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**Datasheet for the decision  
of 29 May 2018**

**Case Number:** T 1315/13 - 3.3.01

**Application Number:** 06735465.4

**Publication Number:** 1849002

**IPC:** G01N33/53

**Language of the proceedings:** EN

**Title of invention:**

CYR61 AS A BIOMARKER FOR DIAGNOSIS AND PROGNOSIS OF CANCERS OF  
EPITHELIAL ORIGIN

**Applicant:**

CHILDREN'S MEDICAL CENTER CORPORATION

**Headword:**

Cancer biomarker Cyr61/CHILDREN'S MEDICAL CENTER CORPORATION

**Relevant legal provisions:**

RPBA Art. 15(3)  
EPC Art. 54(2)

**Keyword:**

Oral proceedings - held in absence of appellant  
Novelty - (no)  
Admission of requests for which claims were not formulated -  
(no)

**Decisions cited:**

G 0004/92, G 0001/04, T 0382/96

**Catchword:**



**Beschwerdekammern**  
**Boards of Appeal**  
**Chambres de recours**

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Case Number: T 1315/13 - 3.3.01

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.01**  
**of 29 May 2018**

**Appellant:** CHILDREN'S MEDICAL CENTER CORPORATION  
(Applicant) 55 Shattuck Street  
Boston, Massachusetts 02115 (US)

**Representative:** White, Martin Paul  
Whites IP Ltd  
24A Carnatic Road  
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**Decision under appeal:** Decision of the Examining Division of the  
European Patent Office posted on 7 January 2013  
refusing European patent application No.  
06735465.4 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 whereby European patent application No. 06735465.4, based on an international application published as WO 2006/089212, was refused under Article 97(2) EPC.
  
- II. The documents cited in the examination and appeal proceedings include the following:  
  
D2 Muramatsu Y et al., 2002, Kidney International, 62, 1601-1610
  
- III. The decision of the examining division is based on the set of claims of the main request and auxiliary requests which were filed by letter of 24 August 2012. The examining division decided that the subject-matter of claim 8 of the main request as well as of auxiliary requests 1 and 2 was not drafted in a form according to Article 54(5) EPC because it did not relate to a method practised on the human or animal body according to Article 53(c) EPC, as further explained in G 1/04. Claim 8 therefore lacked novelty over the disclosure of document D2, while auxiliary requests 3, 4 and 5 lacked inventive step.
  
- 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 according to the main request or any of the first to sixth auxiliary requests, all filed with the notice of appeal.
  
- V. The **main request** comprises 10 claims. Claim 8 reads as follows:

"8. A kit for detecting Cyr61 in a urine sample comprising a container for holding a urine sample, and at least one antibody that specifically binds Cyr61; wherein the kit is for use in diagnosing a cancer of epithelial origin."

Claim 8 of the **first auxiliary request** differs from claim 8 of the main request as follows:

~~"8. An kit for detecting Cyr61 in a urine sample comprising a container for holding a urine sample, and at least one antibody-based binding moiety that specifically binds Cyr61; wherein the kit is for use in a method of diagnosing a cancer of epithelial origin in a human or animal body."~~

Claim 7 of the **second auxiliary request** differs from claim 8 of the first auxiliary request in that the cancer is further defined as follows:

"87. ... ; wherein the cancer of epithelial origin is selected from the group consisting of: breast cancer, basal cell carcinoma, adenocarcinoma, gastrointestinal cancer, lip cancer, mouth cancer, esophageal cancer, small bowel cancer, stomach cancer, colon cancer, liver cancer, bladder cancer, pancreas cancer, ovarian cancer, cervical cancer, lung cancer, skin cancer, and renal cell carcinoma."

