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D E C I S I O N
of 8 May 1996

Case Number: T 0694/92 - 3.3.4

Application Number: 84302533.9

Publication Number: 0122791

IPC: C12N 15/00

Language of the proceedings: EN

Title of invention:
Plant gene expression

Patentee:
Mycogen Plant Science, Inc.

Opponent:
Unilever N.V.
Centerns Ungdomsförbund
Sandoz Ltd.
Monsanto Company
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Stichting Oppositie Plantoctrooi p/a Studium Generale
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Max-Planck-Gesellschaft zur Förderung der Wissenschaften e.V.
Godehard Graf Hoensbroech
Die Grüne Alternative (Grüne)

Headword:
Modifying plant cells/MYCOGEN

Relevant legal provisions:
EPC Art. 54, 56, 83, 84, 123(2)(3)

Keyword:
"Main request - support by the description (no)"
"Sufficiency of disclosure (no)"
"First auxiliary request - support by the description (no)"
"Sufficiency of disclosure (no)"
"Second auxiliary request - added subject-matter (yes)"
"Third auxiliary request - support by the description (yes) - fair generalisation"
"Sufficiency of disclosure (yes)"
"Novelty (yes)"
"Inventive step (yes) - no reasonable expectation of success"

Decisions cited:
T 0068/85; T 0292/85; T 0032/82; T 0301/87; T 0060/89
T 0019/90; T 0158/91; T 0409/91; T 0435/91; T 0626/91
T 0612/92; T 0939/92; T 1055/92; T 0296/93; G 0010/91

Headnote:
I. Where an invention relates to the actual realisation of a technical effect anticipated at a theoretical level in the prior art, a proper balance must be found between, on the one hand, the actual technical contribution to the state of the art by said invention, and, on the other hand, the terms in which it is claimed, so that, if patent protection is granted, its scope is fair and adequate (see point 3 of the Reasons).

II. In cases where the gist of the claimed invention consists in the achievement of a given technical effect by known techniques in different areas of application and serious doubts exist as to whether this effect can readily be obtained for the whole range of applications claimed, ample technical details and more than one example may be necessary in order to support claims of a broad scope. Accordingly, claims of broad scope are not allowable, if the skilled person, after reading the description, is not able to readily perform the invention over the whole area claimed without undue burden and without needing inventive skill (see points 5 and 19 of the Reasons).

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Modifying plant cells/MYCOGEN

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EPC Art. 54, 56, 83, 84, 123(2)(3)

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T 0612/92; T 0939/92; T 1055/92; T 0296/93; G 0010/91

Headnote:
follows

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0694/92 - 3.3.4

D E C I S I O N
of the Technical Board of Appeal 3.3.4
of 8 May 1996

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Decision under appeal: **Interlocutory decision of the Opposition Divis of the European Patent Office dated 5 June 199 concerning maintenance of European patent No. 0 122 791 in amended form.**

Composition of the Board:

Chairman: U. M. Kinkeldey
Members: L. Galligani
W. Moser
F. Davison-Brunel
J.-C. Saisset

Summary of Facts and Submissions

I. European patent No. 0 122 791 was granted on 29 March 1989 with twenty claims for eleven contracting states. It was based on European patent application No. 84 302 533.9, claiming US priority of 15 April 1983.

II. Opposition was filed against the grant of the patent by eleven parties (opponents 01 to 11) all requesting its revocation in part or in toto on the grounds of lack of novelty, lack of inventive step, lack of sufficiency of disclosure and non-compliance with Articles 52(2)(a) and 53 EPC. The opposition by opponent 09 was deemed not to have been filed since the opposition fee was not paid. During the proceedings before the opposition division, the parties relied upon a large number of documents, including in particular the following (numbering as used by the opposition division):

(3) E.C. Cocking et al., Nature, Vol. 293, 1981, 265-269;

(5a) Transcript of an oral presentation by J.D. Kemp at the "Genetic Engineering: Applications to Agriculture" symposium held on 16 to 19 May 1982 at the Beltsville Agricultural Research Center, Beltsville, Md., USA;

(9a) J. Schell et al., "Ti plasmids as experimental gene vectors for plants", Proceedings of the Miami Winter Symposia, January 1983, Academic Press, New York, N.Y., USA, Vol. 20, 1983, 191-209;

(14) EP-A-0 116 718 together with its priority document (14a) EP application No. 83 100 255.5 of 13 January 1983;

(15) EP-A-0 131 623 together with its priority document (15a) US Serial No. 458 414 of 17 January 1983.

(16) C.H. Shaw et al, "Engineering Bacteria and Plants for Enhanced Nitrogen Fixation", Proceedings of the 12th International Congress of Soil Science, New Delhi, 1982, 54-68;

(17) M-D. Chilton et al., "Tailoring the Agrobacterium Ti Plasmid as a Vector for Plant Genetic Engineering", Stadler Symposium, Vol. 13, 1981, University of Missouri, Columbia, Mo, USA, 39-52;

(18) A.J. de Framond et al., "Mini-Ti Plasmid and a Chimeric Gene Construct: New Approaches to Plant Gene Vector Construction", Proceedings of the Miami Winter Symposium, January 1983, Academic Press, New York, N.Y., USA, Miami Winter Symposia, Vol. 20, 1983, 159-170;

(19) Ph.D. thesis of J. Leemans, Free University of Brussels, academic year 1981-82, "Technieken vor het Gebruik van Ti-Plasmieden van **Agrobacterium Tumefaciens** als Vectoren voor de genetic engineering van Planten";

(21a) J.D. Kemp et al., "Transfer of a functional gene via the Ti plasmid", Curr. Top. Plant Biochem. Physiol., Proc. Inaug. Plant Biochem. Physiol. Symp. 1982 (published 1983), Randal Douglas et al. eds., University of Missouri, Columbia, Mo., USA, Vol. 1, 170-179.

