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**Datasheet for the decision
of 7 March 2019**

Case Number: T 1479/15 - 3.3.04

Application Number: 06802936.2

Publication Number: 1941046

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Language of the proceedings: EN

Title of invention:

Vectors and methods for improved plant transformation efficiency

Applicant:

Monsanto Technology, LLC

Headword:

Vectors for plant transformation/MONSANTO

Relevant legal provisions:

EPC Art. 84, 123(2)

Keyword:

Main request, auxiliary request 1 - clarity (no)
Auxiliary request 2 - amendments - allowable (no)

Decisions cited:

G 0001/04, T 0768/08

Catchword:



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Case Number: T 1479/15 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 7 March 2019

Appellant:
(Applicant)

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Decision under appeal:

**Decision of the Examining Division of the
European Patent Office posted on 6 February 2015
refusing European patent application No.
06802936.2 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chair G. Alt
Members: R. Morawetz
P. de Heij

Summary of Facts and Submissions

- I. The appeal of the applicant ("appellant") lies against the decision of the examining division refusing European patent application No. 06 802 936.2, entitled "*Vectors and methods for improved plant transformation efficiency*".
- II. The application had been filed as an international application under the PCT, published as WO 2007/030432 ("application as filed" or "application").
- III. In the decision under appeal, the examining division held that claim 1 of the main request before it contained subject-matter extending beyond the content of the application as filed (Article 123(2) EPC). The subject-matter of claim 1 of both auxiliary requests before it was considered to lack novelty (Article 54 EPC).
- IV. With the statement of grounds of appeal, the appellant filed sets of claims of a new main request and of a new first auxiliary request.
- V. The board issued a summons to oral proceedings and informed the appellant in a communication under Article 15(1) RPBA that, in its preliminary opinion, the subject-matter of claim 1 of the main and auxiliary requests failed to meet the requirements of Article 123(2) EPC.
- VI. In reply, the appellant filed sets of claims of a new main request and of a new auxiliary request by letter dated 9 October 2018.

Claim 1 of the main request reads as follows:

"1. Use of a DNA construct comprising:
(i) at least one T-DNA border region;
(ii) at least one heterologous transgene adjacent to the border region;
(iii) a coding region for a bacterial selectable marker; and
(iv) at least one segment of DNA, comprising a cis and/or trans element of a *repABC* replication origin from *Agrobacterium rhizogenes* for achieving transformation events having lower frequencies of backbone incorporation and higher frequencies of one- or two-copy T-DNA transformation events."

VII. During the oral proceedings, the appellant filed a set of claims of a second auxiliary request. The pending auxiliary request became the first auxiliary request.

Claim 1 of the first auxiliary request reads as follows:

"1. Use of a DNA construct comprising:
(i) at least one T-DNA border region;
(ii) at least one heterologous transgene adjacent to the border region;
(iii) a coding region for a bacterial selectable marker; and
(iv) at least one segment of DNA, comprising a *repABC* replication origin from *Agrobacterium rhizogenes* selected from SEQ ID NOs:32-36 for achieving transformation events having lower frequencies of backbone incorporation and higher frequencies of one- or two-copy T-DNA transformation events."

Claim 1 of the second auxiliary request reads as follows:

"1. Use of a DNA construct in a method for transforming plants, said DNA construct comprising:

(i) at least one T-DNA border region;

(ii) at least one heterologous transgene adjacent to the border region;

(iii) a coding region for a bacterial selectable marker; and

(iv) at least one segment of DNA, comprising the *repABC* replication origin from *Agrobacterium rhizogenes* for achieving transformation events having a frequency of backbone integration of less than or equal to 15% of the transformation events and a frequency of one- or two-copy T-DNA transformation events of greater than or equal to 70%, as measured using Southern blotting."

At the end of the oral proceedings, the chair announced the board's decision.

VIII. The appellant's arguments submitted in writing and during the oral proceedings can be summarised as follows.

Main request and first auxiliary request

Clarity (Article 84 EPC) - claim 1

From the claim wording it would have been clear to the skilled person that the improvement was to be achieved by reference to transformation events obtained with constructs not comprising all of the features (i) to (iv) as defined in claim 1. These constructs were provided as control vectors in Example 1.