No claims were submitted for the third, fourth, fifth and sixth auxiliary requests, which were merely described as follows:

"This is as for any preceding request, but with the term 'antibody-based binding moiety that specifically

binds to Cyr61' replaced with 'antibody or antibody fragment that specifically binds to Cyr61" (**third auxiliary request**) or "(...) but with the final claim thereof deleted" (**fourth auxiliary request**), "(...) but with the diagnostic use claim deleted" (**fifth auxiliary request**), and "(...) but with the cancer of epithelial origin limited to being 'selected from the group consisting of: breast cancer, basal cell carcinoma, adenocarcinoma, gastrointestinal cancer, lip cancer, mouth cancer, esophageal cancer, small bowel cancer, stomach cancer, colon cancer, liver cancer, bladder cancer, pancreas cancer, ovarian cancer, cervical cancer, lung cancer and skin cancer'" (**sixth auxiliary request**).

- VI. The board sent a summons to oral proceedings scheduled for 29 May 2018 and subsequently sent a communication pursuant to Article 15(1) RPBA, summarising the case and expressing a detailed preliminary opinion on the relevant issues, including novelty and inventive step for the main, first and second auxiliary requests and admission of the third to sixth auxiliary requests.
- VII. The appellant did not file any substantive reply to the board's communication but instead informed the board, by letter dated 22 May 2018, that it would not attend oral proceedings.
- VIII. Oral proceedings took place on 29 May 2018 as scheduled, in the absence of the appellant as had been announced in writing. At the end of oral proceedings the chairman announced the board's decision.
- IX. The appellant's arguments where relevant to the present decision may be summarised as follows:

There was no requirement for a medical use claim to refer to the "human or animal body", and hence the same should also apply to diagnostic use claims. G 1/04 did not discuss the format of allowable medical or diagnostic use claims. There was no prior art disclosing the use of the kit of claim 8 of the main request (or of the antibody-based binding moiety of claims 8 and 7, respectively, of the first and second auxiliary requests) in a diagnostic method for cancer of epithelial origin, and therefore the claim was novel. As to the first and second auxiliary requests, the wording referring to "a human or animal body" made clear that, even under the analysis of the examining division, the diagnostic use was a truly limiting feature of the claim.

- X. The appellant requested in writing that the decision under appeal be set aside and that a patent be granted on the basis of the main request or alternatively on the basis of one of auxiliary requests 1 to 6, all submitted with the notice of appeal.

### **Reasons for the Decision**

- 1. The appeal is admissible.
- 2. The oral proceedings before the board took place in the absence of the appellant who had been duly summoned but decided not to attend. In fact, the board interprets the appellant's statements in its letter of 22 May 2018 as a withdrawal of its request for oral proceedings. In that letter the appellant indicated that it would not attend oral proceedings and requested "a decision according to the state of the file based on the written

submissions made"; it also stated that it was its understanding that the board could "issue the decision requested without the need for Oral Proceedings" and that it had "no objection to Oral Proceedings being cancelled".

The present decision is based on facts and evidence put forward during the written proceedings 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 is not 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.

3. Main request - novelty

3.1 Claim 8 is directed to a kit comprising a container and an antibody, the kit being for use in diagnosing a cancer of epithelial origin (for the exact wording of the claim, see section V).

3.2 The subject-matter of this claim is a product (a kit) which is defined by given components. As stated in the appealed decision (section 21.1) and not disputed by the appellant, such a product is disclosed in D2 (abstract; page 1602, right column, line 51, to page 1603, left column, line 10; page 1603, right column, lines 41 to 47; page 1606, left column, line 11, to right column, line 3; page 1607, caption of Figure 7). The further feature defining the kit, namely the functional feature "wherein the kit is for use in



diagnosing a cancer of epithelial origin", is not considered limiting but simply an indication of suitability ("suitable for use") and therefore not relevant for the assessment of novelty. The product of D2 was in fact used for Cyr61 detection and is clearly also suitable for use in diagnosis. The board thus comes to the conclusion that claim 8 of the main request lacks novelty (Article 54(2) EPC).

