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**D E C I S I O N**  
of 28 July 2000

**Case Number:** T 0289/97 - 3.3.4

**Application Number:** 87903791.9

**Publication Number:** 0270615

**IPC:** C12N 15/82

**Language of the proceedings:** EN

**Title of invention:**

TRANSFORMATION AND FOREIGN GENE EXPRESSION IN BRASSICA SPECIES

**Patentee:**

Calgene LLC

**Opponent:**

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DSM Gist Holding B.V.  
Mogen International N.V.

**Headword:**

Brassica/CALGENE

**Relevant legal provisions:**

EPC Art. 123(2)(3)

**Keyword:**

"Main request and first to third auxiliary requests - added subject-matter (yes)"  
"Fourth auxiliary request - broadening of scope of claims (yes)"

**Decisions cited:**

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**Catchword:**

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Case Number: T 0289/97 - 3.3.4

**D E C I S I O N**  
of the Technical Board of Appeal 3.3.4  
of 28 July 2000

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**Decision under appeal:** Decision of the Opposition Division of the  
European Patent Office posted 13 January 1997  
revoking European patent No. 0 270 615 pursuant  
to Article 102(1) EPC.

**Composition of the Board:**

**Chairwoman:** U. M. Kinkeldey

**Members:** L. Galligani

W. Moser

## Summary of Facts and Submissions

I. The appeal is against the decision of the opposition division issued on 13 January 1997 whereby the European patent No.0 270 615 was revoked under Article 102(1) EPC on the ground that none of the claim requests then on file (a main request and two auxiliary requests) fulfilled the requirements of Article 123(2) EPC.

Claims 1, 5, 12 and 16 of the patent as granted read as follows:

"1. Transgenic Brassica species cells and progeny thereof comprising an expression cassette wherein said cells are characterised as oncogene-free and capable of regeneration to morphologically normal whole plants and wherein said expression cassette comprises in the 5' to 3' direction of transcription

(1) a transcription initiation region functional in said Brassica;

(2) a DNA sequence comprising an open reading frame having an initiation codon at its 5' terminus or a nucleic acid sequence complementary to an endogenous transcription product;

(3) a transcription termination region functional in Brassica species cells; and

(4) a structural gene capable of expression in said Brassica providing for selection of transgenic Brassica species cells;

wherein said expression cassette is capable of altering

the phenotype of said Brassica species cells when said cells are grown under conditions whereby said DNA sequence or said nucleic acid sequence is expressed."

"5. A method for transforming Brassica cells to produce Brassica plants, said method comprising:

co-cultivating Brassica cells with disarmed A. tumefaciens comprising a disarmed plasmid containing an insertion sequence resulting from joining in vitro a transcription cassette to at least the right T-DNA border of a Ti or Ri plasmid whereby said Brassica cells are transformed with said insertion sequence which becomes integrated into the plant cell genome to provide transformed oncogene-free cells;

transferring said transformed oncogene-free cells to callus inducing media wherein said callus inducing medium contains at least one auxin and a means for selecting for transformed cells as a result of a marker carried on said plasmid whereby callus comprising transformed cells is produced;

transferring said callus to regeneration media containing less than about 2% sucrose or organic caloric equivalent to produce shoots; and

transferring said shoots to a growing medium to produce plants capable of having an altered phenotype when grown under conditions whereby a DNA sequence in said insertion sequence is expressed."

"12. A Brassica plant comprising cells according to any of claims 1 to 4"



"16. A plant produced according to the method of any one of claims 5 to 11."

The opposition division reasoned also that there was no basis in the application as filed for the combination of the feature "transcription cassette" with the feature "to produce plants capable of having an altered phenotype".

- II. With the statement setting out the grounds of appeal, the appellants (patentees), in addition to substantive arguments on the Article 123(2) issue, submitted that a substantial procedural abuse had been made by the opposition division which justified the reimbursement of the appeal fee.
- III. Respondents II-V and VII (opponents 02-05 and 07) submitted comments on said statement.
- IV. In communications issued on 2 February 2000 and 5 May 2000, respectively, the board outlined the points to be discussed during oral proceedings.
- V. In reply thereto, the appellants submitted a new main request and three auxiliary requests on 14 April 2000 and an amended claim 9 of the main request on 9 May 2000.
- VI. Respondents II made further submissions on 14 April 2000.
- VII. Oral proceedings took place on 16 May 2000. The appellants filed a new third auxiliary request in replacement of the previous one and a fourth auxiliary request.

The **main, first and second auxiliary requests** contained the same claim 1 which was essentially identical to claim 5 as granted (cf Section I supra), as only the term "media" had been replaced by the term "medium". This claim was also identical to claim 1 of the first auxiliary request before the opposition division.

Claim 1 of the **third auxiliary request** differed from claim 1 of the preceding requests in that it contained at the end of its text the expression "wherein said sequence comprises a transcription initiation region and a translational initiation region 5' to a gene of interest, and a transcriptional and translational termination region 3' to said gene of interest, said gene of interest having a phenotypic property."

