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D E C I S I O N
of 26 April 1999

Case Number: T 0116/95 - 3.3.4

Application Number: 84306494.0

Publication Number: 0142924

IPC: C12N 15/05

Language of the proceedings: EN

Title of invention:

Insect resistant plants

Patentee:

Mycogen Plant Science, Inc.

Opponent:

Plant Genetic Systems NV
Monsanto Company
Novartis AG

Headword:

Insect resistant plants/MYCOGEN

Relevant legal provisions:

EPC Art. 123(2), (3), 84, 111(1)

Keyword:

"Main request - extension of protection conferred (no)"
"Added subject-matter (no)"
"Clarity (yes)"
"Remittal (yes)"

Decisions cited:

T 0249/93

Catchword:

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Boards of Appeal

Chambres de recours

Case Number: T 0116/95 - 3.3.4

D E C I S I O N
of the Technical Board of Appeal 3.3.4
of 26 April 1999

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Decision under appeal:

Decision of the Opposition Division of the
European Patent Office posted 28 November 1994
revoking European patent No. 0 149 924 pursuant
to Article 102(1) EPC.

Composition of the Board:

Chairman: U. M. Kinkeldey
Members: L. Galligani
S. C. Perryman

Summary of Facts and Submissions

- I. The European patent No. 0 142 924 was granted with seventy-nine claims. Claim 1 read as follows:

"A plant comprising a genetically modified plant cell containing an insecticide structural gene under control of a plant expressible promoter, provided that said cell is not a tobacco cell containing the vector pA-ocs-B-proI-ESI as disclosed in EP-A-0 140 556."

Other independent claims were directed inter alia to a plant tissue (claim 7), a DNA vector comprising an insecticide structural gene under control of a plant expressible promoter (claim 32), a bacterial strain transformed therewith (claim 45), all these claims having the same features as claim 1, and a method of genetically modifying a plant cell (claim 53).

- II. Four oppositions were filed against the grant of the patent on the grounds of Article 100(a) and (b) EPC. With decision issued on 28 November 1994, the opposition division decided to revoke the European patent because the amendments which characterised the claims of the main request as well as those of the first and second auxiliary requests then on file offended against the requirements of Article 123(2) or (3) EPC.
- III. The appellants (patentees) lodged an appeal against the said decision and with the statement of grounds of appeal they filed a new main claim request and new auxiliary claim requests. The respondents I to III (opponents 01 to 03, former opponents 03 and 04 having

- fused in the meantime into one party) filed their comments in response thereto.
- IV. In reply to the respondents' comments, the appellants filed a new main request and four new auxiliary requests.
- V. The board expressed its provisional, non-binding opinion in the communication dated 1 February 1999. On 11 February 1999, in reply thereto, the appellants amended their claim requests by reinstating the disclaimer which was present in the claims as granted. The respondents commented thereupon. Respondents I (opponents 01) introduced a new document.
- VI. In a communication dated 12 March 1999 the board informed the parties that in the event that the appeal on the Article 123(2) and (3) and Article 84 EPC issues should succeed, the parties would be given the opportunity to address the board on whether a remittal to the first instance on the issues of novelty, inventive step and sufficiency of disclosure was appropriate or not, but that the substance of those issues would not be dealt with by the board at the same oral proceedings.
- VII. Oral proceedings took place on 26 April 1999, during which the appellants filed a new main request. Independent claims 1, 7, 45 and 53 therein read as follows:
- "1. A plant comprising plant cells which are genetically modified to contain an insecticide structural gene which is a bacterial gene or a modified

bacterial gene, under control of a plant expressible promoter, whereby expression of said gene renders said plant insect resistant, provided that said cells are not tobacco cells containing the vector pA-ocs-B-proI-ESI as disclosed in EP-A-0 140 556."

"7. A plant tissue comprising plant cells which are genetically modified to contain an insecticide structural gene which is a bacterial gene or a modified bacterial gene, under control of a plant expressible promoter, whereby expression of said gene renders said plant tissue insect resistant, provided that said cells are not tobacco cells containing the vector pA-ocs-B-proI-ESI as disclosed in EP-A-0 140 556."

"45. A bacterial strain transformed with a vector comprising an insecticide structural gene which is a bacterial gene or a modified bacterial gene, and a plant expressible promoter, the gene and the promoter being in such position and orientation with respect to each other that the gene is expressible under control of the promoter in a plant cell, whereby to render plant tissue comprising such plant cells insect resistant, provided that the vector is not pA-ocs-B-proI-ESI as disclosed in EP-A-0 140 556."

"53. A method of genetically modifying a plant cell to render plant tissue comprising such modified cells insect resistant, by transforming the cell with a vector comprising an insecticide structural gene which is a bacterial gene or a modified bacterial gene, and a plant expressible promoter, the gene and the promoter being in such position and orientation with respect to each other that the gene is expressible under control

of the promoter in said plant cell, provided that the vector is not pA-ocs-B-proI-ESI as disclosed in EP-A-0 140 556."