- 3.3 The appellant essentially argued that claim 8 was not a product claim but a purpose-restricted product claim according to Article 54(5) EPC, and that this purpose limitation rendered the claimed subject-matter novel over D2. The board disagrees. Article 54(5) EPC could only apply if the claimed subject-matter were directed to use in a method falling under the exclusions from patentability set out in Article 53(c) EPC. However, the use referred to in the claim, namely "for detecting Cyr61 in a urine sample" and "for use in diagnosing a cancer of epithelial origin", is not considered to relate to methods excluded from patentability under Article 53(c) EPC, as it concerns neither "methods for treatment" nor "diagnostic methods practised on the human or animal body" (emphasis added by the board). According to G 1/04 (OJ EPO 2006, 334), the "practised on the human or animal body" criterion is satisfied if the method steps involve any interaction with the human or animal body, necessitating its presence (Reasons 6.4.2), but is not complied with in respect of method steps carried out in vitro in a laboratory (Reasons 6.4.3). It is readily apparent that the diagnostic method referred in the claim, which essentially consists in the laboratory analysis of urine samples, does not satisfy this criterion.

4. First auxiliary request - novelty

4.1 Claim 8 of the first auxiliary request is directed to "an antibody-based binding moiety that specifically binds Cyr61; for use in a method of diagnosing a cancer of epithelial origin in a human or animal body". The board considers that this claim too is a product claim and not a purpose-restricted product claim according to Article 54(5) EPC and that, accordingly, for the same reasons as discussed in relation to the main request, it lacks novelty over D2 (Article 54(2) EPC).

4.2 According to the appellant, the introduction of the feature "in a human or animal body" makes clear that the antibody-based binding moiety is used in a method included in those contemplated under Article 53(c) EPC and therefore is limiting and renders the claim novel. The board however fails to see how the claim is to become a purpose-restricted product claim by virtue of this amendment, which is interpreted as referring only to the diagnosis of a clinical situation which is "a cancer of epithelial origin in a human or animal body" and not to a diagnostic method which is to be "practised on the human or animal body" (for which there appears to be no basis in the application as filed).

5. Second auxiliary request - novelty

5.1 Claim 7 of the second auxiliary request differs from claim 8 of the first auxiliary request merely in that a list of epithelial cancer types to be diagnosed has been added (for the exact wording of the claim, see section V). Since the claim is not considered limited by any of these uses, it still lacks novelty over D2

for the same reasons as discussed above for the first auxiliary request.

6. Third to sixth auxiliary requests - admission

6.1 None of these requests was filed with formulated claims. Instead, only indications were given, such as: "This is as for any preceding request, but with the term 'antibody-based moiety that specifically binds to Cyr61' replaced with 'antibody or antibody fragment that specifically binds to Cyr61'" (third auxiliary request; see section V). So in fact the third auxiliary request appears to comprise three different auxiliary requests (i.e. corresponding to the main request and first and second auxiliary requests, all comprising the described amendment), the fourth auxiliary request appears to comprise six different auxiliary requests, etc. Moreover, the amendment indications are not clear: e.g. the exact wording specified in the third auxiliary request to be replaced in any preceding request is not present in claim 1 of the main request although similar wording is in claim 4, step (a), leaving the intent of the third auxiliary request uncertain. For the fifth auxiliary request it is further indicated that "the diagnostic use claim [is] deleted", but it is not apparent what this claim should be, since the claims in the formulated requests are either method claims (claims 1 to 7 and 10 of the main request) or product claims (claims 8 and 9 of the main request) and not use claims.

6.2 According to established case law, the applicant carries the responsibility for defining the subject-matter to be claimed and cannot offload this responsibility onto the EPO by filing incompletely formulated requests, this amounting to an abuse of

procedure (see e.g. T 382/96, Reasons 5.2 and 5.3). The board thus considers that the so-called third, fourth, fifth and sixth auxiliary requests, not being formulated as such but merely indicating how previous claims are to be amended to result in a multitude of alternative requests, are inadmissible.

## Order

**For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

The Chairman:



M. Schalow

A. Lindner

Decision electronically authenticated