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Datasheet for the decision of 31 October 2019

Case Number: T 2148/13 - 3.3.01

Application Number: 03700843.0

Publication Number: 1463945

IPC: G01N33/543, G01N33/52, G01N31/22

Language of the proceedings: EN

Title of invention:
LIQUID SAMPLE ASSAY DEVICE

Applicant:
Alere Switzerland GmbH

Headword:
Urine assay device/ALERE

Relevant legal provisions:
EPC Art. 123(2), 54(2), 56
RPBA Art. 12(4)

Keyword:
Amendments - allowable (yes)
Novelty - (yes)
Inventive step - (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
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Beschwerdekammern

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Case Number: T 2148/13 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 31 October 2019

Appellant: (Applicant)	Alere Switzerland GmbH Bahnhofstrasse 28 6300 Zug (CH)
Representative:	Atkins, James Gordon John Kilburn & Strode LLP Lacon London 84 Theobalds Road London WC1X 8NL (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 16 May 2013 refusing European patent application No. 03700843.0 pursuant to Article 97(2) EPC**

Composition of the Board:

Chairman	A. Lindner
Members:	T. Sommerfeld
	P. de Heij

Summary of Facts and Submissions

I. The appeal lies from the decision of the examining division in which European patent application 03700843.0, based on an international application published as WO 03/058245, was refused under Article 97(2) EPC.

II. The documents cited in the examination and appeal proceedings include the following:

D1 US 3 811 840
D2 EP 0 560 411
D3 US 4 677 079
D4 WO 99/04256
D5 JP 6 201689 (English translation D5a, entitled "Translation of Prior Art Reference D1", submitted by the appellant by letter dated 24 April 2009)
D6 JP 2001 221798 (automatic translation by Thomson Reuters)
Annex IV: "Bicomponent Fiber" (www.fibersource.com/f-tutor/biocomponent.htm)
Annex V: "Bicomponent Fibers" (monograph by Hegde et al., www.engr.utk.edu/mse/Textiles/Bicomponent%20fibers.htm)
Annex VI: Definition of "Bicomponent Fiber" (www.answers.com/topic/bicomponent-fiber)
Annex VII: Abstract of Thesis submitted to North Carolina State University by Feng He (http://repository.lib.ncsu.edu/ir/bitstream/l 840.16/6543/1/etd.pdf)
Annex VIII: K. Porter, (ICI Fibres) pages 473-474; Kirk-Othmer, "Concise Encyclopedia of Chemical Technology" (1985)
Annex A: Experimental data submitted by letter of 1 October 2019

III. The decision of the examining division is based on the sets of claims of the main request and first to fifth auxiliary requests, all filed by letter of 22 March 2013.

The examining division decided that the main request and the first auxiliary request contravened Articles 123(2), 54 and 56 EPC, and that the second to fifth auxiliary requests contravened Article 123(2) EPC.

IV. The applicant (hereinafter, the appellant) lodged an appeal against the decision of the examining division, requesting that the decision be set aside and that a patent be granted or the case be remitted to the examining division with a set of claims according to the main request or auxiliary requests 1 or 2, all filed with the statement of the grounds of appeal. It also submitted new documents, labelled Annexes IV to VIII.

V. The board sent a communication pursuant to Rule 100(2) EPC and Article 17(1) RPBA, providing its preliminary opinion on Articles 123(2) and 54 EPC.

VI. The appellant filed a reply dated 11 February 2019, in which it submitted new auxiliary requests 2 and 3 and re-submitted the previous auxiliary request 2 as auxiliary request 4.

VII. With a further letter, dated 1 October 2019 and sent in preparation for oral proceedings, the appellant submitted experimental data labelled Annex A.

VIII. Oral proceedings took place as scheduled. At the end of oral proceedings the chair stated that the main request

was considered to fulfil the requirements of the EPC and announced the board's decision.

The **main request** comprises 12 claims, with claim 1 reading as follows:

"1. An assay device for use in the determination of the presence of at least one analyte of interest in a urine sample; the device comprising a reaction zone in which a reagent reacts with the analyte of interest and a bibulous member upstream of the reaction zone, which bibulous member, when contacted with the liquid sample, draws liquid therefrom towards the reaction zone; the bibulous member being formed of bicomponent fibres and comprising means to change colour when wetted by the sample, said means to change colour being a chemical species that changes colour in response to a property of the urine sample."

Dependent claims 2 to 12 are directed to various embodiments of the assay device of claim 1.

