

Internal distribution code:

- (A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

**Datasheet for the decision
of 14 March 2014**

Case Number: T 0206/11 - 3.3.04

Application Number: 98906429.0

Publication Number: 1009395

IPC: C07K14/47, A61K31/00,
A61K33/00, A61K38/00,
C12N15/11, C12Q1/68

Language of the proceedings: EN

Title of invention:
Bak promotor expression system

Applicant:
Tanox, Inc.

Headword:
Bak promotor/TANOX

Relevant legal provisions:
EPC Art. 54, 84, 111(1), 123(2)

Keyword:
"Main request - appeal allowed"

Decisions cited:

Catchword:

-



**Beschwerdekammern
Boards of Appeal
Chambres de recours**

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T 0206/11 - 3.3.04

**D E C I S I O N
of Technical Board of Appeal 3.3.04
of 14 March 2014**

Appellant: Tanox, Inc.
(Applicant) 10301 Stella Link
Houston, TX 77025 (US)

Representative: Andrew Wright
Potter Clarkson LLP
The Belgrave Centre
Talbot Street
Nottingham, NG1 5GG (GB)

Decision under appeal: **Decision of the Examining Division of the European Patent Office posted on 14 June 2010 refusing European patent application No. 98906429.0 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman: C. Rennie-Smith
Members: B. Claes
R. Morawetz

Summary of Facts and Submissions

- I. The appeal was lodged by the applicant (hereinafter "appellant") against the decision of the examining division to refuse European patent application 98906429.0 with the title "*Bak promotor expression system*" which was published as international patent application WO 98/35659.
- II. The examining division decided that the subject-matter of claim 1 of the sole request (claims 1 to 19) before them, which was filed as the main request on 4 September 2007, lacked novelty (Article 54 EPC) in respect of part c) of the claim. Claim 1 furthermore lacked clarity with respect to parts c) and d) and support with respect to part d) (Article 84 EPC). The decision was silent on the compliance of the claims and application in relation to other substantive provisions of the EPC.

Independent claim 1 of the sole request before the examining division read:

"1. An isolated polynucleotide selected from the group consisting of:

(a) an isolated polynucleotide consisting of SEQ ID NO:1;

(b) an isolated polynucleotide consisting of the bak promoter (positions 1 - 4021 of SEQ ID NO:1);

(c) an isolated polynucleotide consisting of a fragment of the polynucleotide of (a) or (b) wherein the

polynucleotide is capable of activating transcription;
and

(d) an isolated mutated polynucleotide of (a), (b) or (c) wherein the mutated polynucleotide differs from the polynucleotide of (a), (b) or (c) by one or more

mutations consisting of one or more point mutations and/or one or more deletions, and wherein the mutated polynucleotide has **interferon- γ (IFN- γ) activated transcriptional activity.**" (emphasis added by the board)

- III. With the statement of the grounds of appeal dated 21 October 2010 the appellant submitted a new main request (claims 1 to 19) and ten auxiliary requests.
- IV. After having been summoned to oral proceedings, the appellant withdrew its request for oral proceedings in a letter dated 2 August 2013. The board subsequently cancelled the oral proceedings.
- V. In a communication pursuant to Article 17(1) of the Rules of Procedure of the Boards of Appeal (RPBA) dated 16 September 2013, the board expressed its preliminary and non-binding opinion in particular on the main request.
- VI. With a response dated 15 November 2013, the appellant submitted a new main request and auxiliary requests 1 to 3.
- VII. In a telephone conversation held on 25 February 2014 the rapporteur informed the appellant that certain issues under Articles 84 and 123(2) EPC raised in the board's communication still applied to claim 1 of the new requests as filed with the letter of 15 November 2013.
- VIII. With a letter dated 7 March 2014, the appellant submitted a new main request (claims 1 to 11) to replace the previous main request on file.

Independent claim 1 of the main request read:

"1. An isolated polynucleotide selected from the group consisting of:

(a) an isolated polynucleotide consisting of SEQ ID NO:1;

(b) an isolated polynucleotide consisting of the bak promoter (positions 1 - 4021 of SEQ ID NO:1); and

(c) an isolated polynucleotide consisting of a fragment of the polynucleotide of (a), wherein the **fragment** comprises **an ISRE site** (positions 2945-2967 of SEQ ID NO:1), **an SP1 site and a GAS site** (positions 1646-1662 of SEQ ID NO:1) **and confers transcriptional up-regulation in response to interferon- γ (IFN- γ) on a heterologous gene.**" (emphasis added by the board)

Claims 2 to 5 were dependent on claim 1. Independent claims 6 and 8 to 11 and dependent claim 7 corresponded to independent claims 11, 13 and 16 to 18 and dependent claim 12 of the main request before the examining division.

IX. The appellant's arguments relevant for the present decision can be summarised as follows:

Main request - claim 1

Added matter (Article 123(2) EPC

Embodiment (c) found support in claim 1 of the application as filed combined with the disclosure on page 12, lines 9 to 20 and the paragraph bridging bridging pages 13 and 14.