VIII. The following documents are referred to in the present decision:

(16) Maugh, T., Science, Vol. 216, May 1982, pages 722 to 723;

(34) EP-A-0 126 546.

IX. The appellants maintained that the amendments introduced in the claims neither resulted in the extension of the protection conferred in comparison with the claims as granted nor in the creation of subject-matter which extended beyond the content of the application as filed.

They submitted, with particular reference to decision T 249/93 of 27 May 1998, that parties did not necessarily have a right to have each issue decided by two instances, especially when - as in the present case - a late stage of the proceedings had been reached. Under Article 111(1) EPC, the board had the power to decide the outstanding issues in the present case and was invited to do so, as remittal would result in an unnecessary prolongation of the proceedings almost up to the expiration of the patent, in a case where (i) the respondents were believed to infringe the patent, (ii) the appeal had been filed in 1995 and expedited examination had been requested, and (iii) the opposition division was clearly wrong in their decision. Under these circumstances, remittal was

justified only if the appellants-patentees so requested. However they did not so request.

X. The respondents essentially argued as follows:

- (a) The introduction of the term "a modified bacterial gene" in the claims 1 and 45 inadmissibly extended the scope of protection because the meaning of "insecticide structural gene" according to the granted patent did not encompass a "modified bacterial gene". Furthermore, plant and bacteria claims as granted did not have dependent claims directed to a "modified" structural gene. It had to be further observed that this amendment was not initiated by any grounds of opposition and was thus contrary to Rule 57a EPC.
- (b) The terms "a modified bacterial gene" and "whereby expression of said gene renders said plant insect resistant" found no support in the application as filed. In fact, nothing mentioned or suggested that the modified gene be a "bacterial gene" and/or that specifically the expression of such a gene caused the toxic effect on the insects.
- (c) Both the expressions "a modified bacterial gene" and "whereby expression of said gene renders said plant insect resistant" were unclear because there was no indication in the description as to what was meant by "modified" or by "insect resistant". In the absence of a definition, "a modified bacterial gene" could be considered to correspond to any bacterial gene modified by deletion, substitution or insertion of bases, thus including

known genes encoding insect resistance factors or lectins (cf. document (34)). The limits of the claims were not clearly defined by use of said term. The qualification of a plant as "insect resistant" was vague as it could mean a plant which was lethal to insects or a plant which was less susceptible to insect infestation or a plant which was resistant only at the level of one tissue at only one stage of development as for example a plant with seed-specific expression in consequence of the use of the phaseolin promoter.

- (d) The reinsertion of the disclaimer was unclear as the claims into which it was reintegrated were different from the claims as granted.
- (e) Since none of the pending substantive issues had been examined by the opposition division, remittal was necessary, especially in view of the fact that appeal proceedings were by their very nature less investigative than opposition proceedings. This was a matter of fairness to the parties.

XI. The appellants requested that the decision under appeal be set aside and that the patent be maintained on the basis of the set of claims submitted as main request at the oral proceedings on 26 April 1999 or the claims filed as first, second, third or fourth auxiliary request on 11 February 1999 and that the board decide on all issues without remittal to the first instance.

The respondents requested as a main request that the appeal be dismissed or as auxiliary request that should any request be found allowable under Articles 84 and

123 EPC that the case be remitted to the first instance for further prosecution.

Reasons for the Decision

The main request

Article 123(3) EPC

1. Claim 1 of this request differs from claim 1 as granted essentially in that it additionally states that the insecticide structural gene "is a bacterial gene or modified bacterial gene" and that "expression of said gene renders said plant insect resistant".

2. In the board's judgement, both features have a restrictive effect as they state more precisely, respectively, the kind of insecticide structural gene which is contained in the plant cells (in the granted claim: any gene; now only a bacterial gene or a modified form thereof) and the result of the genetic modification in the plant (in the granted claim: no insect resistance had necessarily to result from the genetic modification; now insect resistance must result therefrom). The same restrictive effect occurs also in all other independent claims of this request (cf. eg claims 7, 45 and 53) where the same features have been introduced. The fact that, as submitted by the respondents, plant and bacteria claims as granted did not have a dependent claim referring to a "modified" structural gene is immaterial in the context of the discussion of the question whether the amendments

extended the scope of protection conferred, in view of the restrictive nature of the amendments. Thus, the requirement of Article 123(3) EPC is fulfilled.

3. The said amendments had their origin in a lack of novelty objection (*inter alia* vis-à-vis document (34)) which was raised by the respondents and are thus allowable under Rule 57a EPC.