IX. The appellant's arguments, in so far as they are relevant to the present decision, may be summarised as follows:

The claimed subject-matter differed from the disclosure of D5a in two ways. First, D5a did not disclose a structure composed of bicomponent fibres. The term "bicomponent fibre" had a specific meaning to the skilled person. The passage on page 7, lines 9 to 10 of the application described one particular type of bicomponent fibre. It did not provide a definition of bicomponent fibres; this was given by Annexes IV, V and VII, which defined a bicomponent fibre as a fibre composed of two polymers in one single filament such

that the two polymers are in contact with each other along the entire length of the filament, from start to finish. This was different from printing a polymer composition "wetting checker" on a monocomponent fibre wick, as disclosed in D5a. Such a structure would not be understood as a bicomponent fibre, as explained in Annex A, page 10, which showed the different cross-sections for the absorbent structure prepared according to D5a and the bibulous member prepared with bicomponent fibres according to the application. Some portions of fibres in the structure of D5a could be coated with polymer, but there were no filaments composed of two polymers as in the bicomponent fibres because D5a did not disclose filaments being printed along their length: there was merely an amorphous structure, like a paste, covering and filling the gaps between fibres, not discrete filaments comprising two polymers each. Second, the claimed subject-matter required bicomponent fibres to not only be present, but also to constitute the scaffold of the bibulous member (page 4, second paragraph of the application as filed); it was not enough for some bicomponent fibres to be scattered around or on the surface of the structure. The surface fibres of D5a, which were the ones that could comprise two polymers, did not form the body-fluid collecting section, which was the structure disclosed in paragraph [0012] of D5a, not yet printed with the polymer-containing composition of paragraph [0021].

X. The appellant requests that the decision under appeal be set aside and a patent be granted on the basis of the main request or, alternatively, of auxiliary request 1, both filed with the statement of grounds of appeal dated 16 September 2013, or alternatively on the

basis of auxiliary requests 2 to 4, all filed with the letter dated 11 February 2019.

Reasons for the Decision

1. The appeal is admissible.

Main request

2. The main request was filed with the statement of grounds of appeal. Despite being a new request which had not been submitted before the examining division, the board considered it a legitimate attempt to redress the decision under appeal and therefore decided to admit it into the proceedings, pursuant to Article 12(4) RPBA.

3. Article 123(2) EPC

3.1 Claim 1 of the main request corresponds to claim 1 as filed, with the following amendments:

"1. An assay device for use in the determination of the presence of at least one analyte of interest in a ~~liquid~~ urine sample; the device comprising a reaction zone in which a reagent reacts with the analyte of interest and a bibulous member upstream of the reaction zone, which bibulous member, when contacted with the liquid sample, draws liquid therefrom towards the reaction zone; the bibulous member being formed of bicomponent fibres and comprising means to change colour when wetted by the sample, said means to change colour being a chemical species that changes colour in response to a property of the urine sample."

3.2 The basis for these amendments is found in the following passages of the application as filed: page 3, second paragraph ("urine sample"); page 3, third paragraph, line 1 ("upstream of the reaction zone"); page 4, second paragraph ("the bibulous member being formed of bicomponent fibres"); page 5, fourth paragraph and claim 2 as filed (the "means to change colour being a chemical species..."). All the features of the claim are thus considered to have a basis in the application. There is also a basis for the combination of said features, in particular for the combination of urine sample and bicomponent fibres; in fact, the urine sample is the only specific example of a liquid sample given in the application (discussed e.g. in the summary of the invention on page 3, second paragraph), and the choice of bicomponent fibres from among other possible fibres (page 4, second paragraph) requires just a single selection. The feature of the bibulous member being upstream of the reaction zone generally applies to all embodiments (page 3, third paragraph).

3.3 The dependent claims have a basis in either the claims as originally filed or passages of the description as filed, such as page 4, second paragraph (claims 3 and 5); page 4, last sentence (claim 4); page 7, second paragraph (claim 6), and Example 2.1 on page 13 (claim 12).

3.4 The board thus comes to the conclusion that the main request fulfils the requirements of Article 123(2) EPC.

4. Article 54(2) EPC

4.1 Document D5a discloses an assay device with all the claimed features, except that it does not disclose that

the bibulous member is formed of bicomponent fibres. In the decision under appeal, the examining division appears to have considered that D5/D5a did not disclose the use of bicomponent fibres in its device but that it did disclose the use of polymer fibres coated by other polymers which, although possibly produced by a different method from that used for producing bicomponent fibres, were structurally identical in the final product: according to the application (page 7, second paragraph), bicomponent fibres included sheath-core fibres, i.e. fibres in which only one of the components has an external boundary, which would thus be structurally indistinguishable from the "coated fibres" described in paragraph [0021] of D5a.