(22) R.T. Fraley et al., "Use of a Chimeric Gene to confer Antibiotic Resistance to Plant Cells", Proceedings of the Miami Winter Symposium, January 1983, Academic Press, New York, N.Y., USA, Miami Winter Symposia, Vol. 20, 1983, 211-221;

(31) J.L. Marx, Science, Vol. 219, 18 February 1983, 829-830;

(36) P.B. Goldsbrough et al., Mol. Gen. Genet., Vol. 202, 1986, 374-381;

(38) L. Herrera-Estrella et al., Nature, Vol. 303, May 1983, 209-213.

III. On 5 June 1992 the opposition division issued an interlocutory decision within the meaning of Article 106(3) EPC in which the patent was maintained in amended form on the basis of claims 1 to 11 filed on 31 March 1992.

Claims 1, 10 and 11 therein read as follows:

"1. A method for genetically modifying a plant cell, comprising the steps of:

(a) inserting a plant gene comprising a plant promoter and a plant structural gene into T-DNA, thereby forming a T-DNA/plant gene combination, the plant promoter

being adjacent to the 5'-end of the plant structural gene and the plant structural gene being downstream from the plant promoter in the direction of transcription; and

(b) transferring the T-DNA/plant gene combination into a plant cell, such that expression of the protein encoded by the said plant structural gene is detectable in said plant cell.

10. A plant cell produced according to the method of any of Claims 1-9.

11. A plant or plant tissue grown from a plant cell according to Claim 10."

Dependent claims 2 to 9 concerned specific embodiments of the method according to claim 1.

IV. In the opinion of the opposition division, the novelty of these claims was not affected by document (5a). The claims were found to be inventive having further regard to documents (16) to (19) and (21a). The opposition division considered document (5a) as the closest prior art and defined the underlying technical problem as the achievement of full expression (transcription and translation) of plant structural genes in plant cells. It was satisfied that this problem had been solved by the method according to claim 1. In its opinion, as there was no suggestion in the prior art as to the use of plant promoters instead of promoters from the Ti plasmid (see documents (17) to (19)), a skilled person starting from the oral disclosure (5a) would not have tried to use a plant gene with its own promoter and

would not have had a reasonable expectation of success in this respect. As for the other grounds for opposition (objections under Article 52(2)(a), 53 and 83 EPC), the opposition division did not see any conflict with the requirements of the EPC.

V. An appeal was lodged against this decision by six parties (opponents 01-04, 06, 08). Opponent 06 later withdrew its appeal. Opponents 01-04 and 08 are appellants I-IV and V.

VI. The respondents (patentees) filed a response to the statements of grounds of the appellants on the basis of the claims as maintained by the opposition division. They referred to three additional documents including:

(49) Sun et al., Nature, Vol. 289, January 1981, 37-41.

VII. On 15 February 1996, the board issued a communication containing a preliminary analysis of the case. Appellants III and the respondents sent their comments in reply to this communication. The respondents filed four auxiliary requests and asked the board to refer two questions to the Enlarged Board of Appeal in case it was minded to refuse the main request, ie for maintenance of the patent in amended form on the basis of claims 1 to 11 as filed on 31 March 1992 (see section III above), either on the grounds of lack of novelty or on the grounds that the subject-matter of claim 10 or 11 was excluded from patentability under Article 53(b) EPC.

VIII. Oral proceedings were held on 7 and 8 May 1996. During the proceedings, the respondents filed three new auxiliary requests to replace the four previous auxiliary requests. An amended page 9 of the description was also filed in connection with the third new auxiliary request.

Claim 1 of the **first auxiliary request** reads as follows:

"A method for genetically modifying a dicotyledonous plant cell, comprising the steps of:

(a) inserting a plant gene comprising a dicotyledonous plant promoter and a dicotyledonous plant structural gene into T-DNA, thereby forming a T-DNA/plant gene combination, the plant promoter being adjacent to the 5'-end of the plant structural gene and the plant structural gene being downstream from the plant promoter in the direction of transcription; and

(b) transferring the T-DNA/plant gene combination into a plant cell, such that expression of the protein encoded by the said plant structural gene is detectable in said plant cell."

Claim 1 of the **second auxiliary request** reads as follows:

"A method for genetically modifying a dicotyledonous plant cell, comprising the steps of:

(a) inserting a plant gene comprising a phaseolin promoter and a plant structural gene into T-DNA, thereby forming a T-DNA/plant gene combination, the promoter being adjacent to the 5'-end of the plant structural gene and the plant structural gene being downstream from the plant promoter in the direction of transcription; and

(b) transferring the T-DNA/plant gene combination into a dicotyledonous plant cell, such that expression of the protein encoded by the said plant structural gene is detectable in said plant cell."

Claims 1 and 7 of the **third auxiliary request** read as follows:

"1. A method for genetically modifying a dicotyledonous plant cell, comprising the steps of:

(a) inserting a plant gene comprising a phaseolin promoter and a phaseolin structural gene into T-DNA, thereby forming a T-DNA/plant gene combination, the promoter being adjacent to the 5'-end of the structural gene and the structural gene being downstream from the plant promoter in the direction of transcription; and

(b) transferring the T-DNA/plant gene combination into a dicotyledonous plant cell, such that expression of the protein encoded by said structural gene is detectable in said plant cell.

7. A plant cell produced according to the method of any of claims 1-6."

This request no longer contains a claim directed to a plant (see claim 11 in section III above).

