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**Datasheet for the decision
of 5 December 2007**

Case Number: T 1048/05 - 3.3.04

Application Number: 94102080.2

Publication Number: 0610937

IPC: C12Q 1/66

Language of the proceedings: EN

Title of invention:

Process for detecting luciferase

Patentee:

PerkinElmer LAS, Inc.

Opponent:

Promega Corporation

Headword:

Luciferase/PERKIN ELMER LAS

Relevant legal provisions (EPC 1973):

EPC Art. 84, 123(2)(3), 111(1), 114(2)
RPBA Art. 10(a), 10(b)

Keyword:

"Main request - admission into the proceedings (no)"
"Auxiliary requests 1, 2, 4, 6 - added subject-matter (yes)"
"Auxiliary requests 2, 5 - support by the description (no)"
"Auxiliary request 7 - added subject-matter (no), clarity and support (yes), remittal (yes)"

Decisions cited:

T 0284/94, T 1091/00, T 0397/01, T 0127/02

Catchword:

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Case Number: T 1048/05 - 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 5 December 2007

Appellant:
(Patent Proprietor)

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Decision under appeal:

Decision of the Opposition Division of the
European Patent Office posted 17 May 2005
revoking European patent No. 0610937 pursuant
to Article 102(1) EPC.

Composition of the Board:

Chairman: R. Gramaglia
Members: M. Wieser
D. S. Rogers

Summary of Facts and Submissions

I. The appeal was lodged by the Patent Proprietor (Appellant) against the decision of the Opposition Division, whereby the European patent No. 610 937 was revoked pursuant to Article 102(1) EPC.

II. The Opponent's opposition was based on Article 100(a) EPC on the grounds of lack of novelty (Article 54 EPC) and lack of inventive step (Article 56 EPC) and on Article 100(b) EPC.

III. The Opposition Division decided that claims 1 to 20 of the Patent Proprietor's main request (the claims as granted) lacked inventive step (Article 56 EPC).

In addition they decided that claim 1 of each of auxiliary requests 1 to 5 lacked clarity contrary to the requirements of Article 84 EPC.

IV. The Board expressed its preliminary opinion in a communication dated 7 May 2007.

Oral proceedings were held on 5 December 2007.

V. The Appellant requested that the decision under appeal be set aside and that the patent be maintained upon the basis of the main request dated 5 December 2007, or on the basis of any of the auxiliary requests 1 to 7 dated 5 December 2007.

The Opponent (Respondent) requested that the appeal be dismissed.

VI. Claim 1 of Appellant's new main request read as follows:

"A method for screening a large number of samples for detecting the presence of luciferase in a biological sample by measuring luminescence, said method comprising:

(a) mixing the biological sample suspected of containing luciferase with a reaction mixture containing luciferin, adenosine triphosphate, co-factors necessary for luciferase catalytic activity, adenosine monophosphate, a free radical scavenger and a chelating agent and

(b) measuring said luminescence produced by said reaction mixture containing said sample,

wherein the luminescence can be detected for at least 30 minutes."

VII. Claim 1 of each of auxiliary requests 1 to 7 referred to:

"A method for detecting the presence of luciferase in a biological sample by measuring luminescence, said method comprising: ..."

They all contained points (a) and (b) of claim 1 of the main request, however, each of these claims contained a different wording following "wherein" at its respective end.

Auxiliary request 1:

"... wherein the luminescence can be detected for at least 30 minutes and the luminescence signal half-life is more than 4 hours."

Auxiliary request 2:

"... wherein the luminescence can be detected for at least 30 minutes with a linear decrease of photon emission during the life of luciferin luciferase reaction."

Auxiliary request 3:

"... wherein the luminescence can be detected for at least 30 minutes and the luminescence signal half-life is more than 4 hours with a linearity of decrease of photon emission during the life of luciferin luciferase reaction."

Auxiliary request 4:

"... wherein the luminescence can be detected for at least 30 minutes and the luminescence signal half-life is more than 4 hours with a photon emission detectable from the luciferin luciferase reaction, which photon emission decays linearly for up to 8 hours."

Auxiliary request 5:

"... wherein the luminescence can be detected for at least 30 minutes with a linearity of decrease of photon emission during the life of luciferin luciferase

reaction, wherein forty-eight 96-well plates can be easily measured."