4.2 The board is convinced by the appellant's arguments that a bibulous member formed of bicomponent fibres, as claimed, is structurally distinct from the body-liquid collecting member of D5/D5a. In view of the evidence on file, in particular Annexes IV, V and VII, the board accepts that the term "bicomponent fibres" is a term with a defined meaning in the art and would thus be interpreted by the skilled person as referring to a fibre which is "comprised of two polymers of different chemical and/or physical properties (...) with both polymers within the same filament" (Annex IV, under "Definition"). A similar definition is also provided in Annex V, first sentence of "Introduction", which also states that "both polymers [are] contained within the same filament", and in Annex VII, first sentence, which reads "Bicomponent fiber technology combines two polymers by coextruding them to form a single filament with a designed cross-sectional arrangement". Examples of such bicomponent fibre configurations are shown as cross-sections in Annex IV and in Annex V (second page). Annex V, page 3 further shows configurations of

sheath-core bicomponent fibres, which are defined as "fibers where one of the components (core) is fully surrounded by the second component (sheath)" (page 3, first sentence of section 5.2). It is thus apparent from these definitions that the concept of bicomponent fibres requires not only that two different fibres are present but also that they are present within one single filament, in a designed cross-sectional arrangement; it is also apparent that sheath-core bicomponent fibres are one particular type of bicomponent fibres. Hence the board accepts the appellant's arguments that the passage on page 7, lines 9 and 10 of the application is not a definition of bicomponent fibres but merely an exemplification of one possible embodiment, namely of a sheath-core fibre.

4.3 The assay device of D5a, and in particular its "body fluid collecting section" or "absorption unit", which is the structure corresponding to the bibulous member of the device as claimed, does not exhibit a structure of a bicomponent fibre. While the "body fluid collecting section" of D5a can be made of any suitable material, including those which are recognisably fibrous polymers (e.g. cellulose, in paragraph [0012]), there is no disclosure that it should be composed of two different polymers within one filament. Even when combined with the teaching of paragraph [0021], which discloses that the "urine wetting-checker" (which has a composition also comprising fibre polymers) is "printed on a part or the entirety of the urine-collecting section", the resulting product is still not structurally identical to the device as claimed. This is because, although some or even all of the polymers on the surface of the urine-collecting section may be coated with polymers of the urine wetting-checker, the obtained structure is not one where single fibre

filaments comprise the two polymers over their full length, as is the case for bicomponent fibres: the two polymers do not necessarily run in parallel along a fibre filament, but rather have completely independent distributions. In addition, as the appellant correctly pointed out, there is no indication in document D5a that the printing also affects the core polymers. It can therefore not be concluded that the absorption unit/bibulous member is formed of bicomponent fibres as it may also include monocomponent fibres. Hence the board comes to the conclusion that the assay device as claimed is structurally distinct from that disclosed in D5a.

4.4 Claim 1 of the main request is thus novel (Article 54(2) EPC).

5. Article 56 EPC

5.1 In the decision under appeal, the examining division came to the conclusion that even if the claimed subject-matter were considered novel over D5a it would still not be allowable for lack of inventive step. Without formulating a technical problem, the examining division essentially argued that there was no evidence demonstrating an unexpected technical effect and that therefore the claimed subject-matter lacked inventive step.

5.2 The board agrees that document D5a, which like the present application is related to assay devices for the examination of body fluids (in particular urine), is the closest prior art. The difference from the claimed subject-matter is, as discussed above, that D5a does not disclose that the absorbent member is formed of bicomponent fibres. The board also agrees with the

examining division that the application contains no evidence of an unexpected technical effect associated with said difference. The technical problem thus has to be formulated as the provision of an alternative assay device for the examination of urine samples. The solution is the device as claimed and the board is satisfied that the technical problem is solved.

5.3 It next has to be examined whether the skilled person starting from the closest prior art D5a would arrive at the claimed solution without the need for inventive skill.

5.4 There is no hint or suggestion in D5a that would lead the skilled person to consider using other types of configurations for the assay device, in particular making use of bicomponent fibres. Hence, from document D5a alone the skilled person would not arrive at the claimed subject-matter in an obvious way. No further document has been cited by the examining division in the context of the claimed subject-matter. Document D1 had been discussed but in the context of the then broader claims, which were not restricted to the use of bicomponent fibres (international preliminary examination report, section V, and communication of the examining division dated 14 December 2007, page 2), and document D6 was relied upon at a later stage in order to substantiate that the use of phloxine B as the indicator reagent for urine samples was known (communication of the examining division dated 24 April 2013, last paragraph of page 2). None of these documents refers to bicomponent fibres, either explicitly or implicitly. The same is also true for the other documents on file, D2 to D4. In addition, the board sees no reason to assume that the use of bicomponent fibres is one of several options the

skilled person, applying their common general knowledge, would contemplate when asked to provide an alternative assay device and from which they would then make an arbitrary selection. Accordingly, the board considers that the skilled person would not arrive at the claimed subject-matter in an obvious way.

5.5 Claim 1 of the main request is thus considered to comply with the requirements of Article 56 EPC. The same applies to the dependent claims.

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 with the order to grant a patent on the basis of the set of claims of the main request, filed with the statement of grounds of appeal, and a description to be adapted thereto.

The Registrar: The Chair:

M. Schalow A. Lindner

Decision electronically authenticated