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**Datasheet for the decision
of 12 April 2016**

Case Number: T 1036/13 - 3.3.08

Application Number: 06781024.2

Publication Number: 1932908

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C12N1/21, C12N5/10, C12Q1/02,
G01N33/15, G01N33/50

Language of the proceedings: EN

Title of invention:
REPORTER VECTOR FOR USE IN EVALUATION OF CYP1A2 INDUCTION

Applicant:
Eisai R&D Management Co., Ltd.
TOHOKU UNIVERSITY

Headword:
Reporter vector of CYP1A2 induction/EISAI R&D MANAGEMENT Co.,
TOHOKU UNIVERSITY

Relevant legal provisions:
EPC Art. 123(2), 111(1)

Keyword:
Main request - claim 1(a), Article 123(2) EPC (yes)

Decisions cited:

Catchword:



Beschwerdekammern
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Case Number: T 1036/13 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 12 April 2016

Appellant: Eisai R&D Management Co., Ltd.
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Appellant: TOHOKU UNIVERSITY
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted on 14 December 2012 refusing European patent application No. 06781024.2 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman M. Wieser
Members: B. Stolz
D. Rogers

Summary of Facts and Submissions

- I. The appeal has been filed against the decision of the examining division whereby European patent application No. 06781024.2 was refused. The examining division decided that part (a) of claim 1 of the sole request before it, filed on 22 October 2012, did not meet the requirements of Article 123(2) EPC.
- II. The appellant requested that the decision under appeal be set aside and a patent be granted on the basis of its main request, in the alternative on the basis of auxiliary request 1, both filed with the statement of grounds of appeal.
- III. The appellant was summoned to oral proceedings. A communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA), annexed to the summons, informed it of the preliminary non-binding opinion of the board that the subject matter of part (a) of claim 1 was directly and unambiguously derivable from the patent application as originally filed and that the board intended to set aside the decision under appeal and remit the case to the examining division for further examination.
- IV. In a letter dated 30 March 2016, the appellant withdrew its request for oral proceedings and requested that the decision under appeal be set aside and the case be remitted to the examining division for further examination.
- V. Claim 1 of the main request reads as follows:

"1. An expression vector comprising a reporter gene operably linked to the 3' end of any one of DNAs of the following (a) to (g) wherein said DNA consists of:

(a) the nucleotide sequence consisting of the nucleotide numbers 1 to 9690, the nucleotide numbers 19134 to 19946, and the nucleotide numbers 23030 to 24448 in SEQ ID NO: 1,

(b) the nucleotide sequence consisting of the nucleotide numbers 1 to 19946 and the nucleotide numbers 23030 to 24448 in SEQ ID NO: 1,

(c) the nucleotide sequence consisting of the nucleotide numbers 1 to 5658 and the nucleotide numbers 23030 to 24448 in SEQ ID NO: 1,

(d) the nucleotide sequence consisting of the nucleotide numbers 1 to 2866 and the 23030 to 24448 in SEQ ID NO: 1,

(e) the nucleotide sequence consisting of the nucleotide numbers 1 to 2866 and the nucleotide numbers 22167 to 24448 in SEQ ID NO: 1,

(f) the nucleotide sequence consisting of the nucleotide numbers 1242 to 2866 and the nucleotide numbers 23697 to 24448 in SEQ ID NO: 1 , or

(g) a nucleotide sequence consisting of the nucleotide numbers 1 to 5658 and the nucleotide numbers 23030 to 24448 in SEQ ID NO: 1 including deletion of any of the nucleotide numbers 1535 to 1541, the nucleotide numbers 1930 to 1936, the nucleotide numbers 2018 to 2024, the nucleotide numbers 2093 to 2099, and the nucleotide numbers 2411 to 2417."

VI. Appellant's arguments can be summarized as follows:

Paragraph [0009] of the application as filed explained that the induction of CYP1A2 could only be observed by using a genomic region neighbouring CYP1A1 which therefore had to be contained in the expression vector of the invention. Paragraph [0019] generally explained the function of reporter genes and stated explicitly that the disclosure of the application was not limited to the specific reporter genes also mentioned therein. Thus, the combination of vector C of paragraph [0053] with any reporter gene was directly and unambiguously derivable from the application as filed.

Reasons for the Decision

1. The only issue addressed in the decision under appeal is whether the subject matter of part (a) of claim 1 of the main request is directly and unambiguously derivable from the patent application as originally filed.
2. The subject matter of part (a) of claim 1 is an expression vector comprising a reporter gene operably linked to the 3' end of a DNA consisting of nucleotide numbers 1 to 9690, 19134 to 19946 and 23030 to 24448 of Seq ID NO: 1 (cf. item V, above).
3. The examining division has not disputed that Figure 2 and paragraphs [0051-0053] disclose a vector construct, "C", comprising these partial sequences (cf. the examining division's communication dated 22 June 2012) but decided that the combination of the regulatory element of vector construct "C" with any reporter gene was not directly and unambiguously derivable from the patent application as filed.

4. At a general level, the patent application discloses that the transcriptional regulatory region located between the human *cyp1A1* and *cyp1A2* genes has been analysed in order to construct reporter vectors enabling the evaluation of CYP1A2 induction by a drug (paragraphs [0006-0010]). Vector constructs comprising specifically defined sequence elements are disclosed in paragraph [0011].
5. According to paragraph [0014], an expression vector of the invention is constituted so as to contain a region neighbouring CYP1A1 as a transcriptional regulatory region, to reflect CYP1A2 induction by a drug. Further, according to paragraph [0019], an expression vector which reflects CYP1A2 expression, i.e. a vector of the invention, can be prepared "*by operably linking a reporter gene to a DNA comprising a region neighbouring CYP1A1 on the side linked to the CYP1A2 gene*".
6. Paragraph [0022] then states: "*Further, as shown in Fig. 2, a large number of XREs (xenobiotic response elements) are distributed between the CYP1A1 gene and the CYP1A2 gene. By referring to this distribution, appropriate transcriptional regulatory regions can be chosen and combined, and the **region prepared** can be used as a transcriptional regulatory region of the expression vector*" (emphasis added).
7. Figure 2 and the examples disclose the preparation of specific combinations of XRE elements from the regulatory region defined by Seq ID NO: 1 (or in other words from "*a region neighbouring CYP1A1 on the side linked to the CYP1A2 gene*"). These specifically disclosed combinations correspond also to the "region prepared" of paragraph [0022].

8. Thus, the regulatory region of construct "C" represents a specifically disclosed regulatory element obtained by choosing and combining XREs distributed between the *cy1A1* gene and the *cy1A2* gene.
9. Since a region prepared by combining and choosing XREs can be used as a transcriptional regulatory region of the expression vector of the invention (paragraph [0022]), and the reporter genes of the vector are not limited to particular examples ([paragraph [0019]), the subject matter of part (a) of claim 1 is implicitly, yet directly and unambiguously, derivable from the patent application as filed.
10. Claim 1(a) therefore meets the requirements of Article 123(2) EPC.

Article 111(1) EPC

11. The Examining division only decided that the subject-matter of part (a) of claim 1 of the main request did not meet the requirements of Article 123(2) EPC. The board, having reached the opposite conclusion from that of the examining division on this point, exercises its discretion under Article 111(1) EPC and remits the case to the examining division for further prosecution.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the examining division for further prosecution on the basis of the main request filed with the statement setting out the grounds of appeal.

The Registrar:

The Chairman:



A. Wolinski

M. Wieser

Decision electronically authenticated