Datasheet for the decision
of 11 May 2009

Case Number: T 1108/08 - 3.3.08
Application Number: 99926414.6
Publication Number: 1080208
IPC: C12N 15/63
Language of the proceedings: EN

Title of invention:
dsRNA-mediated regulation of gene expression in plants

Patentee:
Syngenta Participations AG

Opponents:
BASF Plant Science GmbH
Pioneer Hi-Bred International
Monsanto Technology, LLC
Commonwealth Scientific and Industrial Research Organisation
AVEBE U.A.
Bayer BioScience N.V.

Headword:
dsRNA-mediated gene regulation/SYNGENTA

Relevant legal provisions:
EPC Art. 123(3)
EPC R. 99(1)(c)
RPBA Art. 12(4)

Relevant legal provisions (EPC 1973): -
Keyword:
"Admissibility of the appeal (yes)"
"Main request - admission into the proceedings (no)"
"First auxiliary request - extended protection (yes)"

Decisions cited:
T 0007/81, T 0089/85, T 0840/93

Catchword:
-
Case Number: T 1108/08 - 3.3.08

DECISION
of the Technical Board of Appeal 3.3.08
of 11 May 2009

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Decision under appeal: Decision of the Opposition Division of the European Patent Office posted 3 April 2008 revoking European patent No. 1080208 pursuant to Article 101(2),(3)(b) EPC.

Composition of the Board:
Chairman: L. Galligani
Members: M. R. Vega Laso
C. Heath
Summary of Facts and Submissions

I. European patent No. 1 080 208 with the title "dsRNA-mediated regulation of gene expression in plants" based on European patent application No. 99 926 414.6 (published as WO 1999/061631) was granted with 12 claims.

II. Claims 1 and 5 as granted read:

"1. A method for altering expression of a target gene in a plant cell, comprising introducing into a plant cell a sense RNA fragment of said target gene and an antisense RNA fragment of said target gene, wherein said sense RNA fragment and said antisense RNA fragment are capable of forming a double-stranded RNA molecule.

5. A method for altering expression of a target gene in a plant cell, comprising introducing into a plant cell a first DNA sequence capable of expressing in said cell a sense RNA fragment of said target gene, wherein (i) said first DNA sequence and said second DNA sequence are comprised in two different DNA molecules; and (ii) said first DNA sequence and said second DNA sequence are stably integrated in the genome of said plant cell; and (iii) said sense RNA fragment and said antisense RNA fragment are capable of forming a double-stranded RNA molecule."

III. The patent was opposed by six parties on the grounds of Article 100(a) EPC 1973, in particular that the claimed subject-matter lacked novelty (Article 54 EPC 1973) and inventive step (Article 56 EPC 1973), and that the claimed invention was not susceptible of industrial
application (Article 57 EPC 1973), as well as on the grounds of Article 100(b) and (c) EPC 1973.

IV. In a decision posted on 3 April 2008, the opposition division found that claims 2 to 4 of the main request then on file were not allowable under Article 123(3) EPC, and that the sole claim of the first auxiliary request did not fulfil the requirements of Article 84 EPC because the expression "linker comprising intron processing signals" was unclear and open for interpretation and, therefore, determination of the scope of protection conferred by the claim was not possible. A second auxiliary request filed during the oral proceedings was not admitted into the proceedings on the grounds that, besides having been filed late, it changed the subject of the proceedings. The patent was thus revoked pursuant to Article 101(2),(3)(b) EPC.

V. The appellant (patent proprietor) lodged an appeal against the decision of the opposition division and, together with the statement setting out the grounds of appeal, filed four amended sets of claims identified as main request and first to third auxiliary requests, and additional evidence. In the event that the board did not intend to allow the main request, the appellant requested that oral proceedings be held.

VI. Respondents I, II, IV and VI (opponents 01, 02, 04 and 06) filed observations on the grounds of appeal and requested that the appeal be found inadmissible and/or the sets of claims filed with the statement of grounds of appeal not be admitted into the proceedings. As a subsidiary request, oral proceedings were requested. No
observations were filed by respondent V (opponent 05). A request by respondent III (opponent 03) to extend the term for replying to the statement of grounds of appeal was not granted by the board.

