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**Datasheet for the decision
of 6 December 2018**

Case Number: T 0589/13 - 3.3.01

Application Number: 06737827.3

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IPC: G01N33/543, G01N33/52,
G01N33/53, C12Q1/00

Language of the proceedings: EN

Title of invention:
DUAL PATH IMMUNOASSAY DEVICE

Applicant:
Chembio Diagnostic Systems, Inc.

Headword:
Immunoassay device/CHEMBIO DIAGNOSTIC SYSTEMS

Relevant legal provisions:
EPC Art. 122, 123(2)

Keyword:
Re-establishment of rights - (yes) - time limit for filing
statement of grounds
Amendments - allowable (no)

Decisions cited:
G 0002/10

Catchword:



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Case Number: T 0589/13 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 6 December 2018

Appellant: Chembio Diagnostic Systems, Inc.
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Medford, NY 11763 (US)

Representative: K&L Gates LLP
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Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 23 May 2012
refusing European patent application No.
06737827.3 pursuant to Article 97(2) EPC**

Composition of the Board:

Chairman A. Lindner
Members: T. Sommerfeld
M. Blasi

Summary of Facts and Submissions

- I. The appeal lies from the decision of the examining division in which European patent application no. 06737827.3, based on an international application published as WO 2006/099191, was refused under Article 97(2) EPC.

At oral proceedings, the examining division decided that the set of claims of the main request was not allowable for lack of novelty and inventive step, and that the set of claims of the auxiliary request fulfilled the requirements of the EPC. An amended description filed at oral proceedings was also considered allowable. The examining division then issued a communication under Rule 71(3) EPC, dated 11 October 2011, informing of the intention to grant a patent on the basis of the claims of the auxiliary request, the amended pages of the description and the drawings, together with further amendments proposed by the examining division. The applicant disapproved of the proposed grant based on the amended auxiliary request, and requested that the patent be granted based on the main request. The examining division then issued the presently appealed decision, according to which the amended description and drawings submitted with letters of 10 January 2010, 27 October 2010 and 2 August 2011 were found to contravene Article 123(2) EPC and the claims according to the main request, submitted at the oral proceedings on 12 September 2011, to contravene Articles 54(2) and 56 EPC.

- II. 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 on the basis of the application

documents of the main request, comprising claims 1 to 3 and 10 to 21 filed with the grounds of appeal and claims 4 to 9 attached to the communication under Rule 71(3) EPC, or, alternatively, on the basis of the application documents of the auxiliary request attached to the communication under Rule 71(3) EPC, with further corrections to the description.

Claim 1 of the **main request** reads as follows:

"1. An immunoassay test device (10,10a,10b,10',110,10c,10d,10e,210) for use with an immunoassay conjugate having a marker, the test device for determining the presence of a ligand in a liquid sample, the test device comprising:

- a) a first sorbent strip (30,30',130,230) having a solution receiving location (24,24',124) arranged to receive a solution of an immunoassay conjugate having a marker, or a buffer solution when a dry system including an immunoassay conjugate having a marker supported by said first sorbent strip is used, and to define a horizontal solution migration path;
- b) a test site (33,33',133,233) having an immobilized ligand-binding mechanism and being in communication with said solution migration path;
- c) a second sorbent strip (32,32',32''',132,232) having a sample receiving location (26,26',126) arranged to receive the liquid sample; and
- d) a horizontal sample migration path extending from said sample receiving location to said test site, characterised in that said second strip is a separate piece to said first sorbent strip, the first and second sorbent strips being non-parallel, with the second sorbent strip touching and overlying the first sorbent strip at the test site, the second sorbent strip defining the horizontal migration path such that

application of the liquid sample to the sample receiving location requires the liquid sample to flow through said sample migration path to said test site, wherein said horizontal sample migration path is distinct from said solution migration path and is not in communication therewith except via the test site."

Claim 1 of the **auxiliary request** differs from claim 1 of the main request essentially in that item d) has been amended as follows:

"1. ...

d) a horizontal sample migration path extending from said sample receiving location to said test site, characterised in that said ~~second strip is a separate piece to said first sorbent strip~~ **first sorbent strip has pores of a first pore size and said second sorbent strip has pores of a second pore size larger than the first pore size, the and in that said first sorbent strip and said second sorbent strip** ~~first and second sorbent strips being~~ **are arranged** non-parallel, ~~with the~~ **such that said** second sorbent strip ~~touching~~ **touches** and ~~overlying~~ **overlies** the **said** first sorbent strip at the test site, ~~the second sorbent strip defining~~ **and defines** the horizontal **sample** migration path such that ..."

The statement of ground of appeal was filed after expiry of the relevant time limit, together with a substantiated request for re-establishment of rights. The fee for re-establishment had been duly paid.

III. In a first communication of 17 December 2013, the board informed the appellant that re-establishment of rights in respect of the time limit for filing the statement of grounds of appeal would be granted. At a later stage

and as an annex to the summons to oral proceedings (Article 15(1) RPBA), the board issued a communication providing a preliminary opinion on some issues to be discussed, in particular Article 123(2) EPC.

