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Datasheet for the decision of 15 November 2013

Case Number: T 1592/10 - 3.3.02

Application Number: 06801773.0

Publication Number: 1960784

IPC: G01N33/558, C12Q1/37

Language of the proceedings: EN

Title of invention:
DETECTION OF SECRETED ASPARTYL PROTEASES FROM CANDIDA SPECIES

Applicant:
KIMBERLY-CLARK WORLDWIDE, INC.

Headword:
Detection of Candida Protease/KIMBERLY-CLARK

Relevant legal provisions:
EPC Art. 123(2)
EPC R. 103(1)(a)

Keyword:
Oral proceedings - held in absence of appellant
Amendments - allowable (no)
Reimbursement of appeal fee - (no)

Decisions cited:

Catchword:

Beschwerdekammern
Boards of Appeal
Chambres de recours

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Case Number: T 1592/10 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 15 November 2013

Appellant: (Applicant)	KIMBERLY-CLARK WORLDWIDE, INC. 401 North Lake Street Neenah, WI 54956 (US)
Representative:	Zimmermann & Partner Postfach 330 920 80069 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 19 April 2010 refusing European patent application No. 06801773.0 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman: U. Oswald
Members: T. Sommerfeld
R. Cramer

Summary of Facts and Submissions

I. The appeal lies from the decision of the examining division pronounced on 16 March 2010 and posted on 19 April 2010, in which the European patent application 06801773.0, based on international application published as WO 2007/070123, was refused under Article 97(2) EPC.

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

D1 Na Byoung-Kuk et al., 1999, Clin. and Diagn. Labor. Immunol., vol. 6, no. 6, pages 924-929

D2 Borg-von Zepelin m. et al., 1993, J. of Med. and Veterin. Mycol., vol. 31, no. 1, pages 1-15

III. The decision of the examining division is based on the set of claims of the main request, which consisted of the claims as published, and auxiliary request 1 filed during oral proceedings on 16 March 2010.

The set of claims according to the main request comprised 21 claims, of which independent claims 1 and 11 read as follows:

"1. A diagnostic test kit for detecting a secreted aspartyl protease protein within a test sample, the diagnostic test kit comprising:

an assay device comprising a fluidic medium, the fluidic medium defining a detection zone within which is immobilized a receptive material, wherein the detection zone is capable of generating a detection signal that corresponds to the presence or absence of a secreted aspartyl protease protein; and

a detection probe conjugated with a binding member;

wherein the receptive material, the binding member, or both contain a first antibody that is capable of specifically binding to the secreted aspartyl protease protein."

"11. A method for detecting the presence of a secreted aspartyl protease protein within a test sample, said method comprising:

i) providing an assay device that comprises a fluidic medium, the fluidic medium defining a detection zone within which is immobilized a receptive material, the detection zone being in fluid communication with detection probes conjugated with a binding member, wherein the receptive material, the binding member, or both contain a first antibody that is capable of specifically binding to the secreted aspartyl protease protein;

ii) contacting the assay device with the test sample; and

iii) generating a detection signal within the detection zone that corresponds to the presence or absence of the secreted aspartyl protease protein."

Claims 1 and 7 of auxiliary request 1 differed from claims 1 and 11, respectively, of the main request by the following amendments (additions underlined, deletions struck through).

"1. A diagnostic test kit for detecting a secreted aspartyl protease protein within a test sample, the diagnostic test kit comprising:

~~an~~ lateral flow assay device (20) comprising a porous membrane (23) or one or more fluidic channels as a fluidic medium, the fluidic medium defining a detection zone (31) within which is immobilized a receptive material, wherein the detection zone (31) is

capable of generating a detection signal that corresponds to the presence or absence of a secreted aspartyl protease protein; and

a detection probe conjugated with a binding member;

a calibration zone (32) upstream or downstream from the detection zone (31);

wherein the receptive material, the binding member, or both contain a first antibody that is capable of specifically binding to the secreted aspartyl protease protein."

"7. A method of ~~for~~ detecting the presence of a secreted aspartyl protease protein within a test sample, said method comprising:

i) providing a~~n~~ lateral flow assay device (20) that comprises a porous membrane (23) or one or more fluidic channels as a fluidic medium, the fluidic medium defining a detection zone (31) within which is immobilized a receptive material, the detection zone (31) being in fluid communication with detection probes conjugated with a binding member, wherein the receptive material, the binding member, or both contain a first antibody that is capable of specifically binding to the secreted aspartyl protease protein;

ii) contacting the assay device with the test sample; ~~and~~

iii) generating a detection signal within the detection zone (31) that corresponds to the presence or absence of the secreted aspartyl protease protein~~.~~; and

iv) generating a calibration signal within a calibration zone (32), the calibration zone (32) being either upstream or downstream from the detection zone (31), the calibration zone comprising a receptive material that is capable of binding to calibration probes that do not bind to the receptive material of the detection zone (31)."

IV. The examining division decided that the main request lacked clarity (Article 84 EPC), because the term "fluidic medium" in independent claims 1 and 11 was considered unclear and not suitable to confer novelty over the prior art, and that the auxiliary request did not fulfil the requirements of Article 56 EPC, because independent claims 1 and 7 lacked inventive step in view of the disclosures of documents D1 and D2.

V. The applicant (hereinafter, the appellant) lodged an appeal against the decision of the examining division, requesting the decision to be set aside and a patent to be granted according to the sole claim request filed with the statement of the grounds of appeal. Moreover the appellant requested reimbursement of the appeal fee.