Claim 1 of the **fourth auxiliary request** differed from claim 1 of the third auxiliary request in that the term "a transcription cassette" was replaced by the term "a cassette providing for transcription and translation".

VIII. The appellants argued that, contrary to the position taken by the opposition division, the combination of the feature "transcription cassette" with the feature "to produce plants capable of having an altered phenotype" in claim 1 of the main and first to third auxiliary requests, respectively, had a basis in the application as filed. In support of their view, they submitted essentially that:

- (a) Although some expressions and phrases referring to transcription and translation were used "in a looser way", the skilled person would have recognised that the application as filed concerned

methods and means for adding phenotypic properties to a plant (cf eg page 1, lines 13 to 16; page 4, lines 20 to 26 and page 35, lines 5 to 8) and that reference was made to a broad concept of transformation.

- (b) Notwithstanding some apparent contradictions in the use of the terms "expression cassette" and "transcription cassette" (cf eg page 10, second paragraph; cf claim 1 as filed), the term "transcription cassette" would have been understood to mean a cassette which provided for transcription **as a minimum requirement**, as it was not excluded that the transcribed RNA could also be translated (cf page 4, line 36 to page 5 line 1 and claim 7 as filed);
- (c) The terms "express" and "expression" were used throughout the application to mean either or both of transcription alone or transcription plus translation (cf claim 1 as originally filed). When referring to the genes of interest on page 9, the application as filed did not make a limitation only to genes which were transcribed **and** translated.
- (d) Thus, the reference to the use of a "transcription cassette" for modulating the expression of endogenous products on page 10 unambiguously indicated to the skilled person that this could include phenotypic genes and could thus result in an altered phenotype.

As regards the **fourth auxiliary request**, the appellants argued that the amendments introduced in claim 1

resulted in a limitation of the scope of protection in comparison with the claims as granted. This was in particular because:

- i) as regards the replacement of the term "a transcription cassette" by the term "a cassette providing for transcription and translation", the previous term "transcription cassette" did not exclude the translation of the RNA (cf item b supra), as evidenced also by the use of the term "expressed" at the end of granted claim 5; and
- ii) as for the expression "wherein said sequence comprises..." (cf Section VII, third paragraph supra) at the end of the text of the claim, this merely specified the inserted sequence.

As claim 1 required transformation with a "disarmed A. tumefaciens comprising a disarmed plasmid", it pointed to a normal morphology of the whole plant like claim 1 as granted.

- IX. The respondents essentially argued that there was no basis in the application as filed for combining the features "transcription cassette" and "to produce plants capable of having an altered phenotype" as done in claim 1 of the main request and first to third auxiliary requests, respectively. The aspect of the application in relation to the use of an "expression cassette" comprising a phenotypic or non-phenotypic gene of interest was distinct from that related to the use of a "transcription cassette". The latter was meant for a "modulation" of the expression of endogenous products by way of the production of a RNA sequence complementary to a transcription product, and did not

have to result in a change of the phenotype. A "modulation" could have a multiplicity of meanings and manifestations, and, although it could possibly include also phenotype alterations, these were nowhere mentioned or suggested. Nor could they be implied from the description of the "expression cassette".

The change from "transcription cassette" to "a cassette providing for transcription and translation" in claim 1 of the fourth auxiliary request offended against Article 123(3) EPC as the claim now covered the expression of a protein which was not covered by the granted claim 5. Moreover, the use of an expression cassette in the claims as granted was in conjunction with a normal morphology, which was no longer the case in the amended claim.

- X. The appellants requested that the decision under appeal be set aside and that the patent be maintained on the basis of the following documents: (a) claims 1 to 8 and 10 to 17 filed on 14 April 2000 as main request, and claim 9 filed on 9 May 2000; or (b) claims 1 to 8 filed on 14 April 2000 as first auxiliary request; or (c) claims 1 to 7 filed on 14 April 2000 as second auxiliary request; or (d) claims 1 to 7 submitted during oral proceedings as third auxiliary request; or (e) claims 1 to 7 submitted during oral proceedings as fourth auxiliary request. The appellants further requested reimbursement of the appeal fee.

The respondents requested that the appeal be dismissed.

- XI. At the end of oral proceedings, the chairwoman announced that the debate was closed and that the decision would be given in writing.

## Reasons for the Decision

*The main request and first to third auxiliary requests:*

*Article 123(2) EPC*

1. The respective claim 1 of these requests contains the combination of the feature "transcription cassette" with the feature "to produce plants capable of having an altered phenotype" which was found by the opposition division to offend against Article 123(2) EPC (cf Section I supra).
  
2. The board does not share the appellants' view that the said combination of the features has a basis in the application as filed (cf Section VIII supra) for the following reasons:
  - (a) The application as filed concerns a method for transforming Brassica cells to produce Brassica plants with **improved** genotypes and associated phenotypes (cf page 1, lines 13 to 16), which does not necessarily always imply an alteration of the phenotype. To this extent, the application describes two quite **distinct** ways (cf the expression "instead of..." on page 10, line 7), namely the introduction into Brassica cells of **either** an "expression cassette" comprising a **phenotypic** or **non-phenotypic** gene of interest (cf page 8, line 19 to page 10, line 6) **or** a "transcription cassette", comprising a sequence complementary to an endogenous transcription product (cf page 10, lines 7 to 14). In both cases, a selection marker can be associated with

the cassette.

