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# Datasheet for the decision of 22 November 2012

**Case Number:** T 2128/09 - 3.3.08

**Application Number:** 04005833.1

**Publication Number:** 1574857

**IPC:** G01N 33/50, G01N 33/566

**Language of the proceedings:** EN

**Title of invention:**
Assay system for specific inhibitors of protein kinase C-related kinases

**Applicant:**
Universitätsklinikum Freiburg

**Headword:**
Inhibitors of PRKs/FREIBURG

**Relevant legal provisions:**
EPC Art. 83
RPBA Art. 13(1)

**Keyword:**
"Main request, first and second auxiliary requests: sufficiency of disclosure (no)"
"Third and fourth auxiliary requests: admission into the proceedings (no)"

**Decisions cited:**
G 0010/93

**Catchword:**
-


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**Case Number:** T 2128/09 - 3.3.08

# D E C I S I O N
**of the Technical Board of Appeal 3.3.08**
**of 22 November 2012**

**Appellant:** (Applicant)
Universitätsklinikum Freiburg
Hugstetter Straße 49
D-79106 Freiburg (DE)

**Representative:**
Ledl, Andreas
Maiwald Patentanwalts GmbH
Elisenhof
Elisenstraße 3
D-80335 München (DE)

**Decision under appeal:** **Decision of the Examining Division of the European Patent Office dated 28 April 2009 refusing European patent application No. 04005833.1 pursuant to Article 97(2) EPC.**

**Composition of the Board:**

**Chairman:** M. Wieser
**Members:** T. J. H. Mennessier
D. S. Rogers

## Summary of Facts and Submissions

I. The applicant (appellant) lodged an appeal against the decision of the examining division dated 28 April 2009, whereby European patent application No. 04 005 833.1 with the title "*Assay system for specific inhibitors of protein kinase C-related kinases*" was refused.

II. The decision was based on a main request, filed on 26 February 2009, and on an auxiliary request, filed on 6 March 2009 at the oral proceedings before the examining division. The examination division decided that both requests did not meet the requirements of Article 84 EPC.

III. The appellant filed a statement setting out the grounds of appeal which was accompanied by three sets of claims filed as auxiliary requests I to III to replace the auxiliary request of 6 March 2009.

IV. The Board issued a communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA) together with the summons to oral proceedings. In this communication, the Board informed the appellant that, exercising its power (see decision G 10/93 (OJ EPO, 1995, 172), to examine whether a requirement of the EPC, which the examining division regarded as having been met in the examination proceedings, was complied with, it intended to assess whether the formal requirement of sufficiency of disclosure (Article 83 EPC) was met. The Board also mentioned that the requirements of Article 84 EPC did not seem to be met by the main request.

V. In reply to the Board's communication, the appellant submitted on 22 October 2012 a new main request and first and second auxiliary requests. These requests corresponded to the first, second and third auxiliary requests filed with the statement of grounds of appeal.

VI. At the oral proceedings which took place on 22 November 2012, the appellant filed in addition a third and fourth auxiliary request.

VII. Each of the five requests on file consisted of a single claim only.

Claim 1 of the main request read:

"1. An *in vitro* process for an identification of inhibitors acting only on protein kinase C-related kinases (PRKs) selected from the group consisting of PRK1, PRK2 and PKNβ, said inhibitors allowing to selectively block the activity of the Androgen Receptor (AR) wherein said process comprises the steps of
- selecting an inhibitor to be tested for its protein kinase C-related kinase inhibitor capacity;
- providing at least two reactions involving at least one of said PRKs and at least the AR acted upon by at least one of said PRKs under physiological conditions, wherein said two reactions comprise the ligand-dependent activation of the AR by RhoA V14;
- adding distinguishable effective amounts of said inhibitor to be tested to said at least two reactions so as to obtain an inhibitor effect of said inhibitor on said PRKs; and
- measuring said measurable effect in dependency upon the distinguishable effective amounts of said inhibitor

to be tested so as to ascertain an inhibitory effect of said inhibitor on said PRKs in said reaction."

Claim 1 of auxiliary request I read:

"1. An *in vitro* process for an identification of inhibitors acting only on protein kinase C-related kinase PRK1, said inhibitors allowing to selectively block the activity of the Androgen Receptor (AR) wherein said process comprises the steps of
- selecting an inhibitor to be tested for its PRK1 inhibitor capacity;
- providing at least two reactions involving at least PRK1 and at least the AR acted upon by PRK1 under physiological conditions, wherein said two reactions comprise the ligand-dependent activation of the AR by RhoA V14;
- adding distinguishable effective amounts of said inhibitor to be tested to said at least two reactions; and
- measuring the effect of said distinguishable effective amounts of said inhibitor to be tested on said PRK1 in said reaction."

Claim 1 of auxiliary request II differed from claim 1 of auxiliary request I in that the following feature had been added at the end of the claim:

"*wherein an abolishment of the RhoA V14 dependent activation of the AR by PRK1 indicates that the inhibitor to be tested is specific for PRK1*."

Claim 1 of auxiliary request III differed from claim 1 of auxiliary request II in that the said added feature had been amended to read:

"*wherein an abolishment of the RhoA V14 dependent activation of the AR by PRK1* ***to the level of the ligand-dependent activation of the AR*** *indicates that the inhibitor to be tested is specific for PRK1.*"
(emphasis added by the Board to show the amendment)

Claim 1 of auxiliary request IV differed from claim 1 of auxiliary request III in that the said added feature had been further amended to read:

"*wherein an abolishment of the RhoA v14 dependent activation of the AR by PRK1 to the level of the ligand-dependent activation of the AR* ***without RhoA V14*** *indicates that the inhibitor to be tested is specific for PRK1.*"
(emphasis added by the Board to show the additional amendment)

VIII. Appellant's written submissions, insofar as they are relevant to the present decision, may be summarised as follows:

Main request (compliance with Article 83 EPC)

The steps of the claimed method were described in Example 2 in which two substances were tested for their capability to inhibit PRKs selected from the group of PRK1, PRK2 and PKNβ. The inhibitory effect of the substances on the activation of the androgen receptor

was measured in two different reactions involving one of said PRKs and the androgen receptor.