VII. The parties were summoned to oral proceedings. In a communication under Article 15(1) of the Rules of Procedure of the Boards of Appeal (RPBA), the board provided some comments and its provisional opinion on several issues to be discussed during the oral proceedings, in particular concerning the admission into the proceedings of the four sets of claims filed with the statement of grounds of appeal, and issues in connection with Articles 123(2)(3) and 84 EPC.

VIII. In response to the communication of the board, the appellant on 23 April 2009 filed two sets of amended claims as its main request and auxiliary request, respectively, which replaced the requests previously on file.

IX. Claim 1 of the set of claims according to the main request reads as follows:

"1. A method for reducing expression of a target gene in a plant cell, comprising introducing into a plant cell a sense RNA fragment of said target gene and an antisense RNA fragment of said target gene, wherein said sense RNA fragment and said antisense RNA fragment are capable of forming a double-stranded RNA molecule; and wherein said introducing is achieved either by stably integrating into the genome of said plant cell a DNA sequence which comprises a linker comprising intron processing signals between DNA encoding said sense and
antisense RNA fragments, or by the use of a plant transformation vector comprising a selectable marker gene which is EPSPS or DHFR."

Claims 2, 3 and 4 are identical to, respectively, granted claims 10, 11 and 12, except that each of these claims includes as additional feature that the plant cell (in claim 2), the plant and progeny thereof (in claim 3) or the seeds (in claim 4) further comprise(s) a selectable marker gene which is EPSPS or DHFR.

X. The sole claim according to the auxiliary request, which is identical to the claim according to the auxiliary request I on which the opposition division decided, differs from claim 1 of the main request in that the word "either" and the features "or by the use of a plant transformation vector comprising a selectable marker gene which is EPSPS or DHFR" have been deleted.

XI. Respondent I's representative submitted further arguments and additional evidence and, by letter dated 6 May 2009, rectified the designation of the respondent used in previous submissions. Except for respondent V, all respondents expressed their intention to attend oral proceedings.

XII. Oral proceedings before the board were held on 11 May 2009. Although duly summoned, respondent V was not represented.

XIII. The submissions made by the appellant, as far as they are relevant to this decision, may be summarized as follows:
Admissibility of the appeal

The notice of appeal identified the decision of the opposition division and stated that this decision was appealed in its entirety. It was absolutely clear that the appellant defined the subject of the appeal as the decision of the opposition division, requesting its reversal. There was no requirement in Rule 99 EPC 2000 for a notice of appeal to specify the precise route or claims whereby the impugned decision was to be amended or set aside.

Admission of the main request into the proceedings

Claim 1 according to the main request was derived from the first auxiliary request refused by the opposition division under Article 84 EPC, but modified to refer also to particular selectable marker genes.

The history of the handling of the case before the opposition division was highly relevant to the question of admissibility of the present main request. Even though the limiting feature concerning intron processing signals was clearly put forward as an option in a set of claims filed in response to the notices of opposition, the preliminary opinion issued by the opposition division did not contain any indication that there were concerns about clarity of the claims in relation to the feature in question. Thus, the patent proprietor had no clue from the opposition division that there was a potential issue regarding lack of clarity.
Moreover, objections to the intron processing signals feature were raised for the very first time in the opponents' final submissions prior to the oral proceedings, notwithstanding their prior knowledge of the issue for some 16 months since the initial defence. The proprietor learnt only very late on the first day of two days scheduled for oral proceedings that the opposition division had apparently changed its position, and saw a problem with the lack of clarity of the intron processing feature. An attempt on the part of the proprietor to deal with this problem by filing a claim with a different novelty-imparting feature was refused notwithstanding the availability of more time for argument on the following day.

