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Datasheet for the decision of 2 December 2022

Case Number: T 3103/19 - 3.3.04

Application Number: 17152976.1

Publication Number: 3228713

IPC: C12N15/82, A01H5/12, C12Q1/68

Language of the proceedings: ΕN

Title of invention:

Alfalfa plant and seed corresponding to transgenic event KK179-2 and methods for detection thereof

Applicants:

Monsanto Technology LLC Forage Genetics International, LLC

Headword:

Alfalfa event/MONSANTO

Relevant legal provisions:

EPC Art. 56

Keyword:

Inventive step - (no)

Decisions cited:

G 0001/12, T 0775/08, T 2239/08, T 0915/10



Beschwerdekammern **Boards of Appeal** Chambres de recours

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Case Number: T 3103/19 - 3.3.04

DECISION of Technical Board of Appeal 3.3.04 of 2 December 2022

Appellants: Monsanto Technology LLC

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Forage Genetics International, LLC

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Uexküll & Stolberg Representative:

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Decision under appeal: Decision of the Examining Division of the

European Patent Office posted on 15 July 2019

refusing European patent application No. 17152976.1 pursuant to Article 97(2) EPC.

Composition of the Board:

(Applicant 2)

Chairwoman M. Pregetter Members: D. Luis Alves

R. Romandini

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Summary of Facts and Submissions

- I. The appeal concerns the decision of the examining division to refuse European patent application No. 17 152 976.1, entitled "Alfalfa plant and seed corresponding to transgenic event KK 179-2 and methods for detection thereof". The application was filed as a divisional application of European patent application No. 12 738 287.7, which was filed as an international patent application and published as WO 2013/003558.
- II. The decision under appeal dealt with a main request and an auxiliary request, both filed on 17 May 2019. As regards the main request, the examining division held that the subject-matter of claims 1 and 4 to 8 did not involve an inventive step (Article 56 EPC). The same conclusion applied, for the same reasons, to the corresponding claims in the auxiliary request (in the following "auxiliary request 1").

The examining division found that the subject-matter of claim 8 was not limited to plants having the insert (corresponding to SEQ ID NO 5, which together with flanking genomic sequences of the alfalfa plant, corresponds to SEQ ID NO 6 in claim 1) in the same insertion site as event KK179-2, and for this reason any technical effects associated with that insertion site could not be taken into account for the formulation of the objective technical problem.

Moreover, also claims defining the specific event would not comply with the requirements of Article 56 EPC.

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III. The application had been filed by joint applicants (appellants) Monsanto Technology LLC and Forage Genetics International, LLC.

An appeal was filed in the name of the applicant Monsanto Technology LLC. In reply to a communication under Rule 101(2) EPC by the registry of the board, the applicants' representative stated that both the notice of appeal and the statement setting out the grounds of appeal had been filed in the name and on behalf of both joint applicants.

- IV. With the statement setting out the grounds of appeal, the appellants maintained the sets of claims on the basis of which the decision under appeal was taken and filed sets of claims of auxiliary requests 2 and 3.
- V. Claims 1 to 3 and 8 of the main request and auxiliary request 1 read as follows:
 - "1. A recombinant DNA molecule comprising
 - a. the polynucleotide molecule of SEQ ID NO:6; or
 - b. a polynucleotide molecule fully complementary to a).
 - 2. A microorganism comprising the DNA molecule of claim 1.
 - 3. The microorganism of claim 2, wherein said microorganism is a plant cell.
 - 8. An alfalfa plant comprising a plant cell of claim 3."

Claims 1 and 2 of **auxiliary requests 2 and 3** are identical to those reproduced above for the main request.

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- VI. The board appointed oral proceedings and in a communication pursuant to Article 15(1) RPBA indicated its preliminary opinion that, inter alia, the appeal was not admissible and none of the claim requests was allowable. The board agreed with the examining division's claim interpretation.
- VII. In reply, the appellants filed further arguments and requested that the oral proceedings be held in the form of a videoconference. The board informed the appellants that the request was rejected. In a subsequent letter, the appellants maintained the request.
- VIII. The following documents are referred to in this decision:

D2: Undersander, D. et al., "Low Lignin Alfalfa: Redefining the Yield/Quality Tradeoff", 2009 Western Alfalfa & Forage Conference, "Improving Your Odds of Profitability", December 2009

D4: Chen, F. et al., The Plant Journal 48, 2006, pages 113-124

D6: WO 01/73090

D7: Guo, D. et al., The Plant Cell 13, 2001, pages 73-88

D8: Marita, J.M. et al., Phytochemistry 62, 2003, pages 53-65

Declaration by Mr McCaslin

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- IX. Oral proceedings were held in person. At the end of the oral proceedings, the Chair announced the board's decision.
- X. The appellants' arguments relevant to the decision may be summarised as follows.

