow focusing channels adjoining the one or more elongate sample channels ***from opposing sides of said at least one of the sample channels***".

1.4.1 Instead, Claim 1 at issue (feature b)ii)) does not define that the two flow focusing channels adjoin the one elongate sample channel **from opposing sides of the (one) sample channel**.

1.4.2 This first generalisation is accompanied by another generalisation, insofar, according to the description, for a test system with two flow focusing channels (see in particular Figure 4G), a common intersection point appears to be necessary.

1.4.3 Therefore, Claim 1 at issue contravenes the requirements of Article 123(2) EPC also in this respect.

1.5 Original Claim 11 refers back to original Claim 1 and *inter alia* defines (last feature thereof) the limitation that the mentioned fluorescence is "*the fluorescence of the distinct fluorescent spectrum for said each conjugates*".

1.5.1 Claim 1 at issue contains the additional features of original Claim 11 but does not contain the said limitation of Claim 11.

1.5.2 This generalisation too does not comply with Article 123(2) EPC.

1.6 Summing up, Claim 1 at issue does not comply with Article 123(2) EPC, and the Main Request is not allowable already for this reason.

Amendments - Clarity and support by the description - Article 84 EPC

2. Claim 1 concerns a test system, i.e. a physical entity made up of several devices combined in a unit, which system includes the test molecules (BRM and markers) for the target determination.

2.1 This physical entity is defined in terms of physical/ apparatus features and use/purpose/functional features.

2.2 However, the use features are not limiting for the apparatus, apart from its suitability for the defined use. Claim 1 does not express clearly the suitability.

2.3 As the majority of the use features are not worded as suitability for the sought-for purpose (for instance, compare "*is conjugable*" with "*the BRMs and target marker fluorophores form ...*"), or "*with the buffer exiting from the flow focusing channels operatively directing ...*", a first objection of lack of clarity arises therefrom.

2.4 A second objection arises from the mixing up of physical and use features in Claim 1 at issue, compared to the wording of the original claims.

2.5 As Claim 1 does not define clearly that the marker molecules are distinct from the BRMs and that the flow focusing channels adjoin the sample channels from opposite sides thereof at a common intersection, it is not supported by the description either.

2.6 Thus, the Main Request is not formally allowable either in respect of the requirements of Article 84 EPC.

3. It follows from the foregoing reasons that the sole, Main Request of the Appellant does not comply with the EPC, and therefore is not allowable.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Magliano J.-M. Schwaller

Decision electronically authenticated