The claim requests submitted on appeal reflected the situation in opposition proceedings. It could not have come as a surprise to the respondents that the appellant in its claims sought to include an alternative novelty-distinguishing feature, namely the use of a plant transformation vector comprising one of two particular selectable marker genes. All parties had been aware of the content of the specification, and hence of the possibly limiting features for a considerable period of time.

The primary function of an appeal was understood and accepted. However, it had never previously been the general practice of the boards of appeal that a proprietor faced with revocation of its patent was bound by requests and submissions before the first instance. By admitting the main request, the board would not merely allow a just consideration of the matter by all parties involved taking into account the
complexity of the matter and the proprietor's boa fide attempts to deal with a hitherto unexpected position of the opposition division, and an absence of timely comment from the opponents.

**Auxiliary request - Article 123(3) EPC**

Claim 1 as granted covered the introduction of sense and antisense fragments which hybridised to form a double-stranded RNA species, either in the form of two separate RNA molecules (as specified in claim 2 as granted) or a single RNA molecule (as in claim 3 as granted). In all cases, RNA species could be introduced via DNA as an intermediary. Thus, the auxiliary request was more limited in scope than claim 1 as granted because DNA was used to introduce the RNA and two alternative limiting features had been added, namely the presence of a linker comprising intron processing signals between DNA encoding the sense and antisense RNA fragments, and, as an alternative, the use of a plant transformation vector comprising a selectable marker gene which was EPSPS or DHFR.

XIV. The submissions by the respondents, as far as they are relevant to this decision, were as follows:

**Admissibility of the appeal**

Rule 99(1)(c) EPC 2000 required a notice of appeal to contain "a request defining the subject of the appeal", otherwise the appeal was to be considered inadmissible under Rule 101(1) EPC. Since the notice of appeal indicated that "the decision is appealed in its entirety", it had to be inferred therefrom that the
The circumstances of the present case were extremely similar to those of the case decided in T 840/93 of 11 July 1995: the requests on file had not been considered by the opposition division, there was a divisional application pending, the requests submitted could reappear in slightly amended form in the divisional application, and the appeal was not the last opportunity for the appellant to obtain a patent.

**Admission of the main request into the proceedings**

The board was requested to exercise its discretion to refuse any requests not considered by the opposition division.

**Auxiliary request - Article 123(3) EPC**

In the patent as granted, methods comprising the introduction of RNA and those comprising the introduction of DNA were clearly separated. The term "introducing" could not be interpreted as "generating" but should be interpreted literally.

XV. The appellant (patentee) requested that the decision under appeal be set aside and that the patent be
maintained on the basis of the main request or the first auxiliary request filed on 23 April 2009.

XVI. The respondents (opponents) requested that the appeal be dismissed.

Reasons for the Decision

Admissibility of the appeal

1. According to Rule 99(1)(c) EPC 2000, a notice of appeal shall contain "a request defining the subject of the appeal". This latter refers to the requirement of identifying the extent to which cancellation of the decision is requested. In the case at issue, the patent was revoked in opposition, and the decision was "appealed in its entirety". The Board regards this as a request to set aside the decision under appeal and, in default of any request different therefrom, to maintain the patent as granted. The opponents argue, however, that the above assumption was contradicted by the statement of grounds of appeal, where the appellant submitted different claims. This argument could only be conclusive, though, if the appellant was bound by its original request as filed with the notice of appeal. This, however, is not the case. The appellant is free to amend its original request when filing the statement of grounds. A request for maintaining the patent as granted, filed with the grounds of appeal, may be replaced by a different request filed with the statement of grounds. The fact that the (implicit) request contained in the notice of appeal differs from the requests subsequently filed with the statement of
grounds is thus no reason for finding the appeal inadmissible. Otherwise, the admissibility of a notice of appeal could only be determined once the grounds of appeal have been examined, which is certainly incorrect, as the notice of appeal must in itself be sufficient in order to determine whether the requirements of Rule 99(1) EPC 2000 have been complied with. The above interpretation is consistent with case law established under the EPC 1973, namely decision T 7/81 (OJ EPO 1983, 98), where the notice of appeal did not contain any specific request other than to set aside a decision that revoked the patent, and decision T 89/85 of 7 December 1987, where the request filed with the notice of appeal was all but clear apart from the fact that the decision of the opposition division to revoke the patent was appealed in its entirety. The appeal in the current case is thus admissible.