IX. Appellants V, in particular, objected to the **admissibility** under Article 123(2) EPC of the three auxiliary requests essentially because they considered that the introduction into claim 1 of a limitation:

- to a dicotyledonous plant cell into which a dicotyledonous plant promoter with a dicotyledonous plant structural gene is transferred (first auxiliary request), or

- to a dicotyledonous plant cell into which a phaseolin promoter with a plant structural gene is transferred (second auxiliary request), or

- to a dicotyledonous plant cell into which a phaseolin promoter with a phaseolin structural gene is transferred (third auxiliary request),

resulted in the selection of specific subject-matter which was not unambiguously derivable from the application documents as filed.

All the appellants emphasised that, if consistent criteria were applied to the examination of the questions of support, sufficiency of disclosure and inventive step, it was clear that the patent in suit was incapable of simultaneously satisfying all these requirements.

As regards the issues of **clarity, support and sufficiency of disclosure** (Articles 83 and 84 EPC), the appellants submitted essentially the following arguments:

- In the light of document (5a), the contribution to the state of the art by the patent in suit, if any, was not such as to justify the maintenance of the patent on the basis of claims which contained no technical features other than a reference to the result to be achieved (see the feature "such that expression of the protein encoded by the said plant structural gene is detectable in said plant cell" in claim 1).

- The description failed to indicate the technical measures which had to be taken in order to successfully achieve without undue burden the desired effect (expression of a plant structural gene in a plant cell) over the whole area claimed.

- The patent specification contained only the example of the expression in plant cells of a phaseolin gene containing its own promoter, something that had already been suggested in the prior art (see document (5a)).

- The scanty description with its reference to a series of intended experiments which had never been carried out did not provide a disclosure sufficient for a skilled person to obtain the technical effect of expression in any plant, not even in any dicotyledonous plant, of any desired plant structural gene with any plant promoter.

- As unsuccessful attempts to this effect had already been reported in the state of the art before and after the priority date (see, for example, documents (17), (36) and (38)), it was not acceptable under the provisions of Articles 83

and 84 EPC to maintain a patent with claims directed to a mere "desideratum" (so-called "free beer" claims) for which no sufficient technical support was given in the patent specification.

- Broad claims that failed to recite the critical technical features which truly distinguished the claimed subject-matter over matter known from the prior art should not be allowed.

- In the view of appellants V, these considerations also applied to the third auxiliary request because the phaseolin promoter referred to was an unidentified entity and the description did not provide the skilled person with adequate instructions for its unambiguous identification, and thus for performing the invention as claimed.

With respect to **novelty**, the appellants argued that the earlier European patent application EP-A-0 131 623 (document (15)) disclosed all the elements of claim 1 of the main request and thus was prejudicial to its novelty under Article 54(3)(4) EPC. Appellants V submitted that the earlier European patent application EP-A-0 116 718 (document (14)) also affected the novelty of the said request under Article 54(3)(4) EPC. Furthermore, it was argued, in particular by appellants V, that document (5a) inherently affected the novelty of claim 1 of all the requests, including the third auxiliary request.

As regards **inventive step**, the appellants essentially submitted that, since a vector comprising the entire phaseolin gene including its own promoter regions was known from document (5a), it was obvious for the skilled person to carry out the final experiment

indicated in the same document, ie to insert it into a plant cell and to measure expression. The phaseolin promoter regions were also easily obtainable on the basis of document (49). The performance of this final experiment was simply a matter of diligence and required no inventive skill. The skilled person would not have been discouraged from trying it by the prior art, and there was a reasonable expectation of success, especially since the successful demonstration of heterologous gene expression in plants reported in the art (see, for example, documents (9a), (22), (31)) rendered obvious the general proposition that plant genes comprised of plant promoters and plant structural genes would be functional in plants.

X. As regards the **admissibility** of the auxiliary requests under Article 123(2) EPC, the respondents submitted that support for the limitations introduced therein was found in the application as filed where an example of the insertion into a dicotyledonous plant cells (sunflower) of a dicotyledonous plant structural gene (phaseolin) with its own promoter was given and reference was made to the use of the same experimental approach with promoters and structural genes from the same or different plant sources, including modified versions thereof.

As regards the issues of **clarity, support and sufficiency of disclosure** (Articles 83 and 84 EPC), the respondents argued essentially as follows:

- According to the rationale set out in decision T 292/85 (OJ EPO 1989, 275), fair protection had to be granted to inventions which provided a real progress in the art. In the present case, the key contribution to the state of the art was the first

demonstration of a method which allowed the expression (transcription and translation) of plant genes in plant cells and in plants and plant tissue derived therefrom under the control of a plant promoter.

- Before the patent in suit, there were neither indications nor expectations in the prior art that this could be achieved, inter alia because of the highly specialized nature of plant promoters and all the uncertainties linked to the presence of introns and to the placement of a plant promoter into T-DNA.

- Prior art reports of foreign gene expression in plants were based on the use of Ti promoters (see, for example, documents (9a) and (31)) which were known to be recognized by the plant cell machinery. Attempts to achieve expression of plant gene fragments, where it was not even clear whether they contained promoter regions, had failed (see document (17) and document (38) published shortly after the present priority date).

- The disclosure of the patent in suit opened a previously closed door and, by providing the first demonstration that transcription and translation of a plant structural gene could indeed be achieved in a plant cell under the control of its own promoter via T-DNA insertion, paved the way for the expression of other plant structural genes by use of the same approach.

- The specification of the patent in suit illustrated by way of its examples that a plant promoter could be used to achieve a detectable

level of expression of a plant structural gene in plant cells within the context of T-DNA (Examples 1 to 3), that introns could be removed from a gene (Example 4), and that plants could be regenerated from transformed gall tissues (Examples 9 to 11).

- The phaseolin gene and its fully characterised promoter region served as a model for a method of general applicability. In fact, on the basis of the information and guidance given, the skilled person could carry out the teaching of the invention in respect of other plant genes and other plant promoters.