Auxiliary request 6:

"... wherein the luminescence can be detected for at least 30 minutes with a photon emission detectable from the luciferin luciferase reaction, wherein forty-eight 96-well plates can be measured."

Auxiliary request 7:

"... wherein the luminescence can be detected for at least 30 minutes, wherein 100 ml of the admixture contains between 0.2 to 30 mg luciferin, between 10 to 300 mg ATP, between 0.2 to 30 mg AMP, between 200 to 2000 mg dithiothreitol and between 10 to 50 mg EDTA."

Claims 2 to 15 of auxiliary request 7 referred to preferred embodiments of the method of claim 1.

Claims 16 and 17 referred to the composition used in claim 1 and to a preferred embodiment thereof.

VII. The submissions by the Appellant, as far as they are relevant to the present decision, may be summarised as follows:

The main request and auxiliary request 7 had to be considered as direct reactions to submissions made by the Respondent and should therefore be allowed into the proceedings.

The term "large number of samples" in claim 1 of the main request was clear. A skilled person reading the

patent in suit would have understood that those numbers of samples are meant, which are handled in High-Throughput-Screening (HTS) technology.

The subject-matter of claim 1 of auxiliary requests 1, 3, 4 and 6 had a basis in the application as originally filed and met the requirements of Article 123(2) EPC.

The subject-matter of claim 1 of auxiliary requests 2 and 5 was clear and supported by the description as required by Article 84 EPC.

Claims referring to the subject-matter of auxiliary request 7, wherein the used reaction mixture was defined by the nature and amount of its specific components had not yet been examined by the department of first instance. Therefore the case should be remitted according to Article 111(1) EPC.

VIII. The submissions by the Respondent, as far as they are relevant to the present decision, may be summarised as follows:

Appellant's main request and auxiliary request 7 should not be admitted into the proceedings as being late filed.

The subject-matter of claim 1 of auxiliary requests 1, 3, 4 and 6 was considered to result from the generalisation of specific examples and contravened therefore the requirements of Article 123(2) EPC.

The subject-matter of claim 1 of auxiliary requests 2 and 5 was contradictory to the results shown in

figures 1 to 5 and therefore not supported by the description contrary to the requirements of Article 84 EPC.

Remittal of the case to the department of first instance for further prosecution on the basis of the claims of auxiliary request 7 was considered to be a further unwelcome delay.

Reasons for the decision

Admission into the proceedings of Appellant's requests

1. In accordance with the Rules of Procedure of the Boards of Appeal (Articles 10a(2) and 10b(1) RPBA), the statement of grounds of appeal shall contain a party's complete case. Any amendments filed thereafter may be admitted at the board's discretion.

The principles applicable to the admission in the appeal proceedings of new requests filed at a late stage are referred to in Article 10b(1) RPBA: "The *[Board's]* discretion shall be exercised in view of inter alia the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy." (*[added by the Board]*)

There is a plethora of decisions by the Boards of Appeal which define the circumstances which may arise, and the criteria which should be fulfilled, to justify that these requests be admitted (see "Case Law of the Boards of Appeal of the European Patent Office", 5th Edition 2006, Chapter VII.D.14, pages 640 to 649).

These circumstances and criteria are reviewed in, for example, T 397/01 of 14 December 2004, see point (1), and may be summarised as follows:

- the amendments must be filed in response to objections or comments which were raised during the appeal proceedings.
 - they do not extend the frame of discussion as determined by the decision under appeal and by the statement of grounds of appeal.
 - they are clearly allowable and can easily be dealt with.
2. Appellant's new main request has been filed during the oral proceeding before the Board, thus more than two years after submission of the written statement setting out the grounds for appeal. Claim 1 corresponds to claim 1 as granted with the amendment that after the first two words "[A] method" the phrase "for screening a large number of samples" has been introduced.

The Appellant argued, that a skilled reader of the patent in suit would have understood that the term "large number of samples" referred to such numbers of samples only as were normally handled in High-Throughput-Screening (HTS) technology.

3. The word "large" is an unspecific term which is vague and open to interpretation. Thus, prima facie, claim 1 of the main request appears to violate Article 84 EPC. In addition, to examine whether or not in a specific technical field there exists a generally accepted

interpretation of this term, would lead to an extension of the frame of discussion as determined by the decision under appeal and by the statement of grounds of appeal.