Admissibility of the appeal

The appeal was admissible. An appellant could remedy any deficiency under Rule 99(1)(a) EPC within the period indicated in the board's communication pursuant to Rule 101(2) EPC.

In the notice of appeal and statement of grounds of appeal, the identification of the second applicant, namely Forage Genetics International, LLC, had been omitted due to a clerical error.

However, the appellants rectified the error as soon as the board's communication pursuant to Rule 101(2) EPC had been received. With their reply, the appellants clarified that the notice of appeal and statement of grounds of appeal had been filed in the name of both legal entities registered as applicants.

Moreover, the common representative for both applicants had remained the same in examination and appeal proceedings and had been authorised by both applicants. The notice of appeal was filed by the common representative, and therefore filing it in the name of only one of the two entities listed as the applicants was not possible and not intended.

The case at hand differed from that underlying decision T 755/09 in numerous aspects. Decision G 3/99 of the

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Enlarged Board of Appeal dealt with a case in which there was no duly appointed common representative. In fact, this decision supported the appellants' case. In decision G 1/12, the Enlarged Board of Appeal concluded that when the identification of the appellant had been wrong due to an error, it was possible to replace it with that of the true appellant provided the true intention had been to file the appeal in the name of the legal entity that should have filed the appeal. Thus, this decision also supported the appellants' case. The reasoning in decision T 819/15 applied in the case at hand because the second appellant was identifiable.

Request to hold the oral proceedings in the form of a videoconference

As this was an ex-parte appeal case, there was no party disagreeing with the appellant's request to hold the oral proceedings by videoconference. The request was in agreement with EPO policy promoting online meetings for environmental reasons. Article 15a RPBA did not indicate that special reasons needed to be provided by a party requesting videoconference. Decision G 1/21 of the Enlarged Board of Appeal did not indicate a general emergency as a requirement for holding the oral proceedings by videoconference.

Main request
Claim construction

Claim 8 defined, by reference to SEQ ID NO: 6 in claim 1, the insertion site of the transgenic insert, i.e. SEQ ID NO:5, in the alfalfa plants. This claim construction was in line with that adopted by the board

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in decision T 915/10 when considering claim 4 (see Reasons 8, 35 and 36).

Inventive step - Article 56 EPC Closest prior art

The disclosure in document D2 on transgenic alfalfa plants with reduced lignin content was insufficient. No details were provided on the method of generating the plants, the constructs used or the genomic insertion site. The plants described in this document had not been made available to the public before the priority date claimed by the application (see declaration by Mr McCaslin). None of documents D6 to D8 disclosed the insertion site either.

The reduction in lignin content disclosed in document D6 was much lower than that shown in the application for event KK179-2. The reduction disclosed in document D7 was 17%, whereas it reached 18 to 22% in the current application with event KK179-2. Document D8 disclosed a reduction of 21% in lignin content. However, none of documents D6 and D8 disclosed the values for neutral detergent fibre digestibility (NDFD). Document D4 disclosed that a reduction of caffeoyl CoA 3-0-methyltransferase (CCOMT) expression in alfalfa did not result in reduction of S-lignin units or wall-bound ferulate (see abstract and page 120, right-hand column, last paragraph). Figure 6 showed that downregulation of caffeic acid 3-O-methyltransferase (COMT) resulted in a greater reduction in lignin content than downregulation of CCOMT. Thus, the prior art provided contradictory teachings on the effect of a reduction in CCOMT expression in the alfalfa lignin content.

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Objective technical problem

The claimed plants differed from those described in document D2 in the genomic insertion site of the transgenic insert.

The technical effect of this difference was a greater reduction in lignin content. Example 3 of the application showed for event KK179-2 a reduction of 18 to 22% in lower stem acid detergent lignin (ADL), and Example 4 showed a corresponding increase in NDFD, both of which were not accompanied by a decrease in yield (see Example 8). The objective technical problem could be formulated as the provision of an improved alfalfa plant.

Obviousness

It would not have been obvious to provide alfalfa plants with the extent of reduction in lignin content shown for event KK179-2, i.e. 18 to 22%. This extent was related to the insertion site and thus could not have been expected. Furthermore, in view of the prior art as a whole, which disclosed variable success in obtaining alfalfa with reduced lignin content (see document D4), the 18-22% extent of reduction could not have been expected. Surprising improvements caused by a transgenic event involved an inventive step (see decisions T 2239/08 and T 915/10).