- Although it was true that the expression of some other genes or of genes yet to be discovered could involve additional inventions, these would nevertheless be within the concept made available by the patent in suit. For these reasons fair protection had to be granted to the contribution it made. This could be done only on the basis of general claims such as those on file which contained all the essential technical features of the invention and provided instructions clear enough for testing whether the functional definition had been met (see decision T 68/85, OJ EPO 1987, 228, in particular point 8.4.3 of the Reasons). None of the appellants had provided evidence that a separate invention was needed in order to perform the invention as claimed or that some essential elements were missing from the disclosure in the specification of the patent in suit. Nor could it be argued that it was unclear what fell under the scope of the claims. Under these circumstances, the requirements of Articles 83 and 84 EPC were satisfied.

As regards **novelty**, the respondents submitted that none of the cited documents disclosed a method for the expression of a plant structural gene in a plant cell under the control of a plant promoter.

As for **inventive step**, the respondents argued that a major research effort was needed in order to test whether the vector disclosed in document (5a) was capable of providing expression of phaseolin. The skilled person had no reasonable expectation of success because the prior art was not encouraging in respect of the use of plant promoters (see documents (9a), (17), (38)). In fact, Ti promoters had actually been used in the prior art (see documents (9a) and (31)) and there were uncertainties regarding the effect of placing a plant promoter into the bacterial DNA (T-DNA) used for insertion into plant cells. Under these circumstances, the skilled person would not have been able to predict a reasonable chance of success from the disclosure of document (5a) (see, for example, decision T 296/93, OJ EPO 1995, 627, in particular point 7.4.4 of the Reasons).

XI. The appellants requested that the decision under appeal be set aside and the patent be revoked.

The respondents requested that the appeals be dismissed or, alternatively, that the decision under appeal be set aside and the patent be maintained **(a)** with claims 1 to 10 according to the first auxiliary request, or **(b)** with claims 1 to 10 according to the second auxiliary request, or **(c)** with claims 1 to 7 according to the third auxiliary request and amended page 9 of the description, as submitted during oral proceedings.

Reasons for the Decision

1. The appeals are admissible.

The main request

2. No objections have been raised by the appellants under **Article 123(2) and (3) EPC** in respect of this request. The board notes that claim 1 differs from claim 10 as granted in that it contains in its final part the sentence "such that expression of said plant structural gene is detectable in said plant cells". The introduction of this feature, which the skilled person can derive from the "Summary of the invention" on pages 14 to 15 of the application as filed in combination with the examples therein reporting the expression of detectable levels of phaseolin (see in particular Example 1.6), does not give rise to new subject-matter nor does it lead to an extension of the protection conferred. Thus, no objections under Article 123(2) and (3) EPC arise.

3. The present case is a typical example of a not uncommon situation - especially in the context of inventions in the field of biotechnology - in which the contribution to the state of the art by the invention disclosed in a patent or patent application resides in the actual realisation of a technical effect anticipated at a theoretical level in the prior art. In such a situation, a proper balance must be found between, on the one hand, the **actual** technical contribution to the state of the art by the invention disclosed in said patent or patent application, if any, and, on the other hand, the **manner of claiming** so that, if patent protection is granted, its scope is fair and adequate.

This need for fair and adequate protection has been emphasized in several decisions of the boards of appeal (see, for example, T 292/85 above, and T 301/87, OJ EPO 1990, 335). The board deems it appropriate to consider the interrelation between the requirements of Articles 84, 83 and 56 EPC in order to find a fair balance in the present case.

4. **Article 84 EPC** requires that the matter for which protection is sought be defined in the claims in a clear and concise manner and that the claims be supported by the description. This means not only that a claim must be non-ambiguous and comprehensible, but also that all the essential features of the claimed invention have to be indicated in the claim, these being the features which are necessary in order to obtain the desired effect (see, for example, T 32/82 OJ EPO, 1984, 354 and T 1055/92, OJ EPO 1995, 214). The essential technical features may also be expressed in general functional terms, if, from an objective point of view, such features cannot otherwise be defined more precisely without restricting the scope of the claim, and if these features provide instructions which are sufficiently clear for the skilled person to reduce them to practice without undue burden, ie with no more than a reasonable amount of experimentation, and without applying inventive skill (see, for example, T 68/85 above). Although Article 84 EPC is not open to objection under the terms of Article 100 EPC, it may nevertheless constitute a proper ground for revoking a patent if objections to either clarity or support arise out of amendments to the patent as granted (see G 10/91, OJ EPO 1993, 420, point 19 of the Reasons). Furthermore, questions of clarity or support may affect

the decision on issues under Article 100 EPC such as novelty (Article 54 EPC), inventive step (Article 56 EPC) or sufficiency of disclosure (Article 83 EPC) (see, for example, T 435/91 OJ EPO 1995, 188 and T 626/91 of 5 April 1995).

5. **Article 83 EPC** requires an invention to be disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. As made clear in T 409/91 (OJ EPO 1994, 653, see in particular points 3.3 to 3.5 of the Reasons), the extent to which an invention is sufficiently disclosed is highly relevant when considering the issue of support within the meaning of Article 84 EPC, because both these requirements reflect the same general principle, namely that the scope of a granted patent should correspond to its technical contribution to the state of the art.

Hence it follows that, despite being supported by the description from a purely formal point of view, claims may not be considered allowable if they encompass subject-matter which in the light of the disclosure provided by the description can be performed only with undue burden or with application of inventive skill. As for the amount of technical detail needed for a sufficient disclosure, this is a matter which depends on the correlation of the facts of each particular case with certain general parameters, such as the character of the technical field, the date on which the disclosure was presented and the corresponding common general knowledge, and the amount of reliable technical detail disclosed in a document (see decision T 158/91 of 30 July 1991).