- IV. Oral proceedings took place on 6 December 2018 as scheduled. At the end of the oral proceedings, the chairman announced the board's decision.
- V. The appellant's arguments may be summarised as follows:

For the purposes of Article 123(2) EPC, the whole application, including the drawings, should be taken into account. Basis for claim 1 of the main request was found in claims 1, 3, 13 and 32 as filed; Figures 1 to 5, in particular Figures 1A and 1B; and description paragraphs [0017], [0018], [0021], [0023], [0050] and [0051]. The "non-parallel" feature had no literal basis in the application as filed but was implicit in the disclosure of paragraph [0021] (last 4 lines). Article 123(2) EPC did not require literal support. Instead the "gold standard" according to G 2/10 was to be applied. As to claim 1 of the auxiliary request, basis for the additional feature was found in claims 9 and 10 as filed.

- VI. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the claims and the description as specified in the statement of grounds of appeal (main request), or alternatively, on the basis of the auxiliary request identical to auxiliary request 1 attached to the communication under Rule 71(3) EPC dated 11 October 2011 subject to the further amendments to the description as specified in the statement of grounds of appeal.

Reasons for the Decision

1. Request for re-establishment of rights and admissibility of the appeal

1.1 As reasoned in the board's communication dated 17 December 2013, this request was found to be admissible, since it was filed within the time limits specified in Rule 136(1) EPC. It was also found to comply with the requirements of Article 122(1) EPC, because the board was convinced by the appellant's arguments that the failure to meet the time limit for filing the statement of grounds of appeal was due to an isolated mistake, which occurred in spite of all due care having been taken.

1.2 Hence, in accordance with Article 122(3) EPC, the legal consequences of the failure to observe the time limit is deemed not to have ensued. Thus, the appeal is considered to have complied with the four-month time limit of Article 108, third sentence, EPC.

1.3 The further requirements under Articles 106 to 108 and Rule 99 EPC have likewise been met. Thus, the appeal is admissible.

2. Article 123(2) EPC

2.1 Main request

2.1.1 According to Article 123(2) EPC, the European patent application or European patent must not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed.

As defined by the Enlarged Board of Appeal in decision G 2/10 (OJ EPO 2012, 376), the "gold standard" for Article 123(2) EPC is that any amendment to any part of a European patent application or patent relating to the disclosure (description, claims and drawings) can only be made within the limits of what a skilled person would derive directly and unambiguously, using common general knowledge, and seen objectively and relatively to the date of filing, from the whole of these documents as filed (G 2/10 cited above, reasons 4.3).

2.1.2 Claim 1 as filed reads as follows:

"1. A test device for determining the presence of a ligand in a liquid sample, comprising:
a) a first sorbent strip having a first location for receiving a solution and defining a first migration path;
b) a second sorbent strip distinct from said first sorbent strip having a second location for receiving the liquid sample and defining a second migration path distinct from said first migration path; and
c) a test site located on or in at least one of said first sorbent strip and said second sorbent strip, said test site having an immobilized ligand-binding mechanism, and said first and second sorbent strips touching each other at the test site."

2.1.3 As is apparent below, claim 1 of the main request differs from claim 1 as filed in that a number of amendments were made, such as insertions (in bold) and deletions (struck through):

"1. **An immunoassay test device (10,10a,10b,10',110,10c, 10d,10e,210) for use with a immunoassay conjugate having a marker, the** ~~A~~-test device for determining the

presence of a ligand in a liquid sample, **the test device** comprising:

a) a first sorbent strip (**30,30',130,230**) having a ~~first location for receiving a solution~~ **receiving location (24,24',124) arranged to receive a solution of an immunoassay conjugate having a marker, or a buffer solution when a dry system including an immunoassay conjugate having a marker supported by said first sorbent strip is used,** and ~~defining to define a first horizontal solution migration path;~~

e) ~~b) a test site (33,33',133,233) located on or in at least one of said first sorbent strip and said second sorbent strip, said test site having an immobilized ligand-binding mechanism, and said first and second sorbent strips touching each other at the test site.~~ **and being in communication with said solution migration path,**

b) ~~c) a second sorbent strip (32,32',32'',132,232) distinct from said first sorbent strip having a second sample receiving location (26,26',126) arranged to receive for receiving the liquid sample and defining a second migration path distinct from said first migration path; and~~

d) a horizontal sample migration path extending from said sample receiving location to said test site, characterised in that said second strip is a separate piece to said first sorbent strip, the first and second sorbent strips being non-parallel, with the second sorbent strip touching and overlying the first sorbent strip at the test site, the second sorbent strip defining the horizontal migration path such that application of the liquid sample to the sample receiving location requires the liquid sample to flow through said sample migration path to said test site, wherein said horizontal sample migration path is

distinct from said solution migration path and is not in communication therewith except via the test site."