Furthermore, the skilled person would not have expected a further reduction in lignin content to be advantageous because of a possible negative effect on the viability of the plants (stiffness and strength of the stem) (see the mention of "standability issues" in document D2). Therefore, it was not obvious to provide plants with a further reduction in lignin content.

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The considerations supporting the presence of an inventive step of the plants characterised by the genomic insertion site of the transgenic insert also supported the presence of an inventive step for the claimed sequences.

Auxiliary requests 1 to 3

Reference was made to the arguments provided for the main request.

XI. The appellants requested that the decision of the examining division be set aside and that a patent be granted on the basis of the sets of claims of the main request or auxiliary request 1, filed on 17 May 2019 as the main request and the auxiliary request, respectively, or on the basis of the sets of claims of auxiliary requests 2 or 3 filed with the statement setting out the grounds of appeal.

Reasons for the Decision

Admissibility of the appeal

1. The application was filed by two joint applicants,
Monsanto Technology LLC and Forage Genetics
International, LLC. In the request for grant of a
European patent, the two joint applicants of the
application designated a common representative. This
common representative filed both the notice of appeal
and the statement of grounds of appeal, however, on
behalf of only one of the two joint applicants, namely

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Monsanto Technology LLC. Following a communication under Rule 101(2) EPC, the applicant stated that both the notice of appeal and the statement of grounds of appeal were filed in the name and on behalf of both the joint applicants. The board understood this statement as a correction of the notice of appeal in response to the communication sent under Rule 101(2) EPC.

- 2. The question to be decided by the board is whether it is possible to add a missing joint applicant in reaction to a communication sent under Rule 101(2) EPC. According to decision G 1/12, point 22 of the Reasons, Rule 101(2) EPC applies to deficiencies which do not affect the establishment of the true appellant's identity. In the board's view, it follows from decision G 1/12 that a correction should be possible if two requirements are met:
 - (i) the original appellant was identifiable before the two-month period set out in Article 108 expired (point 27 of the Reasons);
 - (ii) the correction reflects the true intention of the appellant(s) on the basis of the information in the appeal or otherwise on file, i.e. "ascertain who must be deemed in all likelihood to have filed the appeal and, consequently, replace the name indicated in the appeal with that of another natural or legal person" (points 23-29 of the Reasons).
- 3. The board is of the opinion that these requirements also apply where the correction does not consist in replacing one of the names originally indicated but in adding a name to the name(s) originally indicated. These requirements are met in the current case. The appellant added was identifiable. There were only two joint applicants in the proceedings leading to the

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contested decision. On the balance of probabilities, the correction - the addition of the second applicant to the notice of appeal - seems to reflect the true intention of the two joint applicants. Indeed, the omitted applicant never revoked the authorisation granted to the common representative. Furthermore, it was also represented by the same representative in the first-instance proceedings. The board therefore considered the appeal to be admissible.

Request to hold the oral proceedings in the form of a videoconference

4. The appellants requested that the oral proceedings be held by videoconference. The board refused this request. Pursuant to Article 116(1) EPC, the party has the right to request that oral proceedings be held but not the right to choose the format. This is at the discretion of the board (see Article 15a(1) RPBA). In this case, the board considered that the face-to-face format was more appropriate in light of the issues to be addressed, including the admissibility of the appeal and claim construction. This exercise of discretion requires no further justification. The same applies to the choice of the alternative format, namely videoconference, unless there are special activities to be carried out, such as hearing a witness or inspecting a physical object. In this case, the board must explain why it still considers a videoconference to be appropriate also for the purpose of gathering and examining the evidence in question.

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Main request - claims 1 and 8 Introduction

- 5. The application concerns alfalfa plants with reduced lignin content for improved digestibility with a view to being used as animal feed. Lignin is a cross-linked copolymer of guaiacyl (G), syringyl (S) and p-hydroxyphenyl (H) units. A reduction in lignin content can be achieved by reducing the expression of the enzyme caffeoyl CoA 3-0-methyltransferase (CCOMT), involved in the monolignol pathway, which leads to the synthesis of the constituting monomers of lignin.
- 6. The application describes that a CCOMT suppression cassette was introduced into alfalfa plant cells by Agrobacterium-mediated transformation. With this technique, the DNA may be inserted at any location in the plant genome, the chromosomal position of this insertion being random and unpredictable. One of the resulting transformation events is designated KK179-2. It includes in the plant genome the transgenic DNA consisting of SEQ ID NO:5, including the CCOMT suppression cassette. Event KK179-2 contains in its genome the DNA SEQ ID NO: 6, which is a sequence comprising the inserted transgenic DNA SEQ ID NO:5 and flanking genomic sequences of the alfalfa plant.