In certain cases a description of one way of performing the claimed invention may be sufficient to support broad claims with functionally defined features, for example where the disclosure of a new technique constitutes the essence of the invention and the description of **one way** of carrying it out enables the skilled person to obtain without undue burden the same effect of the invention in a broad area by use of suitable variants of the component features (see T 292/85 above). In other cases, more technical details and **more than one example** may be necessary in order to support claims of a broad scope, for example where the achievement of a given technical effect by known techniques in different areas of application constitutes the essence of the invention and serious doubts exist as to whether the said effect can readily be obtained for the whole range of applications claimed (see T 612/92 of 28 February 1996). However, in all these cases, the guiding principle is always that the skilled person should, after reading of the description, be able to readily perform the invention over the whole area claimed without undue burden and without needing inventive skill (see T 409/91 and T 435/91 above). On the other hand, the objection of lack of sufficient disclosure presupposes that there are serious doubts, substantiated by verifiable facts, in this respect, see T 19/90 (OJ EPO 1990, 476, see point 3.3 of the Reasons).

6. **Article 56 EPC** requires the claimed invention, ie the proposed technical solution for a given technical problem, not to be obvious to a person skilled in the art. If the non-obviousness of a claimed invention is based on a given technical effect, the latter should, in principle, be achievable over the whole area claimed (see, for example, T 939/92, OJ EPO 1996, 309).

7. For the purposes of Articles 56 and 83 EPC the same level of skill is required from the **person skilled in the art** (see T 60/89, OJ EPO 1992, 268) in two different technical situations: whereas for the purpose of evaluating inventive step the skilled person has knowledge of the prior art only, for the purpose of evaluating sufficiency of disclosure (and, hence, support) he or she has knowledge of the prior art **and** of the invention as disclosed.

8. The above considerations show how closely interrelated and how critical the issues of support of the claims, sufficiency of disclosure and inventive step are in cases - such as the present one - where it is particularly difficult to find a proper balance between the breadth of the claims and the actual contribution to the state of the art by the disclosure of the patent in suit.

9. In the present case, the **closest prior art** is represented by document (5a). This document is a transcript of an oral disclosure by Dr J.D. Kemp which was made before the priority date. This disclosure included inter alia the construction of a DNA vector comprising T-DNA having inserted therein "the entire phaseolin gene including its own promoter regions" (see page 4, lines 7 to 8). Dr Kemp also stated: "But as you've heard, this has been done by a number of people now and nobody has shown a functional gene when one includes the endogenous promoter" (see page 4, lines 8 to 10). Although it is not immediately evident which reports Dr Kemp was referring to, it was known in the art that previous attempts to transfer a variety of bacterial, yeast and animal genes into plant cells did not lead to expression of the foreign genes because their own control sequences were not recognised by the

plant machinery (see document (31)). Dr Kemp stated that he could not report the final experiment because "it hasn't been completed" (see page 4, lines 3 to 4). As it can be inferred from document (5a) (see passage starting on page 3 and continuing on page 4), this experiment consisted in the determination of whether transcription and translation would take place in plant cells subsequent to the transfer into them of the vector.

10. On examination of the **description** of the patent in suit, it can be observed that Examples 1 and 2 report the successful expression of detectable levels (on average 10 ng per gram tissue/fresh weight) of phaseolin in sunflower plant cells into which the DNA coding sequence was transferred with its own promoter via a T-DNA vector. In Example 3 manipulations of the gene for phaseolin and in Example 4 the removal of introns from the same gene are reported. Examples 5 to 8 describe mutated Ti plasmids. Examples 9 and 10 refer in general to the regeneration of plants from carrot and tobacco tumours, respectively, without any reference to any foreign gene expressed therein. Example 11 refers to the introduction of expressible phaseolin gene into regenerated alfalfa plants, but fails to report any actual experimental data. Example 12 is concerned in general with techniques for extracting, fractionating and detecting RNA. Example 13 refers to micro-ELISA assays for the detection of phaseolin. Finally, Example 14 describes in general the accomplishment of triparental matings.

11. Thus the **actual technical contribution to the state of the art** by the disclosure of the patent in suit essentially consists of providing experimental support for the transfer and expression into plant cells of a

DNA sequence encoding phaseolin under the control of its own promoter. In other words, the technical contribution is not a new general technique for achieving expression of a plant structural gene in a plant cell, but the successful completion of the experiment anticipated by Dr Kemp in his oral disclosure by testing the effect of the transfer into plant cells of the known vector construct comprising the phaseolin gene including its own promoter regions (see point 9 above). Through reference to the prior art, the description indicates how plant regeneration can be obtained from these cells. The specific teachings of the examples are then generalised in the description, where it is stated: "The invention in principle applies to any introduction of plant genes into any plant species into which T-DNA can be introduced and in which T-DNA can remain stably replicated. In general these species include, but are not limited to, dicotyledonous plants..." (see page 8, lines 51 to 54). The description also indicates on page 9, lines 3 to 17 that the promoter and structural gene may be derived from the same or different plant sources, that a plant gene can be placed downstream either from its own promoter or from a different plant promoter and that the promoter and coding regions may also include modifications, either naturally or artificially induced, and may include chemically synthesized segments. However, no examples are given in this respect.

12. **Claim 1** at issue is generally directed to a method for genetically modifying a plant cell by transferring into it a combination T-DNA/plant promoter-plant gene, **such that expression of the protein encoded by the said plant structural gene is detectable in said plant cell** (feature "such that..."). No specific details are given

in the claim in respect of the structural arrangement of the combination T-DNA/plant promoter-plant gene, except for the self-evident indication that the plant promoter is adjacent to the 5'-end of the structural gene which is downstream from the promoter in the direction of transcription (see item (a)). Thus, the skilled person is essentially instructed by the claim to transfer a DNA vector such as the one disclosed in document (5a) (see point 9 above) into a plant cell "such that expression of the protein encoded by the said plant structural gene is detectable in said plant cell". Failing any limitations in respect of the kind of plant cell and/or plant gene and/or plant promoter, the claim is thus directed to a method **whenever it works** (see the feature "such that...") for a whole range of applications. In other words, the skilled person is told that patent protection is claimed whenever expression of any desired plant gene is detected upon transfer of the said gene with its own promoter or any other plant promoter into any plant cell via a T-DNA vector in a manner known in the art.