Novelty (Article 54 EPC)

The amendment to claim 1 (c) clarified that it was the *fragment* of part (c) of claim 1 which was capable of activating transcription. Claim 1(c) was therefore novel over any promoter known in the art.

Clarity (Article 84 EPC)

The amended claims rendered the objections of the examining division in respect of the requirements of Article 84 EPC moot.

- X. The appellant requested that the decision under appeal be set aside.

Reasons for the Decision

- 1. The appeal is admissible.

The appealed decision

- 2. The appealed decision only concerns embodiments (c) and (d) of claim 1 of the sole request before the examining division (see section II above), i.e. the novelty (Article 54 EPC) of embodiment (c) and clarity and support issues (Article 84 EPC) concerning embodiments (c) and (d).
- 3. The decision reasoned in particular:
 - 3.1 The second part of embodiment (c) did not specify whether "the polynucleotide" which was "capable of activating transcription" was "the polynucleotide" of the preamble of the claim or "the polynucleotide" of the first part of embodiment (c). Accordingly, the

claim read on an isolated polynucleotide capable of activating transcription. Any known promoter therefore anticipated this subject-matter and was thus not novel (Article 54 EPC).

3.2 It was not clearly stipulated that the fragments of embodiments (c) and (d) were alone and in themselves sufficient to activate transcription without the need for further sequences (Article 84 EPC) since the term "capable of activating transcription" did not establish that further sequences, such as a minimal promoter or, e.g. a TATA box, were not required. The expression "capable of activating transcription" was conventionally used in the art to indicate that a given sequence could activate transcription in conjunction with a minimal promoter.

3.3 The very broad structural scope of embodiment (d) was a mere desideratum without commensurate technical teaching in the application, resulting in a lack of clarity and support according to Article 84 EPC.

Main request

4. During the appeal proceedings the appellant has deleted embodiment (d) from the wording of claim 1 and has substantially amended the wording of embodiment (c) (see section VIII).

Claim 1 - embodiment (c)

Added matter (Article 123(2) EPC)

5. Embodiment (c) of claim 1 differs from embodiment (c) of claim 1 of the request considered by the examining division in that it now specifies that the fragment

comprises certain structural elements (ISRE site, SP1 site and GAS site) and confers transcriptional up-regulation in response to interferon- γ (IFN- γ) on a heterologous gene (see section VIII above).

6. The board is satisfied that embodiment (c) with the amended structural and functional features finds support in the application as filed in the disclosure on page 12, lines 15 to 20, page 13, lines 3 to 8, the sentence bridging pages 13 and 14, claims 2 and 3 as filed and example 7.
7. The board is accordingly satisfied that embodiment (c) of claim 1 complies with the requirements of Article 123(2) EPC.

Novelty (Article 54)

8. Embodiment (c) now specifies that it is the "fragment" which has the structural and functional features. This renders the general novelty (Article 54 EPC) objection of the examining division (see point 3.1 above) moot.

Clarity and support (Article 84 EPC)

9. The isolated polynucleotide defined in embodiment (c) of claim 1 now specifies all the structural elements as required by the description for the polynucleotide to confer transcriptional up-regulation in response to interferon- γ (IFN- γ) on a heterologous gene (see e.g. page 12, lines 18 to 20, page 13, line 28 to page 14, line 3 and example 7). Furthermore, example 7 provides examples of such polynucleotides. Accordingly the amendments to embodiment (c) of claim 1 render the objections of the examining division with respect to the requirements of Article 84 EPC moot. In view of the

above consideration, the board is satisfied that embodiment (c) of claim 1 complies with the clarity and support requirements of Article 84 EPC.

Procedural matter

10. In view of the above considerations the board decides to allow the appeal.
11. The sole reason for the refusal of the patent application referred to in the appealed decision is the non-compliance of two aspects of claim 1 of the sole request pending before the examining division with the requirements of Article 84 EPC and a related novelty objection (Article 54 EPC). The appealed decision does not contain an opinion on the other requirements of the EPC. Independent claim 1 of the main request contains extensive amendments to the appellant's case as follows from a comparison of its wording with that of claim 1 of the request before the examining division (compare sections II and VIII above).
12. Pursuant to Article 111(1) EPC, following the examination as to the allowability of the appeal, the board shall decide on the appeal and, in this respect, it may either exercise any power within the competence of the department which was responsible for the decision appealed or remit the case for further prosecution.
13. In a case such as the present one where the appealed decision is based solely on the requirements of Article 84 EPC (and a related novelty objection) and does not contain an opinion of the other requirements of the EPC and substantial amendments have been made to the claims to overcome the objections in the appealed

decision, the board considers that it is not in a position to judge all the possible relevant facts and it is more appropriate that the prosecution in relation to further requirements of the EPC should be carried out by the department of first instance thereby also securing the applicant's right to two instances.

14. For the above reasons, the board has decided to exercise its discretion under Article 111(1) EPC to remit the case to the first instance department for further prosecution on the basis of the patent application documents on file including the claims of the main request.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance for further prosecution on the basis of the main request filed with the appellant's letter of 7 March 2014.

The Registrar:

The Chairman:



P. Cremona

C. Rennie-Smith

Decision electronically authenticated