Auxiliary requests I and II (compliance with Article 83 EPC)

The same reasoning applied a fortiori to auxiliary request I as PRK1 was that particular PRK involved in Example 2, and also to auxiliary request II, wherein it was specified that an abolishment of the RhoA V14 dependent activation of the androgen receptor indicated that the tested substance was specific to PRK1.

Auxiliary requests III and IV (admissibility)

Claim 1 of both requests specified further that an abolishment of the RhoA V14 dependent activation of the androgen receptor indicated that the tested substance was specific for PRK1. The requests were filed in direct reaction to the Board's comments with regard to the requirements of Article 83 EPC and were supported, within the meaning of Article 123(2) EPC, by Example 2 when read together with Figure 2.

IX. The appellant requested that the decision under appeal be set aside and a patent be granted on the basis of the main request, or on the basis of auxiliary request I or II, all requests filed under cover of the letter dated 22 October 2012, or alternatively, upon the basis of auxiliary request III or IV, both filed at the oral proceedings of 22 November 2012.

## Reasons for the Decision

Main request

1. The Board, exercising its power to examine whether a requirement of the EPC that the examining division regarded as having been met in the examination proceedings (see decision G 10/93, OJ EPO, 1995, 172), has examined whether the requirements of Article 83 EPC are complied with.

2. Claim 1 refers to an in vitro process for identifying inhibitors acting only on PRKs selected from the group consisting of PRK1, PRK2 and PKNβ. The claimed process consists of the following steps:
- selecting a potential inhibitor,
- providing at least two reactions involving at least one of said PRKs and the androgen receptor (AR), wherein one reaction comprises the ligand-dependent activation of the AR by RhoA V14,
- adding distinguishable amounts of the potential inhibitor to the at least two reactions, and
- measuring an inhibitory affect of the tested, potential inhibitor.

Thus, claim 1, while containing steps that would allow the determination of whether or not a tested inhibitor indeed acts on PRKs selected from the group consisting of PRK1, PRK2 and PKNβ, does not contain any step which would allow a skilled person to decide whether or not it acts on these PRKs **only** or also on other substances, such as other protein kinases.

3. The appellant referred to Example 2 and argued that it disclosed a process according to claim 1 for identifying inhibitors acting **only** on PRKs selected from the group consisting of PRK1, PRK2 and PKNβ.

4. The two substances, referred to as Ro31-8220 and HA 1077, which were tested for their inhibitory effect on PRK1 in the assay of Example 2 (see paragraphs [0055] to [0057], together with Figure 2), are acknowledged in the published application (see paragraph [0041] as having only a low specificity for PRKs and showing an inhibitory effect on a number of protein kinases.

5. The Board seeing that Example 2 describes the steps of the process of claim 1, cannot find any hint in the description of this example that would assist a skilled person in defining the working steps, referred to in point (2) above, that are necessary to identify inhibitors acting **only** on PRKs selected from the group consisting of PRK1, PRK2 and PKNβ, which working steps are not present in claim 1.

6. Therefore, the invention according to claim 1 is not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. Thus, the main request does not meet the requirements of Article 83 EPC.

Auxiliary request I

7. The claim of auxiliary request I differs from the claim of the main request only in so far as the process is directed to the identification of inhibitors acting **only** on PRK1. It is clear from the Board's comments in

points (1) to (6) above, that also auxiliary request I does not meet the requirements of Article 83 EPC.

Auxiliary request II

8. The claim of auxiliary request II differs from the claim of auxiliary request I in so far as the process is further defined in that an abolishment of the RhoA V14 dependent activation of the AR by PRK1 indicates that the inhibitor to be tested is specific for PRK1.

9. The Board considers that this additional feature does not permit the selection of inhibitors acting **only** on PRK1. It is expressly stated in the application (see paragraph [0057] in column 13, lines 5 to 7) that Ro31-8220 and HA 1077, two inhibitors which are acknowledged as not acting only on PRKs, let alone PRKs selected from the group consisting of PRK1, PRK2 and PKNβ, also abolish the required activation (see Figure 2).

10. Thus, auxiliary request II also does not meet the requirements of Article 83 EPC.

Auxiliary requests III and IV

11. These requests were filed at the oral proceedings and represent amendments which may be admitted and considered at the Board's discretion pursuant to Article 13(1) RPBA.

12. The claim of each of the request is based on the claim of auxiliary request III. Each contains an additional

feature specifying the exact degree and kind of the abolishment of the Rho V14 dependent activation of AR by PRK1, which is considered as being a sign that the tested potential inhibitor acts on PRK1 **only**.

13. The disclosure test which is applied by the Boards of Appeal in order to assess whether an amendment meets the requirements of Article 123(2) EPC, implies a direct and non-ambiguous disclosure of the amendment in the application as filed. In the present case, it would be necessary to interpret the results of Example 2 in the light of a disclosure that is not directly and unambiguously derivable from Figure 2 in order to find support within the meaning of article 123(2) EPC for the added features of claim 1 of auxiliary requests III and IV.

14. As auxiliary requests III and IV show clear deficiencies with regard to the requirements of Article 123(2) EPC, the Board, exercising its power, decides not to admit them into the proceedings.

**Order**

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

The appeal is dismissed.

The Registrar The Chairman

A. Wolinski M. Wieser