**Main request - Admission into the proceedings**

2. The primary function of an appeal is to give a judicial decision upon the correctness of an earlier decision by a department of the European Patent Office. While fresh sets of claims filed for the first time on appeal can be admitted and considered upon discretion of the board, it is not the purpose of the appeal to give the patent proprietor the opportunity to recast its claims as it sees fit, as the Boards have the discretionary power to hold inadmissible any requests which could have been presented or were not admitted in the proceedings before the opposition division (see Article 12(4) of the Rules of Procedure of the Boards of Appeal).
3. In the present case, the appellant together with its
statement of grounds of appeal filed four sets of
amended claims identified as main request and first to
third auxiliary requests. In its communication in
preparation for the oral proceedings, the board
observed that the fresh requests included claims which
had been amended by introducing a feature only
disclosed in the description of the original
application, if at all. Since these claims represented
a line of defence that completely differed from the
approach followed in opposition proceedings, and since
the appellant had not put forward any reasons
justifying why the amendments in question had not been
made during opposition proceedings, the board indicated
that it was, provisionally, inclined to disregard the
four sets of claims.

4. In response to the board's communication the appellant
filed an amended main request and an auxiliary request
which is identical to auxiliary request I in opposition
proceedings. In the amended main request, the admission
of which is under consideration, the method according
to claim 1 (see section IX above) differs from the
method claimed according to auxiliary request I in the
previous proceedings, in that it provides, as an
alternative ("... either ... or") to the stable
integration of a DNA sequence which comprises a linker
including intron processing signals into the genome of
a plant cell, the step using a plant transformation
vector comprising a selectable marker gene which is
EPSPS or DHFR.

5. The appellant's sole line of argument concerning the
admission of the present main request was that the
request could not have been filed in opposition proceedings because the appellant was not given any indication prior to the oral proceedings before the opposition division that a claim including the language "intron processing signals" could contravene Article 84 EPC.

6. It is true that the comments provided by the opposition division in the communication accompanying the summons to the oral proceedings did not address the clarity issue in connection with the expression "intron processing signals", as a request including this language was considered not to be allowable under Article 123(2) EPC. However, a corresponding objection under Article 84 EPC was raised by the opponents in their submissions filed in January 2008, ie. two months before the oral proceedings.

7. Having been alerted to a possible clarity deficiency concerning the expression "intron processing signals", the appellant could have attempted to remedy this deficiency by filing an amended request within the two months prior to the oral proceedings, but chose not to. Under these circumstances, the board cannot accept the appellant's argument that the present main request could not have been filed in opposition proceedings.

8. It was not denied by the appellant that the alternative step introduced into claim 1 goes in a direction different from the line of defence taken in the auxiliary request I filed in opposition proceedings. Moreover, the appellant did not even try to argue that the amended main request might overcome - or at least represent a serious attempt to overcome - the objection
under Article 84 EPC on which the opposition division based its refusal of auxiliary request I. It is immediately apparent that it does not, because the expression "intron processing signals" objected to by the opposition division under Article 84 EPC is still present in the claim, and the additional features introduced into the claim of the main request cannot contribute to the clarity of the claim as they are technically unrelated to the objected feature, and - as stated above - represent a completely different technical teaching.

9. For these reasons the main request cannot be admitted into the proceedings.

Auxiliary request - Article 123(3) EPC

10. The present first auxiliary request is identical to the auxiliary request I filed during the oral proceedings before the opposition division. The sole claim of this request was held to comply with Article 123(2) EPC, but not to meet the requirements of Article 84 EPC. As concerns Article 123(3) EPC, the opposition division only stated that in the request in question all claims except claim 1 had been deleted to overcome objections under Article 123(3) EPC raised by the opponents against a previous request. However, the opposition division did not express any opinion in this respect.