The description provided an explanation of what the feature "lower frequencies of backbone incorporation" and "higher frequencies of one- or two-copy T-DNA transformation events" meant (see pages 16 and 17).

Second auxiliary request

Amendments (Article 123(2) EPC) - claim 1

The subject-matter of claim 1 found a basis in claims 1 and 5 as originally filed in combination with the passage on page 17, lines 13 to 22, of the application. The recited frequency values for transformation with non-T-DNA and one or two-copy transformation events, respectively, were disclosed in the passage bridging pages 16 and 17 of the description. From the second full paragraph on page 17, the skilled person would have understood that these values were achieved by the use of the *repABC* replication origin from *Agrobacterium rhizogenes*, *oriRi*.

- IX. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the set of claims of the main request or, alternatively, the first auxiliary request, both filed by letter dated 9 October 2018 or further, alternatively, the second auxiliary request, submitted during the oral proceedings.

Reasons for the Decision

1. The appeal complies with Articles 106 to 108 and Rule 99 EPC and is therefore admissible.

Main request and first auxiliary request

Clarity (Article 84 EPC) - claim 1

2. Article 84 EPC requires the claims - which shall define the matter for which protection is sought - to be clear. This requirement serves the purpose of ensuring that the public is not left in any doubt as to what subject-matter is covered by a claim and what is not. It follows that a lack of clarity arises if a claim does not allow this distinction to be made.
3. Claim 1 of both claim requests is directed to the use of a DNA construct "for achieving transformation events having lower frequencies of backbone incorporation and higher frequencies of one- or two-copy T-DNA transformation events" (see section VI, above).
4. The terms "higher" and "lower" in claim 1 are, *per se*, relative terms. Relative terms have often been considered unclear, for example, if the skilled person would not have related them with an unambiguous meaning or because they were not further defined in relation to a specific reference point.
5. The appellant has not provided any evidence, nor is the board aware of any itself, that the terms "higher" and "lower" in relation to frequencies of backbone incorporation or of one- or two-copy T-DNA transformation events have an unequivocal, generally

accepted meaning in the field of plant transformation technology.

6. Moreover, in present claim 1, there is no further, direct definition of "higher" or "lower", for example, by comparison to frequencies of backbone incorporation and of one- or two-copy T-DNA transformation events resulting from the use of a reference DNA construct. In particular, the claim wording does not indicate that the improvement is made by reference to transformation events obtained with DNA constructs not comprising all the features (i) to (iv).
7. Neither do the remaining features of claim 1 help to clarify the definition of "higher" and "lower". None of them defines the DNA construct in such a manner that its use would result inevitably in transformation events having specific frequencies of backbone incorporation and of one- or two-copy T-DNA transformation events. Thus, for example, the DNA construct is defined using open language ("comprising"), as is feature (iv) of the DNA construct: "one segment of DNA, comprising a cis and/or trans element of a *repABC* replication origin from *Agrobacterium rhizogenes*".
8. Thus, the skilled person is not able to unambiguously determine which transformation events are encompassed by the claims. As a consequence, neither are they able to unambiguously distinguish which uses of a DNA construct fall within the scope of the claims and which do not.
9. The appellant's argument that the skilled person would have understood the meaning of the terms "higher" and "lower" in relation to frequencies of backbone

incorporation and of one- or two-copy T-DNA transformation events by referring to pages 16 and 17 of description does not persuade the board.

10. It is established jurisprudence that, to satisfy the requirements of Article 84 EPC, the meaning of the terms of a claim should be clear from the wording of the claim alone (see decision G 1/04, OJ EPO 2006, 334, Reasons point 6.2 and Case Law of the Boards of Appeal of the European Patent Office, 8th edition 2016, II.A.3.1). In this respect, the board agrees with the finding of decision T 768/08 (see Reasons, point 4.4) that, for meeting the requirements of Article 84 EPC, reliance on the description cannot be considered as a substitute for an amendment which would remove the lack of clarity.
11. The board concludes that claim 1 of both the main request and the first auxiliary request does not comply with the clarity requirement of Article 84 EPC.