Claim construction

7. By reference to claim 1, the plant as defined in claim 8 is required to have plant cells comprising a DNA molecule comprising the polynucleotide of SEQ ID NO: 6. The board agrees with the examining division's claim construction. In the board's view, the presence of a polynucleotide of SEQ ID NO: 6 does not

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define the insertion site of the transgenic insert SEQ ID NO: 5, so the polynucleotide of SEQ ID NO: 6 can be present at any position in the alfalfa genome. Thus, claim 8 is not restricted to alfalfa plants comprising event KK179-2 and also encompasses plants in which the whole of SEQ ID NO: 6 has been inserted at any (unspecified) location in the genome.

8. The appellant's reference to decision T 915/10, of this board in a different composition, did not convince the board to change the claim construction set out above. In that decision, the board considered a claim 4, which, like current claim 1, defined a DNA sequence comprising the transgenic insert and the flanking sequences of the plant genome. The board came to the conclusion that the claimed subject-matter involved an inventive step. In reaching this conclusion, the board referred to the reasons for recognising the presence of an inventive step for the plants defined in claim 1 (see Reasons 35 and 36). Those plants were defined by, inter alia, reference to deposited biological material so that they necessarily were characterised by the same insertion site as the deposited material. By contrast, in the current case, there is no reference to a deposit. Therefore, the facts in that case differed from the current case.

Inventive step - Article 56 EPC

Closest prior art

9. In the following, the presence of inventive step is assessed for the most specific embodiment encompassed by claim 8, namely an alfalfa plant comprising the event KK179-2.

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- 10. The examining division considered that transgenic alfalfa plants having reduced lignin content as a result of reduced expression of CCOMT, as disclosed in document D2, represented the closest prior art to the claimed subject-matter. The appellants have not offered a different starting point for the assessment of inventive step. Instead, the appellants contested that this document provided an enabling disclosure of such plants.
- Document D2 discloses alfalfa plants with reduced 11. lignin content obtained by reduced expression of CCOMT. Although experimental details of the generation of the transgenic plants are not disclosed, the board considers that the missing details were known to the skilled person. Document D2 makes reference in this regard to document D8 in the current proceedings. Several other documents disclose how to obtain alfalfa plants with reduced CCOMT expression (see, for example, documents D4, D6 and D7). While the board recognises that document D2 does not disclose in an enabling manner specific alfalfa transgenic plants (events), such as alfalfa plants which present a 12% reduction in lignin content compared to the control (as mentioned in document D2 on page 3), it does disclose generally alfalfa plants with reduced lignin obtained by reduced expression of CCOMT.
- 12. As put forward by the appellants, the insertion site of the CCOMT suppression cassette influences the level of reduction in CCOMT expression, and this insertion site is not disclosed for the plants described in the cited documents D4 and D6 to D8.
- 13. The board relied on these documents for disclosing methods of randomly obtaining transgenic alfalfa plants

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which display average reduction in CCOMT expression and average reduction in lignin content, as well as the resulting alfalfa plants, and not for disclosing alfalfa plants with a particular level of reduction in lignin content. For this purpose, the extent to which CCOMT is reduced is not relevant, and consequently disclosure of the insertion site is not relevant either. Crucial in the board's view is how frequently such events with reduced lignin content were obtained when following the Agrobacterium-mediated transformation as disclosed in those documents. If these events were very low frequency, obtaining plants with reduced lignin content would be dependent on "chance events", and this would not be considered to be disclosed in these documents. On the basis of document D7, however, the board finds that in the case at hand obtaining alfalfa plants with reduced lignin did not depend on "chance events".

- 14. Indeed, document D7, which concerns the generation of transgenic alfalfa plants with reduced expression of CCOMT and reduced lignin content, discloses that out of 20 plants, two displayed reduced expression of CCOMT. According to Table 1 (see page 79), the line ACC305 displayed a Klason lignin content of 14.58 (as a % of dry weight). According to page 79, left-hand column, second paragraph, the corresponding value for the control lines was 17.6. This can be calculated to correspond to a reduction of 17% in lignin content in line ACC305.
- 15. In the board's view, the disclosure in document D4 is fully consistent with that in documents D2 and D7.

