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Datasheet for the decision of 17.06.2020

Case Number: T 1987/16 - 3.3.04

Application Number: 06754739.8

Publication Number: 1874936

IPC: C12N15/82, C12N15/85, C12N15/79, A01H5/00

Language of the proceedings: EN

Title of invention:
Improved methods controlling gene expression

Patent Proprietor:
BASF Plant Science GmbH

Opponent:
White, Nina Louise

Headword:
Controlling gene expression/BASF

Relevant legal provisions:
EPC Art. 100(c)

Keyword:
Amendments - extension beyond the content of the application as filed (no)

Decisions cited:

Catchword:

Europäisches Patentamt
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Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 1987/16 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
# of 17.06.2020

Appellant: (Patent Proprietor)	BASF Plant Science GmbH 67056 Ludwigshafen (DE)
Representative:	Altmann Stößel Dick Patentanwälte PartG mbB Dudenstrasse 46 68167 Mannheim (DE)
Respondent: (Opponent)	White, Nina Louise Boult Wade Tennant Verulam Gardens 70 Gray's Inn Road London WC1X 8BT (GB)
Representative:	Boult Wade Tennant LLP Salisbury Square House 8 Salisbury Square London EC4Y 8AP (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 17 June 2016 concerning maintenance of the European Patent No. 1874936 in amended form.**

Composition of the Board:

Chairwoman	G. Alt
Members:	B. Rutz
	P. de Heij

Summary of Facts and Submissions

I. The appeal lodged by the patent proprietor ("appellant") lies from the opposition division's interlocutory decision concerning the maintenance of European patent No. 1 874 936 in amended form on the basis of auxiliary request 3. The patent is entitled "*Improved methods controlling gene expression*".

II. An opposition was filed against the patent. The patent was opposed under Article 100(a) EPC on the ground of lack of inventive step (Article 56 EPC) and under Article 100(b) and (c) EPC.

III. In the decision under appeal the opposition division decided that claims 1 and 2 of the main request and claim 1 of auxiliary requests 1 and 2 contravened the requirements of Article 123(2) EPC. By contrast, it decided that the subject-matter of the claims of auxiliary request 3 complied with the requirements of Article 123(2) EPC, was sufficiently disclosed (Article 83 EPC) and involved an inventive step (Article 56 EPC).

IV. With the statement setting out the grounds of appeal the appellant requested, as a main request, that the patent be maintained as granted. In the alternative, they requested that the patent be maintained on the basis of the sets of claims of auxiliary requests 1 and 2, which are identical, respectively, to auxiliary requests 1 and 2 on which the decision under appeal was based. A further request, namely "*to remit the case to the Opposition Division for further examination under Art. 56 and 83 EPC*", was later withdrawn.

V. Claims 1 and 2 of the main request (claims as granted) read:

"1. A method to reduce or eliminate leakiness of transgene expression in monocotyledonous plants said method comprising the steps of:

a) providing an expression construct comprising a promoter sequence functional in said plant or plant tissue and functionally linked thereto said transgene to transcribe a chimeric RNA sequence, said transgene comprising

i) an open reading frame encoding a protein of interest that is capable to confer a preferred phenotype or beneficial effect to said plant, and ii) a sequence substantially complementary to an endogenous microRNA sequence, wherein said endogenous microRNA is expressed in tissues, at times, and/or under environmental conditions, where expression of the chimeric RNA sequence is not desired, and wherein said endogenous microRNA is not or substantially less expressed in tissues, at times, and/or under environmental conditions, where expression of the chimeric RNA sequence is desired, wherein sequence i) and sequence ii) are heterologous to each other, and

b) introducing said expression construct into a plant, wherein the sequence being substantially complementary to the microRNA is positioned in a location of said transgene corresponding to the 5'-untranslated region or the 3'-untranslated region of said transgene and wherein expression of said chimeric RNA is suppressed in tissues, at times, and/or under environmental conditions where said endogenous miRNA is expressed.