- (b) While the integration of the "expression cassette" may provide, as one possibility, novel phenotypic properties (cf page 35, lines 5 to 9) when a phenotypic gene of interest is used therein, the integration of the "transcription cassette", which produces a RNA sequence complementary to an endogenous transcription product (also called anti-sense), is said to result in the **modulation** of the expression of various endogenous products (cf page 10, lines 13 to 14).
  
- (c) The said "modulation" effect is not further defined. In the board's judgment, in agreement with the respondents' view, this has a multiplicity of meanings and manifestations, possibly including in some instances also phenotype alterations, which, however, are nowhere mentioned or suggested. Nor can they be considered to be necessarily implied from the description of the "expression cassette", which is a separate embodiment.
  
- (d) Given the fact that the application as filed explicitly contemplates the use of phenotypic and non-phenotypic genes only in respect of the "expression cassette" (cf page 8, line 19 to page 10, line 6), and in consideration of the generality of the statement about the modulating effect in relation to the "transcription cassette" (cf item (c) supra), the combination of the feature "transcription cassette" with the feature "to produce plants capable of having an altered phenotype" constitutes **specific** information, ie a

limitation of the modulating effects to those resulting in an alteration of the phenotype. This specific limitation cannot be directly and unambiguously derived from the application as filed.

3. In sum, the board finds that the respective claim 1 of these requests offends against Article 123(2) EPC. The requests can therefore not be allowed.

*Fourth auxiliary request: Article 123(3) EPC*

4. In comparison with independent claim 5 as granted, claim 1 of this request contains: **(a)** the term "a cassette providing for transcription and translation" in replacement of the term "a transcription cassette" and **(b)** the expression "wherein said sequence comprises..." (cf Section VII, third paragraph supra) at the end of its text. The question here is whether these amendments give rise to an extension of the protection conferred in comparison with that conferred as a whole by the claims as granted.
5. While independent method claim 5 as granted, in view of the feature "transcription cassette" and the interpretation thereof in the light of the description (cf page 10, lines 7 to 14), necessarily implied **only** the production of an RNA sequence complementary to an endogenous **transcriptional** product, ie another RNA (cf point 2, item (b) supra), claim 1 of this request, because of feature **(a)**, covers now also the production of an RNA sequence which is translated, ie a sequence that is read into an amino acid sequence. The "product-by-process" claim 16 as granted, which had a broader



ambit of protection than the said claim 5, was equally limited, by virtue of its reference to the method of claim 5, to plants in which the stably integrated "transcription cassette" produced an RNA sequence complementary to an endogenous **transcriptional** product, ie another RNA. It has thus to be concluded that claim 1 at issue, seen also from the point of view of Article 64 (2) EPC, has a broader scope than granted claims 5 and 16. The appellants' reference to the term "expressed" in granted claim 5 cannot change this conclusion, because, as also admitted by the appellants (cf Section VIII, item (c) supra), the term "express" is used throughout the application to mean either or both of transcription alone or transcription plus translation. In the context of granted claim 5, and in relation to the "transcription cassette", the term referred only to transcription, namely to the production of an RNA complementary to an endogenous transcription product.

6. It still has to be examined whether, in spite of being broader than claims 5 and 16 as granted, claim 1 at issue is nevertheless within the scope of any of the other granted claims, in particular of product claim 1 or 12, the first being directed to transgenic Brassica species cells and the second being directed to a Brassica plant comprising said cells (cf Section I supra).
7. Since claims 1 and 12 as granted are directed to a product, no problems of extension of protection would arise **if** the method according to claim 1 at issue necessarily resulted in a product falling within the scope of said claims. This is, however, not the case as there are differences in a number of essential features

between the claims. It is sufficient here to refer to the fact that, while claims 1 and 12 as granted had the feature "morphologically normal whole plants" as an obligatory requirement, claim 1 at issue does not have this qualification, and thus also covers a plant product which falls outside the scope of claims 1 and 12 as granted. In this respect, the argument put forward by the appellants that the reference in the claim at issue to a "disarmed A. tumefaciens comprising a disarmed plasmid" points to normal morphology is not convincing because granted claims 1 and 12, although they referred to oncogene-free cells, which implied transformation with a "disarmed" plasmid (cf patent specification, page 4, lines 49-50), nevertheless made additional reference to the feature "morphologically normal whole plants", thereby showing that the latter had in fact an essential restrictive character.

8. In conclusion, the board finds that claim 1 of this request offends against Article 123(3) EPC. The request can therefore not be allowed.

*Other matters: request for reimbursement of the appeal fee.*

9. Rule 67 EPC provides for the possibility of reimbursement of the appeal fee "where the Board of Appeal deems an appeal to be allowable". In the present case, as the appeal is to be dismissed, that particular condition for reimbursement of the appeal fee is not fulfilled.

## **Order**

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

The appeal is dismissed.

The Registrar:

The Chairperson:

M. Beer

U. Kinkeldey