 Indeed, document D4 discloses that a reduction in CCOMT expression led to a reduction in lignin content (see Figure 3). This reduction was accompanied by a change

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in the composition of the polymer (see the sentences referring to Figure 3, on page 116, left-hand column, third paragraph, first sentence and right-hand column, first paragraph, last sentence). The authors highlight that downregulation of CCOMT had no effect on the accumulation of S-lignin unit or wall-bound ferulate (see page 120, right-hand column, last full paragraph). However, this observation does not imply that the lignin content was not reduced, as can be seen from Figure 3. Instead, the authors conclude that it calls into question the role of CCOMT in the synthesis of S-lignin and wall-bound ferulate within the monolignol pathway as depicted in Figure 1 (see sentence bridging the left- and right-hand columns on page 114). The authors' conclusion is not contradicted by the results presented in Figure 6 of document D4, according to which the extent to which lignin was reduced was larger with the suppression of the enzyme caffeic acid 3-O-methyltransferase (COMT) than with suppression of CCOMT. From the foregoing, the board concludes that the disclosure in document D4 does not call into question the disclosure in documents D2 and D6 to D8 that alfalfa plants with reduced CCOMT expression displayed reduced lignin content.

Objective technical problem

16. The specific embodiment considered here differs from the closest prior art in the insertion site of the CCOMT suppression cassette. According to the appellants, the technical effect that may be attributed to this difference is a greater reduction in lignin content. As regards the event KK179-2, the board sees the objective technical problem in the provision of an improved alfalfa plant, i.e. with a larger reduction in lignin content.

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- 17. In accordance with the case law of the boards, a course of action can be considered obvious to the skilled person not only when the results are clearly predictable but also when there is a reasonable expectation of success. Whether there is a reasonable expectation of success is to be assessed on a case-by-case basis.
- 18. In the case at hand, this requires determining whether, in view of the state of the art, the skilled person had a reasonable expectation that an alfalfa plant with a larger reduction in lignin content than disclosed in document D2 could be obtained with the random methods disclosed in the prior art. The appellants argued that the skilled person would not have expected a further reduction (to the extent shown in the application) in lignin content of alfalfa to be possible.
- 19. The board does not find this argument convincing. As summarised above (see point 14.), document D7 discloses the production of transgenic alfalfa plants with reduced expression of CCOMT and reduced lignin content. Out of 20 plants, two displayed reduced expression of CCOMT, with one of them displaying a 17% reduction in Klason lignin content relative to the control. In view of this disclosure, the skilled person would have expected that further alfalfa plants with reduced lignin content could be generated by the same methods with relatively high frequency. Moreover, the skilled person would have expected to obtain reductions of lignin content of the order shown in the application for the event KK179-2.
- 20. The appellants argue that the extent of reduction in lignin content shown for event KK179-2 is larger than

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that reported in document D7. The board is not persuaded by this line of argument.

The application shows, for event KK179-2, ADL values ranging from 18 to 22%, depending on the field, the year and dormancy type (see Tables 4 to 8).

In view of the different measurement methodology (Klason versus ADL) and the impact of multiple parameters on the measured lignin content, as apparent from the application, the board cannot recognise any significant difference between the lignin reduction as expected by the skilled person and that displayed by event KK179-2.

21. In a second line of argument, the appellants submitted that the skilled person would not have expected a further reduction in lignin content to be advantageous because of a possible negative effect on the viability of the plants.

The board is not convinced that concerns with structural issues would have diminished the expectation of succeeding in providing a plant with a larger reduction in lignin content. The board has not seen evidence of such structural issues. The remark in document D2 on "standability issues" does not relate to all transgenic alfalfa plants with reduced lignin but to one line only (see page 4, sentence preceding the "Conclusion"). Moreover, no such issues are reported in document D7, summarised above, reporting on alfalfa plants with lignin reduction comparable to the level shown in the application for event KK179-2.

22. In view of the foregoing, the board concludes that no "elements of surprise" in the sense of decisions

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T 775/08 (Reasons 12 to 12.4), T 2239/08 (Reasons 15 and 19) and T 915/10 (Reasons 26) have been identified for the embodiment "event KK179-2". Thus, the subject-matter of claim 8 does not involve an inventive step. Claim 1 is directed to a DNA molecule present in this embodiment (or complementary to it), so that no additional technical effects beyond those considered above for the event are present, and the reasons why no inventive step can be recognised for the event encompassed by claim 8 apply equally to the subject-matter of claim 1.

Auxiliary requests 1 to 3

- 23. Claim 1 in each of these requests is identical to claim 1 of the main request. The conclusion that the subject-matter of claim 1 does not involve an inventive step applies equally to claim 1 of these requests.
- 24. Consequently, none of the requests on file is allowable.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairwoman:



I. Aperribay

M. Pregetter

Decision electronically authenticated