In view of the requirements of Rule 10b(1) RPBA and of the established case law of the Boards of Appeal (see point (1) above), Appellant's new main request, filed at the oral proceedings before the Board is not admitted into the proceedings (Article 114(2) EPC).

4. Auxiliary requests 1, 3, 4 and 5 are identical to auxiliary requests 1, 4, 5 and 6, respectively, filed by the Appellant with letter dated 5 October 2007.

Auxiliary requests 2 and 6 corresponds to auxiliary request 2 and 7 filed with letter dated 5 October 2007.

The Respondent has not objected to the admission of these requests. Appellant's auxiliary requests 1 to 6 are therefore admitted into the proceedings.

5. Claim 1 of auxiliary request 7, filed at the oral proceedings before the Board, is a combination of claims 1 and 4 as granted. Claims 2 to 17 of this request are identical to claims 5 to 20 as granted, with the only exception that in claims 9 to 17 (claims 12 to 20 as granted) the respective back references have been adapted.

The request is filed in response to objections raised during the appeal proceedings. The amendments made are clearly allowable and do not extend the frame of

discussion as determined by the decision under appeal and by the statement of grounds of appeal.

Thus, Appellant's auxiliary request 7 is admitted into the proceedings.

Auxiliary requests 1, 3 and 4

Amendments - Article 123(2) EPC

6. Claim 1 of each of these three requests has been amended with regard to claim 1 as granted and refers to a method wherein "the luminescence signal half-life is more than 4 hours".

The only basis for this feature can be found on page 20, lines 12 to 14 of the application as originally filed which reads:

"The stabilisation of the bioluminescence signal from a half-life of a few minutes to more than four hours allows for the automation of the assay by using the newly available microplate single photon counters."

7. This part of the description belongs to example 2 which explicitly refers to "High-capacity Luciferase Reporter Gene Assay for HIV-Rev-RRE-Interaction".

The establishment of the assay and its exact working conditions are disclosed from page 19 onwards of the application as filed. It is said that the assay has been adapted to microplate technology and can be automated (page 20, lines 8 to 9 of the application as filed).

The statement referred to by the Appellant as forming the basis for claim 1 of auxiliary 1 (see point (6) above) is followed by a list disclosing the exact composition of all buffers and reagents used in example 2. Amongst others the exact composition of the used "luciferase-substrate solution" is disclosed on page 21, lines 23 to 34 of the application as originally filed.

8. The Appellant argued that, the sentence on page 20, lines 12 to 14 (see point (6) above) is of general nature and its message cannot be restricted to the specific assay disclosed in example 2.
9. The board notes that this sentence is embedded in the description of an experimental set up described as the assay of example 2 which is defined by an exact assay protocol using precisely defined buffers and reagents.

In fact, the feature "the luminescence half-life is more than 4 hours" is disclosed only once in the application as filed in a specific technical context, namely in connection with the specific assay of example 2. According to established case law of the Boards of Appeal it is not permissible under Article 123(2) EPC to isolate a technical feature from the description where it is disclosed in a specific context, and to generalize it in a claim (see for instance decision T 284/94, OJ EPO 1999, 464; point (2.1.5) of the reasons)

Thus, auxiliary requests 1, 3 and 4, do not meet the requirements of Article 123(2) EPC.

Auxiliary requests 2 and 5

Support by the description - Article 84 EPC

10. Claim 1 of auxiliary requests 2 and 5 has been amended with regard to claim 1 as granted and refers to "a linear" (auxiliary request 2), respectively "a linearity of" (auxiliary request 5) "decrease of photon emission during the life of luciferin luciferase reaction".

This formulation finds formal support on page 16, lines 13 to 14 of the application as originally filed (Article 123(2) EPC).

11. However, a formal support is not sufficient for fulfilling the requirements of Article 84 EPC. For these requirements to be met, the claimed subject-matter must necessarily have a technical support in the description too, in the sense that it has to reflect the applicant's effective contribution to the art (see decision T 127/02 of 16 September 2003; point (3) of the reasons).

The question therefore arises whether or not the description provides such a technical support for the claimed subject-matter.