The sole claim **request** on file comprises 7 claims, claim 1 of which reads as follows (amendments shown in relation to claim 11 of the main request considered by the examining division):

"1. A method for detecting the presence of a secreted aspartyl protease protein within a test sample, said method comprising:

i) providing ~~a~~ an lateral flow assay device (20) that comprises a porous membrane (23) or one or more fludic channels as a fluidic medium, the fluidic medium defining a detection zone (31) within which is immobilized a receptive material, the detection zone (31) being in fluid communication with detection probes conjugated with a binding member, wherein the receptive material, the binding member, or both contain a first antibody that is capable of specifically binding to the secreted aspartyl protease protein;

ii) contacting the assay device with the test sample, the test sample being blood, vaginal fluid, or urine; ~~and~~

iii) generating a detection signal within the detection zone (31) that corresponds to the presence or absence of the secreted aspartyl protease protein~~.~~;

iv) generating a calibration signal within a calibration zone (32), the calibration zone (32) being either upstream or downstream from the detection zone (31), the calibration zone (32) comprising a receptive material that is capable of binding to calibration probes that do not bind to the receptive material of the detection zone (31); and

v) measuring the intensity of the signals produced at the detection zone (31) and calibration zone (32) to semi-quantitatively of quantitatively detect the secreted aspartyl protease protein."

VI. On 25 June 2013, the board sent a summons to oral proceedings, scheduling oral proceedings for 15 November 2013.

In a communication sent on 28 August 2013, the board summarized the situation and expressed a detailed negative opinion on the set of claims on file, including observations in relation to admissibility (Article 12(4) RPBA), added subject-matter (Article 123(2) EPC) and inventive step (Article 56 EPC). In addition, the board indicated that, since the appellant had not given any reasons to justify its request for reimbursement of the appeal fee, it was likely that this request would be refused.

VII. The appellant did not file any substantive reply to the board's communication but instead informed the board, by letter dated 10 October 2013, that it would not

attend oral proceedings and that it withdrew its request for oral proceedings.

VIII. Oral proceedings took place on 15 November 2013 as scheduled and in the absence of the appellant.

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

Claim 1 of the new claim request is based on claim 7 according to the auxiliary request filed during oral proceedings before the examining division. It differs from said claim in that it specifies the test sample to be blood, saliva, vaginal fluid or urine, an amendment which finds basis in claim 14 of the above mentioned auxiliary request, as well as on paragraph [0065], page 21, lines 16 to 18 of the description as originally filed. The further amendment concerning step (v) of claim 1 is based on paragraph [0059], page 18, lines 21 to 25 of the description as originally filed.

The appellant did not submit any arguments to support its request for reimbursement of the appeal fee.

X. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the sole request filed with the grounds of appeal. Moreover, the appellant requested reimbursement of the appeal fee.

Reasons for the Decision

1. The oral proceedings before the board took place in the absence of the appellant who was duly summoned but decided not to attend.

The present decision is based on facts and evidence put forward during the written proceedings and on which the appellant has had an opportunity to comment. Therefore the conditions set forth in Enlarged Board of Appeal opinion G 4/92, OJ EPO 1994, 149, are met.

Moreover, as stipulated by Article 15(3) RPBA the board shall not be obliged to delay any step in the proceedings, including its decision, by reason only of the absence at the oral proceedings of any party duly summoned who may then be treated as relying only on its written case.

2. The appeal is admissible.

3. Amendments (Article 123(2) EPC)

3.1 Claim 1 of the present claim request is based on claim 7 of the auxiliary request pursuant to the appealed decision, wherein the test sample in item (ii) has been restricted to "blood, saliva, vaginal fluid, or urine" and step (v) "measuring the intensity of the signals..." has been added. In relation to this latter feature, the appellant has indicated as basis paragraph 59 of the description, on page 18, in particular lines 21 to 25. It is however noted that, in said passage of the description, measurement is to be done with an optical reader: "(...) *when it is desired to semi-quantitatively or quantitatively detect an analyte, the intensity of any signals produced at the detection zone 31 , indicator zone 35, and/or calibration zone 32 may be measured with an optical reader.*" In contrast thereto, step (v) of present claim 1 does not further define how the measurement should be performed. The

board thus considers that the above mentioned passage of the description does not constitute a suitable basis for this amendment.

3.2 In the absence of any arguments from the appellant to overcome the above objection, raised by the board in its communication of 28 August 2013, the board concludes that the present request does not fulfil the requirements of Article 123(2) EPC.

4. Request for reimbursement of the appeal fee

4.1 With the notice of appeal, the appellant made a request for reimbursement of the appeal fee, but did not substantiate this request either in the notice of appeal or later in the statement of the grounds of appeal, or after the communication of the boards of appeal drawing attention to this point.

4.2 Apart from the fact that it is the appellant's duty to reason its requests, the board also does not discern any reason why this request should be justified. In any case, the appeal is deemed unallowable and thus the condition laid in Rule 103(1)(a) EPC for reimbursement of the appeal fee is not fulfilled.

4.3 The board thus refuses the request for reimbursement of the appeal fee.

Order

For these reasons it is decided that:

1. The appeal is dismissed.

2. The request for reimbursement of the appeal fee is refused.

The Registrar: The Chairman:

A. Counillon U. Oswald

Decision electronically authenticated