Article 123(2) EPC

4. The application as filed explicitly states that its objective is to confer **insect resistance** to a plant by stably inserting a gene coding for an insecticidal protein (cf. page 20 under the heading "Summary of the invention", first paragraph). On page 26, under the heading "Insecticide structural gene", the application indicates that the said gene, which must include a portion of DNA encoding the insecticidal protein, may contain **one or more modifications** including mutations, insertions, deletion etc.. On page 27, under the heading "Insecticidal protein", the application refers to "a bacterial protein toxic in any way to insects" and in particular to the crystal protein of *B. thuringiensis*. The application as filed outlines on pages 23 to 35 the experimental plan for achieving the aimed objective and reports in the examples the application of such a strategy to a Hind III fragment of the gene encoding the *B. thuringiensis* insecticidal protein (cf. Examples 1 to 6) or to the complete protoxin gene (cf. Example 11). Example 2.4 (relating to the Hind III gene fragment) reports that "transformed tobacco tissue is lethal to tobacco

hornworms" and that "...regenerated plants and their insecticidal protein-containing de[s]cendants are resistant to infestation by larvae of insects such as tobacco hornworm by virtue of the toxic effect such larvae experience when eating tissue from such plants". Example 11 (relating to the complete gene) reports that "Tobacco hornworms fed on transformed tobacco callus tissue containing the plant expressible full-length insecticidal protein gene were observed to display symptoms attributable to B. thuringiensis crystal protein toxicity".

5. In the board's judgement, the above analysis of the application as filed shows that the features "a bacterial gene", a "modified bacterial gene" and "whereby expression of said gene renders said plant insect resistant" are explicitly disclosed therein from formal point of view, as what was meant was to achieve in a plant or plant cell expression of a gene or a modified form thereof encoding a given bacterial insecticidal protein so as to confer thereon toxic or growth inhibitory properties (resistance) vis-à-vis insects. Therefore, the requirement of Article 123(2) EPC is fulfilled.

Article 84 EPC (clarity)

6. As regards the clarity objections raised by the respondents, the following is observed:
 - (a) The term "modified bacterial gene" is broad, but clear. The description explains what is meant thereby, namely "one or more modifications in either the coding segments or untranslated regions

which could affect the biological activity or chemical structure of the expression product, the rate of expression or the manner of expression control. Such modifications could include, but are not limited to, mutations insertions, deletions, substitutions... (cf. page 26 of the application as filed under the heading "Insecticide structural gene"). Obviously, such modifications have as a starting point a given structural gene and no matter how extensive, they are carried out with the objective of keeping the insecticidal activity. The contention by the respondents that radical modifications of the gene structure could lead to a totally different gene is an assumption without a realistic basis. Whether or not the technical information in the patent specification is sufficient to justify the broad wording in the claim is a question which may be at issue in the context of the substantive examination of the case under Articles 83/84 EPC (sufficiency of disclosure and support by the description).

- (b) The term "insect resistant" is also broad, as it includes a wide range of possibilities going from a lethal effect to a growth inhibitory effect on the insects, and also including tissue specific resistance. The term *per se* is clear as it is usual in the art (cf. eg document (16)). Thus, the board is convinced that the skilled person has no difficulty understanding its meaning. A separate question is here again whether the broad range of possibilities covered by the claim is sufficiently disclosed in the patent specification in terms of Articles 83/84 EPC. However, this question is not

at issue at this stage of the proceedings.

- (c) As for the reintroduction of the disclaimer, in the board's view no questions of lack of clarity arise under Article 84 EPC. The disclaimer had been introduced before grant in order to avoid any possible novelty anticipation by EP-A-0 140 556 where the quoted vector comprising an insecticide structural gene is described. Also in the context of the claims at issue the disclaimer excludes only that subject-matter, and causes no ambiguities of any kind.

7. For these reasons, the clarity requirement of Article 84 EPC is met.

Procedural matters

8. The patent in suit was revoked by the opposition division on the grounds that the claim requests then on file did not comply with the requirements of Article 123(3) EPC or Article 123(2) EPC. Having now found that the appellants have filed claims with suitable amendments which overcome such grounds, the board has to decide whether or not to remit the case to the department of the first instance for further prosecution.

9. As regards this question, it is noted with particular reference to the appellants' submissions (cf. Section IX *supra*), that:

- (a) No examination whatsoever of any of the substantive issues raised by the respondents-

opponents was carried out by the opposition division. This renders the case at issue different from that of decision T 249/93 (*supra*) where only the inventive step issue had to be decided.

- (b) In view of the number of the yet to be examined issues and of their complexity, *prima facie* it must be considered as the most appropriate course that first the opposition division investigate and decide on the issues, thus allowing the parties in any further appeal to argue against a reasoned decision and giving the board of appeal the benefit of considering the decision and reasoned arguments thereon.
- (c) All respondents here request remittal to the opposition division, in case the appellants succeeded in presenting admissible claims, unlike in decision T 249/93 (*supra*) where consideration of the issues by the first instance had advanced much further, and only one of the opponents had asked for remittal.
- (d) While it is true that the appellants had requested the expedited prosecution of the appeal, and the board regrets the time it has taken to hear the appeal, their request was not based on there being any infringement action before a national court in a contracting state. Merely because the case is old cannot be considered a sufficient reason by itself to depart from the most appropriate course.

Under these circumstances, the board considers it appropriate to make use of its power under

Article 111(1) EPC to remit the case to the opposition division for further prosecution.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the first instance for further prosecution.

The Registrar:

The Chairperson:

U. Bultmann

U. M. Kinkeldey