2. The method of claim 1, wherein said promoter is selected from the group consisting of constitutive promoters, tissue-specific or tissue-preferential promoters, and inducible promoters."

VI. The opponent did not appeal against the opposition division's decision and is thus respondent and party as of right.

VII. The respondent did not reply to the appeal.

VIII. The board summoned the parties to oral proceedings as requested and informed them, in a communication pursuant to Article 15(1) RPBA, of its preliminary opinion that the subject-matter of the European patent (main request) did not extend beyond the content of the application as filed (points 11 to 13). The board also noted that further objections to the claims of the main request did not need considering as the respondent had not replied to the appeal, and that it saw no reason to examine the further grounds for opposition of its own motion. The board informed the parties that it intended to grant the appellant's request to maintain the patent as granted.

IX. The respondent did not reply to the board's communication.

X. Oral proceedings were cancelled.

XI. The appellant's arguments submitted in writing and as far as relevant to the present decision may be summarised as follows:

Main request (claims as granted)

Extension beyond the content of the application as filed (Article 100(c) EPC)

Page 6, lines 14 and 15 of the application as filed (hereinafter the "application") disclosed an indication that there was a need for improvement of tissue-specificity or the control of promoter leakiness. The next sentence in lines 16 and 17 explicitly stated that the invention provided such means and methods without being limited to a certain type of promoter such as a tissue-specific promoter. Thus, the skilled person could directly and unambiguously derive from the application that the promoter to be used in the method for controlling leakiness could be any type of promoter.

To fulfil the requirements of Article 123(2) EPC, it was not necessary for the description to contain a passage discussing leakiness in the context of e.g. constitutive promoters, as stated in the opposition division's decision, because claim 1 as granted referred to promoters in general, not to a specific promoter (such as a tissue-specific promoter). Furthermore, the application defined the term "promoter" as a constitutive, tissue-specific, tissue-preferential or inducible promoter (see for example pages 27 and 28). This definition made it clear that the promoter referred to on page 6, lines 14 and 15 could be a promoter as set forth in claim 2 as granted.

Furthermore, page 38, lines 24 to 29 of the application disclosed that the nucleotide sequence for expression of the chimeric RNA could be combined with a number of promoters. Constitutive, inducible and tissue-preferential promoters were explicitly mentioned.

In the decision under appeal, the opposition division was wrong to find that the skilled person reading the application would conclude that leakiness was not a property of constitutive promoters. Taking into account the application as a whole, the skilled person would also have derived that the leakiness of constitutive promoters could be reduced; see for example Figure 4.

The table on page 143 of the application dealt with "*Vectors and miRNA tags used for leakiness control*" (see title of the table, emphasis added). Six different vector constructs were disclosed, all of them using the ScBV promoter, which conferred constitutive expression.

Further examples in the application for leakiness control of constitutive promoters were e.g. the AHAS gene under control of the Ubi promoter (see page 134, lines 23 to 37) and the constitutive expression of the Bt protein (see page 134, lines 17 to 21).

Reasons for the Decision

Admissibility of the appeal

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

Extension beyond the content of the application as filed (Article 100(c) EPC)

2. The decision under appeal found that "a method to reduce or eliminate leakiness of transgene expression" using "an expression construct comprising a promoter sequence" as referred to in claim 1 had no basis in the application as filed with regard to constitutive promoters as referred to in dependent claim 2 because "*the application does not contain a single passage, which would discuss leakiness in the context of e.g. constitutive or inducible promoters*" (see page 4, paragraph 4). The decision furthermore found "*that the concept of 'leakiness' would be difficult to reconcile with a truly constitutive promoter*" (see page 4, paragraph 5).

3. The board first of all notes that the passage on page 6, lines 14 to 16 provides a summary of the purpose of the invention: "*Thus, there remains substantial need for improvement of tissue-specificity or control of promoter leakiness. The present invention provides such means and methods...*". The control of promoter leakiness in this passage is not limited to specific promoters.