13. Formal support for this broadly formulated claim can indeed be found in the general statements in the description (see point 11 above). However, the question is whether the skilled person, on the basis of the description of the patent in suit (see point 10 above) and of the prior art, would have been in a position at the priority date to carry out the method for the whole range of applications claimed without finding himself/herself in a situation where, despite using reasonable effort to make the method work, he or she would not have achieved the technical effect for some applications or would have achieved it only with undue burden.

14. The present case is a delicately balanced one because:

- If it is maintained that the achievement of the technical effect (expression) is the inevitable result of the technical measure of placing a plant structural gene into a T-DNA vector adjacent and downstream from a plant promoter, then substantiation by way of one example could be considered sufficient, but there would indeed be little merit in such a proposition because this measure had already been anticipated in explicit, though predictive terms by document (5a);

- If, however, it can be inferred that the achievement of the technical effect is by no means certain, especially when working in areas of application other than the one given by way of example, and possibly requires more work than the simple placing of a plant structural gene downstream from a plant promoter, then, although merit could possibly be seen in the specific achievement concerned, more technical details would be required to support a claim to the whole range of envisaged applications.

15. The board notes that, in their arguments in favour of inventive step (see section X above), the respondents submitted that major research was needed in order to test whether the vector construction disclosed in document (5a) was capable of bringing about expression of phaseolin. If this is accepted to be the case notwithstanding the explicit indications already provided in document (5a), then there must be serious doubts as to whether the mere completion of the experiment announced by Dr Kemp, this being the actual contribution to the state of art by the patent in suit (see point 11 above), can give the proper technical

support to a claim with such a wide range of applications as present claim 1. This is because it can reasonably be expected that the skilled person would face similar difficulties when trying to obtain the same technical effect with the whole range of different combinations of plant structural gene/plant promoter claimed. In fact, these comprise not simply suitable variants of the exemplified component features, eg variant forms of the phaseolin gene and/or phaseolin promoter, but also a wealth of structurally and functionally different entities, eg plant structural genes encoding a protein other than phaseolin or promoters other than the phaseolin promoter, or technical situations, eg monocotyledonous or other dicotyledonous plants, in respect of which difficulties and uncertainties in achieving the claimed technical effect still remain, in spite of the reported specific example of phaseolin with its own promoter. Confirmation of the fact that success can be achieved with phaseolin with its own promoter is not necessarily of any help to the skilled person trying to obtain the same effect with totally different plant gene/promoter combinations.

16. The above considerations find support in some later evidence on file. For example, document (36) shows that, upon transfer via T-DNA into sunflower cells (dicotyledonous plant cells) of a monocotyledonous gene (maize zein) containing sufficient information within the 5' flanking regions to direct transcription, no protein was detected, notwithstanding the presence of mRNA, (see in particular page 379, last paragraph, and page 380). Also document (38), published shortly after the present priority date, reports that attempts to express, for example, a plant gene encoding

leghaemoglobin into tobacco cells via Ti-plasmid gene vectors were unsuccessful, presumably due to the lack of recognition of the transcription signals (promoter sequences) (see, in particular page 209, last paragraph).

17. In a technically similar case relating to a patent with generic claims directed to a method for incorporating foreign DNA into the genome of monocotyledonous plants via a T-DNA, the then competent board of appeal decided that the requirements of Article 83 were not fulfilled because there were serious doubts as to whether such a method could be performed over the whole range that was claimed, namely with any monocotyledonous plant (see T 612/92 above).

18. In summary, the following observations can be made:

(a) the art of genetically modifying plant cells so as to achieve detectable levels of expression of a transferred foreign gene was not very well established at the priority date of the patent in suit and was faced with a number of uncertainties and problems such as stability of alien DNA into T-DNA and into the plant genome, presence of introns, stability of the proteins, effects of regulatory controls etc. (see document (5a), in particular page 1);

(b) While confirming the validity of the technical indications given in document (5a), the patent in suit, by providing the single example of successful expression of phaseolin in plant cells following transfer via T-DNA of a phaseolin coding DNA with its own promoter, did not generally remove the problems and uncertainties mentioned under (a) above. The patent in suit did not make

it plausible that the same effect would be obtained routinely in any plant cell by operating in an analogous manner with any combination of any plant structural gene with any plant promoter. In fact, the specification of the patent in suit leaves to the skilled person the whole burden of finding out and testing how and whether the transfer of any such combination into a plant cell is such that expression of the protein encoded by the plant structural gene is detectable in said plant cell. Under these circumstances, the feature "such that..." in claim 1 is seen as being not more than an invitation to perform a research programme in order to find the combinations which, if successful, are stated by the claim to fall under its scope (see T 435/91 above, in particular point 2.2.1 of the Reasons);

(c) later publications (see point 16 above) indeed show that the transfer of foreign DNA via T-DNA into some classes of plants, eg monocotyledonous plants, as well as the expression of the transferred gene under its own signals, were largely empirical and thus involved a large amount of trial and error with a high risk of failure.

19. In view of the above considerations, the board has decided that the experimental evidence and technical details in the description of the patent in suit are not sufficient for the skilled person to reliably achieve without undue burden the technical effect of expression in **any** plant cell of **any** plant structural gene under the control of **any** plant promoter and that, consequently, they do not provide sufficient support for a claim, such as present claim 1, broadly directed to such a method.