- 2.1.4 The appellant indicated a number of passages in the application as filed as basis for claim 1 of the main request, namely: claims 1, 3, 13 and 32; Figures 1 to 5, in particular Figures 1A and 1B; and description paragraphs [0017], [0018], [0021], [0023], [0050] and [0051].
- 2.1.5 Claims 3, 13 and 32 as filed are all solely dependent on claim 1 as filed, further characterising the claimed test device of claim 1 by defining that the "first sorbent strip supports a conjugate" (claim 3), that the "said solution comprises a buffer" (claim 13) and that "said first sorbent strip and said second sorbent strip are arranged in a non-parallel configuration" (claim 32). None of these claims (nor any other claims as filed) relates to an immunoassay test device or discloses the use of an immunoassay conjugate or provides basis for any of the other amendments in present claim 1.
- 2.1.6 As to the cited passages of the description as filed, paragraphs [0017] and [0018] disclose immunoassay devices which can use either a dry or a liquid conjugate system but fail to disclose any of the other features of the claim, including "sorbent strip" or that the two sorbent pieces, let alone strips, should be non-parallel. Likewise, paragraphs [0021] and [0023] do not disclose sorbent strips either, nor the non-parallel configuration, but rather refer to "sorbent material", which does not impose any restrictions as to the form of the material, let alone that it should be in the form of a strip and that the two strips should be non-parallel. Instead, paragraph [0021] refers to

"test cells with a first sorbent material" and to "a second sorbent material" and paragraph [0023] teaches that "the first sorbent material and second sorbent material are separate pieces which overlie one another". Paragraphs [0050] and [0051], on the other hand, are part of the section entitled "Detailed description of the preferred embodiments" and describe in detail Figures 1A and 1B. Again, none of these paragraphs discloses "sorbent strips" which should be non-parallel to each other. Moreover, they disclose specific devices defined by a number of characterising features which are not part of the claim: e.g. "test cell", "T-shaped housing", "first and second holes", etc. Hence, these passages of the description as filed, while disclosing some of the features added to claim 1, cannot provide a basis for the claimed combination of features.

2.1.7 Finally, Figures 1 to 5 as filed and, in particular, 1A and 1B, cannot provide a basis for the amendments either. While these drawings show representations of devices with rectangular and T-shaped forms, it is not at all evident and unambiguous that these are strips. Nor can this be considered implicit in light of description paragraphs [00050] and [0051], which constitute the detailed disclosure of Figures 1A and 1B as set out above. Paragraphs [0052], [0057], [0059] and [0061], which also provide a detailed disclosure of Figures 1, 3, 4 and 5, respectively, disclose the use of "strips", but these are always further defined as being nitrocellulose strips, a feature which is not part of the present claim. Moreover, further characterising features are disclosed in these paragraphs which are not part of the claimed subject-matter.

- 2.1.8 The appellant essentially argued that, while the "non-parallel" feature had no literal basis in the application as filed, it was nevertheless implicit in the disclosure of paragraph [0021] and that by reading the application as filed as a whole, it would be evident that the figures represented strips in accordance with the claims as filed.
- 2.1.9 The board disagrees that paragraph [0021] of the description as filed provides an implicit disclosure of non-parallel sorbent strips as required by claim 1. Paragraph [0021] discloses that the first and second paths, defined, respectively, by the first and second sorbent materials, should be both horizontal and distinct from each other and further explains that "the term 'distinct' when used in conjunction with the words 'flow path' or 'migration path' shall be understood to mean 'not in fluid communication except via a test zone'". The board fails to see how this definition can be interpreted to imply that the two sorbent materials/ strips should not be parallel to each other. In fact, it can only be deduced from this passage that the two migration paths, defined by the two sorbent materials, should be horizontal and should not communicate with each other except in the test zone. The board can conceive configurations fulfilling this requirement and still having a parallel disposition of the two sorbent materials: e.g. two overlying, parallel, sorbent strips, separated from each by an impermeable material (hence, not allowing fluid communication between the two), except at the test site, where fluid communication between the two strips is made possible by the absence of the impermeable material.

2.1.10 As to the interpretation of the drawings in light of the claims, the board notes that the drawings, as set out above, have been extensively and explicitly described in the above-mentioned passages of the description as filed and would thus have been interpreted according to these passages rather than according to the claims as filed, which made no reference at all to the drawings.

2.1.11 The main request is thus considered to contravene Article 123(2) EPC.

2.2 Auxiliary request

2.2.1 Claim 1 of this request differs from claim 1 of the main request essentially in that one further feature has been added (see section II for the exact wording). Although a basis for this added feature can be found in claims 9 and 10 as filed, this claim still suffers from the same deficiencies under Article 123(2) EPC as claim 1 of the main request, further aggravated by the combination with one additional feature.

2.2.2 The auxiliary request thus also contravenes Article 123(2) EPC.

3. As neither the main nor the auxiliary request complies with the requirements of the EPC, the appeal must be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



M. Schalow

A. Lindner

Decision electronically authenticated