Second auxiliary request

Article 123(2) EPC - claim 1

12. Claim 1 is directed to the use of a DNA construct in a method for transforming plants wherein the DNA construct comprises also:

"at least one segment of DNA, comprising the *repABC* replication origin from *Agrobacterium rhizogenes* for achieving transformation events having a frequency of backbone incorporation of less than or equal to 15% of the transformation events and a frequency of one- or two-copy T-DNA transformation events of greater than or

equal to 70%, as measured using Southern blotting" (see section VII above).

13. The appellant submitted that the basis for the combination of the use of the repABC replication origin from *Agrobacterium rhizogenes* for achieving the transformation events specified in claim 1 was provided in the second full paragraph on page 17 - from which the skilled person would have understood that these values were achieved by the use of the repABC replication origin from *Agrobacterium rhizogenes*, oriRi - in combination with the paragraph bridging pages 16 and 17.

14. The second full paragraph on page 17 discloses that:

"[t]hus, certain embodiments of the present invention provide methods involving use of repABC element such as oriRi from Agrobacterium rhizogenes and repABC origin from plasmid p42b of Rhizobium etli, including the sequences set forth herein, to reduce the frequency of plants transformed with non-T-DNA vector region. The present invention is also directed to the use of repABC element such as oriRi from Agrobacterium rhizogenes and repABC origin from plasmid p42b of Rhizobium etli, including the sequences set forth herein, to increase the frequency of one- or two-copy T- DNA transformation events."

Finally, the paragraph discloses that:

"[i]n some embodiments, both methods are employed in combination to achieve transformation events having

lower frequencies of backbone incorporation and higher frequencies of one- or two-copy T-DNA transformation events."

15. The board is satisfied that the skilled person would derive, directly and unambiguously, from this paragraph that the *repABC* replication origin from *Agrobacterium rhizogenes* can be used for achieving transformation events having lower frequencies of backbone incorporation and higher frequencies of one- or two-copy T-DNA transformation events.

16. The appellant relied on the passage bridging pages 16 and 17 of the description as providing a basis for the specific frequencies of backbone integration and of one- or two-copy T-DNA transformation events recited in the claim. This passage reads in full as follows:

"[t]he present methods yield improved transformation efficiencies, significantly reducing the frequency of plants transformed with vector backbone DNA, or "non-T-DNA." In some embodiments, the frequency of plants transformed with non-T DNA is less than or equal to about 20%. In some embodiments, the frequency of plants transformed with non-T DNA is less than or equal to about 15%, or less than equal to about 10%, or less than or equal to about 8% or 5%". Additionally, the methods of the invention yield very high one- or two-copy T-DNA transformation events. For example, in some embodiments, the frequency of one- or two-copy T-DNA transformation events is greater than or equal to about 70% or 75%, as measured using Southern blotting. In some embodiments, that frequency is greater than or equal to about 80% or 85%, and in some cases, 90% or 95%, as measured with Southern blotting."

17. Thus, this passage discloses that in some embodiments certain frequencies of plants transformed with non-T-DNA are achieved. It also discloses that in other embodiments certain frequencies of one- or two-copy T-DNA transformation events are achieved. However, the passage does not disclose in which context these frequencies are achieved, e.g. which DNA construct is used - or how - to achieve any particular frequency.

18. The passage does not disclose that certain frequencies of plants transformed with non-T-DNA are achieved in combination with particular frequencies of one- or two-copy T-DNA transformation events or even that particular combinations of frequencies are achieved by the use of the same DNA construct. In the board's judgement, it is thus not directly and unambiguously derivable from that passage that the use of one and the same DNA construct results in the combination of frequencies of backbone integration - less than or equal to 15% - and a frequency of one- or two-copy T-DNA transformation events - greater than or equal to 70% - recited in claim 1. Therefore, this passage does not provide any basis for the transformation events specified in claim 1.

19. Thus, the subject-matter of claim 1 extends beyond the content of the application as filed and fails to meet the requirements of Article 123(2) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chair:



S. Lichtenvort

G. Alt

Decision electronically authenticated