20. For these reasons the main request, of which claim 1 is part, is refused under the provisions of Articles 83 and 84 EPC.

First auxiliary request

21. Compared with claim 10 as granted, claim 1 of this request, apart from the feature "such that..." (see point 2 above), contains a limitation of the method to the modification of a dicotyledonous plant cell by transfer of a dicotyledonous plant promoter with a dicotyledonous plant structural gene. In the board's judgement, this amendment narrows the scope of protection conferred in comparison with the claims as granted so that no objection under Article 123(3) EPC arises. Moreover, in the board's view, the basis for this amendment can be derived from page 15 of the application as filed, where specific reference is made to any introduction of plant genes into any plant species, including dicotyledonous plants, in combination with the passage starting on page 15 and continuing on page 16 of the description, where the definition of a plant gene is given. Thus, the amendment in question does not result in the creation of subject-matter extending beyond the content of the application as filed and, consequently, no objection under Article 123(2) EPC arises.

22. The limitation of claim 1 of this request to a dicotyledonous plant cell into which a dicotyledonous plant promoter with a dicotyledonous plant structural gene is transferred does not remove the objections under Articles 83 and 84 raised in respect of the subject-matter of claim 1 of the main request because, for the same reasons as given above (see points 3 to 19), the description of the way expression at

detectable levels was achieved in respect of the phaseolin gene with its own promoter does not allow the skilled person to perform the invention without undue burden within the whole area claimed, ie to genetically modify **any** dicotyledonous plant cell by inserting into it **any** dicotyledonous plant structural gene under the control of **any** dicotyledonous plant promoter.

23. For these reasons the first auxiliary request has also to be refused under the provisions of Articles 83 and 84 EPC.

Second auxiliary request

24. Compared with claim 10 as granted, claim 1 of this request, apart from the feature "such that..." (see point 2 above), contains a limitation of the method to the modification of a dicotyledonous plant cell by transfer of a phaseolin promoter with a plant structural gene. In the board's judgement, this amendment narrows the scope of protection conferred in comparison with the claims as granted so that no objection under Article 123(3) EPC arises. However, while it is true that:

(i) the application as filed refers on page 15 to any introduction of plant genes into any plant species, including dicotyledonous plants;

(ii) in the passage starting on page 15 and continuing on page 16 of the description it is stated that the promoter and structural gene may be derived from the same or different plant sources and that a plant gene could be either with its own promoter or with a different plant promoter; and

(iii) a specific example of the combination of the phaseolin structural gene including the phaseolin promoter is provided,

the combination of the phaseolin promoter with any plant structural gene constitutes nevertheless specific subject-matter which is not disclosed in this individualized form in the application as filed and thus extends beyond its contents. This contravenes the provisions of Article 123(2) EPC and for this reason the second auxiliary request must be refused as well.

Third auxiliary request

25. Compared with claim 10 as granted, claim 1 of this request, apart from the feature "such that..." (see point 2 above), contains a limitation of the method to the modification of a dicotyledonous plant cell by transfer of a phaseolin promoter with a phaseolin structural gene. By way of this amendment the scope of protection is narrowed over the claims as granted so that no objection under Article 123(3) EPC arises. The combination of the phaseolin structural gene with its own promoter is disclosed in the examples of the application as filed (see Example 1). This application also refers on page 13 to the homology of the molecular species of phaseolin and on page 16 to the naturally or artificially induced modifications of the promoter and/or coding regions of plant genes. This constitutes direct and unambiguous support not only for the combination of a specific phaseolin structural gene with its own promoter, but also for various combinations of variant forms of both. For these reasons it is considered that the amendments in

question do not result in the creation of subject-matter extending beyond the content of the application as filed and, consequently, that no objection under Article 123(2) EPC arises.

26. The limitation of claim 1 of this request to a dicotyledonous plant cell into which a phaseolin promoter with a phaseolin structural gene is transferred brings the subject-matter of this claim into compliance with the requirements of Articles 83 and 84 EPC. In fact, the description of how expression at detectable levels was achieved in respect of the phaseolin gene with its own promoter provides the skilled person with sufficient guidance for performing the invention as claimed in claim 1 without undue burden and for reliably obtaining the same technical effect, including when suitable variants of the component features concerned are used (eg variant forms of the phaseolin gene or phaseolin promoter) (see T 292/85, above; see point 5 above). The board considers that, unlike the case with genes and promoters other than phaseolin, the technical circumstances in the case of variants of the phaseolin gene and promoter are so similar that it is plausible that the claimed invention can be put into practice routinely within this framework. In the light of the contribution to the state of the art by the patent in suit, this is considered by the board to be a fair generalisation.

27. In his oral disclosure, Dr J.D. Kemp (see document (5a)), while making reference to the construction of a DNA vector comprising T-DNA having inserted into it "the entire phaseolin gene including its own promoter regions" (see page 4, lines 7 to 8; compare with feature (a) in claim 1), stated that he could not report on the final experiment because this had not yet been completed (see page 4, lines 3 to 4). Thus, the

transfer of said DNA vector construct into a dicotyledonous plant cell and/or the tests of the level of expression of the protein encoded by the inserted plant gene (see feature (b) in claim 1) were not disclosed by Dr Kemp. In the board's judgement, these cannot be considered to be an implicit part of his disclosure as inevitably derivable from the description of the DNA vector. In fact, failing any further details and reports of experimental data, the skilled person at the priority date was not in a position to inevitably derive from document (5a) the technical effect produced by the DNA vector in a dicotyledonous plant cell, in view of the many uncertainties and problems of this technical area. Thus the difference between the statements in document (5a) and the claimed subject-matter is not merely in the wording, but in the technical teaching. For these reasons the subject-matter of claims 1 to 7 of the present request is novel having regard to document (5a). Novelty over the other documents on file is undisputed.