12. The patent contains two examples. The results of example 1, a "Reporter-gene Assay Using a Luciferase cDNA", are disclosed in figure 5, where the light production over eight hours is shown. The figure contains two curves, a so-called "high-activity" curve and a "low-affinity" curve, distinguished by the

respectively used cellular concentration. Both curves are not decreasing in a linear manner.

The results of example 2, a "High-capacity Luciferase reporter Gene Assay for HIV-Rev-RRE-Interaction" are shown in figures 6 and 7. These figures show the inhibitory effect of Compounds A and B respectively on HIV-rev regulatory protein (RRE) and do not allow to draw any conclusion on the nature of photon emission during the luciferin luciferase reaction.

The patent in addition contains figures 1 to 4, showing the effects of varying concentrations of different substances, like AMP, DTT, AMP plus DTT, EDTA and Coenzyme A on luciferase-luciferin light production. All four figures have in common that the light production (photon emission) during the first 30 minutes of the reaction is not shown. Therefore, they cannot support a claim referring to a method having a linearity of decrease of photon emission during the life of luciferin luciferase reaction.

13. In view of the foregoing, the Board arrives at the decision that the subject-matter of claim 1 of both, auxiliary request 2 and 5, is not supported by the description. These requests do not meet the requirements of Article 84 EPC.

Auxiliary request 6

Amendments - Article 123(2) EPC

14. Claim 1 of auxiliary request 6 has been amended with regard to claim 1 as granted and refers to a method "wherein the luminescence can be detected for at least 30 minutes with a photon emission detectable from the luciferin luciferase reaction, wherein forty-eight 96-well plates can be measured."

15. Page 17, lines 6 to 8 of the application as originally filed reads:

"Thus with a linear emission of photons of eight hours, forty eight 96-well plates can be easily measured."

16. The claim thus refers to the measurement of forty-eight 96-well plates without disclosing the specific conditions disclosed in the application as filed in order to achieve this goal, namely a linear emission of photons for eight hours.

This is considered to amount to the generalisation of a feature, which, in the application as originally filed, is disclosed in a specific context.

In accordance with the Board's decision with regard to auxiliary requests 1, 3 and 4 (see points (6) to (9) above), auxiliary request 6 does not meet the requirements of Article 123(2) EPC.

Auxiliary request 7

Amendments, Clarity - Articles 123(2)(3) and 84 EPC

17. Article 100(c) EPC has not been a ground for opposition.

Claim 1 of auxiliary request 7 is a combination of claims 1 and 4 as granted. Claims 2 to 17 are identical to claims 5 to 20 as granted, with the only exception that in claims 9 to 17 (claims 12 to 20 as granted) the respective back references have been adapted.

By introducing the subject-matter of claim 4 into claim 1, the extent of protection with regard to the claims as granted has been reduced.

Claim 1, which in fact is identical to claim 4 as granted, and claims 2 to 17 are not open to an objection under Article 84 EPC, which is not itself a ground for opposition under Article 100 EPC.

Thus, the requirements of Article 123(2) and (3) and Article 84 EPC are met.

Remittal - Article 111(1) EPC

18. According to Article 111(1) EPC the Board of Appeal may either exercise any power within the competence of the department which was responsible for the decision appealed or remit the case to the department for further prosecution.

Remittal to the department of first instance is at the discretion of the board (cf decision T 1091/00 of 2 July 2002, Point (4) of the reasons).

Although Article 111(1) EPC does not guarantee an absolute right to have all the issues in the case considered by two instances, it is well recognised that a party should preferably be given the opportunity to have two instances consider the important elements of its case.

19. The Board notes, that the substantial requirements of the EPC have not yet been examined by the department of the first instance with regard to a request corresponding to present auxiliary request 7. In claim 1 of this request the specific components of the used reaction mixture are indicated and their quantity is defined according to a preferred embodiment of the invention.

Although being aware that this could lead to a considerable delay of the procedure, the Board considers it to be justified and appropriate to allow the set of claims according to Appellant's auxiliary request 7 to be examined by two instances, and therefore exercises its discretion under Article 111(1) EPC to remit the case to the department of first instance for further prosecution.

Order

For these reasons it is decided:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance for further prosecution upon the basis of claims 1 to 17 of Auxiliary Request 7 filed on 5 December 2007 at the Oral Proceedings.

Registrar:

Chair:

P. Cremona

R. Gramaglia