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# D E C I S I O N
# of 8 May 2001

**Case Number:** T 1052/98 - 3.3.4

**Application Number:** 90901863.2

**Publication Number:** 0455667

**IPC:** C12N 15/54

**Language of the proceedings:** EN

**Title of invention:**
Gene Switch

**Applicant:**
Syngenta Limited

**Opponent:**
-

**Headword:**
Gene switch/SYNGENTA

**Relevant legal provisions:**
EPC Art. 83

**Keyword:**
"Disclosure - sufficiency (no) - undue burden"

**Decisions cited:**
T 0292/85, T 0694/92, T 0639/95

**Catchword:**
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Beschwerdekammern | Boards of Appeal | Chambres de recours

**Case Number:** T 1052/98 - 3.3.4

**D E C I S I O N**
**of the Technical Board of Appeal 3.3.4**
**of 8 May 2001**

**Appellant:** Syngenta Limited
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**Representative:** Lindsey R. Kent
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**Decision under appeal:** **Decision of the Examining Division of the European Patent Office posted 20 May 1998 refusing European patent application No. 90 901 863.2 pursuant to Article 97(1) EPC.**

**Composition of the Board:**

**Chairman:** U. M. Kinkeldey
**Members:** L. Galligani
S. U. Hoffmann

## Summary of Facts and Submissions

I. The applicants lodged an appeal against the decision of the examining division issued on 20 May 1998 whereby the European patent application No. 90 901 863.2 (published as WO-A-90/08826 = EP-0 455 667) was refused. Basis of the refusal were claims 1 to 3 of the main request and claim 1 of the auxiliary request.

Claim 1, which was the same in both requests, read:

"A method of controlling the expression of a foreign gene or series of genes in a transgenic plant, characterised in that a coding region is placed under the control of the promoter of a gene specifying the 27kd subunit of the maize glutathione-S-transferase gene (GSTII) whereby application to the plant of an effective concentration of a chemical inducer of the promoter induces expression of the coding region."

II. The examining division remarked that there was no description of at least one way of carrying out the invention (cf T 292/85, OJ EPO 1989, 275). The description contained only a list of general procedural steps which could be found in any handbook, and no data were provided which could assist the skilled person in performing the invention, like eg a description of the actual N-terminal sequence of the GST II protein or of the probes to be used or of cloning vectors etc. Moreover, it was not disclosed how the promoter itself could be retrieved from the theoretical genomic DNA fragments. No methods were described by which the GSTII gene promoter activity could be tested. Under these circumstances, undue burden and/or inventive talent was

needed for the skilled person to isolate and test the GSTII promoter fragment (cf decision T 694/92, OJ EPO 1997, 408). A mere reference to standard techniques was considered not to be suitable to satisfy the requirements of Article 83 EPC.

III. With the statement of grounds of appeal, the appellants filed three declarations (one by Dr Ian Jepson and the others by two of the inventors) and six new documents in support of their case. They essentially submitted that the finding that GSTII could be used as an inducible system to regulate gene expression by application of a synthetic chemical was the key factor of the invention in the present case, and that, once the gene was identified, its isolation was routine. The description of the patent application set out the steps required to isolate the GSTII promoter fragment. As stated also by Dr Ian Jepson in his declaration (and confirmed by two of the inventors in their declarations), these were routine steps found in any standard textbook which neither posed an undue burden nor required an inventive activity for the skilled person.

IV. The examining division did not rectify its decision under Article 109(1) EPC, and remitted the appeal to the board of appeal, cf Article 109(2) EPC.

V. In view of the appellants' request for oral proceedings, the board issued on 6 April 2001 a communication pursuant to Article 11 of the rules of procedure of the boards of appeal with a provisional opinion on the case, making inter alia reference to the case of decision T 639/95 of 21 January 1998.

VI. On 23 April 2001, the appellants informed the board that they did not wish to attend the oral proceedings and would therefore not be represented on the date proposed by the board. They withdrew their request for oral proceedings. The board then cancelled oral proceedings.

VII. The appellants request that the decision under appeal be set aside and a patent be granted on the basis of either the main request or the auxiliary request rejected by the examining division.

## Reasons for the Decision

1. The board fully agrees with the examining division's reasons for refusing the patent application. Also in the board's judgment, the mere listing of general procedural steps, in absence of any concrete data and technical information concerning the GSTII promoter, cannot be considered sufficient for a clear and complete disclosure under the terms of Article 83.

2. In this respect, the arguments, the declarations and the further documents submitted by the appellants do not add any decisive elements for a different appreciation. In particular, the board does not find convincing the argument that the identification of the GSTII gene as a suitable switchable gene constituted for the skilled person sufficient information which enabled the isolation of the GSTII promoter fragment as this could be achieved by the routine steps referred to in the specification.

In order to perform the method of claim 1 of both

requests on file, the skilled person has to isolate the specific promoter referred to, namely the promoter of a gene specifying the 27kd subunit of the maize glutathione-S-transferase gene (GSTII). In the board's view, in the absence of any meaningful technical information about the promoter (location, structure etc.) and/or about the gene which contains it, the skilled person is left completely to his or her own resources in order to isolate it. Such information is not even found in the prior art to which the skilled person could refer. Under these circumstances, undue burden is placed on the skilled person who cannot be expected to perform scientific research in areas which are not yet explored. To find that a gene is inducible by a chemical implies directing the skilled person's attention to that specific gene, but does not per se amount to a sufficient disclosure of the technical details necessary to isolate its promoter fragment. It is not sufficient to set out for the skilled reader the general steps of a theoretical protocol which could be used for said isolation, if no data or information whatsoever are made available or are available from prior art references which indicate that any part of the said protocol is indeed valid in respect of the achievement of the final goal, ie the isolation of the specific promoter fragment.

3. The above finding is in line with that of decision T 639/95 (supra) the technical circumstances of which were quite similar to those of the present case. There it was decided the claimed method for producing PHB biopolymers in a host transformed with genes encoding the enzymes ß-ketothiolase, acetoacetyl-CoA reductase and polyhydroxy butyrate (PHB) synthetase was not enabled, because, while the description of the genes

encoding the first two genes was sufficiently clear and complete, that of the gene encoding PHB synthetase was incomplete. The board found that the experimental plan for identifying and isolating the PHB synthetase gene was very general, and that some references were missing and/or incomplete, that there were no results and no details which could facilitate the repetition of the work. Thus, in the board's view, even if each individual experimental step per se could be considered as being feasible with a certain amount of trial and error, the total amount of experimental effort necessary to successfully advance step by step towards the desired final goal was **undue** for a skilled person.

4. Similarly in the present case, where - in comparison with the said case - considerable less technical information is made available by the description, the amount of experimentation needed to perform the claimed invention based on the vague guidance provided by the specification was "**undue**" for a person of ordinary skill at the time the disclosure was presented. Thus, the requirements of Article 83 EPC are not satisfied.

5. As for the argument that the work was accomplished afterwards (cf WO-A-93/01294) by using techniques similar to those described in the present specification, it does not help the appellants as a later more detailed disclosure (the document referred to discloses inter alia the structure and location of the GSTII promoter within the isolated gene) cannot be used to compensate for a deficient disclosure .

## Order

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

The appeal is dismissed.

The Registrar: The Chairperson:

U. Bultmann U. Kinkeldey