28. *Inventive step (Article 56 EPC)*

28.1 Document (5a) represents the closest prior art for the claims at issue. Its contents have already been discussed under point 9 above.

28.2 In the light of this document, the technical problem to be solved is the achievement of detectable levels of expression of phaseolin in a dicotyledonous plant cell.

28.3 The claims under discussion are intended to solve this problem by measuring the level of expression of phaseolin in a dicotyledonous plant cell after transfer thereto of a T-DNA/plant gene combination wherein a plant gene comprising a phaseolin promoter and a phaseolin structural gene is inserted into T-DNA, the

plant promoter being adjacent to the 5'-end of the plant structural gene and the plant structural gene being downstream from the plant promoter in the direction of transcription. The latter is in fact a DNA vector construct such as the one known from document (5a) so that it can be said that the proposed solution consists in the measurement of the level of expression of phaseolin in a dicotyledonous plant cell after transfer thereto of the DNA vector known from document (5a).

28.4 In view of the examples disclosed in the patent in suit, in particular Examples 1 and 2, the board is satisfied that the above-stated technical problem has been solved since it has been shown that detectable levels of phaseolin are measured in sunflower plant cells when the proposed method is applied.

28.5 The relevant question in respect of inventive step is whether the skilled person, starting from the oral disclosure of Dr Kemp (document (5a)), would have carried out the experiment referred to in it with a reasonable expectation of success. In this respect, the statement in decision T 296/93 (above) that "a reasonable expectation of success" should not be confused with the understandable "hope to succeed" (see loc.cit., point 7.4.4 of the Reasons) is of relevance. In fact, while it can be said that, in the light of document (5a), the experiment in question was "obvious to try" for the skilled person, it is not necessarily true that this person would have had any reasonable expectation of success when embarking on it. The announcement by Dr Kemp that such an experiment was in progress in his laboratory was not in itself a guarantee in this respect, especially in view of the warning given by the same Dr Kemp that "... this has been done by a number of people now and nobody has

shown a functional gene when one includes the endogenous promoter". Thus, the outcome of the said experiment was still uncertain. The question to be decided is therefore whether the average skilled person was in a position to reasonably predict its successful conclusion, on the basis of the existing knowledge, before starting the experiment.

28.6 As stated above (see point 18, item (a)), in early 1983 the art of genetically modifying plant cells so as to achieve detectable levels of expression of a transferred foreign gene was **not yet routinely** established. Although some success had been reported in respect of T-DNA vector constructs where the foreign gene was placed under the control of Ti promoters (see, for example, documents (9a) and (31)), the skilled person still faced a number of uncertainties and problems, such as stability of alien DNA into T-DNA and into the plant genome, presence of introns, stability of the proteins, effects of regulatory controls etc. (see document (5a), in particular page 1). This should be taken into account when making an objective analysis of the degree of confidence of the skilled person on the priority date that he or she would have succeeded in solving the underlying technical problem by embarking on the experiment referred to by Dr Kemp.

28.7 When trying to make a reasonable prediction of the prospects of success for the experiment indicated in document (5a), the skilled person would have had to have taken the following facts into account:

(a) the uncertainties and difficulties of the technical field (see point 28.6 above);

(b) while there were reports of expression in a plant cell of a foreign gene inserted into T-DNA downstream from Ti regulatory sequences (see documents (9a) and (31)), there were no positive reports of functional genes when the endogenous promoter was included (see document (5a));

(c) although from a theoretical point of view it was conceivable that a plant promoter could be recognised by the plant transcription machinery, no prediction could have been made as to whether it would be actually recognised when placed into a T-DNA (see item (b) above). Moreover, in view of the highly specialised nature and regulation of the phaseolin promoter - a seed promoter - (see the general background information as reported on page 8, lines 5 to 20 of the patent specification), it was difficult to predict whether it would operate in dicotyledonous plant tissues other than the seed;

(d) although the isolation and partial nucleotide sequence of a phaseolin genomic clone containing the entire gene together with extensive sequences flanking its 3' and 5' ends and of a cloned cDNA had been reported (see document (49)), the expression of phaseolin in a recombinant organism had not yet been disclosed. An indirect report in the literature (see document (3), in particular page 266, left-hand column, fifth paragraph) referred to an experiment in which, using Agrobacterium with a gene of unspecified structure coding for phaseolin inserted into its T-DNA, transcription of bean globulin mRNA in tissue cultures from sunflower tumours had been obtained, but not its translation.

28.8 All the above factors and considerations would have negatively influenced the degree of confidence of the skilled person in the successful outcome of the experiment referred to in document (5a). He or she would therefore not have reasonably expected that expression of detectable levels of phaseolin in a dicotyledonous plant cell would be easily achievable and, owing to this, would have received the results of the patent in suit with some surprise.

28.9 For these reasons the board concludes that the subject-matter of claim 1 of the request at issue involves an inventive step (Article 56 EPC). The same applies to claims 2 to 6 of this request, which represent embodiments of the invention as claimed in claim 1, as well as to the subject-matter of claim 7, i.e. the plant cell produced according to the method of claims 1 to 6.

Conclusion

29. From the above it follows that the patent in suit can be maintained on the basis of claims 1 to 7 of the third auxiliary request.

30. Since the respondents' main request was refused neither on the ground of lack of novelty nor on the ground that the subject-matter of claim 10 or 11 was excluded from patentability under Article 53(b) EPC, the board does not have to decide on the respondents' request to refer two questions of law to the Enlarged Board of Appeal (see section VII above).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance with the order to maintain the patent on the basis of claims 1 to 7 according to the third auxiliary request and the amendment on page 9, line 21 of the description, both submitted during oral proceedings.

The Registrar: The Chairperson:

L. McGarry U. Kinkeldey