11. Whether or not the opposition division accepted that the then auxiliary request I - the present first auxiliary request - complied with Article 123(3) EPC is immaterial. Since the patent was revoked by the opposition division and the patent proprietor seeks
reversal of the decision and maintenance of the patent on the basis of the sole claim according to the first auxiliary request, the board must ascertain that the claim and the invention to which it relates fulfil the requirements of the EPC. In doing so, the board is not bound by any (explicit or implicit) findings of the opposition division.

12. In order to assess whether or not the amended claim according to the first auxiliary request (see section X above) meets the requirement of Article 123(3) EPC, the question to be decided is whether or not, in view of the amendments introduced into the claim, the latter would extend the protection conferred by the claims as granted.

13. The appellant maintains that the amendments in question introduce a further limitation rather than an extension of the scope of protection conferred by claim 1 as granted. The board disagrees with this view.

14. Claim 1 as granted (see section II above) is directed to a method of altering expression of a target gene in a plant cell that comprises the step of introducing a sense RNA fragment and an antisense RNA fragment of the target gene into the plant cell, these two RNA fragments being capable of forming a double-stranded RNA molecule. Contrary to the appellant's view, the board does not believe that, when reading the claim, a person skilled in the art may understand that "introducing a [...] RNA fragment" can be done either directly or indirectly, i.e., via DNA as an intermediary. Claim 1 as granted specifies clearly that RNA fragments are introduced (i.e., brought) into the cell, and in
dependent claims 2 to 4 as granted only RNA fragments or molecules are mentioned. Nothing in these claims suggests a teaching of indirectly introducing RNA fragments via DNA as an intermediary.

15. This is different in independent claim 5 of the patent as granted (see section II above) which relates to a method for altering the expression of a target gene in a plant cell by introducing into the plant cell two different DNA molecules capable of expressing, respectively, a sense and an antisense RNA fragment of the target gene, both DNA sequences being introduced in such manner that they become stably integrated in the genome of the plant cell. Thus, in the claims as granted a clear distinction is made between a method which involves introducing RNA fragments (independent claim 1 and dependent claims 2 to 4), and a method in which DNA molecules capable of expressing the RNA fragments are introduced (independent claim 5 and dependent claims 6 to 9). The same distinction is made in the patent specification (see eg. paragraphs [0009] and [0010]).

16. Thus, neither the language "introducing a [...] RNA fragment" in claim 1 itself, nor the patent as a whole, and in particular the way in which the granted claims are drafted, justify the feature in question being interpreted as "introducing a [...] RNA or DNA fragment". Whether or not a national court dealing with infringement cases may construe the feature in claim 1 in a different manner - as the appellant contended - is not relevant for assessing compliance with Article 123(3) EPC in the present proceedings before the board of appeal.
17. Turning now to the amended claim according to the first auxiliary request, the board observes that, although the language in the first part of the claim is identical to that of claim 1 as granted (except for the word "altering" being replaced by "reducing"), the additional features "... whereby said introducing is achieved either by stably integrating into the genome of said plant cell a DNA sequence which comprises a linker comprising intron processing signals between DNA encoding said sense and antisense RNA fragments" transform the claimed method in an aliud, namely in a method comprising the introduction and stable integration into the genome of the plant cell of a DNA sequence encoding both the sense and the antisense RNA fragments. Such a method is neither encompassed by claim 1 as granted, according to which RNA fragments are introduced into the plant cell, nor by claim 5 as granted, which specifies that two distinct DNA sequences, one encoding the sense RNA fragment and the other encoding the antisense fragment, are introduced and stably integrated into the genome of the plant cell.

18. It follows from the above that the amendments introduced in the claim according to the auxiliary request do not constitute a further limitation, but rather have the effect of extending the scope of protection conferred by the patent. Thus, since Article 123(3) EPC is infringed, the first auxiliary request cannot be granted.

19. As no allowable request is on file, the appeal must fail.
Order

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

The appeal is dismissed.

The Registrar: The Chairman:

A. Wolinski L. Galligani