4. The board also points to the passage on page 34, lines 7 to 16: "*It is not unusual that some 'tissue-specific' promoters having leakiness of expression in*

other tissues which could result in undesirable phenotype such as phytotoxicity", which was considered in the decision under appeal to be an indication that the control of leakiness was limited to tissue-specific promoters. However, the paragraph goes on to indicate that "*[i]n other cases, it has been proved very challenge* [sic] *to generate tissue-specific promoter* [sic]" (emphasis added). In the board's view, the skilled person would infer from the cited passage as a whole that the invention also addresses "*other cases*", i.e. those in which tissue-specific promoters are not available.

5. The statement "*one could design a generic vector with a miRNA tag* [...] *so that leakiness of transgene expression in the tissues where miRNA are expressed will be reduced or eliminated*" in the same paragraph reinforces the interpretation that the reduction or elimination of leakiness is not limited to a single type of promoter because it refers to a "*generic vector*", i.e. one which is useful in many instances, e.g. in different tissues or developmental stages.

6. On page 38, lines 25 to 29 the application as filed discloses that "*the promoters can be selected based on the desired outcome. Thus, the nucleotide sequence for expression of the chimeric RNA can be combined with constitutive, tissue-preferred, inducible, developmental, or other promoters for expression in plants depending upon the desired outcome. Specific promoters are described below*". In the board's view, this means that the chimeric RNA can be combined with all types of promoters.

7. On page 39, lines 16 to 18 the promoters to be used are listed as "*constitutive promoters, tissue-specific or*

tissue-preferential promoters, and inducible promoters". Contrary to the decision under appeal (page 4, third paragraph), the board construes the statement following that cited above ("*A tissue specific promoter in this context, does - preferably - mean which is leaky (i.e. having expression activity in other than the preferred or main tissue) to a small but measurable extent*") as referring to a particular example of a tissue-specific promoter, namely one which is leaky. In the context of the invention, it makes sense to interpret this disclosure in that way - and not to mean that the reduction or elimination of leakiness is restricted to tissue-specific promoters - because only a leaky tissue-specific promoter would need to be improved using an miRNA tag while a "perfect" (non-leaky) tissue-specific promoter would not need such improvement.

8. Furthermore, as highlighted by the appellant, the table on page 143 and the accompanying text provide examples of a promoter (ScBV promoter) which confers constitutive expression in plants and which is included in "*Vectors and miRNA tags used for leakiness control*" (see title of the table; emphasis added). Lines 23 to 37 on page 134 provide a further example of a construct that comprises a constitutive promoter (Ubi promoter) and an miRNA tag and shows reduced or eliminated mRNA levels in seeds.

9. Finally, Figure 4b and its accompanying legend on page 12 provide another example of the concept of the invention, namely "*If the gene of interest (GOI) is NOT intended to express in seeds* [...], *but promoter used is leaky in seeds, one can incorporate a tag* [...] *to make a generic vector to control undesirable expression of the GOI in seeds* [...] *(Fig. 4-B)*" (emphasis added).

Here too, the text and the figure only refer to a leaky promoter in general and not to any specific type of promoter.

10. In conclusion, and in contrast to the opposition division, the board finds that the application as filed provides a basis for a method as referred to in claim 1 with regard to all of the promoters referred to in dependent claim 2. As no further added subjectmatter objections were put forward, the subject-matter of claims 1 and 2 must be held not to extend beyond the content of the application as filed (Article 100(c) EPC).

Further grounds referred to in the notice of opposition: Article 100(a) in combination with Article 56 EPC and Article 100(b) EPC

11. The respondent did not reply to the appeal. Therefore no further objections to the claims of the main request need to be considered (Articles 12(3) and 25(2) RPBA 2020 and Article 12(4) RPBA 2007). In addition, the board saw no reason to examine any of the further grounds for opposition of its own motion.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is maintained as granted.

The Registrar: The Chair:

I. Aperribay G. Alt

Decision electronically authenticated